A study of factors that influence the choice of primary surgical procedure for stress urinary incontinence from the perspective of patients and clinicians

A thesis submitted to the University of Manchester for the degree of Master of Philosophy in the Faculty of Biology, Medicine and Health

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School of Medicine
Contents
List of tables......................................................................................................................5
List of figures.....................................................................................................................5
List of abbreviations.........................................................................................................6
Overall abstract..................................................................................................................8
Declaration..........................................................................................................................9
Copyright statement.........................................................................................................10
Acknowledgements..........................................................................................................11
The Author........................................................................................................................12

Chapter 1: Introduction....................................................................................................13
1.1 Background information.............................................................................................14
1.2 Definition......................................................................................................................15
1.3 Pathophysiology..........................................................................................................15
1.4 Epidemiology................................................................................................................17
1.5 Aetiology.......................................................................................................................18
1.6 Effect of SUI on Quality of Life...................................................................................21
1.7 Clinical assessment of SUI.........................................................................................22
1.8 Surgical treatments for SUI........................................................................................23
1.9 What is known about the choice of SUI procedures?...............................................35
1.10 Conclusion and aims of the research.......................................................................41

Chapter 2: Methodology..................................................................................................43
2.1 Introduction..................................................................................................................44
2.2 Qualitative research methodology.............................................................................44
2.2.1 Inhabiting a position..............................................................................................45
2.3 Study methods............................................................................................................49
2.3.1 Design....................................................................................................................50
2.3.2 Data Collection.......................................................................................................54
2.3.3 Data Analysis..........................................................................................................56
2.4 Quality assessment in qualitative research...............................................................58
Chapter 3: Results of the patient interviews

3.1 Introduction

3.2 Participants

3.3 Results

3.3.1 External forces: The influence of others on decision making

3.3.2 Intrinsic factors: The personal values of participants

3.3.3 The final choice: A process of best fit

3.4 Discussion

3.4.1 Strengths and limitations

3.5 Conclusion

Chapter 4: Results of the clinician interviews

4.1 Introduction

4.2 Participants

4.3 Results

4.3.1 Patient characteristics

4.3.2 Clinician preferences

4.3.3 Variation in information provision

4.3.4 Perception of what the clinician role in decision making should be

4.3.5 Surgeon sign off

4.4 Discussion

4.4.1 Limitations

4.5 Conclusions

Chapter 5: Final Conclusions

5.1 Conclusions

5.1.1 Definitions, meaning and value

5.1.2 Information provided versus information wanted
5.1.3 The overall decision of surgical procedure: A truly preference sensitive decision?...................................................................................................126

5.2 Future work........................................................................................................................................127

5.2.1 How to give experiential evidence to women............................................................................127
5.2.2 Defining terminology..................................................................................................................127
5.2.3 Determining comparative risks and benefits............................................................................128
5.2.4 Hierarchical treatment...............................................................................................................128
5.2.5 Understanding the dynamics of clinical care...........................................................................129

5.3 Final Conclusion..........................................................................................................................129

References..............................................................................................................................................131

Appendix 1: Patient interview topic guide......................................................................................147
Appendix 2: Clinician interview topic guide.....................................................................................148
Appendix 3: Patient framework........................................................................................................149
Appendix 4: Clinician framework....................................................................................................152
Appendix 5: ‘Voice your choice’ paper............................................................................................154

Total word count: 34,940
List of tables

Table 1: Bulking agent brand names with constituent substance..................................25
Table 2: Acceptability of treatments..................................................................................38

List of figures

Figure 1: Lateral view of urethral support........................................................................16
Figure 2: Injection of a urethral bulking agent..................................................................24
Figure 3: Retropubic TVT tape.........................................................................................29
Figure 4: TOT tape placement.........................................................................................29
Figure 5: Open (Burch) colposuspension.........................................................................32
Figure 6: AFSP procedure.................................................................................................34
List of abbreviations

SUI  Stress urinary incontinence
UDS  Urodynamic studies
USI  Urodynamic stress incontinence
ATFP Arcus Tendineus Fascia Pelvis
ISD  Intrinsic sphincter deficiency
MUCP Maximum urethral closure pressure
VLPP Valsalva leak point pressure
MUS  Mid Urethral Sling
BMI  Body mass index
POP  Pelvic organ prolapse
HRT  Hormone replacement therapy
PGWBI Psychological General Well-Being Index
UTI  Urinary tract infection
PFMT Pelvic floor muscle training
AFSP Autologous Fascial Sling Procedure
TVT  Trans-vaginal tape
TOT  Trans-obturator tape
TVT-O Tension free vaginal obturator tape
DVT  Deep vein thrombosis
FDA  Food and Drugs Administration
MHRA Medicines and Healthcare Products Regulatory Agency
NICE National Institute for Health and Care Excellence
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>GMC</td>
<td>General Medical Council</td>
</tr>
<tr>
<td>PDA</td>
<td>Patient decision aid</td>
</tr>
<tr>
<td>PI</td>
<td>Principal investigator</td>
</tr>
<tr>
<td>CAQDAS</td>
<td>Computer assisted qualitative data analysis software</td>
</tr>
<tr>
<td>COREQ</td>
<td>Criteria for reporting qualitative research</td>
</tr>
<tr>
<td>CCG</td>
<td>Clinical Commissioning Group</td>
</tr>
<tr>
<td>IUGA</td>
<td>International Urogynaecology Association</td>
</tr>
<tr>
<td>MDT</td>
<td>Multi-disciplinary team</td>
</tr>
<tr>
<td>PGI-I</td>
<td>Patient global impression of improvement</td>
</tr>
<tr>
<td>BSUG</td>
<td>British Society of Urogynaecologists</td>
</tr>
<tr>
<td>BAUS</td>
<td>British Association of Urological Surgeons</td>
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Overall Abstract

A study of factors that influence the choice of primary surgical procedure for stress urinary incontinence from a patient and clinician perspective

Introduction: Operations available to treat SUI range from office-based procedures to significant pelvic surgery. These procedures have individual risk and benefit profiles and it is currently unknown what factors women with SUI consider when deciding upon a surgical procedure. It is also unknown what factors clinicians consider when they counsel and offer procedures to women and how this may influence the overall procedure chosen. This research aimed to investigate the factors considered by both groups when choosing a primary surgical procedure for SUI.

Method: Qualitative semi-structured interviews were conducted with 14 women with SUI who had recently opted for a primary surgical procedure. Women were purposively sampled to ensure that those who had chosen each available operation were represented. Fifteen consultant urogynaecologists from 11 hospitals across the North of England were interviewed. Interviews were analysed by thematic analysis using the framework method.

Results: Women were influenced by the views and experiences of others outside of the clinical team and valued experiential information in their decision-making. They also had key internal values they considered important, such as return to normal activities, success and risk. Their attitude towards certain procedural factors, such as type of anaesthetic, use of a foreign body and the need for incisions were also considered. Women attached differing levels of importance to these factors and ranked them in terms of this. These hierarchies were compared to characteristics of offered surgical procedures and the procedure that best fit was selected. Clinicians considered clinical factors, including age, BMI, anatomy, severity of SUI and family completion status, to be important when considering surgery. Clinicians appeared to have individualised cut offs for these, with some clinicians limiting the options they gave women depending upon these factors. These cut offs were influenced by training and personal clinical experience in many cases. Directed counselling was used by some, especially for women with perceived high-risk characteristics. Clinicians appeared to have the ultimate decisional power of which procedure to proceed with, appearing to sign off any decision made by women.

Conclusion: The overall decision of primary surgical procedure is complex, with preferences being formed by both patients and clinicians. This study highlights the need to investigate and formally recognise women’s feelings towards the key values identified, as this will significantly influence their preferences. There is also a need to incorporate experiential information in to the counselling process to better support women in their decision making. This study showed a variation in surgical threshold between clinicians. This should be further researched as it could lead to an inequality of choice for patients.
Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

This research was funded by an unrestricted education grant from Contura. The study was investigator led and sponsored by the Manchester University Hospital NHS Foundation Trust.
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Acknowledgements

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This piece of work would not have been possible without the unwavering support of my friends and colleagues in the Warrell Unit. Dr Emily Fairclough, Miss Lucy Dwyer, Dr Charlotte Mahoney, Dr Joanne Sentence— you have all kept me sane during this project and have provided the much-needed advice, support and laughs during some very difficult times. For this I am truly grateful.

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The Author

I graduated from the University of Manchester in 2009 with an MBChB. I have been a Speciality Trainee doctor in Obstetrics and Gynaecology since 2011. I developed an interest in Urogynaecology early on in my career, loving the patient-centred approach adopted and the positive impact treatments can have on quality of life. This led me to pursue a clinical research fellowship from August 2016- September 2018 at the Warrell Unit, St Mary’s Hospital, Manchester. The research presented in this thesis was conducted during this time and was done alongside clinical and surgical training.

Since completing this research, I have commenced the advanced training skills module (ATSM) in Urogynaecology and Vaginal Surgery on a full-time basis. I hope this research will contribute to the current understanding of decision making for stress urinary incontinence surgery and provide clinicians further insight in to the process from the patient perspective.

The supervisory team

Dr Fiona Reid  
Chief Investigator the Latitude Study; main supervisor

Dr Rachael Powell  
Senior lecturer in Health Psychology; co-supervisor

Professor Richard Edmondson  
Division of cancer sciences; co-supervisor
Chapter 1: Introduction
Chapter 1: Introduction

1.1 Background Information

Stress urinary incontinence (SUI) is a common problem that is thought to affect between 24-27% of women in the UK (1)(2). The exact prevalence of SUI may be higher than this, as many women do not report their symptoms due to embarrassment, a perception that it is a normal part of ageing and fear of being offered surgery (3)(4). It can have a significant impact on the quality of life of women who experience such symptoms, causing substantial changes to activities, lifestyle adaptations and psychological well-being (4).

The treatments available for SUI include conservative treatments, such as physiotherapy, and surgery. Surgical treatments for SUI range from minimally invasive office-based procedures to substantial pelvic surgery. Each of the surgical options have different risks and benefits associated and are known to have different levels of success. For many women, the decision of which surgical procedure to have is preference sensitive, and as such, it is recommended that shared decision making is utilised (5). However, little is known about what factors women consider when making their overall decision of surgical procedure. Concerns have also been raised about the range of surgical treatment choices that are offered and the degree of choice given to women, which may affect their decision making.

SUI is a condition that affects the quality of women’s lives, but not their longevity. Hence, in considering all treatment options, potential side effects are very important. It is not currently known how women measure and compare the risk and benefit profiles of the surgical treatment options for SUI in order to make a treatment decision.

This review will discuss literature concerning SUI, the treatments available and current thought on how patients and clinicians make decisions about the treatment of SUI. It will also discuss the gaps in what is known and how the proposed research project aims to investigate these issues.
1.2 Definition

SUI is a diagnosis that can be defined by both subjective symptomatic terms as well as objective measurement. The symptomatic definition describes SUI in terms of how a patient would describe the problem, as ‘loss of urine on physical exertion or….on sneezing or coughing’ (6).

The objective diagnostic description is defined by Urodynamics (UDS). This is an investigation which involves combination of tests to examine bladder function during the filling and voiding phases. Urodynamic stress incontinence (USI) is defined as ‘the finding of involuntary leakage during filling cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction’ (6). This confirms that the normal mechanism that prevents urine from leaking at times of raised intra-abdominal pressure has failed and excludes other causes for urinary leakage.

1.3 Pathophysiology

The mechanism by which SUI occurs has been extensively researched yet remains incompletely understood. Current mechanisms proposed include:

1. Loss of urethral support
2. Reduced closure pressure of the urethral sphincter (Intrinsic sphincter deficiency)
3. Loss of normal coordination of the reflexive contraction of the striated urethral muscle, levator ani muscle and other pelvic floor support musculature (7).

Loss of urethral support leads to urethral hypermobility. The two most commonly described theories of urethral hypermobility are Delancey’s Hammock theory and Petros and Ulmestens’s Integral theory. The Hammock theory describes how the urethra lies in a hammock created inferiorly by the endopelvic fascia and superior vaginal wall (see figure 1). The endopelvic fascia joins with the arcus tendinous fascia pelvis (ATFP) superio- laterally, which in turn is continuous with the levator ani. At times of increased abdominal pressure, downward pressure is placed on the urethra.
The levator ani muscles contract in response to this pressure, lifting the ATFP and, consequently, the endopelvic fascia and anterior vaginal wall towards the pubic bone. The urethra becomes compressed in between the downward force and the firm inferior endopelvic fascia. Delancey likens it to stopping the flow of water in a hose pipe by standing on it against a pavement (7).

**Figure 1:** Lateral view of urethral support. A= pubic bone; B= urethra; C= vagina; D= Arcus Tendineus Fascia Pelvis (ATFP); E= Levator ani; F= downward force with increased intra-abdominal pressure(8). Reproduced with permission.

The Integral theory proposes that SUI results from laxity of the anterior vaginal wall and its supporting ligaments (9). It suggests that, during active closure of the urethra, the pubococcygeus muscle pulls the anterior vaginal wall upwards towards the pubic bone, whilst the levator plate and longitudinal muscle of the anus pull the bladder neck back and down to cause a ‘kink’ in the urethra. The Integral theory proposes that damage to the connective tissue of the pubourethral ligaments causes an imbalance in these forces, as the pubococcygeus can no longer contract against it. Therefore, the backwards forces over power the anterior force, leading to poor closure and SUI (9).

Intrinsic sphincter deficiency (ISD) is caused by the failure of the mechanical/closure integrity of the urethra (10). The diagnosis of ISD was previously made at UDS, with a Maximum Urethral Closure Pressure (MUCP) of less than 20cmH2O, or a Valsalva Leak Point Pressure (VLPP) of less than 60cmH2O being diagnostic (11) . It previously
had an impact on clinical decision making, with some feeling that urethral bulking agents were the treatment of choice for patients thought to have ISD (12). However, the term has since been disregarded as the previous most popular treatment for SUI, the Mid Urethral Sling (MUS; further discussed below), appeared to have equivalent treatment success for those diagnosed with ISD (12). It is unclear whether, in light of the current MUS pause (13), ISD may return as a consideration in guiding the choice of surgical procedures offered for SUI.

1.4 Epidemiology

Large population studies, such as the EPINCONT study, have shown that SUI is the most common type of incontinence described in premenopausal women (14). In this longitudinal health questionnaire survey study, occurring in 2 phases between 1995-7 (EPINCONT 1) and 2006-8 (EPINCONT 2), all women in a Norwegian county over the age of 20 were invited to participate. Women were initially asked if they had involuntary leakage of urine, in keeping with the International Continence Society (ICS) symptomatic definition of incontinence (6). Further questions were then asked regarding the type of incontinence and severity of incontinence. In the EPINCONT 1 study, a total of 27,936 women responded. Of these, 6876 (25%) reported urinary incontinence. Of these women with incontinence, 50% reported symptoms of SUI, having the highest incidence in the 45-49 years age range (15).

In the EPINCONT 2 study, 21,804 women participated. Of these, 6332 women (29%) reported having urinary incontinence. Of these women with incontinence, 42.9% reported SUI, being reported most commonly in the 35-39 age group (14).

Other, smaller population studies from different countries have also found SUI to be the most commonly reported in these age groups, supporting the stability of this observation and highlighting the scale of the problem (16)(17)(2). It is not clear why SUI rates seem to reduce after the age of 60, with some postulating it could be due to limiting of physical activities and the rise of bladder over activity (18).

Despite being the most common form of incontinence in younger women, many do not report their symptoms or seek help. A 2005 cross sectional postal survey study carried out in Leicestershire demonstrated that only 109 of 717 (15.2%) women
reporting SUI symptoms several times a month had actively sought help from a healthcare professional in the preceding 12 months (19). Factors found to be associated with seeking help were: increasing severity of symptoms, severe impact on quality of life and increasing age. Barriers to seeking help for urinary incontinence have been explored in other studies and include embarrassment, a perception that it is a normal part of ageing, a lack of knowledge of effective treatments and fear of being offered surgery (3)(20). There is clearly more that needs to be done to encourage women with SUI to report their symptoms and to seek help. These results also highlight a general concern over surgical procedures, and more research is needed to fully understand the root cause of this concern in order to provide help for more women with SUI.

1.5 Aetiology

The recognised and potential risk factors for developing SUI include:

- Age
- Pregnancy and Childbirth
- Obesity
- Hysterectomy
- Hormonal factors, e.g menopause
- Smoking (21)

Many of the above factors are modifiable, being open to risk reducing interventions.

Age

As discussed above, SUI appears to be most commonly reported in pre-menopausal women (15)(14). However, ageing does appear to be linked with an increased risk of developing SUI. This may be due to more women becoming pregnant and giving birth as they get older, sustaining damage to the pelvic floor and, consequently, developing urethral hypermobility. It may also be linked with the ageing effect on the urethra itself. A study of 82 nulliparous women aged between 21-70 years investigated the effect of age on urethral function; this showed that the MUCP appeared to decrease with age, which could lead to loss of coaptation and ISD (22).
It has also been shown that the number of urethral striated muscle fibres reduce with age, which could potentially contribute to the risk of subsequent incontinence (23).

**Pregnancy and Childbirth**

It is thought that SUI is experienced by up to 50% of pregnant women and that the rate of persistent symptoms postnatally is high (18). A systematic review of studies examining postpartum urinary incontinence found that the prevalence of SUI, 3 months following delivery, for parous women was 24.6% and 12.6% for primiparous women (24). It also found that women who had a caesarean section had reduced rates of postpartum incontinence (all types). This finding of higher rates of urinary incontinence following a vaginal birth has been demonstrated in longer term studies. A 2008 study by Gyhagen et al surveyed 5118 women 20 years after a single pregnancy episode resulting in either a vaginal birth or a caesarean section. It reported that women who had undergone a vaginal birth appeared to have a higher incidence of all types of urinary incontinence, with SUI being 4.4% higher when compared to the caesarean group. Women in the vaginal birth group also appeared to have higher rates of moderate to severe incontinence (all types) and rated all incontinence as more bothersome (25).

The prevalence of SUI has been shown to increase with increasing parity (14). A 2018 narrative review of the literature on objective measures for pelvic floor dysfunction following vaginal birth reported that the greatest change in bladder neck descent, mobility and urethral pressure occurred following the first birth (26). This may be explained by evidence that a vaginal birth may cause de-innervation injuries to the pudendal nerve, which ultimately supplies the urethra (27). This is postulated to be associated with the observed urethral striated muscle loss, which is involved in the urethral closure mechanism (28).

**Obesity**

Obesity has been found to affect the severity of SUI, with studies reporting a ‘dose-dependent’ relationship between incidence of SUI and increasing Body Mass Index (BMI) (29). It is thought that women with a larger BMI have an increased intra-
abdominal pressure, hence exerting more stress on the pelvic floor (29). However, it is not clear whether it is solely the BMI value or the location of the obesity that is related to the increased risk of SUI (30).

Further analysis of the previously described EPINCONT study showed a 2.4 times increased risk of SUI for women with a BMI of 40 or above than for women with a BMI of less than 25 (31). The prevalence of worldwide obesity is known to be increasing (32) and this may impact the prevalence of SUI in years to come.

**Hysterectomy**

Women undergoing a Hysterectomy have been shown to have an increased risk of developing SUI (33)(34). A 2012 nationwide cohort study showed that women undergoing a vaginal hysterectomy for a pelvic organ prolapse (POP) had the greatest risk of developing SUI. It also reported that women undergoing an abdominal hysterectomy had their chance of undergoing an SUI procedure double in comparison to women who did not require one (35). The authors of this study postulate that this effect may be a consequence of injury to pelvic nerves that ultimately leads to chronic changes in urethral function and incontinence.

**Hormonal factors**

Oestrogen and Progesterone receptors have been identified in the urogenital tract. It is thought that oestrogen increases the urethral closure pressure by increasing the number of periurethral vessels (36). Therefore, the loss of oestrogen around the time of menopause would be thought to increase the risk of developing SUI. This theory corresponds with some studies that show the prevalence of SUI peak around the time of menopause (19). However, this has been disputed by other large population studies, that show an increased prevalence in the pre-menopausal age group (15). There also appears to be no consistent evidence for the benefit of Oestrogen replacement on SUI, and in some cases, systemic replacement of Oestrogen within a hormone replacement therapy (HRT) regime may increase the risk of developing SUI (37)(38). Therefore, further work is required to firmly describe the relationship between SUI and menopausal status.
**Smoking**

Coughing, as a result of smoking, is thought to cause damage to the pelvic floor and supporting structures of the urogenital tract, which in turn is thought to increase the risk of SUI (39). However, there is conflicting evidence concerning the degree of risk. Previous studies have suggested that smokers may be as much as 2.4 times more likely to suffer with SUI (40). However, other studies have not confirmed this finding (41)(31); therefore the link between smoking and SUI is still an area requiring further research.

### 1.6 Effect of SUI on Quality of Life

SUI can have a significant impact on women. A 2006 cross sectional questionnaire study surveyed 506 women in an age range of 24-80 years using validated measures of urinary incontinence and the Psychological General Well-being Index (PGWBI). The PGWBI is a measure of well-being, combining measures of anxiety, depression, positive well-being, self-control, general health, and vitality. Scores are added to give a final score out of 110, which is the score of best achievable well-being. Of the women who reported incontinence, women who had SUI had significantly worse scores on the PGWBI (77.8) when compared to women without incontinence (81.6) (42). There may be many explanations for this, with other questionnaire studies reporting a significant negative impact of SUI on activities, confidence, self-perception and social activities (43).

Sexual function can also be affected by SUI. A prospective questionnaire study surveyed 66 sexually active women with SUI and 95 sexually active women without SUI. Women with SUI had significantly fewer episodes of sexual activity, were more sexually dissatisfied and demonstrated more avoidance behaviour when compared to women without SUI (44). This potentially could have a significant impact on relationships, leading to more distress.
1.7 Clinical Assessment of SUI

There are structured national guidelines available to guide clinicians in their assessment of women with SUI (5). These recommend that an initial medical history should be taken to screen for risk factors of SUI and other pelvic floor problems that may also cause concern. Following this, an abdominal and pelvic examination will usually take place to screen for potential pressure related causes of SUI, such as a pelvic mass or extreme obesity. A digital vaginal examination should be carried out to assess the strength of pelvic floor contraction (45). During examination, SUI may be demonstrated by asking the patient to bear down or cough. A mid-stream sample of urine should be tested to ensure that there is no presence of urinary tract infection (UTI) that could be causing, or worsening, symptoms.

Initial recommended management for women reporting symptoms of SUI includes altering modifiable risk factors, including BMI and smoking. Treatments for other conditions that may contribute to and worsen SUI, such as chronic cough and diabetes, should be optimised. Following this, supervised pelvic floor muscle training (PFMT) exercises are recommended as a first line treatment for all women with symptoms of SUI (45). A 2018 review of PFMT versus no treatment or inactive controls reported that women who underwent PFMT were 8 times more likely to report cure of SUI, and 6 times more likely to report cure of significant improvement in comparison to women in the other groups (46). It also highlighted that objective measures of SUI were improved following PFMT, with those receiving treatment reporting less leakage episodes and having reduced volumes of urine lost during 1-hour pad tests (46). Therefore, it can be surmised that PFMT provides an effective treatment for SUI that is low risk, minimally invasive and suitable for most women presenting with SUI.

If these conservative treatments fail to have a substantial impact upon SUI symptoms, then secondary treatments for SUI can be offered. There has been uncertainty regarding the use of UDS investigation to determine USI prior to proceeding with surgery to treat SUI symptoms, with several randomised trials reporting that outcomes are not significantly affected by proceeding to surgery based on thorough clinical assessment alone (47)(48). The VALUE study was a large
multicentre study that compared the subjective outcomes of women 12 months after surgery for SUI following either evaluation only or evaluation and urodynamic testing. This reported that treatment success rate was 77.2% in the evaluation only group versus 76.9% in the urodynamic testing group, proving non-inferiority of evaluation only (48). Further research also reported that the UDS diagnosis did not significantly affect clinician opinion as to what procedure to perform (49). Therefore, NICE guidance has updated its recommendation in line with these findings, now meaning that UDS are not always required for women with uncomplicated SUI diagnosed on detailed clinical assessment prior to offering surgery (5).

1.8 Surgical treatments for SUI

Surgical treatments for SUI include:

- Urethral bulking agents
- Mid Urethral Sling (MUS)
- Colposuspension, which can be performed via an open or laparoscopic approach
- Autologous fascial sling procedure (AFSP)

Historically, other procedures performed included Needle Suspension and Anterior Urethral Buttressing. These procedures have been superseded by current techniques, which offer superior success rates with minimally invasive insertion methods. Therefore, they are no longer recommended for the treatment of SUI (45)(50). Ideas regarding the objective of surgery for SUI have also changed. It was originally thought that the bladder neck contributed the most to continence and that elevation of this area above the levator plate would restore continence. However, it is now thought that the mid urethra is the most important area contributing to continence. Therefore, procedures are now aimed at elevating and supporting this region (51).

Each of the operations available will be described in turn below.

_Urethral bulking agents_
Urethral bulking agents are substances that can be injected, by either a transurethral or para-urethral approach, into the submucosa of the urethra. This is commonly done under direct visualisation, using a urethroscope, to ensure optimum placement of the agent and to observe a good bulking effect (see figure 2). There are devices that inject without direct visualisation of the urethra, but these are infrequently used in current practice.

The mechanism by which Urethral Bulking Agents are thought to work is twofold; firstly, the increased volume of the urethral wall directly increases the urethral closure pressure and coaptation, and secondly, the increased bulk stretches the circular muscle layers of the urethra. This is thought to cause urethral muscular contraction strength to be greater and to be responsible for the observed increased abdominal leak point pressures following treatment (52).

**Figure 2:** Injection of Urethral Bulking Agent.

There are several substances that have been used for bulking. They have been developed to try to satisfy the ideal criteria for an ideal bulking agent, which includes a durable substance that is non-immunoallergic and creates as little inflammatory reaction as possible (53). Table 2 summarises the available substances commonly used
<table>
<thead>
<tr>
<th>Brand name of Bulking Agent</th>
<th>Bulking Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulkamid™</td>
<td>2.5% polyacrylamide and 97.5% hydrogel</td>
</tr>
<tr>
<td>Macroplastique™</td>
<td>Poly-dimethyl-siloxane particles within a polyvinylpyrrolidone hydrogel</td>
</tr>
<tr>
<td>Contigen™</td>
<td>Glutaraldehyde cross-linked bovine collagen in phosphate buffered physiological saline</td>
</tr>
<tr>
<td>Coaptite™</td>
<td>Calcium hydroxylapatite in an aqueous gel carrier</td>
</tr>
<tr>
<td>Durasphere™</td>
<td>Carbon-coated zirconium beads in a polysaccharide hydrogel</td>
</tr>
</tbody>
</table>

**Table 1:** Bulking agent brand names with corresponding constituent substance (53).

In the 2013 NICE guidance for management of urinary incontinence in women, carbon beads (Durasphere), silicone (Macroplastique) or hyaluronic/dextran copolymer (which, has subsequently been removed from the market due to injection site complications (53)) were the only bulking agents recommended (45). However, the updated version of this guidance published in 2019 does not give recommendation as to what material should be offered (5).

The main risks associated with bulking agents are failure, need for repeat injection, urinary tract infection (UTI), urinary retention and pain, either during the procedure or on passing urine following the procedure (54). Very rarely, peri-urethral abscesses (following Bulkamid and Durasphere) and suburethral mass formation (following Macroplastique) have been reported (55)(56). To reduce the risk of particle migration, the majority of bulking agents contain particles that are greater than 80 micrometres in diameter (53).

Bulking agents can be injected as an outpatient procedure, needing only local anaesthetic. This poses a great advantage for women who wish to have a minimally invasive procedure, those that do not wish a period of convalescence and those that
are too medically unfit for a more invasive surgical option (57). A questionnaire study of 131 women with SUI has reported that one of the reasons women reported a delay in seeking help for their SUI symptoms is the fear of being offered surgery (4). Therefore, due to their minimally invasive nature, urethral bulking agents may prove to be a more acceptable choice for women who are apprehensive about surgery.

This study of choice of surgical procedure for SUI will include Bulkamid as the urethral bulking agent. This is because it is the common bulking agent used across the Hospital Trusts that have agreed to participate in the research.

Bulkamid is a polyacrylamide hydrogel that consists of 2.5% polyacrylamide and 97.5% water based gel (58). There has been much interest in this bulking agent due to its long-standing safety record in aesthetic surgery prior to its use for SUI (59). The longest published follow up of women following injection of Bulkamid for treatment of SUI was presented by Mouritsen in 2014, which followed up 24 women 8-9 years following their original treatment. Of these, 10 remained cured or significantly improved (42%) and of 11 women who underwent pelvic ultrasound scan, all had visible deposits of Bulkamid, supporting its durability (60). It also found that, of the 24 women followed up, 7 had undergone subsequent treatment with a MUS. These women remained continent and satisfied at the 8 year follow up, suggesting that Bulkamid did not affect the efficacy of subsequent MUS. However, it must be noted that the numbers within this observational study are very small, with further longer-term studies needed to support these original findings.

A 2010 multi-centre study published follow up data of women 24 months following primary treatment with Bulkamid. This included 116 women who were recruited from 10 centres across 5 countries. It showed a non-statistically significant drop in the subjective cure rate between 12 months (67%) to 24 months (64%), with 35% of women requiring a repeat injection to give this effect (61). Quality of life scores, as measured by a visual analogue scale, were also found to be significantly improved at both 12- and 24-months following treatment with Bulkamid.
At present, there are limited data about any longer term follow up outcomes, or of the outcomes of women who have undergone repeat injection. A systematic review of Bulkamid for the treatment of SUI reviewed 8 studies, inclusive of 767 women. This reported that Bulkamid appeared to significantly reduce the number of incontinence episodes per 24-hour period and the amount of leakage in millilitres/24-hour period. It also reported that 186 women required a repeat injection with Bulkamid (24.3%), but that only 1 study reported the outcome of these women at the 12-month follow up point (62). This study reported a subjective success rate (measured as a self-report of responding “cured” or “significantly improved) of 57% for women having a second dose of Bulkamid (59). Whilst the reports of short and mid-term apparent success in both objective and subjective measures are encouraging, it must be acknowledged that many studies are inclusive of relatively small numbers of women.

Bulkamid has been compared to MUS, in the form of retropubic TVT, in a 2019 published randomised control trial. A total of 208 women were randomised to either MUS or Bulkamid, with 101 in the MUS arm and 107 in the Bulkamid arm. The exclusion criteria ensured that women included in both groups suffered from primary SUI and that the characteristics of both patient groups were similar. The primary outcome measure was patient satisfaction 12 months following a procedure, with satisfaction being set as a score of 80 or more out of a possible maximum of 100 on a visual analogue scale. The secondary outcome measures focused on effectiveness and complication rates of the procedures. This study reported that Bulkamid was inferior to MUS in terms of patient satisfaction, with 59.8% of women meeting the study set definition of success in comparison to 95% of the MUS group. It also reported that objective success following up to 2 doses of Bulkamid was reduced in comparison to MUS in objective tests measured by cough tests and pad tests (66.4% vs 95% and 63.6% vs 95% respectively) (63). However, despite this reduced rate of satisfaction and objective cure, 91.6% of the women who received treatment with Bulkamid considered themselves cured or improved 12 months following the procedure, with only 5 women out of the 107 going on to have a MUS. This suggests that patient perception of treatment success is complex,
not necessarily having a linear relationship with objective cure and satisfaction. It is also unclear as to what the difference in individualised satisfaction there may be with a given treatment of a score less than 80 than those who score over this threshold and if indeed some women considered it satisfactory treatment. Further work is needed to better understand this before firm conclusions can be drawn.

**Mid Urethral sling (MUS)**

Since its introduction in the mid-1990s, Mid Urethral sling (MUS) has become the most common surgical procedure performed for the treatment of SUI in the UK (64). It is a minimally invasive procedure that has been shown to be effective over a long term period, with NICE advising that 56-85% women are continent 10 years following a retropubic vaginal tape procedure (45). It has also been shown to be more cost effective when compared to the previous gold standard procedure open Colposuspension (65).

This procedure involves the placement of a type 1 polypropylene macroporous tape under the mid urethra to provide active resistance against the descent of the urethra during times of increased intra-abdominal pressure. This causes dynamic obstruction of the urethra, preventing the leaking of urine. Type 1 macroporous polypropylene tape (also referred to as mesh) was used as it was thought to have the best safety profile and allowed for in-growth of host tissue (66) (67).

The most common method of insertion is via a retropubic approach, also known as tension free vaginal tape (TVT). A vertical incision is performed in the vagina at the level of the mid urethra and bilateral tracts are dissected to the pubic rami. Using curved trocars, the tape is passed behind the pubis bilaterally and across the retropubic space, through the rectus sheath to exit through 2 small suprapubic skin incisions (see figure 3)(66).
In comparison to this, the trans-obturator approach places the tape under the mid urethra, passing through the obturator foramen bilaterally, through obturator internus and externus and potentially through the 4 adductor muscles of the hip (adductor longus, adductor brevis, adductor magnus and gracilis), to exit via 2 small incisions in the groin. This can be performed as an ‘out to in’ approach (trans-obturator tape, TOT) or as an ‘in to out’ approach (tension free vaginal obturator tape, TVT-O) (see figure 4) (50).

Figure 3: Retropubic TVT tape.

Figure 4: TOT tape placement (68).
MUS procedures are commonly performed under general or regional anaesthetic, although it was originally described by Ulmsten as a procedure performed under local anaesthetic (69). It has general risks of surgery associated, such as bleeding, infection, anaesthetic risk and the risk of developing a deep vein thrombosis (DVT). The specific risks to the procedure include failure to fully treat SUI symptoms, voiding dysfunction and the need to self-catheterise, development of overactive bladder symptoms, short term and long term pain, dyspareunia and mesh exposure (70).

A 2015 Cochrane review of MUS for the treatment of SUI concluded that MUS was a highly effective treatment of SUI in the short and medium term, irrespective of the method of insertion (71). There are, however, different risk profiles for each method of insertion. A 2010 large multicentre trial investigating retropubic insertion versus trans-obturator insertion found that certain adverse events, such as bladder injury, urinary tract infection and voiding dysfunction were higher in the TVT group. However, TOT was associated with a significantly higher rate of neurological sequelae, such as weakness in the upper leg (72).

Concerns have been raised about the safety profile of mesh used in these procedures. The US Food and Drug Administration Authority (FDA) originally issued a public health notification in 2008, to alert clinicians of the adverse events in relation to the use of mesh, including events of mesh exposure and pain. The outcomes of women receiving mesh for both SUI procedures and for treatment of POP were monitored by the FDA, and an official safety communication was published in 2011. This stated that mesh exposures were ‘not rare’, and that consequences, such as chronic pain, could be life-altering for those affected (73). However, this review commented on literature in relation to complications following mesh inserted for the treatment of POP and did not give further comment to complications related to mesh inserted for treatment of SUI, despite commenting that 1371 adverse events out of the total 3979 were secondary to SUI treatment. In the UK, public concern regarding mesh complications was increasing, with women who had been affected by mesh complications launching legal cases. This led to large scale reviews on the use of mesh by the Medicines and Healthcare Products
Regulatory Agency (MHRA), NHS Scotland and NHS England. The conclusions of these reviews were similar, supporting the use of mesh for SUI surgery, with significant evidence of benefit that can be weighed against the apparent risk (74)(75)(76). However, there was recognition of the lack of long-term complication data, and this has been re-iterated in the latest guidance from the National Institute for Health and Care Excellence (NICE) (5).

MUS procedures are currently on a nationwide pause in the UK, despite there being no significant change in the evidence base in favour of their use (13). Conditions have been set out that must be met before their re-introduction, but despite significant work towards meeting these and the publication of the latest NICE guidance, there has been no formal report. Therefore, the future of MUS as a treatment for SUI remains uncertain.

**Colposuspension**

Colposuspensions are performed under a general anaesthetic and involve the insertion of delayed dissolvable sutures or non-absorbable sutures from the lateral fornices of the vagina and paravaginal tissues to the ipsilateral iliopectineal ligament (Cooper's ligament) (77). This elevates the vagina, in turn elevating the urethra and bladder neck (see figure 5). It can be performed via both an open and laparoscopic approach. The open procedure requires a low transverse suprapubic incision, with dissection required between the rectus sheath superiorly and peritoneum posteriorly, to reach the retropubic space. Laparoscopically, sutures are placed in the same way as in the open procedure to lift the vagina and urethra.
A 2016 Cochrane systematic review of open colposuspension, inclusive of 55 trials including 5417 women, reported that the overall success rate was between 68.9-88% and this effect was maintained over 5 years (78). Comparing open to laparoscopic colposuspension, there was not enough evidence to conclude which was better in terms of subjective or objective outcome, but hospital stay was less for laparoscopic procedures (78). This is in contradiction to a 2006 Cochrane review of laparoscopic colposuspension, which reported that there appeared to be poorer objective outcomes for the laparoscopic approach in the short and medium term, although this may have been related to the relative inexperience of the operating surgeons with the procedure, with subsequent progression over the following 10 years (79).

Colposuspensions are recognised as having specific risks. These include the risk of POP, specifically rectocele, in the long term. This is currently quoted as a 14% risk on the IUGA colposuspension information leaflet (80), but up to 25% is quoted on the NICE patient decision aid (81). Other studies suggest that the occurrence of POP after colposuspension may be even higher. A prospective cohort study followed the
progress of 77 women after having a colposuspension. At 7-8 years post-operatively, a total of 65 were available for assessment. Of these, 29 (44%) had symptomatic prolapse, and a further 29 (44%) had asymptomatic prolapse (82).

Other risks include the risk of voiding dysfunction, visceral damage to organs, chronic pain and dyspareunia, all being quoted in the NICE patient decision aid as up to a 10% risk (81). In this decision aid, all the risks of the above are combined with the risks of these events occurring after MUS and AFSP; therefore, it is difficult for isolated risks of each procedure to be presented individually to women making a choice of SUI surgery.

**Autologous fascial sling procedure (AFSP)**

This procedure involves the creation of a supportive pubovaginal sling using the patient’s own tissue. The most common tissue to be used is that of the rectus sheath, and this has been found to be superior in comparison to biological xenograft materials (83).

There are 2 methods of AFSP; the traditional Aldridge procedure and the ‘sling on a string’ technique. Both procedures begin with a transverse lower abdominal incision down to the level of the rectus sheath. Bilateral transverse incisions are made in the rectus sheath in line with the external oblique fibres to create 2 strips of mobilised sheath (Aldridge technique) or to excise a complete strip of sheath (‘sling on a string’ technique). In the Aldridge technique, the sheath flaps are left attached in the mid line, whilst the mobilised lateral ends are passed inferiorly through the retropubic space to be sutured underneath the urethra (51). For the sling on a string technique, the extracted fascial strip is mounted on non-absorbable sutures at each end that are then passed through the retropubic space and tied to the rectus sheath, suspending the fascial strip from the rectus sheath like a hammock (see figure 6) (84).

Operative risks associated with AFSP include hernia, haemorrhage, haematoma formation, urinary retention and obstructed voiding. These complication rates have been found to be similar between the two techniques. However, the operating time
and amount of sheath harvested have been found to be significantly less with the sling on a string technique (84).

**Figure 6:** AFSP procedure. Reproduced with permission from Albo et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence N Engl J Med 2007; 356:2143-2155, Copyright Massachusetts Medical Society.

A large multicentre randomised control trial inclusive of 655 women published by Albo et al in 2007 compared Burch (open) colposuspension AFSP. This showed that at 24 months, women had significantly better success rates following AFSP compared to open colposuspension. However, rates of morbidity, secondary to UTI and urinary retention, were significantly higher in the AFSP group (85).

The numbers of AFSP procedures performed in the UK reduced with the popularity of the MUS (64). However, following the controversy surrounding mesh and NICE recommending it as a first line procedure from 2013, there appears to have been an increase in its use (86).
1.9 What is known about the choice of SUI procedures?

As discussed above, the procedures currently available for SUI have varying success rates and present different risks to patients. NICE have recommended that colposuspension, AFSP and MUS are the recommended first line procedures to be offered, based on their superior success rates in comparison to urethral bulking agents. However, bulking agents can be selected if the other procedures are not acceptable to patients or the other procedures are not suitable, but NICE does not specify in what way patients may be deemed unsuitable (5).

The decision of which surgical procedure to choose appears to be preference-sensitive. The definition of this type of decision has been forwarded by Wennberg (87) and is as follows:

‘A preference-sensitive condition is one for which at least two valid, alternative treatment strategies are available. Since the risks and benefits of the options often differ, the choice of treatment involves trade-offs; therefore, the choice should depend on informed patients making decisions on the basis of their preferences and values.’

In situations where a preference-sensitive decision is to be made, it is recommended that shared decision making be utilised (88). Shared decision making is defined as ‘a process in which healthcare professionals and patients work together to select tests, treatments, management or support packages, based on clinical evidence and the patient’s informed preferences. It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and a system for recording and implementing patients’ informed preferences’ (88). This decision-making model differs from the traditional paternalistic model, whereby clinicians are the dominant decision-makers and patients play a more passive role. However, paternalism is not simply limited to clinicians dictating treatments to patients; more subtle forms have been described, encompassing selective information giving and encouraging patients to consent to what clinicians feel is best (89).
Women who had been affected by mesh complications raised concerns that they had not been adequately involved in the decision of which SUI surgery to have. The Mesh Oversight interim report published in 2015 stated that patient members strongly criticised the consent process for SUI procedures, explaining they felt they were not given a choice, enough time to consider surgery or enough accurate information about the potential long term consequences of mesh to make an informed decision (90). This suggests there may have been a limited choice offered for the treatment of SUI and that mesh free alternatives were either not discussed or not offered. This may have led to a perception that the consent that was given for the MUS may not have been informed for some women.

Informed consent is a fundamental right in healthcare. This is reflected by its inclusion in the General Medical Council’s (GMC) ‘Duties of a Doctor’, which states that doctors must allow patients to be involved in their treatment decisions and that consent must be assured prior to any investigation or treatment commencing (91). Patient involvement in treatment has also been a priority set out by the Government, with patient centred care being at the centre of healthcare policy (92) with the ultimate aim being ‘no decision about me without me’ (93).

The importance of Informed consent has also been highlighted through the 2014 high court ruling of Montgomery vs Lanarkshire Health Board. This case has led to a change in the law, with doctors now being legally required to ‘take reasonable care to ensure that the patient is aware of any material risks involved in any recommended medical treatment, and of any reasonable alternative or variant treatments’ (94).

Applying this principle to surgery for SUI, patients must be offered a choice, be given relevant information on alternatives in a format they can understand and be given time to fully contemplate their treatment decision.

Patient decision aids (PDAs) have been developed to support decision making around SUI surgery. The use of decision aids versus standard care has been found to improve patient knowledge of their options, reduce decisional conflict, improve participation in decision making and make decisions that are more in line with
individual values (95). The decision aids currently published for SUI surgery all aim to encourage users to rate and identify key values that could be influential in decision making and constructing preferences (81)(96)(97). However, the values included in these PDAs were all generated by clinicians and were subsequently checked by lay members of relevant committees or tested by volunteers. This may mean there is bias within the PDAs with a view to include information that clinicians feel is important, rather than including values that have been generated by women themselves.

There is limited evidence regarding what women consider when deciding on a SUI procedure and this will be further discussed below.

**Choice of procedure: Patient perspective**

There is some evidence to suggest that women may favour less invasive options for treatment of SUI. In a 2003 study by Robinson et al, 100 healthy women who attended a tertiary unit for UDS were asked a theoretical question about what treatment they would find acceptable for SUI. The options given and results are shown in table 2.

The surgical options represented Burch (open) colposuspension (major operation), TVT (minor operation) and urethral bulking agent (clinic procedure) respectively. Of the women who responded to these questions, the most popular option was the urethral bulking agent (98). The same 100 women were surveyed to review their expectations of the outcome of treatment. Forty three percent of women aimed to have a good improvement so that the symptoms no longer interfered with their lives, in contrast to 17% who expected complete cure. This suggests that some women are prepared to make certain trade-offs regarding how effective a procedure is with how invasive a procedure is, and this may be linked to the expectation of symptomatic improvement rather than complete cure. However, it must be taken in to account that this is a hypothetical study, with only 24% of the women surveyed being diagnosed with USI and 15% having mixed incontinence (although the predominant symptom was not reported). Therefore, this theory had not been tested in real-life clinical practice.
<table>
<thead>
<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic floor exercises for 6 months</td>
<td>60%</td>
<td>26%</td>
</tr>
<tr>
<td>Pelvic floor exercises for life</td>
<td>41%</td>
<td>44%</td>
</tr>
<tr>
<td>Regular drugs for life</td>
<td>14%</td>
<td>69%</td>
</tr>
<tr>
<td>Drugs to take as needed</td>
<td>51%</td>
<td>32%</td>
</tr>
<tr>
<td>Major operation (85% cure, 2% risk of self-</td>
<td>23%</td>
<td>57%</td>
</tr>
<tr>
<td>catheterisation)</td>
<td></td>
<td></td>
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<tr>
<td>Minor operation (85% cure, 2% risk of self-</td>
<td>38%</td>
<td>43%</td>
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<tr>
<td>catheterisation)</td>
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<tr>
<td>Clinic procedure (60% improvement with no long-</td>
<td>57%</td>
<td>24%</td>
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<tr>
<td>term risks)</td>
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A survey study undertaken between 2002 and 2004 across 3 hospitals asked 104 women with USI what treatment they would choose and the main reason for their choice after reading information leaflets. Treatment options included were PFMT, TVT and open colposuspension, with these options being presented in the form of information leaflets detailing risks. PFMT was the preferred option by 65%, with 91% of these women accepting that PFMT produced a gradual response over time and 56% reporting they were too concerned about the risks of surgery (99). This supports the theory that some women will accept a treatment with a lower success rate to avoid surgery and that the thought of being offered surgery may negatively impact help seeking behaviour. However, it must be taken in to account that the information leaflets were generally presented in the order of PFMT followed by TVT then open colposuspension. Women were, therefore, presented with the options with the emphasis being on increasing risks, rather than being positively framed with
the greatest success rate first. It is unclear whether this may have had any influence on the findings of this study.

A further hypothetical exploratory study asked 58 women referred to a Urogynaecology clinic with some form of urinary incontinence ‘if it was determined that you may benefit from either surgical therapy, which is approximately 90% successful but requires post-operative convalescence, or an injectable therapy with a minimal post-operative convalescence, what is the lowest success rate that you would accept and still try injectable therapy with an unspecified agent?’ Women were then given options in increments of 10% blocks. The mean lowest acceptable rate women were willing to accept for injectable therapy was 34% (range 10%-90%) (100). Although it was not found to be statistically significant, there was a suggestion that older women were more open to lower success rates (mean lowest acceptable success rate in the 80 years and above category was 22%, compared to 39% for the under 60s). It may be that women in the older age groups had different expectations and goals of treatment, resulting in the lower acceptability levels.

There was only 1 study that found age to be positively correlated with the likelihood to accept an office based procedure, such as a bulking agent, in preference to other surgical procedures (101). In this 2010 study, 100 women with SUI presenting to a single hospital were given a questionnaire to rate their distress from SUI symptoms, quality of life and asked them to choose one of 4 possible treatment options. The surgical treatment options offered and associated risks were the same as those used in the 2003 Robinson study, representing Burch colposuspension, TVT and urethral bulking (98). Multivariate analysis was used to test correlations between treatment choice, age, symptom severity and quality of life. This study found that increasing severity and younger age were positively correlated with the choice of major surgery, whereas older age was associated with an increased likelihood of choosing a urethral bulking agent (101). This study was not hypothetical, with all women included suffering from SUI and going on to be counselled regarding treatment choices. However, women filled out the treatment questionnaire prior to their UDS and counselling with a doctor, with 34% changing to a different treatment after this. The finding of urethral hypermobility on clinical examination was associated with an
increased chance of the women being advised to undergo MUS, and women choosing urethral bulking agents or medical treatment with a VLPP < 60cmH20 (diagnostic of ISD) were advised to undergo a pubovaginal sling. This is an example of practice in 1 unit. It highlights that women were initially offered choice, but this was later modified in conjunction with a recommendation by the doctor. It is unclear whether this recommendation was paternalistic in nature or part of a shared decision-making process and raises questions regarding what surgical choices for SUI are being offered on a wider scale and how much influence clinicians have on the overall treatment decision.

The above studies suggest that women may prefer minimally invasive procedures, accepting lower success rates in exchange for reduced risks. This finding was not supported by a qualitative study by Basu et al. This 2010 study utilised qualitative semi-structured interviews with 16 women who had SUI and/or POP to investigate factors that were considered important when making treatment decisions. This study reported that women with SUI seemed to base much of their treatment decisions on success of the discussed procedures, how much their symptoms affected their quality of life, and they did not appear to often discuss the issue of complications (102). Some of these findings were also found in a 2018 study by Casteleijn et al, which also utilised qualitative semi-structured interviews with 20 women with primary SUI to investigate the treatment decision factors that determined preference between a urethral bulking agent or MUS. They reported that symptom severity was influential to the decision, as well as procedural factors such as perceived invasiveness and efficacy. They also reported that the advice received from clinicians was a decisional factor, being particularly valued by older and indecisive women (103). This highlights the potential influence clinicians can have on the decision of surgical procedure for SUI.

**Choice of procedure: Clinician perspective**

As discussed above, there is clear national guidance to support clinicians in what procedures to offer women who have SUI. However, the guidance leaves some decision-making regarding procedures to the clinician, stating that if the
recommended surgical options are not deemed suitable for a patient then urethral bulking agents can be considered (5). What factors would make a woman unsuitable for certain procedures are not discussed.

Certain characteristics have been investigated in relation to effectiveness of SUI surgery, such as BMI (104)(105), age (106)(107) and the effect of child bearing post SUI surgery (108). These reviews mainly focus on the impact on efficacy of MUS, and mostly include observational studies. To the authors knowledge there are no studies confirming what factors are considered by clinicians and how this may relate to their offering of surgical procedures for primary SUI.

1.10 Conclusion and aims of the research

SUI is a common condition that can have a significant impact on the lives of women affected by it. There are 4 main procedures available for SUI, each with differing levels of success and risk associated. The decision of which operation to choose is deemed to be preference-sensitive, but there are limited data regarding what factors women consider when making their decision that would inform their preferences. It is the hope of the research team that important factors identified by women themselves may help inform the future development of decision aid materials that improve clinical care.

Following the controversy with polypropylene mesh, clinical decision-making surrounding SUI procedures has come under intense scrutiny, as concerns were raised that some women were not receiving information on all treatment options. However, national guidance recognises that all SUI surgeries may not be appropriate for all women but does not give any recommendations about what may make a patient suitable for one type of procedure but not another. There are no studies detailing what factors clinicians consider when deciding on what procedures to offer women with primary SUI.

This research is, therefore, important to further investigate these important questions that have substantial impacts on current clinical practice. It will be the first study to formally assess factors considered important by clinicians providing surgical
procedures for SUI, providing a further insight into the decision making process as a whole. It will also investigate choice at a vital time of change in SUI surgery, with potential preferences shifting in both women and clinicians due to the mesh controversy.

Research Aims

The aims of this research were to investigate:

1. Factors that influence patient choice of surgical treatment for primary stress urinary incontinence, and;
2. Factors that influence clinicians’ choice of surgical options for primary stress urinary incontinence.

To best explore these, qualitative methods were used. This will be further discussed in Chapter 2.
Chapter 2: Methodology
Chapter 2: Methodology

2.1 Introduction

This study utilised qualitative methods to explore issues surrounding influential factors impacting on the choice of primary surgery for SUI from both a patient and clinician perspective. At present, little is known about what specific factors are considered by women making this decision, and as such a qualitative approach was chosen to explore these issues in greater detail.

This chapter will discuss qualitative methodological issues, as well as the study method.

2.2 Qualitative Research Methodology

Several definitions of qualitative research have been presented:

‘Qualitative research is a form of social enquiry that focuses on the way people interpret and make sense of their experiences and the world in which they live.’ (109)

‘At its core, qualitative research is about capturing some aspect of the social or psychological world. It records the messiness of real life, puts an organising framework around it and interprets it in some way.’ (110)

‘Qualitative research methods are strategies for the systematic collection, organisation, and interpretation of textural material obtained from talk or observation, which allow for the exploration of social events as experienced by individuals in their natural context.’ (111)

From these definitions it can be surmised that qualitative research is concerned with the experiences of individuals and how they experience the world. This is a different paradigm to that of quantitative research, which commonly aims to test a hypothesis to obtain a single reproducible answer. Braun and Clarke state that qualitative research ‘tends not to assume one correct version of reality or knowledge’ (110). Therefore, qualitative research is inherently subjective, and the context of the research is important to interpretation. This study will investigate the real-life
choices made by women choosing a surgical procedure for SUI and the choices made
by the clinicians treating them. As explained in Chapter 1, there is little known about
what factors affect the choice from the patient and clinician perspective. Therefore,
by choosing a qualitative approach to the research question, the research team
aimed to provide in depth explanations of what issues are considered by both
groups. An inductive approach was therefore also applicable to the research
questions.

Qualitative research recognises the link between the researcher and the research
itself, with choices made by researchers ultimately affecting the research outcome.
Savin-Baden and Howell Major describe 5 ‘essential choice moments’ in qualitative
research design that must be addressed to ensure reliability in research findings
(112). These essential choice moments include:

1. Inhabiting a position
2. Framing the Study
3. Using a research approach
4. Collecting data
5. Working with data

The study was designed by addressing these issues in turn. The first of the choice
moments is particularly pertinent to a discussion of qualitative methodology, and so
is further discussed below.

2.2.1 Inhabiting a position

Qualitative researchers should be aware of their world view and the effect it may
have on the research (112). The positions the above authors prompt researchers to
define are their philosophical and personal stances, as well as provide a reflexivity
statement.

*Philosophical stance*

A philosophical stance is underpinned by a researcher’s personal views on the nature
of reality (ontological assumptions) and the nature of knowledge (epistemological
assumptions). These assumptions help to inform researchers of an appropriate qualitative methodology, which in turn ally with certain philosophies.

As described above, qualitative methodologies differ significantly from quantitative methodologies. Quantitative research is commonly underpinned by a realist ontological position, assuming one common ‘truth’ that can be known. It is also commonly associated with a positivist epistemological position, assuming a straightforward relationship between the world and an observer, and so the one common ‘truth’ can be accessed by appropriate scientific methods by limiting variables and removing bias (110).

Due to my background as a doctor, I do relate to aspects of the realist assumption, and use some of these ideals in my daily practice, using evidence-based medicine in order to choose treatments that have been shown, through quantitative methods, to be the most appropriate and efficacious for my patients. However, in relation to reality, I do not fully agree that there is a ‘one size fits all’ truth. I most relate to the critical realist position, acknowledging there is a degree of authenticity to a one true reality experienced by all, but that the knowledge of it is only partially accessible because knowledge is socially influenced and knowledge can be dependent upon the context in which it is created and interpreted (110)(113). In terms of this research, this means that I accept that participants will provide different responses, and this will reflect their realities that are based upon their individual backgrounds and beliefs in relation to the research question. However, I am of the belief that there should be valid commonalities within the shared experience of the same phenomena of choosing a surgical procedure that can contribute to meaningful findings that are applicable to clinical practice.

These beliefs fit with many qualitative methodologies, but as a new qualitative researcher, I found the pragmatic paradigm the most applicable to me and this research study. The pragmatic paradigm is not aligned with any particular research methodology, giving flexibility so that the most appropriate method can be used to answer the research question (112). This research philosophy has been described as different from others in terms of its aims:
‘Rather than having a goal of thick description (such as ethnography), theory development (grounded theory) or interpretive understanding of experience (phenomenology), pragmatic qualitative research aims for a description of an experience or event as interpreted by the researcher.’ (112)

**Personal Stance**

Alongside my role as a clinical researcher, I am a registrar in Obstetrics and Gynaecology with a specialist interest in Urogynaecology. As part of my training I have been able to move between hospitals and work for different consultants and have observed variation in offering SUI procedures. In some units, women with SUI were offered 1 procedure and alternatives were not discussed. Up to the commencement of this research (2016), I understood this to be routine practice and had limited personal knowledge of the alternative operations available.

I was the main researcher for this study and main investigator, collecting the data and interpreting it. I was supervised by 3 people, all of which were experienced with both qualitative and quantitative methods. Two of the supervisors had dual roles as clinicians and academics, whilst my remaining supervisor was a pure academic. This ensured that I received support from supervisors who understood the clinical side to the data whilst a critical eye was kept on the methods and analysis.

Simultaneously with this study taking place, there was significant and mounting media coverage of potential complications associated with polypropylene mesh. As a clinician offering options for SUI treatment, I was noticing more patients becoming worried about having a MUS and wanting an alternative. I therefore had an idea I might find these ideas prominently in the research. Other than the media influences, I was not sure as to other considerations patients may consider in making their decisions. Therefore, I felt that my approach was still inductive. From a clinician perspective, I was not sure as to why there was such differing patterns of option offering; therefore, I feel I entered into this research relatively open minded to what I would find.

As a doctor I am scientifically minded and like to look for patterns in any data. I like to look for causes and effects and feel that this underlying inquisitiveness provided
a sound starting point for my qualitative enquiry. I ensured that during all the interviews I used open questions and questioning, ensuring that I approached the research as a researcher first, and aimed to observe impartially. Importantly, I introduced myself as a research doctor and made it clear that I was discussing the research and not my own opinions or thoughts about various treatments.

**Reflexivity**

I trained in Medicine in the early 2000s, which was in the post paternalism era of medical decision making. I remember lectures on shared decision making, learning that the patient should always be the decision maker for any treatment. This stayed with me throughout my medical career, and I have always been very keen to empower patients to make independent decisions about their care. However, as I have progressed through my training, I have come to realise that it is not quite so simple; what should be done for patients that make unwise decisions, or how should decisions be made for those unable to decide? I have also observed during my career that there are consultants I have worked for who have remained paternalistic at heart, and similarly there have been patients that did not want to make an independent-decision and would rather doctors decide for them. I understand and accept that decision making in healthcare is not perfect and that multiple decision-making models may be at play, all being appropriate in different situations. However, I strongly believe that, where possible, patients should be at the centre of their own treatment decision and they should have access to all relevant information and applicable options. I understood at the commencement of this research that this belief may not be the same as those of the participants. I found keeping reflective notes as part of my field notes helpful in documenting where there were conflicting ideas. I am confident that by keeping to my role as a researcher and observer I did not influence the outcome of the interviews or the expression of thoughts and views by participants.

When interviewing clinicians, I was aware that I had an insider perspective, understanding SUI surgeries and being able to easily discuss the issues involved when deciding on procedures. I had also worked for some of the clinician participants, which helped because they were already at ease with me. However, it
also may have set up a power imbalance during the interviews, with the consultants knowing that I am not as senior as them in my training and feeling that I might be questioning their rationale. To avoid this as much as possible I explained that I would use a semi-structured topic guide and that all clinicians were being asked questions around the same topics. However, meeting them in a different role, as a researcher and not their trainee, may also have created an imbalance in that I would have control over interpretation and presentation of their data. This may have influenced how open some clinicians felt they could be with me.

When interviewing patient participants, I was aware that my being a doctor may create a barrier to frank and open discussion. I ensured that I introduced myself as a researcher rather than a doctor to reinforce this as my role and I established an open rapport before commencing any interviews to try to put them at ease. I felt that being a woman helped with this openness and honesty, as from my clinical experience, large numbers of patients comment on how they are relieved to speak to another woman about their symptoms. Despite trying to present myself as a researcher rather than a doctor, I did recognise that this may still have impacted on how open some of the patients may have been in their answers and this is something that I bore in mind during my analysis. I also recognised that, whilst actively trying to remain in my researcher role, I would never be able to fully ignore my inner instinct as a doctor who regularly discusses SUI procedures with women. This, in combination with being unblinded about which procedure each woman chose, may have affected my analysis of the interview data.

2.3 Study method

Choice of SUI surgery was chosen as the research topic following general observations by members of the research team that the surgical options offered were changing and the procedures becoming unacceptable to patients also appeared to be changing. There was limited knowledge of what influenced the choice of SUI surgery from a patient perspective, and the research team wished to better understand these to help in future clinical practice. In thinking about how
decisions were made, it was thought that the clinicians offering choice were also involved. Therefore, the clinician arm of the interview study was included.

2.3.1 Design

**Participant Selection: The Latitude Study**

Participants for this study came from a larger study call Latitude. This study was a multi-centre observational study of patient choice and of the long-term effectiveness of the urethral bulking agent, Bulkamid, and its effect on subsequent TVT. There were 2 arms to the study; firstly, women opting to have a Bulkamid procedure were followed up at set time points to measure ongoing effectiveness of the procedure (called the ‘Latitude 1’ study). The second arm utilised a questionnaire to collect data on the operations offered to the participant and what operation the participant opted for (called the ‘Latitude 2’ study). It also collected demographic data about participants, such as age and BMI, and had 2 free text boxes posing the questions ‘What was the most important issue to you when making your treatment decision?’ and ‘Was there any further information you would have liked to help you make your decision?’ This enabled all women who were deciding to have a procedure for SUI to be recruited. Those participating in the Latitude 2 study were able to indicate on the questionnaire if they would be interested to participate in an audio recorded interview exploring issues related to their choice in greater detail. Those who indicated yes were the study population of the interview study.

Fourteen hospital centres recruited to the Latitude study:

- Manchester University Hospitals Foundation Trust
- Lancashire Teaching Hospitals NHS Foundation Trust
- Wrightington, Wigan and Leigh NHS Foundation Trust
- Royal Bolton Hospital NHS Foundation Trust
- Newcastle-Upon-Tyne NHS Foundation Trust
- East Lancashire Hospitals NHS Trust
- Stockport NHS Foundation Trust
- Sheffield Teaching Hospitals NHS Foundation Trust
These sites are part of the northern research collective ‘53 degrees north’, which is a group of Urogynaecology centres that aim to improve collaboration in, and the production of, high quality research in the North of England. These centres offer both secondary and tertiary level care in Urogynaecology, with all centres being able to provide at least 2 operations for SUI, including Bulkamid and MUS (either TVT or TOT). All centres were able to offer onward referral for colposuspension and AFSP. There was no standardisation for the provision of urethral bulking agents, with there being a mix of centres that provided this in the outpatient and theatre setting. Standardisation was not applied to ensure that the study was conducted in the real-life clinical setting and reflected current clinical practice within the units. Urogynaecologists recruiting to the Latitude Study at these sites served as the clinician population for the study.

**Patient Interview Study**

**Inclusion Criteria**

Patients who were recruited to Latitude 2 were eligible to be approached for interview. These participants all met the following inclusion criteria:

1. Have primary SUI confirmed with Urodynamic testing;
2. Have failed conservative treatment with Physiotherapy;
3. Have decided to undergo a procedure for SUI;
4. Be eligible for at least 2 operations for SUI.

These inclusion criteria ensured that those participating in the patient interviews had primary SUI, were actively deciding on what operation to undergo and had at least 2 options to choose from.
Exclusion criteria

Patients recruited for the interview study had to be free of the following confounding factors:

1. Overactive bladder predominant mixed urinary incontinence;
2. Previous surgery for SUI;
3. Concomitant prolapse surgery;
4. Detrusor over activity on Urodynamics;
5. Residual volume > 100mls at Urodynamics;
6. Bladder capacity < 300mls;
7. Acute Urinary Tract Infection;
8. History of allergy to any of the local anaesthetic agents used in the treating unit;
9. History of allergy to all antibiotics that could be used as prophylaxis;
10. Ongoing treatment with corticosteroids;
11. Pregnancy;
12. Active autoimmune or connective tissue disease;
13. Non-English speaking requiring an independent interpreter.

Although the research team acknowledged that the experiences of all women deciding on a SUI procedure were valuable, they were unable to offer an independent face to face interpreter for all women who were not fluent in English. Therefore, women who required an interpreter were excluded from participation.

Participant recruitment

Patients participating in the Latitude 2 study were the population for the interview study. Patients received an information leaflet and gave consent on the Latitude 2 questionnaire to be contacted about the interview study. The researcher (SC) contacted potential participants via telephone to further discuss the study and to arrange a mutually convenient time for the interview to take place. This ensured that enough time was given to consider participation and that enough time would be available for the interviews.
Patients were purposively sampled based on the procedure chosen. This ensured that patients who had chosen each of the possible procedures were represented.

Patients were recruited over 12 months, and effort was made to recruit patients from a variety of locations. The study opening was staggered in different locations over the 12 months; therefore, patients were recruited opportunistically from available recruitment centres. Fourteen women out of a total of 212 who participated in Latitude 2, were interviewed during this time, with data collection closing due to the lack of new ideas being expressed within the interviews.

**Clinician Interview Study**

*Inclusion criteria*

The consultant urogynaecologist named as the Principal Investigator (PI) at each recruitment site was invited to participate in the clinician interview study. Other consultant urogynaecologists working at the recruitment sites were also invited to participate. The research team chose to include clinicians at consultant level only because these individuals were ultimately responsible for the care provided to women with SUI, and trainees would be heavily influenced by the approach of their trainer. No standardisation was applied to the counselling process and procedure offering was left at the discretion of the clinicians.

*Exclusion criteria*

Clinicians who were not at consultant level or were not trained to a specialist interest level in Urogynaecology were not eligible for inclusion.

*Participant recruitment*

The researcher (SC) emailed each recruitment site PI to invite them to participate in the study. A leaflet further detailing the study was attached, and consultants responding with interest became the participants. Details of other interested consultant urogynaecologists working at recruitment sites were provided by the PIs at each site and was with their colleagues’ consent.
2.3.2 Data Collection

Audio recorded semi-structured interviews was the selected method of data collection for this study.

Patient Interviews

Research Setting

Patients were being recruited from 15 sites across the North of England; therefore, it was felt that telephone interviews would be less of a burden for participants, preventing re-attendance to recruitment sites solely for research purposes. It was also hoped that participants would be in a comfortable and familiar environment when the interview was taking place, allowing for candid and frank discussion. However, it is recognised that some information may be missed from subtle cues relayed in body language.

Consent

All participants gave audio recorded verbal consent over the telephone prior to the interview and were sent a paper copy to sign and return by post. All participants were assured that they could withdraw from the study at any time and they did not have to give any reason.

Topic guide

A semi-structured topic guide was developed by the research team, drawing on the clinical experience of those involved to cover topics thought to be important (appendix 1). This guide acted as a prompt for each of the interviews. It allowed each interview to have a similar format, whilst allowing for new topics to be pursued from participant responses. Over time new questions were added, being informed by previous interviews. Flexibility in structure was allowed, meaning the researcher followed the participant’s ideas and topics were not covered in a certain sequence, especially if raised spontaneously by the participant.

Field notes
Notes were taken during the interviews to enhance understanding and to serve as a memory aid. Reflective notes were also made after the interviews to note interesting points raised.

**Clinic Interview**

*Research Setting*

The researcher (SC) visited each participant at a location chosen by the participant. This was mainly their hospital site, but some interviews were performed opportunistically at other locations chosen by the participants. These included quiet areas at conferences that were attended by both the participant and the researcher. Each interview took place in a quiet area in privacy, with discussion taking place between the researcher and participant only.

*Consent*

All participants gave verbal consent that was audio-recorded at the commencement of the interview and they were given a consent form to sign. All participants were informed that they could withdraw from the study at any time.

*Topic Guide*

A semi-structured topic guide was developed by the research team (appendix 2), but flexibility was also allowed so that interesting concepts could be explored further from participant responses. As the researcher became more experienced in interviewing participants and recurring ideas were highlighted, the questions asked changed to reflect this.

*Field notes*

Notes were recorded during and following the interviews to act as a memory aid and to help with making sense of the data.

**Ethical Considerations**

*Approvals for the study*
The Latitude study received a favourable ethical opinion from the Greater Manchester Research Ethics committee (17/NW/0155).

Confidentiality and Anonymity

All participants were allotted a study number and all participant names and study numbers were stored on the hospital research drive as agreed within the ethics approval.

All interview transcripts were anonymised by the researcher to ensure there were no identifying details within the data.

Data protection

All anonymised interview transcripts were kept on hospital or University computers accessible only by the research team as agreed within the ethics approvals. Any other items used in the study, such as consent forms and the digital audio recorder itself, were kept in a locked cabinet within a locked office.

2.3.3 Data Analysis

An inductive thematic analysis was performed using the framework method. This method was developed by Ritchie and Spencer for use in large scale policy research (114). It is a method that allows for charting of the data in to cases (rows) and codes (columns), allowing for logical reduction of the data and for patterns to be searched for between participants.

The framework method involves the following steps (115):

1. Transcription
2. Familiarisation
3. Coding
4. Developing an analytical framework
5. Applying an analytical framework (indexing)
6. Charting
7. Interpreting
The steps of analysis will be described in relation to the above steps.

**Transcription**

All interviews were transcribed verbatim by an independent typist. This was to allow the researcher (SC) greater time to check the transcripts. The transcripts were checked against the recordings and any identifiable information was removed. The process of familiarisation occurred simultaneously with transcription checking.

**Familiarisation**

The researcher immersed themselves in the data by reading and re-reading the interview transcripts. A selection of transcripts was also read by 2 other members of the research team. Interesting thoughts and ideas about the research were noted down to help with analysis.

**Coding**

Following data immersion, codes were searched for and developed by the researcher (SC). This was an active and inductive process, whereby great thought and consideration was given to sections of text that appeared to have meaning to the participant and to the research question. The texts were completely coded, so that all interesting concepts were covered. Codes were compared and refined using the constant comparative method. This method encourages researchers to constantly compare codes, categories and emerging themes with the data to ensure that no complexity is lost (110). Codes were chosen to closely reflect the data and ideas expressed within.

Computer assisted qualitative data analysis software (CAQDAS), such as NVIVO, were not used during this process. Whilst this software can be useful for organising large volumes of data, it does not affect the analysis steps or the way the data is analysed (110). As this project was inclusive of 29 transcripts, it was felt that using comments boxes on the word documents were enough to allow for coding and indexing, and this was the method most familiar to the research team.

**Developing and applying an analytical framework (indexing)**
The researcher met with other members of the research team to discuss and agree on codes. These codes were grouped together into similar ideological categories (see appendices 3 and 4). These codes then had a number associated with them, and the numbers were applied to sections of the data (indexing).

*Charting*

Once the data set had been indexed, the researcher reduced the data by creating spreadsheets of charts. Each row represented a participant, and each column represented a section of the analytical framework, with codes relating to the same category being included. Both direct quotes and summarised passages were entered. Charting is a valuable tool in organising and logically reducing data so that an overview can be seen to allow for analysis; therefore, the matrices do not necessarily have to map onto a theme, as these are identified following charting. Charts containing data relevant to the research question were extremely large and contained large volumes of raw data; for these reasons it has not been possible to include these as appendices.

*Interpretation*

Once charting was complete, the researcher was able to review the data set for patterns and connections. The field notes and were used as prompts to support the analysis. This process was supervised by 2 other members of the research team who were proficient in qualitative research. They provided support and guidance during interpretation. Themes and codes that did not appear to be related to the research question have not been reported in this work.

2.4 Quality assessment in qualitative research

There is no one accepted method of assessing quality within qualitative research (112). Some authors have suggested checklist criteria, such as Braun and Clarke’s 15-point checklist for good thematic analysis (110). Tong et al developed the consolidated criteria for reporting qualitative research (COREQ), which is a 32-point checklist that divides points of quality into 3 main domains (116). Firstly, that of the research team and reflexivity; secondly the study design; and lastly data analysis and
reporting. The research method has been described in line with these points to ensure that the quality of the work is of a high standard.

Several strategies have been suggested to contribute to assuring quality, such as member checking and triangulation (112). Of these, this research has used triangulation of investigators, with data analysis receiving input from 2 members of the wider research team as well as the main researcher (SC). This ensured that the findings were consistent with the data. It has also been triangulated with the questionnaire study included in the Latitude study (Latitude 2), of which 2 members of the research team (SC and FMR) were contributing authors. The answers to the free text questions regarding why participants chose certain procedures were thematically analysed and have been presented in a manuscript titled ‘Voice your choice. A study of women’s choice of surgery for primary stress urinary incontinence: a mixed methods study’ (appendix 5).
Chapter 3: Results of the patient interviews
Chapter 3: Results of the patient interviews

3.1 Introduction

There are 4 operations available to women who wish surgical management for SUI. These are: injection of a urethral bulking agent; insertion of a mid-urethral sling (MUS); colposuspension; and autologous fascial sling (AFSP). Each operation has unique risks and benefits, and at present it is not known how women with SUI come to their overall decision about which procedure to choose. This chapter presents the results of qualitative interviews with women who have chosen to undergo surgery for SUI. The interviews were designed to explore and understand how women chose a surgical treatment. This work was conducted prior to the “pause period of high vigilance” introduced by NHS England (13). The overall objectives of the research were to understand how women chose between procedures and, to determine the factors which are important to women in choosing an operation with a view to better support their decision-making process in the future.

3.2 Participants

This was a purposive sample of women with primary SUI who participated in a larger study of surgery for SUI. A full description of the methods can be found in chapter 2. A total of 14 women participated in audio-recorded semi-structured interviews with the researcher (SC). Of the 14 participants, 5 chose a urethral bulking agent (36%), 4 chose a MUS (29%), 3 chose a colposuspension (21%), and 2 chose an AFSP (14%). In comparison to the entire Latitude 2 cohort, proportionally more patients that chose colposuspension and AFSP were included in the interview study to ensure that women who had chosen all possible SUI surgeries had been represented. Within the Latitude 2 study cohort (212 women), 64% chose urethral bulking agents, 23% chose a MUS, 12% chose a colposuspension and 2% chose an AFSP.

All participants had a diagnosis of SUI, had recently decided on their first surgical procedure to treat their symptoms and were free from any of the exclusion criteria described in chapter 2. Demographic data was not collected. Thirteen of the 14 interviews were conducted via telephone, whilst 1 was conducted opportunistically in person. This interview was conducted in a quiet room, with only the researcher
3.3 Results

There were 3 main themes identified from the data regarding how women decide which procedure to choose. These were:

1. External forces: the influences of others on decision-making
2. Intrinsic factors: personal values of the participants
3. The final choice: a process of best fit

These will be described and discussed in turn below.

3.3.1 External Forces: The influence of others on decision making

The views and experiences of others, outside of the clinical team, appeared to be influential in the decision-making process of the participants.

Direct experience of others

Many of the participants had talked about their urinary symptoms with other people that they felt comfortable with. For most, this had been with other women who were of a similar age or were perceived to be in a similar situation to the participant. For some of the participants, this process of sharing their symptoms provided an opportunity to gain knowledge about their condition and information about treatments. For some this process prompted them to seek medical help.

“Well a friend of mine she had the same thing done [fascial sling], she said it benefitted her and I thought maybe it would be something for me as well. I thought I would look into it, you know?” – Participant 10 [AFSP]

“Well I will be quite honest, it was my hairdresser... I just actually started telling her...she said ‘have you been to the Doctors?’ I said ‘no I am too embarrassed’. And my hairdresser said ‘[participant name] go’, the same thing happened to her and she [pause] I don’t know what kind of surgery she
had but she had it and she said it was 100% brilliant and that’s what prompted me to go” - Participant 1 [Laparoscopic colposuspension]

Desire for greater amounts of experiential advice from women

Many participants wanted the opportunity to speak to other women who had been through a procedure for SUI. Some expressed that they would value women’s experiences of a procedure more than statistical information.

“I think people benefit more from sharing their overall [pause] you know, their experiences of something rather than just a statistic.” – Participant 9 [Urethral bulking agent]

“I think they should make it easier and more accessible that women can just walk into a clinic and discuss it with other women” – Participant 2 [Urethral bulking agent]

This wish to gain experiential information from others seemed to be underpinned by the feeling that other women would provide a more honest account.

“I think women are quite reassuring to each other as well and they tell the truth” - Participant 12 [Urethral bulking agent]

Impact of positive and negative experiences

Participants appeared to be influenced by stories of individual experiences, both positive and negative. Some expressed choosing a procedure based on the positive reviews of others.

“[the doctor] said to me ‘well which one do you want to go for?’, and I said ‘the Bulkamid’ because I knew 2 other girls that had had it and they said it was brilliant.” – Participant 12 [Urethral bulking agent]

“when I went for my consultation last week I really did want the tape…I think it’s ‘cause my sister had it done and it’s been successful for her.” – Participant 8 [MUS]
Descriptions of negative experiences of SUI surgery also appeared to be influential to participants. For some, these accounts influenced the choice of procedure, leading to certain procedures being discounted.

“One friend in particular...she had one of the operations and it didn’t go well for her and her results from that operation weren’t good and so that made me decide I wasn’t going to have that particular operation [MUS]” – Participant 5 [AFSP]

Many commented on the negative reports about mesh in the media. They discussed the complications experienced by women who have shared their experience via the media. These reports appeared to influence the decision of some women to exclude the use of mesh in their continence surgery

“Well at the time that I had gone to the hospital it was all over the news as well about the mesh, so I was like ‘oh my God, I can’t, I am not having that’, because you panic don’t you, thinking it is going to be like chronic pain” – Participant 12 [Urethral bulking agent]

Some of the negative experiences described by participants were extreme cases with very significant outcomes, and it appeared that this had frightened some, feeling that they could be at risk of suffering the same complications.

“I’d read that so many [pause] that a lot of women had had a bad experience with it. That... people had ended up in wheelchairs and it breaking up, damaging the bladder and the bowel ...they felt like there was something stabbing into them and it was like cheese wire...I’d read all this sort of thing and it just put me off totally having it (MUS).” – Participant 5 [AFSP]

However, not all participants who had seen reports of mesh complications discounted MUS, with some still choosing this option. For example, participants 6 and 11 chose a MUS despite reading the reports of complications in the media and knowing people first hand with negative experiences.

“my Mother who had it done years and years ago, but she was one of the first ones and it didn’t particularly work, which could have been one of the reasons
why I kept putting it off…but...things have moved on now. The first heart
transplants didn’t really work but, you know, now it is sort of second nature
isn’t it?” – Participant 6 [MUS]

“No, obviously I had heard all the reports about the mesh in the news but I
must admit I tend not to look on the internet or listen to the news about things
like that because you do generally hear about the bad side of things and not
the good side, so I did steer clear of them and kind of thought I would just
seek advice and see what the options were.” – Participant 11 [MUS]

These participants appeared to place more trust in the statistical facts or information
given to them by their clinician than in the media, relatives or friends. This contrasts
with the earlier finding which suggested more trust was placed in first-hand accounts
shared in the media.

**Non experiential advice**

Some participants appeared to be influenced by the decisive views of other people,
family and friends even when these were not based on experiences.

*Interviewer: “And did you feel that you needed to share your decision with
someone else?*

“Yes, my Mum. Yes definitely my Mum and she just said straightaway ‘no you
try the one that’s less invasive, you know, you’ve got to give it a go’.” –
Participant 12 [Urethral bulking agent]

For most participants, the sphere of influence was friends or relatives. Interestingly,
participant 4 took the view of their friend to help make their decision because the
friend was a doctor. Therefore, participant 4 felt they had a better opinion than
herself when coming to the decision.

“regarding that which operation I need to go to is I’ve got a friend here who
is a consultant. He’s not a gynaecologist or a urogynaecologist, but him and
his wife both are doctors and they’ve got plenty of friends, so [pause] in his
business. So I spoke to him and he said, ‘Just send me the details, I’ll have a
look.’... he [friend] mainly spoke to me about colposuspension. He said, ‘I’ve
**Going against the advice of peers**

Not all women accepted the recommendation of friends or family. For example, participant 14 was recommended the MUS by her best friend, but she did not feel this was an acceptable option as she did not want a foreign body.

“Her mesh was brilliant, she totally asked me to go for the mesh ... So she went, ‘yeah, you’ve got the same problem as me you need to have the mesh’. But I didn’t want the mesh because I didn’t like the thought of a foreign body.”

– Participant 14 [Laparoscopic colposuspension]

Participant 2 knew women who had good results from the MUS. However, she wanted the procedure with the quickest recovery, and she chose to have a urethral bulking agent. This suggests that, whilst positive experiences of others can be influential, these experiences are weighed against other factors which the individual considers are important (the “intrinsic factors” as discussed below).

Interestingly, of those who discussed how negative reports of SUI surgery had influenced their decision (9 participants), only 2 participants had direct contact with women who had suffered a complication. This is in contrast with those who had been influenced by positive experiences, with them all having direct contact. This may reflect a lack of opposing positive experiences shared in the media at the time.

### 3.3.2 Intrinsic Factors: The personal values of participants

It appeared that participants came to the decision-making process with pre-set priorities and perceptions of what was important to them, for example with a desire for a quick recovery or to have a procedure to make them completely dry. Triangulation of this work with the Latitude 2 questionnaire results, supported this
finding (appendix 5). Depending on which values were deemed most important by participants, this seemed to affect how much decisional value was placed on each factor and how much influence it had on the overall decision.

**Return to normal activities**

Most participants discussed recovery from a procedure as a consideration in their choice. Some prioritised a swift return to their normal activities over all other considerations. The activities discussed most frequently were driving, which would have a direct impact on childcare, getting back to work and exercising.

“I work for myself...obviously if I don’t work then I don’t earn any money...so I can’t really afford to be either in bed or in hospital or not be able to drive” – Participant 2 [Urethral bulking agent]

“I don’t want to be away for long and to be honest, with the injections I can go straight back to my exercise class, whereas, the other one I’d have to wait for 2 weeks before I could do anything” – Participant 9 [Urethral bulking agent]

For some participants, it appeared that this was a key issue and a lot of decisional weight was attached to it. Others, however, were willing to accept a longer time to return to regular activities. These participants had weighed recovery against another factor and appeared to attach greater decisional weight to the other factor.

“I know, like, with the operation...I can’t do so many things for 6 weeks which is... I can accept that. I always look at the long-term gain and when I’m looking at the long-term, if this stops the problem I’m going through at the moment, then I’ll be more flexible to start with.” – Participant 4 [Laparoscopic colposuspension]

In this case the patient traded the recovery time against the long-term cure rate.
Variation in the concept of success

Many participants cited the success rate of procedures as an influential factor. For some this was valued as their most important priority.

“Just that it would fix the problem, that’s why I want it doing, you know, it’s got a high success rate. I think she said something like 90% of patients are happy with it. That’s the reason I chose it really.” – Participant 8 (MUS)

There appeared to be variation between the participants as to what treatment success meant on an individual level. For some, it was a physical definition, where they had a complete cessation, or improvement, of leakage. These participants were also keen to stop using continence aids, such as pads.

“Basically I don’t urinate when I sneeze or cough, that’s my success” – Participant 4 [Laparoscopic colposuspension]

“Being able to go out and not wear a nappy.” – Participant 6 [MUS]

Others had more of a functional view of success, defining it as the ability to participate once more in activities currently limited by their symptoms.

“I used to do boot camp, I can’t do that anymore, I can’t do running. So it would be important for me to get back to those things” – Participant 5 [AFSP]

Some discussed a psychological element to success, wishing to be free of worry over leaks.

“I mean back to what I was like before I had kids would be my dream, so I didn’t ever worry about it, in so far as that would be possible that would be, that would be what I would love to have, that I didn’t need to worry about it.” – Participant 3 [Urethral bulking agent]

These different elements of individual success reflected the effects SUI had on the lives of the participants. Most participants discussed a restriction of activities, a dislike of the feeling of leakage and a significant emotional impact of the symptoms.
“I was like jumping up and down cheering one of my kids at her sports day and I was finding myself leaking and that kind of really upset me.” – Participant 13 [Urethral bulking agent]

Irrespective of individual definition, all participants discussed success as an important concept to them. However, the amount of decisional weight attached to it varied. Some participants appeared to value other factors to a greater degree and were willing to choose a procedure that offered benefits other than the highest success rate.

“I was thinking about trying to balance the success rate with the less sort of invasive procedure and...how inconvenient it would be or the impact it would have on my day to day life” – Participant 2 [Urethral bulking agent]

The concept of long-term success was discussed by some participants, particularly those who had not chosen a urethral bulking agent. They placed value on the idea of permanence and considered this when deciding on a treatment.

“It is like I have got to go through all this process again if I have that done [Urethral bulking agent] and it doesn’t work.” – Participant 1 [Laparoscopic colposuspension]

“I didn’t like the sound of the needles, the injections and [the doctor] said it may not work. I think it was a 60% to 70% success rate on that and you may have to have it redone as well, which is why I really wanted to go for the tape option ‘cause I knew that, you know, that’d be in for the rest of my life basically and I wouldn’t have to have it redone or anything.” – Participant 8 [MUS]

**Perceived Risk**

Participants recurrently discussed risk as a concept they considered in their decision-making process. When discussing risk, participants described it in two ways; firstly, in terms of recognised risk of complications of procedures, and secondly, in terms of how at risk they perceived themselves to be of those complications.

**Recognised risks of complications**
Some participants appeared to be strongly influenced by how high or low risk they perceived procedures to be. For some, this appeared to be the most influential factor in their ultimate decision and choice of procedure.

“I would prefer to go for a less interventive, try that first, ‘cause obviously [if] it’s a more minor procedure then...there’s less risks involved” – Participant 9 [Urethral bulking agent]

“I suppose I wanted to do something that had the least risk” – Participant 3 [Urethral bulking agent]

For participants who valued a low risk procedure, they appeared willing to compromise on other values, such as success.

“I mean the one that I have gone for…it might not work I suppose that’s a risk, but it is relatively low risk otherwise.” - Participant 3 [Urethral bulking agent]

They also appeared to be more willing to consider a stepwise approach to treatment, starting with the lowest risk procedure and considering further options only if necessary.

“I want to start with this one and then if this doesn’t work then I will obviously consider having the sling or the tape” – Participant 2 [Urethral bulking agent]

This contrasted to other participants who placed more value in success, with these participants seeming willing to accept more perceived risk.

“The one that really appeals was this [AFSP], although, you know, they realised that it was going to be a much bigger operation it just felt that that one would be worth it in the end.” – Participant 5 [AFSP]

Perceived risk of mesh complications was recurrently discussed as a consideration by many. Some considered this to be such a risk that they deemed this an unacceptable option. This was strongly linked to the experiences of complication by other women shared in the media as discussed above.
“I was frightened in case it didn’t agree with me and it wasn’t for me the mesh” – Participant 10 [AFSP]

General Perception of risk: Optimists and pessimists

Participants appeared to vary in how they viewed their individual risk of experiencing a complication, and these views appeared to influence how the recognised procedural risks were perceived.

Some participants accepted risk as part of agreeing to a surgical procedure and do not perceive themselves to be at greater risk than others.

“To be honest I am not particularly bothered about it. If it happens it will get sorted but I don’t feel it is a great risk.” – Participant 6 [MUS]

In contrast, others felt that they were at higher risk of encountering a complication because they have experienced an unlikely event before. They appeared to place high decisional value on low risk procedures.

“A statistic, I’ll look at a statistic and go, ‘Well, that’s probably higher up for me ‘cause I always seem to manage to luck out in that department.’” – Participant 9 [Urethral bulking agent]

Other participants appeared to view statistics regarding risk as reassuring, feeling that the chances were in their favour.

“I don’t [pause] people should read the small letters what say, “Can have this, this this.” Of course, I do read as well, but I don’t think or I don’t put that in my head that I’ll be that person. If it happens, I’ll deal with it, but then I wouldn’t think, like, ‘Oh my God. There’s 9% of the people don’t get success from that. I’ll be within that 9%.’ No, I will be within that 91%, that’s the way I think, so those things particularly help me to make the decision” – Participant 4 [Laparoscopic colposuspension]

However, participant 3 felt that they could be part of the quoted percentage who did experience a problem, and this influenced their decision of treatment.
“it was more the sort of side-effects of it [mesh] and wondering whether it is a sort of percentages game and wondering whether that would be, you know, whether you are gambling a little bit because you don’t quite know if it is going to work perfectly or if you are going to be one of the unlucky 10%” – Participant 3 [Urethral bulking agent]

**Attitude towards procedural factors**

Various procedural factors were discussed by participants, and their response to some of these influenced how acceptable or not certain procedures were perceived to be.

**General Anaesthetic**

Some of the participants considered the type of anaesthetic required for the procedure in their decision making. Some were deterred from choosing certain procedures because of the need for general anaesthetic. The reasons appearing to underly this were fear of a general anaesthetic and the complications that could arise, and a feeling that having a general anaesthetic was only required for treatment of serious conditions. In the case of participant 7 who expressed this idea, it may reflect that she did not consider SUI to be as serious health threat.

“I don’t really want to have a general anaesthetic unless I can absolutely help it. I also have a bit of fear of having a general anaesthetic... I always have a fear that they’re going to get a [pause] I would be the unlucky person where they get the gas mixed up” – Participant 2 [Urethral bulking agent]

Interestingly, participant 7 chose to have a MUS. However, originally, she chose a bulking agent until she found out this was not available under local anaesthetic at that hospital. She, therefore, changed to choose to have a perceived more successful treatment if she was going to have to have a general anaesthetic anyway.

“I originally was of the opinion that the bulking was done by, sort of, a local anaesthetic and that it wouldn’t be a major undertaking and it was only then through talking through the options with the consultant that I then became
Data was not collected on how many centres offered urethral bulking agents under local anaesthetic versus those that did not. As highlighted above, the availability of this may have a degree of influence on decision making in some women.

**Foreign body versus own tissue**

Many participants discussed their views on mesh, and many related it with the term ‘foreign body’. Some attached negative associations to this, taking it to mean ‘unnatural’ and ‘artificial’. These views were linked with participants perception of risk of complications, feeling there may be less risk of a complication using their own tissue.

“I would rather, if there’s a choice of having using your own tissue or using a piece of plastic I would rather have something that if it’s your own tissue it can it’s part of you, it’s not something that’s foreign. A piece of plastic, I just can’t help but think isn’t natural, it’s not natural that a piece of plastic is inside your body, whereas, your own tissue, I would imagine, would adhere back into your body, whereas, a piece of plastic, it’s not a natural thing that should be there” – Participant 5 [AFSP]

Only one participant (P5) considered a urethral bulking agent to be a foreign body.

“it seemed to say that half of the women felt it worked and half didn’t, and it said it might not cure it and again it could made with none man-made materials” – Participant 5 [AFSP]

Others talked about the unacceptable risks of foreign bodies and yet had chosen a bulking agent. This suggests they were unaware that the agent used was permanent.

“I think of course if you’re going to put in something artificial that doesn’t belong in the body, there is a risk of infection and a risk of corrosion, so I’m realistic about that. That’s not a risk I’d want to take” – Participant 9 [Urethral bulking agent]
Women who chose a urethral bulking agent who cited foreign body as a decisional factor discussed the concept of foreign body in relation to mesh alone, not linking this with a urethral bulking agent, even though it is a manmade implantable device.

Participants who chose a MUS were not concerned by the idea of mesh being a foreign body. Some recognised that there are other accepted implants used in the body, and that mesh was no different. For some, having a permanent mesh implanted was a reassuring thought, in that it would provide long term treatment for their symptoms. Underlying the acceptance of the use of mesh by these participants was a trust in the material because it was deemed to be medical, and that it would not be offered unless it was thoroughly tested and proved to be safe for use.

“Before things like this are used they are tested and tested. I mean we have had heart valves and all sorts of manmade things put into us don’t we?... We have got steel kneecaps and all sorts so, you know, if it works, it works.” – Participant 6 [MUS]

“I read everything on it and just trusted that it [mesh] was medical. You know, it was a medical environment and medical like stuff and things and that it would be okay” – Participant 12 [MUS]

**Incisions**

One participant commented that whether a procedure involved an incision or not was highly influential for them. They wished to avoid any incisions; therefore, this contributed to their choice of a Urethral Bulking Agent.

“the fact that they have to make incisions and things like that, I just thought I have never sort of messed with anything down there and I was lucky with my kids, and I just didn’t like the idea of getting cut and re-stitched” – Participant 12 [Urethral bulking agent]
3.3.3 The final choice: A process of best fit

Ultimately participants appeared to choose the procedure which had the best fit to their individual personal values. They appeared to evaluate each operation against their own list of important factors. Hence procedures could either be ruled in or ruled out.

“when [the clinician] told me that it was the recovery period could be 4 to 6 weeks [following a MUS] and I wouldn’t be able to drive, that would have a great impact on my life because, you know, I am Mum taxis to my kids so I have got 2 active [children] I just couldn’t not drive for like that length of time, it would be really, you know, so that also had a [pause] that’s why I sort of dismissed that one” – Participant 2 [Urethral bulking agent]

“I was debating between TVT and colposuspension…I always look at the side-effect and the success rate. I think TVT and colposuspension got most success, like, 93%/94% success rate. That’s the first thing I look at.” – Participant 4 [Laparoscopic colposuspension]

Another factor was the number of options that women perceived to have been offered. Some participants felt they were offered 2 procedures, others discussed 3, and some 4. It is not possible to know if women were offered all four options or not, with other methods being necessary to investigate this further in the future.

“Yes, the options were the sling, which I opted for or an injection similar to the Botox that bulks up the muscles” – Participant 6 [MUS]

“I was offered the bulkamid, I was offered the mesh and I was offered the full operation where they like attach everything together and pull it all up” – Participant 12 [Urethral bulking agent]

“I was offered about 4 different procedures that could have been beneficial for me. The doctor explained the different operations involved and how some are more major than others.” – Participant 10 [AFSP]

Participants expressed a range of comfort levels of being allowed to make this decision independently. Some felt very comfortable making their choice without any
help from the clinical team, feeling that it should be solely their decision. Others, however, were keen to have recommendations from doctors.

“If a decision affects me, I will make the decision.” – Participant 11 [MUS]

“In a way it was nice that it was ‘it’s your body, it is your decision what you have done’. But it might have been nice to say ‘well we don’t think this will work this will be the better one’” – Participant 6 [MUS]

**Option of best fit per procedure group**

**Urethral bulking agent**

Five of the participants chose a urethral bulking agent. These participants seemed to value minimal disruption to their daily activities.

“when [the clinician] told me that it was the recovery period could be 4 to 6 weeks [following a MUS] and I wouldn’t be able to drive, that would have a great impact on my life because, you know, I am Mum taxis to my kids so I have got 2 active [children] I just couldn’t not drive for like that length of time, it would be really, you know, so that also had a [pause] that’s why I sort of dismissed that one.” – Participant 2

Minimal risk from a procedure also appeared to be a priority to all those choosing a urethral bulking agent.

“for me it was just, like, it’s the minimal, it’s a bulking agent and see if that works. If that reduces that, then brilliant, because I guess it is still something [pause] I don’t know, I just [pause] when I was talking it just feels like the least risk that could have an impact and help provide support in that area.” – Participant 9 [Urethral bulking agent]

Some participants actively prioritised these factors over others, such as success, accepting that they may have to have further procedures in the future.

“It was just the fact that you were in and out in a day and that it was [pause] I mean the only thing that I didn’t like was the percentage I just thought ‘oh I could do all this and it might not work’, but I just thought it is the least
invasive, it just seemed quite an easy fix really.” – Participant 12 [Urethral bulking agent]

Participants in this group appeared willing to adopt a stepwise approach to treatment, being prepared to choose again if the success of the procedure was judged inadequate.

“I want to start with this one and then if this doesn’t work then I will obviously consider having the sling or the tape” – Participant 2 [Urethral bulking agent]

**Colposuspension**

Three participants chose a colposuspension. These participants appeared to place high decisional value on success of the procedure and apparently less on the duration of time to return to normal activities.

“I know, like, with the operation I know ...[pause] I can’t do so many things for 6 weeks...I always look at the long-term again and when I’m looking at the long-term, if this stops, the problem I’m going through at the moment, then I’ll be more flexible to start with.” – Participant 4 [Laparoscopic colposuspension]

Participants in this group also appeared to find the risks presented by mesh to be unacceptable, therefore ruling out the MUS. The idea of a foreign body was recurrently discussed by these participants.

“I didn’t want the mesh because I didn’t like the thought of a foreign body” – Participant 14

“So the others didn’t appeal to me but this one that I am having done did appeal to me. It is mending what is not working anymore isn’t it, it is not putting any foreign bodies in my body is it” – Participant 1 [Laparoscopic colposuspension]

**MUS**

Four participants chose to have a MUS. Like participants in the colposuspension group, those choosing MUS seemed to highly value success and considered this a
key decision point. Having a single procedure was also recurrently discussed by these participants.

“I just wanted something that would, that had quite a high percentage of working. Something that, like I said, I could go in, have it done, come out and hopefully that’s the end of it, and that’s it really, I am quite a ‘let’s get in there, get it done and get it over and done with’, type of person. I am not somebody that likes things to carry on forever.” – Participant 11 [MUS]

The risk of mesh was not broadly discussed, with participants being more concerned about perceived risks presented by other procedures.

“and then the other one where they pull everything forward [colposuspension], that was a definite no for me, I thought I am sure that is going to have more complications in the future and that it could [pause] I just didn’t like the fact that everything was pulled forward to a certain extent, and that didn’t appeal to me in the slightest” – Participant 11 [MUS]

**AFSP**

Two participants decided on having an AFSP. These participants highly valued success and were willing to compromise on being able to return to normal activities quickly. Long term success was also discussed as important by both participants, with both ruling out urethral bulking agents for this reason.

“the more I read up on it I thought it [AFSP] would be suitable, but I had a bit more time off work and what have you but [pause] I thought what was suitable for my needs.” – Participant 10 [AFSP]

“part of what I read said that it [Urethral bulking agent] didn’t last very long and that you might have to have it done again. I just felt that it seemed [pause] it sounded like it was a short-term thing, to me, so I didn’t see any point in that one” – Participant 5 [AFSP]

Both participants discussed their significant concerns regarding mesh, preferring procedures that did not involve foreign bodies.
“the fascial sling is using your own tissue and I would prefer that to having a piece of plastic inside me” – Participant 5 [AFSP]

However, despite not finding the risk of mesh acceptable, both seemed to find the risks presented by the AFSP procedure itself as acceptable.

“It was explained about how things could go wrong like infection and what have you, maybe puncturing organs and what have you, but I thought it is just a risk you have got to take, it is one of those risks you need to take to move forward.” – Participant 10 [AFSP]

Both participants had considered colposuspension in their decision making, as it too provided a perceived foreign body free procedure. Interestingly, participant 5 would have opted for a colposuspension, but she was told by the consulting clinician that it would not be suitable for her. Participant 5 understood she had been told that she ‘did not have enough tissue to pull up’, which was taken by the researcher to mean urethral mobility. Participant 10 had also considered colposuspension, but had the understanding that it involved cutting the bladder, which she felt was less of a risk with the AFSP.

3.4 Discussion

This is the first study to evaluate how women with SUI, in a real clinical setting, after receiving counselling from their regular clinicians and having time to consider their options, make their choice of surgery. This research has found that women’s choice of surgery appeared to be influenced by others from outside the clinical team. Some women placed more value on the experience of other women than on conventional statistics. It appeared some women were offered limited choices or did not recall being offered all the options. The study identified specific factors related to each operation which women found important. However, it also found that women attached an individualised weight of importance to each of these factors. Women appeared to construct their own framework, formed by the hierarchy of factors, against which each operation was judged.
External Forces: The Influence of others

The first prominent finding was the influence that other individuals, outside of the clinical team, had on the decision of the participants.

A study by Casteleijn et al (103) examined factors that determined the preference of women between a urethral bulking agent or a MUS in a group of patients with primary SUI. They also found that the opinions and experiences of social contacts was a factor influencing the preference of women. However, Casteleijn et al performed their interviews before the women had had their clinical consultation and before they had made their final decision, hence the importance of social factors could be affected by the subsequent clinical counselling. The experiences of others have also been found to be influential in other treatment decisions. In a study examining decision making around the choice to take risk reducing medication for Breast Cancer, the uptake of the medication was shown to be affected by participants having known someone with a good or bad experience of taking the medication (117). This suggests that experiential factors are key to many treatment decisions and perhaps should be formally considered in clinical care.

These are important findings because, at present, in clinical practice experiential information is not provided to women. Most hospitals and clinicians use either information leaflets or more recently PDAs, such as that provided by NICE. These information leaflets and PDAs focus on presenting statistical data, mainly related to success and complication rates, and do not address women’s desire for experiential information. This represents an area that could be developed to better support patients with SUI.

Intrinsic factors and the overall decision: weighing of personal values and option of best fit for personal priorities

This study found that women considered several factors and, depending on which they valued most, influenced how acceptable the different procedures were deemed to be. The main priorities described by participants included return to normal activities, success of the procedure, perceived risks of the procedure and specific procedural factors. These included what happened during the procedure, including
what material was used and how it was performed, including if it was under local or general anaesthetic.

Some of these priorities have been described in other works. For example, Basu et al (102) investigated the factors women considered important when deciding on treatment of pelvic floor disorders. They found that participants with SUI were keen to pursue treatments that had the best chance of long-term success, with a willingness to accept more invasive procedures in pursuit of this goal. This was confirmed in the current study, with a group of women describing their priority was success. However, others appeared to value minimally invasive procedures and were willing to accept lower success rates. This trade-off has been confirmed in several other studies (118)(98)(100). From a list of decisional factors, it appeared that women ordered these in a hierarchy of most to least important and used this as a mental decision-making framework to determine which procedure was the best fit for their individual needs and wishes.

It is important to recognise the complexity of individual decision making. Even within the list of factors that influence an individual, there is variation in their definitions. For example, success had different meanings to individual women ranging from being dry, to having no fear of leakage, to being able to resume a specific activity such as running or to just be a bit better. Some women just referred to treatment success as a concept, without giving an individualised definition but still clearly regarded it as important. Other research has demonstrated the importance of individuals’ goals; the challenge is incorporating these goals into PDAs.

Casteleijn et al (103) found that women with SUI who preferred a urethral bulking agent were keen to avoid invasive procedures, hospitalisation and general anaesthesia. They found that women choosing MUS surgery valued a higher chance of cure, a one session procedure, and felt more familiarity with MUS treatment and expressed safety concerns about urethral bulking agents. These findings align, to some extent, with some of the findings in the current study. However, in this study, safety concerns were not raised about urethral bulking agents. To the contrary, participants seemed to regard this procedure as presenting the least amount of risk and based their treatment decision on this perception. This difference may be
because the study was performed in Holland and information in their media may be different. It was also conducted at a different point in the patient journey, prior to seeing a doctor. It may also represent different clinician bias and the impact this has on the presentation of information to the patient.

The main safety concerns discussed within the current study were strongly linked to the possible complications of mesh, such as chronic pain and erosion of the material. These were in turn linked to stories of negative personal experience of the mesh and to the idea of the material being regarded as a foreign body. Interestingly, other procedures chosen by participants who raised these concerns also involve materials that may be man-made and are designed to be permanent. For example, the urethral bulking agent that was chosen by participants was Bulkamid, which is a polyacrylamide hydrogel that is designed not to dissolve and to remain at the site of injection to provide bulking of the urethra (62). Only 1 participant discussed this as being a foreign body, and this participant chose an AFSP because they valued the use of their own tissue. Some participants who had selected a urethral bulking agent described they did not want a procedure that involved a foreign body due to the risk of complications, but never discussed the fact that Bulkamid itself is a foreign body. Colposuspension and AFSP similarly may involve the use of sutures, such as Ethibond or Prolene, that do not dissolve and can erode. However, none of the participants choosing these procedures discussed this. This may be for several reasons. Firstly, participants may not have been aware of this when they chose these procedures, perhaps not having been informed that permanent material would be used. Alternatively, they may have been aware, but their perception of foreign body may be very specific to mesh, possibly due to coverage in the press, television reports and social media.

Over the last decade, in the UK, continence surgery has been the subject of controversy and there a have been several Government inquiries and reviews of safety of mesh. These reviews include reports by the MHRA (74), the Scottish Independent Enquiry (75) and the NHS England Review (76). The most recent inquiry in England, the Independent Medicines and Medical Devices Safety Review, was
commissioned by the Government in February 2018, is chaired by Baroness Cumberlege and has yet to report its conclusion.

One of the recurring themes in these inquiries was the poor counselling provided by clinicians to women. MUS procedures were by far the most common procedure performed. There were 84 MUS procedures performed for every one non-tape procedure between 2008 to 2017 (64). It is uncertain whether tapes were chosen over other procedures because of biased counselling by clinicians. Our study found some variation in the number of surgical options offered to participants. Some women describe having knowledge of only 2 procedures, others 3 and some 4. It is unclear as to whether this reflects an error in their memory, understanding or a covert limitation of choice by their clinician.

More recently, clinicians have considered ways to improve the information they provide women. There have been several papers published describing PDAs to help clinicians and women engage in a process of shared decision making (81)(96)(97). Although these PDAs may be useful, they were developed by experts rather than through conversations with women. The PDA following the comprehensive systematic review by NICE highlights how little information there is for women to decide between operations.

One of the primary reasons for undertaking this research was to use the information to develop a PDA that included decisional factors raised to be important by women themselves. Determinants which women stated to be important included type of anaesthesia, duration until return to activities of daily living, use of foreign body, risk of complications, especially those of mesh, and success rates. However, ‘success’ represented variable definitions.

PDAs may help women realise that there are 4 choices available. There is currently inadequate data to guide women to one type of surgery over another based on their characteristics such as BMI, age, maximum urethral closure pressure, urethral mobility, or future childbirth. However, the findings of this patient arm of the
research suggests that women do not necessarily consider their own clinical characteristics. Instead, they focus on what they want to achieve from the procedure and what priorities are important to them. Also, the finding that women value experience of other women needs, somehow, to be woven in to the design of future patient information and PDAs.

3.4.1 Strengths and Limitations

Qualitative methods have allowed for an in-depth investigation into the decision-making process of women choosing a procedure for SUI, allowing for greater understanding of the experience from their perspective. A strength of this study is that it has included participants who were in a genuine clinical setting who had chosen a procedure. Another strength was that the participants came from many different centres and had been counselled by different clinicians. Previous studies of choice and decision factors have not included women who have been given a full range of surgical options for SUI, excluding either colposuspension or AFSP.

There was a degree of triangulation within the analysis in that 3 members of the research team were involved in the generation of the thematic framework and the overall generation of themes; therefore, this adds to the reliability of the findings. As discussed in chapter 2, the current study was a sub-study within a larger multicentre study called Latitude. This included a questionnaire that surveyed participants as to why they chose a certain procedure and what options they had been offered by their clinical team. This study surveyed 212 women across 12 hospitals, and found they considered efficacy, invasiveness, recovery times and risk of complications when choosing a surgery for SUI. These support the decisional factors identified in the current study. It also highlighted there may have been some clinician influence in the decision making of some women, being recommended certain treatments. The results have been submitted for publication, and the paper can be viewed as appendix 5.

A limitation of this study was that only 14 participants were interviewed. It was felt by the researcher that data saturation had occurred within the 14 interviews, with
no new themes being uncovered by this time. However, saturation was not formally confirmed by conducting a further number of confirmatory interviews as is recommended in some texts (119).

Another limitation of the study was that all women who chose to have a colposuspension were recruited from centres that offered laparoscopic colposuspension, rather than an open approach. This may have changed how this procedure was viewed, as a laparoscopic approach may be viewed as less invasive and may have made the procedure more acceptable to women. However, an open approach to this procedure may have changed their overall decision; therefore, in future work there should be distinction to approach of procedure considered.

The researcher was a novice interviewer at the commencement of the current study, and this may have led to certain topics not being explored as fully as if the interviews were performed by an individual with more experience. However, they did have years of experience with clinical history taking, which requires careful listening and attention to detail that are necessary pre-requisites for qualitative interviewing. During the interviews, a difficulty was encountered with exploring participant’s perception of foreign body. The researcher did want to pursue this further, but also did not want to make the participants start questioning their own choice of surgery or cause undue alarm about issues regarding mesh complications. Therefore, it was felt that probing too far may not be appropriate and could interfere with the researcher’s role as observer and could potentially have an effect of the relationship between the participant and their clinical team.

3.5 Conclusions

This research found that women appear to come to their treatment decision by constructing an individualised hierarchy of important factors against which they compared the procedures offered to determine the one which best fit.

The identification and ranking of important factors appeared to be influenced by the views and opinions of other people, especially by the experiences of other women.
who had undergone a SUI procedure. Experiences shared in the media, both national press and social media, also appeared to affect their choice. However, this mainly related to MUS and may change with time as it was not apparent in a study conducted in Europe (103).

Despite this study being a study of choice, there was evidence to suggest some women were unaware of all the operations available for SUI. It appeared some were either not offered all procedures or did not recall being offered all procedures. This is a major limiting factor of the study as it unknown how a full knowledge of all the procedures available for SUI may have affected the choice of these women. This may be a consequence of the pragmatic nature of the study and could reflect a range in the options offered to women and clinical explanations given in clinical practice. Further investigation into the range of options offered to women should be undertaken in future research projects.

Considering Government investigations and legal reports which also found women were not adequately counselled nor offered adequate choice, clinicians should endeavour to use PDAs and ensure formal written documentation of choice.
Chapter 4: Results of the clinician interviews
Chapter 4: Results of the clinician interviews

4.1 Introduction

There has been a move away from paternalistic decision making in medicine towards shared decision making, with the purpose being to empower patients to have more control in their medical treatment (93). The decision of which surgical procedure to have for stress urinary incontinence (SUI) is commonly regarded as a ‘preference sensitive’ decision. Preference sensitive decisions are defined as those that involve several options with no treatment having clear superiority over another; therefore the treatment will depend on patient values and preferences (120). As discussed in the previous chapters, there are 4 main operations available to treat SUI, each with associated risk and benefit profiles. Whilst NICE have recommended colposuspension, AFSP and MUS as primary surgical options, urethral bulking agents may also be considered (5). There remains no clear best option for all women. Recently, concerns have been raised by patient groups that women having surgery for SUI may not have always been fully informed during the decision-making process. They may not have been aware of all the treatment options for SUI and may not have been fully aware of the risks, especially the specific risks associated with polypropylene mesh (121). In 2019, NHS England recommended that women should be fully informed to enable them to make an informed decision regarding the choice of procedure for SUI treatment (5).

It is unknown what degree of choice women receive in clinical practice and what role clinicians play in the decision-making process. It is also unknown what factors are considered important by surgeons when counselling women and how this effects how options of surgery for SUI are offered. This chapter reports the results of semi-structured interviews with consultant urogynaecologists exploring how they offer women the choice of surgery for SUI and what factors affect the options offered.

4.2 Participants

Fifteen consultant urogynaecologists were interviewed as part of this study between June 2017 and June 2018, prior to the pause on the use of polypropylene mesh
introduced by NHS England. Of those interviewed, 6 clinicians had been trained to sub-speciality level and 9 had been trained to an advanced training level within the National Training Programme. Clinicians were interviewed from District General Hospitals (9) and from Teaching Hospitals providing Tertiary level Urogynaecology services (6) across the North of England. The median number of years-experience at consultant level was 12 (range 0-22 years). There were 5 men and 10 women in the sample.

The dominant themes from the data have been identified using a thematic analysis, using the framework method as described in chapter 2. The framework can be viewed as appendix 4. The interview transcripts, thematic framework chart and overall themes were generated by the researcher (SC) as well as 2 research supervisors (RP and FMR). All interviews were conducted in quiet spaces with only the researcher and participant present, were audio-recorded and later transcribed verbatim.

4.3 Results

The major themes which appeared to influence clinician decision making concerning what procedure to best offer were:

1. Patient characteristics
2. Clinician preferences

Other major themes were identified that related to how clinicians may influence the decision of the patients they treat. These included:

3. Variation of information provision
4. Variation in the perceived role of the clinician in decision making
5. Surgeon sign off

These will be described and discussed in turn below.

4.3.1 Patient Characteristics

Clinicians frequently stated that certain patient characteristics influenced their decision making about which treatment options to offer. These characteristics
included clinical and non-clinical factors and were associated with a change to the clinicians perceived risks of procedures for that patient group.

**Clinical Characteristics**

All clinicians discussed various clinical factors that influenced their decision making about which operation to offer women. Common factors included anatomical factors, such as the presence or absence of urethral mobility, previous radiotherapy and the presence or absence of prolapse. These factors influenced which operation the clinician felt was optimum to perform.

“I think if they have a very fixed immobile urethra then I will tell them that a colposuspension may not be the right procedure for them, simply because of I can’t elevate the urethra and bladder neck, then it’s unlikely to be successful.” – Clinician 3

“if they’ve had a colposuspension...then I usually go for an obturator [tape]...I just think ...compared to the risk of going through that surgical field, it is probably better putting an obturator in. But otherwise [pause] any sort of ... pelvic fracture or something I would probably think about ... abnormal anatomy.” – Clinician 2

Presence of coexisting vaginal wall prolapse was specifically commented on in the context of whether to perform SUI surgery prior to treating the prolapse, or to treat the prolapse and SUI at the same time, and whether a colposuspension may address both conditions. There was diversity of opinion regarding this, as some clinicians favoured the staged approach and others favoured a joint approach. This may lead to women receiving different options depending on which clinician they consult.

“If they’ve got a prolapse then if it’s more than the stage 1, I tend to fix the prolapse first rather than put a tape in or anything at the same time.” – Clinician 13

“lots of centres don’t do concurrent prolapse repairs with stress incontinence procedures, I always have.” – Clinician 8
“If they have a symptomatic anterior wall prolapse at the same time you may discuss that a laparoscopic colposuspension will treat the symptomatic prolapse as well as the stress incontinence” – Clinician 3

Elevated BMI and obesity were highlighted by the majority clinicians as a strong influence on their clinical decisions. Women with higher BMI were regarded as high risk, with clinicians expressing increasing surgical difficulty, higher risks of complications and worse success rates for this patient group. This was commonly discussed specifically in the context of colposuspension and AFSP.

“In terms of people who are more problematic I think they do need a bit more guidance, so I’ve said to patients about colposuspensions, they’ve said, ‘Well, I’d really like a colposuspension.’ I’ve said, ‘Well, that’s absolutely fine, but you’re currently weighing 100 kilos and I need you to be 80 kilos or less. Is that realistic? If it is, we’ll happily wait and do it, but I’m not going to do it until you’ve got your weight down by 10 or 15 kilos because I know we’re not going to have a good a result and you’re going to put yourself at more danger from that.’” – Clinician 5

“somebody has a BMI of over 35 I would be saying to them, ‘Look, you know, the risks in a fascial sling are hernia and wound breakdown.’ I probably don’t recommend fascial sling” – Clinician 1

A proportion of clinicians described specific BMI limits above which they decline to operate. The value given for this cut off differed between individual clinicians, suggesting that women may receive different options depending on which clinician they consult.

“I don’t do surgery on anybody with a BMI more than 30, I’m very, very, prescriptive about that” – Clinician 13

“rarely do we agree to operate on people with BMI’s of more [than] 35” – Clinician 12

“most of our ladies have got a BMI of more than 30, so we couldn’t use that as a cut off, it would exclude far too many patients. Thirty-five similarly I
One clinician explained that their limit was imposed upon them by their organisation, rather than being self-imposed, implying that there is also limitation of options for women in this group depending on their local healthcare authority’s policy.

“our CCG [Clinical Commissioning Group] would not want us to operate on anybody with a [pause] for whatever on a body with a BMI more than 30.” – Clinician 14

This contrasts with others, whose judgement is based more on whether they can physically perform the procedure and how severely the patient is affected by the symptoms.

“I do like the BMI to be under 35 but I’m very individualised about it. I don’t feel that we should refuse care...to leave a woman desperately incontinent when there’s actually a 75 per cent chance of improvement from a procedure, to me feels like the wrong thing to refuse her that option of improvement, but it’s not as good as if her BMI was 25 of course not, but that doesn’t mean you sit there I don’t think leaving her for years and years struggling to lose weight when realistically there’s a very small chance of it happening.” – Clinician 9

Some clinicians felt more comfortable to offer certain procedures, such as a urethral bulking or MUS, to patients with an increased BMI. This may suggest that having an elevated BMI is a factor that could reduce the surgical options available to women, with the degree of limitation being determined by the individual clinician.

“I have a patient who needs a continence procedure, she’s declined a TVT, her BMI is 47, I’ve refused to do either of the other 2 [colposuspension or AFSP] until she loses weight. So, I [pause] you know, if she said she wanted TVT I would do it at a raised BMI of [pause] you know, but I would refuse to do a colpo, open, lap or a fascial sling.” – Clinician 6
The clinicians’ perception of the severity of the woman’s SUI appeared to be another factor which influenced the procedure offered. Clinicians described making judgements on severity of symptoms based on the circumstances which caused leakage, or the severity of leakage observed during urodynamic tests. Some clinicians appeared to direct women who they felt had mild SUI to have a urethral bulking agent, which they felt was a minimally invasive option.

“So, for example, if a patient leaks with just clearing their throat, that’s quite severe incontinence. [Compared to] If a patient...you know, you have to get them to do star jumps in clinic. I’m not saying it’s less bothersome, but that means that she does have a degree of pelvic floor [dysfunction] and to my mind that is mild incontinence. So, if somebody has mild incontinence then they might just need a bulking agent” – Clinician 6

“there’s some women where you sit there in urodynamics and they say ‘I only leak a tiny bit and it’s only occasional, and I just want a very minimal’ [pause] and I think ‘oh gosh you’ve got Bulkamid written all over you’.” – Clinician 9

However, whilst clinicians described reservations about how effective a urethral bulking agent may be in cases of severe incontinence, they did not describe feeling that it was an inappropriate treatment for this group to choose. Therefore, it appears that having perceived severe incontinence is not a limiting factor to the choice of treatment options offered. However, having perceived mild incontinence might be. One reason cited for this was the potential risk of complications associated with some procedures was perceived by the clinicians to be worse than the symptoms of mild SUI.

“in somebody with very severe stress incontinence maybe wants a bulking agent they can have a bulking agent. But I guess, it’s [pause] well, yeah and I won’t say to them it won’t work, but I sometimes feel it, so they get offered the same thing, but I’m aware that I could [pause] in the back of my head I’m going, ‘I’m not sure this is going to work’” – Clinician 12

“if someone had really severe stress incontinence, do you know what, it’s easier than if they’ve got moderate stress incontinence. So, if somebody leaks
just when they’re running, I’m a bit cautious now because I’m thinking if they only leak when they’re running then okay it’s a quality of life issue, don’t get me wrong. However, if they’re not leaking in the rest of their life, and I do an operation that has a complication, then they might not [pause] so you’re almost judging their level of what might be satisfaction but more importantly what might be dissatisfaction.” – Clinician 7

Extremes of age were viewed as difficult groups to treat; some clinicians expressed a general anxiety about operating on older patients, whilst others made a judgement based more on general health than age. The individual clinician’s attitude towards age did appear to be an important factor, with some explaining that they would guide patients towards or away from certain procedures based on age.

“I know I’m nervous of the elderly but that’s offering them anything” – Clinician 1

“I saw an 82-year-old lady this morning and I wasn’t pushing a colposuspension very hard, I mentioned it but I certainly didn’t push her in that sort of direction, so I am conscious of my own bias, so you know, for a fit as a fiddle 82 year old it might be different but she wasn’t.” – Clinician 12

The influencing factor associated with young age was predominantly family completion status. Like BMI, clinicians appeared to be polarised about this issue, and some declined to operate on this patient group. The reasons cited included the risk of symptom recurrence following pregnancy and birth and reduced success rates of potential secondary procedures.

“Yes, I am quite hard-core with those women… I don’t offer anything...You know from prolapse, from pelvic floor dysfunction, I just say I am not doing anything until you’ve got, until you’ve completed your family... I just think, you know, you are just [pause] having a pregnancy has such an impact on your pelvis... Just because the outcomes are so[pause] the long term outcomes for their long term are so poor and the other [pause] if you are going to have one, you know, you want surgery, your outcome for your first surgery is your best chance at long term success and if you, you know, then
you need second surgery after you have had your baby then for your whole
life it is the worst outcome.” – Clinician 2

Whilst it was generally felt that operating on women once they had completed their family was optimum, some would offer surgery to this group if they perceived that the patient’s quality of life was being significantly affected.

“I talk to women and say ideally we’ll do surgery once your family is finished…but if they say ‘no my baby’s one year of age and I might not but it might be two or three or four years in the future and I can’t or I’m struggling to manage my everyday life with this level of incontinence’ then I would offer them the, [a] procedure” – Clinician 9

There also appeared to be differing attitudes towards specific procedures for the young patient group. Most clinicians did not refer to a specific age, instead referring to women as in the ‘reproductive’ years. Others, however, were clear this meant under 30. Some felt that colposuspension and MUS were not optimum procedures for this population, suggesting that there may be a limitation of options offered by clinicians to women in this group.

“If you’re in the reproductive age group I still wouldn’t offer you tape [MUS] or colposuspension because I think, well, it’s best to, kind of, leave that until there’s no strain on the pelvic floor anymore.” – Clinician 13

“under the age of 30 we have always been loath to do Mid-Urethral Slings, believe it or not. Between 30 and 40 we’ve been reluctant, and this is something that predates the mesh problems, this is something that in our unit we’ve always felt. We only have 20-year data on this procedure, at that time 17 year or before that 15-year data. How can you do an operation on a 24-year-old who, you know, is going to have this procedure or need this procedure for much longer? So those are huge factors I think that influence, at least my decision-making in terms of, you know, how we decide what we think might be the best option for the patient.” – Clinician 6
Medical co-morbidities, such as diabetes and chronic pain syndromes, were also discussed. There appeared to be a general reluctance to place polypropylene mesh in women affected by these issues, with clinicians being concerned about higher risks of mesh complications, such as infection and pain.

“I’m concerned about diabetes and implants, permanent implants with tapes [MUS]...I had a terrible case, a diabetic, a terrible infection with a tape, so I’m very, very cautious with diabetics and I’ll say to them, ‘I need your diabetes better controlled than it is. I’m not doing a tape operation, we’ll do something else or you can get your diabetes sorted out, but we’re not going to do this operation until it is sorted,’ or something like that.” – Clinician 5

“And I occasionally, the other people that I might be a little bit worried about are people with chronic pain anyway...Having tapes for instance, because you know it will be blamed for it even if it is nothing to do with it.” – Clinician 11

From the interview data it is clear the clinical factors discussed above had significant influence on the decision-making process of the clinicians. What was unexpected, however, is the apparent inter-clinician variability in attitude towards each of the factors, with some placing more importance on certain factors than others. Clinicians appeared to have individualised parameters for what they would find acceptable, hence patients with identical clinical backgrounds may be offered different sets of options based on which clinician they see. This may be due to the clinician’s degree of concern for risk in relation to the clinical factors, which was a common theme throughout the data set. This was closely related to clinicians feeling that they were accountable for the decisions made, and therefore, there was a degree of self-protection by imposing certain clinical criterion.

“You know, say for example, I decided to do someone with a 40 BMI and she ends up in ITU because I’ve gone and buggered some vessel, it might have happened if she had a BMI of 20, but I would knock myself saying, ‘Well, it’s because I’ve done it on somebody I shouldn’t have done it on because I don’t normally do it in that group.’ And so rather [than] get in that pickle, I’d rather be seen as being mean.” – Clinician 13
“I don’t want to have complications…I don’t do complications, and I get quite hurt and upset, and antsy about why it’s happened and mither [worry] over it” – Clinician 7

Preference per individual patient’s characteristics

As discussed above, clinicians appeared to consider various patient characteristics when considering which operation to offer. Whilst clinicians may have an underlying, personal preference of procedure or procedures, these appear to be compared to the characteristics of the individual patient to conclude what options are deemed appropriate.

“in terms of Bulkamid under GA [pause] well I suppose previous surgery, age, diabetes, actually if they’ve had atrophic vagina, that sort of thing, then I wouldn’t put a mesh in, I might try some Bulkamid first.” – Clinician 2

“your average woman who’s normal BMI and then I would offer them loads of things. If a woman comes up with a raised BMI then or maybe very elderly and depending on their voiding studies or urodynamics and all that you may change your approach.” – Clinician 4

Non-Clinical Characteristics

Non-clinical factors influencing decision-making included the clinician’s perception of what was important to the individual patient they were treating. All clinicians recognised that it was important to treat each patient as an individual, recognising their specific treatment goals.

“everybody’s different, you will get people saying ‘oh I can’t possibly take time off work’. You will get people who will say ‘I want the thing that’s most successful’.” – Clinician 11

“There are some women who don’t [pause] you know, they’re not that bothered if they leak a tiny bit...Whereas, there are other women who their absolute goal is to be bone dry.” – Clinician 1
By exploring the factors which were acceptable to their patients, clinicians appeared to build a picture of what may and may not be appropriate surgical options.

“on balance we are getting people now saying ‘I am not having anything to do with the mesh’. We get people who say ‘I am not having anything that’s unnatural’, so that counts Bulkamid out then you end up having to have a colposuspension.” – Clinician 11

“When you are talking about bulking agents and you’re using phrases like it’s got virtually no complications other than perhaps cystitis, the success rates are a little less than you might wish, certainly less than TVT or colposuspension, but many of them [patients] say ‘but I don’t want to keep coming back’. They want something that they know is long lasting and therefore that takes you back to TVT.” – Clinician 7

Clinicians observed that an increasing number of women were attending their consultations with pre-formed opinions about polypropylene mesh, not willing to consider it as an option. The main reason discussed for this change in patient perception of the MUS was the media coverage of polypropylene mesh complications. Many clinicians perceived this resulted in patients discounting mesh and giving consideration to other alternatives which they may not have done prior to the media coverage.

“with the media news regarding mesh complications many are now very worried about having mesh and are then in a position where they either consider what they feel is a bigger procedure or they go for a less effective procedure.” – Clinician 3

It was highlighted that the media coverage was affecting the way in which counselling of options was conducted, with one clinician even directing patients away from mesh.

“Say that they want a sling [MUS] I maybe subconsciously try to deviate them away from that. I don’t think I do consciously but I think I have to emphasise that, yes, I’m happy with slings, we’ve performed slings for many years but
there is an ongoing [pause] [problem] as you know. Most patients are fine but if somebody has problems with pain then for that person it’s a problem”
– Clinician 14

4.3.2 Clinician Preference

Personal Preferences

Clinicians described personal preferences for certain surgical procedures. There was a strong preference for MUS, either in the form of retropubic TVT or trans-obturator TVT-O. Reasons cited included ease of procedure, low risk profile to the patient, reproducibility and a good success rate.

“TVT, retropubic TVT, I still think is the best operation we have. I do accept it’s not perfect because of the issues with mesh. If I was to have an operation, I would still go for a TVT over a colposuspension personally.” – Clinician 5

“I love TVTOs, it’s just quick, it’s fantastic I’ve never had any problem with them, and I can do loads on the list and it just, you know, it’s just very good and my patients usually come back happy.” – Clinician 10

There appeared to be a clear feeling of surgical familiarity described with MUS, with many clinicians explaining that it had been the most common operation they had performed in their clinical practice. This was felt to be due to a significant practice shift after the introduction of MUS, whereby most units offered this primarily.

“in my last 15 years I probably did about 5 colposuspensions a year, about 10 fascial slings and the rest tapes [MUS] with again only about 5 injectables. So very low numbers of those and at my peak I was putting 120 tapes [MUS] in a year.” – Clinician 8

“Traditionally when I first started, we offered colposuspension then TVT came along and we adopted that in line with, you know, pretty much everybody else.” – Clinician 4

Some clinicians described having limited exposure to all the procedures during their training.
“I just came when TVTs were really taking off and were established, so when I really started stress incontinence surgery the TVT was now well established, so my exposure to colposuspension is even, you know, how old I am is still fairly limited really because we just [pause] TVT had become the norm.” – Clinician 2

Conversely, some clinicians indicated their preference was dependent on their aim, preferring MUS for success but Urethral Bulking Agents for their low risk profile. This highlights the differing attitudes to risk between clinicians and how this can possibly influence which operation is ultimately decided upon.

“The preference in terms of more likely to have a successful outcome I would say is a suburethral sling [MUS]. The preference in terms of the bigger picture and in terms of the risks and the risk profile, safety, well, I would say bladder neck bulking...I’ve been doing it for a few years, for many years now, I’m happy with the technique and I’m happy that actually I think most patients [pause] again, most of the patients will say, if you explain that they can get back to their normal activity fairly straightaway, local anaesthetic, they go for that.” – Clinician 14

Reasons cited to not favour a procedure included the risks involved, perceived surgical difficulty and poor personal experience with a specific procedure.

“colposuspensions have gone up which is a pain because I hate them, they’re so fiddly.” –Clinician 2

“I certainly moved away from colposuspensions as an issue with the operating because it has serious downsides; (a) it’s a bigger operation, it’s a more morbid operation, [there] is a long-term problem with prolapse” – Clinician 5

None of the clinicians indicated a preference for AFSP. There was a diversity of opinion regarding AFSP being offered as a primary procedure. Whilst it is a procedure that can be offered as a first line treatment, some clinicians felt it was better as a secondary procedure. This opinion was based on their prior experience.
of it being offered in such instances and that more minimally invasive, lower risk procedures are available.

“I’ve never considered fascial slings as a first-line procedure, I mean, perhaps I should. It’s got such a high voiding dysfunction rate, I mean, figures of 20% void, significant voiding dysfunction rate are [pause] what was quoted when we were doing them and they were viewed as a, ‘Well, we’re going to salvage [pause] use it as salvage operation from failed colpos.’” – Clinician 5

“I don’t like to do it [AFSP] as a primary continence procedure and that probably comes across to my patients…I think it’s a far more invasive operation than a lap colpo or a TVT. I think a lap colpo or TVT are pretty equivalent in terms of invasiveness and a fascial sling is not, I think that is a more invasive procedure, in my mind. Having been brought up to accept this as a second line operation and then from the NICE guidance of 2013 suddenly being told this is now a first-line, is the change in that mind-set. Yes, I have changed my mind-set to accept that this is now a primary continence procedure, but I think somewhere in my memory I still consider this because that’s how I was brought up, to always do this as a secondary continence procedure.” – Clinician 6

Some also felt unable to provide the procedure at their unit, which also influenced if it was discussed as an option. Consequently, some clinicians do not discuss or offer AFSP.

“No because we don’t offer it here [AFSP] and I have [pause] you know, so that’s why I don’t usually discuss or offer anything that I know nothing about…So I don’t feel it is necessary and I don’t think it is even in our patient information leaflet or in our local guidelines to discuss fascial slings.” – Clinician 10

However, even if AFSP was discussed, some clinicians explained that they would actively steer patients away from this as an option because they felt that other, more suitable options were available. Therefore, it is not known how willing some clinicians are to provide AFSP as a realistic option.
“We say what the sling [AFSP] involves...and say it’s a fairly big surgery and we generally don’t do that as a first line option because there are more minimally invasive options that have quicker recovery and less risk of complication to you, but it’s important that I give you all the options.” – Clinician 9

“I mean, so we now say, ‘Okay, well, there are alternatives that you consider before mesh,’ and those alternatives may have, you know, more morbidity than mesh such as Colposuspension or the slings [AFSP]...I truly say to them, ‘Actually, I think a mesh is [pause] you know, the tape [MUS] is better. A less morbid procedure in the long run.’” – Clinician 4

Some who did discuss feeling prepared to offer and perform AFSP as a first line treatment felt more comfortable with it as an option if there was another factor complicating the SUI, such as congenital anomaly of the urinary tract. Others felt that if the patient had considerable concern about a foreign body being implanted then they would regard AFSP as an appropriate option, regardless of clinical complexity.

“I have done sling operations [AFSP] as primary usually when there’s been some other underlying, driving [pause] it hasn’t been just a straightforward case of primary stress incontinence. There have been other factors involved and it is things like congenital abnormalities, a previous surgery, radio[therapy] [pause] you know, if they’d had previous cancer surgery, whatever, there may well be reasons why you wouldn’t want to put in a tape or do other procedures. But for somebody a fit, healthy, young woman, if she came up and said she wanted a sling, I haven’t been in that situation yet, but, you know, it’s difficult, but if you are offering choice then you’ve got to be prepared to offer, you know, to provide that for them if that’s what they want. So I would be prepared to provide it, yeah” – Clinician 8

“for patients that don’t [pause] patient doesn’t want mesh that, you know, colpos are inappropriate [for]. Patients that don’t mind a high risk of voiding dysfunction, I think it’s totally appropriate” – Clinician 15
Clinicians discussed feeling directly responsible for procedures they performed and any resultant complications, despite these being recognised in literature and being discussed in the consent process. There was a general preference for procedures perceived to be minimally invasive, having lower surgical risk associated with them. Minimally invasive procedures appeared to pose the least risk to the clinician as well as the patients they treat.

“the choice you offer lies with the clinician… I would have to be able to defend what [pause] why I offered those choices and why if I withheld something, why would I withhold it...you have to be able to defend the choices.” – Clinician 1

Clinicians preferences also appeared to be influenced by individual perception and interpretation of available clinical evidence. This was discussed manly in relation to support of the preference for MUS, with some commenting that there have been comparative studies looking at this procedure, whereas other procedures still required investigation.

“It [TVT] worked well, it was successful, it was thought to be [pause] you know, people thought compared in randomised trials, it’s been compared to Colposuspension” – Clinician 1

“we have got 1 year, 2 year, 5 year, 10 year and some 20 year data on that [TVT] and we’ve just [pause] we’ve only ever done the one procedure and we’ve stuck with that and hopefully, you know, we’re protected by that evidence.” – Clinician 8

“I do like bulking, I think it has a place, but it needs to be investigated.” – Clinician 1

These personal preferences and attitudes towards certain procedures may result in the clinicians not having equipoise, even before they clinically assess a patient with SUI. This may influence what options are ultimately given and how they are discussed.
“So I do have equipoise between a bulking agent and I think it’s patient choice. You know, if they want to choose something that’s an out-patient procedure, very straightforward, very low risk, they might need another procedure. I do have equipoise for that...in terms of between the others, do I have equipoise? No, I don’t have equipoise.” – Clinician 1

“I don’t encourage them, I just say, ‘Look, as far as I am concerned it’s a safe procedure,’ [TOT] and if they say, ‘Would you have one?’ I’d say, ‘Yes, I would actually’...and when they say, ‘Well, what about Bulkamid or what about any injectables?’ I’ll say, ‘Well, yes I’ve done maybe 50 of those in my career as opposed to 500 tapes [MUS].’ You know, so my own experience comes into it a little bit as well, probably not truly equipoise about this” – Clinician 4

**4.3.3 Variation in information provision**

**Directed Counselling**

Many clinicians described that they would ‘guide’ or ‘steer’ a patient towards a treatment option that they felt would be most appropriate for the individual they were treating. These practices ranged from giving a direct recommendation to a patient, to selectively emphasising advantages or risks associated with certain procedures. This appeared to occur if patients had factors which the individual clinician perceived to increase their risk of complications.

“I will say in light of this perhaps if somebody’s got, I don’t know, loads of co-morbidities and the risks are fairly [high]... a long head down laparoscopic [operation] ....and they seem to have mildish stress incontinence then perhaps some outpatient periurethral bulking would be less risky for them. So, yeah, I might well say these are the options however in view of this and this, so and so maybe a better option for you. So, I’ll certainly guide them” – Clinician 9

Other clinicians actively tried to dissuade patients away from procedures which they felt were inappropriate for them.
“inevitably I’m going to be extremely reluctant to perform a colposuspension now on somebody who had primary stress incontinence, for instance and certainly I wouldn’t, you know, recommend an Aldridge sling [AFSP] for them, kind of. So, I would steer them towards a more minimally invasive procedure.” – Clinician 4

The order in which the options were presented, and the language used appeared a method by which clinicians may covertly present their own preference to the patient. Some clinicians explained that by positively or negatively framing the options, the choice of the patient could be swayed.

“If we are steering people we emphasise what we think the advantage is for that particular person, would be a very particular procedure that we think is the right thing for them I suppose rather than, it is difficult isn’t it, because you don’t think about it as you do it, but I suspect that’s what we do rather than anything else” – Clinician 12

“The options of a procedure which is a day case, you go home the same day, you’ll be back into action in a couple of days and you’ve got a good chance your stress incontinence will be cured. Alternatively, you can have an operation where you might need a 5 day stay in hospital with complications of voiding difficulties increase and needing for a catheter for a short period of time, 3 months off work/8 weeks off work.’ And I usually find that the patient goes ‘Oh, okay, that sounds to me like, you know, take the injection will be better.” – Clinician 4

When describing certain procedures, language describing the size of the operation was commonly used. For example, when describing colposuspension or AFSP, these were commonly described as ‘big’ procedures, or ‘the biggest’ procedure. This is in contrast with the way that MUS and urethral bulking were described, using phrases such as ‘simple’ and ‘easy to do’.

“we talked about bulking agents, we talked about tapes [MUS] and then I said, ‘there is a bigger operation [colposuspension]’.” – Clinician 12
Interviewer to Clinician 8: “And you mentioned, kind of, the standard spiel. What would be or what would constitute to you as standard spiel?

“Well...tapes that they have been the most popular operation in the last 20 years, [and] that they are very easy to do” – Clinician 8

Some clinicians appeared not to present urethral bulking as a surgical procedure, instead describing it separately and as an alternative to surgery. This may remove any connotations which the term ‘surgery’ is associated with and may evoke a different response from the patient.

“So, I will say ‘well these are your options’, if they decide they want to go for surgery then these are the options and I will say ‘or we have Bulkamid [urethral bulking agent] as an alternative’” – Clinician 2

**Historically mesh for all**

Some clinicians expressed an awareness of the practice of steering patients to a certain procedure. Some felt that there was a culture, in the recent past, of steering most patients towards MUS, with little consideration of the available alternatives. However, there was recognition that efforts were being made to change this and to discuss alternatives in greater depth.

“I’d like to think I always counsel patients extensively, but I wouldn’t say I was as neutral as I am now, I would ease them towards the TVT because it’s effective and simple, and safe.” – Clinician 7

“I must say, when the tapes were there, although we offered everything, looking back I wonder whether we were biased towards saying, ‘Well, these things are available, but the tape is what you want.’ Whereas, now I’m feeling that I need to take a bit of a step back and try and be, you know, unbiased about things” – Clinician 8
**Variation in presentation of the risks**

When discussing the information given to patients, there appeared to be variability in how the risks of operations were presented. Some clinicians presented numerical information about the risks, whereas others used descriptive language such as ‘high’, ‘low’, or ‘very low’. There was also variation in the numbers attached to specific risks. Hence, patients do not appear to be receiving standardised information during their counselling.

*Interviewer to Clinician 10: “And what numbers do you quote?” [Regarding mesh complications]*

“I don’t quote. I would say in my experience it is very rare” – Clinician 10

“undoubtedly there are people who have pain [from mesh] and it’s a big problem to them, but it is not actually very common and we have done about 1,000 [MUS] over the years here and I have got 2 or 3 people who’ve got pain” – Clinician 11

“we say 5% [mesh complication risk].” – Clinician 2

Some clinicians chose to present the risk data from their local unit rather than national risk data, representing another way that patients may receive differing risk information based on the clinician they consult.

“we’ve audited our own procedures and because I know [what our] own complication…and our own success rate is, and I tell the patients specifically about [pause] our...success rates and exposure rates.” – Clinician 4

However, clinicians did discuss using information leaflets, produced both by the local unit and international societies, such as the International Urogynaecology Association (IUGA). However, one clinician did question the accuracy of the local information leaflets, explaining that they may not be thoroughly fact checked. Therefore, the local information leaflets may represent another source of bias.

“Because, you know, what I write in our information leaflet I could write the moon is made of green cheese ’cause it goes through the patient body and all
the rest of it to make sure it makes sense to patients but actually nobody checks it for fact.” – Clinician 12

4.3.4 Perception of what the clinician role in decision-making should be

There was evidence of different types of clinician, ranging from the technician to the paternalistic.

Many felt that they offered all patients all the options of operations and allowed the patient to make the decision, with at one extreme, some feeling their role was that of a technician.

“I will still explain the, you know, the pros and cons of each approach and say, ‘Right, well, actually you need to make the decision. This is your decision. I’m just a technician here.’” – Clinician 4

“we give the patients [pause] we don’t give them directive counselling. We give them the choices, we give them the information leaflets, we ask them to decide which one they want to go for.” – Clinician 6

Others described feeling that clinicians should have an active role within the decision-making process, taking an advisory role on the different risks and benefits of each procedure for an individual patient, ultimately suggesting that they should be able to profess a preference.

“I don’t think that the doctor is a technician. So if somebody [pause] you know, the extreme of that is the patient who comes in and says, ‘I really don’t like my left leg. I want it chopped off,’ just ‘cause I can technically do it, I don’t think I necessarily should. I have a duty of care to patients to actually try and provide them with what we think [is] medically the right procedure” – Clinician 1

“Yes, I think it’s quite important that when you offer them the choices you also advise them whether there’s any specific choice that might be less suitable for them or more risky for them.” – Clinician 3
Others actively helped their patient come to a decision, rather than sharing a preference, taking into account what factors are described as important to an individual patient.

“I say ‘well I don’t know because what I would do for me in my situation is not the same as for you, but let’s talk a bit and try and put me in your situation and then I can help you decide what I would do if I were you’.” – Clinician 11

Some clinicians described the decision as a two-step process; the first being the decision to have surgery, and the second being the decision of procedure. Some clinicians felt that the decision of the options given, and which procedure should be the responsibility of the clinician, taking a more paternalistic view on the process.

“I think to go for an operation it’s the patient making the decision to go for an operation. Which operation, I think ultimately patients still look to us as clinicians and trust our experience based on what we think is better for them”
– Clinician 14

Possibly the most common approach of clinicians was succinctly summarised by clinician 1’s statement.

“Choice lies with the patient. What you offer, the choice you offer lies with the clinician” – Clinician 1

Clinicians appear to straddle the technician/modern role of shared decision making and paternalistic approach by the subtle way they present and frame the choices.

Reasons cited for guiding and advising a patient on what was best included patient safety and fear that an unwise decision would be made. The gap in knowledge between the clinician and patient was raised as an issue, with the clinicians discussing their greater knowledge of the options and being able to better judge what would be the best procedure per patient.

“I think there is a degree of leading them to [pause] and I can’t get rid of it. I can’t just sit there and be unbiased because patients, I think, would make decisions that are just not sensible and you do, you juggle with that because as I say everybody else keeps telling us that, ‘No, it has to be patient choice,
what they want,’ but we’ve got to be sensible about it. You know, the patients, a vast majority are not medically trained, don’t have the knowledge…it’s difficult, I can’t just sit there and let them make the decision because then I’m just a technician doing what, you know, what the public say, what they think they want. There has to be, some [value to] the fact that I have 20 years’ knowledge in there and that I do know a little bit of what I’m talking about, [to] give them all the choice...we know all of the pros and cons, we know the complications, we know what the ins and outs of every procedure. The patients by and large have no idea what the implications are of that operation for them in the future, so you have to lead, you have to help them make a decision.” – Clinician 8

“The golden patient”

There appeared to be variability in the amount of choice given to patients depending on their clinical characteristics. There appeared to be an ideal patient to whom most clinicians would offer a free choice of any operation. Therefore, they may be subject to a different method of decision making with their choice being truly preference sensitive.

“So, if a patient has got primary stress incontinence and there’s nothing particularly wrong with her that’s contraindicating any of the operations, so she’s not massively obese, she’s not got a previous load of vaginal surgery, she’s not got medical issues, then I’m going to give her the information. And I’m going to explain the operations to her, give her written information and I’m going to send her away to make a decision and I’ll ask her to make that decision. I’m not going to guide her at all... Because in that kind of patient I don’t think it’s my role to be taking her responsibility... In terms of people who are more problematic I think they do need a bit more guidance” – Clinician 5
**Pressure of time**

Limitation of time was discussed as a factor influencing the clinician role in decision making. It was recognised that the amount of time given to explore and counsel about the options was limited and impacted the depth of counselling given. One clinician described that they are more likely to intervene and help decide if the appointment had taken a prolonged amount of time.

“If I am sitting there and I am thinking this is taking 20 minutes, I am going to have to make the decision for them.” – Clinician 2

**4.3.5 Surgeon ‘Sign Off’**

Once a decision has been reached by a patient, clinicians described performing a rationality assessment of that decision. If the clinician felt the decision was reasonable, they would agree to perform the procedure. However, if they felt the decision of the patient did not align with their opinion then, they could decline to “sign off” the surgery.

“we’re paid to be able to give some direction and does that mean that if a patient chose an operation that I was fundamentally opposed to, I would do it? No, I wouldn’t.” – Clinician 7

“It depends on the patient. Some patients [pause]somebody will come in and sit down and say ‘this is what I am having’...you know you are well informed, you’ve gone away and, that’s fine, they’re easy in some ways, unless they are wanting something completely bananas” – Clinician 2

This sign-off process also continues at the wider level, with clinicians explaining that decisions must be discussed and agreed by other urogynaecologists at multi-disciplinary team meetings (MDTs). Therefore, patient decisions do not only have to be signed off by the individual clinician, but also by the wider team. Patient decisions could be changed based on this judgement.

“Everything goes through the MDT and sometimes that [pause] most of the time it’s just rubber stamping what, you know, what I think is going to happen, but I take things to the MDT that sometimes my colleagues disagree
and say, ‘Well, why didn’t you talk about this?’ And then I’ll bring the patient back and say, ‘Well, this was the result of the MDT and in light of that we probably need to discuss this again.’” – Clinician 8

4.4 Discussion

This is the first study to evaluate the role clinicians play and the factors they consider important in counselling women choosing an operation for primary SUI. The study found significant variation in the information clinicians provide to women about the risks and benefits of each procedure.

The decision to offer certain operations appears to depend on the specific characteristics of patients. These commonly include age, BMI, co-morbidities, perceived severity of their condition and previous pelvic surgery. However, there is apparent variation between clinicians, each appearing to have individual rules and variable thresholds for patient characteristics which they perceive may influence the potential risks and benefits of each procedure.

The procedures offered also appear to be influenced by ability of the clinician to perform each operation and their inherent preferences for each operation.

The study found that clinicians appear to utilise an internal decision-making process separate from that of the patient. This suggests that in clinical practice, the current decision-making process is probably not wholly preference sensitive. It also appears that clinicians have the final ‘sign off’ of any decision, being able to agree to a procedure or to disagree and decline to operate.

These are important findings because it suggests that women with the same characteristics may receive different treatment options depending on which clinician they consult. The question remains as to why this variation exists.
**Choice limited by patient characteristics**

At present, there is no national guidance to inform clinicians in how to manage patients with perceived high-risk characteristics. In these circumstances, individual clinicians appear to appraise available evidence to form their own conclusions as how best to proceed. In the case of many of the above characteristics however, there is limited evidence as to how these factors may impact the various available procedures. There are few large randomised trials comparing these procedures in these specific groups. Hence clinicians rely on anecdotal evidence and experiential factors when deciding on the best option to offer to women with perceived high-risk characteristics.

The clinical factors that demonstrated the most marked variation in the threshold to offer or withhold surgery appeared to be BMI, family completion status and extremes of age; these factors will be discussed in greater detail below.

**BMI**

Current evidence regarding the impact of BMI on the outcomes of SUI surgery, for any of the 4 procedures, is inconclusive. The majority of available evidence pertains to MUS (104)(122). This may explain why some clinicians feel more comfortable to offer MUS to women with an elevated BMI in comparison to other surgical procedures. Most studies define obesity using the World Health Organisation’s definition, as BMI equal or greater than 30. However, many clinicians consider a BMI of 35 and above as clinically relevant, and therefore, it is difficult to apply the findings of certain studies to clinical practice.

A 2017 meta-analysis of 11 prospective and retrospective cohort studies examining objective and subjective outcomes of women undergoing MUS with elevated BMIs found that the objective success rate for women in the overweight and obese category (BMI >25) was worse in comparison to those who had a normal BMI (<25). These finding, on initial viewing, would seem to support clinicians who decline to operate on women with a BMI above 30 because of poorer outcomes. However, on
further evaluation, the strength of this evidence is limited as the statistical analysis for the objective outcome comparison domain within the meta-analysis showed the risk ratio to be close to 1. Therefore, the authors conclude that BMI should not be a limiting factor when considering a TVT (123). This conclusion would support the clinicians who do not impose a strict threshold for BMI on women wishing surgery for SUI.

Subjective success rates post MUS have been reported to be lower for women in larger BMI ranges compared to lower ones. A retrospective cohort study by Bach et al analysed the patient global impression of improvement (PGI-I) scores of 7429 cases submitted to the British Society of Urogynaecology (BSUG) database at differing time points post MUS to investigate the differences in results per BMI group. They reported that the PGI-I scores relating to patients feeling ‘improved’ or ‘very much improved’ reduced with increasing BMI. Of those in the BMI group 18 to <25, 91.2% reported improvement, versus a 72-87.7% report of improvement in the >30 category (105). However, whilst the reduction in PGI-I may be statistically significant in the study, what this reduction in PGI-I meant for the women in clinical practice is unclear. Women who do not report the top 2 levels of improvement on the PGI-I may still be clinically satisfied with their procedure, or they may be cured from their SUI symptoms but perhaps have developed other symptoms, such as overactive bladder. There was also a spread of time points at which the follow up data was collected, with the longest follow up being reported 12 months post operatively. Therefore, these findings are only valid in the short and medium term.

These studies highlight the limited and conflicting evidence clinicians are presented with. In the face of limited evidence, clinicians may have to rely on anecdotal evidence, contributing to the apparent practice variation observed within the results.

There is even less evidence regarding the outcome of surgery for SUI in women with raised BMI after a colposuspension (open or laparoscopic), urethral bulking agent or AFSP.
In 2007, a multi-centre randomised control trial of open colposuspension or AFSP found both objective and subjective outcomes were statistically better in the group undergoing AFSP (85). Women with an elevated BMI were recruited to this study, with the mean BMI of participants being 29.6 +/- 6.1 in the Burch Colposuspension group versus 30.3 +/- 6.1 in the AFSP group. However, there was no further stratified analysis of the results by BMI. Therefore, it is difficult to comment as to whether the outcome findings would be the same for women within more elevated BMI groups, such as equal to or greater than 35.

A 2002 single site retrospective case series study examined the outcomes following either a laparoscopic colposuspension or a TVT in women with an elevated BMI (124). Of the 51 women in the colposuspension group, only 18 women had a BMI of 30 or above, with 13 having a BMI between 30-34, and 5 having a BMI between 35-39 and none over 40. In comparison, 60 out of a total of 91 women undergoing a TVT had a BMI of over 30, with 21 in the 30-34 group, 17 in the 35-39 group and 22 in the over 40 range. The study reports that the women who underwent TVT had no recurrence of SUI, regardless of BMI, and had no intra-operative complications. However, the authors did comment on the disparity in numbers between the groups, recognising that their team mainly offered laparoscopic colposuspension to women with a normal BMI or ‘obesity 1’ (30-34) due to a fear of post-operative failure and increased surgical difficulty. Other non-randomised trials found less obese women in the colposuspension group to compared to TVT (125). This seems to reflect the views of some of the clinicians interviewed in our current study, and clinical opinion has not changed in 16 years. The general reluctance to operate on women with an elevated BMI leads to a paucity of evidence that reinforces the opinions and biases held by clinicians. The proportion of the population with obesity is rising and hence there is a need to determine the best management option for these women.

**Family completion status**

At present, there are limited data concerning the impact of childbirth on the risk of recurrent SUI for women who have had an operation for SUI. The data available consist mainly of case reports and case series, the largest of which reports 20 cases of birth following insertion of MUS (126). These reports indicate that there appears
to be no difference in the rate of recurrence in SUI symptoms dependent on the mode of delivery or the birth weight. However, there appears to be some evidence that SUI symptoms in the antenatal period is an independent factor related with an increased risk of post-partum SUI (108). These findings, although representative of relatively small numbers, support the views of clinicians who offered SUI surgery to women of reproductive age who have yet to complete their family. However, due to the small numbers reported, others could argue that not enough is known to confidently offer SUI surgeries to those who would like to have more children. All the reviews concerning birth after SUI surgery focus on MUS, with there being no available literature to the knowledge of the author concerning birth after the other SUI procedures available. This, therefore, supports the clinicians who felt most comfortable to offer the more minimally invasive procedures, such as MUS, to this population of women but only because there is an absence of evidence for other procedures.

Extremes of Age

There is limited evidence regarding the extremes of age and what are the optimum procedures to offer in these circumstances. This has been formally recognised by the International Consultation of Incontinence Research Society, who have called for further research into this area to help guide best clinical practice (106).

Regarding patients who are deemed to be young, the ideal surgical procedure should have high rates of long term efficacy with low risk of long term complications (106). The two procedures that have been studied most extensively for their long term efficacy appear to be colposuspension and MUS, having 69% success rate at 20 years and 90% objective success at 17 years respectively (127)(128). However, both have long term risks of complications, such as prolapse and the unknown long-term risk of polypropylene mesh. As discussed above, there is little evidence regarding the effect of childbirth on the long-term efficacy of these procedures. Therefore, it is understandable that clinicians may feel it best to wait to offer certain surgical
Clinicians in this study were concerned about offering procedures to women who were older, being concerned about the risk of complications. There is limited evidence to support this, with most of the data concerning older age related to outcomes of MUS. A 2007 study analysed the effect of age on complications from MUS that were performed between 1999-2001. A total of 1356 MUS procedures were performed in this time for women aged 65 or above. The 12 month follow up data showed that rates of new onset urge incontinence, treatment failure and obstruction secondary to the MUS were greater in women aged 75 and above in comparison to women aged 65-74 (107). It also reported that women in the over 75 age group who had more co-morbidities had higher rates of nonurological complications, such as pulmonary embolism and cardiac events, in the 12 months following surgery (107). These findings have not been supported by other large retrospective studies. Toosz-Hobson et al reported no significant difference in short term post-operative complications following MUS depending on the age in their review of 7600 cases (129). This study also reported that the subjective improvement in SUI remained high across all age groups of women receiving a MUS, with 93% in the 70-79 age group reporting improvement or cure, as compared to 98% in the under 50 age group (129). This highlights the conflicting data that clinicians have available to base their judgements on, and that further research is required to help guide practice.

The use of PDAs should reduce the variation seen in this study; however, on reviewing the recently published PDA from NICE (81), the lack of evidence available to directly compare procedures per different patient characteristics may limit their effectiveness.

**Clinician Preferences**

Clinicians appeared to favour procedures that they felt most familiar with, and in most cases that was the MUS. They appeared to favour it because they had the most experience with it as a surgical procedure, and they felt their patients had good
outcomes from it. This is reflected by the number of MUS procedures that were previously being performed, being the most popular SUI procedure in the UK (64). Some clinicians felt they had limited exposure to non-MUS procedures during their training, and thus felt unfamiliar with them. This may have contributed to the apparent strong preference for MUS.

Training also appeared to influence some of the clinicians’ attitude towards some of the procedures, most notably towards the AFSP. Some regarded this as a secondary procedure, only to be considered if a procedure that is perceived to be first line, such as MUS, fails. Others described only being willing to perform AFSP if there was another complicating factor to the SUI, such as a congenital abnormality.

Clinicians seemed to prefer procedures that incurred lower perceived risk to their patients. There appeared to be a dimension of self-protection linked with this, as many clinicians described how they felt worried and anxious about complications, feeling responsible for the outcome. A 2017 systematic review of the emotional, psychological and behavioural impact following adverse surgical outcomes found that many surgeons feel strong feelings of guilt and self-blame, which can lead to alterations in behaviour in the future (130). There was evidence of this in the current study. Several clinicians expressed negative opinions about certain procedures, such as colposuspension and AFSP, due to their recollection of complications from these procedures. This is another example of how anecdotal evidence can influence the operations clinicians will offer for SUI.

Choice limited by presentation of information

Clinicians appeared to vary in what information they provided and how it was presented to patients. They discussed how, for some women, they felt it was necessary to give direction towards a certain procedure they felt to be best for the patient. This was strongly linked with those who were perceived to have high-risk characteristics. The way in which this direction was given appeared to be via directed counselling. Some clinicians described they may do this via a non-conscious process of exaggerating the disadvantages, or risks, associated with certain procedures they
do not consider to be best for the patient. This practice has been recognised in other studies, and has been labelled as implicit persuasion (131). Some clinicians described giving a direct recommendation, briefly discussing other options but pointing patients towards other, perceived lower-risk procedures that were perceived to be more acceptable. This directed counselling appears to contravene the recommended shared decision making approach to this decision (5). Instead, it appears that some clinicians may direct patients towards a certain procedure they wish the patient to choose, and in this way, it could be seen as a form of paternalism. This is an important finding as it may mean that in clinical practice at present, shared decision making may not always be being utilised when deciding on a SUI procedure.

Other clinicians described using comparative language, such as bigger versus smaller, or high versus low, when describing certain procedures and the rate of risk attached. Other studies have shown that subtle descriptors of procedures can affect patient perceptions. Fitzgerald et al (132) investigated the effect that describing an AFSP and MUS as ‘new’ or ‘old’ had on patient perceptions and overall choice. A large proportion of participants (79%) felt that newer procedures were better in general than older procedures, with the majority (92%) choosing an AFSP when it was described as ‘new’ compared to the MUS as ‘old’. These findings suggest that other descriptors, such as those used by the clinicians in this study, could also influence patient perceptions that could ultimately influence the overall decision of SUI procedure.

Clinicians described using different descriptors for rates of risk, with some using numerical data, some giving different individual numbers, and some using describing language. This was particularly seen in relation to the risks of mesh used in MUS’. This is an important finding as it has medicolegal implications, with patients potentially being given differing risk data that may influence their decision. It is recommended that women should be aware of all the risks of the various surgical options when coming to a decision (5). However, it is also recognised that there is limited evidence for the long-term complications of mesh, which may be a reason why clinicians choose to use their own regional data to provide some idea for patients from their experience. NICE have recommended that all women undergoing
a SUI procedure should be added to a national registry, such as the BSUG database, to ensure that this data will be available in the future.

**Perception in what the clinician role in decision-making should be**

Clinicians appeared to hold inconsistent beliefs about what their role in the decision-making process should be. Many felt that the overall decision was the responsibility of the patient, with some even describing themselves to be like technicians. This was akin to the informed decision-making model. This model assumes that the clinician role is not to help make a decision but to inform patients, increasing patient knowledge by imparting information and then allowing patients to come to a decision with the knowledge that has been given to them (89). This assumes that the decisional responsibility for any treatments decided in this way resides with the patient.

However, this contrasted with others, who described that they should hold responsibility for what operations to offer. Many discussed their duty of care to patients and cited wishing to provide procedures they felt were in the best interests of patient safety. Along this line, others feared that without guidance patients would make unwise decisions as they are unable to know and understand the information concerning risk and benefit as well as the clinician. In some instances, these opposing beliefs were held by the same clinician.

How the clinician positions themselves in the decision-making process could potentially influence how choice is presented to patients, as those who feel their role is more to guide patients could provide more directed counselling than those who don’t. However, as this was an interview study and did not observe real-time counselling, further work is needed to investigate this possibility.

**Surgeon Sign Off**

Clinicians appeared to have the overall power over the decision process, being able to agree to the overall decision or to reject it. This was also described at a wider level, with the decisions being able to be accepted or rejected at MDT meetings.
Therefore, it appears that, whilst individual decisions can be made by patients, they may not have the ultimate decisional power.

4.4.1 Limitations

Participants were recruited from centres that were recruiting to the Latitude Study (described in chapter 2). Therefore, whilst this covered a wide spread of clinicians across the North of England, it did not cover clinicians from across the entire country. Other clinicians in centres outside those recruiting to the Latitude Study may have had different views and provided further valuable insight on the research topic.

A total of 15 clinicians were interviewed, with the researcher feeling that data saturation had been reached within this number. However, some sources advocate the interviewing of further participants as a way to further ensure saturation had been reached (119).

This research was the first qualitative work undertaken by the researcher, and as such, they had limited experience when performing the semi-structured interviews. Due to their level of training in Urogynaecology (registrar), it may be that the researcher did not ask questions that perhaps a clinician with more training would have. There was also a power dynamic that may have served as both a strength and a weakness. Some clinicians may have felt at ease to talk more openly and boldly about their thoughts with a junior doctor. However, some may have felt that the questions they were being asked by a junior colleague may have been questioning of their practice and they may not have answered as fully as if a colleague at their same level of training had interviewed them.

4.5 Conclusions

This study showed that clinicians appeared to make a judgement about what procedure they felt was best for individual patients they treat. This judgement appeared to be based upon several key clinical characteristics, as well as the clinician’s personal preferences. These preferences appeared to be heavily
influenced by anecdotal evidence, personal experience, training and surgical familiarity. There also appeared to be differing levels of choice provided to women who were regarded as high risk due to their characteristics. These women seemed to be more likely to receive a limitation of surgical choices and directed counselling. These findings suggest that, in clinical practice, the decision of which SUI procedure to have may not be a preference sensitive procedure, but in some instances, there may be a certain procedure that is perceived by clinicians to confer particular benefit to an individual patient.

There appeared to be a general belief amongst clinicians that patients held the responsibility for the overall decision of procedure, but they also held simultaneous inconsistent beliefs that some patients need guiding, which is more consistent with a paternalistic approach to decision-making. Clinicians also appeared to have the overall decisional responsibility, having power to accept or reject the patient’s decision.
Chapter 5: Final Conclusions
Chapter 5: Final Conclusions

5.1 Conclusion

This thesis presents a qualitative study of the factors that influence the choice of primary surgical procedure for SUI from both the patient’s and clinician’s perspective.

The introductory chapter provides an overview of the different procedures available for SUI and highlights that currently there is no single best procedure recommended. The recently published NICE guideline for SUI recommends that colposuspension, AFSP and MUS should be offered as first line procedures to women, but urethral bulking agents may be considered if the other options are unsuitable or unacceptable to women (5). However, this recommendation is based purely on the success rates of these procedures and does not take into account other factors that patients may find important when choosing a surgical procedure. Also, NICE provide no guidance regarding the factors which would make women unsuitable for each of the procedures. Therefore, decision-making about which operation is best for an individual with SUI is open to substantial variation.

Recently PDAs for the surgical treatment of SUI have been published (81)(97)(96). These tools aim to formalise the options offered and to identify important decisional values for patients. However, these have been developed by clinician experts with limited input from patients.

Hence the ongoing need for this study to determine, using formal qualitative research methods, the issues considered important by both patients and clinicians when choosing a surgical procedure to treat primary stress predominant urinary incontinence.

Women were purposively sampled to ensure that all procedures were represented. To ensure that the interviews did not affect the decision-making process, they took place once women had selected a procedure for SUI. Clinicians from both district general hospitals and tertiary centres were interviewed to ensure a breadth of training and experience. A thematic analysis was conducted using the framework
method to identify themes from the data. This is the first study to reflect decision-making in real-life clinical practice.

5.1.1 Definitions, meaning and value

This study found that women construct a framework of values which are important to them as individuals. This consists of a list of values, for example length of recovery, use of foreign body and chance of success. Individuals also place a variable weight of importance on each of these values. This process of assigning importance to each factor appears to be influenced by individuals external to the clinical team and by the experiences of other women, with negative experiences appearing particularly influential. Women compare their framework to the information given to them, by the clinician, about each operation and decide on a procedure which best fits their values.

Some of the women’s values are simple to quantify, for example use of general anaesthesia. Others are much more opaque, difficult to define and potentially open to misinterpretation between the woman and the clinician; for example, undefined terms such as “minimally invasive,” “cure,” “risk”, or “success”.

Similarly, clinicians appear to have variable meanings for common clinical characteristics. For example, many clinicians quote high BMI as a factor they consider, yet few define this in terms of a numerical value. This is also true of age. Of those who did define these factors, different numbers are quoted as being a concern. Severity of SUI is also considered by clinicians, but the meaning of this varied, with some quoting this in terms of impact to patients while others assess this during urodynamics. Also, clinicians appear to regard each of these clinical factors with different levels of importance.

Risk is a poorly defined term, used commonly, throughout the study, by both clinicians and patients. On reviewing the literature, it is apparent that there is very little high-quality evidence available to enable clinicians to determine which operation would be best for specific clinical risks. In most cases the clinician’s
definitions of risk are based on personal experience and anecdote rather than objective clinical evidence. Choice may be further limited by clinicians preferring one operation, which they feel most at ease with. Overall this results in diverse thresholds for surgical intervention and significant variations in clinical practice. Hence it appears an individual woman’s choice of surgery may vary depending on which clinician she encounters.

5.1.2 Information provided versus information wanted

There is variation in the information given to women, some clinicians use statistical data based on their own local audit whilst others use national outcome data, and some use only descriptive terms such as “big” “simple” or “low”. However, the patient interviews found that women place a high value on experiential rather than statistical information and want to talk with women who have undergone SUI surgery.

Whilst data on success and risk are necessary, currently experiential information is not provided to women. This gap in provision of information should be addressed.

5.1.3 The overall decision of surgical procedure: A truly preference sensitive decision?

Patients and clinicians appear to form their own opinions about which procedure would be best, and these appear to be informed by consideration of different factors, as discussed above. The ranking of these factors in terms of personal importance is highly individualised to both patients and clinicians and it may be that these preferences, and the reasons behind them, are not communicated between the two groups.

If a patient has none of the previously described “clinician perceived risk factors” then they may be offered a free choice although this may still be influenced by the clinician’s, covert or overt, preference for one of the four procedures.

Some clinicians appear to practice paternalistic decision making. Although describing their role as to guide and advise, they provide directed counselling and
limitation of choice to some women. From the patient interviews, it appears these women were probably unaware that their choices were being limited by their clinicians.

A common view expressed amongst clinicians is that women decided on having a procedure, but that clinicians are responsible for the options offered. The reason for this appeared to be related to the degree of perceived risk to patients, with clinicians understandably not wishing to cause harm. However, there remains a lack of evidence to guide clinicians in what the optimum procedures are for certain patient populations and this leads to non-evidence-based variation in practice.

It appeared that clinicians had the final decisional power, being able to ‘sign off’ the chosen procedure and could decline the patient’s decision. There was also evidence that clinicians used the MDT to support their decision if it was at odds with the patient’s views. Therefore, the overall decision could be viewed as preference sensitive, but the preference of clinicians can ultimately override the preference of patients.

5.2 Future work

5.2.1. How to give experiential evidence to women

Further work is required to determine the best way to present women with the experiential information they wish to have about surgery for SUI. It maybe that short films could suffice, or it may require local volunteer groups of “expert patients” or patient support groups.

5.2.2 Defining terminology

In the past IUGA and ICS have produced standardisation and terminology documents for clinicians. From the variation seen in the current study it appears this work on standardisation should be extended to patient information. However, there are also large gaps in information about relative risks and benefits of each procedure.
5.2.3 Determining comparative risks and benefits

The clinician arm of the study highlighted that clinical factors are key to the decision-making process and can lead to limitation of choice by clinicians to some patients. However, there is a lack of data to guide clinicians as to which procedures may be best for certain patient groups. Therefore, research is required to address what the difference in risk is to patients with regarded high risk characteristics, such as extremes of age, different BMI ranges, voiding difficulty or future childbirth for all procedures.

There is a need for larger comparative studies to determine the true risk of each procedure in specific groups. SUI surgery is very common, and it should be possible to obtain this information. Ideally this would be through randomised controlled trials. Alternatively, information collected in national and international databases could be used. However, this method is subject to potential bias due to incomplete reporting during routine clinical practice. It also assumes that clinicians would be prepared to offer and perform all available SUI procedures on patients in these high-risk groups, which may not be the case in clinical practice. Despite these difficulties, these are important areas that must be further reviewed to provide clinicians with the information they need to counsel their patients.

Current PDAs are extremely limited in their effectives due to lack of this information. Women did not appear to consider their own clinical characteristics, such as BMI, as important however clinicians based much of their decision on these. The impact of these clinical characteristics should be shared with patients, potentially via a PDA, so that patients are fully aware that they may receive different options based on these.

Only with better information can the observed variation practice and inequality of choice be improved.

5.2.4 Hierarchical treatment

Further research should evaluate the value, both health economic and clinical, of a hierarchical approach to the surgical treatment of SUI. For example, undergoing a
urethral bulking agent, which presents the lowest surgical risk to women, as a first line procedure followed by either a colposuspension or a sling (native tissue or polypropylene). This hierarchical approach is applied in the initial management of SUI, with PFMT being recommended due to its proven efficacy and represents a minimally invasive intervention that is appropriate for most women. Urethral bulking agents, such as Bulkamid, could prove to be a useful first line surgical procedure if found to be effective as it represents a low risk, easily accessible option that is suitable for most women with SUI. However, evidence on long term efficacy is limited and further research is needed.

5.2.5 Understanding the dynamics of clinical care

In the patient arm of the study there is evidence that patients may not receive a full range of surgical choices. However, they may equally be given a full choice of operations but perceive being offered a limited choice. To further investigate this, patients and clinicians would need to be interviewed immediately following a filmed consultation to explore the range of choice perceived and observed.

5.3 Final Conclusion

This qualitative study of choice has highlighted how complex and highly individualised the choice of primary surgery for SUI is, from both a patient and clinician perspective. There appears to be an added layer of complexity added to decision-making for patients who may have clinical factors deemed to be high risk, with patients perhaps not being aware of this external decision-making process taking place around them. The decision of primary surgery for these patients appeared to have more clinician involvement when compared to women who had no high-risk factors, the so called ‘golden patient’. There also may be a degree of choice inequality, dependent on the services provided locally to patients and by the experiences and personal views of the clinician consulted, with further work needed to investigate this.

From the patient perspective, this study found that key factors and priorities were weighed up against each other and appeared to be sorted in order of perceived importance. The factor/s deemed most important appeared to align with
characteristics offered by the overall chosen procedure. This weighing of factors has been described in other studies as trade-offs, with some describing women choosing procedures with a lower success rate in favour of the low risk profile presented by a certain procedure (98), or choosing a procedure with a higher risk profile in the aim of a higher chance of long term success (102).

Patient choice is of increasing interest in current clinical practice in Urogynaecology, with national guidelines now reflecting the importance of patient involvement in decisions regarding SUI surgery and stating that informed decision making should be employed (5). Whether this is occurring in clinical practice remains unknown, and further work, as outlined above, should be a priority to investigate this further.
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woman who wants to get pregnant after a sub-urethral tape placement?


Appendix 1: Patient interview topic guide

Understanding Patient Choice: Patient Interview Topic Guide

Introduction
- Thank for participation
- No right or wrong answers
- Can withdraw at any time
- Audio-recorded consent

Symptoms
- Effect of symptoms
- Prompts to seek help

Treatment options
- Treatments offered
  - Information given?
- Thoughts about the options offered
  - Mesh?
- What led to treatment decision?
- Aims of treatment

Finally
- Anything I haven’t asked about that you feel is important?
Appendix 2: Clinician interview topic guide

Understanding patient choice of surgical treatment for SUI: Clinician Topic Guide

Introduction

• Thank for participation
• No right or wrong answers
• Can discontinue at any time
• Audio-recorded consent

Background

• Training and experience in Urogynaecology
• Experiences of SUI surgery throughout this time
  o Effect of mentorship?

Offering options of SUI surgery

• What options
  o change over time?
• Patient involvement
  o How?
  o What do they think is important to patients?

• Thoughts about the treatment options
  o How are they discussed?

• Views on shared decision making

Finally

• Is there anything I haven’t asked about that you feel is important?
Appendix 3: Patient Framework

Patient Framework

1. Barriers to getting help and decision making
   - 1.1 Information giving
     o 1.1.1 Overload
     o 1.1.2 terminologies
     o 1.1.3 lack of detail
   - 1.2 Waiting times

2. Options offered
   - 2.1 Full range of options offered
   - 2.2 Limitation of options offered
   - 2.3 full range of options discussed

3. Experiences of others
   - 3.1 Positive
   - 3.2 Negative
     o 3.2.1 In the media
     o 3.2.2 Mesh
     o 3.2.3 Personal
   - 3.3 Experience sharing
     o 3.3.1 Word of mouth
     o 3.3.2 Talk to other women
     o 3.3.3 desire to hear experiences of others
   - 3.4 Opinion of others

4. Procedure related factors affecting choice
   - 4.1 Return to usual activities
     o 4.1.1 Effect on driving
     o 4.1.2 Recovery times
   - 4.2 Risks of procedure
     o 4.2.1 Risk of complications
     o 4.2.2 Concerns-mesh complications
     o 4.2.3 Concerns regarding mesh removal
     o 4.2.4 Potential impact on prolapse
     o 4.2.5 Low risk
     o 4.2.6 Invasiveness of procedure
   - 4.3 Practical aspects of procedure
     o 4.3.1 General anaesthetic
     o 4.3.2 Needles
     o 4.3.3 incisions
     o 4.3.4 Material used
- Plastic
- Foreign body
- Own tissue

- 4.4 Approach
  - 4.4.1 Single procedure
  - 4.4.2 Stepwise

- 4.5 Success rates

- 4.6 Individual Understanding
  - 4.6.1 Understanding of cause
  - 4.6.2 Understanding of surgical procedure

5. Consequences of SUI

- 5.1 Effect on activities
  - 5.1.1 restriction
  - 5.1.2 adjustments

- 5.2 Pad usage
  - 5.2.1 Concealment of pads

- 5.3 Emotional impact
  - 5.3.1 Embarrassment
  - 5.3.2 Feeling unclean
  - 5.3.3 Shame
  - 5.3.4 SUI joked about
  - 5.3.5 Negative impact on mood
  - 5.3.6 Feel old
  - 5.3.7 Leakage with sex
  - 5.3.8 Smell

- 5.13 Trigger to act

6. Attitude to risk

- 6.1 Positive perception of risk
  - 6.1.1 Minimal concern of complications
  - 6.1.2 Trust in medical devices

- 6.2 Negative perception of risk

7. Decision making

- 7.1 Patient as decision maker
- 7.2 Directed counselling
- 7.3 Wanted guidance from doctors on choice
  - Trust in the consultant
- 7.4 Option of best fit
8. Miscellaneous
• 8.1 Limited awareness of treatment options
• 8.2 Wish to not disclose procedure

9. Goal of treatment
• 9.1 Prevention of SUI deteriorating
• 9.2 return to perceived normality
• 9.3 Dry
• 9.4 stopping pad usage
• 9.5 improvement of symptoms
• 9.6 exercise
Appendix 4: Clinician Framework

Clinician Framework

1. Clinical factors
   • 1.1 Anatomical factors
   • 1.2 Age
   • 1.3 BMI
   • 1.4 Severity
   • 1.5 Family completion

2. Perception of patient personality

3. Clinician preferences
   • 3.1 opinion of procedures
   • 3.2 surgical difficulty
   • 3.3 surgical familiarity

4. Clinician perception of what is important to women
   • 4.1 success
   • 4.2 invasiveness
   • 4.3 mesh in the media
   • 4.4 length of stay
   • 4.5 complications
   • 4.6 opinions of friends and family

5. Opinion of their role in decision making
   • 5.1 technician
   • 5.2 guide/advisor

6. Counselling
   • 6.1 directive
   • 6.2 non-directive

7. Clinician perception of surgical risk
   • 7.1 surgical risk to patient
   • 7.2 risk to self
8. Clinician’s personal experience
   • 8.1 Training
   • 8.2 single case complications

9. Clinical evidence
   • 9.1 In relation to procedures
   • 9.2 national guidance

10. Patients not wanting mesh
    • 10.1 Complications

11. Surgeon Sign off
    • 11.1 surgeon veto

12. Systemic pressures
    • 12.1 time
    • 12.2 number of consultations
    • 12.3 finance

13. Variation of procedures offered
    • 13.1 full choice
    • 13.2 limited choice

14. External influences
    • 14.1 Law
    • 14.2 organisational
    • 14.3 media

15. Variation in procedure description
    • 15.1 simple/easy/safe
    • 15.2 big/risky/complex
    • 15.3 negative framing
    • 15.4 positive framing
Appendix 5

“Voice your choice”
A study of women’s choice of surgery for primary stress urinary incontinence: a mixed methods study

Abstract

Objective

An observational study aiming to determine factors which influence women’s choice of surgery for primary stress urinary incontinence (SUI).

Design

Mixed-methods

Setting

12 Hospitals in the North of England.

Population

212 women undergoing a primary SUI procedure.

Methods

Having chosen a procedure, women were asked to complete a standardised semi-structured questionnaire about their health, demographics and a free text box to record factors important to them when choosing their procedure.

Statistical analysis was performed to determine the impact of demographic, lifestyle or healthcare factors on women’s decision making. Qualitative thematic analysis of the free text data was performed to identify factors important for women when choosing a surgical procedure.

Results

64% of women chose urethral bulking. There was no significant difference between age, BMI, smoking status or previous laparotomy between women choosing the 4 types of
surgery. Women were less likely to choose urethral bulking if seen in a tertiary centre compared with a secondary centre (p<0.001).

Major themes in decision making were efficacy, invasiveness, recovery, risk of complications, use of mesh, the clinician, the media, hierarchy of treatments and type of anaesthetic. Some women expressed a hierarchical approach to treatment.

Conclusions

Our findings suggest decision making is not influenced by patient factors such as age, BMI, smoking status or previous laparotomies. Women’s choices are a complex mix of factors and not simply related to efficacy.

Funding

Investigator led study funded by Contura.

Keywords

SUI, choice, decision making, urethral bulking, mid urethral tape, fascial sling, colposuspension.

Introduction

Urinary incontinence is a very common condition. There are a number of procedures to treat stress urinary incontinence (SUI) these include bulking agents, mid-urethral tapes, autologous fascial slings and colposuspension. Over the last decade, continence surgery has been the subject of controversy in the UK and there have been several Government inquiries and reviews of safety, primarily in relation to mesh. The most recent inquiry in England, the Independent Medicines and Medical Devices Safety Review, was commissioned by the Government in February 2018 and has yet to report its conclusion. Up until “the pause“ on mesh tapes, introduced in England in 2018, tapes were by far the most common procedure performed, with 84 tapes for every one non-tape procedure (NHS Digital, 2018).
One of the recurring themes in these inquiries was the poor counselling provided by clinicians to women undergoing surgery for SUI. This has led clinicians to consider ways to improve the information they provide. The recently published NICE guideline on incontinence and prolapse (NICE, 2019) contains patient decision aids (PDA). However, it contains very little hard data on how women can make a choice between 3 operations, with fairly similar outcomes, and it treats bulking as a separate category of treatment. Other PDAs for SUI have been published (Jha and Duckett, 2019 and Ong et al, 2019), however these are based on expert opinion rather than a systematic meta-analysis of the evidence which NICE undertook. Furthermore, none of the PDAs were informed by how women chose an operation for SUI.

A UK study, exploring acceptability of treatments for stress urinary incontinence found 57% of women would accept a simple outpatient procedure, with a 60% chance of improvement and no long-term risks. Whereas only 38% of women said they would accept a minor operation, as an in-patient, with an 85% cure rate and 2% risk of intermittent catheterisation. (Robinson et al, 2003). The first of these two scenarios could be considered to represent a bulking agent and the latter a mid-urethral sling. However, the data was collected in a hypothetical situation and therefore may not reflect true decision making. Furthermore, participants were not asked about decision making between specific SUI procedures, instead they were asked about the acceptability of different scenarios based upon the risk of complications, likelihood of cure and invasiveness of a procedure. Therefore, while these findings offer some insight into the hypothetical considerations for SUI procedures, it is still not known how women make the choice between different surgical treatments for SUI and what issues they weigh up when making their decision. It is important clinicians understand what matters to women considering treatment.
Therefore, this study endeavoured to gain greater insight into the process of women’s decision making when choosing a SUI procedure. This knowledge may lead to patient focused PDAs and may help to identify gaps in current evidence which require further research.

Methods

Study design

Latitude is a multi-centre observational study to investigate the long-term effectiveness of the urethral bulking agent, Bulkamid®, as a primary treatment for SUI (ClinicalTrials.gov Identifier: NCT03474653). A qualitative study was embedded within Latitude with the objective of exploring factors which influence patients’ choice of surgical treatment for SUI. Eligible participants were recruited between June 2017 and July 2018 from 12 sites in the North of England. It is important to note that data for this study was collected before NHS England paused the use of polypropylene mesh tapes for continence surgery (NHS Improvement and NHS England, 2018).

All women who had made a choice about which SUI procedure they wanted were approached. The inclusion criteria required that women were having their first procedure for SUI, had stress predominant mixed urinary incontinence, no evidence of detrusor overactivity or voiding difficulties and were deemed suitable by the surgeon for at least 2 of four surgical options (Urethral Bulking, Mid Urethral Sling, Colposuspension or Fascial Sling). The full eligibility criteria are detailed within Table 1. Participants were counselled in their routine clinical setting, there was no pre-determined script used by the clinician and options were presented according to their own clinical practice.
Participants were asked to complete a semi-structured questionnaire (Appendix). The questionnaire recorded patient demographics, lifestyle and medical information, the surgical procedures discussed with the clinician and the surgical procedure the patient chose. In a free text box, women were asked: “What was the most important issue to you when making your treatment decision?” In another free text box, they were also asked if they would have liked any additional information to help them make that decision.

**Analysis**

Analysis of the quantitative data collected was carried out using R 64 3.5.1. Continuous variables were compared using Mann-Whitney U test and categorical ones using Chi-squared test to explore whether factors such as age, BMI, smoking status, hospital type or history of laparotomies impacted upon patient decision making.

To assess choice, a free text response to an open question was chosen because we did not wish to presume what mattered most to women making a choice about primary surgery for SUI. We used the qualitative method of thematic analysis to identify, analyse, and report themes within the free text data. Thematic analysis of the free text was conducted independently by two members of the research team who were blinded to the procedure chosen and all other patient data. Codes were then compared, rationalised and emerging themes identified (Guest et al 2012). The frequency of codes was also recorded.

**Results**

216 women completed the questionnaire. Four questionnaires were excluded from analysis because two decided not to go ahead with their SUI treatment and another two women were identified to be ineligible as this was not their first continence procedure.
The analysis of 212 women found 64% opted for Urethral Bulking \((n=135)\), 23% a Mid Urethral Sling \((n=48)\), 12% for Colposuspension \((n=25)\) and 2% a Fascial Sling \((n=4)\).

Characteristics of the sample population are detailed within Table 2. There was no significant difference in age, BMI, smoking status, or previous laparotomies and the procedure chosen for SUI (Table 3). Hospital type was a significant factor in determining the procedure chosen \((P<.001)\) with Mid Urethral Sling and Colposuspension or Fascial Sling all most likely to be chosen by women attending a tertiary referral hospital than those attending a secondary care hospital (Table 3). However, at both hospital types Urethral Bulking was the most frequently chosen procedure \((75\%\) in secondary care hospitals and 57\% in tertiary referral hospitals).

Thematic analysis of the qualitative data found the major themes associated with patient decision making were;

**Invasiveness of the procedure**

Women’s concerns about the “invasiveness” of the procedure were expressed by 53 women \((25\%)\). While invasiveness was frequently cited as a factor which affected decision making, only a small number of women defined what made them consider a procedure more or less invasive:

‘Less cuts’

*(Chose urethral bulking)*

It was apparent from the analysis that some women did not consider the injection of a urethral bulking agent to be surgery:
‘(I) feel that my condition isn’t severe enough for an operation’

(Chose urethral bulking)

‘I was very relieved when…the bulking agent was offered, I have lived with symptoms for years thinking surgery was (the) only option.’

(Chose urethral bulking)

Of the 53 women who reported that invasiveness was an important factor in decision making, 83% had opted for Urethral Bulking \((n=44)\), 9% a Colposuspension \((n=5)\) and 8% a Mid Urethral Sling \((n=4)\).

**Chance of success**

The success rate and “invasiveness” of the procedure were jointly the most frequently mentioned factors in women’s decision making. 53 women, 25% of the total cohort reported the success rates of different procedures influenced their choice. Reassuring statistics about likelihood of cure was of overriding importance as illustrated in the following quotes:

‘Percentage of how many women it has worked for’

(Chose MUS)

‘It was 90% it worked’

(Chose MUS)

‘Better percentage for success’

(Chose colposuspension)
However, five of the 53 women stated success rate was not the most important factor in their decision making and whilst a consideration, avoiding mesh or having the least invasive procedure was their primary concern.

The 53 women who cited efficacy as important to their decision were most likely to opt for a Mid Urethral Sling (42%) followed by Urethral Bulking (36%) and Colposuspension (23%).

**Duration of recovery**

46 women (22%) cited recovery as an important consideration for them when deciding upon a procedure. For many (n=11) this was due to concerns about needing to take time off work. For others, it was due to their responsibilities as a carer within their family (n=6).

‘I have 2 toddlers to look after so having an operation was not an option for me at this time. I am a working mum running my own business. My husband works full time. The treatment I have picked is best as I would only be off work for a day.’

(Chose urethral bulking)

Of the women who expressed recovery as a factor which influenced their choice, the majority opted for Urethral Bulking (n=31, 67%). However, ten chose a Mid Urethral Sling (22%), two a Colposuspension (4%) and one a Fascial Sling (2%).

**Risk of complications**

The risk of post-operative complications was a factor in the decision making process for 26 women (12%). Most did not specify the post-operative risks they had considered; instead they used generic terms such as: ‘complications,’ ‘side-effects’, ‘risks’ and ‘safety’.
However, three women from two different sites had concerns regarding post-operative voiding dysfunction and the possibility of self-catheterisation. Only one woman had concerns about pain.

Use of mesh

24 women (11%) stated the use of mesh impacted upon their decision making. For all but two of these women (n=22, 92%), avoidance of mesh influenced the procedure they opted for. Two women (9%) specified they didn’t want a foreign body inside them and one woman (4%) had concerns about rejection of the mesh.

‘Colposuspension is using natural own body tissues which hopefully will be less likely to be rejected and there are no tapes so less likely tearing or infected’

(Chose colposuspension)

Despite acknowledging the risks of mesh procedures, two women (8%) decided to proceed with a Mid Urethral Sling. Both weighed up the risk of mesh compared with the anticipated effectiveness of the procedure. One woman conducted her own research to enable her to make her decision:

‘Efficacy/outcome balanced with acceptable risks. Lots of media scare stories about mesh/tape but on reading NICE guidance and the few research documents I could Google, I felt on balance it was a better option long term.’

(Chose MUS)

Another woman had prior history of a mesh procedure and based upon this positive experience wanted mesh again:
‘Works the most percentage, already had the mesh used in a bowel prolapse, its worked
100% for me.’
(Chose MUS)

Influence of the clinician

The clinician was cited as a factor which affected decision making for 20 women (9%). Most of these women (n=15) felt they had been advised or guided by the clinician to choose a particular procedure as demonstrated by the following quotes:

‘The one which the consultant thought would be best for me’
(Chose urethral bulking)

‘Done right, trusting the doctors decisions.’
(Chose urethral bulking)

There was evidence some clinicians modified counselling regarding SUI procedures based upon patients’ co-morbidities. Women recognised they had been guided towards a particular procedure by their clinician:

‘I wasn’t offered any other treatment other than Bulkamid, as I was told I was too overweight for other options.’ (Chose urethral bulking BMI-40)

‘Advice from doctor (I), listened to the options as I have other medical conditions that affect my treatment options.’
(Chose urethral bulking)
Another four women decided upon their SUI procedure based upon the reputation or expertise of the clinician or hospital they were receiving care from:

‘The hospital’s reputation and the surgeon, I trusted both on my first meeting’
(Chose urethral bulking)

‘(The) Reputation and experience of surgeon in this area carrying out this type of procedure’
(Chose MUS)

The distribution of procedures chosen by women who reported a clinician had influenced their choice were in similar proportions to the overall study population however upon comparison of participants depending on their hospital type, those who cited clinician influence at a secondary care hospital were most likely to choose Urethral Bulking (73% n=8) over a Mid Urethral Sling (27% n=3). No patients seen at a secondary care hospital who reported their decision making was influenced by a clinician chose a Colposuspension or Fascial Sling. At tertiary care hospitals, patients who cited that clinicians influenced their choice were more evenly spread across all four procedures; Urethral Bulking (33% n=3), Mid Urethral Sling (33% n=3), Colposuspension (22% n=2) and Fascial Sling (11% n=1).

The media
Thirteen women (6%) stated stories in the media had influenced their decision making:
‘I was concerned about the safety of the tape being used due to reading about problems in Scotland and watching TV programme highlighting concerns. I opted for colposuspension but after discussing complications ... I was persuaded by the consultant to go for the TVT.’
(Chose MUS)

‘I didn’t want the mesh (TVT) due to press’
(Chose urethral bulking)

‘Had opportunity to have the TVT but declined due to negative publicity’
(Chose urethral bulking)

Hierarchy of Treatments
A recurring theme identified amongst women who opted for urethral bulking was the concept of a stepped hierarchical approach to SUI treatments, starting with what they perceived to be the least invasive procedure and having alternative procedures if bulking was ineffective. Twelve women (6%) recorded this influenced their decision making as illustrated in the quotes below:

‘That I started at the lower end of operations. This would give me future options if needed’
(Chose urethral bulking)

‘I prefer to try least invasive method before I would even consider any other. I was told other alternative would not be affected by having the least invasive treatment’
(Chose urethral bulking)

Type of anaesthetic
The type of anaesthetic required factored in the decision making of nine women (4%). All preferred a treatment option which did not require a general anaesthetic:

‘Don’t like being put to sleep as I am scared’
(Chose urethral bulking)

‘I wasn’t very keen on anaesthetic’
(Chose urethral bulking)

Risk analysis
40 women (19%) cited risk as a factor which influenced their decision making regarding which SUI procedure to have. However, some expressed desire for the procedure they perceived had the lowest risk whilst others described a process of balancing risk with efficacy.

16 women within this group (40%) opted for the procedure they perceived to have the lowest risk as demonstrated in the following quotations:

‘The safest way’
(Chose urethral bulking)

‘I was going to choose the TVT but I work in a solicitors and we have had a lot of cases of women having problems with TVT. This made me change my mind and choose the Bulkamid even though the success rate is not as good. I didn’t want to take the risk at having problems’
(Chose urethral bulking)
However, a separate subgroup of 18 women (45%) made statements which suggested they had understood and weighed up the risks associated with a procedure but balanced this against other factors in their decision making:

‘Low risk with reasonable outcome’

*(Chose urethral bulking)*

‘Success rate, recovery time and after operation complications (this changed my opinion)’

*(Chose MUS)*

‘What has the best results and no/minimal side effects’

*(Chose colposuspension)*

A further six women (15%) stated they had considered risk, however they did not clarify whether this influenced them to opt for their perceived lowest risk procedure or whether the risk could be outweighed by other factors such as efficacy.

**Other Themes**

In addition to the themes previously discussed, a small number of women cited different factors which influenced their choice. These included knowing someone who had previously had the procedure (*n*=6), perceiving the procedure to be definitive treatment (*n*=5), their plans for further pregnancies (*n*=5), pain (*n*=5), and advice from family or friends (*n*=2)
Despite the questionnaire asking women “What was the most important issue to you when making your treatment decision?” 46 women (22%) recorded comments which did not relate to their decision making or choice of procedure mentioning only the impact of the condition.

‘Getting help and treatment for urinary leakage as this is having a negative effect on my life/confidence’
(Chose urethral bulking)

‘Quality of life affecting, needed to be sorted’
(Chose MUS)

Discussion

Main findings

This study was conducted before the pause on the use of tapes was introduced in England. It found that when women, in a real clinical situation, across 12 hospitals were offered a choice of four treatments for primary SUI, urethral bulking was most the most popular choice (64%). This was despite there being less published data on the outcome of bulking compared to the other procedures. There was no association between operation chosen and any patient factors such as age, BMI or co-morbidities. There was however a suggestion of a narrow field of choice in secondary care.

This is the first study to investigate, in real life, the factors women consider important when choosing an operation for primary SUI. The study found that although success was important this was balanced against the perceived “invasiveness” and “risk” of the procedure. This supports the concept that any treatment must be less morbid than the
condition treated. The fear of treatment complications may also explain why so many women currently do not seek treatment for urinary incontinence (Shaw et al, 2006).

**Interpretation**

A recent qualitative study by Casteleijn et al (2018), in which women were asked to choose between two operations, either a bulking agent or a tape, reported patients would consider bulking as their primary option if it has a cure rate of 70% after 1 year. However, our study found several women expressed a hierarchical framework in their approach to treatment for SUI. These women first wished to try urethral bulking, which they perceived to be a low risk simple procedure with a short recovery. They accepted the treatment may fail and they may need further treatment at a later date. Such hierarchical approaches to treatment are common in other areas of medicine. In 1994, just before outcomes of polypropylene mid urethral slings were first reported, a seminal meta-analysis of continence surgery by Jarvis, demonstrated urethral buttress was less effective as a first surgical treatment for SUI compared to colposuspension. However, Jarvis also stated urethral buttress had markedly lower complication rates compared to colposuspension and this was important to some women. Jarvis highlighted that following colposuspension, post-colposuspension syndrome, which consists of lower abdominal or pelvic pain, occurred in up to 12% of women, prolapse was reported in an average of 13.6% of women (range 2.5%-26.7%) and there had also been case reports of ureteric obstruction. However, at the time it was also thought that, if a urethral buttress failed as a first line treatment for SUI, it would reduce the efficacy of further treatments such as colposuspension or fascial sling. Hence the hierarchical approach was discouraged.

Before a modern hierarchical treatment approach is promoted, for treatment of SUI there is a need for further research to determine not only the overall economic cost and the risk
of treatment fatigue but importantly the impact on efficacy of further treatments if the first treatment in the hierarchy fails.

Our study shows the large range of factors that influence women’s choices and the highly individual nature of choice. Women were balancing the variable severity of their SUI, against, competing risks of complications and differing success rates; all of which were couched in poorly defined terms such as “invasiveness” and “success”. Understanding the importance of these factors and their meaning to each individual enables clinicians to provide information to women which meets their needs.

Concerns about polypropylene mesh and the media’s representation of mesh procedures were frequently found to have influenced women’s decision making. It is important to provide women with accurate evidence-based information about mesh complications and complications of other treatment options, to ensure they are not required to seek it from unverified sources.

This study has highlighted the complexity of information about SUI procedures being presented to women. Different methods of presenting information, both in written and audio-visual formats should be explored to ensure we meet patient’s information needs. The factors identified as important to women within this study should be used to develop decision making tools. The meaning of terms such as risk, success, natural, minor, simple and invasiveness should be explored, qualified and ultimately standardised. The recently published NICE PDA tool (NICE, 2019) demonstrates how little objective evidence is available for each of these complex competing factors. Furthermore, there is no evidence to help women decide on a treatment based on their physical characteristics such as age or BMI.
As identified, most women considered a number of factors and tried to weigh these against each other, before making their decision. An electronic decision-making tool could help woman to weigh various factors and facilitate their decision making.

**Limitations**

One limitation of the study is that the number of women opting for each procedure was not equal therefore there may be a bias in the views expressed. However, the study was designed to ensure it captured a real life cohort of women undergoing primary stress incontinence procedure to determine the frequency of their choice.

There was a compromise in the study design between capturing information on a large number of women to determine the frequency of choice and the level of detail in the reasons behind their choice. We did not wish to presume to know why they made their choice and hence used an open free-text question and qualitative analysis technique. This question may not have been sufficiently clear as 25% of responses related to a desire for SUI treatment rather than specifying why they had chosen one procedure over another. Alternatively, this may accurately reflect that for some women, the type of treatment is less of a concern than the pressing need for amelioration of their urinary symptoms.

Further in depth qualitative interviews are needed to clarify terms such as “risk”, “success” and “invasiveness”.

**Conclusion**

When women were offered a choice of 4 treatments for primary stress urinary incontinence the most common choice was a urethral bulking agent (64%). Women appear
to consider a hierarchical approach to treatment for SUI. There was also some evidence that the degree of choice varied in different clinical settings, with more variety in procedures chosen at tertiary centres. This may suggest an inherent bias in the counselling that clinicians at secondary care hospitals offer to their patients. There is a need to define and standardise the terminology to describe procedures their risks and benefits, and their outcomes. There is also a need to further evaluate the health economic impact and effect on further treatment if a hierarchical approach to treatment is used.
References

Barbour RS. Checklists for improving rigour in qualitative research: a case of the tail wagging the dog?. BMJ. 2001;322(7294):1115-7


NHS Improvement and NHS England, 2018. Vaginal Mesh: High Vigilance Restriction Period: Immediate action required, all cases should be postponed if it is clinically safe to do so. i.emlfiles4.com/cmpdoc/9/7/2/8/1/1/files/47633_mesh-letter-to-acute-ceos-and-mds.pdf


# Table 1

**Eligibility criteria**

- Patient has urodynamic stress incontinence
- Patient has had pelvic floor physiotherapy
- Patient does not have overactive bladder predominant, mixed urinary incontinence
- Patient does not have a diagnosis of detrusor overactivity
- Patient has not had any previous surgery for urinary incontinence
- Patient has not had any previous surgery for stress urinary incontinence
- Patient is not listed for concomitant prolapse surgery
- Patient had a residual urine of <100ml
- Patient has a bladder capacity >300ml
- Patient does not have an acute urinary tract infection
- Patient does not have an allergic reaction to all local anaesthesia medication suitable for use during bulking
- Patient does not have an allergic reaction to all antibiotics suitable for prophylactic use during bulking
- Patient is not currently being treated with system corticosteroids
- Patient is not currently pregnant
<table>
<thead>
<tr>
<th>Table 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n=212</strong></td>
</tr>
<tr>
<td><strong>Age</strong></td>
</tr>
<tr>
<td>Median=50</td>
</tr>
<tr>
<td>IQR=44.58</td>
</tr>
<tr>
<td>Range=27-84</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
</tr>
<tr>
<td>Median=28</td>
</tr>
<tr>
<td>IQR=25.32</td>
</tr>
<tr>
<td>Range=17-58</td>
</tr>
<tr>
<td><strong>Smoking status</strong></td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>n=27 (13%)</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>n=185 (87%)</td>
</tr>
<tr>
<td><strong>Site Type</strong></td>
</tr>
<tr>
<td>Secondary</td>
</tr>
<tr>
<td>n=111 (52%)</td>
</tr>
<tr>
<td>Tertiary</td>
</tr>
<tr>
<td>n=101 (48%)</td>
</tr>
<tr>
<td><strong>Laparotomy</strong></td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>n=130 (62%)</td>
</tr>
<tr>
<td>One</td>
</tr>
<tr>
<td>n=63 (30%)</td>
</tr>
<tr>
<td>Two or more</td>
</tr>
<tr>
<td>n=19 (9%)</td>
</tr>
<tr>
<td>Missing data n=1</td>
</tr>
</tbody>
</table>
Table 3

<table>
<thead>
<tr>
<th></th>
<th>Mid Urethral Sling</th>
<th>Urethral Bulking</th>
<th>Fascial Sling/ Colposuspension</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=48 (23%)</td>
<td>n=135 (64%)</td>
<td>n=29 (14%)</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>Median 48</td>
<td>Median 50</td>
<td>Median 54</td>
<td>P&lt;0.73</td>
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<td></td>
<td>Range 31-81</td>
<td>Range 27-84</td>
<td>Range 30-71</td>
<td></td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td>Median 27</td>
<td>Median 28</td>
<td>Median 27</td>
<td>P&lt;0.59</td>
</tr>
<tr>
<td></td>
<td>Range 21-58</td>
<td>Range 17-50</td>
<td>Range 21-41</td>
<td></td>
</tr>
<tr>
<td><strong>Smoker</strong></td>
<td>Yes 7 (15%)</td>
<td>Yes 18 (13%)</td>
<td>Yes 2 (7%)</td>
<td>P&lt;0.58</td>
</tr>
<tr>
<td><strong>Hospital</strong></td>
<td>Secondary 20 (42%)</td>
<td>Secondary 83 (61%)</td>
<td>Secondary 8 (28%)</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Tertiary 28 (58%)</td>
<td>Tertiary 52 (39%)</td>
<td>Tertiary 21 (72%)</td>
<td></td>
</tr>
<tr>
<td><strong>Laparotomy</strong></td>
<td>0 29 (60%)</td>
<td>84 (62%)</td>
<td>17 (59%)</td>
<td>P&lt;0.96</td>
</tr>
<tr>
<td></td>
<td>1 15 (31%)</td>
<td>38 (28%)</td>
<td>10 (34%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 or more 4 (8%)</td>
<td>13 (9%)</td>
<td>2 (7%)</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix

<table>
<thead>
<tr>
<th>Which treatment options were offered to you? (Please circle)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid Urethral Sling (also known as ‘Tape’ ‘TVT’ or ‘TOT’)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Which treatment did you choose? (Please circle)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid Urethral Sling (also known as ‘Tape’ ‘TVT’ or ‘TOT’)</td>
</tr>
</tbody>
</table>

Age ________ Height (cm/feet/inches) ________ Weight (stones/Lbs/ Kg) ________

Current employment

______________________________

Do you smoke tobacco cigarettes? (Please circle) Yes/No

If yes, how many cigarettes per day? __________________

Please list any operations you have had before:

______________________________

______________________________

______________________________

<table>
<thead>
<tr>
<th>What was the most important issue to you when making your treatment decision?</th>
</tr>
</thead>
</table>

Was there any further information you would have liked to help you make your decision?