Study Title: Knowledge, Awareness, and Understanding of Stress Urinary Incontinence in Patients Attending a Urogynecology Clinic
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NCT number – unassigned yet
Document : Protocol

Study Proposal
Background
Stress urinary incontinence (SUI) is a very frequent pelvic floor dysfunction; it affects about 35% to 45% of women in their lifetime. [1-3] SUI is defined as the involuntary leakage of urine in response to actions that increase intra-abdominal pressure including but not limited to coughing, sneezing, physical exercise, or lifting heavy weights. [4] Contributory factors include vaginal deliveries or operative vaginal deliveries; advanced age; menopause; obese patients; patients with chronic cough; previous pelvic surgical intervention; and connective tissue diseases. [1,5,6]

Despite its high prevalence and significant impact on women physical, social, sexual, and emotional well-being, SUI remains underreported and undertreated [7-8] SUI is both underdiagnosed and undertreated because many patients are normalizing the symptoms; misunderstanding the pathophysiologic mechanism; or simply because the patients are ignorant about conservative management and surgical management. [9-11] Myths about SUI may include: SUI is just an expected result of aging or childbearing; only surgical management is successful or SUI only occurs in old-aged women after vaginal delivery. [12-14]

Well-known and studied treatment options for SUI involves pelvic floor muscle exercises, lifestyle modifications, continence pessaries, medications, and surgery, e.g. mid-urethral slings. [15-18]

To promote successful SUI shared decision-making conversations, it is essential that the patient has adequate understanding of their disease and its treatment alternatives. [19] Nevertheless, there are few studies that have explored the pre-existing levels of the affected individuals under the context of urogynecology practice. [20,21] It is critical to identify knowledge gaps and misconceptions in patients to fully optimize counseling in SUI patients.[22] This research will specifically assess the existing understanding of the individual with SUI attending a urogynecology practice.

Aim
To identify the baseline knowledge and awareness among patients with SUI and to find out various descriptive factors associated with this knowledge. Results will impact instructional and counseling approaches, ultimately increasing awareness and understanding among patients with SUI and hence sooner medical attention will be sought.

Research Objectives
Primary objective

- The change in SUI knowledge before and after intervention as measured by the change in total score (of a 15 item questionnaire)

Secondary objectives

- Examine relationships between knowledge level and demographic/clinical variables (age, education, parity, menopause, race, treatment modality will be collected)
- Investigate the relationship between knowledge and patient preference for treatment

Study Design

This prospective study will recruit female adult patients with a clinical diagnosis of stress urinary incontinence (SUI) presenting to a urogynecology clinic at Sunnybrook Health Centre. Consenting participants will complete a self-administered questionnaire (15-item questionnaire) assessing knowledge related to SUI definition, pathophysiology, risk factors, natural history, and available treatment options. Demographic and clinical data, including age, education level, parity, menopausal status, symptom severity, and prior exposure to SUI treatment and level of education, will be collected. Then they will be given the standardized patient information SUI pamphlet by the American Urogynecology Society (AUGS) to read. At the end of the clinic visit patients will be re-tested with the same self-administered questionnaire. Descriptive statistics will be used. The primary outcome will be the change in the questionnaire (SUI knowledge) total score. Secondary outcomes include patient characteristics and their treatment preferences.

Study Schedule

Recruitment for a period of 3 to 4 months post-REB approval. Pre-testing regarding knowledge(pre-counseling), prior to pamphlet read and post-testing with regard to knowledge (post-counseling) immediately following pamphlet read. Data analysis and writing would require a period of 1 to 2 months. Total study duration would be 5 to 6 months.

Study Population

The Participants are patients referred to Sunnybrook Health Sciences Centre Urogynecology Clinics with manifestations and objective evidence of SUI for whom a course of management is required.

Exclusion Criteria

- Under the age of 18 years
- Urge-predominant, urge, or pure urinary urge incontinence
- Inability to respond to research questionnaires in English
- Cannot provide informed consent

Recruitment and Consent

Patient population will be recruited from the Urogynecology clinics at Sunnybrook Health Science Centre. Although the attending staff may invite the patient to participate, consent will be obtained by other members of the team such as the fellow physician. After obtaining permission from the patient, a written consent will be obtained from the patient. Then a 15-question questionnaire will be given to the

patient to fill. Then they will be asked to read the SUI patient leaflet published by AUGS found in Appendix C, which will include a written visual aid that will be discussed with the patient during their consultation with the urogynecologist.

Study Procedures

After the participant has provided written informed consent, the procedure involves:

1. Baseline (Pre-Counselling)

- Factors Questionnaire - Demographic & Clinical
- SUI knowledge questionnaire (Appendix A)
- Severity of Symptoms (ICIQ-UI Short Form, Appendix B)

2. Standardized Counseling Intervention

- Standard physician counseling about SUI and its causes, prognosis, and treatments (PFMT, continence devices, and surgery).
- AUGS SUI Patient pamphlet (Appendix C) to read, that will be printed.

3. Assessment after Counseling

- Repeat SUI Knowledge Questionnaire

Total time required to complete all questionnaires: 15 to 20 minutes.

Primary Outcome Measure

SUI Knowledge Questionnaire (Appendix A)

The SUI Knowledge Questionnaire will be a structured instrument developed specially for this study from literature available and expert consensus. We will mainly use the Pelvic Floor Health Knowledge Questionnaire, adapted from the domains and structure of the Pelvic Floor Health Knowledge Test (PFHKT) developed by Al'deges & Toprak Çelenay (2021). [23]

Content validity will be checked and validated by urogynecology faculty members before a study can be performed. Six main domains will be evaluated in the knowledge questionnaires:

- Understanding SUI
- Risk Factors and causes
- Diagnosis & Treatment
- Surgical alternatives
- Treatment Expectations and Prognosis

Each correct answer will carry one mark. The total marks will vary from 0 to 15, with higher scores reflecting greater knowledge.

Secondary Measures

- Change in knowledge score from pre-test to post-test
- Symptom severity (ICIQ-UI SF) Appendix B
- Preference in treatment options following counseling

- Prior education or treatment exposure to SUI

Sample Size determination

Based on previous studies on educational interventions for improving pelvic floor disorders, the effect size for improving knowledge scores after counseling would be moderate (Cohen's d value of 0.5). With a paired t-test at alpha=0.05 (two-tailed), with power of 80%, to identify this difference, the sample size would be found to be 64. Considering potential missing data points or withdrawal of participants from the study, the target sample would be estimated to be between 70 to 90 participants.

Risks and benefits

This study is a minimal risk study since it requires the participants to only fill questionnaires and the study in no way changes the participants' care. The study does not have any direct benefits to the participants, but the findings can be beneficial to the patients in the sense that the study shall improve the way of educating and counseling the patients. It might also be a beneficial tool for future participants by decreasing future consultation time and having more knowledge so medical attention can be sought sooner.

Data Analysis

The data will be analyzed using descriptive statistics to determine the characteristics of the participants and the knowledge scores. The knowledge scores before and after counseling will be compared using a paired t-test. The relationships between the knowledge scores and other variables such as age will be tested using independent samples t-test. The multiple linear regression test will be used to determine the independent predictors of knowledge. The results will be evaluated based on the significance level of $p \leq 0.05$.

Data Storage & Confidentiality

All data will be coded so that no identifiable information can be derived from it. Data will be saved on a password protected computers in research offices. Hard copies will be kept in locked file cabinets in secured research offices. The master linking file will be kept in a separate location and will be accessible only by the investigators.

Ethics

Ethical approval will be sought before the initiation of the study. This will be done at the Sunnybrook Health Sciences Centre Research Ethics Board. Informed consent will also be sought for all the participants in the study. This will have no effect on the care the participant will receive, considering the aspect of volunteering. Patients may withdraw at any time without affecting their clinical care

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APPENDIX A: STRESS URINARY INCONTINENCE KNOWLEDGE QUESTIONNAIRE

Instructions: Please answer the following questions to the best of your ability. Choose the single best answer unless otherwise specified.

Section 1: Understanding SUI

1- Stress urinary incontinence is best described as:

- Leakage of urine with coughing, sneezing, or physical activity
- Sudden leakage associated with urgency
- Leakage during sleep only
- I am not sure

2. The main cause of stress urinary incontinence is:

- Weakness of the pelvic floor and urethral support
- Bladder infection
- Excess fluid intake
- Aging alone

Section 2: Risk Factors and causes

3- Pregnancy and childbirth can weaken pelvic floor muscles

- Yes
- No
- l don't know

4- Being overweight, chronic cough and lifting heavy weights can increase the risk of stress urinary incontinence.

- Yes
- No
- I don't know

5- Menopause can affect pelvic floor strength.

- Yes
- No
- I don't know

6- Constipation can worsen pelvic floor dysfunction.

- Yes
- No
- I don't know

7- Pelvic floor problems can occur even without childbirth.

- Yes
- No

- I don’t know

8- Genetics and smoking can play a role in pelvic floor disorders.

- Yes
- No
- I don’t know

9- Stress urinary incontinence is a normal and unavoidable part of aging:

- Yes
- No
- I don’t know

Section 3– Diagnosis & Treatment

10- Pelvic floor muscle training is a first-line treatment for SUI.

- Yes
- No
- I don’t know

11- Correct pelvic floor exercises must be done regularly to be effective, and can be done at home

- Yes
- No
- I don’t know

12- Surgery is always required to treat stress urinary incontinence.

- Yes
- No
- I don’t know

s13- Conservative treatments should usually be tried before surgery:

- Yes
- No
- I don’t know

Section 4: Surgical Management

14- Surgery for SUI:

- Is the only effective treatment
- Is an option if conservative treatments fail or are declined
- Always causes complications
- I am not sure

Section 5: Expectations and Prognosis

15- Many women experience significant improvement in symptoms after appropriate treatment:

- Yes

- No
- I don’t know

Scoring:

APPENDIX C: SUI AUGS patient leaflet
https://www.voicesforpfd.org/wp-content/uploads/2025/09/SUI.pdf

Stress Urinary Incontinence

Voices for PFD

AUGS

Stress urinary incontinence (SUI) is loss of urine that occurs at the same time as physical exertion. Activities like sneezing, coughing, or exercise increase the pressure or "stress" on the bladder. This pushes urine out of the body.

About SUI

SUI affects one in three women over 45 years old. Women most commonly develop SUI from changes that happen in pregnancy or childbirth which weaken the support to the urethra. Chronic coughing, constipation, obesity, aging, smoking, or extreme weight lifting can also cause SUI. Genetics may also play a role.

The bladder walls are made of muscles. As urine flows into the bladder, the walls expand to make room for more fluid, like a water balloon. Sudden pressure caused by activity or "stress" unintentionally pushes urine through the urethra, the tube that carries urine out of the body.

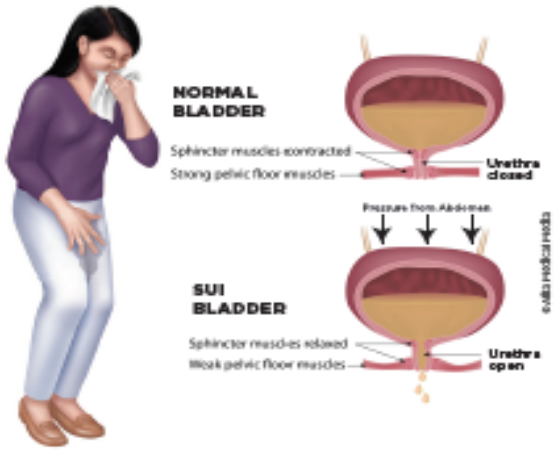
Some women leak occasionally, for example, only with intense exercise, heavy coughing, or when their bladder is very full. Others leak with activities such as walking or laughing. Women may limit physical and social activities to avoid SUI. There is no need to do this-talk to your medical provider about treatments that can help.

Diagnosis

There are different kinds of urine leakage. To diagnose your problem, you will be asked questions about when and how often you leak urine. A physical exam will help identify other conditions that influence the bladder, such as pelvic organ prolapse. As part of the exam, you will be asked to cough or strain with a full bladder to see if you leak.

Additional tests might include:

- Urine analysis to check for a urinary tract infection and blood in your urine.
- Ultrasound to assess how much urine remains in your bladder after urinating.
- Urodynamics to provide information on your bladder and urethra.



LEARN THE TERMS

Stress urinary incontinence (SUI): Urine leakage with physical activity such as laughing, sneezing, lifting, or exercise.

Urinary urgency incontinence (UUI): Urinary leakage that occurs with the sudden, strong desire to pass urine.

Pelvic organ prolapse (POP): Dropping of the pelvic organs, such as the bladder, uterus and rectum, caused by a loss of vaginal support.

Urethra: A tube that carries urine from the bladder out of the body when you urinate.

Mid-urethral sling: Placement of synthetic mesh in a strap-like fashion under the urethra to treat symptoms of stress urinary incontinence.

Urethral bulking: Low risk procedure involving "bulking agents" injected into the urethra. Usually a temporary fix.

Urodynamics: A group of tests performed in the office using a machine to evaluate how well your bladder fills and empties.

Stress Urinary Incontinence

Treatments

The ideal SUI treatment depends on your symptoms and bother. You may want to first try conservative treatments such as lifestyle changes, pelvic floor muscle exercises, or a vaginal pessary. There are no medicines that help this problem.

LIFESTYLE CHANGES

There are lifestyle changes you can embrace to reduce symptoms:

- Keep your bladder empty. Try to urinate every 2 to 3 hours.
- Maintain your weight in a normal range and lose weight, if you are overweight.
- Quit smoking.
- Treat constipation and stop straining with bowel movements.
- Stop extreme weight lifting activities and avoid repeated heavy lifting.

PELVIC FLOOR PHYSICAL THERAPY

Most women find that pelvic floor muscle exercises (Kegels) help improve symptoms. For the best effect, work with a specialized physical therapist to learn the techniques. Ask your provider for a referral. Then use these exercises consistently daily and every time you feel a cough or sneeze coming. It may take 3 to 6 months of regular pelvic floor muscle exercise to see results.

VAGINAL PESSARY

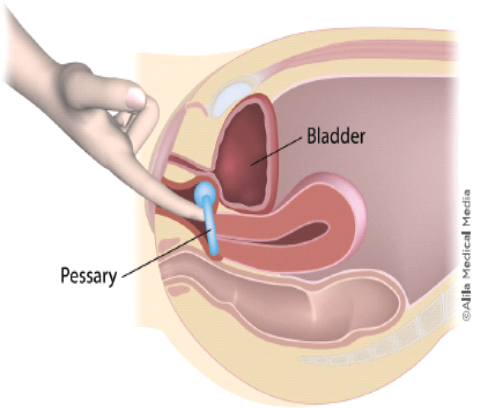
A pessary is a silicone device inserted into the vagina. It is similar to a diaphragm. Pessaries push the urethra closed to help control urine leakage. They still allow you to urinate normally when you need to. Some women wear a pessary only when they exercise. Others leave it in all the time.

URETHRAL BULKING AGENTS

In this procedure, a substance is injected near the urethra to "bulk up" the walls. This works well when a sphincter muscle that circles the urethra weakens. There are different types of bulking agents. This outpatient procedure is done in the office or opearting room. It is low risk and allows you to continue to be active immediately, but it can wear off after several months. Most of the time the injections may need to be repeated.

SURGERY

SUI surgery addresses the weakened supports around the urethra. There are different SUI surgeries, including mid-urethral or fascial slings and urethral suspensions. Surgery is typically very successful and often low risk. But, not all women are candidates for surgery. Women who plan to get pregnant may want to wait until after their last pregnancy to have SUI surgery. Your provider will discuss each of these options with you to help tailor the best treatment for your specific condition.



Three Takeaways

1. **SUI is common but not normal—it can be successfully treated so you can resume your active life!**
2. **Non-surgical options like lifestyle changes, pelvic floor muscle exercises and pessaries can manage symptoms.**
3. **There are several successful surgeries to treat SUI—ask your provider if you are a good match for surgery.**

APPENDIX B: ICIQ-UI s

Initial number

ICIQ-UI Short Form

CONFIDENTIAL

DAY MONTH YEAR

Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1 Please write in your date of birth: ☐☐ ☐☐ ☐☐

DAY MONTH YEAR

2 Are you *(tick one)*: Female ☐ Male ☐

3 How often do you leak urine? *(Tick one box)*

never	☐	0
about once a week or less often	☐	1
two or three times a week	☐	2
about once a day	☐	3
several times a day	☐	4
all the time	☐	5

4 We would like to know how much urine <u>you think</u> leaks.
How much urine do you <u>usually</u> leak (whether you wear protection or not)?
(Tick one box)

none	☐	0
a small amount	☐	2
a moderate amount	☐	4
a large amount	☐	6

5 Overall, how much does leaking urine interfere with your everyday life?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all a great deal

ICIQ score: sum scores 3+4+5 ☐☐

6 When does urine leak? *(Please tick all that apply to you)*

never – urine does not leak	☐
leaks before you can get to the toilet	☐
leaks when you cough or sneeze	☐
leaks when you are asleep	☐
leaks when you are physically active/exercising	☐
leaks when you have finished urinating and are dressed	☐
leaks for no obvious reason	☐
leaks all the time	☐

Thank you very much for answering these questions.