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Original Research Article

Comparison of various modalities to diagnose occult stress urinary incontinence in pelvic organ prolapse

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ABSTRACT

Background: Approximately a quarter of continent women with Pelvic organ Prolapse (POP) may develop Stress urinary incontinence (SUI) on prolapse reduction which is known as Occult SUI (OSUI). Aim of the study was to evaluate the incidence OSUI in women with pelvic organ prolapse (POP). To compare the diagnostic value of ambulatory ring pessary trial, urodynamics and clinical examination in detecting occult stress urinary incontinence and to find out an association of OSUI with demographic profile and the stages of POP.
Methods: It was a prospective cohort study conducted between September 2017 to June 2019 in the department of obstetrics and gynaecology, AIIMS, New Delhi. The study was approved by Institutional Ethics Committee. Ref no. IECPG-201/23.08.2017, RT-05/07.09.2017.
Results: The incidence of OSUI in this study was 22.8%. It was observed that OSUI is more prevalent in patients with parity of >/=3. Association with factors like age, BMI, mode of delivery and place of delivery was not found to be significant. Among screening tests to diagnose OSUI, ring pessary detected 88.88%, clinical examination and urodynamics (UDS) detected 77.77% and 33.33% cases respectively. The sensitivity of the pessary test, speculum test and UDS were found to be 88.89%, 77.78%, and 33.33% respectively and the diagnostic accuracy of these tests was 97.47%, 94.94% and 84.81% respectively.
Conclusions: The pessary was found to detect the maximum number of cases pre-operatively as compared to Urodynamic study and clinical examination.

Keywords: Occult, Stress urinary incontinence (SUI), Pessary trial, Pelvic organ prolapse, Kelly's stitch

INTRODUCTION

There has been an increase in the life expectancy of women all across the globe resulting in an increase in incidence of pelvic organ prolapse to as high as 50%.[1] Pelvic organ prolapse and stress urinary incontinence are two common health-related conditions affecting women worldwide. These two conditions occur from pelvic floor damage in the form of fascial defects, muscular weakness or nerve injuries leading to distortion of the normal anatomy and the continence mechanisms.[2] Therefore, these two conditions may often coexist.

Though benign in nature both POP and urinary incontinence (UI) may seriously impair the physical, psychological and social wellbeing of the affected woman and are associated with considerable resource implications for the health services.

The demand for pelvic reconstructive surgeries for prolapses and SUI is expected to increase in the near future.[3] Approximately a quarter of the continent women with POP may develop stress urinary incontinence on prolapse reduction. This phenomenon is referred to as occult, stress urinary incontinence (OSUI).[4] It occurs as a result of either kinking or external compression of the

urethra.[5-7] Reposition of the prolapsed tissue by any means (pessary/ surgical method) can lead to unmasking of occult stress urinary incontinence.

Diagnosing OSUI is important. Many studies have revealed that OSUI is an important reason of post-operative SUI (POSUI).[8] Optimal treatment of OSUI hence becomes important. Also, an additional anti-incontinence procedure necessitates a repeat surgery, repeat anaesthesia, additional recovery period, surgery in a previously operated field and increased monetary burden on the patient and her family.

Prevalence of OSUI in women with genitourinary prolapse varies from 27-68% in literature.[9] This wide variation in prevalence is owing to variations in methods used for diagnosis of OSUI. Cough stress test performed on full bladder after reduction of prolapse, double urodynamic evaluation before and after reduction of prolapse and ambulatory pessary trial have been described as the methods for diagnosis of OSUI.

In this present study, we have compared clinical examination, multi-channel urodynamics and use of a pessary trial for diagnosis of OSUI and expand our scope of understanding of the various factors which effect OSUI.

METHODS

This was a prospective cohort study, conducted from September 2017 to June 2019 at a tertiary care centre in India. The study was approved by the Institutional Ethics Committee. Ref no. IECPG-201/23.08.2017, RT-05/07.09.2017.

Sample size calculation

The reported prevalence of prolapse is around 40% presuming about 15% increased prevalence in high-risk target population, expected prevalence will be 55%.[10] Number of subjects that would be required for 80% power at 5% level of significance are 70. Considering a dropout rate of 10%, a total number of 77 [approximately n=80] were recruited in the study.

Participants

Total number of patients included in the study was 81. All women attending Gynaecology OPD who were diagnosed as POP with no complaints of SUI after detailed history and clinical examination and planned for surgical correction were considered for recruitment. Women fulfilling the inclusion criteria were recruited after explaining them the detailed plan, purpose and duration of the study in their own language. A copy of patient information sheet was provided and an informed written consent was obtained. Women with recurrent prolapse, SUI, previous anti- incontinence or prolapse surgery or neurological complaints were excluded.

Workup

Detailed clinical history was taken and general physical, systemic and pelvic examination done. Pelvic examination was initially done with comfortably full bladder and cough stress test was done before and after reducing prolapse in these subjects to demonstrate any obvious or occult stress urinary incontinence. Prolapse was reduced using Sims speculum to maintain uniformity in all cases. The patient was then made to empty her bladder and then a detailed POP-Q examination was performed. All the patients who fulfilled the inclusion criteria, were then asked to fill the Pelvic Floor Distress Inventory questionnaire -20 [PFDI-20]. Subsequently all patients were fitted with an appropriately sized ring pessary for 7 days and were asked to report any SUI or any discomfort and complaints following pessary insertion. PFDI-20 scoring was done again for these patients post pessary insertion at the end of 1 week.

After a period of 1-week, ring pessary (Figure 1) was removed and these patients were subjected to urodynamic evaluation to identify urodynamic OSUI.

When either of test [clinical examination, ring pessary and UDS] diagnosed OSUI it was considered test positive.[3]

Patients were admitted for surgery within 2 weeks of urodynamic evaluation.

All patients with prolapse alone, underwent vaginal hysterectomy with pelvic floor repair and those with positive OSUI, diagnosed by any method underwent an additional anti- incontinence surgery [Kelly's stitch].

Post-operative PFDI scores were assessed at 1, 2- and 3-months post-surgery (Figure 2).

Follow up

After surgery follow up was done at 1, 2 and 3month post operatively. Objective cures rates were determined by demonstrable SUI on clinical examination.

Pelvic floor distress inventory score [PFDI-20] was calculated at 1, 2 and 3 month post-operatively and improvement in PFDI domains after Kelly´s stitch application as treatment of OSUI was calculated.

Statistical analysis

Data analysis was carried out using statistical software version 12.0. Continuous variables were tested for normality assumption using Kolmogorov-Smirnov test. Descriptive measures such as mean, standard deviation, range values were calculated for normally distributed data. Categorical variables were presented as number and frequency. Comparison of frequency data across categories was carried out using chi-square/ fisher's exact test. Also 95% confidence interval for each measure was

calculated. A two-sided probability of p<0.05 was considered as statistically significant.

To assess the cut off value for POPQ indication points receiver operating characteristic curve (ROC) analysis was carried out. Using ROC analysis, area under the curve (AUC) and 90% confidence interval was calculated. Univariate logistic regression analysis was carried out to assess the significant variables in predicting risk factors for development of OSUI. Odds ratio and 95% confidence interval were calculated.

RESULTS

In this study, a total of 83 patients with POP-Q of grade II or more were admitted as in-patients for surgical management. Out of these, 4 (4.8%) patients were excluded from the study as 2 (2.4%) opted for pessary and 2 (2.4%) were found to be unfit for surgery. Hence a total of 79 patients were included for final analysis.

Table 1: Incidence of OSUI by pessary, pelvic examination and UDS.

Diagnostic test	Number of patients with OSUI (N)	Detection rate (%)	Confidence interval (upper limit-lower limit)
Ring pessary	16	20.3	11.4-29.1
Clinical examination	14	17.7	9.3-26.1
Urodynamic study	6	7.6	1.8-13.4
Total*	18	22.8	13.5-32.0

*- total cases included a combination of one or more tests and not direct sum of individual method

Table 2: Sensitivity, NPV, diagnostic accuracy of different diagnostics techniques for OSUI.

Screening test	Sensitivity %	NPV%	Diagnostic accuracy%
Clinical examination	77.78	93.85	94.94
Pessary	88.89	96.83	97.47
UDS	33.33	83.56	84.81

Notes: NPV: negative predictive value, Accuracy: (TP+TN) divided by total number of patients; measure of how well the test correctly identifies or excludes a condition depending upon prevalence

Table 3: Comparison of various methods to detect OSUI.

Study number	Author	Year	Total cases of OSUI	Clinical examination N (%)	Pessary N (%)	UDS N (%)	POSUI
1	Chughtai et al[3]	2011	26	13 (50)	16 (61)	6 (23)	1
2	Present study	2019	18	14 (77.7)	16 (88.9)	6 (33.3)	2

Table 4: Improvement in PFDI-20 score after pessary insertion and post-surgery.

	Pre-treatment mean (SD) score	Post-treatment mean (SD) score	Percentage reduction (%)	P value
At admission	83.44 (31.46)			
After pessary		45.80 (34.80)	45.11	<0.001
		Post-surgery		
Follow up -1		11.62 (13.19)	86.07	<0.001
Follow up -2		2.73 (8.19)	96.72	<0.001
Follow up -3		1.89 (7.90)	97.73	<0.001

Out of 79, 61 (77%) remained continent and 18 (22.8%) patients had urinary incontinence on reduction of uterine prolapse on either one or more of the tests. The overall incidence of OSUI was 22.8%. Incidence of OSUI by pessary test, examination and UDS was 20.3%, 17.7 % and 7.6 % respectively (Table 1). Out of the 18 cases detected in total, 1 (5.6%) was exclusively detected by clinical examination and 4 (22.2%) cases were exclusively detected by pessary reduction test.

Demographic characteristics

Mean age and BMI of the patients having OSUI was found to be 51 years and 24.08 kg/m^2 and of those without OSUI was 51.61 years and 24.93 kg/m^2. There was no significant difference in age and BMI with respect to OSUI. OSUI was more prevalent in women with parity index of ≥3 (p 0.008) and in those with higher stage prolapse. The place and mode of delivery, patient's occupation and pelvic floor

exercises post-delivery and smoking did not have any significant association with OSUI (p>0.05) in this study.

Screening tests

Number of cases detected by pessary alone was 22.2% and by clinical examination was 5.5%. 61 (77.21%) women showed no evidence of SUI by pessary trial, clinical examination, or urodynamic study and underwent prolapse repair without an accompanying anti-incontinence procedure. Two of these women had stress urinary incontinence post-operatively. One of the patients did not demonstrate SUI pre-operatively. 18 patients (22.8%) were diagnosed to have occult stress urinary incontinence by at-least one of the tests (pessary trial, physical examination, or UDS) and underwent a concomitant Kelly's stitch application.

Specificity of all tests was considered as 100%. There is no single gold standard to detect OSUI till date. So, a composite reference standard was used instead of a single gold standard.[11]

Sensitivity, positive predictive value, negative predictive value and diagnostic accuracy of all the tests is shown in Table 2.

POPQ indication points Aa and Ba were evaluated as a threshold to predict development of OSUI. ROC curves were plotted for both Aa and Ba point. POP-Q indication point Aa was not found significant as a threshold to predict the incidence of OSUI. The area under curve was 0.548 and p- value was 0.616.

However, for Ba point, chosen cut off of + 3.5 as a threshold or predicting SUI post-operatively was found to be borderline significant [p value 0.06] according to ROC curve for Ba point (Figure 3). The sensitivity of this was 72.2 % and specificity was 49.2%, AUC was 0.64 (p value-0.06).

From this it can be concluded that at a cut-off of >3.5 cm, OSUI is likely to occur.

Surgery and follow up

Total of 79 patients underwent surgery out of which two patients developed SUI post-operatively. Out of the two patients, 1 was detected in pre-operative period itself, however Kelly's stitch was not done because patient got operated outside. One patient developed SUI post-operatively which was undetected pre-operatively.

Subjective and objective cure following surgery

Objectively cures rates were determined by demonstrable SUI on clinical examination. Two patients were found to have SUI post-operatively. Pelvic floor distress inventory score-20 (PFDI 20) was calculated at 1, 2 and 3 month post-operatively and improvement in PFDI domains after Kelly´s stitch application as treatment of OSUI was calculated. The pre-treatment mean score of all patients with OSUI was found to be increased (mean= 105.25) Post anterior colporrhaphy and Kelly's stitch application, the scores were found to be reduced thereby suggesting a significant improvement in their symptoms (Table 4).

DISCUSSION

Occult stress urinary incontinence manifests after reduction of prolapse due to the de kinking of the urethra.

This study dwells on various aspects of OSUI like risk factors for its development and various modalities to diagnose OSUI. Studies done so far on incidence of OSUI state that the incidence ranges from 36 to 80% in women with advanced POP.[6,7,12-14] Chaikin et al reported that 14 out of 24 patients (58%) manifested OSUI after using a pessary.[14] Blaivas et al detected incidence of OSUI to be 32%.[15] Another study done by Gallentine et al, found 50% of patients to be affected with OSUI.[16]

Overall incidence of OSUI in this study was 22.8% (Table 3). The incidence of OSUI by pessary test, examination and UDS was 20.3%, 17.7% and 7.6% respectively. Various different methods available for reduction of prolapse have been studied by Visco et al in their study.[17] He concluded that various reduction tests showed large differences in detecting OSUI: from 6% with a pessary to 30% with a speculum.

Demographic characteristics

In our study, mean age of the patients having OSUI was found to be 51 years and that of without OSUI was 51.61 years. Ingrid et al, found higher parity had higher prevalence of incontinence. It was found to be 32.4% for ≥3 deliveries.[2] Similar to the previous study, parity was found to be significant in this study. At a parity ≥3 a total of 17 patients (94.4%) had OSUI which was found to be significant (p value: 0.008). This finding fortifies the belief that parity has an impact on urethral sphincter competence.

In a study by Ingrid et al the prevalence of OSUI was found to be 30.4% in obese women and 26.3% for overweight and 15.1% for normal weight women.[2] However, in our study the result revealed the women with OSUI to have a mean BMI of 24.08 kg/m^2, whereas the mean BMI in patients without OSUI was found to be 24.93 kg/m^2. There was no significant difference in BMI with respect to OSUI. This can be attributed to small sample size of the patients with high BMI.

A higher grade of prolapse was found to be associated with OSUI.[9] In our study the total number of patients with stage 2 were 1 (5.56 %) and the number of patients with stage 4 prolapse and OSUI were 5 in number (27.78%) and the number of patients with OSUI in stage 3 was maximum i.e.12 (66.67%).

In a study published by Chaughtai et al in 2011, whose primary objective was to determine if ambulatory pessary trial can identify women with OSUI before prolapse repair and found that 20 % of patients with OSUI were diagnosed by pessary alone.[3]

Since there is no specific gold standard in diagnosing OSUI, we considered the combination of all the three tests as equivalent to gold standard and have derived the sensitivity, PPV, NPV, and diagnostic accuracy of all the three tests as compared to the combined result.

The number of cases detected by UDS in this study was less compared to other tests. This may be because of the non-physiologic nature of testing and also because urodynamic study was performed in supine position and with catheters in-situ. A study conducted by Hayek et al has also similarly concluded earlier that UDS done in supine position underestimates both SUI and detrusor over activity.[19]

The advantage that pessary offers as described by Chughtai et al was that pessary offers length of time and different conditions at home and is more physiological.[3] In addition to detecting OSUI that would have been missed otherwise, it also helps in predicting incomplete emptying, as well as persistent urgency urinary incontinence, thereby preparing the patient regarding the outcome of the surgical treatment. The major advantage of a pessary is the cost and ease of use as compared to urodynamic study.

However, pessary comes with its own limitations. In a study by Visco et al the number of cases detected by pessary was less as compared to other methods, because of the urethral compression that can give false negative results.[20]

In this study, the sensitivity of the pessary test, speculum test and UDS (reduction by vaginal gauge) were found to be 88.89%, 77.78% and 33.33% respectively and the diagnostic accuracy of these tests was 97.47%, 94.94% and 84.81% respectively.

In a study conducted by Liu C et al in 2015 to determine the correlation between POP Q indication points (Aa, Ba) in predicting the incidence of OSUI and found a cut off value of +1.5 cm for Aa point as the threshold to predict incidence of de novo SUI.[21] This was done according to the ROC curve, area under the curve of which was 0.889 ($p<0.05$), the sensitivity was 88.9% and specificity was 73.9%. Using the same calculation for Ba point, a cut off value of +2.5 cm was chosen as the threshold to predicting incidence of de novo SUI post-surgery. The sensitivity of 66.7% and specificity of 82.6%, AUC was 0.766 ($p<0.05$).

In this study, a cut off of + 3.5 cm for Ba point was chosen as the threshold for predicting the incidence of OSUI, the sensitivity was found to be 72.2% and specificity was however found to be 49.2% making an AUC of 0.64 and p value borderline significant (p 0.06).

Also in this study, while evaluating the symptom improvement by PFDI-20, it was found that the symptom score improved after pessary insertion and post-surgery. The percentage reduction after pessary use was 45.11% and 1 month after surgery was 86.07% and after 2nd and 3rd follow up was 96.72% and 97.73% respectively.

Even in patients with positive test by any of the diagnostic tests, the percentage reduction in symptoms in 1, 2 and 3month follow up was 88.39%, 93.35% and 97.58% respectively.

Limitations of this study include the small sample size. Another limitation was the type of surgery chosen as an anti-incontinence surgery. Kelly's stitch was chosen as the anti-incontinence procedure because of its cost effectiveness which is particularly of significance in India. Another major limitation in this study is the inadvertent incorporation-bias that we introduced due to the use of index test as the component of composite reference standard.

CONCLUSION

Recognition of OSUI is important in order to counsel and prepare the patient for need of an additional anti-incontinence surgery. Incidence of OSUI in various studies has been found to be 7-22%. This wide range of the incidence is due to non- availability of a single reliable test to detect its presence. The incidence in this study was found to be 22.8% which is consistent with the other studies. The pessary was found to detect the maximum number of cases preoperatively. Therefore, pessary trial may be used as an effective method for pre-operative diagnosis of OSUI. One of the major advantages of pessary is the length of time it gives to detect SUI which is a dynamic process. It has definite advantages over urodynamic study in terms of cost, operator dependence and risks of infections that can occur during urodynamic study. Hence, we conclude that in patients with POPQ grade 2 or more, offering an ambulatory ring pessary trial can be beneficial. We also observed that none of the patients with pre-operative OSUI who had an anti-incontinence surgery developed SUI post-operatively in a period of follow up for 3 months. However, the shortcomings of this study were the shorter term follow up. Studies with longer follow up periods are needed to detect the presence of POSUI,

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