RESEARCH ARTICLE

Does concurrent pelvic organ prolapse surgery affect outcomes of mid-urethral Sling? A tertiary care experience

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Abstract

Objective: To compare the efficacy of mid-urethral sling surgery with and without concurrent pelvic organ prolapse surgery.

Method: The retrospective chart review was conducted in May 2022 at the Aga Khan University Hospital, Karachi, and comprised data of female patients who underwent mid-urethral sling surgery either through tension-free vaginal tape or trans obturator tape for stress urinary incontinence between January 2010 and December 2020 and had a complete 12-month follow-up data available. Two groups were formed: Group A had mid-urethral sling surgery cases, while Group B, had cases with concurrent mid-urethral sling and pelvic organ prolapse surgery. Documented parameters, including preoperative data, postoperative complications and satisfaction levels using urogenital distress inventory-6 and incontinence impact questionnaire-7 tools, were compared between the groups. Negative cough stress test was defined as objective cure. Data was analysed using SPSS 19.

Results: Of the 345 females, 122(35.4%) were in Group A, with 68(55.7%) aged <50 years. There were 223(64.6%) females in Group B, with 127(57%) aged >50 years($p>0.05$). Parity >3 and menopause were significantly higher in Group B ($p<0.05$), but a positive preoperative cough stress test was high in Group A ($p=0.001$). At 12-month follow-up, objective and subjective cure rates were not significantly different between the groups ($p>0.05$). However, at 6 months, urogenital distress inventory-6 scores were significant between the groups ($p<0.05$). Body mass index was associated with objective failure at 6months. Mid-urethral sling type and the presence of concurrent prolapse surgery had no significant effect ($p>0.05$).

Conclusion: Undergoing simultaneous prolapse surgery and mid-urethral sling surgery had similar risks and success rates as undergoing mid-urethral sling surgery alone.

Key Words: Concurrent surgery, Pelvic organ prolapse, Mid-urethral sling, Treatment outcome, Survey and questionnaires.

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Introduction

Both stress urinary incontinence (SUI) and pelvic organ prolapse (POP) are pelvic floor illnesses that significantly lower a woman's quality of life (QOL).[1] There are around 19.7% (range: 3.4-56.4%) and 28.7% (range: 5.2-70.8%) of POP and urinary incontinence cases worldwide, respectively.[2] There are 12.1% cases of POP and 12.5% cases of POP with urinary incontinence (UI) in rural Pakistan.[3] Concomitant anti-incontinence surgery is frequently performed at the same time as POP repair for this reason.[4] Furthermore, preventive sling insertion during POP surgery is routinely performed during POP repair, and reflects additional clinical scenarios in which concurrent sling placement and POP repair are frequently seen due to the high incidence of de novo SUI after POP surgery.[5] Due to the loss of pelvic muscle support, sexual dysfunction, pelvic organ prolapse as well as urinary and anal incontinence may all manifest at the same time because of similar underlying causes.[6] For cases of SUI needing surgical therapy, numerous vaginal and abdominal surgical methods have been devised. The tension-free vaginal tape (TVT) approach, first outlined in 1996, is the most used surgical method.[7] Various ways have been devised to lessen the problems of this operation, which include the Delorme's 2001 trans obturator tape (TOT) method[8]. The intervention's main goal is to rectify the damaged anatomy and restore normal function. It has been recommended that incontinence operations be included in routine prolapse repair, since they are assumed to have a similar underlying mechanism.[5] As such, it is important to assess the impact of POP repair combined with incontinence surgery. The current study was planned to compare the effect of concurrent prolapse surgery on QOL and objective and subjective success of mid-urethral sling (MUS) surgery.

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Materials and Methods

The retrospective chart review was conducted in May 2022 at the Aga Khan University Hospital, Karachi, and comprised data of female SUI patients who underwent MUS surgery either through TVT or TOT between January 2010 and December 2020 and had a complete 12-month follow-up data available. Patients who underwent isolated rectocele repair with MUS were excluded, and so were those with a history of anti-incontinence surgery, surgery for isolated posterior colporrhaphy, neurogenic bladder, and those lost to follow-up. Two groups were formed: Group A had patients who underwent MUS surgery alone, and Group B had patients who underwent MUS and POP surgery.

After exemption from the institutional ethics review committee, the Sample size was calculated using a two-proportion z test, assuming a 10% difference in objective cure rate between the two groups, with 80% power and 5% significance level. To account for potential losses to follow-up, the sample was inflated by <25%. Data was collected using International classification of disease ICD-109 codes 68.59 and 59.79. Data was extracted from patients' medical records with no patient encounter. Data quality was ensured by creating a structured form for data-collection. A pretest was applied to 5% of the study sample size, and all necessary changes were made in the collection tool accordingly. The fellow and supervisor responsible for data collection were trained on data-collection tools, data extraction methods, study objectives, patient confidentiality, and ethical issues.

Data was collected on demographic characteristics, co-morbidities, POP stages, findings of cough stress test (CST), type of MUS, type of concurrent prolapse surgery, perioperative and postoperative complications, and follow-up tests.

Preoperative evaluation for urinary incontinence, as per institutional policy, included history-taking, urine analysis, urine culture, urogynaecological examination, standardised CST, and, in some patients, urodynamic studies (UDS). According to the European guidelines on non-neurogenic female lower urinary tract symptoms (LUTS) 2022, UDS is not a mandatory investigation before surgery for SUI.[10] Therefore, UDS was not routinely performed for every patient preoperatively, and was limited to cases of mixed urinary incontinence to rule out neurogenic bladder.[11] The CST involved injecting 300ml of saline into the bladder and observing whether urine leaked when the patient coughed while standing, sitting or jumping.[12] SUI, according to the International Continence Society[13] (ICS), is defined as "the complaint of any involuntary loss of urine on effort or physical exertion (or on sneezing, coughing)".

After surgery, newly developing symptoms of urinary incontinence upon an increase in intra-abdominal pressure are referred to as de novo SUI. Occult SUI refers to urine leakage observed during evaluation or testing when prolapse is being supported in a woman who has no symptoms of SUI. During an examination or test, the patient is made to cough with a full bladder in a procedure known as prolapse reduction testing.[12]

The Stamey incontinence score was used to assess the severity of SUI, with grade 0 - continence, grade 1 = loss of urine with a sudden increase in abdominal pressure, such as from coughing, sneezing or laughing, grade 2 = leaks with less strenuous physical activity, like sitting up in bed or standing up from a sitting position, grade 3 = complete incontinence, where urine is leaked regardless of physical activity or position.[14] A urogynaecology examination was conducted, and the POPquantification (POP-Q) technique was utilised to assess POP (stages 0-4).[9,15] Incontinence-specific QOL was assessed with the validated urogenital distress inventory-6 (UDI-6) and incontinence impact questionnaire-7 (IIQ-7) tools.[16]

The IIQ-7 is a seven-item self-report questionnaire that assesses disease-specific QOL in women with SUI. It includes questions about how SUI affects the ability to do household chores, engage in physical recreation and entertainment activities, travel by car or bus more than 30 minutes from home, participate in social activities, and maintain emotional health (e.g., feeling frustrated).[17] The 20-item pelvic floor distress inventory (PFDI-20) is shortened into UDI-6. According to International consultation on Incontinence ICI ratings, the level of validation for the UDI-6 is A.[18] The UDI-6 comprises 6 items: frequent urination is the primary symptom, followed by leakage linked to an urge to urinate, leakage related to activity, leakage related to coughing or sneezing, difficulty emptying the bladder, and pain or discomfort in the lower abdomen or genitalia. Higher UDI-6 scores indicate more impairment[18]

The selection of slings was based on no set standards. After receiving thorough information about both surgeries, the type of sling was chosen based on patients' preferences, or, if the patient was unable to decide, based on the surgeon's preferences. These operations were performed by a total of three surgeons. The TVT procedure was carried out as specified in literature[7], while the TOT procedure was performed according to Delorme's outside-in method.[8] POP repair surgeries consisted of vaginal hysterectomy with or without

cystocele repair with native tissue repair.

At follow-up, all women were assessed with a detailed physical examination. Complications during and following surgery were compared between the two groups. Women were questioned about de novo urgency, postoperative voiding issues, and ongoing groin pain. A 3-day bladder diary was used where needed, and CST and completion of IIQ-7 and UDI-6 questionnaire were carried out at 2 weeks, 6 weeks, 6 months and 12 months.

A positive cough stress test at a 300ml bladder fill was an objective sign of SUI. Patients who answered "yes" to the question, "Does urine leak when you are physically active, exert yourself, cough, or sneeze?" were said to have subjective SUI. The success of the treatment was determined by a consultant urogynaecologist or fellow of urogynaecology, who examined and interviewed patients, and labelled patients as "cured" (neither subjective complaints of leakage nor objective leakage on CST) or "improved" (rare leakage subjectively, but satisfaction regardless of leakage). All the remaining cases were regarded as “failure”. The type of persistent or recurring incontinence was not considered when determining the treatment's success, as urinary incontinence, regardless of the form, may be more pertinent to patients.

Postoperative evaluations were routinely performed at 6 and 12months after treatment. According to their incontinence status, the patients were divided into success and failure groups. The success rates at 6 and 12 months were compared between groups A and B. Several clinical and demographic variables were also compared between the groups to identify the factors influencing the cure rate.

Data was analysed using SPSS.[19] For numerical variables, mean +/- standard deviation, or median with interquartile range (IQR) were calculated. Data normality was assessed using the Shapiro-wilk test. An independent sample t-test or Mann-Whitney U test was used for mean/median comparisons between the groups. Frequencies and percentages were computed for categorical data, and it was compared using chi-square or Fisher's exact test. A binary logistic regression model was used to assess the factors that influenced the cure rate, and the odds ratio (OR) and 95% confidence interval (CI) were worked out. P<0.05 was considered statistically significant.

Results

Of the 345 females, 122(35.4%) were in Group A, with 68(55.7%) aged <50 years. There 223(64.6%) females in Group B, with 127(57%) aged >50 years (p>0.05). Regarding the stages of prolapse, 125 (36.3%) had stage 2, 122 (35.5%) had stage 3, and 95 (27.8%) had stage 4. Of the women who underwent concomitant prolapse surgery for POP, 217(63%) had vaginal hysterectomy and concomitant pelvic floor repair, and 128 (36%) had POP surgery, including anterior colporrhaphy. Parity >3 and menopause were significantly higher in Group B (p<0.05), but a positive preoperative cough stress test was high in Group A (p=0.001) (Table 1).

Table-1: Comparison of demographic and clinical characteristics between the groups (n=345).

Demographics	Group B surgery n=223	Group A n=122	P-Value
Age (Years)			
≤ 50	96(43%)	68 (55.7%)	0.025
≥ 50	127(57%)	54 (44.3%)	
Parity			
≤ 3	40 (17.9%)	54 (44.3%)	0.0005
> 3	183 (82.1%)	68 (55.7%)	
Body mass index (BMI) (kg/m^2)			
≤25	71 (31.8%)	38 (31.1%)	0.895
>25	152 (68.2%)	84 (68.9%)	
Menopause			
Yes	131(58.7%) *	54(44.3%)	0.010
No	92(41.3%)	68(55.7%)	
Pre-operative cough stress test			
Positive	104(46.6%)	80(65.6%) *	0.001
Negative	119(53.4%)	42(34.4%)	

The rate of perioperative complications was not significantly different between the groups (p=0.231). The rate of postoperative complications was also not significantly different between the groups (p=0.982). The most common immediate postoperative complications were pain at the site n=18(5.2%) and fever n= 14(4.1%),

Table-2: Comparison of perioperative and postoperative complications between the groups.

Complications	Group B n=223	Group A n=122	p-Value
Perioperative	**14(6.3%)**	**12(9.8%)**	**0.231**
UTI	2(0.9%)	2(1.6%)	0.616
Urinary retention	6(2.7%)	4(3.3%)	0.747
Haematoma	2(0.9%)	0(0%)	0.542
Urethral injury	0(0%)	2(1.6%)	0.124
Bladder injury	4(1.8%)	4(3.3%)	0.46
Postoperative	**40(17.9%)**	**22(18%)**	**0.982**
Hispareunia	0	2(16%)	0.124
Dyspareunia	4(1.8%)	2(1.6%)	0.998
De novo urge	3(1.3%)	0	0.555
Pain	13(5.8%)	6(4.9%)	0.723
Fever	10(4.5%)	4(3.3%)	0.777
Mesh Complication	**12(5.4%)**	**10(8.2%)**	**0.306**

Table-3: Comparison of outcome in terms of objective and subjective cure between the groups.

Outcome	Group B n=223	Group A n=122	P-Value
Cure rate the end of 6th month			
Objective cure Cough stress test			
Positive	12(5.4%)	8(6.6%)	0.655
Negative	211(94.6)	114(93.4%)	
Subjective cure Incontinence			
Cured	205(91.9%)	108(88.5%)	0.06
Improved	16(7.2%)	8(6.6%)	
No change at all	2(0.9%)	6(4.9%)	
Cure rate at the end of 12th month			
Objective cure Cough stress test			
Positive	14(6.3%)	8(6.6%)	0.909
Negative	209(93.7%)	114(93.4%)	
Subjective cure Incontinence			
Cured	207(92.8%)	106(86.9%)	0.06
Improved	12(5.4%)	8(6.6%)	
No change at all	4(1.8%)	8(6.6%)	

which were controlled with antipyretics and analgesics. Postoperative urinary retention occurred in n=10(2.9%) women, for whom an indwelling catheter was kept for 7days, and all of them recovered without the need for prolonged catheterisation or clean intermittent catheterisation (CIC). The cumulative rate of mesh complications during the 12-month follow-up was also not significantly different between the groups (p>0.05). No patient required mesh removal or reoperation for SUI in both the groups (Table 2).

Table-4: Comparison of satisfaction score between the groups.

Outcome UDI-6	Group B n=223 Mean ± SD Median[25- 75percentile]	Group A n=122 Mean ± SD Median[25-75percentile]	p-Value
Pre	27.82±11.12	27.60±11.26	
	29.17[16.67-37.5]	25[16.67-37.5]	0.859
Pre versus 6 months	9.83±9.54	11.48±10.94	
	8.33[0-16.67]	8.33[0-16.67]	0.168
6th months vs 12 months	4.44±7.7	6.9±10.79	
	0[0-8.33]	0[0-8.33]	0.040*
IIQ7			
Pre	37.26±18.81	42.38±19.44	
	38.09[19.05-47.62]	42.86[32.14-61.90]	0.022*
Pre versus 6 months	8.71±10.62	11.48±13.39	

The objective cure rate at 6-month and 12-month follow-up was n=210(94.2%) and n=208(93.3%) in Group B, and

Table-5: Factors that influenced the mid-urethral sling outcome at the end of 6 and 12 months.

Factors		end of the 6th month				end of the 12th months			
	N	Wald	P-Value	OR	95%CI (OR)	Wald	P-Value	OR	95%CI (OR)
Age (Year)									
≤50	164	1.93	0.16	Ref	0.67-10.47	2.41	0.12	Ref	0.75-11.67
>50	181			2.65				2.96	
Parity									
≤3	94	1.33	0.25	Ref	0.61-6.74	1.79	0.18	Ref	0.68-7.50
>3	251			2.03				2.26	
BMI (kg/m^2)									
≤25	109	3.46	0.06	Ref	0.16-1.05	5.83	0.016*	Ref	0.13-0.81
>25	236			0.41				0.32	
Menopause									
Yes	185	1.00	0.32	2.03	0.51-8.14	1.05	0.31	Ref	0.52-8.22
No	160			Ref				2.06	
Surgery									
TVT	150	0.75	0.757	1.17	0.43-3.14	.008	0.928	1.045	0.40-2.73
TOT	195			Ref				Ref	
Prolapse									
Yes	225	2.95	0.086	0.23	0.04-1.22	2.129	0.145	0.343	0.08-1.44
No	122			Ref				Ref	
VH									
Yes	141	2.17	0.140	3.25	0.67-15.58	1.63	0.20	2.39	0.63-9.16
No	204			Ref				Ref	

BMI: Body mass index, TVT: Tension-free vaginal tape, TOT: Trans obturator tape, Vaginal hysterectomy VH: OR: Odds ratio, CI: Confidence interval.

n=114(93.4%) and n=114(93.4%) in group A, respectively (p>0.05) (Table 3).

There were no significant intergroup differences in terms of UDI-6 scores preoperatively and at 6 months, but the mean UDI-6 score was significantly lower in Group B women compared to their counterparts in Group A (p=0.04) at 12 months compared to 6 months. The mean IIQ7 scores were also noted separately (Table 4).

Body mass index (BMO) was associated with objective outcome (p<0.05), while MUS type and the presence of concurrent prolapse surgery had no significant effect (p>0.05) (Table 5).

Discussion

After unsuccessful conservative treatment for SUI, surgery is the best option for patients.[19] Objective and subjective recovery rates range from 71% to 97%[20], making MUS the most effective and safe surgical therapeutic intervention to date.[21]

The current study evaluated the need for concurrent or two-step operation in patients with POP and SUI by analysing the outcomes of MUS in patients who underwent concurrent prolapse corrective surgery compared to those who only had anti-incontinence surgery. The choice of whether to perform anti-incontinence surgery at the time of prolapse repair remains a clinical challenge for many practitioners.[22, 23].

Cumulative data of women with both symptomatic POP and SUI have shown significantly lower rates of postoperative SUI in women who undergo concurrent POP repair and a continence procedure than in those who undergo POP repair alone.[24, 25]

The current study involved 345 women. Although 99.1% of women with prolapse had undergone concomitant prolapse surgery, the rate of postoperative complications was not significantly different between MUS surgery with and without POP surgery.

Similarly, the objective cure rate, assessed by CST, and the subjective assessment at 6 and 12 months were not significant different between the groups. However, the mean UDI-6 score was significantly lower in women with MUS with POP compared to those without POP.

A Cochrane analysis included 18 randomised controlled trials (RCTs) and found that concomitant MUS in women with symptomatic POP and SUI improved the postoperative rate of subjective SUI and decreased the need for further continence surgery.[26]

Despite many Asian nations having a high rate of concurrent anti-incontinence and POP surgery, some surgeons prefer a two-stage technique where POP is repaired first, arguing that the approach may impact surgical success, reduce complications, or prevent postoperative voiding dysfunction.[27]

In a study, patients were randomly assigned to MUS or MUS+POP surgery groups. Overall, 65% of those treated with MUS alone and 53% of those treated with MUS and POP reported a subjective improvement in their SUI symptoms. However, when comparing group-specific cure rates, there was no discernible difference.[28] A study in Turkey further supported the findings, suggesting no significant variation in SUI outcomes across different POP repair techniques.[29]

Another study found that TOT-TVT with concurrent pelvic organ prolapse correction was a dependable and successful treatment for SUI. The two groups of participants who underwent MUS revealed no discernible difference in complications, urinary dysfunction, pelvic pain, vaginal erosion, and initial improvement in overactive bladder (OAB) or urge urinary incontinence (UUI)[30].

The current study has limitations, such as the limited 12-month follow-up period, a retrospective design, and data from a single tertiary care centre. As such, caution should be exercised in the clinical application of the findings. Multi-centre, prospective trials are required to validate the current results.

Conclusion

Simultaneous prolapse surgery and MUS surgery had similar risks and success rates as MUS surgery alone, without any additional negative outcomes.

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AUTHOR'S CONTRIBUTION:
SA: Design, protocol, data collection, writing, final approval and agreement to be accountable for all aspects of the work.
UK & SM: Literature search, review and final approval.
NC: Managed the analysis, writing, final approval and agreement to be accountable for all aspects of the work.