Original Research Paper

Volume - 11 | Issue - 09 | September - 2021 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Gynaecology

RANDOMIZED CONTROLLED TRIAL COMPARING USE OF MID URETHRAL SLING (TOT) VERSUS NO SLING (SHAM INCISION) FOLLOWING VAGINAL PROLAPSE REPAIR TO REDUCE STRESS URINARY INCONTINENCE IN PATIENTS WITH VAGINAL PROLAPSE WITHOUT STRESS URINARY INCONTINENCE.

Dr Rathindra Nath Ray — Assistant Professor, Department Of Gynaecology And Obstetrics, IPGME&R And SSKM Hospitals, Kolkata

Dr Chiranjib Bagchi* — Associate Professor, Department Of Clinical And Experimental Pharmacology, School Of Tropical Medicine, Kolkata. *Corresponding Author

Dr Gourishankar Kamiliya — Professor, Department Of Gynaecology And Obstetrics, IPGME&R And SSKM Hospitals, Kolkata

ABSTRACT

AIM: To compare occurrence of stress urinary incontinence, urinary tract infection, bleeding, postvoid residual urine and mean operative time between two study groups.

MATERIALS AND METHOD: We conducted a randomized controlled trial involving women attending our Gynecology OPD with prolapse, without symptoms of stress incontinence. Patients with anterior prolapse (of stage 2 or higher on pelvic organ prolapse quantification system examination) had undergone vaginal prolapse surgery.Women were randomly assigned to receive either a mid- urethral sling (92 subjects) or sham incision during surgery (92 subjects).

RESULT: Mean age of the patients were higher in control group compared to case group which was statistically significant ($p<0.0001$).In case group, the mean post void residual urine volume by USG at 1 year (mean± s.d.) of patients was 51.96±1.60 ml. In control group, the mean post void residual urine volume by USG at 1 year (mean± s.d.) of patients was 55.93±2.76 ml. Mean post void residual urine volume by USG at 1 year in both groups were significantly different ($p<0.0001$). Association of urinary tract infection at 1 year and bleeding in group vs group was not statistically significant ($p=0.3159$). On the other side mean time of operative procedure was higher in case group which was also statistically significant ($p<0.0001$).

CONCLUSION: Transurethral sling operation during vaginal prolapse surgery resulted in significantly less urinary incontinence, less post void residual urine upto one year post surgery compared to women undergone prolapse surgery without sling operation.

KEYWORDS : Urethral Sling, Stress, Urinary Incontinence, Vaginal Prolapse.

INTRODUCTION

One in five women will undergo surgery for pelvic-organ prolapse in her lifetime,[1] and urinary incontinence commonly occurs with pelvic-organ prolapse. In previously continent women with pelvic-organ prolapse, urinary incontinence develops in approximately a quarter of them after prolapse repair; this phenomenon is referred to as occult, latent, de novo, iatrogenic, or potential stress urinary incontinence. In 2006, the Colpopexy and Urinary Reduction Efforts (CARE) trial[2] showed that adding a bladder-neck suspension at the time of abdominal prolapse surgery in women without preoperative stress incontinence significantly reduced the risk of postoperative stress urinary incontinence [POSUI] (23.8%, vs. 44.1% in the control group).

Recently, prolapse repairs have been increasingly performed transvaginally, and midurethral slings have largely replaced bladder-neck suspensions.[2]Extrapolating from the CARE trial data, many surgeons prophylactically insert a concomitant midurethral sling in all continent women undergoing vaginal prolapse surgery[3]; others perform this additional procedure selectively, in women who have urinary stress incontinence on preoperative cough testing. An alternative strategy is to treat only those women in whom bothersome urinary incontinence develops postoperatively.The relative benefits and risks of these strategies are unclear.

Combination surgery reduces the risk of POSUI compared with prolapse surgery only. However, only a minority of the women will need subsequent treatmentof POSUI and more women face a serious adverse event(SAE) after vaginal prolapse repair with a midurethralsling (MUS) compared with prolapse surgery only (14%vs 8%; RR, 1.7; 95% CI, 1.1–2.7). When one considers combination surgery, the risks and benefits have to be weighed and it is essential to gauge a woman's risk of facing POSUI. Although the stress test is commonly used to identify women with a high POSUI risk, its value is questionable.[4]

Jelovsek et al[4] developed a model for predicting therisk of de novo SUI after prolapse surgery and published an online calculator. Their model is applicable to women without preoperative SUI symptoms, which is about 50%of the women undergoing prolapse surgery.[5]We aimed to develop an easily applicable prediction model for postoperative bothersome SUI and/or subsequent treatment of SUI in all women undergoing vaginal prolapse repair.In addition, we aimed to study the incremental value of a preoperative stress test with respect to other readily available preoperative characteristics.

In our clinical setup, we counter many patients with uterovaginal prolapse without stress urinary incontinence. But unfortunately it is found during the follow-up period, some of the patients amongst them who had undergone repair surgery for prolapse, have been complaining of stress urinary incontinence.If we give a support in the mid urethral region by a mid- urethral sling during the time of prolapse repair it may reduce the future risk of stress urinary incontinence. With this background hypothesis the present study was conceived.

AIMS AND OBJECTIVE

1. To compare the occurrence of urinary stress incontinence at 3 months and 1 year post surgery between two study groups
2. To compare the occurrence of urinary tract infection, bleeding, post void residual urine and mean operative time in both groups of study population

MATERIALS AND METHOD

Duration of study: One year

Follow up at: Six weeks to check residual urine volume. Three months and one year to check for presence or absence of stress urinary incontinence.

Place of study: Department of Obstetrics and Gynaecology, IPGME&R and SSKM Hospital, Kolkata

Inclusion criteria: Patients presenting with anterior vaginal wall prolapse within one centimeter of hymeneal ring with strain.

Exclusion criteria:

- Patients having preexisting stress urinary incontinence with vaginal prolapse
- Previous sling placement
- Receiving or received treatment for stress urinary incontinence
- Has contraindications for mid urethral sling like previous urethral surgery, pelvic irradiation etc,
- Two or more days hospitalization for medical illness in the previous year.

Primary Outcome: Presence of urinary incontinence at three months and one year post surgery.

Secondary Outcome:
Urinary tract infection
Significant bleeding
Incomplete bladder emptying in terms of postvoid residual urine
Time of operative procedure

METHODS: We performed a randomized controlled trial involving women attending our gynaecology OPD with vaginal prolapse, without symptoms of stress incontinence. A total of 184 women with vaginal prolapse were recruited in the study after fulfilling study selection criteria and obtaining written informed consent. Patients with anterior prolapse (of stage 2 or higher on pelvic organ prolapse quantification system examination) had undergone vaginal prolapse surgery. They were randomly assigned to receive either a mid- urethral sling or sham incision during vaginal prolapse surgery comprising of 92 subjects each in case group and in the control group. The operation was done by same team of gynecologists in both groups. The study was started after receiving requisite approval from the institutional ethics committee.

RESULT AND ANALYSIS

We found in case group, 40(43.5%) patients were ≤45 years old, 44(47.8%) patients were 46-50 years old, 4(4.3%) patients were 51-55 years old and 4(4.3%) patients were 56-60 years old. In the control group, 9(9.8%) patients were ≤45 years old, 17(18.5%) patients were 46-50 years old, 14(15.2%) patients were 51-55 years old, 4(4.3%) patients were 56-60 years old, 19(20.7%) patients were 61-65 years old and 29(31.5%) patients were 66-70 years old [Figure 1].

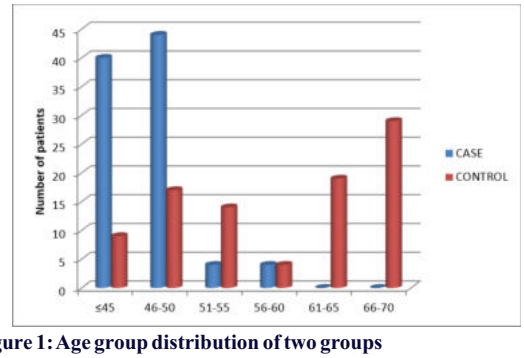


Figure 1: Age group distribution of two groups

Association of Age in group vs group comparison was statistically significant (p<0.0001) [Table 1].

Table 1: Comparison of age distribution between treatment groups

AGE GROUPS	CASE	CONTROL	TOTAL
≤45	40	9	49
Row %	81.6	18.4	100.0
Col %	43.5	9.8	26.6
46-50	44	17	61
Row %	72.1	27.9	100.0
Col %	47.8	18.5	33.2
51-55	4	14	18
Row %	22.2	77.8	100.0
Col %	4.3	15.2	9.8
56-60	4	4	8
Row %	50.0	50.0	100.0
Col %	4.3	4.3	4.3
61-65	0	19	19
Row %	0.0	100.0	100.0
Col %	0.0	20.7	10.3
66-70	0	29	29
Row %	0.0	100.0	100.0
Col %	0.0	31.5	15.8
TOTAL	92	92	184
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 85.1186; p-value:<0.0001

In control group, 30(32.6%) patients had urinary incontinence at 3 months. Association of urinary incontinence at 3 months in group vs group comparison was statistically significant (p<0.0001).In control group, 37(40.2%) patients had urinary incontinence at 1 year. Association of urinary incontinence at 1 year in group vs group comparison was statistically significant (p<0.0001) [Table 2].

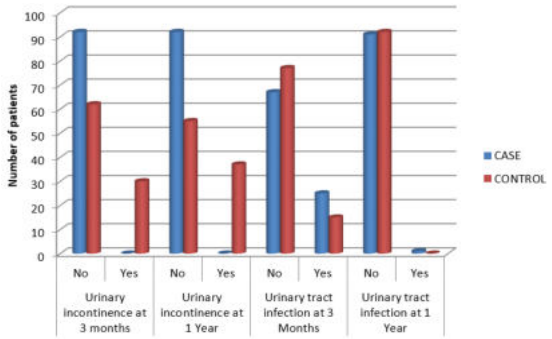
Table: 2 Association of urinary incontinence between groups

		Case	Control	Total	Chi-square value	p-value
Urinary incontinence at 3 months	No	92	62	154	35.8442	<0.0001
	Row %	59.7	40.3	100.0		
	Col %	100.0	67.4	83.7		
	Yes	0	30	30		
	Row %	0.0	100.0	100.0		
	Col %	0.0	32.6	16.3		
	Total	92	92	184		
	Row %	50.0	50.0	100.0		
	Col %	100.0	100.0	100.0		
Urinary incontinence at 1 year	No	92	55	147	46.3129	<0.0001
	Row %	62.6	37.4	100.0		
	Col %	100.0	59.8	79.9		
	Yes	0	37	37		
	Row %	0.0	100.0	100.0		
	Col %	0.0	40.2	20.1		
	Total	92	92	184		
	Row %	50.0	50.0	100.0		
	Col %	100.0	100.0	100.0		
Urinary tract infection at 3 months	No	67	77	144	3.1944	0.0738
	Row %	46.5	53.5	100.0		
	Col %	72.8	83.7	78.3		
	Yes	25	15	40		
	Row %	62.5	37.5	100.0		
	Col %	27.2	16.3	21.7		
	Total	92	92	184		
	Row %	50.0	50.0	100.0		
	Col %	100.0	100.0	100.0		
Urinary tract infection at 1 year	No	91	92	183	1.0055	0.3159
	Row %	49.7	50.3	100.0		
	Col %	98.9	100.0	99.5		
	Yes	1	0	1		
	Row %	100.0	0.0	100.0		
	Col %	1.1	0.0	0.5		
	Total	92	92	184		
	Row %	50.0	50.0	100.0		
	Col %	100.0	100.0	100.0		

In case group, 25(27.2%) patients had urinary tract infection at 3 months. In control group, 15(16.3%) patients had urinary tract infection at 3 months [Figure 2]. Association of urinary tract infection at 3 months in group vs group comparison was not statistically significant (p=0.0738).

Our study showed that in case group, 1(1.1%) patient had urinary tract infection at 1 year [Figure 2].

Figure 2: Distribution of urinary incontinence in two groups



Association of urinary tract infection at 1 year in group vs group comparison was not statistically significant (p=0.3159)[Table 2].In case group, 2(2.2%) patients had bleeding.[Figure 3] Association of bleeding in group vs group comparison was not statistically significant (p=0.1550) [Table 3].

Table: 3 Association of bleeding between groups

Bleeding	CASE	CONTROL	TOTAL
No	90	92	182
Row %	49.5	50.5	100.0
Col %	97.8	100.0	98.9

Yes	2	0	2
Row %	100.0	0.0	100.0
Col %	2.2	0.0	1.1
TOTAL	92	92	184
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

Chi-square value: 2.0220; p-value: 0.1550

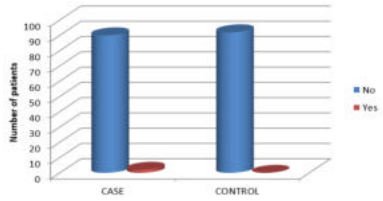


Figure 3: Distribution of bleeding episodes between the groups

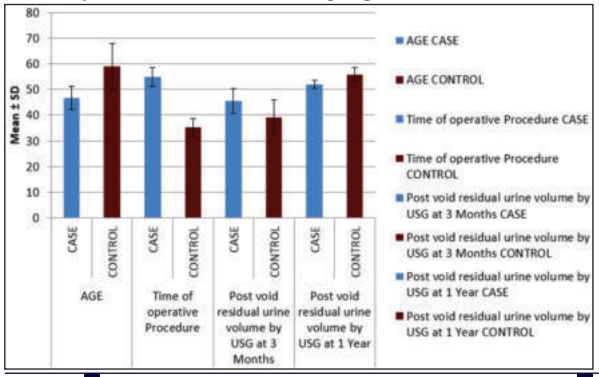
In case group, the mean Age (mean± s.d.) of patients was 46.67±4.51years. In control group, the mean Age (mean± s.d.) of patients was 58.88±9.03 years [Table 4].

Table: 4 Comparison of AGE, Time of operative procedure, Post void residual urine volume by USG at 3 months and Post void residual urine volume by USG at 1 year between two groups

		Number	Mean	SD	Minimum	Maximum	Median	p-value
AGE	Case	92	46.67	4.51	39.00	58.00	47.50	<0.0001
	Control	92	58.88	9.03	45.00	70.00	62.00	
Time of operative Procedure	Case	92	54.85	3.57	50.00	60.00	54.00	<0.0001
	Control	92	35.27	3.47	30.00	40.00	36.00	
Post void residual urine volume by USG at 3 Months	Case	92	45.67	4.83	35.00	50.00	48.00	<0.0001
	Control	92	39.19	6.75	30.00	50.00	40.00	
Post void residual urine volume by USG at 1 Year	Case	92	51.96	1.60	50.00	55.00	52.00	<0.0001
	Control	92	55.93	2.76	51.00	60.00	56.00	

Mean Age of both groups were significantly different (p<0.0001).In case group, the mean time of operative procedure(mean± s.d.) of patients was 54.85 ± 3.57 minutes. In control group, the mean time of operative procedure (mean± s.d.) of patients was 35.27 ± 3.47 minutes. Mean time of operative procedure was significantly different in two groups (p<0.0001).In case group, the mean post void residual urine volume by USG at 3 months (mean± s.d.) of patients was 45.67 ± 4.83 ml. In control group, the mean post void residual urine volume by USG at 3 months (mean± s.d.) of patients was 39.19 ±6.75ml (Figure 4).

Figure 4: Distribution of AGE, Time of operative procedure, Post void residual urine volume by USG at 3 months and Post void residual urine volume by USG at 1 Year between two groups



Mean post void residual urine volume by USG at 3 months between both groups was significantly different (p<0.0001) [Table 4].In case group, the mean post void residual urine volume by USG at 1 year (mean± s.d.) of patients was 51.96 ± 1.60 ml. In control group, the mean post void residual urine volume by USG at 1 year (mean± s.d.) of patients was 55.93±2.76 ml. Mean post void residual urine volume by USG at 1 year post surgery between both groups was significantly different (p<0.0001) [Table 4].

DISCUSSION

In a study done by Richter HE et al.[7], a total of 597 women were randomly assigned to a study group; 565 (94.6%) completed the 12-month assessment. The rates of objectively assessed treatment success were 80.8% in the retropubic-sling group and 77.7% in the transobturator-sling group (3.0 percentage-point difference; 95% confidence interval [CI], -3.6 to 9.6). The rates of subjectively assessed success were 62.2% and 55.8%, respectively (6.4 percentage-point difference; 95% CI, -1.6 to 14.3). The rates of voiding dysfunction requiring surgery were 2.7% in those who received retropubic slings and 0% in those who received transobturator slings (p=0.004), and the respective rates of neurologic symptoms were 4.0% and 9.4% (p=0.01). There were no significant differences between groups in postoperative urge incontinence, satisfaction with the results of the procedure, or quality of life.

The 12-month rates of objectively assessed success of treatment for stress incontinence with the retropubic and transobturator approaches met the prespecified criteria for equivalence; the rates of subjectively assessed success were similar between groups but did not meet the criteria for equivalence. Differences in the complications associated with the two procedures should be discussed with patients who are considering surgical treatment for incontinence.

In a study by Al-Mandeel H et al [8] to estimate the incidence of stress urinary incontinence (SUI) following vaginal repair of pelvic organ prolapse (POP) in preoperatively continent women and to evaluate the impact of the problem. Women were eligible if they had undergone vaginalrepairs for any degree or type of POP with no anti-incontinence procedure between July 1, 2004 and June 30, 2006, and had been continent preoperatively, as defined by a negative cough stress test with or without reduction of prolapse. Demographic, preoperative, operative, and postoperative data were retrieved from hospital charts. The incidence of postoperative SUI(POSUI) and its quality of life (QoL) impact were assessed by mailed questionnaire. The POSUI end point was defined by the report of SUI symptoms on the mailed questionnaire and/or affirmation of postoperative treatment for SUI. Forty-two out of 100 respondents reported POSUI within the 2-year average follow-up period. Twelve of 37 symptomatic women (32%) were moderately or greatly bothered by their symptoms. The QoL(Quality of Life) impact score was generally low but was statistically greater in women with POSUI compared to those with no POSUI (13 vs. 3, p=0.0006). The risk of POSUI following vaginal repairs of POP may be higher than previously reported and approximately one-third of women are bothered by these symptoms.

In a study by Meschia M et al [9] between February 2000 and June 2001, 50 women with severe genital prolapse and occult SUI were enrolled. They had mean age of 65±8 years (range, 50-75 years), body mass index of 25±3 kg/m2 , and vaginal parity of 2.2 ±0.8 pregnancies (range, 1-5 pregnancies). All of the women were postmenopausal, and none of the women were using hormone replacement therapy at the time of operation. There were no significant differences between the 2 surgical groups with respect to any of these parameters and no difference in the severity of genital prolapse. Average time to resumption of spontaneous voiding was only slightly longer in the TVT group than in the fascia plication group. Four women (2 in each group) had postoperative urinary retention that resolved spontaneously after 8 of 9 and 7 of 10 days, respectively. In the TVT group, 1 patient had a uneventful bladder perforation and 1 patient experienced a retropubic hematoma that resolved spontaneously. The median follow-up time for the TVT and fascia plication groups was 26 months (range, 15-31 months) and 24 months (range, 15-31 months), respectively. One woman (4%) who received TVT and 9 women (36%) who had fascia placation reported postoperative symptoms of SUI (p=0.01). All women reported SUI within the first year of follow-up. In one half of the patients, SUI was classified as mild according to the Ingelman-Sundberg symptoms score and required no treatment. The other 5 women, all in the fascia plication group, had moderate or severe SUI; 3 of the women underwent reoperation (1 periurethral silicone injection and 2 TVT procedures, between 8 and 14 months after the original operation). Two patients who refused repeat surgery were

enrolled in a pelvic floor muscle training program. Objectively, 23 patients (92%) in the TVT group were stress continent during the postoperative cough provocation test compared with 14 patients (56%) in the fascia plication group (p=0.01). De novo urge incontinence was reported by 3 women (12%) in the TVT group and only 1 woman in the other group 4%; (p=0.66). At follow-up visits, 4 women complained of voiding difficulties with recurrent urinary tract infections; 3 women had undergone the TVT procedure (p=0.61). All patients underwent urodynamic evaluation 6 months after surgery. Pre- and postoperative urodynamic data by surgical group are shown in Table II. After surgery, prolapse-related symptoms were reported by 12 patients (24%), 4 patients in the TVT group and 8 patients in the fascia plication group. The median cotton swab angle dropped after surgery from 50 degrees (range, 30-90 degrees) to 15 degrees (range, 0 - 40 degrees) and from 60 degrees (range, 30-90 degrees) to 25 degrees (range, 10-50 degrees) in the TVT and in the fascia plication groups, respectively (P< 0.001 for both groups). The anatomic outcome was unsatisfactory in 15 women (30%), 7 women in the fascia plication group and 8 women in the TVT group. Eleven women had an isolated stage II prolapse of the anterior (9 cases) and posterior (2 cases) vaginal segment. Two women had a stage II prolapse in >1 vaginal segment, and only 2 patients had a clinically relevant anatomic recurrence with anterior and apical stage III prolapse. One of these women underwent a subsequent prolapse repair that included sacrospinous fixation and vaginal/paravaginal repair, whereas the other, who refused surgery, was treated conservatively with the insertion of a pessary.

In our study, both the study groups had the equal number of subjects (92 patients in each group).

Our study showed that in case group, number of patients [44(47.8%)] were higher in 46-50 years age group where in control group number of patients [29(31.5%)] were higher in 66-70 years age group. Association of Age in group vs group comparison was statistically significant (p<0.0001). In Case Group, the mean Age (mean± s.d.) of patients was 46.67±51 years. In control group, the mean Age (mean± s.d.) of patients was 58.88 ± 9.03 years. Mean Age with both groups were significantly different (p<0.0001).

We found that no patients had urinary incontinence at 3 months in case group but in control group, 30 (32.6%) patients had urinary incontinence at 3 months. Association of urinary incontinence at 3 months in group vs group comparison was statistically significant (p<0.0001).

We also found that no patients had urinary incontinence at 1 year in case group but in control group, 37 (40.2%) patients had urinary incontinence at 1 year. Association of urinary incontinence at 1 year group vs group comparison was statistically significant (p<0.0001).

Our study showed that, rate of urinary tract infection at 3 months was higher in case group [25 (27.2%)] compared to patients of control group [15 (16.3%)]. Association of urinary tract infection at 3 months in group vs group comparison was not statistically significant (p=0.0738).

In our study it was found that, only 1(1.1%) patient had urinary tract infection at 1 year in case group but in control group, no patients had urinary tract infection at 1 year. Association of urinary tract infection at 1 year group vs group comparison was not statistically significant (p=0.3159).

We found that, only 2 (2.2%) patients had bleeding in case group where no patients had bleeding in control group and the association of bleeding in group vs group comparison was not statistically significant (p=0.1550).

It was found that in case group, the mean time of operative procedure (mean± s.d.) of patients was 54.85±3.57 min [Table 4]. In control group, the mean time of operative procedure (mean± s.d.) of patients was 35.27±3.47 min. Mean time of operative procedure between both groups were significantly different (p<0.0001) [Figure 4].

We found that in case group, the mean post void residual urine volume by USG at 3 months (mean± s.d.) of patients was 45.67±4.83 ml. In control group, the mean post void residual urine volume by USG at 3 months (mean± s.d.) of patients was 39.19±6.75 ml. Mean post void residual urine volume by USG at 3 months in both groups was significantly different (p<0.0001). In case group, the mean post void residual urine volume by USG at 1 year (mean± s.d.) of patients was 51.96±1.60 ml. In control group, the mean post void residual urine volume by USG at 1 year (mean± s.d.) of patients was 55.93±2.76ml. Mean post void residual urine volume by USG at 1 year with both groups were significantly different (p<0.0001).

CONCLUSION

Transurethral sling operation during vaginal prolapse surgery resulted in significantly less chance of urinary incontinence, less post void residual urine at one year and non-significant increased occurrence of bleeding and urinary tract infection in comparison to women with sham sling operation during vaginal prolapse surgery. The operative time was significantly higher in the former group. So, our present study points towards beneficial role of transurethral sling operation in selected group of patients during vaginal prolapse surgery but further study with larger sample size and longer follow-up will definitely strengthen the evidence base.

REFERENCES

1. Smith FJ, Holman CD, Moorin RE, Tsokos N. Lifetime risk of undergoing surgery for pelvic organ prolapse. ObstetGynecol 2010;116:1096-100.
2. Richter HE, Albo ME, Zyczynski HM, et al. Retropubic versus transobturatormidurethral slings for stress incontinence. N Engl J Med 2010;362:2066-76.
3. Fatton B. Is there any evidence to advocate SUI prevention in continent women undergoing prolapse repair? An overview. IntUrogynecol J Pelvic Floor Dysfunct 2009;20:235-45.
4. Jelovsek JE, Chagin K, Brubaker L, et al. A model for predicting the risk of de novo stress urinary incontinence in women undergoing pelvic organ prolapse surgery. Obstet Gynecol. 2014;123(2 pt 1):279–87.
5. Lensen EJ, Withagen MI, Kluivers KB, Milani AL, Vierhout ME. Urinary incontinence after surgery for pelvic organ prolapse. NeurourolUrodyn. 2013;32(5):455–59.
6. Smith. Fiona J. B1-11thSc (lions); Holman, C. D'Arcy J. MPH, PhD; Moorin, Rachael E. PhD, MMRS; Tsokos, Nicolas MBBS, FRANZCOG, CU Obstetrics & Gynecology: November 2010 - Volume 116 - Issue 5 - p 1096-100
7. Richter HE, AIboME, Zyczynski HM, et al .Retropubic versus transobturator mid urethral sling for stress incontinence. N Engl J Med 2010;362:2066-76
8. Mandeel H, Ross 5, Robert M, Milne J. Incidence of stress incontinence followingvaginal repair of pelvic organ prolapse in objectively continnt women. NeurourolUrodyn 2011;30:390-4
9. Meschia M , Pifarotti P, Spennacchio M, Buonaguidi A, Ggattei U, Somigliana E. A randomized comparison of tension free vaginal tape and endopelvic fascia plication in women with genital prolapse and occult stress urinary incontinence. Am J Obstet Gynecol 2004;190:609-13.