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Full Length Research Paper

Prophylactic Sub-Urehral Sling Surgery in Women with Advanced Organ Prolapse and Asymptomatic Urinary Incontinence, comparative study

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Abstract
Background: Pelvic organ prolapsed and stress urinary incontinence coexist in up to 80% of women with pelvic floor dysfunction, and because of limited value of the occult test, post-operative correction of stress urinary incontinence may not be affected. Study objective is to measure the value of prophylactic TOT in patients with advanced pelvic organ prolapse and a symptomatic woman. Study design: Prospective comparative study that was carried out in the Gynecology and Obstetrics Department, Farwania Hospital, Kuwait for a period of 6 months starting from March 2016 to August 2016 with follow up period of 18months. Included 30 patients, of advanced apical and anterior vaginal wall prolapse with asymptomatic urinary incontinence, divided into 2 groups. Intervention: concomitant surgery (prolapse surgery with TOT) in the first group and prolapse surgery alone in the second group. Measurement: post-operative DE novo stress urinary incontinence Results: Sensitivity and negative predictive value of occult test was (46.1 %), and was (22.2%), respectively and the accuracy of the test was (53.3%). The incidence of DE novo SUI in group (2) was (86.7%), compared to (0%)in group (1). Conclusion: prophylactic (TOT) is recommended and should be offered in all women with advanced prolapse irrespective of occult test.
Brief summary: asymptomatic urinary incontinence in advanced pelvic organ prolapse is a common condition, and incomplete treatment affect the patient satisfaction, soprophylactic TOT will add such a benefit for surgical management.

Keywords: *occult test, concomitant surgery, prolapse surgery, TOT. sub-urethral sling, Denovo incontinence.*

Introduction

Pelvic organ prolapse (POP) and stress urinary incontinence (SUI) coexist in up to 80% of women with pelvic floor dysfunction[1]. While these conditions are often concurrent, one may be mild or asymptomatic. Women without symptoms of SUI who undergo surgery for prolapse are at risk for postoperative urinary incontinence[2].

Deciding whether to perform a combined surgical procedure to treat both prolapse and SUI or a single procedure that addresses only one condition requires balancing the risk of incomplete treatment with the risk of exposing the patient to unnecessary surgery[3].This decision must be based on the best approach to address the patient's goals, rather than simply on anatomic correction. Advanced POP (pelvic organ prolapse quantitation system [POP-Q] stage II to IV) commonly coexists with SUI, however, for many women the SUI may become apparent only when the prolapse has been corrected[4] This phenomenon is known as occult SUI.

Women with occult SUI undergo prolapse repair without a concomitant continence procedure, the rate of postoperative de novo SUI ranges in studies from 13 - 72 % (mean 54%)[5].

However, women who have negative preoperative testing for occult SUI and undergo prolapse repair without a continence procedure may still develop SUI after surgery, but at a lower rate than women who test positive[6].

Materials and Methods

Study objectives: is to evaluate the effectiveness of prophylactic Transobturator Tape (TOT) in advanced pelvic organ prolapse surgery with negative occult test.

Study design

This is prospective comparative study, that was carried out in the urogynecology unit of the Gynecology and Obstetrics Department, Farwania Hospital, Kuwait for a period of 6 months starting from March 2016 to August 2016 with follow up period of 18months. This study included 30 patients, of advanced apical and anterior vaginal wall prolapse with asymptomatic urinary incontinence, divided into 2 groups, according to the women choice of surgery. Group (1) included15 patients whom undergo combined surgery (prolapse surgery and TOT), and Group (2) included15 patient whom undergo prolapse surgery without incontinent surgery (TOT).Studied groups are matched regarding personal data, age, parity, diabetes and occult test.

The methodology included in this manuscript is approved by Farwania Hospital Institutional Review Board/Ethical Committee.

Inclusion criteria:

1. Apical prolapse, stage 2 or more
2. Anterior vaginal wall prolapse stage 2 or more
3. Vault prolapse stage 2 or more.
4. Asymptomatic stress urinary incontinence;(Occult test positive, or negative)
5. Completed family

Exclusion criteria:

1. Stage 1 apical and anterior vaginal wall prolapse
2. Symptomatic stress urinary incontinence
3. Urgency incontinence or OAB syndrome
4. Uterine preserving surgery.
5. Voiding dysfunction and high post-void residual volume.
6 Previous incontinence surgery
7. Recurrent prolapse surgery

Intervention

All patients were evaluated by thorough history, physical examination, occult test, the S-POP-Q, cough and office test, with urinary bladder filled with 300ml normal saline. Also, nature of procedure, principal, counseling and basic information was done. After patients counseling about treatment either through combined surgery or prolapse surgery only. Patients were divided into two groups. Group (1) will undergo combined surgery (prolapse surgery and TOT), and Group (2) will undergo prolapse surgery without TOT. Bothgroups were followedup for 18 months regarding the development of DE novo stressurinary. Also, rigid cystoscopy 30 degree, was done to exclude bladder and urethral injuries in the TOT group.

Office testing

Urinary tract infection was excluded in all women with urinary incontinence by microscopic urine test and culture. Urethral hypermobility was assessed by the severity of point Aa prolapse (stage II or higher).Pre-operative urodynamic evaluation wasn't done in the present study.

Urinary stress test:

The bladder was filled by 300 mL, for Confirmation of the diagnosis of stress urinary incontinence (SUI) and measurement of the post-void residual volume which was less than 50ml in all patients.

Occult SUI was detected by medical history (symptoms), coughtest, and stress bladder test after the bladder was filled by 300ml normal saline and afterreduction of prolapsed structuresusing single speculum.

Simplified POPQ was used for measurement of pelvic organ prolapse.

- Stage 2:

Prolapse where the given point descends to the introitus, defined as an area extending from 1 cm above to 1 cm below the hymenal remnants.

- Stage 3:

Prolapse where the given point descends greater than 1 cm past the hymnal remnants.

- Stage 4:

Complete vaginal vault eversion or complete uterine procidentia.

Procedure

a) Vaginal hysterectomy
b) Anterior vaginal wall prolapse repair
c) Apical and anterior vaginal wall prolapse repair by native tissues
d) TOT (trans-obturator tension free vaginal tape; out- in technique)

All the surgical procedure was done by the same surgeon the incontinence surgery was trans-obturator mid-urethral sling out-in technique,(TOT) set and mesh type wasObtryx II (Boston scientific Halo needle).

Follow –up:
The two groups were followed up for 18 months with regular visits after 3,6,12 and18 months toestimate the development of DE novo stress urinary incontinence.

Measurements: the DE novo stress urinary incontinence was measured clinically (symptomatology) through coughing and bladder stress test.

Statistical analysis:
Statistical analysis was done using statistical package of social sciences SPSSsoftware 21 (SPSS INC, USA, IL) the normality of data was first tested with Shapiro test. Qualitative data were described using number and percent. Association between categorical variables was rested using Chi-square test or Fischer exact test as cell count less than 5, continuous variable was presented as mean+SD(standard deviation) for parametric data and median for non-parametric data. The two groups were compared with student t test for parametric data and Mann Whitney test for non-parametric data. For all above mentioned statistical tests, results were considered significant < 0.05.

Results
The present study showed that the prophylactic TOT in advanced organ prolapse (apical and anterior vaginal wall prolapse) is strongly efficient in avoiding of DE novo stress urinary incontinence which developed in the prolapse surgery alone .The sensitivity and specificity of occult test was (46.1%) and (100%) respectively. The PPV was (100%), and NPV was (22.2%) as shown in table (3). The incidence of DE novo SUI in the group of prolapsed surgery without TOT (2) was (86%) compared to (0%) in the group (1)as shown in table and figure (2).The number of patient with negative (continent) occult test in the group (2) was 9 and 7 of them (false negative) develop DE novo SUI as shown in table (3) and figure (2).

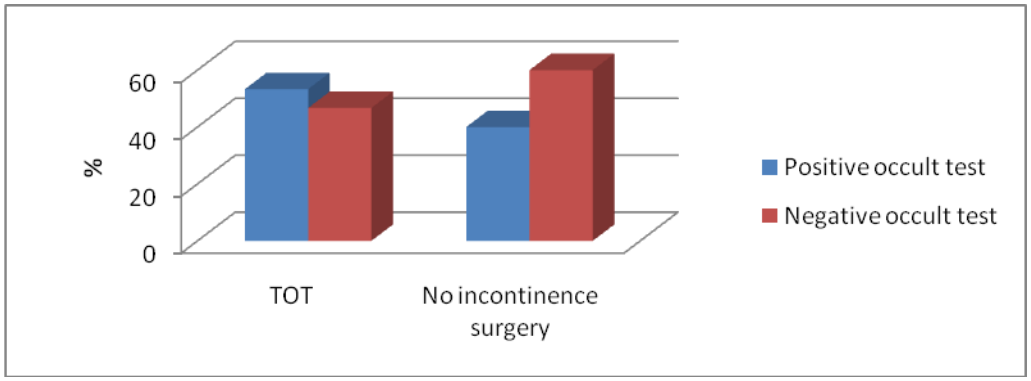

Fig (1): Occult test among the studied groups

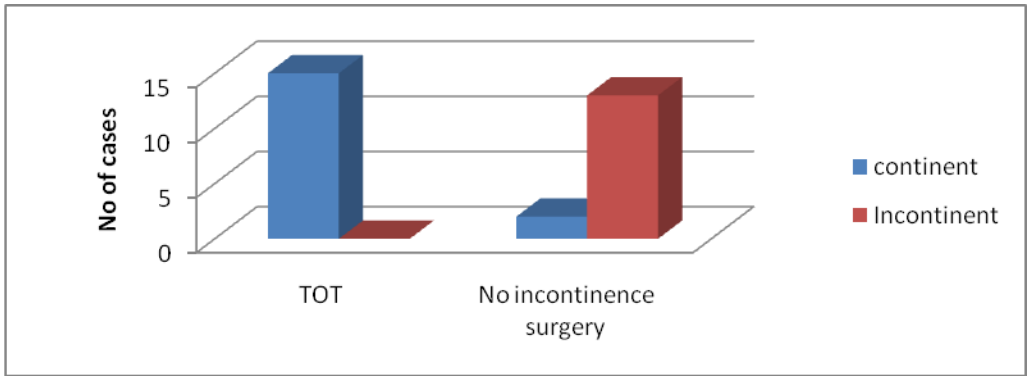

Fig (2): DE NOVO SUI among the studied groups at 3 months

Table (1): Patients characteristics among the studied group

Patients characteristics	TOT (n=15)	No incontinence surgery (n=15)	p-value
Age / years			
Mean ± SD	56.67±6.45	53.67±7.79	0.261
Min-Max	48–68	42–86	
≤ 60 y	10 (66.7%)	11 (73.3%)	0.690
> 60 y	5 (33.3%)	4 (26.7%)	
Parity			
Median (Min-Max)	6 (3–11)	7 (3–11)	0.415
P ≤ 5	6 (40.0%)	4 (26.7%)	0.439
P >5	9 (60.0%)	11 (73.3%)	
Diabetes mellitus			
Yes	6 (40.0%)	5 (33.3%)	0.705
No	9 (60.0%)	10 (66.7%)	
Occult test			
Positive	8 (53.3%)	6 (40.0%)	0.464
Negative	7 (46.7%)	9 (60.0%)	
S-POP-Q			
uterine prolapse	12 (80%)	5 (33.3%)	0.019*
anterior vaginal wall prolapse	3 (40%)	6 (40.0%)	
Combined uterine prolapse and vaginal wall prolapse	0 (0.0%)	4 (26.7%)	
Prolapse surgery			
anterior vaginal repair	3 (20%)	5 (33.3%)	0.039*
vaginal hystrectomy , Mac call culdoplasty	12 (80%)	6 (40%)	
vaginal hystrectomy and Mac call culdoplast, anterior vaginal wall prolapse	0 (0.0%)	4 (26.7%)	

**significant p <0.05*

Table (2): DE NOVO SUI

Follow up	TOT (n=15)	No incontinence surgery (n=15)	p-value
3 months			
continent	15 (100%)	2 (13.3%)	<0.001*
Incontinent	0 (0%)	13 (86.7%)	
6 months			
continent	15 (100%)	–	–
Incontinent	0 (0%)	–	
12 months			–
continent	15 (100%)	–	
Incontinent	0 (0%)	–	–
18 months			
continent	15 (100%)	–	–
Incontinent	0 (0%)	-	

Table (2) shows that, there is statistically significant difference between 2 groups regarding DE NOVO SUI at 3-month p value <0.001. All 15 cases in TOT group are continent while only 2 cases are continent, and 12 cases are incontinent in no incontinence surgery group.

Discussion

In the present study the value of occult test is limited by very low negative predictive value which is (22.2%) and low sensitivity (46.1%) , and the accuracy of the test is (53.3%), and very high false negative 7 out of 9 cases. The incidence of De novo SUI in the prolapse surgery without TOT was (86.7%) compare to the combined or concomitant surgery it was (0%). So, there was strong evidence to recommend prophylactic sub-urethral sling trans-obturator (TOT)in advanced apical and anterior vaginal wall prolapse, and asymptomatic urinary incontinence and this was agree with Raman et al[7]who documented that The rate of concurrent prolapse repair and continence procedures appears to be increasing. Data from the United States National Inpatient sample showed that for apical prolapse repair procedures, the rate of concurrent continence surgery increased from (38%) in 2001 to (47%) in 2009. Compared to the study by Visco et al[8] and Wei et al[9], they documented that , the rate of postoperative de novo SUI was (58%) for

women who tested positive for preoperative occult SUI and 38% for those who tested negative and In the other study, the rate of de novo SUI was (72%) for women who tested positive and (38%) for women who tested negative.

In the future studies, both asymptomatic urinary incontinence in advanced pelvic organ prolapse and the importance of occult test in detecting the Denovo urinary incontinence after prolapse surgery showed much more investigated.

Limitations of the study: the small sample size limits the generalization of the results.

Table (3): Validity of occult test in diagnosis of incontinence in no incontinence surgery group

Occult test	DE NOVO SUI		Total
	Incontinent	continent	
positive	6 (TΠ)	0 (FP)	6
Negative	7 (FN)	2 (TN)	9
Total	13	2	15

TP: true positive, FP: false positive, FN: false negative, TN: true negative

Sensitivity	Specificity	PPV	NPV	Accuracy
46.1%	100%	100%	22.2%	53.3%

PPV: positive predictive value, NPV: negative predictive value

Conclusion

Prophylactic sub-urethral trans-obturator sling surgery (TOT) should be offered and strongly recommended in advanced pelvic organ prolapse and a symptomatic urinary incontinence irrespective of the of occult test, and the benefit out weight of the risk.

The "Significance Statement"

This study highlights the benefits of prophylactic sub–urethral sling surgery in asymptomatic urinary incontinence in women with advanced pelvic organ prolapse and thus will help more researchers to uncover the critical areas of combined surgery, occult test and Denovo incontinence in advance pelvic prolapse.

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