Eyeball (Office) Urodynamics: Is There Value to Predict Hidden (Occult) Stress Urinary Incontinence with Sims Speculum Reduction in Patients with Pelvic Organ Prolapse? – A Retrospective Descriptive Study

CANDIDATE: Dr NM Grootboom

Registrar, Department of Obstetrics and Gynaecology Stellenbosch University and Tygerberg Hospital

SUPERVISOR: Dr JA van Rensburg

Consultant, Head of Urogynaecology Unit Department of Obstetrics and Gynaecology Stellenbosch University and Tygerberg Hospital

DATA ANALYSIS: Dr BT Ayele

Biostatistician, Division Epidemiology and Biostatistics, Faculty of Medicine and Health Sciences, Stellenbosch University

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DECLARATION

By submitting this dissertation electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the authorship owner thereof (unless to the extent explicitly otherwise stated) and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

Dr NM Grootboom

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ABSTRACT

Introduction: Occult stress urinary incontinence (OSUI) is an accepted predictor of postoperative stress urinary incontinence (POSUI) in stress continent women with pelvic organ prolapse (POP)(1). De novo stress urinary incontinence (SUI) occurs in 22% of women following POP surgery(2). This newly developed postoperative SUI leads to patient dissatisfaction after reconstructive surgery if the patient was not adequately counselled preoperatively. Currently there is no standardised reduction test for OSUI but in the literature different methods have been described(3).

Aims and Objectives: The objective of this study is to determine sensitivity, specificity and predictive values of Sims speculum reduction of pelvic organ prolapse as a preoperative test to predict occult stress urinary incontinence with the help of eyeball/ office urodynamics (UDS).

Methods: This is a retrospective study of 123 patients who have undergone POP surgery during a three year period from January 2014 until December 2016 in our institution. POP was assessed by history and the clinical POP-Q grading system. Routine preoperative UDS (eyeball or laboratory) with Sims speculum reduction of the prolapse in a sitting position were performed. To test for OSUI at maximum bladder capacity or to a maximum of 500ml, the Sims speculum was placed in the posterior fornix for the intact uterus or in the vault with a previous hysterectomy. Posterior compartment prolapse only on its own was excluded from routine UDS

Frank or OSUI patients were counselled for either 1-step (combined POP surgery with anti-incontinence procedure) or 2-step surgery (POP surgery only). At the 6 week visit, postoperative SUI was checked by history, clinical examination and ICIQ-SF questionnaire. Retrospective data was available for at least 2 years postoperatively to determine SUI and reoperation rates. Statistical analysis was performed with SPSS version 25 software.

Results: A total of 123 patients were entered with a mean age of 60.37 years, BMI 29.5kg/m^2, and median parity of 3. 83.7% had grade 2 -3 anterior POP, while 3.3% had grade 4. UDS tests were performed in 95 of the 123 patients with POP. Of those, 66 received eyeball/office UDS and 29 laboratory UDS.

In the eyeball UDS group, 18 patients had frank SUI, 17 with OSUI and 30 without OSUI. One had severe involuntary urine leakage and SUI could not be assessed. Of the 17 OSUI patients, 6 had 1-step surgery performed while 11 had 2-step surgery. Among the 14 OSUI patients that presented for 6 week follow up, postoperative SUI was clinically demonstrated in two cases, where one was from the 2-step surgery group and none required anti-incontinence surgery.

Only 4 patients overall had bothersome postoperative SUI and 3 required mid urethral sling (MUS). The rate of secondary surgery for MUS insertion in the current study was low even for those patients who had frank SUI preoperatively and 2-step surgery (5.6%). The outcome for the Sims speculum reduction test for OSUI can be reported as follows: the sensitivity is 20%, the specificity is 78.12%, the positive predictive value is 12.5% and the negative predictive value is 86.21%. Overall, 31.7% of the patients had postoperative anterior compartment prolapse grade 2 and 1 (0.8%) patient with grade 3 anterior compartment prolapse. A total of 7 patients required reoperation for POP. The overall incidence of postoperative SUI in women with recurrence of anterior compartment prolapse was 15%, while the incidence was lower at 10% for women without recurrence of anterior POP.

Conclusion: The Sims speculum reduction method with eyeball UDS in a sitting position has poorly predicted postoperative SUI, in OSUI patients diagnosed preoperatively. The limitation in our study is the retrospective design, small sample size, non-standardised cough stress test and recurrence of anterior compartment prolapse. The protective effect of anterior POP recurrence against POSUI as mentioned in Lensen's study was not observed(2). Caution should be exercised before statistical conclusions can be made from current findings.

Keywords: Eyeball urodynamics, office urodynamics, stress urinary incontinence, pelvic organ prolapse.

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ABBREVIATIONS

BMI - Body mass index

C - Combined urodynamics (eyeball and formal)

CARE trial - The Colpopexy and Urinary Reduction Efforts randomised surgical trial

CVP - Central venous pressure

E - Eyeball urodynamics only

ICIQ –SF - International Consultation on Incontinence Questionnaire – Short Form

IUGA/ICS - International Urogynaecological Association (IUGA)/ International Continence Society (ICS)

MUI - Mixed urinary incontinence

MUS - Mid-urethral sling

OSUI - Occult stress urinary incontinence

POP - pelvic organ prolapse

POP-Q - Pelvic Organ Prolapse Quantification System

POSUI - Postoperative stress urinary incontinence

SUI - Stress urinary incontinence

TVT - Tension-free vaginal tape

TVT -O - Trans-obturator tension-free vaginal tape

TVT -R - Retropubic tension-free vaginal tape

UDS - Urodynamics

USI - Urodynamic stress incontinence

UUI - Urge urinary incontinence

1. INTRODUCTION

Stress urinary incontinence (SUI) is defined by International Urogynaecological Association (IUGA)/ International Continence Society(ICS) as observation of involuntary leakage from urethra synchronous with exertion or physical activity or coughing or sneezing(4).

Occult or latent stress urinary incontinence is stress incontinence only observed after the reduction of co-existent prolapse(4). This occurs because the prolapse mechanically obstructs the urethra and masks stress urinary incontinence(5–7).

IUGA/ICS describes urodynamics (UDS) as “a general term used to describe all measurements that assess function and dysfunction of the lower urinary tract by any appropriate method”(8). In other words, it is an interactive diagnostic study of lower urinary tract function and it evaluates bladder filling, urine storage and bladder emptying(9).

Eyeball or office-urodynamics is a non-invasive pressure measurement study performed after urination where it measures post-void residual volume, bladder capacity and objectively demonstrates any incontinence(10). Uroflow is measured using a stopwatch and a jug. Intravesical pressure as an option can be measured by connecting the filling intravesical catheter via a 3-way stopcock to a CVP set. The pressure can be charted against bladder capacity.
Laboratory UDS differs from eyeball UDS in that intravesical, intra-abdominal and intra-urethral pressures are recorded electronically in the former (10). It is not always feasible to maintain the equipment and software for laboratory UDS. Furthermore, the procedure is invasive, time-consuming and not universally available(11).

Occult stress urinary incontinence (OSUI) is an accepted predictor of postoperative stress urinary incontinence (POSUI) in stress continent women with pelvic organ prolapse (POP)(1). *De novo* SUI occurs in 22% of women following POP surgery(2). This leads to patient dissatisfaction after reconstructive surgery when new stress incontinence develops if the patient was not adequately counselled preoperatively (2). Diagnosing occult stress urinary incontinence (OSUI) before POP surgery aids in patient counselling and planning the type of surgery that will be offered to the patient, i.e. one step (anti-incontinence surgery at the time of POP repair) vs two step (POP surgery first, then evaluate for SUI after procedure) (6,9,11).

There are a number of prolapse reduction methods described in the literature(3,12), however, there is currently no standardised reduction test for OSUI.

Some studies used basic office evaluation with Valsalva/cough stress test at a determined bladder capacity with and without prolapse reduction(1). There is also extensive literature on laboratory UDS as a preoperative evaluation in women with POP(3,13–15). In CUPIDO II trial, preoperative UDS was part of the inclusion criteria, but some of the centres participated in their study did not routinely perform preoperative UDS. Their inclusion criteria was extended to include those patients that had basic office evaluation only(7).

Literature obtained on eyeball/office urodynamics has only been descriptive and not addressing the research question.(16) No data is available on eyeball UDS and Sims Speculum reduction as a diagnostic tool for OSUI, we opted to explore office UDS with Sims speculum reduction as an affordable and effective alternative to laboratory UDS.

2. LITERATURE REVIEW

2.1 Urodynamic study in preoperative patients with POP

Subjective symptoms of SUI do not always concur with objective urodynamic stress incontinence therefore, it is necessary to perform UDS in patients where the results of such evaluation will affect clinical management/type of surgical intervention(13,17,18). UDS offers additional information to provide to patients during informed consent. Performing UDS may prevent an expensive, potentially morbid and irreversible surgical intervention in women without urodynamic stress incontinence i.e. detrusor overactivity which won't resolve with anti-incontinence surgery(11,13,18,19).

A large proportion of women with high grade POP without SUI symptoms will be found to have OSUI upon prolapse reduction(3,9,20). The incidence of OSUI varies widely depending on reduction method used(3).

OSUI in women with POP is a strong predictor of SUI post prolapse surgery therefore, urodynamic testing for occult SUI is crucial as counselling can be done for anti-incontinence procedures as well(1,3,20).

2.2 Reduction methods of pelvic organ prolapse to determine occult stress urinary incontinence during UDS

International Urogynaecological Association (IUGA)/ International Continence Society (ICS) 2016 defines Pelvic organ prolapse as descent of one or more of anterior vaginal wall, posterior vaginal wall, the uterus (cervix) or apex of the vagina (vaginal vault or cuff scar after a hysterectomy)(21). The degree of prolapse is described according to the POP-Q staging system(21,22).

Prolapse can be reduced with a number of methods including a pessary, ring forceps, vaginal pack/swabs, sims speculum or digital manual reduction(6,12,15). In all the above cases/instances, the investigator should be aware that the instrument used for POP reduction may also obstruct the urethra, creating a falsely elevated urethral pressure or preventing the demonstration of SUI(9). Janse Van Rensburg's laboratory UDS study used manual reduction and cough test in standing position at maximum bladder capacity(23). Similar to reduction methods, patient position is also not standardised. The patient can either be standing or sitting or in lithotomy or semi-lithotomy position during reduction testing at UDS.

Schierlitz used a sims speculum or open sponge forceps as reduction methods in his trial(15). The CARE trial by Visco and colleagues compared 5 different prolapse reduction methods (the pessary ring, manual, swab, forceps and speculum) and tested the sensitivity of each method in predicting postoperative SUI(3). The pessary had the lowest preoperative urodynamic SUI detection rate of 6% compared to speculum reduction method which had highest detection rate of 30%. The ring pessary has been associated with raised intraurethral pressure and while reducing a coexistent prolapse has been used to treat SUI. This explains the low detection rate with ring pessary However, the swab technique had the highest positive predictive value (79%) for postoperative stress incontinence in the control group (no Burch) while other methods had positive predictive value between 50 and 55% with speculum method at 55%. All methods had low sensitivity with speculum method at 39% with its specificity at 74% and negative predictive value of 60%. In both Burch and no Burch groups they confirmed that a positive UDS stress test with prolapse reduction preoperatively was associated with higher postoperative stress incontinence (32%) vs 21% in women that had negative test

preoperatively in Burch group and 58% vs 38% in the no Burch group (controls)(3). The current study explores performing speculum reduction test in a sitting position

2.3 POP surgery and anti-incontinence surgery

There is evidence to suggest that a significant proportion of women with high grade POP without SUI symptoms will have occult SUI upon prolapse reduction. It is therefore, crucial to diagnose occult SUI as counselling can be done for anti-incontinence procedures as well at surgery for prolapse repair(9,20). A randomised trial by Schierlitz and colleagues showed that even though occult SUI is a predictor of post-operative urodynamic SUI in patients having prolapse surgery, a routine sling is controversial as majority of patients are asymptomatic(15). He randomised 80 women with both POP and OSUI into two arms, 43 had prolapse repair surgery alone while 37 had a one-step procedure which involves prolapse repair surgery combined with tension-free vaginal tape (TVT). Only 60 patients (27 from TVT arm and 33 from no TVT arm) participated in post-operative UDS evaluation, some declined due to lack of symptoms for SUI, others were lost to follow-up while 2 died due to conditions not related to surgery. In the TVT arm 4 out of 27 women had urodynamic stress incontinence (USI) and the no TVT arm had 22 out 33 women with USI. However, the majority of these women had no symptoms of SUI, only 4 (from no TVT group) were symptomatic and required a two-step procedure with 3 sling insertions at 6 month and 1 at 24 month follow-up. Because there were few insertions of slings for symptomatic stress incontinence in the 1st 24 months, the authors concluded that routine sling insertion at POP repair surgery to prevent postoperative SUI in women with occult SUI is controversial and recommend patient counselling and shared decision-making with the patient(15).

Svenningsen's trial showed only 6 out of 137 women post-POP repair had post-operative SUI significant enough to require intervention(1).

In a large Dutch study of 907 women who had POP repair, it was found that 22% of the women that were continent preoperatively developed de novo SUI while 39% of women who had pre-existing SUI were cured by POP surgery alone(2)

In a systematic review by Matsuoka and colleagues, they found that prophylactic anti-incontinence surgery reduced the incidence of postoperative SUI (RR 0.51; CI 0.38-0.68) and the retro-pubic mid-urethral sling (MUS) was most beneficial(6). However, there was 24 times higher risk of bladder injury with tension-free vaginal tape + POP repair compared to POP repair alone. The risk of major bleeding also doubled with the former. But, the CUPIDO I trial did not find statistically significant complications with the MUS insertion at POP repair group vs POP repair alone(24). Their numbers-needed-to-treat was 10, to prevent one woman having subsequent MUS for SUI in the 1st year post POP repair. With CUPIDO II trial which randomised women with occult SUI, they found that 38% of women with occult SUI and POP surgery alone had postoperative SUI compared to women without occult SUI that had POP surgery alone which was 8%(7). When comparing women with combined surgery (one-step) with those that had POP surgery only, 21% of the latter required additional treatment for SUI. 13% of the POP surgery only group required insertion of a midurethral sling (MUS) for de novo SUI. Numbers-needed-to-treat was 8 combined surgeries to prevent one MUS insertion for de novo SUI. They had more complications in the combined surgery group than the POP surgery only group, though mostly mild.
Following King's literature review with aim to develop an algorithm on who to offer anti-incontinence procedure to during POP repair, they favoured offering their clients with OSUI an anti-incontinence procedure at POP repair(12). Schierlitz study differs from this as its

findings showed that though there was a high postoperative SUI rate in their prolapse surgery only group, only 9.3% of women with OSUI needed intervention for postoperative SUI(15). The risks and benefits of either surgery need to be discussed with the individual patient to allow them an informed choice(7). Some patients decline anti-incontinence surgery at POP repair to avoid complications that may arise. Some opt for it to avoid the 2nd surgery. Some decline 2nd surgery even though they have urodynamic SUI because it's not bothersome(3,12).

Seeing that there is a 4.4 to 13% rate of anti-incontinence surgery in the 2-step surgery patients that had OSUI preoperatively and high numbers needed to treat to prevent one postoperative SUI in one-step surgery patients, routinely offering MUS puts additional surgical risk with minimal or no benefit.

3. DEFINING THE RESEARCH

3.1 Research question

Is there value to predict hidden (occult) stress urinary incontinence with Sims speculum reduction in patients with pelvic organ prolapse with the aid of eyeball urodynamics?

3.2 Aims and objectives

The objective of this study is to determine sensitivity, specificity and predictive values of Sims speculum reduction of pelvic organ prolapse as a preoperative test to predict occult stress urinary incontinence with the help of non-invasive pressure study of eyeball urodynamics (UDS).

The secondary aim is to compare incidence of stress urinary incontinence postoperatively in the 1-step vs 2-step procedure groups.

4. STUDY METHODS

4.1 Study design and data collection

This is a retrospective study of 123 patients who have undergone pelvic organ prolapse surgery during a three year period from January 2014 until December 2016 in the urogynaecology unit at Tygerberg Hospital, comparing three groups of women with pelvic organ prolapse:

- Prolapse with frank stress incontinence
- Prolapse with occult stress incontinence
- Prolapse without stress incontinence

An *a priori* sample was calculated using G-Power 3.1 software and an estimated sample size of 133 patients with OSUI given medium effect size of 0.3, α error = 0.05 and power (1-β error) = 0.8.

123 women that had surgery for pelvic organ prolapse during the stipulated period were considered. Theatre records were reviewed for all women who had undergone prolapse surgery. Women who did not have urodynamics prior to surgery were excluded as well as those with missing clinical records. Data was collected using the clinical records from exclusive urogynaecology folders with POP-Q charts and ICIQ-SF questionnaires that the patients completed pre-surgery and 6 weeks post-surgery. Voiding diary data was not captured due to poor patient compliance. Where a separate urogynaecology folder was not found, the patient records were accessed from the electronic hospital records. Missing urodynamics reports were reprinted from the UDS machine for those that were performed.

With our country's past, race was not captured for demographic data as it is no longer made available on patient folders.

All data was entered onto an Excel database in a logical organisation similar in flow to the format of the original clinical records, POP-Q and ICIQ-SF Questionnaires and different variables were coded.

4.2 Methods of assessment

POP was assessed by history and the POP-Q grading system and data was obtained from the urogynaecology unit folders. The patients received routine preoperative UDS (eyeball or laboratory) with Sims speculum reduction of the POP. To test for OSUI at maximum bladder capacity or to a maximum of 500ml in the sitting position, the Sims speculum was placed in the posterior fornix for the intact uterus or in the vault with a previous hysterectomy. Posterior compartment prolapse only was excluded from routine UDS. Unlike laboratory multichannel UDS, eyeball UDS was performed in the absence of pressure catheters and sophisticated software. In our setting, we used the laboratory UDS Laborie machine without the pressure catheters for eyeball UDS. First the patient emptied her bladder normally, and then a size 8 French catheter was inserted to measure the post-void residual volume which was registered on the monitor. Thereafter, the bladder was gradually filled with saline. The patient was asked about first sensation, normal bladder capacity and maximum bladder capacity or 500ml where the infusion was occluded. The patient was asked to cough at maximum bladder capacity while the examiner watched for involuntary urinary leakage. Then the pelvic organ prolapse was reduced with the Sims speculum in the posterior vaginal fornix and the cough procedure was repeated.

Based on urodynamic findings for frank or OSUI, the patients were counselled for either 1-step (combined POP surgery with anti-incontinence procedure) or 2-step surgery (POP surgery only).

At the 6 week postoperative visit, SUI was checked by history, clinical examination and ICIQ-SF questionnaire, but for analysis, only the clinical examination findings are used. Retrospective data was available from the urogynaecology folders for at least 2 years postoperatively to determine SUI and reoperation rates for SUI and POP.

4.3 Statistical methods

Statistical analysis was performed with SPSS version 25 software using frequencies, proportions, pie charts, histograms and 2x2 tables to summarize the data. Means were used for normal distribution and medians for skewed data.

5. ETHICAL APPROVAL

Approval to access hospital records and proceed with the study was granted by Tygerberg Hospital and the Health Research Ethics Committee of Stellenbosch University on 20/03/2018.

Ethics reference number: s17/10/210

6. RESULTS

139 patients had prolapse surgery between January 2014 and December 2016. Sixteen folders were lost and could not be included in the study. A total of 123 patients were entered into the study with the demographics as illustrated in Table 1.

Table 1: Demographic data

DEMOGRAPHIC DATA		
	Number (%)	Range
Mean Age (years)	60.37	31-90
Median parity	3	0-10
BMI (kg/m2)	29.5	16.2-47
Smoker	31 (25.2%)	

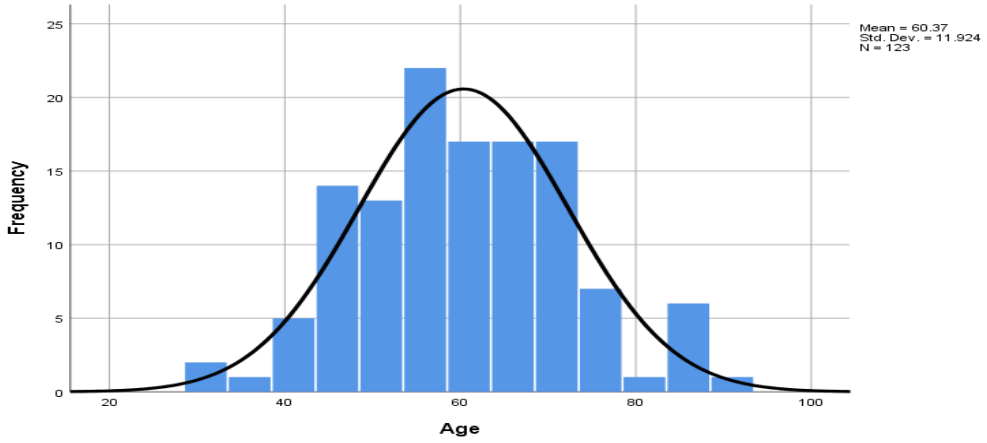

FIGURE 1: Demographic data - Age

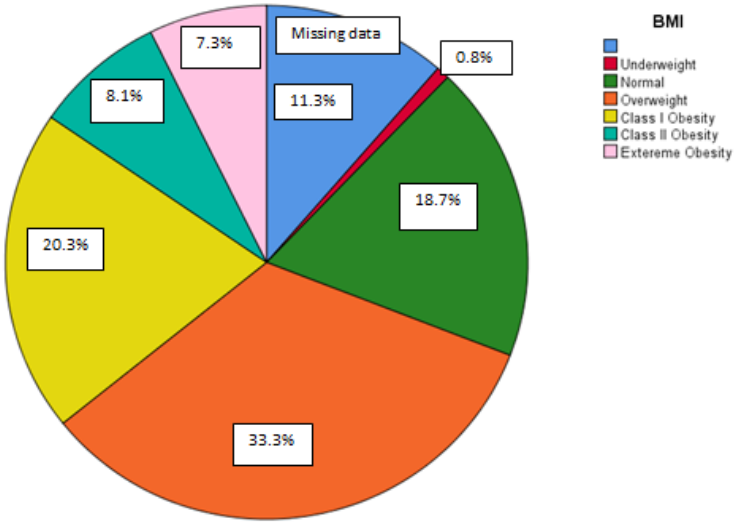

FIGURE 2: Demographic data – BMI according to WHO classification

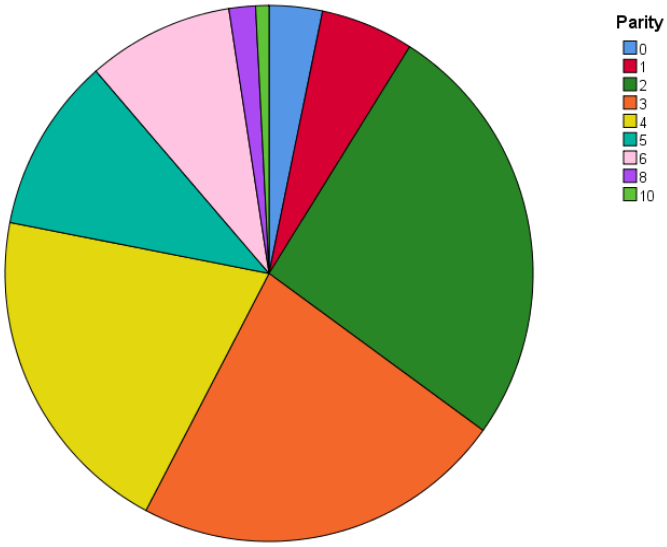

FIGURE 3: Demographic data – Parity

The prevalence of urinary symptoms was as follows:

- 25 (20.3%) women had pure SUI
- 43 (35%) had mixed urinary incontinence (MUI).
- 18 (14.6%) had pure urge urinary incontinence (UUI)
- 34 (27.6%) had no history of incontinence.

The most common prolapse symptom reported was a symptomatic bulge/ heaviness present in 84.6% (N=104) of the patients. Delayed initiation of micturition occurred in 30.1% (N=37) and digitalization was reported in 10.6% (N=13).

The preoperative POP-Q staging showed 38.2% (N=47) of the patients had anterior prolapse grade 2, 45.5% (N=56) had grade 3 and 3.3% (N=4) patients had grade 4 anterior POP. Urodynamic tests were performed in 95 of the 123 patients with pelvic organ prolapse. Of those, 66 received eyeball UDS and 29 had laboratory UDS. (See flowchart1). From the 95 patients who had UDS, frank SUI, OSUI and no OSUI occurred in 34, 22 and 37 patients, respectively. SUI could not be evaluated in two patients (one eyeball and one laboratory UDS) due to severe involuntary urine leakage.

From the 66 patients who had eyeball UDS, frank SUI occurred in 18, OSUI in 17 and no OSUI in 29 patients. Of the 17 OSUI patients, 6 had 1-step surgery performed while 11 had 2-step surgery.

The 28 patients that did not have UDS and the 37 (eyeball and laboratory UDS combined) who tested negative for OSUI received prolapse surgery only.

One hundred and twelve (91%) patients presented for 6 week postoperative evaluation while 11 were lost to follow up. An overall postoperative SUI was reported by history, ICIQ-SF and clinical examination combined in 20 patients. SUI was clinically demonstrated in 14 patients overall. The ICIQ-SF questionnaires had a high frequency of missing data (unanswered) for both preoperative (N=47) and postoperative (N=41) assessments. From the 82 patients who completed their postoperative questionnaire, 15 patients reported SUI which was clinically demonstrated in 9. Correlation between postoperative SUI by ICIQ-SF questionnaire and demonstrable postoperative SUI was calculated with Pearson Chi-square = 60.609, (degrees of freedom =4, and *p* value =0.000), which is statistically significant. Approximately 93% of 67 patients who had negative SUI on ICIQ-SF were also negative for demonstrable SUI clinically. The correlation was reduced to 60% when the answer was affirmative for SUI on ICIQ-SF when compared to clinical findings.

Of the 14 that were clinically demonstrated, only two were from those that had OSUI preoperatively with one in the 2-step surgery group (See flowchart 1).The incidence of postoperative SUI in the different groups is summarised in Table 2 below.

Table 2: Incidence of postoperative SUI in different surgical groups

Incidence of postoperative SUI				
Surgical group	Eyeball (E) UDS only	Combined (C) UDS	Lost to follow up	Secondary MUS
Frank SUI 1-step	1/9 (11%)	2/19 (10.5%)	2C	1E
Frank SUI 2-step	2/7 (28.6%)	4/11 (36.36%)	2E	1C
OSUI 1-step	1/6 (16.7%)	1/7 (14.28%)	0	0
OSUI 2-step	1/8 (12.5%)	1/12 (8.3%)	3E	0
No OSUI	4/29 (13.8%)	4/36 (11.1%)	1E	1E
OAB/DO features	0/1(0%)	0/1(0%)	1C	0
No UDS	2/26 (7.69%)		2	0

C = Combined UDS
E = Eyeball UDS

Only 4 of the 14 were bothersome and three required mid urethral sling surgery. One patient was continent preoperatively and the others had frank SUI at UDS.

From the 14 OSUI patients in the eyeball UDS group who presented for the 6 week follow up, postoperative SUI was reported in 3 patients of whom, 2 were clinically demonstrated. None were bothersome to require anti-incontinence surgery. From the 30 patients who tested negative for occult SUI, one was lost to follow up and postoperative demonstrable SUI was present in 4 patients (one MUS inserted) where 25 remained continent postoperatively. The outcome for the Sims speculum reduction test for OSUI can be reported as follows: the sensitivity is 20% (95%CI, 0.51% - 71.64%), the specificity is 78.12% (95%CI, 60.06% - 90.72%), the positive predictive value is 12.5% (95%CI, 2.15% - 48.14%) and the negative predictive value is 86.21% (95%CI, 79.54% - 95.95%). Analysis of combined data for both eyeball and laboratory UDS did not yield a significant difference.

An overall recurrence of anterior compartment POP was 31.7% (N=39) for grade 2 POP and 0.8% (N=1) for grade 3. When reviewing the 86 UDS patients who presented for follow up, the recurrence of grade 2 anterior prolapse was 36.8% (7/19) for OSUI group, 44% (16/36) for no OSUI group and 40% (12/30) for frank SUI group. One of the 2 patients who had severe involuntary urine leakage at UDS presented for 6 week evaluation and did not have postoperative SUI or UUI nor recurrence of anterior POP. Overall 7 patients required reoperation for POP. The overall incidence of postoperative SUI in women with recurrence of anterior compartment prolapse was 15%, while the incidence was lower at 10% for women without recurrence of anterior POP.

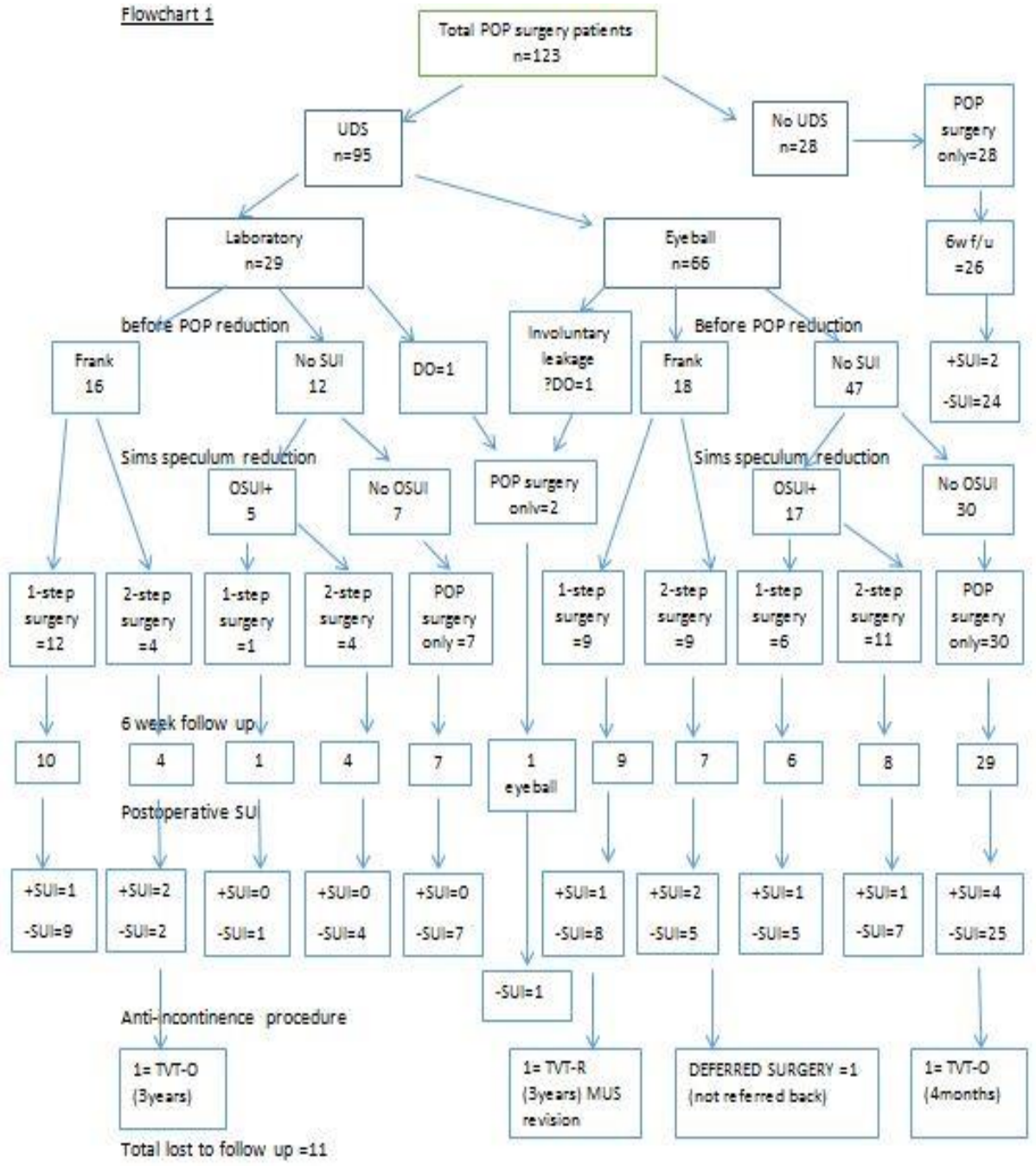

Figure 4: Flowchart of 123 patients who have undergone POP surgery during the 3 year period (January 2014 till December 2016)

Table 3: 2x2 Table – OSUI in eyeball UDS vs Postoperative SUI

		Screen for OSUI in eyeball UDS group		
		Positive	Negative	**total**
Postoperative SUI (2-step)	Yes	1	4	5
	No	7	25	32
	Total	8	29	37

sensitivity = 1/(1+4) =20%

Specificity = 25/(25+7) =78.12%

Positive predictive value =1/(1+7) =12.5%

Negative predictive value = 25/(7+25) =86.21%

Table 4: 2x2 Table – OSUI in combined UDS vs Postoperative SUI

		Screen for OSUI in Combined UDS (Laboratory +eyeball)		
		positive	Negative	**total**
Postoperative SUI (2-step)	Yes	1	4	5
	No	11	32	43
	Total	12	36	48

sensitivity same as eyeball only

specificity = 32/(32+11) =74.42%

Positive predictive value =1/(1+11) =8.3%

Negative predictive value =32/(4+32) =88.9%

Likelihood ratio =0.2/(1-0.74) =0.77

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7. DISCUSSION

There is a debate whether stress continent women with pelvic organ prolapse require preoperative UDS in order to unmask occult stress urinary incontinence(OSUI)(25). The concern is the increased risk of postoperative SUI than in women who do not have OSUI. SUI is not a life-threatening condition but affects one's quality of life and psyche. Due to the embarrassing nature of the condition, one may isolate oneself from society and be at risk of developing a depressive disorder(26). As part of holistic patient management, this condition also needs to be addressed.

Performing UDS is invasive and time consuming especially in limited resource-setting like our institution and country. The current study considered the use of eyeball UDS with Sims speculum reduction method to unmask OSUI in patients with POP before undergoing prolapse surgery. Since some studies have shown benefit in offering one-step surgery (combined POP and anti-incontinence surgery) in patients with OSUI in order to prevent postoperative SUI, there is also good evidence to support two-step surgery (prolapse surgery alone and evaluate for MUS later) (3,7,15). In the current study, patients were offered either one-step or two-step procedure. At 6 week follow-up they completed an ICIQ-SF questionnaire and had clinical examination at subjectively full bladder to determine prolapse recurrence and any postoperative SUI.

When looking at the patients with OSUI who opted for 2 step surgery in the eyeball UDS group (11/17), only 8 came for follow-up at 6 weeks and of those only one had demonstrated postoperative SUI. This patient did not have SUI bothersome enough to require surgery. Of the six patients that opted for one-step surgery, one developed postoperative SUI, implying a failed anti-incontinence procedure. A small fraction (4/29) of those who were continent even with prolapse reduction (no OSUI group) also demonstrated postoperative SUI. Overall 14 women had demonstrable SUI postoperatively but only 3 required anti-incontinence surgeries. Though our patients did not have a standardised postoperative evaluation, this concurs with Schierlitz that very few patients will need a secondary anti-incontinence procedure. Offering patients with OSUI prophylactic midurethral sling increases surgical risks with minimal benefit(15).

Our prolapse reduction method has not demonstrated postoperative SUI as expected from eyeball UDS findings even when both laboratory and eyeball UDS groups were combined. Almost 1/3 of the patients that had OSUI preoperatively showed recurrence of anterior prolapse grade 2 and one can postulate its role in protecting against postoperative SUI due to persistent urethral kinking by the POP(2). The recurrence of anterior compartment POP did not illustrate the protective effect against postoperative SUI, to the contrary there was 5% higher incidence of postoperative SUI compared to those without recurrence of anterior POP.

Furthermore, Lensen's findings demonstrated that 39% of patients who had preoperative SUI were cured of SUI by prolapse surgery alone and 19% had improvement of SUI postoperatively. Seven of the 11 patients (63.6%) that had frank SUI preoperatively and undergone 2-step surgery did not have postoperative SUI at 6 week follow up suggesting cure with POP surgery alone. The small sample size and short follow up interval in the current study contributed to the difference in findings compared to Lensen's study of 907 subjects and a 1 year follow up period.

Unlike large multicentre trials that have been conducted in countries like Norway and the Netherlands as mentioned in the literature, the sample for the current study was small, from one institution and retrospective. The postoperative evaluation was also not standardised. In

Svenningsen's trial and the CARE trial, they filled the bladder to maximum bladder capacity up to maximum of 300ml at postoperative visit and cough test performed(1). A similar standardised evaluation would enhance the findings in the current study. Though the bladder was subjectively full at clinical evaluation, this is not a reliable measure. Lost folders and non-adherence to follow-up also contributed to a small sample size and its findings cannot be generalised for the population.

The strengths of this study are that the UDS and the surgery were performed by the same individual during the study time period. Data collection was commenced at least 2 years after the surgery was performed which allows ample time to detect reoperation cases.

8. CONCLUSION

The Sims speculum reduction method with eyeball UDS in a sitting position has poorly predicted POSUI, in OSUI patients diagnosed preoperatively. The limitation of the study is the retrospective design, small sample size, non-standardised postoperative cough - stress test and the recurrence of anterior compartment prolapse. Caution should be exercised before statistical conclusions can be made. The protective effect of anterior compartment prolapse against postoperative SUI as reported in Lensen's study was not observed in current study(2). In a randomised controlled trial by Schierlitz, only 9.3% of the patients with OSUI that had 2-step surgery required a secondary mid-urethral sling for postoperative SUI(15). This low secondary MUS rate was observed in current study even among the frank SUI group who had 2 step surgery. One-step surgery carries an additional surgical risk with minimal benefit. Though performing UDS brings additional information for patient counselling, it is advisable to offer patients with OSUI two-step surgery and treat postoperative stress urinary incontinence when it presents.

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10. APPENDICES

10.1 Appendix 1: ICIQ-SF questionnaire

Name

Folder nr

Birth date

Date

ICIQ-SF

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 you date of birth:

DAY MONTH YEAR

2. Are you (tick one): **Female** □ **Male** □

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

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

None □ 0
A small amount □ 2
A moderate amount □ 3
A large amount □ 4

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

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 cough or sneeze □
Leaks when you are asleep □
Leaks when you are physically active/exercising □

10.2 Appendix 2:Ethics approval

UNIVERSITEIT STELLENBOSCH UNIVERSITY

Health Research Ethics Committee (HREC)

Approval Notice

New Application

21/02/2018

Project ID :1664

HREC Reference #: S17/10/210

Title: EYEBALL URODYNAMICS: IS THERE VALUE TO PREDICT HIDDEN STRESS URINARY INCONTINENCE WITH SIMS SPECULUM REDUCTION IN PATIENTS WITH PELVIC ORGAN PROLAPSE?

Dear Dr Nombongo Grootboom,

The **New Application** received on 25/10/2017 14:13 was reviewed by members of **Health Research Ethics Committee 2** (HREC2) via **expedited** review procedures on 20/03/2018 and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: **This project has approval for 12 months from the date of this letter.**

Please remember to use your project ID [1664] on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review

Please note you can submit your progress report through the online ethics application process, available at: Links Application Form Direct Link and the application should be submitted to the HREC before the year has expired. Please see Forms and Instructions on our HREC website (www.sun.ac.za/healthresearchethics) for guidance on how to submit a progress report.

The HREC will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility, permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Please consult the Western Cape Government website for access to the online Health Research Approval Process, see: https://www.westerncape.gov.za/general-publication/health-research-approval-process. Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and instructions, please visit: Forms and Instructions on our HREC website https://applyethics.sun.ac.za/Project/View/Index/1664

If you have any questions or need further assistance, please contact the HREC office at 021 938 9677.

Yours sincerely,

Francis Masiye ,

HREC Coordinator,

Health Research Ethics Committee 2 (HREC2).

National Health Research Ethics Council (NHREC) Registration Number:

Approval Letter
Progress Report

27/03/2019

Project ID #: 1664

Ethics Reference #: S17/10/210

Title: EYEBALL URODYNAMICS: IS THERE VALUE TO PREDICT HIDDEN STRESS URINARY INCONTINENCE WITH SIMS SPECULUM REDUCTION IN PATIENTS WITH PELVIC ORGAN PROLAPSE?

Dear Dr Nombongo Grootboom,

Your request for extension/annual renewal of ethics approval dated 25/03/2019 19:33 refers.

The Health Research Ethics Committee reviewed and approved the annual progress report you submitted through an expedited review process.

The approval of this project is extended for a further year.

Approval date: 26 March 2019

Expiry date: 26 March 2020

Kindly be reminded to submit progress reports two (2) months before expiry date.

Where to submit any documentation

Kindly note that the HREC uses an electronic ethics review management system, Infoneticx, to manage ethics applications and ethics review process. To submit any documentation to HREC, please click on the following link: https://sunethics.sun.ac.za.

Please remember to use your **Project ID** 1664 and Ethics Reference Number S17/10/210 on any documents or correspondence with the HREC concerning your research protocol.

Yours sincerely,

Mrs. Ashleen Fortuin

Health Research Ethics Committee 2 (HREC2)

National Health Research Ethics Council (NHREC) Registration Number:
REC-130408-012 (HREC1)+REC-230208-010 (HREC2)

Federal Wide Assurance Number: 00001372
Office of Human Research Protections (OHRP) Institutional Review Board (IRB) Number:
IRB00002240 (HREC1)+IRB00002239 (HREC2)

The Health Research Ethics Committee (HREC) complies with the SA National Health Act No. 61 of 2003 as it pertains to health research. The HREC abides by the ethical norms and principles for research, established by the World Medical Association (2013), Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects; the South African Department of Health (2006), Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2nd edition); as well as the Department of Health (2015), Ethics in Health Research: Principles, Processes and Structures (2nd edition).

The Health Research Ethics Committee reviews research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research (United States Code of Federal Regulations Title 45 Part 46); and/or clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services.

10.3 Appendix 3: Hospital approval

Western Cape Government
Health

TYGERBERG HOSPITAL
REFERENCE:
Research Projects
ENQUIRIES: **Dr GG Marinus**
TELEPHONE:**021 938 5752**

Ethics Reference: **S17/10/210**

TITLE: **EYEBALL URODYNAMICS: IS THERE VALUE TO PREDICT HIDDEN STRESS URINARY INCONTINENCE WITH SIMS SPECULUM REDUCTION IN PATIENTS WITH PELVIC ORGAN PROLAPSE?**

Dear Dr Nombongo Grootboom

PERMISSION TO CONDUCT YOUR RESEARCH AT TYGERBERG HOSPITAL.

1. In accordance with the Provincial Research Policy and Tygerberg Hospital Notice No 40/2009, permission is hereby granted for you to conduct the above-mentioned research here at Tygerberg Hospital.

2. Researchers, in accessing Provincial health facilities, are expressing consent to provide the Department with an electronic copy of the final feedback within six months of completion of research. This can be submitted to the Provincial Research Co-Ordinator (Health.Research@westerncape.gov.za).

DR GG MARINUS
MANAGER: MEDICAL SERVICES

DR D ERASMUS
CHIEF EXECUTIVE OFFICER
Date: 22 May 2009

Administration Building, Francie van Zijl Avenue, Parow, 7500 Private Bag X3, Tygerberg, 7505
tel: +27 21 938-4267 fax: +27 21 938-4890 www.capegateway.gov.za