CLINICAL PREDICTORS FOR EARLY POST

OPERATIVE URINARY RETENTION:

A COHORT STUDY



A dissertation submitted to the Tamil Nadu Dr.M.G.R.Medical University in partial fulfilment of the requirement for the award of M.S. (Obstetrics and Gynaecology) degree April, 2016.

DECLARATION

I hereby declare that this dissertation titled

"Clinical predictors for early post-operative urinary retention: A cohort study", is carried out by me under the guidance and supervision of Dr.Aruna Kekre, Professor in Obstetrics and Gynaecology Unit II, Christian Medical College, Vellore.

This dissertation is submitted in partial fulfilment of the requirements for the degree of MS in Obstetrics and Gynaecology examination of the Tamil Nadu Dr.M.G.R.Medical University to be held in April 2016.

Vellore,

Dr.V. Annie Prasanthi

Date:

CERTIFICATE

This is to certify that this dissertation,

"Clinical predictors for early post-operative urinary retention: A cohort study", is an original work of research done by Dr.V.Annie Prasanthi that was carried out under my guidance and supervision towards partial fulfilment of the requirements for the award of MS, Obstetrics and Gynaecology examination to be held in April 2016.

> Signature of the Guide: Dr.Aruna Kekre, Professor, Dept of Obstetrics and Gynaecology, Christian Medical College Hospital, Vellore 632004.

CERTIFICATE

This is to certify that this dissertation,

"Clinical predictors for early post-operative urinary retention: A cohort study", is an original work of research done by Dr.V.Annie Prasanthi that was carried out under the guidance and supervision of Dr.Aruna Kekre, Professor in Obstetrics and Gynaecology Unit II, Christian Medical College, Vellore towards partial fulfilment of the requirements for the award of MS, Obstetrics and Gynaecology examination to be held in April 2016.

Signature of the Head of the Department:

Dr.Abraham Peedicayl,

Professor and Head of the Department,

Dept of Obstetrics and Gynaecology,

Principal,

Christian Medical College Hospital,

Vellore 632004.

Christian Medical College,

Vellore 632004.

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INTRODUCTION

Pelvic organ prolapse is a significant health issue in Indian population(1). It is a disease seen frequently in post-menopausal women(2).Parity shows a strong relationship with pelvic organ prolapse(3).Pelvic organ prolapse is a disease which primarily affects quality of life(4).

The life time risk of women undergoing surgery for prolapse or incontinence is 11%. Post-operative urinary retention may be transient and cause little patient discomfort, but if not relieved it may permanently damage urinary function(5). The most common complication following pelvic reconstructive surgery is urinary retention. The patients who have undergone pelvic reconstructive surgery may take days and sometime months to resume the normal voiding. Voiding dysfunction range from irritative symptoms to complete obstruction(6).

2.5 to 24 percent of the patients can have postoperative voiding dysfunction among patients who undergo surgery for urinary incontinence and pelvic organ prolapse(6).

In most patients, POUR occurs for a short time. But still this complication is bothersome to the patient(7).Postoperative voiding dysfunction is associated with increased length of hospital stay, cost, and anxiety for women.

The mechanism of voiding is complex(8).In patients with pelvic organ prolapse, several risk factors like age of the patient, size of the genital hiatus, stage of prolapse, tone of levator ani are known to be associated with early post-operative voiding

disorders(1). Sensation for voiding is limited by post-surgical pain and associated spasm of the muscles leading to retention of urine.

Incidence of postoperative urinary retention varies between different type of surgeries(9).

Catherization of bladder is the standardized treatment for urinary retention post operatively. It is done either by prolonged catheterization or clean intermittent catherization until normal voiding pattern is restored.

It is during this period that patient experiences disappointment and frustration due to discomfort and restricted mobility. It is important to recognize POUR as significant factor which influences quality of life and satisfaction of patient in the immediate post operative period(10).

Clinician's perception of the condition and vigilance in its diagnosis play a vital role in successful care of patients undergoing surgical repair.

If early voiding dysfunction can be accurately predicted, pre operatively patient can be counselled appropriately(1).

ABBREVIATIONS

- POUR POST OPERATIVE URINARY RETENTION
- PVR POST VOID RESIDUE
- VH VAGINAL HYSTERECTOMY
- PFR PELVIC FLOOR REPAIR
- SSF SACRO SPINOUS FIXATION
- LAM LEVATOR ANI MUSCLE
- TBL TOTAL BLOOD LOSS
- POP Q PELVIC ORGAN PROLAPSE QUANTIFICATION
- CIC CLEAN INTERMITTENT CATHERIZATION

AIMS AND OBJECTIVES

The aim of this study is to

1. Determine the prevalence of post-operative urinary retention in patients who had pelvic reconstructive surgery.

2. Study the clinical predictors for early post-operative urinary retention.

REVIEW OF LITERATURE

The life time risk of women undergoing surgery for prolapse or incontinence is 11%(11). Urinary retention is one of the most common and feared complications of pelvic reconstructive surgeries. Post-operative urinary retention may be transient and cause little patient discomfort, but if not relieved it may permanently damage urinary function(5). In women who had pelvic reconstructive surgery, resumption of normal voiding can be delayed for days to weeks. Among patients who undergo surgery for urinary incontinence and pelvic organ prolapse, 2.5 to 24 % of the patients can have postoperative voiding dysfunction (6). Hence patients who undergo vaginal surgery for pelvic organ prolapse require continuous bladder drainage in the immediate postoperative period(6).

ANATOMY OF BLADDER:

Bladder is a hollow and muscular organ(12). The bladder can be divided into two portions: the dome and the base. It is ovoid when distended and flattened tetrahedron when empty. The superior surface of the bladder is dome shaped and is covered by peritoneum. Superior surface of bladder is continuous with trigone of bladder. Superior angles of trigone are pierced with ureters and inferior is continuous with neck of bladder(12).

Apex of bladder lies behind symphysis pubis when empty. It rises out of the pelvis as the bladder fills up. Inner surface is rugose when empty and smooth when it is distended. It is lined by transitional epithelium. Muscular layer of the bladder consists of outer longitudinal, middle circular and inner oblique and incomplete fibres(12).

Blood and lymphatic Supply:

The urinary bladder is supplied by a plexus of blood vessels from the superior and inferior vesical arteries and veins, branches of the internal iliac vessels. The lymphatics run along with it and drain into the internal iliac and sacral lymph glands (12).

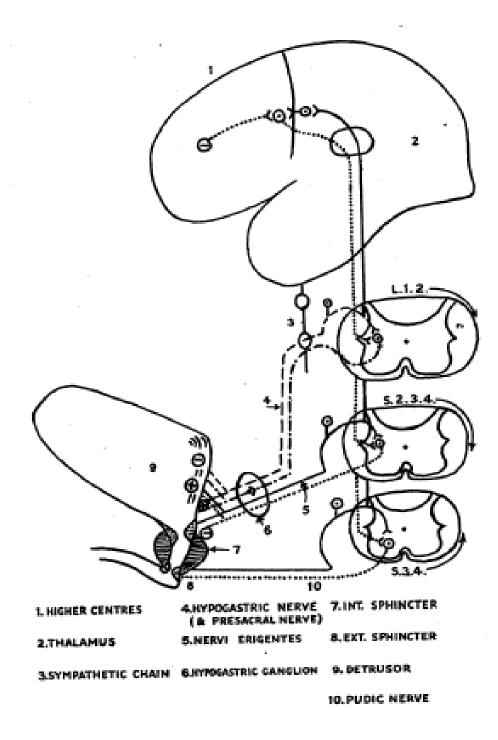
Nerve Supply:

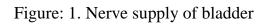
Bladder receives its nerve supply from Nervi erigentes which carry parasympathetic fibres from nuclei in lateral horns of second, third and fourth sacral segments of cord (Figure 1). These fibres also carry sensory fibres from bladder wall thereby sub serving sensation of touch, pain and pressure back to the cord through posterior column and postero-lateral path to post Rolandic area in cerebral cortex.

Other supply is from hypo gastric plexus which carry sympathetic fibres from first and second lumbar segments and terminate in internal sphincter and detrusor.

Pubic nerve arises from first, second, third and fourth sacral segments and supplies external sphincter.

Beta receptors are predominant in the dome of the bladder and produce relaxation. Alpha receptors are abundant in the bladder base producing contractions. Visceral reflex arc has lumbo-sacral cord in the centre, which is under the influence of the higher centres(12).





PHYSIOLOGY OF MICTURITION

Micturition is a dynamic physiologic process. It consists of alternating storage and expulsion phases. Micturition is accomplished by complex interactions among innervation, smooth muscle, connective tissue, urothelium and supportive structures(13). The voluntary control over bladder develops within the first few years and it involves coordination between frontal cortex, pontine centres and spinal segments influencing the control over the bladder(14).Two phases can be distinguished during micturition: Storage phase and micturition phase (Figure a). These are governed by spinal reflexes, and regulated by the Pontine Storage Centre and the Pontine Micturition Centre(12).

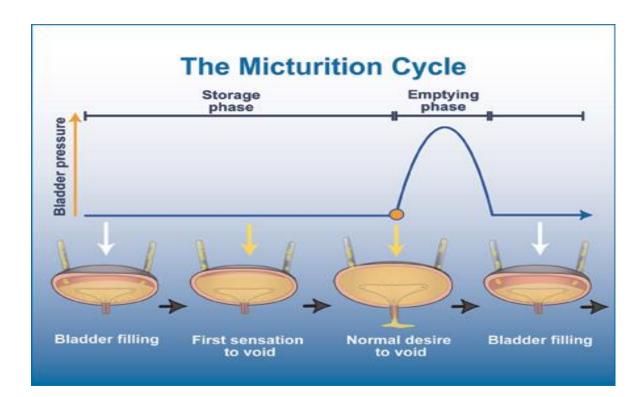


Figure a : Micturition cycle

The first urge to void is when the bladder volume is 150ml. Sensation of fullness occurs at bladder volume of 300 ml when stretch receptors are activated. Stretch receptors propagate the signal through A α and C fibres which reach spinal cord. These fibres further activate parasympathetic system. Activation of parasympathetic system contracts detrusor muscle. When the intra vesical pressure reaches voiding threshold, there is increase in intensity, frequency and duration of detrusor contractions. Thus helping in complete and effective emptying of the bladder(12).If micturition is not desired, then afferent stimuli from stretch receptors along with proprioceptive receptors from urethra, vagina, perineum and anal sphincter activate sympathetic system and inhibit parasympathetic system. Final effect is to prevent micturition by relaxation of detrusor and contraction of sphincter(12).

Retention of urine

Urinary retention is a common problem following surgery. It causes pain, anxiety, increased cost and prolonged hospital stay in many patients(15).

Definition:

Inability to void in the presence of a full bladder is urinary retention(16,17).Retention of urine is a common postoperative problem causing bladder over-distension and permanent detrusor damage. Detrusor damage can cause problems of bladder motility and atony(18).Damage to the detrusor muscle makes bladder unable to contract and empty.

Urinary retention can also occur when the bladder neck muscle or sphincter does not relax due to problems with nerve innervations which do not co-ordinate well between the brain and the bladder signals(19).

Urinary retention can be clinically divided into

- Overt retention
- Covert retention(20)

• OVERT RETENTION:

Overt retention is symptomatic and characterized by the inability to void accompanied by pain and discomfort.

• COVERT RETENTION:

Covert retention is asymptomatic. Women cannot empty bladder completely and the retention is detected only by catheterisation or ultrasound. It is usually self limiting(20,21).

COMPLICATIONS OF URINARY RETENTION

BLADDER OVERDISTENSION:

Bladder distension accounts for 44% of complications which is one of the major complications of post-operative urinary retention(16). As the bladder gets distended, there is atonia of the bladder followed by urinary retention and urinary infection.

Few human and animal studies showed that acute over distension can cause structural and functional abnormalities of the bladder. This can occur in a short duration of time as short as 4 hours which is due to bladder ischemia.Baldini et al. showed a direct correlation between post operative bladder volume and risk of persistent urinary retention(16).

Persistent urinary retention can exacerbate the storage dysfunction of the bladder by decreasing the bladder capacity and producing the sensation of incomplete voiding. This further results in frequency of micturition, urinary urgency and overflow incontinence(16).

URINE INFECTION

Urine infection is a direct complication of postoperative urinary retention because there is stasis of urine due to incomplete bladder emptying. This acts as a good source for growth of organisms. Heavy bacterial colonization of the perineum, periurethral region, and short urethra all contribute to the urinary tract infection(9). Urinary catheters further increase the risk of bacterial colonisation by interfering with normal host defence mechanisms and formation of bio film. Urinary tract infection is an indirect complication of post operative urinary retention since it necessitates catheterisation. The incidence of urinary infection after one episode of catheterisation is around eight percent(9). But shorter duration of catheterization is associated with high rates of post operative urinary retention(7).

DIAGNOSIS

Clinically urinary retention can be diagnosed by

- History and Clinical examination
- Ultrasound examination

Pain and discomfort in lower abdomen is one of conventional predictor of urinary retention(16). Palpation and percussion of bladder in supra pubic region is a clinical method to diagnose urinary retention. But it lacks sensitivity in providing accurate measure. Dullness of bladder to a level of umbilicus gives an rough estimate of 500ml of urine(22).

Measurement of residual urine in bladder after an act of voluntary void is one of the non-invasive methods of assessing bladder dysfunction. Post void residue is the measurement of urine in bladder by ultrasound within twenty minutes after last void(23).Bladder catheterisation was considered gold standard for measuring post void residue but measurement of bladder volume with portable ultrasound has demonstrated accuracy and reliability(23).Lamonerie et al suggested ultrasound scan for assessing bladder volume after surgery, in order to identify cases of over distension early and to enable prompt treatment(19).Threshold values for post void residue are poorly defined(24). Post void residue more than 300 ml causes complications(24).

The causes of urinary retention after vaginal prolapse surgery are multi factorial. Predictors for post-operative urinary retention after pelvic reconstructive surgery are stage of prolapse, age, body mass index, menopausal status, size of genital hiatus, tone of levator ani muscle, pre-operative post void residue, type of anaesthesia, type and technique of surgery, operation time, intra-operative blood loss (12).

STAGE OF PROLAPSE

In cystocele, protrusion of the bladder into the vagina causes kinking of the urethra. This leads to retention of urine preoperatively. Post operatively the degree of prolapse plays a major role in postoperative urinary retention. Among the various variables, degree of prolapse and type of surgery has a major role to play to predict the rate of urinary retention(16). Postoperative voiding dysfunction following cystocele repair is a common complication affecting a large number of women(25). Postoperative voiding dysfunction is associated with increased length of hospital stay, cost, and anxiety for women.

The uterine vessels pass over ureters. Due to exteriorization of the uterine corpus and vasculature in severe prolapse, ureteral or urethral kinking occurs. Hence, women with advanced prolapse are at risk for hydroureter, hydronephrosis, and subsequently impaired renal function(26). According to multicentre, prospective, cohort study of women undergoing pelvic reconstructive and/or incontinence surgery done by Komesu et al; vaginal apex suspension or the preoperative presence of grade III and IV vaginal apex descent associated with prolonged postoperative are catheterization(27).

According to retrospective analysis done by Benjamin J.Steinberg, patients with higher pre-operative anterior stage prolapse and combined anterior and posterior compartment repair are associated with post-operative urinary retention(10).Larger cystocele and amount of intra-operative blood loss during surgery were considered direct predictors for occurrence of post-operative urinary retention after a vaginal prolapse surgery(7).

AGE

Post-operative urinary retention increase with age, the risk increases by 2.4 times in patients over 50 years of age(16). Several studies have demonstrated age as a predictor of postoperative voiding efficiency. According to study done by Keita, Age : more than or equal to fifty years, was independent predictive factor for post-operative urinary retention(18). Possible reason could be age related progressive neuronal damage leading to bladder dysfunction(16). The coordination of bladder filling, storage of bladder and voluntary micturition is under the control of supra spinal central, somatic and visceral neurons in thoracic, lumbar and sacral spinal segments. Degeneration of this pathway due to aging explains the increased incidence of postoperative urinary retention in the elderly(29). Aging and parity are associated with fibrosis, variation in fibre diameter and centralization of nuclei in levator ani muscle. Weak detrusor contractility is a good predictor of postoperative occurrence of large post void residue. Lamonerie et al suggested that age more than 60 years along with anaesthesia and duration of surgery was associated with increased risk of urinary retention(30).

BODY MASS INDEX

Obesity is a common health problem. The global prevalence of obesity is increasing rapidly. Morbid obesity is a known risk factor for developing symptoms of urinary incontinence. In older women, obesity is identified as significant independent risk factor for urinary incontinence(31). The prospective cohort study done in 2002 demonstrated association between reduction of weight and improvement in urinary incontinence(31). Weight reduction should be considered as part of non-surgical treatment for urinary incontinence in women who are obese(31). The way in which obesity cause incontinence is unknown. It is hypothesized that excess body weight is associated with increased abdominal pressure during physical activity. This in turn increases bladder pressure and urethral hyper mobility. This in turn leads to urinary incontinence. If incontinence of urine is primarily due to increased intra-abdominal pressure, then reduction of weight in obese women should decrease the urinary incontinence(31,32). But there is no association between body mass index and perioperative incontinence and urinary retention (35). According to study done by Revicky, there is no statistically significant influence of obesity on the incidence of bladder injury or urinary retention(37).

BMI Classifications	BMI (kg/m²)				
Underweight	<18.5				
Normal weight	18.5-24.9				
Overweight	25.0-29.9				
Obesity (Class 1)	30.0-34.9				
Obesity (Class 2)	35.0-39.9				
Extreme obesity (Class 3)	≥40.0				

Figure b: WHO Classification of body mass index

MENOPAUSAL STATUS

Pelvic organ prolapse is seen frequently in post-menopausal women(2). In women with pelvic organ prolapse, it has been demonstrated that protein content and oestrogens in utero sacral ligaments, in the vagina, and in the parametrium of women with prolapse were reduced(2). According to a retrospective study done at the Cleveland Clinic Foundation between August 1999 and July 2003, Menopausal status is potential predictor of prolonged post- operative urinary retention.

According to a prospective study, failure of relaxation of the striated urethral sphincter contributes to postoperative urinary retention(38).

SIZE OF GENITAL HIATUS

Larger genital hiatus may be a marker of levator muscle disruption or pelvic muscle atrophy. A wide urogenital hiatus, decreased levator ani contraction strength, increasing age and increased post void residue was associated with an increased chance of early postoperative emptying disorders. Pelvic floor denervation is thought to result in decreased levator tone and widening of genital hiatus. According to retrospective study done in Mississippi, patients with genital hiatus greater than 5 cm were 3 times more likely to have emptying disorders than those with less than 5cm(1).

LEVATOR ANI TONE

The mechanisms of evacuation are complex. Levator ani muscle is a muscle of evacuation and levator ani muscle dysfunction could lead to defecation and urination disorders. The levator ani muscle maintains a constant tone unlike other skeletal muscles except during voiding, defecation and the valsalva manoeuvre(39). Chronic straining, prolonged stage of labour or use of forceps often are the reason for levator muscle dysfunction(8). It has been established that levator ani muscle injury increases the risk of pelvic organ prolapse. There is a direct correlation between the size of the defect and the symptoms and signs of prolapse. Women with bilateral avulsion are more likely to suffer from uterine prolapse(39). The most independent predictors of urinary retention are decreased levator contraction strength and increased preoperative PVR urine(8).



Pelvic floor muscle contraction

- 0: nil
- 1: flicker of muscle contraction
- 2: weak contraction
- 3: medium slight lift of examiner's finger, no resistance
- 4: strong elevation of examiner's finger against light resistance
- 5: very strong elevation of examiner's finger against strong resistance

Isherwood PJ, Rane A. Br.J Obstet Gynaecol. 2000;107:1007-1011.

Figure b Oxford scale for scoring tone of levator ani muscle.

UROFLOWMETRY AND PRE OPERATIVE POST VOID RESIDUE

Large post void residual urine develops occasionally after pelvic organ prolapse surgery. Uroflowmetry and post void residue can help in selecting patients who should undergo more sophisticated urodynamic studies(24). According to a retrospective study, Urodynamic evaluation of stress urinary incontinence and pelvic organ prolapse pre operatively help in predicting voiding dysfunction(19). Absence of detrusor contraction on pre-operative urodynamic evaluation is an indicator for post-operative urinary retention. Detrusor pressure <12 cm H2O was considered weak pressure(41).

The International Continence Society recommends urodynamic evaluation in diagnostic workup of patients with pelvic organ prolapse scheduled for surgical repair(19).

Flow rate is defined as the volume of fluid expelled via the urethra per unit time. It is expressed in millilitres per second. Maximum flow rate is the maximum measured value of the flow rate after correction for artefacts(40). Certain objective measurements were standardized by the International Continence Society to be recorded during uroflow measurement. These include flow pattern, voided volume, maximum flow rate (Q_{max}), voiding time, and time to maximum flow. Of these, flow pattern, Q_{max} , and volume voided are clinically useful for both screening and following patients(24).

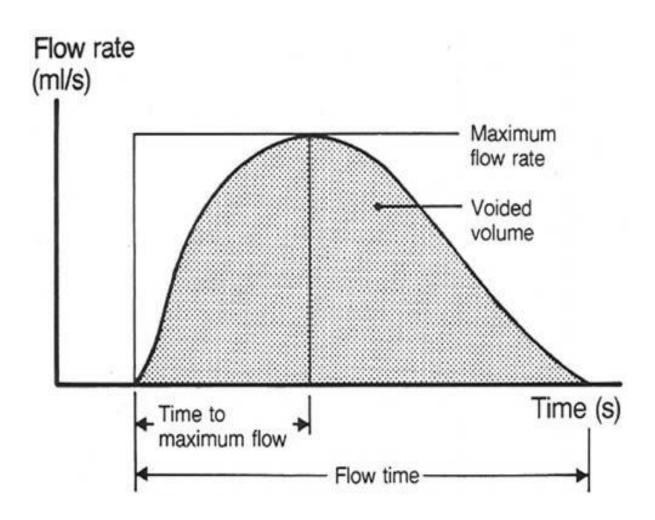


Fig 3: Uroflowmetry recording

(International Continence Society recommended nomenclature)

According to a study done by Miller et al, post-void residual urine volume predicted delayed return to normal voiding. Peak flow rate, capacity or compliance of bladder were not significantly associated with urinary retention, delayed return to normal voiding or postoperative urgency symptoms(41).

After pelvic reconstructive surgery, most patients with elevated post-void residual volume had normalization of the post-void residual volume(42). Measurement of the amount of residual urine in the bladder after a voluntary void is defined as post void residual urine volume (PVR). Portable bladder scanners are convenient, accurate, cost-effective and non-invasive screening test for evaluating voiding dysfunction(24).

Threshold values for abnormal post void residue are not clearly defined. The volumes of 50 ml to 100 ml are considered as abnormal residual urine volume by most urologists. There is an increased risk of upper urinary tract dilation and renal insufficiency with very large post void residue (>300 ml).Large post void residue may be caused by bladder hypo contractility. Poor bladder contractility may result from neurogenic, myogenic, psychogenic, or pharmacologic causes(24).

ANAESTHESIA

Incidence of post-operative urinary retention is common after anaesthesia and is between 5% and 70%.General anaesthetic agents interfere with the autonomic nervous system and cause bladder atony. After intrathecal injection of local anaesthetics, the sensation of urgency to void disappears within 30–60 seconds. Bladder analgesia is due to the block of the transmission of the afferent nerve fibres from the bladder to the micturition centre in the brain(16). In the post operative period pain and soft tissue swelling can at times make bladder emptying difficult (43). Local anaesthetic infiltration has been shown to decrease analgesic requirements and the risk of post operative urinary retention. According to Baldini etal, type of anaesthesia influences the development of postoperative urinary retention (POUR).

TYPE OF SURGERY

Sensation for voiding is limited by post-surgical pain and associated spasm of the muscles leading to retention of urine. Incidence of postoperative urinary retention varies between different type of surgeries(9).

The incidence in general surgical population is about 3.8 percent. Anorectal surgery and hernia repair were considered surgery with high risk for urinary retention. But after gynaecological surgery, there are conflicting results(16).

In patients who have undergone vaginal hysterectomy with pelvic floor repair, spasm oedema and tenderness of the puboccocygeous muscle in anterior colporraphy may pose a problem in voiding (9,43).

Hakvoort etal in 2004, Kamilya et al 2010, Weemhoff etal in 2011 mentioned urinary retention after anterior colporraphy(44) On the other hand Shekavat etal in 2008 and Thapa etal in 2010 in their studies did not find urinary retention in these surgeries(45,46).

DURATION OF SURGERY

The reason for increased blood loss intra operatively as risk factor for urinary retention can be explained as prolonged operating time and extensive damage to innervations of detrusor muscle .Levator plication appeared to be strongly related to postoperative urinary retention(7). In a retrospective study by Petros, duration of surgery was found to be significantly associated with post-operative urinary retention(16).According to a prospective study done in 2005, prolonged anaesthesia time was identified as an independent risk factor for post-operative urinary retention. Prolonged anaesthesia time(>2 hours) was associated with significant increase in odds ratio for post-operative urinary retention(5).

INTRA OPERATIVE BLOOD LOSS

According to retrospective study done in Netherlands, urinary retention after vaginal prolapse surgery occurs more frequently in women with larger cystoceles, severe intra-operative blood loss and the application of levator plication(7).

Several predictors were found for occurrence of the urinary retention after surgery for vaginal prolapse. Hence it is necessary to identify the high risk patients and to establish safe bladder volume ranges to avoid over-distension of the bladder and its complications of persistent bladder dysfunction.

Pre-operative counselling of the patient about consequences of prolapse surgery could be optimized when risk factors would be identified for urinary retention after prolapse surgery.

Furthermore, the catheterization regime could be adjusted to an individual risk for post-operative urinary retention(7).

MATERIALS AND METHODS

This study is as an observational cohort study. This study is approved by institutional review board.

Study is done among the patients who underwent pelvic reconstructive surgery in Christian Medical College, Vellore between August 2014 and July2015. Informed written consent is taken from all the patients.

The aim of the study is to identify the clinical predictors for early post-operative urinary retention after pelvic reconstructive surgery. The following clinical predictors were studied

- Stage of prolapse
- Age
- Body mass index
- Menopausal status
- Size of genital hiatus
- Tone of levator ani
- Pre- operative post void residue
- Type of surgery
- Duration of surgery
- Type of anesthesia
- Intra operative blood loss

INCLUSION CRITERIA: Patients who are planned for pelvic reconstructive surgery which include pelvic floor repair with or without vaginal hysterectomy and vault prolapse repair.

EXCLUSION CRITERIA: Patients with pelvic organ prolapse who are planned for hysterectomy with concomitant mid urethral sling surgeries and those who require long term catheterization due to intra operative complications.

Patients are recruited and given a study number after informed written consent.

PRE OPERATIVE WORK UP

All patients planned for pelvic reconstructive surgery had

- Thorough clinical examination which included
 - Staging of pelvic organ prolapse according to POP Q –Quantification system.
 - Scoring of tone of Levator ani muscle by oxford scale.
- Pre- operative uroflowmetry and post void residue

Pelvic reconstructive surgery was done as per surgeon's decision. Details of type and technique of surgery, type of anaesthesia, duration of surgery and amount of blood loss were noted. All patients were catheterized for a maximum of 72 hours as per the discretion of the operating surgeon (catheterized for 48 hours for large cystoceles or 72 hours for sacrospinous fixation according to type of surgery).

Patient was encouraged to void by 6-8 hours after catheter removal. After the patient voids, residual volume was recorded with ultrasound scan by principal investigator or ultrasound technicians. If post void residue was

• More than 300ml and patient was comfortable, she was encouraged to void. However, repeat post void residue was done for women who had frequency and sense of incomplete voiding.

• More than 300 ml or patient was unable to void or has symptoms of distention, the patient was recatheterized for 72 hours. Patient was encouraged to void after 72 hours. Patients who failed to void were recatheterized for 7 days or taught intermittent self-catheterization. If patients failed to regain normal voiding pattern even after 7 days, then patients were planned for urodynamic evaluation.

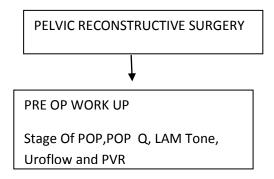
All the information was computerised and confidentiality maintained.

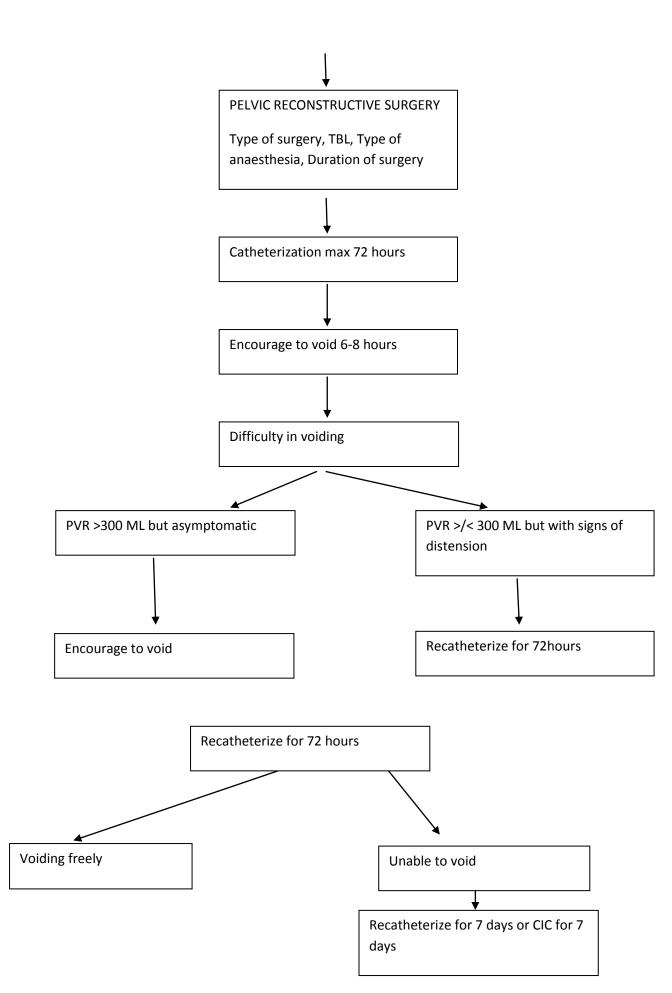
The risk factors associated were analyzed.

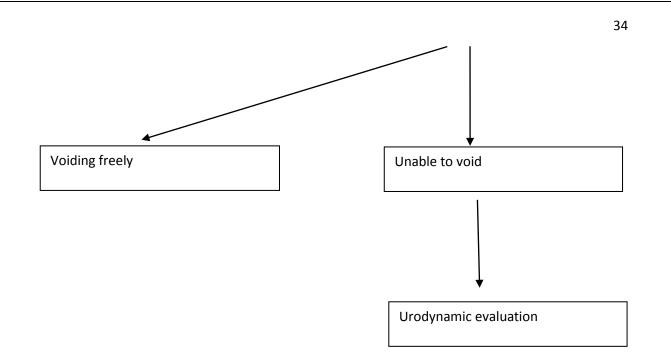
The primary outcome was to determine the prevalence of early post- operative urinary retention in patients who had pelvic reconstructive surgery and the contribution of stage of prolapse to early post-operative urinary retention.

The secondary outcome was to study the clinical predictors for early post-operative urinary retention.

SUMMARY OF THE METHODOLOGY







STATISTICAL ANALYSIS

Prevalence of post-operative urinary retention was given as a percentage and 95% confidence interval for the prevalence was estimated. Descriptive of continuous covariates and categorical risk factors are presented with mean (SD) and frequencies (%) respectively. Chisquare test or Fisher's exact test was used to assess the association between the clinical predictors and early post-operative urinary retention in univariate analysis. Clinical predictors which were significant at less than 0.10 level of significance in univariate analysis were taken into multiple logistic regressions to assess its independent association with early postoperative urinary retention. p-value of less than 0.05 was considered to be statistically significant in multiple logistic regression to indicate the corresponding risk factor as an independent predictor.Association of risk factors with post-operative urinary retention in multiple logistic regression were presented with odds ratio and its 95% confidence interval.

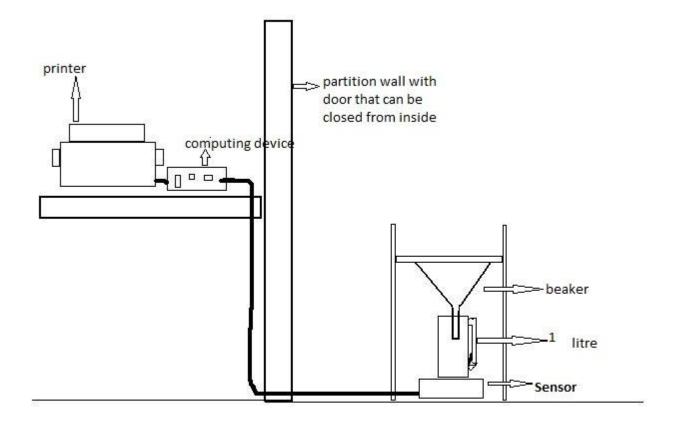


Figure 4 : Diagrammatic representation of Uroflowmetry room in our department.

RESULT

Seventy patients were recruited in this study. Five patients were excluded from the study as two patients had prolonged catheterization due to intra operative complications like bladder injury and rectal injury and other three patients had excessive blood loss and required intensive care monitoring.

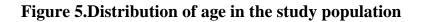
The following eleven clinical predictors for early post-operative urinary retention after pelvic reconstructive surgery were analysed as shown in TABLE 1: Age, body mass index, menopausal status, size of genital hiatus, degree of prolapse, tone of levator ani muscle, pre-operative post void residue, type of anaesthesia, type and technique of surgery, operation time and intra-operative blood loss.

TABLE 1

DEMOGRAPHIC PROFILE

	Frequency	Percentage
AGE	I	I
Less than 50 years	25	35.71
More than or=50years	45	64.29
BMI		
Underweight	10	14.29
Normal	35	50
Overweight	20	28.7
Obese	5	7.14
PARITY		
Primigravida	4	5.71
Multigravida	66	94.29
MENOPAUSE		
Premenopause	52	74.29
Postmenopause	18	25.71
SIZE OF GENITAL HIATUS		
< 5 cm	16	22.86
>/=5 cm	54	77.14
TONE OF LAM	l	
1,2	3	4.48

3	39	58.21
4,5	25	37.31
TYPE OF SURGERY		
PFR	01	1.44
VH-PFR	49	70
VH-PFR+SSF	15	21.42
Vault repair with SSF	5	07.14
DURATION OF SURGERY		
Less than 2 hours	23	32.86
>/= 2 hours	47	67.14
INTRA OPERATIVE BLOOD	LOSS	
< 500 ml	47	67.14
>/= 500 ml	23	32.86
>/= 500 ml ANAESTHESIA	23	32.86
	23	32.86 82.86
ANAESTHESIA		



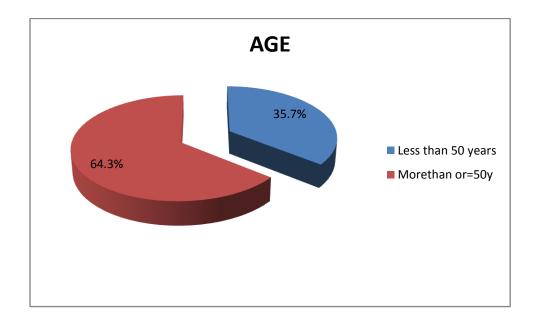
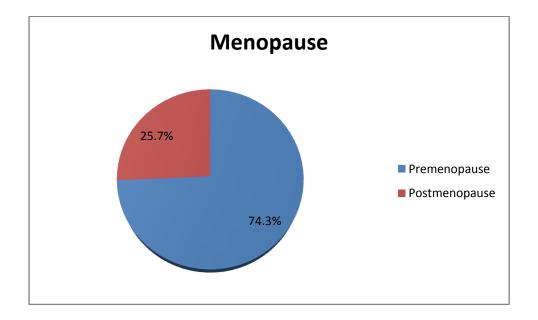


Figure 6.Distribution of menopausal status in study population



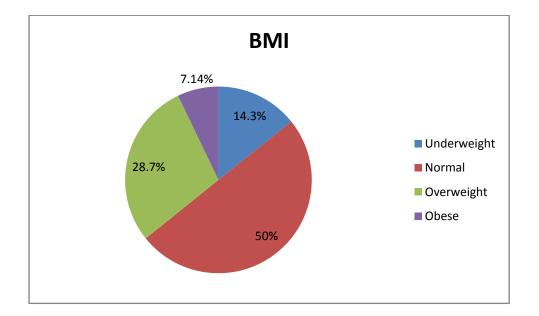
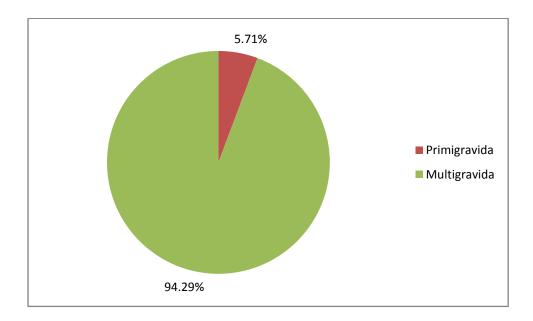


Figure 7.Distribution of body mass index in population

Figure 8 Distribution of parity in the population



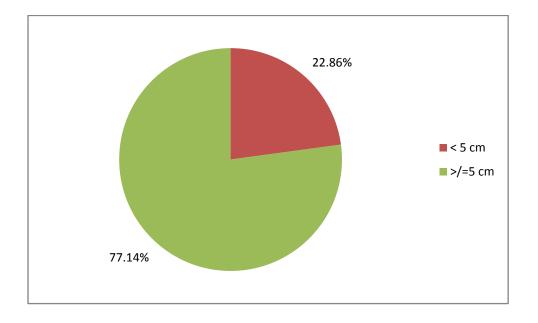
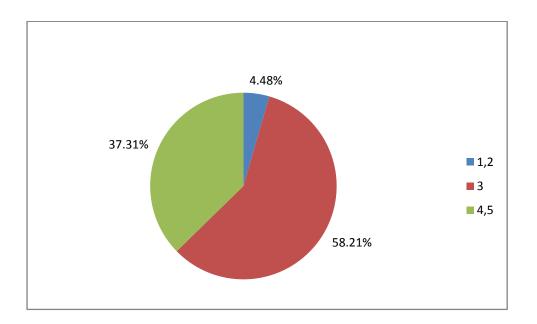


Figure 9 Distribution of size of genital hiatus in the population

Figure10 Distribution of tone of levator ani in the population



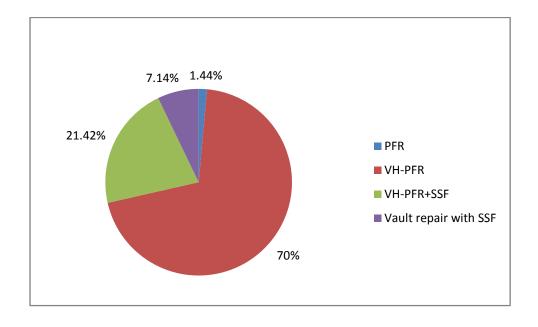
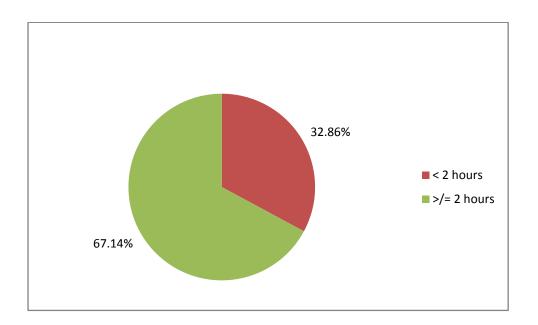


Figure11 Distribution of type of surgery in the population

Figure12 Distribution of duration of surgery in the population



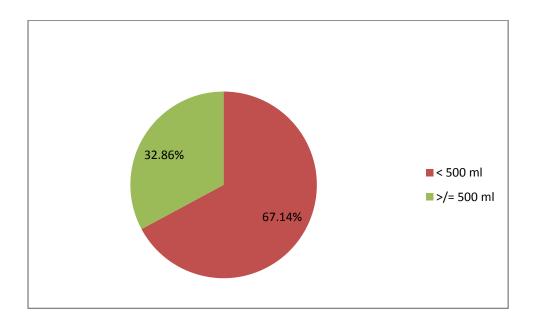
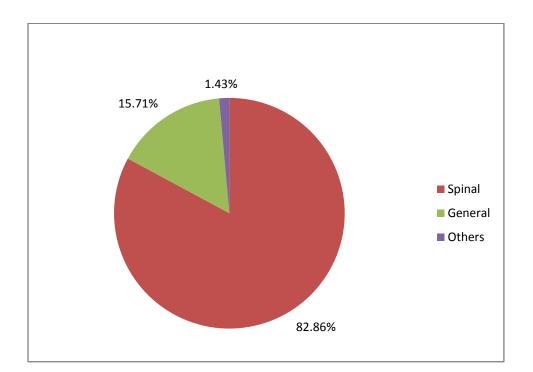


Figure 13 Distribution of amount of blood loss in population

Figure 14 Distribution of type of anaesthesia in population



Nine patients had early post-operative urinary retention.

The prevalence of early post-operative urinary retention after pelvic reconstructive surgery was 13.85 %.

Out of nine patients, 5 patients (55.55%) had covert retention and 4 (44.44%) patients had overt retention (Figure 15, 16)

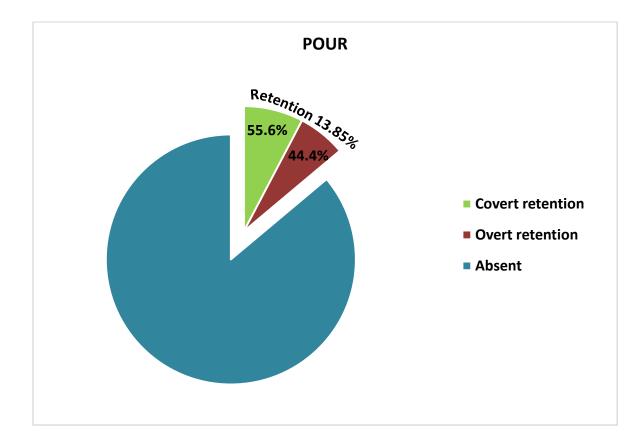
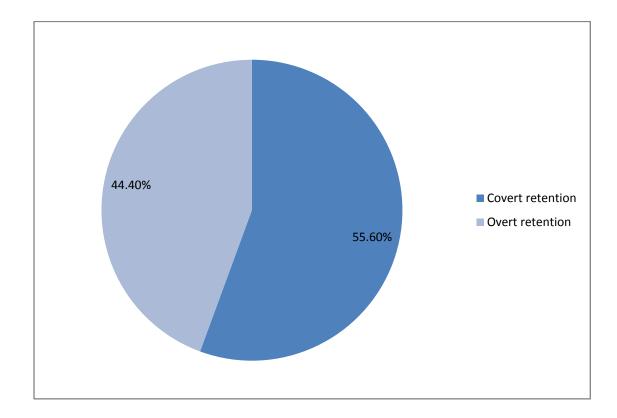


Figure 15 PREVALENCE OF POUR

Figure 16 Division of POUR



Out of the nine patients, one patient required urodynamic evaluation. She was referred to urology and was evaluated and diagnosed to have atonic bladder (underactive detrusor with overflow incontinence). She opted for clean intermittent catheterization. The investigations of the patient who had atonic bladder are attached.

Gender: Date of birth: Patient number: Investigation date	Male 01/01/1952 232380g : 04/08/2015		Investigation nr: Hospital: Investigator: Referred by:	01 CMCH Dr pank Dr nitin I	aj kekre		
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Pump tom 40r Firme po:00 Iling phase resu fused volume plume lost throug adder filling	lts	ni 160mi 180mi 200mi 220mi 240mi 2 1 15:00	637 ml 631 ml 631 ml	Domi 440m	11 480mi 520mi 560mi	600ml 1 45:00	•
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Name: AYISHA 232380G Age: 63 years/ Female HISTORY:

63 years old Mrs.Ayisha Para 9 Living 9 sterilized, with surgical menopause (hysterctomy 14 years back) presented with mass descending per vaginum and associated with bowel and bladder disturbances for 14 years, and was found to have vault propalse, for which she underwent Anterior& posterior colporrhaphy+ SSF+ excision of anal polyp on 29/7/15.

There was prior history of splinting,increase in frequency,poor stream, urgency,occasional SUI,and a sense of incomplete voiding. There was history of constipation and digital evacuation of stools for 14 years. Post operatively, after catheter removal she could not void and had overflow incontinence. She was put on catheter for 4 weeks, and then TWOC was given, which failed. Then she was advised CIC, which she is doing irregularly. She had no DM, HTN. She has constipation.

No H/O neurologic trauma or surgery History of febrile UTI/calculuria/Hematuria - none History of psychiatric symptoms/diagnosis/medications - No

Examination: Bladder palpable: No EUM- normal, P/V : no prolapse Rectal examination: Tone reduced Lower limb sensation and Power was normal.

INVESTIGATIONS Urine C/S: Mixture of organisms (catheter sample) Creatinine: 0.6 mg% Uroflow (Qmax/voided volume/PVR): could not void Bladder diary: maximum voided volume 330 ml(on irregular CIC)

Urodynamic question: ? Acontractile detrussor CMG findings: Filling phase: Sensation delayed, Compliance normal(Pdet at end filling:22) Overflow incontinance present

Voiding phase: Voided only 84 ml with a lot of abdominal straining, and Pdet at Qmax 18 cm H2O PVR : 540 ml

Impression: Filling phase: Sensation were delayed,compliance normal,no DOA present. Overflow incontinance present. Voiding phase: Underactive detrussor.

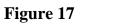
D/w Dr. Nitin Kekre CMG finding were suggestive of Underactive detrussor with overflow incontinance Patient was advised: CIC q 4H

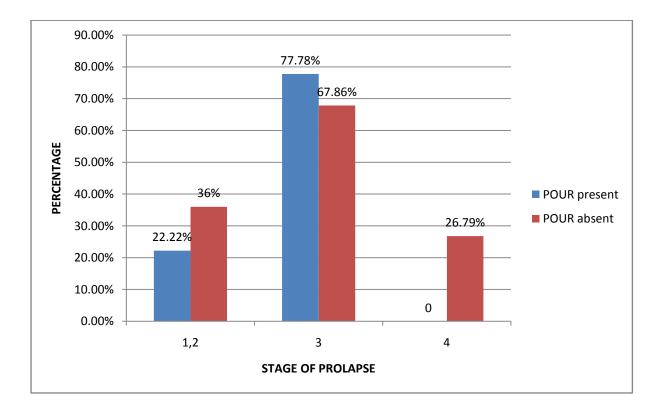
STAGE OF PROLAPSE

TABLE 2

STAGE OF	POUR		
PROLAPSE	Present	Absent	p-value
1,2	2(22.22%)	3(5.36%)	
3	7 (77.78%)	38 (67.86%)	
4	0	15 (26.79%)	0.062

Fisher's exact test is used to assess the association between stage of prolapse and early post-operative urinary retention. Among the patients who had post operative urinary retention, seven patients (77.78%) belonged to stage III pelvic organ prolapse category (Table 2). In this study, it is not statistically significant. P value is 0.062.





AGE

TABLE 3

Age	POUR		p-value
	Present	Absent	
<50 years	3 (33.3%)	20 (35.71%)	0.89
>=50 years	6 (66.7%)	36 (64.29%)	

Fisher's exact test is used to assess the association between age and early postoperative urinary retention. Among the patients who had post operative urinary retention, six patients (66.7%) belonged to age group more than or equal to 50 years. In this study, it is not statistically significant. P value is 0.89 (Table 3).

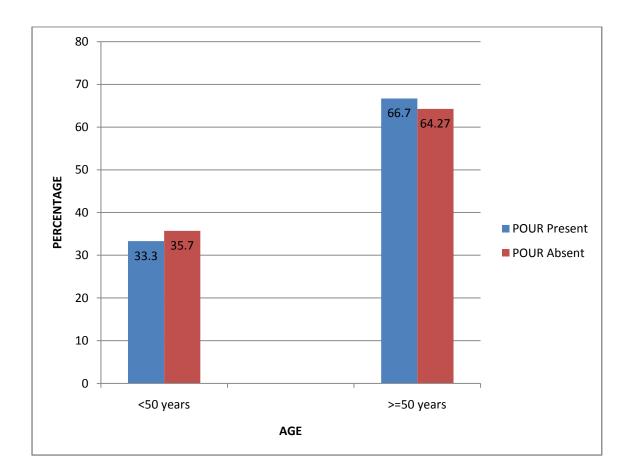


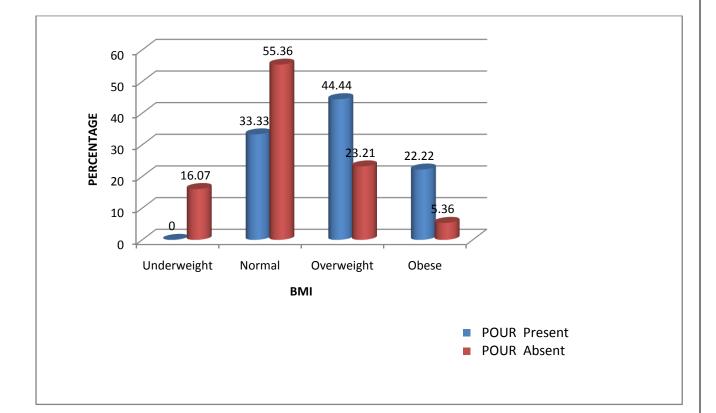
Figure 18

BODY MASS INDEX

TABLE 4

BMI(kg/m ²⁾	POUR		P value
	Present	Absent	
Underweight (<18.5)	0	9(16.07%)	
Normal (18.5-24.99)	3(33.33%)	31(55.36%)	
Overweight (25-29.99)	4(44.44%)	13(23.21%)	0.093
Obese (>=30)	2(22.22%)	3(5.36%)	

Figure 19



Fisher's exact test is used to assess the association between body mass index and early post-operative urinary retention. Among the patients who had post operative urinary retention, four patients (44.44%) belonged to overweight category. This is not statistically significant. P value is 0.093 (Table 4).

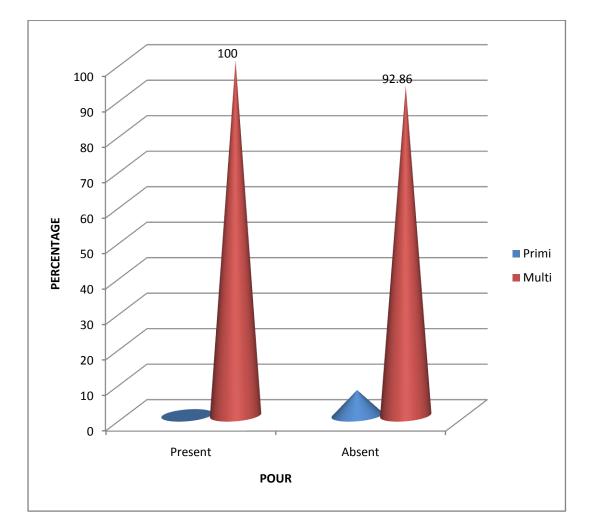
PARITY

TABLE 5

Parity	POUR		P value
	Present	Absent	
Primi	0	4(7.14%)	>0.99
Multi	9(100%)	52(92.86%)	

Fisher's exact test is used to assess the association between parity and early postoperative urinary retention. Among the patients who had post operative urinary retention, nine patients (100%) belonged to multiparous category. In this study, it is not statistically significant. P value is more than 0.99 (Table 5).





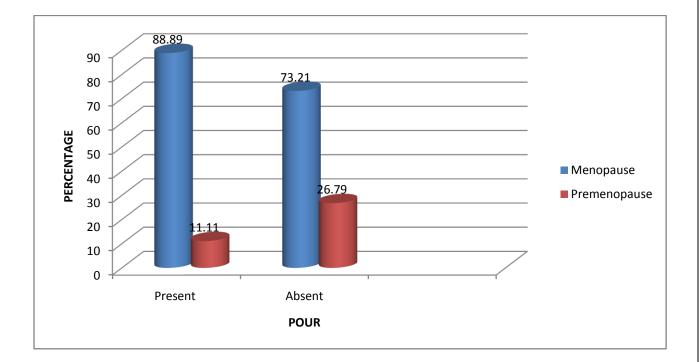
MENOPAUSE

TABLE 6

Menopause		POUR	
	Present	Absent	
			0.331
Yes	8(88.89%)	41(73.21%)	
No	1(11.11%)	15(26.79%)	

Pearson chi square test is used to assess the association between menopause and early post-operative urinary retention. Among the patients who had post operative urinary retention, eight patients (88.89%) belonged to menopause category (Table 6). In this study, it is not statistically significant. P value is 0.331.





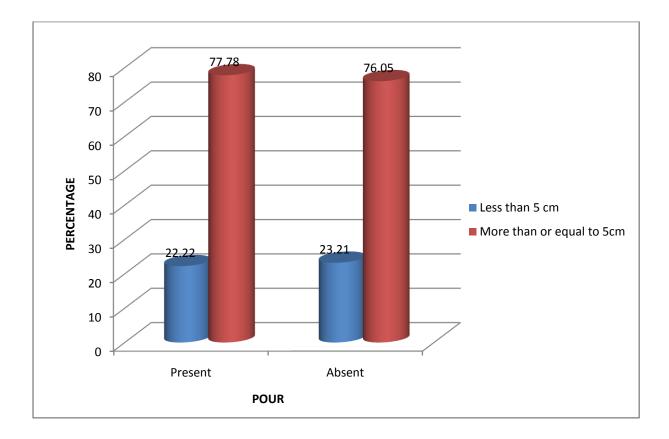
SIZE OF GENITAL HIATUS

Table 7

Size of genital hiatus	POUR		P value
	Present	Absent	
			- 0.948
Less than 5 cm	2(22.22%)	13(23.21%)	
More than or equal	7(77.78%)	46(76.05%)	-
to 5cm			

Fisher's exact test is used to assess the association between size of genital hiatus and early post-operative urinary retention. Among the patients who had post operative urinary retention, seven patients (77.78%) belonged to size of genital hiatus more than 5cm category. In this study, it is not statistically significant. P value is 0.948 (Table 7).

Figure 22



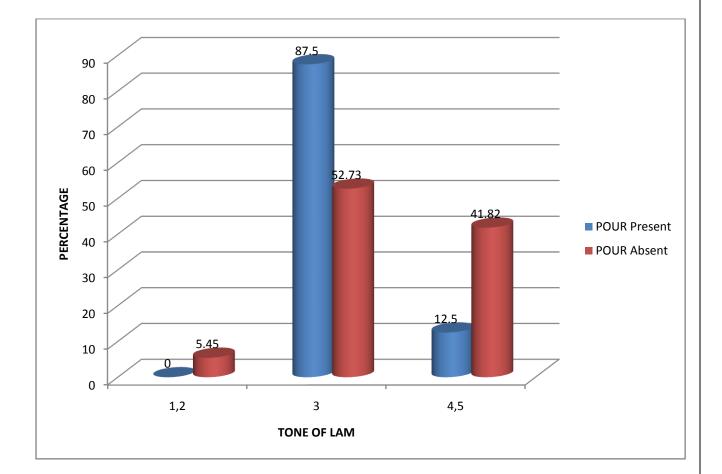
TONE OF LEVATOR ANI

TABLE 8

Tone	POUR		P value
	Present	Absent	
1,2	0	3(5.45)	
3	7(87.5)	29(52.73)	0.192
4,5	1(12.5)	23(41.82)	

Fisher's exact test is used to assess the association between tone of levator ani and early post-operative urinary retention. Among the patients who had post operative urinary retention, seven patients (87.5%) belonged to category where tone of LA is 3. In this study, it is not statistically significant. P value is 0.192 (Table 8).

Figure 23



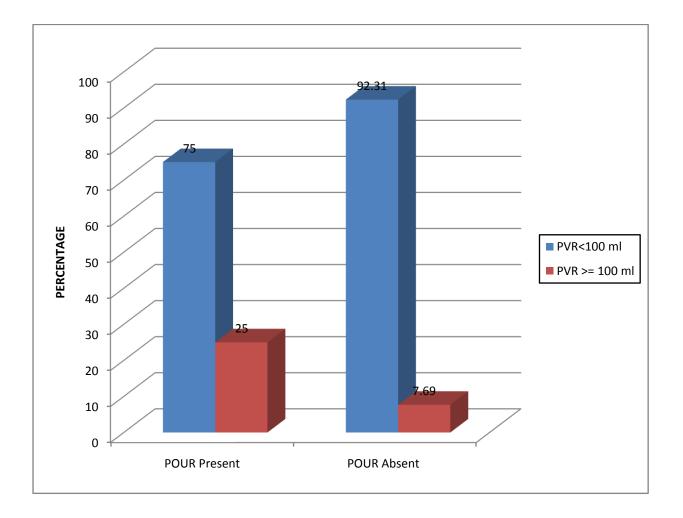
PRE OPERATIVE POST VOID RESIDUE

TABLE 9

Pre op PVR	POUR		P value
	Present	Absent	
<100 ml	6(75%)	48(92.31)	0.129
>= 100 ml	2(25%)	04(07.69)	

Pearson chi square test is used to assess the association between pre-operative PVR and early post-operative urinary retention. Preoperative PVR is missing for 3 patients. Among the patients who had post operative urinary retention, two patients (25 %) belonged to PVR group more than or equal to 100 ml. In this study, it is not statistically significant. P value is 0.129 (Table 9).





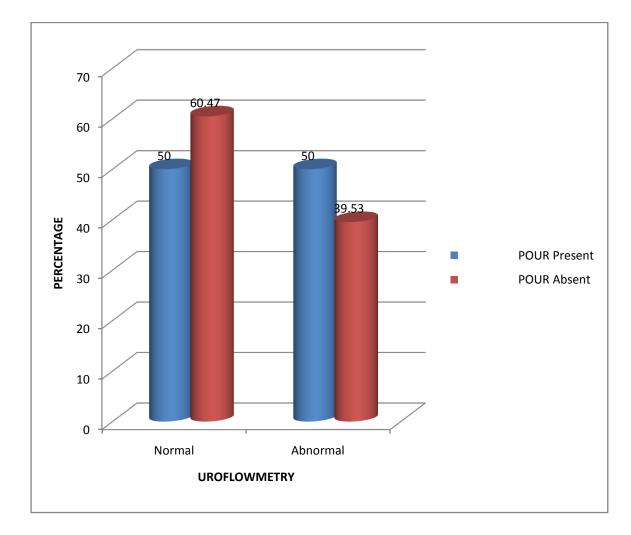
UROFLOWMETRY

TABLE 10

	POUR		
Uroflowmetry	Present	Absent	P value
Normal	2(50%)	26(60.47%)	0.68
Abnormal	2(50%)	17(39.53%)	

Pearson chi square test is used to assess the association between uroflowmetry and early post-operative urinary retention. Ten patients were unable to undergo this investigation as they were unable to void in sitting position. Uroflowmetry is missing for ten patients. Among the patients who had post operative urinary retention, two patients (50 %) belonged abnormal uroflowmetry result group. In this study, it is not statistically significant. P value is 0.68(Table 10).

Figure 25



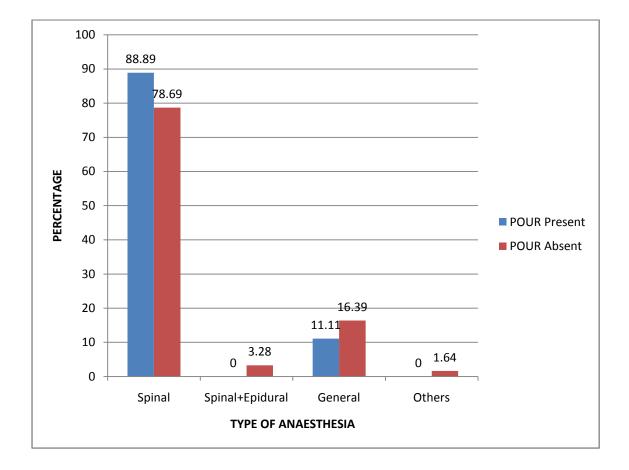
ANAESTHESIA

TABLE 11

	POUR		
Anaesthesia	Yes	No	p-value
Spinal	8(88.89%)	48(78.69%)	
Spinal+Epidural	0(0%)	2(3.28%)	
General	1(11.11%)	10(16.39%)	
Others	0(0%)	1(1.64%)	>0.99

Fisher's exact test is used to assess the association between anaesthesia and early postoperative urinary retention. Among the patients who had post operative urinary retention, eight patients (88.89%) had spinal anaesthesia. In this study, it is not statistically significant at five percent level of significance. P value is more than 0.99(Table 11).

Figure 26



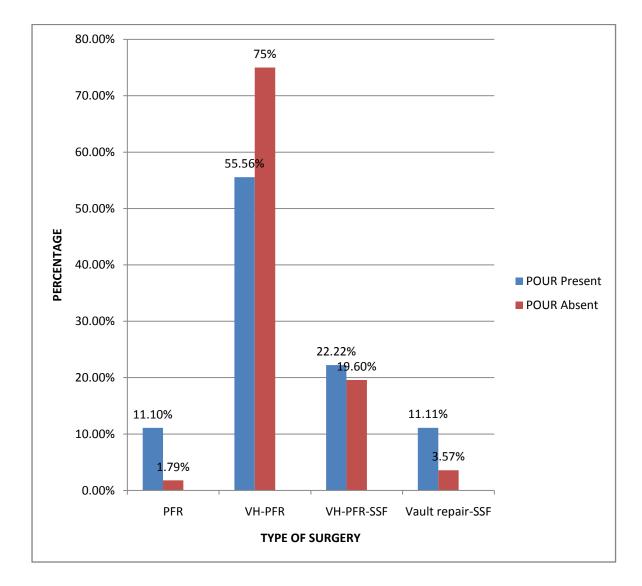
TYPE OF SURGERY

TABLE 12

	POUR		
Type of Surgery	Present	Absent	p-value
PFR	1(11.1%)	01(1.79%)	
VH-PFR	5(55.56%)	42(75.00%)	
VH-PFR-SSF	2(22.22%)	11(19.64%)	
Vault repair-SSF	1(11.11%)	02(3.57%)	0.162

Fisher's exact test is used to assess the association between type of surgery and early post-operative urinary retention. Among the patients who had post operative urinary retention, five patients (55.56%) belonged to VH-PFR category. In this study, it is not statistically significant. P value is 0.162 (Table 12).

Figure 27



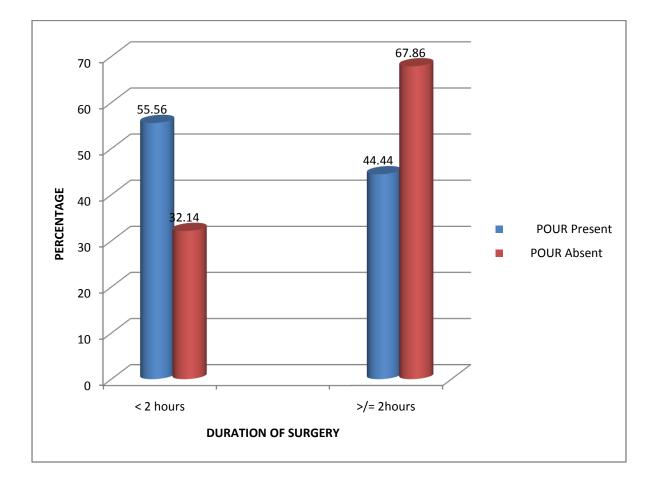
DURATION OF SURGERY

TABLE 13

Duration of surgery	POUR		P value
	Present	Absent	
Less than 2 hours	5(55.56%)	18(32.14%)	0.173
More than or equal to 2hours	4(44.44%)	38(67.86%)	

Pearson chi square test is used to assess the association between duration of surgery and early post-operative urinary retention. Among the patients who had post operative urinary retention, five patients (55.56%) had duration of surgery less than two hours. In this study, it is not statistically significant. P value is 0.173 (Table 13).

Figure 28



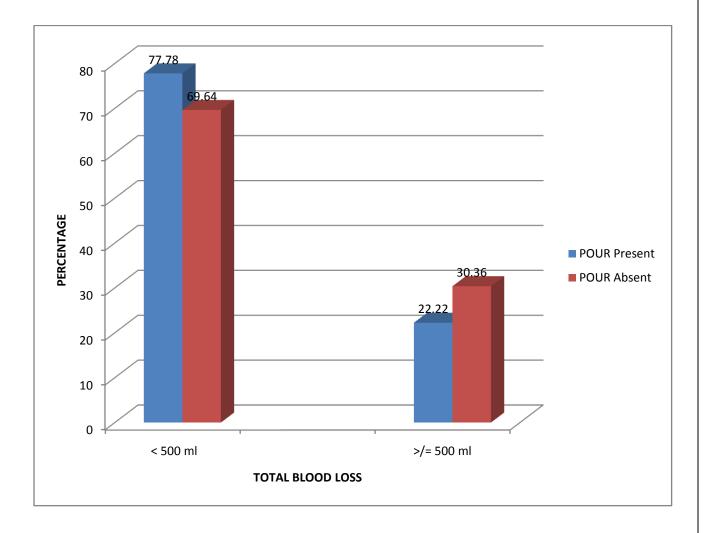
INTRA OPERATIVE BLOOD LOSS

TABLE 14

Total blood loss	POUR		P value
	Present	Absent	
Less than 500 ml	7(77.78%)	39(69.64%)	0.618
More than or equal to 500 ml	2(22.22%)	17(30.36%)	

Pearson chi square test is used to assess the association between intra operative blood loss and early post-operative urinary retention. Among the patients who had post operative urinary retention, seven patients (77.78 %) had blood loss less than 500 ml. In this study, it is not statistically significant. P value is 0.618(Table 14).

Figure 29



DISCUSSION

The life time risk of women undergoing surgery for prolapse or incontinence is 11%(11). Sensation for voiding is limited by post-surgical pain and associated spasm of the muscles leading to retention of urine. Postoperative voiding dysfunction among the patients who undergo surgery for urinary incontinence and pelvic organ prolapse is estimated to be 2.5-24%(6).The most common complication following pelvic reconstructive surgery is urinary retention. Post-operative urinary retention may be transient and cause little patient discomfort, but if not relieved it may permanently damage urinary function(5). Following the pelvic reconstructive surgery, patients may take significant time to resume the normal voiding. Voiding dysfunction may range from irritative symptoms to complete obstruction. Hence patients who undergo vaginal surgery for pelvic organ prolapse require continuous bladder drainage in the immediate post-operative period (6).

In patients with pelvic organ prolapse, several risk factors like age of the patient, size of the genital hiatus, stage of prolapse, and tone of levator ani are known to be associated with early post-operative voiding disorders(1).

Catherization of bladder is the standardized treatment for urinary retention post operatively. It is done either by prolonged catheterization or clean intermittent catherization until normal voiding pattern is restored. It is during this period that patient experiences disappointment and frustration due to discomfort and restricted mobility(10) Clinician's perception of the condition and vigilance in its diagnosis play a vital role in successful care of patients undergoing surgical repair. If early voiding dysfunction can be accurately predicted, pre operatively patient can be counselled appropriately(1)

Retention of urine

Urinary retention is a common problem following surgery. It causes pain, anxiety, increased cost and prolonged hospital stay in many patients(15).

Definition:

Inability to void in the presence of a full bladder(16,17)

Retention of urine is a common postoperative problem causing bladder overdistension and permanent detrusor damage. Detrusor damage can cause problems of bladder motility and atony. Damage to the detrusor muscle makes bladder unable to contract and empty(18).

- Urinary retention can be clinically divided into
 - Overt retention
 - Covert retention(20)

• OVERT RETENTION:

Overt retention is symptomatic and characterized by the inability to void accompanied by pain and discomfort.

• COVERT RETENTION:

Covert retention is asymptomatic. Women cannot empty bladder completely and the retention is detected only by catheterisation or ultrasound. It is usually self limiting(20,21).

COMPLICATIONS OF URINARY RETENTION

BLADDER OVERDISTENSION:

Bladder distension accounts for 44% of complications. It is one of the major complications of post-operative urinary retention(16). As the bladder gets distended there is atonia of the bladder followed by urinary retention and urinary infection.

Few human and animal studies showed that acute over- distension can cause structural and functional abnormalities of the bladder. This can occur in a short duration of time as short as 4 hours which is due to bladder ischemia(16). Persistent urinary retention can exacerbate the storage dysfunction of the bladder by decreasing the bladder capacity and producing the sensation of incomplete voiding. This further result in frequency of micturition, urinary urgency and overflow incontinence(16)

Baldini et al. showed a direct correlation between post operative bladder volume and risk of persistent urinary retention(16).

URINE INFECTION

Urine infection is a direct complication of postoperative urinary retention because there is stasis of urine due to incomplete bladder emptying. This acts as a good source for growth of organisms. Heavy bacterial colonization of the perineum, periurethral region, and short urethra all contribute to the urinary tract infection (9). It is an indirect complication of post operative urine retention since it necessitates catheterisation. The incidence of urinary infection after one episode of catheterisation is around eight percent(9).

DIAGNOSIS

Clinically urinary retention can be diagnosed by

- History and Clinical examination
- Ultrasound examination(16)

Pain and discomfort in lower abdomen is one of conventional predictor of urinary retention(16). Palpation and percussion of bladder in supra pubic region is a clinical method to diagnose urinary retention. But it lacks sensitivity in providing accurate measure(22). Lamonerie et al suggested ultrasound scan for assessing bladder volume after surgery, in order to identify cases of over distension early and to enable prompt treatment(19). Measurement of residual urine in bladder after an act of voluntary void is one of the non-invasive methods of assessing bladder dysfunction(23). Post void residue is the measurement of urine in bladder by ultrasound within twenty minutes after last void(24).

The causes of urinary retention after vaginal prolapse surgery are multifactorial. Predictors for post-operative urinary retention after pelvic reconstructive surgery are stage of prolapse, age, body mass index, menopausal status, size of genital hiatus, tone of levator ani muscle, pre-operative post void residue, type of anaesthesia, type and technique of surgery, operation time, intra-operative blood loss(12).

STAGE OF PROLAPSE

In cystocele, protrusion of the bladder into the vagina causes kinking of the urethra. This leads to retention of urine preoperatively. Post operatively the degree of prolapse plays a major role in postoperative urinary retention.Among the various variables, degree of prolapse and type of surgery has a major role to play to predict the rate of urinary retention(16).

According to multicentre, prospective, cohort study of women undergoing pelvic reconstructive and/or incontinence surgery done by Komesu et al ; vaginal apex suspension or the preoperative presence of grade III and IV vaginal apex descent are associated with prolonged postoperative catheterization(27).

According to this study, P value is 0.062. Among the patients who had post operative urinary retention, seven patients (77.78%) belonged to stage III pelvic organ prolapsed category (Table 2). Stage of prolapse is not significant as predictor for POUR.

AGE

Post-operative urinary retention increase with age, the risk increases by 2.4 times in patients over 50 years of age (16).Several studies have demonstrated age as a predictor of postoperative voiding efficiency. According to study done by Keita, Age: more than or equal to fifty years, was independent predictive factor for post-operative urinary retention(18). Possible reason could be age related progressive neuronal damage leading to bladder dysfunction (16). Aging and parity are associated with fibrosis, variation in fibre diameter and centralization of nuclei in levator ani muscle.

In this study, 64.29 % of women are more than fifty years of age. Among the patients who had post operative urinary retention, six patients (66.7%) belonged to age group more than or equal to 50 years. P value is more than 0.89 and this variable is not statistically significant in this study (Table 3).

BODY MASS INDEX

4).

It is hypothesized that excess body weight is associated with increased abdominal pressure during physical activity. This in turn increases bladder pressure and urethral hyper mobility(31,32).

According to study done by Revicky, there is no statistically significant influence of obesity on the incidence of bladder injury or urinary retention(37). In this study, among the patients who had post operative urinary retention, four patients (44.44%) belonged to overweight category. P value is 0.093. According to this study, there is no association between body mass index and early post-operative urinary retention (Table

MENOPAUSE

In women with pelvic organ prolapse, it has been demonstrated that protein content and oestrogens in utero sacral ligaments, in the vagina, and in the parametrium of women with prolapse were reduced(2).

According to a retrospective study done at the Cleveland Clinic Foundation between August 1999 and July 2003, Menopausal status is potential predictors of prolonged post- operative urinary retention. In this study, P value is 0.33. Among the patients who had post operative urinary retention, eight patients (88.89%) belonged to menopause category (Table 6). Association between menopause and early postoperative urinary retention was not statistically significant.

SIZE OF GENITAL HIATUS

Pelvic floor denervation is thought to result in decreased levator tone and widening of genital hiatus(1). According to retrospective study done in Mississippi, patients with genital hiatus greater than 5 cm were 3 times more likely to have emptying disorders than those with less than 5cm(1). In this study, P value is 0.948. Among the patients who had post operative urinary retention, seven patients (77.78%) belonged to size of genital hiatus more than 5cm category (Table 7). Association between size of genital hiatus and early post-operative urinary retention was not statistically significant.

TONE OF LEVATOR ANI

It has been established that levator ani muscle injury increases the risk of pelvic organ prolapse. There is a direct correlation between the size of the defect and the symptoms and signs of prolapse(39). In the study done by Shafik etal, the most independent predictors of urinary retention are decreased levator contraction strength and increased pre-operative PVR urine(8). In our study, P value is 0.192. Among the patients who had post operative urinary retention, seven patients (87.5%) belonged to category where tone of LA is 3 (Table 8). Levator ani as clinical predictor for early post-operative urinary retention was not statistically significant.

PRE OPERATIVE PVR

According to a study done by Miller et al, post-void residual urine volume predicted delayed return to normal voiding(41). After pelvic reconstructive surgery, most patients with elevated post-void residual volume had normalization of the post-void residual volume(42).

Preoperative PVR is missing for 3 patients. Among the patients who had post operative urinary retention, two patients (25 %) belonged to PVR group more than or equal to 100 ml. In this study, it is not statistically significant. P value is 0.129 (Table 9).

UROFLOWMETRY

The International Continence Society recommends urodynamic evaluation in diagnostic workup of patients with pelvic organ prolapse scheduled for surgical repair(19).

According to a retrospective study, Urodynamic evaluation of stress urinary incontinence and pelvic organ prolapse pre operatively help in predicting voiding dysfunction(19). Absence of detrusor contraction on pre-operative urodynamic evaluation is an indicator for post-operative urinary retention. Detrusor pressure <12 cm H2O was considered weak pressure(41)

Uroflowmetry is missing in 10 patients and the other 10 patients were unable to perform this test as they were unable to void in sitting position. Ten patients were unable to undergo this investigation as they were unable to void in sitting position. Uroflowmetry is missing for ten patients. Among the patients who had post operative urinary retention, two patients (50 %) belonged abnormal uroflowmetry result group. In this study, it is not statistically significant. P value is 0.68(Table 10).

ANAESTHESIA

General anaesthetic agents interfere with the autonomic nervous system and cause bladder atony. After intrathecal injection of local anaesthetics, the sensation of urgency to void disappears within 30–60 seconds(16).According to a prospective study done in 2005, prolonged anaesthesia time was identified as an independent risk factor for post-operative urinary retention(43).

Among the patients who had post operative urinary retention, eight patients (88.89%) had spinal anaesthesia. In this study, it is not statistically significant at five percent level of significance. P value is more than 0.99(Table 11).

TYPE OF SURGERY

Sensation for voiding is limited by post-surgical pain and associated spasm of the muscles leading to retention of urine. Incidence of postoperative urinary retention varies between different types of surgeries(9).

Shekavat etal in 2008 and Thapa etal in 2010 in their studies did not find urinary retention in pelvic reconstructive surgeries(45,46). In patients who have undergone vaginal hysterectomy with pelvic floor repair, spasm oedema and tenderness of the puboccocygeous muscle in anterior colporraphy may pose a problem in voiding(9,43). Among the patients who had post operative urinary retention, five patients (55.56%) belonged to VH-PFR category. In this study, it is not statistically significant. P value is 0.162 (Table 12).

DURATION OF SURGERY

In a retrospective study by Petros, duration of surgery was found to be significantly associated with post-operative urinary retention(16). The reason for increased blood loss intra operatively as risk factor for urinary retention can be explained as prolonged operating time and extensive damage to innervations of detrusor muscle (7). Among the patients who had post operative urinary retention, five patients (55.56%) had duration of surgery less than two hours. In this study, it is not statistically significant. P value is 0.173 (Table 13).

INTRA OPERATIVE BLOOD LOSS

The reason for increased blood loss intra operatively as risk factor for urinary retention can be explained as prolonged operating time and extensive damage to innervations of detrusor muscle. According to retrospective study done in Netherlands, urinary retention after vaginal prolapse surgery occurs more frequently in women with severe intra-operative blood loss(7).

Among the patients who had post operative urinary retention, seven patients (77.78 %) had blood loss less than 500 ml. In this study, it is not statistically significant. P value is 0.618 (Table 14).

In univariate analysis, all the eleven predictors for early post operative urinary retention are not significant. However, two variables: stage of prolapse and body mass index are analysed by multiple logistic regression as P value is <0.1.

TABLE 15 Multiple logistic regression assessing the association of risk factors with POUR

	Odds Batia		
Variables	Ratio (OR)	95% CI of OR	p-value
Stage of prolapse			
1,2 [†]	1.00	-	_
3	0.29	0.02, 3.52	0.382
4	1.00	-	NA
	1.00		
BMI (kg/m2)			
Underweight (<18.5)	1.00	-	NA
Normal [†] (18.5-24.9)	1.00	-	-
Overweight (25-29.9)	2.29	0.32, 16.51	0.413
Obese (>=30)	8.00	0.80, 79.65	0.076

[†]Reference category; NA-Not Available due to zero's in either of the outcome category

Patients with stage 3 pelvic organ prolapse (OR: 0.29) had low risk for POUR compared to patients with stage 1 and 2 pelvic organ prolapse (OR: 1) .This is however not statistically significant.

Patients who are overweight (OR: 2.29) had higher risk for POUR than patients with normal BMI (OR: 1). This is not statistically significant.

CONCLUSION

- The prevalence of early post-operative urinary retention following pelvic reconstructive surgery was 13.8 %. Covert retention was seen in 55.55% of the patients while 44.44% of patients had overt retention.
- 2. All the eleven variables: stage of prolapse, age, body mass index, menopausal status, size of genital hiatus, tone of levator ani muscle, pre-operative post void residue, type of anaesthesia, type and technique of surgery, operation time, and intra-operative blood loss were statistically insignificant as predictors for early post operative urinary retention.
- 3. Patients with stage 3 pelvic organ prolapse (OR: 0.29) had low risk for POUR when compared to patients with stage 1 and 2 pelvic organ prolapse (OR: 1). This is however not statistically significant. Patients who were overweight (OR: 2.29) had higher risk for POUR than patients with normal BMI (OR: 1). This is not statistically significant.

LIMITATION OF THE STUDY

This is a cohort study.

This study does not reflect exact prevalence of early post-operative urinary retention due to its small sample size. Hence larger sample size is required for determining prevalence.

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ANNEXURES

CLINICAL PREDICTORS FOR EARLY POST OPERATIVE URINARY RETENTION

Name :	Hospital number :	Mobile no:					
Age (in years) :							
Height :							
Weight:							
Parity : 1.Primi	[]						
2.Multi							
Menopause : 1.Yes	[]						
2.No							
Stage of Prolapse : I/I	I/III/IV []						
Aa Ba	С						
Gh Pb	TVL						
Ap Bp	D						
Pre op flow and PVR :	[]						
Date of surgery :							
Type of surgery : []						
•PFR							
•VH+PFR							
•VH-PFR WITH SSF							
•VAULT REPAIR+/-SS	F						

Intra operative complications : 1. Yes 2.No []
Duration of surgery (hours) : []
Anesthesia []
1.Spinal
2.Epidural
3.General
4.others
Total blood loss: []
Duration of catheter:[]
1. 48hours
2. 72hours
Post operative PVR: []
1.<300 ML
2.>300 ML
Voided volume :
Total bladder volume:PVR + VOIDED VOLUME
Second PVR :

2.No First recatheterization: 1.Yes []

Second recatheterization/Self intermittent catheterization []

1.Yes

2.No

Urodynamic evaluation: []

1.Yes 2.No

INFORMATION SHEET

Difficulty in passing urine after pelvic reconstructive surgery is a common complication. It occurs in 2.5% to 24% of patients. Inability to pass urine properly after catheter removal can cause urinary infection, damage to urinary bladder, prolonged hospital stay and further increase in pain and suffering to patients. This is a study to find out the risk factors associated with urinary retention like age,

menopause, stage of prolapse, type of surgery and anesthesia.

You are invited to participate in this study –

CLINICAL PREDICTORS OF EARLY POST OPERATIVE URINARY RETENTION AFTER PELVIC RECONSTRUCTIVE SURGERY

Your participation is voluntary. If you are happy to participate in this study, your details will be noted and kept confidential. You will receive the routine treatment for the problem. There is no monetary incentive provided for participation in this study. You will have no bearing on the quality of care given and can withdraw from the study if you wish so.

Your participation will be of tremendous help in management of urinary retention. Contact details:

Dr.V.Annie Prasanthi

PG REGISTRAR

CMC, Vellore. Mobile no: 9843676327

Informed Consent form to participate in a research study

Study Title: CLINICAL PREDICTORS OF EARLY POST OPERATIVE URINARY RETENTION AFTER PELVIC RECONSTUCTIVE SURGERY

Study Number: _____

Initials: Subject's Subject's

Name:

Date of Birth / Age: _____

(Subject)

- I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. []
- I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. []
- I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. []
- I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
- (v) I agree to take part in the above study. []

Signature (or Thumb impression) of the Subject/Legally Acceptable
Date://
Signatory's Name:
Signature:
Or
Representative:
Date://
Signatory's Name:
Signature of the Investigator:
Date:/
Study Investigator's Name:
Signature or thumb impression of the Witness:
Date://
Name & Address of the Witness:

Master data

					Meno		Tone			
slno	name	age	height	weight	pause	sizeGH	LAM	UF	prePVR	typesurg
1	021650g Chinnathai	55	153	51	1	5	3	9	27	1
2	020149g anjali roy	49	141	50.1	1	5	3	9		2
3	247553a lavanya	61	144	49	1	4	5	1	27	2
4	014635gseetabai	46	151	40.9	2	7	3	9	71	2
5	042407gMuniya	68	150	66	1	4	4	1	58	3
6	048148G VIMALA	52	144	64	1	5	3	3	44	2
7	067363g Suniti	61	144	44.5	1	5	3	1	26	2
8	425575Anavanee	44	155	44.46	1	6	3	1	42	3
9	060939GJamuna	43	154	61	2	5	4	1	15	2
10	070709GPalani	45	150	46.2	2	5	3	1	87	2
11	004511CPRIYADEV	40	157	70	2	4	4	1	12	2
12	334645DJAVITHRI	60	145	46	1	5	3	1	64	2
13	024718GMALLIGA	58	150	41	1	5	3	2	46	2
14	049246GRANI	62	149	59	1	5	3	1	0	2
15	090900GPUSHPA	58	148	56	1	5	3	3	280	2
16	071612GRABEYA	53	148	46.3	1	5	4	1	79	2
17	573625BGAYATHRI	66	167	67.2	1	5	3	2	0	2
18	021934GKOMALA	46	149	47	2	5	3	2	5	2
19	089723Gsabeerun	60	152	43	1	5	3	2	100	3
20	719826CTHANJEYA	51	148	60.7	1	5	3	2	79	2
21	066955FTUSUKNDU	68	147	40.7	1	5	4	2	20	2
22	125365GBACHHUDE	56	142	36.2	1	5	2	1	0	2
23	285789DHABIBABE	42	142	42	1	5	3	1	26	2
24	126197GVANITHA	46	153	54.5	1	6	3	3	0	3
25	101539GANNAMAL	49	153	61.4	2	5	3	1	25	2
26	133570GMALADAS	34	155	43	2	4	4	1	721	3
27	128637GSUBULAGA	64	145	35	1	4	4	2	25	2
28	931484FBEULAH	42	152	65.5	2	5	4	1	68	2
29	094431GJAMUNIDE	46	152	43	1	5	4	2	43	2
30	158202GSARASWAT	44	152	43.3	1	6	4	2	0	4
31	090041gmalarsel	49	147	51	1	5	4	2	31	2
32	039789gflora	49	153	53.9	1	5	4	1	25	2
33	143726gBrajeshw	46	148	64.4	2	5	4	9	0	2
34	159179gpattamma	75	150	35.5	1	5	3	9		2
35	119014gnagamani	66	149	60.5	1	4	3	4	59	3
36	788804bradha	50	149	84	1	5	3	1	58	3
37	408804bhema	42	149	38.4	2	4	4	1		2
38	145154ajanaki	59	163	61.4	1	5	3	1	74	2
39	026020avanajaks	68	147	41.2	1	4	3	9	34	3
40	174108g Sikha	63	153	51.7	1	7	3	2	32	2

42 771307dsamundee 43 149 53 2 5 4 1 0 2 43 164589gRamani 38 160 81.5 2 5 4 2 15 2 44 148842gBanumath 56 164 67 1 6 4 1 76 2 45 909109cpattamma 80 143 49 1 5 3 2 147 2 46 17323granjidha 50 147 50.8 1 5 3 1 2 47 826280cindrani 58 148 68 1 6 3 2 26 2 48 307511fAnmal 55 153 46.9 1 6 3 2 26 2 3 3 5 19480gsaguntha 63 145 63 1 6 2 9 22 3 3 5 2 3 1 123 22 3 5 5 3 1 123 2	r	1									
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45 909109cpattamma 80 143 49 1 5 3 2 147 2 46 173239granjidha 50 147 50.8 1 5 3 1 2 47 826280cindrani 58 148 68 1 6 3 3 86 2 48 307511fAnmal 55 153 46.9 1 6 3 2 26 2 49 188396CRajammal 62 156 36.8 1 7 1 9 63 33 50 194800gsaguntha 63 145 63 1 6 2 9 22 33 51 021325arosejose 77 149 55 1 5 3 1 123 22 52 194433galokadas 52 153 66 1 6 3 3 9 2 53 600190fhelen 45<	43	164589gRamani	38	160	81.5	2	5	4	2	15	2
46 173239granjidha 50 147 50.8 1 5 3 1 2 47 826280cindrani 58 148 68 1 6 3 3 86 2 48 307511fAnmal 55 153 46.9 1 6 3 2 26 2 49 188396cRajammal 62 156 36.8 1 7 1 9 63 3 50 194800gsaguntha 63 145 63 1 6 2 9 22 3 51 021325arosejose 77 149 55 1 5 3 1 123 22 52 194433galokadas 52 153 66 1 6 3 3 9 2 53 660394dvasuki 51 155 50.3 1 6 4 1 90 2 54 648152dlapari 53 <td>44</td> <td>148842gBanumath</td> <td>56</td> <td>164</td> <td>67</td> <td>1</td> <td>6</td> <td>4</td> <td>1</td> <td>76</td> <td>2</td>	44	148842gBanumath	56	164	67	1	6	4	1	76	2
47 826280cindrani 58 148 68 1 6 3 3 86 2 48 307511fAnmal 55 153 46.9 1 6 3 2 26 2 49 188396cRajammal 62 156 36.8 1 7 1 9 63 33 50 194800gsaguntha 63 145 63 1 6 2 9 22 33 51 021325arosejose 77 149 55 1 5 3 1 123 22 52 194433galokadas 52 153 66 1 6 3 3 9 22 53 660394dvasuki 51 155 50.3 1 6 4 1 90 22 54 648152dlapari 53 146 48 1 4 4 2 36 22 55 400190fhelen 45 155 54.4 1 5 3 1 12 2 <td>45</td> <td>909109cpattamma</td> <td>80</td> <td>143</td> <td>49</td> <td>1</td> <td>5</td> <td>3</td> <td>2</td> <td>147</td> <td>2</td>	45	909109cpattamma	80	143	49	1	5	3	2	147	2
48 307511fAnmal 55 153 46.9 1 6 3 2 26 2 49 188396cRajammal 62 156 36.8 1 7 1 9 63 3 50 194800gsaguntha 63 145 63 1 6 2 9 22 3 51 021325arosejose 77 149 55 1 5 3 1 123 22 52 194433galokadas 52 153 66 1 6 3 3 9 22 53 660394dvasuki 51 155 50.3 1 6 4 1 90 22 54 648152dlapari 53 146 48 1 4 4 2 36 22 55 400190fhelen 45 155 68.5 2 7 3 1 12 22 57 171359dmirarudr 38 157 71 2 4 3 9 56 11 </td <td>46</td> <td>173239granjidha</td> <td>50</td> <td>147</td> <td>50.8</td> <td>1</td> <td>5</td> <td>3</td> <td>1</td> <td></td> <td>2</td>	46	173239granjidha	50	147	50.8	1	5	3	1		2
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52 194433galokadas 52 153 66 1 6 3 3 9 2 53 660394dvasuki 51 155 50.3 1 6 4 1 90 2 54 648152dlapari 53 146 48 1 4 4 2 36 2 55 400190fhelen 45 155 68.5 2 7 3 1 28 3 56 218612gebenezer 65 155 54.4 1 5 3 1 12 22 57 171359dmirarudr 38 157 71 2 4 3 9 56 11 58 257099fprabhapr 66 140 34.6 1 4 3 2 33 2 59 207672gnagama 60 164 50.9 1 4 4 1 2 61 225714gnaseemab 38 153 76.8 2 6 3 2 76 3	50	194800gsaguntha	63	145	63	1	6	2	9	22	3
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54 648152dlapari 53 146 48 1 4 4 2 36 2 55 400190fhelen 45 155 68.5 2 7 3 1 28 33 56 218612gebenezer 65 155 54.4 1 5 3 1 12 2 57 171359dmirarudr 38 157 71 2 4 3 9 56 11 58 257099fprabhapr 66 140 34.6 1 4 3 2 33 22 59 207672gnagama 60 156 58 1 5 4 2 93 4 60 303000fkantha 60 164 50.9 1 4 4 1 22 61 225714gnaseemab 38 153 76.8 2 6 3 2 76 3 63 238181gdhanalax 62 147 52.1 1 4 3 3 235 3	52	194433galokadas	52	153	66	1	6	3	3	9	2
55 400190fhelen 45 155 68.5 2 7 3 1 28 3 56 218612gebenezer 65 155 54.4 1 5 3 1 12 2 57 171359dmirarudr 38 157 71 2 4 3 9 56 11 58 257099fprabhapr 66 140 34.6 1 4 3 2 33 22 59 207672gnagama 60 156 58 1 5 4 2 93 4 60 303000fkantha 60 164 50.9 1 4 4 1 2 61 225714gnaseemab 38 153 76.8 2 6 3 2 52 2 62 220124glakshmi 56 135 51 1 6 3 2 76 33 63 238181gdhanalax 62 147 52.1 1 4 3 3 235 33	53	660394 dvasuki	51	155	50.3	1	6	4	1	90	2
56218612gebenezer6515554.4153112257171359dmirarudr3815771243956158257099fprabhapr6614034.6143233259207672gnagama6015658154293460303000fkantha6016450.91441261225714gnaseemab3815376.8263252262220124glakshmi5613551163276363238181gdhanalax6214752.1143144264325695dkannama6615243.51433235365232380gayisha6314958159322466214291gramathul5314756154284267244961gtsivagam711505914930368312792fmamatha3515653294233269226458gkabeera37145532942332	54	648152dlapari	53	146	48	1	4	4	2	36	2
57 171359dmirarudr 38 157 71 2 4 3 9 56 1 58 257099fprabhapr 66 140 34.6 1 4 3 2 33 2 59 207672gnagama 60 156 58 1 5 4 2 93 4 60 303000fkantha 60 164 50.9 1 4 4 1 2 61 225714gnaseemab 38 153 76.8 2 6 3 2 76 3 62 220124glakshmi 56 135 51 1 6 3 2 76 3 63 238181gdhanalax 62 147 52.1 1 4 3 1 44 2 64 325695dkannama 66 152 43.5 1 4 3 3 235 3 65 232380gayisha 63 149 58 1 5 9 3 22 4	55	400190fhelen	45	155	68.5	2	7	3	1	28	3
58 257099fprabhapr 66 140 34.6 1 4 3 2 33 2 59 207672gnagama 60 156 58 1 5 4 2 93 4 60 303000fkantha 60 164 50.9 1 4 4 1 2 61 225714gnaseemab 38 153 76.8 2 6 3 2 52 2 62 220124glakshmi 56 135 51 1 6 3 2 76 3 63 238181gdhanalax 62 147 52.1 1 4 3 1 44 2 64 325695dkannama 66 152 43.5 1 4 3 3 235 3 65 232380gayisha 63 149 58 1 5 9 3 22 4 66 214291gramathul 53 147 56 1 5 4 2 84 2	56	218612gebenezer	65	155	54.4	1	5	3	1	12	2
59 207672gnagama 60 156 58 1 5 4 2 93 4 60 303000fkantha 60 164 50.9 1 4 4 1 2 61 225714gnaseemab 38 153 76.8 2 6 3 2 52 2 62 220124glakshmi 56 135 51 1 6 3 2 76 3 63 238181gdhanalax 62 147 52.1 1 4 3 1 44 2 64 325695dkannama 66 152 43.5 1 4 3 3 235 3 65 232380gayisha 63 149 58 1 5 9 3 22 4 66 214291gramathul 53 147 56 1 5 4 2 84 2 67 244961gtsivagam 71 150 59 1 4 9 3 0 3 <td< td=""><td>57</td><td>171359dmirarudr</td><td>38</td><td>157</td><td>71</td><td>2</td><td>4</td><td>3</td><td>9</td><td>56</td><td>1</td></td<>	57	171359dmirarudr	38	157	71	2	4	3	9	56	1
60 303000fkantha 60 164 50.9 1 4 4 1 2 61 225714gnaseemab 38 153 76.8 2 6 3 2 52 2 62 220124glakshmi 56 135 51 1 6 3 2 76 3 63 238181gdhanalax 62 147 52.1 1 4 3 1 44 2 64 325695dkannama 66 152 43.5 1 4 3 3 235 3 65 232380gayisha 63 149 58 1 5 9 3 22 4 66 214291gramathul 53 147 56 1 5 4 2 84 2 67 244961gtsivagam 71 150 59 1 4 9 3 0 33 68 312792fmamatha 35 156 53 2 4 4 9 15 2 <	58	257099fprabhapr	66	140	34.6	1	4	3	2	33	2
61225714gnaseemab3815376.8263252262220124glakshmi5613551163276363238181gdhanalax6214752.1143144264325695dkannama6615243.51433235365232380gayisha6314958159322466214291gramathul5314756154284267244961gtsivagam711505914930368312792fmamatha3515653244915269226458gkabeera37145532942332	59	207672gnagama	60	156	58	1	5	4	2	93	4
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64325695dkannama6615243.51433235365232380gayisha6314958159322466214291gramathul5314756154284267244961gtsivagam711505914930368312792fmamatha3515653244915269226458gkabeera37145532942332	62	220124glakshmi	56	135	51	1	6	3	2	76	3
65232380gayisha6314958159322466214291gramathul5314756154284267244961gtsivagam711505914930368312792fmamatha3515653244915269226458gkabeera37145532942332	63	238181gdhanalax	62	147	52.1	1	4	3	1	44	2
66214291gramathul5314756154284267244961gtsivagam711505914930368312792fmamatha3515653244915269226458gkabeera37145532942332	64	325695dkannama	66	152	43.5	1	4	3	3	235	3
67244961gtsivagam711505914930368312792fmamatha3515653244915269226458gkabeera37145532942332	65	232380gayisha	63	149	58	1	5	9	3	22	4
68 312792fmamatha 35 156 53 2 4 4 9 15 2 69 226458gkabeera 37 145 53 2 9 4 2 33 2	66	214291gramathul	53	147	56	1	5	4	2	84	2
69 226458gkabeera 37 145 53 2 9 4 2 33 2	67	244961gtsivagam	71	150	59	1	4	9	3	0	3
	68	312792fmamatha	35	156	53	2	4	4	9	15	2
70 965244fvendamma 61 150 33.6 1 5 9 3 3	69	226458gkabeera	37	145	53	2	9	4	2	33	2
	70	965244 fvendamma	61	150	33.6	1	5	9	3		3

anaesthesi	TBL	dofcathete	pvrvol	dursurg1
1	250	2	150	
1	200	1	120	45
1	200	1	10	45
1	200	1	26	
1	300	2	40	30
1	200	2	240	30
1	200	1	65	30
3	200	2	210	30
1	500	1	64	30
1	600	1	90	
1	500		0	30
1	200	1	13	40

1	E00	1	01	
3	500	2	81 170	
1	400			20
1	300	2	276 36	30
	200	2		
1	500	2	35	20
1	200	2	36	30
1	700	2	150	30
1	200	2	250	30
4	200	1	91	30
1	300	1	17	30
1	500	2		15
1	200	1	10	15
1	300	1	58	
1	500	1	50	
1	200	1	20	20
1	500	1	41	
1	200	1	37	15
1	200	2	10	30
1	800	2	12	30
1	400	1	16	
3	200	1	68	
1	600		0	
1	300	2	27	30
1	200	1	180	30
3	200	1	86	
1	200	1	74	
3	700	2	24	30
3	1500		23	
1	500	1	13	
1	1000	1	16	
1	400	1	13	
1	200	2	16	
1	300	1	72	30
1	700	2	38	30
1	200	1	0	30
1	300	1	50	30
1	500	2	38	30
1	300	2	42	
1	100	1	0	30
3	200	1	56	30
1	200	1	56	
3	200	1	176	
3	400	1	20	
1	200	1	0	

1	200	1	250	
1	200	1	258	
1	200	1	30	30
1	200	1	33	
1	400	2	0	0
1	400	1	0	20
1	500	2	86	
1	400	2	320	30
1	500	2	310	0
1	300	2	324	45
1	200	1	18	30
1	1500		56	
1	600	1	56	
3	800		84	
3	800		57	45



OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical) Director, Christian Counseling Center, Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho Chairperson, Research Committee & Principal

Dr. Nihal Thomas,

MD., MNAMS., DNB (Enuo), FRACP (Endo), FRCP (Edin), FRCP (Glasg) Deputy Chairperson Secretary, Ethics Committee, IRB Additional Vice Principal (Research)

October 07, 2014

Dr. V. Annie Prasanthi PG Registrar Department of Obstetrics & Gynaecology Christian Medical College, Vellore 632 004

Sub: Fluid Research Grant:

Clinical predictors of early post-operative urinary retention after pelvic reconstructive surgery.

Dr. V. Annie Prasanthi, Obstetrics & Gynaecology –Unit - 2, Dr. Aruna Kekre, Dr. Lilly Varghese, Obstetrics & Gynaecology –Unit - 2, Dr. Nitin Kekre, Urology 2, CMC, Vellore.

Ref: IRB Min No: 9046 [OBSERVE] dated 04.09.2014

Dear Dr. V. Annie Prasanthi,

I enclose the following documents

1. Institutional Review Board approval 2. Agreement CHRISTIAN MEDICAL COLLEGE

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas Secretary (Ethics Committee Institutional Review Board Dr. NIHAL 'THOMAS MD.,MNAMS, DNB(Endo), FRACP(Endo), FRCP(Edin), FRCP(Glasg) SECRETARY - (ETHICS COMMITTEE) Institutional Review Board, Christian Medical College, Vellore - 632 002.

Cc: Dr. Aruna Kekre, Obstetrics & Gynaecology -Unit - 2, CMC, Vellore.

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OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) HRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical) Director, Christian Counseling Center, Chairperson, Ethics Committee.

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Dr. Nihal Thomas,

MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg) Deputy Chairperson Secretary, Ethics Committee, IRB Additional Vice Principal (Research)

October 07, 2014

Dr. V. Annie Prasanthi PG Registrar Department of Obstetrics & Gynaecology Christian Medical College, Vellore 632 004

Sub: Fluid Research Grant:

Clinical predictors of early post-operative urinary retention after pelvic reconstructive surgery.

Dr. V. Annie Prasanthi, Obstetrics & Gynaecology –Unit - 2, Dr. Aruna Kekre, Dr. Lilly Varghese, Obstetrics & Gynaecology –Unit - 2, Dr. Nitin Kekre, Urology 2, CMC, Vellore.

Ref: IRB Min No: 2046 [OBSERVE] dated 04.09.2014

Dear Dr. V. Annie Prasanthi,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Clinical predictors of early post-operative urinary retention after pelvic reconstructive surgery," on September 4th 2014.

CHRISTIAN MEDICAL COLLEGE

The Committees reviewed the following documents:

- 1. IRB Application format
- 2. Curriculum Vitae' of Dr. V. Annie Prasanthi, Dr. Aruna Kekre, Dr. Lilly Varghese, Dr. Nitin Kekre
- 3. Proforma
- 4. Informed Consent form (English, Telugu, Bengali, Hindi & Tamil)
- 5. Information Sheet (English, Telugu, Bengali, Hindi & Tamil)
- 6. No of documents 1-5

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on September 4th 2014 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) HRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical) Director, Christian Counseling Center, Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho Chairperson, Research Committee & Principal

Dr. Nihal Thomas,

MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg) Deputy Chairperson Secretary, Ethics Committee, IRB Additional Vice Principal (Research)

Name	Qualification	Designation	Other Afril'
Dr. Benjamin Perakath	MBBS, MS, FRCS	Professor, Colorectal	Other Affiliations Internal, Clinician
Dr. Rajesh Kannangai	MD, Ph D.	Surgery, CMC, Vellore Professor & In-charge Retrovirus Laboratory (NRL under NACO), Department of Clinical Virology, CMC, Vellore	Internal, Clinician
Dr. Anup Ramachandran Dr. Simon Pavamani	Ph. D	The Wellcome Trust Research Laboratory Gastrointestinal Sciences, CMC, Vellore	Internal, Basic Medical Scientis
	MBBS, MD	Professor, Radiotherapy, CMC, Vellore	Internal, Clinician
Dr. Niranjan Thomas	DCH, MD, DNB (Paediateres)	Professor, Neonatology, CMC	Internal, Clinician
Dr. Mathew Joseph	MBBS, MCH CHRISTIAN MEDIC VELLOI	Corres de la la	Internal, Clinician
Dr. Visalakshi. J	MPH, PhD	Lecturer, Dept of Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Inian amarasam	MS, FRCS, FRACS	Professor, Surgery, CMC, Vellore	Internal,
Dr. Anand Zachariah	MBBS, PhD	Professor, Medicine, CMC, Vellore	Clinician Internal, Clinician
Dr. T. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician

IRB Min No: 9046 [OBSERVE] dated 04.09.2014



OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

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Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho Chairperson, Research Committee & Principal

Dr. Nihal Thomas,

MD., MNAMS., DNB (Enco), FRACP (Endo), FRCP (Edin), FRCP (Glasg) Deputy Chairperson Secretary, Ethics Committee, IRB Additional Vice Principal (Research)

		domonal vice rincipal (Kes	earch)
Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology), Dr. Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Mrs. Pattabiraman	B. Sc, DSSA	Social Worker, Vellore	,
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL.	Sr. Legal Officer, CMC, Vellore	Lay Person Internal,
Rev. Joseph Devaraj	B. Sc, BD	Chaplaincy Department, CMC, Vellore	Legal Expert Internal, Social Scientist
Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Mrs. Sheela Durai	MSc Nursing	Addl. Deputy Nursing Superintendent, Professor of Nursing in Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Mr. C. Sampath	BSC BL VELLOR	Legal Expert Vellore	External, Legal Expert
Dr. Nihal Thomas,		Professor & Head, Endocrinology. Additional Vice Principal (Research), Deputy Chairperson, IRB, Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician

IRB Min No: 9046 [OBSERVE] dated 04.09.2014

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OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

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Dr. Nihal Thomas, MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg) Deputy Chairperson Secretary, Ethics Committee, IRB Additional Vice Principal (Research)

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any adverse events occurring in the course of the project, any amendments in the protocol and the patient information / informed consent. On completion of the study you are expected to submit a copy of the final report. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

Fluid Grant Allocation:

A sum of 50,000/ - INR (Fifty Thousand only) will be granted for 1 year.

Yours sincerely

Dr. Nihal Thomas Secretary (Ethics Committee) Institutional Review Board Christiania Review Board

Christian Medical College, Vellore - 632 002.

VELLORE

Cc: Dr. Aruna Kekre, Obstetrics & Gynaecology -Unit - 2, CMC, Vellore.

IRB Min No: 9046 [OBSERVE] dated 04.09.2014

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