



A RANDOMIZED CONTROLLED TRIAL OF EARLY VERSUS ROUTINE REMOVAL OF SELF RETAINING URINARY CATHETER AFTER UNCOMPLICATED TOTAL LAPROSCOPIC HYSTERECTOMY

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INTRODUCTION-

- During Total laparoscopic hysterectomy (TLH), standard care is to place an indwelling catheter, usually self retaining, during surgery to avoid iatrogenic injuries of the bladder, monitor urinary output and check for hematuria.
- Time of removal of this catheter in uncomplicated cases is usually after 24 hours. There is limited guidelines for catheter removal post TLH.
- Although early removal of catheter may overcome all these issues but also have been associated with higher urinary retention rates and re-catheterisation.
- With this in mind, we intend to evaluate if early catheter removal (ECR- <4 hours) after TLH was associated with similar or better outcomes compared with routine catheter removal (RCR- >24hrs) through this study.
- If ECR outcomes are found to be similar or better than RCR , patients may be discharged earlier reducing hospital stay and well being.

AIM AND OBJECTIVES-

Aim- To assess voiding difficulty in Early Catheter Removal versus Routine Removal of Catheter in Total Laparoscopic Hysterectomy patients.

A. Primary objective:

Voiding difficulty after Early Catheter Removal (time frame: 6 hours after removal of catheter) in uncomplicated Total Laparoscopic Hysterectomy patients.

B. Secondary objective:

- Post Void Residual urine (PVR)
- Rate of recatheterization
- Incidence of Urinary Tract Infection in post-operative period in Total Laparoscopic Hysterectomy patients.

Inclusion & Exclusion criteria-

Inclusion criteria-

- All patients posted for total laparoscopic hysterectomy for benign indication (e.g.- Abnormal Uterine Bleeding, Fibroids)
- All patients posted for total laparoscopic hysterectomy for low-grade malignancy (endometrial, cervical)
- Patients willing to participate in study

Exclusion criteria-

- Patients not willing to participate in the study
- Pregnant women
- Patients having concomitant procedures such as prolapse surgery
- Patients with extensive adhesions like endometriosis surgery or advanced oncological dissection including nodal dissection
- Patients with stress and urge incontinence
- Patients with pre-operative Urinary tract infection
- Patients unable to void (Paraplegia, Multiple Sclerosis)

Study design: A prospective randomized controlled trial, non-inferiority based

SAMPLING-

- Sample size-** 50 in each group and total sample size of 100, Due to covid-19 pandemic, non-covid services were stopped for more than 5 months leading to not achieving the target / calculated sample size of 100, So only 64 patients were enrolled for TLH, out of which one patient had ureteric injury which was excluded from study and not included in statistical analysis. So total 63 patients were analyzed. 27 patients were in ECR and 36 patients were in RCR group analyzed.
- Sampling technique:** Simple Random Sampling
- Randomization details-** A computer-generated random number list was generated before start of study of the total sample size (100). The numbers were kept in sealed envelopes in the operation theatre. For the even numbers early removal of urinary catheter was planned (GROUP ECR) and for the odd number routine catheter removal (GROUP RCR) was planned. After the operation, the envelope was selected out of the many and patient assigned to either group ECR or RCR according to the number selected from envelope.

Study procedure-

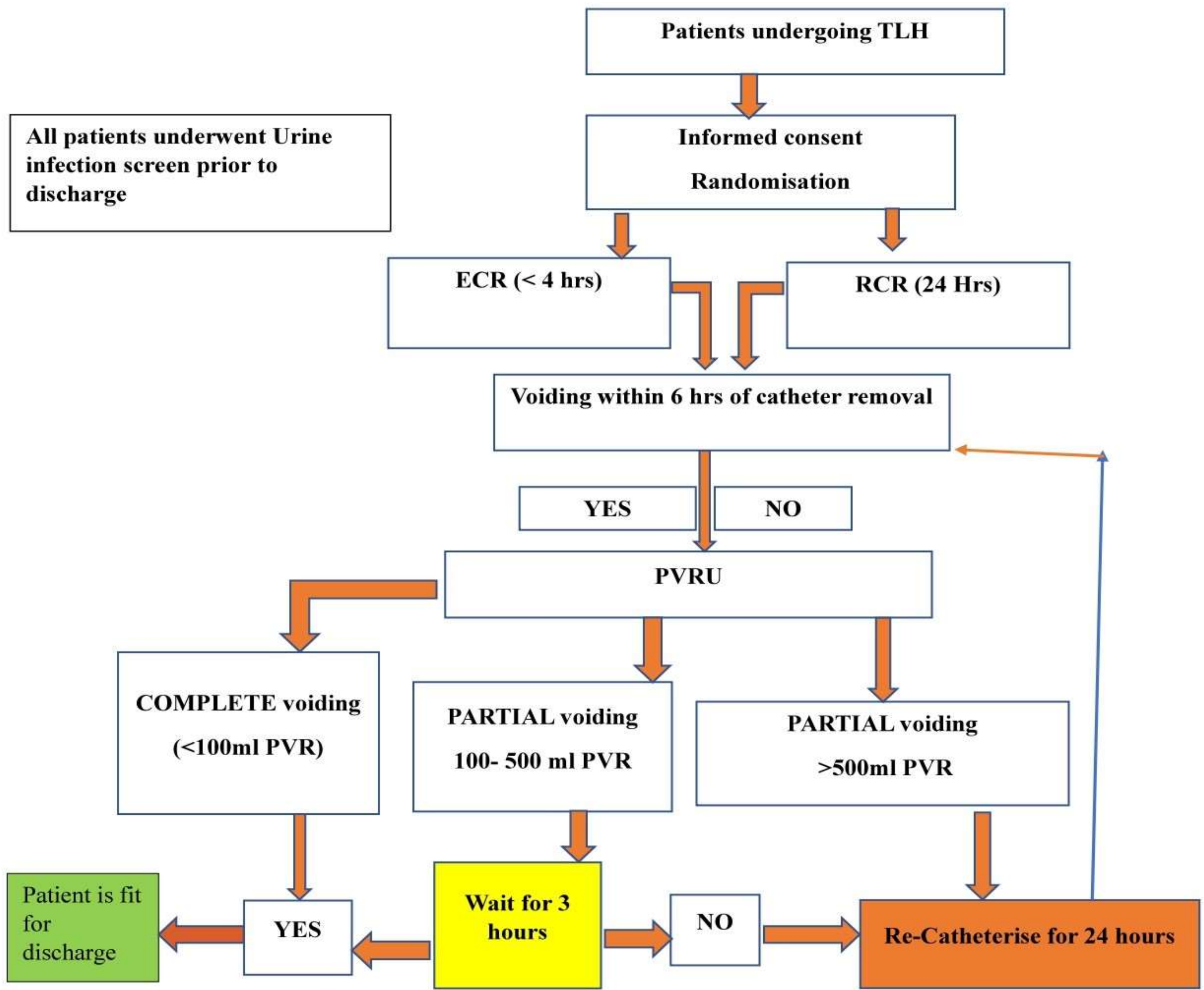


Figure 1: Flowchart summarizing the methodology of study

Results-

Voiding Difficulty: Slightly higher in the ECR group (7.4%) compared to the RCR group (2.7%), but the difference was not statistically significant (p=0.798).

Recatheterisation: Similar between groups, with 2 patients in ECR and 1 patient in RCR requiring Recatheterisation (p=0.798).

Post Void Residual (PVR): No significant difference was observed between ECR (79.78 ml) and RCR (83.25 ml) groups (p=0.878).

Urinary Tract Infection (UTI): Postoperative UTI rates were comparable, with 1 patient in each group testing positive for Escherichia coli (p=1.000).

Time to Ambulation: Patients in the ECR group ambulated significantly earlier (12 hours) compared to the RCR group (17.14 hours) (p=0.000).

Hospital Stay: The duration of hospital stay from surgery to discharge was significantly shorter in the ECR group (3.67 days) compared to the RCR group (4.94 days) (p=0.004).

Other Parameters: No significant differences were found in total blood loss, duration of surgery or hemoglobin levels between the groups.

Discussion-

Voiding Difficulty:

Present study: 7.4% in ECR vs 2.7% in RCR (not significant).

Sandberg et al.: 13.5% in ECR vs 0% in RCR.

Most voiding issues resolved within 9 hours without intervention.

Recatheterization Rates:

Present study: 2 in ECR, 1 in RCR.

Other studies also show higher recatheterization in ECR groups.

Post-Void Residual (PVR):

No significant difference (Present & Sandberg: ~47 mL in ECR vs ~37 mL in RCR).

PVR cutoff of 100 mL used, though not standardized in literature.

Patient & Surgical Characteristics:

No significant differences in age, parity, indications (mostly leiomyoma), surgical time or blood loss across groups.

Findings consistent with Joshi, Sandberg, Chai, and Alessandri studies.

Risk Factors:

No predictive factors identified for urinary retention, aligning with Won et al.

Conclusion:

Early catheter removal after TLH is safe and generally well-tolerated, though it may result in a slightly higher but not statistically significant risk of voiding difficulties and recatheterization. Further research is needed to define optimal catheter removal timing and establish standardized PVR thresholds.