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RESEARCH PROPOSAL FOR MASTER OF MEDICINE
(OBSTETRICS AND GYNAECOLOGY)
DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY
UNIVERSITY MALAYA

TITLE:

SELF BLADDER EMPTYING COMPARED WITH CATHETER PLACEMENT FOR PLANNED CAESAREAN SECTION: A RANDOMISED CONTROLLED TRIAL

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Self-Bladder Emptying Compared with Catheter Placement for Planned Caesarean Section: A Randomised Controlled Trial

INTRODUCTION AND LITERATURE REVIEW

2010–2018 data from 154 countries covering 94.5% of world live births shows a 21.1% caesarean delivery rate, ranging from 5% in sub-Saharan Africa to 42.8% in Latin America and the Caribbean.[1] A bladder catheter is usually placed for the caesarean section as a distended bladder is assumed to be at higher risk of injury during surgery and to compromise surgical field exposure of the lower uterine segment.[2]

Several trials which compared self-bladder emptying to bladder catheter placement for caesarean section did not report interference with surgical exposure of the lower uterine segment, accidental cystotomy or injury to the urinary tract.[2-5] However, a 2019 trial has reported a significantly higher incidence of postpartum urinary retention needing re-catheterisation in those who catheter was removed immediately after caesarean section compared to the intermediate (6 hours) and delayed (12 hours) removal arms with rates of 13.6, 2.5 and 0%, respectively[6], indicating that functional recovery of the bladder after caesarean may take 6-12 hours. On the other hand, time to ambulation, first postoperative voiding, oral rehydration, bowel movement, and length of hospital stay were significantly shorter with self-bladder emptying group, with most patients being able to self-void after surgery without any intervention.[5] Trial evidence also strongly implicate the indwelling bladder catheter as a main cause of urinary tract infection.[2, 5, 7] The 2018 Enhanced Recovery After Surgery (ERAS) Guideline for care in caesarean delivery has recommended that any bladder catheter should be removed immediately after caesarean delivery, if placed during surgery.[8]

In June 2018, the International Continence Society revised the definition of acute urinary retention as a generally (but not always) painful, palpable, or percussable bladder, when the patient is unable to pass any urine when the bladder is full.[9] The ICS did not include objective bladder urine volume in the current definition.

There is no consensus definition of postpartum urinary retention (PPUR), especially in women delivered by Caesarean. The reported incidence of PPUR varies from 0.5 to 45%; the variability among studies may be due to its unclear definition.[10] A common literature definition for overt PPUR is the inability to void 6 hours after birth or after catheter removal in case of caesarean section[11] and covert PPUR after caesarean delivery defined as post voiding residual volume (PVR) of >150 ml by bladder ultrasound after spontaneous voiding.[11] PPUR after caesarean delivery occurs in 3.2-24.1%[12-15] with caesarean section protective compared to spontaneous vaginal birth in causing PPUR[16].

A pretrial fact-finding exercise that involved 23 women delivered by planned caesarean section in UMMC and 64 UMMC health care providers was performed from 1st-27th October 2021 to gain their opinion and input on the proposed trial. The 23 patients also consented to self-urinate (urine volume measured) in the toilet of the antenatal ward at the call to despatch to the operating theatre and to have their catheter (as current standard bladder care for Caesarean) urine volume measured at (a) 5 minutes after insertion, (b) completion of the operation and (c) 6 hours after the operation to gauge urine production and potential bladder filling dynamics over that perioperative period.

Table 1. Patient and health care provider opinion/input on trial proposal and trial interventions

Likert scale response	Patients (n = 26)	Health care providers[1] (n = 64)
	This study is important to help guide patient care	This trial is important to guide management
Strongly agree	17 (73.9%)	29 (45.3%)
Agree	6 (26.1%)	28 (43.8%)
Neither agree nor disagree	0	5 (7.8%)
Disagree	0	2 (3.1%)
Strongly disagree	0	0
	If asked, I am likely to participate	Will request my patient to participate
Strongly agree	17 (73.9%)	20 (31.3%)
Agree	4 (17.4%)	33 (51.6%)
Neither agree nor disagree	2 (8.7%)	10 (15.6%)
Disagree	0	1 (1.6%)
Strongly disagree	0	0
	Personal preference (preop)	Personal preference for my patient
Self-bladder emptying	9 (39.1%)	25 (39.1%)
Catheter	12 (52.2%)	34 (53.1%)
No preference	2 (8.7%)	5 (7.8%)
	Personal preference (at discharge)	
Self-bladder emptying	10 (43.25%)	
Catheter	11 (47.8%)	
No preference	2 (8.7%)	

[1]Care provider designation: Faculty 4 (6.3%), Medical Officer 21 (32.8%), House Officer 39 (60.9%)

Table 2. Urine volumes at various time points around planned Caesarean delivery

Timing	Urine volume ml		
	Median	Interquartile range	Full range
Self-voided at OT call	100	80-200	30-300
5 minutes after catheter placement in OT	20	10-50	0-100
Completion of Caesarean	80	50-90	10-190
Completion to 6 hours after Caesarean	360	120-500	20-890
Cumulative after self-void to 6 hours after Caesarean	480	240-650	120-955

All 23 patients responded positively on the importance of the study to help guide patient care, 21/23 (91.3%) will likely agree to participate in the trial and their personal preference is for catheter placement by a small margin which narrows further when asked after they had experienced bladder prior to their hospital discharge. HCP also responded positively 57/64 89.1% agreeing the trial is important to guide management and only 2/64 (3.1%) disagreeing, 53/64 (82.9%) agree to request their patients participate and only 1/64 disagreeing and a majority would currently prefer their patients to have the catheter placed 34/64 (53.1%) vs. 25/64 (39.15) preferring self-emptying of bladder by patients. These preference findings indicate effective equipoise in both patients and HCPs for the experimental intervention against an established convention.

However, after their caesarean section, 4/12 (25%) women switched from preferred bladder catheterisation to self-bladder emptying and 3/9 (33%) women switched from preferred self-bladder emptying to bladder catheterization. On further exploration, the reasons for the switches were discomfort due to presence of a urinary catheter and post-surgery feeling that they did not have enough strength to ambulate to the toilet or that ambulation will cause them to feel pain respectively. These responses highlight the need for a RCT to provide quality evidence on the merits of the trial interventions particularly from the patients' perspective.

The aim of this trial is to evaluate self-bladder emptying (natural urination) compared with bladder catheter placement at planned caesarean section primarily on PPUR and maternal satisfaction with the allocated bladder care.

1. RESEARCH HYPOTHESES

STUDY OBJECTIVES :

- To evaluate self-bladder emptying (natural urination) compared with bladder catheter placement at planned caesarean section primarily on PPUR and maternal satisfaction with the allocated bladder care

We hypothesize that:

- Pre-caesarean section indwelling bladder catheterisation vs. self-voiding is superior with respect to PPUR
- Self-voiders are more satisfied with their bladder care compared to having an indwelling bladder catheter

END POINTS

Primary outcomes

- PPUR rate
- Maternal satisfaction with their allocated peri-caesarean bladder care

Secondary outcome

Intraoperative outcomes [2-5]

a. Surgical field impairment
b. Distressed catheterization (need for catheterization during caesarean section)
c. Operative blood loss
d. Bladder injury
a. Duration of surgery

According to RCTs done by Ghoreishi et al, 2003[3] , Senanayake et al, 2005[2,] Acharya et al, 2009[4] and AM Nasr et al, 2009[5]: these studies find no increase in intraoperative complications or interference with surgical exposure of the lower uterine segment, accidental cystotomy or injury to the urinary tract after self-voiding compared to catheter placement. Duration of surgery was also not significantly different.

Postoperative outcomes [3-5, 12]

a. Urinary tract infection
b. LUTS by IPSS questionnaire[17]
c. Time to first bowel flatulence
d. Time to first satisfactory breastfeeding experience
e. Time to first satisfactory urination
f. Time to first satisfactory ambulation
g. 11-point 0-10 VNRS pain score at first post-caesarean urination
h. Length of hospital stay post-surgery
i. 11-point 0-10 VNRS pain score upon movement at discharge

2. METHODOLOGY

2.1 Type of study design
Randomised controlled trial

2.2 Settings
Antenatal ward, Kompleks Wanita dan Kanak-Kanak, UMMC

2.3 Duration of study
This study will be conducted from as soon as possible as approved by Ethical Committee Board and trial registration should run for 12 months barring unexpected events.

2.4 Study population
Women admitted for their planned caesarean section for various indications in UMMC

Inclusion criteria

- Planned caesarean section
- Age 18 years and above
- Gestational age (supported by dating US) ≥ 37 weeks
- Singleton pregnancy
- Reassuring fetal heart rate tracing

Exclusion criteria

- Patients with evidence of urinary tract infection or recurrent antenatal UTI
- Presence of large (> 4 cm) ovarian or uterine masses
- Anticipated pelvic adhesion
- Anticipated difficult surgery or prolonged surgery time such as cases of placenta previa or accreta spectrum
- Patients with severe pre-eclampsia or any other conditions requiring postoperative monitoring of urinary output

DEFINITIONS OF OPERATIONAL TERMS

- **Post partum urinary retention (PPUR)**
  - Overt PPUR is defined as: "the inability to void spontaneously within six hours after removal of an indwelling bladder catheter after caesarean section, requiring catheterization"[11] – from hospital record
  - Covert PUR is defined as "a post void residual bladder volume (PRV) ≥150 ml after spontaneous micturition, verified by ultrasound or catheterisation".[11] The ultrasound for PRV will be conducted just prior to hospital discharge unless clinical indication for earlier assessment.

- **Urinary tract infection (UTI)**
  - Patient's midstream urine sample will be sent for culture and sensitivity at hospital discharge.
  - Urinary tract infection defined as (quantitative urine culture yielding at least 10^3 colony forming units of an identified single uropathogen per ml).

3. SAMPLE SIZE CALCULATION

a. Using *NK Aref, 2019* [6] as pilot data with PPUR rate 13.6% without catheter and 2.5% at 6-hour catheter removal (0% PPUR at 12-hour catheter removal). Taking a more conservative stance, we adopt a narrower PPUR rate difference of 10% vs. 3% instead of 13.6% vs 0-2.5%; applying alpha = 0.05, beta = 0.2 (80% power), 1 to 1 ratio and Chi Square test, 194 participants are required in each arm. N = 388

b. For maternal satisfaction, assuming a 1-point difference to be clinically relevant in the use of the 11-point 0-10 VNRS, and that the standard deviation in satisfaction score is 2.5, applying alpha = 0.05, beta = 0.2 (80% power), 1 to 1 ratio and t test, 99 participants are required in each arm. If applying the Mann Whitney U test as satisfaction score is ordinal, the sample size is conventionally uplifted by 15%, to 116.5 in each arm. N = 233

c. We rounded N up to 400 to adequately cover the calculated sample sizes for both primary outcomes

4. METHOD

4.1 Patient recruitment

4.1.1 All women scheduled for planned caesarean section are identified by health care providers in antenatal clinic or antenatal ward. They will be assessed for eligibility to be recruited into this study [Eligibility Form with inclusion and exclusion criteria]

4.1.2 Patients will be recruited once they are admitted to the ward, typically 1 day prior to surgery date

4.1.3 Those whom fulfilled the study criteria will be provided with patient information sheet. Questions are encouraged and answered by investigator or care provide

4.1.4 Written informed consent will be taken from those who agree to participate

4.2 Randomisation: sequence generation and allocation concealment mechanism

4.2.1 Randomization sequence will be generated by investigator not directly involved in the study using blocks of 4 or 8 using a random number generator (random.org). The random allocation will be carried out by opening lowest number sealed opaque envelope remaining to the latest recruit.

4.2.2 Patients will be randomised into 2 arms – self emptying of the bladder arm or indwelling bladder catheter arm.

4.2.3 Antibiotic prophylaxis for Caesarean will be according to provider choice and recorded.

4.2.4 Patients randomised to self-emptying of the bladder arm will be asked to empty their bladder at OT call in the ward toilet before despatch to the operation theatre (in case of delay in starting of surgery - they will be asked again to passed urine in OT, ideally within 1 hour prior to start of surgery as per Senanayake et al [2]).

4.2.5 Patients randomised to indwelling bladder catheter will have their catheter inserted as per usual practice under aseptic technique using Foley catheter size 16F, after regional anaesthesia has been given in the operating theatre. The Foley catheter will be removed the next day according to current UMMC standard practice.

4.3 Data collection, management and analysis.

4.3.1 All patient's relevant demographic and clinical outcome data will be transcribed onto the Case Report Form.

4.3.2 Intraoperative outcomes collected :

4.3.2.1 Surgical field impairment by VNRS
4.3.2.2 Catheterization during caesarean section
4.3.2.3 Operative blood loss
4.3.2.4 Bladder injury
4.3.2.5 Duration of surgery

4.3.3 Postoperative outcomes collected :

4.3.3.1 Time to first bowel flatulence
4.3.3.2 Time to first satisfactory breastfeeding experience
4.3.3.3 Time to first satisfactory urination
4.3.3.4 Time to ambulation
4.3.3.5 Pain score at first post-caesarean urination by VNRS

4.3.4 On day of hospital discharge :

4.3.4.1 Maternal satisfaction with allocated bladder care by VNRS
4.3.4.2 Bladder scan for post-void residual volume
4.3.4.3 Midstream urine sample sent for culture and sensitivity
4.3.4.4 An interview-based LUTS by the IPSS questionnaire
4.3.4.5 Length of hospital stay (operation to discharge)
4.3.4.6 Pain score upon movement by VNRS

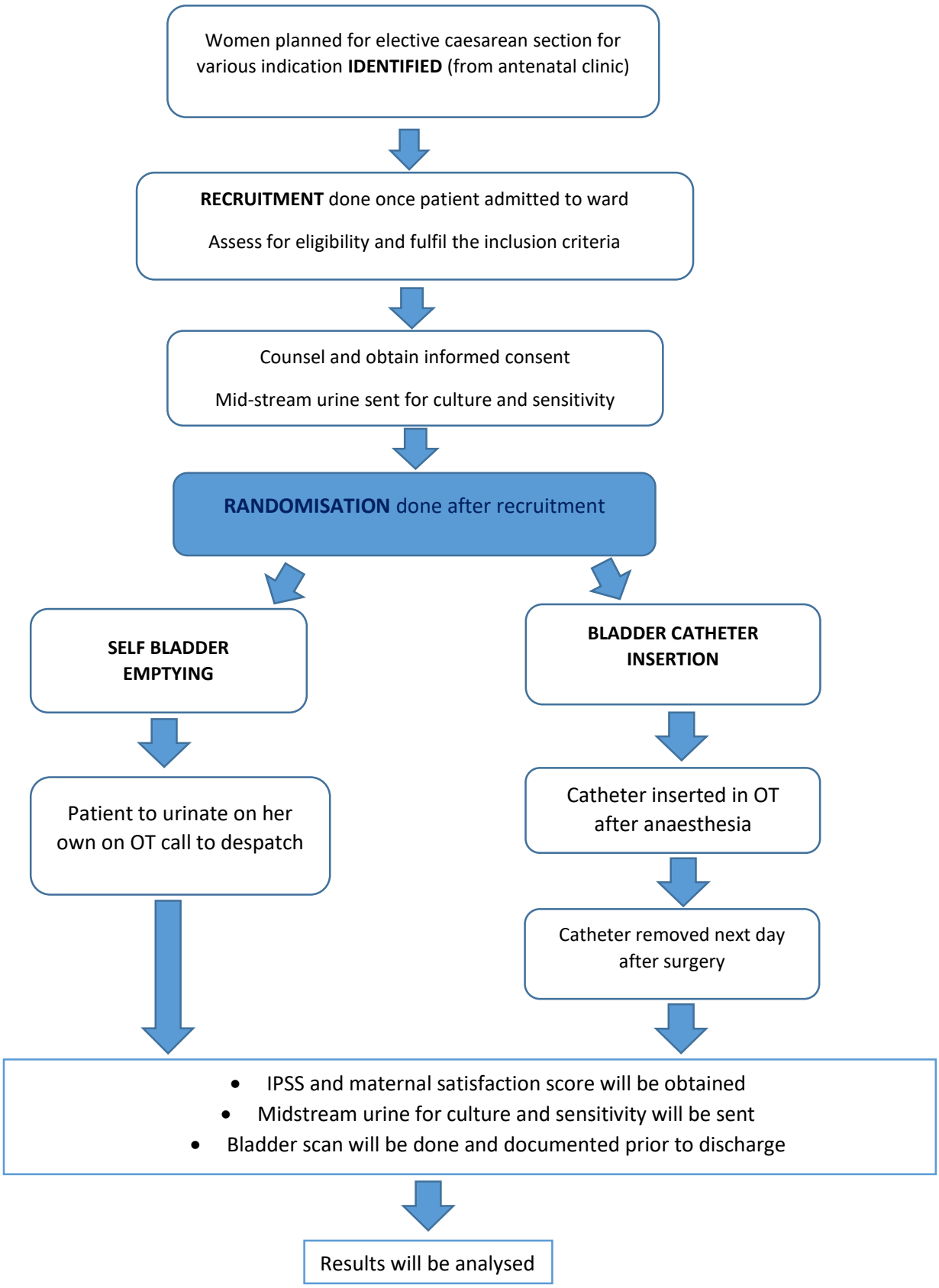
5. STATISTICAL ANALYSIS

Data will be entered into SPSS statistical software. Normally distributed continuous data will be analysed with t test. Chi square test will be used for categorical or nominal data and Mann-Whitney U test will be used on non-normally distributed or ordinal data. Two-sided p values are generated and $P < 0.05$ is taken as significant.

6. ETHICAL CONSIDERATION

This study will be submitted to the UMMC Medical Research and Ethics committee, the local institutional review board for approval. All the participants involved in this study will be reassured about the confidentiality and informed written consent is compulsory. This trial is designed as randomised controlled trial. Patient will be given an information sheet, have their oral queries addressed and written informed consent obtained to participate in the study. There is no conflict of interest to report by investigators in this study.

7. STUDY FLOW CHART



8. GANTT CHART

	2021				2022											
	SEPT	**OCT**	**NOV**	**DEC**	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUNE**	**JULY**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
RESEARCH PROPOSAL AND PREPARATION																
PRESENTATION TO ETHICS COMMITTEE AND APPROVAL																
PATIENT RECRUITMENT AND DATA COLLECTION																
DATA ENTRY																
DATA ANALYSIS																
THESIS WRITING																
THESIS SUBMISSION																

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