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A randomized controlled trial of 12 hours versus 24 hours urinary catheter removal following uncomplicated caesarean section in Ekiti State, Nigeria

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Abstract

Catheter-associated urinary tract infection (CA-UTI) is one of the common nosocomial infection. Minimizing the length of stay of indwelling urinary catheter has been reported as a key strategy in reducing the rate of the infection. This study compared the incidence of significant bacteriuria in patients who had removal of their urinary catheter in 12 hours compared to those removed after 24 hours following uncomplicated caesarean section. A total of 140 women were randomized into two groups of either 12-hour catheter removal (group A) or 24-hour catheter removal (group B) post-caesarean section. The socio-demographic characteristics, pre-operative and post-operative urine microscopy, culture and sensitivity, time of first ambulation, length of hospital stay and the cost of treatment for all the participants were analyzed using SPSS version 21. P value was set at 0.05. results showed the overall incidence of catheter associated significant bacteriuria was 26.3% in this study while participants in group A (20.9%) had lower incidence of microscopic bacteriuria compared to those in group B (31.8%) though not statistically significant [OR= 1.8: 95%CI (0.8-3.9); p=0.1]. The mean time of first ambulation was statistically lower in group A compared to group B (16.2 ± 7.7 hours versus 24.8 ± 4.3 hours, p<0.001 respectively). The socio-demographic characteristics, incidence of urinary retention, mean length of hospital stay and cost of treatment did not differ significantly between the groups, p >0.05. The study demonstrated that catheter removal at 12 hours post uncomplicated caesarean section can enhance early ambulation and reduce the incidence of post-operative microscopic bacteria. ClinicalTrials.gov identifier PACTR201912777385309. *(Afr J Reprod Health 2023; 27[6s]: 44-50).*

Keywords: Urethral catheter, urinary tract infection, significant microscopic bacteriuria

Résumé

L'infection des voies urinaires associée à un cathéter (AC-UTI) est l'une des infections nosocomiales courantes. Minimiser la durée de séjour de la sonde urinaire à demeure a été signalé comme stratégie clé pour réduire le taux d'infection. Cette étude a comparé l'incidence d'une bactériurie importante chez des patientes dont la sonde urinaire a été retirée dans les 12 heures par rapport à celles retirées après 24 heures après une césarienne sans complication. Un total de 140 femmes ont été randomisées en deux groupes de retrait du cathéter de 12 heures (groupe A) ou de retrait du cathéter de 24 heures (groupe B) après la césarienne. Les caractéristiques socio-démographiques, la microscopie urinaire préopératoire et postopératoire, la culture et la sensibilité, l'heure de la première ambulation, la durée du séjour à l'hôpital et le coût du traitement pour tous les participants ont été analysés à l'aide de SPSS version 21. La valeur P a été fixée à 0,05. Les résultats ont montré que l'incidence globale de la bactériurie significative associée au cathéter était de 26,3 % dans cette étude, tandis que les participants du groupe A (20,9 %) présentaient une incidence plus faible de bactériurie microscopique par rapport à ceux du groupe B (31,8 %) bien que non statistiquement significatifs [OR = 1,8 : IC à 95 % (0,8-3,9) ; p=0,1]. Le temps moyen de la première marche était statistiquement inférieur dans le groupe A par rapport au groupe B (16,2 ± 7,7 heures contre 24,8 ± 4,3 heures, p<0,001 respectivement). Les caractéristiques socio-démographiques, l'incidence de la rétention urinaire, la durée moyenne d'hospitalisation et le coût du traitement ne différaient pas significativement entre les groupes, p > 0,05. L'étude a démontré que le retrait du cathéter 12 heures après une césarienne sans complication peut améliorer la marche précoce et réduire l'incidence des bactéries microscopiques postopératoires. Identifiant ClinicalTrials.gov PACTR201912777385309. *(Afr J Reprod Health 2023; 27[6s]: 44-50).*

Mots-clés: Cathéter urétral, infection des voies urinaires, bactériurie microscopique importante

Introduction

About 3-8% of pregnant women suffer from asymptomatic bacteriuria which may be due to physiologic changes in pregnancy[1]. Greater percentage of these women will be included among the 25% of pregnant women who will undergo cesarean section[2].This procedure further exposes them to passage of urinary catheter. Though catheter may minimize intra-operative injury to the urinary system and give better access to the lower uterine segment, it has not been without its own complications including urinary tract infection which accounts for more than 80% of nosocomial infection and post-operative pain[1,3]. It also prolongs post-operative immobilization which is a risk factor for the development of deep venous thrombo-embolism and increases hospitalization time and the cost of treatment[4].

The recommendation on optimal duration of urethral catheterization remains unclear**[4]**.In addition, there is a lack of consensus on the duration of use in uncomplicated caesarean sections in the literature. Much of the practices are based on knowledge derived from customary procedures rather than evidence-based studies**[4]**.Thus, clinical application varies between clinicians. Some clinicians remove catheters immediately after surgery hoping to minimize or reduce the incidence of accompanying complications, whereas others wait for 12–24 hours before catheter removal to avoid urine retention[5].

It increases maternal morbidity and mortality together with increasing hospital stay[6,7]. It accounts for up to 10-70% of all nosocomial infections especially in intensive care units[6,8,9]. Urinary-tract infections can be asymptomatic or symptomatic. Asymptomatic bacteriuria is defined as the presence of up to 100,000 colony forming units (CFUs) of a single pathogen per milliliter of two consecutive freshly voided midstream, clean catch urine specimens or a single catheterization specimen without symptoms of urinary tract infection[7,10]. Symptomatic infection may involve the lower urinary tract and cause cystitis, or it may involve the renal calyces, pelvis and parenchyma and cause pyelonephritis. A diagnosis is made when positive urine culture (10^5 CFUs/ml) with 2 bacterial species or at least one positive outcome in the dipstick test, pyuria, and gram stain[10].Bacteria gain entry into the bladder either via intraluminal migration by passing through the inside of the catheter or by extra-luminal migration involving passage of micro-organism along the urethral mucosa and outside of the catheter tubing[8].

In a study by Bongyoung *et al*, 24% of patients with bacteriuria developed symptomatic CA-UTI[9]. Despite closed sterile drainage system and aseptic insertion of the catheter which significantly reduces the incidence of catheter associated UTI, 1-48% of hospitalized patients with indwelling catheter still acquire infection[10]. A study by Onyegbule *et al*[10] in Nnewi involving 156 women randomized into immediate and 24 hours catheter removal,14 (9.0%) had significant bacteriuria in 72 hour urinary culture giving the incidence of catheter associated urinary tract infection in Nnewi to be 9.0%, and this was more among the women in the 24 hour group[10]. Oriji *et al*[11] did a comparative analysis of duration of urethral catheterization involving 160 women who underwent elective caesarean section and randomized into four groups (no catheter, immediate, 6 hours and 24 hours catheter removal groups after surgery) and found out that 13.8% of the patients in the 24 hour group had UTI in their mid-stream urine analyzed 72 hours after the surgery[11]. This was similar to 11% reported by Onile *et al* in their prospective randomized study of 200 women with about 44% patients who had catheter removed after 24 hours post operatively[3]. Postoperative early mobilization is important to protect patients from the risk of venous thromboembolism[4]. Many women with urethral catheter may avoid moving in the early period after CS due to pain[4].It was also evident in the study that those whose catheters were removed earlier mobilized faster than others[3-5]. This study evaluated the length of indwelling catheter post uncomplicated caesarean section.

Methods

The study was a randomized controlled trial of women who had uncomplicated caesarean section conducted in the post-natal ward of Ekiti State University Teaching Hospital (EKSUTH), Ado-Ekiti, Nigeria between 01 June, 2019 to 30 December, 2019. The hospital receives referrals from other towns in Ekiti State, parts of Ondo, and Kogi States. Ekiti State is one of the six southwestern states in Nigeria, and it is situated entirely in the tropics. It has a total land area of 5887.89 km2 with a human population of

2,398,957. The design and reporting were done in accordance with the CONSORT Statement 2010. Inclusion criteria were eligible women who had uncomplicated caesarean section at EKSUTH and gave consent to participate in the study while women with severe pre-eclampsia, eclampsia, obstructed labour, urinary tract infection in pregnancy, unconscious patients and non-consenting patients were excluded from the study.

Sample size calculation was based on the prevalence of catheter–associated significant bacteriuria in a study in the same region,[5] setting a study power of 80%, confidence interval of 95%, level of significance of 5% and an acceptable drop-out rate of 10%. A total of 140 women were recruited with 70 women in each arm of the study.

Randomisation

Resident doctors, theatre and labour ward staff were informed about, and trained to recruit participants for the study. After obtaining a written informed consent, antenatal history and physical examination were done along with the review of the antenatal records of the index pregnancy. Participants were assigned using computer-generated random numbers in blocks of five into group A (catheter removal at 12hrs) and group B (catheter removal at 24hrs). Group allocation was predetermined and placed in consecutively numbered and sealed opaque envelopes, all kept in a box sequentially. Allocation of patients started from the first sealed opaque envelope until the last pack was completed sequentially. Using this method, equal numbers of subjects were assigned to each treatment arm.

Data collection

Pre-operative mid-stream urine sample was collected for microscopy culture and sensitivity to exclude patients with asymptomatic bacteriuri before surgeries, only those who were negative for bacteriuria were included in this study. All parturients were told and encouraged while in the theater to sit out of bed by 8 hours after the surgery irrespective of presence of catheter or not and to ambulate 10 hours post-surgery[13] (wall clocks were stationed in visible places on the ward for patients to see and the trained nurses on duty helped in monitoring the patients). All participants had sub-arachnoid block (spinal anesthesia with 5% buvi-marcain) and received parenteral 750mg of Cefuroxime 12hourly and Metronidazole 500mg 8hourly for 24hours[14] at the induction of anaesthesia. Adequate hydration and analgesics (Pentazocine and Diclofenac) were given alternatively 4-6 hourly. In all participants, a Foley's urethral catheter (French size16 Nelaton catheter by AGARY Pharmaceutical Limited Shanghai, China) was inserted under aseptic condition using non-touch technique, with the help of an assistant having explained the procedure to them and this was done on the operating table after anaesthesia was administered.

The labia was parted with the non-dominant hand, the right labium was swabbed down using Chlorhexidine solution and the second swab was used to clean the left labium while the third swab was used to swab down the central part of the vulva. The catheter under aseptic technique was gently inserted into the bladder through urethral orifice. About 5mls of sterile water was used to inflate the balloon while the tube was connected to a closed system called the urine-bag. The procedure of caesarean section was done in the theatre under sterile conditions according standard surgical procedure.

For patients in group A, the catheter was removed 12 hours after the procedure, while in group B, the catheter was removed after 24 hours post-surgery.

Microscopy and culture of urine

Post caesarean section mid-stream urine samples were obtained from the first voided urine 24 hours after surgery into a wide mouthed sterile universal bottle which was provided by the researcher for microscopy, culture and sensitivity. The specimens were immediately sent to the laboratory for processing. Urine microscopy was performed on uncentrifuged urine specimen to detect the presence of leukocytes, erythrocytes and other cells. A sterile calibrated wire loop was used to deliver a loopful (0.01ml) of urine onto each of Blood MacConkey plates and incubated aerobically at 37ºC for 18 - 24 hours[12]. Significant growth of ≥100 bacteria/ml of urine was interpreted as at least one colony of bacterial organism per plate. Pure colonies of isolated organism on the culture plates whereas biochemically characterized to identify the different species of organisms isolated[19].

If for any reason the samples could not be processed immediately, they were refrigerated at

4°C because it takes viable E. coli 12.5 minutes to double in number (generation time) while for other organisms the generation time may be hours[13]. Re-catheterization was performed if spontaneous micturition is not possible 6 hours after removal of catheter with urinary retention detected at the suprapubic region by abdominal examination. The time of first ambulation was defined as the interval between the onset of surgery and the time of patient first ambulation. Patients who are positive for bacteriuria were given appropriate antibiotics according to the departmental protocols. Primary investigator was responsible for maintaining the sequence of the numbered envelopes.

Data analysis

Data collected was entered into and analysed using Statistical Package for Social Sciences version 21 (SPSS 21, IBM, NY, USA). Continuous variables were analysed using mean and standard deviation while categorical variables were presented in frequency and percentages. Test of significance was done with student t-test or ANOVA for continuous variables, while Chi-square test and Fischer's exact test were used for categorical variables. Level of significance is set at a Pearson value of less than 0.05($p < 0.05$).

Results

Data analysis was based on 133 participants [in two groups based on the time of urethral catheter removal following uncomplicated caesarean sections: 67 participants in the 12hrs arm (group A) and 66 women in the 24hrs arm group B)], because seven out of the 140 randomized women were excluded due to positive urine culture pre-operatively (Figure 1). Table 1 showed the socio-demographic characteristics of the women included in the study. About 55% of the participants in each group were in the age group 30-39years. The mean age and gestational age at delivery of the participants in groups A and B were comparable (31. ± 4. years versus 32. ± 5.1 years; p = 0.5 and 38. ± 1. weeks versus 38. ± 0.7 weeks; p = 0. respectively). The parity, educational, marital, occupational and religious status of the participants in both groups were also not significantly different as shown in Table 1.

Thirty-five participants had catheter-associated microscopic bacteriuria putting the overall incidence to 26.3%. However, participants in group A 14(20.9%) had lower incidence of positive microscopic bacteriuria compared to those in group B 21(31.8%), though not statistically significant [OR =1.; 95%CI (0.8-3.), p = 0.]. The mean time of first ambulation after caesarean section for participants in the 12 hour group was statistically lower than those in the 24 hour group; 16.2 ±7.7 hours versus 24.8 ± 4.3hours, $p < 0.001$ respectively.

These are shown in Table 2. Also, table two showed that the overall incidence of urinary retention in the 12 hour and 24 hour catheter removal group was less than 1%. One (1.5%) participant in the 12 hour group had urinary retention while none of those in the 24 hour group had retention and this was not statistically significant, p =1.0. There were no significant differences between the participants groups A and B in the mean cost of treatment (97.0 ± 5.3 thousand naira versus 98.6 ± 5.3 thousand naira; p = 0. respectively) and the mean length of hospital stay (74.1 ± 6.9 hours versus 76.7 ± 9.6 hours; p = 0. respectively) after caesarean section.

Discussion

The overall incidence of catheter associated significant bacteriuria was 26.3% in this study. The finding was similar to 26.9% incidence of significant bacteriuria reported by Oriji *et al* in a study carried out in Port-Harcourt, Nigeria"[11]. This might be due to the fact that both studies were done in the southern part of Nigeria with similarity in study population and techniques.

The incidence of significant microscopic bacteriuria was about 20.9% in the 12-hour (group A), this was slightly higher than the incidence of 15.2% reported by Alper *et al* in a study of early versus delayed removal of catheters in patients after elective caesarean section[4]. This relationship could be due to the same sample size that was used. There was a higher incidence of 31.8% of microscopic bacteriuria in the 24 hour arm (group B) though not statistically significant. This was relatively similar to the finding of Amat-Al Karem *et al*[3] but higher than the reported incidence by Oriji *et al*[11]and Onile *et al*[17]in their separate studies. Differences in sample size, and the timing of catheter removal and the collection of first voided urine sample after surgery might account for the wide variation in the reported incidences of microscopic bacteriuria from

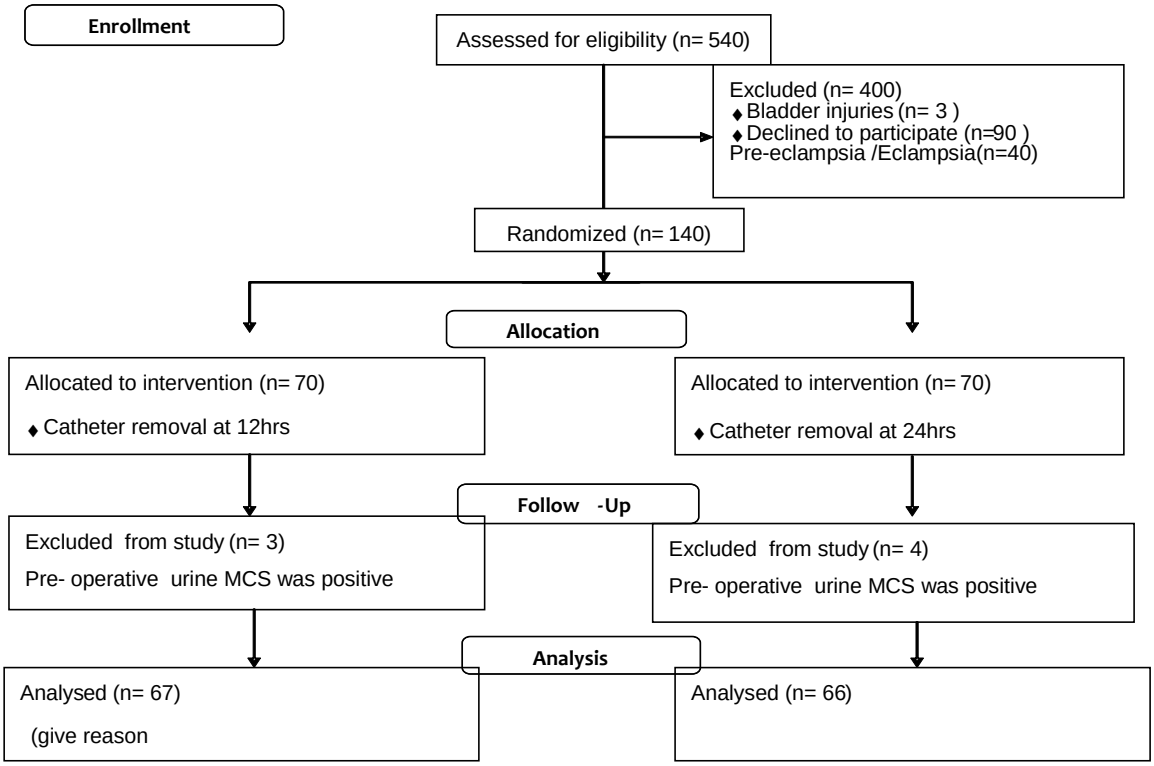

Figure : The study flow diagram

these various studies. In addition to these reasons, the participants in the study by Onile *et al*[17] were on continuous antibiotics throughout the period of admission. The mean time of first ambulation in this study was statistically lower in the 12hour group compared to 24hour group, (P = 0.001). It took about 15.0 ±1.7 hours for participants in group A compared to 25.2 ± 3.2 hours for participants in group B to ambulate after the surgery. This finding is in keeping with reports from most studies[3,4,6]. Even though in this study, we calculated the time from onset of surgery to the first ambulation and these other studies used the interval between catheter removal and first ambulation of the participants, the assertion is still the same. Akmat-Al Mazny *et al* concluded in their study that the earlier the catheter is removed, the earlier the ambulation time[5]. The delayed ambulation in late catheter removal has been adduced to the fact that, most patients find it distressing and difficult ambulating with the catheter in-situ. This prolonged catheterization predisposes to patient immobilization and might result in deep venous thrombosis especially in patients that have abdominal surgeries.

The overall incidence of urinary retention in this study was 0.8%. Only 1 (0.8%) participant in 12hour group had urinary retention that warranted re-catheterization compared to none in the 24 hour group. The finding is comparable to 1.3% reported in the early catheter removal group by Alper *et al*[4] and to none reported in the late catheter removal group by Armat-Al Karem *et al*[3] in their studies. The low non-statistical significance of urinary retention in 12 hour group may be due to early removal and ambulation in this group while in the 24 hour group, most participants were willing to ambulate if not for the catheter in-situ. The present study showed that there was no significant difference in the mean cost of treatment between the two groups A and B (97.0 ± 5.3 thousands naira versus 98.6 ± 5.3 thousands naira; P=0.073). Though the 24 hour group spent higher money which was not significant statistically, this may be

due to the higher incidence of microscopic bacteriuria reported from their urine microscopy, culture and sensitivity, for which they would have procured more drugs to treat the infection.

It was also observed in the study that the mean length of hospital stay in groups A and B were comparable (74.1 ± 6.9 hours versus 76.7 ± 9.6 hours; P=0.078). It shows that the difference between mean length of hospital stay between the two groups was just 2 hours. However, when compared with thispresent findings from Ghoreishi *et al* showed that the shorter mean length of hospital stay among the catheterized participants (76.7 ± 9.6 hours versus 64.0 ± 10.7 hours) respectively in it 24 hour group[18].

Onile *et al*, however reported a higher mean length of hospital stay that was about twice as much as reported in this study (165.84 hour versus 76.7 ± 9.6 hours respectively) in the 24 hour group[14]. The variation in the length of hospital stay may be due to institutional differences on patient's admission and discharge policy[14]. In our center, patients are usually discharged on the third post–operative day except there are other co-morbidities that could undermine their discharge from the hospital. The early discharge of our patients is one of the measures taken to prevent prolonged immobilization that could predispose them to deep venous thrombosis.

The limitation of the study included that One could not be fully ascertained if proper procedure of mid-stream urine collection was strictly followed by the participants who have just undergone major surgery, though it was explicitly explained to them. However, bias in the study was eliminated being a randomized controlled study.

In conclusion, the study demonstrated that the removal of urinary catheter at 12hours after uncomplicated caesarean section is associated with lower incidence of catheter associated microscopic bacteriuria, early ambulation, reduced cost of treatments and ultimately shorter hospital stay. Therefore, urinary catheter can be safely removed 12 hours post uncomplicated caesarean section and this should be introduced into clinical practice. This will further make the procedure safer with minimal morbidity and mortality.

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Authors' contribution

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by BTA. The first draft of the manuscript was written by BTA, OPA and OJA. All authors revised the manuscript for the intellectual content and approved the final manuscript.

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Data availability

The data can be obtained from the trials registry, or from the authors after due permission from the institution.

Conflict of interest

The authors declare that there are no conflicts of interests.

Ethical statement

The study was done in accordance with the 1964 Declaration of Helsinki. All recruited patients were adequately counseled and their written informed consent obtained. They were at liberty to decline participation without any negative impact on the quality of care they will receive in the hospital. The institution's Ethics and Research Committee gave approval for the study, which was designed and reported in line with the CONSORT Statement 2010.

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