**COMPARATIVE STUDY OF CHLORHEXIDINE ALONE VERSUS CHLORHEXIDINE AND POVIDONE-IODINE FOR PRE-OPERATIVE SKIN PREPARATION AT CAESAREAN DELIVERY IN THE NIGER-DELTA REGION OF NIGERIA**

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**Abstract**

**Background:** Post-caesarean surgical-site infection (SSI) is an important cause of maternal morbidity and mortality, and the skin is an important source of pathogens in surgical wound infections.

**Aims and Objectives:** To determine if pre-operative skin preparation with sequential chlorhexidine and povidone-iodine has higher efficacy than chlorhexidine-only at reducing the incidence of post-cesarean SSI.

**Design of the study:** Randomized comparative trial

**Setting:** Departments of Obstetrics and Gynecology, Delta State University Teaching Hospital, Oghara, and Central Hospital, Warri, Nigeria.

**Materials and Methods**: the study was conducted over eight months involving 570 participants who were randomized equally into either non-sequential arm utilizing 0.5%-chlorhexidine only, or sequential arm utilizing 0.5%-chlorhexidine followed by 10%-povidone-iodine. The primary outcome was occurrence of SSI within 30 days of surgery, while secondary outcomes were adverse skin reaction, prolonged length of post-Caesarean admission, and infection-related readmission. Analysis was performed using SPSS Version 22. Comparison of variables was by chi-square tests (or Fisher’s exact) for categorical variables, and Student’s t-test for continuous variables. Differences were considered significant if p-value <0.05.

**Results:** A total of 524 (91.9%) of the participants completed the study: 261 in the sequential and 263 in the non-sequential arms. There were no significant differences in the baseline characteristics among the women in the two groups. SSI was identified in 69 (13.2%) participants: 28 were in the sequential arm giving an SSI rate of 10.7% and 41 were in the non-sequential arm giving an SSI rate of 15.6% (p=0.100). There was no statistically significant difference between the two arms in the incidence of adverse skin reaction, 6 (2.3%) versus 4 (1.5%) (p= 0.544), prolonged length of stay, 4(1.5%) versus 7 (2.7%) (p=.367), and infection-related re-admission, 5 (1.9%) versus 8 (3.0%)(p= 0.407).

**Conclusion:** The use of sequential chlorhexidine-povidone-iodine antiseptic for pre-operative skin preparation at cesarean delivery was not superior to chlorhexidine alone in reducing the incidence of post-Caesarean SSI. Therefore, we recommend that chlorhexidine gluconate should be the antiseptic agent of choice for cesarean delivery, until further studies dictate a superior antiseptic protocol.

**Keywords:** Surgical site infections, Povidone-iodine, Chlorhexidine, Skin-preparation, Caesarean delivery.

**Introduction**

Caesarean delivery remains the most commonly performed operation in obstetrics.1,2The Caesarean rate in Nigeria is between 11.8% and 40.1% of all deliveries and still rising.3-8 Unfortunately, this surgery is commonly complicated by infection of the surgical site (SSI), defined as infection at or near the surgical incision and all tissues manipulated during surgery within 30 days of an operative procedure and could be incisional (superficial or deep) or organ space (pelvic peritonitis and endometritis).9-12While SSI complicates 3.7% to 9.9% of Caesarean deliveries in advanced countries,13-16values of 9.1% to 16.2% have been reported in Nigeria.3,17-21 Yet these values may have been underestimated since most of these studies were based on in-patient observation, excluding the larger proportion of infections that usually occur after discharge from hospital.11,16,22

The consequences of both genital (eg puerperal sepsis/endometritis) and non-genital (eg incisional wound infection, mastitis, UTI) postpartum infections are enormous. Prolonged hospital stay and hospital readmissions increase the overall cost of care. There is impairment of breastfeeding and infant-mother bonding. Postpartum infection is among the commonest causes of maternal mortality. Long term morbidities may include infertility, chronic pelvic pain, and increased risk of extrauterine gestation.23-28

Bacterial contamination is a necessary precursor of surgical site infection.10 The source of pathogens to Caesarean surgical sites is the endogenous flora of the patient’s skin, and the lower genital tract. The skin contains a large number of bacteria.9 The dose of bacteria wound contamination, the virulence of the bacteria and the resistance of the host determine the likelihood of actual surgical site infection.11 Studies have shown that the risk of surgical site infection becomes markedly increased if the surgical site is contaminated with >105microorganisms per gram of tissue.10 It is therefore clear that reduction in the number of bacteria on the skin at the time of surgical incision will reduce the likelihood of occurrence of surgical site infection.9-12 Therefore, preoperative skin antisepsis has the potential to decrease the risk of post-Caesarean surgical-site infection.

Although regulatory bodies favour Chlorhexidine (CHG) over Povidone-Iodine (PVI)9-11,29,significant differences exist in the onset and duration of action, mechanisms of actions, and antibacterial activities of these two agents.9,10,12,30-33 In terms of onset and duration of action, CHG has slower onset (1hour) but longer duration of action (6hours) which could complement PVI that has faster onset (4 minutes) but shorter duration of action (1-2hours). CHG disrupts cell membranes and leaks cellular contents while PVI causes oxidation of cellular constituents. Unlike CHG, PVI is effective against fungi, viruses, mycobacterium, and antiseptic-resistant bacterial organisms.The question is whether sequential protocol could provide both faster onset and longer duration of action compared to the individual agent and whether it would provide wider coverage of infection-causing organisms and hence reduce the risk of surgical site infections.As at commencement of this trial, only a single study was identified on literature search that had compared sequential and single use of chlorhexidine and povidone-iodine in caesareandelivery.34 Studies that compared chlorhexidine-based agents with iodophors-based agents as antiseptics in caesarean section were inconclusive on which agent was superior.35Similar lack of conclusion is seen in comparative studies in the general and surgical sub-specialties.34,35 In all these studies, there is wide heterogeneity in the composition of the antiseptic agents used, and in the techniques and duration of antiseptic applications that make objective comparison difficult.34-36

**Patients and Methods**

This was a randomized comparative trial involving two study arms: the sequential arm, where participants had skin preparation with 0.5% alcohol-CHG followed by 10% aqueous solution of PVI, and the non-sequential arm, where participants had skin preparation with 0.5% alcohol-CHG alone. The primary outcome was occurrence of surgical site infection within 30 days of Caesarean delivery, while secondary outcomes were occurrences of adverse skin reaction within one week of Caesarean delivery, prolonged length of hospital admission, and infection-related readmission within 30 days of Caesarean delivery. The study was conducted in two state-owned tertiary hospitals in Delta State (Department of Obstetrics and Gynecology, Delta State University Teaching Hospital, Oghara, Nigeria and Department of Obstetrics & Gynaecology, Central Hospital, Warri, Nigeria) over a period of 8 months, from January 2019 to August 2019. The combined annual total deliveries in the two hospitals was 4,804 (vaginal birth was 3,754 and Caesarean sections was 1,050), with a caesarean section rate of 48.9% in Oghara and 19.9% in Warri. The study population consisted of pregnant women going for Caesarean sections, both elective and emergency. Inclusion criteria were completed 28 weeks gestations and consent to participate in the study. Those who were on antibiotics, had known medical or obstetric risk for postoperative infection (such as immunosuppressive disorders, steroid drug therapy, prolonged rupture of membranes, prolonged active phase labor, clinical chorioamnionitis, infection around the proposed site of surgical incision), were allergic to CHG or Iodine, or who may not be accessible by telephone for follow-up were excluded.

The minimum sample size was calculated using the formula for interventional comparative study with qualitative outcome.38

***N =***

Where:

N = desired sample size per group

Zα = standard normal variate for the level of significance

Zβ = standard normal variate for desired power or type 2 error

P1 = Prevalence of event in the control arm

P2 = Prevalence of event in the experimental arm

P = Pooled prevalence =

Assuming a baseline incidence of SSI of 16.2% (i.e P1=0.162) in Nigeria19; and aiming to have an 80% power (Zβ = 0.84) at 5% level of significance (Zα = 1.96) to detect 50% differences in the incidence of SSI between the two study arms (P2 [= 50% of P1] = 0.081),it was estimated that 259 participants per arm would be required. After correction for anticipated 10% attrition, 570 participants were required, 285 in each arm. Institutional Ethical approval to conduct the study was obtained from the Ethics and Research Committee of the Delta State University Teaching Hospital, Oghara.

Ten Research Assistants who were resident doctors in the obstetric units of the study centres were trained by the Principal Investigator to facilitate protocol adherence and data collection. Consecutive patients going for caesarean delivery were assessed for eligibility; and those eligible were counseled and consent was obtained. The parturients for elective surgery were counseled in the antenatal clinics and this was reinforced in the antenatal wards on the eve of the surgery and consent was then obtained. Counseling and obtaining of consent in emergency cases was done in the labour ward or in the triage area. Thereafter, participants were randomized equally into the two study arms of 285 participants per arm using computer-generated random number allocation. This was achieved by picking one sealed envelope containing a random number from a bag containing 570 sealed envelopes with random numbers (without replacing), and checking the picked random number on a master list of all the random numbers pre-assigned in alternate order as it appears on the master list to one of two study groups. Upfront allocation of the sealed envelopes to the two study centres was based on the relative proportion of total caesarean section performed in each of the two centres in the previous years; hence 85% and 15% of the sealed envelopes were allocated to Warri and Oghara respectively. The allocated group was immediately communicated to the scrub nurse and the surgeons.

Participants had routine pre-operative care which consisted of a full evaluation, anesthetists review, consent for surgery and administration of intravenous Ceftriaxone 1g immediately after induction of anesthesia. At surgery, skin preparation procedure depended on the study arm. Those in sequential study arm had 3 applications of 0.5% chlorhexidine gluconate solution in 95% alcohol, one application of 95% alcohol, followed by 2 applications ofaqueous10% povidone-iodine solution. Those in the non-sequential arm had 3 applications of 0.5% chlorhexidine gluconate in 95% alcohol, then one application of 95% alcohol. During the postoperative period participants’ vital signs were monitored to identify pyrexia, the scrubbed area of the skin was inspected for changes suggestive of allergy, the wound was exposed and inspected from the second day onwards and the abdomen and lochia were examined for evidence of infection. Following counselling about post-discharge monitoring, participants were discharged on the fourth or fifth day, depending on the managing units’ preference, if no medical or obstetric complications had occurred. Post-discharge monitoring consisted of direct inspections at 2 weeks postoperative visit and telephone survey on the 30thpost-operative day using a survey tool adapted from WHO model (attached).39 Finally, participants’ records were reviewed for evidence of infection-related readmission in the previous 30 days.

Data were collected on demographiccharacteristics (age, parity, occupational skill level based on International Standard Classification of Occupation 2012 version40, highest level of education attained),and obstetric characteristics (booking status, gestational age at delivery, indication(s) for caesarean delivery, urgency of caesarean delivery, onset & duration of labour, numbers of vaginal examinations performed in the preceding 24 hours before recourse to caesarean sections, and preoperative haematocrits).Others were intra-operative characteristics(the type of anaesthesia used, the status of the lead surgeon, the type of skin incision used, the duration of surgery estimated in minutes from time of skin incision to the end of skin repair, the estimated blood loss, and need for blood transfusion), postoperative characteristics, (post-operative PCV and length of post-operative hospital admission), as well as the study outcomes. Surgical site infection was identified by a combination of direct clinical observation and telephone survey based on CDC criteria where incisional SSI was defined as occurrence of pain, swelling, redness, discharge and or wound dehiscence and organ space SSI was defined as occurrence of pelvic pain, fever (temperature >38°C on two occasions at least 6 hours apart), offensive vaginal discharge, uterine sub-involution, abdominal tenderness, and/or adnexal tenderness, within 30 days of surgery.10,11,41 Adverse skin reaction was identified by erythema, wheals and or pruritus limited to the scrubbed areas of the skin within the period patient was on admission. Prolonged length of hospital admission was defined as admission beyond 7 days after surgery.

**Data Management and Analysis**

Information was extracted using a data collection sheet designed for the purpose. The data were collated, coded and analysed using Statistical Package for Social Sciences (SPSS) version 22. Categorical data were summarised as frequencies and percentages while continuous data were summarised as means and standard deviations. Comparisons of characteristics and outcome between the two study arms were achieved using chi-square tests (with Fisher exact correction where applicable) for categorical variables, and student’s t-test for continuous variables. Differences were considered significant if p<0.05.

**Results**

**Excluded** (n= 41)

* Not Eligible (n=32)
* Declined to Participate (n=9)

**Assessed for eligibility (n= 611)**

**Randomized (n= 570)**

**NON-SEQUENTIAL ARM** (n= 285)

* Received allocated intervention (n=285)

**SEQUENTIAL ARM** (n= 285)

* Received allocated intervention (n=285)

## Allocation

**Discontinued intervention** (withdrew. n=1)

**Protocol Deviation** (Caesarean hysterectomy n=3)

**Lost to follow-up** (n= 20)

**Discontinued intervention** (n=0)

**Protocol Deviation** (Caesarean hysterectomy n=2)

**Lost to follow-up** (n= 20)

## Follow-Up

**Excluded from analysis** (n= 22)

**Analysed** (n= 263)

**Excluded from analysis** (n= 24)

**Analysed** (n= 261)

## Analysis

**Figure 1: Algorithm of the randomization and follow-up of study participants**

Figure 1 shows the algorithm of the randomization and follow-up of study participants. A total of 570 women were recruited and data were available for analysis on 524 participants (completion rate of 91.9%). All the participants received their allocated interventions. Forty-six women were excluded from analysis because of loss to follow-up, protocol deviation or patient discontinuation.

Table 1 shows the baseline demographic and obstetric characteristics of the participants. The mean age of the women was 32.3±5.4 years. Most of the participants, 490 (93.5%) had had at least secondary school education and 314 (59.9%) were in occupational skill levels 1 or 2**.** The mean gestational age of the participants at the time of surgery was 38.0±2.3 weeks. Majority, 484 (92.4%) of the women had booked their pregnancies. There were no significant differences, between the two groups, in the mean ages, levels of education and occupational skill levels. There were also no significant differences in their mean parities, booking status and mean gestational ages at delivery. There were no significant differences in the proportions that were in labour or in the number of vaginal examinations that had been performed prior to the Caesarean section.

Table 2 shows the baseline peri-operative characteristics of the participants. The commonest indication for surgery was two or more previous Caesarean sections (17.2%). Spinal anesthesia was the choice in 499(95.2%) of the women. The mean duration of surgery was 54.3±15.4minutes and mean estimated blood loss at surgery was 695.7±251.0 mL. The mean length of hospital admission following surgery was 4.5±1.3 days. There were no significant differences, between the two groups, in the indications for and urgency of the surgery, the types of anaesthesia used, the status of the surgeon or the type of skin incision used. The mean duration of surgery, the mean blood loss at the operation, the mean post-operative haematocrits and the mean duration of post-operative hospital stay were not significantly different between the two groups. The proportions that had blood transfusions were also not significantly different.

Table 3 shows the primary and secondary outcomes of the study. Of the 524 participants, 69 had one or more sub-categories of infections of the surgical site giving a surgical site infection rate of 13.2%; 60 (87.0%) were incisional infections and 9 (13.0%) endometritis. Twenty seven of the 69(39.1%) cases of SSI were diagnosed after discharge from the hospital. Of this, 11 (40.7%) and 16 (59.3%) were in the sequential and non-sequential arms respectively. The infection rate among participants in the sequential arm was 10.7% (28 out of 261) while the infection rate among those in the non-sequential arm was 15.6% (41 out of 263). The difference was not statistically significant (p=0.100). Among those who had SSIs there was no significant difference in the proportions of different types of SSIs between the two groups; neither was there any significant difference in the proportions that had the infection diagnosed before or after discharge from hospital. There was adverse skin reaction in 10 (1.9%), prolonged length of hospital stay in11 (2.1%) and infection-related re-admissions in 13 (2.5%) of the participants. The differences in these outcomes were not statistically significant between the two groups.

**Discussion**

The overall surgical site infection rate in this study of 13.2% was within the range of 7.1% to 19% described in Nigeria and other low-income countries3,17-21 but much higher than the range of 3.7% to 9.9% documented in advanced countries. Surgical site infection has continued to be an issue of public health importance in the developing world. Postoperative infection, in general, is a concern in LMIC. In the recently concluded African Surgical Outcomes Study, postoperative complications rate was 18.2% of which post-operative infection was the most common, occurring in 10.2% of the patients. One-third of participants studied had caesarean surgery.42 Infection after a caesarean delivery should be regarded as an unfortunate occurrence. Surgical site infection occurring after caesarean sections will undoubtedly accentuate the incidence of maternal mortality, and morbidities in this setting. Incisional infections were the commonest form. This was in keeping with several previous studies,34,43 and established patterns.10,11 The difference in infection rates between the two arms of this study was not statistically significant. Ngai et al, in a three-arm study comparing chlorhexidine-only, povidone-iodine only and sequential combination of the two in elective Caesarean sections, found no significant differences in the SSI rates.34 The differential advantages brought by povidone-iodine to the antiseptic combinations of chlorhexidine and povidone-iodine were not enough to achieve a statistically significant difference in infection rate. The antimicrobial benefit of povidone-iodine over chlorhexidine gluconate is its superior activities against non-bacterial organisms11,12,30,44, but the role of these non-bacterial organisms in the causation of surgical site infection is probably very limited. In addition, more bacterial organisms including resistant strains such as methicillin-resistant *Staphylococcus aureus* are known to be more sensitive to povidone-iodine relative to chlorhexidine gluconate.31,45 However, such organisms possibly still retain significant sensitivity to chlorhexidine-gluconate in alcohol, or may not even be implicated in the causation of surgical site infections in the two study centres.

The overall adverse skin reaction rate was 1.9%. This was in keeping with findings of 1.5% to 2.1% reported by other workers in advanced countries46,47, but much lower than 4.8% reported by Aworinde et al48 in Nigeria. In this study, there was no statistically significant difference in adverse skin reaction rate between the two groups. Previous investigators had observed similar adverse reaction rates between iodine and chlorhexidine.46,48,49

In this study, there was no significant difference in the mean duration of admission or the rate of prolonged length of admission between women in the two arms. Tuuli et al46 in St. Louis, USA noted similar lengths of hospital stay in their comparison of chlorhexidine-alcohol and povidone-iodine-alcohol, although they found significantly lower rates of SSI in the former. Amer-Aishiek et al47 in Tel Aviv on the hand found longer length of admission among the povidone-iodine group relative to chlorhexidine-alcohol group. Similar lengths of admission in the two study arms found in this study is expected since the impact of antiseptic types on the length of hospital admission is an indirect reflection of the occurrence of surgical site infection in the participants.

Only 2.5% of the women were re-admitted for infection-related complications. This was not unexpected because most women with incision site infections were treated with dressings and antibiotics on outpatient basis, and most secondary wound procedures such as incision and drainage, and secondary closures were done as day cases. Women in our environment are not favourably disposed towards hospital admission because it interferes with their daily activities and the care of their newborn babies. Admission was accepted more commonly among women with severe puerperal sepsis and deep wound dehiscence. The difference in infection-related re-admission rates was not statistically significant. Findings from studies that compared readmission rates between antiseptic protocols are conflicting: Tuuli et al46 noted similar readmission rates between chlorhexidine group and povidone-iodine group, while Salama et al49 and Amer-Alshiek et al47found higher readmission rates in povidone-iodine groups relative to chlorhexidine group. Again, readmission rates after surgery mostly mirror the occurrence or otherwise of surgical site infections. This study has established that sequential application of PVI after primary skin preparation with CHG confers no significant advantage over the use of the latter alone when rates of SSIs are considered. Therefore, the sequential antiseptic skin preparation cannot be recommended for routine use among women undergoing caesarean section.

It is instructive to note that the conduct of post-discharge monitoring increased the detection rate of post-caesarean infections by ensuring that additional cases of surgical site infections that would have been missed following discharge were captured. However, the thirtieth-day post-discharge monitoring would seem limited as it was by telephone survey which relied on patients’ judgments for the diagnosis of surgical site infection. Available evidence however indicates that this method remains one of the most practical and acceptable worldwide11,50, especially in developing countries where routine home visits are not common place, places of patients’ residence are at long distances from the hospital, and where financial constraints hamper patients’ presentation after discharge.39,51In this study, measures were not put in place to ensure that those who performed post-operative assessments of the women were blinded to the group they belonged to. This might have introduced variable degrees of detection bias into the study; however, we believe that with the detailed training given to the study team members as to the diagnostic symptomatology of wound infection, and careful education of the parturients as to the signs contained in the WHO-adapted model(see attached) that served as the telephone guide, the potential impact of the non-blinding on the outcomes was significantly mitigated. The microbiology of the specific organisms responsible for surgical site infections was not studied in this trial as it was not part of the study protocol. This may appear as a limitation, and it is certainly advocated for assessment in subsequent studies. Lastly, the impact of the exclusion of participants with certain characteristics that conferred increased risk for post-operative infections (such as immunocompromised states, immunosuppressive therapy, prolonged rupture of membrane, and others as itemized in the exclusion criteria) on the result of this study remains unknown.

**Conclusion**

In conclusion, this study has established that sequential application of PVI after primary skin preparation with CHG confers no significant advantage over the use of the latter alone when rates of SSIs are considered. Sequential antiseptic skin preparation cannot therefore be recommended for routine skin preparation among women undergoing caesarean section. Against the backdrop of additional cost and longer antiseptic application time consequent upon secondary application of PVI, it might be prudent to simply limit antiseptic use to CHG alone.

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**Table 1:** Baseline demographic and obstetric characteristics of the participants

|  | **Total** | **Sequential Arm** | **Non-Sequential Arm** | **Statistics** | ***P*-value** |
| --- | --- | --- | --- | --- | --- |
|  | **N=524** | **N=261** | **N=263** |  |  |
| 1. **DEMOGRAPHICS** | **n (%)** | **n (%)** | **n (%)** |  |  |
| **Age (Years)** |  |  |  |  |  |  |
| Mean Age ±SD | 32.3±5.4 | 32.2±5.3 | 32.3±5.4 | t= -0.290 | 0.772 |
| **Highest Educational Level** |  |  |  |  |  |
| None | 6 (1.1) | 2 (0.8) | 4 (1.5) |  |  |
| Primary | 28 (5.3) | 12 (4.6) | 16 (6.1) |  |  |
| Secondary | 204 (38.9) | 101 (38.7) | 103 (39.2) |  |  |
| Tertiary | 286 (54.6) | 146 (55.9) | 140 (53.2) | χ2= 1.376 | 0.711 |
| **Occupational Skill Level** |  |  |  |  |  |
| Unemployed | 87 (16.6) | 46 (17.6) | 41 (15.6) |  |  |
| Level I | 173 (33.0) | 74 (28.4) | 99 (37.6) |  |  |
| Level II | 141 (26.9) | 80 (30.7) | 61 (23.2) |  |  |
| Level III | 116 (22.1) | 58 (22.2) | 58 (22.1) |  |  |
| Level IV | 7 (1.3) | 3 (1.1) | 4 (1.5) | χ2= 6.596 | 0.159 |
| 1. **OBSTETRICS** |  |  |  |  |  |
| **Gestational age (weeks)** |  |  |  |  |  |
| Mean GA ±SD | 38.0±2.3 | 37.9±2.4 | 38.1±2.3 | t= -0.588 | 0.557 |
| **Parity** |  |  |  |  |  |
| Mean Parity ±SD | 1.6±1.5 | 1.6±1.5 | 1.7±1.6 | t= -0.994 | 0.320 |
| **Booking Status** |  |  |  |  |  |
| Unbooked | 40 (7.6) | 15 (5.7) | 25 (9.5) |  |  |
| Booked | 484 (92.4) | 246 (94.3) | 238 (90.5) | χ2= 2.625 | 0.105 |
| **Labour History** |  |  |  |  |  |
| Not in Labour | 315 (60.1) | 156 (59.8) | 159 (60.5) |  |  |
| Latent Phase labour | 80 (15.3) | 42 (16.1) | 38 (14.4) |  |  |
| Active phase labour | 129 (24.6) | 63 (24.1) | 66 (25.1) | χ2= 0.291 | 0.865 |
| **Vaginal examination** |  |  |  |  |  |
| None | 264 (50.4) | 128 (49.0) | 136 (51.7) |  |  |
| One or Two | 155 (29.6) | 55 (21.1) | 50 (19.0) |  |  |
| More than two | 105 (20) | 78 (29.9) | 77 (29.3) | χ2= 0.479 | 0.787 |

**Table 2:** Baseline peri-operative characteristics of the study participants

|  | **Total** | **Sequential Arm** | **Non-Sequential Arm** | **Statistics** | ***P*-value** |
| --- | --- | --- | --- | --- | --- |
|  | **n (%)** | **n (%)** | **n (%)** |  |  |
| **Primary indication for Surgery** |  |  |  |  |  |
| Two or more Previous Sections | 90 (17.2) | 47 (18.0) | 43 (16.3) |  |  |
| One previous Scar, Ineligible for TOLAC | 86 (16.4) | 41 (15.7) | 45 (17.1) |  |  |
| Malpresentation/Abnormal Lie | 81 (15.5) | 42 (15.7) | 40 (15.2) |  |  |
| Hypertensive disorders | 71 (13.5) | 36 (13.8) | 35 (13.3) |  |  |
| Slow progress of labour | 44 (8.4) | 25 (9.6) | 19 (7.2) |  |  |
| Fetal distress | 40 (7.6) | 19 (7.3) | 21 (8.0) |  |  |
| Antepartum Haemorrhages | 25 (4.8) | 11 (4.2) | 14 (5.3) |  |  |
| Obstructed labour | 24 (4.6) | 14 (5.4) | 10 (10) |  |  |
| Failed Induction | 24 (4.6) | 11 (4.2) | 13 (4.9) |  |  |
| Other Indications (e.g fetal macrosomia, Fetal growth restrictions, maternal request, adverse obstetric history) | 39 (7.4) | 16 (6.1) | 23 (8.7) | χ2= 3.751 | 0.927 |
| **Urgency of surgery** |  |  |  |  |  |
| Emergency delivery | 307 (58.6) | 153 (58.6) | 154 (58.6) |  |  |
| Elective delivery | 217 (41.4) | 108 (41.4) | 109 (41.4) | χ2= 0.000 | 0.988 |
| **Status of surgeons** |  |  |  |  |  |
| Consultant | 105 (20.0) | 55 (21.1) | 50 (19.0) |  |  |
| Senior resident | 241 (46.0) | 109 (41.8) | 132 (50.2) |  |  |
| Junior resident | 178 (34.0) | 97 (37.2) | 81 (30.8) | χ2= 3.864 | 0.145 |
| **Anaesthesia Types** |  |  |  |  |  |
| Spinal | 499 (95.2) | 247 (94.6) | 252 (95.8) |  |  |
| General | 25 (4.8) | 14 (5.4) | 11 (4.2) | χ2= 0.402 | 0.526 |
| **Skin Incision Types** |  |  |  |  |  |
| Midline sub-umbilical | 29 (5.5) | 16 (6.1) | 13 (4.9) |  |  |
| Suprapubic Transverse | 495 (94.5) | 245 (93.3) | 250 (95.1) | χ2= 0.353 | 0.552 |
| **Duration of surgery(min)** |  |  |  |  |  |
| ≤ 60 | 404 (77.1) | 196 (75.1) | 208 (79.1) |  |  |
| > 60 | 120 (22.9) | 65 (24.9) | 55 (20.9) | χ2= 1.182 | 0.277 |
| Mean Duration ±SD | 54.3±15.4 | 55.0±15.5 | 53.7±15.2 | t= 0.960 | 0.337 |
| **Estimated Blood Loss (mL)** |  |  |  |  |  |
| ≤ 1000 | 453 (86.5) | 220 (84.3) | 1. (88.6) |  |  |
| > 1000 | 71 (13.5) | 41 (15.7) | 30 (11.4) | χ2= 2.070 | 0.150 |
| Mean EBL ±SD | 695.7±251 | 703.5±260 | 688.0±241 | t=0.708 | 0.480 |
| **Blood Transfusion** (Pints) |  |  |  |  |  |
| No | 490 (93.5) | 247 (94.6) | 243 (92.4) |  |  |
| Yes | 34 (6.5) | 14 (5.4) | 20 (7.6) | χ2= 1.084 | 0.298 |
| **Postoperative Haematocrits (%)** |  |  |  |  |  |
| ≤ 29 | 217(41.4) | 105 (40.2) | 112 (42.6) |  | |
| ≥ 30 | 307 (58.6) | 156 (59.8) | 151 (57.4) | χ2= 0.30 | 0.584 |
| Mean PCV ±SD | 30.1±3.9 | 30.1±4.0 | 30.1±3.9 | t= 0.000 | 1.000 |
| **Length of Admission (days)** |  |  |  |  |  |
| ≤7 | 513 (97.9) | 257 (98.5) | 256 (97.3) |  |  |
| >7 | 11 (2.1) | 4 (1.5) | 7 (2.7) | χ2=0.813 | 0.368 |
| Mean ±SD | 4.5±1.3 | 4.5±1.3 | 4.5±1.3 | t= 0.000 | 1.000 |

TOLAC – Trial of Labour After Caesarean

**Table 3:** Primary and Secondary Outcomes of the study

| **Variables** | **Total** | **Sequential Arm** | **Non-Sequential Arm** | **Statistics** | **P-value** | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **n (%)** | **n (%)** | **n (%)** |  |  | | |
| **Primary Outcome** |  |  |  |  |  | | |
| Surgical site infection | 69 (13.2) | 28 (10.7) | 41 (15.6) | χ2=2.708 | 0.100 |
| **Types**  Incisional | 60 (87.0) | 25 (89.3) | 35 (85.4) |  |  |
| Endometritis  **Timing**  Before Hospital discharge  After Hospital discharge | 9 (13.0)  42(60.9)  27(39.1) | 3 (10.7)  17(60.7)  11(39.3) | 6 (14.6)  25(61.0)  16(39.0) | χ2=4.262  χ2=0.0 | 0.235  1.0 |
| **Secondary Outcomes** |  |  |  |  |  | |
| Adverse Skin reaction | 10 (1.9) | 6 (2.3) | 4 (1.5) | 1FET | 0.544 | |
| Prolonged Length of Admission | 11 (2.1) | 4 (1.5) | 7 (2.7) | χ2=0.813 | 0.367 | |
| Infection-Related Readmission | 13 (2.5) | 5 (1.9) | 8 (3.0) | χ2=0.687 | 0.407 | |

FET: Fisher’s Exact Test

**TELEPHONE INTERVIEW GUIDE FOR POST DISCHARGE SURVEILLANCE**

Hospital No: \_\_\_\_\_\_\_\_\_\_ Data Proforma S/N: \_\_\_\_\_\_\_\_\_\_\_\_ Date of surgery: \_\_\_\_\_\_\_\_\_\_\_\_\_

Dates of 1st Follow: \_\_\_\_\_\_\_\_\_ Date due for Interview: \_\_\_\_\_\_\_ Date of interview: \_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
|  | Preliminaries: Greetings. Introduction of the interviewer. Confirm identity information. State purpose of telephone call. Request to ask few questions now (or may need to call back at suitable time). Enquire about general state of patient’s health and that of her baby | | |
|  |
|  | Ask about the wound sites: Ask if there had been any of these: | * Pain * Reddening * Discharge * Breaking down * Swelling |  |
|  | Ask about lochia/vaginal discharge. Ask if there had been any of these: | * Vaginal discharge? * Discharge required use of sanitary pads? How many? * Is Discharge malodorous? * Is Discharge blood stained? |  |
|  | Ask about other symptoms | * Is there lower abdominal pains * Does she feel ill, and feverish? * Are there any other symptoms? |  |
|  | Ask about Hospital care received so far | * Has she been to the hospital for these complaints? * Where? When? What treatments were offered? * Was she admitted for any of these complaints? * Did a doctor have to open the wound? * Did a doctor have to re-suture the wound? * Was she given antibiotics? * Does the wound still need dressing? |  |
|  | **ASSESSMENT** | **Presumptive Diagnosis of SSI:** YES NO |  |

**If yes,** counsel patient on the findings, and give advice on hospital visit and treatment.