
**"IMPACT OF AN EVIDENCE BASED SURGICAL BUNDLE ON
SURGICAL SITE INFECTION IN CESAREAN DELIVERY -
RANDOMIZED CONTROL TRIAL."**

**By
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LIST OF ABBREVIATIONS

HAC	:	Hospital acquired condition
SSI	:	Surgical site infection
LMIC	:	Low and middle income countries
WHO	:	World Health Organization
CDC	:	Centre for Disease control
ERAS	:	Enhanced recovery after surgery
RR	:	Relative Risk
CI	:	Confidence Interval
FDA	:	Food and Drug Administration
MRSA	:	Methicillin resistant Staph. Aureus
DTA	:	Deep transverse arrest

ABSTRACT

“Impact of an evidence based surgical bundle on surgical site infection in caesarean delivery” -Randomized Control Trial”

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Introduction and objectives

SSI are an important global cause of morbidity and mortality for patients undergoing all types of surgeries. The most common complication after caesarean section is post partum surgical site infection (SSI) and it is one of the major causes of maternal morbidity is the post- operative period.It is seen in around 2 to 15 % ¹of patients who undergo caesarean sections . Hence this study has been under taken to assess the incidence of surgical site infection (SSI) after implementing evidence based surgical bundle for prevention of cesarean delivery related SSI.

OBJECTIVE:

To analyse whether evidence based surgical bundle is better than the standard routine care for prevention of cesarean delivery related SSI.

METHODS:

The antenatal women who will be coming to the obstetric wards and free labor room of OBG department of teaching hospital attached to KAHER University’s JN Medical College, Belagavi. In this randomised control trial, women undergoing cesarean delivery from January 2020 and December 2020 will be randomized into two groups based on a computer generated randomization table .The two groups include an interventional group and a control group

Key words: SSI (surgical site infection), surgical bundle, caesarean section.

RESULTS

Data contains measurements on 287 subjects which are divided into control and interventional groups with 144 and 143 subjects respectively .Patients with SSI in the control group were 28 (19.4 %) and SSI in interventional group were 14 (9.7 %) with a statistically significant “p” value of 0.02 obtained after applying chi square test .

CONCLUSION:

In this study when compared to conventional routine care, the evidence-based surgical bundle was found to be successful in reducing cesarean delivery-related SSI. We believe that if the bundle is applied collectively, it will lower the risk of SSI significantly. The adoption of this method would be useful in terms of focusing the funds in more critical areas in low income countries as well enhancing maternal health in cesarean sections.

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1. INTRODUCTION

Globally infection associated with pregnancy and sepsis is one of the major cause of maternal mortality .Cesarean deliveries were observed to have a 5-20 fold increased risk of infectious morbidity, when compared to women delivering vaginally^[1].

In the last three decades the incidence of cesarean deliveries has risen sharply in view of improving maternal and perinatal outcome. Cesarean sections are one of the commonest obstetric surgeries, with the cesarean section rates varying from 10 to 50 % ^[1] in various centres. Most of these cesarean sections result in fairly good outcomes, but some are associated with certain undesirable Hospital acquired condition (HAC) such as surgical site infection (SSI). The most common complication after caesarean section is post-partum surgical site infection (SSI) and it is one of the major causes of maternal morbidity in the post-operative period^[2]. A WHO survey in LMIC the incidence rate of SSI range from 1.2- 23.6 %, whereas in countries with better resources the SSI rate was between 1.2 and 5.2 %^[3].. SSI is more commonly seen in women undergoing a cesarean section and have associated risk factors such as inadequate prenatal care, anemia with a poor nutritional status, extremes of BMI (underweight and obesity), GDM, emergency cesarean sections, PROM, prolonged labor, co-existing infections and co-morbidity, inappropriate surgical techniques and prolonged duration of surgery^[3].. SSIs can also affect the quality of life of the woman, resulting in chronic pelvic pain, a significant delay in returning to normalcy and sometimes even post partum depression^[3].

SSI result in a longer duration of hospital stay and increases financial burden not only to the patient but also to the health care system especially in low and

middle income countries(LMIC) and it may also require readmission of the patient to the hospital for further treatment. Interventions and techniques must be identified to decrease the risk of cesarean deliveries SSI. Cesarean sections is an important area for SSI modelling and assessment of interventions , as CS is generally performed on younger women who do not suffer from any disease and age related risks of infections and comorbidities seen in other various surgical surveys ^[3].

Previous literature has shown that certain evidence based interventions can lower SSI associated with cesarean deliveries. A large number of clinical studies have reported the use of perioperative, intraoperative and post operative intervention strategies to reduce cesarean section associated infections. Global organizations such as WHO, CDC have recommended set of interventions which would help reduce the cesarean delivery associated SSI. Evidence based bundles in infection prevention and safety are simple sets of 3 or more evidence-based practices that, when implemented collectively, improve the reliability of their delivery and improve patient outcomes^[4,5].

Thus the objective of our study was to assess efficacy of evidence based surgical care bundle to reduce cesarean section related SSI when compared to routine standard care..

OBJECTIVE

To analyse whether evidence based surgical bundle is better than the standard routine care for prevention of cesarean delivery related SSI.

2. REVIEW OF LITERATURE

Disruption of the normal structure and function of the skin with its associated soft tissue structures is called wound.

Types of wound

Acute wounds: abrasions, crush injury, gunshot, surgery.

Chronic wounds: peripheral artery disease, microvascular thrombosis and occlusion.

2.1 Phases of wound healing

Hemostasis: Hemostasis is caused by the constricting of small vessels around the incision. Platelets clump together in injured arteries, activating the clotting cascade and releasing essential growth factors and cytokines for wound healing (eg, platelet-derived growth factor, transforming growth factor beta). The fibrin matrix that develops stabilises the wound and serves as the foundation for wound healing ^[6].

Inflammation: Various steps in this stage. Macrophages are generated when mononuclear leukocytes clump together. Several events control the maturation of blood-derived monocytes into macrophages, including the production of vimentin, a structural filament protein involved in wound healing. Mast cells release histamine and other mediators of vasodilation and cellular migration as they degranulate. Small arteries become permeable to molecular and cellular mediators of inflammatory changes when stromal mast cells release vasoactive chemicals. Edema or swelling is the clinical manifestation of the resultant buildup of plasma and cellular components. Chemotaxis causes the migration and concentration of polymorphonuclear leukocytes, which use lysosomal enzymes to digest pathogens, foreign debris, and necrotic tissue ^[7].

Epithelialization (Migration): Inside a clot, basic cell growth and epithelial cell migration can be seen in the fibrin bridgework. Individual cells continue to proliferate until they are surrounded by cells of the same type. Epithelial cells move downhill to meet deep in the dermis in a clean surgical wound. When this layer is renewed, migration ceases. Within 48 hours after surgery, the epithelialization process is complete. The epithelium's surface layer acts as a barrier against bacteria and other foreign things, but it is relatively thin, easily damaged, and has little tensile strength^[8].

Fibroplasia: At this stage, fibroblasts proliferate, ground substance accumulates, and collagen is produced. Fibroblasts are produced from local mesenchymal cells and appear in the wound within 24 hours, with the majority of them appearing by the tenth postoperative day. The ground material is formed when fibroblasts connect to the fibrin matrix of the clot, multiply, and create glycoprotein and mucopolysaccharides. Myofibroblasts, which have the features of smooth muscle cells with the ability to contract, are produced by fibroblasts and are found in the wound by the fifth day. The ability to pull the wound's margins together is determined by tissue characteristics. Collagen, the body's principal structural protein, is also produced by fibroblasts. On the second postoperative day, collagen production begins. Angiogenesis is stimulated by the growing collagen matrix. Granulation tissue is made up of a combination of collagen synthesis and capillary development^[9].

Maturation Collagen cross-linking, collagen remodelling, wound contraction, and repigmentation are all things to consider. The amount of collagen present in a wound is directly related to its tensile strength. Types I and III collagen are mostly found in the skin and aponeurotic layers. Tensile strength is determined by covalent cross-

links. By six weeks after surgery, the tissue had restored approximately 80% of its former strength. After 180 days, the morphology returns to normal.^[10]

2.2 Impaired wound healing

The risk factors associated with impaired wound healing and wound complications are:

- Infection
- Smoking
- Aging
- Malnutrition
- Immobilization
- Diabetes
- Vascular disease
- Immunosuppressive therapy
- Others.

2.3 Surgical site infection (SSI)

Surgical site infection (SSI) is defined as an infection related to an operative procedure that occurs at or near the surgical incision (incisional or organ/space) within 30 days of the procedure, or within 90 days if prosthetic material is implanted at surgery by the US Centers for Disease Control and Prevention. One or more of the following clinical criteria are used to define SSI: A purulent exudate draining from a surgical site; a positive fluid culture acquired from a surgical site that was closed largely; and a surgical site that is reopened with at least one clinical symptom of infection (pain, edoema, erythema, warmth) and is culture positive or not cultured. The infection is diagnosed by the surgeon. SSIs are classified as incisional or organ/space.

Incisional SSIs are further divided into superficial (ie, those involving only the skin or subcutaneous tissue) or deep (ie, those involving deep soft tissues of an incision). An organ/space SSI may involve any part of the anatomy (other than the incision) that was opened or manipulated during the operative procedure^[11].

2.4 Wound classification:

A widely accepted wound classification system has been developed by the National Academy of Sciences and the National Research Council based upon the degree of expected microbial contamination during surgery clean wounds are uninfected operative wounds with no visible inflammation and a primary closure. Operative wounds in which a viscus is entered under regulated conditions and without contamination, according to clean-contaminated wounds Open, fresh accidental wounds, procedures with substantial breakdowns in sterile technique, or excessive spilling from a viscus are examples of contaminated wounds. Acute, nonpurulent inflammation in wounds was also included in this category. Dirty wounds are defined as ancient traumatic wounds with devitalized tissue, foreign bodies, or faecal contamination, or wounds with a clinical infection or ruptured viscus.^[12]

2.5 Patient preparation

Antimicrobial prophylaxis:

2.5.1 Hand hygiene

Preoperative skin washing with chlorhexidine-based preparations is preferable to povidone-based preparations for clean and clean-contaminated surgery, according to systematic evaluations (risk ratio 0.70; 95 percent CI, 0.60-0.83). Because chlorhexidine is not inactivated by blood or serum, it may be preferable to iodine^[13].

2.5.2 Hair removal:

Hair removal before surgery has been linked to an increased incidence of SSI. A meta-analysis of 19 trials found that no hair removal was linked with a considerably lower incidence of SSI than shaving (relative risk [RR] 0.56, 95 percent confidence interval [CI] 0.34 to 0.96). Shaving was linked to the highest risk of SSI, followed by trimming and depilatory creams. SSI rates linked with shaving, clipping, or depilatory creams were 5.6, 1.7, and 0.6 percent, respectively, in one study.^[14]

2.6 Other operative measures

Other perioperative methods that may reduce SSI include preserving normothermia, oxygenation, glucose control, decreasing red blood cell transfusion, limiting traffic through the operating room, and possibly using laminar flow in some circumstances. Enhanced recovery after surgery (ERAS) programmes and surgical safety checklists aid in the reduction of postoperative complications like SSI^[15].

Maintain normothermia: Perioperative hypothermia has been shown to increase the incidence of SSI by producing vasoconstriction and lowering subcutaneous oxygen tension. Only two randomised trials investigating the effects of hypothermia and SSI were found in a systematic review. When hypothermia was compared to

normothermia, the pooled odds ratio for SSI was 1.6. (95 percent CI 1.14-2.23). Nonsignificant differences resulted from the inclusion of nonrandomized trials in the analysis.^[15]

Limit traffic through operating room.

Use of laminar airflow.

Supplemental oxygen.

Minimize red cell transfusion.

Glucose control.

2.7 Surgical technique

Topical and local antibiotic delivery:

A systematic review found that incisional wound irrigation with an aqueous povidone-iodine solution reduced the risk of SSI in clean and clean-contaminated wounds (odds ratio [OR] 0.31, 95 percent confidence interval [CI] 0.13-0.73; 50 fewer SSIs per 1000 procedures, 95 percent confidence interval 19-64). Antibiotic irrigation had no effect on SSIs (OR 1.16, 95 percent confidence interval 0.64-2.12). While there was no overall clear difference between any irrigation and no irrigation in a separate systematic review and meta-analysis evaluating intracavitary and wound irrigation, the risk of SSI was lower in those treated with antibacterial irrigation compared to non-antibacterial irrigation (relative risk [RR] 0.57, 95% CI 0.44-0.75)^[16].

Intraoperative wound protectors:

A systematic evaluation found 14 randomised studies with 2684 people in total. When compared to normal care, using a wound protector lowered the chance of SSI (15 versus 21 percent; RR 0.70, 95 percent CI 0.51-0.96). When compared to a

single ring device, a two ring device proved more effective (4.4 versus 17.8 percent; RR 0.31, 95 percent CI 0.15-0.58). These findings support the use of an abdominal wound protector to help avoid abdominal SSI, as evidenced by additional meta-analyses and following trials^[17].

2.8 Antimicrobials

2.8.1 Azithromycin

Category

Macrolide

Mechanism of Action

Inhibits RNA-dependent protein synthesis at the chain elongation step; binds to the 50S ribosomal subunit resulting in blockage of transpeptidation^[18].

Pharmacodynamics and Pharmacokinetics

Oral: Rapid absorption from the GI tract.

Extensive tissue; well distributed into skin, lungs, sputum, tonsils, and cervix; weak penetration into CSF; Vd: 31 to 33 L/kg.Oral, IV: 7% to 51% protein binding (concentration dependant and depending on alpha1-acid glycoprotein concentrations).

Hepatic metabolism

Oral bioavailability: tablet 34 percent to 52 percent for immediate release oral suspension; 28 percent to 43 percent for extended release oral suspension Infants and Children 4 months to 15 years: 54.5 hours is the half-life elimination. Adults: 68 to 72 hours for immediate release. Immediate release: 2 to 3 hours; Extended release: 3 to 5 hours Oral: Immediate release: 2 to 3 hours; Extended release: 3 to 5 hours.

Excretion: Oral, IV: Biliary (major route 50%,); urine (6% to 14 %)^[19].

Spectrum of activity: Azithromycin is effective against a wide range of gram-positive bacteria, including erythromycin-resistant *Streptococcus pneumoniae*, Group A, B, C, and G streptococcus, and methicillin-resistant *Staphylococcus aureus*. *Haemophilus* spp., *Moraxella catarrhalis*, *Escherichia coli*, *Salmonella* spp., *Yersinia enterocolitica*, *Shigella* spp., *Campylobacter jejuni*, *Vibrio cholerae*, *Neisseria gonorrhoeae*, *Helicobacter pylori*, and *Bordetella pertussis* all have increased activity against susceptible gram-negative bacteria. Azithromycin is also effective against *Mycoplasma pneumoniae*, *Legionella pneumophila*, *Chlamydia pneumoniae*, *Babesia microti*, and *Ureaplasma pneumoniae*, and *Ureaplasma* spp^[19].

Pregnancy

In females undergoing caesarean delivery, azithromycin is recommended as an additional prophylactic antibiotic^[22]. Azithromycin is indicated for the treatment of several infections in pregnant patients, including Chlamydia, Gonococcal infections, and *Mycobacterium avium* complex (see current guidelines) according to the CDC^[23].

Azithromycin is a pregnancy category B medicine according to the US Food and Drug Administration (FDA) (meaning there is no evidence of risk in pregnant humans). While some research imply that azithromycin is linked to congenital abnormalities, the link isn't consistent across studies, and it's unclear whether the link is causal. When compared to penicillin, maternal azithromycin use during pregnancy was found to increase the incidence of significant medical abnormalities (95 percent CI 1.55 [1.19-2.03]) in a population-based cohort research that followed over 100,000 children for a median of 5.8 years after birth. However, the results were not adjusted for antibiotic use, so causality is unknown. Patients with cervical chlamydial infection were given a 1 g dosage of azithromycin and monitored for efficacy and toxicity in

two studies. In another trial, 123 pregnant women using azithromycin were followed prospectively along with two groups of matched controls. The frequency of significant abnormalities was comparable in the azithromycin-exposed and -unexposed groups and was within the range of 1 to 3% expected in the general population. All three abnormalities were seen in the newborns of azithromycin-exposed women who had been treated for upper respiratory tract infections for five days. The study's ability to identify a difference between azithromycin-exposed and -unexposed groups was insufficient^[21].

2.8.2 Chlorhexidine:

Mechanism of Action

Chlorhexidine is bacteriostatic and bactericidal, depending on the dose, against gram-positive and gram-negative bacteria, facultative anaerobes, aerobes, and yeast. The cationic molecule of chlorhexidine attaches to negatively charged bacterial cell walls and extramicrobial substances, giving it bactericidal effect. This has a bacteriostatic action by changing the osmotic balance of bacterial cells and causing potassium and phosphorous leaks at low concentrations. At high chlorhexidine concentrations, the cytoplasmic components of the bacterial cell precipitate, resulting in cell death.

Obesity, nulliparity, multiple pregnancy, previous C-section, intrapartum factors like premature rupture of membranes, chorioamnionitis, prolonged labour, prolonged duration of surgery, increased depth of thickness of subcutaneous tissue (more than 3 cms), and increased blood loss during surgery were all found to be risk factors for SSI in a study conducted by Kawakita et al in the United States. Obesity, nulliparity, multiple pregnancy, previous C-section, intrapartum factors such as

premature rupture of membranes, chorioamnionitis, prolonged labour, prolonged duration of surgery, increased depth of thickness of subcutaneous tissue (more than 3 cms), and increased blood loss during surgery were all found to be risk factors for SSI in a study conducted by Kawakita et al in the United States^[24].

According to Christina Davidson's research, the total incidence of caesarean SSIs was 1.89 percent (76 SSIs in 4014 caesarean deliveries). The pre-bundle mean was 2.44 and dropped to 1.1 when the SSI bundle was implemented (P =0.013). This represents a 221 percent fall in the SSI rate^[25].

In a research undertaken at Maulana Azad Medical College in New Delhi, 63 (10.3%) of the 611 cases included were identified with LSCS wound infections. The diagnosis of SSI was made in 28 (44.4%) cases before the patient was discharged, whereas 19 (30.2%) cases were detected after the patient was readmitted, and 16 (25.4%) cases were identified during post-discharge follow-up in the outpatient department. The majority of the SSIs (42; 66.7 percent) were superficial, with only four (6.3 percent) involving organs or spaces. The majority of the patients (77.6%) were between the ages of 21 and 30. The average age of patients with SSI was 27, while the average age of patients without SSI was 26.5. Univariate analysis revealed that anaemia, past LSCS as an indication of LSCS, intra-operative blood transfusion, and women with medical illnesses such as heart disease, hypothyroidism, chronic liver, and renal disease were all linked to SSI. Other risk variables, such as previous pregnancies, PROM, pregnancy-induced hypertension (PIH), diabetes, and emergency LSCS, did not indicate a significant difference between patients with and without SSI. When antibiotic prophylaxis was not administered prior to surgery, SSI was found to be substantially linked with SSI (p value 0.05). The most common prophylactic antibiotic administered was intravenous ampicillin, followed by intravenous

ceftriaxone with metronidazole and intravenous ceftriaxone with metronidazole and intravenous ceftriaxone with metronidazole and intravenous ceftriaxone with metronidazole and intra (alone). Patients with SSI spent more time in the hospital (14.1 9.35 days versus 7.7 3.87 days) than those who did not have a post-surgical infection. Gram negative and gram-positive bacteria were recovered in 21 (55.3%) and 17 (44.7%) cases, respectively, from bacterial growth collected from pus specimens. Aminoglycosides, fluoroquinolones, and carbapenems were found to be susceptible to Gram-negative bacteria, while cephalosporins and amoxicillin- clavulanate were found to be resistant. Aminoglycosides, fluoroquinolones, clindamycin, and vancomycin were most effective against Gram-positive bacteria isolated from SSI cases, although amoxicillin- clavunate and erythromycin resistance was common.

In a research conducted at Manipal University in Udupi, 20 of the 305 CS cases experienced surgical site infection. 17 (85%) of patients had surgical superficial site infection during their hospital stay, 2 (10%) developed deep surgical site infection. The majority of surgical site infections were classified as superficial skin infections (75%), deep infections (12.5%), and organ space infections (12.5%)^[26]. In a multicenter trial in Ukraine, the probability of SSI after CSEC was 14.7 percent [95 percent confidence interval (CI) 14.0-15.4]." There were 152 (44.4%) superficial incisional SSIs, 99 (28.9%) deep incisional SSIs, 91 (26.6%) organ/space SSIs, and 25.7 percent of endometritis SSIs. Infections were found in 29.5 percent of the cases (101/342) while they were in the hospital and 70.5 percent (241/342) after they were discharged. The incidence rate of SSI following an elective caesarean operation was 10.7% [95 percent confidence interval: 10.1–11.3], and the rate after an urgent caesarean section was 18% [95 percent confidence interval: 17.2–18.8]"^[27]. In a study

undertaken by the Government MCH Kottayam, Kerala, almost 1500 post-LSCS patients were investigated, and we observed 62 had postoperative SSI in the first post-operative week. A 4.1 percent incidence rate developed as a result of this. After Chi-square and Fishers exact tests, 11 factors were identified to be significantly linked with SSI. The patient's BMI, socioeconomic level, anaemia, hypertension, diabetes mellitus, renal disease, usage of perioperative prophylactic antibiotics, kind of surgery (emergency or elective), pre-operative hospital stay, hospital stay, and surgeon who conducted the surgery are all factors to consider.^[28]

In a research undertaken by the University Clinical Center of Kosovo (UCCK), 305 patients (93.8 percent) underwent regional anaesthetic, making it the Clinic's most common anaesthetic procedure. 35 patients (10.8%) had one or more co-morbidities, such as hypertension (17.2%), anaemia (16.9%), diabetes (6.8%), tuberculosis (1.3%), and five patients (1.5%) were morbidly obese. In 214 individuals, antibiotic prophylaxis was provided prior to surgery (65.8 percent). A total of 32 patients (9.85%) had a postoperative wound infection during the study (overall SSI rate 9.85 percent). From this group, the most common infections were superficial primary incisional surgical site infection (93.75%) and deep primary incisional surgical site infection (6.25%), with no Organ/Space SSI found. The chi-square test revealed statistically significant correlations between SSI and co-morbidity, preoperative antibiotic use, operation time, age, and previous C-section history (P = 0.000; 0.0001; 0.023; 0.000, respectively). When compared to patients aged 35 and over > 35 years, those aged less than 35 years had a lower risk of developing SSI (RR 0.425; 95 percent CI; 0.199– 0.906 and P = 0.027). The average number of problems for patients who underwent a repeat C-section was seven. Patients who had many C-sections were 7.4 times more likely to acquire SSIs than those who had never had a

previous C-section (RR 7.457; 95 percent CI: 3.392–16.3395; P = 0.000). When compared to patients without co-morbidities, those with one or more co-morbidities had an eightfold greater chance of developing SSI (RR 8.428; 95 percent CI; 3.681–19.300 and P = 0.000). Those who got antibiotics before surgery had a decreased risk of getting SSI (RR 0.232; 95 percent CI: 0.107–0.502 and P = 0.000) than patients who did not receive antibiotics before surgery. Patients who have surgery for less than 1 hour had a lower risk of developing SSI than those who have surgery for more than 1 hour (RR 0.135; 95 percent CI; 0.054–0.338 and P = 0.000). *Staphylococcus aureus* was the most commonly isolated pathogen in 28.1 percent (n = 9), followed by *Enterococcus faecalis* in 15.6 percent (n = 5) and *Escherichia coli* in 9.4 percent (n = 3), according to the microbiological profile. There were two cases of clinical infection with negative (sterile) wound culture, accounting for 6.25 percent of all cases, and two cases of mixed microbial infection, one with *Escherichia coli* and *Serratia marcescens* and the other with *Escherichia coli* and *Proteus mirabilis* ^[29].

Another study conducted at the Ohio State College of Medicine in Columbus, Ohio, examined the impact of three evidence-based bundles in reducing caesarean delivery rates SSI. Bundle 1 had no effect on the odds of post-caesarean section SSI, but bundles 2 and 3, which included nurses preparing with a longer preparation time and chlorhexidine, and bundle 3 which included vaginal preparation and the use of 500 mg azithromycin, both had a lower risk of post-caesarean delivery SSI^[30]. A study conducted by Chaur Dong Hsu, Rebecca Caban, and Inna Cohn at Nassau University Medical Center in New York included hospital infection control policies and a pre-surgical checklist that included clippers for hair removal, chlorhexidine for skin preparation, antibiotics: cefazolin, traction on the cord to remove the placenta, and closure of deep subcutaneous tissue >2 cm^[31]. According to a study conducted at

Queensland University of Technology's Institute of Health and Biomedical Innovation, the incidence of SSI after a caesarean section ranged from 4.5 to 9%. Pre-incision antibiotic prophylaxis, vaginal preparation with an iodinepovidone solution, and spontaneous placenta removal are three perioperative caesarean section treatments and surgical approaches that have been identified as having solid evidence for universal application to reduce SSI risk^[15].

The risk of surgical site infection was 6.8% in a research conducted in Eutopia, which tracked 384 women who had given birth by caesarean section during a three-year period at Lemlem Karl hospital from July 1, 2013 to June 30, 2016. The duration of labour, rupture of membrane prior to caesarean section, and forms of abdominal incision were all highly related with a high risk of SSI in the multiple logistic analysis^[32]. A retrospective case-control study was done to estimate the rate of surgical site infection at Aminu Kano Teaching Hospital in Kano, Nigeria (SSI). The cases were patients whose CS was linked to SSI, whereas the controls were patients who were delivered by CS but did not have SSI. Case and control hospital records were then compared. The SSI rate was 9.1 percent. The majority of the instances were preceded by extended labour, extensive operative times, and significant blood loss. The most common pathogen was *Staphylococcus aureus*, which was susceptible to cephalosporins. In CS wound infections, more gramme negative organisms such as *E. coli*, *Proteus mirabilis*, *Pseudomonas*, and *Klebsiella* were detected. Antibiotic prophylaxis and strategies for decreasing delayed obstructed labour were found to be effective^[33].

The prevalence of SSI seen on post-operative day 10 was 10.9 percent in a research conducted at Rwanda's Kirehe District Hospital (60 women). The following factors were found to be significantly associated with SSI in the multivariable

analysis: bodyweight greater than 75 kg (OR 5.98, 1.56 to 22.96; P = 0.009); spending more time travelling to the health centre (OR 2.42, 1.31 to 4.49; P = 0.005); being a housewife versus a farmer (OR 2.93, 1.08 to 7.97; P = 0.035); and skin preparation with a single antiseptic versus a combination of two Antibiotics used either before or after surgery were not linked to SSI^[34].

According to a meta-analysis conducted by Ebony B. Carter, MD, MPH, surgical bundles incorporating at least three evidence-based therapies were related with a 67 percent reduction in the risk of any surgical site infection after caesarean delivery, with a number needed to treat of 24. With a number needed to treat of only 21, the effect on superficial or deep surgical site infection was significantly greater (an 81 percent reduction in risk)^[35].

A total of 1147 patients were enrolled in a research at the University of South Florida in Tampa; 572 were assigned to the chlorhexidine–alcohol group and 575 to the iodine–alcohol group. Surgical-site infection was seen in 23 patients (4.0%) in the chlorhexidine–alcohol group and 42 (7.3%) in the iodine–alcohol group in an intention-to-treat analysis (relative risk, 0.55; 95 percent confidence interval, 0.34 to 0.90; P=0.02). The rate of superficial surgical-site infection was 3.0% in the chlorhexidine–alcohol group and 4.9 percent in the iodine–alcohol group (P=0.10), while the rate of deep infection was 1.0 and 2.4 percent, respectively (P=0.07)^[36]. Hager conducted a double-blind, randomised trial in which a narrow-spectrum cephalosporin (cefazolin; n = 63) was compared to an expanded-spectrum cephamycin (cefoxitin; n = 66) and a broad-spectrum cephalosporin (cefotaxime; n = 60) as a single-dose prophylaxis in patients undergoing a nonelective caesarean Only 189 of the 194 patients who registered in the research were examined. There were no significant differences in mean age, gravidity, parity, labour duration, ruptured

membranes duration, number of vaginal examinations, or socioeconomic position across the groups (socioeconomic status was defined by third-party coverage). There was no difference in the incidence of acute or delayed postoperative infections among the antibiotics. These findings suggest that a less expensive, narrow-spectrum cephalosporin can be just as effective as more expensive, broader-spectrum cephamycins and cephalosporins as prophylaxis for patients undergoing caesarean delivery without elective surgery^[37].

The primary outcome was seen in 62 women (6.1 %) who received azithromycin and 119 (12.0 percent) who received placebo in a study done by Tita,(relative risk, 0.51; 95 percent confidence interval [CI], 0.38 to 0.68; P0.001). Endometritis (3.8 percent vs. 6.1 percent, P = 0.02), wound infection (2.4 percent vs. 6.6 percent, P0.001), and major maternal adverse events (1.5 percent vs. 2.9 percent, P = 0.03) were also significantly different between the azithromycin and placebo groups^[20]. Between July 1, 2016, and June 30, 2017, 989 CDs were evaluated in a study conducted at the University of Saskatchewan in Regina, SK, as shown in the study flow diagram. An infection rate of 3.5 percent was discovered. Between August 1, 2017, and July 31, 2018, 1033 patients were evaluated after receiving adjunctive azithromycin, with an infection rate of 2.9 percent. CDs were not included if they were rated as class 3 (contaminated) or class 4 (unclean), or if the class was unknown. The 0.6 percent decrease in SSI was not statistically significant (P = 0.42). There were no statistically significant variations in SSI rates between the elective and non-elective CD groupings. When elective CDs were delayed because to the busyness on the labour and delivery ward and when a delay was essential to suit the surgeon's availability, azithromycin was given more than 6 hours before skin incision. STAT CD was used in the majority of cases of administration after incision. For the

following reasons, azithromycin was not given: STAT CD was used in 26 cases, allergy was seen in six cases, patient requests were made in two cases, surgeon requests were made in one case, and 19 cases were not documented ^[38].

3. MATERIALS AND METHODS

1. **Study setting:** KAHERs Dr Prabhakar Kore Charitable Hospital.
2. **Study design-** A randomized controlled trial.
3. **Study period-** Total study period 12 months. (January 2020 -July 2021)
4. **Sample size-**

“The minimum sample size formula based on two proportions is

$$n = \frac{(z_{\alpha} + z_{\beta})^2 \bar{p}(1-\bar{p})}{d^2}$$

where P_1 and P_2 are the proportions of the two groups.

$$p = \frac{P_1 + P_2}{2} \text{ and } d = p_1 - p_2$$

z_{α} is linked with the level of significance and z_{β} is linked with the power of the test.

For 5% level of the significance $z_{\alpha} = 1.96$ and $z_{\beta} = 0.84$ for 80% power of the test.”

“Reference: Chaur Dong Hsu, Rebecca Caban, Inna cohn. Reduction and sustainability of SSI after caesarean delivery: seven years of experience. American journal of obstetrics and gynecology”

By taking proportion of infection, $P_1 = 6.16\%$ and $P_2 = 0.12\%$ the sample size obtained is 131.

“To make the study more confirmative, the sample size will be raised to 150”

Since it is a comparative study there will be two groups each with the above sample size

Inclusion criteria:

- Women admitted in labour room/obstetric ward for cesarean section (elective/emergency).

Exclusion criteria

1. Antenatal women with PROM.
2. Overt DM and GDM.
3. Severe anemia (<7 gm%)
4. Antepartum hemorrhage
5. Women with any pre-existing infection (on ANTIBIOTICS) at the time of surgery.
6. Pregnancy associated with heart disease.
7. Immunosuppressed individuals (HIV).
8. Patients not willing to participate.

Methodology:

The antenatal women who will be coming to the obstetric wards and free labor room of OBG department of teaching hospital attached to KAHER, JN Medical College, Belagavi. In this randomised control trial, women undergoing cesarean delivery from January 2020 and December 2020 will be randomized into two groups on the basis of a computer generated randomization table. The two groups include an interventional group and a control group. In the control group we would be implementing the existing standard practices for a cesarean delivery.

Control group

Pre operative interventions:

1. Inj (IV) ceftriaxone 1 gm (15 minutes prior)
2. Betadine (10%) scrubbing of abdomen before surgery in recovery room.
3. Painting parts with betadine (10%) solution as the antiseptic on OT table.
4. Ethanol (70%) (Surgical spirit) painting at site of surgical incision.

Intra operative strategies

1. Placenta removal (CCT/MRP)
2. Closure of skin by mattress sutures using Ethilon/ subcuticular sutures using Vicryl 2-0/ 3-0 .

Post-operative strategies:

1. Removal of dressing on fourth day post operatively.
2. Post operative antibiotic
 - Inj(IV) Ceftriaxone 1gm x 3 doses
 - Inj Mezol (IV) 100ml x 3 doses
 - Tab (P/O) Ciplox Tz 1-0-1 for 5 days.

Interventional group

Pre operative interventions:

1. Inj (IV) Ceftriaxone 1 gm + Inj(IV) Azithromycin 500mg (60 minutes prior surgical incision/15 mins prior in emergency cases)
2. Chlorhexidine scrubbing before surgery in recovery room.
3. Vaginal vault painting with betadine solution (10%).
4. Chlorhexidine scrub as the antiseptic on OT table for painting parts.
5. Ethanol (70%) (Surgical spirit) painting at site of surgical incision.

Intra operative strategies

1. Placenta removal by CCT
2. Closure of skin by mattress sutures using Ethilon/ subcuticular sutures using Vicryl 2-0/ 3-0.

Post-operative strategies:

1. Dressing to be done 48 hours post operatively.
2. Post operative antibiotics not given prophylactically .If wound unhealthy, appropriate antibiotic started.

The primary outcome is to look for incidence surgical site infections (superficial, deep, and organ or space surgical site infections) occurring up to 6 weeks postpartum (base on CDC 2018 guidelines).

Operational definitions

“CDC definition describes three levels of SSI^[39]:

- *Superficial incisional*, affecting the skin and subcutaneous tissue. These infections may be indicated by localised signs such as redness, pain, heat or swelling at the site of the incision or by the drainage of pus.
- *Deep incisional*, affecting the fascial and muscle layers. These infections may be indicated by the presence of pus or an abscess, fever with tenderness of the wound, or a separation of the edges of the incision exposing the deeper tissues.
- *Organ or space infection*, which involves any part of the anatomy other than the incision that is opened or manipulated during the surgical procedure, for example joint or peritoneum. These infections may be indicated by the drainage of pus or the formation of an abscess detected by histopathological or radiological examination or during re-operation. Organ infection is not included within the scope of this guideline”.

Superficial incisional SSI must meet the following criteria:

Date of event occurs within 30 days after any NHSN operative procedure (where day 1 = the procedure date) AND involves only skin and subcutaneous tissue of the incision AND patient has at least one of the following:

- a. purulent drainage from the superficial incision.
- b. organism(s) identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue by a culture or nonculture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing (ASC/AST)).

c. superficial incision that is deliberately opened by a surgeon, physician* or physician designee and culture or non-culture based testing of the superficial incision or subcutaneous tissue is not performed AND patient has at least one of the following signs or symptoms: localized pain or tenderness; localized swelling; erythema; or heat.

d. diagnosis of a superficial incisional SSI by a physician* or physician designee. * The term physician for the purpose of application of the NHSN SSI criteria may be interpreted to mean a surgeon, infectious disease physician, emergency physician, other physician on the case, or physician's designee (nurse practitioner or physician's assistant).

Reporting Instructions for Superficial SSI the following do not qualify as criteria for meeting the NHSN definition of superficial incisional SSI:

- Diagnosis/treatment of cellulitis (redness/warmth/swelling), by itself, does not meet criterion "d" for superficial incisional SSI. Conversely, an incision that is draining or that has organisms identified by culture or non-culture based testing is not considered a cellulitis.
- A stitch abscess alone (minimal inflammation and discharge confined to the points of suture penetration).
- For an NHSN operative procedure, a laparoscopic trocar site is considered a surgical incision and not a stab wound.
- A localized stab wound or pin site infection is not considered an SSI; depending on the depth, these infections might be considered either a skin (SKIN) or soft tissue (ST) infection.

Deep incisional SSI Must meet the following criteria:

The date of event occurs within 30 or 90 days after the NHSN operative procedure (where day 1 = the procedure date) .Deep soft tissues of the incision (for example, fascial and muscle layers) AND patient has at least one of the following:

- a. purulent drainage from the deep incision.
- b. A deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, physician* or physician designee AND organism(s) identified from the deep soft tissues of the incision by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing (ASC/AST)) or culture or non-culture based microbiologic testing method is not performed. A culture or non-culture based test from the deep soft tissues of the incision that has a negative finding does not meet this criterion. AND patient has at least one of the following signs or symptoms: fever (>38°C); localized pain or tenderness.
- c. An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test

Organ/Space SSI Must meet the following criteria:

Date of event occurs within 30 or 90 days after the NHSN operative procedure (where day 1 = the procedure date) and involves any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure AND patient has at least one of the following:

- a. Purulent drainage from a drain that is placed into the organ/space (for example, closed suction drainage system, open drain, T-tube drain, CTguided drainage).
- b. Organism(s) identified from fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing (ASC/AST)).
- c. An abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam, or imaging test evidence suggestive of infection.

4. RESULTS

This study was conducted at KAHER'S Prabhakar Kores hospital KLE, Belagavi from January 2020 to July 2021. A total of 447 women were screened. Out of which 127 were excluded as they did not meet the inclusion criteria .320 women who consented and eligible as per the inclusion criteria for the study were randomized into a control (160) and interventional group (160).

16 participants from the control group and 17 participants from the interventional group respectively were lost to follow up. A total of 144 participants in control group and 143 participants in the interventional group were analyzed (**figure 1**).

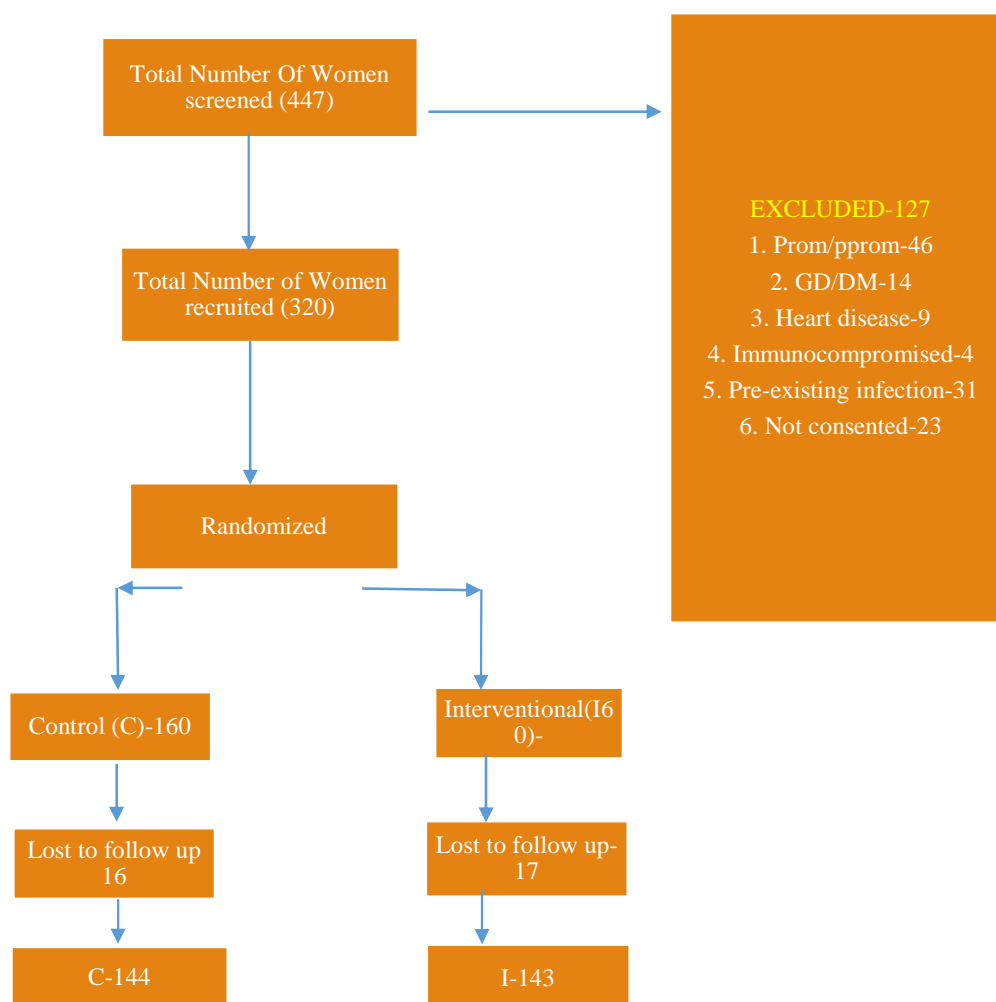


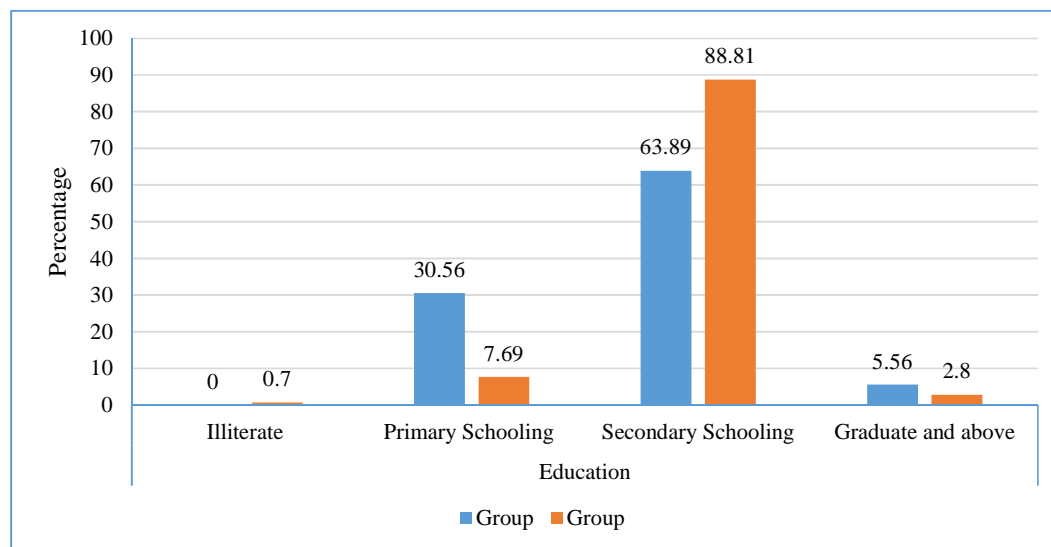
Table 1: Socio demographic characters of study participants.

Variables	Sub Category	Control	Interventional	Total	p-value
Age (years)	≤20	21 (14.58%)	28 (19.58%)	49 (17.07%)	0.4337 ^C
	21-25	66 (45.83%)	65 (45.45%)	131 (45.64%)	
	26-30	38 (26.39%)	28 (19.58%)	66 (23%)	
	>30	19 (13.19%)	22 (15.38%)	41 (14.29%)	
	Mean ± SD	25.01 ± 3.92	24.78 ± 4.51	24.9 ± 4.22	0.2779 ^{MW}
	Median (Min, Max)	25 (19, 37)	24 (18, 39)	24 (18, 39)	
Social Economic Status	Upper class	0	0	0	0.59 ^{MC}
	Upper middle class	1 (0.69%)	3 (2.1%)	4 (1.39%)	
	middle class	30 (20.83%)	12 (8.39%)	42 (14.63%)	
	Lower middle class	105 (72.92%)	121 (84.62%)	226 (78.75%)	
	Lower class	8 (5.56%)	7 (4.9%)	15 (5.23%)	
Literacy	illiterate	0	1 (0.7%)	1 (0.35%)	< 0.001 ^{MC*}
	Primary schooling	44 (30.56%)	11 (7.69%)	55 (19.16%)	
	Secondary Schooling	92 (63.89%)	127 (88.81%)	219 (76.31%)	
	Graduate and above	8 (5.56%)	4 (2.8%)	12 (4.18%)	

“Abbreviation: C – Chi square test, MC – Chi square test with Monte Carlo simulation, MW – Mann Whitney U test, * indicates statistical significance.

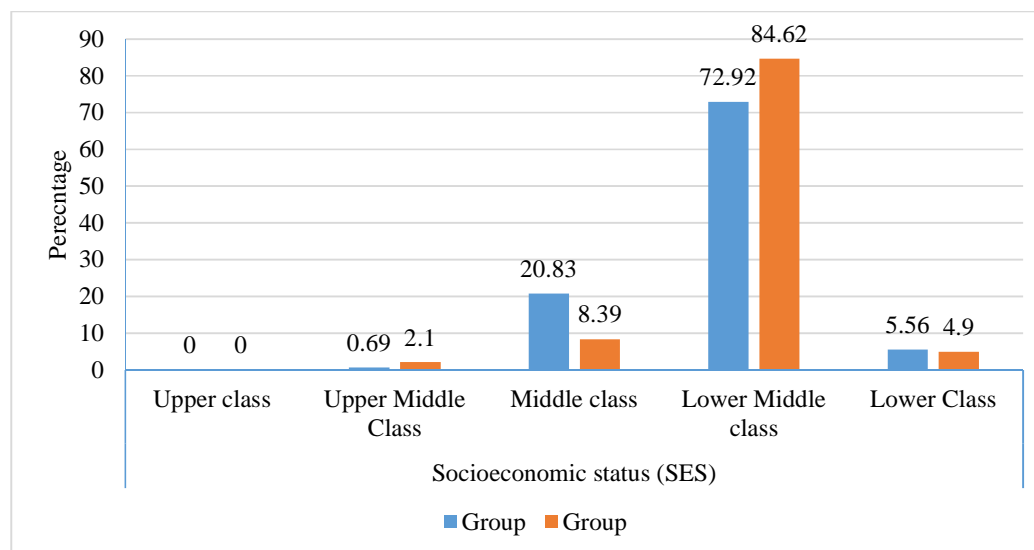
Majority of the participants in the study were aged between 21-25 years belong to the lower middle class socio-economic status with secondary schooling as the level of education in maximum number of participants. From Chi square test and Mann Whitney U test, we observe that, there is no significant difference in the distribution of age and socio-economic status over the groups but there was a significant difference in the distribution over the literacy rates in the the two groups of the study (**table 1**).

Fig. 1: Education status of women in the control and interventional group



Majority of the participants over the two groups belong to the secondary level of schooling (63.89 % in control group and 88.81% in interventional group) (Fig 1).

Fig 2: Socio-economic status of study participants in both groups



We observed that maximum number of participants belonged to the lower middle class i.e 72.9% in the control group and 84.62 % in the interventional group . (fig 2)

Table 2: Comparison of clinical details over groups

Variables	Sub Category	Control	Interventional	Total	p-value
Gestational Age (weeks)	≤34	1 (0.69%)	0	1 (0.35%)	0.5957 ^{MC}
	34-36	6 (4.17%)	3 (2.1%)	9 (3.14%)	
	36-38	26 (18.06%)	25 (17.48%)	51 (17.77%)	
	38-40	78 (54.17%)	87 (60.84%)	165 (57.49%)	
	>40	33 (22.92%)	28 (19.58%)	61 (21.25%)	
Gravidity	Multigravid	81 (56.25%)	79 (55.24%)	160 (55.75%)	0.8639 ^C
	Primigravid	63 (43.75%)	64 (44.76%)	127 (44.25%)	
BMI (kg/m ²)	Under Weight (<18.5)	9 (6.25%)	8 (5.59%)	17 (5.92%)	0.5217 ^{MC}
	Normal (18.5-24.9)	98 (68.06%)	94 (65.73%)	192 (66.9%)	
	Over weight (25-29.9)	35 (24.31%)	41 (28.67%)	76 (26.48%)	
	Obese (≥30)	2 (1.39%)	0	2 (0.7%)	
	Mean ± SD Median (Min, Max)	22.69 ± 2.95 22 (17, 32)	22.91 ± 2.7 23 (18, 29)	22.8 ± 2.82 23 (17, 32)	0.3265 ^{MW}
Pallor	No	110 (76.39%)	107 (74.83%)	217 (75.61%)	0.7577 ^C
	Yes	34 (23.61%)	36 (25.17%)	70 (24.39%)	
Hemoglobin	Pre-Op	11.68 ± 1.3 11.8 (8.2, 14.4)	11.63 ± 1.35 11.9 (8.7, 14.4)	11.66 ± 1.33 11.9 (8.2, 14.4)	0.7782 ^t
		Post Op	10.48 ± 1.09 10.2 (7.8, 13.4)	10.49 ± 1.22 10.3 (8, 13.8)	10.49 ± 1.16 10.2 (7.8, 13.8)
	Within Group p-value	< 0.001 ^{W*}	< 0.001 ^{W*}	-	-
	Difference	1.2 ± 0.69 1 (0.1, 3.2)	1.14 ± 0.63 1 (-0.2, 3.4)	1.17 ± 0.66 1 (-0.2, 3.4)	0.8578 ^{MW}
Blood Sugar	Mean ± SD Median (Min, Max)	108.99 ± 7.62 110 (68, 124)	108.31 ± 9.41 111 (72, 134)	108.66 ± 8.55 110 (68, 134)	0.8482 ^{MW}

“Abbreviation: C – Chi square test, MC – Chi square test with Monte Carlo simulation, t – Two sample t test, MW – Mann Whitney U test, W – Wilcoxon test, * indicates statistical significance”.

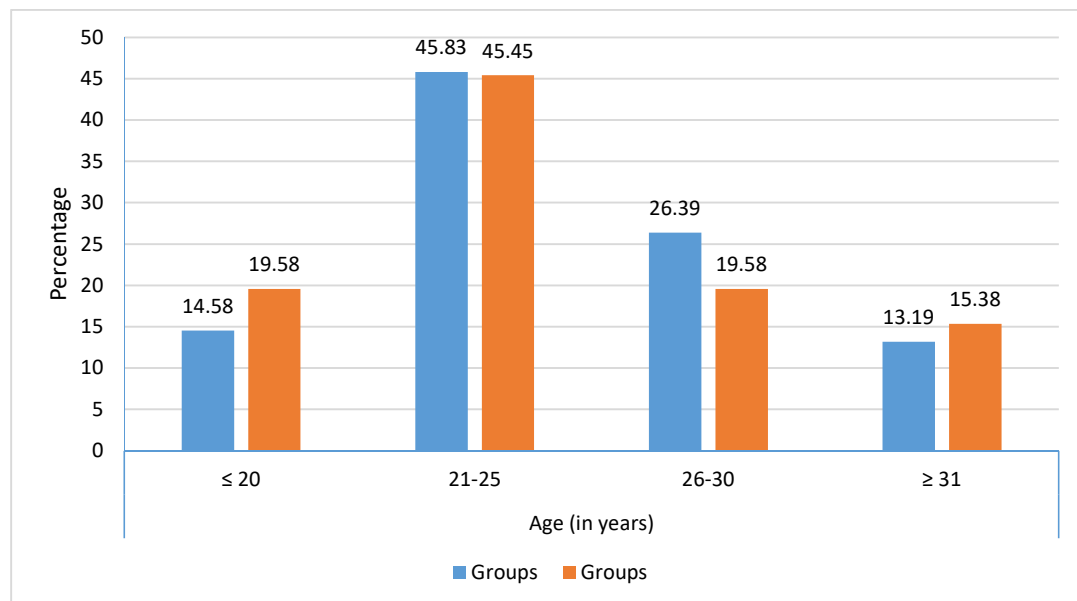
From Chi square test, we observe that, there is no significant association of gestational age, gravidity, BMI and Pallor with groups.

From Mann Whitney U test, we observe that, there is no significant difference in the distribution of BMI, Post Op Hb, Change in Hb and Blood sugar over groups.

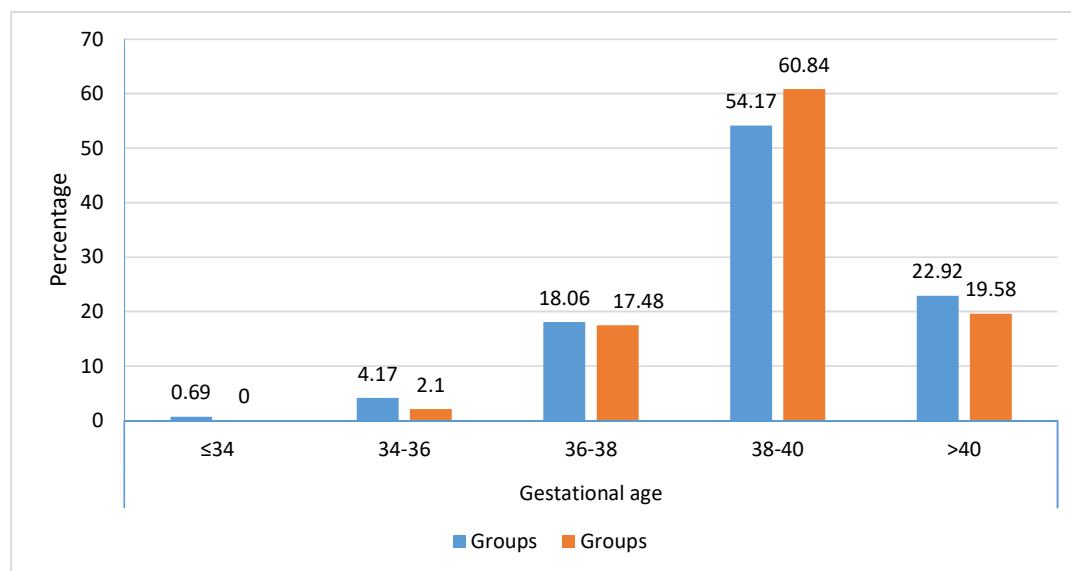
From two sample t test, we observe that, there is no significant difference in mean pre-Op HB over groups.

From Wilcoxon test, we observe that, there is significant difference in the distribution of Hemoglobin before $p < 0.001$ and after operation in both control and interventional groups $p < 0.001$ (table 2).

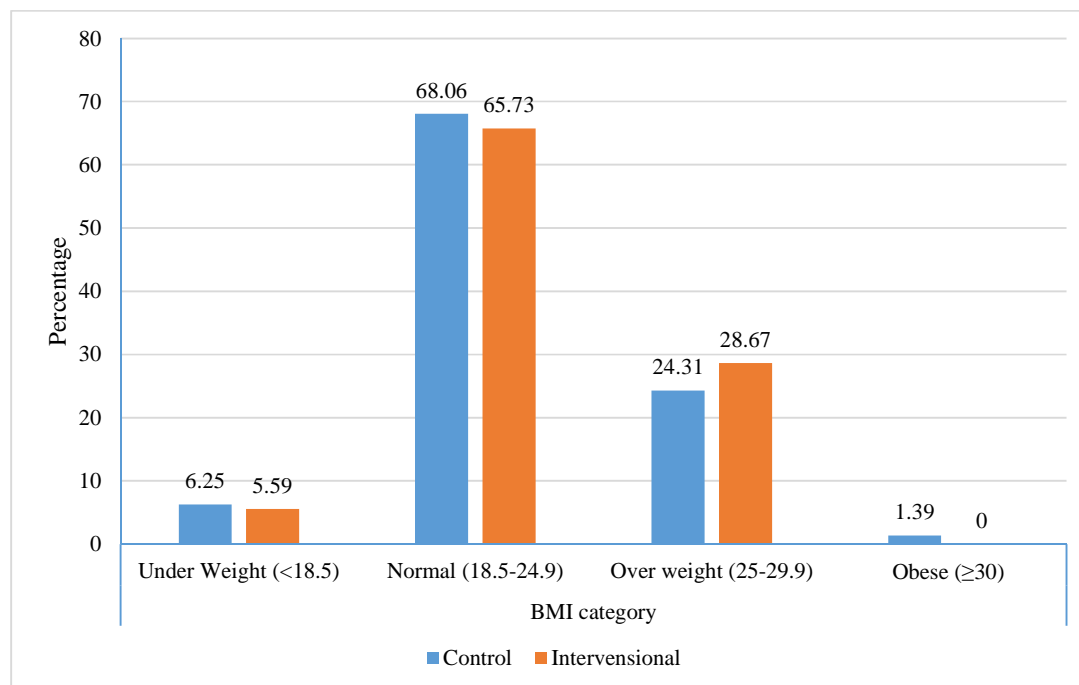
Fig 3: Distribution of the age of the participants in the study



Majority of the participants in the study were falling under the age group of 21 – 25 years (45.83 % in control group and 45.45% in interventional group) (Fig 3).

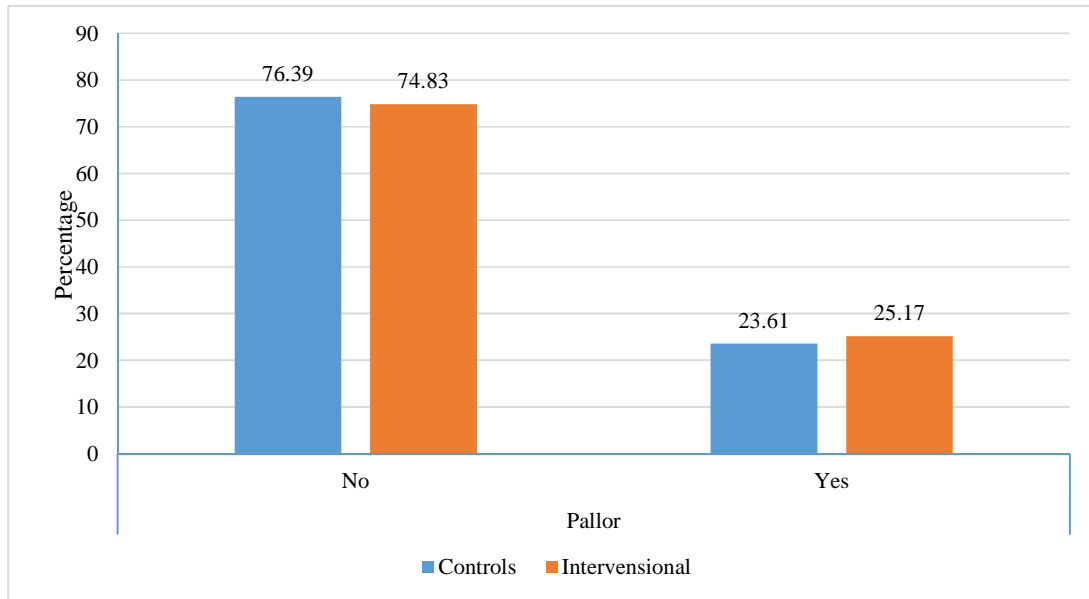
Fig 4: Gestational age of the participants in the study

Majority of the participants had a mean gestational age ranging from 38 weeks – 40 weeks over the two groups (54.17% in control group and 60.84 % in interventional group) (**Fig 4**).

Fig 5: Distribution of BMI in participants in the study.

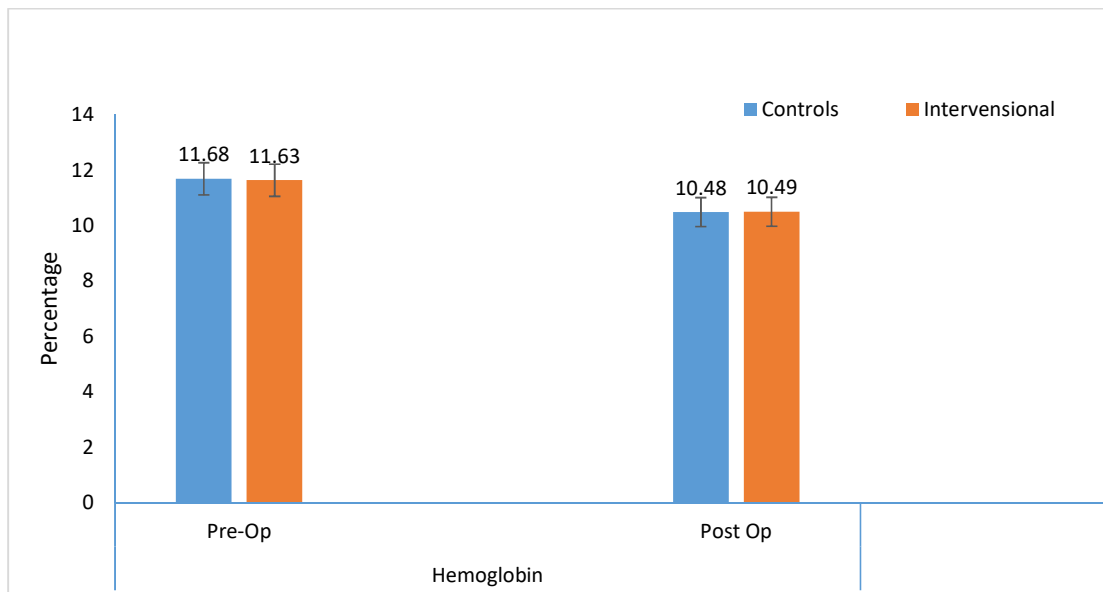
Majority of the patients in the study had a normal BMI ranging from 25 -29.9 kg/mt²(68.06 % in control group and 65.73 % in interventional group) (**Fig 5**).

Fig 6: depicts the pallor amongst the participants in the study



It was seen that maximum number of the participants had no pallor, which is suggestive that majority of them were not anemic (Fig 6).

Fig 7: Pre-operative and post operative hemoglobin in the participants of the study



The mean preoperative hemoglobin noted in the pre-operatively was 11.68 gm % and 11.63% in the control and study group respectively. The post-operative haemoglobin was 10.4 gm % and 10.49 gm % in control and interventional group respectively (fig7).

Fig 8: Mean plot of Hemoglobin preoperatively and post-operatively in the participants of the study.

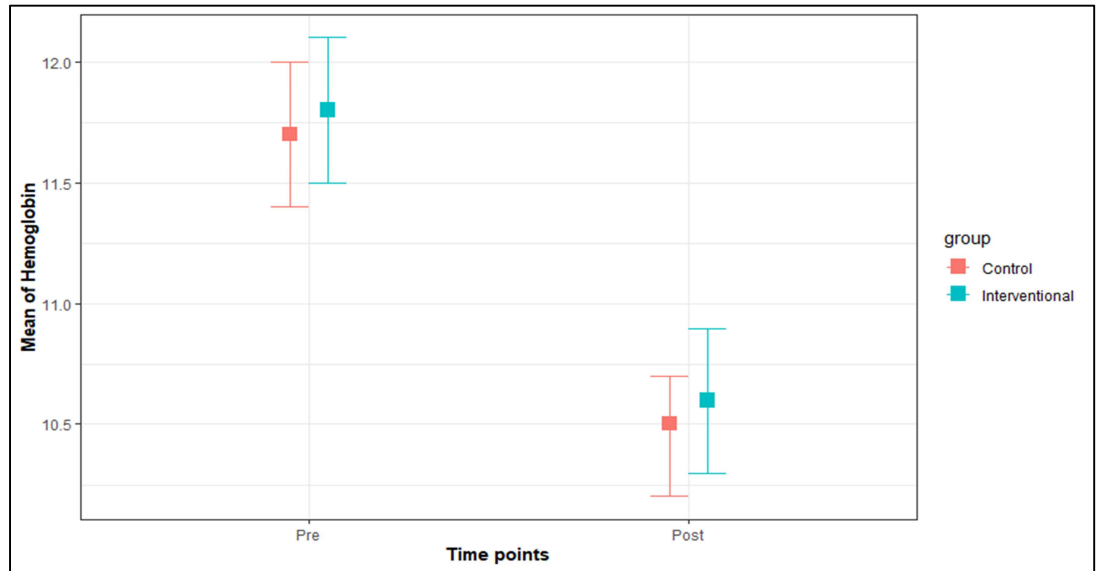


Table 3: Comparison of type of LSCS.

Type of LSCS		Sub Category	Control	Interventional	Total	p-value
Primary Section	Emergency LSCS	No	46 (31.94%)	49 (34.27%)	95 (33.1%)	0.6761 ^C
		Yes	98 (68.06%)	94 (65.73%)	192 (66.9%)	
	Elective LSCS	No	144 (100%)	142 (99.3%)	286 (99.65%)	0.5072 ^{MC}
		Yes	0	0	0	
Repeat section	Emergency LSCS	No	99 (68.75%)	98 (68.53%)	197 (68.64%)	0.9682 ^C
		Yes	45 (31.25%)	45 (31.47%)	90 (31.36%)	
	Elective LSCS	No	142 (98.61%)	140 (97.9%)	282 (98.26%)	0.6237 ^{MC}
		Yes	1 (0.69%)	4 (2.1%)	4 (1.39%)	

Abbreviation: C – Chi square test, MC – Chi square test with Monte Carlo simulation.

From Chi square test, we observe that, there is no significant association of different types of LSCS with groups. In the control group 68.06 % were primary LSCS and 31.25% were repeat LSCS .In the interventional group 65.73% were primary LSCS and 31.47 % were repeat LSCS .All of these were emergency LSCS. Only a total of 5 elective LSCS were included in the study out of which 1 was from the control group and 4 were from the interventional group (table 3).

Fig 9: Distribution of women according to type of LSCS

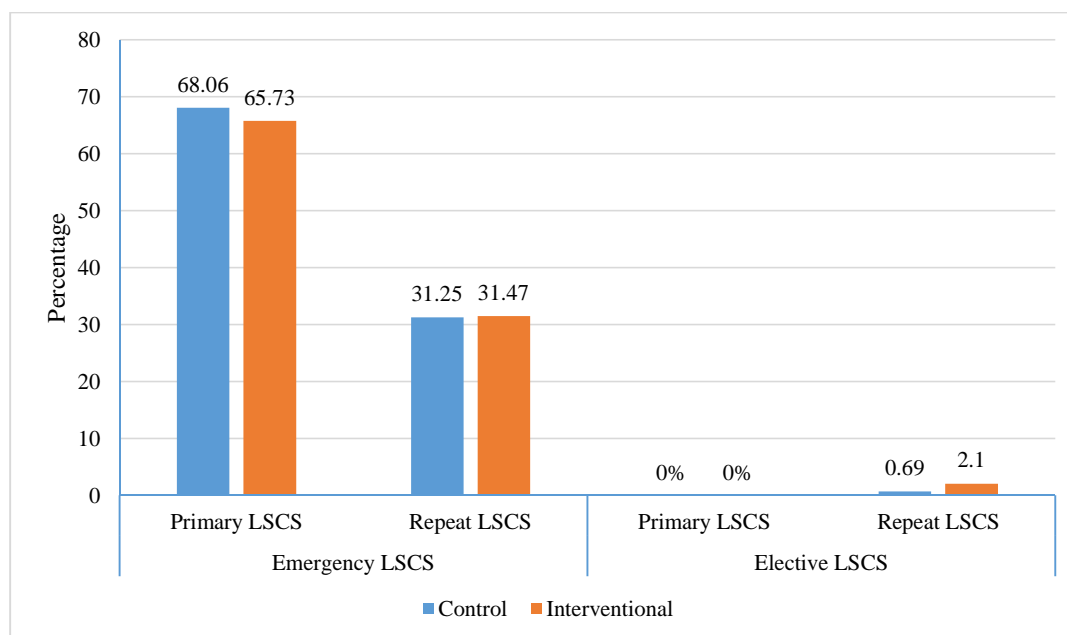


Table 4: Indications for cesarean sections

Indications for caesarean section	INTERVENTIONAL GROUP(143)	CONTROL GROUP(144)
Fetal distress	68(47.5 %)	61 (42.3 %)
Previous lscs /previous 2 lscs	45 (31.4 %)	47 (32.6 %)
CPD	11 (7.69%)	16 (11.1 %)
Malpresentation	4(2.79 %)	7 (4.86 %)
DTA	5 (3.49%)	3 (2.08%)
FGR	3 (2.09 %)	2 (1.3%)
CDMR	3(2.09 %)	3(2.08 %)
Uncontrolled hypertension	2 (1.39%)	2 (1.3%)
Anamnios	02(1.39 %)	3 (2.08%)

(CPD –cephalopelvic disproportion, DTA-deep transverse arrest, CDMR-cesarean delivery at maternal request)

In the interventional group 47.5 % of the participants had an LSCS done in view of fetal distress and 42.3 % participants had an LSCS done in view of fetal distress in the control group (**table 4**).

By two sample t-test, there is no significant difference in the mean of age, BMI, gestational age, blood sugar and hemoglobin over groups. By paired t-test, mean of pre hemoglobin level is significantly more compared to post hemoglobin level in both groups. By two sample t-test, there is no significant difference in the mean of mean change in hemoglobin over groups. By Chi-square test, there is no significant difference in the distribution of age, Gestational age, literacy level, SES, elective LSCS, emergency LSCS, pallor over groups.

Table 5: Distribution of Pre-operative preparations in interventional group.

Pre-operative preparations in Interventional group	Yes	No
Chlorhexidine Scrubbing of surgical parts	143(100%)	0
Surgical Hand Scrubbing	143 (100%)	0
Antibiotic Injection	143 (100%)	0
Vaginal Vault Painting With Betadine	115 (80.4%)	28(19.6 %)
Chlorhexidine Scrubbing On OT Table	143 (100%)	0
CCT Placenta Removal	143 (100%)	0
MRP Placenta Removal	0	143 (100%)
>2cm S.C Fat Closure	128 (89.5 %%)	15 (10.5%)
skin closure by subcuticular sutures	143 (100%)	0
Skin Closure By Mattress sutures	0	143 (100%)

In the interventional group chlorhexidine scrubbing, surgical hand scrubbing preoperative antibiotic, CCT for placental delivery , skin closure with subcuticular sutures was followed for 100 % of the participants .Vaginal vault painting was done for 80.4 percent of the cases (**table 5**) .

Table 6: Distribution of Pre-operative preparations in control group

Pre-operative preparations in control group	Yes	No
Betadine Scrubbing of surgical parts	144 (100%)	0
Surgical Hand Scrubbing	144 (100%)	0
Antibiotic Injection CEFTRAXONE	144 (100%)	0
Parts Painting With Betadine	144 (100%)	0
Ethanol At Surgical Site	144 (100%)	0
CCT Placenta Removal	144 (100%)	0
MRP Placenta Removal	0	144 (100%)
>2cm S.C Fat Closure	139 (96.53%)	5 (3.47%)
Skin Closure by subcuticular sutures	144 (100%)	0
S.C Skin Closure By Mattress sutures	0	144 (100%)

Table 7: Comparison of post-operative strategies and clinical features of the participants in the study.

Variables	Sub Category	Control	Interventional	Total	p-value
Antibiotics used	No	0	97 (67.83%)	97 (33.8%)	<0.001 ^{MC*}
	Yes	144 (100%)	46 (32.17%)	190 (66.2%)	
Dressing 48 hrs	No	0	1 (0.7%)	1 (0.35%)	-
	Yes	0	142 (99.3%)	142 (49.48%)	
Healthy wound	Yes	91 (65.28%)	102 (71.33%)	196 (68.29%)	0.14 ^C
redness	No	91 (63.19%)	103 (72.03%)	194 (67.6%)	0.1099 ^C
	Yes	53 (36.81%)	40 (27.97%)	93 (32.4%)	
Tenderness	No	92 (63.89%)	104 (72.73%)	196 (68.29%)	0.1077 ^C
	Yes	52 (36.11%)	39 (27.27%)	91 (31.71%)	
Induration	No	93 (64.58%)	105 (73.43%)	198 (68.99%)	0.1053 ^C
	Yes	51 (35.42%)	38 (26.57%)	89 (31.01%)	
Local Rise in Temp	No	111 (77.08%)	115 (80.42%)	226 (78.75%)	0.4897 ^C
	Yes	33 (22.92%)	28 (19.58%)	61 (21.25%)	
Serous /serosanguinous Discharge	No	133(92.3%)	136(95.1%)	269(93.7 %)	0.33
	Yes	11 (7.7%)	7 (4.9%)	18 (6.3%)	
Purulent discharge	No	137 (95.1%)	141 (98.6%)	278 (96.82%)	0.09 ^{MC}
	Yes	7 (4.9%)	2(1.4 %)	9 (3.2 %)	
Edges Separation	No	134 (93.06%)	138 (96.5%)	272(94.7%)	0.18 ^C
	Yes	10 (6.94%)	5 (3.5%)	15 (5.3%)	
Fever	No	126 (87.5%)	127 (88.8%)	253 (88.1%)	0.73 ^C
	Yes	18 (12.5%)	16 (11.2%)	34 (11.9%)	
Lochia Foul Smelling	No	144 (100%)	143 (100%)	287 (100%)	-
	Yes	0	0	0	

Abbreviation: C – Chi square test, MC – Chi square test with Monte Carlo simulation, * indicates statistical significance.

From Chi square test, we observe that, there is significant association of antibiotics used with groups. 97(67.8 %) of the participants in the interventional group did not require post – operative antibiotics. A healthy wound was noted in 91(65.2 %) and 102(71.3 %) of the participants in the control and interventional group respectively. Serous discharge was seen in 11(7.7 %) and 7(4.9 %) of the participants in the control and interventional group, purulent discharge was seen in 7(4.9 %) and 2(1.4 %) of the cases respectively in the control and study group. Separation of wound edge was seen in 10(6.9 %) and 5(3.5 %) of the cases in the control and interventional group. None of the cases of the study had foul smelling lochia. However, there is no significant association of health status, inflammation, tenderness, induration, local rise in temperature, incisional site discharge, pus, edges separation, fever and Lochia foul smelling antibiotics used with groups (**table 7**).

Table 8. Comparison of Microbiological investigations over groups

Variables	Sub Category	Control	Interventional	Total	p-value
Wound Culture Sent	No	126 (87.5%)	134 (93.7%)	260 (90.5%)	0.07 ^C
	Yes	18 (12.5%)	9 (6.3%)	27 (9.5%)	
Organisms Found	No	11 (61.1%)	7 (77.7%)	18 (66.6%)	0.38 ^{MC}
	Yes	7 (38.9%)	2 (22.3%)	9 (33.4%)	

Abbreviation: C – Chi square test, MC – Chi square test with Monte Carlo simulation.

Out of the 18 cases of discharge in the control group only 7 had organisms found. Similarly in the interventional group out of the 9 case with discharge from wound site only 2 had organism found. From Chi square test, we observe that, there is no significant association of wound culture sent and organisms found with groups (table 8).

Fig 9: Post-operative strategies and clinical features of the participants in the study

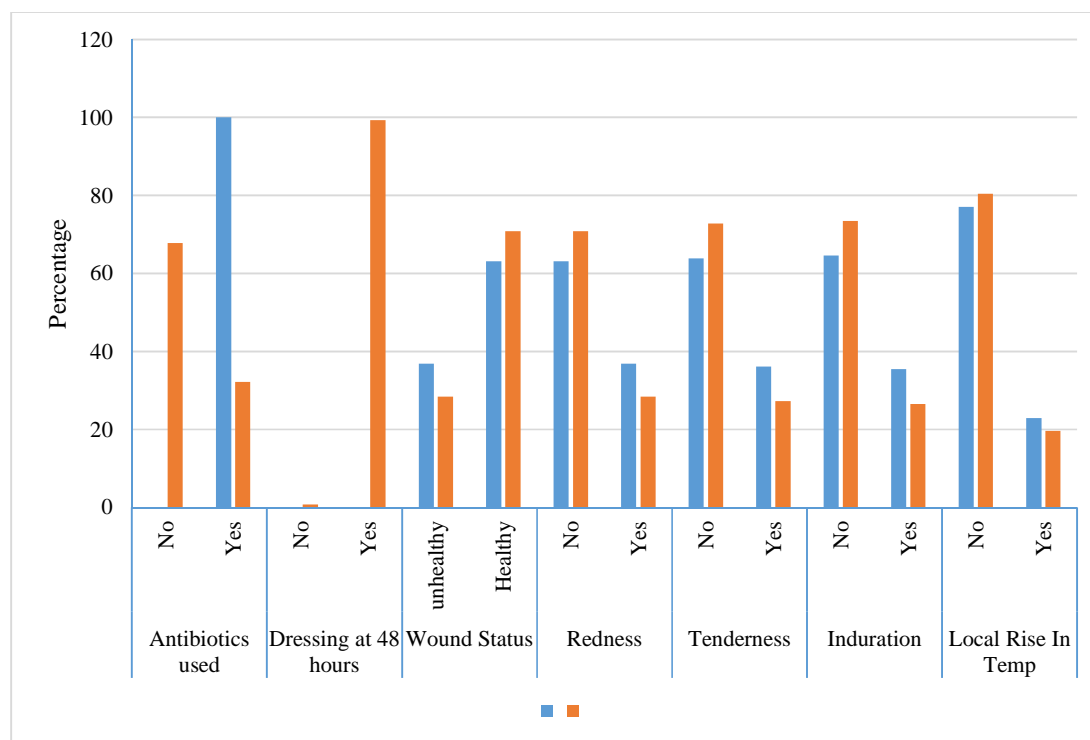


Fig 10: Post-operative strategies and clinical features of the participants in the study

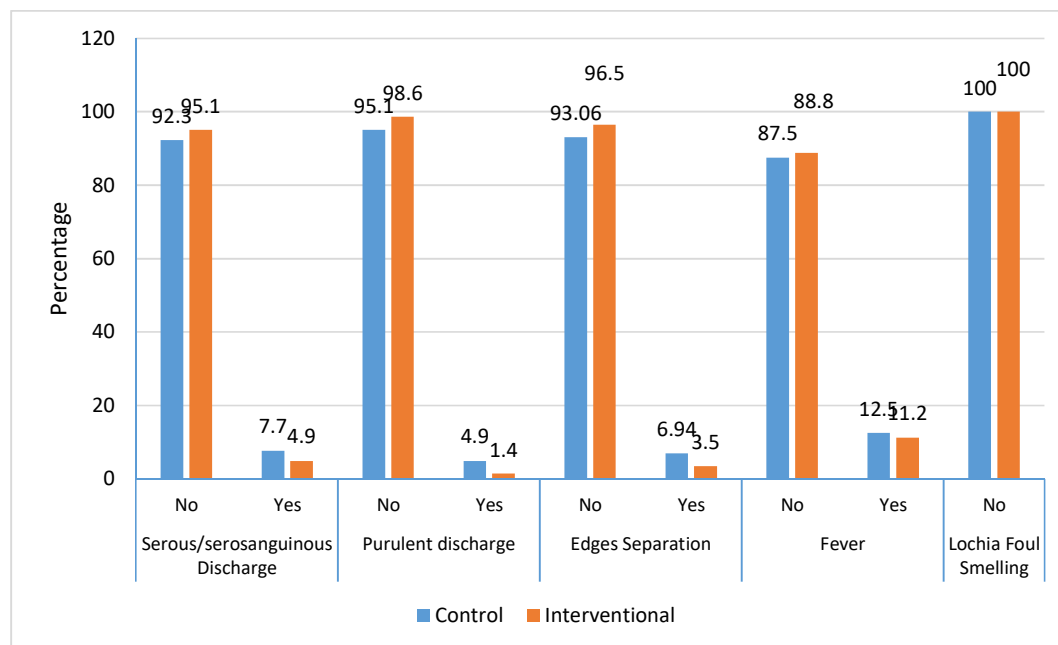


Table 9: Wound culture and sensitivity interventional group.

Case	Micro-organisms	Amoxyclav	Azithromycin	Levofloxacin	Gentamicin	Ciprofloxacin	Linezolid	Cefotaxime	Piptaz
1.	MRSA	R	R	R	R	R	S	-	S
2.	MRSA	R	R	R	S	R	S	-	S

R- RESISTANCE S- SENSITIVE

Most common organism found in the interventional group was MRSA (methicillin resistant staph. Aureus). Linezolid and Piperacillin were the antibiotics to which majority of the organisms were sensitive (**table 9**).

Table 10: Wound culture and sensitivity in both groups

Micro-organism	Control group	Interventional group	Sensitivity
MRSA	5 (60 %)	2(100 %)	Gentamycin, Linezolid, Piptaz, Azithromycin, Ciprofloxacin, Levofloxacin.
Citrobacter	1(20 %)	0	Linezolid,Piptaz , Ciprofloxacin, Levofloxacin.
Enterococcus faecalis	1(20 %)	0	Linezolid,Piptaz.

Organisms found in the control group were 5 MRSA, 1 Citrobacter and 1 enterococcus faecalis. In the interventional group organism found was 2 MRSA (table 10).

Table 11: Wound culture and sensitivity of SSI in control group.

Case	Micro-organisms	Amoxyclav	Azithromycin	Levofloxacin	Gentamicin	Ciprofloxacin	Linezolid	Cefotaxime	Piptaz
1.	MRSA	R	R	R	R	S	S	-	S
2.	MRSA	R	R	S	S	R	S	-	S
3.	Citrobacter	R	R	S	-	R	S	R	S
4.	Enterococcus faecalis	R	R	R	-	R	S	R	-
5.	MRSA	R	S	R	S	R	S	-	S
6.	MRSA	R	S	S	R	R	S	R	S
7.	MRSA	R	R	R	R	R	S	R	R

R- RESISTANCE S- SENSITIVE

Most common organism found in the control group was MRSA. Linezolid and Piperacillin were the antibiotics to which majority of the organisms were sensitive (table 11).

Table 12: Number of women with SSI with secondary suturing

Control group (n-144)	Interventional group(n-143)
10 (6.9 %)	5 (3.49 %)

Patients requiring secondary suturing in the control group was 6.9 % and 3.4 % in the interventional group. (table 12).

Table 13: Classification of SSI based on CDC definition (2021)

SSI	CONTROL (n-144)	INTERVENTION (n- 143)	“P” VALUE
SUPERFICIAL	18 (64.2 %)	9(64.2%)	0.07
DEEP	10(35.7%)	5(35.7%)	0.18
ORGAN SPACE	0	0	-
TOTAL SSI	28(19.4 %)	14(9.7 %)	0.02*

Patients with SSI in the control group were 28 (19.4 %) and SSI in interventional group were 14 (9.7 %) with a statistically significant “p” value of 0.02 obtained after applying chi square test .Out of which 18 (64.2 %) participants had superficial SSI and 10(35.7 %) participants had deep SSI in the control group .In the interventional group 9(64.2 %) participants had superficial SSI and 5(35.7 %) participants had deep SSI.

5. DISCUSSION

This one year RCT was carried out from January 2020 to July 2021, at KAHER'S Prabhakar Kore hospital, Belagavi, to assess the effectiveness of evidence based surgical bundle to prevent cesarean section related SSI.

Surgical site infections (SSIs) are a leading cause of morbidity and mortality in patients following surgery. These infections also lengthen hospital stays and raise the financial strain on the health-care system. In our study the the number of women with SSI in control group were 28 (19.4 %) and 14(9.7%) women had SSI in interventional group with a “p” value of 0.02* which was statistically significant. We report a 50 % reduction in SSI with our bundle. We recommend that when implemented together the bundle will reduce the SSI risk. Globally rates of SSIs vary from 3-15% in different settings based on the hospital infection control and surveillance. Developing nations reported higher SSI rates than developed nations. Cesarean section SSI rate was reported to the extent of 48.2% in Tanzania^[38]. According to a study conducted at the Lady Hardinge Medical College in New Delhi, the SSI rate in India is 24.2 percent^[20]. In our study we noted that in the interventional group, 10(64.2 %)were superficial SSI and 5(35.7 %) were deep SSI whereas in the control group, superficial and deep SSI rates were 18(65%) and 10(35%) respectively. Participants who had deep SSI required secondary suturing and participants with superficial SSI were successfully managed with antibiotic and antinflammatory treatment. The number of participants requiring secondary suturing was doubled in the control group when compared to the interventional group. 67.0 percent of SSI cases were superfical, 21.6 percent were deep infections, and 11.4 percent were organ/space infections,acin a study by Amenu et al^[38]. Another multicenter study conducted in three African nations discovered that 93.0% of SSIs were superficial^[38].

The bundle components like pre-incisional administration of primary and adjunctive antibiotics (azithromycin 500 mg along with ceftriaxone 1gm) preferably 60 minutes prior to the surgery , Chlorhexidine scrubbing over operative area, preoperative vaginal preparation with an iodine povidine solution and postoperative dressing at 48 hours post surgery proved as effective measures for prevention of SSI following CS . Antibiotic prophylaxis helps to prevent SSI by reducing the amount of bacterial inoculum in the wound at the time of surgery^[19].Extended-spectrum antibiotics have shown to be effective when used in conjunction with first-generation cephalosporins^[40].Azithromycin is a macrolide antibiotic that blocks protein synthesis by attacking to bacterial ribosomes and halting translation^[19]. Following CS, Ureaplasma species has been discovered as a major pathogen in chorioamnionitis and SSI^[40].Azithromycin has a broad spectrum of activity against Ureaplasma species^[40]. It has a half life of 68 hours.A single dose of azithromycin stays in the body for over a week. Based on these features, global bodies like WHO and CDC recommend it as an adjunctive preoperative antibiotic for prevention of CS related SSI .It has low potential for fetal transfer^[19].Azithromycin is effective against both aerobic and some weakly anaerobic organisms .American College of Obstetricians and Gynecologists recommended that women undergoing non-elective CD use azithromycin as part of their usual antibiotic regimen in September 2018^[38]. In 2013, Tita et al. looked at the impact of 500 mg of IV azithromycin administered over 1 hour in addition to a normal antibiotic prophylactic regimen in women having emergency CS. Within 6 weeks, the primary composite outcome, which included endometritis, wound infection, and other infections, was reduced by 50% in absolute terms^[20]. Antibiotic therapy up to 60 minutes before skin incision, compared to antibiotic administration after cord clamping, significantly lowers infection rates. In CS, however, giving

antibiotic prophylaxis more than 1 hour before incision was linked to a twofold increase in the likelihood of SSI compared to giving it 1 hour before incision. As a result, giving antimicrobial prophylaxis as soon as to the time of incision as possible may ensure optimal antibacterial levels in tissue at the surgical site^[20]. In our study preoperative antibiotics were strictly administered 1 hour before to incision in our trial; only in cases of fetal distress (47.5 percent interventional group and 42 percent control group) was the 1 hour standard not observed, but antibiotics were nevertheless administered at least 15 minutes prior to incision. The superiority of chlorhexidine-based antiseptic agents over iodine-based antiseptic agents for the prevention of surgical-site infection has been demonstrated in randomised trials including patients undergoing general surgical procedures. Pre-operative scrubbing with chlorhexidine was followed diligently in all the participants of the interventional group . It was found in 887 individuals with wound thickness larger than 2 cm in a research described by David Chelmow, of which just one demonstrated a statistically meaningful protective effect on its own^[41]. In our study the interventional group 89.5 % of the the pariticipants had subcuticular fat layer of more than 2 cm for with closure of the layer was done ,no patient with SSI had an seroma , hematoma or tunneling of the wound at the subcuticular plain, which show the importance of implementing this step to the surgical bundle . The United States Centers for Disease Control and Prevention (CDC) and the United Kingdom's National Collaborating Centre for Women's and Children's Health, NICE (2008) agreed that surgical incisions should be covered with a bandage for 48 hours after surgery^[42]. With uncovered or early exposed wounds, there was an increased risk of contamination and SSIs, but some research imply that prolonged dressing durations aren't beneficial^[59]. Preoperative vaginal washing using povidone iodine reduced the incidence of endometritis,

according to Starr and colleagues^[63] Asghania et al. showed the role of preoperative vaginal toileting in decreasing endometritis^[63]. According to a Cochrane evaluation published in 2014 by Hass DM et al, vaginal washing with povidone iodine dramatically reduced the risk of postoperative endometritis. Another meta-analysis published in 2017 by The American College of Obstetricians and Gynecologists (ACOG) found that vaginal cleanliness before a caesarean section lowers the risk of endometritis when compared to no vaginal toileting^[44]. In our study vaginal toileting with povidine iodine was done for 80 % of the participants in the interventional group. No cases of endometritis were seen in the study. Martin et al reported that the three strategies, administration of prophylactic antibiotic 15-60 minutes prior to incision , preoperative vaginal painting with povidine iodine solution and removal of placenta spontaneously with gentle cord traction had clear strong evidence of reducing the cesarean section SSI.number^[43]. Obesity, smoking, blood transfusions, age, malnutrition, immunological incompetence, immunosuppressive medication, lengthier preoperative hospitalisation, and diabetes mellitus have all been linked to an increased incidence of SSI in previous investigations^[59]. Our results are not showing higher prevalence of SSI with age , BMI and hemoglobin levels. In this study the majority of the participants were aged between 21-24 years and BMI of 22.8 kg/m² . The post operative mean hemoglobin of the participants was 10.2 gm % and 10.3 gm % in the control and interventional group respectively. A large number of the participants for the study were belonging to the lower middle class with an educational level of secondary schooling . The educational level and financial status of individuals determines the health care behavior of the pregnant women has direct relation to the medical status and health issues faced by a country . In developing countries due to the lack education and low financial status of families specially in

the rural area in India ,lack of awareness about hygiene and the inability to access adequate health care and acquire adequate nourishment due to low financial status lead to health crisis .After observing the sociodemographic status and clinical parameters in both the control group and the interventional group we could conclude that both the groups were matched well , which reduce the errors due to confounding while analyzing the the results for the study.

An association between type of CS (emergency or elective) and SSI was planned to be analysed in the study , unfortunately due to the pandemic and low rates of elective CS most of the participants recruited in study underwent an emergency CS (99%) in both the interventional and control group. Therefore this association could not be determined which is one of the limitations of the study.

The two most common indications for emergency CS in the study were fetal distress and previous CS in labor. CS due to fetal distress were 47% and 42 % in interventional and control group respectively in this study.

Though majority of the CS performed in the study were due to fetal distress which makes it difficult to adhere to all the interventions required for the study, a good compliance to adhering to the checklist in the interventional group was observed with only (19%) of participants due to lack of time, to avoid poor fetal prognosis.

Staphylococcus aureus and MRSA are reported to be the predominant organism to be cultured from a discharge of a SSI. In our study MRSA has a large distribution i.e 100% in interventional group and 60 % in the control. Multidrug resistance in hospital-acquired organisms is becoming a global problem. The most frequently used pre-operative prophylactic antibiotics in our setup is ceftriaxone. Microorganisms identified in our investigation, both gram positive and gram negative, were shown to be extremely resistant to antibiotics. Thus this emphasizes the need of

azithromycin as the adjunctive preoperative antibiotic in our study showed that the interventional group had organism cultured rate of 22% and 38 % in the control group.

Providing adequate health care in a developing country like India has always been a challenge. As we know SSI not only is detrimental to the health status of the a patient but it also has a financial troll on both the patient and health care system as duration for treatment and hospital stay increases. As observed in our study a single dose preoperative ceftriaxone and azithromycin and which was used in the interventional group no post operative antibiotics ; which when compared to single preoperative dose of ceftriaxone and 3 dose postoperative antibiotics (ceftriaxine and metronidazole) showed a lesser rate of cesarean section related SSI in the interventional group. This can prove to be a key factor to help battle the financial crisis faced by the health system by avoiding the use prophylactic post operative antibiotics.

6. CONCLUSION

In this study the evidence surgical bundle approach for CS related SSI prevention, was effective in decreasing the SSI risk to half when compared with standard routine practice. Hence we recommend the incorporation of these evidenced based practices into the comprehensive surgical quality programs for women undergoing cesarean deliveries. This will reduce the cost of management of cesarean deliveries in resource poor settings and improve the health outcome in cesarean sections.

7. SUMMARY

This was a randomized control trial antenatal women who will be coming to the obstetric wards and free labor room of OBG department of teaching hospital attached to KAHER University's JN Medical College, Belagavi, Karnataka. Employing a convenience sampling technique, a sample size of a minimum 131 pregnant women on each arm who satisfied inclusion criteria were recruited for the study. Women undergoing cesarean delivery from January 2020 and December 2020 were randomized into two groups on the basis of a computer generated randomization table. The two groups include an interventional group and a control group. The rate of SSI was analyzed in both the arms of the study.

Patients with SSI in the control group were 28 (19.4 %) and SSI in interventional group were 14 (9.7 %) with a statistically significant "p" value of 0.02 obtained after applying chi square test. Out of which 18 (64.2 %) participants had superficial SSI and 10 (35.7 %) participants had deep SSI in the control group. In the interventional group 9 (64.2 %) participants had superficial SSI and 5 (35.7 %) participants had deep SSI.

From Chi square test, we observe that, there is significant association of antibiotics used with groups. 67.8 % of the participants in the interventional group did not require post-operative antibiotics. A healthy wound was noted in 65.2 % and 71.3 % of the participants in the control and interventional group respectively. Serous discharge was seen in 7.7 % and 4.9 % of the participants in the control and interventional group, purulent discharge was seen in 4.9 % and 1.4 % of the cases respectively in the control and study group. Separation of wound edge was seen in 6.9 % and 3.5 % of the cases in the control and interventional group. None of the cases of the study had foul smelling lochia. However, there is no significant association of

health status, inflammation, tenderness, induration, local rise in temperature, incisional site discharge, pus, edges separation, fever and Lochia foul smelling antibiotics used with groups. Patients requiring secondary suturing in the control group was 6.9 % and 3.4 % in the interventional group .

Bundle approach for CS related SSI prevention was effective in decreasing the SSI risk to half when compared with standard routine practice. Single azithromycin injection 60 minutes prior to incision, Pre-operative painting of vagina with povidine iodine, chlorhexidine scrubbing of operative area and postoperative dressing after 48 hours with no postoperative antibiotics were found to be effective tools to reduce the infectious morbidity in cesarean sections . Hence we recommend the incorporation of these evidenced based practices into the comprehensive surgical quality programs for women undergoing cesarean deliveries. Also it will help to decrease the financial burden to the individuals.

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ANNEXURE - I - ETHICAL CLEARANCE



K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed - to- be- University)

Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)

JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)

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Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/190

Date: 24/12/2019

To,
REG. NO. BJ0119002
PG student in Obstetrics and Gynecology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled
"IMPACT OF AN EVIDENCE BASED SURGICAL BUNDLE ON SURGICAL SITE
INFECTION IN CESAREAN DELIVERY – A RANDOMIZED CONTROL TRIAL", is
ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional
Ethics Committee on Human Subjects Research.

(Dr. Anita Dalal)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANEXXURE II- CONSENT FORM

This ICF is for women attending Teaching hospital attached to KAHER, Belagavi, and who we are inviting to participate in research on evaluation of efficacy of evidence based surgical bundle to reduce caesarean section related SSI .

The title of my research is “Impact of an evidence based surgical bundle on surgical site infection in caesarean delivery-“a randomized control trial”

Principal Investigator:

Dr. _____

Associate Professor

Department of Obstetrics & Gynaecology

J.N. Medical College, Belagavi

Co-investigator:

REG. NO. BJ0119002

Post Graduate

Department of Obstetrics & Gynaecology

J.N. Medical College, Belagavi

This Informed Consent Form has two parts:

1. Information sheet (To share the information about my study)
2. Certificate of Consent

You will be given a copy of the full Informed Consent Form

Purpose of the study

I have been informed by **REG. NO. BJ0119002**, Post Graduate in M.S. Obstetrics and Gynecology under the guidance of Dr. _____, Department of Obstetrics and Gynaecology, J.N. Medical College, KAHER University, Belagavi is conducting a study to reduce SSI in post cesarean section patients. Cesarean sections is one of the commonest obstetric surgeries, with the caesarean section rates varying from 10 to 50 %¹ in various centers. Cesarean section rate at KLE hospital is 44.61 %⁸. The most common complication after caesarean section is post partum surgical site infection (SSI) and is one of the major causes of maternal morbidity is the post-operative period. It is seen in around 2 to 15 %¹ of patients who undergo caesarean sections. SSI result in a longer duration of hospital stay and increased monetary burden to the patient and also increases the financial burden to the health care system. Hence this study has been under taken to assess the incidence of surgical site infection (SSI) after implementing evidence based surgical bundle for prevention of cesarean delivery related SSI in a teaching hospital attached to KAHER University's J. N. Medical College, Belagavi.

Study procedure:

Once I have signed the informed consent form, the personal details like name, age, place, address, my education, my health, reproductive history and other information will be noted down. In this randomised control trial, women undergoing cesarean delivery at 37 weeks of gestation and beyond from January 2020 and January 2021 will be randomized into two groups based on a computer generated randomization table. The two groups include an interventional group and a control group. In the control group we would be implementing the existing standard practices

for a cesarean delivery .In the study group an evidence-based surgical bundle will be implemented .

Preoperative strategies-

1. Shaving of pubic hair done only if its is in line of incision 1
2. Chlorhexidine scrubbing before surgery ¹
3. Surgical hand scrubbing ¹
4. Vaginal vault painting with betadine ¹.
5. Painting parts with Chlorhexidine as the antiseptic ¹
6. Antibiotic injection Cefazolin 1 gm IV + injection azithromycin 500mg IV (60 minutes before surgical incision) in emergency cases atleast 15 minutes before surgery.

⁹ Intraoperative strategies

7. Removal of placenta by controlled cord traction
8. Closure of subcutaneous fat if subcutaneous fat is >2cm deep
9. Closure of skin by subcuticular sutures monocryl¹⁰.

Postoperative strategies-

10. Dressing done 48 hours post operatively ¹.
11. If wound discharge present, wound culture sent and based on antibiotic sensitivity appropriate antibiotic started.

Potential Risks

There are no observable risks associated with the study.

Benefits

Based on reference articles and latest WHO guidelines, application of the bundle of care would significantly reduce the incidence of SSI related with cesarean deliveries.

Financial incentive for participation

You will not be given any money or gifts to take part in this study. If any participant becomes ill during the administration of drugs, immediate treatment will be given at Teaching hospital attached to KAHER. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Alternatives

If I decide not to participate in the study, my health care provider will provide the usual standard care during my pregnancy, delivery and up to through 6 weeks after delivery.

Privacy

To protect my privacy, all the collected information will be given a number rather than using my name. Any information collected during the study will remain confidential. My medical files will be reviewed only at the hospital (or study doctor's office) to check the information and verify the result without breaking my confidentiality. Only de-identified information on my pregnancy will be shared so as to learn the results of the study.

Authorisation to publish results

The information about me will be analysed together with other study participants. Results of this study will be published and presented to scientific groups for scientific purposes, but I will never be individually identified in the presentation of the study results.

Institutional Policy

In case I have any questions related to the study, in future or in case of study related injury or illness, I can contact **REG. NO. BJ0119002**, Department of Obstetrics and Gynaecology, KAHER, J.N Medical College, Ph. No. _____ or phone number: _____ or Dr. _____, Dept. Of Obstetrics and Gynaecology, KAHER University's J.N Medical College, Belagavi Ph.: _____ or phone number: _____.

Voluntary Participation

My participation in the study is voluntary. In case I need any further information regarding my rights as study participant, I may contact Dr. Roopa M Bellad, Professor of Paediatrics, as Chairman of J. N. Medical College Institutional Ethics Committee on Human Subjects Research, Phone No.0831 2473777 ext-1527 at J. N. Medical College, Belagavi. My doctor will take care of me during this pregnancy or in the future. I am free to stop participation in this study at any time and for any reason.

Certification Of Consent

I have read the whole information, or it has been read to me. I have asked all the questions about it and those have been answered to my satisfaction. I consent voluntarily to participate in this research.

I also agree to be contacted for follow-up.

Print Name of Participant_____

Signature of Participant_____

Date_____ (dd/mm/yyyy)

If illiterate,

A literate witness must sign (if possible, this person should be selected by the participant and should have no relation to the research team).

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given the consent freely.

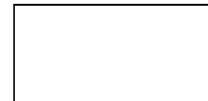
Print name of witness_____

Signature of witness_____

Date_____ (dd/mm/yyyy)

Thumb Print of Participant

Statement by the Researcher



I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the following will be done:

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered to the best of my ability. I confirm that the individual has not been coerced into giving consent and it has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print name of Researcher_____

Signature of Researcher_____

Date_____ (dd/mm/yyyy)

Screening and recruitment form

ENROLLENT NUMBER:

First name: _____ Middle name: _____ Last name: _____

Age (years):

IP number:

Husband's name: _____

Address: _____

If any one of the following criteria present, patient not eligible for the study.(yes =1 and no =2)

1. Uncontrolled diabetes mellitus
 2. Severe anemia (<7 gm%)
 3. Cardiac disease
 4. PROM AND PPROM
 5. Immunocompromised status or pre-existing infection:
 6. Patient consent not obtained
- Eligible Consented

Data collection instrument

1. Socio demographic information:

1. How old are you? (years)

2. What is the level of schooling?

1= no formal schooling, illiterate

2= no formal schooling, literate

3= schooling

4= Don't know

a. number of years of schooling

2. Socio-economic status (according to modified B.J Prasad classification)

1 =upper class

2=upper middle class

3=middle class

4=Lower middle class

5=lower class

3. Group allotment:

1= control

2=interventional

Abortion:

Stillbirth:

7. General physical examination:

Pallor : _____

Icterus : _____

Edema: _____

Clubbing: _____

Thyroid status: _____

Pulse rate : _____

Blood pressure : _____

Weight: _____

Height: _____

BMI: _____

8. Systemic examination :

Respiratory system : _____

Cardiac system : _____

Central nervous system : _____

Abdominal examination : _____

9. Clinical diagnosis: _____

10. Investigations:

Blood group:

Haemoglobin

Platelets :

RBC :

WBC:

DLC:

Urine routine and microscopy:

HIV:

Hepatitis :

VDRL:

TSH:

DIPSI:

11. Type of caesarean section :

Elective :1)Primary section

2) Repeat section section

Emergency: 1) Primary section

2) repeat section

Indication : _____

12. Preoperative preparation: (yes =1 and no =2)

Interventional group :

1. Clipping of pubic hair if done
2. Chlorhexidine gluconate(20 %) scrubbing before surgery
in the labor room Or recovery room prior to the patient is shifted to OT.
- 3.Surgical hand scrubbing.
- 4.Antibiotic injection
Ceftriaxone 1 gm IV + injection azithromycin 500mg IV
atleast 15 minutes prior to surgery
- 5.Vaginal vault painting with betadine

- 6.Painting parts with Chlorhexidine gluconate (20 %) as the antiseptic on the OT table
- 7.Placenta removal by CCT (with MRP)
- 8.Closure of subcutaneous fat if subcutaneous fat is>2cm deep
- 9.Closure of skin by subcuticular sutures.
10. Post operatively if antibiotics used

- Postoperative strategies-
8. Dressing done 48 hours post operatively ¹.
- 9.If wound discharge present, wound culture sent and based on antibiotic sensitivity appropriate antibiotic started

Control group:

- 1. Shaving of pubic hair .
- 2. Betadine scrubbing of abdomen before surgery .
- 3. Surgical hand scrubbing .
- 4. Antibiotic injection ceftriaxone 1 gm IV
prior to surgery (15 minutes).
- 5. Painting parts with betadine solution (10 %) as the antiseptic
- 6. Ethanol at site of surgical incision
- 7. removal of placenta by controlled cord traction(MRP done)
- 8. Closure of skin by mattress sutures using ethilon
- Postoperative strategies-
- 9. Removal of dressing on day 3 post operatively
- 10. Post operative antibiotic Tablet ciplox tz for 5 days
- 11. If wound discharge present, wound culture sent and based on antibiotic sensitivity appropriate
antibiotic started

13 Post operative diagnosis: _____

14. Post operative follow up :

Status of the wound after 48 hrs:

- 1. Healthy :
- 2. Unhealthy:

Signs of infection and inflammation: (yes = 1 and no =2)

- 1. Redness at incision site
- 2. Pain at incision site
- 3. Swelling at incision site
- 4. increase in temperature at incision site
- 5. discharge from incision site
- 6. pus from abcess
- 7. Separation of edges at incision site
- 8. Fever with tenderness at the site of incision

Post operative antibiotics:

- 1. yes reason : _____
- 2. no

Culture swab report (if sent): _____

Post operative hospital stay duration: _____

Secondary suturing : (yes =1 and no = 2)

CHECKLIST

PATIENT NAME:

IP NUMBER:

DIAGNOSIS:

11.Type of caesarean section :

- Elective: 1)Primary section
- 2) Repeat section section
- Emergency: 1) Primary section
- 2) repeat section

Indication : _____

12. preoperative preparation : (yes =1 and no =2)

Interventional group :

- 1.Shaving of pubic hair .
- 2.Chlorhexidine gluconate(20 %) scrubbing before surgery
in the labor room Or recovery room prior to the patient is
shifted to OT.
- 3.Surgical hand scrubbing.
- 4.Antibiotic injection
Ceftriaxone 1 gm IV + injection azithromycin 500mg IV
atleast 15 minutes prior to surgery
- 5.Vaginal vault painting with betadine

- 6. Painting parts with Chlorhexidine gluconate (20 %) as the antiseptic on the OT table
- 7. Placenta removal by CCT (with MRP:1 , without MRP :2)
- 8. Closure of subcutaneous fat if subcutaneous fat is >2cm deep
- 9. Closure of skin by subcuticular sutures.
- 10. Post operatively if antibiotics used

DETAILS OF ANTIBIOTICS :

Control group :

- 1. Shaving of pubic hair .
- 2. Betadine scrubbing of abdomen before surgery .
- 3. Surgical hand scrubbing .
- 4. Antibiotic injection ceftriaxone 1 gm IV prior to surgery (15 minutes).
- 5. Painting parts with betadine solution (10 %) as the antiseptic
- 6. removal of placenta by CCT(MRP done:1, without MRP:2)
- 7. Closure of subcutaneous fat if subcutaneous fat is >2cm deep
- 8. Closure of skin by subcuticular:1, mattress sutures:2

Details of Antibiotic:

