COMPARISON OF STAPLES VERSUS SUBCUTICULAR SUTURES FOR SKIN CLOSURE IN CAESAREAN SECTION-A RANDOMIZED CONTROLLED STUDY



THESIS

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DOCTOR OF MEDICINE (MD) (OBSTETRICS & GYNECOLOGY)

JUNE, 2022 AIIMS, JODHPUR **DR. SHAFAQ BHANDARI**

DECLARATION



I hereby declare that the thesis titled "Comparison of staples versus subcuticular sutures for skin closure in caesarean section-A Randomized controlled study." embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

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LIST OF ABBREVIATION

CS	Caesarean Section
WHO	World Health Organisation
CSMR	Caesarean Section on Maternal Request
TOLAC	Trial of Labour After Caesarean
e.g.	For Example
SSI	Surgical Site Infection
Vs	Versus
AD	Anno Domini
BC	Before Christ
aOR	Adjusted Odd's Ratio
OR	Odd's ratio
POSAS	Patient and Observer Scar Assessment Scale
NRS	Numeric Rating Scale
RR	Relative Risk
CI	Confidence Interval
PSAS	Patient Scar Assessment Scale
OSAS	Observer Scar Assessment Scale
Min	Minutes
RCT	Randomized Controlled Trial
BMI	Body Mass Index
MD	Mean Difference
AIDS	Acquired Immune Deficiency Syndrome
CKD	Chronic Kidney Disease

VAS	Visual Analog Scale
TDS	Ter die sumendum
SPSS	Statistical Package for Social Sciences
POG	Period of Gestation
LSCS	Lower Section Caesarean Section
MSL	Meconium Stained Liquor
CPD	Cephalo Pelvic Disproportion
DTA	Deep Transverse Arrest
АРН	Antepartum haemorrhage

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ABSTRACT

Background- Caesarean section is the most common surgery performed worldwide. Pfannenstiel incision is the most common incision used in caesarean section. Variety of materials and techniques are used for skin closure after caesarean section. Common methods of skin closure are sutures and staples. The optimal caesarean section skin closure technique on one hand should be simple, quick, and provide good cosmesis and on other hand should limit the wound complications and pain, and there is a need to identify which provide the best outcomes for women.

Aims & objectives- The aim of the study was to compare the skin staples and the subcuticular sutures for skin closure in caesarean section. The primary objective of the study was to compare wound complication rates between surgical skin metallic staples and the subcutaneous sutures for skin closure in caesarean section. The secondary objectives of the study were comparing skin closure time, post-operative pain and patient satisfaction rate between the two techniques used for skin closure.

Materials and methods- It was a randomized controlled trial conducted over a period of 21 months from February 2020 to November 2021 in 300 women undergoing caesarean section - scheduled or unscheduled and primary or repeat caesareans with low transverse/ Pfannenstiel incision with viable pregnancies (>26 weeks). The patient's baseline characteristics were assessed like anaemia, fever and other antenatal investigations were performed as per the existing protocol and according to the individual case. They underwent usual peri-operative management. Women were randomized into two groups using sealed envelopes opened by the attending nurse who was not involved in the study. The surgical procedure was same for both the groups till the closure of rectus sheath. Skin closure was done and time was noted. The wound was then dressed with abdominal pad and occlusive dressing was applied immediately after the skin closure. The wound was assessed on day 3 post operatively to look for wound condition, pain score and patient satisfaction rates.

Results– A total of 300 patients were enrolled in the study out of which, 150 patients underwent skin closure with subcuticular suture and 150 patients underwent skin closure with metallic surgical skin staples. Wound morbidity rates were compared on day 3 and 6 weeks post operatively. On day 3 post operatively, 78% patients in each group had normal healing,

while 22% patients in each group had abnormal healing (p value 1.00). On 6 weeks post operatively, 98.62% patients with sutures versus 96.55% patients with staples had normal healing (p value- 0.25) while 1.37% patients with sutures and 3.44% patients with staples had abnormal healing (p value - 0.39). Wound morbidity rates were comparable between both the groups on day 3 and 6 weeks post operatively. A total of 10 patients (3.33%), 5 in each group underwent resuturing within 6 weeks post operatively. Skin closure time was lesser with staples as compared to sutures (65.55 ± 30.26 vs 459.09 ± 124.77 , p value <0.001). Mean pain score on day 3 post operatively with sutures was 3.78 ± 1.94 and staples 3.39 ± 2.02 . Similarly, at 6 weeks post operatively mean pain score with sutures was 0.31 ± 0.84 and staples 0.25 ± 0.52 . Pain score was comparable in both the groups on day 3 post operatively (p value - 0.08) and on 6 weeks post operatively (p value - 0.45). Patient satisfaction score calculated on 6 weeks post operatively, taking in account the appearance and the comfort of the scar was comparable in suture versus staples group (p value - 0.25)

Conclusion- In our study, skin staples and subcuticular sutures were equivalent to each other for the skin closure method in caesarean section. Staples had less time consumption for skin closure as compared to suture. Pain score, wound complications and patient satisfaction scores were comparable in both the groups. Composite wound morbidity rate in our study was 2.42% which was lower as compared to previous studies. We conclude that staples and subcuticular sutures are equivalent to each other in terms of composite wound morbidity and the choice of skin closure material is at the discretion of the surgeon.



INTRODUCTION

Caesarean section is the most common surgery performed worldwide. Literature suggests that globally caesarean section (CS) rates are 15%, which are parallel to the CS rates recommended by World Health Organisation (WHO). It is, however, acknowledged that "optimal" caesarean section rate is still not known.^{1,2,3} Caesarean section rates have risen from 7% in 1990 to 21% in 2021, and its prevalence is still rising.^{4,5,6,7} The rate of caesarean deliveries is doubled in India in comparison previous stats, from 8% of deliveries in 2005 to 17% of deliveries in 2016 and 32.6% in 2021.^{8,9}

In some countries, the current caesarean section rates is even more than 40%.¹⁰ This high percent can be advocated because of increase demand of caesarean section on maternal request (CSMR), further leading to repeat caesarean section in view of previous caesarean not willing for trial of labour after Caesarean (TOLAC), with the highest rate reported from Middle Eastern and East Asian countries.¹¹

The most common indications of caesarean section worldwide are foetal distress (31.2%), previous caesarean section (23.9%), breech (16%) and prolonged labour (11.2%).¹²

Pfannenstiel incision is the most common incision used in caesarean section, it's a transverse incision given in the lower abdomen.³ Major fear after caesarean section is the cosmetic appearance of scar. That is why preferred skin incision is usually Pfannenstiel; unless vertical incision is required for obstetrics indication. Besides the site of scar of caesarean section, patient satisfaction rates also depends on pain at incision site, wound healing and cosmetic appearance of scar. Therefore various techniques and materials for skin closure have been in practice to improve the patient satisfaction rates.

Techniques and materials for skin closure -

At the end of the surgery, skin closure can be carried out with stitches that go beneath the skin or above the skin. Each method has its specific indications, contraindications, advantages and disadvantages. Among the large variety of materials and techniques available for skin closure after caesarean section, there is a need to recognize which provides the best outcomes and results for the patient.^{13,14} Broadly, the materials for skin closure can be

divided into sutures and staples. Studies done in past have not been able to conclude the single best skin closure material in caesarean section.

Suture - Suture closure permits primary wound healing. Using sutures, the tissue is held in proximity to allow enough healing so as to withstand stress without mechanical support. Suture material is a foreign body and will provoke tissue reaction on implantation in body.^{15,16} Suture material can be natural or synthetic, absorbable or non-absorbable, single-filament or multifilament/braided. They can be applied in a continuous or interrupted manner. Absorbable synthetic sutures include polyfilament sutures made of polyglycolic acid (Dexon) and polyglactin (Vicryl). These sutures are mainly used to close the skin in subcuticular fashion. The foremost advantages of sutures are their elasticity, tensile strength, non toxic nature and in vivo degradation properties.^{13, 17}

Non absorbable synthetic sutures can be monofilament or braided. Monofilament sutures include nylon (e.g.Ethilon), polypropylene (e.g.Prolene), and polybutester (e.g.Novafil). Braided monofilament sutures include Polyethylene terephthalate (e.g.Dacron, mersilene) and polyester (e.g.Ethibond).Silk suture is rarely used now due to its predisposition to produce severe inflammatory response and it acts as a source of infection. In case of tight application of full thickness interrupted stitches, it may result in oedema, swelling, pain and disfiguring cross-hatching.^{13,17}

Staples – They are mainly made of stainless steel, although staples made of absorbable materials are now available. They are comparatively costlier as compared to suture.^{18,19} Staples attract because of the speed of application.^{17,20} They decease the operative time duration by 7 minutes.¹⁷ The capillaries present in the subcuticular layer are not damaged during placement of the staples, hence reducing the chances of bacterial migration into the wound. This lowers the wound infection rates.¹³ However, the main benefit of surgical staples, in the existing literature, remains that of speed.^{17,18}

The most frequently reported materials used for skin closure are Prolene- polypropylene (41%), Vicryl- polyglactin(17.5%), Dexon- polyglycolic acid (13.5%), Staples (10.4%) and clips (6%) and Ethilon- polyamide((5.2%)).²¹

Goals of wound closure include obliteration of dead space, distribution of tension evenly along deep suture lines and maintenance of tensile strength across the wound. Prerequisites for good skin closure include reduced mechanical tension, eversion of edges after adaptation and absence of marks on the skin by skin closure material.^{15,16}

Although the sutures are the most common material for wound closure, they are prone to increase the risk of wound infection. This complication is seen more with multifilament than monofilament suture. Proposed reason for this is that the monofilament suture is made of single strand and is fairly more resistant to harbouring microorganisms. Multifilament sutures have more capillarity as compared to monofilament suture, resulting in increased absorption of fluid which acts as a tract for the introduction of microbes. Sutures, monofilaments to be precise, are less stiff but demand a great care in handling them as suture strength can deteriorate on crushing or crimping the suture leading to premature suture failure. Multifilament suture have several filaments braided and twisted together resulting in better tensile strength, enhanced pliability and flexibility than monofilament suture.^{13,15}

Sutures are known to cause the ischemia of the wound flaps causing hindrance in the normal pathway of wound healing. Traditional subcuticular suture is thought to be useful for healing wounds with similar tissue thickness with little to no existing strain.¹⁶ However, because it does not hold each stitch, it is prone to produce tension across the skin's margins.¹³

Staples have a potential benefit in wound closure because of their minimal tissue reactivity.

Due to lack of introduction of external material, there is concomitant reduction of the local immune response resulting in higher resistance to infection in contaminated wounds.¹³ Using staples reduces the time for wound closure, local inflammation, distance across the wound and residual cross marks.^{13,20} Even though sutures are commonly used to close the skin incision, staples appear to be superior in terms of effectiveness of fixation, cosmetic effects, and application speed.²²

Caesarean section is considered as clean surgery. The aim of the surgical wound closure is moving the skin flaps closer together which in turn favours rapid wound healing.^{23,24} Although skin closure is a small part of the Caesarean section, it is considered as the "lasting impression" of the surgeon's technique and may perhaps change the wound outcomes in terms of infections, dehiscence, pain, cosmetic appearance and patient satisfaction.^{23,25,26} Even though cosmetic appearance of the scar is relatively more worrisome to the young patients, but skin scarring can cause discomfort, soreness, tenderness and itching in patients.²⁷

Such symptoms have an overall negative effect on the quality of life of the patient. They can cause a great deal of distress, as well as a loss of self-esteem and stigmatisation. ^{28,29,30,31} The technical factors including the closure material and the technique used for skin approximation, which affect the final appearance and function of the healed skin, are completely in control of the surgeon. Hence, surgeon should carefully select an effective surgical technique avoiding local inflammation, dehiscence of the wound and poor cosmetic results. Efficiency is particularly important in obstetrics as it helps to reduce the delay in mother- infant bonding and makes more surgical staff available to manage awaiting emergencies. Inadequately treated postoperative pain is a significantly contributes to patient's morbidity. It delays the recovery of the surgical patients and ability to return to daily functional life activities.^{24,25} Thus, the optimal caesarean section skin closure technique on one hand should be simple, quick, and provide good cosmesis and on other hand should limit the wound complications and pain.^{13,26,27}

The method chosen relies on the surgeon's preference. There are numerous studies comparing various absorbable sutures and absorbable with non-absorbable sutures.^{2,32,33,34,35,36,37,38,39,40} But there is paucity of literature on the comparison of absorbable sutures with staples for skin closure during caesarean section. The data in the literature do not provide adequate evidence to say which method for skin closure is best in patients undergoing caesarean section. The impact of these methods on post-operative pain, skin closure time, aesthetic results, wound dehiscence and infections remain controversial.³¹

Risk factors for wound complications in caesarean section -

When compared to women who gave birth vaginally, women who had a caesarean section have a 5 to 20 times higher risk of peri-partum infective problems.⁴¹ Infections complicate 2% to 15% of the surgical wounds.^{42,43,44} Risk factors specific to caesarean section can be classified under three categories-

<u>Host-related factors</u>- They consist of maternal age, dwelling in rural area(compared to urban), obesity, diabetes mellitus (overt and gestational), Previous caesarean section, Maternal preoperative condition (American Society of Anesthesiologists score >3).^{41,43,44,45}

- Pregnancy and intrapartum-related factors- The various factors are Hypertensive disorders, diabetes mellitus (gestational and overt), Preterm rupture of membranes, Twin pregnancy, Number of vaginal examinations, Prolonged trial of labour before surgery, use of epidural, Internal fetal monitoring, Chorioamnionitis.^{46,47,48,49,50,51}
- Procedure-related factors- Some of the common factors include emergency Caesarean sections as compared to Elective Caesarean, Not using prophylactic antibiotics, Surgeries of longer duration >1 hour (increases the risk of infections more than two fold), Associated uterine rupture, Caesarean hysterectomy, Need for blood transfusions and Failure to close the subcutaneous tissue.^{43,45,46,47,48,49,50,51}

Even though the use of prophylactic antibiotics, skin preparation using alcohol based agent, meticulous aseptic technique and correct suture selection has significantly decreased the risk of wound infection, still the rates are as high as 16% in high risk patients undergoing Caesarean section and is associated with maternal mortality of 3%.^{25,45,51,52,53,54,55} The rates are expected to rise given the constant increase in the number of caesarean deliveries.

Wound complications following caesarean delivery result in significant morbidity such as wound infection, hematoma formation, seroma formation, wound dehiscence, rupture of fascia leading to increase in duration of hospital stay, further treatment and investigations, readmission, increased time away from work and so consequently increasing the cost of health care.^{25,52,56,57,58} Thus, wound infection is an expensive complication and poses a significant financial strain on both the patient and the healthcare system.^{29,47} Specifically in case of caesarean sections, these complications decrease the infant bonding time and hence can be depressive and annoying for the new mother trying to recover from the surgical procedure and at the same time taking care of newborn.^{60,61,62} It is, therefore, essential to identify the surgical method that reduces wound complications, increases effectiveness and efficiency, decreases pain, favourable cosmetic outcome and improves patient satisfaction. Recognizing risk factors, especially modifiable ones related to the woman, pregnancy, or the method itself, and putting in place strategies to prevent, diagnose, and treat infection as soon as possible are all critical steps in minimising the incidence of SSI and its implications.

Owing to number of detrimental side effects of wound complications in caesarean section, it is of utmost importance to decide the most effective and safest skin closure technique so as to lessen patient morbidity. There exists in the literature a long-standing dispute regarding the superiority of suture versus staples in terms of wound complications, pain, skin closure time and cosmesis. Studies postulated that the sutures act as foreign material and they cause tissue damage, thereby increasing the risk of infections while staples are widely believed to result in decreased operating time.^{63,64,65} In most trials, use of prophylactic antibiotics use to prevent infection was not reported.^{17,63}

Initial small studies regarding caesarean skin closure materials looked upon operative time, pain scores, cosmesis scores and patient satisfaction scores and yielded conflicting findings.^{17,66,67} One randomized controlled trial analyzing the wound disruption or infection rates at 2-4 weeks (evaluated by phone interview supplemented with record review) as the primary outcome, suggested increased wound complication rates with staples as compared to suture closure whereas staples are faster to apply, thus decreasing overall operative timing.²² Current knowledge supports that metallic skin staples is faster, while subcuticular suture has superior wound outcomes. Studies have also compared other parameters between different skin closure techniques. These are suturing time, post-operative pain, patient satisfaction rate and cosmetic appearance of skin. Staples are favoured because quick application, ease of compatibility and good cosmetic results, but they are expensive and associated with higher wound dehiscence rates.^{13,17} Subcuticular sutures made from Poliglecaprone 25 (Monocryl) yield good wound cosmesis; however, their use has the disadvantage of being time-consuming.

The ideal skin closure technique should be safe, efficient, economical, not time consuming with minimal patient discomfort and good cosmetic outcomes. It should also have a low rate of wound complications and require minimum follow-up examination.

Given the paucity of trials that satisfactorily examined wound morbidity outcomes of skin closure methods in caesarean delivery, we proposed a randomized controlled study to compare wound complication rates between surgical skin metallic stapler and the subcutaneous sutures for skin closure in caesarean section. We also compared other parameters including skin closure time, post-operative pain and patient satisfaction rate between the two techniques used for skin closure.



AIM AND OBJECTIVES

AIM OF STUDY-

1. To compare the rate of wound complication following surgical staples and subcuticular sutures for skin closure after Caesarean delivery.

2. To compare the skin suturing time and post-operative pain after skin closure with metallic surgical staples and subcuticular suture.

OBJECTIVES-

PRIMARY OBJECTIVE

To compare wound complications by 6 weeks post operatively following metallic surgical staples vs subcuticular sutures for skin closure after Caesarean delivery.

SECONDARY OBJECTIVE

- To compare pain score post operatively on day 3 and 6 weeks between metallic surgical staples and subcuticular sutures for skin closure after Caesarean delivery.
- To compare skin closure time between two groups.
- To compare patient satisfaction rates between two groups.



REVIEW OF LITERATURE

The history of caesarean sections can be traced all the way back to Ancient Rome. During this era, the caesarean section technique was employed to save a baby from a mother who had died while giving birth (Lex Caesarea or The Caesar's Law and hence the word Caesarean Section). The term Caesar refers to all the Roman Emperors and not only Julius Caesar.⁶⁸ In the year 1580s in Switzerland, a pig gelder named Jacob Nufer is claimed to have performed the operation on his wife when her labour was not advancing.^{69,70}

The last step of a caesarean section is wound closure, which is usually done by suturing the wound. The first written account of sutures used in operational procedures is found in Papyrus and dates back to 16th century BC. In 900 AD, Rhazes of Arabia is credited with being the first to use sheep intestine to repair abdominal wounds (catgut).⁶⁹

Surgical operations have used a wide range of materials over the years to close the incision, including silk, linen, cotton, horsehair, animal tendons and intestines and precious metal wire.⁷¹ Up until the eighteenth century, there was little advancement, following which prototypes of mechanical suturing equipment (staplers) were constructed. They were first used in clinical settings in the early twentieth century.⁷² Most advancements in wound suturing were seen following World War II, with the development of improved stapler machinery and the manufacture of synthetic non-resorbable and resorbable fibres.⁶⁹

There are studies available in the literature comparing absorbable and non absorbable sutures but the studies comparing sutures with skin staples have shown conflicting results.^{20,22,28,66,74,75,76,80,82} Total operating time, skin closure time, pain perception rates, wound complication and dehiscence rates, wound cosmesis were some of the common outcomes studied. Outcomes were studied varyingly among studies on day 1 post operatively, on discharge (day3/4), 3 weeks post operatively, 6 weeks post operatively or 6 months post operatively. None of the study could absolutely notify the best skin closure technique.

• Rousseau *et al*⁶⁶ compared skin closure in caesarean section using staples vs subcuticular sutures in a randomised control trial on 101 women in 2009. At 6 weeks after surgery, staples caused significantly less pain (0.17 vs 0.51; P = 0.04). The researchers employed a 0-10 analogue pain scale and a 0-10 satisfaction scale. With staples, the duration of surgery reduced (24.6 vs 32.9 minutes; P value - 0.0001). No difference was noted for

incision appearance and women's satisfaction. At 6 weeks after surgery, a digital image of the incision was obtained and reviewed by three blinded observers. They concluded that staples are method of choice for skin closure for elective term caesareans in their population.

- Basha *et al*⁵⁵ compared the wound complication rates of subcuticular suture versus staples for skin closure in caesarean delivery on 435 patients in a randomised controlled trail in 2010. According to their study, staple closure was linked to a four-fold higher risk of wound separation aOR 4.66; 95% confidence interval, 2.07-10.52; p value< .001). Wound complication was associated with a 5-fold drop in patient satisfaction (aOR, 0.18; 95% CI, 0.09-0.37; p value < .001) There was no difference in satisfaction between the treatment groups once confounders were taken into account (aOR, 0.71; 95% CI, 0.34-1.50; p value = 0.63). They concluded that use of staples for caesarean delivery closure is associated with an increased risk of wound complications and occurrence of a wound complication is the most important factor that influenced patient satisfaction.
- Clay *et al*⁷³ did a meta-analysis of 5 randomised controlled trials in 2011 comparing staples vs subcuticular sutures for skin closure at caesarean sections, taking a total of 877 women. They concluded that wound separation (pooled OR, 4.01; p value < 0.0001) and composite wound complications were higher with staples (pooled odds ratio, 2.11; p value = 0.003). Staples reduced the total operating time (weighted mean difference, 5.05 minutes; p value = 0.021). They concluded a possible benefit of subcuticular sutures compared to skin staples for skin closure at Caesarean section.
- Huppelschoten *et al*²⁸ did a Randomized controlled trial in 2013 to study the impact of subcutaneous tissue closure and the use of staples or sutures as a skin closure technique during caesarean section on long-term cosmetic outcomes. Long-term cosmetic result was evaluated 1 year postoperatively. They also examined operating time, post-operative pain and wound complication rates. After a year of follow-up, out of 218 randomised women, 145 were analysed. They concluded that except for operating time, there were no significant variations in long-term cosmetic success, post-operative discomfort, or wound complication rates between the groups

- Figueroa *et al*²² did a randomised controlled trial on 398 patients in 2013 comparing surgical staples with subcuticular suture for skin closure after caesarean delivery. They concluded that staples were associated with significantly increased rates of composite wound morbidity (7.1%) as compared to subcuticular suture (0.5%) at caesarean delivery on 3 days post operatively (p value < 0.001, RR 14.1; 95% CI 1.9-106). The cumulative risk of the primary outcome was 14.5% for staples and 5.9% for suture; p value =0.008 (RR 2.5; 95% CI 1.2-5.0) on 4-6 weeks follow up. Pain scores, Cosmosis Score and Patient Satisfaction Score didn't were comparable between the two groups.
- Aabakke *et al*⁷⁴ did a randomised controlled trial in 2013 including 63 women comparing subcuticular sutures with staples for skin closure following caesarean delivery. Each woman was her own control. Half of the skin incision was closed with subcuticular suture and remaining half was closed with staples. The primary outcome was the overall preferred side of the skin scar 6 months after surgey. At any point in time, there were no significant variations in pain scores. One plastic surgeon preferred the stapled side (OR 2.8; 95% CI 1.01-7.78) and scored it significantly higher on a Cosmetic Visual Analog Scale (p value =0.031); the other found no significant difference. There were four (6.8%) cases of infection-three on the sutured side and one bilateral. Significantly more women preferred the stapled side, both overall (OR 2.55; 95% CI 1.18-5.52) and cosmetically (OR 2.67; 95% CI 1.24-5.74), and reported staples as their preferred technique for skin closure (OR 2.00; 95% CI 1.10-3.64).
- Rukiyat Adeola Abdus-Salam *et al*⁷⁵ did a randomised controlled trial in 2014 aiming at patient's satisfaction and outcome of caesarean section wound closure between skin staples and subcuticular sutures at Caesarean Section in Black-Skinned women, on discharge and 6 weeks post-operative. Staples, in comparison to sutures, decreased the total operating time (40.26 ±16.53 mins vs 47.55 ±14.55 mins; p value= 0.025) and skin closure time (118.62 ±69.68 second versus 388.70 ±170.40 second; p value <0.001). There was no difference in pain experienced, wound assessment by the participants and patients' satisfaction. Participants in the staple group scored higher on both scar assessment scales by the nurse (P = 0.044). The study concluded that participants were satisfied with both wound closure techniques.

- Sharma *et al*⁷⁶ did a randomised controlled trial in 2014 on 130 women comparing staples with subcuticular sutures for skin closure in emergency caesarean sections. Primary objective was cosmetic outcome at 6 weeks post-operative using PSAS and OSAS scales. Secondary objectives were wound complications, post-operative pain, operating time and duration of hospital stay. Cosmesis with staples was better compared to sutures (PSAS and OSAS: p value 0.022 and 0.000, respectively), with significantly lesser duration of surgery (24 vs. 32 min: p value 0.000) and comparable post-operative pain (pain on day 3 and 6 weeks post-operatively: p value 0.474 and 0.179, respectively) and wound complications (p value 0.737). However, duration of stay in hospital was increased (6 vs. 3 days; p value 0.001). They concluded that staples are the method of choice for skin closure in emergency Caesarean section in terms of cosmesis and duration of surgery. Post-operative pain and wound complications are comparable in two groups.
- Mackeen *et al*²³ did a meta-analysis in 2015 on absorbable suture versus metallic staples for skin closure after caesarean. Twelve randomized trials with total of 3112 women were identified. Staples had higher risk of wound complications than sutures (Risk ratio, 0.49; 95% CI 0.28–0.87). This difference remained significant even when wound complications were stratified by obesity. There was no significant difference in infection, hematoma, seroma or readmission rate (risk ratio, 0.29; 95% CI, 0.20–0.43). Both groups were comparable in terms of pain score, patient satisfaction and cosmetic assessments. Operating time was approximately 7 minutes more with sutures. They concluded that suture significantly decreases wound morbidity, specifically wound separation, without significant differences in pain, patient satisfaction or cosmesis.
- Ikeako et al⁷⁷ in 2016 did a randomised controlled trial, comparing subcuticular sutures versus percutaneous staples for skin closure after Caesarean Delivery, including 220 women randomised into 2 groups. There was increased risk of composite wound complications with staples than suture (11.9% vs 3.8%, p value 0.041). Maternal satisfaction rate with staples was significantly less as compared to suture (8.05±0.54 vs 9.5±0.75, p=0.011). Mean operation time (staples- 50.7±6.88 vs suture- 69.5±5.71 minutes, p<0.001) and mean post operation pain (staples -1.8±1.1 vs suture -1.1±0.99, p<0.001) was significantly less with staples. They concluded that women in their study were more satisfied with subcuticular absorbable suture for skin closure over staples.

- Wang *et al*²⁰ conducted a meta-analysis in 2016 comparing incidence of wound complications of subcuticular sutures with staples. Ten RCTs were included in this analysis. Subcuticular sutures were associated with significantly decreased incidence of wound complications compared to staples (RR 1.88, 95% CI 1.45-2.45). The operation time was shortened with use of staples (MD -8.66 min, 95% CI -10.90 to -6.42). The two groups were comparable regarding cosmetic outcome at 6-8 weeks postoperatively, whereas subcuticular sutures were associated with a better cosmesis at 6-12 months postoperatively. There were no significant differences between groups in terms of hospital stay, postoperative pain and patient satisfaction. They concluded that compared with staples following caesarean delivery, subcuticular sutures are associated with decreased risk of wound complications and better long-term cosmetic outcome, but slightly prolonged duration of surgery.
- Fitzwater *et al*⁷⁸ in 2016 did a secondary analysis of a randomised controlled trial on 350 patients to determine if the risk of post-caesarean wound morbidity in patients undergoing staple versus suture closure is modified by diabetic status. In previous RCT, skin was closed with staples or subcuticular suture monocryl 4-0. They compared the wound disruption rates with the diabetic status (also stratified by gestational n= 35 or pregestational n= 32). 67(19.1%) patients of total 350 study population were diabetic. Composite wound morbidity in non-diabetics was significantly higher with staples than suture (16.7% versus 3.6%, p ≤ 0.001, RR: 4.6, 95% CI: 1.8-11.8); while in diabetics the wound morbidity rates were higher with suture than staples (15.6% vs 5.7%, p = 0.25, RR: 0.4, 95% CI: 0.1-1.7). The corresponding Breslow-Day p value indicated a significant difference between diabetics and non-diabetics (p = 0.002). They concluded that the use of staples is associated with increased wound morbidity compared with subcuticular suture for caesarean skin closure in non-diabetic patients, while further studies are required for assessment in diabetics.
- Tierney *et al*⁵⁸ in 2017 conducted a retrospective cohort study of all 1580 women who had a Caesarean section at the University of California, San Diego between March 1, 2011 and February 28, 2012 (mainly staples) and March 1, 2013 and February 28, 2014 (primarily suture). When compared to sutures, staples had a greater rate of wound complications (10.1% vs 4.5%; OR 2.4, 1.4-4.1). Wound complication rates were increased with vertical skin incision (OR 3.6, 1.6-8.1), CS for failed labour (OR 2.9, 1.1-

7.4) and diabetes (OR 2.1, 1.4-3.9). After adjusting for confounders, there were over two fold increased odds of wound complication with staple closure. They concluded that suture closure appears to decrease the risks of wound complications post caesarean section.

- Hanan-al-Kadri *et al*⁷⁹ did a randomized controlled trial in Saudi Arabia in 2018 comparing subcuticular and staple skin closure techniques for Caesarean Section. Sample size was 240, with 120 patients randomized in each group. Primary outcomes were wound complications, postoperative pain, analgesia requirement and the length of postoperative hospital stay. Patient satisfaction score was taken as secondary outcome. They concluded that both methods of skin closure were comparable in terms of short and long-term patient satisfaction although the incidence of wound complications was higher with subcuticular suture (OR=2.41; 95% CI: 1.17-4.98; p=0.02). This conclusion, however, could be explained by the higher prevalence of diabetes and a high BMI in pregnant women, as well as the relative experience of the operating surgeon performing the procedure.
- Fayyoux *et al*²⁹ at Eisenhower Medical Center, California in June 2018 did an analysis of literature for Staples versus Sutures after Caesarean section. A 2011 meta-analysis of five RCTs and one prospective cohort study compared wound closure with staples (n = 803) or subcuticular sutures (n = 684) in women undergoing primary, repeat, elective, or urgent CS. Wound complication was the primary outcome. They reported that staples increased the risk of wound complication (13% vs. 6.6%; pooled odds ratio = 2.1; 95% CI 1.4 to 3.0). Cosmesis was reported as a secondary outcome in three of the studies. Two of these studies (n = 215) reported cosmesis as assessed by blinded assessors to be equivalent for both techniques. In the third study (n = 50), the unblinded assessor cosmosis was better with sutures.

In 2016, an updated meta-analysis included five additional RCTs for a total of 10 (n = 2,327) and excluded the cohort study from the previous meta-analysis. The studies compared incision closure after caesarean delivery using staples vs subcuticular sutures. Wound complication was the primary outcome and cosmesis was the secondary outcome. In pooled data from all 10 studies, the staples group had an increased risk of wound complications compared with the sutures group (relative risk = 1.9; 95% CI, 1.5 to 2.5). Four RCTs used the 10-point Patient Scar Assessment Scale (PSAS) and Observer Scar

Assessment Scale (OSAS) to assess cosmesis. At six to eight weeks postpartum, there was no significant difference between the groups in PSAS scores (two studies, N = 270; mean difference [MD] = -0.87; 95% CI, -2.0 to 0.25) or OSAS scores (two studies, N = 270; MD = -1.6; 95% CI, -5.4 to 2.2). However, at six to 12 months postpartum, the suture group had lower mean OSAS scores (three studies, N = 392; MD = 2.5; 95% CI, 1.2 to 3.8) but similar PSAS scores (three studies, N = 392; MD = 1.0; 95% CI, -0.80 to 2.9).

- Cooper *et al*⁸⁰ in 2019 did a secondary analysis "Does Time of Wound Complication after Caesarean Delivery Differ by Type of Skin Closure?" The results of a randomised trial in which women who had a caesarean section at 24 weeks of pregnancy were randomly assigned to either metallic staples or subcuticular suture for skin closure after surgery. The study included 350 participants, with a follow-up period of 4 to 6 weeks postpartum. A wound complication that occurred after discharge from the hospital on postoperative day 4 was the primary outcome. When compared to suture, staples were related with more wound complications (14.5% vs 5.9%, p = 0.008). Wound problems that occurred after hospital discharge accounted for 58.3% of all wound complications. After multivariable correction, wound complication after discharge from the hospital was not linked with the kind of skin closure approach (OR: 1.29; 0.52–3.17). They concluded that there were no significant differences between skin closure types in the frequency of wound complications occurring after hospital discharge.
- Adeeb Khalifeh *et al*⁸¹ analyzed secondary findings from a randomised controlled trial in 2020 looking into patient preferences for caesarean skin closure method. This was a secondary analysis of a 746-person randomised controlled trial that looked at suture and staples for CS skin closure. The explanations for each patient's reported preferences were elicited. A total of 550 patients were polled prior to surgery and 627 individuals were surveyed subsequently. Suture is preferred over staples for future closure when the number of previous CS increases (p value 0.05). Suture was found to be better than staples for skin closure in women who had caesarean births, according to the study.
- Nayak G et al⁸²conducted a randomised controlled trial in 2020 at PGIMER, Chandigarh, to analyze wound complications in emergency caesarean sections using various skin closure procedures. The 300 patients who took part in the trial were divided into three groups. Skin closure was done with staples in group A (n=100), monocryl 3-0

subcuticular suture in group B (n=102), and mattress suture nylon 2-0 in group C (n=98). Infection, seroma, gaping, and the need for resuturing and antibiotic treatment were the key outcomes. Skin closure time, pain perception, patient satisfaction, and cost were secondary outcomes. They concluded that the composite wound complication rate was significantly higher with staples than with other skin closure techniques. Infection was the most common wound complication observed in the entire study group (86%) and was significantly higher with staples than sutures (p value ≤ 0.001). They concluded that the use of staples for caesarean section skin closure is associated with an increased risk of wound complications, prolonged hospital stay and postoperative visits.



METHODOLOGY

MATERIALS AND METHODS:

Study Setting: Study was conducted in the Department of Obstetrics and Gynecology, AIIMS Jodhpur.

Study design: Randomized controlled trial.

Study population: Women with viable pregnancies (≥ 26 weeks) undergoing caesarean delivery at AIIMS, Jodhpur

Study Period: The study was conducted over a period of 21 months from February 2020 to November 2021

Ethical approval: 01 January, 2020 (AIIMS/IEC/2019-20/951)

CTRI trial registration number - CTRI/2020/06/033480

Sample Size: 300 with 150 cases per group.

Group A – Skin closure in caesarean delivery using absorbable subcuticular suture (Monocryl 3-0, Figure 1)

Group B – Skin closure in caesarean delivery using surgical skin metallic stapler (Covidien Appose ULC Auto Suture Slim Body Skin Stapler 35W, Figure 2)



Figure 1: Monocryl 3-0 Suture



Figure 2: Covidien Appose ULC Auto Suture Slim Body Skin Stapler 35W

INCLUSION CRITERIA:

• Women with viable pregnancies (≥ 26 weeks) undergoing caesarean delivery at AIIMS, Jodhpur.

• All caesarean types - scheduled or unscheduled and primary or repeat caesareans with low transverse/pfannenstiel incision

EXCLUSION CRITERIA-

- Inability to obtain informed consent
- Immune compromising disease (e.g. AIDS)
- Chronic steroid use
- Contraindication to routine postpartum pain medications (ibuprofen, narcotics) e.g. CKD patient
- Chorioamnioinitis
- Caesarean section done by vertical incision.

All subjects fulfilling the above-mentioned criteria and willing to participate were approached for enrolment into the study. Patients were counselled and informed written consent was taken. Those who require caesarean section had detailed history and examination, including anthropometric examination recorded. The patient's baseline characteristics were assessed like anaemia, fever, and other antenatal investigations were performed as per the existing protocol and according to the individual case. They underwent usual perioperative management (surgical skin preparation with Povidone Iodine solution and prophylactic antibiotics). Once the consent for caesarean section was taken by the attending doctor, patients were randomized into two groups using sealed envelopes opened by the attending nurse who was not involved in the study. For randomization, computer generated random numbers in blocks of 10 were used. The numbers were written on small slips and placed in serially numbered opaque sealed envelopes. These envelopes were made by a person not involved in enrollment, treatment and follow up of study. According to the code written in the letter, Patient was allocated in group A or group B.

Group A- Skin closure in caesarean delivery using absorbable subcuticular suture (Monocryl 3-0)

Group B -Skin closure in caesarean delivery using surgical skin metallic stapler (Covidien Appose ULC Auto Suture Slim Body Skin Stapler 35W)

METHODOLOGY

Patients were assigned either of the group- absorbable subcuticular suture group or metallic surgical stapler group depending on the randomisation.

The surgical procedure was the same for both the groups until closure of the rectus sheath, which was conducted using Vicryl 1-0 suture. The subcutaneous layer was closed with 3-0 Vicryl for all women with a subcutaneous layer >2.0 cm (Figure 3). Women in the subcuticular suture group had absorbable sutures placed in one continuous closure with knots buried at the lateral edges of the wound (Figure 4). Those in the surgical staples group had the skin edges everted for stapler placement (Figure 5). The wound was then dressed with abdominal pad and occlusive dressing was applied immediately after the skin closure (Figure 6,7).



Figure 3: Appearance of incision after closing subcutaneous layer



Figure 4: Using Monocryl 3-0 suture for subcuticular suture technique

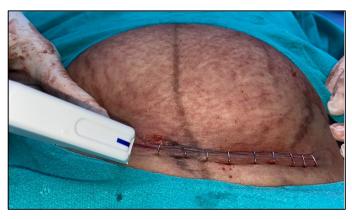


Figure 5: Application of Metallic surgical skin staples

The wound dressing was removed on postoperative day 3 and the wound was assessed and the pain score was calculated with the help of Visual Analog Scale (VAS) in all patients.

Subcuticular sutures were left in situ. Knots were trimmed. In the metallic surgical stapler group, the staples were removed on post-operative day 7. A standardized physical examination of the wound was performed by trained obstetric providers on 3 days post operatively and 6 weeks postoperatively for patients in both groups. For patients who were not able to return for their postpartum visit at 6 weeks, standardized telephonic phone assessment was done; any report of a wound complication was validated by medical record review.



Figure 6: Subcuticular suture on skin incision



Figure 7: Metallic surgical skin staples on skin incision

The primary outcome was a composite of wound disruption or infection occurring within 6 postoperative weeks. Wound disruption is defined as subcutaneous skin dehiscence (from any cause including seroma or hematoma) or fascial dehiscence.⁸³ Wound infection was defined as purulent drainage, cellulitis, abscess or wound requiring drainage, debridement, and antibiotics associated with a clinical diagnosis of infection.²²

The wound condition was assessed using the Southampton wound scoring system. (Bailey IS et al)^{84, 85} It categorises wound complications on a grade from 0 to V, 0 being normal healing and the latter being deep or severe wound infection.

Using this scale, the scores were assigned from 0 to 18 depending on the condition of the wound. Score of 0 being normal healing. Gradual increasing scores as the wound condition worsens varying from mild bruising erythema (score 1, I), erythema plus other signs of inflammation (score 5, II), clear or serosanguinous discharge (score 10,III), purulent discharge (score 15, IV) to deep or severe wound infection with or without tissue breakdown (score 18, V) (Figure 8-17). As per the scale, lesser score was assigned to the wound infection localised to one point and higher score if the infection was present all along the wound. The details of the Southampton wound scoring system are enclosed in the Appendix 1.



Figure 8: Normal healing of wound using staples on day 3 post operatively



Figure 9: Normal healing of wound using subcuticular sutures on day 3 post operatively



Figure 10: Mild bruising/ erythema of wound using suture (Grade 1)



Figure 11: Mild bruising/ erythema of wound using staples (Grade 1)



Figure 12: Erythema with other signs of inflammation using sutures (Grade 2)



Figure 13: Erythema with other signs of inflammation using staples (Grade 2)



Figure 14: Clear or serosanguinous discharge using suture (Grade 3)



Figure 15: Clear or serosanguinous discharge using staples (Grade 3)



Figure 16: Pus discharge from wound (Grade 4)



Figure 17: Deep or severe wound infection (Grade 5)

Key pre-specified secondary outcomes for our study included: skin closure time, Analog pain score by visual analog scale on 3 days postoperatively and on 6 weeks post operatively and patient satisfaction score on 6 weeks post operatively.

Skin closure time was measured in seconds by the nurse present during the caesarean section, using the stop watch. The time was measured from the time of first skin prick till tying of

knots in case of Group A and from the time of first staple application till last stapler was applied in case of Group B.

Pain score was measured using VAS score (Mackeen *et al*¹⁷, De Graaf *et ^{al18}*, Sharma *et al*⁷⁶). The visual analog scale (VAS) is a validated, subjective measure for acute and chronic pain. Scores were recorded by making a handwritten mark on a 10-cm line that represents a continuum between "no pain" and "worst pain".⁸⁶ The pain score was categorised as no pain (0), mild pain (1-3), moderate to severe pain (4-6), very severe pain (7-9) and worst pain (10). Patient was asked to indicate his/her perceived pain intensity (most commonly) along a 10 cm horizontal line, and this rating was then measured from the left edge. Routine analgesics (Diclofenac 50 mg TDS/ Paracetamol 500 mg TDS) was given to all patients for 3 days post operatively. The details of the scoring system are given in Appendix 2

Patient satisfaction score was measured by three parameters - general appearance, location of the scar and comfort of the scar (Figure 18,19). The rating was ranged from 1 to 5, with 1 being worst,2 as bad, 3 as good,4 being better, 5 being best, in all 3 parameters studied (Figueroa et al).²² The details of the scoring system are given in Appendix 3.



Figure 18: Wound appearance at 6 weeks post operatively using staples



Figure 19: Wound appearance at 6 weeks post operatively using sutures

We divided the patients into 2 sub groups – patients undergoing Primary LSCS and patients undergoing Repeat LSCS and did analysis in terms of wound complications rates on 3 days and 6 weeks post operatively, pain score at 3 days and 6 weeks post operatively, skin closure time and patient satisfaction rates on 6 weeks post operatively between 2 sub groups.

SAMPLE SIZE

- Considering the following assumption from the RCT by Figueroa *et al*²² wound morbidity rate between 2 groups as 7.1 % with staple and 0.5% with subcuticular suture p₁= 7.1 %, p₂=0.5 %, q₁=92.9%, q₂=99.5%
 P= p₁+p₂ 2
 Z (1-a/2) = 1.96 at a = 5%
 Z (1-B)= 0.842 at B = 20 %
 Power = 80%
 - Power = 80%n= 131 per group Total sample size = $131 \times 2 = 262$ Taking the attrition to be 10%Final sample size = 290 with 145 cases per group. We included 300 patients with 150 patients in each group

* Figueroa D, Jauk VC, Szychowski JM, Garner R, Biggio JR, Andrews WW, Hauth J, Tita AT. Surgical staples compared with subcuticular suture for skin closure after cesarean delivery: a randomized controlled trial. Obstetrics and Gynecology. 2013 Jan;121(1).

STATISTICAL ANALYSIS

The statistical analysis was carried out using IBM SPSS (Statistical Package for Social Sciences) statistical version 21. The analysis includes frequency table, bar, pie chart, association of variables based on Chi-square. All quantitative variables were estimated using measures of central location "mean" and measures of dispersion (standard deviation). For normally distributed data, mean were compared using independent t-test (for two groups). For not normality distributed data, Median were compared using Mann Whitney U test (for two groups).

Level of significance "p" is the probability signifies level of significance. The mentioned p in the text indicates the following:

p > 0.05	Not significant
p <0.05	Significant
p <0.01	Highly significant

ETHICAL CONSIDERATION

The following study was conducted after approval from the Institutional Ethics Committee. Informed consent was taken from the women being enrolled for the study by providing them a proper printed consent form along with patient information sheet and after properly explaining the purpose.



OBSERVATION AND RESULTS

During the study period, a total 433 patients were approached for enrollment. 133 patients didn't meet the inclusion criteria. Therefore 300 patients were randomized into 2 groups, which were assessed at 3 days post operatively. 10 patients underwent resuturing of the wound by mattress suture before 6 weeks and therefore, 290 patients were assessed on 6 weeks post operatively (Figure 20).

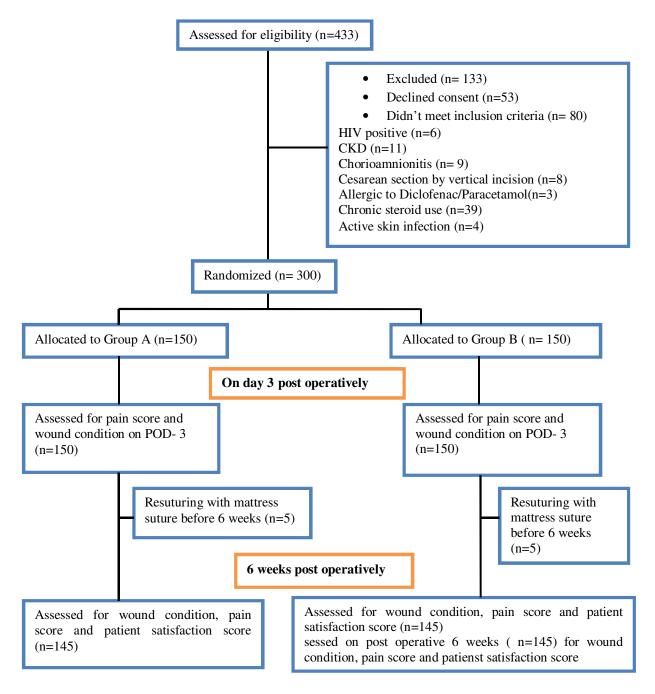


Figure 20: Consort Flow Chart

DEMOGRAPHIC VARIABLES

The demographic profile of patients in two different groups is depicted in Table 1.

Variable	Group A	Group B
Age (years)	26.99±4.27	26.87±4.14
BMI (kg/m ²)	24.21±3.59	24.45±4.10

Table 1: Demographic profile of patients in two groups

Data expressed as Mean ±SD

Used Student's T test,

p value < 0.05 is significant

<u>Age</u> – The patients included in the study were between 18-40 years age group. Mean age of patients in the study was 26.93 ± 4.14 years. Table 1 shows the distribution of patients according to age in the study population.

Figure 21 & 22 shows mean age of patients in group A (26.99±4.27 years) and group B (26.87±4.14 years). It is a bell-shaped curve. The subjects in two groups were comparable in terms of age (p value- 0.80).

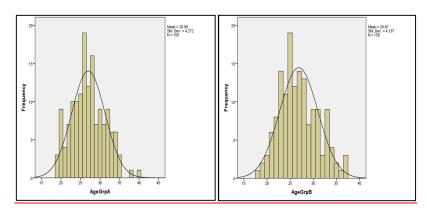


Figure 21: Histogram showing distribution of patients according to age

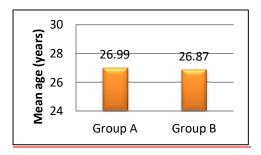


Figure 22: Distribution of age in two groups

- 2. <u>BMI (Body Mass Index)</u>: It was calculated with Quetelet Index according to the pre pregnancy weight.
 - $BMI = \underline{Pre pregnancy weight (kg)}$ Height (m²)

As is evident from the *Bell shaped curve* in Figure 23, BMI was normally distributed in the study population. Mean BMI was 24.9 ± 3.84 kg/m². Table 2 demonstrates the mean BMI of patients in group A (24.21 ± 3.59 kg/m²) and group B (24.45 ± 4.10 kg/m²). The two groups were comparable in terms of BMI (p value- 0.59).

 Table 2: Distribution of patients according to BMI in the study population

BMI (kg/m ²)	Group A	Group B
Divii (kg/iii)	n=150 (%)	n=150 (%)
Underweight*	5(3.33%)	10(6.66%)
Healthy*	88(58.66%)	79(52.66%)
Overweight*	45(30%)	47(31.33%)
Obese*	12(8%)	14(9.33%)

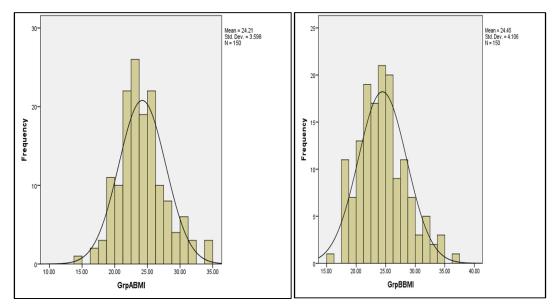


Figure 23: Histogram showing distribution of patients according to BMI in the study population

3. <u>Education:</u>

The majority of patients were graduates in both the groups - 30.33% in group A and 30% in group B. Table 3 and Figure 24 shows the distribution of the patients according to education in the study population.

Age group	Group A	Group B
	n=150 (%)	n=150(%)
Post graduate	38(25.33%)	27(18%)
Graduate	50(33.33%)	45(30%)
High Sec	22(14.67%)	25(16.67%)
Metric	25(16.67%)	36(24%)
Middle	1(0.67%)	(0%)
Primary	9(6%)	7(4.67%)
Illiterate	5(3.33%)	10(6.67%)

Table 3: Distribution of the patients according to education in the study population

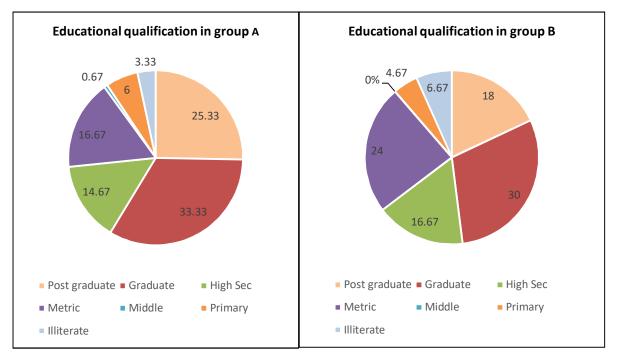


Figure 24: Distribution of the patients according to education in the study population

4. <u>Occupation</u>- Majority of the patients in both the groups was house wives - 84.67% in group A and 86% in group B.

Desk job included Bank Employee, Chartered Accountant, Advocate, Beautician and Handicraft workers. Field jobs included Anganwadi workers, Saleswomen and Daily wager. Table 4 and Figure 25 show the distribution of patients according to occupation in the study population.

	Group A	Group B
Occupation	n=150 (%)	n=150 (%)
Housewife	127(84.67%)	129(86%)
Desk job	5(3.33%)	12(8%)
Field work	4(2.67%)	5(3.33%)
Nurse	4(2.67%)	(0%)
Doctor	3(2%)	1(0.67%)
Student	2(1.33%)	3(2%)
Prof/Lecturer/Teacher	5(3.33%)	(0%)

Table 4: Distribution of the patients according to occupation in the study population

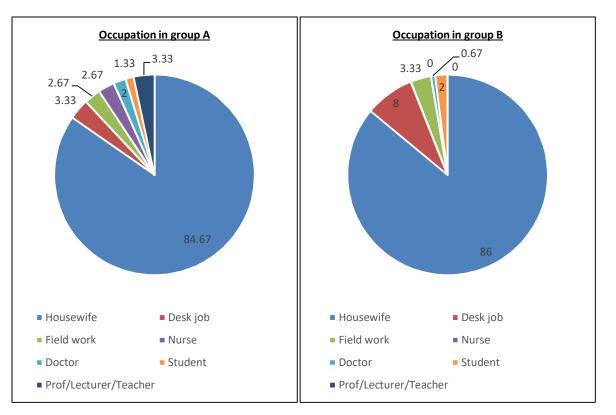


Figure 25: Distribution of the patients according to occupation in the study population

BASELINE CHARACTERISTICS

1. Period of gestation (POG) at delivery-

Mean POG at delivery in the study population was 38.39 ± 2.17 weeks. Both the groups were comparable in terms of POG at delivery (p value - 0.89). Table 5 and Figure 26 shows the mean POG at delivery for group A (38.5 ± 2.17 weeks) and group B (38.29 ± 2.17 weeks).

Table 5: Comparison of POG	at delivery between two groups
-----------------------------------	--------------------------------

POG (weeks)	Group A	Group B	p value
Mean*	38.5±2.17	38.29±2.17	0.89

Data expressed as Mean±SD

*Used Student's T test,

p value < 0.05 is significant

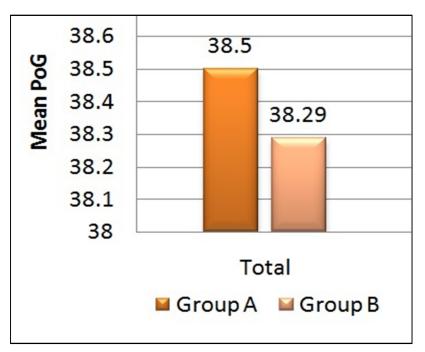


Figure 26: Comparison of POG at delivery between two groups

2. Indication of Lower Segment Caesarean section (LSCS)-

The most common indication for LSCS in the study population was previous LSCS not willing for Trial of Labour after Caesarean section (TOLAC). It accounted for 36% in group A and 30 % in group B. Table 6 elicits the indications for LSCS in our study population.

Indication Group A Group B				
	n=150 (%)	n=150 (%)		
Previous LSCS not willing for TOLAC	54 (36)	45 (30)		
Pathological CTG (fetal distress)	18 (12)	20 (13.33)		
Thick MSL	16 (10.66)	8 (5.33)		
Malpresentation	11 (7.33)	19 (12.66)		
CSMR	7 (4.66)	11 (7.33)		
CPD	6 (4)	3 (2)		
Failed induction	6 (4)	6 (4)		
Arrest of descent	4 (2.66)	9 (6)		
DTA	4 (2.66)	1 (0.66)		
Previous 2 LSCS	5 (3.33)	16 (10.66)		
АРН	5 (3.33)	2 (1.33)		
Acute fetal bradycardia	1 (0.66)	1 (0.66)		
Twin gestation	2 (1.33)	1 (0.66)		
Impending scar rupture	4 (2.66)	2 (1.33)		
Impending Eclampsia	4 (2.66)	1 (0.66)		
Short interconception period	1 (0.66)	4 (2.66)		
MCTA gestation	-	1 (0.66)		
Congenital septum obstruction	1 (0.66)	-		
CPT in previous pregnancy	1 (0.66)	-		

Table 6: Distribution of patients according to indication of LSCS

RISK FACTORS

There are several risk factors which complicate the normal wound healing. The risk factors analysed in the study were - Fever, anaemia, smoking, alcohol, PPROM, Diabetes Mellitus.

Anaemia was the most common risk factor in the study population. It accounted for 32% patients in group A and 42.66% patients in group B.

Table 7 shows the comparison of patients according to risk factors. Patients in both the groups were comparable in terms of their risk factors.

Risk factors	Group A	Group B	p value
	n=150(%)	n=150 (%)	
Anaemia	48 (32)	64 (42.66)	0.056
Fever	7 (4.66)	4 (2.66)	0.35
Alcohol	0	0	-
Smoking	1 (0.66)	0	0.31
PPROM	2 (1.33)	4 (2.66)	0.41
Diabetes Mellitus	25 (16.66)	24 (16)	0.87

Table 7: Comparison of patients according to risk factors

Used Chi Square test, p value <0.05 is significant

PRIMARY OUTCOME

1. Wound condition on day 3 post operatively-

It was analysed using Southampton wound grading system. It is divided into 5 categories ranging from normal wound healing to deep and severe wound infection depending on the condition of the wound.

Details of patients in each category of wound condition is given in the Table 8.

Table 8: Comparison of patients in both groups and wound category according to
wound condition on day 3 post operatively

Wound condition on day 3	Group A	Group B	p value
post operatively	n=150 (%)	n=150 (%)	
0.Normal healing	117 (78)	117 (78)	1.00
1.Mild bruising / erythema	23 (15.33)	12 (8)	0.047
2.Erythema + others signs of	1 (0.66)	1 (0.66)	1.00
inflammation			
3.Clear or serosanguinous	8 (5.33)	15 (10)	0.13
discharge			
4.Pus	1 (0.66)	4 (2.66)	0.17
5.Deep or severe wound	0	1 (0.66)	0.31
infection			

Used Chi square test, p value < 0.05 is significant

As described in Table 8, a significantly higher number of patients had mild bruising/ erythema in group A as compared to Group B on day 3 post operatively day 3 (p value – 0.047)

Only one patient in the study population had deep or severe wound infection. She was primigravida and underwent LSCS for thick MSL in early labour. Skin closure was done using staples. Post operatively, she had one fever spike on day 3 and was diagnosed with urinary tract infection. Pus discharge from stitch line was seen along with 3 cm of rectus sheath gaping. Wound culture reported negative. She was managed with antibiotics and resuturing of the wound was done on post-operative day 20. Patient was not anaemic, no h/o diabetes / PPROM/ smoking or alcohol consumption.

2. <u>Wound condition at 6 weeks post operatively</u>

It was analysed using Southampton wound grading system. Details of patients in each category of wound condition at 6 weeks post operatively is given in the Table 9.

Majority of the patients in the study (97.58%) had normal healing at 6 weeks post operatively. In group A, 98.62% patients and in group B, 96.55% patients had normal wound healing. Total 10 patients underwent resuturing before 6 weeks. Resuturing rate in study population was 3.33% (10/300). Fifty six patients (18.66%) with abnormal wound healing on day 3 post operatively, who didnot require wound resuturing, underwent a course of antibiotics and wound dressing till wound was in healthy condition.

 Table 9: Comparison of patients in both the groups according to wound condition at 6

 weeks post operatively

Wound condition on 6 weeks post	Group A	Group B	p value
operatively	N (%)	N (%)	
0.Normal healing	143 (98.62)	140 (96.55)	0.25
1.Mild bruising / erythema	1 (0.68)	3 (2.06)	0.31
2.Erythema + others signs of	0	1 (0.68)	0.31
inflammation			
3.Clear or serosanguinous discharge	1 (0.68)	1 (0.68)	1.00
4.Pus	0	0	-
5.Deep or severe wound infection	0	0	-
Total	145	145	-
• RESUTURING	5	5	-

Used Chi Square test, p value < 0.05 is significant

SECONDARY OUTCOMES

1. <u>Skin closure time</u>- The skin closure time was measured in seconds. Mean skin closure time in group A (459.32 ± 124.77 seconds) and group B (65.55 ± 30.26 seconds) is represented in Table 10. Median skin closure time in group A was 450 seconds (90-1082 seconds) and in group B was 60 seconds (19-200 seconds). It is a bell shaped curve depicted in Figure 27. Skin closure time with staples is significantly less as compared to subcuticular sutures. (p value <0.001)

 Skin closure time (in seconds)
 Group A
 Group B
 p value

 Mean*
 459.09±124.77
 65.55±30.26
 <0.001</td>

 Median**
 450 (90-1082)
 60 (19-200)
 <0.0001</td>

 Table 10: Comparison of both the groups for skin closure time

p value < 0.05 is significant,

*Used Student's T test,

**Used Mann Whitney test

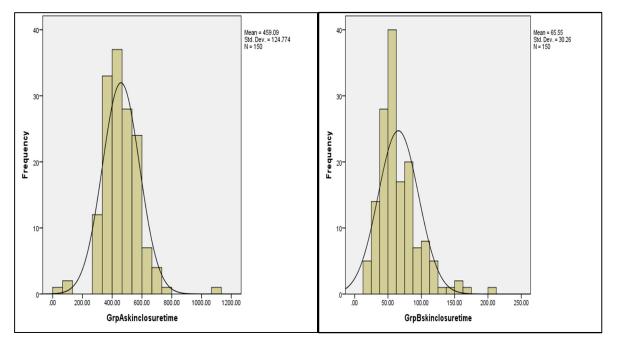


Figure 27: Histogram representing skin closure time in both the groups

2. Pain perception

A. On day 3 post operatively-

Pain score was assessed using VAS ranging from 0-10. The number of patients in each pain category are as shown in the Table 11 and Figure 28.

A significantly lower number of patients had mild pain in group A as compared to group B (0.034) but a significantly higher number of patients had moderate pain in group A as compared to group B (p value 0.0078).

operatively				
Pain score on day 3 post operatively	Group A n=150 (%)	Group B n=150 (%)	p value	
No pain*	7 (4.66)	10 (6.66)	0.45	
Mild pain*	51 (34)	69 (46)	0.034	
Moderate to severe*	82 (54.66)	59 (39.33)	0.0078	
Very severe *	10 (6.66)	12 (8)	0.66	
Worst possible pain*	0 (0)	0 (0)	-	

*Used Chi Square test,

p value < 0.05 is significant

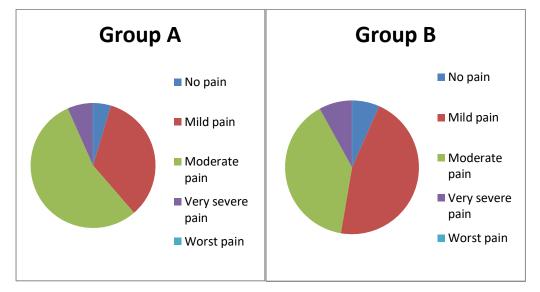


Figure 28: Comparison of patients in each group according to pain score on day 3 post operatively

As seen in the table 11, mean pain score on day 3 post operatively in group A is 3.78±1.94 vs 3.39±2.02 in group B. P value was 0.08 indicating pain score was comparable in both the groups.

B. At 6 weeks post operatively -

The number of patients in each pain score category are as shown in the Table 12 below. In group A, 78.62% of patients had no pain as compared to 79.31% of patients in group B but the difference was not significant. None of the patient experienced worst pain at 6 weeks post operatively.

Table 12 and Figure 29 shows the distribution of patients into pain score categories at 6 weeks post operatively

operatively			
Pain score at 6 weeks post	Group A	Group B	p value
operatively	n=145 (%)	n=145 (%)	
No pain *	114 (78.62)	115 (79.31)	0.88
Mild pain*	28 (19.31)	30 (20.68)	0.77
Moderate to severe*	2 (1.37)	0	0.15
Very severe*	1 (0.68)	0	0.31
Worst possible pain*	0	0	-

 Table 12: Distribution of patients according to pain scores at 6 weeks post

*Used Chi Square test,

p value <0.05 significant,

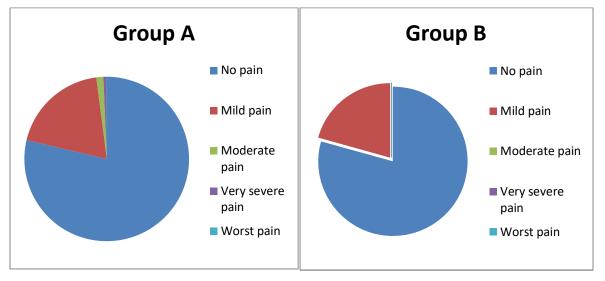


Figure 29: Distribution of patients according to pain scores at 6 weeks post operatively

Mean pain score at 6 weeks post operatively in group A was 0.31 ± 0.84 and was 0.25 ± 0.52 in group B. The pain score was comparable in both the groups (p value 0.45).

3. <u>Patient satisfaction score</u>

A. <u>Appearance of wound</u> – Patient satisfaction score in terms of appearance was assessed at 6 weeks post operatively. The score ranged from 1 to 5.

Ninety eight patients (67.58 %) in group A versus ninety two patients (63.44%) in group B assigned the best score for the appearance of the wound. The mean score for scar appearance was 4.54±0.79 in group A vs 4.41±0.92 in group B (p value 0.22) as shown in Table 13.

Appearance of scar	Group A, n=145(%)	Group B, n=145(%)	p value
Worst*	1 (0.68)	1 (0.68)	1.00
Bad *	4 (2.75)	8 (5.51)	0.24
Good*	9 (6.20)	13 (8.96)	0.37
Better*	33 (22.75)	31 (21.37)	0.77
Best *	98 (67.58)	92 (63.44)	0.46

Table 13: Distribution of patients according to appearance of scar in both the groups

*Used Chi Square test

p value<0.05 is significant

Reasons for assigning lower score in Group A was the blackening/whitening of the stitch line over a period of time and appearance of raised area over the stitch line. Reason for assigning lower score in Group B was that the points of staple pin sites were visible.

B. <u>Comfort of the scar-</u>

Patient satisfaction score in terms of comfort was assessed at 6 weeks post operatively, ranging from 1 to 5 (worst to best).

Majority of the patients in the study were comfortable with the scar. One hundred and eleven patients (76.55 %) in group A vs ninety nine patients (68.27 %) in group B assigned a score of 5 (best). The mean score for scar comfort is 4.7 ± 0.6 in group A and 4.62 ± 0.61 in group B. Both the groups were comparable in terms of patient satisfaction rate according to comfort of scar (p value 0.29). Distribution of patients in each group is described in Table 14 below.

Reason for low score in group A was appearance of raised area over the stitch line and itching associated with the wound. Reason for low score in group B was requirement of removal of staplers on day 7 and the itching associated with the wound.

Comfort of scar	Group A n=145(%)	Group B n=145(%)	p value
Worst *	0	0	-
Bad *	1 (0.68)	1 (0.68)	1.00
Good*	8 (5.51)	7 (4.82)	0.79
Better *	25 (17.24)	38 (26.2)	0.06
Best *	111 (76.55)	99 (68.27)	0.11

Table 14: Distribution of patients according to comfort of scar in both the groups

*Used Chi Square test

p value <0.05 significant

C. <u>Location of the scar</u>- The location of the scar was same in all the patients i.e. pfannenstiel incision in the lower abdomen. So, the patient satisfaction score for location of the scar was same in all the patients.

<u>SUBGROUP ANALYSIS</u> – We did subgroup analysis comparing both the groups in patients undergoing primary LSCS (n=149) and in patients undergoing repeat LSCS (n=151). The distribution of patients in the sub groups is as given in table 15

Sub group	Group A, n	Group B, n	Total
Primary LSCS	75	74	149
Repeat LSCS	75	76	151
Total	150	150	300

 Table 15: Distribution of patients in sub groups

1. Period of gestation (POG) at delivery

Table 16 and Figure 30 shows the comparison of mean POG at delivery between two groups and subgroups.

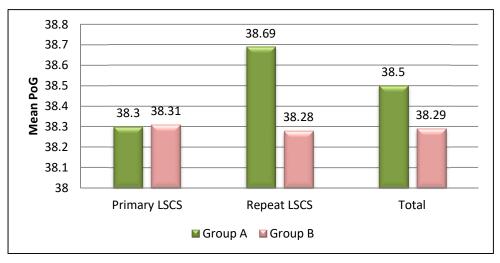
 Table 16: Comparison of POG at delivery between two groups and subgroups

POG (weeks)	Group A	Group B	p value
Primary LSCS	38.3±2.65	38.31±2.42	0.97
Repeat LSCS	38.69±1.54	38.28±1.91	0.88
Total	38.5±2.17	38.29±2.17	0.90

Data expressed as Mean±SD

Used Student's T test

p value < 0.05 is significant





2. Wound condition on day 3 post operatively

Wound condition on day 3	Group A, n(%)	Group B n(%)	p value
Normal healing	117 (78)	117 (78)	1.00
Primary LSCS	50 (66.66)	47 (63.51)	0.68
Repeat LSCS	67 (89.33)	70 (92.10)	0.55
Abnormal healing	33 (22)	33 (22)	1.00
Primary LSCS	25 (33.3)	27 (36.4)	0.7
Repeat LSCS	8 (10.67)	6 (7.9)	0.79

Table 17: Wound condition on day 3 post operatively in two groups and sub groups

A. For the patients undergoing primary LSCS- Majority of the patients (66.66 % in group A vs 63.51% in group B) had normal healing (p value 0.68). Abnormal wound healing in group A was seen in 33% patients while it was 36.48% in group B (p value - 0.7).

B. For patients undergoing repeat LSCS - Majority of the patients (89.33 % in group A vs 92.10% in group B) had normal healing (p value- 0.55). Abnormal wound healing in group A was seen in 10.67% patients while it was 7.89% in group B (p value 0.79).

3. Wound condition at 6 weeks post operatively

Wound condition at 6 weeks	Group A	Group B	p value
post operatively			
Normal healing	143 (98.62)	140 (96.55)	0.25
Primary LSCS	70 (93.33)	66 (89.18)	0.64
Repeat LSCS	73 (97.33)	74 (97.36)	0.90
Abnormal healing	2 (1.37)	5 (3.44)	0.39
Primary LSCS	1 (0.68)	3 (2.06)	0.31
Repeat LSCS	1 (0.68)	2 (1.37)	0.56
Resuturing	5 (3.33)	5 (3.33)	1.00
Primary LSCS	4 (5.33)	5 (6.75)	0.71
Repeat LSCS	1 (0.66)	0	0.31

Table 18: Wound condition at 6 weeks operatively in both groups and sub groups

A. In patients undergoing primary LSCS, majority of the patients (93.33 % in group A vs 89.18% in group B) had normal healing (p value 0.64). Abnormal wound healing was observed in 2.74% patients, with 0.68% patients in group A and 2.06 % patients in group B (p value 0.31).

Total nine patients (6%) underwent resuturing in which 5.33% patients were in group A (subcuticular suture) and 6.75% patients were in group B (staples).

B. In patients undergoing repeat LSCS, majority of the patients (97.33 % in group A vs 97.36% in group B) had normal healing (p value – 0.90). Abnormal wound healing was observed in 3 patients (1.98% patients), with 1.33 % patients in group A and 2.63 % patients in group B (p value 0.56)

Only one patient (0.66%) underwent resuturing, who had skin closure by subcuticular suture. No patient from group B (staples) underwent resuturing.

4. <u>Skin closure time</u>

In patients undergoing primary caesarean section, mean skin closure time is significantly higher in group A vs Group B (p value <0.001). Similarly in patients undergoing repeat LSCS, mean skin closure time is significantly higher in group A vs Group B (p value <0.001).

Table 19 and Figure 31 shows comparison of both the groups and sub groups for skin closure time

Skin closure time (seconds)	Group A	Group B	p value
Primary LSCS	436.45±117.79	65.8±33.46	<0.001
Repeat LSCS	485.73±119.12	64.23±28.69	<0.001
Total	459.09±124.7	65.13±31.69	<0.001

Table 19: Comparison of both the groups and sub groups for skin closure time

Data expressed as Mean±SD

Used Student's t test,

p value < 0.05 is significant

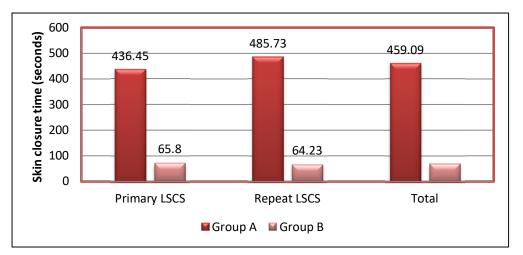


Figure 31: Graph representing skin closure time in both groups

5. Pain score

Pain score	Crown A	Crown P	n valua
ram score	Group A	Group B	p value
On day 3 post operatively	3.78±1.94	3.39±2.02	0.08
Primary LSCS	3.99±1.99	3.66±2.27	0.35
Repeat LSCS	3.57±1.88	3.12±1.72	0.12
At 6 weeks post operatively	0.31±0.84	0.25±0.52	0.45
Primary LSCS	0.46±1.04	0.26±0.53	0.14
Repeat LSCS	0.16±0.55	0.24±0.51	0.39

Table 20: Pain score in different groups and sub groups

Data expressed as Mean±SD

Used Student's T test,

p value <0.05- significant

Pain score was comparable in both the subgroups (Primary LSCS and Repeat LSCS) on day 3 post operatively and 6 weeks post operatively. The details of the same are depicted in the Table 20.

6. <u>Patient satisfaction score</u> – It was calculated at 6 weeks, ranging from 1 (worst) to 5 (best) on the basis of appearance of scar and the comfort of scar. Both the groups were comparable in terms of patient satisfaction score (p value – 0.25). Scar appearance and scar comfort was comparable in both the sub groups (primary LSCS and repeat LSCS) at 6 weeks post operatively. The details of the patients satisfaction score in both groups and sub groups is shown in table 21 below.

Figure 32 depicts the graph presenting mean score for appearance of scar in both the groups and sub groups. Figure 33 represents the mean score for comfort of scar in both the groups and sub group.

Patient satisfaction score	Group A	Group B	p value
Appearance	4.54±0.79	4.41±0.92	0.22
Primary LSCS	4.34±0.92	4.22±0.97	0.45
Repeat LSCS	4.73±0.58	4.59±0.84	0.24
Comfort	4.7±0.6	4.62±0.61	0.29
Primary LSCS	4.58±0.62	4.51±0.66	0.98
Repeat LSCS	4.81±0.57	4.72±0.56	0.32
Patient satisfaction score	4.62±0.69	4.51±0.76	0.25

Table 21: Patient satisfaction score in different groups and sub groups

Data expressed as Mean±SD Used Student's T test,

p value<0.05 is significant

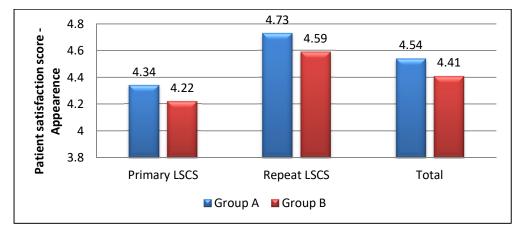


Figure 32: Graph showing mean appearance of scar score in both groups and subgroups

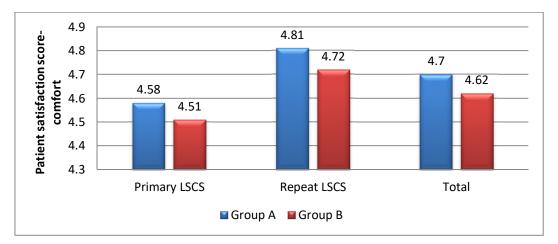


Figure 33: Graph showing mean comfort of scar score in both groups and subgroups

Table 22 summarizes the primary and secondary outcome of the study in both the groups.

Parameter	Group A	Group B	p value
Wound condition on day 3 post operatively			
Normal healing*	117 (78)	117 (78)	1.00
Abnormal healing*	33 (22)	33 (22)	1.00
Wound condition at 6 weeks post operatively			
Normal healing*	143 (98.62)	140 (96.55)	0.25
Abnormal healing*	2 (1.37)	5 (3.44)	0.39
Resuturing*	5 (3.33)	5 (3.33)	1.00
Skin closure time**	459.09±124.7	65.13±31.69	<0.001
Pain score			
Day 3 post operatively**	3.78±1.94	3.39±2.02	0.08
6 weeks post operatively**	0.31±0.84	0.25±0.52	0.45
Patient Satisfaction score		_	
Appearance**	4.54±0.79	4.41±0.92	0.22
Comfort**	4.7±0.6	4.62±0.61	0.29
Location	-	-	-

Table 22: Summarizing the outcomes of the study

*Data expressed as N(%)

**Data expressed as Mean±SD

p value<0.05 is significant



DISCUSSION

Caesarean section is the most commonly performed surgery. Approximately 15% of pregnant women worldwide deliver by caesarean section. ¹ The current caesarean section rates in India are about 32.6 %. Caesarean section is usually done by an incision in the lower abdomen. Variety of sutures and surgical techniques are available for closing the caesarean section incision. Despite the sophistication of incision closure techniques, wound complications are seen in upto 15% of the wounds. These complications lead to increase in duration of hospital stay, further treatment and investigations, readmission, increased time away from work and subsequently increasing the cost of health care.²⁵ Thus, wound infection poses a significant burden to the patient and financial resources of the healthcare system.^{29,47} They further hamper mother and infant bonding time leading to increased frustration for the new mother and care of newborn is also suffered.

Various skin closure methods have been described in the literature so as to improve the patient satisfaction rates, to decrease the pain and to minimize the wound complications among the patients undergoing caesarean section.^{13,14}

Most of the studies done in the past have compared different types of sutures with each other. Literature compares various absorbable sutures with each other, and absorbable sutures with non absorbable sutures. ^{32,33,34,35,36,37,38,39,40} Some studies done in past have compared the subcuticular sutures with the staples, but they vielded contradictory findings.^{22,28,51,58,76,77,78,79,80,82} Common outcomes studied were post-operative pain, skin closure time, total procedure time, cost of the skin closure technique, wound complications, patient satisfaction rates and cosmetic appearance of the wound. Current knowledge supports that metallic skin staples is less time consuming, while suture has superior wound outcomes.

We did a randomized controlled trial comparing the wound complication rates between surgical skin metallic staples and the subcuticular sutures for skin closure in caesarean section. We also compared other parameters including skin closure time, post-operative pain and patient satisfaction rate between the two techniques used for skin closure.

The baseline characteristics were comparable to most of the previously conducted studies.

The demographic profile of the patients including age and body mass index (BMI) in the present study were compared to the previous studies. The reported age in various studies was ranging from 20-34 years (Table 23). The mean age of patients included in our study is comparable to that in the previous studies.

Age (in years)	Subcuticular suture (in years)	Staples (in years)
Basha <i>et al</i> (2010) ⁵⁵	28.9±6.1	29.0±5.7
Figueroa <i>et al</i> $(2013)^{22}$	26.9±5.9	26.7±6.1
Sharma <i>et al</i> (2014) ⁷⁶ *	26 (20-42)	26 (19–36)
Ikeako <i>et al</i> (2016) ⁷⁷	30.0±5.54	29.9±3.97
Tierney <i>et al</i> $(2017)^{58}$	31.6±5.7	31.2±5.7
Hanan el kadri <i>et al</i> $(2018)^{79}$	32.44±5.09	32.37±5.45
Nayak et al (2020) ⁸²	26.5±3.8	27.0±4.3
Present study	26.99±4.27	26.87±4.14

Table 23: Age distribution in various studies

Data expressed as Mean±SD

*Data expressed as Median (Interquartile range)

The reported BMI in various studies is given in Table 24. Mean BMI in our study population was 24.9 ± 3.84 kg/m². Even though the BMI of the studied population was in the overweight category (Asian criteria based BMI), it was less as compared to other studies. Ethinicity, sedentary lifestyle and obesity could be the reason for higher BMI in other studies.

BMI (in kg/m ²)	Subcuticular suture	Staples
Basha <i>et al</i> $(2010)^{55}$	29.0±7.3	28.6±7.6
Figueroa <i>et al</i> $(2013)^{22}$	35.9±8.5	36.7±8.1
Huppelschoten <i>et al</i> (2013) ²⁸ *	29.4 (21.6–44.9)	29.8 (17.1–44.9)
Abdus-Salam <i>et al</i> $(2014)^{75}$	28.25±5.13	27.04±4.84
Sharma <i>et al</i> (2014) ⁷⁶	26.1 ± 0.8	25.7 ± 0.9
Present study	24.21±3.59	24.45±-4.106

 Table 24: BMI distribution in various studies

Data expressed as Mean ± SD

*Expressed as Median (Interquartile range)

The mean Period of gestation (POG) at delivery in the study population was comparable to the previous studies as shown in Table 25.

POG at delivery (in weeks)	Subcuticular suture	Staples
Basha <i>et al</i> (2010) ⁵⁵	38.4±2.7	38.1±2.9
Sharma <i>et al</i> $(2014)^{76}$	38.4±0.6	38.4±0.4
Abdus-Salam <i>et al</i> $(2014)^{75}$	38.33±2.07	38.39±2.04
Tierney <i>et al</i> $(2017)^{58}$	38.1±3.2	38.1±3.6
Nayak <i>et al</i> (2020) ⁸²	36.2±2.5	36.3±2.7
Present study	38.5±2.17	38.29±2.17

 Table 25: POG at delivery in various studies

Data expressed as Mean \pm SD

In the present study we have taken into account the risk factors for wound complications namely Diabetes Mellitus, anaemia, PPROM, fever, smoking and alcohol consumption. Most of the previous studies have analysed only diabetes as a risk factor for wound complications. The incidence of Diabetes Mellitus in our study was comparable to the previous studies as shown in table 26.

Table 26: Incidence of Diabetes Mellitus in various studies

Diabetes Mellitus	Subcuticular suture -n(%)	Staples -n(%)	p value
Basha <i>et al</i> (2010) ⁵⁵ *	33 (15)	35 (16)	0.74
Figueroa <i>et al</i> $(2013)^{22}$	18%	19%	0.841
Abdus-Salam <i>et al</i> $(2014)^{75}$ *	12 (8.0)	19(12.7)	0.184
Tierney <i>et al</i> (2017) ⁵⁸ *	120 (19.3)	127 (13.2)	0.68
Nayak <i>et al</i> (2020) ⁸² *	7(6.86)	4 (4)	0.57
Present study *	25 (16.66)	24 (16)	0.87

*Data expressed as N (%)

Wound complications following caesarean section was studied in various studies. Different studies assessed different components of wound complications such as seroma formation, hematoma formation, infection, wound disruption varying from few centimetres of gaping to complete wound dehiscence. The wound complications were assessed post operatively on day 1, day 2, day 3, day 7, at 6 weeks and upto 6 months post operatively varying from study to study.

Composite wound morbidity in our study was 22% in each group on 3rd day post operatively (Table 27). The results were comparable to study by Nayak *et al.*⁸² However, these composite wound morbidity rates were higher in our study as compared to most of the previous studies (Figueroa *et al*²², Clay *et al*⁷³, Al kadri *et al*⁷⁹ and Cooper *et al*⁸⁰). The attributed reason for this could be the use of Southampton wound grading system for calculating the wound morbidity in our patients as it included bruising, erythema, serosanguinous discharge, pus discharge and deep infection as part of composite wound morbidity whereas most of the studies considered infection and wound disruption rates only to analyse composite wound morbidity rates. Another reason for higher wound infection in our study could be anaemia and poor nutritional status of our patients. Anaemia as a risk factor for wound complications was not studied in most of the studies previously.

Composite wound morbidity	Subcuticular	Staples	p value
on day 3 post operatively	suture		
Figueroa <i>et al</i> $(2019)^{22}$	1 (0.5%)	14 (7.1%)	0.07
Basha <i>et al</i> (2010) ⁵⁵	20 (9%)	43 (22%)	<0.001
Clay <i>et al</i> $(2011)^{73}$	28 (5.74%)	50 (12.9%)	0.0032
Hana el kadri <i>et al</i> (2018) ⁷⁹	26 (2.6%)	12 (0.08%)	0.02
Cooper et al $(2019)^{80}$	5.9 %	14.5%	0.008
Nayak <i>et al</i> (2020) ⁸²	30 (30%)	12 (11.76%)	0.02
Present study	33 (22%)	33 (22%)	1.00

Table 27: Composite wound morbidity on day 3 post operatively in various studies

Data expressed as N (%)

Abnormal wound healing at 6 weeks post operatively was evaluated in our study. In the study by Basha *et al*⁵⁵, Hanan-el-kadri *et al*⁷⁹, Tiereney *et al*⁵⁸, Fitzwater *et al*⁷⁸, Ikeako *et al*⁷⁷, the patients with subcuticular suture had significantly lesser composite wound infection rates as compared to the patients with staples. These results were comparable with our study in which patients with subcuticular suture had lower composite wound infection rates; however the difference was not statistically significant in our study as depicted in Table 28. These results were contradictory to the study by Abdus-Salam *et al*⁷⁵, Fitzwater *et al*⁷⁸.

The reason for low composite wound infection in our study can be attributed to the fact that most of the patients were discharged on day 4/5 post operatively and the wound infections were picked up at the earliest and appropriate management was started in the hospital itself. Another reason for less wound morbidity can be low BMI in our population compared to others.

Composite wound morbidity at 6	Subcuticular	Staples	p value
weeks post operatively	suture		
Basha et al (2010) ⁵⁵ *	20 (9%)	43 (22%)	< 0.001
Figueroa et al $(2013)^{22}$ *	10 (5.9 %)	26 (14.5%)	0.40
Huppelschoten <i>et al</i> $(2013)^{28}$ *	35 (24.1%)	35 (24.1%)	-
Abdus-Salam <i>et al</i> $(2014)^{75}$	No	Yes	>0.05
Ikeako <i>et al</i> (2016) ⁷⁷ *	4 (3.8%)	13 (11.9%)	0.041
Fitzwater <i>et al</i> (non diabetic) 2016^{78}	3.6%	16.7%	<0.001
Fitzwater <i>et al</i> 2016(diabetic) ⁷⁸	15.6%	5.7%	0.25
Tierney et al (2017) ⁵⁸ *	28(4.5%)	97 (10.1%)	< 0.0001
Hanan-el-kadri et al(2018) ⁷⁹	Half of staples	<i>Twice</i> of subcuticular	0.02
Cooper <i>et al</i> $(2019)^{80}$ *	5.3%	6.7%	0.57
Nayak <i>et al</i> (2020) ⁸² *	12 (11.76%)	30 (30%)	0.04
Present study*	2 (1.37%)	3 (2.06%)	0.65

Table 28: Composite wound morbidity at 6 weeks post operatively in various studies

*Data expressed as N (%)

Wound dehiscence requiring resuturing was analysed in some studies. In the study by Basha *et al*⁵⁵, Clay *et al*⁷³, Ikeako *et al*⁷⁷, Tiereney *et al*⁵⁸ and Nayak *et al*⁸², patients having skin closure with staples had higher rates of resuturing. These results were contradictory to the analysis by Hana-el-kadri *et al*⁷⁹ who concluded that patients with staples had lower incidence of wound separation as compared to the subcuticular suture group. However in our study, the wound separation rates were same in both the groups, irrespective of the skin closure method used as described in Table 29. The wound separation rates were also less in our study as compared to other studies. This can be attributed to meticulous aseptic techniques used and use of antimicrobials pre and post operatively.

Resuturing	Subcuticular suture	Staples	p value
Basha et al (2010) 55	0	3 (9.09%)	-
Clay <i>et al</i> (2011) ⁷³	11 (2.25%)	38 (9.87%)	<0.001
Ikeako <i>et al</i> (2016) ⁷⁷	4 (3.8%)	13 (11.9%)	0.021
Tierney <i>et al</i> (2017) 58	27 (4.2%)	96 (9.8%)	<0.0001
Hanan el kadri <i>et al</i> (2018) ⁷⁹	2 (0.02%)	0	-
Nayak <i>et al</i> (2020) ⁸²	1 (0.98%)	3 (3%)	0.07
Present study	5 (3.33%)	5 (3.33%)	1.00

Table 29: Wound resuturing rates in various studies

Data expressed as N (%)

Skin closure time between the subcuticular suture group and staples was compared during LSCS using a stop watch and the time was noted in seconds. Skin closure time was significantly less with staples as compared to subcuticular sutures in our study. The findings were comparable to the previously conducted studies (Table 30). All studies have shown that staples take significantly less time for skin closure as compared to subcuticular sutures.

Table 30: Skin closure time in various studies

Skin closure time	Subcuticular suture	Staples	P value
Huppelschoten <i>et al</i> (2013) ²⁸ **	5.00 (2.00-12.00) min	1.0 (0.25-5.00) min	<0.01
Hanan-el-kadri <i>et al</i> (2018) ⁷⁹ *	8.91±3.93 (min)	1.89±1.51 (min)	< 0.001
Abdus-Salam <i>et al</i> (2014) ⁷⁵ *	388.70±170.40 (sec)	118.62±69.68 (sec)	<0.01
Nayak <i>et al</i> (2020) ⁸² *	5.68 ±0.70 (min)	0.68±0.30(min)	< 0.001
Present study*	459.09±124.77 (sec)	65.55±30.26 (sec)	< 0.001

*Data expressed as Mean ± SD

**Expressed as Median (Interquartile range)

Pain score between the suture group and staples was compared on day 3 post operatively in some of the studies. Different studies used different pain score scales for assessing pain score. Figueroa *et al* ²² and Ikeako *et al* ⁷⁷ used VAS scale, Abdus-Salam *et al*⁷⁵ used Box Numeric Pain Scale and Huppelschoten *et al* ²⁸ used Numeric Rating Scale. We used VAS scale. In the studies by Figueroa *et al* ²², Abdus-Salam *et al* ⁷⁵ and Huppelschoten *et al* ²⁸, pain score in both the groups was comparable on day 3 post operatively. Our study was comparable to the findings of these studies where pain score in both the groups was not significantly different, although patients with staples had less pain score than patients with subcuticular suture as illustrated in Table 31. In contrast, the study by Ikeako *et al*⁷⁷ has shown that patients with staples experienced more pain as compared to patients with subcuticular suture. The reason for higher pain score with staples was described by them as allergic or inflammatory reactions occasioned by the delayed removal of the staples on day 6 (versus day 3/4 in other studies).

Pain score at 3 days	Subcuticular suture	Staples	p value
Figueroa <i>et al</i> (2013) ²² **	5 (4-7)	5 (3-7)	0.285
Huppelschoten et al (2013) ²⁸ **	1.0(0.0-8.0)	1.0(0.0-6.0)	0.62
Abdus-Salam et al (2014) ⁷⁵ *	2.74 ±2.24	2.83 ±2.27	0.855
Ikeako <i>et al</i> (2016) ⁷⁷ *	0.2 ±0.51	0.6±0.76	0.001
Present study*	3.78±1.94	3.39±2.02	0.08

Table 31: Pain score on day 3 post operatively in various studies

*Data expressed as Mean ± SD

** Data expressed as Median (Interquartile range)

Pain scores between the subcuticular suture group and staples was compared at 6 weeks post operatively in some of the studies. When two groups were compared in terms of pain score, the difference was not statistically significant as show in Table 32.

Pain at 6 weeks post operatively	Subcuticular suture	Staples	p value
Figueroa <i>et al</i> (2013) ²² **	0 (0-2)	0 (0-1)	0.066
Sharma <i>et al</i> (2014) ⁷⁶ **	2 (2-4)	2 (1-4)	0.149
Abdus-Salam <i>et al</i> (2014) ⁷⁵ *	0.28 ± 0.74	0.26±0.67	0.885
Hanan-el-kadri et al (2018) ⁷⁹ *	4.53±1.06	4.49 ±1.10	0.87
Present study*	0.31±0.84	0.25±0.52	0.45

 Table 32: Pain score at 6 weeks post operatively in various studies

*Data expressed as Mean ± SD

** Data expressed as Median (Interquartile range)

Patient satisfaction score according to appearance of scar was analysed in handful of studies. Different scales were used to look for appearance of scar. These included NRS (Numeric Rating Scale), OSAS (Observer Scar Assessment Scale), POSAS (Patient and Observer Scar Assessment Scale), POSAS (Patient and Observer Scar Assessment Scale), PSAS (Patient Scar Assessment Scale). In our study, patients were satisfied both with staples and subcuticular sutures for the appearance of scar. The differences were not statistically significant. These results were comparable to the previous studies (Table 33).

Appearance of scar	Subcuticular suture	Staples	p value
Figueroa <i>et al</i> (2013) ²² **	4 (4-5)	4 (4-5)	0.842
Huppelschoten <i>et al</i> (2013) ²⁸ **	8.0 (2.0-10.0)	7.0 (2.0-10.0)	0.48
Abdus-Salam <i>et al</i> (2014) ⁷⁵ *	9.04±1.63	9.23±1.63	0.555
Hanan-el-kadri et al (2018) ⁷⁹ *	4.61 ±1.08	4.51±1.18	0.41
Present study *	4.54±0.79	4.41±0.92	0.22

Table 33: Patient satisfaction score (appearance of scar) in various studies

*Data expressed as Mean ± SD

** Data expressed as Median (Interquartile range)

There were few studies analyzing the patient satisfaction score according to the comfort of scar. In our study, there was no difference in the patient satisfaction rates according to the comfort of scar in both the groups. These findings were comparable to the previous studies as represented in Table 34.

Comfort of scar	Subcuticular suture	Staples	p value
Figueroa et al (2013) ²² **	4(4-5)	4 (4-5)	0.894
Hanan-el-kadri et al (2018) ⁷⁹ *	4.61±0.88	4.72±0.76	0.13
Present study*	4.7±0.6	4.62±0.61	0.29

Table 34: Patient satisfaction score (comfort of scar) in various studies

*Data expressed as Mean ± SD

**Expressed as median (Interquartile range)

So in our study, subcuticular sutures and staples were equivalent to each other for the skin closure method in caesarean section. Although staples take significantly less time for skin closure as compared to sutures, yet composite wound morbidity rates, pain score and patient satisfaction scores were comparable in both the groups.



STRENGTH AND LIMITATIONS

Strength of study- It was a randomized controlled trial, and one of the few studies done in western India. Total 300 patients were randomized in the study. No previous study has analyzed the outcomes depending on primary LSCS or repeat LSCS. We looked at risk factors for wound complications which were not included in most of the previous studies. The patients were followed till the entire post partum period. None of the patient was lost to follow up from the study population.

The limitation of the study was that the patient satisfaction score was based as per patient perception and was a subjective finding. Due to COVID 19 pandemic and restrictions imposed by the Government, patients were not able to return at 6 weeks for evaluation and objective scoring couldnot be done.

Longer follow up may be required regarding patient satisfaction scores as the appearance of scar and the comfort of scar changes over time. This can form a baseline for patient preference for skin closure method in next Caesarean section.

The higher rates of wound morbidity on day 3 post operatively in our study can be attributed to the use of Southampton wound grading score for calculating the wound morbidity as we included bruising, erythema, serosanguinous discharge, pus discharge and deep infection as part of composite wound morbidity whereas most of the studies described wound infection and wound disruption rates to calculate composite wound morbidity rates in their studies.

The lower rate of wound morbidity at 6 weeks post operatively in our study can be attributed to the fact that the study was done in a tertiary care centre with all the facilities for prevention of wound infections. These facilities may not be available at peripheral hospital; hence the findings of the study cannot be implemented for the entire population. Another reason for lesser wound morbidity can be low BMI in our population compared to others.

Other options of skin closure methods like Vacuum dressing can be compared with the sutures and staples in further studies.



SUMMARY & CONCLUSION

- This was a randomized controlled trial of two different methods of skin closuresubcuticular sutures versus staples conducted in the department of Obstetrics and Gynaecology at AIIMS, Jodhpur from February 2020 to November 2021.
- Total 300 patients were randomized into two groups- 150 patients had skin closure with subcuticular sutures and 150 patients had skin closure with metallic surgical skin staples.
- Inclusion criteria included women with viable pregnancies (≥ 26 weeks) undergoing caesarean delivery at AIIMS, Jodhpur. All caesarean types were included - scheduled or unscheduled and primary or repeat caesareans with low transverse/ pfannenstiel incision.
- Exclusion criteria included inability to obtain informed consent, immune compromising disease (e.g.AIDS), Chronic steroid use, Contraindication to routine postpartum pain medications (ibuprofen, narcotics) e.g.CKD patient, Chorioamnioinitis and Caesarean section done by vertical incision.
- Mean age of the patients was 26.93±4.20 years. Mean age of patients was 26.99±4.27 in subcuticular suture group and mean age of patients in staples group was 26.87±4.14. The patients in two groups were comparable in terms of age.
- Mean BMI of the patients was 24.9±3.84 kg/m². The mean BMI of patients in subcuticular group was 24.21±3.59 kg/m² and staples were 24.45±4.106 kg/m². The two groups were comparable in terms of BMI.
- Majority of patients were graduates in both the groups 30.33% in subcuticular suture and 30% in staples group.
- Majority of the patients in both the groups were house wives 84.67% in subcuticular suture and 86% in staple group
- Mean POG at delivery in the study population was 38.4±2.17 weeks. Mean POG at delivery for suture group was 38.5±2.17 weeks and for staple group was 38.29±2.17 weeks. Both the groups were comparable in terms of POG at delivery.
- The most common indication for LSCS in the study population was previous LSCS not willing for Trial of Labour after Caesarean section (TOLAC). It accounted for 36% in suture group and 30 % in staple group.
- The most common indication for primary LSCS was pathological CTG and the most common indication for repeat LSCS was previous LSCS not willing for trial of labour.
- Anaemia was the most common risk factor in the study population. 32% patients in subcuticular suture group and 42.66% patients in staples group were anaemic.

- Wound condition on day 3 post operatively- Normal healing of the wound was seen in 98.62% of patients with subcuticular suture and 96.55% with staples. A significantly higher number of patients had mild bruising/erythema with subcuticular suture as compared to staples on day 3 post operatively (p value = 0.047). Only 1 patient in the study population had deep or severe wound infection. She had skin closure with staples.
- On day 3 post operatively, patients undergoing primary LSCS, majority of the patients (66.66 % with subcuticular suture vs 63.51% with staples) had normal healing. The rates were comparable in both the groups.
- Abnormal wound healing rate in primary LSCS on day 3 post operatively was 34.89%.
 With subcuticular suture, 33% had abnormal wound healing while it was 36.48% with staples. However, the difference was not significant.
- On day 3 post operatively, patients undergoing repeat LSCS, majority of the patients (89.33 % in group A vs 92.10% in group B) had normal healing. The rates were comparable in both the groups.
- Total wound complication rate in repeat LSCS on day 3 post operatively was 9.27%.
 Wound complications with subcuticular suture was 10.67% while it was 7.89% with staples. The difference in the rates was not significant.
- Wound condition on 6 weeks post operatively Normal healing of the wound was seen in 98.62% of patients with subcuticular suture and 96.55% with staples.
- Total 10 patients underwent resuturing during the study period. Resuturing rate in study was 3.33%.
- At 6 weeks post operatively, patients undergoing primary LSCS, majority of the patients (93.33% in group A vs 89.18% in group B) had normal healing. The rates were comparable in both the groups.
- Abnormal wound healing in primary LSCS at 6 weeks post operatively was seen in 2 patients (1.32%). With subcuticular suture, composite wound morbidity rates were 1.33% and with staples, the rates were 4.05%. However the results were not statistically significant.
- Nine (6%) patients with primary LSCS underwent resuturing. Of these 9 patients, 4 patients had skin closure with subcuticular suture (5.33%) while 5 pateints (6.75%) had skin closure with staples.

- Rest of the 43 patients (28.85%) who had wound infection for whom resuturing was not required, underwent a course of antibiotics and repeated wound dressing till wound was in healthy condition.
- At 6 weeks post operatively, patients undergoing repeat LSCS, majority of the patients (97.33% in group A vs 97.36% in group B) had normal healing. The rates were comparable in both the groups.
- Abnormal wound healing in repeat LSCS at 6 weeks post operatively was in 3 patients (1.98%). Out of these 3 patients, 1 patient (1.33%) had skin closure with suture and 2 patients (2.63%) had skin closure with staples. However the results were not statistically significant. Only 1 patient underwent resuturing, who had skin closure with subcuticular suture . No patient with staples closure who had repeat LSCS underwent resuturing. Resuturing rate in repeat LSCS at 6 weeks post operatively was 0.66%.
- Rest of the 13 patients who had abnormal wound healing (8.6%) for whom resuturing was not required, underwent a course of antibiotics and repeated wound dressing till wound was in healthy condition
- Skin closure time- Mean skin closure time with subcuticular suture was 459.32±124.77 seconds. Mean skin closure time with staples was 65.55±30.26seconds. Time taken for skin closure time with staples is significantly less as compared to subcuticular sutures.
- **Pain score** Mean pain score on day 3 post operatively was 3.78±1.94 in subcuticular suture group vs 3.39±2.02 in staples group. Both the skin closing techniques were equivalent in terms of pain score.
- A significantly lower number of patients had mild pain in group A as compared to group B (0.034) but a significantly higher number of patients had moderate pain in group A as compared to group B.
- Both the skin closing techniques were equivalent in terms of pain score for patients undergoing primary LSCS in both the group and patients undergoing repeat LSCS in both the groups.
- At 6 weeks post operatively, majority of the patients had no pain. With subcuticular suture, 78.62% patients and 79.31% with staples had no pain. Mean pain score with subcuticular suture was 0.31±0.84 and with staples was 0.25±0.52 at 6 weeks post operatively. Results were comparable in both the groups.

- In patients undergoing primary LSCS, the pain score was comparable between the staples and subcuticular group. Similarly, patients going repeat LSCS, pain score were comparable between staples and subcuticular group.
- Patient satisfaction score was majored by appearance and comfort of scar.
- Majority of the patients assigned score of 5 (best) for the appearance of scar. It was 67.58% in group A vs 63.44% in group B. The mean score for appearance of scar was 4.54±0.79 in group A vs 4.41±0.92 in Group B. It was comparable in both the groups.
- Reasons for assigning lower score for scar appearance of subcuticular suture- blackening of the stitch line and raised area over the stitch line. Reasons for assigning lower score for appearance of scar with staples points of staple pin sites were visible.
- Majority of the patients in the study were comfortable with the scar score of 5 was given by 76.55% patients with suture vs 68.27 % with staples. The mean comfort score with subcuticular suture was 4.7±0.6 and with staples was 4.62±0.61. Both the groups were comparable. Reason for low comfort score with subcuticular suture- appearance of raised area over the stitch line. Reason for low comfort score with staples– requirement of removal of staple pins at day 7 post operatively.
- Location of the scar was same in all patients i.e. pfannenstiel incision in the lower abdomen. So, the patient satisfaction score for location of the scar was same in all the patients.

It is concluded from our study that staples and subcuticular suture are equivalent to each other for skin closure in terms of wound morbidity. Although staples have significantly less time consumption as compared to subcuticular suture, pain score and patient satisfaction score were comparable in both the groups. Hence, the choice skin closure material is at the discretion of operating surgeon.



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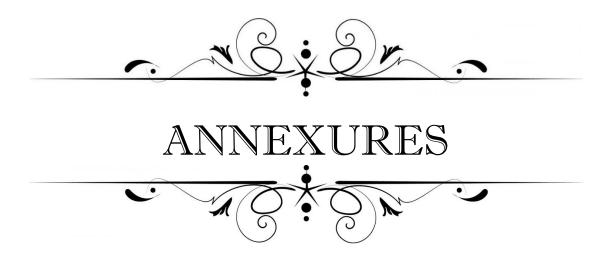
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ANNEXURES

Annexure No.		TITLE
1.	:	IEC Certificate
2.	:	Patient Information Sheet in English
3.	:	Patient Information Sheet in Hindi
4.	:	Consent Form in English
5	:	Consent Form in Hindi
6.	:	Case Record Form
7.	•	Master Chart



अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर All India Institute of Medical Sciences, Jodhpur संस्थागत नैतिकता समिति Institutional Ethics Committee

No. AIIMS/IEC/2020/ 2069

Date: 01/01/2020

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: AIIMS/IEC/2019-20/951

Project title: "Comparison of staples versus subcuticular sutures for skin closure in caesarean section- A Randomized controlled study"

Nature of Project:Research ProjectSubmitted as:M.D. DissertationStudent Name:Dr.Shafaq BhandariGuide:Dr. Manu GoyalCo-Guide:Dr.Pratibha Singh & Dr.Shashank Shekhar

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on 23-12-2019 and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

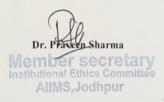
The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- · Any unethical principle or practices are revealed or suspected
- · Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.



Enclose:

1. Annexure 1

Page 1 of 2

Basni Phase-2, Jodhpur, Rajasthan-342005, Website: www.aiimsjodhpur.edu.in, Phone: 0291-2740741 Extn. 3109 Email: ethicscommittee@aiimsjodhpur.edu.in Annexure 1



Institutional Ethics Committee All India Institution of Medical Sciences, Jodhpur

Meeting of Institutional Ethics committee held on 23-12-2019 at 10:00 AM at Committee Room, Admin Block AIIMS Jodhpur.

Following members were participated in the meeting:-

S/No. Name of Member		Qualification	Role/Designation in Ethics Committee	
1.	Dr. F.S.K Barar	MBBS, MD (Pharmacology)	Chairman	
2.	Justice N.N Mathur	LLB	Legal Expert	
3.	Dr. Varsha Sharma	M.A (Sociology)	Social Scientist	
4.	Mr. B.S.Yadav	B.Sc., M.Sc. (Physics), B.Ed.	Lay Person	
5.	Dr. K.R.Haldiya	MD (General Medicine)	Clinician	
6.	Dr. Arvind Mathur	MBBS, MS (General Medicine)	Clinician	
7.	Dr. Surajit Ghatak	MBBS, MS (Anatomy)	Basic Medical Scientist	
8.	Dr. Vijaya Lakshmi Nag	MBBS, MD (Microbiology)	Basic Medical Scientist	
9.	Dr. Sneha Ambwani	MBBS, MD (Pharmacology)	Basic Medical Scientist	
10.	Dr. Kuldeep Singh	MBBS, MD (Paediatric), DM (General Medicine)	Clinician	
11.	Dr. Abhinav Dixit	MBBS, MD (Physiology), DNB (Physiology)	Basic Medical Scientist	
12.	Dr. Pradeep Kumar Bhatia	MBBS, MD (Anaesthesiology)	Clinician	
13.	Dr. Tanuj Kanchan	MBBS, MD (Forensic Medicine)	Basic Medical Scientist	
14.	Dr. Pankaj Bhardwaj	MBBS, MD (CM&FM)	Clinician	
15.	Dr. Praveen Sharma	M.Sc., Ph.D. (Biochemistry)	Member Secretary	

Dr. Pravees Sharma Member secretary Institutional Ethics Committee AllMS,Jodhpur

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Patient Information sheet (PIS) (English)

You are invited to take part in this study entitled "Comparison of staples versus subcuticular sutures for skin closure in caesarean section-Randomised controlled study"

It is informed that it is entirely voluntary and you may refuse to take part or discontinue at any time without losing your right to adequate gynaecological care.

This research is aimed at comparing the wound complication rates alongwith the operating time, patient satisfaction at 6 weeks and pain perception at day 3 and 6 weeks post operatively following the skin closure method in caesarean delivery. After your consent you will be divided into two groups In group A, absorbable subcuticular suture will be used for skin and in group B, metallic surgical stapler will be used. Even if you refuse to participate in this study, the investigations and the appropriate treatment will be carried out as a regular protocol.

The study requires routine surgical procedure to be performed and hence the cost of the procedure has to be borne by you, as these are not any extra procedures.

The expected duration of your participation in this study is 6 weeks. There is no specific complication due to the study.

All the records will be kept confidential.

You have the right to ask for any further information that you require.

In case of any doubt regarding the study you are welcome to contact the undersigned personally or by telephone. (9878828814)

रोगी सूचना पत्र (पीआईएस)

आपको इस अध्ययन में भाग लेने के लिए आमंत्रित किया गया है जिसका शीर्षक है "सीज़ेरियन सेक्शन में त्वचा के बंद होने के लिए स्टेपल बनाम सबकटिक टांके का याद्दच्छिक नियंत्रित अध्ययन"

यह सूचित किया जाता है कि यह पूरी तरह से स्वैच्छिक है और आप पर्याप्त स्त्रीरोग संबंधी देखभाल के अधिकार को खोए बिना किसी भी समय हिस्सा लेने या बंद करने से इनकार कर सकते हैं। यह शोध ऑपरेटिंग समय के साथ घाव की विकृति की दर, 6 सप्ताह में रोगी की संतुष्टि और सीज़ेरियन सेक्शनके दिन 3 और 6 सप्ताह में दर्द धारणा की तुलना में है, जो कि सिजेरियन डिलीवरी में त्वचा बंद करने की विधि के बाद होता है। आपकी सहमति के बाद आपको दो समूहों में विभाजित किया जाएगा समूह 1 में, सोखने योग्य चमड़े के नीचे सिवनी का उपयोग त्वचा के लिए किया जाएगा और समूह 2 में, धातु सर्जिकल स्टेपलर का उपयोग किया जाएगा। यहां तक कि अगर आप इस अध्ययन में भाग लेने से इनकार करते हैं, तो जांच और उचित उपचार नियमित प्रोटोकॉल के रूप में किया जाएगा।

अध्ययन के लिए नियमित शल्य चिकित्सा प्रक्रिया की आवश्यकता होती है और इसलिए प्रक्रिया की लागत आपके द्वारा वहन की जानी चाहिए, क्योंकि ये कोई अतिरिक्त परीक्षण नहीं हैं। इस अध्ययन में आपकी भागीदारी की अपेक्षित अवधि 6 सप्ताह है। अध्ययन के कारण कोई विशिष्ट जटिलता नहीं है। सभी रिकॉर्ड गोपनीय रखे जाएंगे।

आपके पास कोई और जानकारी मांगने का अधिकार है, जिसकी आपको आवश्यकता है। अध्ययन के संबंध में किसी भी संदेह के मामले में, आपका व्यक्तिगत रूप से या टेलीफोन द्वारा संपर्क करने के लिए स्वागत है। (9878828814)

INFORMED CONSENT FORM

All India Institute of Medical Sciences Jodhpur, Rajasthan

Title of Thesis/Dissertation: Comparison of staples versus subcuticular sutures for skin closure in caesarean section-Randomised controlled study

Name of PG Student : Dr. Shafaq Bhandari Tel. No. : 9878828814.

Patient/Volunteer Identification No. : _____

R/o_____

I,______W/o or D/o______

_____ give my full,

free, voluntary consent to be a part of the study "Staples versus subcuticular sutures for skin closure in caesarean section - RCT ". The procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions. I fully understand that any of the above mentioned observation can be given to me; still I want to be a part of trial. I understand that my participation is voluntary and is aware of my right to opt out of the study at any time without giving any reason. I understand that the information collected about me and any of my medical records may be looked at by responsible individual from AIIMS, Jodhpur or from regulatory authorities. I give permission for these individuals to have access to my records.

Date:			
Place:			Signature/Left thumb impression
This to certify t	hat the above conser	t has been obtained in	n my presence
Date:			
Place:			Signature of PG Student
Witness 1		2. Witness _	
Signature	Signature		
Name		Name:	
Address:		Address:	

<u>ANNEXURE - 5</u> अखिल भारतीय आयुर्विज्ञान संस्थान जोधपुर, राजस्थान सूचित सहमति प्रपत्र

मौ	थीसिस / शोध प्रबंध का शीर्षक: सीजेरियब	न सेक्शन में त्वचा के बंद होने के लिए स्टेपल
रौगी / स्वयंसेवक पहचान संख्या:	बनाम सबकटिक टांके का यादच्छिक नियंत्रि	त अध्ययन
मौ	पीजी छात्र का नाम: डॉ. शफाक भंडारी क्रमां	क: 9878828814
पता	रोगी / स्वयंसेवक पहचान संख्या:	
स्वतंत्र, स्वैच्छिक सहमति है "सीजेरियन सेक्शन में त्वचा के बंद होने के लिए स्टेपल बनाम सबकटिक टांके का एक याइच्छिक नियंत्रित अध्ययन" जिसकी प्रक्रिया और प्रकृति मुझे अपनी भाषा में समझाया है। पूर्ण संतुष्टि, मैं पुष्टि करतीहूं कि मुझे सवाल पूछने का अवसर मिला है। मैं पूरी तरह से समझती हूं कि उपर्युक्त अवलोकन में से कोई भी मुझे दिया जा सकता है, फिर भी मैं परीक्षण का हिस्सा बनना चाहती हूं। मैं समझती हूं कि मेरी भागीदारी स्वैच्छिक है और बिना किसी कारण के किसी भी समय अध्ययन से बाहर निकलने के अधिकार से अवगत हूं। मैं समझती हूं कि मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में एकत्रित जानकारी को एम्स, जोधपुर के जिम्मेदार व्यक्ति या नियामक अधिकारियों से देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं। दिनांक: स्थान: हस्ताक्षर / बाएं अंगूठे का निशान यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है दिनांक: जगह: पीजी छात्र के हस्ताक्षर साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नाम:	मॅ,	पति / पिता
सबकटिक टांके का एक याद्दच्छिक नियंत्रित अध्ययन" जिसकी प्रक्रिया और प्रकृति मुझे अपनी भाषा में समझाया है। पूर्ण संतुष्टि, मैं पुष्टि करतीहूं कि मुझे सवाल पूछने का अवसर मिला है। मैं पूरी तरह से समझती हूं कि उपर्युक्त अवलोकन में से कोई भी मुझे दिया जा सकता है, फिर भी मैं परीक्षण का हिस्सा बनना चाहती हूं। मैं समझती हूं कि मेरी भागीदारी स्वैच्छिक है और बिना किसी कारण के किसी भी समय अध्ययन से बाहर निकलने के अधिकार से अवगत हूं। मैं समझती हूं कि मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में एकत्रित जानकारी का एम्स, जोधपुर के जिम्मेदार व्यक्ति या नियामक अधिकारियों से देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं। दिनांक:	पता	अध्ययन का एक हिस्सा बनने के लिए मेरी पूर्ण,
अपनी भाषा में समझाया है। पूर्ण संतुष्टि, मैं पुष्टि करतीहूं कि मुझे सवाल पूछने का अवसर मिला है। मैं पूरी तरह से समझती हूं कि उपर्युक्त अवलोकन में से कोई भी मुझे दिया जा सकता है, फिर भी मैं परीक्षण का हिस्सा बनना चाहती हूं। मैं समझती हूं कि मेरी भागीदारी स्वैच्छिक है और बिना किसी कारण के किसी भी समय अध्ययन से बाहर निकलने के अधिकार से अवगत हूं। मैं समझती हूं कि मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में एकत्रित जानकारी को एम्स, जोधपुर के जिम्मेदार व्यक्ति या नियामक अधिकारियों से देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं। दिनांक: स्थान: हस्ताक्षर / बाएं अंगूठे का निशान यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है दिनांक: जगह: पीजी छात्र के हस्ताक्षर साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नाम:	स्वतंत्र, स्वैच्छिक सहमति है "सीजेरियन से	क्शन में त्वचा के बंद होने के लिए स्टेपल बनाम
मिला है। मैं पूरी तरह से समझती हूं कि उपर्युक्त अवलोकन में से कोई भी मुझे दिया जा सकता है, फिर भी मैं परीक्षण का हिस्सा बनना चाहती हूं। मैं समझती हूं कि मेरी भागीदारी स्वैच्छिक है और बिना किसी कारण के किसी भी समय अध्ययन से बाहर निकलने के अधिकार से अवगत हूं। मैं समझती हूं कि मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में एकत्रित जानकारी को एम्स, जोधपुर के जिम्मेदार व्यक्ति या नियामक अधिकारियों से देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं। दिनांक:	सबकटिक टांके का एक यादच्छिक नियंत्रि	त अध्ययन" जिसकी प्रक्रिया और प्रकृति मुझे
सकता है, फिर भी मैं परीक्षण का हिस्सा बनना चाहती हूं। मैं समझती हूं कि मेरी भागीदारी स्वैच्छिक है और बिना किसी कारण के किसी भी समय अध्ययन से बाहर निकलने के अधिकार से अवगत हूं। मैं समझती हूं कि मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में एकत्रित जानकारी को एन्स, जोधपुर के जिन्म्मेदार व्यक्ति या नियामक अधिकारियों से देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं। दिनांक:	अपनी भाषा में समझाया है। पूर्ण संतुष्टि, व	मैं पुष्टि करतीहूं कि मुझे सवाल पूछने का अवसर
स्वैच्छिक है और बिना किसी कारण के किसी भी समय अध्ययन से बाहर निकलने के अधिकार से अवगत हूं। मैं समझती हूं कि मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में एकत्रित जानकारी को एम्स, जोधपुर के जिम्मेदार व्यक्ति या नियामक अधिकारियों से देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं। दिनांक: स्थान: हस्ताक्षर / बाएं अंगूठे का निशान यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है दिनांक: जगह: पीजी छात्र के हस्ताक्षर साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नाम:	मिला है। मैं पूरी तरह से समझती हूं कि	उपर्युक्त अवलोकन में से कोई भी मुझे दिया जा
अधिकार से अवगत हूं। मैं समझती हूं कि मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में एकत्रित जानकारी को एम्स, जोधपुर के जिम्मेदार व्यक्ति या नियामक अधिकारियों से देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं। दिनांक: स्थान: हस्ताक्षर / बाएं अंगूठे का निशान यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है दिनांक: जगह: पीजी छात्र के हस्ताक्षर साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नाम:	सकता है, फिर भी में परीक्षण का हिस्सा ब	ानना चाहती हूं। मैं समझती हूं कि मेरी भागीदारी
एकत्रित जानकारी को एम्स, जोधपुर के जिम्मेदार व्यक्ति या नियामक अधिकारियों से देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं। दिनांक: स्थान: हस्ताक्षर / बाएं अंगूठे का निशान यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है दिनांक: जगह: पीजी छात्र के हस्ताक्षर साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नाम:	स्वैच्छिक है और बिना किसी कारण के	किसी भी समय अध्ययन से बाहर निकलने के
जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं। दिनांक: स्थान: हस्ताक्षर / बाएं अंगूठे का निशान यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है दिनांक: जगह: पीजी छात्र के हस्ताक्षर साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नाम:	अधिकार से अवगत हूं। मैं समझती हूं कि	मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में
दिनांक: स्थान:हस्ताक्षर / बाएं अंगूठे का निशान यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है दिनांक: जगह: जगह: पीजी छात्र के हस्ताक्षर साक्षी 1 हस्ताक्षर हस्ताक्षर नाम नाम:	एकत्रित जानकारी को एम्स, जोधपुर के जि	म्मेदार व्यक्ति या नियामक अधिकारियों से देखा
स्थान: हस्ताक्षर / बाएं अंगूठे का निशान यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है दिनांक: जगह: पीजी छात्र के हस्ताक्षर साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नाम:	जा सकता है। मैं इन व्यक्तियों को अपने वि	रेकॉर्ड तक पहुंचने की अनुमति देता हूं।
स्थानः हस्ताक्षर / बाएं अंगूठे का निशान यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है दिनांकः जगहः पीजी छात्र के हस्ताक्षर साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नामः	दिनांक:	
दिनांक: जगह: पीजी छात्र के हस्ताक्षर साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नाम:	स्थान:	हस्ताक्षर / बाएं अंगूठे का निशान
जगह: पीजी छात्र के हस्ताक्षर साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नाम:	यह प्रमाणित करने के लिए कि मेरी उपस्थि	ाति में उपरोक्त सहमति प्राप्त हुई है
साक्षी 1 2. गवाह हस्ताक्षर हस्ताक्षर नाम नाम:	दिनांक:	
हस्ताक्षेर हस्ताक्षेर नाम नाम:	जगह:	पीजी छात्र के हस्ताक्षर
नामः	साक्षी 1	2. गवाह
	हस्ताक्षर	हस्ताक्षर
पता पता:	नाम	नाम:
	पता	पता:

CASE RECORD SHEET:- (Principal Investigator- Dr. Shafaq Bhandari)

- Name :
- Age: Qualification:
- Occupation: Residence:
 - Phone Number-

Registration Id:

- Chief complaint-
- HOPP

	Yes	No
Fever		
PPROM		
Diabetes		
Anaemia		
Smoking		
Alcohol		

• Menstrual History:

Menstural cycle

LMP- EDD- POG-

- Obstetric History:
- Past History:
- Personal History:

On Examination:

- General condition
- Pulse rate /min Blood pressure mmHg
- Respiratory rate/min Temperature sPO₂
- Pallor Icterus Cyanosis Clubbing Lymphadenopathy Edema
- Weight(Kg): Height(cm): Body Mass Index(Kg/m2)

- Central Nervous System:
- Respiratory System:
- Cardio-Vascular System:
 - Per-Abdomen : Indication-

Primary LSCS/Repeat LSCS

Final Diagnosis:

•

CBC (post op)Hb TLC Platelet

POST OP PERIOD

	Yes	No
Wound infection		
Fever		
UTI		
Anaemia		

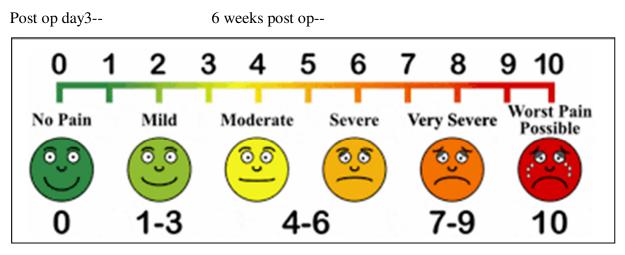
SKIN CLOSURE TECHNIQUE—subcuticular sutures/ metallic surgical staples SKIN CLOSURE TIME-

	POD 3	POD 6 week
Wound condition (0-18)		
Pain Score (VisualAnalog scale)0-10		
Patient satisfaction score (POD 6 weeks)		
• Appearance of scar	Worst / Bad / Good /	Better / Best
Comfort of scar	Worst / Bad / Good /	Better / Best
• Location of scar	Worst / Bad / Good /	Better / Best

WOUND CONDITION

Wound condition	Post op Day 3	6 weeks post op
Normal healing 0		
Mild bruising/ erythema 1		
Some bruising 2		
Considerable bruising 3		
Mild erythema 4		
Erythema plus other signs of inflammation 5		
At one point 6		
Around sutures 7		
Along wound 8		
Around wound 9		
Clear or hemoserous discharge 10		
At one point only (<2 cm) 11		
Along wound (>2 cm) 12		
Large volume 13		
Prolonged (>3 days) 14		
Pus/ purulent discharge 15		
At one point only (<2cm) 16		
Along wound (>2cm) 17		
Deep or severe wound infection with or without		
tissue breakdown 18		

PAIN SCORING



PATIENT SATISFACTION SCORE-

6 weeks post op-

	Worst	Bad	Good	Better	Best
General appearance	1	2	3	4	5
Location of scar	1	2	3	4	5
Comfort of scar	1	2	3	4	5

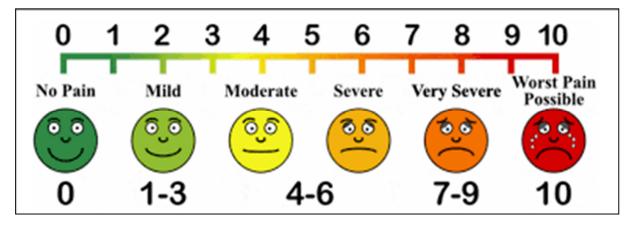
<u>APPENDIX</u>

Grade	Wound condition	Point allotted in EXCEL		
0	Normal healing	0		
1	Mild bruising / erythema	1		
1a	Some bruising	2		
1b	Considerable bruising	3		
1c	Mild erythema	4		
2	Erythema + others signs of inflammation	5		
2a	At one point	6		
2b	Around sutures	7		
2c	Along wound	8		
2d	Around wound	9		
3	Clear or serosanguinous discharge	10		
3a	At one point (<2cm)	11		
3b	Around wound (>2cm)	12		
3c	Large volume	13		
3d	Prolonged (>3days)	14		
4	Pus	15		
4a	At one point (<2cm)	16		
4b	Along wound (>2cm)	17		
5	Deep or severe wound infection	18		

Appendix 1- Southampton wound grading system

Appendix 2 – Pain scoring

Day 3 post operatively and 6 weeks post operatively-



Appendix 3 – Patient satisfaction score

At 6 weeks post operatively-

	Worst	Bad	Good	Better	Best
General appearance	1	2	3	4	5
Location of scar	1	2	3	4	5
Comfort of scar	1	2	3	4	5

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2017/20200267 Secondary Housewife M 2 years primigravida 2020/2020/267 Secondary Dealo (M 1) M 2 years primigravida	NI	29.98 38			356 second Uneventful 5			4	5	Pod 3-2	
2020/08/009983 Secondary Daskinh MI 3 years 04P0030											
		23.5 36	+2 Malpresentation	Primary LSCS Staples	40 seconds Uneventful 2	0 4	0	4	5	yes	No
2020/08/005798 Graduate Housewife ML 7 years G2P101	Diabetes Anaemia	20.54 35		Primary LSCS Staples	120 seconds Anaemia 2	0 0	0	4	5	09	No
2021/01/016278 Illefrate Housewife ML 16 years, 02P0010	Anaemia	27.39 38			60 seconds Anaemia 0			4		Day20-7 pain 2	No
2019/12/007097 Primary Housewile MI 2 years, g2p0010, a1-2 years back, mised abortion at 2.5 monthspog, lib d n c	ACI .	21.22 35	1+6 failed induction	Démonit CCC Debutinute	410 seconds Uneventful 4	1 0		4	4	No	RHD with severe MS wuth grade 1 NYHA
2020101020451 Maharah Mi 2 yana pengaputan mananaka kata na mananaka kata na mananaka kata na mananaka kata na ta	NI	24.76 40	+5 thick MSL in early labour	Primary LSCS Subcuticular	460 seconds Uneventful 4	0 0	ő	6	6	No	No.
201904-00706 Polgradu Huberto Line Housening Mill year Himigarda	Diabetes	27.34 37		Dimany LOCO Subsularia	410 seconds Uneventful 4	2 0	0	3	4	No	No
2020/11/09/91 Match/01 Housening (SI2002)	Anaemia	23.62 40			56 seconds Uneventful 0					No	No
2020/11/00/11/ Material Daking Mt.2 years 03/2022	Diabetea	25.91 32								No	No
				Primary LSCS Staples	52 seconds Uneventful 3	0 0	0	4		No	No
2019/08/001255 Illietrate Housewife MI 1.5 years Primigravida	Smoking	25.1 40		Primary LSCS Subcuticular	720 seconds Anaemia 4	1 0	0			No	NO
2018/07/002285 Postgraduate Housewife ML 3 years, primigravida	Anaemia	21.7 35	+4 Pathological CTG		70 seconds anaemia 6			5		POD10- pus at 1 point, pain 7, dressing done	No
2019/08/016035 Graduate Housewife MI 4 years Primigravida	Diabetes	24.77 39	+2 Pathological CTG		470 second Uneventful 1					No	No
2020/08/000749 Graduate Housewife mi 6 years, G2P1001, 1-5 years, TVD	Nil	22.43 35 23.71 35	+1 Pathological CTG	Primary LSCS Subcuticular	310 second Uneventful 6	1 0	0	4	4	No	No
2021/03/006539 Illetrate Housewife ML1 year, primigravida	Nil	23.71 35	+2 failed induction	Primary LSCS Staples	80 seconds Uneventful 0	0 0	0	5	5	09	No
2020/09/001140 Graduate Housewile ML 1 year, primigravida	Diabetes Anaemia	19.05 39			70 seconds Uneventful 2			5	4	09	No
2020/07/006249 Graduate Housewife ML 2 years primoravida	Anasmia	24.21 41			49 seconds Anaemia 7			3	3	POD 15- wound 12, pain - 3- drassing done	No
2019/00/007652 Graduate Housewife MI 10 months Primioravida	Anaemia	22.76 40			550 seconda Uneventiul 2			4	6	00	No
2019/06/01/21 Graduate Housenia Millionary and Alling Andrea State Sta	ALL	31.24 40			450 seconds Uneventful 4					10	- No.
2019/00/07/16 CHarbara Polyamina in 2 year Printgravia 2020/10/00/75 Seconday Studen III.2 year Printgravia	Diabetea	27.68 41	+2 Pathological CTG	Primary LSCS Subcuricular Primary LSCS Staples	51 second Uneventful 4	0 0	0	3	5	No	NO
		27.00 41	+2 Pathological CTG					4	3		ND
2020/11/005040 Postgraduate Housewife ML 3 years, primigravida	Anaemia	25.29 40	+1 Pathological CTG	Primary LSCS Steples			0	5	5	yes	PPH+
2020/01/031082 Primary Housewife MI 1 year Primigravida	Nii	24.88 38	+6 thick MSL in early labour	Primary LSCS Subcuticular	400 seconds Uneventful 3	0 0	0	5	5	no	No
2018/03/004522 Graduate Housewife MI 5 years, g2p1000, P1-2 yearsback, still birth, VD, difficult delivery , CPT repair after 3 months, BW 4kgs	Nil	25.14 38	+0 H/o CPT repair in previous pregnancy	Primary LSCS Subcuticular	335 seconds Uneventful 7	1 0	0	4	5	No	No
2019/08/005259 Matric/10th Housewife ML 11 years, g3P2001, p1-8 years girl, alive and healthy, tvd. P2-IUD at 39 weeks, 7 oligohydramnios	Anaemia	23.91 37		Primary LSCS Subcuticular	520 seconds Anaemia 1	0 0	0	5	5	No	No
2015/05/007188 Graduate Daskiob MI 5 waas primicravida	Diabetes	28.69 35			375 seconds Uneventful 4			3	4	No	No
2020/10.007852 Graduate Housewife ML I vear.trimioravida	fever	20.56 40	+3 arrest of descent/dilatation	Primary I SCS Stanles	90 seconds Fever, Anaemia 3	0 0	0	5	4	No	PPH+
2019/02/015187 Graduate Field work ML11 years GP0111. P1-10 years. PTLSCS. Boy, breech with anhydroamniosl. An H. HO postpartum edampsia & CVT	Anaemia	24.65 38			465 seconds Anaemia 4			6	c c	No	PPH+
2020/10.006488 Graduate Housewife ML 6 years 02P1001. P1-5 years back LSCS. 2 loops of cost around neck. Girl, anh	NCI .	23.8 35		Page 1909 Stelar	52 seconds Uneventful 1	1 0		5	5	00	No
202101012586 Graduate Housening ML5 years (2010). F1:5 years (2004 2010) and anothing (2014) and anothing	ALL ALL	20.02 35			660 seconds Uneventful 1				5	10	- No.
2021/03/07672665 Generative Potential August, C2F (101), P1-3 years,	NI	18.64 40			435 seconds Uneventful 2			5	5	10	No
	NI							5			
2020/09/002514 Postgraduate Housewife ML 2.5 years, G2P1001, G1-1 year, LSCS (thick MSL), AnH	Ni	27.04 38	+5 previous LSCS not willing for TOLAC		36 seconds Uneventful 4			5	5	yes	No
2 2020/12/001998 Graduate Field work: ML 12 years, G4P2012, P1-12 years, LSCS (transverse lie), girl, AnH, P2-8 years, LSCS (previous LSCS), girl, AnH	Nii	24.34 40		Repeat LSCS Staples	78 seconds Uneventful 1	0 0	0	5	5	00	No
2020/09/011785 Secondary Housewife ML 6 years, G2P1001, P1- 4 years, LSCS (raised BP, failed induction), AnH	Anaemia	31.23 37			335 seconds Anaemia 1			-	-	resuturing on day 14	No
2020/09/002299 Graduate Housewife ML 6 years, G2P1001, P1 - 5 years, boy, AnH, LSCS (failed induction)	Diabetes	23.43 35			26 seconds Uneventful 4			3	3	00	No
2 2021/02/008511 Matric/10th Housewife ML-6 years, G2P1001, P1-3 years, LSCS(thick MSL),boy, AnH	Nil	19.47 40			560 seconds Uneventful 2			5	5	00	No
2020/08/003906 Matric/10th Housewife ML-7 years (32P1001, P1-6 years, LSCS (lailed induction), boy, AnH	Diabetes	21.48 39	+0 previous LSCS not willing for TOLAC	Repeat LSCS Subcuticular	560 seconda Anaemia 3	1 0	0	5	5	00	No
2018/06/017181 Secondary Housewife ML3 years G2P1001, P1-2 years TVD, boy, AnH	Diabetes	22.13 38		Primary LSCS Subcuticular	410 seconds UTI 0	1 0	0	5	5	No	No
2020/11/006403 Secondary Housewife ML 4 years (22P101). P1-2.5 years TVD. old AnH	Anasmia	22.03 35		Primary LSCS Staples	35 seconds Anaemia 3	0 0	0	5	5	09	No
2021/03/011172 Illetrate Housewife ML 11 years G302002, P1/P2-10 years TVD	NI	25.63 42	+2 CPD in labour	Primary LSCS Staples	200 seconds Anaemia 1	0 0	0	5	5	00	PPH+
2019/02/005233 Graduate Housewife ML 5 years, 02P010, A1- spontaneos abortion at 2nd month POG	NI	19.1 35			90 seconds Uneventful 4				4	No	No
2020/08/002821 Secondary Housewife ML7 years, 02P0010, A1- spontaneos abortion at 2nd month POG	Anaemia	19.53 37		Démond CCC Debudineday	410 seconds Anaemia 0	0 0		6	5	No	No
2000/12/00/12/ Graduate Daskio M. Z years finingavida	NI	23.87 32		Dimension Contractor	64 seconds Anaemia 3			<u>,</u>	4	00	PPH ₄
zucuri zolavi v orazonare Dorazio ili zurazi primigravia 2020/12/00/331 Ilietate Housevile II.4 years/migravia	NI	24.06 35	Newsaled acrophon with suspicious of G	Primary LSUS Staples	35 seconds Uneventful 2	1 0	0	3	5	10	No.
	NI			Primary Louis Staptes	35 seconds Unevention 2	0 0				110	
2020/07/001536 Graduate Deskjob ML1 year, primigravida	Nil	26.34 35		Primary LSCS Steples	70 seconds Uneventful 4	0 0	0	5		00	No
2020/09/002821 Secondary Housewille ML 2 years, 02P0100, P1-IUD at 8th month, PTVD	fever, Anaemia	26.67 37		Primary LSCS Subcuticular	660 seconds Fever, Anaemia 8	1 1	4 0	2	3	POD 15- wound 14, pain 7-> resuturing done	No
2020/09/003460 Postgraduate Daskjob ML 3 yaers, primigravida	Diabetes	26.83 39		Primary LSCS Steples	59 seconds Uneventful 5	0 0	0	5	5	00	NO
2020/08/000418 Secondary Housewife ML1 year, primigravida	Nil	22.22 40			440 seconds Uneventful 4					No	No
2020/12/001931 Graduate Field work ML 1 year, G2P0010, A1- spontaneos abortion at 2nd month POG	NEI	27.98 37			57 seconds Uneventful 5					00	No
2019/09/012861 Postgraduate Doctor ML4 years, Primigravida	Nil	31.19 35			600 seconds Fever, UTI 4					No	No
2017/02/04550 Postgraduate Housewife ML 9 months, primigravida	Nil	19.53 38	+0 Pathological CTG	Primary LSCS Subcuticular	524 seconds Anaemia 8	0 2	0	5	5	yes	No
2020/08/007174 Illetrate Housewife ML12 years, primigravida	Nil	19.81 28	+0 severe pre eclampsia with DIC	Primary LSCS Subcuticular	405 seconds Uneventful 2	0 0	0	5	5	No	No
2021/01/014259 Matric/10th Housewile ML 2 years, primigravida	Anasmia	21.51 35			22 seconds Anaemia 3			5	5	09	No
2020/03/011698 Matter10th Housewife ML 9 years (3P2002	Diabetes Anaemia	27.81 37		Pepeat LSCS Staples	75 seconds Anaemia 5	1 0	0	5	4	08	No
2020/03/00926 Postoraduate Housewife ML4 years (321011, P1-3 years, LSCS for fetal distress, AnH	Anaemia	34.61 35			99 seconds Anaemia 2			5		No	No
2016/10/02/37 Primar Housening ML + years Captorin, 1-9 years, Educition Hair Order and Amini- 2016/10/02/37 Primar Housening ML + years, Captorin, 1-5 years, expension both 700. All MTP at 6 weeks ostation	Anaemia	04.00			110 seconds Anaemia 2					00	- No.
2016/1000223 Pmmary Polamene Bic 9 Van GAP2012, P1, 2-5 36, 3 Space, Don 1 VG, A- MF z M Owing generation 2018/09.00124 12th Housewile BiL 4 years (2010) IC: P1 - 2 years 1 CSC (stransverse line), girl, A-H		21.33 33	Hz previous 2 LCCS		390 seconds Uneventful 0			2	5	10	NO
2010/2019/244 12/11 Planeten Br. 4 years, CAT 100, F1 - 2 years, CAS (International International In	Anaemia	23.12 38	+5 previous LSCS not willing for TOLAC					2	5	00	no
2020/09/000212 Graduate Housewife ML 8 years, 02P1001, P1-4 years, LSCS (fetal disreas), AnH, girl	Nil	22.83 31	1+1 previous LSCS not willing for TOLAC		330 seconds UTI 2			5	4	00	NO
2018/01/019503 Postgraduate Housewife ML 7 years, G2P1001, P1-6 years, LSCS (mised BP), boy, AnH	Nil	26.17 33					0	5	5	00	NO
2020/07/002385 Postgraduate Housewife ML 7 years, G2P1001, P1-2.5 years, LSCS (letal distress), girl AnH	Anaemia	25.95 38			360 seconds Uneventful 1				5	00	No
2020/08/000996 Matric/10th Housewife ML 6 years, G3P1011, P1-5 years, LSCS(failed induction), boy, AnH	Nil	26.01 37			86 seconds Uneventful 2			5	5	00	No
2014/04/003397 Graduate Housewife ML 8 years, G2P1001, P1- 7 years, LSCS (obstructed labour), boy, AnH	Nil	24.11 35	1+1 previous LSCS not willing for TOLAC	Repeat LSCS Staples	26 seconds Uneventful 5	0 0	Ó	3	4	00	No
2020/07/004964 Graduate Housewife ML11 years, G4P0122, P1-8 years, PTLSCS (twins), both AnH	Nil	20.82 35			80 seconds Uneventful 2			5	5	09	No
2019/02/00956 Graduate Housewife ML3 years (32P1001, P1-20 months LSCS (failed induction), box. AnH	Anaemia	23.61 35			600 seconds Uneventful 4			3	3	08	No
2020/08/003174 Pottmoniste Houseville ML8 years 02P001 P1-7 years LSCS IEBB and jaised RPI hov AnH	Diabetes	38.5 37			70 seconds Uneventful 4					10	No
ADJOINSY03377 Programstee Proceedings (bc years, Cafford), r1 - / years, L3-C3 (r0h mar tasked or), tooy, AHT 2020/07/20279 Programstee Proceedings (bc years, Cafford), r1 - / years, L3-C3 (r0h mar tasked or), tooy, AHT 2020/07/20279 Programstee Proceedings (bc years, Cafford), r1 - / years, L3-C3 (r0h mar tasked or), tooy, AHT	Diabetes	24.83 35	+2 previous LSCS not writing for TOLAC previous LSCS not willing for TOLAC		462 seconds Anaemia 4				-		No
										n0	142
202107-0007301 F Ostphateset Totalements BL 3 Feater, Control 1, 111-3 Feater, 2021000 (La 0), USI, Mill	hri h										
2027/08/2027/140 Oddatak HouseNe Mc 4 value, 02/97101 / Fr. 3 value 711:00 Fluid disease bor, Anti 02011/00/2724 Parghaduat Doct Mc 8 value, 02/97101 / Fr. 4 value ALSOS for theta disease	Nil Diabetes	22.95 38 29.27 35	1+2 previous PTLSCS	Repeat LSCS Staples	45 seconds Uneventful 2 370 seconds Uneventful 2	0 0	0	5	5	no	COVID positive