"A PROSPECTIVE COHORT STUDY TO STUDY THE EFFECTIVENESS OF SURGICAL BUNDLE IN REDUCING SURGICAL SITE INFECTION IN CAESAREAN DELIVERIES".

ABSTRACT

OBJECTIVE: - To study the effectiveness of surgical bundle in reducing Surgical Site Infection following caesarean deliveries.

METHODS: - A prospective cohort study was conducted in the Department of Obstetrics and Gynaecology in Deen Dayal Upadhyay Hospital, New Delhi from April 2021 to June 2022 for and included 620 women undergoing emergency caesarean section. A surgical bundle comprising of: - (i)pre-operative antibiotic prophylaxis- Inj Ceftriaxone 1gm i.v after skin sensitivity testing at the time of skin incision. (ii) Preoperative vaginal cleaning with betadine 5% after Foleys catheterisation and before abdominal scrubbing. (iii) Chlorhexidine - alcohol solution (2.5% chlorhexidine + 70% ethanol) for skin preparation, was tried to be implemented in emergency caesarean deliveries. Patients were divided into two groups on the basis of surgical bundle adherence and implementation. Group 1(n=310; surgical bundle not used) and Group 2 (n=310; surgical bundle used). Data was collected in patient proforma and outcomes were observed for 30 days postoperative period for surgical site infection.

RESULTS: - There was a significant decrease in number of surgical site infections in the group where the surgical bundle was used (all three measures applied). Rates of SSI in surgical bundle not used vs used were 41/310 (13.2%) vs 19/310 (6.1%) respectively with p-value <0.001.

CONCLUSION: - As there is more than 50% reduction in rates of surgical site infection it is concluded that use of a combination of evidence based surgical measures significantly reduce surgical site infection in caesarean deliveries.

KEYWORDS: - Surgical Site Infection (SSI), Caesarean Section/Deliveries, Surgical Bundle, Preoperative Betadine Vaginal Cleaning, Prevention of SSI in caesarean deliveries.

SYNOPSIS: - It was observed that adherence to the proposed surgical bundle was associated with a 53% overall reduction of surgical site infections after caesarean delivery.

INTRODUCTION

Caesarean section is a fetal delivery operation performed through an abdominal incision (laparotomy) and an incision in the uterus. The frequency of cesarean sections is increasing all over the world.[1]

Due to the continuous increase in the incidence of cesarean section in the world, the number of women with postpartum infection is expected to increase. Cesarean delivery carries a 5 to 20 times greater risk of infection than a normal delivery.[2] Surgical site infections (SSI) are the most common nosocomial infections, and the frequency of hospital-acquired infections varies between 2% and 10%. [3,4]

There are some risk factors for surgical site infection. These risk factors are higher maternal age, incision site hematoma, intraoperative blood loss, emergency cesarean section, obesity, duration of hospital stay, diabetes, history of urinary tract infection, and premature rupture of membranes.[5] There may be internal factors related to the patient that cause the infection, as well as external factors that may affect the risk of infection such as operative management and surgical field care. Although the internal factors of the patient cannot be changed, external factors are definable and manageable in terms of the risk of infection. In women undergoing cesarean section, the use of prophylactic antibiotics reduces the incidence of wound infection, endometritis, and serious infection complications by 60– 70%.[6]

Surgical site infections increase the cost burden on healthcare systems in addition to the medical adverse effects they give to the patient.[7] Increase in the frequency of caesarean operations has increased both the frequency of surgical wound infections and the need for the use of antiseptics required for skin cleansing. Developing countries have sought simple and cheaper solutions to this increasing financial burden.[8] However, it is not yet clear what type of skin disinfection and surgical site care would be most effective in preventing and reducing surgical site infections after caesarean section.[9]

The rate of caesarean deliveries is increasing in India as per the latest NFHS-4 report (2015-16)[10], the rate of C-sections has doubled, from 8.5 percent in 2005-06 to 17.2 percent in 2015-16. Caesarean section imposes 5-20-fold increased risk of infections and its related morbidity compared to those undergoing vaginal delivery and thus adding to the economic burden.[11] Surgical site infections result in significant maternal morbidity, including increased length of stay, readmission and cost. There is also an emotional burden caused by the

maternal–neonatal separation associated with treatment. The consequences of Surgical Site Infection following caesarean section for women include pain and delay returning to normal activities, chronic pelvic pain, persistent seroma and depression, as well as out-of-pocket costs. Costs for a health system include additional staff time, use of pharmaceutical and healthcare supplies, and increased length of stay or re-admission to hospital – potentially occupying a hospital bed that could be used by another patient.

There has been advance in Surgical Site Infection control practices which include: improved operating room ventilation, sterilization methods, use of barriers, surgical techniques and availability of antimicrobial prophylaxis. Despite these, Surgical Site Infections still occur and remain common causes of morbidity and mortality in the hospital setting mostly in developing countries. This is partly contributed by the emergence of antimicrobial resistant pathogenic bacteria.

The beneficial effect of antibiotic prophylaxis in reducing occurrences of infection associated with elective or emergency caesarean section is already well established.[12] Use of prophylactic antibiotics in women undergoing caesarean section substantially reduced the incidence of episodes of fever, endometritis, wound infection, urinary tract infection and serious infection after caesarean section.[13]

Several clinical trials have identified evidence-based interventions to reduce the risk of surgical site infection after caesarean delivery, including antibiotic prophylaxis before skin incision [14], chlorhexidine–alcohol skin preparation[15] and preoperative vaginal cleaning with betadine[16].

The present study was planned to see the risk reduction of surgical site infection from these interventions when they are bundled as a group.

AIM AND OBJECTIVES

Aim: To study the effectiveness of surgical bundle in reducing Surgical Site Infection following caesarean deliveries.

Objectives:

1. To evaluate the surgical site infection in caesarean deliveries in women receiving the surgical bundle.
2. To compare it with those not receiving the surgical bundle.

MATERIALS AND METHODOLGY

Study Area: Department of Obstetrics and Gynaecology at Deen Dayal Upadhyay Hospital, Hari Nagar, New Delhi

Study Design: A prospective cohort study was conducted in the Department of Obstetrics and Gynaecology in Deen Dayal Upadhyay Hospital, New Delhi (Tertiary Care Hospital)

Study Period 15 Months

Study Duration: 15 Months (April 2021 - June 2022)

Study Population: The study population includes women undergoing emergency caesarean section during the study period.

Inclusion criteria-

- women undergoing emergency caesarean section (irrespective of indication, including previous caesarean section)
- period of gestation ≥28 weeks
- live baby

Exclusion criteria –

- Immunocompromised patients
- Chorioamnionitis
- Severe anaemia (Hb<7gm/dl)
- Diabetes Mellitus
- Prolonged leaking (>18hrs)
- Prolonged labour
- Allergy to chlorhexidine, alcohol or iodine
- Allergy to Ceftriaxone
- Patients having skin infection near the operative site.

SAMPLE SIZE

At 95% confidence level and taking the incidence of surgical site infection as 3.7% after cesarean section in infection prevention measure group and 9.3% in control group (Temming LA et al)[14], sample size was calculated as 303 per group. The study was undertaken with sample size of 310 per group.

$$n = \frac{[Z_{1-\alpha/2}\sqrt{\{(1+1/m)p*(1-p)\}} + Z_{1-\beta}\sqrt{\{p_0*(1-p_0/m)\ p_1(1-p_1)\}}]^2}{(p_0-p_1)^2}$$

n = Total number of desired study subjects (case) to identify true relative risk with two-sided Type-I error

m = Number of subjects (control) per experimental subject

$z_{1-\beta}$ = It is the desired power (0.84 for 80% power and 1.28 for 90% power)

$z_{1-\alpha/2}$ = Critical value and a standard value for the corresponding level of confidence.

(At 95% CI it is 1.96 and at 99% CI or 1% type I error it is 2.58)

p_0 = Possibility of event in controls

p_1 = Possibility of event in experimental

$p = p_1 + m\ p_0/m+1$

METHODOLOGY

The study was conducted in Deen Dayal Upadhyay Hospital (Tertiary Hospital in Delhi) from April 2021- June 2022. Informed consent was taken from all the subjects willing to participate and fulfilling the inclusion and exclusion criteria before recruiting them in the study.

Approval from scientific review committee DDUH and from Institutional Ethics Committee - Deen Dayal Upadhyay Hospital were taken prior to study (IEC-DDUH/upn20/2021-03-16/20/v1;16/03/2021). During the study period from April 2021 to June 2022, 620 women undergoing emergency caesarean section with period of gestation ≥28 weeks with live baby were included.

All the patients undertaken for the study were subjected to detailed history taking, thorough examination- general, systemic and local, investigations and the data will be entered in Patient Proforma.

Surgical bundle was used in this study. Proposed surgical bundle used in this study was developed based on published literature.

A bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes.[64]

Components of proposed surgical bundle (Annexure 2) used in this study included :-

i. Pre-operative antibiotic prophylaxis- Inj Ceftriaxone 1gm i.v after skin sensitivity testing at the time of skin incision
ii. Preoperative vaginal cleaning with betadine 5% after Foleys catheterisation and before abdominal scrubbing
iii. Chlorhexidine - alcohol solution (2.5% chlorhexidine + 70% ethanol) for skin preparation

We tried to implement surgical bundle in patients undergoing emergency caesarean delivery.

Patients were divided into two groups on the basis of bundle adherence and implementation.

Group 1 included patients in whom surgical bundle could not be applied and were included in surgical bundle not used group.

Group 2 included the patients in whom all measures as mentioned in the surgical bundle were followed and applied during their caesarean section :-

i. Pre-operative antibiotic prophylaxis- Inj Ceftriaxone 1gm i.v after skin sensitivity testing at the time of skin incision
ii. Preoperative vaginal cleaning with betadine 5% after Foleys catheterisation and before abdominal scrubbing
iii. Chlorhexidine - alcohol solution (2.5% chlorhexidine + 70% ethanol) for skin preparation

Outcome (Surgical Site Infection) was defined according to United States Centers for Disease Control and Prevention – National Healthcare Safety Network surgical site infection definition criteria[35] (Annexure 1). Follow-up of each subject was recorded in outcome proforma (Annexure 4) and presence of following signs and symptoms were noted

- Infection symptoms – pain/ tenderness/ localized swelling/erythema/warm to touch/ discharge from wound/ fever > 38^{o} C (100.4^{o} F)
- Purulent drainage (pus) from superficial incision/ deep incision/ organ/ space/ drain
- Incision dehiscence (spontaneous) or deliberately opened by surgeon
- Deep infection/abscess found on imaging/ examination
- Organism identified from surgical site/ fluid/ tissue from organ/ space (if culture done)
- Surgeon/attending physician diagnosis

DATA ENTRY AND STATISTICAL ANALYSIS:

Data was collected using a structured proforma.

The collected data was transformed into variables, coded and entered in Microsoft Excel. Data was analyzed and statistically evaluated using SPSS-PC-20 version.

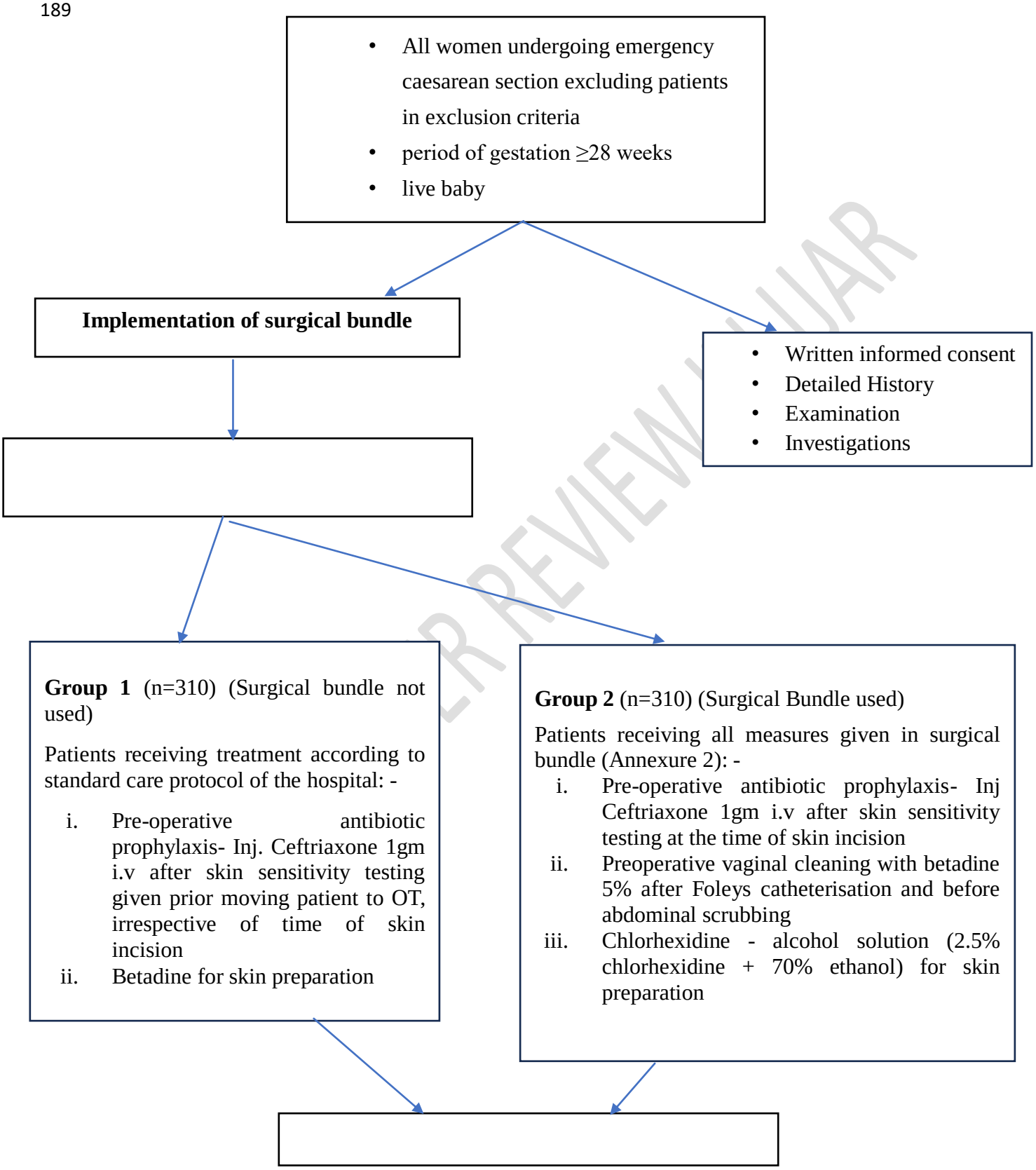
Quantitative data was expressed in mean, standard deviation while qualitative data was expressed in percentage. Comparison of quantitative data between two group was tested by student 't' test or Man Whitney U test. Statistical differences between the proportions between tested by chi square test or Fisher's exact test.

A p-value of <0.05 was considered statistically significant whereas p value <0.001 was considered highly significant.

188

CONSORT FLOWCHART

189



RESULTS AND OBSERVATIONS

Most of the patients were in the age group 25-30 years. There was no significant difference in age between two groups (Table 1& Fig 1).

Mean BMI in both groups was almost similar - 23.71 ±2.20 kg/m^2 and 23.70±2.21 kg/m^2 respectively (p value 0.94) (Table 2)

No significant difference was observed in anthropometric measurements between two groups (Fig 2).

There was no significant difference in gestational age between the two groups (Table & Fig 3).

There was no significant difference in obstetric history of two groups (Table & Fig 4).

There was no significant difference between medical comorbidities between two groups (Table & Fig 5).

There was no significant difference in primary caesarean and previous caesarean between two groups (Table & Fig 6).

There was no significant difference in socio-economic status of two groups (Table & Fig 7).

There was no significant difference in family history of two groups (Table & Fig 8) .

There was no significant difference in dietary history of two groups (Table & Fig 9) .

There was no significant difference in status of rupture of membranes between two groups (Table & Fig 10).

There was no significant difference in amount of blood loss during surgery in both groups (Table & Fig 11).

There was no significant difference in duration of surgery between the two groups (Table & Fig 12).

Tobacco use was nil in both the groups.

There was no significant difference in duration of postoperative stay between the two groups (Table & Fig 13).

There was no significant difference in number of vaginal examinations between the two groups (Table & Fig 14).

Incidence of SSI in partially applied surgical bundle group was found out to be 13.2% and in fully applied surgical bundle group it was 6.1% (Table & Fig 15).

Incidence of superficial SSI in partially applied surgical bundle and fully applied surgical bundle group was 9.0% and 4.2% respectively whereas incidence of deep SSI in partially applied surgical bundle and fully applied surgical bundle group 3.9% &2.2% respectively (Table & Fig 16). No incidence of organ/space SSI was observed in the study.

DISCUSSION

A prospective cohort study was conducted in Department of Obstetrics and Gynaecology, Deen Dayal Upadhyay Hospital, New Delhi from April 2021 to June 2022. Women undergoing emergency caesarean section fulfilling the inclusion and exclusion criteria were included in the study. Informed consent was taken and they were subjected to detailed history taking, thorough examination- general, systemic and local, investigations.

A surgical bundle (Annexure- 2) was tried to be implemented in emergency caesarean deliveries. Patients were divided into two groups based on surgical bundle adherence and implementation. 310 patients were included in each group: - **Group 1(Surgical bundle not used)** and **Group 2 (Surgical bundle used)**. Data was collected in patient proforma and outcomes were observed for 30 days postoperative period. Data were analysed and statistically evaluated using SPSS software and results were compiled. The analysis of the outcome and discussion is as follows: -

Demography

In our study, most of the patients were in the age group of 25-30 years - 62.6% and 61.9% in Group 1 and Group 2 respectively (p-value 0.98) which was comparable to that of a study conducted by Temming et al[2] with mean age in partially applied bundle and fully applied bundle as 28.6 ± 5.8 years and 28.0 ± 5.7 years respectively (p-value 0.16)

In our present study, mean BMI in Group 1(Surgical bundle not used) and Group 2(Surgical bundle used) was 23.71 ±2.20 kg/m^2 and 23.70±2.21 kg/m^2 respectively (p-value 0.94).

The findings were similar to study conducted by Kaur et al[17], in which most patients were in BMI of 18.5-24.9 kg/m^2 (normal weight) – 91% and 93% in case and control respectively (p-value 0.6).

In our study, most patients had gestational age between 37-39 weeks- 71.6% in Group 1(Surgical bundle not used) and 69.4% in Group 2 (Surgical bundle used) (p-value 0.82). This was comparable to study by Kawakita et al[18] with mean

gestational age 38.5±2.6 weeks and 38.4±2.7 weeks respectively in pre implementation group and postimplementation group with a p-value of 0.61.

In our study, the percentage of primigravida patients in Group 1(Surgical bundle not used) and Group 2 (Surgical bundle used) was 25.5% and 20.8% respectively (p-value 0.33).

In a similar study by Temming et al[2], the percentage of primigravida patients in two groups was 25.2% and 25.8% respectively with p value of 0.85.

In our study, there was no significant difference in the baseline characteristics of patients in the two groups.

Risk factors

In our study, hypertensive disorders of pregnancy in Group 1(Surgical bundle not used) and Group 2 (Surgical bundle used) were present in 14.8% and 13.5% of patients respectively (p-value 0.64) and chronic hypertension in 2.6% and 3.9% respectively (p-value 0.49). In a study by Temming et al[2], patients with pregnancy-induced hypertension in two groups were 13.9% and 11.5% respectively (p-value 0.26) which was comparable to our study and chronic hypertension was present in 10.2% and 10.3% respectively (p-value 0.97) which is much higher than our study population. This difference may be there due to differences in population characteristics, race, ethnicity and other lifestyle differences.

In our study, anaemia in two groups was 28.1% and 23.9% respectively (p-value 0.23). GDM in the two groups was 3.9% and 2.6% (p-value 0.23). There was no significant difference in medical comorbidity between the two groups.

There was no significant difference in family history, dietary history, or usage of tobacco.

In our study, rupture of membranes was present in 37.7% and 37.4% of patients in Group 1(Surgical bundle not used) and Group 2 (Surgical bundle used)

respectively (p-value 0.93). This was comparable with a study conducted by Kawakita et al[57] in which rupture of membranes was present in 37.6% and 37.8% in pre implementation group and post-implementation group respectively (p-value 1.0)

There was no significant difference in the status of rupture of membranes, number of vaginal examinations done, duration of surgery, intraoperative blood loss and post-operative stay between the two groups.

In our study, the distribution of patients was equal in both groups (n=310 in each group) whereas in a study conducted by Temming only 349 patients out of 1082 patients received all measures (32.3%) and 733/1082 did not receive all measures (67.7%).

Surgical Site Infection

In our study, incidence of surgical site infection in Group 1(Surgical bundle not used) and Group 2 (Surgical bundle used) was 13.2% and 6.1% respectively (p-value <0.01). In a similar study conducted by Temming et al (2017), incidence of surgical site infection in patients who did not receive all measures was 6.9% and in fully applied measures group was 1.6% (6.9% vs1.6%, RR 3.74, 95% CI 1.18, 11.92)

In our study, incidence of superficial surgical site infection in Group 1(Surgical bundle not used) and Group 2 (Surgical bundle used) was 9.0% and 4.2% respectively whereas incidence of deep surgical site infection in Group 1(Surgical bundle not used) and Group 2 (Surgical bundle used) was 3.9% &2.2% respectively.

DIFFERENCE IN SSI BETWEEN TWO GROUPS AND COMPARISON WITH OTHER STUDIES (Table 17)

In our study, it was observed that there was a significant decrease in number of surgical site infections in the group where the surgical bundle was used (all three measures applied), rates in surgical bundle not used vs used were 41/310 (13.2%) vs 19/310 (6.1%) respectively with p-value <0.001.

In our study, all were emergency caesarean section which itself is a known risk factor for surgical site infection hence the rates in both groups are high as compared to other

studies. The high rate of surgical site infections can also be attributed to the fact that our study was based in referral hospital where maximum patients are high risk patients referred from peripheral hospitals.

In a similar study conducted by **Temming et al**[2] (2017), he used four evidence-based measures and found the number of surgical site infection to be 6.9% in the group where patients did not receive all four measures and 1.1% in those who received all four measures but, in that study, scheduled caesarean and unscheduled caesarean both were included.

Kawakita et al[18] [2019] conducted a quasi-experimental, pre-intervention and post-intervention study of women undergoing elective caesarean delivery with the implementation of a surgical bundle. In the unmatched cohort, women who underwent caesarean delivery in the post-implementation period compared to those in the pre-implementation period were less likely to have surgical site infections (2.2% [33/1,523] vs. 4.5% [73/1,624]; odds ratio 0.47 [95%CI 0.31–0.71]; P <.001

In a multidisciplinary team approach and project designed with evidence-based interventions by **Corbett et al**[19]- A care bundle was designed targeting preoperative personal patient preparation, preoperative prophylactic antibiotics, and strict skin preparation technique, all measured using a patient survey. It was found that surgical site infection rate decreased from 6.7% (n = 684 caesarean sections, n = 46 SSI) to 3.45% (n = 3,206 caesarean sections, n = 235 SSI), p = .0006. Reduction occurred in both elective (4.4%-2.7%) and emergency (9.1%-4.1%) caesarean section groups.

Ernest et al[20] studied the impact of multicomponent safe surgical interventions in Tanzania and it was observed that after implementation of safe surgical interventions, SSI after CS reduced from 14% baseline to 1% (p=0.002).

In our study, we observed that adherence to the surgical bundle was associated with reduced overall risk of surgical site infection after caesarean delivery; the reduction in risk was 53.8% (13.2% vs 6.1%). The effect on superficial surgical site infection was even greater i.e. 56.7% reduction (9% vs 3.9%). In deep superficial infection reduction in risk was 47.7% (4.2% vs 2.3%). The rate of organ/space surgical site infection was

zero in our study which may be attributed to our exclusion criteria of excluding known high-risk factors.

STRENGTHS:

Most of the previous studies used a number of measures which are impossible to perform in a setting where majority are emergency caesarean deliveries and time is less to perform all measures. In our study, the proposed surgical bundle comprised of three evidence-based measures which are feasible, easy to use and can be implemented easily in a setting like ours which is a government facility with a huge patient load, less staff, busy OT and other constraints.

Literature suggests that antibiotics should be given within 0- 60 minutes prior to skin incision but in a busy setup with huge patient load, planned patient gets postponed due to some other more emergent caesarean section, so one is unable to maintain this timeframe. In our surgical bundle, we used preoperative antibiotic at the time of skin incision to ensure this. (sensitivity testing may be done before i.e., at the time of admission)

LIMITATIONS

The literature on evidence-based bundles to reduce surgical site infection after caesarean delivery is limited and there is significant heterogeneity between other studies which makes it difficult to determine which bundle components are additive, synergistic, or neutral. The heterogeneity is most likely attributable to clinical variation in the way interventions were implemented and differences in bundle contents.

In addition, the sample size for this study was fixed and we did not evaluate each evidence-based measure and it's outcome with respect to composite outcome.

High rate of SSI in our patients means our findings may not be applicable to clinical settings with low-risk patients and developed countries.

Because bundles are a group of evidence-based interventions implemented as a whole, these results represent the collective effect of the interventions rather than any singular intervention. Future research can focus on which components and combinations of bundles are most efficacious.

CONCLUSION

There was significant decrease in number of surgical site infection in the group where surgical bundle was used and it was observed that adherence to the proposed surgical bundle was associated with a 53% overall reduction of surgical site infections after caesarean delivery.

As there is more than 50% reduction in rates of surgical site infection it is concluded that use of a combination of evidence based surgical measures significantly reduce surgical site infection in caesarean deliveries.

However, in our study it was observed that even when women received all measures of surgical bundle, the rate of surgical site infection remained high which is explained by the fact that our study was conducted in a referral hospital where most of the patients are high risk patients being referred from other hospitals and also by the fact that all patients in our study were emergency caesarean deliveries which itself is a known risk factor for surgical site infection. The findings highlight the need for additional innovative interventions to reduce surgical site infection in Emergency caesarean deliveries who remain at risk for surgical site infection even after receiving current surgical bundle.

AUTHOR CONTRIBUTIONS

1. **DR. SNEH TANWAR [MBBS, DNB] –** performed study, collected data, performed analysis, data interpretation, drafted the manuscript.
2. **DR. HARVINDER KAUR [MD, DNB]-** conceptualized the study, designed the methodology, reviewed the manuscript.
3. **DR. NEETA BINDAL [MD]-** conceptualized the study, provided critical feedback on the study

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TABLES AND FIGURES

Table-1: Distribution of age between the groups

Age in years	Surgical bundle not used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
<25	83	26.8	85	27.4	0.98
25-30	194	62.6	192	61.9	
>30	33	10.6	33	10.6	

[1]Chi-square test

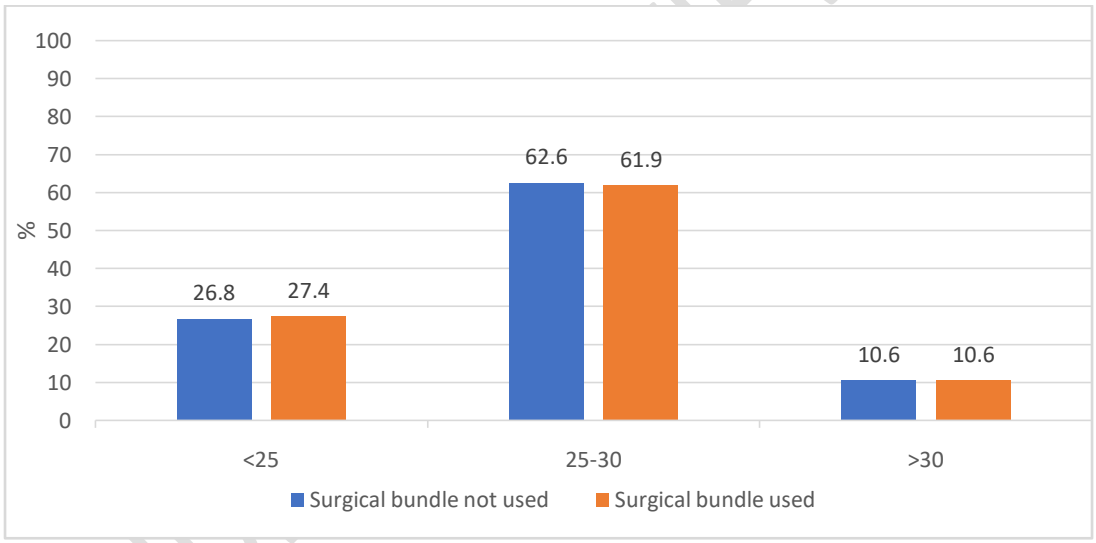


Fig. 1: Distribution of age between the groups

Table-2: Comparison of anthropometric parameters between the groups

Anthropometric parameters	Surgical bundle not used (n=310)	Surgical bundle used (n=310)	p-value[1]
Height in cms	155.08±3.80	154.88±3.85	0.51
Weight in kgs	56.89±5.34	56.72±5.36	0.68
BMI in kg/mtr^2	23.71±2.20	23.70±2.21	0.94

Unpaired t test used

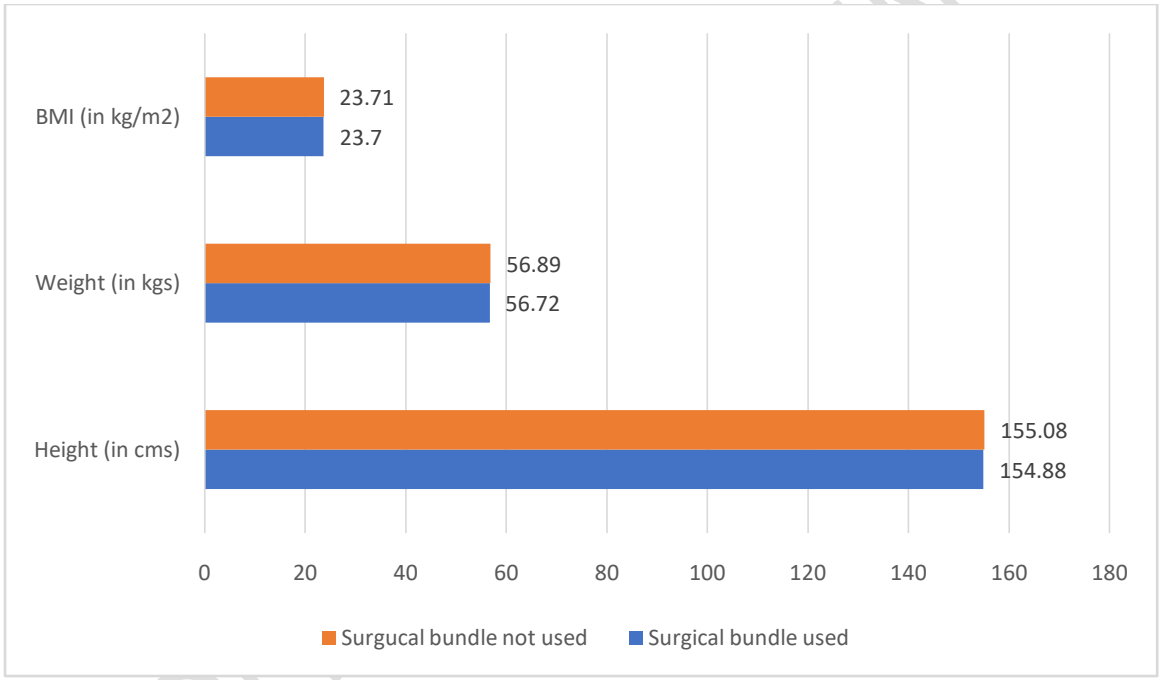


Fig. 2: Comparison of anthropometric parameters between the groups

Table-3: Comparison of gestational age between the groups

Gestational	Surgical bundle not used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
34-36 weeks	19	6.1	20	6.5	0.82
37-39 weeks	222	71.6	215	69.4	
40-41 weeks	69	22.3	75	24.2	

[1]Chi-square test

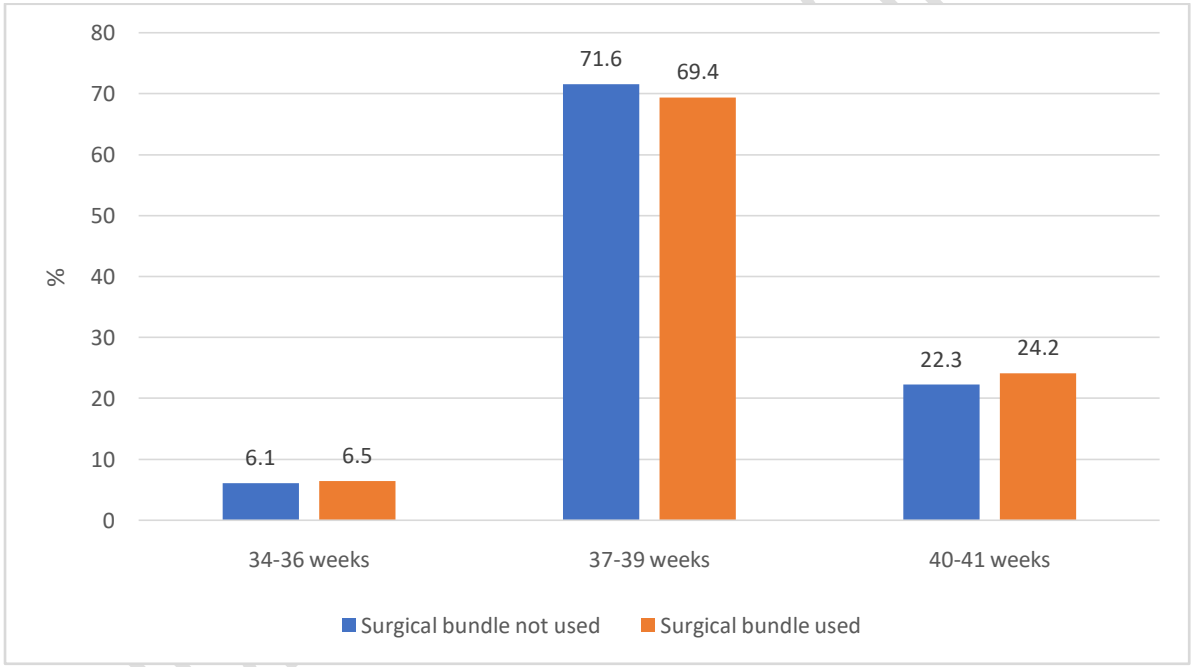
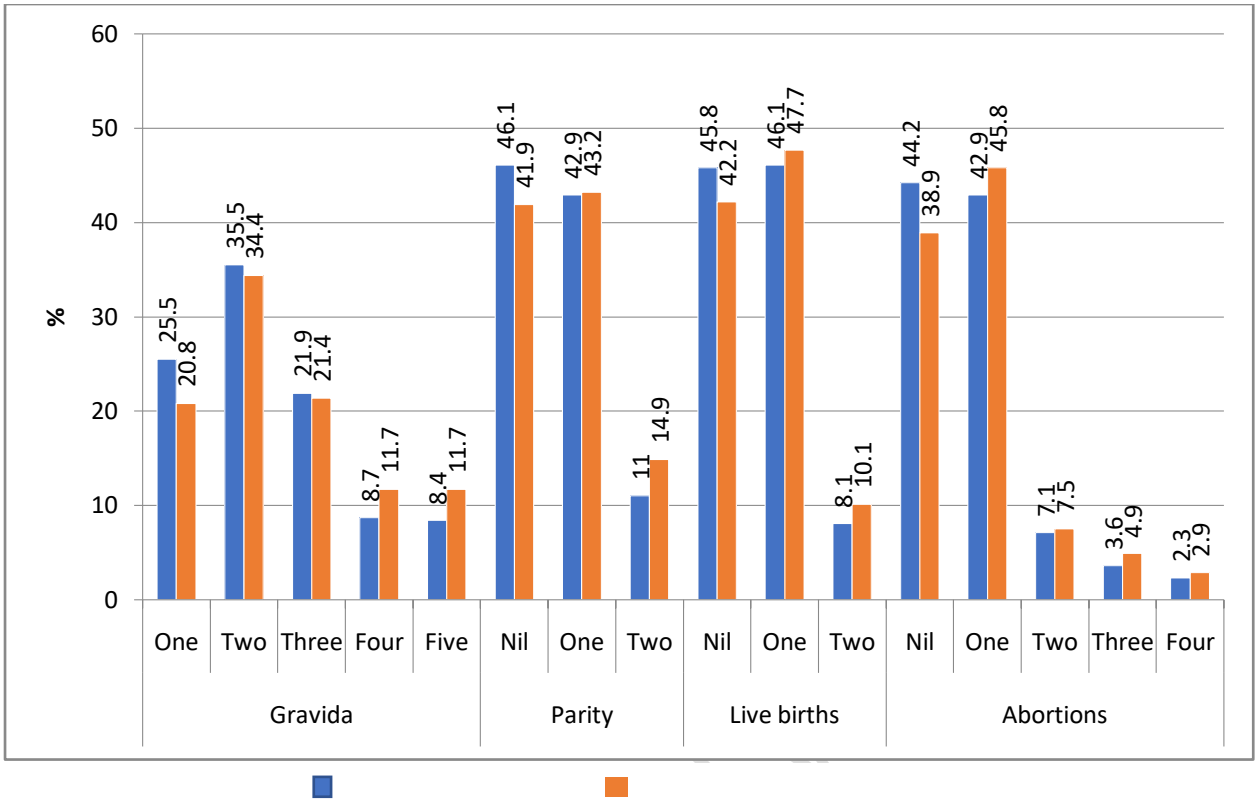


Fig. 3: Comparison of gestational age between the groups.

Table-4: Comparison of Obstetric History between the groups

Obstetric History	Surgical bundle not used (n=310)		Surgical bundle used (n=308)		p-value[1]
	No.	%	No.	%	
Gravida					
One (primi)	79	25.5	64	20.8	0.33
Two	110	35.5	106	34.4	
Three	68	21.9	66	21.4	
Four	27	8.7	36	11.7	
Five	26	8.4	36	11.7	
Parity					
Nil	143	46.1	129	41.9	0.28
One	133	42.9	133	43.2	
Two	34	11.0	46	14.9	
Live births					
Nil	142	45.8	130	42.2	0.54
One	143	46.1	147	47.7	
Two	25	8.1	31	10.1	
Abortions	n=310		n=306		
Nil	136	44.2	119	38.9	0.69
One	132	42.9	140	45.8	
Two	22	7.1	23	7.5	
Three	11	3.6	15	4.9	
Four	7	2.3	9	2.9	

[1]Chi-square test



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475 **Fig. 4: Comparison of Obstetric History between the groups**

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Table-5: Medical comorbidity between the groups

Medical comorbidity	Surgical bundle not used (n=310)		Surgical bundle used (n= 310)		p-value[1]
	No.	%	No.	%	
HDP	46	14.8	42	13.5	0.64
GDM	12	3.9	8	2.6	0.49
Hypothyroidism	22	7.1	16	5.2	0.40
IHCP	18	5.8	22	7.1	0.62
Anemia	87	28.1	74	23.9	0.23
Chronic hypertension	8	2.6	12	3.9	0.49

Chi square of fisher exact test used

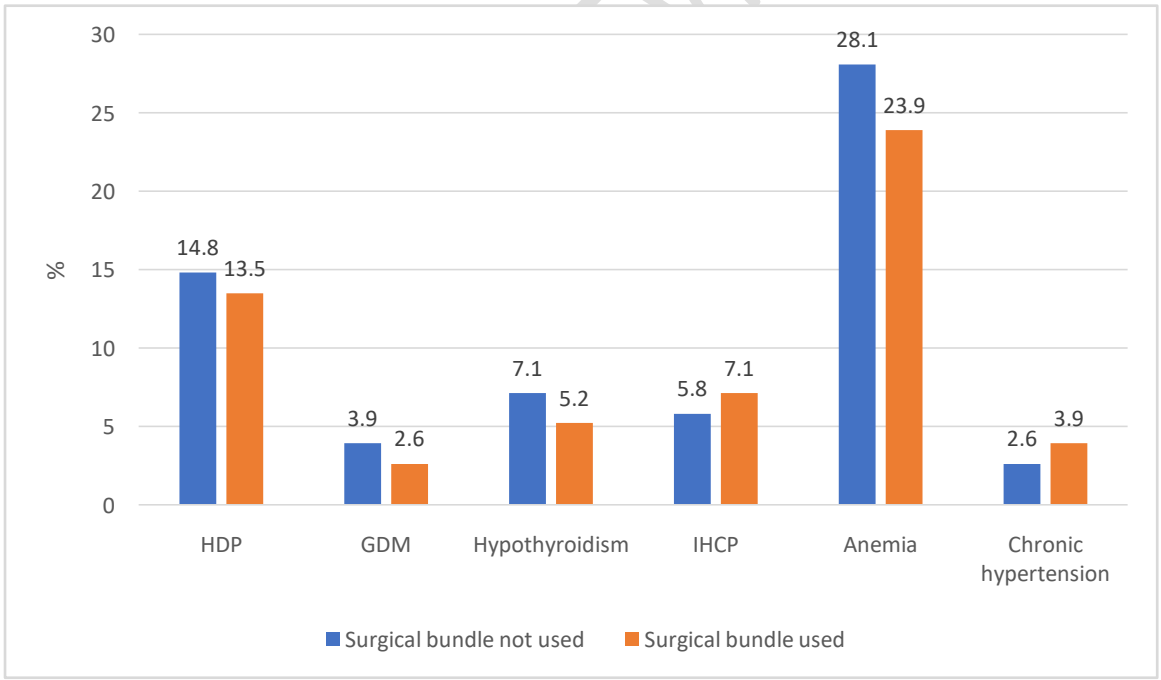

Fig. 5: Comparison of medical comorbidities in two groups.

Table-6: Comparison of Previous caesarean section between the groups

Caesarean section	Surgical bundle not used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
Present (previous caesarean)	86	27.7	102	33.0	0.15
Absent (Primary caesarean)	224	72.3	207	67.0	

[1]Chi-square test

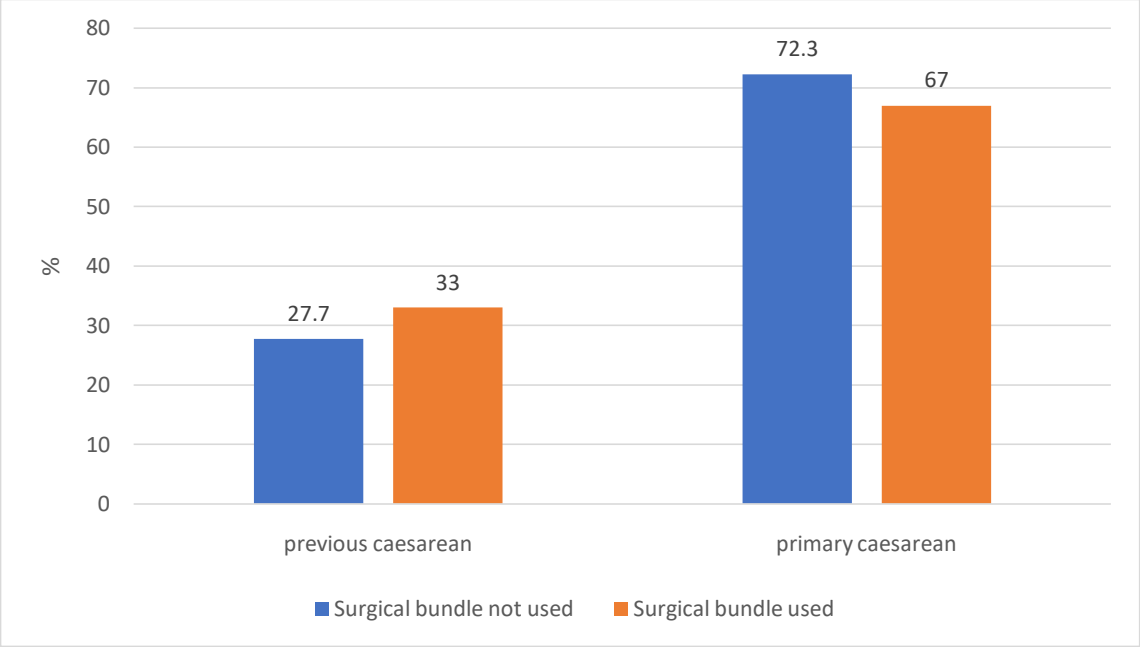

Fig. 6: Comparison of Previous caesarean section between the groups.

Table-7: Comparison of Socio-economic status between the groups

SES	Surgical bundle used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
Lower	88	28.4	82	26.4	0.5
Upper lower	133	42.9	142	45.8	
Lower middle	83	26.8	78	25.2	
Upper middle	6	1.9	8	2.6	
Upper	0	0	0	0	

[1]Chi-square test

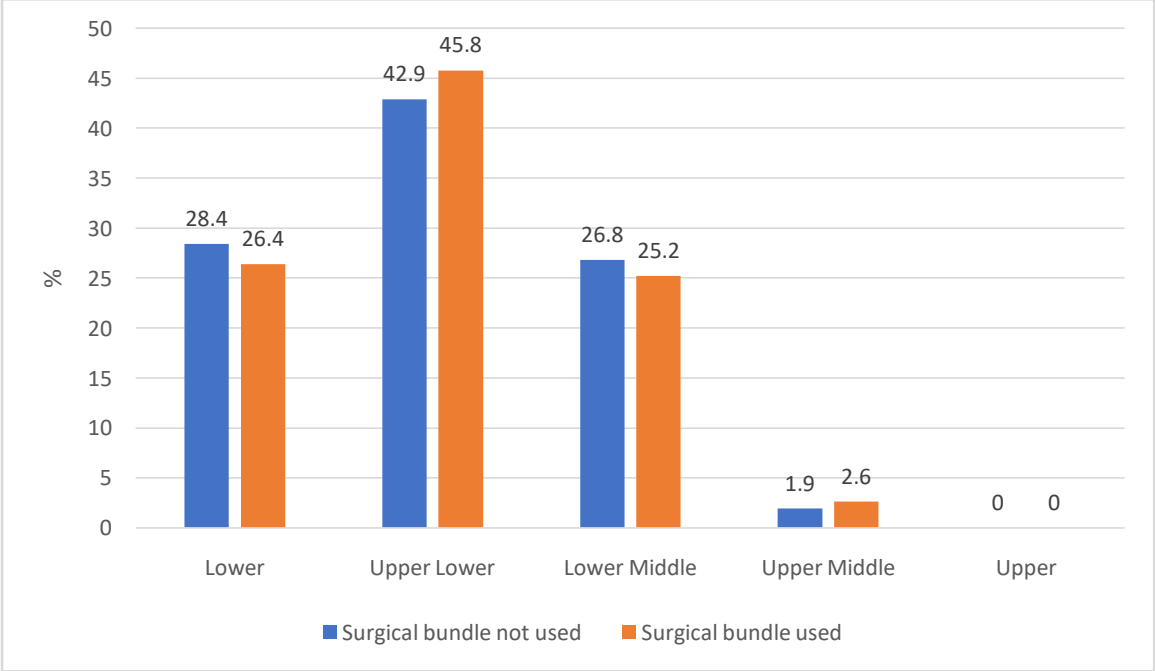

Fig. 7: Comparison of SES between the groups

Table-8: Comparison of family History between the groups

Family History	Surgical bundle not used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
DM	3	1.0	3	1.0	0.70
HTN	14	4.5	13	4.2	
OTHER	2	0.64	6	1.9	
None	291	93.9	288	92.9	

[1]Chi-square test

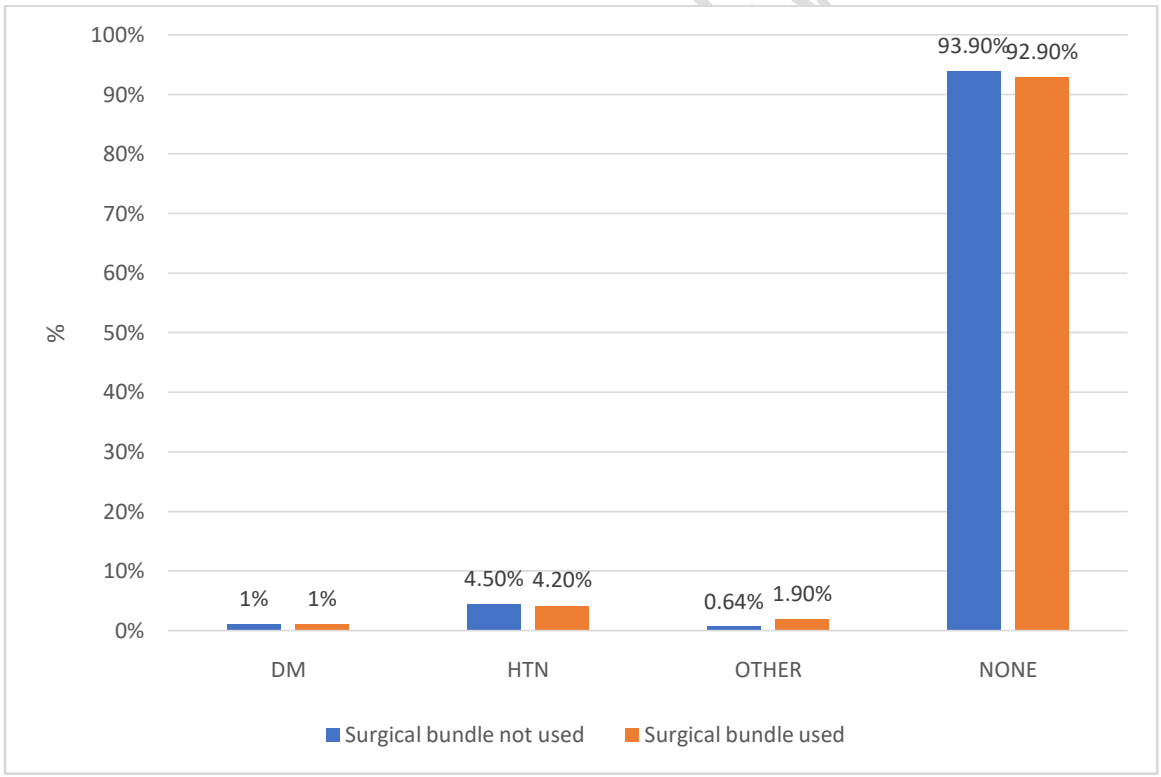

Fig. 8: Comparison of family History between the groups

Table-9: Comparison of dietary habit between the groups

Dietary habit	Surgical bundle not used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
Mixed	258	83.2	256	82.6	0.83
Vegetarian	52	16.8	54	17.4	

[1]Chi-square test

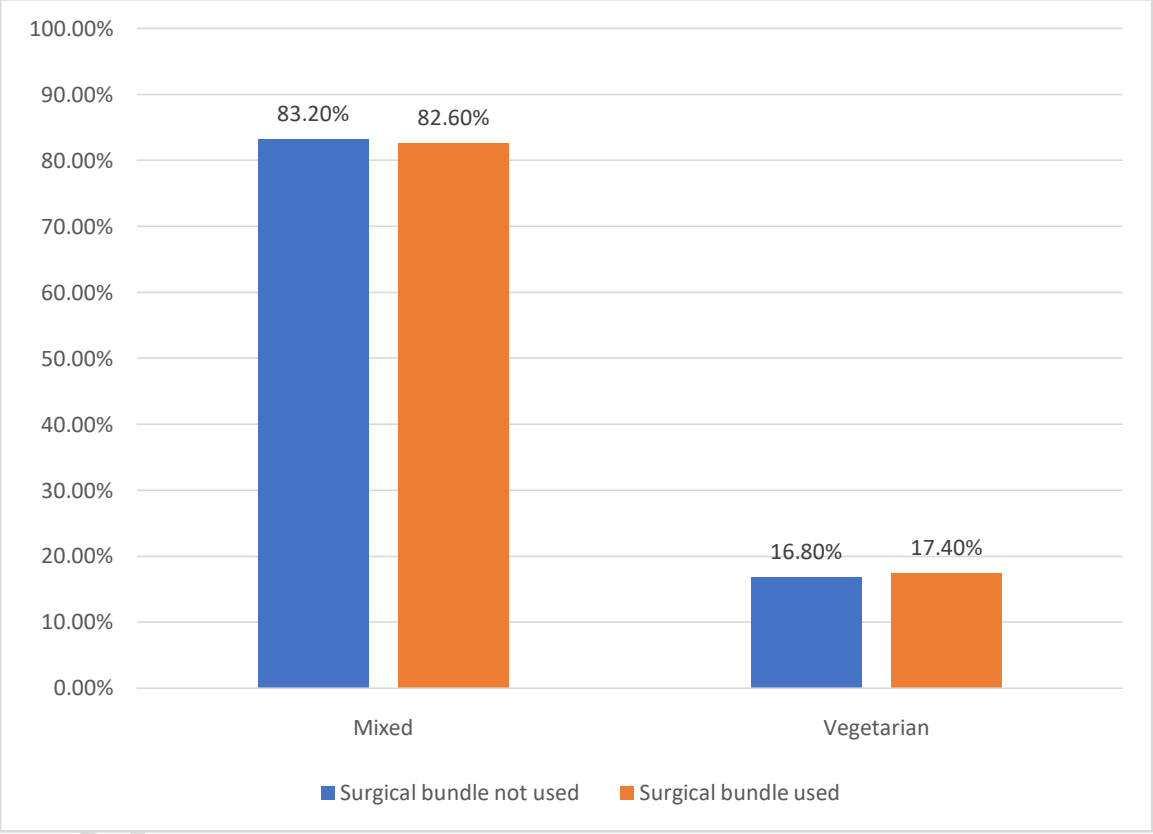

Fig. 9: Comparison of dietary habit between the groups

Table-10: Comparison of rupture of membranes between the groups

Comorbidity	Surgical bundle partially used (n=310)		Surgical bundle fully used (n=310)		p-value[1]
	No.	%	No.	%	
Leaking per vaginum (<18HRS)	117	37.7	116	37.4	0.93

[1]Chi-square test

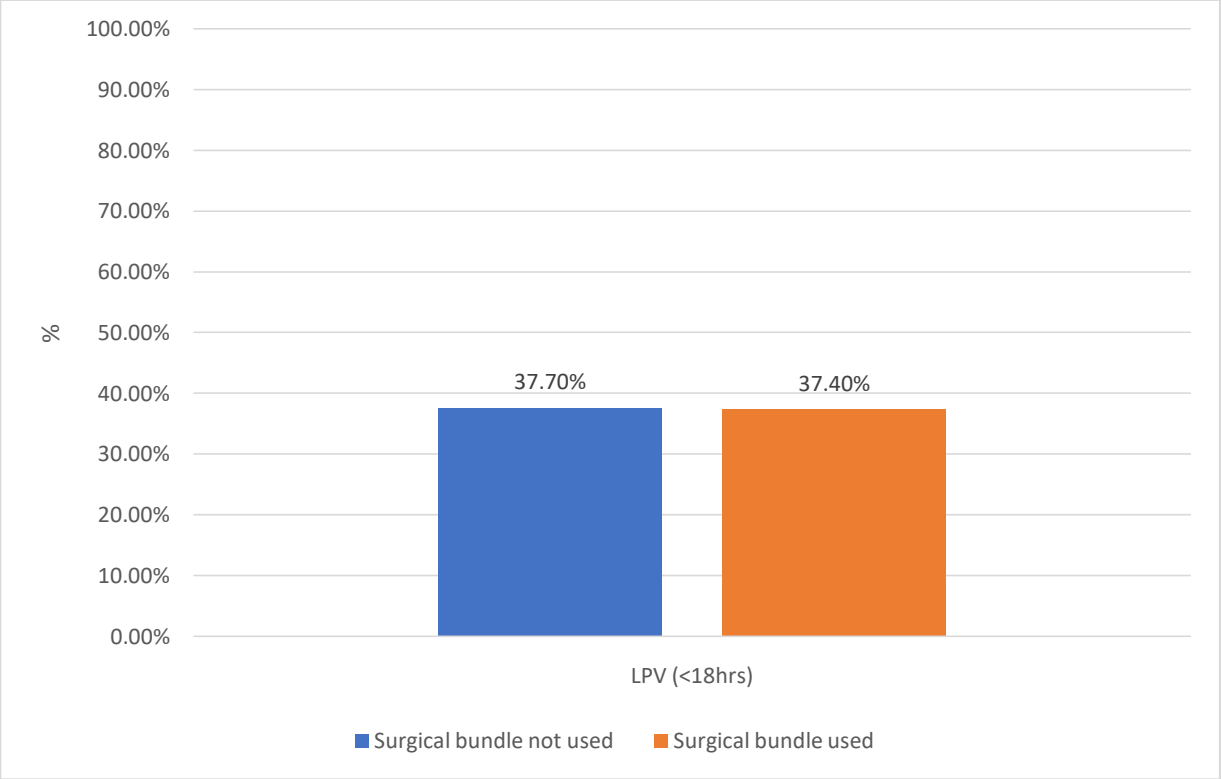

Fig. 10: Comparison of rupture of membranes between the groups

Table-11: Comparison of Intraoperative blood loss between the groups

	Surgical bundle not used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
<1000ml	215	69.4	217	70.0	0.86
≥1000ml	95	30.6	93	30.0	

[1]Chi-square test

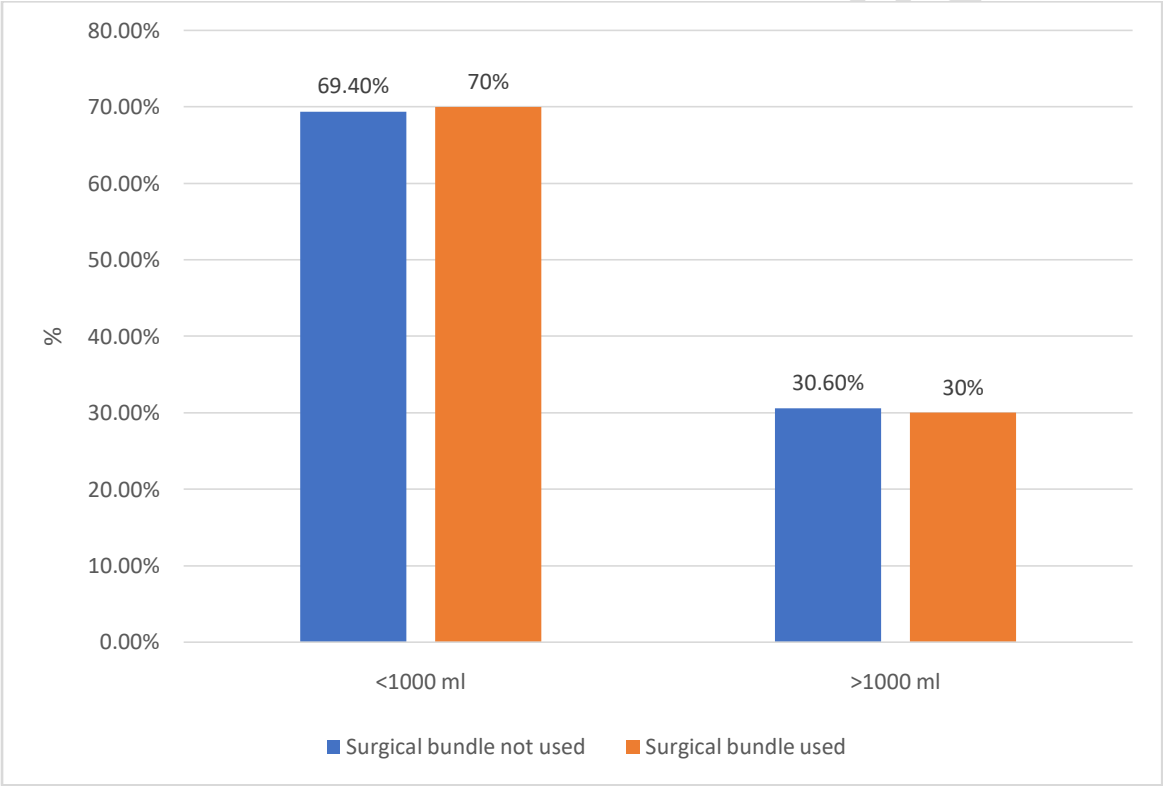

Fig. 11: Comparison of Intraoperative blood loss between the groups

Table-12: Comparison of Duration of surgery between the groups

	Surgical bundle not used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
<45 minutes	108	34.9	118	38.1	0.40
≥45 minutes	202	65.1	192	61.9	

[1]Chi-square test

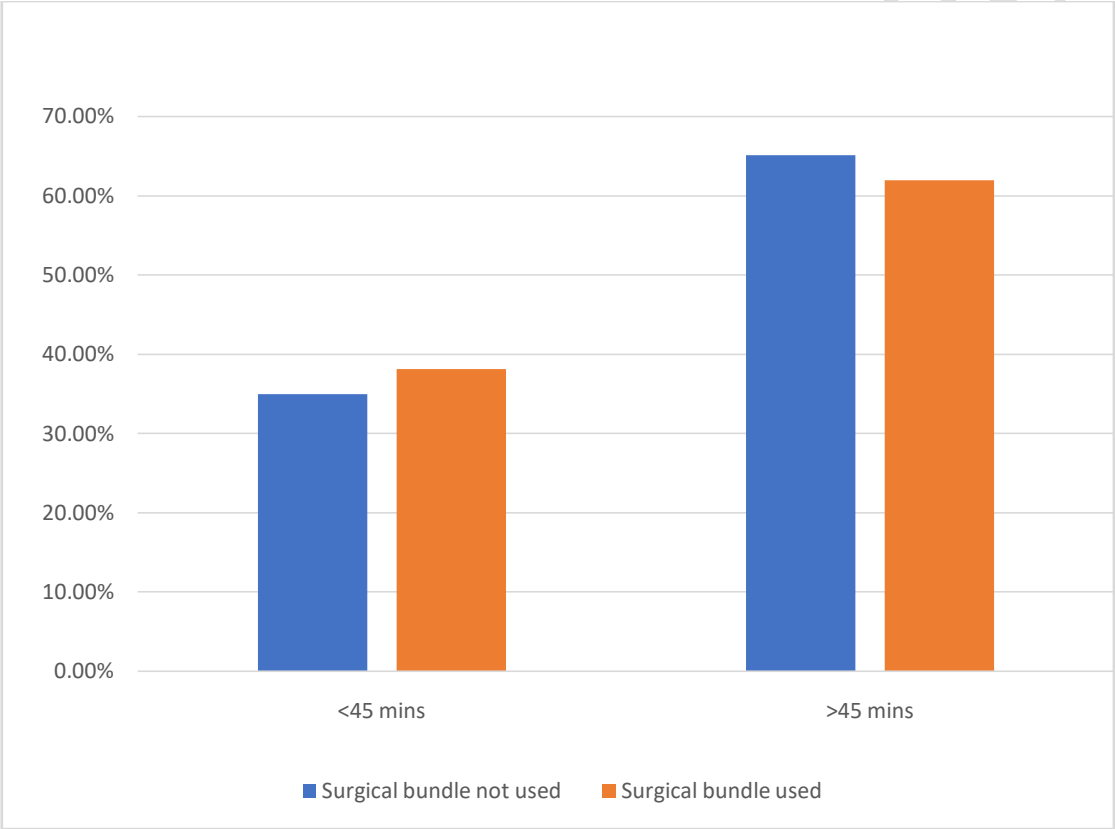

Fig. 12: Comparison of Duration of surgery between the groups

Tobacco use is nil in both the groups

Table-13: Comparison of Post-operative stay between the groups

Post op stay	Surgical bundle partially used (n=310)		Surgical bundle fully used (n=310)		p-value[1]
	No.	%	No.	%	
<3 days	129	41.6	128	41.3	0.93
≥3 days	181	58.4	182	58.7	

[1]Chi-square test

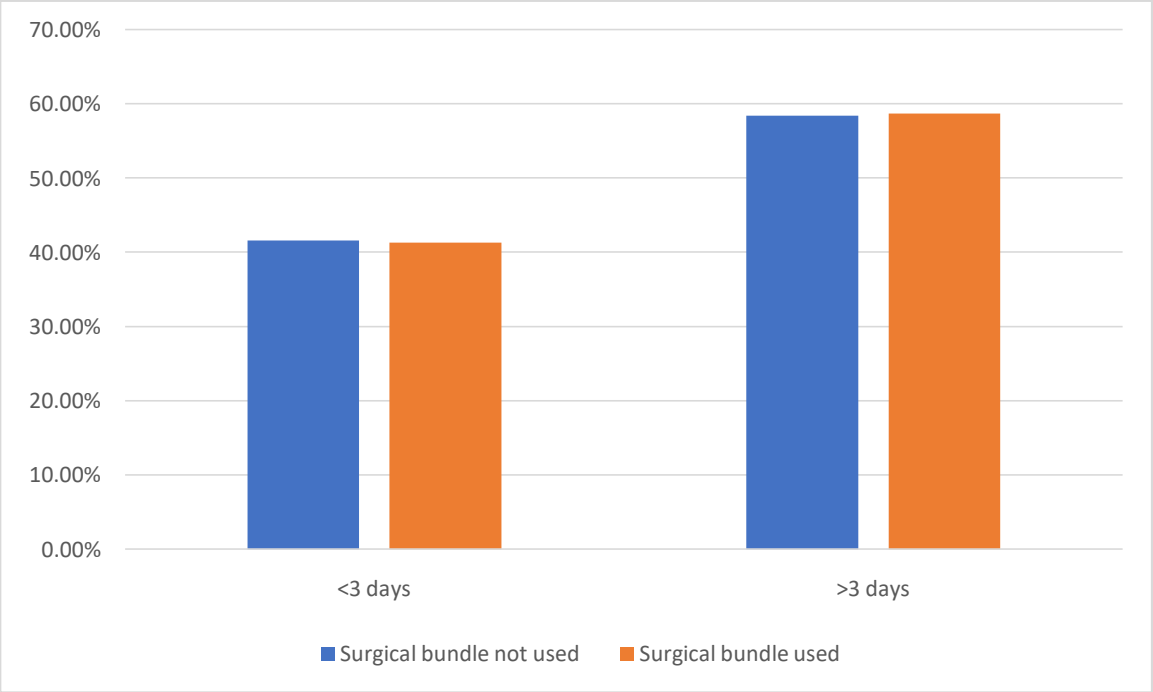

Fig. 13: Comparison of Post-operative stay between the groups

549 **Table-14: Comparison of Vaginal examinations between the groups**

	Surgical bundle not used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
PV >5	65	21.0	63	20.3	0.84
PV <5	245	79.0	247	79.7	

550 [1]Chi-square test

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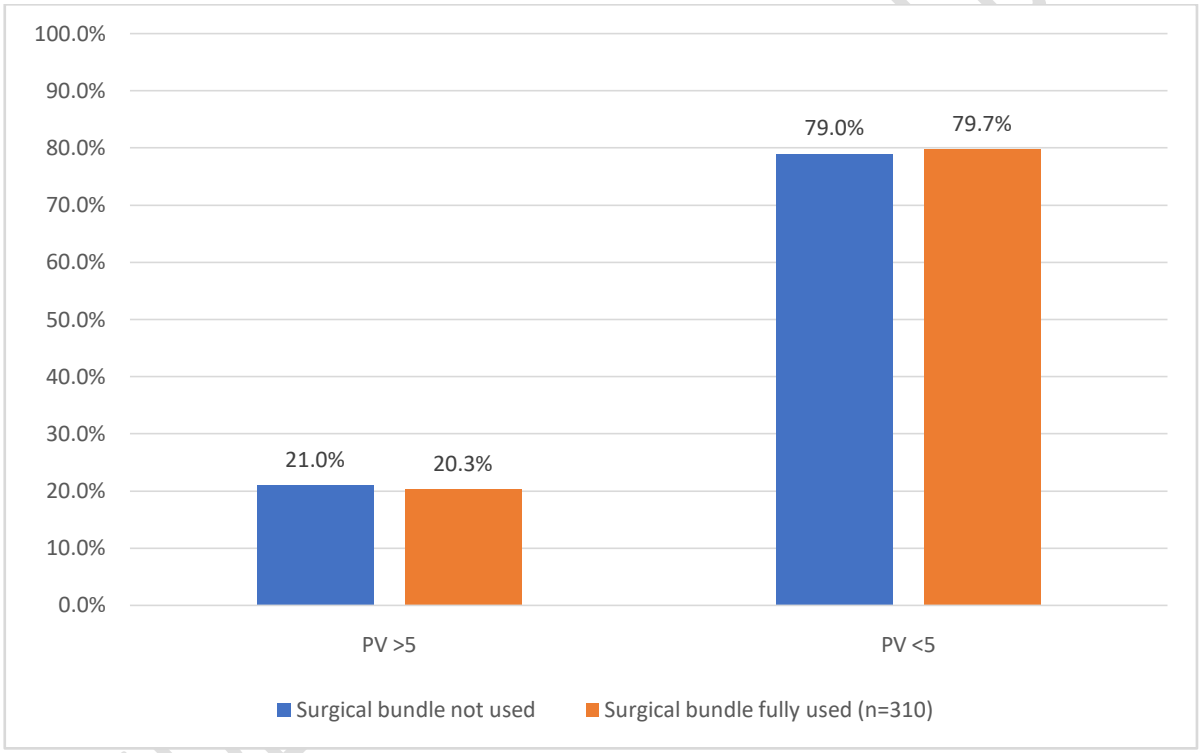

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553 **Fig. 14: Comparison of Vaginal examinations between the groups**

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Table-15: Comparison of Surgical site infection between the groups

Surgical site infection	Surgical bundle partially not used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
Yes	41	13.2	19	6.1	<0.01*
No	269	86.8	291	93.9	

[1]Fisher exact test, *Significant

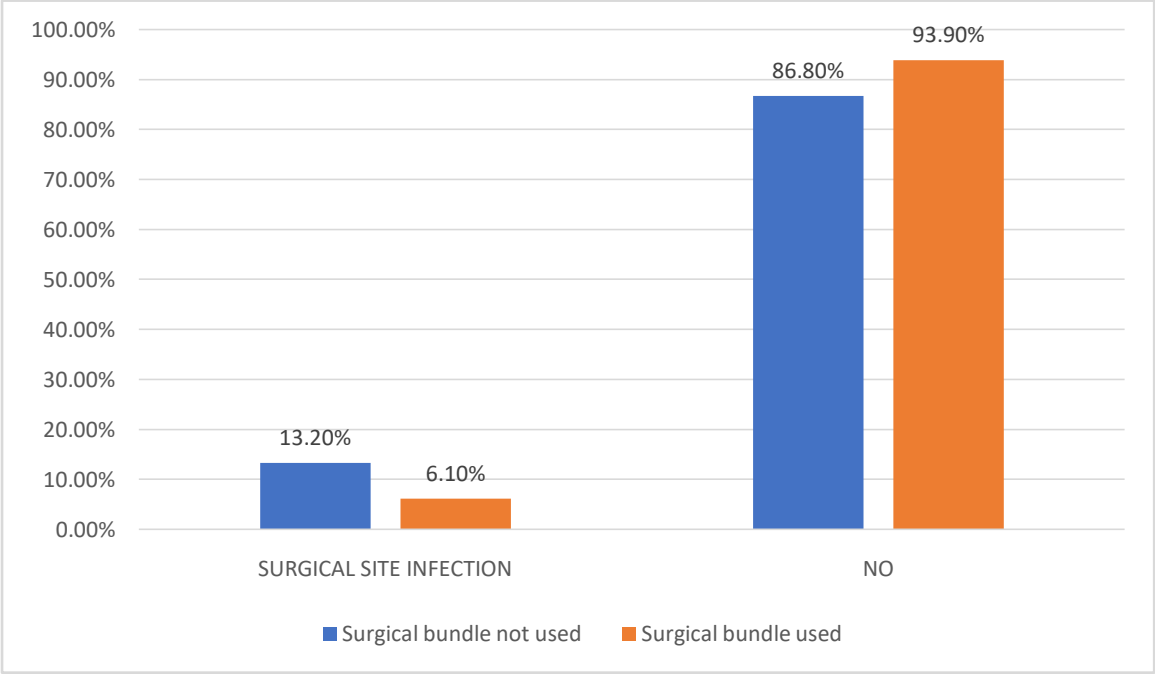

Fig. 15: Comparison of Surgical site infection between the groups

Table-16: Comparison of type of Surgical site infection between the groups

Type of Surgical site infection	Surgical bundle partially used (n=310)		Surgical bundle used (n=310)		p-value[1]
	No.	%	No.	%	
Superficial SSI	28	9.0	12	3.9	0.77
Deep SSI	13	4.2	7	2.2	

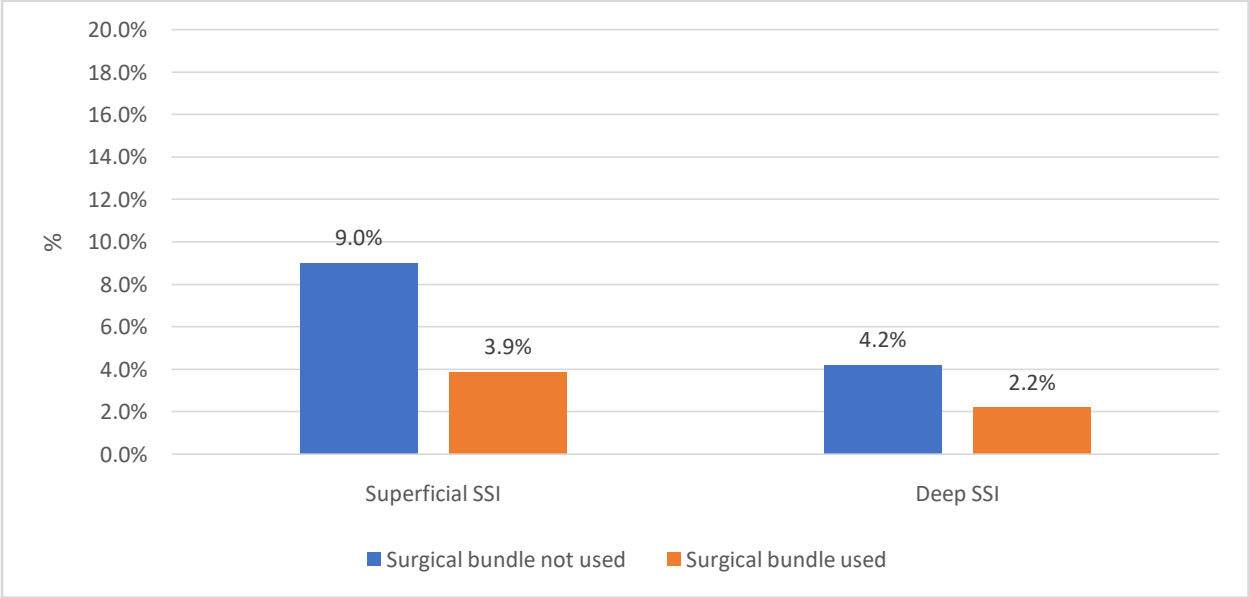

Fig-16: Comparison of type of Surgical site infection between the groups

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569 **Table 17: Surgical site infection rates in various studies**

	Rate of Surgical site infection (SSI)		
Study	Surgical bundle not used / Not all measures in bundle used	All measures in surgical bundle used	p value
Our study (2021-22)	13.2%	6.1%	<0.001
Temming et al[2] (2017)	6.9%	1.1%	<0.001
Kawakita et al[18] (2019)	4.5%	2.2%	<0.001
Corbett G.A et al[19] (2020)	6.7%	3.45%	0.006
Ernest et al[20] (2021)	14%	1%	0.002

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ANNEXURE 1: Outcome Definition (Surgical Site Infection Definition Criteria)

Outcome	Definition
Surgical Site Infection (SSI:)	**Centers for Disease Control and Prevention National Healthcare Safety Network Definition:** [35] Infection occurs within 30 days after operative procedure AND
Superficial SSI	Involves only skin and subcutaneous tissue of the incision; AND patient has at least one of the following: **a.** Purulent drainage from the superficial incision, **b.** Organisms isolated from an aseptically-obtained culture from the superficial incision or subcutaneous tissue, **c.** Superficial incision that is deliberately opened by a surgeon, attending physician, or other designee and is culture-positive or not cultured; and patient has at least one of the following signs or symptoms: pain or tenderness; localized swelling; erythema; or heat. A culture- negative finding does not meet this criterion, **d.** Diagnosis of a superficial incisional SSI by the surgeon or attending physician
Deep Incisional SSI	Involves deep soft tissues of the incision (e.g., fascial and muscle layers; AND patient has at least one of the following: **a.** Purulent drainage from the deep incision, **b.** A deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, attending physician, or other designee and is culture positive or not cultured; and patient has at least one of the following signs or symptoms: fever (>38 degrees C), localized pain, or tenderness. A culture negative finding does not meet this criterion, **c.** An abscess or other evidence of infection that is detected on gross anatomical or histopathologic exam, or imaging test
Organ/Space SSI	The infection appears to be related to the operation and the infection involves any part of the anatomy (organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following: **a.** Purulent drainage from a drain placed in the organ/space **b.** Organisms isolated from an aseptically obtained culture of the organ/space **c.** An abscess or any other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination **d.** Diagnosis of an organ/space SSI by a surgeon or attending physician **e.** Endometritis, defined as maternal temperature >38.0 ° C on two occasions over a four-hour period, or any temperature > 39.0° C over a period of >12 hours after delivery with associated uterine tenderness, was considered organ/ space SSI

Annexure 2:- Surgical Bundle that will be used in the study

S.No.	Evidence based measure	Compliance (YES/NO)	Remarks
i.	Preoperative antibiotic prophylaxis: -Inj Ceftriaxone 1gm i.v after skin sensitivity testing at the time of skin incision		
ii.	Preoperative vaginal cleaning with 5% betadine after Foleys catheterisation and before abdominal scrubbing		
iii.	Chlorhexidine 2.5% + alcohol 70% skin preparation		

Annexure 3 :- Patient details (Proforma)

Serial number: Registration number:

Name of the Patient: Age:

Address:

Phone Number-

Socio-Economic status-L/UL/LM/UM/U

Education: Illiterate /Primary/ Middle/ High scchool/ Intermediate/ Diploma/ Graduate/Professional degree

LMP: POG:

Obstetric History: G P A L D

Menstrual History:

Past History: DM/HTN/Thyroid/TB/Chronic illness/ Br Asthma

Surgical History:

Family History: DM/HTN/TB

Personal History: Pure Veg/ mixed diet/Non-Veg

Tobacco use-

Examination:

Height: Weight: BMI:

Vitals: Pulse- B.P- Temp- R/R-

Pallor- Icterus- Lymphadenopahy- Clubbing - Edema –

Systemic Examination:

CNS: Per abdomen:

CVS: Per vaginal (if reqd.)

RS:

Investigations:

BG with Rh typing:

Haemoglobin:

VDRL: Reactive/Non-Reactive

HIV: : Reactive/Non-Reactive

HBsAG: : Reactive/Non-Reactive

Glucose Challenge Test(2hrs after 75gm glucose):

TSH:

Urine(R/M):

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RISK FACTORS	COMMENT
MATERNAL AGE	
PARITY	
P.O.G	
HAEMOGLOBIN	
CHRONIC HYPERTENSION	
PREGNANCY INDUCED HYPERTENSION	
PREMATURE RUPTURE OF MEMBRANES <18HRS	
TYPE OF CS	ELECTIVE/ EMERGENCY
INDICATION OF CS	
TYPE OF SKIN INCISION	LONGITUDINAL/ PFANNELSTEIL
LENGTH OF INCISION	
PREVIOUS CS	
INTRA-OPERATIVE BLOOD LOSS	
DURATION OF SURGERY	
OBESITY +/-	
TOBACCO USE +/-	
BLOOD TRANSFUSION	
POST-OPERATIVE HOSPITAL STAY	
NUMBER OF PV DONE	

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630 **Annexure 4: Surgical site infection surveillance post-operative data**
631 **collection form**

	POD-3	Suture removal	6 WEEKS	OTHER VISIT (if signs/ symptoms develop)
☐ **Superficial SSI** (skin/subcutaneous) e.g. cellulitis ☐ Purulent drainage (pus) from superficial incision **OR** ☐ Organism identified (if culture done) **OR** ☐ Superficial incision deliberately re-opened **AND** ☐ Infection symptoms[a] **OR** ☐ Surgeon/attending physician diagnosis				
☐ **Deep SSI** (fascia/muscle) e.g. deep abscess ☐ Purulent drainage (pus) from deep incision **OR** ☐ Deep incision dehiscence or deliberately opened by surgeon **AND** ☐ Organism identified (if culture done) **AND** ☐ Infection symptoms[a] **OR** ☐ Deep infection/abscess found on imaging/examination				
Organ/space SSI ☐ Deeper than fascia/muscle e.g. endometritis (organ), peritonitis (space) ☐ Purulent drainage (pus) from sterile organ or space (from an inserted drain) **OR** ☐ Organ or space infection/abscess found on imaging/examination **OR** ☐ Organism identified from fluid/tissue from organ/ space				

Microbiology Culture results Specimen taken- • Date • Type Organism (s) identified Antibiotic resistance /sensitivities				
Remarks				

a.) Infection symptoms – pain/ tenderness/ localised swelling/erythema/warm to touch/ discharge from wound/ fever> 38^{o} C (100.4^{o} F)

PATIENT INFORMATION SHEET

DEEN DAYAL UPADHYAY HOSPITAL

HARI NAGAR, NEW DELHI-110064

TOPIC: "TO STUDY THE EFFECTIVENESS OF SURGICAL BUNDLE IN REDUCING SURGICAL SITE INFECTION IN CAESAREAN DELIVERIES"

Patient name: Age/sex: CR number:

Son/Daughter/Wife of: Date:

You are being invited to participate in a research study.

Before you take part in this research study, we wish to explain the study to you and give you the chance to ask questions. Please read the information provided here. If you agree to participate, please sign the informed consent form.

Title: 'To study the effectiveness of surgical bundle in reducing Surgical Site Infection in caesarean deliveries.'

Background & purpose of the study: The study is being conducted to study the effectiveness of surgical bundle in reducing Surgical Site Infection in caesarean deliveries.

Study procedure and visit schedule: It's a prospective study which will be conducted in Department of Obstetrics and Gynaecology, DDUH, Hari Nagar, New Delhi. Women undergoing emergency caesarean section with POG $\geq$ 28 weeks with live baby will be enrolled for study. Preoperative infection prevention measures will be applied to the patients. All the patients will be followed on 3rd day, at time of suture removal and at 6 weeks post caesarean and both groups will be compared for surgical site infections.

Drugs used and their side-effects : The study doesn't cause any harm to the baby and the mother, and no unnecessary investigations and medication is given to the patient. The study will use Betadine solution, Chlorhexidine-alcohol based antiseptic solution and Ceftriaxone antibiotic. Before giving Ceftriaxone and using Betadine or Chlorhexidine-alcohol solution, sensitivity testing will be done. The antibiotic or solution will not be used if patient is found allergic to them, patient will not be included in the study and will be managed according to best possible treatment.

Common side effects of Betadine solution and Chlorhexidine solution are skin inflammation, redness, burning, irritation of skin, allergic reaction and anaphylaxis.

Common side effects of Ceftriaxone are rash, diarrhoea, nausea, vomiting, stomach upset, change in taste, allergic reaction and anaphylaxis.

Freedom to participate: You are free to participate or not to participate. If you or your patient chooses not to participate, you will still receive the usual care. Also, you can freely opt out of the study any time during the whole study period. It will not affect the usual care given for your medical problem.

If you take part- There will be no extra hospital stay, no extra visit to the hospital, no extra investigation compared to if you were not taking part in the study.

Complications/ Risks: No complication or risk is perceived.

Cost of participation: No cost will be incurred by participation in this study. As this is a Government Institute, the cost of additional investigation and treatment will be borne by the Government only. There will be no financial burden, no extra hospital stay, no extra visit to the hospital, no extra investigation compared to if you were not taking part in the study.

Confidentiality of Study and Medical Records -Your name or full house address will not be identifiable. Your identification, personal information will be kept confidential during and after the study. Data will be stored securely and will be made available only to the person conducting the study and to the regulatory authorities. The results of the study and related information may be used for academic publication and presentations purpose only and not for any commercial use. Any publication and presentations of data in a scientific forum will not reveal any of your personal details.

Compensation : No compensation will be provided to the participants for their participation in the study.

For further information /complaint about the study -In case you/your patient feels that you or your patient have not been adequately informed as to the risks, benefits, alternative procedures or rights as a subject or feel under pressure to continue against your wishes, or should you have any complaint or concern related to study, you can contact -

Principal Investigator: Dr. Sneh Tanwar,
DNB DDUH
Phone no.8826702746

Guide- Dr. Neeta Bindal
CMO (SAG)
Deptt. Of Obstt & Gynae

रोगी सुचना पत्र
दीन दयाल उपाध्याय अस्पताल ,
हरी नगर- नई दिल्ली

रोगी का नाम: सी आर नंबर:

पुत्र /पुत्री :

दिनांक :

आपको इस शोध अध्यन में भाग लेने के लिए आमंत्रित किया गया है| इससे पहले की आप इसमें भाग ले, हम आपको इस शोध अध्यन के बारे में बताना चाहते है। कृपया दी गयी जानकारी को पढ़े | अगर आप भाग लेने के लिए सहमत है तो रोगी सुचना सहमति फॉर्म पर हस्ताक्षर कर दे |

शीर्षक : **TO STUDY THE EFFECTIVENESS OF SURGICAL BUNDLE IN REDUCING SURGICAL SITE INFECTION IN CAESAREAN DELIVERIES**.

पृष्ठभूमि व शोध का उद्देश्य :- ऑपरेशन के घाव में इन्फेक्शन को कम करने वाले तरीको के इस्तेमाल से यह देखना के देखना वह कितने प्रभावशाली है।

शोध अधययन की विधि व अस्पताल आने का समय :- यह शोध दीन दयाल उपाध्याय अस्पताल , हरी नगर के प्रसूति विभाग में होगा। जिन महिलाओं के २८ हफ्ते या उससे ज़्यादा के जीवित बच्चे के जन्म के लिए इमरजेंसी / आपातकालीन सीजेरियन ऑपरेशन होगा उन महिलाओ को अध्ययन में लिया जायेगा। ऑपरेशन के घाव पर होने वाले इन्फेक्शन/ संक्रमण से बचने के कुछ तरीको का इस्तेमाल किया जाएगा। महिलाओ को ऑपरेशन के तीसरे दिन , ताके काटने के समय , ऑपरेशन के ६ हफ्ते पर या इन्फेक्शन के लक्षण आने पर अस्पताल आने पर जांच की जायेगी ।

शोध में प्रयोग होने वाली दवा और उनके दुष्प्रभाव :- इस शोध अध्ययन में बेटाडीन, क्लोरहेक्सिडिन-अल्कोहल और एंटीबायोटिक सेफट्रीएक्सॉन का प्रयोग होगा और दवा या सोल्युशन लगने से पहले जांच कि जाएगी और कुछ भी एलर्जी पाए जाने पर वह दवा या सोल्युशन प्रयोग नहीं किया जाएगा और मरीज़ के सर्वोत्तम इलाज के लिए सावधानिया बरती जाएँगी।

बेटाडीन व क्लोरहेक्सिडिन- अल्कोहल के सामान्य दुष्प्रभाव में सूजन, लालपन, चमड़ी व सारे में जलन, खारिश , एलर्जी व तीव्रग्राहिता हो सकती है।

सेफ्ट्रियक्सोन से एलर्जी, खारिश, चमड़ी में धब्बे, उलटी, दस्त, पेट खराब, स्वाद बदल जाना व तीव्रग्राहिता हो सकती है।

इस अध्ययन से माँ एवम बच्चे को कोई भी अलग से नुक्सान नहीं है और कोई भी फ़ालतू जांच या दवा की आवश्यकता नहीं होगी ।

शोध अध्ययन में स्वेच्छा से भाग लेने की आज़ादी - आप शोध अध्यन में भाग लेने या न लेने के लिए आज़ाद हे। अगर आप/ आपका रोगी इस शोध में भाग नहीं लेना चाहते तो भी उचित इलाज किया जायेगा। यही नहीं आप

किसी भी समय शोध अध्यन से हथ सकते है, इससे इलाज पर कोई असर नहीं पड़ेगा। अगर आप शोध अध्ययन में भाग लेते है तो आपका अस्पताल में रहना, अस्पताल में दिखाने के लिए आना, हर प्रकार कीउपयुक्त जांच वैसे ही होगी जैसे शोध में भाग नहीं लेने की इश्थिति में होते है।

शोध अध्ययन में जोखिम ,दुष्प्रभाव व परेशानी - शोध अध्यन के दौरान अगर आपकी बीमारी व इलाज से सम्बंधितअतिरिक्त जानकारी उपलभ्ध होती है तो आपको उससे अवगत करवाया जायेगा.

भाग लेने के लिए लागत- शोध अध्ययन में भाग लेने के लिए आपको कोई खर्चा नहीं उठाना पड़ेगा चूकि दीन दयाल उपाध्याय अस्पताल एक सरकारी संसथान है, जांच और इलाज का खर्चा अस्पताल वहन करेगा।

शोध अध्ययन की गोपनीयता - आपका नाम , पता , निजी जानकारी शोध के दौरान व बाद में भी गोपनीय रखी जायेगी।शोध अध्ययन से सम्बंधित अभिलेख व परिणामो का प्रयोग शैक्षिक प्रकाशन और प्रस्तुतीकरण के लिए किया जा सकता है।इसका व्यावसायिक प्रयोग नहीं किया जाएगा। किसी भी वैज्ञानिक मंच पर आपकी निजी जानकारी का खुलासा नहीं किया जाएगा।

शोध से सम्बंधित चोट - शोध अध्ययन में अपनाये जाने वाले तरीके यथोचित सुरक्षित है। फिर भी शोध अध्ययन से सम्बंधित हानि होने की स्थिति में दीन दयाल उपाध्याय अस्पताल की तरफ से मुफ्त इलाज़ करने की व्यवस्था है।

शोध अध्ययन में भागीदारी से सभंधित अतिरिक्त जानकारी/ शिकायत - अगर आप या आपके मरीज़ को लगता है कि शोधअध्ययन में होने वाले जोखिम ,लाभ ,हानि,अतिरिक्त विकल्प या आपके अधिकारों के बारे में पर्याप्त जानकारी नहीं दी गयी है या आपको अपनी इच्छा के खिलाफ शोध अध्ययन में जारी रहने के लिए दबाव डाला जा रहा है या आपको शोध अध्ययन से सम्बंधित किसी विषय पर चिंता या शिकायत है तो आप संपर्क कर सकते है-

प्रधान अन्वेषक -डॉ स्नेह तंवर, 1ST YR DNB, DDUH, मोबाइल नंबर – 8826702746

गाइड- डॉ नीता बिंदल , CMO (SAG), प्रसूति विभाग, DDUH

PATIENT INFORMED CONSENT FORM

DEEN DAYAL UPADHYAY HOSPITAL

HARI NAGAR, NEW DELHI-110064

TOPIC: "TO STUDY THE EFFECTIVENESS OF SURGICAL BUNDLE IN REDUCING SURGICAL SITE INFECTION IN CAESAREAN DELIVERIES

Study Case Number:..... CR number--------

Title of study: To study the effectiveness of evidence based surgical bundle in reducing surgical site infection following caesarean deliveries.'

Name of the principal investigator: Dr. Sneh Tanwar Contact No.-8826702746

The content of the information sheet dated.....that was provided to me has been read carefully by me / explained in detail to me in a language that I understand and I have fully understood the contents.

I confirm that

- I have had the opportunity to discuss the research study and ask questions.
- The nature and purpose of the study and its potential risks / benefits / expected duration of the study and other relevant points have been explained to me in detail.
- I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care and legal right being affected.
- I understand that the information collected about me from my participation in this study and sections of any of my medical records may be looked at by responsible individuals involved in the study. I give permission to these individuals to access my records and use them for academic purposes.
- I agree to take part in the above study.

Signature/ Thumb Impression (Right/Left)

Place:..... Date:.....

Name of the Participant:..... Phone No. ….....

Son/Daughter/Wife of:.....

Complete postal address:.....

Signature /Thumb impression of Legally accepted Representative ……

(If subject is minor or unable to sign for themselves) Date:…….

This is to certify that the above consent has been obtained in my presence.

Signature of investigator…….. Place…….. Date-…….

(1) Witness-1	(2) Witness -2
Signature:	Signature:
Name:	Name :
Address:	Address:
Ph no.	Ph no.

रोगी सूचित सहमति पत्र

दीन दयाल उपाध्याय अस्पताल ,

हरी नगर- नई दिल्ली

शोध अधययन रोगी संख्या:

मरीज का नाम: सी.र. नंबर :

अध्ययन का शीर्षक: **TO STUDY THE EFFECTIVENESS OF SURGICAL BUNDLE IN REDUCING SURGICAL SITE INFECTION IN CAESAREAN DELIVERIES**.

प्रधान अन्वेषकः डॉ स्नेह तंवर मोबाइल नंबरः 8826702746

मुझे दिनांक ---------- को जो रोगी सूचना पत्र दिया गया था , मैंने उसे धयान से पढ़ लिया है/मुझे मेरी समझ में आने वाली भाषा में विस्तार से समझा दिया गया है। मैंने इसे पूर्ण रूप से समझ लिया है ।

मैं इस बात की पुष्टि करता/करती हूँ -

•मुझे शोध अध्ययन पर चर्चा करने और सवाल पूछने का मौका दिया गया है।

•शोध अध्ययन की प्रकृति,उदेश्यय ,संभावित जोखिम,लाभ, अपेक्षित अवधि व् अन्य प्रासंगिक विवरण के बारे में विस्तार से बता दिया गया है ।

•मैं समझता हूँ की मै अपनी मर्जी से इस शोध अध्ययन में भाग ले रहा हूँ और मै किसी भी समय बिना कोई कारण बताये,बिना मेरी चिकित्सा ,देखभाल और क़ानूनी अधिकार प्रभावित हुए शोध अध्ययन से हट सकता हूँ ।

•मै जानता हूँ कि इस शोध अध्ययन में भाग लेने पर मुझसे मेरे बारे में प्राप्त की गयी जानकारी व् मेरे चिकित्सा रिकॉर्ड इस शोध से सम्बंधित जिम्मेदार व्यक्तियों के द्वारा देखे जा सकते हैं। मै इन् व्यक्तियों को उपरोक्त जानकारी का शैक्षिक प्रयोग करने की अनुमति देता हूँ।

मै उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूँ ।

रोगी का हस्ताक्षर / हाथ के अंगूठे का निशान (दायां/बायां) हस्ताक्षर की तारीख:

रोगी का नाम:

पुत्र / पुत्री / पति …….

पूरा पता…….

यह प्रमाणित किया जाता है की उपरोक्त सहमति मेरी उपस्थिति में ली गयी है।

प्रधान अन्वेषक का हस्ताक्षर …….

स्थान-…… दिनांक-……

(1) गवाह -1 (2) गवाह -2

हस्ताक्षर: हस्ताक्षर:

नाम: नाम:

पता: पता:

KEY TO MASTERCHART

PREOP AB	–	PREOPERATIVE ANTIBIOTIC AT THE TIME OF SKIN INCISION
VG BET	–	VAGINAL BETADINE CLEANING
CHLR-ALC	–	CHLORHEXIDINE-ALCOHOL SOLUTION
S.E.S	–	SOCIO-ECONOMIC STATUS
L	–	LOWER
UL	–	UPPER LOWER
LM	–	LOWER MIDDLE
UM	–	UPPER MIDDLE
U	–	UPPER
G	–	GRAVIDA
P	–	PARA
L	–	LIVE
A	–	ABORTION
CS	–	CAESAREAN SECTION
GDM	–	GESTATIONAL DIABETES MELLITUS
HDP	–	HYPERTENSIVE DISORDERS OF PREGNANCY
IHCP	–	INTRAHEPATIC CHOLESTASIS OF PREGNANCY
CHR HTN	–	CHRONIC HYPERTENSION
LPV	–	LEAKING PER VAGINUM
PV	–	PER VAGINUM
SSI	–	SURGICAL SITE INFECTION

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