Original Article

Implementation of Surgical Site Infection Prevention Bundle in Gynaecological Surgeries: A Quality Control Initiative

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Abstract

Background: Surgical site infection (SSI) is the most common post operative morbidity after gynaecological surgeries. There can be multiple risk associated that may or may not be modifiable. Therefore, perioperative bundled approach is designed to reduce surgical site infections.

Aim/Objective: To determine whether surgical site infection (SSI) prevention bundle reduces the risk of SSI by 30 days postoperatively compared with the standard hospital protocol.

Methods: A randomized control trial was conducted on women who underwent elective gynaecologic surgery from January 2019 to May 2020. The subjects were divided into intervention and control group. The primary outcome was the rate of SSI by 30 days postoperatively.

Results: Total 192 women were randomized. the intervention group included 94 and 98 were assigned to the control group. The SSI rate at 30 days after surgery was 8 /85 (9.5%) in intervention group and 22/85 (25.8%) in control group (p value=0.005; RR=0.36;95% confidence interval [CI], 0.17-0.77). The relative risk reduction of SSI was 64% (p value=0.005) after the bundle was implemented. In subgroup analysis, the primary outcomes were affected by the subgroups like age, co morbidities and operative characteristics.

Conclusion: SSI prevention bundle intervention led to significant decrease in overall SSI rate in electively planned gynecological surgeries.

Keywords: Antibiotic prophylaxis, Chlorhexidine, Closing pan, Quality control initiative, Gynaecological surgeries, Surgical site infection(SSI)

Introduction

Surgical site infection (SSI) is the most common post operative morbidity after gynaecological surgeries. Surgical site infection is defined as infection at or near the surgical incision within 30 days of operative procedure. According to the Center for Disease Control and prevention (CDC) Surgical

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Site Infections (SSIs) are classified as being either incisional or organ space. Incisional SSIs involves only skin and subcutaneous tissue (superficial incision SSI) and those involving the deeper soft tissue of the incision (deep incisional SSI). Organ/ space SSIs involve any part of the anatomy (e.g. organ/space) other than incisional body wall layers that was opened or manipulated during an operation.[1,2]

SSIs have now emerged as the most common and most costly cause of health care associated infections.[3] A prevalence survey undertaken in 2017 in India estimated approximately 10% SSI rate in the women who underwent gynecological surgeries.[4] A recent study of 2023 also observed similar incidence of 9.2% SSI, with risk factors of high BMI and blood sugar levels implicating towards SSI.[5] The international epidemiology data on SSI shows even lesser prevalence of SSI worldwide of just 2.5% which necessitates the need of surgical site infection prevention bundle implementation at a routine level.[6]

SSIs are associated with considerable morbidity ranging from a relatively trivial wound discharge to a life-threatening condition. Other clinical outcomes of SSIs include poor scars (hypertrophic/keloid scar) that are cosmetically unacceptable, persistent pain and itching and a significant impact on emotional wellbeing.[7]

Several patient related factors (old age, nutritional status, pre-existing infection, co-morbid illness) and procedure related factors (emergency/ elective, poor surgical technique, prolonged duration of surgery, pre-operative part preparation and inadequate sterilization of surgical instruments) can influence the risk of SSIs significantly.[4,8]With the feedback of validated outcomes data provided by the American College of surgeons National Surgical Quality Improvement Program, the Centers for Medicaid and Medicare Services initiated the Surgical Care Improvement Project (SCIP) to reduce surgical complications.[9]Despite high compliance to guidelines related to perioperative antibiotic administration, hair removal, normothermia, and blood glucose control, these interventions alone have not been proven to lower surgical site infection rates,which suggests additional interventions are needed. [9,2,10]

There are evidences that the bundle of interventions during the preoperative, intraoperative and post operative period might cause significant reduction in SSI rate rather than single intervention during any of the phase. The bundled intervention has gained special interest in complicated surgery where risks of infection are already more. Surgical site infection risk can be complex with many risk factors that may or may not be modifiable, and there may not be adequate time to address modifiable risk factors. Therefore, perioperative bundles of evidence-based practices performed collectively and designed to reduce surgical site infections have been introduced. [11-15]

The effect of bundled interventions has been reported in the past, but no such randomized control trial is available in the literature for gynecological surgeries. This study was planned to implement and identify the effect of bundled intervention on the rate of SSI.

Material and Methods

This single center, two arm, parallel randomized control trial was conducted from May 2019 to May 2020 in the Department of Obstetrics & Gynecology, UCMS and GTB Hospital, New Delhi, India.

The sample size was calculated considering the baseline infection rate of 24% which was analyzed retrospectively during 2017-18. Assuming the power of the study to be 80%, taking two sided confidence interval to be 95% and intervention to control ratio to be 1:1, the sample size of 85 was calculated for each group. The sample size was further inflated to allow 10% follow up loss. We therefore aimed for a sample size at least 94 in each case and control arm.

All women undergoing elective gynecologic surgeries through abdominal route for any indication were included in the study. Participants were randomly assigned in a ratio of 1:1 to the intervention and control group after allocating the randomization number by computer generated randomization table. Women who were not operated in GTB hospital or coming with surgical site infection after 30 days of getting discharge from the hospital were excluded. A written and informed consent was taken from all the women. Demographic and clinical details (medical

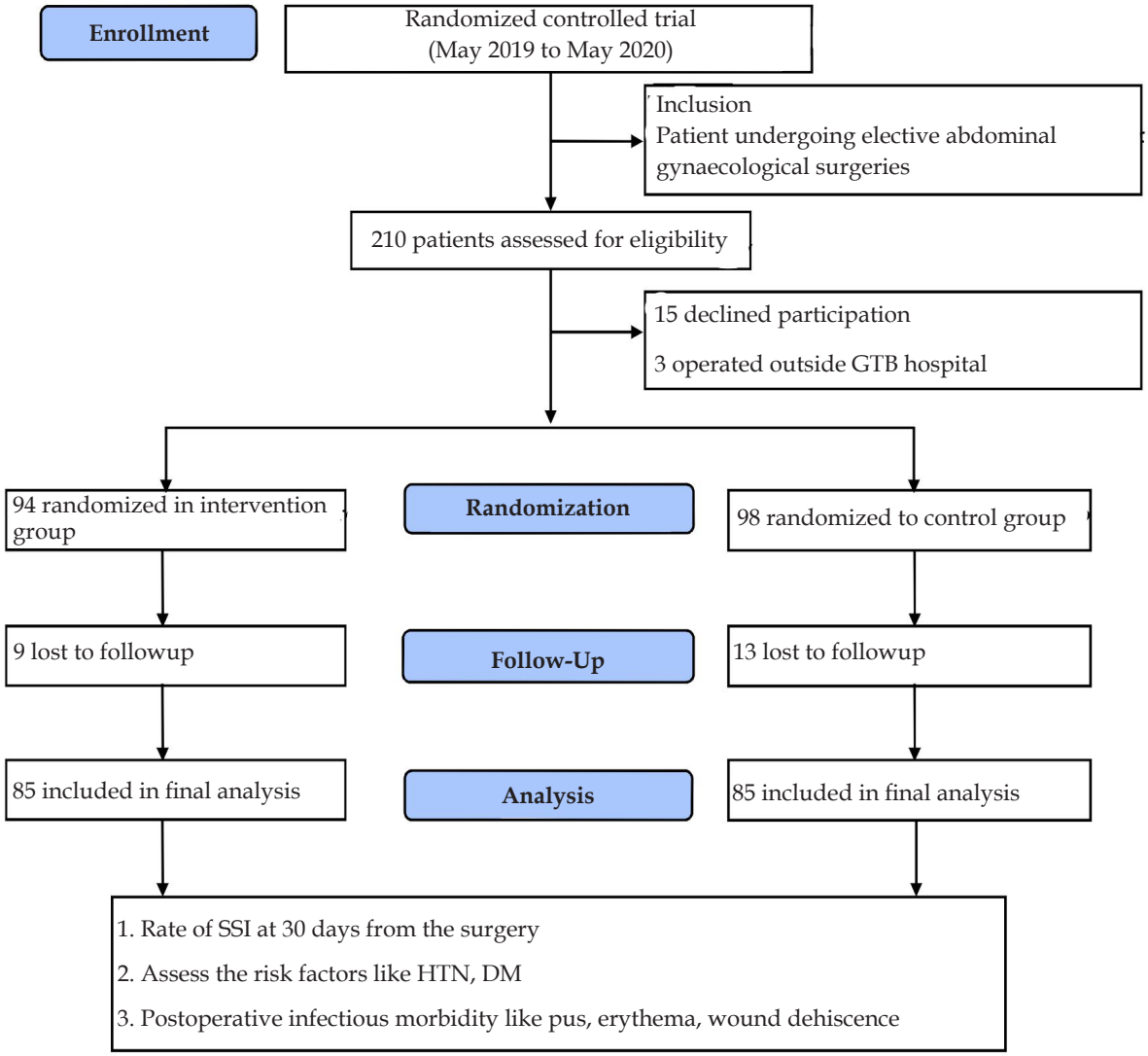

Figure 1: Randomization and follow up of study participants

disorder, operative characteristics of procedure, blood transfusion) of the women were recorded as per the pre designed Performa.

Intervention group

The pre operative interventions include, shower with soap on morning of surgery, hair removal on pubic area was only done if required, by depilate or creams. Routine antibiotic (Injection Cefazolin 2 gm IV) was given at least 30 minutes before the surgery after the test dose. Women who were allergic to cefazolin received Clindamycin or vancomycin. The timing and the dose of the antibiotics were in the consensus of antimicrobial prophylaxis guidelines by American Society of Health-System Pharmacists (ASHP) 2013. Skin was prepped with 2% Chlorhexidine-gluconate (CHG) solution followed by 70% isopropyl alcohol and dried 3-5 minutes. Pre operative vaginal preparation was done with CHG solution.

The intra operative interventions include re-dosing of antibiotics after 4 hours, maintaining normothermia and normoglycemia and closing pan. At the end of procedure, the closing pan was used which included the fresh sterile abdominal sheet, sterile instruments, fresh electrocautery, fresh pair of gloves for fascial and skin closure and changing surgical gown, if vaginal or perineal contamination.

Control group

The control group had the perioperative protocols as per the hospital policy. This included

the preoperative shower with soap, hair removal by shaving, prophylactic antibiotic 30 minutes before the surgical incision, prepping the skin by 5% betadine and wound closure.

On postoperative day 3 in both intervention and control group, dressing of surgical site was done with spirit and 5% betadine and wound was examined for any discharge, erythema and induration. Patients were discharged as per the primary clinician's discretion. For Pfannenstiel incision stitches were removed on postoperative day 8 and midline incisions stitch removal were done on postoperative day 10. Temperature was recorded twice a day during hospital stay. Wound cultures for aerobes and anaerobes were sent in case of wound infections and appropriate antibiotics were given. Patients who underwent re-suturing or conservative management of wound (as per hospital protocols) were recorded on Performa. Any readmission within 30 days of discharge was recorded.

The primary outcome was the rate of SSI (superficial, deep and organ space infectionas per CDC guidelines)by 30 days after discharge from hospital. Secondary outcomes included the risk factors for SSI, post operative infectious morbidity like fever, erythema, wound dehiscence, etc, resuturing, blood transfusion and duration of hospital stay. In addition, patients were contacted at 2-3 weeks from hospital discharge to ascertain any SSI or any related complications. The study was compiled as per CONSORT guidelines for reporting randomized control trials and the checklist was used to ensure compliance (Fig 1).

Statistical analysis

Participant characteristics and surgical characteristics were compared in the intervention and control groups using the two-sample t test for the continuous variables and chi square or fisher exact test for the categorical variables. Relative risk and corresponding 95% confidence interval were estimated using logistic regression models for the case and control group. All calculated P values were two-sided and that < .05 was considered statistically significant.

Results

Figure 1 depicts the enrollment, randomization, follow up and patients finally kept for analysis. The baseline characteristics of case and control group are depicted in Table 1. There was no significant difference in two groups except co- morbidities. The co- morbidities like diabetes (11.76% vs. 3.5%, p value=0.043) and hypertension (30.5% vs. 16.4%, p value=0.030) were significantly more in intervention group. The preoperative, intraoperative characteristics of both the groups are depicted in Table 2.

Table 1: Clinical characteristics in intervention and control groups

Parameters	Intervention group n=85 (%)	Control group n=85 (%)	p value
Mean Age (in years)	42.88±13.76	44.95±12.57	0.479
Parity >2	78(91.7)	79(92.9)	0.773
Nullipara	7 (8.3)	6(7.1)	
Body Mass Index(BMI) (kg/m2)	25.44±5.116	25.06±3.806	0.194
Co-morbidities present	40(47.05)	22(25.8)	0.004
Diabetes	10(11.76)	3(3.5)	0.043
Hypertension	26(30.5)	14(16.4)	0.030
Obesity (BMI>30 Kg/ m2)	4(4.7)	5(5.8)	0.731

Table 2: Surgical characteristics of intervention and control groups

Parameters	Intervention group n=85 (%)	Control group n=85 (%)	p value
Preoperative hemoglobin (mean gm%)	10.99±1.18	10.55±1.296	0.083
Pre operative blood transfusion	7(8.2)	13(15.3)	0.153
Indication for surgery			
Benign	41	51	
Malignancy	44	34	0.124
Ca ovary	6	11	
Ca endometrium	18	9	
Ca cervix	18	16	
Type of incision			
Midline vertical incision	52(61.1)	41(48.23)	0.164
Transverse incision	33(38.8)	44(51.8)	
Mean duration of surgery(minutes)	198.49±89.5	181.41±90.7	0.826
Operating time>180 minutes	48(56.47)	36(42.35)	0.065
Post-operative blood transfusion	30(35.2)	34(40)	0.527
Post operative fever	27(31.7)	39(45.8)	0.059
Mean duration of stay(days)	8.72±3.824	10.1±8.48	0.58

The SSI rate at 30 days after surgery was 8/85 (9.5%) in intervention group and 22/85 (25.8%) in control group which was significantly lower than the control group (p value=0.005) (Table 3). The relative risk of having SSI in intervention group was much lower than control group (RR=0.36;95% confidence interval [CI], 0.17-0.77). After implementation of SSI bundle, the relative risk reduction of SSI was 64% (p value=0.005). The frequency of superficial, deep and organ space SSI are shown in Table 3**.** Only one woman required wound resuturing in case group whereas five women needed resuturing for deep SSI. One woman had organ space infection in control group and was managed by antibiotics. The wound healed by secondary intention over due course of time. The secondary outcome at 30 days like, wound discharge, induration, post operative fever, wound culture status and women requiring resuturing for wound deep SSI is depicted in Table 3.

Table 3: Outcomes at 30 days after abdominal Gynecological surgery

	Intervention group (n=85)	Control group (n=85)	Relative risk(95%CI)	p value
Primary outcome				
Total SSI(%)	8(9.4)	22(25.8)	0.36(0.17-0.77)	0.005
Superficial SSI (%)	7(87.5)	16(72.7)	0.43(0.18-1.00)	0.043
Deep SSI (%)	1(12.5)	5(22.7)	0.2(0.02-1.67)	0.096
Organ space SSI (%)	0(0)	1(4.5)	-	-
Secondary outcomes				
Wound discharge	8(9.4)	21(24.7)	0.38(0.17-0.81)	0.049
Wound induration	6(7.05)	13(15.2)	0.46(0.184-1.15)	0.088
Post operative fever	27(31.7)	39(45.8)	0.69(0.47-1.02)	0.059

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Wound culture report			-	
No growth	7(8.2)	13(15.2)	0.53(0.22-1.2)	0.153
E.coli	1(1.1)	4(4.7)	0.25(0.02-2.19)	0.173
Acinetobacter	0(0)	3(3.5)	-	-
Kleibsella	0(0)	2(2.3)	-	-
Resuturing	1(1.1)	5(5.8)	0.2(0.02-1.67)	0.094

In subgroup analysis, the primary outcomes were affected by the co- morbidity of diabetes and hospital stay >10 days (Table 4).

Table 4: Subgroup analysis of the primary outcome.

Risk factors	**Intervention group SSI/Total no (%)**	**Control group SSI/Total no (%)**	**Relative risk (95%CI)**
Age >60			
Yes	3/18 (16.6)	6/15 (40)	0.5(0.14-1.74)
No	5/67 (7.4)	16/70 (22.8)	0.37(0.14-0.96)
BMI >30KG/m2			
Yes	2/4 (50)	5/5 (100)	0.66(0.18-2.42)
No	6/71 (8.4)	17/80 (21.2)	0.44(0.18-1.07)
Diabetes			
Yes	6/10 (60)	1/3 (33.3)	1.5(0.24-9.17)
No	2/75 (2.6)	21/82 (25.6)	0.12(0.03-0.52)
Hypertension			
Yes	7/26 (26.9)	4/14 (28.5)	0.95(0.32-2.8)
No	1/59 (1.6)	18/71 (25.3)	0.08(0.01-0.6)
Pre operative Blood transfusion			
Yes	2/7 (28.5)	6/13 (46.1)	0.70(0.17-2.8)
No	6/78 (7.6)	16/72 (22.2)	0.39(0.16-0.95)
Malignancy surgery			
Yes	7/44 (15.9)	15/34 (44.1)	0.44(0.2-1.0)
No	1/41 (2.4)	7/51 (13.7)	0.19(0.02-1.5)
Midline vertical incision			
Yes	7/52 (13.4)	17/41 (41.4)	0.40(0.18-0.90)
No	1/33 (30.3)	5/44 (11.3)	0.28(0.03-2.3)
Operating time >180 minutes			
Yes	5/48 (10.4)	15/36 (41.6)	0.32(0.12-0.81)
No	3/37 (8.1)	7/49 (14.2)	0.6(0.16-2.18)

Post operative blood transfusion			
Yes	6/30 (20)	16/34 (47.0)	0.52(0.226-1.2)
No	2/55 (3.6)	6/51 (11.7)	0.33(0.07-1.58)
Duration of hospital stay>10 days			
Yes	7/31 (22.5)	21/31 (67.7)	0.45(0.21-0.96)
No	1/54 (1.8)	1/54 (1.8)	1(0.06-15.57)

Discussion

SSI rate is a key indicator of quality care offered by healthcare institution. This study has shown the positive impact of implementation of SSI prevention bundle on the women who underwent open gynaecological surgeries at our center. After one year of implementation of SSI prevention bundle, the SSI rate was 9.4%, representing approximately 3- fold decrease in SSI, as compared to control group. Though the fall in SSI was not as much as observed in the western studies, but no Indian study has ever practiced SSI prevention bundle as per the best of our knowledge.[16]Most of the previously published studies on SSI prevention bundle in gynaecological surgeries which included both benign and oncology surgeries, have been able to demonstrate successful reduction in SSI in different patient population. Guo et al reported a decrease in SSI rate from 2.7% to 0.4% (odds ratio, 7.41; 95% confidence interval, 1.67–32.75) including the sterile closing pan and gloves change before skin and fascial closure.[16]Andimanetal also reported a decline in SSI rate from 4.51% to 1.87% (aOR=0.46, p=0.01) after implementation of SSI prevention bundle in gynaecologic surgeries. It included multidisciplinary team designed bundled intervention with additional intervention of chlorohexidine impregnated preoperative wipes.[17]

Our findings added to existing surgical site infection prevention bundle data and apply current knowledge to the gynaecological surgeries. However, the higher baseline infection rate is probably due to combination of factors. Importantly, due to non-uniformity of the surgical site infection prevention policy in the study institution. In addition, this study included all the gynaecologic surgeries at the study institution. Thus, all the morbid and complex cases expected to have higher SSI were included in the present analysis.[16,18] The relative risk of develpoing SSI in control group was three times higher than case group, which suggest clear benefits of implementation of bundled intervention in the prevention of SSI. Therefore, results were consistent with the other studies.[18,4]

As expected, theco morbidities like diabetes and hypertension in our study had significant impact on SSI rate. The odds of having SSI were more in women with having age>60 years, co-morbidities like BMI >30 kg/m2, diabetes and hypertension. The increasing age is correlated with greater likelihood of certain chronic conditions, malnutrition and a fall in the body's immunological efficiency, causing more extensive SSI. Similarly, the chronic conditions like diabetes and hypertension also contributes to SSI in similar fashion. High BMI and obesity results in decrease in blood circulation in fat tissues is associated with increase in infection rate.[19]The diabetes as co morbidity and duration of hospital days>10 days were associated with higher relative risk of SSI in case as well as control group, when subgroup analysis of risk factors for the primary outcome was done. Similar results were obtained in the study done by Bharatnur etal.[20]

Overall, the current quality control initiative for reducing and preventing SSI was successful in reducing the rate of SSI in gynaecological open surgeries in our hospital. It also added to the current gynaecologic data in demonstrating that bundles are effective in reducing infection rates in benign as well as malignant surgeries. Further sustained implementation of bundle in all type of gynaecological surgeries will ensure reduced SSI rate, even in long term.

Conclusion

Wound infection is the major cause of post operative morbidity in gynaecoogical surgeries. Complete elimination of SSI is nearly impossible but reduction in rate of SSI can be operationalized by implementation of SSI prevention bundle. The bundled intervention should include all the aspect of women including pre, intra and post operative period.

Ethical Clearance: Ethical clearance was taken from the institutional ethical committee with reference number GTBHEC 2018/P-108 dated 05/02/2019.The trial was registered with clinical registry trial of India with trial number CTRI/2019/05/019083.

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Conflicts of interest: None

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