
Reducing surgical site infection rate in gynecologic oncologic cases: effect of a gynecology specific bundle

Marwa Magdy Mahmoud El Shennawy,
Rafik Ibrahim Barakat, Kamal Ibrahim Anwar, Nermeen Shams-Eldin.
Obstetrics and gynecology,
Faculty of Medicine, Mansoura University, Egypt.

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Abstract

Objective: To evaluate the effect of a preventive bundle on surgical site infection rates in Gynecologic Oncology surgery in Mansoura University Hospital.

Subjects and methods: Prospective Randomized Controlled Trial that was conducted over a period of 24 months during 2020 and 2022 on 80 patients admitted to Obstetrics and Gynecology department at Mansoura University Hospital. General, abdominal, and pelvic examinations and lab investigations were performed. Randomization of patients into 2 groups: group I (bundle implementation), group II (without bundle).

Results: SSI was more common in group (2) after first week and one month of follow up, and no statistically significant variation in 2ry interventions among SSI cases of the studied groups. There is significant association between BMI and cases of SSI. SSI was more common in cases with BMI more than 25, diabetic cases and cases who received radiotherapy. There is no significant statistical association between SSI and suspected primary pathology of the studied groups, but there is statistically significant association with operative time.

Conclusion: This study showed that implementation of a perioperative surgical site infection prevention bundle was associated with a marked reduction in surgical site infection rate in patients undergoing gynaecological oncology surgeries.

Keywords: surgical site infection, gynecologic oncology, preventive bundle.

Corresponding author:

Marwa Magdy Mahmoud El Shennawy
Email : marwa_magdy27315@gmail.com
Mobile number:01204481194

INTRODUCTION

Surgical site infection (SSI) is any infection occurs within 30 days after an operation in any part of the body where the surgery was performed, that classified into superficial incisional, deep incisional or in other organs or spaces manipulated or opened during an operation(1).In gynecologic surgery, surgical site infections include superficial incisional cellulitis, deep incisional abscesses, and vaginal cuff or pelvic cellulitis or formation of abscess. (2)

The Gynecologic Oncology field has an elevated risk of SSIs due to high-complexity surgeries, patient co-morbidities, and liability for contamination from endogenous vaginal, cervical and gastrointestinal microorganisms to the operative area. (3)

SSIs remain the most common complication of gynaecological surgeries, nearly 10 to 35% of gynecologic oncology surgeries. SSIs are associated with delayed initiation of adjuvant therapy and worse overall survival(4,5).

Infections of the surgical wound commonly occur either late in the hospital course or soon after discharge. Wound infection symptoms can include fever and increased pain at the incision site. Clinical features may reveal skin erythema, or induration, purulent discharge from the incision, and possible fascial dehiscence on probing the deeper layers. (6)

The risk factors for SSI can be divided into patient and procedure related risk, modifiable or non modifiable. SSIs are usually the result of many non modifiable risk factors. Procedure related risks are considered to be modifiable (2).

Patients undergoing gynaecological oncology surgery are considered immuno-compromised, so it is vital to minimize the risk of SSI by the use of surgical site infection reduction bundles. Best practices to lower SSIs include preoperative, intraoperative, and postoperative activities.(7)

SSI is managed through antibiotic therapy, wound drainage, and wound debridement as appropriate. Specific management of the wound depends on the nature and location of infection. Whenever feasible, and if systemic signs of infection are absent, microbiological culture data should be obtained before starting broad-spectrum antibiotics, so that culture findings can guide changes in antibiotic therapy.(8)

Patients and methods

Prospective Randomized Controlled Trial that was conducted over a period of 24 months during 2020 and 2022 on 80 patients admitted to Obstetrics and Gynecology department at Mansoura University Hospital after obtaining acceptance from institutional research board faculty of medicine, Mansura university.

All gynecologic Oncology elective cases had been included in the study except:

Women who had received antimicrobial therapy within 7 days before entrance into study, had history of hypersensitivity to study drug, with un-controlled diabetes, had infection at time of screening for enrolment of study, undergoing emergency operations, who are using corticosteroids, or other immunosuppressive drugs.

Study design

A detailed history of each patient was taken with an explanation of the study protocol, and then informed consent was obtained. General, abdominal, and pelvic examinations and lab investigations were performed. Randomization of patients into **2groups: groupI** (bundle implementation), **groupII**(without bundle implementation). Group I was subjected to specific bundle used to prevent surgical site infections based on ACOG practice bulletin 2018.(4).

Gynecology Specific Bundle included

Preoperative measures: Advise patient showering at night before operation using chlorhexidine gluconate shower soap, Maintain euglycemic (RBS<200mg/dl), any necessary hair removal should be done immediately preoperative by electric clippers, prophylactic antibiotics administration, all patients without any allergy received Cefazolin (1stgen cephalosporins) the recommended does is 2g for patients weighing <120kg and 3g for patients >120kg, administered up to 30 minutes before incision, while metronidazole & clindamycin used for patients with allergies.

Intraoperative measures: Preoperative skin preparation at surgical site with Betadine surgical scrub, maintain adequate aseptic technique, minimize operating room traffic.

Postoperative measures: Maintain euglycemia, Patient education about symptoms and signs of SSI, Sterile dressing removal after 48 H.

Group II: patients without bundle implementation: Included

Preoperative measures: Prophylactic antibiotics administration, all non-allergic patients received Cefazolin (1stgen cephalosporins) the recommended does is 2g for patients weighing <120kg and 3g for patients >120kg, given up to 30 minutes prior to incision, while metronidazole & clindamycin used for patients with allergies.

Intraoperative measures: Preparing the incisional area with povidone iodine (Betadine surgical scrub).

Postoperative measures: Sterile dressing removal after 48 h.

Follow up

Cases of the two groups were followed up in hospital then at gynecology outpatient clinic after one week and after one month to detect any sign of surgical site infection, Wounds were assessed using ASEPSIS score for surgical site infections (9) as follows:

(ASEPSIS Score):

Additional treatment	<ul style="list-style-type: none"> • Antibiotics 10 • Drainage of pus under local anaesthesia 5 • Debridement of wound general anaesthesia 10
Serous Discharge	Daily 0 – 5
Erythema	Daily 0 – 5
Purulent exudates	Daily 0 – 10
Separation of deep tissues	Daily 0 – 10
Isolation of Bacteria	10
Stay as inpatient prolonged over 14 days	5
Total Score	

Category of infection	
0-10	Satisfactory healing
11- 20	Disturbance of healing
21-30	Minor wound infection
31-40	Moderate wound infection
<40	Severe wound infection

Sample size

was based on infection rate among cases with Full Bundle Implementation pre and post intervention (4.51% and 1.87, respectively) retrieved from previous research (Andiman et al et al., 2018). Using G*power version 3.0.10 using McNemar test, 2-tailed, with α error = 0.05 and power = 80.0% and effect size = 2.48. The calculated sample size will be 48 patients and by adding 10% to avoid drop out then the total calculated sample size will be 50 patients at least.

Ethical consideration

A written informed consent was taken from each participant after being informed about the objectives of the study. During the study, confidentiality and privacy were maintained.

Statistical analysis

Statistical Package of Social Science (SPSS) program for Windows (Standard version 26) was used to analyze data. The normality of data was tested first with one-sample Kolmogorov-Smirnov test. Qualitative data were clarified using number and percent. Association between categorical variables had been tested using Chi-square test. Continuous variables were described as mean \pm SD (standard deviation) for normally distributed data. The threshold of significance is fixed at 5% level. The result had been considered significant when $p \leq 0.05$. The smaller p-value obtained, the more significant were the results.

Results

The current study showed that mean age was 59.42 years, mean BMI was 30.52, 55% were rural residents, 70 % were married, and 70 % were housewives and 42.5% had primary education. In regard to the control group mean age was 58.67, mean BMI was 29.25, 62.5% were rural residents, 75% were married, 65 % were housewives, and 47.5%

had primary education. There was non-statistically significant difference between the 2 groups ($P > 0.05$). As shown in table (1).

The current study showed that in regard to study group multigravida were 87.5%, 55% were diabetic, 75% had positive surgical history, 90% had negative past history of SSI, 7.5% had history of radiotherapy, while in regard to control group multigravida were 77.5 %, 50% were diabetic, 67.5% had positive surgical history, 82.5% had negative past history of SSI and 5% had history of radiotherapy. There was non-statistically significant difference between the 2 groups ($P > 0.05$). As shown in table (2).

As regard pre-operative suspected primary pathology among studied groups, table (3). showed no significant variation among studied groups.

The wound was assessed after one week of surgery by ASEPSIS score for all cases then after one month but few cases missed long term follow-up, results showed after one month of following up of the cases that only 10.5% of the cases of group (1) showed signs of SSI, 30% of group (2) showed signs of SSI. There was statistical significant association between type of the study and SSI. Table (4) showed that SSI is more common in group (2) after first week and one month of follow up. Table (5) showed no statistically significant variation in 2ry interventions among SSI cases of the studied groups.

Table (6) showed that there is significant association between BMI and cases of SSI. SSI was more common in cases with BMI more than 25, while no significant association between SSI and other socio-demographic data (age, residence, marital status, occupation and educational level).

Table (7) showed that there is significant association between SSI cases and Diabetes and past history of radiotherapy. SSI was more common in diabetic cases and cases who received radiotherapy. Table (8) showed that there is no statistical significant association

between SSI and suspected primary pathology of the studied groups. Table (9) showed that there is statistically significant association among SSI and operative time. SSI were more common in staging laparotomy operations and in lengthy operation.

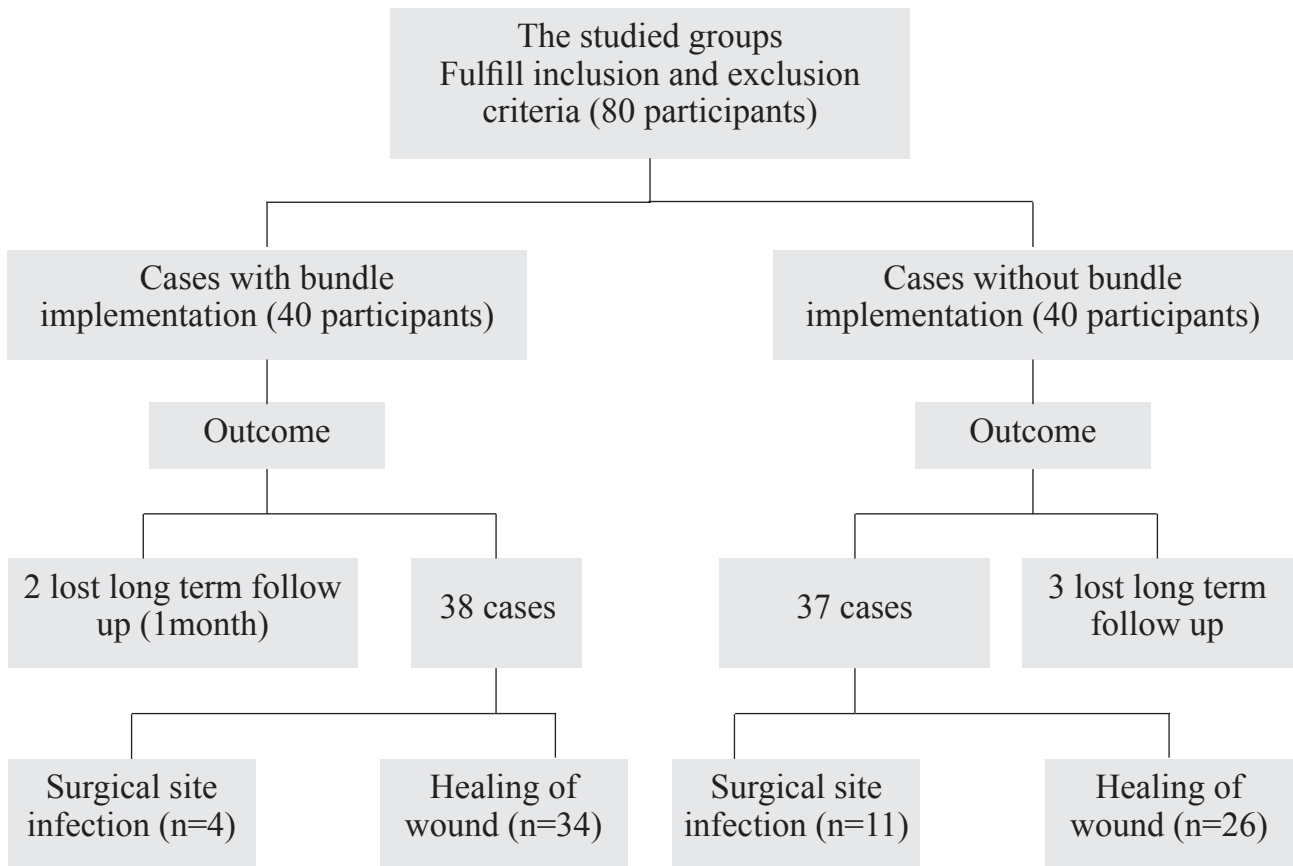


Figure (1): Flow chart of the studied groups

Table (1): Sociodemographic data among the studied groups.

Sociodemographic data	Group (1) (n=40)	Group (2) (n=40)	Test of significance	P value
Age (Years) Mean ± SD Min-Max	59.42±13.66 34-76	58.67±14.12 32-71	t=0.241	0.810
BMI Mean ± SD	30.52±2.82	29.25±3.27	t=1.86	0.066
Residence Urban Rural	18 (45.0%) 22 (55.0%)	15 (37.5%) 25 (62.5%)	χ ² =0.464	0.496
Marital status Married Single Divorced Widowed	28 (70.0%) 2 (5.0%) 3 (7.5%) 7 (17.5%)	30 (75.0%) 1 (2.5%) 4 (1.0%) 5 (12.5%)	MC	0.847

Occupation Worker House wife	12 (30.0%) 28 (70.0%)	14 (35.0%) 26 (65.0%)	$\chi^2 = 0.228$	0.633
Education level Illiterate Primary Secondary High	2 (5.0%) 17 (42.5%) 14 (35.0%) 7 (17.5%)	1 (2.5%) 19 (47.5%) 15 (37.5%) 5 (12.5%)	$\chi^2 = 0.521$	0.914

t: Independent t test, χ^2 : Chi square test, MC: Monte carlo test

Table (2): Obstetric, medical, surgical and past history among the studied groups

Items	Group (1) (n=40)	Group (2) (n=40)	Test of significance	P value
Gravidity Multigravida Null gravida	35 (87.5%) 5 (12.5%)	31 (77.5%) 9 (22.5%)	$\chi^2 = 1.38$	0.239
Comorbidities Diabetes Hypertension Thyroid disorder Asthma Anemia	22 (55.0%) 10 (25.0%) 3 (7.5%) 3 (7.5%) 5 (12.5%)	20 (50.0%) 14 (35.0%) 4 (10.0%) 2 (5.0%) 2 (5.0%)	$\chi^2 = 0.201$ $\chi^2 = 0.952$ FET FET FET	0.654 0.329 1.0 1.0 0.432
Surgical history Positive Negative	30 (75.0%) 10 (25.0%)	27 (67.5%) 13 (32.5%)	$\chi^2 = 0.167$	0.683
Past history of SSI Positive Negative	4 (10.0%) 36 (90.0%)	7 (17.5%) 33 (82.5%)	$\chi^2 = 0.949$	0.330
History of radiotherapy	3 (7.5%)	2 (5%)	FET	1.0

t: Independent t test, χ^2 : Chi square test , FET: Fisher exact test, SSI: surgical site infection

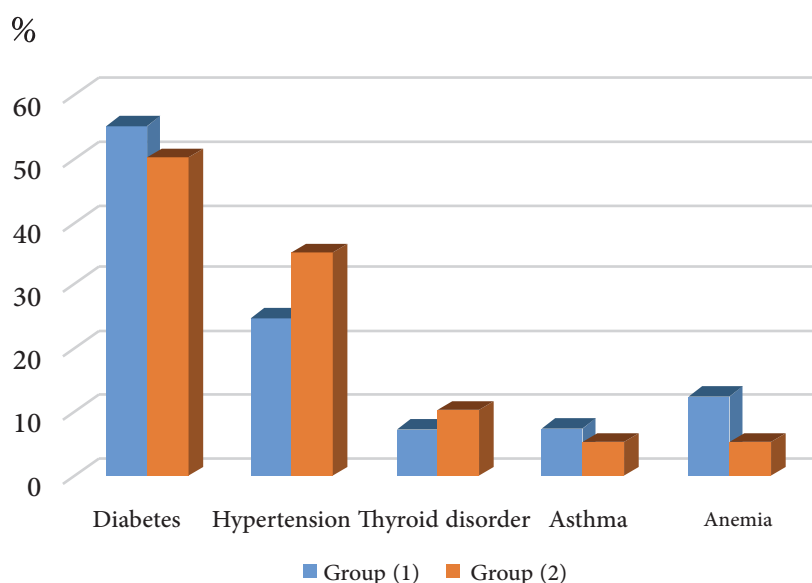


Figure (2): Co-morbidities among the studied groups

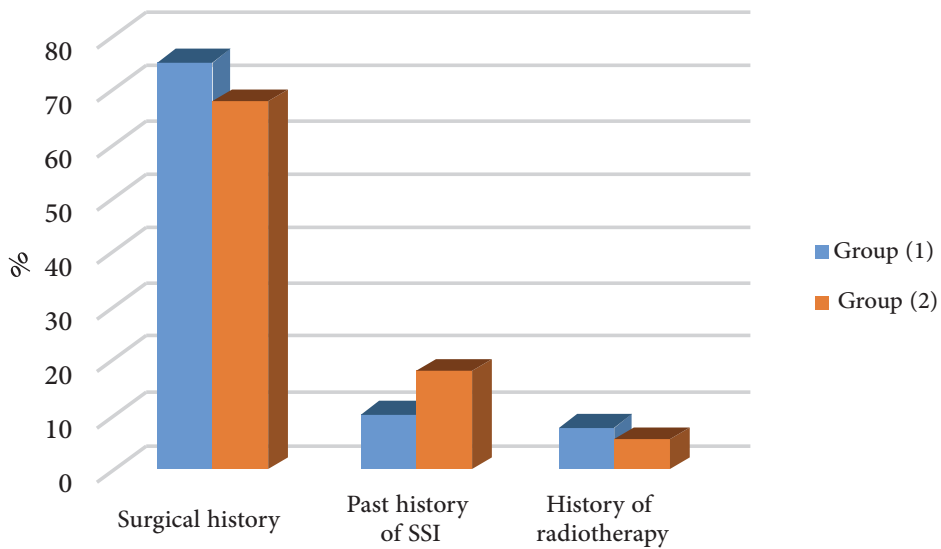


Figure (3):Previous surgical, SSI and radiotherapy history among the studied groups

Table (3) Pre-operative suspected primary pathology among studied groups:

Suspected lesion	Group (1) (n=40)	Group (2) (n=40)	Test of significance	P value
Ovarian	21 (52.5%)	25 (62.5%)	$\chi^2 = 1.41$	0.494
Uterine	17 (42.5%)	12 (30.0%)		
Cervical	2 (5.0%)	3 (7.5%)		

Table (4): Assessment of wound healing and SSI cases among the studied groups

	Group (1) (n=38)	Group (2) (n=37)	Test of significance	P value
Total Number of SSI	4 (10.5%)	11 (30%)	$\chi^2 = 4.32$	0.037*
Cases after one week	2 (5.25%)	7 (19%)	FET	0.086
Cases after one month	2 (5.25%)	4 (11%)	FET	0.430

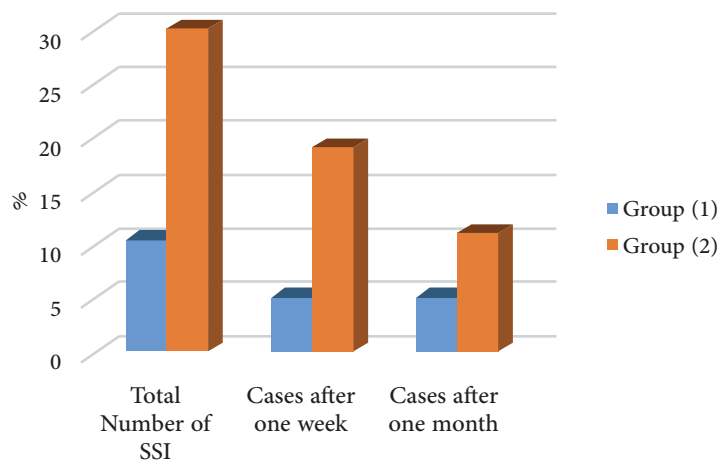


Figure (4): SSI cases among the studied groups

Table (5): Secondary outcome in cases with SSI among studied groups

SSI cases	Group (1) n=4	Group (2) n=11	P value
Additional antibiotic treatment	4 (100%)	11 (100%)	1.0
Drainage of pus	2 (50.0%)	7 (63.6%)	1.0
Secondary suture	1 (25.0%)	3 (27.2%)	1.0
Hospital readmission	1 (25.0%)	3 (27.2%)	1.0

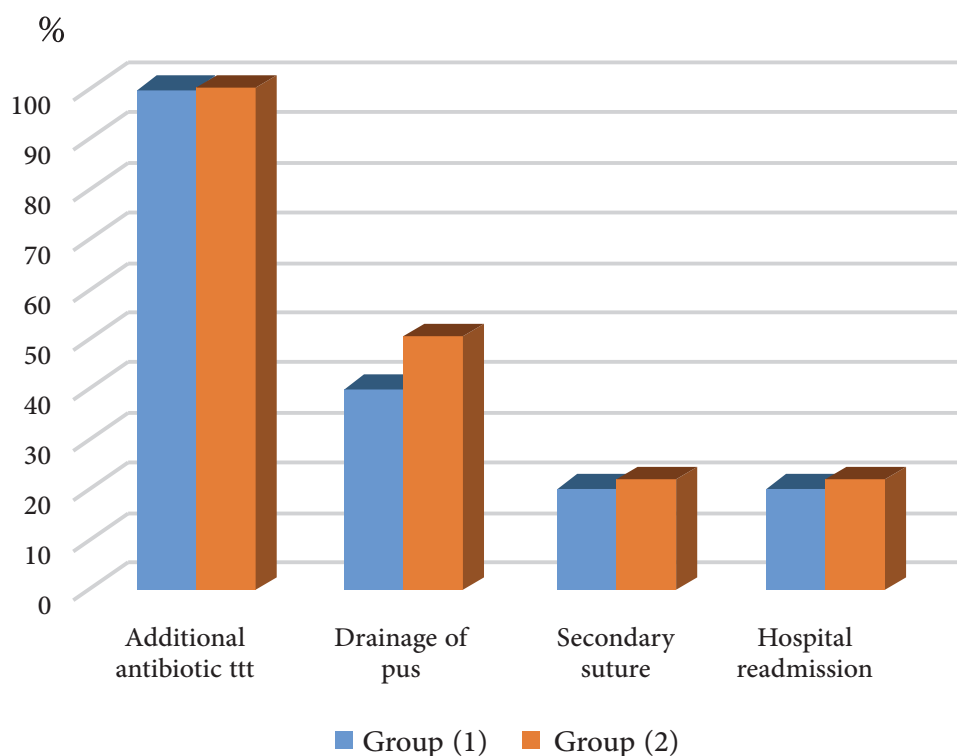


Figure (5): Secondary outcome in cases with SSI among studied groups

Table (6): Association between surgical site infection and sociodemographic data among the studied groups

Sociodemographic data	Group (1) (n=4)	Group (2) (n=11)	Test of significance	P value
Age (Years) Mean ± SD Min-Max	59.42±13.66 34-76	58.67±14.12 32-71	t=0.091	0.928
BMI Mean ± SD	31.52±2.82	27.25±3.27	t=2.31	0.038*
Residence Urban Rural	1 (25%) 3 (75%)	4 (36.3%) 7 (63.7%)	FET	0.450

Marital status				
Married	2 (50%)	9 (81.8%)	MC	0.740
Single	1 (25%)	0 (0%)		
Divorced	0 (0%)	0 (0%)		
Widowed	1 (25%)	2 (18.2%)		
Occupation				
Worker	1 (25%)	2 (18.2%)	FET	0.789
House wife	3 (75%)	9 (81.8%)		
Education level				
Illiterate	0 (0%)	0 (0%)	MC	0.730
Primary	1 (25%)	5 (45.5%)		
Secondary	3 (75%)	4 (36.3%)		
High	0 (0%)	2 (18.2%)		
t: Independent t test, FET: Fisher exact test, MC: Monte carlo test				

Table (7): Association between surgical site infection and obstetrical, medical, surgical and past history among the studied groups

Items	Group (1) (n=4)	Group (2) (n=11)	P value
Gravidity			
Multigravida	3 (75.0%)	8 (72.7%)	1.0
Null gravida	1 (25.0%)	3 (27.3%)	
Comorbidities			
Diabetes	3 (75%)	6(54.5%)	0.064*
Hypertension	2 (50%)	5 (45.5%)	1.0
Thyroid disorder	0 (0%)	1 (9.1%)	1.0
Asthma	1 (25%)	2 (18.2%)	0.154
Anemia	2 (50%)	1 (9.1%)	
Surgical history			
Positive	3 (75%)	9 (81.8%)	1.0
Negative	1 (25%)	2 (18.2%)	
Past history of SSI			
Positive	3 (75%)	5 (45.5%)	0.569
Negative	1 (25%)	6 (54.5%)	
History of radiotherapy	3 (75%)	1 (9.1%)	0.033*

Table (8): Association between SSI and pre-operative suspected primary pathology among studied groups

Suspected lesion	Group (1) (n=4)	Group (2) (n=11)	Test of significance	P value
Ovarian	3 (75%)	7 (63.6%)	MC	1.0
Uterine	1 (25%)	2 (18.2%)		
Cervical	0 (0%)	2 (18.2%)		

Table (9): Association between SSI and operative data among the studied groups

Items	Group (1) (n=4)	Group (2) (n=11)	Test of significance	P value
Type of incision				
Midline	3(75.0%)	8 (72.7%)	FET	1.0
Low transverse abdominal	1(25.0%)	3 (27.3%)		
Type of surgery				
Staging laparotomy	3 (75%)	7 (63.6%)	MC	1.0
TAH+BSO	1 (25.0%)	2 (18.2%)		
Wertheim operation	0 (0%)	2 (18.2%)		
Operative time				
Less than 2h	1 (25.0%)	4 (36.4%)	FET	0.001*
More than 2h	3 (75.0%)	7 (63.6%)		
Blood loss during surgery				
Less than 500ml	2 (50%)	6 (54.6%)	FET	1.0
500-1000 ml	2 (50%)	5 (45.4%)		
Blood transfusion				
Yes	1 (25%)	4 (36.4%)	FET	1.0
No	3 (75%)	7 (63.6%)		

FET: Fisher exact test, MC: Monte carlo test

Discussion

Surgical site infections had been reported to be the most common hospital acquired infections by the American College of Surgeons (ACS), nearly 20%. SSIs are linked to significant morbidity as increased length of hospital stay by approximately 10 days, hospitalization costs by approximately \$20, 000 per admission, readmission rates, significant reduction in the quality of life, and increased mortality ⁽¹⁰⁾.

In the field of gynecologic oncology, in spite of the reported SSI rate of 3–36% for main procedures and about 30% hospital readmission rate owing to postoperative SSIs; the studies on the use of preventive bundle to reduce SSI are scant. ⁽¹¹⁾

The current study included 80 gynecologic Oncology elective cases, divided into 2 groups: study group (40Cases with bundle implementation, 2 lost follow up after month) and control group (40Cases without bundle implementation, 3 lost follow up).

The current study showed there was non-significant statistical difference between the 2 groups in socio-demographic characteristics ($P>0.05$), also in obstetrical, medical, surgical and past history of the studied groups. ($P>0.05$).

In concordance with our findings, Van Nguyen et al, 2019 evaluated gynecologic oncology patients, 339 patients (control) underwent surgery without using the bundle, and 224 patients following it (study group) at a large academic tertiary centre in Toronto, Canada, there was insignificant difference in demographics as their age, BMI, diabetes and hypertension. ⁽¹²⁾

Similarly, Van Nguyen et al, 2019 showed non-statistically significant difference among the 2 groups in primary malignancy ($P=0.14$), coping with our study ⁽¹²⁾

In disagreement with that, Johnson et al, 2016 compared the preintervention and intervention groups as regard primary malignancy distribution, procedure of

surgery and Operative time (min), and there was significant statistical difference between them ($P \leq 0.001$).⁽¹³⁾

The majority of published bundles in gynecologic oncology were successful to reduce the rate of SSIs in many. Johnson et al, 2016 concluded a significant reduction in the risk of SSI after carrying out a bundle before laparotomy in gynecologic oncology cases (6% to 1.1%, relative risk reduction of 82.4%, $p = 0.01$), which included sterile closing tray and changing staff glove for fascial and skin closure, removal of dressing at 24 to 48 hour postoperatively, chlorhexidine soap on discharge and follow-up nursing phone call.⁽¹³⁾

Agarwal et al, 2019 showed significant reduction in overall surgical site infection and readmission rate after investigating the incidence of 30-day SSI before and after the introduction of evidence-based "bundled interventions" in gynaecologic malignancy.⁽¹⁴⁾

Interestingly, the current study illustrated association between SSI rate and different parameters. There was statistically significant association between SSI and socio-demographic data, SSI was associated with BMI, SSI was more common in obese patients ($P=0.038$).

Moreover, the current study found statistically significant association between SSI and obstetric, medical, surgical and past history, SSI was associated with diabetes and history of radiotherapy. There was statistically significant association between SSI and operative details, SSI were associated with type of surgery and operative time, as SSI were more common in staging laparotomy operations than TAH+BSO and Wertheim operations, also SSI were more common in operations lasted more than 2 hours than operations lasted less.

In harmony with our findings, Van Nguyen et al, 2019 demonstrated independent predictive factors associated with an increased risk for overall SSIs in gynecological surgery as surgery prior to carrying out of the bundle,

BMI > 30 kg/m² and operative duration >180min, also Diabetes has been identified as a risk factor.^(12,15)

Prolonged surgical procedure (>180 min) in both abdominal and laparoscopic approaches has been demonstrated to be a risk factor for SSI, also, an incision length ≥ 20 cm could serve a role in SSI development.⁽¹⁶⁾

The rates of SSI in gynaecological procedures appear to be low in vaginal and laparoscopic hysterectomy techniques (50% reduction in SSI incidence) in comparison to laparotomy (3.9% rate of SSI for open hysterectomies and 1.4% for minimally invasive procedures). Robotic interventions in some reviews may be associated with a higher risk due to prolonged surgical procedure.⁽¹⁷⁾

Conclusion

This study showed that implementation of a gynecologic perioperative surgical site infection prevention bundle was associated with a significant reduction in surgical site infection rate in patients undergoing gynaecological oncology surgeries.

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Legends to tables

Table (1): Sociodemographic data among the studied groups.

Table (2): Obstetric, medical, surgical and past history among the studied groups.

Table (3) Pre-operative suspected primary pathology among studied groups.

Table (4): Assessment of wound healing and SSI cases among the studied groups.

Table (5): Secondary outcome in cases with SSI among studied groups.

Table (6): Association between surgical site infection and sociodemographic data among the studied groups.

Table (7): Association between surgical site infection and obstetrical, medical, surgical and past history among the studied groups.

Table (8): Association between SSI and pre-operative suspected primary pathology among studied groups:

Table (9): Association between SSI and operative data among the studied groups.

Legends to figures

Figure (1): Flow chart of the studied groups

Figure (2): Co-morbidities among the studied groups

Figure (3): Previous surgical, SSI and radiotherapy history among the studied groups

Figure (4): SSI cases among the studied groups

Figure (5): Secondary outcome in cases with SSI among studied groups

List of abbreviation

(SSIs): Surgical site infections

(ACOG): American College of obstetrics and gynaecology

(RBS): Random blood sugar

(TAH+BSO): Total abdominal hysterectomy and bilateral salpingo-oophorectomy

(ACS): American College of Surgeons

(BMI): Body mass index