ORIGINAL RESEARCH PAPER

General Surgery

A CLINICAL STUDY TO EVALUATE THE EFFECTIVENESS OF IODINE IMPREGNATED PLASTIC ADHESIVE DRAPES DURING ABDOMINAL SURGERIES SO AS TO PREVENT SURGICAL SITE INFECTIONS.

KEY WORDS: Iodine impregnated incise drape, Surgical site infections, Abdominal surgeries.

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ABSTRACT

Introduction : Surgical site infections are one of the common post-operative complications and third most common hospital-acquired infection. It can occur after 3.03% of all clean and 22.41% of all clean-contaminated surgeries. Different techniques are used to prevent bacteria from entering the surgical wound. Patient's skin flora micro-organisms are responsible for most of the SSIs. Antimicrobial impregnated incision drapes help in immobilizing these bacteria and preventing the upward movement of bacteria4–6 from these areas and thus reduces the chance for SSIs. Hence to evaluate this we have undertaken current study. **Objective :** To study the incidence of surgical site infections in emergency and elective surgeries and usefulness of iodine impregnated incision drapes to prevent them. **Material and Methods:** A prospective study was conducted in our tertiary care hospital amongst 62 patients from March 2023 to Feb 2024 . All patients fulfilling inclusion criteria and exclusion criteria were taken up for the study. **Results**: Incidence of surgical site infection was 24.14% in group 1 vs 30.30% in group 2 without any significant difference between the two ($p>0.05$). Also, two groups did not differ with respect to addiction, comorbidities and mean hospital stays ($p>0.05$). SSI was significantly associated with more mean duration of surgery, diabetes mellitus & more mean hospital stays ($p<0.05$). Most common organism isolated from SSI was Escherichia coli (35.2%) followed by Proteus mirabilis (23.5%). **Conclusion:** Findings from our study do not support the use of iodine impregnated incise drapes as a routine practice in laparotomies for preventing SSI. As the purpose of iodine impregnated incise drape is to prevent skin flora micro-organisms from causing SSI, its use should be limited to clean surgeries and long duration procedures.

INTRODUCTION:

Surgical site infection is a common ailment mostly due to a healthcare-associated infection. Surgical site infection is defined by the Centre for Disease Control and Prevention (CDC)[1] as a proliferation of pathogenic micro-organisms which develops in incision site either within the skin and subcutaneous tissue (superficial) or Musculo fascial layers (deep) or in an organ or cavity, if opened during surgery. Surgical site infections are one of the common post-operative complications and third most common hospital-acquired infection. It can occur after 3.03% of all clean and 22.41% of all clean-contaminated surgeries.[2] However prevalence studies tend to underestimate SSI because many of these infections occur after the patient has been discharged from the hospital. SSI associated with an increase in recovery time and hospital stay, thus significantly increases the morbidity and mortality associated with surgeries.

The incidence of SSI depends on many factors like the definition of infection used, the intensity of surveillance, and the prevalence of risk factors in the population studied. Surgical site infections are the major contributor of morbidity and mortality in postoperative patients. SSI is related to, almost one-third of postoperative deaths. Gram-positive cocci, especially staphylococci, cause many of these infections. SSI can range from a relatively mild wound discharge with no other complication to a life-threatening condition. Many risk factors are associated with surgical site infections. Strategies for prevention of SSI help to reduce morbidity, mortality and reduce hospital and save cost for the healthcare system.

Many strategies are being implemented for reducing surgical site infections. Different techniques are in practice to prevent bacteria from entering the surgical wound. Patient's skin flora micro-organisms are responsible for most of the SSIs. The causative bacteria mostly localize on the hair follicles[3]. Anatomy of the skin makes it difficult to maintain the skin free of micro-organisms in the perioperative period. Antiseptics only incompletely reach these areas. Bacteria harbors in the hair follicles will come up to the skin after few hours of skin preparation. Antimicrobial impregnated incision drapes help in immobilizing these bacteria and preventing the upward movement of bacteria[4–6] from these areas and thus reduces the chance for SSIs. Even though theoretically the usefulness of antimicrobial impregnated incision drapes is arguable, several studies shown conflicting results about the usefulness in preventing SSI[7]. In view of this conflicting results, in this study, we evaluated the usefulness of iodine impregnated incision drapes in preventing SSI.

MATERIALS AND METHODS:

Current study was prospective in nature, protocol of which was approved by the Institutional Ethical committee of the medical college. All patients above 18 years of age who were posted for emergency and elective laparotomies. Clean-contaminated and contaminated surgeries constituted our study subjects. Morbidly obese patients, patients who have known allergy to povidone iodine, patients unwilling to undergo the study were excluded from the study. Study was carried out over a period of March 2023 to Feb 2024.

Inclusion criteria - Patients above 18 years of age planned for emergency and elective laparotomy (clean-contaminated and contaminated surgeries) who were willing to participate in the study after giving written informed consent.

Exclusion criteria -

- Morbidly obese patients.
- Patients who have known allergy to povidone iodine.
- Patients unwilling to undergo the study.

At the time of admission, patients were identified and informed written consent was obtained. Patients were assigned to two groups. Group 1 had the standard 5 minutes povidone iodine skin preparation, followed by surgical spirit followed by application of iodine impregnated incise drape. Group 2 had standard 5 minutes provide iodine skin preparation, followed by the surgical spirit. Immediately prior to operation, each patient was randomly allocated either to receive the drape (group 1) or not to receive the drape (group 2). Randomization was achieved by sequential selection from a random number table. Pre-operative shaving was done using shaving razor on the day of operation.

Mupirocin ointment was applied to the nares of the patient prior to the surgery and a dose of prophylactic antibiotic was given prior to the surgery. An extra antibiotic dose was given in case the surgery was extended beyond 4 hours.

The drape used was iodine impregnated incise drape of 60×60 cm size. Patient's skin was prepared with routine skin preparation using povidone iodine and surgical spirit. Cloth side drapes were applied as usual and the skin has to become dry. Using two people the liner over the drape was removed, the incise drape was held over the proposed incision site with adequate tension. The drape was smoothened down, first along the intended incision line and then over the remaining areas. The incision was made over the drape and surgery was proceeded. At the end of the procedure, before skin closure, the crease was created in the drape and separate drape from the skin surface and about 3 cm space created in the skin edge for skin suturing. After completion of skin closure, covered the suture site with sterile dressing and drapes were removed. Patients were assessed pre-operatively, intra as well as post- operatively. Each patient was followed up from the time of admission and post-operatively at days 3, 5, 7 and weekly for 4 weeks (total 30 days). The surgical site was examined with regards to tenderness, purulent discharge, wound gaping, raised local temperature, local tenderness. Wound infection was diagnosed only if following criteria were fulfilled.

- Signs and symptoms of inflammation like rubor, calor , dolor, and edema around the wound covering the area.
- Purulent discharge from the wound site.
- Fever > 38.5 degree Celsius on two consecutive occasions with a gap of fewer than 24 hours.

Stich abscess and seroma were excluded as they do not fulfill the criteria for diagnosing SSIs. Wounds with purulent discharge were opened and swabs were taken under all aseptic precautions and sent for culture and sensitivity.

Data was collected in pre-structured proforma which was pilot tested and after ensuring it's validity. Descriptive analysis was performed. Categorical variables were reported as frequencies or relative frequencies and compared using the X^2 or Fisher exact test as appropriate. Continuous variables were reported as means with standard deviations and compared using the Student t-test.

Sample size calculation -Estimation of sample size with the difference between proportions. According to a previous study [48] P1= 15 % P2= 1.6 %

$$N = \frac{2 \times P \times Q \times [(Z\text{-}\alpha/2) + (z\text{-}\beta)]^2}{(P_1 - P_2)^2}$$

Where,
N = sample size
(Z–) is error and
(Z–) is error
(Z– /2) = 1.96 (at 95 %)
(Z–) = 0.84 (at 80%)
N = 66.46

Based on above calculation, by round it off to next 10, sample size required for this study was around 70 cases. Out of these 70 selected cases, 8 patients was lost in follow-up and sample size (N) was recalculated as 62.

RESULTS:

Majority of study population (58.62% in group 1 vs 45.45% in group 2) belongs to 41-60 years age group. Among both the groups most of the study population were men (51.72% in group 1 vs 60.61% in group 2). These two groups were comparable in age & gender (p>0.05). Amongst most of the cases in both the groups type of surgery was emergency abdominal surgery (65.52% in group 1 vs 63.64% in group 2) and duration of surgery (79.31% in group 1 vs 72.73% in group 2) was <3 hours. Incidence of surgical site infection was 24.14% in group 1 vs 30.30% in group 2 without any significant difference between the two (p>0.05). Also, two groups did not differ with respect to smoking & alcohol addiction, diabetes mellitus, anaemia, obesity and mean hospital stays (p>0.05). (Table 1)

When we analyzed association of surgical site infections (SSI) with the baseline & surgical parameters, it was seen that SSI not associated with age, gender, type of surgery, addictions (smoking & alcohol), obesity & anaemia (p>0.05). SSI was significantly associated with more mean duration of surgery, diabetes mellitus & more mean hospital stays (p<0.05). (Table 2)

Most common organism isolated from SSI was Escherichia coli (35.2%) followed by Proteus mirabilis (23.5%), Klebsiella spp. (17.65%), S. aureus (11.76%) & Pseudomonas spp. (11.76%). (Table 3)

Table 1. Distribution of patients according to baseline & surgical parameters.

Parameter		Group 1 (n=29)	Group 2 (n=33)	p
Age groups	21-40	8 (27.59)	12 (36.36)	0.5
	41-60	17 (58.62)	15 (45.45)	
	61-80	4 (13.79)	6 (18.18)	
Mean age	(Mean ± SD)	48.75 (11.89)	48.24(12.72)	0.8716
Gender	Male	15 (51.72)	20 (60.61)	0.4
	Female	14 (48.28)	13 (39.39)	
Duration of surgery	<3 hrs.	23 (79.31)	24 (72.73)	0.5
	>3 hrs.	06 (20.69)	09 (27.27)	
Type of surgery	Emergency	19 (65.52)	21 (63.64)	0.8
	Elective	10 (34.48)	12 (36.36)	
Smoking	Yes	14 (48.28)	22 (66.67)	0.1
Alcohol	Yes	12 (41.38)	19 (57.58)	0.1
Diabetes mellitus	Yes	14 (48.28)	20 (60.61)	0.3
Obesity	Yes	05 (17.24)	05 (15.15)	0.8
Anemia	Yes	09 (31.03)	13 (39.39)	0.5
SSI	Present	7 (24.14)	10 (30.30)	0.5
	Absent	22 (75.86)	23 (69.70)	
Hospital stays	(Mean ± SD)	7.8(1.53)	8.21(1.49)	0.29

Table 2. Association of surgical site infections (SSI) with the baseline & surgical parameters.

Parameter		SSI present (n=17)	SSI absent (n=45)	p
Mean age		51.24(12.70)	47.44(12.04)	0.2105
Gender	Male	10 (58.82)	25 (55.56)	0.8
	Female	07 (41.18)	20 (44.44)	
Mean duration of surgery		5.33 (1.88)	3.2 (1.66)	<0.01
Emergency surgery		14 (82.35)	26 (57.78)	0.06
Elective surgery		03 (17.65)	19 (42.22)	
Smoking		11 (64.71)	19 (42.22)	0.1
Alcohol		11 (64.71)	17 (37.78)	0.06
Diabetes mellitus		12 (70.59)	17 (37.78)	0.01
Obesity		04 (23.53)	03 (6.67)	0.04
Anemia		08 (47.06)	11 (24.44)	0.09
Mean hospital stays		10.35 (0.61)	7.16(0.41)	0.0001

Table 3. Microbiological spectrum of SSI's.

Microbiological spectrum	No.	%
E-coli	6	35.29
Proteus Spp.	4	23.54
Klebsiella spp.	3	17.65
S.aureus	2	11.76
Pseudomonas spp.	2	11.76

Total	17	100

DISCUSSION:

Majority of study population belonged to 41-60 years age group among both the groups with most of them were men. These two groups were comparable in age & gender (p>0.05). Among most of the cases in both the groups type of surgery was emergency abdominal surgery and duration of surgery was <3 hours. Incidence of surgical site infection was 24.14% in group 1 vs 30.30% in group 2 without any significant difference between the two (p>0.05). Also, two groups did not differ with respect to addiction, comorbidities and mean hospital stays (p>0.05). SSI was significantly associated with more mean duration of surgery, diabetes mellitus & more mean hospital stays (p<0.05). Most common organism isolated from SSI was Escherichia coli (35.2%) followed by Proteus mirabilis (23.5%). Similar, to our study, **Joan Webster et al**[8] in their systematic review reported that there was no evidence from the seven trials that plastic adhesive drapes reduce surgical site infection rates. **Krishan Kumar et al**[9] also observed a significantly higher duration of surgery in the PAD group (iodine impregnated plastic adhesive drapes), as compared to those without PAD (140.4±45.6 vs 112.5±36.7 mins, p value <0.05) and infection rate was found to be 3% in the patients with iodine impregnated PAD and 5% in patients without iodine impregnated PAD, with no significant difference between them (p value = 0.88). Consistent to this study, **P.A Dewan et al**[10] noted that the iodophor-impregnated plastic incise drape reduced the contamination of the wound, in particular, isolates of normal skin organisms were less frequent when the drape was used in clean and clean contaminated procedures but no difference was found between the wound infection rates for the patients on whom the iodophor drape was used and those patients on whom the drape was not used. However, **Nicholson O et al**[11] that iodine-impregnated drapes were beneficial in reducing postoperative SSI, particularly in clean-contaminated surgeries with SSI occurring in 3.8% of surgeries with an iodophor drape and 9.2% of surgeries without (RR 0.45, p=0.02); but the grade of evidence was poor.

CONCLUSION:

The incidence of surgical site infection was found to be higher in emergency surgeries than elective surgeries. As per our study diabetes mellitus and increased duration of surgery were found to be factors associated with the development of surgical site infection. Efforts should be taken to minimize the duration of surgery without affecting the quality of treatment. Escherichia coli was found to be the most common organism causing Surgical Site Infection in abdominal surgeries.

Findings from our study do not support the use of iodine impregnated incise drapes as a routine practice in laparotomies for preventing SSI. As the purpose of iodine impregnated incise drape is to prevent skin flora micro-organisms from causing SSI, its use should be limited to clean surgeries and long duration procedures.

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