ISSN- O: 2458 - 868X, ISSN –P: 2458 - 8687

International Journal of Medical Science and Innovative Research (IJMSIR)

IJMSIR : A Medical Publication Hub

Available Online at: www.ijmsir.com

Volume – 2, Issue –5, September- October - 2017, Page No. : 186 - 191

A Prospective Comparative Study on Role of Medicated and Non Medicated Suture Material in Preventing Surgical Site Infections

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Conflicts of Interest: Nil

Abstract

Background: Common general surgery procedures are associated with a 1–11% risk of infections. These surgical site infection increases morbidity and mortality of patients and require prolonged antibiotic prescription and increase cost of treatment. Moreover, surgical site infections are commonly associated with prolonged hospital stays, and potential comorbidity. The authors prospectively evaluated the incidence of surgical site infection following surgeries performed using either antimicrobial suture (AMS) or conventional suture.

Methods: It is a single-centre, prospective, randomized controlled trial, and the enrolled 532 patients, among whom surgeries were performed over 20 months. The primary outcome measure was the incidence of surgical site infection within 30 days of surgery.

Results: The surgical site infection rate in the study group was 16 (5.59%) of 286 procedures and 18 (7.31%) of 246 procedures in the control group (EX^2=0.02, p >0.05). No suture-related adverse events were reported in either group.

Conclusion: These results support the suggestion that the use of AMS for general surgery procedures is only as effective as non medicated sutures but at increased cost, adding unnecessary financial burden to the patients.

Keywords: Nutrition, Septicemia

Introduction

Surgical site infections are the third most commonly reported nosocomial infection worldwide and they account for approximately 30% of all Nosocomial infections. [19] They have been responsible for the increasing cost, morbidity and mortality related to surgical operations and continues to be a major problem even in hospitals that have access to most modern facilities and follow standard protocols of preoperative preparation and antibiotic prophylaxis.

Many factors influence surgical wound healing and determine the potential and the incidence of, infection [8] . The level of bacterial burden is the most significant risk factor [9][10][11], followed by type of surgery, surgical site preparation method, dose and type of prophylactic antibiotic, pre op hosp stay, type of suture material used for wound closure etc. suture material might also play a significant role in SSI. To reduce the effect of suture material on the risk of developing an infection a polygalactin 910 suture coated with triclosan (Vicryl plus) has been introduced about a decade back. Triclosan (TC) is an antiseptic drug mainly used in dentistry and in several antiseptic soaps. The safety of TC has already been investigated in several studies [41]. The clinical efficacy of vicryl plus over vicryl has been studied by various workers with conflicting results, thus we planned

to undertake a large study to evaluate efficacy of vicryl plus over vicryl in preventing surgical site infection. This paper describes the factors that influence surgical wound healing and effect of medicated suture material and non medicated suture material (triclosan coated vicryl) in reducing surgical site infection. In the present study, we have evaluated the efficacy of coated polyglactin 910 suture material (Vicryl Plus) in reducing the surgical site infection(SSI) in comparison with traditional polyglactin 910 (Vicryl) in various surgeries.

Methods

This was a prospective study conducted on 532 patients admitted for various surgeries in general surgery units of Lala lajpat rai Hospital, affiliated with GSVM medical College, Kanpur. The study was aimed to estimate the efficacy of triclosan-coated polyglactin 910 sutures (vicryl plus) over polyglactin 910 (vicryl) sutures for the reduction of surgical site infection.

Patients were included in the study based on following Inclusion criteria:(1) Patient undergoing one of following surgeries; (a)Open hernioplasty (b)Open cholecystectomy (c)Trans abdominal hysterectomy (d)Open appendicectomy (2)Patients undergoing elective surgery (3) Patient in age group of 20-65 yrs. Following patients were not included in the study group: (a)Patients with Immunocompromised state i.e, patients on age extremes, on corticosteroids, HIV seropositive, those who have taken chemotherapy, radiotherapy (b)Patients with Appendicular abcess/ruptured/perforated appendix, Gangrenous gall bladder/perforated gall bladder, Obstructed hernia/strangulated hernia, Pyometra. Patients were included in the study, based on following crieteria: (1)Type of surgery conducted (2)General nourishment status of the patient (3)Associated comorbidities like obesity, diabetes mellitus and COPD

Surgical wounds were inspected at the time of first dreSSIng on second postoperative day and regularly thereafter for 30 days. [39]Wound infection was diagnosed if any of the following criteria was fulfilled: (a)Serous or non purulent discharge (b)Pus discharge (c)Serous/non purulent discharge from wound with signs of inflammation ie, edema, redness, warmth, raised local temperature, fever > 38 degree C, tenderness (d)Wound deliberately opened by surgeon due to localized collection. [40]

Swabs obtained from infected wounds were collected by standard methods and were sent to department of microbiology, GSVM medical college, Kanpur.

Data collected was analyzed using SPSS software version 15. Chi square statistical test was applied on the applied and finally $P< 0.05$ was considered to be significant.

Results

Out of total 532 patients, majority were operated for open inguinal hernia repair, followed by open appendicectomy, transabdominal hysterectomy and open cholecystectomy. Of the total 532 patients, 34 developed surgical site infection, with overall infection rate of 6.39%. (Table 1)

In hernioplasty group, out of 248 patients, 10 patients developed surgical site infection (4.03%). In this group, vicryl was used in 112 patients and 6 of them developed SSI (5.38%) (table2) whereas in 136 patients, we used vicryl plus sutures and SSI developed in 4 of these patients (2.94%) , ($p>0.05$, $EX^2=0.851$).Amongst diabetics, when vicryl was used, none out of 28 got affected whereas in vicryl plus group, 2 out of 24 developed SSI,(8.33%) Amongst obese patients (BMI>30), out of total 14 patients, 4 were affected. In vicryl group 2 out of 8 were affected, in vicryl plus group, 2 out of 6 were affected. (Table 1)

In open cholecystectomy group, out of 70 patients, 6 developed surgical site infection (8.57%) this group,

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vicryl was used in 28 patients and 4 of them developed SSI (14.28%) (Table 1) whereas in 36 patients, we used vicryl plus sutures and SSI developed in 2 of these patients (5.55%), ($p>0.05$, $EX^2=1.16$). Amongst diabetics, one out of total 6 diabetic patients was infected. We used vicryl in 4 patients, 1 patient got infected. When we used vicryl plus, none out of 2 were affected, ($p>0.05$, $EX^2=0.06$) Amongst obese patients (BMI>30), out of total 3 obese patients, 1 was affected. When we used vicyl, none out of 2 were affected, however in one obese patient that we used vicryl plus, 1 out of 1 was affected, ($p>0.05$, $EX^2=3.0$)

In trans abdominal hysterectomy group, out of 102 patients, 8 developed surgical site infection (7.84%) In this group, vicryl was used in 48 patients and 4 of them developed SSI (8.33%) (Table 1) whereas in 54 patients, we used vicryl plus sutures and SSI developed in 4 of these patients (7.40%), ($p>0.05$, $EX^2=0.132$).Amongst diabetics, one 4 out of total 14 diabetic patients were infected. We used vicryl in 6 patients, 2 patients got infected. When we used vicryl plus, 2 out of 8 were affected, ($p>0.05$, $EX^2=0.11$) Amongst obese patients (BMI>30), out of total 18 obese patients, 6 werw affected. When we used vicyl, 2 out of 8 were affected, however in one obese patient that we used vicryl plus, 4 out of 10 were affected, ($p>0.05$, $EX^2=1.06$)

In appendicectomy group, out of 112 patients, 10 developed surgical site infection (8.92%); In this group, vicryl was used in 54 patients and 4 of them developed SSI (7.40%) (Table 1)whereas in 58 patients, we used vicryl plus sutures and SSI developed in 6 of these patients (10.34%), ($p>0.05$, $EX^2=0.248$).Amongst diabetics, one 2 out of total 20 diabetic patients were infected. We used vicryl in 8 patients, 1 patient got infected. When we used vicryl plus, 1 out of 12 were affected, ($p>0.05$, $EX^2=3.0$) Amongst obese patients (BMI>30), out of total 14 obese patients, 2 were affected. When we used vicyl, 1 out of 8 were affected, however in one obese patient that we used vicryl plus, 1 out of 8 was affected. Amongst obese patients (BMI>30), out of total 14 patients, 2 were affected. In vicryl group 1 out of 8 were affected, in vicryl plus group, 1 out of 8 were affected.

In addition, there was no significant difference in the incidence of surgical site infection amongst patients who had COPD in comparison to those who did not have COPD. Similarly, there was no significant difference in incidence amongst male and female. Though not a part of our study, we also tried to find out the different types of bacterial strains responsible for surgical site infection in our set up.

Amongst 34 cases of surgical site infection, *staphylococcus aureus* was isolated in 16 samples, followed by pseudomonas *aeruginosa in* 8 cases. 2 samples were positive for *E.coli*. Polymicrobial infection by *S.aureus+E.coli* and *S.aureus+Acinetobacter* was found in 1 specimen each. No bacteria grew in 6 pus specimen but when Gram smear was seen of these 6 specimen, Gram Negative bacilli could be seen. The bacteria did not grow probably because patient was on antibiotics.

Discussion

Post operative surgical site infection continues to be a matter of concern for any surgery. It increases patient morbidity and mortality, in addition, post operative surgical site infection is a well known risk factor for hernia recurrence. Previous reports have identified numerous factors associated with surgical site infection, including patient age,[28], skin shaving [11], longer operating times,[7] intra operative glove breach,[28] and participation of surgical trainees etc.[7],[8] Taken together, these risk factors support the conclusion that

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patient factors and surgical technique both directly influence surgical site infection risk. Patient population characteristics did not differ significantly with regard to any factors known or suspected to influence infection risk. No changes in surgery technique were instituted by either surgeon during the study period. Open method of surgery rather than laparoscopic method was chosen to eliminate additional risk factors associated with improper sterilization of laparoscopic instruments, in addition, the suture material used would be comparatively insufficient to carry the same bacterial load, as would be expected in open surgeries.

Most surgical site infections are believed to arise from Intra operative contamination in the operating room, either by skin flora from the host[11]or from surgical personnel .Meticulous surgical technique appears to reduce surgical site infection risk.[7],[11], The use of prophylactic perioperative intravenous antibiotics has been reported to reduce subsequent surgical site infection risk.[29] The medicated suture is another recently developed technology that may be beneficial in the prevention of surgical site infections. Polyglactin 910 suture coated with triclosan was approved for clinical use by the Food and Drug Administration in 2002. The antimicrobial agent, triclosan, is bacteriostatic for a wide range of microbial (including Methicillin sensitive Staphylococcus aureus, Methicillin resistant Staphylococcus aureus, and Staphylococcus epidermidis) at concentrations found in the suture.[30] Triclosan is an antiseptic drug that has been used since the1970s mainly in disinfecting soaps and dentistry. Safety studies have been performed in the past, mainly focusing on systemic toxicity and local adverse reactions. Overall, these studies concluded that triclosan has no carcinogenic, genotoxic, pyrogenic, or teratogenic effects. In addition, systemic levels of triclosan are extremely low due to the use of these products.[21] Recently, however, concern ensued after reports of the formation of toxic byproducts of triclosan containing soaps in household conditions.[22] Laboratory and modelling studies indicate that the formation of chloroform and other chlorinated daughter products can occur when triclosan-containing antimicrobial products react with free chlorine and that these reactions can potentially lead to enhanced chloroform exposures[22].

The presence of conventional suture in a surgical wound is known to lower the size of bacterial inoculi necessary to produce a wound infection[31] and to increase the overall risk of surgical site infections.[32] Triclosan-coated polyglactin 910 suture has been shown in some studies to prevent colonization of the suture by both Gram-positive and Gram negative bacteria.[33] Another in vitro study demonstrated a zone of staphylococcal growth inhibition surrounding the medicated suture material .[34]. However, in our study we did not find similar efficacy in terms of reducing surgical site infection. This study shows that there is no evidence for any effectiveness of triclosan coating. The use in suture material has been tested in animal and in vitro experiments. Handling and tension force of the sutures was found to be comparable to standard suture material. No effect on wound healing was observed [25]. Thus, although triclosan is relatively nontoxic in classical toxicological terms, negative effects such as dermatitis, skin irritation, and allergic reactions have been described [38]. Potential formation of toxic products due to chemical reactions has to be elucidated [37]. Although few studies have validated efficacy of antimicrobial suture in cerebrospinal shunt surgery [35] and in sternal wound closure, but their study population was small and larger trials conclusively proved it to be ineffective [36]

Conclusion

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In conclusion, in our observation, there is lack of clinical and laboratory evidence to support the efficacy of triclosan-containing suture material, suggesting that more clinical research is needed to prove its efficacy .

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TABLE 1: Showing demographic profile and clinical details of patients undergoing various surgeries using VICRYL and VICRYL plus.

NAME OF SURGERY	VICRYL	No of infected wounds using VICRYL	VICRYL plus	No of infected wounds using VICRYL Plus
Age (20-45) (46-65)	92 154	6 12	96 190	4 12
Sex – male female	146 100	9 9	164 122	8 8
BMI- <18 18-30 >30	4 216 26	 13 5	3 258 25	 7 9
DIABETIC	42	4	50	5
OPEN HERNIOPLASTY	112	6	136	4
OPEN CHOLECYSTECTOMY	32	4	38	2
TRANSABDOMINAL HYSTERECTOMY	48	4	54	4
APPENDICECTOMY	54	4	58	6
TOTAL	246	18(7.31%)	286	16(5.59%)

Table 2: showing culture results of infected cases

Column - 1	Column - 2
S.aureus (47.05%)	16
p.aeruginosa (23.52%)	8
E.coli(5.88%)	2
S.aureus+E.coli (2.94%)	1
S.aureus+Acinetobacter (2.94%)	1
Sterile (17.64%)	6

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