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Original Research Article

Impact of using triclosan-impregnated sutures on incidence of surgical site infection: a real world Indian study

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ABSTRACT

Background: Surgical Site Infection is an index of health care system of any hospital. Surgical material is a risk factor for SSI that can be easily changed. One of such measures is the use of antimicrobial suture technology which involves the impregnation of synthetic, absorbable, polymeric sutures with the antiseptic, Triclosan. Triclosan-coated sutures inhibit bacterial colonization of wide-spectrum of pathogens. This study was designed to assess the efficacy of triclosan coated sutures in reducing incidence of surgical site infection in Indian population.
Methods: This is a retrospective 'real-world' study of 150 patients who underwent surgery and wound closure with triclosan-coated suture from May 2015 to December 2015 at Grecian Hospital, Mohali. Incidence of SSI was recorded, and nature of wound was categorized. Data was subject to descriptive analysis.
Results: A 99.3% of wounds sutured with triclosan coated sutures did not have surgical site infection. The single case of SSI encountered was categorized as superficial-incisional. All the evaluated cases were categorized as 'clean' at the time of discharge.
Conclusions: Triclosan-coated sutures were responsible for the reported reduction in SSI, particularly in adult patients with clean wounds. This study justifies that in addition to the mandated core measures of surgical care, adjunctive evidence-based interventions such as Triclosan-coated sutures should be considered in the comprehensive effort to decrease risk of surgical site infection and improve outcome at both patient and institutional levels.

Keywords: Antibiotic-coated sutures, Clean wound, Nosocomial infections, Surgical Site Infection (SSI), Surgical asepsis, Triclosan-coated sutures, Wound infection

INTRODUCTION

Surgical Site Infection (SSI) is the index of the health care system of any hospital. SSIs are the second most frequently reported health-care-associated infections and lead to significant morbidity and mortality. Majority of SSIs (70%) are superficial, involving skin and subcutaneous tissue, whereas deep organ and space infections, although fewer, are commonly associated with greater morbidity, readmissions, intensive care unit admissions, long-term surgical-site complications and mortality.[1,2] Despite the advances in asepsis, SSIs continue to challenge healthcare systems by incurring additional hospital bed occupancy, escalated costs and increased work hours lost.[3]

Burden of SSI in India

Globally, surgical site infection rates have been reported in a range from 2.5 to 41.9 %.[4,5] Compared to these global trends, Singh S et al reported the findings of international nosocomial infection control consortium

from India. This study established that SSI in India are greater in incidence compared to those reported by CDC National Healthcare Safety Network, and hence the issue demands targeted interventions. Another study reported SSI from rural teaching hospital to be as high as 27.7% for emergency surgeries and overall 8.67% for all surgeries.[6] With its high incidence, particularly in low resource setting like rural India, SSI places a burden on both patients and healthcare systems.

Opportunity to intervene

An estimated 40-60% of SSIs are preventable.[7] The measures used to prevent these nosocomial infections include prophylactic antibiotic treatment, preoperative preparation of the patient, proper surgical asepsis and postoperative care protocols.[8] The various factors associated with development of an SSI are enlisted in table 1. Suture material has been recognized as a potential nidus for infection for more than 40 years, especially within the presence of wound contamination.[9] Sutures coated with an antibacterial agent, like triclosan-coated sutures, can substantially decrease the risk for healthcare-associated infection.

World Health Organization recommends the use of triclosan-coated sutures for reducing the risk of SSI in their recent guideline, independent of the type of surgery based on moderate level of evidence.[10] Similarly recent CDC guideline in its recommendation number 2C endorses the use of triclosan coated sutures with a category II evidence of moderate quality.[11]

Properties of triclosan coated suture

Antimicrobial suture technology involves the impregnation of synthetic, absorbable, polymeric sutures with the antiseptic, Triclosan. Triclosan (5-chloro-2 (2,4-dichlorophenoxyphenol) is a broad-spectrum phenol family antiseptic, used for more than 30 years as a safe and effective antimicrobial agent, against the most common pathogen agents that cause SSI: *S. aureus* and *S. epidermidis*.[12] Triclosan-coated sutures inhibit bacterial colonization of wide-spectrum of pathogens related to SSI without altering the physical properties of sutures, and without interfering with the wound-healing process. It targets the Fab I gene, which blocks bacterial fatty acid synthesis (particularly the enzyme enoyl-acyl carrier protein reductase).[13]

Health care systems suffer high economic loss incurred by SSI. Studies conducted by Edmiston et al and Fleck et al have shown that a small additional expense of triclosan-coated suture could significantly decrease the risk of readmission and the length of hospital stay.[14,15] Leaper et al, in their recent meta-analysis reported that the mean savings achieved by using antimicrobial coated sutures versus non-coated sutures per surgical procedure were around £91·25 per surgery.[16]

Need for this study

Multiple global studies have shown level 1A clinical evidence that the use of triclosan coated suture reduces the incidence of SSI by 30%. But Indian practices of wound management differ in terms of hygiene, follow-up, climate and infections. With the increase in incidence of nosocomial infections and multi drug resistance, a meticulous evaluation of treatment approaches in Indian patients is warranted. The aim of this study was to evaluate whether the incidence of SSIs can be reduced when triclosan-coated sutures are used for wound closure, and to evaluate the incidence of SSIs according to each wound classification.

Risk factors for SSI[17-19]

Patient-related factors

- Sex
- Age
- Body mass index (BMI)
- Complications
- Prior surgical procedures
- Lifestyle-related factors

Surgery related factors

- Meticulous surgical technique
- Duration of surgery
- Poor Skin antisepsis
- Efficacy of antimicrobial prophylaxis
- Presence of suture material in wounds

METHODS

Patients

From May 2015 to December 2015, a total of 150 patients underwent surgical wound closure with triclosan-coated sutures at (Grecian Hospital), Mohali. Preoperative characteristics of the patients are comparable and are given in Table 1.

Some confounding factors like type of surgery, American Society of Anesthesiologists (ASA) score, elective or emergency surgery, antibiotic prophylaxis, blood loss, presence or absence of drain and any underlying or predisposing conditions were noted. Swabs were obtained from the post-operative infected wounds and processed by the conventional microbiological methods.[20] CDC criteria were used to define the type of surgical wound i.e. Class I- Clean, Class II- Clean contaminated, Class III- Contaminated, Class IV- Dirty. The ASA score was used for classification of the patients in terms of risk for the development of a surgical site infection.70% patients had ASA score of 2, 23.3% patients had score of 3, 3.3% patients had score of 1, and 2% had ASA score of 4.

Exclusion criteria were on-going sepsis or septicaemia, on-going bacterial infections or antibiotic treatment, other severe disease that might influence wound healing, emergency surgery or known allergy to triclosan.

Table 1. Pre-operative characteristics of patients.

Parameter		Number
No. of cases		150
Height (cm)	Mean	162.27
	SD	10.13
	Range	141-188
Weight (kg)	Mean	65.32
	SD	15.53
	Range	31-109
Sex (%)	Male	57(38.0)
	Female	93(62.0)
Type of surgery	Elective	148(98.7%)
	Emergency	2 (1.3%)
ASA score	1	5 (3.3%)
	2	105 (70%)
	3	35 (23.3%)
	4	3 (2%)
	5	0 (0 %)
Wound class	Clean	150 (100%)
	Clean contaminated	0
	Contaminated	0
	Dirty	0
Blood loss	Yes	150 (100%)
	No	0
Need for blood transfusion	Yes	4 (2.7%)
	No	142 (94.7%)
Use of drain	Yes	130 (86.7%)
	No	16 (10.7%)

Surgical closure

Wound closures were performed by 5 experienced surgeons as per centre's protocol. Prophylactic antibiotics were administered to all patients within one hour after the start of the operation. Surgical areas were shaved just before the operation only in required cases and were aseptically scrubbed with chlorhexidine (5%, soap). The wounds were closed subcutaneously with a 3.0 multifilament polyglactin 910 suture coated with triclosan (Vicryl Plus®, Johnson and Johnson, Pvt. Ltd.,) and intracutaneously with a 4.0 triclosan-coated multifilament Polyglactin 910 suture (Monocryl Plus®, Johnson and Johnson, Pvt. Ltd.,) legal entity. All wounds were then covered with drape, compresses and elastic bandages. The drape was removed on the fourth postoperative day. Author used drainage at the site of surgery in 86.7% cases. Prophylactic antibiotic treatment was performed according to the anesthesiology unit protocol. 2nd generation cephalosporin was used as the prophylactic antibiotic. It was only injected once within one hour and once within 24 hours after the operation, in accordance with the local centre practice. Postoperative anticoagulation was performed if found necessary depending on wound and comorbidity. In cases of poorly healed wounds and the presence of discharge for a long period bacterial culture was considered.

Outcome measures

Patients were daily inspected by attending surgeons for any wound discharge, exudates, wound integrity, and signs of inflammation. In case of a suspected infection, wound swabs for cultures were taken, and evaluation for potential surgical revision was done.

After discharge, if a patient reported any type of wound healing problems including dehiscence, swelling, redness or exudate, they were seen at the outpatient clinic, and the wounds were evaluated. Bacterial cultures were only collected from patients with symptoms of infection and no surveillance cultures were collected. SSI within the 30 first days after surgery were considered to be related to surgery and classified in terms of severity of the infection

Statistics

Data are presented in descriptive manner for this single arm study as mean±standard deviation, median and range or number and percentage. The treatment was considered efficient if observed probabilities were lower than previously reported in literature, not efficient if they were equal, and harmful if the observed rate of complications was greater than the predicted rate.

RESULTS

During the study, wound infection developed in 1 patient (0.7 %). (Table 2). Thus, use of triclosan coated sutures could reduce the incidence of SSI by 99.3%.

Table 2: Incidence of surgical site infection in 150 wounds sutured with triclosan-coated sutures.

Surgical site infection	No. of cases (N = 150)	%
Yes	01	0.7
No	149	99.3

There were no signs of wound dehiscence. The single SSI encountered was categorized as superficial incisional. There was no case of deep incisional or organ/space infection observed. Profile of wound condition at the time of discharge could be evaluated in 149 cases (99.3%). All the evaluated cases were found to be 'clean' at the time of discharge. There was not a single case of intraoperative complications in our cohort. There was no case of adverse effect reported in present study.

DISCUSSION

The development of an SSI is a complex, often multifactorial process, and effective risk-reducing

strategies focus on mechanistic factors which may play a role in these serious postoperative complications. One of the major breakthroughs in SSI research is the appropriate use of antibiotics before and after operation.[21] As most postoperative SSIs occur in incised areas, suture materials play an important role in the development of SSI by providing a local surface for the adherence of microorganisms.[22] Once pathogens have colonized suture materials, a biofilm may subsequently be formed to promote the attachment and reinforce the resistance against attack from the host's immune system and antimicrobial treatment, thus predisposing the wound to infection. Thus, surgical material is clearly a risk factor that can be easily changed. Accordingly, the strategy of coating sutures with antimicrobial agents, such as silver or antibiotics like Triclosan, to reduce the risk of suture-related SSI has been considered since the 1950s. Triclosan, a widely used antibacterial agent, possesses potent activity against the most common bacteria responsible for SSIs. Because triclosan is an antibacterial agent, and not an antibiotic, the risk of resistance is very low.[23] Further, the evidence that triclosan could interfere in physiologic wound healing process has been refuted in many studies.[24]

The results of this analysis suggest that the presence of triclosan-coated sutures within the surgical incision bed appears to be associated with a reduction in the incidence of SSIs. Author could achieve a 99.3% reduction in incidence of SSI in the current study. Other contributing factors may be high socioeconomic class patients visiting our center, majority of cases being elective surgery, the efficient hospital asepsis protocol, type of operation, and the surgeon technique.

Present results are very similar to Fleck T et al, in which a in sternal wound closure study, the rate of SSI after the use of triclosan-coated polyglactin 910 antimicrobial suture was found to be 0 of 103 (0%) versus 24 of 376 (6%) after the use of conventional non-coated sutures.[24] Galal and El-Hindawy reported a prospective, randomized, double-blind study that showed that triclosan-coated polyglactin 910 reduced the incidence of SSIs from 15% to 7%.[25] In another study by Rozzelle and coworkers, in cerebrospinal fluid shunt surgery, the shunt infection rate was 4.3% when triclosan-coated polyglactin 910 antimicrobial sutures were used versus 21% in a conventional polyglactin 910 suture group.[26] Doud FC et al conducted a systematic literature review and meta-analysis which identified 15 randomized controlled trials and produced a risk ratio of 0.67, 95% CI 0.54-0.84 ($p \leq 0.00053$), demonstrating a highly statistically significant, lower risk of SSI following operative procedures in incisions which were closed with triclosan-coated sutures compared to non-antimicrobial closure technology.[27] The literature contains many more studies that examine the efficacy and safety of triclosan-coated sutures and nearly all such studies have come to similar conclusions as our results about triclosan coating and risk of SSI in various types of surgery. Overall, recently the field of TCS in SSI has drawn attention of researchers which is evident by continuous publications in this area including the recent meta-analyses.[25] Present results reiterate this summated evidence.

Wound contamination following surgery often involves both deep and superficial incisional sites. Therefore, to maximize benefit from Triclosan coated sutures, they should be used for both superficial and deep musculofascial layers, as in our study. The practice needs to be inculcated in all levels in the surgery department as fascial and subcuticular closure is often delegated to more junior members of the surgical staff.

There are some limitations to our study. First, the number of cases was limited (n= 150) so the interpretation of our results may lack statistical power. Second, the number of criteria that are included in the model is limited. Third, the study was performed at a single center in Northern India but in different surgeon's hands which may have introduced bias. Fourth, our study does not have a comparator arm in which non-antibiotic-impregnanted sutures were used. Finally, all cases included in this study were categorized as 'clean' at the outset, and majority of surgeries were elective. Thus, the applicability of this study results to future patient care depends on the similarity of the case-mix of future surgical patient populations. There is no denying the superiority of a prospective, randomized study, including a large number of patients will further support the results of present study. Also, more studies are needed to evaluate efficacy of Triclosan coated sutures to reduce the incidence of SSIs in clean-contaminated, contaminated and dirty wound cases. Nevertheless, in face of lack of many randomized controlled trials from this part of the world, a real-world study is a step forward. The very fact that without the controlled environment of a clinical trial, TCS could demonstrate superior efficacy can guide decision making for now.

This study provides data on SSIs with use of triclosan coated sutures from a tertiary care center in India which also re-emphasizes towards importance of proper implementation of antibiotic stewardship and use of strict asepsis treatment protocol.

SSIs are consistently associated with elevated clinical and financial burden on the healthcare system. The financial burden is in terms of direct costs incurred by prolonged hospitalization (hospital resource utilization of medical staff, investigation, and treatment) and in some cases, readmission or even reoperation. The indirect costs are in terms of productive work-days lost and quality of life impaired. National and international recommendations to prevent SSIs have been published, including recent guidelines by the WHO and CDC, but implementation into clinical practice remains an unresolved issue. It requires an integrative approach with measures taken during the pre-, intra- and postoperative care from the varied stakeholders involved. Use of TCS is one such

intervention. Studies have already established the positive budgetary outcomes for a healthcare of a TCS-adoption strategy. It needs to be complemented by controlling other factors like use of invasive devices, surgical procedures, and selection pressure from excessive antibiotic use and environmental factors (contaminated air-conditioning systems, physical layout of the facility, nurse-to-patient ratio and doctor to patient ratio).

CONCLUSION

The results of this retrospective study show that triclosan coated sutures were responsible for the reported reduction in SSI, particularly in adult patients with clean wounds. The study justifies that in addition to the mandated core measures of surgical care, adjunctive evidence-based interventions such as triclosan-coated sutures should be considered in the comprehensive effort to decrease risk of surgical site infection and improve outcome at both patient and institutional levels. With the prevention of surgical site infection, the healthcare costs can be reduced, and greater patient satisfaction can be achieved. The authors are of the opinion that triclosan antimicrobial sutures should be considered for both superficial and deep layer closure after all surgical operations. Evidence-based medicine is at best an evolving discipline, and future randomized controlled trials will be needed to decipher whether this trend of benefit to the Indian population can be generalized within a realm of similar risk. Future studies could also include stratification by risk factors for surgical site infection such as diabetes, steroids and smoking.

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