Review Article

Efficacy of triclosan-coated sutures for reducing risk of surgical site infection in adults : a retrospective real-world study of 306 patients from Northern India

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Surgical site infections (SSIs) are associated with an increased risk of morbidity, readmission, intensive care unit stay, and mortality. The present study aims to assess the efficacy of triclosan coated sutures (TCS) in reducing the incidence of SSI in a tertiary care setting in Northern India and the risk factors associated with it. This is a retrospective 'real-world' study of 306 patients who underwent surgery and wound closure with triclosan-coated suture from July 2016 to Jan 2017 at SMS Hospital, Jaipur. Association of factors with SSI incidence was analyzed using the χ^2 test. During the study, wound infection developed in 13.4 % as superficial/incisional SSI and 1.3% cases as deep incisional SSI. None of the patients had SSI 10 days after discharge. Thus, use of triclosan coated sutures could reduce the incidence of SSI by 85.3%. Significant association of incidence of SSI was observed with 'wound Class 1' and 'age group 58-67 years'. 12 patients of 50 (24%) in class II wound category has SSI with uncoated sutures whereas only 2 of 50(4%) patients had SSI in class II in coated vicryl category. Similarly, 16 patients of 29 (55%) had SSI in class III category which was on 2 of 25 (8%) for vicryl coated suture. There was no case of adverse effect reported in our study. With use of Triclosan coated sutures, SSI could be prevented in 85.3 % cases and class II and III wounds could be effectively prevented. Our study presents a compelling case for using TCS in routine clinical practice.

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Key words **: Triclosan coated suture, antibiotic coated sutures, surgical site infection, age, gender, wound class.**

Epidemiology of SSI :

Surgical site infection (SSI) is defined as microbial contamination of the surgical wound within 30 days of an operation or within 1 year after surgery if an implant is placed in a patient[4]. There have been many technical advances in infection control and surgical practices, still SSI continue to be a challenge, even in hospitals with modern infrastructure[5]. SSIs are the third most common hospital-acquired infection (14%-16%)[6]. In India, the rate of SSI varies from 6.1% to 38.7%[7-10]. However in comparison to the Indian hospitals the rate of infection reported from other countries is quite low, for instance in USA it is 2.8% and in European countries it is reported to be 2-5%[11]. A recent surveillance conducted worldwide by International Nosocomial Infection Control Consortium across 82 hospitals of 66 cities in 30 limited-resource countries including India revealed an overall SSI rate of 2.9% as compared with the incidence rate of 2.0% for the US hospitals[12]. The lack of attention towards the infection control measures, inappropriate hand hygiene practices and overcrowded hospitals can be the major contributory factors for high infection rate in India.

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- **Wound contamination following surgery often involves both deep and superficial incisional sites. Therefore, to maximize benefit from antimicrobial sutures, triclosan coated sutures should be used for both superficial and deep musculofascial layers.**
- **The expected potential beneficial effects of triclosan coated sutures extend beyond merely the prevention of infection. In 2007, Gómez-Alonso *et al* demonstrated the efficacy of these sutures in preventing bacterial colonization and modulating the inflammatory response, which allowed better tissue healing[1].**
- **There are some unanswered areas with triclosan coated suture for instance, to evaluate the risk of antimicrobial resistance to triclosan and the long degradation time of triclosan[2] and its impact on potential risk for bioaccumulation in the environment[3].**
- **Previous studies have shown that the use of conventional antibiotics in patients with SSI can be reduced with triclosan-coated sutures.**

Health-economic Burden of SSI :

SSI impose a substantial burden in terms pharmacoeconomic loss. A cost comparison in India revealed total expenses incurred by patients with SSIs was INR 29,000 (average) as compared to INR 16,000 (average) incurred by non-infected patients[13]. The incidences of mortality were also higher in infected patients (12.8% to 19.9%) as compared to the controls (1.1% to 3.8%)[5,14].

Clinical features of SSI :

SSI are usually caused by exogenous and/or endogenous microorganisms that enter the operative wound either during the surgery (primary infection) or after the surgery (secondary infection). The risk of SSI is markedly increased when a surgical site is contaminated with $>10^5$ microorganisms per gram. However, when foreign material is already present at the site (ie, 100 Staphylococci per gram of tissue introduced on silk sutures), the dose of contaminating microorganisms required to produce infection is much lower. Majority of SSIs are uncomplicated involving only skin and subcutaneous tissue but sometimes can worsen to necrotizing infections. Clinically, SSI present as an infected surgical wound can be characterized by pain, tenderness, warmth, erythema, swelling and pus formation[15].

Factors Impacting SSI :

Many preventable causes of SSI have been identified, and if proper measures are implemented, the incidence could be reduced. A number of patient related factors (old age, preexisting infection, co-morbid illness, nutritional status) and procedure related factors (poor surgical technique, pre operative part preparation, inadequate sterilization of surgical instruments, prolonged duration of surgery) can influence the risk of SSIs significantly[2]. In addition to these risk factors, the virulence and the invasiveness of the organism involved, physiological state of the wound tissue and the immunological integrity of the host are also the important factors that determine whether infection occurs or not[16].

SSI can be controlled by optimal preoperative, intraoperative and postoperative patient care. This encompasses meticulous operative technique, timely administration of appropriate preoperative antibiotics, and a variety of preventive measures aimed at neutralizing the threat of bacterial, viral, and fungal contamination posed by operative staff, the operating room environment, and the patient's endogenous skin flora. Another measure to support the above interventions is use of antibiotic impregnated sutures.

Place of Triclosan Coated Sutures :

Several products have been introduced into the market, including triclosan-coated polyglactin 910 antimicrobial suture (Vicryl Plus; Ethicon, Johnson & Johnson), triclosan-coated poliglecaprone 25 antimicrobial suture (Monocryl Plus; Ethicon, Johnson & Johnson) and triclosan-coated polydioxanone antimicrobial suture (PDS Plus; Ethicon, Johnson & Johnson). It has no toxic, teratogenic, or irritating effects at the standard concentration[17]. Triclosan targets the e Fab I gene, which blocks bacterial fatty acid synthesis (particularly the enzyme enoyl-acyl carrier protein reductase [ENR])[18]. Whilst many randomized controlled trials have supported the evidence of beneficial effect of TCS in the prevention of SSIs[19-21], but some studies have shown inconclusive results[22-24].

The present study aims to assess the efficacy of TCS in reducing the incidence of SSI in a tertiary care setting in Northern India and the risk factors associated with it in the General Surgery.

Material and Methods

Patients :

From July 2016 to Jan 2017, a total of 306 patients underwent surgical wound closure with triclosan-coated sutures at SMS Hospital, Jaipur.This retrospective study was approved by the Institutional Ethics Board. Written informed consent was not applicable as it was a retrospective study. Preoperative and demographic characteristics of the patients are mentioned in Table 1.

Some confounding factors like American Society of Anesthesiologists (ASA) score,elective or emergency surgery, antibiotic prophylaxis, blood loss and presence or absence of drain were noted. CDC criteria were used to define the type of surgical wound ie, 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.29.1% had ASA score of 1, 34.3% patients had ASA score of 2, 17% patients had score of 3, 3.3% patients had score of 1, and 19.6 % had ASA score of 4. The mean duration of surgery was 57.50± 39.41 min.

Profile of wound condition at the time of discharge

Table 1 — *Pre-operative and demographic characteristics of patients*

Parameter	Number	Parameter	Number
No of Cases	306	Wound class :	
Age (years) :		Clean	202 (66%)
Mean	39.63	Clean contaminated	48 (15.7%)
SD	17.52	Contaminated	27 (8.8%)
Range	4-85 years	Dirty	29 (9.5%)
Height (cms) :		Blood loss :	
Mean	158.94	Yes	31 (10.1%)
SD	13.60	No	275 (89.9%)
Range	90-174	Need for blood transfusion :	
Weight (kgs) :		Yes	24 (7.8%)
Mean	64.77	No	282 (92.2%)
SD	11.33	Use of drain :	
Range	15-85	Yes	129 (42.2%)
Sex (%) :		No	177 (57.8%)
Male	204(66.7)	Mean duration of surgery (mins):	
Female	102(33.3)	Mean	57.5
Type of surgery :		SD	39.41
Elective	188 (61.4%)	Range	30 - 190
Emergency	118 (38.6%)		
ASA score :			
1	89 (29.1%)		
2	105 (34.3%)		
3	52 (17%)		
4	60 (19.6%)		
5	0 (0 %)		

was evaluated. 66% evaluated cases were found to be 'clean' at the time of discharge, 15.7% were clean contaminated, 8.8% were contaminated and 9.5 % were dirty. 24.5% of cases had serous discharge followed by 15.0% cases had purulent discharge and 60.5% had clean wound condition at the time of discharge (Fig 1, Table 2).

Exclusion criteria were any severe disease that might influence wound healing or known allergy to triclosan.

Surgical Closure :

Wound closures were performed by 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 Coated Vicryl Plus Antibacterial (polyglactin 910) Suture (Vicryl Plus®, Johnson and Johnson, India Ltd,) and intracutaneously with a 4.0 triclosan-coated Monocryl® Plus Antibacterial (poliglecaprone 25) Suture(Monocryl Plus®, Johnson and Johnson, India Ltd,). All wounds were then covered with drape, compresses and elastic bandages. The drape was removed on the fourth postoperative day. We used drainage at the site of surgery in 42.2 % cases. Prophylactic antibiotic treatment was performed according to the anesthesiology unit protocol. 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.

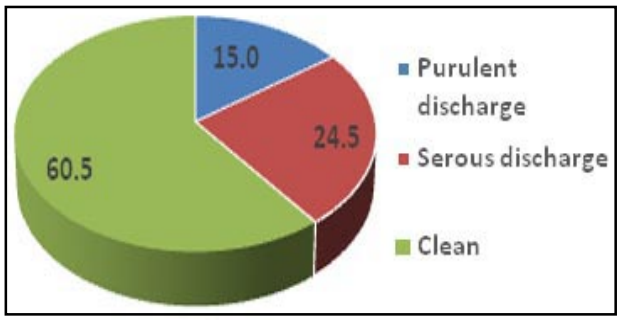

Fig 1 — Profile of wound condition at the time of discharge

Table 2 — *Profile of details of wound condition at the time of discharge and follow-up period*

Type of Wound Condition	At discharge (N = 306)		10th day after discharge (N = 306)	
	No	%	No	%
Purulent discharge	46	15.0	-	-
1 + Purulent discharge	14	04.6	-	-
2 + Purulent discharge	29	09.5	-	-
Mild Purulent discharge	02	00.7	-	-
Minor D/C Purulent (1+)	01	00.3	-	-
Serous discharge	75	24.5	-	-
1 + Serous discharge	37	12.1	-	-
2 + Serous discharge	35	11.4	-	-
Mild Serous discharge	03	01.0	-	-

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. Association of occurrence of SSI with age, gender and class of wound was analyzed.

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. Association of factors with SSI incidence was analyzed using the χ^2 test and reported with risk ratio (RR) with 95% confidence interval (CI). A P-value of <0.05 was considered statistically significant. 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. Statistical analysis was done using Statistical Package for the Social Sciences software program version 20 (SPSS Inc, Chicago, IL).

Results

During the study, wound infection developed in 13.4% as Superficial/Incisional SSI and 1.3% cases as deep incisional SSI (Table 2). None of the patients had SSI 10 days after discharge. Thus, use of triclosan coated sutures could reduce the incidence of SSI by 85.3% (Tables 3-5).

In 2.2% cases with Wound Class 1 had SSI and the association was significant. SSI incidence was 10.5%, 32.7 and 25.0% cases with Wound Class 2, 3 and 4 respectively (non-significant) (Table 6).

Table 6 shows 36 patients of 156 (23%) had SSI in the uncoated sutures group. 10 patients of 149 (6.7%) had SSI in the vicryl coated suture category. In 12 patients of 50 in class II wound category has SSI with uncoated whereas only 2 of 50 patients had SSI in class II in coated vicryl category. Similarly, 16 patients of 29 had SSI in class III category which was on 2 of 25 for vicryl coated suture (Table 7).

In 4.9% cases who belongs to age group 58 – 67 years had SSI and the association was statistically

Table 3 — *Profile of surgical site infection at the time of discharge in study cases*

Surgical site infection	At discharge (N = 306)		10th day after discharge (N = 306)	
	No	%	No	%
Yes	45	14.7	-	-
No	261	85.3	306	100.0

Table 4 — *Profile of SSI type at the time of discharge in study cases*

Types of SSI	At discharge (N = 306)		10th day after discharge (N = 306)	
	No	%	No	%
Deep Incisional	04	01.3	-	-
Organ/Space	-	-	-	-
Superficial Incisional	41	13.4	-	-

Table 5 — *Association between wound class and SSI*

Wound Class	N	SSI	
		No	%
Class 1	89	*02	02.2
Class 2	105	11	10.5
Class 3	52	17	32.7
Class 4	60	15	25.0
Class 5	-	-	-
Unknown	-	-	-
By Chi – Square Test		*P =0.001, Significant	

Table 6 — *Profile of SSI for uncoated and coated sutures*

Class of wound	Non-coated suture (total)	Non-coated suture (non-infected)	Non-coated suture (infected SSI)	Vicryl coated suture (total)	Vicryl coated suture (non-infected)	Vicryl coated suture (infected SSI)
Class I	49	48	1	40	39	1
Class II	50	38	12	52	50	2
Class III	29	13	16	27	25	2
Class IV	28	21	7	30	25	5
Total	156	120	36	149	139	10

significant.Rest no age group showed a statistical correlation (Table 8).

In 12.7% of male cases had SSI which was numerically less as compared to 18.6% of female cases but the difference was not statistically significant.

There were no signs of wound dehiscence. There was not a single case of intraoperative complications in our cohort. There was no case of adverse effect reported in our study.

Discussion

As SSIs continue to pose a challenge within healthcare in India, further studies are required to substantiate the efficacy of TCS in Indian population along with a detailed identification of the factors associated with its prognosis. Infection of the surgical site results mainly from the imbalance between the amount of the microorganisms inoculated, their virulence, and the ability of the immune system to clear them. Therefore, it is logical that creating an

Table 7 — *Association between age groups and SSI*

Age groups	N	SSI	
		No	%
≤ 17	18	03	16.7
18 - 27	80	12	15.0
28 - 37	51	06	11.8
38 - 47	51	08	15.7
48 - 57	46	10	21.7
58 - 67	41	*02	04.9
≥ 68	19	04	21.1
By Chi – Square Test		*P =0.023, Significant	

Table 8 — *Associationbetween gender and SSI*

Gender	N	SSI	
		No	%
Male	204	26	12.7
Female	102	19	18.6
By Chi – Square Test		P =0.171, Not Significant	

antibacterial environment within the wound by virtue of suture material impregnation would be a targeted intervention to reduce the risk of SSIs.Suture materials play an important role in the development of SSIs by providing a local surface for the adherence of microorganisms. At the same time it is a criteria that can be easily changed[25].

Correlation with RCTs :

Ford HR *et al*[26] conducted a prospective, randomized, controlled, open-label, comparative, single-center study in pediatric patients undergoing various surgical procedures. TCS received more "excellent" scores (71% *versus* 59%) by surgeons.Significantly fewer patients treated with TCS reported pain on day 1 than patients who received the other suture (68% *versus* 89%, p = 0.01). Okada n *et al*[27] authored a controlled clinical trial of 198 consecutive patients undergoing pancreaticoduodenectomy. The rates of SSI were significantly less (4.5%) in the TCS group and (14.5%) in the control group (p=0.037). There are few other randomized control trials by Nakamura *et al* and others[28-30] which demonstrated a significant beneficial effect of TCS in the prevention of SSIs after surgery.

Correlation with Meta-analysis :

There are many level 1A evidence to support our results. Wu X *et al*[31] conducted a meta-analysis of 13 randomized controlled trials and 5 observational studies. Antimicrobial sutures significantly reduced SSI risk (for RCTs: OR 0.72, 95 % CI 0.59-0.88, p=0.001, I^2=14%; for observational studies: OR 0.58, 95 % CI 0.40-0.83, p=0.003, I^2=22%). Another meta-analysis by De Jonge *et al*[32] analyzed 21 RCTs including 6462 patients. Pooled effects showed a RR of 0.72 (95% CI 0.60 to 0.86; P<0.001). The trial sequential analysis confirmed a RR reduction of 15 per cent for the use of TCS.

Daoud *et al* meta-analyzed 15 randomized controlled trials and obtained a risk ratio of 0.67, 95% CI 0.54–0.84 (p=<0.00053), demonstrating a highly statistically significant, lower risk of SSI following operative procedures in incisions which were closed with TCS compared to non-antimicrobial closure technology. They had a similar inference to ours in terms of 'class of wound' association. A statistically significant reduction could be expected in clean-contaminated and contaminated incisions but these results were not robust when considered separately from the clean incisions. No conclusions could be drawn based upon this analysis on the impact of triclosan sutures as a risk reduction strategy for SSIs involving dirty incisions. Jonge et al also reiterated the same evidence that the effect of TCS appears to be more robust in clean procedures. On the same line Diener *et al*[33] concluded that efficacy of TCS in a population with mostly non-clean procedures was non statistically significant.

Limitation and Strength :

As a limitation, this was a retrospective historical controlled study having an observational nature conducted in a single institution. Although the big sample size of 306 patients was the study's strength and provides for good reliability. Another strength of the study is its generalizability and robustness due to inclusion of heterogeneous case-mix of patients.

Conclusion

SSIs are associated with an increased risk of morbidity, readmission, intensive care unit stay, and mortality. Hence the need to prevent SSIs is ubiquitous. Several earlier publications have alluded to the benefits of using triclosan coated sutures. Our study adds to the wealth of evidence from an Indian perspective and presents a strong case for implementing such technologies into routine clinical practice. The incidence of SSI in our cohort was 14.7% and SSI could be prevented in 85.3% cases.Triclosan antimicrobial sutures should be considered for superficial and deep layer closure after all surgical operations. Also, recognition of factors associated with SSI allows for having targeted approach.Our study demonstrated a significant protective effect of triclosan-coated sutures on the occurrence of SSI after elective and emergency surgery, in particular for wound class 2 & 3 and age group 58 – 67. We hope that our current study may generate enthusiasm for future prospective studies, with more robust designs, in order to back or negate our results.

Conflict of Interest : We hereby declare that the authors have no conflicts of interest related to this manuscript

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