# 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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## Abstract Background

**Methods:** This is a retrospective 'real-world' study of 306 patients who underwent surgery and wound closure withtriclosan-coated suture from (month, year) to (month, year) at (Hospital), Jaipur. Incidence of SSI was recorded and association with various factors like age, gender and class of wound was drawn. Association of factors with SSI incidence was analyzed using the  $\chi^2$  test.

**Results:** During the study, wound infection developed in 13.5 % 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 85.2%. Significant association of incidence of SSI was observed with 'wound Class 1' and 'age group 58 - 67 years'. There was no association observed with gender. 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 not a single case of intraoperative complications in our cohort. There was no case of adverse effect reported in our study.

**Conclusion:** The incidence of SSI in our cohort was 14.8% and SSI could be prevented in 85.2% cases. Class II and III wounds are in particular prone to develop SSI which could be effectively prevented by using coated vicryl sutures. One may prefer to choose coated sutures especially for class II and III wounds, compared to class I or class IV. Our study presents a compelling case for using TCS in routine clinical practice.

Keywords: Triclosan coated suture, Antibiotic coated sutures, Surgical site infection, Age, Gender, Wound class

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## a. Epidemiology of SSI

## I. Introduction

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.<sup>1</sup> 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.<sup>2</sup> SSIs are the third most common hospital-acquired infection (14%–16%).<sup>3</sup> In India, the rate of SSI varies from 6.1% to 38.7%.<sup>4,5,6,7</sup> 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%.<sup>8</sup> 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.<sup>9</sup> 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.

## **b.** Health-economic burden of SSI

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. 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.

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.<sup>10</sup> 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%).<sup>5</sup>, <sup>11</sup>

#### c. 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 (i.e. 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.<sup>12</sup>

#### d. 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.<sup>2</sup> 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.<sup>13</sup>

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.

#### e. 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 polyglacaprone 25 antimicrobial suture (Monocryl Plus; Ethicon, Johnson & Johnson) and triclosan-coated polydioxanone antimicrobial suture (PDS Plus; Ethicon, Johnson & Johnson). Triclosan is not an antibiotic but an antiseptic. It has no toxic, teratogenic, or irritating effects at the standard concentration.<sup>14</sup>Triclosan targets the e Fab I gene, which blocks bacterial fatty acid synthesis (particularly the enzyme enoyl- acyl carrier protein reductase [ENR]).<sup>15</sup> Whilst many randomized controlled trials have supported the evidence of beneficial effect of TCS in the prevention of SSIs<sup>16, 17, 18</sup> but some studies have shown inconclusive results.<sup>19,20,21</sup>

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.

#### II. Material and Methods

#### a. Patients

From (month, year) to (month, year), a total of 306 patients underwent surgical wound closure with triclosan-coated sutures at (Name of 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.

1		1
Parameter	Number	
No. of Cases	306	
Age (years)	39.63	
Mean	17.52	
SD	4-85yrs	
Range		
Height (cms)	158.94	
Mean SD	13.60	
Range	90-174	
Weight (kgs)	64.77	
Mean SD	11.33	
Range	15-85	
Sex (%)	204(66.7)	

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

Male Female	102(33.3)
Type of surgery	188 (61.4%)
Elective Emergency	118 (38.6%)
ASA score	
1	89 (29.1%)
2	105 (34.3%)
3	52 (17%)
4	60 (19.6%)
5	0 (0 %)
Wound class	202 (66%)
Clean	48 (15.7%)
Clean contaminated	27 (8.8%)
Contaminated Dirty	29 (9.5%)
Blood loss	31 (10.1%)
Yes No	275 (89.9%)
Need for blood transfusion	
Yes	24 (7.8%)
No	282 (92.2%)
Use of drain	
Yes	129 (42.2%)
No	177 (57.8%)
Mean duration of surgery	
(mins)	
Mean	57.5
SD	39.41
Range	
	30 - 190

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 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. 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  $57.50\pm 39.41$  min.

Profile of wound condition at the time of discharge 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.





Table 2. Profile of Details of Wound Condition at the Time of Discharge and Follow-up Period

	At Discharge		$10^{\text{th}}$ Day after Discharge (N =		
	(N = 306)		(N = 306) 306)		
Type of Wound Condition	No	%	No	%	
Purulent discharge	46	15.0	-	-	
1 + Purulent discharge	14	04.6	-	-	

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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	-	-

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

#### **b.** 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 monofilament polyglactin suture coated with triclosan (Vicryl Plus<sup>®</sup>, Johnson and Johnson, India Ltd.,) and intracutaneously with a 4.0 triclosan-coated monofilament polyglecaprone suture (Monocryl Plus<sup>®</sup>, 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.

#### c. 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

## d. Statistics

Data are presented in descriptive manner for this single arm study as mean  $\pm$  standard deviation, median and range or number and percentage. Association of factors with SSI incidence was analyzed using the  $\chi^2$  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).

#### **III.** Results

During the study, wound infection developed in 13.5 % 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%.

 Table 3. Profile of Surgical Site Infection at the Time of Discharge in Study Cases

Surgical site Infection	At Discharge (N = 306)		10 <sup>th</sup> 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

	At Discharge (N = 306)		10 <sup>th</sup> Day after discharge (N = 306)		
Types of SSI					
	No	%	No	%	
Deep Incisional	04	01.3	-	-	

Organ/Space	-	-	-	-
Superficial Incisional	41	13.4	-	-

Wound Class	Ν		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	-	-	-

Table 5. Association between Wound Class and SSI

By Chi – Square Test \*P =0.001, Significant

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, 3and 4 respectively (non significant).

Class of wound	Non- coated	Non- coated	Non- coated	Vicryl coated	Vicryl coated	Vicryl coated	
	suture (total)	suture (non-	suture (infected	suture (total)	suture (non-	suture (infected	
		infected)	SSI)		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	

Table 6. Profile of SSI for uncoated and coated sutures

Table 6 shows 36 patients of 156 (23%) had SSI in the uncoated sutures group. 10patients of 149 (6.7%) had SSI in the vicryl coated suture category. 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.

Age groups	Ν	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	

 Table 7. Association between Age Groups and SSI

By Chi – Square Test \*P =0.023, Significant

4.9% cases who belongs to age group 58 - 67 years had SSI and the association was statistically significant. Rest no age group showed a statistical correlation.

Table 5. Association between gender and SSI					
Gender	Ν	SSI			
		No	%		
Male	204	26	12.7		
Female	102	19	18.6		

Table 0 Association between soundar and CCI

By Chi – Square Test P =0.171, Not Significant

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.

#### IV. 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 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.<sup>22</sup>

To prevent microbial colonization of suture material in operative wounds, triclosan-coated sutures with antibacterial activity have been developed. Triclosan 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 i.e. S. aureus and S. epidermidis. TCS reduces both bacterial adherence to the suture and microbial viability by interfering with microbial lipid synthesis. The effect of surgical sutures embedded with triclosan has been tested in several studies with focus on patient-related and operation-related risk factors. Our study adds to the wealth of evidence from an Indian perspective.

#### a. Incidence of SSI

In our study, wound infection developed in 13.5 % as superficial/incisional SSI and in 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%. Our results are correlated with Akhteret al<sup>23</sup> who conducted an extensive prospective observational study with 1196 Indian patients in 2016. They observed an SSI rate of 11%. Interestingly, Pathaket al<sup>24</sup> evaluated the SSI rate among the 720 patients and found incidence to be very low i.e. 5%.

#### b. Association of incidence of SSI with other factors

In addition to contamination of suture material, numerous factors have been linked to the risk of SSI, including patient related factors (age, gender, body mass index, pre- existing infection, , comorbidities like diabetes and surgical history); and procedure- related factors (elective or emergency surgery, class of wound, quality of pre-surgical preparation, management of infected or colonized surgical equipment, and antimicrobial prophylaxis). In our study reduction in rates of SSI by TCS were significantly higher for wound class 1, than for classes 2, 3 and 4. Also, significantly higher association was seen for age group 58 - 67, than for other age groups. Our study found no association with gender.

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. 12 patients of 50 (24%) in class II wound category has SSI with uncoated 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. This wound class wise distribution suggests that class II and III wounds are in particular prone to develop SSI which could be effectively prevented by using coated vicryl sutures. Hence one may prefer to choose coated sutures especially for class II and III wounds, compared to class IV.

#### c. Correlation with RCTs

Ford HR et al <sup>25</sup> conducted a prospective, randomized, controlled, open-label, comparative, singlecenter study in pediatric patients undergoing various surgical procedures. TCS received more "excellent" scores (71% vs. 59%) by surgeons. Significantly fewer patients treated with TCS reported pain on day 1 than patients who received the other suture (68% vs. 89%, p = 0.01). Okada n et al<sup>26</sup> 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 <sup>27</sup>,<sup>28</sup>,<sup>29</sup> which demonstrated a significant beneficial effect of TCS in the prevention of SSIs after surgery.

#### *d.* Correlation with meta-analysis

There are many level 1A evidence to support our results. Wu X et al<sup>30</sup> 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 Jongeet al<sup>31</sup> 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 Dieneret al.<sup>32</sup> concluded that efficacy of TCS in a population with mostly non-clean procedures was non statistically significant.

#### *e*. 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.

## *f.* Perspectives

- 1. Wound contamination following surgery often involves both deep and superficial incisional sites. Therefore, to maximize benefit from antimicrobial sutures, authors believe TCS should be used for both superficial and deep musculofascial layers.
- 2. The expected potential beneficial effects of TCS 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.<sup>33</sup>
- 3. There are some unanswered areas with triclosan coated suture usage which the further studies may focus on. First, to evaluate the risk of antimicrobial resistance to triclosan.<sup>34</sup> Secondly, the long degradation time of triclosan and its impact on potential risk for bioaccumulation in the environment.<sup>35</sup>
- 4. Some authors have also suggested that the use of conventional antibiotics in patients with SSI can be reduced by 40% with triclosan- coated sutures. Future studies need to validate it.

#### V. 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 14.8% and SSI could be prevented in 85.2% 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**

#### Acknowledgement

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