

Original Research Article

Triclosan coated vicryl versus uncoated vicryl in preventing surgical site infection: a randomized controlled trial

Amitpal Kaur, Mohit Sharma*, Karaninder Singh, Darpan Bansal

Department of Surgery, Sri Guru Ram Das Institute of Medical Sciences and Research, Vallah, Amritsar, Punjab, India

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*Correspondence:

Dr. Mohit Sharma,

E-mail: drmohit.gis@gmail.com

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ABSTRACT

Background: Surgical site infection (SSI) are one of the most frequently reported health care associated infections. They are commonly associated with greater morbidity, readmissions, ICU admissions, long-term surgical site complications and mortality. Multiple global studies have shown level 1A clinical evidence that the use of triclosan coated suture reduces the incidence of SSI by 30%.

Methods: In the proposed prospective study, 100 cases undergoing elective surgery were randomly allocated into Group A and B. Group A were the patients in which wound closure was done using triclosan coated vicryl (vicryl plus) and group B were the patients in which wound closure was done using uncoated vicryl. Then, the patients were followed up for 30 days to observe any signs and symptoms of surgical site infection.

Results: Duration as well as severity of pain was decreased in vicryl plus group as compared to uncoated vicryl. Other signs of inflammation such as erythema, swelling, induration and fever were also less in patients who had wound closure using vicryl plus. Wound dehiscence was not observed in either of the groups. Discharge was seen in 1 patient in vicryl plus group but it was seen in 5 patients in uncoated vicryl group. Surgical site infection was seen only in 1 patient in the vicryl plus group, but it was seen in 10 patients uncoated vicryl group.

Conclusions: It can be concluded that triclosan coated vicryl (vicryl plus) is better than uncoated vicryl for the prevention of surgical site infection.

Keywords: Surgical site infection, Triclosan coated vicryl, Uncoated vicryl, Vicryl plus

INTRODUCTION

Advances in surgical history were made possible only by curbing infections and by providing anaesthesia. Aseptic techniques and use of antimicrobial agents have contributed greatly in decreasing the incidence of surgical site infections.

Surgical site infections (SSI) play a key role in increasing morbidity and mortality associated with surgeries.¹

It is associated with 2-11 fold increased risk of death compared with patients without SSI. 77% of deaths in patients with surgical site infections are as a result of SSI.

It also increases the disabilities in the postoperative patients.²

Global prevalence of hospital acquired infections (HAI) is approximately 1.4 million. It occurs in at least 2% of surgical patients.³ Surgical site infections account for approximately 10-31% of all the hospital acquired infections. A study conducted in USA found that 21.8% of all HAIs are SSIs. Incidence of SSI is higher in developing countries as compared to developed countries. Incidence is highest for gastrointestinal surgeries.⁴

SSIs occur in approximately 2% of patients undergoing surgery in USA.⁵ It complicates approximately 3 to 5

lakh surgeries per year and increases the cost of health care system by approximately \$1.6 billion. It is the most common surgical complication in both the developed as well as developing countries.³

Centers for disease control and prevention (CDC) divided surgical site infections into superficial incisional SSI, deep incisional SSI and organ space infections.⁶

Superficial incisional SSI are the ones which occur within 30 days of surgery, involves only skin and subcutaneous tissue and has atleast one of the following:

Purulent discharge from the wound; or organism isolated from the specimen taken from the wound; or wound that is deliberately opened by the surgeon and has atleast one of the signs of inflammation i.e. pain or tenderness, erythema or swelling; or diagnosis of superficial incisional SSI is made by the surgeon

Deep incisional SSI are defined as one that occur within 30 or 90 days of surgery and involves deep soft tissues such as fascia and muscles and has atleast one of the following:

Purulent discharge from deep incision; or deep incision that undergoes spontaneous dehiscence or is deliberately opened by the surgeon. Along with this, organism is isolated from the specimen obtained from the deep soft tissues of the incision and has atleast one of the signs of inflammation i.e. pain or tenderness, erythema or swelling; or deep abscess that is identified on gross or histopathological examination or on imaging.

Organ space infections are defined as one which occur within 30 or 90 days of surgery and involves the structures deep to the fascial or muscle layers that are opened during the surgery and has atleast one of the following:

Purulent drainage from the drain that is placed into the organ or space; or organism isolated from the specimen obtained from the drain; or abscess that is involving the organ or space on gross or histopathological examination or on imaging.

So, due to increased incidence of morbidity and mortality and also due to increased burden over the healthcare, there is a need to decrease the incidence of SSI. SSIs are multifactorial with patient factors such as age, comorbidities like diabetes mellitus and immunosuppression and surgical factors like asepsis used, duration of surgery, suture material, type of wound (clean to dirty), presence of drain, type of surgery etc.⁷ Patient factors are not modifiable. So, researches on prevention of SSI should focus mainly on surgical factors such as suture materials.⁸

Sterile sutures are used to close the incision of a patient after the surgery. They are important to support wound

healing. But, increased risk of SSI associated with surgical sutures limit their usefulness.^{9,10} They are in direct contact with the wound itself. Different microorganisms colonize the surface of the suture material and form a biofilm over them. This biofilm can lead to development of SSI.¹¹

Common microorganisms that cause SSI are *Staphylococcus aureus*, coagulase negative *Staphylococci* (particularly after implant surgery) and *Enterobacteriaceae/anaerobes* (particularly after colorectal surgery).¹²

Bacteria can colonize monofilament as well braided sutures, but are more likely to colonize the braided sutures.^{13,14}

So, in order to prevent SSI, source has to be removed.¹⁵ One solution is to coat the suture material with an antimicrobial agent which inhibits the adhesion of bacteria on the surface of the suture. Antimicrobial sutures prevent bacterial adhesion and biofilm formation and thus avoids long-term and ineffective use of systemic antibiotics and thus reduce the risk of development of antimicrobial resistance.¹⁶

Some of the agents used to coat the suture materials include triclosan, chlorhexidine diacetate, octanidine, quaternary ammonium compound, silver nanoparticles, tetracycline hydrochloride, levofloxacin hydrochloride etc.¹⁷

Nowadays, commonly used antimicrobial agent to coat sutures is Triclosan [5-Chloro-2 (2,4-dichlorophenoxy)phenol].¹⁸ Triclosan is a broad spectrum antiseptic belonging to phenol family which is used as an effective antimicrobial agent against common pathogens such as *Staphylococcus aureus*, *Staphylococcus epidermidis*, Methicillin-resistant *Staphylococcus aureus* (MRSA), Methicillin-resistant *Staphylococcus epidermidis* (MRSE), Vancomycin resistant *Enterococcus faecalis*, *Pseudomonas aeruginosa* and *E. coli*. Thus, triclosan coated sutures decrease the colonization of both the gram positive as well as gram negative bacteria on the suture material. It is considered to be more effective against gram positive organisms than gram negative.¹⁹

Triclosan is used in products such as antiseptic soaps, toothpastes, fabrics and plastics. It acts on the gene *fabI* which codes for enoyl-acyl carrier protein reductase enzyme (ENR) which in turn inhibits the fatty acid synthesis in the bacteria. Triclosan damages the cell membrane leading to leakage of the cellular contents. Mutations or overexpression of the gene *fabI* prevents this blockage by triclosan.²⁰

Triclosan does not alter the physical properties of the sutures such as intra-operative handling of the suture, strength of the knot, tissue reaction etc. Moreover, it does

not have any carcinogenic potential, genotoxicity and sensitization potential.²¹

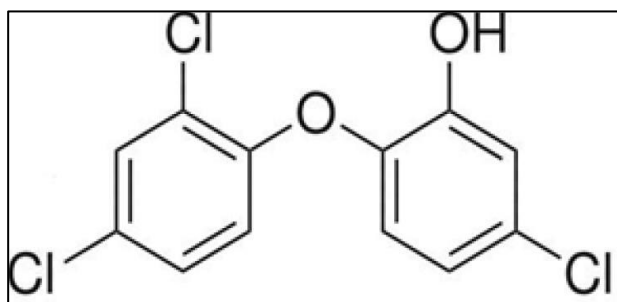


Figure 1: Chemical structure of triclosan.

Objectives

The main objective of the study was to compare the incidence of surgical site infection after wound closure with triclosan coated vicryl (vicryl plus) versus uncoated vicryl.

METHODS

In this study, 100 cases were selected who were admitted in Sri Guru Ram Das Institute of Health Sciences and Research, Vallah, Amritsar from September 2018 to September 2020. Sample size was calculated using G-Power software at 95% confidence interval with precision of 2.75% (prevalence- 2%). Cases were selected on the basis of inclusion and exclusion criteria. Patients were randomized using block randomization method. Group A (50 patients) were the patients in which wound closure was done using triclosan coated vicryl (vicryl plus) and group B (50 patients) were the patients in which wound closure was done using uncoated vicryl. Wound was classified as clean, clean-contaminated, contaminated and dirty-infected. In case of surgical site infection swabs were sent for microbiological examination.

Study design

It was an interventional, comparative, longitudinal, randomized control trial.

Inclusion criteria

Patients above eighteen years; patients of both sexes; patients undergoing elective surgery.

Exclusion criteria

Patients less than 18 years; patients with significant co morbidities like liver cirrhosis, jaundice, hypoalbuminemia, uremia etc. that might influence wound healing; patients on steroids, immunosuppressive agents, radiation, or chemotherapy; patients with ongoing sepsis or septicaemia or bacterial infections;

patients undergoing emergency surgery; patients with known allergy to triclosan.

Surgical closure

Prophylactic antibiotics were given to all the patients one hour before the onset of the surgery. In group A patients, wounds were closed subcutaneously and intracutaneously with a multifilament polyglactin 910 suture coated with triclosan (vicryl plus, Johnson and Johnson, Pvt. Ltd.). While the wounds of the patients in group B were closed subcutaneously and intracutaneously with an uncoated multifilament polyglactin 910 suture (vicryl, Johnson and Johnson, Pvt. Ltd.). All wounds were then covered with an aseptic dressing. The dressing was removed on the third postoperative day. Drainage was used at the site of surgery in some cases. Prophylactic antibiotics were continued postoperatively. In cases of poorly healed wounds and the presence of discharge, swab culture and sensitivity was sent.

Outcome measures

Primary dressing was opened on 3rd post-operative day. So, the wound was inspected on post-operative day 3, 5, 7, 15 and 30 for any signs and symptoms of surgical site infection as per the CDC Criteria such as pain, redness, swelling, fever, discharge, wound dehiscence etc. In case of a suspected infection, wound swabs for culture and sensitivity were taken, and evaluation for any potential redo surgery was done.

After discharge, if a patient reported any type of wound healing problems including dehiscence, swelling, redness or discharge, 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.

The data was analysed using SPSS software version 25.0. t test and Chi square test were used to evaluate and interpret the data. P values less than 0.05 were considered to be statistically significant.

RESULTS

In present study, we used triclosan coated vicryl (vicryl plus) and uncoated vicryl for subcutaneous and intracutaneous closure and compared their efficacy in prevention of surgical site infection. Present study included 100 patients undergoing elective surgery at Sri Guru Ram Das institute of medical sciences and research, Vallah, Amritsar. They were randomly allocated into two groups with 50 patients each. Group A: Patients in which wound closure was done using triclosan coated vicryl (vicryl plus). Group B: Patients in which wound closure was done using uncoated vicryl.

Table 1 shows that maximum number of patients (40%) in group A were in the age range of 61-80 years, while in group B maximum number of patients (40%) were in the age range of 41-60 years.

Table 1: Age distribution.

Age group (years)	Suture material				Total	
	A		B		N	%
	N	%	N	%		
≤20	1	2.00	1	2.00	2	2.00
21-40	12	24.00	13	26.00	25	25.00
41-60	17	34.00	20	40.00	37	37.00
61-80	20	40.00	16	32.00	36	36.00
Total	50	100.00	50	100.00	100	100.00
Mean age	51.70±16.84		51.00±13.59		51.00±13.73	
P value	0.802					

34 (68%) patients in group A were females and 16 (32%) were males. Whereas 32 (64%) patients in group B were females and 18 (36%) patients were males. Thus, a female preponderance is seen in both the groups as depicted in Table 2.

Table 2: Gender distribution.

Gender	Suture material				Total	
	A		B		N	%
	N	%	N	%		
Female	34	68.00	32	64.00	66	66.00
Male	16	32.00	18	36.00	34	34.00
Total	50	100.00	50	100.00	100	100.00

$\chi^2=0.178$; $p=0.833$

Table 3 shows that in group A, 32 patients had clean wound, while 31 patients had clean wound in group B. 18 patients in group A had clean contaminated wound, whereas 19 patients in group B had clean contaminated wound.

Table 3: Distribution of patients according to the type of wound.

Type of wound	Suture material				Total	
	A		B		N	%
	N	%	N	%		
Clean	32	64.00	31	62.00	63	63.00
Clean contaminated	18	36.00	19	38.00	37	37.00
Total	50	100.00	50	100.00	100	100.00

$\chi^2: 0.043$; $df: 1$; $p=0.836$

Table 4 shows that 33 patients had pain till post-operative day 7 in group A, while 42 patients had pain till post-operative day 7 in group B. Only 1 patient had pain after 7 days in group A, while 7 patients had pain after 7 days in group B. None of the patients had pain till post-operative day 30 in group A, whereas 2 patients still had

pain at post-operative day 30 in group B. Data so obtained was statistically significant ($p=0.002$).

Table 4: Distribution of the patients according to duration of pain.

Duration of pain (days)	Suture material				Total	
	A		B		N	%
	N	%	N	%		
5	16	32	1	2	17	17
7	33	66	42	84	75	75
15	1	2	5	10	6	6
30	0	0	2	4	2	2
Total	50	100	50	100	100	100

$\chi^2: 18.982$; $df: 3$; $p=0.002$

Table 5 shows that maximum VAS score of 5 was seen in group A which was seen in 5 patients. Maximum VAS score seen in group B was 6 which was seen in 3 patients, while 16 patients in group B had a VAS score of 5. The data so obtained was statistically significant ($p=0.001$).

Table 5: Distribution of patients according to severity of pain.

Severity of pain (VAS score)	Suture material				Total	
	A		B		N	%
	N	%	N	%		
3	12	24	0	0	12	12
4	33	66	31	62	64	64
5	5	10	16	32	21	21
6	0	0	3	6	3	3
Total	50	100	50	100	100	100

$\chi^2: 20.842$; $df: 3$; $p=0.001$

Erythema was seen in 26 patients in group A and 48 patients in group B at post-operative day 5 as shown in Table 6 which is statistically significant ($p=0.001$).

Table 6: Distribution of patients according to presence of erythema at day 5.

Erythema at day 5	Suture material				Total	
	A		B		N	%
	N	%	N	%		
Present	26	52	48	96	74	74
Absent	24	48	2	4	26	26

$\chi^2: 25.15$; $df: 1$; $p=0.001$

Table 7: Distribution of patients according to presence of swelling at day 5.

Swelling at day 5	Suture material				Total	
	A		B		N	%
	N	%	N	%		
Present	2	4	17	34	19	19
Absent	48	96	33	66	81	81

$\chi^2: 14.62$; $df: 1$; $p=0.001$

Swelling was seen in 2 patients at post-operative day 5 in group A, while in group B, it was seen in 17 patients at post-operative day 5 as shown in table 7 which was statistically significant ($p=0.001$).

Table 8: Distribution of patients according to the presence of fever after complete 30 days follow up.

Fever	Suture material				Total	
	A		B		N	%
	N	%	N	%		
Present	0	0	9	18	9	9
Absent	50	100	41	82	91	91

$\chi^2: 9.89$; df: 1; $p=0.001$

Table 8 shows that after complete 30 days follow up, 9 patients had fever in group B whereas none of the patients in group A had fever which was statistically significant ($p=0.001$).

None of the patients in our study had wound dehiscence in the two groups.

Table 9: Distribution of patients according to presence of wound discharge after complete 30 days follow up.

Discharge	Suture material				Total	
	A		B		N	%
	N	%	N	%		
Present	1	2	5	10	6	6
Absent	49	98	45	90	94	94

$\chi^2: 2.837$; df: 1; $p=0.092$

Table 9 shows that 1 patient in group A and 5 patients in group B had wound discharge but was statistically insignificant ($p=0.092$).

Table 10: Distribution of patients according to the presence of SSI after complete 30 days follow up.

SSI	Suture material				Total	
	A		B		N	%
	N	%	N	%		
Present	1	2	10	20	11	11
Absent	49	98	40	80	89	89

$\chi^2: 8.27$; df: 1; $p=0.004$

Table 10 shows that 10 patients in group B had surgical site infection, whereas only 1 patient in group A had surgical site infection which was statistically significant ($p=0.004$).

DISCUSSION

Poor or delayed healing in the surgical wounds caused by infection is a serious issue that can cause significant morbidity and sometimes mortality. Various factors contribute in the causation of surgical site infection.

Some are modifiable such as anaemia, hypoalbuminemia, smoking, uncontrolled diabetes, duration of surgery, suture material etc. and others are non-modifiable such as age of the patient, type of the wound (clean/contaminated/dirty) etc.²² Suture material especially the braided suture material becomes a nidus for various bacteria which further form a biofilm over the suture material. This biofilm is resistant to host immune response and is mostly resistant to antibiotics.^{23,24} So, to prevent this biofilm formation over the suture material, sutures are coated with antibacterial agents such as triclosan.²⁵

In our study, total 100 patients were included. 50 patients in group A had wound closure using vicryl plus (triclosan coated vicryl) and rest of the 50 patients in group B had wound closure using vicryl (uncoated vicryl). In all patients, the given suture was used subcutaneously as well as intracutaneously.

The following observations were made from the above study.

The demographic characteristics like age and gender distribution were similar in both the groups. Types of surgeries, presence of drain and type of wound were also similar in both the groups.

Pain

In present study, 33 patients (66%) had pain till post-operative day 7 in group A, while 42 patients (84%) had pain till post-operative day 7 in group B. Only 1 patient (2%) had pain after 7 days in group A, while 7 patients (14%) had pain after 7 days in group B. None of the patients had pain till post-operative day 30 in group A, whereas 2 patients (4%) still had pain at post-operative day 30 in group B.

Similar results were obtained by Ford et al who conducted a randomized controlled trial in 2005 to compare the intraoperative suture handling and characteristics of wound healing between triclosan coated polyglactin 910 suture and conventional polyglactin 910 suture in paediatric patients who underwent various types of general surgeries.²⁶ Pain on day 1 was significantly less in patients in whom triclosan coated polyglactin 910 suture was used than the patients in which conventional vicryl suture was used (68% versus 89%, $p=0.01$).

Erythema

In current study, erythema was seen in 26 patients (52%) in group A and 48 patients (96%) in group B at post-operative day 5 which is statistically significant ($p=0.001$).

Comparable results were obtained by a study performed by Jung et al in which vicryl plus was used for wound closure in patients with gastric cancer.²⁷ Incidence of

erythema in their study was 6.42% at post-operative day 30.

Swelling

In present study, swelling was seen in 2 patients (4%) at day 5 in group A, while in group B, it was seen in 17 patients (34%) at post-operative day 5 which is statistically significant ($p=0.001$).

Comparable results were obtained by a study performed by Jung et al in which vicryl plus was used for wound closure in patients with gastric cancer.²⁷ Incidence of edema in their study was 1.26% at day 30.

Fever

In the current study, 9 patients (18%) had fever in group B whereas none of the patients in group A had fever. Data so obtained is statistically significant ($p=0.001$).

Similar study was done by Laas et al in 2012 in patients undergoing breast surgery with and without the use of triclosan coated sutures.²⁸ Fever was observed in 3% of the patients in conventional sutures group and 2% of the patients in Triclosan coated sutures group.

Wound dehiscence

In present study, none of the patients had wound dehiscence in the two groups.

Similarly, Arslan et al did a study to analyse the effect of triclosan coated sutures on SSI after wide local excision and primary closure for pilonidal disease. In their study, superficial wound dehiscence was seen in 13 (7.3%) patients in total: out of which, 5 (5.5%) patients were in the control group whereas 10 (11.6%) were in the study (triclosan) group ($p=0.116$).²⁹

Wound discharge

In present study, 1 patient in group A (2%) and 5 patients (10%) in group B had wound discharge and the data is statistically insignificant ($p=0.092$).

Similarly, Jung et al observed that the incidence for the presence of discharge was 0.76% at day 30 in gastric cancer patients in which vicryl plus was used for wound closure.²⁷

Surgical site infection

In current study, 10 patients (20%) in group B had surgical site infection, whereas only 1 patient (2%) in group A had surgical site infection. Data so obtained was statistically significant ($p=0.004$).

Comparable results were obtained by a study performed by Jung et al in which vicryl plus was used for wound

closure in patients with gastric cancer.²⁷ In this study, incidence of SSI after using vicryl plus for wound closure was 1.39% at day 30.

Arslan et al found that the overall incidence of surgical site infection (SSI) was 15.8% ($n=28$), out of which 19 (20.8%) patients were present in the control group whereas 9 (10.5%) patients were present in the study (triclosan) group ($p=0.044$).²⁹

Rasić et al observed significantly less rate of SSIs in the vicryl plus group (4 patients; 4.3%) compared with vicryl group (12 patients; 13.2%).³⁰ So, they concluded from these parameters that Triclosan coated sutures improve the wound healing process.

Thus, various studies have shown that vicryl plus is better than vicryl in preventing surgical site infections and thus decreasing the duration of hospital stay and the cost of treatment. However, some studies have shown equivocal results.

On the other hand, there were some limitations to our study. Emergency surgeries and contaminated or dirty wounds were not included in present study. Moreover, in this study vicryl and vicryl plus sutures were only used subcutaneously and intracutaneously. Further studies are needed in which all the layers of the wound (including the fascial closure) should be closed using vicryl and vicryl plus suture.

CONCLUSION

Thus, we conclude from our observations that triclosan coated vicryl (vicryl plus) is better than uncoated vicryl for the prevention of surgical site infection. Therefore, triclosan coated vicryl (vicryl plus) is recommended over uncoated vicryl for wound closure in patients undergoing elective surgery.

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