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Review Article

Triclosan coated sutures: an overview of safety and efficacy in reducing risk of surgical site infection

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ABSTRACT

Triclosan, a broad spectrum anti-microbial agent, is in the market for more than 40 years, mainly in personal care products. In 1972, triclosan has been introduced in health care industry, in surgical scrub. The use of triclosan effectively extended other products such as catheters, sutures and urethral stents. We have reviewed toxicity profile of triclosan and clinical publication on Triclosan Coated Suture (TCS). The available toxicity data establishes the acceptable profile of triclosan for using in human being. Till date, 5 systematic reviews and meta-analyses covering 20 randomized control clinical trials have been published, showing the efficacy of TCS in reduction of risk of surgical site infection. Additional, prospective studies are also available to support efficacy of TCS. This compilation may help surgeon to make a conscious decision to use TCS on the basis of evidences.

Keywords: Triclosan, Toxicity, Triclosan coated suture, Surgical site infection

INTRODUCTION

Surgical Site Infection (SSI) is one of the most frequently reported nosocomial infection in hospitalized patients. Considering the health care structure in India mainly in primary health care centers, there is a realistic possibility of SSI leading to major complications such as sepsis and death. It also poses significant health economic burden on patients. Various studies have reported high SSI incidence rate in India.[1] Various guidelines have emphasized on pre and postoperative management of patients to prevent SSI. Antibacterial coated suture could one of the measures to reduce the risk of development of SSI. Triclosan (2,2,4'-trichloro-2'-hydroxyphenyl ether) is synthetic broad-spectrum anti-microbial agent present in the market for more than 40 years, mainly in the personal care or consumer products.[2] Currently, triclosan is found in variety of skin care or personal care products such as hand soaps, shower gels, mouth washes, deodorant soaps, toothpastes, etc.

Use of triclosan in health care industry started in 1972, in surgical scrubs.[3] It has also been used in other medical products such as hand subs, skin antiseptics, ointments, impregnated/coated catheters and sutures.[4]

In recent times, many questions have been raised on the triclosan toxicity, its carcinogenicity potential, and efficacy of triclosan mainly in personal and health care product. Additionally, regulatory authorities from developed nation and various eminent societies have been reviewing the safety and efficacy of triclosan in health care and medical devices. At the same time, new clinical evidences are coming into domain, which could definitely change the outlook towards antibacterial suture. The objective of this article is to review the published literature on triclosan toxicity data and various clinical

studies on triclosan coated suture to assess its effectiveness in reducing the risk of SSI.

TRICLOSAN - SAFETY REVIEW

Acute toxicity

Acute toxicity was evaluated through single dose exposure in animal models thought variety of routes of administration. The LD_{50} value (lethal dose 50) for animal models is given in Table 1. LD_{50} value of 2000 to 5000 mg/kg is considered to be non-toxic.[2,4]

Table 1: Triclosan - LD_{50} values for acute toxicity.

Animal model	Route of administration	LD_{50} value (mg/kg)
Mice	Oral	4350
Rats	Oral	3750-5000
Dogs	Oral	>5000
Rabbits	Dermal	>9300
Rats	Subcutaneous	>14700

Subchronic toxicity

Subchronic toxicity has been evaluated for NOEL (no observed effect level) in approximately 90 day oral administration studies in various animal models. NOEL values and the safety factors for each animal model are given in table 2.[2] NOEL is highest dose tested in an animal species with no detectable effect. The safety factor of 100-1000 fold is considered as safe for many active ingredients.

Table 2: Subchronic toxicity - NOEL and Safety factor.[2,4]

Animal model	Route of administration	Study duration	NOEL (mg/kg)	Safety factor
Rat	Oral	90 days	50	16667
Dog	Oral	13 weeks	12.5	4167
Hamster	Oral	13 weeks	75	25000
Baboon	Oral	1 year	30	10000
Rabbit	Oral	13 weeks	3	1000

Chronic toxicity

Chronic toxicity studies with long duration exposure to oral administration of triclosan have shown favorable response. Studies were conducted in rat and hamster model. The NOEL (rats – 52 mg/kg for male, 67 mg/kg for females, hamster - 75 mg/kg) values were within the acceptable limit.[2,4]

Carcinogenicity

No evidence of carcinogenic changes observed in chronic toxicity studies, showing non carcinogenic property of triclosan at NOEL values and with the acceptable safety factor.

Other toxicity studies

Various other studies have shown no adverse effects of triclosan on pregnancy and reproductive potential. Triclosan is also proved as not potential to develop teratogenicity, mutagenicity and genotoxicities at various NOEL values observed in animal toxicity studies.[2]

TRICLOSAN COATED SUTURE - ASSEMENT OF SAFETY

The triclosan content on various triclosan coated sutures is given in the Table 3. Barbolt TA has evaluated the gradual exposure of triclosan (related to triclosan dissipation profile for each suture) and worst case scenario 'immediate exposure'.[2] The toxicity due to triclosan coated suture are considered to be low due low exposure levels, rapid metabolism and excretion, and lack of accumulation over time.[2]

Considering the dissipation profile of triclosan for each suture type and worst case scenario of 5 m of a 2-0 suture with 472 µg triclosan/m (270 for EU and India) for vicryl™ Plus and 2360 µg/m for PDS™ plus and monocryl™ plus, the maximal single-day exposure to triclosan was calculated to be 0.03, 0.09 and 0.08 mg/kg body weight.[2,4] The safety margin would be in the range of 160 to 2500, good enough to consider triclosan safe.

Table 3: Triclosan coated sutures - safety margin.[2,4,43]

Suture	Polymer	% dissipation in first 24 hours	Triclosan content on suture material	Safety margin
Vicryl™ plus	Polyglactin 910	69	< 270 or <470 µg/m	420-2500
PDS™ plus	Polydiaxanone	46	< 2360 µg/m	140-830
Monocryl™ plus	Poliglecaprone 25	41	< 2360 µg/m	160-94

Thus, Barbolt TA highlighted the extensive clinical experience with triclosan coated suture, availability of favorable toxicity study data and non-carcinogenic potential, precludes the need to conduct genotoxicity studies and other toxicity studies.[2]

TRICLOSAN - MECHANISM OF ACTION AND ANTIBACTERIAL PROFILE

Triclosan exhibits its bactericidal property by inhibiting FabI gene which encodes the enoyl-acyl carrier protein reductase enzyme (ENR). It is essential in fatty acid biosynthesis, which is inhibited by triclosan. Triclosan disrupts the cell membrane causing cell contents to leak.[2,4] Triclosan has bactericidal activity against most of the microorganisms primarily responsible for SSI.

Table 4: Microorganisms susceptible to triclosan coated suture using zone of inhibition studies.

Microorganisms susceptible to triclosan	
Staphylococcus aureus	Methicillin resistant Staphylococcus aureus (MRSA)
Staphylococcus epidermidis	Methicillin resistant Staphylococcus epidermidis (MRSE)
Eeschirichia coli	Klebsiella pneumoniae

Some of the bacteria such as Pseudomonas aeruginosa, Acinitobacter requires high concentration of triclosan for the bactericidal effect. Leaper D et al. pointed out that due to multi-drug efflux pumps that remove triclosan from cell also distinct versions of the ENR, Pseudomonas aeruginosa shows innate resistance to triclosan.[4]

BACTERIAL RESISTANCE

Although various studies have shown resistance to triclosan, but these studies basically are the laboratory studies. However, resistance to triclosan has not been demonstrated in various clinical studies or from epidemiological data. Hence, there is no clinical evidence for triclosan resistance.

ZONE OF INHIBITION AND RELATED STUDIES

Using zone of inhibition studies, antibacterial sutures shown to inhibit bacterial colonization of S. aureus (SA), MRSA, S. epidermidis, MRSE, E. coli and K. pneumonia (Table 4). Sarkar S et al. have conducted in-vitro zone of inhibition studies for triclosan coated and uncoated suture against the bacteria isolated from SSI. In addition to above bacteria, other bacteria such as acinetobacter, Coagulase negative staphyolococcus, Proteus and Pseudomonas. Zone of inhibition was observed in all bacterial plate except for Pseudomonas and Acinetobacter.[5] Edmiston CE et al. has showed substantial reduction in in both gram-positive and gram-negative bacterial adherence to triclosan coated polyglactin 910 (braided) suture compared with non triclosan coated suture, in an in vitro microbiologic model (Standardized cultures (2.0 $\log_{10}$ colony forming units/mL and 5.0 $\log_{10}$ colony forming units/mL of three clinical strains, S, aureus (MRSA), S. epidermidis (biofilm-positive) and Escherichia coli [extended-spectrum beta-lactamase (ESBL)-producer].[6] These results were similar to earlier zone of inhibition study conducted for triclosan coated polyglactine 910 sutures.[7] In another *in vitro* study, triclosan coated polidioxanone sutures found to be effective against S. aureus, MRSA, S. epidermidis, MRSE, K. pneumoniae, and E. coli. Additionally, antibacterial activity was lasted for 17-23 days till the suture dissolved. In animal models, it was found that TCS inhibited *in vivo* colonization of bacteria compared with the non-coated suture (99.9% reduction in S. aureus and a 90% reduction in E. coli).[8] The same author group also published in vivo antibacterial efficacy of triclosan coated poliglecaprone 25 suture. [9]

TRICLOSAN COATED SUTURE - CLINICAL STUDIES PUBLISHED

Since the introduction of triclosan coated sutures, many clinical studies have been published in varied therapeutic area. It includes systematic reviews and meta-analyses, Randomized controlled Clinical Trials (RCTs), and other clinical trials such as cohort studies, case controlled studies and case series. The evidences are published in various therapeutic segment e.g. general surgeries, urosurgery, breast surgery, gynecological procedures, oncology surgery, cardiac and vascular surgery, orthopedic surgery, ENT surgery, etc. The brief information and the study outcome are given in Table 5, 6 and 7.

Table 5: Triclosan coated sutures: published studies.

Publication type	N
Systematic reviews and meta-analyses	5
Randomized controlled clinical trials:	20
Clinical studies (Other than RCTs):	10

Table 6: Triclosan coated sutures: Systematic review and meta-analyses - Level 1a evidence.

First author (year)	RCTs	Sample size		OR	RR	P value
		TCS	NTCS			
Daoud FC (2014)[10]	15	2323	2477	-	0.67	0.00053
Edmiston CE (2013)[11]	13	1654	1914	-	0.73	0.005
Wang ZX (2013)[12]	17	1726	1994	-	0.70	<0.001
Sajid MS (2013)[13]	7	760	871	0.61	-	0.04
Chang WK (2012)[14]	7	433	393	0.77	0.82	0.45 and 0.39
OR-Odds ratio, RR-Relative risk, TCS-Triclosan coated suture, NTCS-Non triclosan coated suture						

Table 7: Triclosan coated sutures: randomized controlled clinical trials.

Study, (year)	Procedure	Follow up period	Sample size		Results (SSI rate)
			TCS	NTCS	
Ford, 2005[15]	General surgery	30 days	98	49	TCS: 3/98 NTCS: 0/49
Rozzelle, 2008[16]	CSF shunt	6 months	46	38	TCS: 2/46 NTCS: 8/38
Mingmalairak, 2009[17]	Appendectomy	12 months	50	50	TCS: 5/50 NTCS: 4/50,
Zhuang, 2009[18]	Laparotomy	12-14 months	150	300 (2 types)	TCS: 0/150, NTCS(1): 3/150, NTCS(2): 15/150
Zhang, 2011[19]	Mastectomy	90 days	50	50	TCS: 2/46 NTCS: 5/43
Galal, 2011[20]	General surgery	12 months	230	220	TCS: 17/230 NTCS: 33/220
Rasic, 2011[21]	Colorectal	Not given	91	93	TCS: 4/91 NTCS: 12/93
Baracs, 2011[22]	Colorectal	30 days	188	197	TCS: 23/188 NTCS: 24/197
Williams, 2011[23]	Breast cancer	6 weeks	75	75	TCS: 10/66 NTCS: 14/61
Turtiainen, 2012[24]	Lower limb revascularization	1 month	139	137	TCS: 31/139 NTCS: 30/137
Seim, 2012[25]	CABG	4 weeks	160	163	TCS: 16/160 NTCS: 17/163
Isik 2012[26]	Cardiac surgery Sternal incision	30 days	170	340	TCS: 4/170 NTCS: 12/340
Nakamura, 2013[27]	Colorectal	30 days	206	204	TCS: 9/206 NTCS: 19/204
Thimour-Bergstom, 2013[28]	CABG	60 days	184	190	TCS :23/184 NTCS: 38/190
Justinger, 2013[29]	Laparotomy	2 weeks	485	372	TCS: 31/485 NTCS: 42/371
DeFazio, 2005[30]	Umbilical incision	6 weeks	43	50	TCS: 4/43 NTCS: 4/50
Deliaert, 2009[31]	Breast surgery	4 weeks	26	26	TCS: 0/26 NTCS: 0/26
Khachatryan, 2011[32]	Abdominal surgery	Not provided	65	68	TCS: 6/65, NTCS:14/65
Mattavelli, 2011[33]	Colorectal surgery	30 days	108	109	TCS: 11/108, NTCS: 12/109
Singh, 2010[34]	CABG	30 days	50	50	TCS: 6/50 NTCS: 16/50

The brief information and the study outcome are given in Table 5, 6 and 7. The meta-analyses published have been discussed in detail. Recent meta-analyses published in last couple of years discussed in detail here.

Daoud FC et al. (2014):[10] The main objective of the Systematic Literature Review (SLR) was to assess the robustness of study results by applying more stringent statistical tests compared to first meta-analysis, to determine the efficacy of TCS in reduction of risk of SSI.

Table 8: Daoud FC et al.: 13 steps analytical strategy.

Risk ratio to measure effect	Publication bias
Heterogeniety between trials	Random effects pooled relative risk (RR)
Sensitivity analysis of robustness	Blinding methodology followed in RCTs
Differences in SSI diagnostic methodologies in each RCTS	Suture materials
CDC incision class	Incision depth or site
Operation type	Confounding relationship between RR and SSI incidence rate
Evaluation of certainty of triclosan effect based on robust ness of results of first 12 steps	

The secondary objectives were to assess potential bias or confounding factors which could invalidate the triclosan effect in the pooled RCTs. RCTs included were selected on criteria used to assess quality of study and publication bias. A rigorous 13 step analytical strategies were used to meet the objectives of SLR (Table 8).The data from 15 RCTs totaling 4000 patients (TCS=2323) and NTCS=2477) were analyzed. Use of TCS was associated with a decrease in SSIs in selected patient populations (RR = 0.67; P = 0.00053), means 33% reduction in risk of developing SSIs. TCS showed highly statistical significant results in lowering risk of SSI. TCS was effective in clean (P = 0.001), clean-contaminated (P = 0.010), and contaminated incisions (P = 0.026). SLR result was robust to the removal of three RCTs. SLR showed highly statistical significant results favoring TCS in reduction of risk of SSI and robustness of clinical results - relative risk independent of confounding factors.

Edmiston CE et al. (2013):[11] The meta-analysis was conducted in response to recently published systematic reviews and meta-analysis which have suggested about no benefits of anti-microbial coated suture in reducing the Surgical Site Infections (SSI). Authors have highlighted poor selection of available RCT and low patient numbers for these meta-analyses. The primary endpoint of the systematic review was to determine the ratio of patients who developed an SSI in two comparative groups: closure with TCS versus NTCS sutures. Total 13 RCTs

were selected, totaling 3568 patients (TCS=1654) and NTCS=1914). Stringent criteria was applied for selection of RCTs such as protocol with defined objective, accurate SSI definition, specified patient population, proper randomization procedure, study design which enables unbiased comparison between two groups, lost to follow up patients <10%, ethical conduct of study, etc. Publication bias (fixed - assuming same patient population and random effect - assuming clinically heterogeneous patient population), heterogeneity and sensitivity analysis was considered to check the robustness of the model used. Use of TCS was associated with a decrease in SSIs in selected patient populations (fixed effect: RR = 0.734; P = 0.005; random-effect: RR = 0.693; P = 0.011), means 27-31% reduction in risk of developing SSIs. No publication bias was detected (Egger intercept test: P = 0.145).

Wang ZX et al. (2013):[12] Total 17 RCTs were selected for the meta-analysis, covering 3720 patients (TCS=1726) and NTCS=1994). The meta-analysis was performed in adherence to the guidelines outlined in the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement. All 17 studies selected were assessed independently by 2 investigators. Risk of bias and methodological quality of included studies were assessed using the Cochrane Collaboration tool for assessing risk of bias. Publication bias also was assessed by using Funnel plots. Results favored TCS with a pooled RR of 0.70 (P <0.001) without statistical heterogeneity (P for Q test = 0.129, I^2=29 per cent), means TCS provided significant advantage in reducing the rate of SSI by 30%. Subgroup analysis indicates statistical significant results of reduction in SSI by using TCS in adult patients, abdominal surgery and clean or clean contaminated wounds. The advantage of TCS over conventional sutures was consistent regardless of length of follow-up. The qualities of the included studies were acceptable with moderate risk of bias and no evidence for significant publication bias was noted.

Twenty RCTs were evaluated in these meta-analyses.[15-34] The brief information on sample size, procedures and SSI rate reported in these RCTs has given in Table 7. Justinger C et al. has published large retrospective study of 2088 patients in mid laparotomy. The results showed the decrease in number of SSIs (TCS: 4.9%, NTCS: 10.8%, P <0.001) for abdominal wall closure.[35] In another prospective comparative study in transverse laparotomy for hepatobiliary resections (n=839), TCS showed significant reduction in SSI compared to NTCS arm (4.3% vs. 9.2%, P = 0.05).[36] In spinal surgery, TCS found to be effective in reduction of wound infection (0.5% vs. 3.9%, p=0.020).[37] A recent paper on gastric cancer surgery via midline laparotomy also showed the reduction of SSI cases in abdominal wall closure.[38] Other prospective studies in digestive tract surgery,[39] breast cancer surgeries,[40] abdominal surgeries,[41] and cardiac surgeries (sternal site infections),[42] TCS was found to be effective in minimizing the risk of development of SSI post-surgery.

SUMMARY

Wide range of published evidences is available for toxicity profile of triclosan, antibacterial profile and clinical effectiveness of TCS. Hence, it assures use of TCS in minimizing the risk of SSI. This effort is an attempt to draw attention to the continuous publication around TCS and reemphasize the efficacy and safety parameter as in these published clinical evidences. This compilation may help surgeon to make a conscious decision to use TCS on the basis of evidences.

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