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BMJ Open The use of triclosan-coated sutures to prevent surgical site infections: a systematic review and meta-analysis of the literature

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ABSTRACT

Introduction and objectives Surgical site infections (SSIs) represent a common and serious complication of all surgical interventions. Microorganisms are able to colonise sutures that are implanted in the skin, which is a causative factor of SSIs. Triclosan-coated sutures are antibacterial sutures aimed at reducing SSIs. Our objective is to update the existing literature by systematically reviewing available evidence to assess the effectiveness of triclosan-coated sutures in the prevention of SSIs.

Methods A systematic review of EMBASE, MEDLINE, AMED (Allied and complementary medicine database) and CENTRAL was performed to identify full text randomised controlled trials (RCTs) on 31 May 2019.

Intervention Triclosan-coated sutures versus non-triclosan-coated sutures.

Primary outcome Our primary outcome was the development of SSIs at 30 days postoperatively. A metaanalysis was performed using a fixed-effects model. **Results** Twenty-five RCTs were included involving 11 957 participants. Triclosan-coated sutures were used in 6008 participants and non triclosan-coated sutures were used in 5949. Triclosan-coated sutures significantly reduced the risk of SSIs at 30 days (relative risk 0.73, 95% Cl 0.65 to 0.82). Further sensitivity analysis demonstrated that triclosan-coated sutures significantly reduced the risk of SSIs in both clean and contaminated surgery.

Conclusion Triclosan-coated sutures have been shown to significantly reduced the risk of SSIs when compared with standard sutures. This is in agreement with previous work in this area. This study represented the largest review to date in this area. This moderate quality evidence recommends the use of triclosan-coated sutures in order to reduce the risk of SSIs particularly in clean and contaminated surgical procedures.

PROSPERO registration number CRD42014014856

INTRODUCTION

Surgical site infections (SSIs) represent a common complication throughout all surgical procedures.¹ It is estimated that SSIs account for 5% of all surgical complications² and 20% of all healthcare-associated infections.^{3 4} It is generally believed that the number of surgical procedures, particularly

Strengths and limitations of this study

- Systematic nature of data collection and analysis.
- Largest review to date in this topic area.
- Analyses performed comparing different classifications of surgery, that is, clean, clean-contaminated, contaminated and dirty.
- Heterogeneous nature of included studies. For example, different age of participants, comorbidities and surgery type.

in elective orthopaedics,⁵ will increase over the next decade, therefore increasing the incidence of SSIs. SSIs are associated with prolonged hospital admission⁶ and increased morbidity and mortality.⁷⁻⁹ In addition to having a significant impact on patient care and experience, SSIs also add substantial costs to healthcare providers. It is estimated that SSIs cost UK healthcare services approximately £61 million in 2012¹⁰ and figures from the US highlight the extensive cost of SSIs with an estimated additional US\$2300 per case.¹¹ Furthermore, Fleck *et al* found that the mean cost of treated a SSI following sternal wound incision was US\$11 200.¹² These are conservative estimates as active surveillance of SSIs not routinely performed.⁶

Due to the wide ranging deleterious effects of SSIs and their treatment, particularly in the context of increasing numbers of surgical procedures, there is a clinical need to reduce the incidence of SSIs. SSIs are multifactorial with patient factors such as age, comorbidities including diabetes, and immunosuppression^{7 13–15} contributing to their development, along with surgical factors. Many patient factors may not be optimised and hence research focus has been placed on surgical factors, including suture material.

SSIs may arise when bacteria colonise the suture material,¹⁶ creating a biofilm as it

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passes through the skin.¹⁷ This biofilm establishes an immunity from both antimicrobial treatment and the host immune system.⁶¹⁷ Once this biofilm develops there is an increased chance of a SSI developing. Research has shown bacteria may colonise monofilament and braided sutures.^{18–20} With this in mind, considerable work has been carried out since the 1950s with regards to coating suture material with an antimicrobial, including silver.²¹²² Triclosan (polychlorophenoxyphenol) has been used for its antiseptic properties for many years in toothpaste and soap and has an established safety profile.⁵ Triclosan has been used to successfully coat the following sutures and gained US food and drug administration approval in 2002: braided polyglactan 910 (Vicryl Plus), poliglecaprone 25 (Monocryl Plus) and polydioxanone (PDS Plus).

In vitro and in vivo studies have shown the effectiveness of triclosan-coated sutures²³⁻²⁵ in killing bacteria associated with SSIs and inhibiting colonisation of suture material, with one study demonstrating a 66% reduction in bacterial colonisation.²⁶ Since then a large number of randomised controlled trials (RCTs) have been performed with contrasting results of the effectiveness of triclosan-coated sutures in the prevention of SSIs. Subsequent meta-analyses have also produced conflicting results and hence the true effect remains unclear.⁶⁷²⁷⁻³² The most recent and largest systematic review to date was performed by de Jonge et al and found triclosan-coated sutures significantly reduced the incidence of SSIs.³² This review searched the literature up until November 2015 and included 6462 patients from RCTs published in peer-reviewed journals as well as conference abstracts. Performing robust methodological appraisal of conference abstracts is not possible, they do not permit thorough risk of bias assessments, and as they have not undergone the formal journal peer-review process, they represent a potentially biassed and unreliable source of data. Since this review, a number of large, high-quality RCTs have been produced.^{33 34} Of note, a recent RCT of 2546 patients found that triclosan-coated sutures did not reduce the incidence of SSIs; a finding in contrast to the previous systematic review.^{32 34} This represents a substantial increase in the number of patients available for meta-analysis since the last review. As a result, we believe it is important to update the existing literature by performing a new, up to date, systematic review and meta-analysis to assimilate the current evidence and inform clinical practice. A new review should include a detailed risk of bias assessment and GRADE (Grading of Recommendations Assessment, Development and Evaluation) assessment of the quality of evidence.

This new systematic review and meta-analysis of the available literature aims to determine whether the use of triclosan-coated sutures reduces the incidence of SSIs in comparison to standard non-coated sutures.

PICOS (Participants, Intervention, Comparator, Outcomes and Study design) statement

The included population encompasses patients of any age and gender undergoing any surgical procedure utilising sutures to close the wound. The intervention studied is the use of triclosan-coated sutured and comparison is made with non-triclosan-coated sutures. The outcomes assessed are the rates of SSIs, including superficial and deep SSIs. This systematic review will only include RCTs.

METHODS

A systematic review of the available literature was conducted and is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidance.³⁵ A protocol for this review was prospectively registered with PROSPERO.

Search methods

Electronic searches were conducted using OVID SP on the following databases: MEDLINE (1946–May Week 4 2019); Excerpta Medica Database (EMBASE) (1974–2019 May 31); Allied and Complementary Medicine (AMED) (1985–May 2019); and Cochrane Central Register of Controlled Trials (CENTRAL). A multipurpose search was performed for all terms and the search terms were: 'Triclosan', 'Anti-bacterial agents', 'Anti-infective agents, local', 'Coated materials, biocompatible', 'Biomimetic material', 'Sutures', 'Vicryl Plus', 'Monocryl Plus', 'PDS Plus', 'Surgical site infection', 'Surgical Wound infection'. The search was conducted on 31 May 2019. A copy of the search strategy can be seen in online supplementary file 1.

Selection of studies

Two authors (IA and AJB) independently selected studies for inclusion. Any discrepancies were resolved by discussion with a third author (ED). Titles and abstracts were screened and full texts obtained for any studies of interest. The eligibility criteria were formed from the PICOS statement and registered on PROSPERO prior to undertaking the search. Only RCTs published in peer-reviewed journals presenting new data were included.

Data extraction

Data were independently extracted from eligible included studies onto predetermined forms by two authors (IA and AJB). Any discrepancies were then resolved following discussion between two authors (IA and AJB) and a third author. Data extracted included baseline patient characteristics, surgical procedures performed, number of centres, suture material, SSI diagnostic criteria, length of follow-up, routine prophylactic antibiotic use and number of SSIs. Data regarding superficial of deep SSI was extracted when possible. Information regarding randomisation, blinding, funding and country of origin was extracted.

Assessment of risk of bias

Two authors (IA and AJB) independently appraised eligible studies according to the Cochrane Collaboration's risk of bias tool, resolving any discrepancies with a third author (ED) as necessary.³⁶ Review Manager V.5.3 was used to generate the summary figures. The parameters used for 'other' sources of bias included source of funding and antibiotic regime.

Two authors (IA and AJB) independently assessed the quality of evidence. We used the GRADE considerations (study limitations, consistence of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence.³⁷ Decisions to upgrade or downgrade body of evidence have been clearly stated in the discussion.

Publication bias was assessed following construction of a funnel plot in order to identify the presence or absence of bias of this kind.

Statistical analysis

Identification

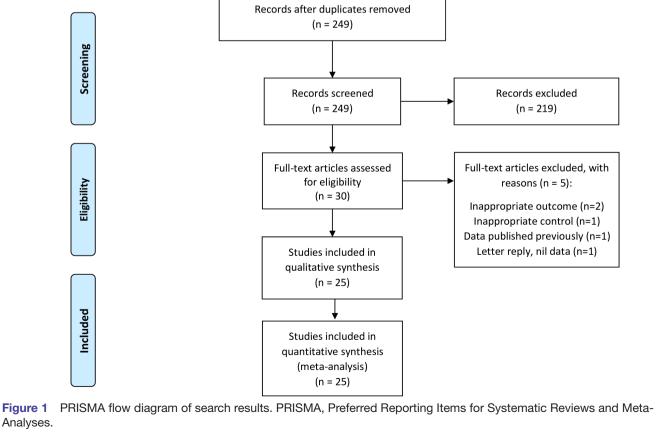
A fixed-effects model was used to calculate the predominant relative risk (RR) and the 95% CIs of the studies included. Statistically heterogeneity was first assessed using a funnel plot and more formally using the I^2 statistic.³⁶ Forest plots were then generated summarising the results of the meta-analysis using Review Manager V.5.3.

Patient and public involvement

Given the design of this study and the retrospective nature, patient and public members were not involved in the development and conduct of this review. With the aid of patient and public members we will produce lay summaries of the results available for patients.

RESULTS

The search revealed 357 records of possible relevance. No other sources of records were identified. Removal of duplicates left 249 records to be examined. Two hundred and nineteen records were excluded based on title and abstract screening. Thirty full texts were assessed for eligibility and 25 studies were included in the meta-analysis (see figure 1).^{271133 34 38-57}



Records identified through

database searching (n = 357)

Study characteristics

Study characteristics are summarised in table 1. Twenty-five RCTs were included in this review involving 11957 patients.^{2 7 11 33 34 38-57} There were 6008 patients randomised to triclosan-coated sutures and 5949 patients to standard sutures. In studies which reported mean age, the mean age reported in 23 out of 25 studies was comparable between the two groups (54.8 vs 54.8). For the studies which reported gender 57% of the included patients were male. Eight studies were multicentre, with the remainder single-centre studies (n=17). Vicryl was compared with Vicryl Plus in 12 studies,^{11 34 39–41 43 46–49 54 56} 3 studies compared PDS versus PDS Plus,^{7 38 55} 1 study compared PDS II with PDS II Plus,⁴⁴ 2 study compared Monocryl against Monocryl Plus,^{45 57} 1 compared Chinese silk with Vicryl Plus,⁵³ 4 studies compared Vicryl and Monocryl versus Vicryl Plus and Monocryl Plus^{33 50-52} and 2 studies compared Vicryl and PDS versus Vicryl Plus and PDS Plus.^{2 42}

To define SSI, the centre for disease control (CDC) criteria were used by 18 studies, ^{2 7 11 33 34 41-44 48 50-57} clinical diagnosis or wound cultures was used by 3 studies studies, ^{39 45 49} and 4 did not provide explicit definitions.^{38 40 46 47} Seventeen studies used a follow-up duration of 30 days or 1 month or 4 weeks, ^{2 7 11 33 34 38 41-43 46 49 51 53-57} 3 for 6 weeks, ^{48 50 52} 2 for 2 weeks, ^{44 45} 1 for 80 days⁴⁰, 1 until discharge⁴⁷ and 1 study did not specify a follow-up regime. ³⁹ Routine prophylactic antibodies were used in 19 studies, ^{2 7 11 34 38 39 42 44-51 54-57} no prophylactic antibiotics in high-risk patients only, ⁵² 1 study used prophylactic antibiotics in 30% of participants³³ and 3 did specify prophylactic antibiotic use. ^{41 43 53}

Surgical site infection

The risk of developing SSI was significantly reduced in the triclosan group compared with the standard suture group (RR 0.73, 95% CI 0.65 to 0.82). Heterogeneity was low to moderate (χ^2 =24.66, p=0.21, I²=17%). There were 420 instances of SSI among 6008 patients in the triclosan-coated suture group and 581 SSIs in 5949 patients in the standard suture group (see figure 2).

Subgroup analysis

Eight studies reported superficial and deep infections separately.^{2 7 33 34 42 46 51 57} There were 152/3507 cases of superficial SSI in the triclosan group and 164/3626 cases in the standard suture group, producing a meta-analysis risk ratio of 0.95 (95% CI 0.72 to 1.25). The risk of developing a deep infection was lower in the triclosan group when compared with the standard suture group; however, this was not significant (RR 0.77, 95% CI 0.55 to 1.07). There were 61/3507 cases of deep infections in the triclosan group and 85/3626 cases in the standard suture group (see figure 3).

Ten studies reported the incidence of SSI for clean surgery.^{33 34 39 43 49-53 56} Triclosan-coated sutures were associated with a significantly lower incidence of SSI

(149/3029) when compared with standard sutures (230/1117) (RR 0.71, 95% CI 0.58 to 0.88).

Six studies reported clean-contaminated surgery and there was no difference between the two groups (160/1540 vs 156/1504) (RR 1.02, 95% CI 0.83 to 1.25).²⁷⁴⁰⁴²⁴⁶⁵⁴

Four studies reported the incidence of SSIs in contaminated surgery.^{11 47 55 57} Triclosan-coated sutures were associated with a significantly lower risk of SSI (22/438) when compared with standard sutures (55/443) (RR 0.43, 95% CI 0.27 to 0.7).

Two further studies reported the incidence of SSI for dirty surgery.^{45 48} There was no significant difference in the incidence of SSIs between the two groups of sutures (25/102 vs 35/105) (RR 0.74, 95% CI 0.46 to 1.18) (see figure 4).

Risk of bias

The results of the risk of bias screening can be seen on figure 2. The majority of studies had a clear randomisation sequence generation and allocation concealment using sealed envelopes. Five out of 25 (20%) had high risk of selection bias, either because the randomisation method was not stated or a quasirandomisation method was used. Two further studies had a risk of selection bias due to unclear allocation concealment methods. Ten out of 25 studies (40%) had high risk of performance and detection bias due to either absence of blinding of the participants and outcome assessors or the methods of blinding were not stated. Four out of 25 (16%) were at high risk of other bias due to source of funding. One study had differences in antibiotic regime between the two groups, with one group not receiving any antibiotic prophylaxis.

The distribution of studies in the funnel plot was symmetrical. No evidence was found for publication bias in this analysis (figure 5).

Statistical heterogeneity was assessed using the τ^2 (0.02) test and the I² (17%) test, indicating there is low heterogeneity between the studies included in this review based on the recommendations in the Cochrane handbook.

DISCUSSION

This large systematic review of 25 randomised clinical trials included 11957 patients and there were 1001 instances of SSI. The subsequent meta-analysis supports the use of triclosan-coated sutures in reducing the risk of SSIs. We report a significantly lower risk of SSI when triclosan-coated sutures were used, compared with standard sutures in RCTs. Triclosan-coated sutures were used in a wide range of surgeries, including both adult and paediatric patients. The use of triclosan-coated sutures significantly reduced the risk of SSI in meta-analyses of clean surgery and also contaminated surgery. Further subgroup analysis revealed a non-statistically significant reduction in the risk of developing deep SSIs with triclosan-coated sutures. Triclosan-coated sutures appear to have no effect on the incidence of superficial SSIs.

-	No of	No of				Duration of	Routine prophylactic
study	participants	centres	surgery type	outures used		dn-woiioi	
Arslan <i>et al⁵⁷</i>	177	-	Surgery for pilonidal disease	Vicryl versus Vicryl plus	CDC criteria	30 days	Yes
Baracs et al ³⁸	385	7	Elective colorectal surgery	PDS versus PDS Plus	Not stated	30 days	Yes
Chen <i>et al</i> ³⁹	241	-	Head and neck surgery	Vicryl versus Vicryl Plus	Local erythema with purulent discharge, wound dehiscence, or skin necrosis	Not stated	Yes
Diener <i>et al⁷</i>	1185	24	Laparotomy	PDS versus PDS Plus	CDC criteria	30 days	Yes
Ford <i>et al</i> ⁴⁰	147	F	Paediatric general surgery	Vicryl versus Vicryl Plus	Not stated	80 days	No
Galal and El-Hindawy ⁴¹	450	-	All surgery	Vicryl versus Vicryl Plus	CDC criteria	30 days	Not stated
Ichida <i>et al</i> ⁴²	1023	-	Gastroenterological surgery	Vicryl and PDS II versus Vicryl Plus and PDS Plus	CDC criteria	30 days	Yes
lsik <i>et al</i> ⁴³	510	-	Cardiac surgery	Vicryl versus Vicryl Plus	CDC criteria	1 month	Not stated
Justinger <i>et al</i> ⁴⁴	856	-	Laparotomy	PDS II versus PDS II Plus	CDC criteria	2 weeks	Yes
Karip et al ⁴⁵	106	.	Pilonidal sinus excision followed by Karydakis flap repair	Monocryl Plus versus Monocryl	Rash, fever or purulent discharge	2 weeks	Yes
Lin <i>et al</i> ⁵⁶	102	-	Total knee replacement surgery	Vicryl versus Vicryl plus	CDC criteria	30 days	Yes
Mattavelli <i>et al²</i>	300	4	Elective colorectal surgery	Vicryl and PDS versus Vicryl Plus and PDS Plus	CDC criteria	30 days	Yes
Mingmalairak <i>et al</i> ⁴⁶	100		Appendectomy	Vicryl versus Vicryl Plus	Not stated	30 days, 6 months and 1 year	Yes
Nakamura <i>et al</i> ' ¹¹	410	-	Elective colorectal surgery	Vicryl versus Vicryl Plus	CDC criteria	30 days	Yes
Rasic <i>et al⁴⁷</i>	184	-	Elective colorectal cancer surgery	Vicryl versus Vicryl Plus	Not stated	To discharge	Yes
Renko et a/ ³³	1633	-	Paediatric surgery	Vicryl and Monocryl and PDS versus Vicryl Plus and Monocryl Plus and PDS Plus	CDC criteria	30 days	In 30%
Roy <i>et al</i> ⁵⁵	110	-	Gastrointestinal surgery	PDS versus PDS plus	CDC criteria	30 days	Yes
Ruiz-Tovar <i>et al⁴⁸</i>	110	ო	Open colorectal surgery with faecal peritonitis	colorectal surgery with Vicryl versus Vicryl Plus I peritonitis	CDC criteria	60 days	Yes

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Table 1 Continued							
Study	No of participants	No of centres	Surgery type	Sutures used	SSI criteria	Duration of follow-up	Routine prophylactic antibiotics?
Seim <i>et al</i> ⁴⁹	328	-	CABG (Coronary artery bypass graft) leg wound	Vicryl versus Vicryl Plus	Positive bacterial culture and clinical judgement	4 weeks	Yes
Sprowson <i>et al</i>	2546	ი	Primary THR (total hip replacment) or TKR (total knee replacement)	Vicryl versus Vicryl Plus	CDC criteria	30 days	Yes
Tabrizi e <i>t al⁵⁴</i>	320	2	Dental implant surgery	Vicryl versus Vicryl plus	CDC criteria	30 days	Yes
Thimour-Bergstrom <i>et</i> a/ ⁵⁰	392	-	CABG (+/-AVR (aortic valve replacement), MVR (Mitral valve replacement)) with saphenous vein graft	Vicryl and Monocryl versus Vicryl Plus and Monocryl Plus	CDC criteria	60 days	Yes
Turtiainen e <i>t al</i> ⁵¹	276	ი	Non-emergency lower-limb arterial surgery	Vicryl and Monocryl versus Vicryl Plus and Monocryl Plus	CDC criteria	30 days	Yes
Williams et al ⁵²	150	-	Mastectomy	Vicryl and Monocryl versus Vicryl Plus and Monocryl Plus	CDC criteria	6 weeks	If considered at risk
Zhang et al ⁵³	101	9	Mastectomy	Chinese silk versus Vicryl Plus	CDC criteria	30 days	Not stated
CDC, centre for disease control; RCTs, randomised controlled trials.	introl; RCTs, random	ised controlled	trials.				

	T -1-1		Standard s			Risk Ratio	Risk Ratio	Risk of Bias
Shudu an Subanaun	Triclosan coated				Walaha			
Study or Subgroup	Events	Total	Events			M-H, Fixed, 95% Cl	M–H, Fixed, 95% Cl	ABCDEFG
Arslan 2018	9	86	19	91	3.2%	0.50 [0.24, 1.05]		4844484
Baracs 2011	23	188	24	197	4.1%	1.00 [0.59, 1.72]		444444
Chen 2011	17	112	19	129	3.1%	1.03 [0.56, 1.88]		4444444
Diener 2014	87	587	96	596	16.5%	0.92 [0.70, 1.20]	1	
Ford 2005	2	91	0	44	0.1%	2.45 [0.12, 49.88]		
Galal 2011	17	230	33	220	5.9%	0.49 [0.28, 0.86]		
Ichida 2018	30	508	35	505	6.1%	0.85 [0.53, 1.37]		•••••••
Isik 2011	9	170	31	340	3.6%	0.58 [0.28, 1.19]	+	
Justinger 2013	31	485	42	371	8.3%	0.56 [0.36, 0.88]		
Karip 2016	15	52	17	54	2.9%	0.92 [0.51, 1.64]		
Lin 2018	0	51	2	51	0.4%	0.20 [0.01, 4.07]		
Mattavelli 2015	18	140	15	141	2.6%	1.21 [0.63, 2.30]		
Mingmalairak 2009	5	50	4	50	0.7%	1.25 [0.36, 4.38]		
Nakamura 2013	9	206	19	204	3.3%	0.47 [0.22, 1.01]		
Rasic 2011	4	91	12	93	2.1%	0.34 [0.11, 1.02]		
Renko 2017	20	779	42	778	7.3%	0.48 [0.28, 0.80]		
Roy 2019	0	55	5	55	1.0%	0.09 [0.01, 1.61]		
Ruiz-Tovar 2015	10	50	18	51	3.1%	0.57 [0.29, 1.10]		
Seim 2012	16	160	17	163	2.9%	0.96 [0.50, 1.83]		
Sprowson 2018	21	1323	32	1223	5.8%	0.61 [0.35, 1.05]		
Tabrizi 2018	11	160	12	160	2.1%	0.92 [0.42, 2.02]		
Thimour-Berastrom 2013	23	184	38	190	6.5%	0.63 [0.39, 1.01]		<u> </u>
Turtiainen 2012	31	137	30	139	5.2%	1.05 [0.67, 1.63]	+	<u> </u>
Williams 2011	10	66	14	61	2.5%	0.66 [0.32, 1.37]	-+	
Zhang 2011	2	47	5	43	0.9%	0.37 [0.07, 1.79]		
								••••••
Total (95% CI)		6008		5949	100.0%	0.73 [0.65, 0.82]	•	
Total events	420		581					
Heterogeneity: Chi ² = 28.97	, df = 24 (P = 0.2	2); $I^2 = 179$	6				0.005 0.1 1 1	0 200
Test for overall effect: Z = 5	.20 (P < 0.00001)						Favours Triclosan coated Favours	
							ravours microsan coated ravours	stanuaru suture

Risk of bias legend

(A) Random sequence generation (selection bias)(B) Allocation concealment (selection bias)

(C) Blinding of participants and personnel (performance bias)

(D) Blinding of outcome assessment (detection bias)

(E) Incomplete outcome data (attrition bias)

(F) Selective reporting (reporting bias)

(G) Other bias

Figure 2 A meta-analysis of all studies included in this review. The forest plot is comparing triclosan coated sutures vs standard sutures on risk of developing surgical site infection. On the right of the figure a summary of our risk of bias assessment can be seen.

There have been 11 previous reviews in this topic area, the results of these reviews have been summarised in table 2.^{27 28 30–32 58–63} Our results support the findings of Konstantelias *et al* who concluded that triclosan-coated sutures were associated with a significantly lower risk of SSI when compared with standard sutures.^{32 61} In addition, the authors concluded that triclosan-coated sutures significantly reduced the risk of SSI in clean,

clean-contaminated and contaminated surgery; in agreement with our findings.⁶¹ de Jonge *et al* reported a meta-analysis of 21 RCTs including 6462 patients, also concluding that triclosan-coated sutures significantly reduced the risk of SSI compared with standard sutures.³² Five out of 11 reviews included a risk of bias assessment^{27 31 32 59 63} and only one review assessed the quality of evidence using the GRADE criteria.⁵⁹

	Triclosan coated	suture	Standard s	uture		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
1.2.2 Superficial infe	ections						
Arslan 2018	8	86	18	91	6.1%	0.47 [0.22, 1.02]	
Diener 2014	53	587	56	596	18.8%	0.96 [0.67, 1.37]	
Ichida 2018	23	505	19	508	9.5%	1.22 [0.67, 2.21]	- - -
Mattavelli 2015	14	140	7	141	5.0%	2.01 [0.84, 4.84]	+
Mingmalairak 2009	5	50	3	50	2.2%	1.67 [0.42, 6.60]	
Renko 2017	17	779	28	778	9.5%	0.61 [0.33, 1.10]	
Sprowson 2018	8	1223	11	1323	4.7%	0.79 [0.32, 1.95]	
Turtiainen 2012	24	137	22	139	11.4%	1.11 [0.65, 1.88]	_ -
Subtotal (95% CI)		3507		3626	67.1%	0.95 [0.72, 1.25]	•
Total events	152		164				
Heterogeneity: Tau ² =	= 0.04; Chi ² = 9.95	, df = 7 (P	= 0.19); I ²	= 30%			
Test for overall effect	Z = 0.38 (P = 0.70)	D)					
1.2.3 Deep infection	s						
Arslan 2018	1	86	1	91	0.6%	1.06 [0.07, 16.65]	
Diener 2014	22	587	25	596	10.4%	0.89 [0.51, 1.57]	- _
Ichida 2018	12	505	11	508	5.7%	1.10 [0.49, 2.46]	_
Mattavelli 2015	4	140	8	141	2.9%	0.50 [0.16, 1.63]	
Mingmalairak 2009	1	50	0	50	0.4%	3.00 [0.13, 71.92]	
Renko 2017	3	779	14	778	2.6%	0.21 [0.06, 0.74]	
Sprowson 2018	13	1223	21	1323	7.5%	0.67 [0.34, 1.33]	
Turtiainen 2012	5	137	5	139	2.7%	1.01 [0.30, 3.43]	
Subtotal (95% CI)		3507		3626	32.9%	0.77 [0.55, 1.07]	•
Total events	61		85				
Heterogeneity: Tau ² =			= 0.46); I ²	= 0%			
Test for overall effect	Z = 1.58 (P = 0.12)	1)					
Total (95% CI)		7014		7252	100.0%	0.88 [0.71, 1.08]	•
Total events	213		249				
Heterogeneity: Tau ² =	= 0.03; Chi ² = 17.8	1, df = 15	(P = 0.27);	$I^2 = 16\%$		Ļ	0.01 0.1 1 10 100
Test for overall effect	: Z = 1.20 (P = 0.23	3)				(J.01 0.1 1 10 100 Favours triclosan Favours standard suture
Test for subgroup dif	ferences: $Chi^2 = 0.9$	95. df = 1	(P = 0.33),	$1^2 = 0\%$			ravours inclosan ravours standalu suture

Figure 3 Subgroup analysis comparing triclosan coated sutures versus standard sutures on the risk of developing superficial and deep infections.

	Triclosan o		Standard			Risk Ratio	Risk Ratio
tudy or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	M-H, Random, 95% Cl
.3.1 Clean surgery							
hen 2011	17	112	19	129	5.4%	1.03 [0.56, 1.88]	
sik 2011	9	170	31	340	4.1%	0.58 [0.28, 1.19]	
in 2018	0	51	2	51	0.3%	0.20 [0.01, 4.07]	· · · · · · · · · · · · · · · · · · ·
enko 2017	20	779	42	778	6.6%	0.48 [0.28, 0.80]	
eim 2012	16	160	17	163	4.9%	0.96 [0.50, 1.83]	
prowson 2018	21	1323	32	1223	6.3%	0.61 [0.35, 1.05]	
himour-Bergstrom 2013	23	184	38	190	7.5%	0.63 [0.39, 1.01]	
urtiainen 2012	31	137	30	139	8.2%	1.05 [0.67, 1.63]	_ _
/illiams 2011	10	66	14	61	4.0%	0.66 [0.32, 1.37]	
hang 2011	2	47	5	43	1.0%	0.37 [0.07, 1.79]	
ubtotal (95% CI)	-	3029		3117	48.3%	0.71 [0.58, 0.88]	\bullet
otal events	149		230			• / •	•
eterogeneity: $Tau^2 = 0.01$;		df = 9($^{2} = 9\%$			
est for overall effect: $Z = 3$			1 = 0.50), 1	- 570			
est for overall effect. 2 = 5	.10 (1 = 0.0	02)					
.3.2 Clean-contaminated	suraerv						
Diener 2014	87	587	96	596	13.6%	0.92 [0.70, 1.20]	_ _
ord 2005	3	98	0	49	0.3%	3.54 [0.19, 67.12]	
chida 2018	35	505	30	508	7.6%	1.17 [0.73, 1.88]	
Attavelli 2015	18	140	15	141	4.9%	1.21 [0.63, 2.30]	
lingmalairak 2009	5	50	4	50	1.5%	1.25 [0.36, 4.38]	
	12		4		3.5%		
abrizi 2018 ubtotal (95% CI)	12	160 1540	11	160 1504	3.5% 31.4%	1.09 [0.50, 2.40] 1.02 [0.83, 1.25]	
		1340		1304	51.4%	1.02 [0.83, 1.23]	Ť
otal events	160		156	2			
leterogeneity: Tau ² = 0.00;			P = 0.85; I	* = 0%			
est for overall effect: $Z = 0$.18 (P = 0.8)	6)					
.3.3 Contaminated							
rslan 2018	9	86	19	91	4.0%	0.50 [0.24, 1.05]	
lakamura 2013	9	206	19	204	3.7%	0.47 [0.22, 1.01]	
asic 2011	4	91	12	93	2.0%	0.34 [0.11, 1.02]	
oy 2019	0	55	5	55	0.3%	0.09 [0.01, 1.61]	
ubtotal (95% CI)		438		443	9.9%	0.43 [0.27, 0.70]	•
otal events	22		55				
leterogeneity: Tau ² = 0.00;			P = 0.67); I	$^{2} = 0\%$			
est for overall effect: Z = 3	.46 ($P = 0.0$	005)					
.3.4 Dirty surgery							
arip 2016	15	52	17	54	5.7%	0.92 [0.51, 1.64]	
uiz-Tovar 2015	10	50	18	51	4.6%	0.57 [0.29, 1.10]	
ubtotal (95% CI)		102		105	10.3%	0.74 [0.46, 1.18]	◆
otal events	25		35				
leterogeneity: Tau ² = 0.01;	$Chi^2 = 1.14$, df = 1 (P = 0.29); I	$^{2} = 12\%$			
est for overall effect: $Z = 1$.25 (P = 0.2	1)					
otal (95% CI)		5109		5169	100.0%	0.77 [0.66, 0.91]	
	250	2103	470	2103	100.0%	0.77 [0.00, 0.91]	▼
otal events	356		476				
leterogeneity: Tau ² = 0.03;			1 (P = 0.15)); $1^2 = 24$	%		0.01 0.1 1 10 1
est for overall effect: Z = 3							

Figure 4 Subgroup analysis comparing triclosan coated sutures versus standard sutures on the risk of developing surgical site infections in clean, clean contaminated, contaminated and dirty surgery.

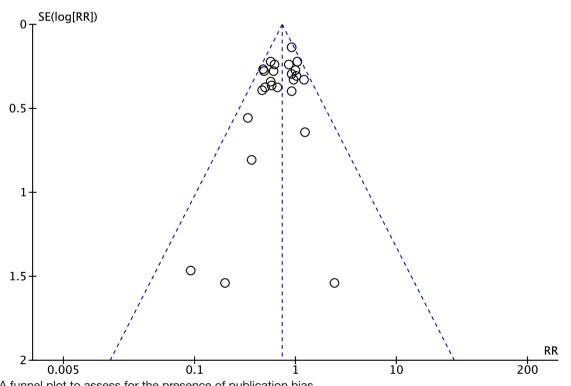


Figure 5 A funnel plot to assess for the presence of publication bias.

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Table 2 A summary of previous systematic reviews on this topic area highlighting number of studies, number	of participants
and key findings	

and key findings			No of	No of		Risk of	
Author	Date	Journal	studies	participants	· · · · · · · · · · · · · · · · · · ·	bias	Grade
Wang et al ²⁷	2013	British Journal of Surgery	17	3720	Triclosan-coated sutures significantly reduced SSI rate compared with standard sutures. RR 0.7 (95% CI 0.57 to 0.85). Triclosan-coated sutures significantly reduced SSI rate in 'clean' and 'clean- contaminated' surgery.	Included	Not included
Edmiston <i>et al</i> ²⁸	2013	Surgery	13	3568	Triclosan-coated sutures significantly reduced SSI rate compared with standard suture. RR 0.734 (95% Cl 0.59 to 0.91). No subgroup analysis was performed.	Not included	Not included
Daoud e <i>t al³⁰</i>	2014	Surgical infections	15	4800	Triclosan-coated sutures significantly reduced SSI rate compared with standard sutures. RR 0.67 (95% CI 0.54 to 0.84). No subgroup analysis was performed.	Not included	Not included
Apisarnthanarak <i>et al⁵⁸</i>	2015	Infection Control and Hospital Epidemiology	29 (22 RCT and 7 non- RCT)	11942	Triclosan-coated sutures significantly reduced SSI rate compared with standard suture. RR 0.65 (95% CI 0.549 to 0.769). RR for RCT alone 0.74 (95% CI 0.61 to 0.89). Triclosan-coated sutures significantly reduced SSI rate for all CDC wound classifications.	Not included	Not included
Guo et al ³¹	2015	Journal of Surgical Research	13	5256	Triclosan-coated sutures significantly reduced risk of SSI compared with standard suture. RR 0.76 (95% CI 0.65 to 0.88). Triclosan-coated sutures significantly reduced risk of SSI in abdominal surgery. RR 0.70 (95% CI 0.63 to 0.99). There was no significant difference in cardiac and breast surgery.	Included	Not included
Sandini <i>et al⁶³</i>	2016	Medicine	6 (only included elective colorectal surgery)	2168	Triclosan-coated sutures did not significantly reduce the risk of SSI compared with standard sutures in elective colorectal surgery. OR 0.81 (95% CI 0.58 to 1.13)	Included	Not included
Wu et al ⁵⁹	2017	European Journal of Microbiology and Infectious Disorders	18 (13 RCTs and 5 non RCTs)	7458	Triclosan-coated sutures significantly reduced risk of SSI compared with standard suture in both the RCTs (OR 0.72; 95% CI 0.59 to 0.88) and the non- RCTs (OR 0.58; 95% CI 0.40 to 0.83). Triclosan-coated sutures significantly reduced the risk of SSIs in clean surgery.	Included	Included
de Jonge <i>et al³²</i>	2017	British Journal of Surgery	21	6462	Triclosan-coated sutures significantly reduced risk of SSI compared with standard suture. RR 0.72 (95% CI 0.60 to 0.86).	Included	Not included
Leaper et al ⁶²	2017	British Journal of Surgery	34 (20 RCTs and 14 non- RCTs)	16762	Triclosan-coated sutures significantly reduced risk of SSI compared with standard sutures. OR 0.61 (95% CI 0.52 to 0.73). No significant difference in SSI rate for 'contaminated' or 'dirty' wounds	Not included	Not included
							Continued

Continued

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Table 2 Conti	nued						
Author	Date	Journal	No of studies	No of participants	Findings	Risk of bias	Grade
Konstantelias <i>et al⁶¹</i>	2017	Acta Chirurgica Belgica 2017	30 (19 RCTs and 11 non- RCTs)	15385	Triclosan-coated sutures significantly reduced risk of SSI compared with standard suture. RR 0.68 (95% CI 0.57 to 0.81). Triclosan-coated sutures significantly reduced risk of SSI in clean, clean- contaminated and 'contaminated surgery'.	Not included	Not included
Henriksen <i>et al⁶⁰</i>	2017	Hernia	8 (only included studies reporting abdominal wall closure)	3641	Triclosan-coated sutures significantly reduced risk of SSI compared with standard suture in abdominal wall closure. OR 0.67 (95% CI 0.46 to 0.98).	Not included	Not included
CDC, centre for	disease c	ontrol; RCTs, rando	omised controlle	ed trials; RR, re	lative risk; SSIs, surgical site infections.		
Quality of eviden		toria the evider	1		1 reviews assessed risk of bias and		

Quality of evide

Using the GRADE criteria, the evidence was graded as 'moderate' quality. The reason for downgrading was due to study limitations. Studies had high risk of selection bias due to unclear randomisation and allocation methods. In addition, studies had a high risk of performance and detection bias due to issues with blinding of participants and outcome assessors. The body of evidence was not downgraded for inconsistency as there was narrow point estimates and low study heterogeneity ($I^2=17\%$). There were no issues with indirectness or imprecision as the outcome measures used are directly aligned to the outcome measures of interest in this review. There were also a large number of participants included in this review with satisfactory event rate numbers. Our symmetrical funnel plot indicated no risk of publication bias. Given the quality of the evidence we are moderately confident in the effect estimate, the true effect is likely to be close to the estimate of the effect.

The strengths of this current review include the thorough and systematic nature of data collection. This review represents the most up to date review of the literature and is the largest review of RCTs to date, including 11957 patients from 25 RCTs. A recent RCT in elective hip and knee surgery included 2546 participants, the largest RCT to date in this subject.³⁴ This review is the only review to include this important and well-conducted study. In addition, this systematic review only included peer-reviewed studies with published full texts. Previous meta-analyses have included conference abstracts which do not go through the same rigorous peer-review process as full journal publications and thus represent a potential danger to review quality.³² Furthermore, robust quality and risk of bias assessment is not possible with these abstract publications.⁶⁴ A further strength of this review is the detailed and systematic quality assessments, along with robust Cochrane risk of bias assessments, of all included studies.^{36 64} As demonstrated in table 2 5 out

vs assessed the quality of evidence. A strength of this review is the inclusion of a thorough risk of bias and GRADE assessment. In addition, this new review included further detailed sub group analysis based on superficial versus deep surgical infections and based on type of surgery, for example, clean, clean-contaminated, contaminated and dirty surgery.

The main weakness of this review is the study population. The review includes procedures which were classed as clean, clean-contaminated, contaminated and dirty. These types of surgery would all have differing rates of SSI. The authors therefore performed a subanalyses of the different categories of surgery. Routine antibiotic prophylaxis was used in 15 studies^{2 7 11 34 38 39 42 44-51} with a variation in the antibiotic agent used and the timing. This is a potential confounder for the frequency of SSI.⁶⁵ A proportion of the included studies assessed patients with an underlying malignancy who may have been immunosuppressed. This influences the rate of SSI and is not accounted for in many of the included studies.⁶⁶ Another weakness is the heterogeneity in the use of triclosancoated sutures. In some studies, triclosan was used for closure of all surgical layers, whereas in other studies triclosan-coated sutures were only used on the superficial layers. This study heterogeneity should be noted when interpreting the meta-analysis result. This review reports trials using CDC criteria for superficial site infections. It is important to note that a stitch abscess does not meet the criteria for a superficial site infections. Patients may present with a stitch abscess to healthcare professionals and undergo treatment. This study does not report the impact of triclosan-coated sutures on stitch abscesses.

Our review is the largest review of RCTs to date in terms of patient numbers and demonstrates clinical effectiveness of triclosan-coated sutures when compared with standard sutures when assessing SSI rate. SSIs have been shown to have a significant impact on patient quality of life, as well as an increased burden on healthcare providers in terms of resource allocation. The cost of triclosan sutures is variable; however, the cost of SSI to patients and healthcare providers is sizeable.¹⁰⁻¹² A robust cost-analysis has not been performed, nevertheless, organisations should consider carefully whether they routinely use triclosan-coated sutures in light of these positive meta-analysis findings. This review also identified that triclosan-coated sutures significantly reduced the risk of SSIs in clean and contaminated surgery, therefore thoughtful consideration should be paid to whether they are routinely used in this patient population. The results demonstrate that triclosan-coated sutures may not be as effective in reducing SSI rate in 'clean-contaminated' and 'dirty' surgery. However, a potential explanation for dirty surgery is the low patient numbers included in this subgroup. This is a potential area of future research given the effectiveness of triclosan-coated sutures in 'clean' and 'contaminated' surgery.

CONCLUSION

This systematic review identified 25 RCTs examining the effect of triclosan in reducing incidence of SSI, compared with non-coated sutures. The subsequent meta-analysis included 11957 patient and revealed an overall a risk ratio of RR 0.73 (95% CI 0.65 to 0.82) of developing SSI in favour of triclosan-coated sutures, thereby demonstrating a statistically significant lower risk of SSI following closure of a surgical wound with triclosancoated sutures. Further analysis has demonstrated that triclosan-coated sutures significantly reduced the risk of SSIs in clean and contaminated surgery. This study is in agreement with previous smaller and less robust reviews which have produced comparable results. This is the largest review of RCTs in terms of number of included studies and number of participants from RCTs to demonstrate the clinical effectiveness of triclosan-coated sutures. Further detailed cost-effectiveness is required to assess the economic benefit of implementing the use of these sutures. The evidence considered in this review suggests that triclosan-coated sutures are effective in reducing SSIs, the use should in particular be considered in clean and contaminated surgery.

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Contributors All authors contributed to the production of this manuscript and meet the ICMJE criteria. IA: conception of review, data collection, analysis and drafted final manuscript. AJB: data collection, analysis and drafted final manuscript. SR and WC: data analysis and revised final manuscript. ED: data collection and revision of final manuscript. NAS: revision of final manuscript. MR: conception of idea and revision of final manuscript.

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