Systematic review

Meta-analysis of the potential economic impact following introduction of absorbable antimicrobial sutures

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Background: **Despite several randomized trials, systematic reviews and meta-analyses that have demonstrated the effectiveness of antimicrobial (triclosan-coated or -impregnated) sutures (TCS), the clinical and economic impact of using these sutures compared with conventional non-antimicrobial-coated absorbable sutures (NCS) remains poorly documented.**

Methods: **An independent systematic review and meta-analysis of all published evidence from January 2005 to September 2016 comparing TCS with NCS was conducted. Surgical-site infection (SSI) was the primary outcome. The results of the meta-analysis were used in a decision-tree deterministic and stochastic cost model, using the National Health Service (NHS England)-based cost of inpatient admissions for infections and differential costs of TCS *versus* NCS.**

Results: **Thirty-four studies were included in the final assessment from an initial 163 identified citations; 20 of 34 studies were randomized, and 17 of 34 reported blinding of physicians and assessors. Using a random-effects model, the odds ratio for SSI in the TCS compared with NCS control groups was statistically significant (odds ratio 0·61, 95 per cent c.i. 0·52 to 0·73; $P < 0{\cdot}001$). There was significant heterogeneity ($I^2 = 49$ per cent). Using random-effects event estimates of SSI for TCS and NCS for each individual wound type, the mean savings per surgical procedure from using antimicrobial sutures were significant: £91·25 (90 per cent c.i. 49·62 to 142·76) (€105·09 (57·15 to 164·41); exchange rate 15 November 2016) across all wound types.**

Conclusion: **The reviewed literature suggested that antimicrobial sutures may result in significant savings across various surgical wound types.**

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Introduction

Antimicrobial suture technology involves the coating or impregnation of synthetic, absorbable, polymeric sutures with the antiseptic, triclosan. Triclosan is a broad-spectrum antiseptic with excellent activity against Gram-positive and Gram-negative bacteria, which are typical surgical pathogens[1,2]. Several experimental studies[3–5] have shown that these bacteria are inhibited from adhering to triclosan-coated or -impregnated sutures together with an antimicrobial effect. The safe amount of triclosan required for an optimal antimicrobial effect is a maximum of 2360 μg/m in impregnated polydioxanone and coated poliglecaprone sutures, and 472 μg/m in coated polyglactin sutures[6,7]. These amounts are miniscule compared with the concentrations of triclosan encountered from other commercial or environmental sources; over the past 13 years no Manufacturer and User Facility Device Experience (MAUDE) database report on the US Food and Drug Administration website has indicated any adverse event associated with the use of triclosan antimicrobial sutures[8].

Studies have shown that surgeons cannot differentiate practically the presence or absence of triclosan in sutures, which makes it possible to design double-blind RCTs[9,10]. Several RCTs have reported a reduced incidence of surgical-site infection (SSI) following use of triclosan-coated sutures (TCS) compared with non-antimicrobial-coated sutures (NCS). Subsequent independent systematic reviews and meta-analyses[11–13], involving several thousand patients, have shown level 1A clinical evidence that the use of TCS significantly reduces the incidence of SSI, by approximately 30 per cent. One of these meta-analyses[13] ruled out several factors of bias and found that TCS significantly reduced SSI, with an overall risk ratio (RR) of 0·67 (95 per cent c.i. 0·53 to 0·84; $P<0{\cdot}001$). Results were also robust to sensitivity analysis and the RR was significant in all clean, clean-contaminated and contaminated surgery subgroups.

The burden of SSI after general surgery, particularly colorectal surgery, has not changed despite the introduction of guidelines and care bundles[14–16]. A study[17] conducted in English National Health Service (NHS) hospitals reported an overall SSI incidence rate of 10 per cent, with a mean attributable excess length of stay (LOS) of more than 9 bed-days per SSI and a directly-related excess cost of over £3000 (€3450; exchange rate 15 November 2016) per SSI. Another study[18], conducted in a single NHS Trust in England, reported an overall SSI incidence of 12·8 per cent with a median excess LOS of 11 bed-days per SSI, and an excess cost of more than £5000 (€5760; exchange rate 15 November 2016) per SSI. Systematic reviews and meta-analysis cannot directly calculate the pooled SSI-attributable excess costs to healthcare. An economic study[19], using a decision analytical model, suggested that converting to TCS could save substantial hospital costs provided the SSI rate was reduced by at least 10 per cent and when the risk of SSI is over 10 per cent. A further model has been constructed in the present study to estimate the potential health service and budget impacts following wound closure with TCS or NCS for NHS (England) as a healthcare provider.

Methods

A systematic review of all evidence available from January 2005 to September 2016, employing the search strategy shown in *Table S1* (supporting information), was conducted using MEDLINE and Embase, and following PRISMA guidelines[20]. All identified publications were reviewed manually for inclusion in the final list of studies.

Study criteria

To be included in the systematic review and meta-analysis, publications had to meet the Patient, Intervention, Comparator, Outcome and Study (PICOS) criteria (*Table 1*). Briefly, all peer-reviewed studies comparing TCS with NCS (control), involving more than 30 patients per arm, with SSI as a primary outcome, were included. Conference abstracts were included when the abstract had been published in 2015 or 2016. Older conference abstracts were eliminated as it was assumed that data from these studies would have been submitted for peer review.

Table 1 PICOS framework for study inclusion

Criterion	Definition
Patients	Any patient undergoing surgery that requires sutures. There was no exclusion criterion for patient type or co-morbidity. Studies included both paediatric and adult patients
Intervention	Antibiotic-coated sutures
Comparator	Non-antibiotic-coated sutures – all types of non-antibiotic-coated comparator were included
Outcome	SSI at any postoperative time point. When more than one time point was provided, the latest time point was selected so that one SSI rate per cohort was included in the final analysis. When sutures were used at multiple sites, thereby creating a potential for infections at multiple sites, each site of potential infection was counted as a unit. Counts of SSIs thus refer to the sum of individual infection sites and not the sum of patients with infections
Study type	Comparative studies of any type were included as long as more than 30 patients were included per arm. Studies described only in conference abstracts were included only when less than 2 years old. Care was taken to eliminate duplicate data points

SSI, surgical-site infection.

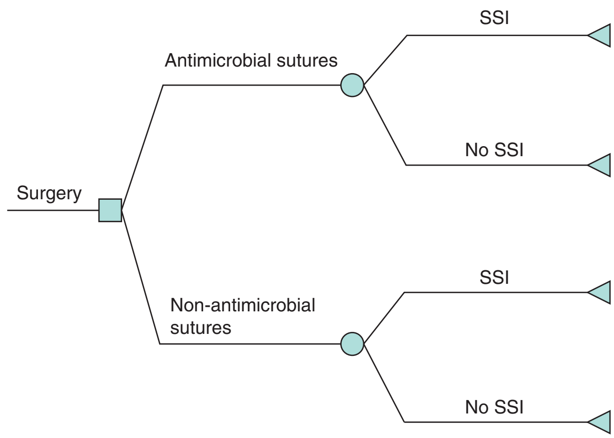


Fig. 1 Basic structure of decision-tree cost model. The model was run for each surgical wound type. SSI, surgical-site infection

Data extraction

All titles and abstracts were reviewed and identified for inclusion by two independent reviewers. When required, adjudication was agreed by the senior authors. Data extraction was conducted by one reviewer and re-examined by the second. For all publications, the surgery wound type was recorded as stated by the authors or defined, based on the criteria established by the US Centers for Disease Control and Prevention, as clean, clean-contaminated, or combined contaminated/dirty wound types. Studies that included multiple wound types, with no further detail on

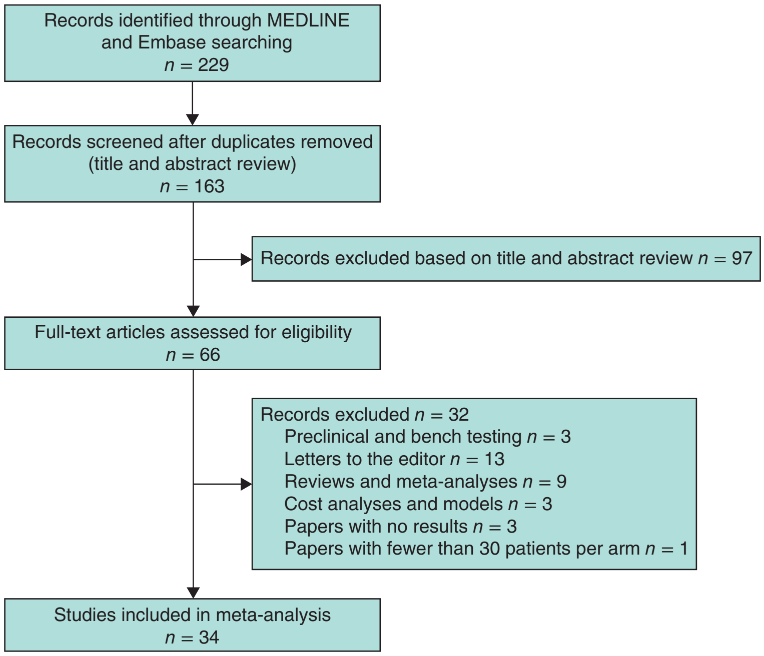


Fig. 2 PRISMA flow chart for the review

SSI outcome per wound type or surgery type, were categorized as undefined. SSI rates were recorded for all groups and studies. When SSIs were provided at multiple time points, the latest available time point was recorded. Only one infection rate per cohort was thereby included in the analysis and no cohort was represented more than once. All data points were independent of one another. When multiple infection sites were reported, the total sum of infection sites (regardless of whether infections were in the same patient or distinct patients) were included in the analysis, with the unit of analysis being infections, not unique patients with infections. When distinct SSI rates were provided for each surgical wound type, these were entered in the model individually.

Statistical analysis

Odds ratios (ORs) for SSI were the primary outcomes of interest. The inverse variance method was used to estimate both fixed-effect and random-effects estimates, with the DerSimonian–Laird method used for the random-effects models[21,22]. Heterogeneity was assessed using the χ^2 test, and the index of heterogeneity (I^2) was calculated using methods described previously[23].

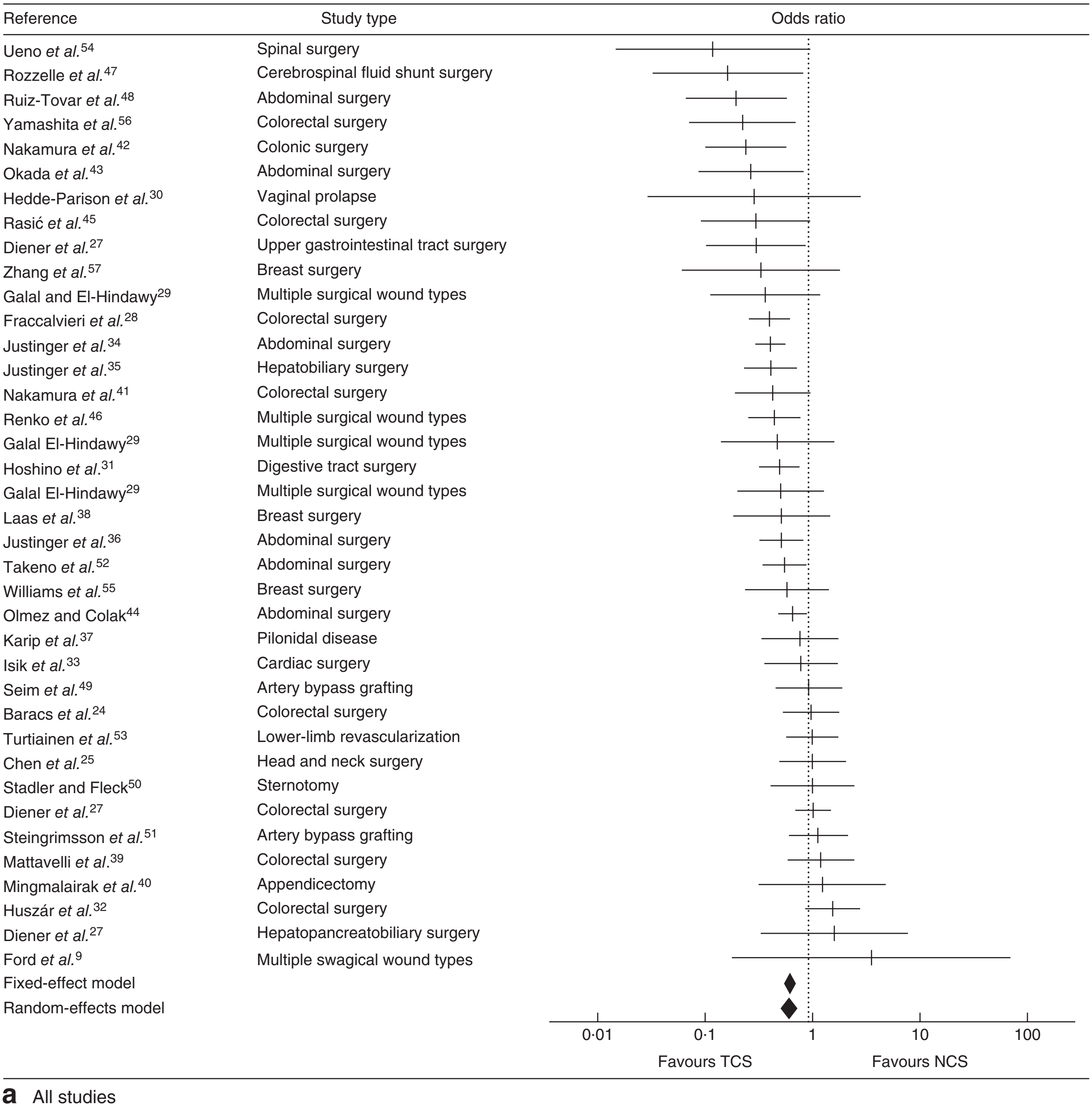
To refine further the estimated ORs for SSI, a subanalysis was conducted, analysing each study based on surgical wound type. For this analysis, studies were grouped as: multiple wound type (group 0); clean wound type (group 1); clean-contaminated wound type (group 2); or contaminated or dirty wound type (group 3). A meta-regression was also conducted to evaluate whether each wound type was a predictor of SSI. Model estimates and 95 per cent confidence intervals are shown. Statistical significance was set at $\alpha = 0{\cdot}05$.

Model design

A decision tree was designed, as shown in *Fig. 1*. Both deterministic and stochastic models were constructed. The probabilistic model was built in this study to address the sensitivity of values taken by key parameters on cost findings. Key variables for each of the tree branches of the model included: differential cost of TCS compared with traditional sutures; probability of developing an SSI when treated with TCS or NCS; and inpatient cost of SSI.

The probability of SSI was evaluated using the data captured for the meta-analysis, but evaluating rates of SSI individually for TCS and NCS, and for each wound type. These rates were used in the cost model.

The differential cost of sutures was estimated by comparing the April 2015 list price of traditional sutures with that of similar TCS (prices were provided by Ethicon, Somerville, New Jersey, USA). The distribution of cost differential was analysed, and the shape of the distribution and mean were evaluated. Inpatient costs of SSI were based on analyses of Hospital Episode Statistics (HES) cost data

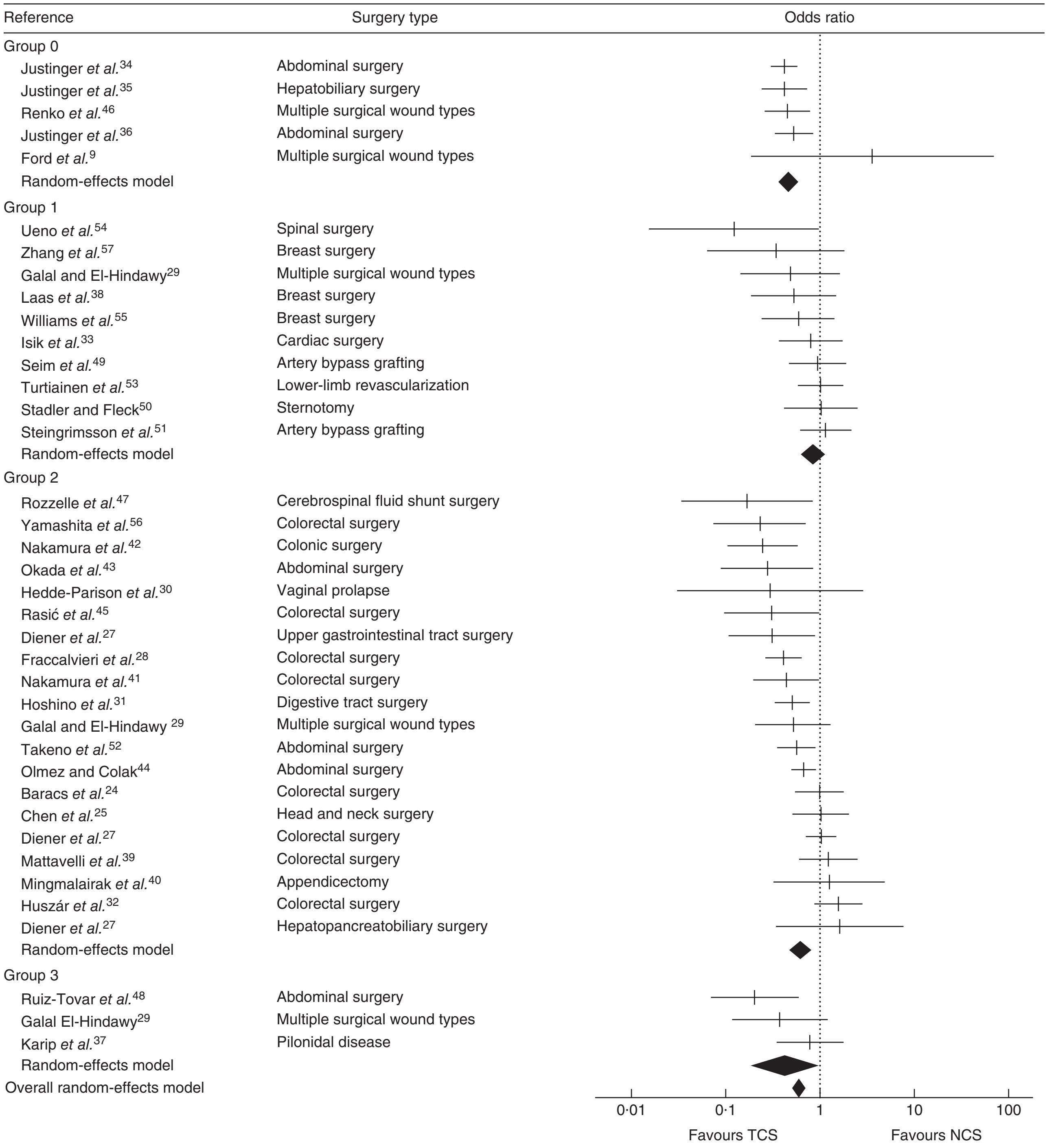


a All studies

Fig. 3 Forest plots comparing surgical-site infections in wounds closed with triclosan-coated sutures (TCS) *versus* non-antimicrobial-coated sutures (NCS) for **a** all studies and **b** all studies according to wound type: group 0, mixed surgical wound types; group 1, clean surgical wound type; group 2, clean-contaminated surgical wound type; group 3, contaminated and dirty wound types. A fixed-effects model was used; odds ratios are shown with 95 per cent confidence intervals

from February 2015 to February 2016 for inpatient visits with a primary ICD-10 diagnosis of T814 (infection following a procedure, not elsewhere classified). A total of 25 678 episodes were identified; the distribution and mean cost per episode were analysed and used in the model.

In addition, the total frequency and relative proportion of clean, clean-contaminated and dirty wound operations in England from 2014 to 2015 was also estimated using HES data (accessed online). These data were used to establish the mean saving per operation. The mean and distribution



b According to wound type

Fig. 3 Continued

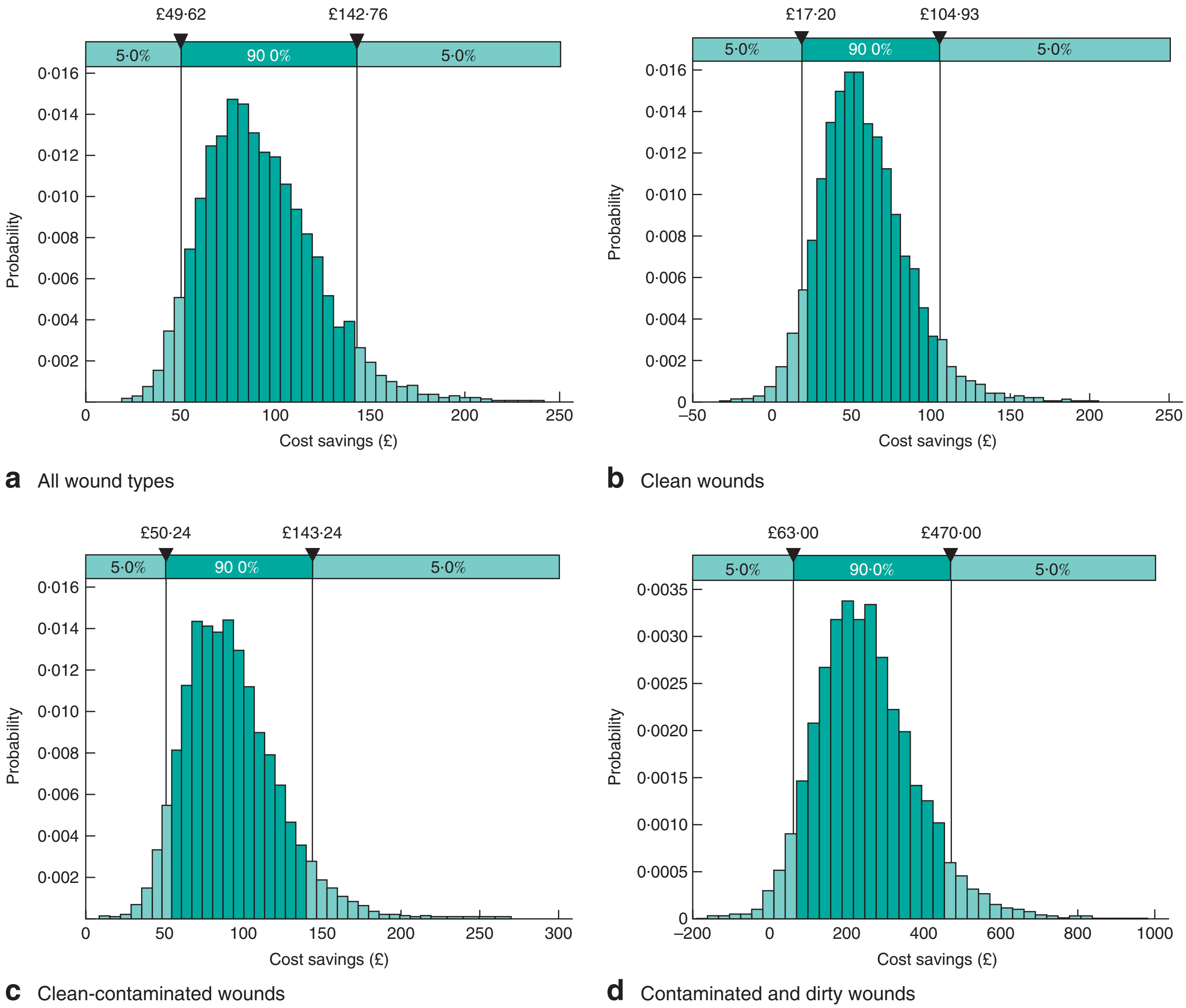


Fig. 4 Mean and distribution of savings per surgical procedure: **a** all wound types, **b** clean wounds, **c** clean-contaminated wounds, **d** contaminated/dirty wounds. The *y*-axis indicates the probability of cost savings being at values shown on the *x*-axis. For all simulations, 90 per cent of all cost savings calculations fell within the boundaries indicated by the black arrowheads

of savings by wound type and overall, assuming a case mix as observed in the UK in 2015 and publicly available HES reporting online. The impact of all variables on total savings was analysed and shown as a tornado chart.

Results

Study identification

The search strategy yielded a total of 163 citations. Manual review of all citations was performed and manuscripts were eliminated if they did not provide original SSI rates in patients treated with TCS *versus* control NCS (*Fig. 2*). After final review, data from 34 distinct studies were included in the final assessment, yielding a total of 38 data points (2 studies had multiple SSIs per surgical wound type)[9,24–57]. Surgical wound types in the included study list are shown in *Table S2* (supporting information).

Included studies

Fourteen of the 34 studies were not randomized, and blinding was not reported in 17. The mean(s.d.) number of patients was 493(436) (median 371) per study. The mean number of TCS-treated patients was 252, compared with

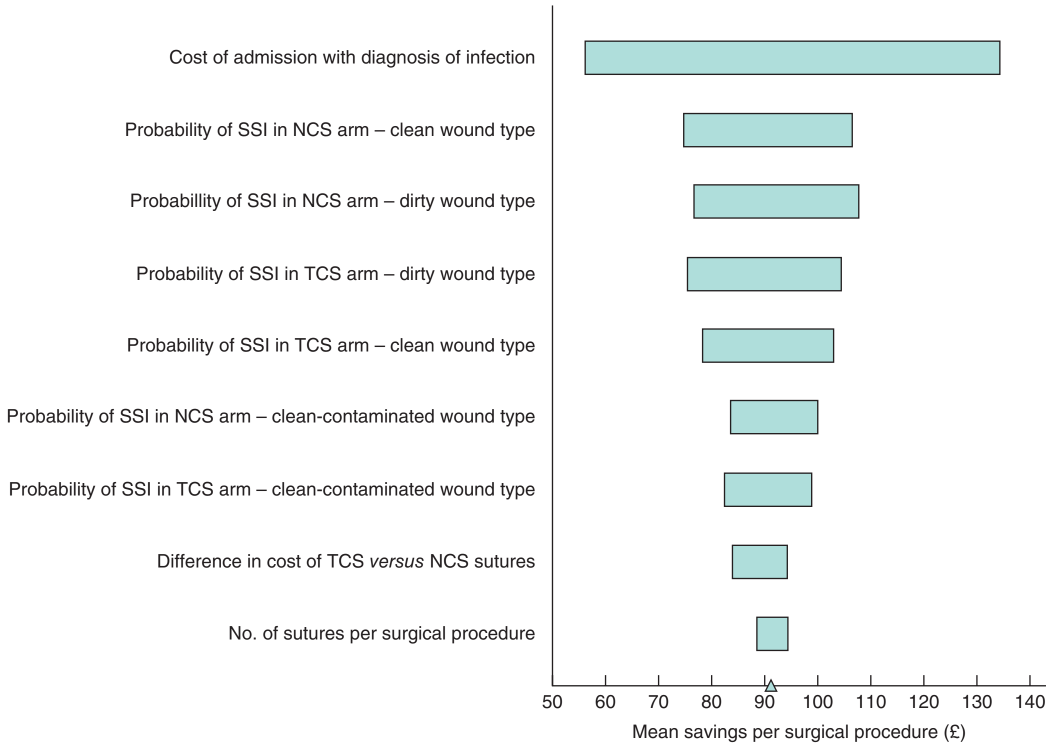


Fig. 5 Tornado chart showing mean cost savings per surgical procedure based on model assumptions. Bar widths represent 95 per cent confidence intervals. Mean savings per procedure across all wound types was £91·25. SSI, surgical-site infection; NCS, non-antimicrobial-coated sutures; TCS, triclosan-coated sutures

241 NCS controls (median 175 and 187 respectively). All studies compared triclosan-coated sutures (polyglactin or poliglecaprone) or triclosan-impregnated sutures (polydioxanone) with non-coated sutures. Coated polyglactin 910 (Vicryl®; Ethicon), poliglecaprone (Monocryl®; Ethicon) and polydioxanone (PDS®; Ethicon) sutures were control sutures in most studies. One study used Chinese silk as control, another used glyconate (Monosyn®; B. Braun, Melsungen, Germany), and five studies did not identify a specific suture but referred to the control simply as a conventional suture. In the majority of studies, SSI was defined as by the US Centers for Disease Control and Prevention, and within a 30-day time frame following surgery[58].

Primary outcome analysis

Forest plots for all studies and for each group of studies are shown in *Fig. 3*. Across all studies, the random-effects OR for SSI in the TCS group compared with the NCS control was 0·61 (95 per cent c.i. 0·52 to 0·73; $P < 0·001$). However, the studies showed a significant degree of heterogeneity ($I^2 = 49$ per cent). Although there was a clear trend showing an increased OR for SSI in more contaminated/dirty wounds, the meta-regression did not identify wound type as a significant predictor of SSI, probably related to the small sample of studies in the contaminated/dirty category. Specifically, using a restricted maximum likelihood model and the clean cohort as reference, the log of OR for clean-contaminated and contaminated/dirty was −0·219 (95 per cent c.i. −0·690 to 0·253; $P = 0·351$) and −0·585 (−1·446 to 0·277; $P = 0·176$).

Cost analysis

Assuming a relative frequency of clean, clean-contaminated and dirty wound categories as described in the HES public data for 2015, mean savings per operation ranged from £56·59 (90 per cent c.i. 17·20 to 104·93) (€65·23 (19·83 to 120·87); exchange rate 15 November 2016) for clean wound procedures to £248·23 (62·71 to 470·45) (€285·93 (72·24 to 541·91); exchange rate 15 November 2016) for contaminated/dirty wound operations, with overall savings per operation estimated at £91·25 (49·62 to 142·76) (€105·09 (57·15 to 164·41); exchange rate 15 November 2016).

Overall per-procedure savings followed a γ distribution (*Fig. 4*). Sensitivity analyses for all included assumptions are shown in the tornado chart (*Fig. 5*). Inpatient cost variability for SSI had the greatest impact on total savings.

Discussion

This systematic review included RCTs as well as large, well designed, cohort and retrospective database analyses that provided a real-world estimate of SSI in non-study settings[52]. The findings thus reflect a comprehensive overview of both RCTs and well designed epidemiological studies. In addition, the most recent NHS cost data were used to evaluate the impact of TCS on total cost of care.

The evidence of efficacy from several independent systematic reviews and meta-analyses, and the healthcare resources savings predicted by the decision-tree deterministic and stochastic cost model used in this study, suggest that antimicrobial sutures could be included in SSI surgical care bundles, which have been shown to reduce the risk of SSI[16,59]. The articles reviewed for this economic analysis model were more inclusive than those in earlier meta-analyses[11–13] and with a less prescriptive standard. Although the evidence from one of these meta-analyses showed a clear benefit of reduction of SSIs after all classes of surgery (clean to contaminated), with little evidence of publication bias, and robustness to sensitivity analysis[13], no doubt more RCTs will continue to be published. RCTs, systematic reviews and meta-analyses generally do not address healthcare costs; the present study therefore focused on the economic benefits of this innovative suture technology to improve patient outcomes. The UK National Institute for Health and Care Excellence (NICE)[60] and the US Healthcare Infection Control Practices Advisory Committee (HICPAC)[58] do not yet recommend the use of TCS for the prevention of SSI. The evidence that triclosan could be hazardous has been refuted[6,7], and this should not present a barrier to its use, particularly as the extra cost is more than compensated for by the economic benefit.

The difficulty of accurately and consistently defining the primary outcome of SSI with adequate, ideally independent and blinded, postoperative (and postdischarge) surveillance has to be addressed[15,61,62]. Equally, the stubborn resistance of SSI rates to fall, and SSI becoming the commonest healthcare-associated infection, must relate to the adequacy of compliance with agreed care bundles. Some of these difficulties are exemplified by the PROUD study[27]. This randomized multicentre study, which took several months to complete, was likely to have been underpowered to show a statistically significant reduction in deep SSI, and antimicrobial sutures (specifically triclosan-impregnated polydioxanone) were used solely in the musculofascial layers of abdominal closure. The authors documented a reduction in SSI in the TCS groups, but the reduction did not reach statistical significance. Triclosan-coated poliglecaprone or polyglactin sutures were not used to close skin or subcutaneous layers; clips were used for skin closure. Clips are prone to later exogenous SSI, so how could superficial incisional SSI be expected to be prevented from sutures placed in much deeper layers? Wound contamination following colorectal surgery often involves both deep and superficial incisional sites. Therefore, to maximize benefit from antimicrobial sutures, they should be used for both superficial and deep musculofascial layers. The number of surgeons involved in closing the abdominal wall may well have influenced the outcome, as fascial and subcuticular closure is often delegated to more junior members of the surgical staff. However, this study and a previous meta-analysis[13] have confirmed that the overall relative risk of SSI across all groups is still favourable for coated sutures *versus* non-coated sutures.

The decision-tree deterministic and stochastic economic cost model used in this study found that the use of antimicrobial sutures results in a significant cost saving for all surgical wound types. Several earlier publications[29,63,64] have alluded to the benefits to healthcare of using antimicrobial sutures, but none used a more accurate, economic cost model such as that in the present study. Triclosan antimicrobial sutures should be considered for superficial and deep layer closure after all surgical operations.

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C.E.H. is an employee of Johnson & Johnson.

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Supporting information

Additional supporting information may be found in the online version of this article:

Table S1 Database searches (Word document)

Table S2 Categorization of surgical sites (Word document)