

# Effectiveness of antimicrobial-coated sutures for the prevention of surgical site infection: a review of the literature

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**Abstract.** – **OBJECTIVE:** Surgical site infections (SSIs) are the third most common hospital-acquired infections and account for 14% to 16% of all such infections, and suture material may play a role in SSI rate. Given this risk of infection, sutures with antimicrobial activity have been developed. Both *in vitro* and *in vivo* experiments have shown that triclosan-coated sutures (TCS) are effective in the prevention of SSIs. Our aim is to analyze currently available RCTs, comparing the effect of antimicrobial-coated suture (ACS) with uncoated suture on the occurrence of SSIs following surgical procedures, we highlighted major contributions of most significant studies and evaluate the current "state of the art" on antimicrobial-coated sutures.

**MATERIALS AND METHODS:** We reviewed 15 RCTs comparing antimicrobial-coated sutures with conventional sutures and assessing the clinical effectiveness of antimicrobial sutures to decrease the risk for SSIs. We focused our attention on each variable in all the analyzed study.

**RESULTS:** Our selected RCTs, produced controversial results: 7 RCTs demonstrated a significant benefit, on the contrary, 8 RCTs presented a comparison in which there was no difference.

**CONCLUSIONS:** On the basis of our selected trial results and the heterogeneous findings of our 7 selected meta-analyses, we conclude that even though the question of whether TCSs could reduce the occurrence of SSI remains still open, the antimicrobial suture was effective in decreasing the risk for postoperative SSIs in a broad population of patients undergoing surgery. Alternative substances are becoming clinically relevant, such as Chlorhexidine (CHX) coated sutures and only 6 *in vivo* scientific studies evaluated them. *In vivo* studies, large and comparative clinical research trials are necessary to validate the efficacy of CHX-coated sutures thus allowing their use in clinical practice.

## Key Words

LncRNA, PTENP1, Polymorphism, OSCC.

## Introduction

Wound infections after surgery are still frequent types of nosocomial infections, and poor healing continues to be among the most complications after surgery too. Despite established systemic antibiotic prophylaxis, surgical site infections (SSIs) are the third most common hospital-acquired infections in the United States, accounting for 14%–16% of infections among hospitalized patients and 38% of infections in surgical patients<sup>1,2</sup>.

In European countries, the estimated SSI incidence range varies from 1,5% to 20%, due to differences among studies regarding how surgical procedures are conducted and how SSI data are collected<sup>3</sup>. However, the true rate of SSI is believed to be underestimated, indicating that SSIs represent a significant problem in Europe as well.

The most widely recognized definition of infection, which is used throughout the United States and Europe, is that devised and adopted by the Centres for Disease Control (CDC) and Prevention<sup>4,5</sup>. SSI is defined as an infection within 30 days of surgery (or within a year in case of prosthetic surgery).

Suture material is an operator-dependent variable, and while little objective data exist to guide the choice of suture, it may play an important role in the development of SSIs by providing a local surface for the adherence of microorganisms<sup>6-8</sup>.

Because of this risk of infection, the strategy of coating sutures with antimicrobial activity has been considered, with the attempt to avoid bacterial colonization of medical materials from the beginning<sup>9</sup>. In 2002, the US Food and Drug Administration approved the first antimicrobial surgical suture (braided polyglactin 910, Vicryl Plus) coated with triclosan (polychlorophenoxyphenol),

a biocide that exhibits broad-spectrum activity against both Gram-positive and Gram-negative bacteria. Several scientific studies well-described the rationale for assuming that the use of suture impregnated with triclosan may reduce the occurrence of SSI, showing a series of robust data obtained by *in vitro* and *in vivo* experiments<sup>10-20</sup>.

On the contrary, some clinical trials have suggested that coating sutures with triclosan do not reduce the risk of SSI<sup>21-28</sup>.

Our aim was to analyze currently available Randomized Clinical Trials (RCTs), comparing the effect of the antimicrobial-coated suture with the uncoated suture on the incidence of SSIs following surgical procedures in order to provide a comprehensive assessment of the available evidence. We highlighted major contributions of most significant studies and evaluate the current “state of the art” on suture materials.

## Materials and Methods

We performed a revision of the peer-reviewed international literature on PubMed, Embase/Medline, Scopus, Ovid, ISI Web of Science, Cochrane database group (Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Health Economic Evaluations Database/Database of Health Technology Assessments) and www.clinicaltrials.gov to identify Clinical Trial of antimicrobial-coated sutures compared with conventional sutures, and to assess the clinical effectiveness of antimicrobial sutures to decrease the risk for SSIs, the last search updated on April 2017.

The search strategy was personalized around specific key-words and combinations of these: “uncoated suture”, “coated suture”, “antimicrobial”, “antiseptic”, “suture”, “triclosan”, “infection”, “surgical site infection” and “surgical wound infection”. In case of overlap of authors, affiliations, or patients, we chose the most recent article.

### Inclusion Criteria

We included only RCTs with pediatric and adult patients comparing the clinical efficacy of triclosan-coated sutures with traditional uncoated sutures in reducing SSI prevalence, for surgical procedures.

### Exclusion Criteria

We did not include *in vitro* experiments, animal studies, non-randomized controlled trials, pi-

lot studies, studies not statistically analyzing the obtained results, abstracts, unpublished studies, letters to Editor, editorials, opinion pieces and finally Conference proceedings.

### Data Extraction

Data taken into account were as follows: first author/year/country, clinical sample size, study design blinding and follow-up length, whether SSI was defined according to CDC criteria, clinical indication and surgical procedures, suture material, outcome/infection (prevalence of SSI), number of patients and events (SSIs).

### Study Quality

The Cochrane Collaborative Evidence-Based handbook formed the basis for or analysis, identifying all relevant clinical studies.

## Results

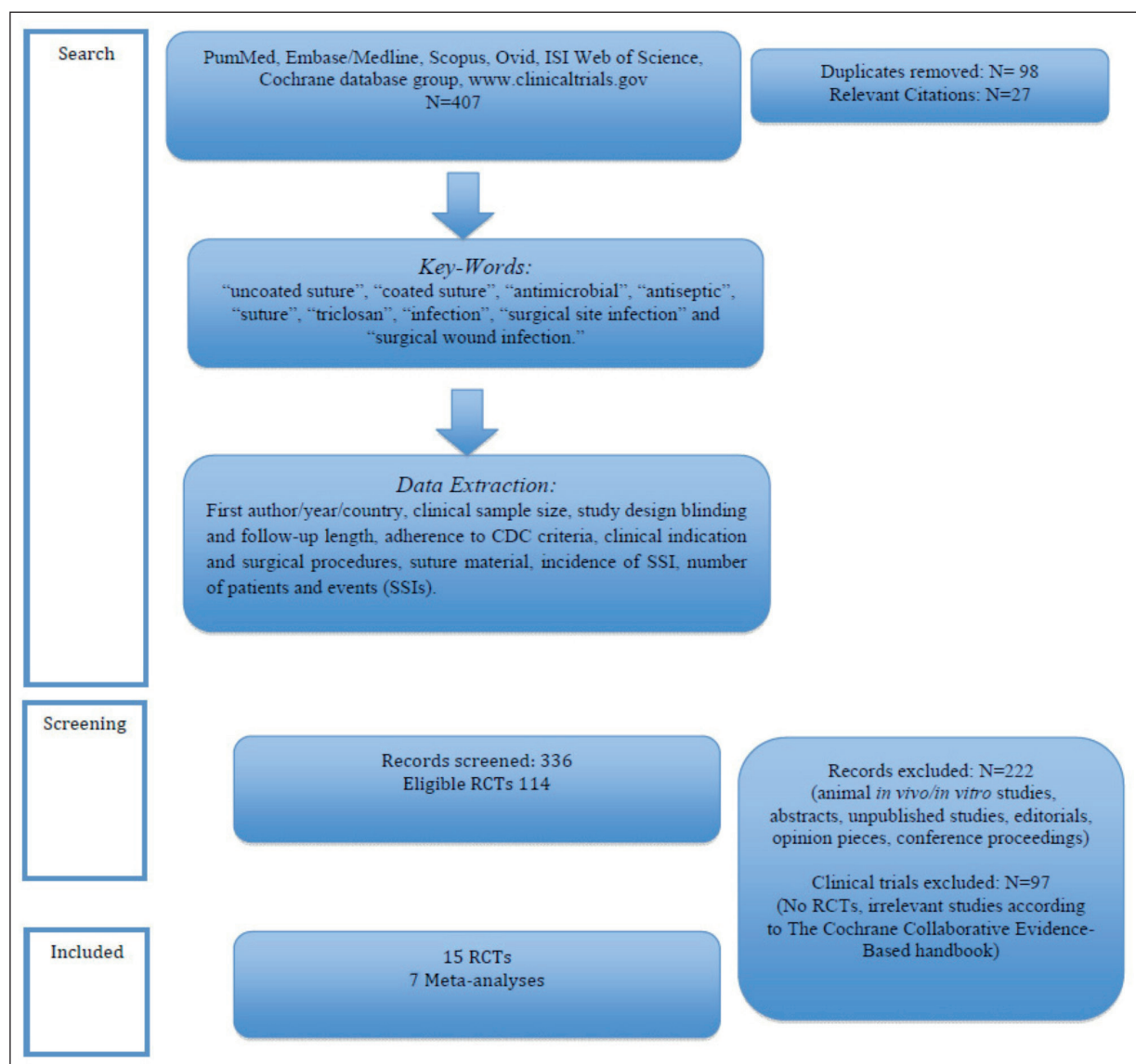
Flow diagram (Figure 1) showed the literature search and article selection. Records identified through database searching were 407. We removed the duplicates (98) and identified 27 potentially relevant citations through the electronic searches. Records screened were 336 RCTs, of them 114 were the RCTs assessed for the eligibility.

We identified 15 peer-reviewed eligible RCTs comparing triclosan-coated sutures (Study Group, SG) with uncoated sutures (Control Group, CG).

The sample size of included RCTs ranged from 84 to 1185 participants.

Of the studies, 10 were single-centre trials<sup>14,15,17-21,23,27,28</sup> whereas 5 were multicentre trials<sup>16,22,24-26</sup>. Follow-up ranged from 4 weeks days to 24 months, with most studies reporting outcomes at 30 days in accordance with CDC criteria<sup>16,18-20,22-26,28</sup>.

Eight RCTs<sup>15,17-19,21,22,24,26</sup> involved abdominal surgeries (1 open appendectomy<sup>21</sup>, 3 laparotomy<sup>15,19,22</sup> for various abdominal operations, 4 colorectal surgery<sup>17,18,24,26</sup>), two RCTs regarded cardiac surgeries<sup>27,28</sup>, two regarded peripheral vascular surgery<sup>20,25</sup>, one RCT concerned breast surgery<sup>23</sup>, and two RCTs<sup>14,16</sup> referred to other surgeries. Detailed characteristics of the included studies are summarized in Table I. Eight trials<sup>14,16-18,21,26-28</sup> compared triclosan-coated Polyglactin (Vicryl Plus) sutures with uncoated Polyglactin (Vicryl) sutures, three trials<sup>19,22,24</sup> compared triclosan-coated Polydioxanone (PDS) sutures with uncoated Polydioxanone (PDS)



**Figure 1.** Flow-chart: literature search and article (randomized clinical trials, RCTs, and meta-analyses).

II) sutures, three trials<sup>20,23,25</sup> compared two types of triclosan-coated (Vicryl plus, Monocryl plus) sutures with the corresponding uncoated sutures. One trial<sup>25</sup> compared two types of triclosan-coated Polyglactin/Polydioxanone (Vicryl plus/PDS plus) sutures with the corresponding uncoated silk sutures. Finally, one trial<sup>15</sup> compared triclosan-coated Polyglactin (Vicryl Plus) sutures with uncoated Polydioxanone (PDS II) and Silk sutures.

Our selected RCTs produced controversial results. 7 RCTs<sup>14-20</sup> demonstrated a significant benefit, on the contrary, 8 RCTs<sup>21-28</sup> presented a comparison in which there is no difference.

## Discussion

The potential reasons for disagreement among study results are the clinical sample size, different study designs, blindness of patients and assessors, length of follow-up, heterogeneity of surgical procedures, methods, definition of SSI, evaluation of risk factors in the analysis, inclusion and exclusion criteria, suture material used, parameters evaluated, and unrecorded data at follow-up.

We analyzed in details each variable, responsible of heterogeneity among the studies.

**Table 1.** Randomized control trials comparing the effect of antimicrobial-coated suture with uncoated suture on occurrence of surgical site infections following surgical procedures.

Authors/year/ country	Sample Size (SG vs. CG)	Design of randomized control trial/ adherence to CDC criteria/Length of follow-up	Surgical procedures	Comparator suture material: ACS vs. NAS	Conclusions ACS (SG, infected patients%) vs. NAS (CG, infected patients%)	Statistical Analysis Conclusion
Rozelle <sup>14</sup> / 2008/ USA	84 (46 SG vs. 38 CG)	Single-centre trial, prospective, double- blinded, and placebo- controlled study CDC not specified 6-months follow-up	Paediatric/adult, cerebrospinal shunt surgery	Triclosan-coated Polyglactin (Vicryl plus) suture vs. uncoated Polyglactin (Vicryl) suture	ACS 2/46 (4.3%) vs. NAS 8/38 (21.1%) Triclosan-coated suture reduced risk of postoperative shunt infection	Reported lowest rate in Triclosan-coated sutures <b>Reduction</b>
Mingmalairak <sup>21</sup> / 2009/ Thailand	100 (50 SG vs. 50 CG)	Single-centre trial, prospective, double blinded CDC not specified 12-months follow-up	Adult, open appendicectomy	Triclosan-coated Polyglactin (Vicryl Plus) suture vs. uncoated Polyglactin (Vicryl) suture	ACS 5/50 % (10%) vs. NAS 4/50 (8%) SSI of appendectomy seemed to be comparable between triclosan- coated suture and uncoated suture.	There was no statistical difference in the SSI of triclosan-coated and uncoated sutures <b>No difference</b>
Zhuang <sup>15</sup> /2009/ China	450 (150 SG vs. 300 CG)	Single-centre trial, prospective, assessor- blinded CDC not specified 12-24 months follow-up	Adult, laparotomy for various abdominal operations	Triclosan-coated Polyglactin (Vicryl Plus) suture vs. Polydioxanone/ Silk suture	ACS (Polyglactin) 0/150 (0%) vs. NAS (Polydioxanone) 3/150 (0.02%) NAS (Silk) 15/150 (0.1%)	Reported lowest rate in triclosan-coated sutures <b>Reduction</b>
Williams <sup>23</sup> /2011/ UK	127 (66 SG vs. 61 CG)	Single-centre trial, prospective, double- blinded CDC 6-weeks follow-up	Adult, breast cancer surgery	Triclosan coated (Vicryl plus, Monocryl plus) sutures vs. (Vicryl, Monocryl) uncoated- sutures	ACS 10/66 (15.2%) vs. NAS 14/61 (22.9%) This trial failed to find a difference	The difference was not statistically significant between the groups. <b>No difference</b>
Rasic <sup>17</sup> /2011/ Croatia	184 (91 SG vs. 93 CG)	Single-centre trial, prospective, not blinded, CDC not specified Follow-up (unspecified, apparently, minimum 14 days)	Adult, colorectal surgery	Triclosan-coated Polyglactin (Vicryl Plus) suture vs. uncoated Polyglactin (Vicryl) suture	ACS 4/91 (4.4%) vs. NAS 12/93 (12.9%) Abdominal closure with an ACS was associated with a decrease in SSI compared to uncoated sutures.	Statistically significant difference between the groups <b>Reduction</b>
Seim <sup>7</sup> /2012/ Norway	323 (SG 160 vs. 163 CG)	Single-centre trial, prospective, not blinded CDC no specified 4 weeks follow-up	Adult, cardiac surgery	Triclosan-coated-Polyglactin suture (Vicryl Plus) vs. uncoated Polyglactin (Vicryl) suture	ACS 16/160 (10%) vs. NAS 17/163 (10.4%) Vicryl Plus did not reduce the occurrence of leg wound infections	There were no significant differences between the two study groups. <b>No difference</b>

Continued

**Table 1.** Randomized control trials comparing the effect of antimicrobial-coated suture with uncoated suture on occurrence of surgical site infections following surgical procedures.

Authors/year/ country	Sample Size (SG vs. CG)	Design of randomized control trial/ adherence to CDC criteria/ Length of follow-up	Surgical procedures	Comparator suture material: ACS vs. NAS	Conclusions ACS (SG, infected patients%) vs. NAS (CG, infected patients%)	Statistical Analysis Conclusion
Isik <sup>28</sup> /2012/ Turkey	510 (170 SG vs. 340 CG)	Single-centre trial, prospective, double- blinded CDC 30 days follow-up	Adult, cardiac surgery	Triclosan coated Polyglactin (Vicryl plus) suture vs. (Vicryl) uncoated Polyglactin suture	ACS 4/170 (2.3%) vs. NAS 12/340 (3.5%) Larger studies may be needed to show the benefit and cost- effectiveness, if any, of triclosan-coated materials over uncoated materials.	No statistically significant difference between the groups <b>No difference</b>
Nakamura <sup>18</sup> /2013/ Japan	410 (206 SG vs. 204 CG)	Single-centre trial, prospec- tive, double-blinded CDC 30 days follow-up	Adult, colorectal surgery	Triclosan-coated Poly- glactin 910 (Vicryl plus) suture vs. (Vicryl) uncoated Polyglactin 910 suture	ACS 9/206 (4.3%) vs. NAS 19/204 (9.3%) Triclosan-coated sutures can reduce the occurrence of wound infections in colorectal surgery.	Statistically significant difference between the groups. <b>Reduction</b>
Justinger <sup>19</sup> /2013/ Germany	856 (SG 485 vs. 371 CG)	Single-centre trial, prospective, double- blinded CDC 2-weeks follow-up	Laparotomy for general and abdominal vascular procedures	Triclosan-coated Polydio- xanone loop (PDS plus) suture vs. uncoated Polydioxanone loop (PDS II) suture	ACS 31/485 (6.4%) vs. NAS 42/371 (11.3%) Triclosan impregnation of Polydioxanone closing suture can decrease wound infections.	Statistically significant difference <b>Reduction</b>
Thimour- Bergstom <sup>20</sup> /2013/ Sweden	371 (184 SG vs. 190 CG)	Single-centre, prospective, double-blinded CDC 60 days follow-up	Leg incision after vein harvesting for CABG	Triclosan coated Polyglactin/ Polydioxanone (Vicryl plus/ Monocryl plus) suture vs. uncoated-coated Polyglactin/ Polydioxanone (Vicryl, Monocryl) suture	ACS 23/184 (12.5%) vs. NAS 38/190 (20%) Leg-wound closure with triclosan-coated sutures in CABG patients reduces SSIs after open vein harvesting.	The difference was statistically significant <b>Reduction</b>
Gatal <sup>16</sup> /2011/ Egypt	450 (230 SG vs. 220 CG)	Multicentre trial, prospective double-blinded CDC 30 days follow-up; 1 year if prosthesis	Adult, general surgery (78%), plastic surgery (19%), other (3%)	Triclosan-coated Polyglactin 910 (Vicryl plus) suture vs. uncoated Polyglactin 910 (Vicryl) suture	ACS 17/230 (7.4%) vs. NAS 33/220 (15%) triclosan-coated sutures lead to reduction of surgical site infection	The difference was statistically significant <b>Reduction</b>

Continued



**Table 1.** Randomized control trials comparing the effect of antimicrobial-coated suture with uncoated suture on occurrence of surgical site infections following surgical procedures.

Authors/year/ country	Sample Size (SG vs. CG)	Design of randomized control trial/ adherence to CDC criteria/Length of follow-up	Surgical procedures	Comparator suture material: ACS vs. NAS	Conclusions ACS (SG, infected patients%) vs. NAS (CG, infected patients%)	Statistical Analysis Conclusion
Baracs <sup>24</sup> /2011/ Hungary	385 (188 SG vs. 197 CG)	Multicentre trial, prospective, not blinded CDC 30-days follow-up	Adult, colorectal surgery	Triclosan-coated Polydioxanone (PDS plus) suture vs. uncoated Polydioxanone (PDSII) suture	ACS 23/188 (12.2%) vs. NAS 24/197 (12.2%)	No significant difference between the groups <b>No difference</b>
Turtainen <sup>25</sup> /2012/ Finland	276 (139 SG vs. 137 CG)	Multicentre trial, prospective, double- blinded CDC 1-month follow-up	Adult, peripheral vascular surgery	Triclosan-coated Polyglactin or Poliglecaprone (Vicryl plus, Monocryl plus) suture vs. uncoated Polyglactin or Poligle- caprone (Vicryl, Monocryl) suture	ACS 31/139 (22.5%) vs. NAS 30/137 (21.9%) Triclosan-coated suture does not reduce the occurrence of SSI n after lower limb vascular surgery	There was no statistically significant difference between the triclosan group and the control group in the occurrence of SSI. <b>No difference</b>
Diener <sup>27</sup> /2014/ Germany	1185 (587 SG vs. 598 CG)	Multicentre trial, prospective, patients surgeons and outcome assessors blinded CDC 30 days follow-up	Adult, elective midline laparotomy (abdominal surgery)	Triclosan-coated Polydio- xanone (PDS Plus) suture vs. uncoated Polydioxanone (PDS II) suture	ACS 87/587 (14.8%) vs. NAS 96/598 (16.1%) The occurrence of surgical site infections did not differ between the PDS Plus and the PDS II group.	The difference was not statistically significant <b>No difference</b>
Mattavelli <sup>26</sup> /2015/ Italy	281 (SG 140 vs. 141 CG)	Multicentre trial, patients and outcome assessors- blinded CDC 30 days follow-up	Adult, colorectal surgery	Polyglactin 910 triclosan- coated suture (Vicryl plus) vs. Polyglactin 910 (Vicryl) uncoated suture	ACS 18/140 (12.9%) vs. NAS 15/141 (10.6%) Surgical sutures triclosan- coated do not appear to be effective in reducing the rate of SSI.	This trial failed to demonstrate a protective effect of triclosan-coated sutures on the occurrence of SSI <b>No difference</b>

SG: Study Group; CG: Control Group; vs.: Versus; ACS: Antimicrobial-coated sutures; NAS: Non-Antimicrobial Sutures. CABG: Coronary Artery Bypass Grafting.

As upon described, the sample size of included RCTs ranged from 84 to 1185 participants.

If we focused our attention on the clinical trial with the lowest number of participants, we can note that Rozzelle et al<sup>14</sup> included in their comparative study, 84 participants and concluded that TCSs reduced the risk of postoperative shunt infection. The sample size in this study was far too small, and thus it was underpowered to draw any conclusions on the effect of TCSs on the risk of SII.

Of the studies, 10 were single-centre trials<sup>14,15,17-21,23,27,28</sup> whereas 5 were multicentre trials<sup>16,22,24-26</sup>.

Our findings showed that in 6 single-center studies<sup>14,15,17-20</sup> and only in 1 multicentre study<sup>16</sup>, TCS was superior to uncoated one in reducing SSI. It is obvious that when TCS is introduced as a single variable in a homogenous and uniform background, the effect is more evident. On the contrary, multicentre studies are characterized by numerous variables affecting results, a situation more similar to reality, and if in this setting a new treatment is truly effective, it should stand the challenge of multifactorial events. In the light of this concept, we analyzed the unique selected multicentre study, confirming the protective effect of TCSs on SSIs<sup>16</sup>. Authors<sup>16</sup> performed a prospective, randomized, double-blinded, controlled multicentre study aimed to compare triclosan-coated polyglactin 910 sutures with polyglactin 910 sutures for the reduction of SSI. Authors' conclusion specified that the use of the TCS leads to a reduction of SSI. Article limitations are related to heterogeneity of study population of surgical patients (vascular surgery, plastic surgery, gastrointestinal surgery, thyroidectomy, lipoma removal). Moreover, some methods such as the closing of the surgical incision together with the type of antibiotic prophylaxis were not standardized. Furthermore, they conducted a multicentre study but reported the results of a single center only.

In our research, follow-up ranged from 4 weeks days to 24 months, with most studies reporting outcomes at 30 days in accordance with CDC criteria<sup>16,18-20,22-26,28</sup>.

It is fundamental, that a clinical trial used CDC Criteria in defining SSIs, such that assessors follow a standard protocol for identifying SSIs. Among a group of RCTs, when a trial did not adhere to these criteria, it may introduce clinical heterogeneity.

In our findings, Seven RCTs<sup>17-19,21,22,24,26</sup> involved abdominal surgeries (1 open appendectomy<sup>21</sup>, 2 elective laparotomy<sup>19,22</sup>, 4 colorec-

tal surgery<sup>17,18,24,26</sup>), two RCTs regarded cardiac surgeries<sup>27,28</sup>, two concerned peripheral vascular surgery<sup>20,25</sup>, one RCT regarded breast surgery<sup>23</sup>, and finally three RCTs<sup>14-16</sup> referred to other surgeries. When Authors compared coated/uncoated sutures for the same surgical procedure, it introduced only a variable (coated suture) in a uniform background, an ideal clinical setting with the lowest risk of heterogeneity. On the other hand, in this case, Authors' results are related only to a specific surgical procedure. If we analyzed trials describing different types of surgical procedures, clinical variables deriving from such heterogeneity of procedures could affect the obtained results. Further, it is important that all incisions should be classified as clean, clean-contaminated, contaminated/dirty and dirty, thus validating the effect of TCS to close all type of incisions, not in all trials incision contamination was described. Meta-analyses by extracting data from multiple trials overcome the limits related to the restricted sample size of the single clinical trial. Further, they perform the quantitative synthesis of data from multiple RCTs, thus providing a more comprehensive estimation with greater statistical power. For this reason, we analyzed, seven meta-analyses investigating the impact of TCSs on SSI rate<sup>29-35</sup>. On the basis of our research, meta-analyses are not completely able to restrict the confounding effect of the differences and heterogeneities among studies and populations. Meta-analyses analyzed together with their limitations are summarized in Table II. In particular, Chang et al<sup>33</sup> published a meta-analysis suggesting that the selective use of TCSs conveys no protection against postoperative SSI. In all of the examined studies, patients undergoing different types of surgery were studied (trials on brain, breast, appendix, colorectum, gynecological, vascular, cardiac, plastic, abdominal, and general surgery were analyzed together). As described previously, in this case, different types of operations contribute to increase the heterogeneity between study populations. Further, not in all trials incision contamination was described. Validity could not be established for the effect of TCSs to close dirty incisions or for operations where incision contamination was not described. Sandini et al<sup>35</sup> selected a specific population of patients undergoing elective colorectal resections to minimize heterogeneity of class of wound contamination and type of operation. They concluded that their findings failed to demonstrate a significant protective effect of TCSs on the occurrence of SSI after elective colorectal resections.

**Table II.** Meta-analyses of randomised trials comparing triclosan-coated sutures (TCSs) with uncoated standard sutures for surgical procedures.

Meta-analysis	Patients (N)/RCTs (N)	Type of surgery	Limitation	Conclusions
Chang WK <sup>33</sup> , 2012  ZX <sup>32</sup> , 2013	7 RCTs, 836 patients (pediatric, adult) 17 RCTs, 3720 patients (pediatric, adult)	General, Cerebrospinal fluid shunt, Abdominal, Breast, Cardiac, Vascular Abdominal, Breast, Cardiac	Small sample size No stratification of the risk for wound class contamination, type of operation, or organ/apparatus involved. Only five of the trials clearly defined the diagnostic criteria for SSI developed by the CDC criteria. Consistently significant results in adult patients abdominal surgery, clear or dirty/contaminated surgery; in paediatric patients, contaminated/dirty incisions, breast or cardiac surgery, such beneficial effect was not clear. The quality of included trials is still not fully satisfactory. Not all studies adhered to CDC criteria. Different settings of participants and for varying surgical procedures. Insufficient individual patient data. Heterogeneity of outcome.	The selective use of TCSs conveys no protection against postoperative SSI. W a n g TCS use has a 30% advantage in reducing SSI risk  A significant reduction in the occurrence of SSI.
Edmiston CE Jr <sup>31</sup> , 2013	13 RCTs, 3568 patients (pediatric/adult)	General, Cerebrospinal fluid shunt, Abdominal, Breast, Cardiac, Vascular	Selective study parameters were missing from some of the RCTs elected studies. Not all studies adhered to CDC criteria. Timing, dosing, and agent used for antimicrobial prophylaxis were not standardized. There was no consistent reporting of other evidence-based interventions, such as glycemic control or maintenance normothermia. Studies didn't address adequately the impact of specific risk factors for patients.	31% reduction of risk associated with the use of TCSs for prevention of SSIs compared with non-antimicrobial-coated sutures.
Daoud FC <sup>30</sup> , 2014	15 RCTs 4800 patients (pediatric/adult)	General, Cerebrospinal fluid shunt, Abdominal, Breast, Cardiac, Vascular	Several trials didn't use CDC criteria in defining SSI incision class.	TCSs reduced the risk of SSI by 33% after clean, clean-contaminated, and contaminated surgeries.
Apisamthanarak A <sup>29</sup> , 2015	22 RCTs, 7 non-RCTs 11942 patients (pediatric/adult)	General, Head/ neck cancer reconstruction, Vascular, Cardiac, Breast cancer.	The potential for bias is greater in non-RCTs. Design, in part, may explain heterogeneity. CDC criteria heterogeneity. The quality of some of the included studies could not be determined with certainty (lack of information, methodological issues).	TCSs reduced the risk of SSI by 26% among patients undergoing surgery. This effect was particularly evident among those who underwent abdominal surgery.
Guo J <sup>34</sup> , 2015	13 RCTs, 5256 adult patients	General, Abdominal, Breast, Cardiac, Vascular	Authors failed to detect an association between coated sutures and reduced risk of SSI for non-abdominal procedures.	TCSs were associated with lower risk of SSI than uncoated sutures across all surgeries, for adult patients
Sandimi M <sup>35</sup> , 2016	6 RCTs, 2168 adult patients	Exclusively colon rectal	No stratification of the risk for SSI. The quality of included trials is still not fully satisfactory. Heterogeneity among studies.	Findings failed to demonstrate a significant protective effect of TCSs on the occurrence of SSI after elective colorectal resections.

SSI: Surgical Site Infection; RCTs: Randomized Control Trials; CDC criteria: Centres for Disease Control Criteria.



In fact, as upon described, even though, trials comparing coated/uncoated sutures for only one type of surgery provide a more uniform setting, on the other hand, they restrict the analysis to only one specific type of population. Further, there were discrepancies of results even among the trials regarding colorectal surgery only<sup>18,26</sup>, probably due to the fact that the composition of the colonic microbiota is substantially different in different population depending on alimentary habit and environmental conditions. Wang et al<sup>32</sup> extracted data from 3720 surgical patients, with more uniform background and less clinical heterogeneity, confirming the beneficial effect of TCS in SSI prevention. On the other hand, Authors described their meta-analysis limitations, consisting of different SSI definition Criteria, different surgical procedures and different quality of the several included RCTs. On the basis of our trial results and the heterogeneous findings of the selected meta-analyses, we conclude that the question of whether TCSs can reduce the occurrence of SSI remains still open. Future well-designed RCTs of high methodological quality are needed, reporting complete data, using CDC criteria in defying SSI together with CDC incision class. *Our limitations:* Similar to other systematic reviews, the quality of some of the included studies could not be determined with certainty due to lack of information provided, and others had methodological issues compromising the overall rigor or quality of the studies.

## Conclusions

SSIs cause major discomfort for the patient, are potentially life-threatening events, prolong hospitalization stays and finally increase direct and indirect costs with a significant overall financial burden for any health care system. The main additional costs are related to re-operation, extra nursing care and interventions, and finally drug treatment costs. The indirect costs, due to loss of productivity, patient dissatisfaction and litigation, and reduced quality of life have been studied less extensively. The treatment of SSI can be very costly, and the use of antibacterial effect suture for wound closure can prevent wound infections after surgery, thus reducing SSI rate.

Among the innovative approaches to reduce the risk of incision infection is the ability to

impregnate suture materials with antimicrobial substances. In fact, microbial adherence to the surface of sutures has been recognized as one of the reasons for the development of incision infections.

On the basis of our research, our findings suggest that, despite controversial results among the clinical studies, the antimicrobial suture was effective in decreasing the risk for postoperative SSIs in a broad population of patients undergoing surgery. To prevent microbial colonization of sutures, in fact, antimicrobial-coated materials have become available, these are made of inert, non-antigenic and safe materials<sup>12-24</sup>. To date, most antimicrobial sutures are coated with triclosan. Alternative substances are becoming clinically relevant too, such as Chlorhexidine (CHS)-coated sutures. CHX is a biguanide antiseptic with antibacterial activity that has been in widespread use since the late 1940s. There is extensive dental, obstetric, and surgical scrub literature on the use of CHX in specialized settings<sup>36-38</sup>. CHX is poorly absorbed across mucosal surfaces and minimally absorbed percutaneously; it has been used in several pharmaceutical products over the past 30 years for its antiseptic properties and safety profile<sup>36-45</sup>. Only 6 scientific studies<sup>36-41</sup> evaluated *in vitro* CHX-coated sutures. They demonstrated that CHX forms an inhibition zone around suture material and it is effective against the pathogens responsible most frequently for SSIs. CHX is positively charged and reacts with the negatively charged microbial cell surface, thereby destroying the integrity of the cell membrane. Subsequently, CHX penetrates into the cell and causes leakage of intracellular components leading to cell death. We focused our attention on a recent research described by Sethi et al<sup>39</sup>, who used coated suture in order to prevent the colonization of periodontal pathogens and to promote inhibition of oral biofilm formation. This is a comparative evaluation of sutures coated with triclosan and CHX. On the basis of Authors' results, the analysis showed maximum biofilm inhibition potential with CHX-coated suture followed by triclosan-coated suture. *In vivo* studies, large and comparative clinical research trials are necessary to validate the efficacy of CHX-coated sutures thus allowing its use in clinical practice.

## Conflict of Interests:

The Authors declare that they have no conflict of interests.

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