Review Article

Antimicrobial coated sutures in Indian Market : A literature review of efficacy and safety in patients to prevent surgical site infections

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Surgical suture material is used to adequately adapt the wound edges. To prevent microbial colonization of the suture material in operative incisions, sutures with antibacterial activity have been developed. In India, triclosan coated sutures (Johnson & Johnson Ethicon Sutures) and chlorhexidine coated sutures (Sutures India, Meril life Sciences Pvt, Ltd, and Dolphin Sutures) are available. Both in vitro and in vivo experiments have shown that triclosan-coated sutures (TCS) are effective in the prevention of surgical site infections (SSIs). Our aim is to analyze the literature on efficacy and safety of antimicrobial sutures available in Indian market for prevention of SSIs following surgical procedures. We reviewed 23 randomized control trials (RCTs) and 5 meta-analyses. comparing antimicrobial-coated sutures with conventional sutures and assessing the clinical effectiveness of antimicrobial sutures to decrease the risk for surgical site infections (SSIs). In 7 RCTs and 4 meta-analyses, TCS coated sutures were statistically superior vs comparators for reducing SSIs; 4 RCTs documented that TCS coated sutures were better than comparator for reducing SSIs; in 6 studies TCS coated sutures were comparable to conventional sutures in reducing SSIs; 2 RCTs and 1 meta-analyses showed that TCS coated sutures were less effective (not statistically significant) than comparator. There was only 1 randomized clinical trial which documented that Chlorhexidine coated sutures is comparable to conventional sutures. The TCS 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 1 in vivo and 6 in vitro scientific studies evaluated them. In vivo studies, large and comparative clinical research trials are recommended to validate the efficacy of CHX-coated sutures thus allowing their use in clinical practice.

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Key words **: Triclosan, chlorhexidine, antimicrobial sutures and SSIs.**

Surgical site infection (SSI) rates in India vary from 5% to 10.3% depending on the chosen type of surgical procedure[1-2].

SSI generally poses a risk for patients due to an increased morbidity and even mortality[3]. Affected patients often need further surgical intervention leading to a higher cost for the health care system[4]. Several factors are involved in the onset of SSI, one of which is the surgical suture itself. The presence of foreign material highly reduces the critical number of bacteria facilitating a clinically relevant infection[5-7]. Furthermore, the capillarity of sutures supports the path of bacteria into wounds by soaked fluids. This so-called 'wicking effect' triggers such infections[8]. Especially, the type of material and structure of the surface determine the ability of bacteria to adhere and induce infections[8]. In this context, the number of viable adhered bacteria is considered an essential trigger for SSI related to suture material. The main issues are the proliferation of attached bacteria and formation of persistent biofilms[8-10]. Once a biofilm has developed, it protects bacteria against the host's immune system as well as systemically[11,12] and locally applied antibiotics.

A possible solution to prevent suture-associated site infections is the use of anti-microbially coated sutures. These sutures can be used to inhibit viable adhered microbes and thus prevent biofilm formation. After several years of research and development, the first antibacterial suture - triclosan coated polyglactin 910 suture was approved in 2002 by Food and Drug Administration (FDA), the United States to reduce the risk of surgical site infections. Furthermore, the use of triclosan coating was extended to other suture materials to overcome bacterial adherence and prevent or reduce surgical site infections[13-15].

The antimicrobial effect of triclosan coated polyglactin 910 suture was consistent over a wide range of suture diameters and treatment conditions even after several passes through the fascia and subcutaneous tissue in the porcine model[16]. The zone of bacterial inhibition surrounding the knotted sutures using triclosan coated suture material in in-vitro colonization experiments showed an antimicrobial effect over Staphylococcus aureus (S aureus)

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and Staphylococcus epidermidis (S epidermidis)[16]. In vivo studies on triclosan-coated sutures exhibited significant inhibition of bacterial colonies on its surface near the infected site without compromising the mechanical property of the suture[17,18]. Similarly, poliglecaprone 25 suture with triclosan exhibited good antibacterial efficacy post-implantation in animal models[19].

The principle function and efficacy of sutures depends on the physico-mechanical properties and it is vital to retain these characteristics while they are modified or coated with bioactive agents and sensors. In addition, to better handling qualities and desired modifications, it should also be noncarcinogenic, nontoxic, free of allergens, and importantly it should not evoke any adverse response in the host tissues. To meet these requirements, it is necessary to conduct detailed pre-clinical studies and evaluate the safety and efficacy in human trials on these emerging sutures.

The Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017 recommends, "Consider the use of triclosan-coated sutures for the prevention of SSI"[20].

As per the World Health Organization (WHO) Global Guidelines for The Prevention of Surgical Site Infection, the panel suggests use of triclosan coated sutures for the purpose of reducing risk of SSI, independent of the type of surgery[21].

American College of Surgeons Surgical Infection Society (ACS & SIS) Surgical Site Infection Guidelines, 2016 Update recommends the use of triclosan coated suture for wound closure in clean and clean-contaminated abdominal cases when available[22].

Triclosan (5-chloro-2-[2.4-dichlorophenoxy] phenol) is a broad-spectrum bactericidal agent that has been used for more than 40 years in various products, such as toothpaste and soaps. Higher concentrations of triclosan work as a bactericide by attacking different structures in the bacterial cytoplasm and cell membrane. At lower concentrations, triclosan acts as a bacteriostatic agent binding to enoyl-acyl reductase, a product of the Fab I gene and thus inhibiting fatty acid synthesis. Several trials have shown that the use of triclosan coated sutures leads to a reduction of the number of bacteria in vitro and also of wound infections in animal and clinical studies. Of note, this effect is not confined to any particular tissue or organ system. Apart from triclosan, several novel antimicrobial coatings are now becoming available, but there are still no reported clinical studies comparing the efficacy of novel antibacterial sutures with non-coated ones. Triclosan-coated polyglactin 910, triclosan-coated polydioxanone, and triclosan-coated poliglecaprone 25 are commercially-available sutures with antimicrobial properties. Commonly used non-coated sutures are polyglactin 910, polydioxanone, poliglecaprone 25, polyglycolic acid and polyglyconate sutures.

In India, triclosan coated sutures (Johnson & Johnson Ethicon Sutures) and chlorhexidine coated sutures (Sutures India, Meril life Sciences Pvt, Ltd, and Dolphin Sutures) are available.

Our aim was to analyze currently available Randomized Clinical Trials (RCTs) and meta-analyses, 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.

Material and Methods

We performed a review of the peer-reviewed international literature on PubMed, 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 November 2018. The search strategy was personalized around specific key-words and combinations of these: "uncoated suture", "coated suture", "antimicrobial", "antiseptic", "suture", "triclosan", "chlorhexidine", "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 :

In this review, we have analyzed randomized controlled trials and meta-analyses.

Exclusion Criteria :

We did not include in vitro experiments and animal studies.

Results

We evaluated 23 RCTs and 5 meta-analyses. Of the 22 RCTs, 11 were for general surgery; 5 in cardiac/ vascular surgery; 4 in breast surgery/ gynecology and 1 each in neurology and orthopedic surgery[23-44].

The sample size of included RCTs ranged from 26 to 2570 participants. Of the studies, 16 were single-center trials whereas 6 were multi-center trials. There were 10 double blind and 3 single blind studies while rest were an open design. Thirteen RCT studies compared Polyglactin 910 with Triclosan (VicrylPlus) *versus* Polyglactin 910(Vicryl); 3 studies compared Polyglactin 910 with Triclosan (VicrylPlus) and Poliglecaprone 25 with Triclosan (Moncryl plus) with Polyglactin 910 (Vicryl) and Poliglecaprone 25(Monocryl); 2 studies compared Polydioxanone with triclosan Suture (PDS plus) *versus*

Polydioxanone Suture (PDS II); 1 study each compared Polyglactin 910 with Triclosan (Vicryl plus) *versus* Polydioxanone Suture (PDS II) *versus* conventional suture, Polyglactin 910 with Triclosan (Vicryl Plus) *versus* different reabsorbable suture, Polydioxanone with triclosan Suture (PDS plus) *versus* Polydioxanone Suture (PDS II), Polyglactin 910 with Triclosan (Vicryl plus) *versus* Chinese silk.

These RCTs assessed outcomes (primary and secondary) of intra operative handling, surgical site infections, pain, cosmetic results, biological inflammation markers, length of stay and wound dehiscence. Intra operative handling, assessed in 1 RCT, showed TCS coated sutures to be better than the comparator. In 7 RCTs, TCS coated sutures were statistically superior vs comparators for reducing SSIs; 4 RCTs documented that TCS coated sutures were better than comparator for reducing SSIs; in 6 studies TCS coated sutures were comparable to comparator in reducing SSIs; 2 RCTs showed that TCS coated sutures were less effective (not statistically significant) than comparator.

TCS coated sutures were statistically better than comparator for pain reduction in 1 RCT while 1 study showed TCS coated sutures to be comparable with the comparator on pain parameter.

For cosmetic results, TCS coated sutures were statistically superior compared to the comparator in 1 study while comparable in another RCT.

In 1 RCT, biological inflammation markers were statistically lower with TCS coated sutures compared to comparators.

For the length of stay TCS coated sutures were statistically better in 1 and comparable in 5 studies.

Wound dehiscence was significantly lesser with TCS coated sutures in 1 study, comparable in 2 studies and statistically inferior in 1 study.

There were 5 meta-analyses which we reviewed[45-49]. Four meta analyses concluded that TCS coated sutures showed a significant advantage in reducing the odds of SSI ranging from 30- 39%. Only 1 meta-analyses showed that TCS coated sutures were not able to reduce SSIs.

There was only 1 clinical trial with 100 patients which documented that Chlorhexidine coated sutures is comparable to conventional sutures.50 In contrast there are 19, 3 and 3 RCTs available with Polyglactin 910 with Triclosan (Vicryl Plus), Polydioxanone with triclosan Suture (PDS Plus) and Poliglecaprone 25 with Triclosan (Monocryl Plus) (Johnson & Johnson Ethicon Sutures) respectively.

The Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017; World Health Organization (WHO) Global Guidelines for The Prevention of Surgical Site Infection and American College of Surgeons Surgical Infection Society (ACS & SIS) Surgical Site Infection Guidelines, 2016 Update recommends, use of triclosan-coated sutures for the prevention of SSI based on RCTs which were done predominantly with TCS ie, Polyglactin 910 with Triclosan (Vicryl Plus), Polydioxanone with triclosan Suture (PDS Plus) and Poliglecaprone 25 with Triclosan (Monocryl Plus) (Johnson & Johnson Ethicon Sutures)

Discussion

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 triclosan coated (antimicrobial) suture was effective in decreasing the risk for postoperative SSIs in a broad population of patients undergoing surgery.

The potential reasons for difference in outcome 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.

To prevent microbial colonization of sutures, in fact, antimicrobial-coated materials have become available, these are made of inert, non-antigenic and safe materials. To date, most antimicrobial sutures are coated with triclosan. The clinical efficacy and safety studies are available extensively for triclosan coated sutures ie, with Polyglactin 910 with Triclosan (Vicryl Plus), Polydioxanone with triclosan Suture (PDS Plus) and Poliglecaprone 25 with Triclosan (Monocryl Plus) (Johnson & Johnson Ethicon Sutures)

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.

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. Only 6 scientific studies[51-56] 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. Only one clinical trial, in 100 patients has documented that CHX coated sutures is comparable to conventional sutures. 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.

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

Limitation and Strength :

As a limitation, this was a retrospective historical controlled study having an observational nature conducted in a single institution. Although the big sample size of 306 patients was the study's strength and provides for good reliability. Another strength of the study is its generalizability and robustness due to inclusion of heterogeneous case-mix of patients.

Conflict of Interest : The Author declare that he has no conflict of interests.

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