Comparison between antimicrobial-coated sutures and uncoated sutures for the prevention of surgical site infections in plastic surgery: a double blind control trial

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Abstract. – OBJECTIVE: Surgical site infection (SSI) produces considerable morbidity and increases health care costs. One of its causes is microbial adherence to the surgical sutures surface. A strategy to avoid microbial colonization is the use of antimicrobial-impregnated sutures. Recently absorbable sutures treated with chlorhexidine (CHX) have been developed. Our study purpose was to compare CHX-coated and uncoated suture in elective plastic surgery.

PATIENTS AND METHODS: We conducted a randomized, double-blind, single-centre controlled trial of 18 patients undergoing elective bilateral mammary surgery and 18 patients undergoing skin lesions removals. Patients were divided into 2 groups receiving antibacterial-coated (study group) and uncoated (controlled group) sutures for wound closure. Patients were evaluated for scar results and signs of SSIs were monitored over a period of 30 days (or 1 year in case of prosthesis surgery). Statistical comparison was performed using dependent t-tests for paired samples.

RESULTS: For patients undergoing mammary surgery, based on Vancouver Scale, there were no significant differences between the two groups. We noticed that in 8 patients the vertical scars belonging to the control group were larger than the contralateral 8 vertical sutures belonging to the study group. For patients undergoing skin surgery, surgical wounds treated with uncoated sutures were significantly more erythematous than the ones belonging to the study group (Media: 0,8333% vs. 1,5556%, respectively; standard deviation: 9,235 vs. 0,6157; 95%; p=0.0092).

CONCLUSIONS: No wounds infection was reported between the two groups. Based on our experience, we conclude that the use of CHX-coated sutures should be considered in case of inflamed lesions removal. Further studies are needed to validate our results.

Key Words: Surgical site infection, Sutures, Antimicrobial-coated sutures.

Introduction

Surgical site infection (SSI) remains one of the most frequent complications after surgery2,3. SSIs prolong hospital stays, cause major discomfort for the patients and increase direct and indirect costs with a significant overall economic burden for any health care system2,4.

The most widely recognized definition of infection, which is used throughout the United States and Europe, is the one adopted by the Centres for Disease Control (CDC) and Prevention4-6, that describes SSI as an infection that occurs within 30 days from surgery, or within a year in case of prostatic surgery.

One of the reasons for the development of SSIs that has been widely reported in literature over the years is microbial adherence to the surface of surgical sutures7-9.

In order to avoid microbial colonization of suture material, sutures with antibacterial and antiseptic activity have been developed10. The suture materials that are most commonly employed in major and minor surgery are mainly made of synthetic materials such as non-absorbable polypropylene and absorbable polydioxanone. At present, all commercially available anti-microbial sutures are exclusively coated with triclosan11,12.

Several scientific studies have assumed 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 experiments13-23. On the contrary, some clinical trials have suggested that coating sutures with triclosan do not reduce the risk of SSI24-31.

Recently, new products have been developed, such as absorbable sutures made with new materials32,33 and with an antibacterial effect such as Poly (glycolide-co-e-caprolactone) monofila-

ment absorbable suture treated with chlorhexi-
dine (Monofil Plus®, Assut Europe, Rome, Italy).
Comparison of antimicrobial-coated and uncoated sutures

Chlorhexidine (CHX) is an antiseptic agent with antimicrobial properties, commonly used, in many pharmaceutical-preparations.

Our study purpose was to compare CHX-coated and uncoated absorbable suture in elective minor and major plastic surgery.

**End Points**

The primary outcome was the occurrence of wound infections, the secondary one the wound healing results (the rate of incision complications and scar evaluation).

**Patients and Methods**

In a period ranging from March 2017 to June 2017, we conducted a randomized, double blind, single-centre controlled trial of 18 patients undergoing primary elective bilateral mammary surgery and 18 patients undergoing skin lesions removals, in order to compare antibacterial-coated and uncoated sutures for wound closure.

Informed consent for participation was obtained from each patient before enrolment in the study. Eligible patients were candidates for “clean” elective major mammary surgery (type of surgery which provides sutures both on the right and left breast, at level of vertical incision) and “clean” minor skin surgery (removal of two skin lesions located on the same anatomical region). The exclusion criteria called for pregnancy and lactation, emergency operations, and ongoing infections. We established that re-operation necessity for any reason during the post-operative course would result in patient dropout from the trial with no replacement.

Wound patients were randomly assigned to either a study or a Control Wound Group (WCG). In the Wound Study Group (WSG), surgical wounds were closed using coated monofilament absorbable suture treated with CHX (Monofil Plus®, Assut Europe, Italy) and uncoated sutures (monofilament polyglycaprone suture). Wounds were dressed with Steri-Strips (3M).

Patients were evaluated for complications (skin swelling, erythema, hematoma, seromas, wound dehiscence, infection) and for scar results (through Vancouver scale, which assesses 4 variables: vascularity, height/thickness, pliability, and pigmentation). Signs of SSIs according to the Centers for Disease Control and Prevention criteria were monitored over a period of 30 days (or 1 year in case of prosthetic surgery). Follow-up was at 1 and 3 weeks and at 1, 3, 6 and 12 months after surgery.

**Statistical Analysis**

Statistical comparison of standard and antibacterial-coated sutures was performed using dependent t-tests for paired samples.

**Patient Characteristics**

The clinical sample included 18 surgical cases undergoing MS (18 women) and 18 surgical cases undergoing SS (12 women and 6 men). Patients undergoing MS included 3 smokers, while none had immunodeficiency and none was taking anticancer/immunosuppressive drugs. Of patients undergoing SS, 1 was smoker and none had immunodeficiency or was taking anticancer/immunosuppressive drugs. Patient characteristics are shown in Table I. According to the traditional wound classification, all wounds were clean. Wounds characteristics are listed in Table II.
Study Groups and Risk Factors

There were no significant differences between patients regarding age, sex, and other risk factors for SSI (except for 3 smokers among patients undergoing MS and 1 smoker among patients undergoing SS), or in relation to the type of wound in each patient (Table I, Table II).

Technique

**SWG**

In 36 patients CHX-coated Poly:glycolide-co-e-caprolactone antimicrobial sutures ((Monofil Plus®, Assut Europe, Rome, Italy) were used in all surgical steps both in subcutaneous tissue and skin closure. The skin closure was performed by a continue suture.

**CWG**

In a total of 36 wounds conventional uncoated sutures were used in all surgical steps. The skin closure was performed by a continue suture.

Occurrence of Surgical Site Infection

The occurrence of surgical site infection within the samples was 0.

Results

For patients undergoing MS, differences between the 2 groups were calculated by the Student t-test. The significance level was set at $p = 0.05$. Based on Vancouver Scale, there were no significant differences between the groups with regard to pigmentation, pliability, vascularity and

Table I. Patients’ data.

<table>
<thead>
<tr>
<th>Patients’ data (MS)</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical sample size</td>
<td>18 patients</td>
</tr>
<tr>
<td>Age (years)</td>
<td>52 (Range 41-63)</td>
</tr>
<tr>
<td>Gender</td>
<td>18 Female</td>
</tr>
<tr>
<td>Risk for SSI</td>
<td>3 current smokers patient</td>
</tr>
<tr>
<td>Surgical Procedures</td>
<td>18 Bilateral Mammary Surgery</td>
</tr>
<tr>
<td></td>
<td>(9 Reductive Mastoplasties, 9 Mastopexies)</td>
</tr>
</tbody>
</table>

Table II. Wounds characteristics.

<table>
<thead>
<tr>
<th>Wounds characteristics (MS)</th>
<th>SWG</th>
<th>CWG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length (cm)</td>
<td>6.65 (6.3-7) cm</td>
<td>6.6 (6.2-7) cm</td>
</tr>
<tr>
<td>Clinical signs</td>
<td>No signs of inflammation</td>
<td>No signs of inflammation</td>
</tr>
<tr>
<td>Wound status (Clean /clean contaminated/ Contaminated/Dirty)</td>
<td>18 clean</td>
<td>18 clean</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wounds characteristics (MS)</th>
<th>SWG</th>
<th>CWG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length (cm)</td>
<td>3.05 (1.3-4.8) cm</td>
<td>3.1 (1.2-5) cm</td>
</tr>
<tr>
<td>Clinical signs</td>
<td>1 Erythema</td>
<td>No signs of inflammation</td>
</tr>
<tr>
<td>Wound status (Clean /clean contaminated/ Contaminated/Dirty)</td>
<td>18 clean</td>
<td>18 clean</td>
</tr>
</tbody>
</table>

List of Abbreviations: MS: Mammary Surgery; SS: Skin Surgery; SWG: Study Wound Group; CWG: Control Wound Group.
Comparison of antimicrobial-coated and uncoated sutures

height of the scars. We noticed that in 8 patients (44%) the vertical scars belonging to the WCG were larger than the contralateral 8 vertical sutures belonging to the SWG (Figure 1, Figure 2).

For patients undergoing SS, differences between the 2 groups were calculated by the Student $t$-test. The significance level was set at $p = 0.05$. Based on Vancouver Scale, there were no significant differences between the groups with regard to pigmentation, pliability and height of the scars. Surgical Wounds treated with standard uncoated sutures were significantly more erythematous than the ones belonging to WSG (Figure 3, Figure 4). (Media: 0.8333% vs. 1.5556 % respectively; standard deviation: 9.235 vs. 0.6157; 95%; $p = 0.0092$).

**Discussion**

Surgical site infection produces considerable morbidity and increases health care costs. A potential strategy to decrease the rates of SSIs may be the use of antimicrobial-impregnated sutures. Several studies have shown the efficacy of triclosan-coated polyglactin 910 antimicrobial sutures (Vicryl* Plus) in decreasing the occurrence of SSIs\textsuperscript{16-23}, on the contrary other clinical studies have led to different conclusions\textsuperscript{24-31}.

We have conducted a review of literature on the effectiveness of antimicrobial-coated sutures...
for the prevention of SSI, analysing Randomized Clinical Trials comparing antimicrobial-coated sutures with uncoated sutures. On the basis of our research, despite the controversial results among the clinical studies upon the efficacy of triclosan-coated sutures in reducing the occurrence of SSI, antimicrobial suture is effective in decreasing the risk for postoperative SSI.37

New substances are becoming clinically relevant, such as Chlorhexidine (CHX) coated sutures, but only 6 in vivo scientific studies34,38-42 evaluated them. In particular, Sethi et al40 reported the use of coated suture in order to prevent the colonization of periodontal pathogens and to promote inhibition of oral biofilm formation. Authors compared triclosan-coated sutures with CHX-coated sutures. Authors’ analysis showed maximum biofilm inhibition potential with CHX-coated suture followed by triclosan-coated suture. We reported the first study comparing uncoated sutures with CHX-coated sutures, in major and minor plastic surgery.

Conclusions

Based on scar evaluation, in patients undergoing MS, no statistical significant differences have been observed between the SWG and the CWG in terms of pliability, pigmentation vascularity and height, but in the 44% of patients wounds treated with CHX-coated sutures were less large than the ones treated with uncoated sutures. For what concerns patients undergoing SS, wounds treated with CHX-coated sutures were less erythematous than the ones treated with uncoated sutures. No statistical significant differences have been observed between the SWG and the CWG in terms of pliability, pigmentation and height. In particular, in 1 case of removal of an inflamed sebaceous cyst, the use of CHX-coated suture allowed us to obtain a no erythematous scar respect to the contralateral wound, not inflamed before surgery (Figure 3, Figure 4).

No wounds infection was reported between the two groups. We can conclude that the use of CHX-coated sutures should be considered in case of inflamed lesions removal. We firstly report a comparative study between uncoated sutures and CHX-coated sutures, larger and comparative clinical research trials are necessary to validate the efficacy of CHX-coated sutures in decreasing the occurrence of SSI.

Conflict of Interests

The Authors declare that they have no conflict of interests. None of the authors received any funds or has any financial interests to disclose.

References


Figure 4. Post-operative aspect: the scar on the left side (belonging to the CWG) appeared more erythematous than the contralateral one (belonging to the SWG).
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6) Berrios-Torres SI. EVIDENCE-BASED UPDATE to the U.S. Centers for disease control and prevention and healthcare infection control practices advisory committee guideline for the prevention of surgical site infection: developmental process. Surg Infect (Larchmt) 2016; 17: 256-261.


