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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 prosthetic 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 surgery[1,2]. 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 system[2,3].

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 Prevention[4-6], that describes SSI as an infection that occurs within 30 days from surgery, or within a year in case of prosthetic 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 sutures[7-9].

In order to avoid microbial colonization of suture material, sutures with antibacterial and antiseptic activity have been developed[10]. 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 triclosan[11,12].

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* experiments[13-23]. On the contrary, some clinical trials have suggested that coating sutures with triclosan do not reduce the risk of SSI[24-31].

Recently, new products have been developed, such as absorbable sutures made with new materials[32,33] and with an antibacterial effect such as Poly (glycolide-co-e-caprolactone) monofilament absorbable suture treated with chlorhexidine (Monofil Plus®, Assut Europe, Rome, Italy).

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Chlorhexidine (CHX) is an antiseptic agent with antimicrobial properties, commonly used, in many pharmaceutical-preparations[34-36].

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 be resulted 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). In the WCG, surgical wounds were closed using uncoated standard absorbable sutures. Patients were randomly assigned into the 2 groups and data were collected prospectively. Risk factors for poor wound healing and the development of SSIs were collected. Further, pre-operative and peri-operative variables such as gender, age, body mass index, comorbidity, drug therapy, smoking habit, amount of wound dressing material used and laboratory parameters were recorded. All the figures involved (surgeon, patient, nurse and the follow-up assessor) were blinded to which type of suture were used. The use of the suture material was made for each procedure at random using a sealed pack for dispensing one of the suture packs at a time. A computer-generated random list was used for randomization.

All the elective surgical operations were performed by experienced surgeons. All patients received antibiotic prophylaxis and trichotomy. Skin disinfection before incision was done with CHX. Patients undergoing mammary surgery (MS) received antibacterial-coated sutures on either the right or left breast and uncoated sutures were used on the contralateral breast. All patients were blinded as to which type of suture was used on which breast or incision half.

The same procedure was performed for patients presenting two lesions located on the same anatomical area, therefore antibacterial-coated sutures were used on one and uncoated sutures on the other one. The skin closure was performed by a continue suture.

The incisions were closed by running suture using 3/0 and 4/0 threads: Poly:glygolide-co-e-caprolactone (Monofil Plus®, Assut Europe, Rome, Italy) and uncoated sutures (monofilament polyglecaprone 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 Centres 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.

Table I. Patients' data.

Patients' data (MS)	Values
Clinical sample size	18 patients
Age (years)	52 (Range 41-63)
Gender	18 Female
Risk for SSI	3 current smokers patient
Surgical Procedures	18 Bilateral Mammary Surgery (9 Reductive Mastoplasties, 9 Mastopexies)
Patients' data (MS)	**Values**
Clinical sample size	18 patients
Age (years)	36,5 (Range 15-58)
Gender	12 Female, 6 Male
Risk for SSI	1 current smoker patient
Surgical Procedures	16 Removals of pigmented cutaneous lesions 2 Removals of subcutaneous cystic lesions

Abbreviations: MS: Mammary Surgery; SS: Skin Surgery.

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:glygolide-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 II. Wounds characteristics.

Wounds characteristics (MS)	SWG	CWG
Length (cm)	6.65 (6.3-7) cm	6.6 (6.2-7) cm
Clinical signs	No signs of inflammation	No signs of inflammation
Wound status (Clean /clean contaminated/ Contaminated/Dirty)	18 clean	18 clean
Wounds characteristics (MS)	**SWG**	**CWG**
Length (cm)	3.05 (1.3-4.8) cm	3.1 (1.2-5) cm
Clinical signs	1 Erythema	No signs of inflammation
Wound status (Clean /clean contaminated/ Contaminated/Dirty)	18 clean	18 clean

List of Abbreviations: MS: Mammary Surgery; SS: Skin Surgery; SWG: Study Wound Group; CWG: Control Wound Group.

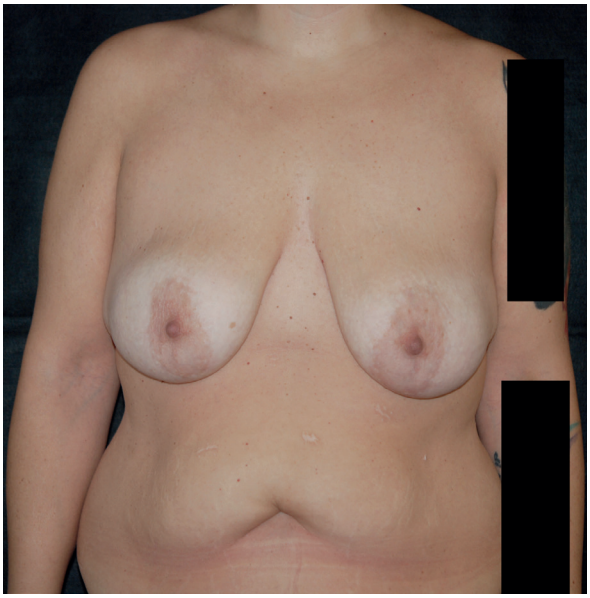

Figure 1. Pre-operatory aspect of a 43-year-old patient eligible for a bilateral mastopexy with prosthesis.

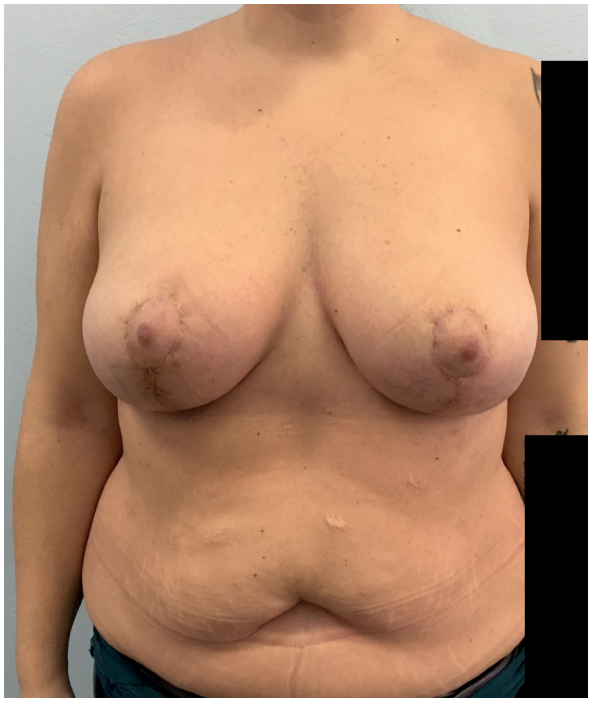

Figure 2. Post-operatory aspect: the vertical scar (belonging to the CWG) on the right breast appeared larger than the contralateral one (belonging to the SWG).

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[16-23], on the contrary other clinical studies have led to different conclusios[24-31].

We have conducted a review of literature on the effectiveness of antimicrobial-coated sutures

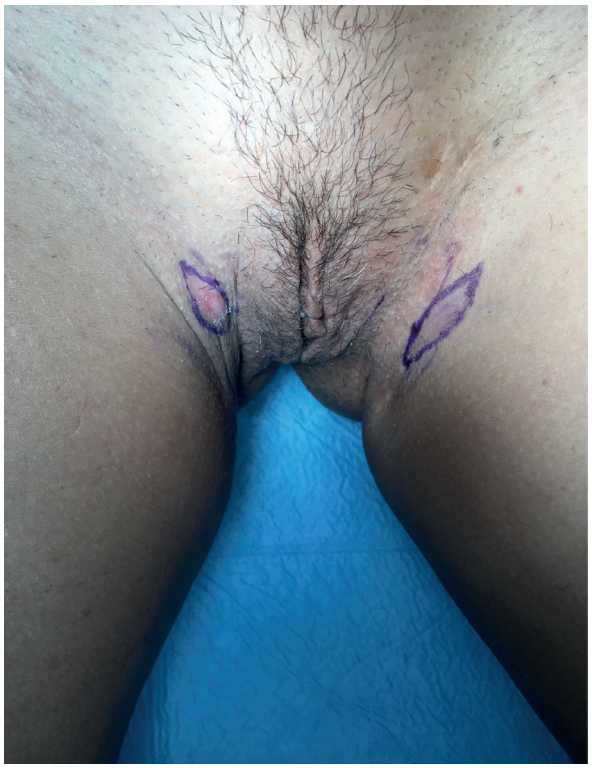

Figure 3. Pre-operatory aspect of a 39-year-old patient undergoing bilateral sebaceous cysts removal. The lesion on the right side appeared more inflamed than the contralateral one.

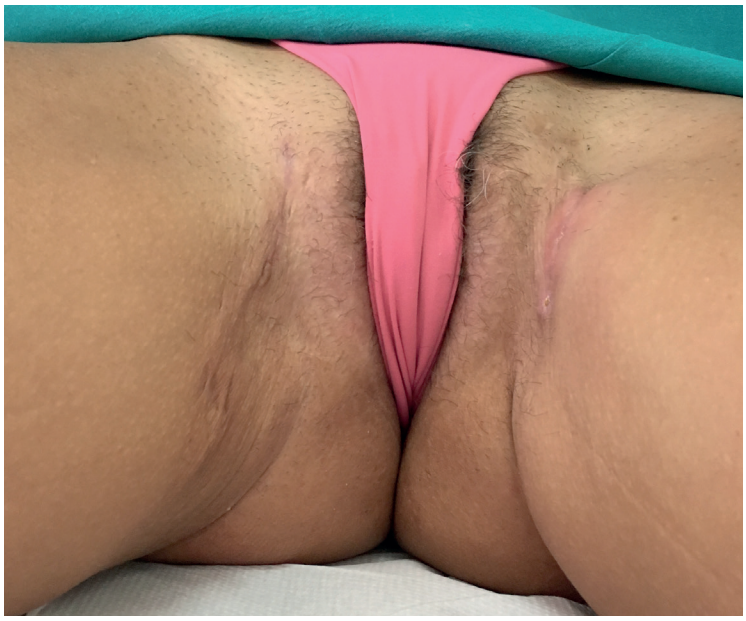

Figure 4. Post-operatory aspect: the scar on the left side (belonging to the CWG) appeared more erythematous than the contralateral one (belonging to the SWG).

for the prevention of SSIs, 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 SSIs[37].

New substances are becoming clinically relevant, such as Chlorhexidine (CHX) coated sutures, but only 6 *in vivo* scientific studies[34,38-42] evaluated them. In particular, Sethi et al[40] 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 SSIs.

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.

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