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Influence of preoperative skin sealing with cyanoacrylate on microbial contamination of surgical wounds following trauma surgery: a prospective, blinded, controlled observational study

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SUMMARY

Objective: Intraoperative bacterial contamination is a risk factor for surgical site infections (SSIs). This prospective, randomized, blinded, controlled trial (Reg. No. BB08/12) investigated the effect of a cyanoacrylate-based skin sealant (IntegüSeal) on intraoperative wound contamination during trauma surgery.

Methods: A total of 128 patients undergoing trauma surgery were assigned randomly to an intervention (n = 62) or a control group (n = 66). Surgical sites were investigated at three locations: maximum incision depth (base), wound margin prior to wound closure (margin), and the surgical sutures (suture). Colony-forming units (CFU) were counted after 48 h of incubation.

Results: Overall, significantly lower CFU counts were obtained for samples from the intervention group at all three sample sites compared to the control group. The difference, however, was only significant for the suture site (p = 0.040).

Conclusions: Preoperative sealing reduced microbial contamination on sutures during surgery, while the overall wound contamination remained unchanged. Hence, prevention of the clinically more relevant deep SSIs may not be expected. However, this study was not designed to detect differences in the rate of SSI. The role of the reduction in suture contamination with regard to the prevention of SSI remains to be evaluated.

1. Introduction

Most surgical site infections (SSIs) may arise endogenously, with the skin and nasal flora providing a source of infection.[1–3] In a study of 40 healthy participants, the median numbers of bacteria yielded from skin swabs following preoperative skin antisepsis with 70% v/v propan-2-ol applied for 1 min to skin with a low concentration of sebaceous glands, or for 10 min to skin with a high concentration of sebaceous glands, were 1.3 log and 3.4 log, respectively.[4] Hence, even after meticulous skin antisepsis, the resident skin flora will prevail at the incision site; this can then be transferred intraoperatively into the surgical site. In addition, standard skin antisepsis will have no effect on bacteria in the lower skin layers such as the border between the epidermis and dermis, or areas with high numbers of bacteria inhabiting the skin appendages, such as hair follicles[5] and sebaceous glands.

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Since preoperative skin antiseptics are not able to completely eradicate the resident skin flora and do not reach the deep skin layer, they do not prevent re-colonization of bacteria inhabiting the deeper skin areas and glands. Therefore, the patient and most of the skin around the incision site are covered with sterile drapes after the preoperative application of an antiseptic. However, this form of covering does not completely prevent the incision site from subsequent contamination with bacteria residing in the vicinity, as the gap between the drape and the surgical site may still allow bacterial contamination.

One preventive strategy has been the use of incision drapes placed directly onto the incision site, tightly sealing the surrounding skin area from the surgical site. Because of the formation of moisture and accumulation of sweat beneath the incision drapes, bodily fluids with a high concentration of bacteria may be spread into the surgical site, particularly after removal of the drape for the final skin closure. Indeed, the subsequent introduction of non-antimicrobial incision drapes has been demonstrated to be associated with an increase in the rate of SSIs.[6] Therefore, antimicrobial incision drapes impregnated with either povidone–iodine or chlorhexidine were developed to kill off emerging skin organisms and to decrease SSI rates. However, the results of meta-analyses have yielded inconclusive findings.[7]

A modification of the above strategy is the application of skin sealants by direct application of a liquid cyanoacrylate-based adhesive (IntegueSeal; Kimberly Clark Health Care, Atlanta, GA, USA) with the intention of blocking skin pores during the entire surgical procedure. The sealant polymerizes and hardens within 4 min to form a coating that adheres completely to the skin. By doing this, bacterial release will be blocked and endogenous contamination of the surgical site will be prevented.[8–11]

The clinical evidence for the prophylactic use of cyanoacrylate-based sealants to prevent SSI is currently controversial. However, the barrier effect of the sealant has so far been studied mostly by measuring bacterial numbers at one location of the surgical site, or by comparing SSI rates in intervention and control groups. To our knowledge, the exact anatomical location at which the sealant may support the prevention of bacterial contamination has not been ascertained microbiologically. Therefore, the aim of this study was to measure the number of bacteria at the base of the wound, along the wound margin, and on the wound sutures in patients undergoing surgery with and without the use of a cyanoacrylate-based adhesive sealant.

2. Materials and methods

2.1. Study design

The study was designed as a prospective, blinded, controlled, randomized clinical trial.

A total of 128 patients were studied (Figure 1): group A ($n = 66$; control group, no sealant) encompassed 38 male and 28 female patients (mean age: 50.7 ± 18.8 years; range: 18–85 years) and group B ($n = 62$; intervention group, IntegueSeal®) encompassed 29 male and 33 female patients (mean age: 53.6 ± 20.4 years; rang: 18–89 years). In group A, 63 suture samples and in group B, 56 suture samples were included.

2.2. Patient management

Patients were included if they were scheduled for spinal surgery (skin with a high density of sebaceous glands) or surgery to the lower extremities (skin with a low density of sebaceous glands). Patients were excluded if they had infected wounds, AIDS, a hepatitis B virus (HBV) or hepatitis C virus (HCV) infection, or if they were known drug users.

The study was designed as a blinded controlled observational study and was approved by the ethics committee of Ernst-Moritz-Arndt University Greifswald (Reg. No. BB 08/12). After assessing eligibility, patients were randomized to one of the two study arms by opening a sealed envelope, which contained the randomization code. Randomization was performed by use of a pre-set computer-generated allocation table.

All patients received perioperative antibiotic prophylaxis using a single shot of 1.5 g cefuroxime intravenous, administered 10–30 min prior to skin incision. All patients provided informed consent to participate in the study.

2.3. Surgical conditions and postoperative surveillance

Surgery was always carried out in the same surgical unit with a laminar airflow ventilation system (ceiling area 3.20×2.40 m) and disinfection of the floor and contact surfaces close to the patient between each operation. The single-use drapes and protective clothing worn by the surgical team were high performance quality (3 M GmbH, Neuss, Germany). Skin antisepsis was performed using a propan-2-ol (70% v/v)-based product (Antiseptica GmbH, Pulheim, Germany); the exposure time was 1 min on skin that had a low density of sebaceous glands (surgery of the lower extremities) and 3 min on skin with a high density of sebaceous glands (spinal surgery).[4] All operative procedures were performed by the same surgeon who has more than 20 years of experience.

Following skin antisepsis, patients allocated to group A (controls) were covered with sterile surgical drapes prior to incision. For group B (intervention) patients, a cyanoacrylate-based sealant (IntegueSeal) was applied after skin antisepsis and before application of a sterile surgical drape. The sealant was applied to the incision site as per the manufacturer's recommendations, using an integrated applicator with a width of 4 cm. The sealant was allowed to dry for 4 min, thereby transforming into a flexible film. In group A, the incision was not made until 4 min after antisepsis. Therefore, the duration of skin antisepsis and the allowed application time was identical in the two groups. The mean operation time for spinal surgery in both groups was 59 ± 28 min, and for surgery of the lower extremities was 74 ± 40 min.

After the procedure, patients were followed-up for up to 3 months to record the development or absence of SSI. Since the frequency of SSI was not the primary study measure, the assessment of SSI (A1–A3) followed a modification of the US Centers for Disease Control and Prevention (CDC) definitions[12] in terms of duration of the surveillance, yet was always observed by the attending surgeon.

2.4. Microbiological sampling

Three intraoperative swabs were taken from each surgical site in both groups by the same trained investigator, the surgeon performing the operation. After reaching the maximum incision depth, a swab was taken from the base of the wound. A second swab was then obtained from the internal upper dermal/epidermal margin of the wound, directly before wound closure using subcutaneous and intra-cutaneous sutures. After closure of the skin incision, a final swab was obtained across the entire length of the closed surgical site.

2.5. Microbiological investigation

After sampling, each swab, which had a polystyrene shaft and pure viscose tip (BBL CultureSwab; Becton Dickinson, Heidelberg,