INTRODUCTION

Catheter-related bloodstream infections (CRBSI) are the most frequent life-threatening complication of vascular access. Although cutaneous antiseptics prior to catheter insertion help minimize bacterial contamination of the insertion site, microorganisms can quickly grow back and pose a risk of causing infection. A novel, breathable, and transparent polyurethane film dressing has been developed for use at catheter insertion sites which has two antimicrobial agents (chlorhexidine and silver) incorporated into a soft silicone adhesive layer to aid minimizing the risk of catheter site infection (Figure 1). The development of cutaneous irritation with prolonged use of dressings is not uncommon in seconds due to the potential release of chemicals as well as skin damage arising from skin stripping that accompanies application and re-application of adhesive products.

AIMS

This poster describes the results of a study that was undertaken to evaluate a film dressing with a soft silicone adhesive layer incorporating chlorhexidine and silver for the induction of contact sensitisation by repetitive applications to the skin of normal healthy volunteers in a repeated insult patch test (RIPT). In addition, the adhesive properties and pain upon removal at selected time points were evaluated and compared to a control and challenge dressing.

METHODS

Repeat patch tests are routinely used to determine the potential irritancy of products. The test evaluates the potential induction of contact sensitisation by repetitive applications of materials to the skin of healthy volunteers using a modified version of the Draize Test1,2. In addition to the film dressing with a soft silicone adhesive layer incorporating chlorhexidine and silver (SSF-CHX/Ag), a reference film dressing with a soft silicone adhesive layer containing no antimicrobial agents (SSF) was used as a control. For comparison studies, a film dressing with an acrylic adhesive border and central pad containing chlorhexidine gel (AAF-CHX) was included in the studies (Table 1). As the AAF-CHX dressing has two distinct areas (central antimicrobial pad (AAF-CHX-1) and adhesive border (AAF-CHX-2)) sensitisation and irritation were assessed in both areas.

This was a single-centre, blinded, within-subject randomised study. The test consisted of three phases, Induction, Rest and Challenge. A total of nine applications of test dressings were applied over a 3-week period to the back of 216 volunteers (63 male, 153 female). Test dressings were worn for 48 or 72 hours. Dressing adhesion and pain on removal were assessed at selected time points (Study Visits 4 and 7) and overall.

RESULTS

Sensitisation

Interpretation of the data was based on the pattern of reactivity of the dressing during Induction Phase when compared to the severity and the reaction(s) observed at the Challenge Phase. Under the conditions of the study, there was no evidence of induced contact sensitisation for SSF-CHX/Ag, SSF and AAF-CHX (AAF-CHX-1 and AAF-CHX-2).

Irritation

Assessment of skin irritation was based upon the Berger and Bowman scale3. Analysis of irritation scores during Induction Phase showed that the SSF-CHX/Ag and SSF showed significantly less irritation (p<0.05) than the surrounding adhesive border of AAF-CHX (AAF-CHX-2) at each evaluation and overall (Figure 2). Additionally, sites covered with the SSF-CHX/Ag and SSF exhibited significantly less irritation (p<0.05) than the central pad area of AAF-CHX (AAF-CHX-1) at two time points (Study Visits 4 and 7) and overall.

Adhesion and pain on removal

Based upon adhesion scores obtained during Induction Phase, AAF-CHX showed a stronger adherence (3.79 ± 0.04, mean ± SEM) compared to the soft silicone adhesive dressings (SSF-CHX/Ag, 3.07 ± 0.07 and control SSF, 2.7 ± 0.08). The film dressings showed the greatest level of skin adhesion also showed the greatest level of pain reported by patients. Based upon pain scores obtained during Induction Phase, SSF-CHX/Ag and SSF exhibited very low pain scores in patients compared with AAF-CHX (AAF-CHX-1) and SSF (Figure 3). For example, patients with SSF-CHX/Ag nor SSF did not score greater than a 3 in the pain scale, whereas a proportion of patients with AAF-CHX experienced significant pain, scoring up to the maximum pain scores (Figure 3).

DISCUSSION

The level of adhesion is an important property of dressing placed on skin. There must be a balance between there being enough adhesion for the dressing to remain in place upon application and for the duration of the wear time but not enough to cause tissue trauma and pain on removal. Many traditional dressings incorporate acrylic as the adhesive but this adhesive can be aggressive leading to pain upon removal, tissue damage and irritation4. Soft silicone is an alternate adhesive technology offering a more appropriate level of adhesion, balancing the need for dressing adhesion to tissue but being easily removed with minimal pain on removal. This study showed that the test subjects using film dressings with a soft silicone adhesive layer (SSF-CHX/Ag and SSF) experienced up to ten times lower pain levels than those with the dressing with acrylic adhesive (AAF-CHX). Acrylic adhesive dressings have a tendency to leave residues on the skin and this, together with the likelihood that these aggressive dressings result in local tissue injury, is likely to lead to the elevated irritation scores seen in skin under the adhesive border of AAF-CHX.

CONCLUSION

The results of this study suggest that the film dressing with a soft silicone adhesive layer incorporated into a soft silicone adhesive layer showing significantly less irritation and minimising irritation and pain on removal.

REFERENCES