Effect of an acrylic terpolymer barrier film beneath transparent catheter dressings on skin integrity, risk of dressing disruption, catheter colonisation and infection


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Objectives: We assessed the effect of a skin-protective terpolymer barrier film around the catheter insertion site on frequency of dressing disruptions and skin integrity issues (hyperaemia, skin irritation, residues of adhesives and moisture under the dressing). Secondary outcomes included colonisation of the central venous catheter (CVC) and rates of central line-associated bloodstream infection.

Research methodology: A monocentric, open-label, randomised controlled trial was performed comparing a control group receiving standard transparent catheter dressings without the skin-protecting barrier film and an intervention group receiving a transparent chlorhexidine-impregnated dressing with use of the skin-protective acrylic terpolymer barrier film (3M™ Cavilon™ No - Sting Barrier Film, 3 M Health Care, St. Paul, MN, USA).

Results: Sixty patients were enrolled and randomised in the study accounting for 60 central venous catheters and a total of 533 catheter days. Dressing disruptions occurred more frequently and at sooner time point in the control group. Skin integrity issues were significantly less observed in the intervention group. No differences in CVC colonisation or central line-associated bloodstream infection were observed.

Conclusions: The application of a barrier film creating a skin-protective polymer layer beneath transparent catheter dressings is associated with less dressing disruptions and less skin integrity issues without altering the risk of infectious complications if used in combination with a chlorhexidine-impregnated catheter dressing.

Implications for clinical practice

- Catheter dressing disruptions and skin integrity issues such as hyperaemia at the insertion or skin irritations are associated with an increased risk of catheter colonisation and subsequent infection.
- Chlorhexidine-impregnated catheter dressings protect against central line-associated bloodstream infection.
- Application of an acrylic terpolymer skin-protective barrier film around the catheter insertion site results in less dressing disruptions and less skin integrity issues while not altering the risk of catheter colonisation or infection, at least not when used in combination with a chlorhexidine-impregnated catheter dressing.
Introduction

Bloodstream infections represent an important source of infectious morbidity in critically ill patients as they rank third among all nosocomial infections (Agbaht et al., 2007; Blot et al., 2009; Vincent et al., 2009; Tabah et al., 2012; Dimopoulos et al., 2013). About one third of nosocomial bloodstream infections are related to the insertion of intravascular catheters, mostly central line-associated bloodstream infection (CLABSI) (Safdar et al., 2002; Blot et al., 2003). Pooled estimates of mean occurrence rates of CLABSI are 4.4 CLABSI per 100 devices inserted (95% confidence interval [CI] 4.1–4.9) and 2.7 CLABSI per 1000 catheter days (95% CI 2.6–2.9) (Maki et al., 2006). In addition, CLABSI carry a substantial economic burden through an added length of hospitalisation and excess hospital costs (Blot et al., 2005; Warren et al., 2006; Higueras et al., 2007; Schwebel et al., 2012). As a consequence a variety of measures to prevent CLABSI are advocated. These include educational initiatives and use of care bundles or checklists to optimise adherence with local recommendations, optimal catheter insertion site selection, maximal sterile barriers during catheter insertion, adequate disinfection of the insertion site and use of chlorhexidine gluconate (CHG)-impregnated washcloths for daily bathing (Hu et al., 2004; Labeau et al., 2008, 2009; Blot et al., 2014a; Afonso et al., 2016; Arvaniti et al., 2016; Labeau et al., 2016; Mimoz et al., 2016; Arvaniti 2017). Recently, the use of CHG-impregnated dressings have demonstrated to significantly reduce the risk of catheter infections (Timsit et al., 2012b). Notwithstanding this innovative dressing, accidental dressing disruptions remain a particular risk factor for CLABSI (Timsit et al., 2012a). Timsit and colleagues demonstrated that the risk for CLABSI increased exponentially with the number of dressing disruptions: a hazard ratio (HR) of 1.2 (95% confidence interval [CI] 0.5–7.5) for a first disruption, a HR 3.3 (95% CI 1.2–9.0) for a second disruption, and a 12.5 HR (95% CI 4.0–39.6) for a third dressing disruption. Therefore, dressings are designed to have an adequate adhesive potential. However, this includes a potential risk of skin breakdown that, on its turn, is a risk factor for CLABSI as well because skin lesions contain a substantial number of potentially pathogenic microorganisms. In order to avoid adheres-related skin breakdown a skin product has been developed creating a polymeric protective film. This film-forming liquid acrylate proved valuable to protect integrity of the peri-wound skin in chronic ulcers (Schuren et al., 2005). To the best of our knowledge however, this barrier film has never been used to protect the skin from adhesive catheter dressings. In addition, it is uncertain to which extent the use of such a barrier film affects the adhesive potential of the catheter dressings. Furthermore, it is uncertain whether the application of this barrier film facilitates CVC colonisation. The objective of this study is to compare the standard use of transparent dressings with transparent CHG-impregnated catheter dressings with use of a skin-protective barrier film. Primary outcomes were skin integrity and risk of dressing disruption. Secondary outcomes were rates of central venous catheter (CVC) colonisation rates and CLABSI rates.

Methods

Setting

The study was executed during a five months period (August to December 2014) in a specialised 12-bed intensive care unit (ICU) for patients with infectious diseases or septic complications at the Pirogov National Medical Surgical Center, Moscow. The local ethics committee approved the study and informed consent was required either from the patient or a legal representative if the patient was unable to do so prior to study enrollment. In the latter case, the patient was informed at a later stage and asked if he/she concurred with the using the data for research purposes. The study data are reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement.

Study design

A monocentric, open-label, randomized controlled trial was conducted to compare standard transparent dressings with transparent CHG-impregnated catheter dressings (3 M Tegaderm CHG®, 3 M Health Care, St. Paul, MN, USA). In addition, in the CHG-dressing group the patients’ skin was treated with a liquid film-forming acrylate (Cavilon® “No Sting Barrier Film”, 3 M Health Care, St. Paul, MN, USA). The barrier film was applied on the skin area immediately around the CVC insertion site. As such the study resulted in a control group of patients with standard transparent polyurethane CVC dressings and an intervention group with CHG-impregnated transparent polyurethane CVC dressings with use of the skin protective ointment. Patients were randomised following a random number generator.

Patient selection and follow-up

Besides informed consent, patients were eligible for study inclusion when they were adult (≥16 years of age), had a clinical indication for central venous catheterisation and an anticipated length of catheter indwelling time of seven days. Exclusion criteria included known allergy to chlorhexidine or dressing adhesives. Patients were randomised to the control or the intervention group before CVC insertion and follow-up of the patients lasted until CVC removal. Patients could only be included once in the trial.

Outcomes

Primary outcomes were average dressing dwell time, number of dressing disruptions and skin integrity. Skin integrity was judged upon the following observations: (i) hyperaemia of the insertion site, (ii) presence of skin irritations under the dressing, (iii) residues of adhesives on the skin and (iv) moisture under the dressing. In dressing disruptions we considered either partial or full dressing disruptions. Partial dressing disruption is defined as loosening of the dressing without revealing the CVC insertion site, while full dressing disruption is defined as loosening of the dressing leaving the CVC insertion site uncovered.

Secondary outcomes included observations associated with either inflammation or infection, i.e. presence of discharge from the insertion site, CVC colonisation rates and CLABSI rates. After removal the CVCs the catheter tips were evaluated for colonisation by semiquantitative (roll-plate) culture (Maki et al., 1977). Hereby, catheter colonisation was defined as a microbial growth of >15 colony forming units (Mermel et al., 2009). As we evaluated the efficacy of dressings, only the external surface of the catheter was evaluated for microbial colonisation.

Patient characteristics

Data were collected in order to compare patient characteristics between the two groups. These included demographics, concomitant medication, underlying conditions and aspects reflecting severity of acute illness. For the latter we reported the acute physiology and chronic health evaluation (APACHE) II score and the sequential organ failure assessment (SOFA) score (Knaus et al., 1985; Vincent et al., 1996). Furthermore, the need for organ support either at the time of study enrollment or during the complete study course was
reported. These included the need for mechanical ventilation, renal replacement therapy and vasopressors or inotropes.

Standard care

Standard catheter care included alcohol-based antiseptic (0.5% chlorhexidine in 70% ethanol) for skin preparation before CVC insertion, maximal sterile barriers including broad coverage of the patients with sterile drapes, and use of sterile gowns and gloves of the operator, mask and hat. After the insertion procedure, the CVC was covered with either the standard transparent dressing or the CHG-dressing according to the result of the randomisation process. Catheter dressings were changed every seven days, or in case of full dressing disruption or if moisture was present under the dressing. Dressings were not changed in case of partial dressing disruption provided the coverage of the insertion site.

Statistics

Descriptive variables are reported as n (%) or mean (standard deviation) and median (interquartile range). Comparisons between the study groups are executed with the Mann Whitney U test or Fisher Exact test as appropriate. Colonisation and CLABSI rates are expressed per 1000 CVC days. The Kaplan-Meier method with a log-rank test was used to compare survival curves of both treatment groups describing time until first dressing disruption. Statistical significance is defined as p < 0.05.

Results

Patient population

Fig. 1 describes the study flow diagram. Sixty patients were enrolled in the study accounting for 60 CVCs and a total of 533 CVC days. No patients were excluded during the study and no patient was lost to follow up. Characteristics of patients with standard and CHG-dressings are shown in Table 1. No important differences were observed between the two groups in gender, age, CVC insertion site and dwell time, use of concomitant therapy, underlying conditions and severity of disease as assessed by organ failure and the need for organ support. All CVCs used were triple-lumen catheters. Reasons for CVC removal were not different between the groups and included no further need for a CVC (n = 28), clinically suspected CLABSI (n = 19), mortality (n = 7), and planned CVC change because of the need to initiate renal replacement therapy (n = 5).

Primary outcomes

Outcomes are reported in Table 2. Dressing dwell time was significantly higher in the intervention group. Main reasons for dressing changes included full dressing disruptions and moisture beneath the dressing, which were more commonly observed in the control group. Fig. 2 describes the Kaplan-Meier survival curves comparing the time until the first dressing disruption. Dressing
disruption occurred more frequently and at a sooner time point in the control group (Log rank test: p < 0.001).

Overall skin integrity issues were more commonly observed in the control group (p = 0.001). This significant difference could mainly be attributed to the presence of moisture under the dressing and hyperaemia at the insertion site.

Secondary outcomes

Discharge from the CVC insertion site was only observed in two cases in the control group. All CVCs were cultured. Rates of CVC colonisation or infection per patient numbers are reported in Table 2. In addition, we calculated these infectious indices per 1000 catheter days. Rates of CVC colonisation were not different (37.9/1000 CVC days in the intervention group vs. 37.0/1000 CVC days in the control arm [relative risk 1.22, 95% confidence interval 0.59–2.5]) as were CLABSI rates (6.9/1000 vs. 20.6/1000 CVC days [relative risk 0.4, 95% confidence interval, 0.08–1.9]).

Discussion

In this randomised controlled trial we assessed the value of a barrier film creating a polymer skin-protective layer around the catheter insertion site on dressing disruptions and skin integrity.
Catheter colonisation and CLABSI rates were secondary outcomes. Dressing disruptions as well as skin integrity issues occurred more frequently in the control group.

This finding is important as dressing disruptions as well as skin breakdown in the immediate surrounding of the insertion site are potential risk factors for CVC colonisation and subsequent infection (Timsit et al., 2012a). While Cavilon® skin barrier film has been proved successful in maintaining integrity of the peri-wound skin, as far as we know it has not been evaluated beneath catheter dressings. As such it remains uncertain what the effect of this barrier film would be on likelihood of dressing disruptions and infectious complications. An absolute decrease in CLABSI rates was observed, but the study lacked power to demonstrate statistical significance. This non-significant reduction in CLABSI risk can be attributed to the fact that a CHG-dressing was used in the intervention group. This dressing significantly reduced CLABSI risk in a large multicenter randomised controlled trial and these results were later on confirmed in a meta-analysis including nine randomised studies (Timsit et al., 2012b; Safdar et al., 2014). While a favorable effect of the barrier film in terms of skin integrity could be expected based on previous studies, and albeit that skin integrity has a negative effect on the risk of CVC colonisation/infection, it remained uncertain whether the use of this barrier film in the immediate zone of the insertion site could have increased the risk of infectious complications. Based on our observations we can state that the use of a product creating a polymer skin-protective film does not negatively influence the risk of catheter infection, at least not when used in combination with a CHG-impregnated catheter dressing.

We must recognise that CLABSI rates in our study were high with rates of about 7/1000 and 20/1000 CVC days in the intervention group and the control group, respectively. In a systematic review of quality improvement initiatives to reduce the risk of CLABSI, six studies were identified with a baseline CLABSI rate >15/1000 CVC days (Blot et al., 2014a). Our study must be situated within this range. The high CLABSI rate might be partially explained by the specific patient population as the study was conducted in an ICU specialised to treat patients suffering from infectious complications. In addition, the cohort was older with about a quarter of patients aged over 70 years and high occurrence rates of organ failure. Older age as well as multiple organ failure are well-recognized risk factors for infectious complications in general (Blot and Vandewoude 2004; Vandewoude et al., 2004; Reynvoet et al., 2009; Reunes et al., 2011; Blot et al., 2014b; Sousa et al., 2017). Furthermore, the standard nurse-to-patient ratio is 1:3 while nursing shifts last for 24 hours. Especially the latter contributes to an excessive workload which is associated with sub-optimal compliance with recommendations in infection prevention and indicated as a main barrier to comply with local protocols in ICUs (Rello et al., 2002; De Wandel et al., 2010; Lambert et al., 2013; Valencia et al., 2016; Battistella et al., 2017; De Wandel 2017; Piras et al., 2017; Sadule-Rios and Aguilera 2017; Velasquez Reyes et al., 2017).

**Limitations**

This study has limitations. As already mentioned the sample size was not powered for detecting differences in CLABSI rates. Moreover, the fact that two different dressing were used makes an evaluation of infectious complications at the catheter site difficult. Because two interventions were combined in the intervention group it is not possible to evaluate the value of the acrylic terpolymer barrier film in combination with a standard polyurethane dressing. As such it is, at least theoretically, possible that the application of the barrier film increases the risk of CVC colonisation, but that in this study this (unproven) deleterious effect has been erased by the use of a CHG-impregnated dressing in the intervention group. In the same line, we cannot rule out that the chlorhexidine gel pad absorbed small proportions of the barrier film, but this unlikely as the substance is compatible with CHG. This might have influenced the properties of the dressing and as such the outcomes. However, the skin-protective barrier film was carefully applied in the zone around the gel pad where the adhesive part
of the transparent dressing secures connection with the skin. As dressing disruption starts when these outer parts of the dressing loose contact with the skin, we believe that the eventual influence of combining the barrier film with the CHG-dressing only marginally might have impacted to study outcome. Finally, subsequent dressing disruptions were not recorded. However, the fact that only the first dressing disruption was considered is unlikely to change the final conclusion, i.e. the barrier film protects against accidental dressing disruptions.

Conclusion

The use of a skin product creating a polymer protective film beneath transparent dressings results in longer dressing dwell times and less skin breakdown. The application of the skin product with barrier film to the skin results in reduced dressing dwell times and less skin breakdown. We believe that the barrier film secures connection with the skin. As a consequence, the dressing disruption rate was reduced.

References

Agbati, K., Diaz, E., Muñoz, E., Lisboa, T., Gomez, F., Depuydt, P.O., et al., 2007. The use of a skin product creating a polymer protective film beneath transparent dressings results in longer dressing dwell times and less skin breakdown. The application of the skin product with barrier film to the skin results in reduced dressing dwell times and less skin breakdown. We believe that the barrier film secures connection with the skin. As a consequence, the dressing disruption rate was reduced.

Ethical statement

This study was approved by the ethics committee at the FGBU "NMHC of NI Pirogov" of the Ministry of Health of Russia (Protocol no. 3 of 4 June 2014). Address: Moscow, Nizhne Pervomaiskaya street 70. All patients or legal representatives gave informed consent for the study.

Conflicts of interest

- S. Blot received lecture fees from 3 M.
- I.V. Zhivoteva received lecture fees from 3 M.
- 3 M supported the study with the free provision of Tegaderm CHG dressing and Cavilon “No Sting Barrier Film” for research purposes only.