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# 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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ABSTRACT

*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 lotion 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 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.

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## 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; Higuera 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 adhesives-related skin breakdown a skin lotion has been developed creating a polymer 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 film-forming lotion 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 lotion affects the adhesive potential of the catheter dressings. Furthermore, it is uncertain whether the application of this lotion 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 protective skin lotion. 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 (lotion) 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

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