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Major article

Clinical evaluation of a chlorhexidine intravascular catheter gel dressing on short-term central venous catheters

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Background: A major source of microbial colonization of short-term central venous catheters (CVC) is the patients' endogenous skin microorganisms located at the CVC insertion site. The aim of this study was to determine if a transparent film dressing incorporating a 2% (weight/weight) chlorhexidine gluconate (CHG) gel decreases CVC and insertion site microbial colonization compared with a nonantimicrobial dressing in adult patients in critical care.

Methods: On CVC removal, samples for microbiological investigation were taken from both the skin surrounding the CVC insertion site and also from sutures securing the CVC. The sutures and intradermal and tip sections of the CVC were also collected for microbiological investigation. Microorganisms recovered from the samples were subsequently tested for susceptibility to CHG.

Results: There was a significant reduction in the number of microorganisms recovered from the CVC insertion site, suture site, sutures, and catheter surface in the CHG dressing group (n = 136) compared with the nonantimicrobial dressing group (n = 137). There was no significant difference in susceptibility to CHG between the microorganisms isolated from the CHG and standard dressing study patients.

Conclusion: A film dressing incorporating a CHG gel pad significantly reduced the number of microorganisms at the CVC insertion and suture sites with concomitant reduced catheter colonization.

Central venous catheters (CVCs) are widely used in patients for treatment and hemodynamic monitoring. A prevalence survey of health care–associated infections in acute hospitals in England in 2006 demonstrated that 7.3% of patients had a CVC inserted while in the hospital.[1] In the critical care environment, CVC utilization rates are high, being 64.6-66.3 per 100 patient days in England.[2]

The use of CVCs is still associated with relatively large number of infections, resulting in increased patient morbidity, mortality, and health care costs.[3] In England, the mean adult critical care acquired central venous catheter–related (CR) bloodstream infection (BSI) rate between 2009 and 2010 was 1.88 per 1,000 CVC patient days.[2] This is despite a reduction in infection risk associated with the use of CVCs and other intravascular (IV) catheters in recent years. The application of best practice guidelines for improved IV catheter insertion and catheter care, incorporated into national guidelines such as the Saving Lives and Matching Michigan programs, have contributed to this success.[2-4] Further reductions in CVC-associated BSI rates may be achievable with improved adherence to CVC care guidelines, including strict aseptic practice during CVC insertion and manipulation and appropriate support of hospital management.[3,5,6]

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Conflicts of interest: Elliott and Karpanen have received honoraria to present at a symposium and attend an International Conference supported by 3M. Elliott has also received honoraria for attendance at advisory board meetings. The other authors have no conflicts to declare.

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Infection prevention strategies target the potential sources of infection. Short-term CVCs may become colonized via migration of microorganisms from the CVC insertion site down the external catheter surface, during manipulation of catheter hubs, hematogenous seeding from another site of infection, or contaminated infusates.[7,8] To prevent microbial contamination of a CVC from the skin at the CVC insertion site, appropriate skin antisepsis is of paramount importance. However, antiseptic skin preparations do not fully eradicate skin microorganisms, which may then recolonize the surface. Furthermore, CVC movement relative to the skin may actively introduce microorganisms from the skin at the insertion site into the catheter tract. Indeed, securement of CVCs onto the skin to prevent CVC movement is not only important in preventing CVC dislodgement, but it also decreases the risk of introducing microorganisms into the catheter tract and the subsequent development of catheter-related infection (CRI).[9]

Sutures are widely used to secure CVCs onto the skin because of their efficacy, ease of application, and low cost. However, sutures can trigger an inflammatory response and may increase the risk of infection. Sutures used for the securement of CVCs disrupt the protective skin barrier at the CVC insertion site and are in contact with subcutaneous tissue and microorganisms present in lower layers of the skin, including the hair follicles. These microorganisms may therefore persist after skin antisepsis.[10] These conditions support microbial multiplication, which may be followed by attachment to and biofilm formation on the suture material. Microorganisms within such biofilms are less susceptible to antimicrobial agents and may serve as a niche for subsequent infection.[11-13] Although Yamamoto et al[14] demonstrated a reduction in CR BSI in a group of patients who had peripherally inserted central catheters secured with a suture-less securement device when compared with securement with sutures, the authors did not investigate microbial colonization at the peripherally inserted central catheter insertion site. To our knowledge, there have been no published studies on suture materials implanted to secure CVCs and their contribution to colonization of the skin around the CVC insertion site and their potential role in CRI. This is despite the recognition that microorganisms present on the skin at the IV catheter insertion site may migrate along the external catheter surface to the catheter tip, therefore potentially contributing to CRI.[7,15] Sutures could thereby be an overlooked potential source of CRI, including infection at the insertion site and CR BSI.

Aims and objectives

The antimicrobial efficacy of a chlorhexidine gluconate (CHG) gel dressing used in patients with a CVC was studied. The assessments included determination of the number of microorganisms at the CVC insertion site, CVC-securing suture sites, sutures, and CVC segments after catheter removal. Any microbial selection between the 2 study groups was monitored, and microbial susceptibility to CHG was investigated. Furthermore, adverse reactions to the study dressing and CRI were monitored.

METHODS

Investigational products

3M Tegaderm CHG I.V. Securement Dressing (3M Health Care, St Paul, MN), an adhesive, semipermeable, transparent polyurethane film dressing incorporating a transparent gel pad containing 2% (w/w) CHG (CHG dressing group), was compared with 3M Tegaderm I.V. Dressing (3M Health Care, St Paul, MN), an adhesive, semipermeable, transparent polyurethane film dressing containing no antimicrobial (standard dressing group).

Study design

Research ethics committee (NRES Committee North West - Greater Manchester South, 11/H1003/4) and the University Hospitals Birmingham NHS Foundation Trust approvals were obtained prior to the study. Written informed consent was received for all study subjects.

The study was a prospective, comparative, single-center clinical study. The study was not blinded because the 2 study dressings could be identified by the user.

The nonantimicrobial standard dressing study phase was divided into 2 study periods, before and after the CHG dressing phase, to negate any coincidental temporal effect unrelated to the study dressing. Prior to the study, the nonantimicrobial 3M Tegaderm I.V. Dressing was part of standard CVC care in our hospital. After recruitment of half of the standard dressing group patients, the CHG dressing was introduced. Appropriate training of staff was undertaken prior to and during the changeover period. After the CHG dressing phase, the standard dressing was reintroduced to the critical care area, and the second half of the standard dressing group was studied.

Study population

The study was carried out between January 2013 and October 2014 at a large university hospital, which had 75 critical care beds divided into 4 units. In addition to general medical and surgical patients, the study participants included patients from the following disciplines: cardiac surgery, neurosurgery, trauma, and liver, heart, and lung transplantation.

Adult patients ($\geq$18 years of age) admitted to the critical care unit and who required a CVC as part of their clinical management were considered to take part in the study. Patients with existing BSI, known hypersensitivity to the study dressing or CHG, pregnant or breastfeeding women, and patients with eczema, rash, lesions, burns, or other skin conditions, which may have affected the skin integrity at the CVC insertion site, were excluded from the study. Only 1 CVC per patient was studied.

Estimation of the number of study subjects

A minimum of 136 CVCs were required in each study group to achieve 80% power at the 5% significance level assuming a baseline rate of CVC tip colonization of 30% and a 50% reduction in this incidence with the use of the CHG dressing.[16] The study was not powered to study BSI rates.

Neutralizing solution

The CHG neutralizing solution contained 2% volume/volume (v/v) Tween 80 (BDH, Poole, UK), 1.17% weight/volume (w/v) lecithin (Fisher Scientific, Loughborough, UK), 0.5% (w/v) sodium thiosulphate (BDH, Poole, UK), and 0.1% (v/v) Triton X-100 (Sigma-Aldrich, Poole, UK) in distilled water.[17]

Determination of the number and type of microorganisms

Samples for microbiological analysis were taken at the time of CVC removal. Samples around the CVC insertion site and around the sutures securing the CVC were taken using a swab moistened in 0.9% (w/v) sodium chloride and a sterile template (2 cm in diameter