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Indwell times, complications and costs of open vs closed safety peripheral intravenous catheters: a randomized study☆

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SUMMARY

Background: Catheter-related infections (CRIs) caused by peripheral intravenous catheters (PIVCs) are an increasingly common iatrogenic complication. To prevent this, recommended timelines for routine replacement of PIVCs have increased from 48 h to 72 h and subsequently to 96 h, despite a lack of supporting scientific evidence.
Aim: To compare closed-system (COS) PIVCs with open-system (MOS) PIVCs.
Methods: This prospective, randomized controlled trial compared the indwell time of COS PIVCs without complications with that of MOS PIVCs, removed only by clinical indication. In total, 1199 PIVCs (642 inpatients) were randomized and 283 PIVCs were cultured. Sixteen catheters (11 patients) were lost to the study after randomization.
Findings: In total, 104,469 catheter-hours (54,173 h in 584 COS and 50,296 h in 599 MOS) were recorded. The median dwell time was 137.1 h for COS PIVCs and 96 h for MOS PIVCs ($P = 0.001$). Among PIVCs in place for ≥24 h, the median dwell time was 144.5 h for COS PIVCs [95% confidence interval (CI) 123.4–165.6] and 99 h for MOS PIVCs (95% CI 87.2–110.8). Use of COS PIVCs reduced phlebitis rates by 29% (31 vs 45 cases/1000 catheter-days; $P = 0.004$). The probability that a MOS PIVC would last for 96 h was 79.9%, and the probability that a COS PIVC would last for 144 h was 80.4%. There were no significant differences in rates of bacterial colonization per 1000 catheter-days (51.1 COS vs 54.1 MOS) or CRI (5.76 COS vs 6.65 MOS). Nevertheless, there was a 20% relative risk reduction in CRI.
Conclusion: Use of COS PIVCs reduced episodes of phlebitis and risk of infection at a cost of only €0.09/day. When PIVCs are replaced based on clinical indication, COS PIVCs last for up to 144 h and MOS PIVCs last for up to 96 h without increased risk and with significant cost savings (€786,257/year/1000 beds).

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Introduction

Peripheral intravenous catheters (PIVCs) are the most commonly used invasive devices (150 million/year in the USA).[1] In Spain, nearly 50% of inpatients receive an intravenous catheter, almost 95% of which are peripheral. PIVCs have been recognized as a source of *Staphylococcus aureus* bacteraemia in 12–50% of all catheter-related bloodstream infections (CRBSI),[2,3] and are the cause of considerable morbidity and mortality, prolonged hospital stay and an increased cost[4,5] of up to €3700 per episode.[6]

It has been reported that nearly half of PIVC-related bacteraemias are associated with phlebitis,[3,7] which is the most important complication of PIVCs[4] (approximately 20% of patients).[7–9]

Catheter-related complication (CRC) rates are thought to be associated with the length of time that the catheter remains in the vein (indwell time). The timelines for routine replacement have been the subject of controversy and uncertainty. Over the years, they have increased from 48 h to 72 h[10,11] and, most recently, to 96 h.[12] However, such recommendations are based primarily on dated studies (1975,[10] 1987[11] and 1998[12]) that did not take recent manufacturing changes in PIVC technology into account.

Safety PIVCs, which reduce the risk of sharps injury, have been introduced recently. Needleless connectors create 'closed systems' that have lower rates of microbial contamination compared with three-way 'stopcocks'.[13,14] However, safety devices cost more than conventional devices, and 'integrated closed devices'[15] cost even more than open ones. To the authors' knowledge, this is the first study to compare open and closed safety PIVCs.

Methods

Objectives and definitions

The COSMOS study was a randomized controlled trial to investigate the clinical performance of two state-of-the-art safety PIVC systems: a 'compact' closed system (COS) and a 'mounted' open system (MOS), both of which should only be removed from patients when clinically indicated. The two systems were compared in terms of effectiveness (insertion success, maintenance, utility), efficacy (indwell time without complications), safety for professionals and patients against accidental needlestick injury or CRC rates (phlebitis, pain, painful haematoma, infiltration/extravasation, occlusion, bacterial colonization, suspicion of infection by unexplained fever, catheter-related infection) and efficiency (cost analysis).

Catheter-related infection (CRI) was defined as the growth of more than 15 colony-forming units of the same species in semiquantitative culture of catheter tips removed as a result of phlebitis, pain or the suspicion of infection due to unexplained fever, or by defervescence within 24 h of catheter removal.[5,16,17]

Study design and sample

This prospective, open label, parallel-group randomized control trial was conducted in three medical (61 beds) and surgical (154 beds) wards at the Hospital Clínico 'San Carlos', a 1000-bed tertiary university hospital in Madrid, Spain, for 108 days between March and July 2008. The 126 nurses who comprised the staff of the three wards participated as field researchers. PIVCs were inserted and maintained in accordance with the guidelines of the US Centers for Disease Control and Prevention (CDC),[5] except for routine replacement recommendations (i.e. catheters were only removed when clinically indicated). The needleless connector was replaced routinely every eight days (after up to 64 activations), which is less than the 70 activations reported by Adams *et al.*[18]

All patients aged ≥18 years needing a PIVC for at least 24 h were evaluated for inclusion in the study. Informed consent was obtained and enrolled patients were randomized into the COS or MOS PIVC group. Patients were excluded if they were participating in another study, had a PIVC placed under emergency conditions, had a synchronous catheter (PIVC, intravenous midline, peripherally inserted central catheter or central venous catheter) or had a fever of ≥38 °C.

The sample size was calculated on the assumption of a phlebitis rate of 15% in the MOS group at 72 h, a 5% reduction in the COS group, alpha error of 0.045 and beta error of 0.20. Phlebitis was chosen as the endpoint because it is the most common complication associated with CRI and PIVC removal.[4,5] The minimum calculated accrual number was 435 catheters in each arm of the study.

After the first 420 patients were enrolled, an interim analysis revealed that nurses had been less familiar with COS PIVCs than MOS PIVCs at study initiation (17.2% vs 82.8% of nurses; respectively), because MOS PIVCs had been used in the hospital for years while COS PIVCs had only been introduced recently. This led the investigators to increase the target sample size to 1200 catheters so that the learning curve would have no impact on clinical outcomes.

At least 141 catheters from each group were selected at random and cultured to determine baseline colonization rates. This sample size assumed a 9.5% rate of catheter contamination[17] with a 95% confidence level and a false-positive sample error rate of 3%. The size of the sample was adequate to detect a difference in the frequency of colonization between the systems of 10%, with an alpha error of 0.05 and a power of 80% (beta error 0.20). Catheters were evaluated using Maki's semiquantitative culture technique.[16] Laboratory technicians and microbiologists who cultured the catheter tips were blinded to the study group assignment.

Randomization was computer generated.[19] Study variables and their definitions have been described elsewhere.[20]

Materials

The COS PIVC (Figure 1) used in this study was the Nexiva closed intravenous catheter system with a Q-Syte luer access split-septum connector (BD, Franklin Lakes, NJ, USA). The catheter is made of Vialon (a proprietary polyurethane) with integrated extension tubing, a stabilization platform (wings) and a passive needle shielding mechanism. A second Q-Syte was added in order to close the Y-connector completely.

The MOS PIVC (Figure 1) used in this study was the Vasocan safety catheter (B. Braun, Melsungen, Germany), made of polytetrafluoroethylene (PTFE). This catheter has wings and a passive safety mechanism. A three-way tap ('stopcock') with 10 cm of extension tubing (BD Connecta) with a luer/luer-lock Sollner cap (Amebil, Basauri, Spain) was added.