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Major Article

A prospective clinical trial to assess peripheral venous catheter–related phlebitis using needleless connectors in a surgery department

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Background: The use of intravascular catheters is often complicated by phlebitis, which is associated with increased morbidity and extended duration of hospitalization. We conducted a study to investigate the impact of needleless intravenous access devices on the rate of phlebitis in peripheral venous catheters (PVCs).

Methods: We prospectively recruited patients in 2 phases. The first group was treated with a regular cap, and the second group was treated with a needleless connector. The incidence of catheter-related phlebitis (CRP) was recorded as the primary end point.

Results: A total of 620 PVCs using regular caps were inserted into 340 patients and CRP rates were recorded. In the second phase of the study, 169 PVCs using needleless connectors were inserted into 135 patients. In the group treated with the regular cap, the CRP rate was 60% compared with 7% in the group treated with the needleless cap ($P < .001$). Consequently, the number of catheter replacements was decreased from 1.9 on average to 1.3 ($P < .001$). In both phases, patients who developed phlebitis had a statistically significant longer mean hospitalization period ($P < .001$), as were patients in the regular cap group ($P < .01$).

Conclusions: The use of needleless connectors was found to be associated with a significant reduction of CRP in peripheral veins in a surgery department setting. The decreased morbidity resulted in a lower number of catheter replacements and duration of hospitalization.

Intravascular catheters represent an essential part of the management of patients. However, their use can be complicated by infection, mostly phlebitis, which is associated with increased morbidity, longer hospital stay, and additional medical costs.[1] The incidence of catheter-related phlebitis (CRP) varies considerably by type of catheter, frequency of catheter manipulation, and patient-related factors, such as underlying disease and severity of illness.[1] Most catheter-related bloodstream infections are associated with central venous catheters,[1] and in prospective studies the relative risk for catheter-related infections was found to be up to 64 times greater with central venous catheters than with peripheral venous catheters (PVCs).[2-5] The rate of phlebitis in PVCs was 20% in a prospective trial that was published this year.[6]

Recently, the Society of Critical Care Medicine, in collaboration with leading societies and associations in the field, published guidelines for prevention of intravascular catheter-related infections.[1] The guidelines recommend using needleless connectors and suggest changing the needleless components at least as frequently as the administration set, but not more frequently than every 72 hours. They also recommend minimizing contamination risk by scrubbing the access port with an appropriate antiseptic (chlorhexidine, povidone iodine, an iodophor, or 70% alcohol) and accessing the port only with sterile devices.

For short-term venous catheters (ie, those in place <10 days), which are most commonly colonized by cutaneous organisms along the external surface of the catheter, the most important preventive systems are those that decrease extraluminal contamination. Such a preventive device is the needleless connector.

The use of needleless intravenous access devices, introduced to reduce the risk associated with occupational exposure of health care workers to bloodborne pathogens,[7] has been associated with an increased rate of catheter-related infections,[8-10] which may be related

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to improper handling and inaccurate use of these devices.[11,12] However, the potential for needleless connectors to increase the risk for catheter-related infections is uncertain, and recent clinical trials have shown that these devices do not increase the risk for infection[13] when they are used correctly and in combination with rigorous aseptic techniques.

CRP, when using PVCs, is associated with significant morbidity, mortality, and additional medical costs.[14] Nevertheless, most PVC-related infections are preventable, and preventive strategies should aim at achieving maximal antiseptic barrier precautions during catheter insertion, catheter site maintenance, and hub handling. Moreover, many of these techniques have proven to be not only effective health-wise but are also cost-effective.[15]

In this study, the rate of phlebitis in peripheral veins was assessed when either a standard luer cap or needleless connector was used in an academic hospital surgery department setting.

METHODS

Hypothesis

Our hypothesis was that phlebitis rates would be lower when using needleless connectors in PVCs compared with the regular luer caps, and that the number of PVC replacements would decrease.

Patients

Patients included were those admitted to the Department of Otolaryngology—Head and Neck Surgery at Galilee Medical Center, and who required a PVC as part of their treatment. Inclusion criteria were patients age >18 years, with no hospital admissions in the previous month, and that were treated with intravenous antibiotic. Exclusion criteria were readmissions within the previous month and single-day admissions.

Clinical protocol

An institutional review board approved the study prior to its initiation. The study was a prospective study with 2 phases. All patients were treated with the same intravenous antibiotics of amoxicillin and clavulanic acid in normal saline. In the first phase of the study a standard luer cap (Heparin cap; Gil Medical, Petach Tikva, Israel) was placed on the catheter, and in the second phase a needleless connector (Needle-free valve 2000E7D, CareFusion, San Diego, CA) was used (Fig 1). The PVC was inserted in a noninfected area. Standard methods for pre-PVC insertion skin preparation and disinfection of the intravenous connections were used as follows: isopropyl alcohol 70% (wt/wt) was used to clean the insertion site of the PVC cap and was allowed to dry, as recommended by the 2011 guidelines of the Healthcare Infection Control Practices Advisory Committee.[1] All other variables, such as patient population, medical staff, sterilization techniques, type of intravenous antibiotic used, and other equipment, were the same in the 2 phases of the study. The incidence of CRP was recorded as well as the catheter size, location, drape used, and demographic and clinical data of the patients. The rate of CRP was the primary end point, and difference in the rate of phlebitis between the 2 phases was calculated.

Assessment of CRP

Any sign of inflammation (redness, pain, swelling, or warmth), regardless of its severity, in the distal vein where the PVC was inserted, was considered to be phlebitis. The PVC was then removed, and a new PVC was inserted in the patient's other arm using the same protocol, and using the same cap type.

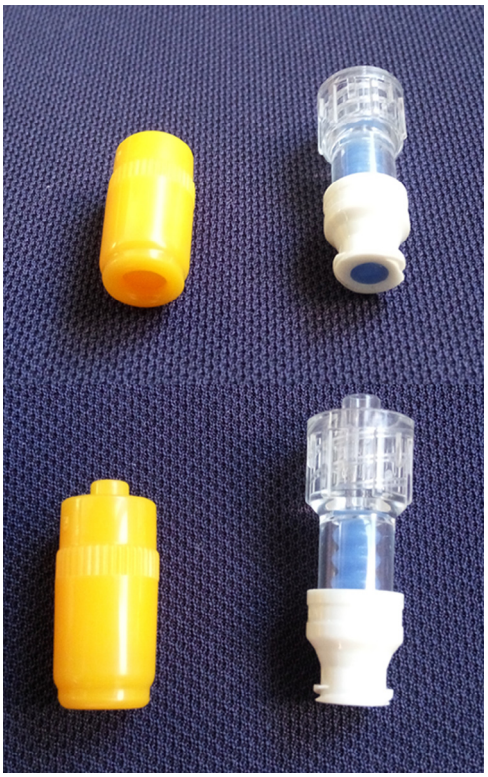

Fig 1. The 2 caps used in the study. On the left is a standard luer cap (Heparin cap) and on the right is a needleless connector (Needle-free valve 2000E7D).

Outcome measures

The main end point was the incidence of CRP in the 2 phases. The secondary end points were the duration the PVC was used, the number of PVCs used in each group, and hospitalization duration.

Statistical analysis

Quantitative data were described by means and SD, and medians and ranges. Qualitative data were described by frequencies and percentages. For the univariate analysis, quantitative data were compared between the phases by independent *t* test or Wilcoxon rank-sum test according to the size of the groups compared and the distribution within the groups. Qualitative data were compared between the phases and groups by χ^2 test or Fisher exact test. For the multivariate model, a multivariate logistic regression model was developed to assess the different variables responsible for CRP rates. A P value <.05 was considered as significant. For sample size calculation, assuming a decrease of 50% (60% phlebitis rate vs 30% after intervention) is a significant result, 340 patients in the baseline phase and 135 patients after intervention, using a 2-sided χ^2 test, with an α of 5%, the achieved power is maximal (100%).

RESULTS

In the first phase, a total of 620 PVCs were inserted using regular luer caps in 340 patients; in the second stage, 169 PVCs using needleless connectors were inserted in 135 patients. There were no differences in the composition of the 2 phases, with equal sex distribution and an average age of 38 years at baseline and 35 years after the intervention. Systemic diseases of the patients at baseline were diabetes mellitus (6%) and hypertension (14%), with no statistically significant differences with the patients followed after