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Short report

Pre-filled normal saline syringes to reduce totally implantable venous access device-associated bloodstream infection: a single institution pilot study

S. Bertoglio [a,b,*], R. Rezzo [a], F.D. Merlo [c], N. Solari [a], D. Palombo [a], F. Vassallo [d], S. Beltramini [e], A. DeMaria [f,g]

[a] *Department of Surgical Sciences (DISC), University of Genova, Largo Rosanna Benzi 10, 16132 Genova, Italy*
[b] *Surgical Oncology Unit, Department of Surgery, IRCCS AOU San Martino–IST National Institute for Cancer Research, Largo Rosanna Benzi 10, 16132 Genova, Italy*
[c] *Epidemiology, Biostatistics and Clinical Trials, IRCCS AOU San Martino–IST National Institute for Cancer Research, Genova, Italy*
[d] *Health Nursing Office, IRCCS AOU San Martino–IST National Institute for Cancer Research, Largo Rosanna Benzi 10, 16132 Genova, Italy*
[e] *Clinical Pharmacy Unit, IRCCS AOU San Martino–IST National Institute for Cancer Research, Largo Rosanna Benzi 10, 16132 Genova, Italy*
[f] *Department of Health Sciences (DISSAL), University of Genova, Largo Rosanna Benzi 10, 16132 Genova, Italy*
[g] *Infectious Diseases Unit, IRCCS AOU San Martino–IST National Institute for Cancer Research, Largo Rosanna Benzi 10, 16132 Genova, Italy*

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SUMMARY

Flushing totally implantable venous access devices (TIVADs) with manually filled saline syringes may increase contamination and catheter-related bloodstream infection (CRBSI). We used a retrospective cohort study to assess the impact of changing from manually filled syringes to manufactured pre-filled syringes on the frequency of CRBSI in 718 TIVADs. Manually filled syringes were used in 269 patients and pre-filled syringes in 449. The CRBSI rate was 2.7% in the pre-filled syringe group and 6.3% in the manually filled syringe group ($P = 0.016$). Sex, tumour type and stage, access site and access body side were not independent risk factors for CRBSI.

Introduction

Totally implantable venous access devices (TIVADs) are used extensively in adult cancer patients. Complications requiring removal can mostly be prevented by adequate insertion and management procedures.[1] These may reduce catheter-related bloodstream infections (CRBSIs) that are associated with mortality, morbidity and increased hospitalization costs. Flushing

* Corresponding author. Address: AOU San Martino–IST National Institute for Cancer Research, Largo Rosanna Benzi 10, 16132 Genova, Italy. Tel.: +39 010 5600869; fax: +39 010 352090.
E-mail address: sergio.bertoglio@istge.it (S. Bertoglio).

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and locking procedures for TIVADs at established intervals are frequently required to ensure catheter patency.[2] There is a 5–8% contamination risk when using manually filled syringes, contributing to CRBSI risk.[3,4] Manufactured pre-filled saline syringes avoid the need for manual filling of disposable syringes on the wards, thereby reducing the risk of contamination. This study compares the use of pre-filled syringes with manually filled syringes for flushing and locking procedures of TIVADs in adult cancer patients with a focus on reducing CRBSIs.

Methods

This was a retrospective observational cohort study of 718 TIVADs implanted in adult cancer patients at the National Institute for Cancer Research, Genova, between September 2009 and August 2011. The study followed the principles of the Helsinki Declaration and was approved by the institutional review board. It compared the outcomes of TIVAD implantation in two consecutive patient groups before and after switching from 10 mL manually filled to 10 mL pre-filled syringes for flushing and locking procedures in April 2010. All patients were outpatients undergoing chemotherapy. TIVADs were used for chemotherapy purposes only. In all, 269 TIVADs were flushed or locked between 1 October 2008 and 31 March 2010 with 10 mL manually filled syringes, and 499 implanted between 1 April 2010 and 30 September 2011 with pre-filled syringes (BD Saline PosiFlush 0.9% saline, 10 mL pre-filled sterile syringe; BD, Franklin Lakes, NJ, USA). Patients were implanted with a 6.5 F silicone open-ended non-antimicrobial-impregnated catheter TIVAD (LP-venous Health Port, Baxter S.A., Lessines, Belgium) by four equally trained surgeons using a standardized technique. The two policies for flushing and locking TIVADs were used consistently in all patients within each of the two study periods. Other aspects of TIVAD management and skin care nursing protocols were unchanged. TIVADs were flushed or locked with a pulsatile method and slow flow rate before their use and after every access. Minimum follow-up was six months. Patients' medical records were reviewed for baseline characteristics, date of implant, complications and TIVAD removal. Patients who died within the follow-up period were retained in the study population and recoded as without complications. The primary aim of the study was to determine the efficacy of pre-filled compared with manually filled syringes in preventing CRBSI. Sex, pathology, disease stage, venous access site and side were evaluated as independent prognostic factors. In the event of CRBSI the TIVAD was always removed. Other reasons for removal, including deep venous thrombosis, pocket infection, fibrin sheathing, catheter occlusion and skin erosion by the TIVAD chamber were investigated.

Definitions

CRBSI was defined according to Infectious Diseases Society of America guidelines:

- isolation of the same micro-organism in peripheral blood and TIVAD cultures, or
- three-fold difference in paired quantitative cultures of blood samples drawn from TIVAD and peripheral vein, or
- 2 h earlier culture positivity in blood collected from TIVAD than in blood from a peripheral vein.

Deep venous thrombosis was defined by ultrasonography showing the presence of a thrombus with partial or complete occlusion of the vein. Fibrin sheathing was defined as the presence of a pericatheter thrombus involving the catheter tip demonstrated by contrast injection radiology. Catheter occlusion was defined as the inability to infuse saline despite the use of manual pressure on the piston of a $\geq$10 mL syringe.

Statistics

We recorded the frequency (%) of CRBSI in the pre-filled and the manually filled syringe groups, and the following factors: sex, pathology (other cancers, breast cancer, colon cancer), stage of the disease (any T/N0, any T/N+, stage IV/M+), access site (internal jugular vein, subclavian vein), and body side (right, left). The associations between CRBSI and study factors were investigated using multivariate logistic regression analyses. The factors were included in a full model as predictors of CRBSI. The final model was obtained by means of a backward procedure (Wald test statistics $P < 0.05$). Odds ratios and 95% confidence intervals were computed. Two-sided $P < 0.05$ was considered significant.

Results

This study included 734 consecutive implanted TIVADs. Medical records of 16 patients were missing, leaving 718 patients for statistical analysis. In all, 269 TIVADs were flushed and/or locked with manually filled syringes and 449 with pre-filled syringes. The two groups were similar with respect to baseline clinical characteristics (Table I).

Sixty-six devices (9.2%) were removed for complications, 32 (11.9%) in the manually filled syringe group and 34 (7.5%) in the pre-filled syringe group. The incidence of CRBSI was significantly higher in manually filled syringe patients (17/269, 6.3%, 0.37 per 1000 catheter-days) than in pre-filled syringe patients (12/449, 2.7%, 0.24 per 1000 catheter-days) ($P = 0.016$). There was never more than one CRBSI per TIVAD. Other complications requiring removal, such as pocket infection, deep venous thrombosis, fibrin sheathing, skin erosion and catheter occlusion, occurred in 15/269 (5.8%) manually filled syringe patients and in 22/449 (4.7%) pre-filled syringe patients ($P = 0.691$). Multivariate analysis confirmed a significant association between pre-filled syringe use and a reduction in CRBSI (odds ratio: 0.40; 95% confidence interval: 0.19–0.86; $P = 0.019$) (Table II). Sex, cancer type, stage of disease, access site and side were not found to be risk factors for CRBSI.

The profile of pathogenic micro-organisms responsible for CRBSI was similar in manually filled and pre-filled syringe groups. Staphylococci (*Staphylococcus aureus* and coagulase-negative staphylococci) were the most frequently isolated micro-organisms accounting for 17/29 (59%) of CRBSIs. Their frequency was 10/17 (59%) in the manually filled syringe group and 7/12 (58%) in the pre-filled syringe group. *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeuruginosa* and *Enterococcus* spp. accounted for 6/17 (35%) CRBSIs in the manually filled syringe group and 5/12 (42%) CRBSIs in the pre-filled syringe group. *Candida albicans* was the cause of CRBSI in one manually filled syringe patient. There was no relevant morbidity (for example endocarditis) or death attributable to infection. No adverse events were recorded with pre-filled syringe use.