CLINICAL STUDY

Complication Rates Observed in Silicone and Polyurethane Catheters of Totally Implanted Central Venous Access Devices Implanted in the Upper Arm

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ABSTRACT

Purpose: To present frequency and types of complications related to silicone (SI) versus polyurethane (PUR) catheters of totally implanted venous access devices (TIVADs) placed in the upper arm.

Material and Methods: A cohort of 2,491 consecutive patients with TIVADs implanted between 2006 and 2015 was retrospectively analyzed. Complications were classified according to SIR guidelines. Pearson χ^2 test was used for categorical variables, and Student t test was used for continuous variables. Nominal P values were reported, and 2-sided P values $< .05$ were considered significant.

Results: Of 2,270 patients meeting the inclusion criteria, 538 had an SI catheter, and 1,732 had a PUR catheter. Total dwell time was 584,853 catheter days. Mean total complication rate was 12.25% (SI, 14.87%; PUR, 11.43%; $P = .040$). Subanalysis revealed significant differences for material failures (eg, catheter fracture [SI, 3.35%; PUR, 0.06%; $P < .001$] and thrombotic catheter occlusion/venous thromboses [SI, 2.79%/0.74%; PUR, 1.33%/3.17%; $P < .001$]) but nonsignificant differences for infections (eg, local infection and catheter-related sepsis [SI, 4.64%; PUR, 4.68%; $P = 1$]) or other nonthrombotic dysfunctions (eg, catheter detachment, line migration, wound dehiscence [SI, 3.35%; PUR, 2.19%; $P = .179$]).

Conclusions: The reported data suggest different risk profiles in SI catheters compared with PUR catheters, with more material failures and thrombotic catheter occlusions in SI catheters and more venous thromboses in PUR catheters.

ABBREVIATIONS

PUR = polyurethane, SI = silicone, TIVAD = totally implanted venous access device

Reliable and convenient vascular access is an integral component of modern multimodality treatment, including chemotherapy, medication administration, parenteral nutrition, supportive treatment, and blood products. Totally implanted venous access devices (TIVADs) such as port systems have gained wide acceptance with increased availability of catheters of different materials, mainly silicone (SI) or polyurethane (PUR) (1,2). Regardless of the benefit (3), in vivo TIVADs are exposed to multifactorial strain and are associated with complications, such as infection, thrombosis, or material failure (2,4–6). Although most complications are non–life-threatening events, they may lead to interruption of medical treatment.

Essentially 2 types of TIVADs have been used since initiating percutaneous placement in our department in 2006 (**Fig 1a, b**). Despite a similar design of multicomponent devices used, there are distinct differences regarding the attached catheters. The Cook Vital-Port Mini Titanium (Cook, Inc, Bloomington, Indiana) is attached to an SI catheter, and the Titanium SlimPort (Bard Access Systems, Inc, Salt Lake City, Utah) is attached to a PUR catheter. The purpose of this study was to present the frequency and types of complications related to an SI catheter versus a PUR catheter for TIVAD placed in the upper arm over a 10-year period in a retrospective single-center observation.

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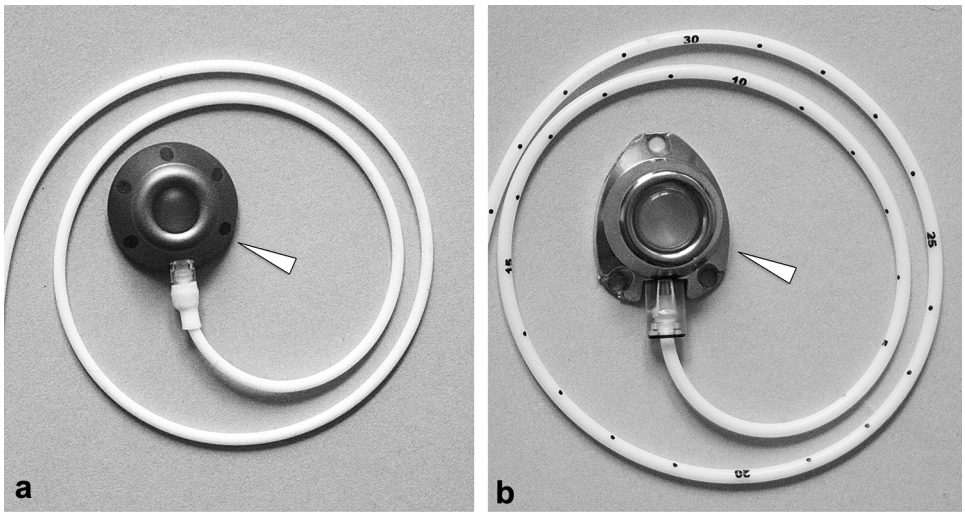

Figure 1. Differently designed TIVADs. **(a)** Cook Vital-Port Mini Titanium composed of a circular, tapered port hub (arrowhead) attached to a 5.0-F SI catheter and **(b)** Titanium SlimPort with a trapezoid port hub (arrowhead) attached to a 6.0-F polyurethane catheter.

MATERIALS AND METHODS

Study Design

The local institutional review board approved this retrospective single-center cohort study and waived the requirement for written informed consent. Between January 2006 and December 2015, 2,491 patients were referred to the interventional radiology department for fluoroscopic-guided implantation of a TIVAD in the upper arm. Data pertaining to the first device for each patient were analyzed. Further inclusion criteria were patients $\geq$ 18 years old at time of procedure, completely documented implantation of either a Cook Vital-Port Mini Titanium or a Titanium SlimPort, and documented follow-up time interval $>$ 1 day. Patient data were censored at the time of first complication, device removal, date of last follow-up, or death. The end of the study was March 2016 (3 months after last TIVAD placement).

TIVAD Implantation Technique

Hemostatic disorders (ie, platelet count $<$ 50,000/μL and international normalized ratio $>$ 1.5), bacteremia, and septicemia were regarded as absolute contraindications. Typically, the nondominant arm was used, with the exception of thrombosis of the implantation site, ipsilateral axillary lymph node dissection, or previously embedded pacemakers or automated implantable cardioverter-defibrillators. The basilic vein was the preferred and prevailing access site, but in individual cases of insurmountable puncture obstacles (eg, preexisting thrombosis), accessible veins were used alternatively.

All procedures were performed by a radiologist with at least 2 years of practice in venous access procedures. Before implantation, deep vein thrombosis of the accessed side was evaluated for using venography (Integris Allura; Philips Healthcare, Best, Netherlands). Thereafter, under strictly aseptic conditions and after local anesthesia, contrast venography-guided vein access was achieved. Port hub placement was performed in the lower third of the upper arm, and the catheter line was tunneled from the puncture site to the port pocket. In accordance with current recommendations, patients did not receive prophylactic antibiotics or routine anticoagulation during the follow-up period. After successful insertion with fluoroscopic confirmation of correct catheter tip positioning at the cavoatrial junction (defined as 2 vertebral bodies below the carina) (7), implanted systems were flushed with sterile heparinized saline (5 mL of a solution containing 100 IU/mL) (3,8).

Specification of TIVADs

From January 2006 to February 2011, the Cook Vital-Port Mini Titanium was used in 553 consecutive patients. This device comprises a tapered titanium port hub (base radius 19.0 mm, height 7.2 mm) attached to a single-lumen 5.0-F SI catheter with inner/outer diameter of 1.0/1.7 mm. From January 2011 to December 2015, the Titanium SlimPort was used in 1,938 consecutive patients. This device comprises a tapered trapezoid titanium port hub (base 19.0 $\times$ 24 mm, height 9.4 mm) attached to a single-lumen 6.0-F PUR catheter with inner/outer diameter of 1.3/2.0 mm.

Follow-up

Patients were assessed by an interventional radiologist 1–4 days after implantation and were immediately referred to the interventional radiology department if TIVAD-related complications were suspected. Medical data were obtained retrospectively by reviewing the radiologic information system (Centricity; GE Healthcare, Little Chalfont, United Kingdom). In patients who were lost to follow-up before removal of the TIVAD or who died within the study period, the last date of documented regular catheter usage was recorded.

Data Analysis

The following characteristics were assessed: technical feasibility, successful implantation with correct catheter tip positioning and aspiration of blood as well as flushing of the