CLINICAL STUDY

Randomized Clinical Trial Evaluating Complications and Complication-Related Removal of Arm-Situated Power-Injectable and Non–Power-Injectable Totally Implanted Venous Access Devices among Cancer Patients

Brent Burbridge, MD, FRCPC, Chris Plewes, MD, FRCPC, Grant Stoneham, MD, FRCPC, Peter Szkup, MMRadD, FCR(D)SA, FRCPC, Rob Otani, MD, FRCPC, Paul Babyn, MD, FRCPC, and Rhonda Bryce, MD, MSc

ABSTRACT

Purpose: To evaluate the hypothesis that power-injectable totally implanted venous access devices (TIVADs) situated in the arm are associated with more frequent complications and complication-related removal than non–power-injectable arm TIVADs among adult cancer patients.

Materials and Methods: In this single-center trial, 211 adult chemotherapy patients were randomized to receive either a power-injectable or a non–power-injectable arm TIVAD. Follow-up involved a standardized telephone interview 1 week after insertion, followed by a chest X-ray, arm X-ray, and Doppler ultrasound at 3 months and 12 months. Online complication reporting was also provided by patients and care providers for a minimum of 1 year. The primary end point was removal for port-related complications; the secondary end point was the occurrence of any port-related complication.

Results: Forty-two complications occurred (19.9% of patients), precipitating the removal of 6 power-injectable ports and 7 standard ports. Time-to-removal did not differ between TIVAD types (hazard ratio 0.75, 95% confidence interval [CI] 0.25–2.24; $P = .61$). Complications were related to thrombosis, infection, or mechanical issues, with no statistical difference between groups for overall occurrence (23.1% vs 17.0%, odds ratio 1.47, 95% CI 0.74–2.92; $P = .27$); however, by type of complication, thrombosis occurred more frequently among power-injectable TIVAD patients (15.2% vs 6.1%, odds ratio 2.79, 95% CI 1.04–7.44; $P = .03$).

Conclusions: There was no difference in port-related complication occurrence or complication-related removal when using the arm power-injectable port compared with the non–power-injectable port among cancer patients.

ABBREVIATION

TIVAD = totally implanted venous access device

When considering totally implanted venous access devices (TIVADs, ports), power injection capability coupled with arm situation is appealing for ease of placement, accessibility, and contrast delivery. However, power-injectable devices (1,2) and peripheral placements (3,4) are not without complications. Literature review concerning

From the Department of Medical Imaging (B.B., G.S., P.S., R.O., P.B.) and Clinical Research Support Unit (R.B.), College of Medicine, University of Saskatchewan, Royal University Hospital, 103 Hospital Drive, Saskatoon, Saskatchewan, Canada S7N 0W8; and Department of Radiology and Diagnostic Imaging (C.P.), University of Alberta, Edmonton, Alberta, Canada. Received July 22, 2017; final revision received November 16, 2017; accepted November 26, 2017. Address correspondence to B.B.; E-mail: brent.burbridge@usask.ca

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Tables E1–E4 and Appendix A are available online at *www.jvir.org*.

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arm-implanted power-injectable TIVADs uncovered a single retrospective chart review with infectious and thrombotic complication rates of 5.9% and 9.9%, respectively (5).

The Smart Port CT Mini Power-Injectable (PI) Port (Angiodynamics, Latham, New York) has a slightly taller hub than the non–power-injectable (NPI) Vital-Port Mini Titanium (Cook Medical, Bloomington, Indiana) at 10.8 mm versus 7.2 mm, and a thicker 6.6-F versus 5.0-F venous catheter. The power-injectable capability of the Smart Port allows for higher flow rates and volumes of injected fluids but potentially at an increased risk of complications. Bonciarelli et al reiterated previous warnings distributed by the United States Food and Drug Administration regarding the risk of catheter and device damage potentially invoked by high levels of power injection (6). Because thrombosis rates around peripherally inserted central catheters (PICCs) show correlation with catheter diameter (7), power-injectable ports also may have higher thrombosis rates.

Additional information about arm power-injectable port complications could help physicians to evaluate device benefits, namely, the facilitation of computerized tomographic and magnetic resonance imaging (important in malignancy surveillance) against risks of venous thrombosis, complication-related failure, and device removal. Therefore, the purpose of the present study was to compare the frequency and nature of complications between port types, hypothesizing a greater frequency of complication-related removal among power-injectable arm ports.

MATERIALS AND METHODS

A concurrent randomized clinical trial of the Smart Port CT Mini and the Vital-Port Mini was performed at Royal University Hospital, Medical Imaging, Saskatoon, Saskatchewan, Canada. Each port was inserted by 1 of 4 fellowship-trained interventional radiologists, each with a minimum of 10 years of experience in TIVAD placement. Before the study, imaging technologists likely to be involved in the care of these patients were instructed in port access, particularly regarding the power-injectable model, to ensure that the devices were used appropriately. The primary end point was removal for port-related complications; the secondary end point was the occurrence of any port-related complication. The project, including the imaging protocol, received approval from the institution's Research Ethics Board before commencement. The trial was registered with ClinicalTrials.gov (NCT02282449). Written informed consent was obtained from every participant at enrollment. Patients provided consent for participation in the research project separate from consent for port placement with the use of a project-specific consent form.

Inclusion criteria for the project included any patient who required a TIVAD for chemotherapy to treat a malignancy. Exclusion criteria excluded patients with any known previous adverse reaction to vein ports or venous catheters, pregnant patients, patients with insufficient venous access for arm port placement, patients in whom chest port placement was requested, and patients <18 years of age.

Table 1. Baseline Subject Characteristics by Port Type, n (%)

Characteristic	Overall	Port Type	
		PI* (Smart Port Mini) (n = 109)	NPI (Vital-Port Mini) (n = 102)
Age (y), mean ± SD	58.7 ± 13.0	58.7 ± 13.4	58.7 ± 12.6
Sex			
Male	70 (33.2)	41 (37.6)	29 (28.4)
Female	141 (66.8)	68 (62.4)	73 (71.6)
Malignancy			
Colorectal	80 (37.9)	44 (40.4)	36 (35.3)
Breast	76 (36.0)	37 (33.9)	39 (38.2)
Other	55 (26.1)	28 (25.7)	27 (26.5)
Arm used			
Right	67 (32.1)	34 (31.8)	33 (32.4)
Left	142 (67.9)	73 (68.2)	69 (67.6)
Vein used			
Basilic	163 (78.0)	83 (77.6)	80 (78.4)
Brachial	37 (17.7)	20 (18.7)	17 (16.7)
Cephalic	9 (4.3)	4 (3.7)	5 (4.9)

NPI = non–power-injectable; PI = power-injectable.
*Arm and vessel missing for 2 subjects.

All chemotherapy patients referred to the interventional radiology division for TIVAD placement during the recruitment period (July 1, 2013, to June 30, 2015) were evaluated for inclusion. Patients and researchers were blinded to port group allocation until consent was obtained; however, further blinding of port type during placement and follow-up was impractical. A computer-generated table was used for simple random allocation of each patient to 1 of the 2 TIVAD types. The randomized table was followed by the interventional radiology team at the time of patient attendance for TIVAD insertion.

Patients

During the enrollment phase of the project, TIVAD insertion was attempted for 211 patients. One patient who was initially randomized to the PI group had technical failure of the placement and returned for an additional insertion attempt of the same port type in the opposite arm, with subsequent success. All patients received a single port of the type indicated by the randomization schedule, with no substitutions or replacements either at insertion or during follow-up. Among the 211 patients, 109 (51.7%) received a PI port and 102 (48.3%) received an NPI device. Table 1 provides a comparison of patient characteristics at insertion, with similar age, malignancy type, arm placement, and vessel placement between the groups. The average age of the sample was 58.7 ± 13.0 years. The ratio of women to men was 2:1, largely due to the predominantly female sex of the breast cancer cases, representing approximately one-third of the total cases (breast: 36.0%; colorectal: 37.9%; other: 26.1%).