A randomized trial of valved vs nonvalved implantable ports for vascular access

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Background: Vascular access devices placed into the central venous system are used routinely in the medical management of many patients. Catheter tip occlusion is a common complication of open-ended catheters, causing difficulty with blood withdrawal and infusion. This study evaluated whether a valved subcutaneous port system would have fewer associated complications than a standard nonvalved port.

Methods: Study subjects requiring port placement were randomized to receive a PASV (valved) port or a nonvalved BardPort. Standard technique was used to place both types of ports. Patients were monitored for 180 days after implantation, and data on major complications were collected. Difficulty with blood return and excess time spent accessing the port were studied as indicators of catheter tip occlusion. This study is an interim analysis of an ongoing prospective study, with an anticipated accrual of 100 patients.

Results: Fifty-four patients were randomized to receive either the PASV port (n = 27) or a BardPort (n = 27). All patients required venous access for treatment of malignancy. No major complications were identified from port placement. No patient had major sepsis due to infected catheters. Overall complications included catheter leakage in 1 patient (3.7%, BardPort) and venous thrombosis in 1 patient in each group (3.7% per group). Difficulty in blood draw was noted in the PASV group on 16 of 273 (5.9%) port accessions and in the BardPort group on 30 of 266 (11.3%) accessions ($P = 0.04$). Thrombolytic agents were required in 14 (5.1%) port accessions in the PASV group and 21 (7.9%) port accessions in the BardPort group ($P = 0.25$). Significantly more total time was spent ensuring adequate blood draw from BardPorts as opposed to PASV ports (870 vs 435 minutes, respectively) ($P = 0.01$).

Conclusion: This initial analysis reveals that the valved PASV port system is associated with significantly fewer instances of poor blood return and thus decreases the time required for nurses to obtain blood return before infusion.

Vascular access devices placed in the central venous system are used routinely in the medical management of many patients. These devices provide access to the vascular system for the delivery of fluids, intravenous medications, blood products, chemotherapy, and parenteral nutrition solutions. They are also useful for frequent blood sampling. Several complications related to these devices are possible, including catheter occlusion, infection, air embolus, and venous thrombosis. Catheter clotting and related complications cost the US health care system an estimated >$1 billion per year, in addition to patient inconvenience and morbidity (1, 2).

The failure to achieve blood return on initial access of the port is a measurement that is rarely reported in clinical studies involving ports. This failure can be due to catheter tip occlusion from thrombus or a fibrin sheath, mechanical kinking or disruption of the catheter, or a catheter tip abutting the wall of a vein. When blood cannot be drawn, nurses usually spend additional time flushing the catheter, replacing the access needle, and possibly repositioning the patient. Chest radiography is used to evaluate the position and structural integrity of the catheter. Suspected thrombotic occlusion of the catheter tip is often treated with thrombolytic agents, which incur significant cost.

Catheter tip thrombosis is possibly due to reflux of blood in the distal tip of the catheter. This may occur when infusions terminate, during significant intrathoracic pressure changes, during infusion bag "run-dry," or when the access needle is removed, generating a negative pressure in the port. In a typical port, blood will fill the distal catheter tip up to 5 mm during removal of the access needle. Strategies to minimize blood reflux in the catheter include valves to prevent retrograde flow of blood. PASV central venous catheters and ports (Boston Scientific Corporation, Natick, Mass) have a pressure-activated safety valve (PASV) that is designed to reduce the incidence of occlusion complications. A small silicone safety valve is positioned close to the port. The valve is designed to allow infusion through a venous access device at normal infusion pressures. The valve opens for aspiration at higher pressures created by aspirating with a syringe. This allows for deliberate withdrawals of blood for testing but significantly reduces the risk of blood reflux into the distal tip of the catheter during normal pressure fluctuations in the superior vena cava. This safety valve reduces the risk of "flow-back" of blood into the catheter when an infusion has ended.

A prior clinical study using valved peripherally inserted central catheter (PICC) lines compared with nonvalved PICC lines showed a decreased rate of catheter clotting (1). The current study evaluated whether rates of catheter occlusion and complications were diminished with use of the PASV port system compared with standard open-ended products currently used.

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METHODS

Patients

This prospective randomized trial was conducted at Baylor University Medical Center and was approved by the institutional review board. Eligible study subjects were ≥18 years with a diagnosis of venous insufficiency requiring central venous access with a single-lumen port. Patients were excluded if they had a central venous access port within the preceding 6 months or if they were fully anticoagulated for any reason. Subjects signed an informed consent for inclusion into the study. This report represents a planned interim analysis of an ongoing prospective study with an anticipated accrual of 100 patients.

Catheters, implantation, and catheter maintenance

PASV catheters are constructed of implant-grade silicone, with a physical appearance similar to that of other open-ended products on the market today. Implant/insertion procedures were identical to those used with other available products. Patients were randomly assigned to undergo implantation of a 9.6F single-lumen valved PASV port catheter or a similar-sized control nonvalved BardPort (Bard Access Systems, Salt Lake City, Utah). The BardPort is currently the single-lumen port most often placed at this institution. Catheter placement was performed by standard technique into either the subclavian or internal jugular vein. Placement was confirmed with intraoperative fluoroscopy and documented by postoperative chest radiograph. The ability to draw blood from the port and to infuse fluid was confirmed by accessing the port intraoperatively.

All therapies infused through the catheter were administered according to the appropriate manufacturer's recommendations. All catheters were flushed with 10 mL of normal saline (PASV port) or heparinized saline (BardPort), as indicated by the port manufacturer, after infusion and every 3 to 4 weeks when not in use. Patients who exhibited signs or symptoms of catheter-related infection were treated appropriately. Catheter occlusion was assessed as to the suspected etiology. Catheters suspected to be occluded with blood products were treated with tissue plasminogen activator (t-PA) per standard hospital protocol.

Data collection

Patients were monitored for the purposes of this study for 180 days or until the port was removed. Patients were interviewed by a study coordinator at baseline, 90 days, and 180 days after catheter implantation. Nursing records were also reviewed to evaluate adequacy of port function. Data collected included any antibiotic treatment, difficulty drawing blood or infusing through the port (including number of events), need for further studies (chest radiography, duplex ultrasonography, or contrast studies), and hospitalizations related to the port. Time to access the port was prospectively documented by nursing personnel at each accession. Uncomplicated access was defined as 0 minutes. Additional time spent ensuring adequate blood draw and flushing was recorded at each visit. The use of thrombolytics to reestablish catheter patency was recorded.

Major complications related to placement of the device were defined as hemothorax and pneumothorax. Major complications during the follow-up period were defined as catheter infection requiring treatment with antibiotics or port removal, catheter tip thrombosis requiring thrombolytics, catheter transection or leakage, and venous thrombosis.

Table 1. Baseline demographic data

Variable	PASV (n = 27)	BardPort (n = 27)
Gender, n (%)		
Female	24 (88.9)	20 (74.1)
Male	3 (11.1)	7 (25.9)
Median age, years (range)	55.3 (23–83)	54.9 (25–76)
Site of malignancy, n (%)		
Breast	18 (66.7)	16 (59.2)
Gastrointestinal	3 (11.1)	3 (11.1)
Hematologic	2 (7.4)	4 (14.8)
Gynecologic	2 (7.4)	1 (3.7)
Genitourinary	1 (3.7)	2 (7.4)
Lung	1 (3.7)	1 (3.7)

Table 2. Major complications during the first 180 days after port implantation

Complication	PASV (n = 27)	BardPort (n = 27)
Port site cellulitis, n (%)	2 (7.4)	0
Catheter sepsis, n	0	0
Catheter leakage, n (%)	0	1 (3.7)
Venous thrombosis, n (%)	1 (3.7)	1 (3.7)

Statistical method

Demographic and disease characteristics were summarized for all patients by using descriptive statistics. Baseline incidence of demographic variables, device complications, and additional time spent caring for catheters was compared between experimental and control groups by using 2-sample asymptotic *t* tests for proportions. Statistical significance was defined as $P < 0.05$. All statistical calculations were performed by using StatView 5.0 (SAS Institute Inc, Cary, NC).

RESULTS

Fifty-four patients were evaluated for 180 days after implantation and comprise the study set for this report. All 54 patients were being treated for an underlying malignancy. Twenty-seven patients were implanted with a PASV port and 27 with a BardPort. Baseline demographic data are shown in *Table 1*. No significant differences were identified between the 2 groups. No major complications due to the placement of these devices occurred.

All 54 patients were monitored for the entire 180-day period. Major complications during this time period are shown in *Table 2*. No significant differences were observed between the 2 groups. One patient in the BardPort group was found to have a fractured catheter at the connection to the port, which was documented by a contrast study. This port was subsequently removed. One patient in each group had an internal jugular venous thrombosis, which was treated with anticoagulation. Two patients in the PASV group were treated for cellulitis surrounding the port

Table 3. Port access the first 180 days after implantation

Variable	PASV (n = 27)	BardPort (n = 27)	*P* value
Total accessions, n	273	266	—
Inability to draw blood, n (%)	16 (5.9)	30 (11.3)	0.04
Tissue plasminogen activator use, n (%)	14 (5.1)	21 (7.9)	0.25
Total time to resolve inadequate blood return, minutes	435	870	0.01
Mean time per patient spent resolving inadequate blood return, minutes/event	27.1	29.0	0.88

pocket that occurred in the perioperative period (before the first accession of the port).

The ability to draw blood was assessed each time the ports were accessed. Port access totals and difficulties withdrawing blood over the 180-day follow-up period are shown in *Table 3*. PASV ports were associated with significantly fewer difficulties drawing blood compared with BardPorts (5.9% vs 11.3%, respectively) ($P = 0.04$). Generally, the inability to obtain blood return led to the use of t-PA. In several patients, t-PA was not required; thus, there was a trend toward less use of t-PA in the PASV group, although this did not reach statistical significance. Additional time spent assessing and treating inadequate blood draw in the BardPort group was twice that in the PASV group, due to the increased frequency of inadequate blood draw in the BardPort group. The mean time spent resolving each occurrence of poor blood draw was similar in the 2 groups.

DISCUSSION

Vascular access devices are commonly used for blood draws, intravenous hydration, and administration of medications in patients with a variety of illnesses. The first devices described by Broviac and then by Hickman were tunneled under the skin and also contained a subcutaneous cuff (3, 4). Totally implantable access ports have the advantages of not requiring an external dressing, allowing more patient activity, and requiring only monthly maintenance flushing, and they are associated with fewer infections and complications than tunneled catheters (5, 6). Implantable venous access devices are associated with an overall complication rate of 10% to 15% (7). The use of central access is often interrupted due to catheter thrombosis inhibiting blood draw or infusion and has been reported in up to 12.5% to 28% of patients (6, 8).

Valved catheters that resist retrograde flow of blood under physiologic pressures will theoretically resist collection of blood in the distal catheter, thereby preventing catheter thrombosis. This would result in facile access of the port by nursing staff and would likely result in fewer treatment interruptions and interventions for the patient. This study examined a valved port system and compared the outcomes with those of the same-sized standard nonvalved port system.

There were no demonstrable differences in infectious complications between the PASV group and the BardPort group. There were 2 episodes of postoperative port-site cellulitis, both of which occurred in the PASV group. Both episodes occurred before first access and use of the port and are considered a perioperative complication and not because of catheter use or design. Sepsis related to catheter infection has not occurred in either group; however, approximately 5% of patients with subcutaneous ports are treated for sepsis, according to published reports (5, 7). This rate of sepsis usually occurs in patients who are monitored long-term with central access compared with the 180-day evaluation period in this study. Other major complications such as venous thrombosis and catheter fracture are much less common, occurring at rates of 2.0% to 2.5% and 0.2%, respectively (7–9). The present study was not powered to detect significant differences in the aforementioned complications due to their low incidence.

The focus of this study was to detect differences in a clinically relevant endpoint: difficulty in drawing blood. Significantly fewer incidents of poor blood draw were reported in the PASV group (5.9%) compared with the BardPort group (11.3%). This is possibly due to the port design and its resistance to blood reflux and potential catheter tip thrombosis. The current study also quantified the extra time it takes an oncology nurse to troubleshoot and treat a potentially occluded catheter when difficulty with blood draw was identified. This time is usually spent reaccessing the port, flushing the system, and repositioning the patient. T-PA is generally utilized in these situations as well. An extra 27.1 to 29 minutes was spent on troubleshooting problem ports in the oncology office, which is a significant inconvenience to the patient, the nurse, and the flow of the office in general. A cost analysis of the inability to draw blood will be reported at the conclusion of the full study.

A previous study randomized 365 patients to peripherally placed PASV PICC lines and standard nonvalved PICC lines. Overall complications, including catheter occlusion and infection, occurred in 6.6% of subjects in the valved group and in 14.2% of subjects in the nonvalved group ($P = 0.02$). Catheter occlusion by itself occurred in 3.3% vs 7.1% in the valved vs nonvalved groups, respectively, but this did not reach statistical significance.

One other reported prospective randomized trial compared a valved with a nonvalved subcutaneous port system (8). A group of 302 patients was implanted with a standard port and catheter or a port connected to a Groshong catheter, which has a valve at the distal tip of the catheter. There were no significant differences between the groups at a mean follow-up of 237 days. There tended to be more difficulties drawing blood with the valved catheter (12.5%) than the nonvalved catheters (2%), although statistical significance was not achieved. Nonrandomized studies have similarly failed to identify a significant benefit to the valved Groshong catheter tip (10, 11). This may be because the Groshong valve is in the bloodstream and requires an inconsistent amount of pressure for aspiration and infusion.

The current study suggests that the PASV valved port is associated with fewer difficulties drawing blood. This is the first trial to evaluate a port system with a valve in the port itself and is the first to show an advantage to a valved port system.

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