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A Randomized, Prospective Trial of Conventional Vascular Ports vs. The Vortex "Clear-Flow" Reservoir Port in Adult Oncology Patients

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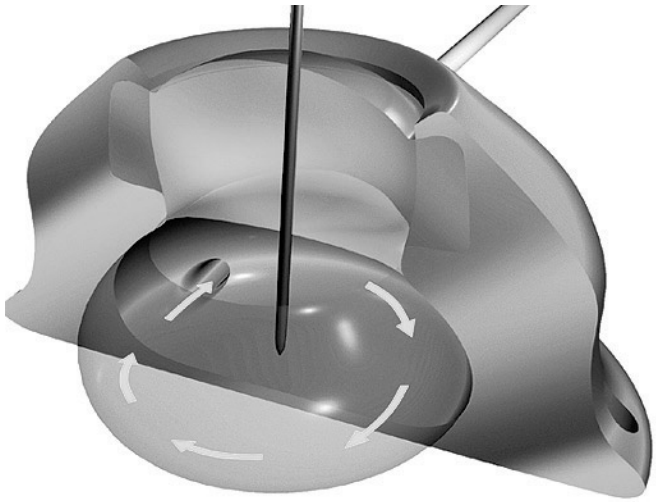
Introduction

Vascular access ports were developed to overcome many of the problems associated with limited peripheral access, combined with the need for frequent venipuncture, in oncology patients receiving long-term, intensive therapy. Since their introduction in 1983, implantable vascular access ports have become a standard of use in the treatment of oncology diseases. Currently, over 200,000 ports are implanted in the United States each year and their popularity is increasing.

Vascular access ports have proven to be very beneficial in overcoming the need for frequent venipuncture in the treatment of long-term venous therapies. However, a review of the literature does reveal many problems associated with their use. The most common complications associated with the use of vascular access ports are occlusions and thrombus formations.



Clinical studies consistently have shown occlusion rates of between 25% and 33%, and infection rates of between 5% and 15% with the use of ports.[1-16] The difficulty frequently experienced with withdrawing blood from a port (withdrawal occlusion) or the complete inability to withdraw blood or infuse fluids (total occlusion) is usually the result of a thrombus, either within the reservoir of the port or the catheter itself or due to fibrin sheath formation at the tip of the catheter. Thrombus formation and/or drug residuals (sludge) within the port reservoir have been associated with occlusions and an increased risk of infections.

Any port that is proven clinically to reduce occlusion and infection rates will have a significant impact on patient care and clinical outcomes. The primary purpose for conducting this study was to compare the performance of conventional vascular ports with that of a port with a differently designed reservoir in a clinical environment, focusing on the areas of access, flushing, occlusions, and overall complications.

Methods

Ninety-five (95) adult oncology patients seen at the Toledo Oncology Clinic, Toledo, Ohio, with the need for long-term central venous access between May 28, 1997 and September 30, 1999, received either a Vortex port (Horizon Medical Products, Manchester, GA) or a conventional port (various manufacturers). The selection process was based on the last digit of the patient's social security identification number, with even-numbered patients receiving a Vortex port and odd-numbered patients receiving a conventional port. This selection process was not revealed to the nursing staff in order to protect the blinding procedure.

Prior to the start of the study, an explanation of the context of the study was sent to area surgeons who had frequently implanted ports for the practice in the past. The surgeons were informed that their secretary would be notified of the port type required at the time a request for implantation was made. Area hospital surgical departments were also informed. When the randomization required a conventional port, the surgeon could choose any port available to him/her. As the study progressed, any new surgeon implanting a port for the practice was provided information regarding the study. Patients were asked to not inform the nurses which port they had implanted in order to continue the blind.

Patient access forms were completed for all patients in the study and kept in an alphabetized folder. Participation in the study was documented on the flow sheet in the patient chart. Every time the patient's port was accessed, the reason for assessing the port, any complications noted, and any interventions that were required to address those complications were recorded on the form. This methodology of data collection made for the easy summation of the data at the conclusion of the study.

No special treatments or unique considerations were given to any patients in the study. The intent of the study was to evaluate the clinical efficiency of the Vortex port when used in the clinical practice. Accordingly, the nurses conducting the patient care did not know the brand or manufacturer of the device implanted within any of their patients. In consideration of patient confidential-

Table I. Comparison of indwelling times, port accesses, and status at the end of the study for oncology patients receiving therapy via either a Vortex port or a conventional port.

	Vortex Port	Conventional Port
Number of patients	48	47
Total Port Indwelling (days)	11,021	7,123
Mean Implant Duration (days)	230	151
Total number of accesses (Uses of the Ports)	818	576
Mean number of accesses - Per Patient	12	8
Status of the Port at the Study Endpoint		
Port in use at end of study	17	7
Port removed due to end of therapy	12	8
Port removed due to complications	0	4
Patient decided to terminate port use	9	16
Patient Expired	10	12

ity, the only reference to the patient was a sequential number assigned upon randomization. In the final data summation, all patient reference was omitted to ensure patient confidentiality.

During the study, the end points were patient death, patient terminating use of port with the port indwelling, or port removal for any reason.

Results and Discussion

A total of 95 patients with various diagnoses who required long-term venous access participated in the study. These patients had ports indwelling for a total of 18,144 days, with 1,394 access attempts made during the indwelling period. Since the patients were randomized as to device, there was no attempt to randomize further as to type of IV solution and medication being delivered with the port, but similar medications and solutions were delivered via either device.

The utilization of the patient's social security number to randomize the study clearly gave a balanced randomization, as the number of patients receiving conventional ports (47) was nearly identical to the number of patients receiving the Vortex port (48) (Table I).

While the number and type of patients receiving each device were similar, patients who had the Vortex port implanted had a mean implant duration of 230 days versus a mean of 151 days for patients who received conventional ports (Table I). The other important difference was that four conventional ports had to be removed prior to the end of therapy due to complications whereas all of the Vortex ports were functioning at the end of the therapy and/or the end of the study. Stated differently, almost one out of ten conventional ports failed before the end of therapy requiring surgical removal. A similar situation was noted in a Memorial Sloan-Kettering Cancer Center study where 14% of their study patients had their ports explanted prior to the end of therapy.[16]

Nine of the conventional ports experienced total occlusions while none of the Vortex ports suffered this complication (Table II). Even more important is the fact that on 26% of all access attempts, the conventional ports exhibited a partial occlusion (the ability to infuse but not aspirate blood), while the Vortex port exhibited a partial occlusion problem on just 7% of all access attempts. This lower rate was realized even though the Vortex ports remained indwelling for longer periods of time and had more accesses than did the conventional ports (Table I). The 26% partial occlusion rate realized with use of the conventional ports is comparable to rates reported in other published studies; however, the 7% partial occlusion rate with the Vortex represents a new level of patient care and reliability. Once a port becomes occluded, nursing intervention is required.

Even though the clinical literature reports rather high incidence rates of infections with the use of ports, none of the patients in this study presented with an infection. We attribute this to the use of highly skilled nursing staff in a controlled work environment following Toledo Clinic guidelines and using consistent technique for maintaining the ports. In addition, the patients in this study were very compliant in their manner of maintaining the devices.

On almost two out of every three access attempts with conventional ports, some type of intervention was required in order to utilize the port

Table II. Complications noted during the use of either a Vortex port or conventional ports in oncology patients.

	Vortex Port	Conventional Port
Total Port Occlusion	0	9
Partial Port Occlusion (Infuse but not Aspirate)	57	141
Occlusions as a Percentage Of Access Attempts	7%	26%
Central Line Infections	0	0
Subcutaneous Infections	0	0

Table III. Types and number of interventions taken to address complications noted with the use of Vortex or conventional ports in oncology patients.

	Vortex Port	Conventional Ports
Repositioned needle	39	91
Changed port position with A cough or deep breath	55	131
Used extra flush solution	51	104
Instilled urokinase	8	15
Urokinase/patient days	0.0007	0.0021
Chest x-ray taken	0	0
Dye study performed	3	7
Surgical removal of port	0	4
Other	0	2
Total Interventions	156	354
Interventions as a Percentage Of Access Attempts	19%	62%

(Table III). With the Vortex port, interventions were required on only 19% of all access attempts. The need for interventions, such as urokinase and dye studies, was more frequent for patients with the conventional ports than for those with the Vortex port. As a result, any costs associated with these interventions (including additional nursing time, supplies, and radiologic intervention on numerous occasions) would be higher for the conventional ports than the Vortex port.

Conclusion

In this patient population, utilizing the Vortex port resulted in better patient outcomes, fewer complications, less nursing time and expenses than when a conventional port was used. The design of the Vortex reservoir appears to contribute to a condition of less build-up of thrombus and/or drug residuals in the device itself, resulting in fewer complications. The Vortex port appears to represent a major breakthrough in port performance, resulting in better patient outcomes, fewer complications, and less nursing time and expense. ❤

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