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Totally Implantable Venous Access Device Placement by Interventional Radiologists: Are Prophylactic Antibiotics Necessary?

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INTRODUCTION

Reliable venous access is critical for cancer patients. Totally implantable venous access devices (TIVADs) are commonly placed to facilitate delivery of intravenous chemotherapy. Compared to exteriorized catheters, TIVADs have the advantages of requiring little maintenance and having a low infection rate. [1]

Although TIVAD infections are uncommon compared to other types of catheters, the consequences of a TIVAD infection can be considerable for the patient in whom infection occurs. Central line associated blood stream infections (CLABSI) are costly, and usually requires removal of the device. In addition, subsequent treatment of the infection can delay administration of chemotherapy and require an increase in the level of care (e.g., hospital admission or home intravenous therapy).

The consequences of CLABSI to both patients and providers have been highlighted in the lay press and medical literature in recent years. Recent policies outlined by the Centers for Medicare and Medicaid Services [4], the Joint Commission [5] and the United States Department of Health [6] have made reduction of CLABSI a priority.

In order to reduce the risk of insertion-related CLABSI, prophylactic administration of an antibiotic prior to central line placement has been recommended by some practitioners [7–9]. For a single patient, the administration of a single dose of an antibiotic may seem

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inconsequential. As a general practice, however, unwarranted antibiotic use adds time, expense, and potential complications in the form of allergic reaction, C. *difficile* infection, and antibiotic resistance [10, 11]. Limiting cumulative exposure to antibiotic therapy for both the individual and the population as a whole is a critical step towards maintaining sensitivity to currently available antibiotics.

Because there is little evidence to justify the use of prophylactic antibiotics for patients undergoing TIVAD implantation in the interventional radiology suite, it has been our practice not to use them. The purpose of this paper is to report the 30 day infection rate for TIVADs placed in cancer patients by interventional radiologists without the use of prophylactic antibiotics.

MATERIALS AND METHODS

An Institutional Review Board waiver was granted for this retrospective review. The patient archiving communication system (PACS) at a single cancer center was queried to obtain a list of all patients who underwent TIVAD placement from January 1, 2009 through December 31, 2009. TIVADs removed within 30 days of placement were identified by cross referencing a PACS query of TIVAD placement with TIVAD removals from January 1, 2009 through January 30, 2010. Review of patient charts and available imaging studies was performed to confirm that TIVADs not removed remained in place at day 30 following placement.

Retrospective chart review was performed to collect patient demographic data including age, sex and cancer diagnosis. Variables in the placement including site, device type and size of the port were also recorded. Laboratory data including white blood cell count (WBC), platelet count, prothrombin time, international normalized ratio (INR), and partial thromboplastin time were recorded at the time of the procedure and for 30 days following implantation. Date, dose and type of any concomitant antibiotic and chemotherapy administered within 30 days of placement were also recorded.

The list of patients with TIVADs removed within 30 days of placement was cross-referenced with microbiology data to identify patients with positive blood cultures. The records of these patients were reviewed using CDC surveillance definitions for laboratory-confirmed central line-associated bloodstream infection (CLABSI) events. These criteria include a primary blood stream infection (1 positive culture for non-skin flora, 2 positive cultures for skin flora) in a patient who had a central venous catheter in place within 48 hours before the development of infection not related to an infection at another site.

Our technique for TIVAD placement has been described previously [12]. Pre-procedure laboratory evaluation includes WBC, platelet count and INR. Patients with absolute neutrophil count (ANC) < 1 at the time of placement were routinely given 1 gm cefazolin sodium pre-procedure. Patients with platelet counts of <20 K/mcl were transfused with 2 units of platelets peri-procedure, and patients with platelet counts of 20-49K/mcl were transfused 1 unit. Patients with INR > 2.0 were treated with Vitamin K until the INR is < 2.0 for placement. Since 2008, we have followed the recommendations of several governing

agencies, including the Institute for Healthcare Improvement (IHI) and the Joint Commission, by adopting as standard procedure the components of the central venous care bundle prior to device insertion bundle [13, 14].

The access site was prepped with chlorhexidine and then draped with sterile towels. Ultrasound was used for venous access, which is achieved with a 21 gauge micropuncture system (Cook biomedical, Bloomington IN). A subcutaneous pocket was created on the anterior chest wall 4-8 cm from the venous access site. The catheter was tunneled from the pocket site to the venous puncture site. The micropuncture was exchanged over a wire for a peel away sheath and the catheter is advanced through the sheath to the high right atrium. The peel away sheath was removed and the catheter was cut to an appropriate length so that the tip was in the high right atrium or distal superior vena cava. The catheter was then attached to the port. The port was aspirated and flushed and placed in the pocket which was closed with interrupted resorbable subcutaneous stitches and either a running subcuticular stitch and/or Dermabond (Ethicon, Somerville, NJ) at the discretion of the operator.

Immediately after placement, the port was accessed with a Huber needle and flushed with heparinized saline. If the patient was scheduled for chemotherapy on the same day, the Huber needle was left in place for use; otherwise, it was removed. A sterile dressing was applied.

Statistical analysis

To determine if pre-procedure WBC, pre-procedure platelet count, post-procedure WBC, or post-procedure platelet count differed between patients who developed CLABSI and to those that did not, two-sample, t-tests were performed. To determine if pre-procedure ANC < 1, administration of antibiotics pre-procedure, or administration of chemotherapy on the day of the procedure differed between patients who developed CLABSI and to those that did not, Fisher's exact tests were performed. All tests were two-sided and P-values <0.05 were considered statistically significant. Analyses were performed in SAS (version 9.2, SAS Institute Inc., Cary, NC).

RESULTS

1183 implantable ports were placed in 1167 patients in the one-year study period. Eighteen patients had 2 implantable ports placed. Patient demographics are shown in Table 1. Mean age was 59.2 years (range 16-92); there were 717 females and 467 males. Breast, colorectal cancer, lymphoma and pancreatic carcinoma were the most common diagnoses. Thirty-seven patients (3.2%) died within 30 days of port placement.

Thirty-seven (3.2%) were double-lumen TIVADs and 1144 (96.7%) were single lumen TIVADs. With the exception of 2 translumbar and one placed from right brachiocephalic access, TIVADs were placed in the right internal (1139, 96.2%) or left internal (42, 3.5%) jugular veins.

The pre placement and 30 day post placement nadir WBC and platelet counts are shown in Table 2.

One hundred forty-eight (12.5%) ports were used on the day of placement for administration of chemotherapy. Eighty-one (6.8%) patients received antibiotics on the day of implantation. Of these, seventy patients (5.9%) received antibiotics at the time of port placement for reasons unrelated to prophylaxis for TIVAD placement. An additional 18 (1.5%) patients were neutropenic at the time of TIVAD placement (ANC < 1) and these patients were administered a prophylactic IV dose of cephalexin 1 hour prior to the procedure.

Thirteen ports (1.1%) were removed within 30 days of placement, 12 of these were removed for suspected or known infection. One port was removed and replaced because the catheter tip had migrated from the superior vena cava into the internal jugular vein. The charts of the 12 patients who had ports removed for suspected or known infection were retrospectively reviewed by an Infection Prevention Practitioner.Using CDC criteria, 7 (0.6% of ports placed, 54% of those removed for suspected infection) were removed for CLABSI. One patient who received an antibiotic (1632 mg gemcitabine IV) the day of implantation developed CLABSI. The remaining 6 patients with CLABSI were not treated with antibiotics prior to TIVAD placement. Bacterial isolates are shown in Table 3. There was no significant difference between the rate of TIVAD removal for CLABSI in patients that received pre-procedure antibiotics vs patient that did not received pre-procedure antibiotics. ($p<0.59$)

Ten of twelve ports removed within 30 days and 6 of 7 with documented CLABSI were in females. None of the 12 patients who had an ANC < 1 at the time of placement (and received prophylaxis) developed CLABSI.

The majority (1164/1167) of patients received chemotherapy within 30 days of port placement. In 148 (12.5%), the port was left accessed with a Huber needle and patients received chemotherapy on the same day of port placement. One of the documented CLABSI was in a patient who received gemcitabine the same day as port placement.

DISCUSSION

Oncology patients often require long-term intermittent access for chemotherapy, frequent blood draws and IV contrast administration for imaging studies. TIVADs are commonly the ideal device to meet these needs while minimizing adverse affects on lifestyle.

Since the 1999 publication by the Institute of Medicine [15] regarding the prevalence of hospital acquired infections, strategies to reduce CLABSI have become a focus of attention and resources. Prophylactic antibiotics prior to TIVAD placement is one of the practices that have been employed to minimize CLABSI related to central line placement [7–9].

There are, however, significant risks of injudicious use of antibiotics. Frequent use of antibiotics and cumulative antibiotic dose are known to promote antibiotic resistance and development of Clostridium difficile colitis [10]. Even a single dose of IV cephalosporin has been shown to change the intestinal flora of healthy volunteers [11].

TIVAD placement in the IR suite is a “clean procedure,” as defined as by The National Academy of Sciences/National Research Council [16] (ie outside of the genitourinary,

gastrointestinal and respiratory tracts, no local inflammation or intra-procedural contamination.) For clean procedures, there is no evidence to support use of antibiotic prophylaxis [17].

Guidelines for adult antibiotic prophylaxis published by the Society of Interventional Radiology in 2004 [8] supported empiric use of antibiotic prophylaxis. The updated 2010 guidelines, on the other hand, indicate that the benefit of antibiotic prophylaxis for central venous access is unproven, and acknowledges a lack of consensus on the use of routine prophylaxis [18]. Many of the references cited in arriving at this inconclusive recommendation are the same studies referenced by the Cochrane Review of 2007 [19] that concluded that antibiotic prophylaxis for placement of tunneled central venous catheters was not justified. Most studies, however, do not distinguish between TIVAD and tunneled catheter placement.

Despite how commonly these devices are placed, there is a paucity of data regarding the role of antibiotic prophylaxis prior to TIVAD placement in the literature. One recent study published in the American Journal of Surgery [7] looked at the infection rate for TIVAD placement by two surgeons. During the 3 year retrospective study, 103 patients were treated by one surgeon who used antibiotic prophylaxis and 356 by a second surgeon who did not. Nine patients (1.9%), all of whom had TIVADs placed by the surgeon who did not use antibiotic prophylaxis, developed blood stream infection within 30 days. The authors concluded that antibiotic prophylaxis may decrease early blood stream infection following TIVAD placement. However, the retrospective, non-randomized, poorly controlled nature of the trial make interpretation of the results difficult to extrapolate to TIVAD placed by interventional radiologists.

Two recent prospective trials from Europe have addressed the issue of surgical site infection in patients undergoing TIVAD placement by surgeons.. In a series from Italy [20], patients with solid tumors and no evidence of active infection were randomized to receive either a single dose of ceftazidime or placebo. TIVADs were placed by surgical cut down using either the cephalic or external jugular vein for access. Surgical sites were evaluated for 30 days after placement and TIVADs were accessed for chemotherapy no sooner than 10 days following implantation. None of the 108 patients developed surgical site or systemic infection. The authors conclude that with strict pre and post operative care, antibiotic prophylaxis is not necessary.

In a similar trial of 404 patients from Turkey [21], patients were randomized to receive either cefazolin or placebo. TIVADS were placed from the subclavian vein using Seldinger technique in the operating room. Superficial infections were seen in 2.7% and 1 TIVAD needed to be removed. There was no significant difference in the rate of infection between the patients who received antibiotic prophylaxis and those who did not. While an excellent study, the sample size was chosen to provide statistical power based on a 6% difference in surgical site infections between the two groups.

In our series, the rate of CLABSI following TIVAD placement without the use of prophylactic antibiotics in our experience is very low, 0.7%. This compares quite favorably

with other series in which prophylactic antibiotics were administered [7–9]. Notably, we did not see any increase in the risk of infection in patients who had ports accessed and used the day of implantation. Patients who developed early CLABSI were noted to have lower WBC and platelet counts within 30 days following placement, but it is difficult to arrive at any risk modification based on this observation. None of the 12 patients who were neutropenic at the time of placement (and received prophylaxis) developed CLABSI.

The strengths of this study are that the same technique and guidelines were observed by all interventional radiologists placing the TIVADs. Because we are a quaternary cancer center and patients are actively followed, we were able to document 30 day follow-up on all patients in this series.

The major limitation of this study is that it is retrospective, and as such is without a comparison group of patients randomized to receive antibiotic prophylaxis. In order to conclusively determine whether antibiotic prophylaxis is warranted for TIVAD placement, a prospective randomized study with a sample size large enough to detect a difference between groups allowing for infection rates of <1-3% is required. Additionally, such a study might afford important information regarding the safety of placing TIVADs in patients who are, or are imminently likely to become, thrombocytopenic or neutropenic, and whose TIVADS are left accessed immediately after placement.

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Table 1.

Demographic data of the patients who underwent IVAD removal within 30 days of placement for documented or presumed infection.

	Tumor type	WBC pre	WBC nadir	Plt pre	Plt nadir	Abx same day	Chemo same day	Port type
CLABSI								
47M	CNS lymphoma	11.4	0.1	138	23			RIJ PowerPort
63 F	Ovarian cancer	9.6	6.4	413	290		Gemcitibine	RIJ MRI port
36 F	Unknown primary	7.2	4.1	216	168			RIJ PowerPort
61F	Ovarian cancer	2.5	1.7	230	25			RIJ PowerPort
70F	Unknown primary	3.8	3.2	257	247			RIJ PowerPort
52F	Breast cancer	10.6	0.5	363	20			RIJ PowerPort
58 F	Uterine cancer	3.6	1.0	329	136			RIJ PowerPort
CELLULITIS/ NON-CLABSI INFECTION								
57F	Hepatocellular carcinoma	6.9	0.6	267	44			RIJ MRI port
70M	Gastric cancer	6.4	3.3	210	100	Ceftriaxone		RIJ MRI port
63F	Lymphoma	5.3	2.9	270	142	Cephalexin		RIJ PowerPort
62 F	Lung cancer	7.6	2.2	139	78	Cefazolin		RIJ PowerPort
23 F	Lymphoma	11.4	0.1	46	2			RIJ MRI port

Table 2.

Pre and post TIVAD placement laboratory values and clinical factors in patients who did and did not develop CLABSI within 30 days of implantation.

	Non-CLABSI	CLABSI	p value
WBC (K/mcl) pre (mean)	8.1	6.5	0.26
WBC (K/mcl) nadir (mean)	6.1	2.3	***0.002***
Platelets (K/mcl) pre (mean)	303	339	0.67
Platelet nadir (K/mcl) (mean)	217	135	***0.049***
Chemotherapy same day	147/1171	1/12	0.39
Antibiotics same day	7/1102	0/81	0.59
ANC <= 1.0 at placement	18/1176	0/7	0.90

WBC: white blood cell count

ANC: absolute neutrophil count

CLABSI: Central line associated blood stream infection

Table 3.

Clinical indication for IVAD removal within 30 days of placement, and bacterial isolates associated with CLABSI.

	Days in place	Indication for removal	Organism 1	Organism 2
CLABSI				
Patient 1 M **	15	bacteremia	Coag negative staph	Pseudomonas aeruginosa
Patient 3 F **	9	bacteremia	Enterobacter cloacae	Enterococcus faecium
Patient 4 F **	21	bacteremia	Beta hemolytic strep G	
Patient 8 F **	19	bacteremia	Coag negative staph	
Patient 9 F **	6	bacteremia	Klebsiella pneumonia	
Patient 10 F **	25	bacteremia	Coag negative staph	
Patient 11 F **	6	bacteremia	Pseudomonas aeruginosa	
CELLULITIS/NON-CLABSI INFECTION				
Patient 2 F	1	Cellulitis (tunnel)	None	
Patient 5 M	21	bacteremia	Strep viridans	
Patient 6 F	15	Fever, leukocytosis	Enterococcus	
Patient 7 F	12	Cellulitis (port pocket)	None	
Patient 12 F	27	bacteremia	Escherichia coli	