Infections Associated with Use of the LifeSite Hemodialysis Access System

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We observed infection rates associated with the LifeSite Hemodialysis Access System, a novel dialysis device consisting of 2 subcutaneously implanted valves accessed by repeated use of fibrous tissue tracts, of 4.8 total infections and 8.1 first episodes per 1000 patient-days. These rates are higher than those observed elsewhere, which may be related to use of the device in a population of chronically ill patients, to the learning curve associated with use of the device, or to inherent qualities of the device.

In August 2000, the US Food and Drug Administration (FDA) granted approval to the LifeSite Hemodialysis Access System (Vasca). The LifeSite system consists of 2 subcutaneously implanted access valves attached to venous cannulas (figure 1). Access to each subcutaneous valve is obtained by repeated use of a single cannulation tract known as a “buttonhole.” Although the LifeSite system was initially approved as a bridge device to be used while awaiting maturation of permanent access, such as arteriovenous fistulae and grafts, premarketing experience suggested that the LifeSite system offered attractive features for patients who had previously experienced failures of dialysis access. These features include high flow rates, low rates of thrombosis, and acceptable rates of device-related infection [1].

We report our experience with the LifeSite system.

Seven patients at our institution (St. Elizabeth’s Medical Center, Boston) had LifeSite systems implanted in subclavian or jugular vessels at some point from 26 October 2000 through 19 April 2001. All 7 patients had experienced failures of dialysis access and had limited options for dialysis access. Three patients recently had received adequate treatment for hemodialysis access infection (methicillin-resistant Staphylococcus aureus [MRSA] bacteremia). Most patients had at least 1 comorbid condition. Three patients had coronary artery disease, 3 had hypertension, 2 had dementia, 1 had multiple myeloma, 1 had systemic lupus erythematosus with prolonged immunosuppression and multiple complications, and 1 had adult-onset diabetes mellitus. The mean age of the patients was 69.7 years (range, 49–89 years). These patients were generally representative of the population of our dialysis unit, which, as an in-hospital facility, tends to have a larger proportion of debilitated, chronically ill patients and to have patients with more comorbidities than would be encountered in an ambulatory dialysis unit.

Patients 6 and 7 died, at 40 and 66 days after LifeSite placement, respectively, without evidence of infection. Patients 1–5 all developed infections associated with the LifeSite system. These occurred 14–184 days (mean, 102.6 days) after implantation. Patient 1 had Proteus mirabilis bacteremia, and patient 2 had MRSA infection of the LifeSite port. Both infections were managed with LifeSite removal and antibiotic therapy. Patient 3 had bacteremia due to Escherichia coli, Staphylococcus epidermidis, and vancomycin-resistant Enterococcus faecium. Despite receiving treatment of 2 months’ duration with linezolid, ciprofloxacin, and gentamicin, patient 3 had ongoing bacteremia at the time of death, which was due to myocardial infarction. Patient 4 experienced recurrent MRSA bacteremia over a period of 7 months, despite multiple cannula changes and repeated courses of vancomycin therapy. Although aggressive measures were taken to salvage the LifeSite system, because the patient had limited options for access, the device was finally removed because of persistent bacteremia.

In only 1 patient was infection associated with the LifeSite system cured without removal of the device. Patient 5 had cultures of blood samples and of purulent drainage from the LifeSite valve that were positive for MRSA. He was treated with a combination of 6 weeks of intravenous vancomycin and daily isopropyl alcohol (IPA) irrigation. Six months later, he developed S. epidermidis bacteremia; this episode of infection also responded to therapy with intravenous vancomycin and valve irrigation.

Among our patients, the incidence of all first episodes of device-related infection was 8.1 infections per 1000 patient-days. The infection rate, reported as the total number of infections divided by the total number of patient-days that the devices were left in place, was 6 infections per 1242 patient-
days, or 4.8 per 1000 patient-days. This lower rate reflects long periods of antibiotic administration for attempted catheter salvage, which, in effect, “dilute” the infection rate. For example, patient 4 received antibiotics for >200 of the 280 days on which the device was in place.

Protocols were reviewed, and device implantation and care were discussed with the manufacturer. One patient, who already had developed LifeSite-associated infection, was noncompliant with daily IPA irrigation of the valve. (LifeSite-associated infections are routinely treated with daily IPA irrigation of the valve, in addition to administration of systemic antibiotics.) Another patient’s valves were closer together than is ideal. This patient also developed hematomas around the valves; the manufacturer indicated that management of this condition required more-vigorous irrigation. Some patients developed fistulae to the skin with use of recommended irrigation volumes, which improved when irrigation volumes were reduced. (The instructions for the implantation and use of the LifeSite system, available online at http://www.lifesite.com/pdf_folder/LifeSite_Hemodialysis_Access_System_Instructions_for_Implantation_and_Use.PDF [accessed 30 May 2002], do not specify the optimal distance between the valves and do not contain recommendations for reduction in irrigation volumes in the event of skin breakdown.)

Premarketing experience suggested that infection associated with the LifeSite system, with a reported incidence of device-related bacteremia of 2.5 infections per 1000 patient-days, was not more common than infection associated with other dialysis access systems [1]. (These data were not reported in the form of first episodes of infection per 1000 patient-days but as total number of infections divided by the total number of patient-days on which the devices were left in place.) However, 18 (78%) of 23 patients in that study ultimately required removal of the LifeSite valve because of infection (in 6 of these patients, the case of bacteremia that required device removal was not thought to be device related). Another author has reported a rate of device-related infection in association with use of the LifeSite system as low as 1.3 infections per 1000 patient-days [2]. Rates of infection associated with tunneled, cuffed hemodialysis catheters in large studies vary, depending on the clinical setting, how rates are reported, and other factors. Rates of infection of 3.9 infections per 1000 patient-days [3] and 4.75 first episodes per 1000 patient-days [4] were seen in 2 of the largest clinical studies. Lower rates of infection are seen in association with Gore-Tex grafts and native arteriovenous fistulae [5]. The rate of infection associated with the LifeSite system at our facility was higher than that reported for previous studies [1, 2]. This might be related to use of the device for permanent access in a population of chronically ill patients with limited options for dialysis access, to the learning curve associated with use of the device, or to inherent qualities of the device.

The design of the LifeSite system incorporates a sinus tract that passes from the skin through the soft tissues to each of the device’s subcutaneous, dome-shaped valves. Each stainless steel and titanium valve contains an internal pinch-clamp device that controls access to the silicone venous cannula. The creation of this fibrous-tissue tract could increase the risk of bacterial colonization and catheter infection, and, in fact, irrigation of the tract and valve with 70% isopropyl alcohol in
30% water before and after use is recommended. *S. aureus* infections might be predicted to be a particular problem, as we observed, given the propensity of *S. aureus* to colonize chronic wounds [6] and the rate of chronic *S. aureus* carriage among patients undergoing hemodialysis (as high as 70%) [7]. *S. aureus* is the pathogen that most commonly causes dialysis access infection [8].

The rate of device salvage in our population was 33%; 2 of 6 infections were cured without removal of the LifeSite device. A salvage rate of 69% has been reported by 1 group, which used a protocol of 2 weeks of intravenous antibiotics and daily IPA irrigation. If cure was not achieved after 2 weeks, the cannulas were exchanged, and administration of antibiotic therapy and daily IPA irrigation were continued for another 2 weeks [9].

On 29 November 2001, the FDA sent a warning letter to Vasca after an inspection of their facility in July 2001 [10]. The investigators noted 129 complaints of death or serious injury related to use of the LifeSite device (these complaints do not include our cases, which were reported to the FDA after this inspection was completed). Vasca was cited for incomplete evaluation or delayed reporting of some events, including infections, skin necrosis, hemorrhage, catheter detachment, flow problems, and patient deaths. The warning letter noted that “the majority of reported deaths and many reported injuries occurred in patients that were not candidates for permanent access” and recommended revision of labeling to warn about risks associated with use of the device “in patients with a history of multiple access failures or access infections, that are catheter dependent for dialysis access, and are not candidates for permanent access placement” [10, p. 4]. The letter also cautioned against use of the LifeSite device in vessels other than the jugular and subclavian vessels [10].

The LifeSite system is currently labeled for use in patients who are awaiting the creation or development of permanent access. Because most of the reported deaths and many reported injuries, as well as all of the infections described in the present article, occurred in patients for whom the device is not specifically labeled, the LifeSite system should be used with caution in patients who are not candidates for more-permanent access devices. Meticulous technique in placement and irrigation of the valves seems essential. Revision of protocols should be considered, to specify placement of valves and describe techniques for management of skin fistulae and hematomas. Further clinical experience is required to ascertain the true risk of infection associated with use of the LifeSite system.

References