Infection rates of the LifeSite hemodialysis access system

To the Editor: We have a number of concerns with the report recently published in *Kidney International* by Schwab et al [1] of low infection rates in the LifeSite Hemodialysis Access System. The comparison of two randomized arms, the Tesio-Cath and LifeSite with oxychlorosene groups, with a nonrandomized arm, the LifeSite with isopropyl alcohol group, is of dubious validity.

The infection rate in the Tesio-Cath group was higher than reported elsewhere for temporary hemodialysis access [2]. Four exit-site infections were diagnosed in the Tesio-Cath group, versus none in either LifeSite group. The criteria for diagnosis of exit-site infection were not specified, but apparently did not include a requirement for positive cultures, as one patient with a locally infected Tesio-Cath had a negative culture.

Schwab et al "suggest that long-term venous access may be provided by a subcutaneous device." This may be true, but only in selected patients. The LifeSite device is labeled only for use in hemodialysis as a bridge device to permanent venous access. In a warning letter to Vasca, Inc., the Food and Drug Administration (FDA) noted 129 complaints of death or serious injury related to the LifeSite device, many inadequately reported to the FDA by Vasca. The letter stated that "the majority of reported deaths and many reported injuries occurred in patients who were not candidates for permanent access," and warned about the risks of use "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" [3]. Our experience with the LifeSite system in chronically ill dialysis patients with previous access failures suggests that subcutaneous devices may be much more prone to infection in this population [4].

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Reply from the Authors

Dr. Ross and his colleagues raise questions regarding the randomized prospective trial of the LifeSite system. The extension phase of the study used isopropyl alcohol instead of oxychlorosene as the port sterilant. It extended from the initial randomized study and used the catheter group as a retrospective but otherwise identically selected control group. The infection rate in the catheter arm (3.3 per 1000 use days) was similar to other nephrology-conducted prospective studies of hemodialysis catheters (3.9 to 5.5 per 1000 use days) [1–3]

The concern that these port devices will perform worse than the prospective trial when patients are selected who have failed all other permanent vascular access is valid. In the experience of the original Dialyis Outcomes Quality Initiative (DOQI) panel, patients who failed permanent artriovenous access and were dependent on catheter-based access had some of the worst long-term outcome of any subset of hemodialysis patients. Whether ports or other techniques will improve these abysmal catheter outcomes in these patients awaits clinical trials.

As clearly expressed in the study, these port devices require expertise in their placement and training in their use. Placement of these devices in non-internal jugular positions and use by untrained centers should be expected to have higher complication rates.

Catheter access for hemodialysis of and by itself is associated with substantially increased risk of death and hospitalization even when other risk factors are controlled [4]. Development and testing of new venous access devices is essential to improving patient outcomes. Used correctly we believe hemodialysis access ports represent just such an improvement.

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