

The Exit Site Management (ESM) catheter - A retrospective evaluation of the first in human use of the NexSite HD catheter

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Objectives: Tunnelled dialysis catheters are associated with relatively high rates of Catheter Related Bloodstream Infections (CRBSI), with reported levels ranging from 1.6 to 5.5 per 1000 catheter days¹. Exit Site Management (ESM) using antibiotic agents has been studied as a potential means of reducing CRBSI, with reported rates of as low as 0.4 per 1000 catheter days². Promotion of dermal tissue ingrowth into the catheter at the exit site is an alternate approach to ESM. The NexSite HD catheter (Marvao Medical Devices, Galway, Ireland) is a tunnelled dialysis catheter with a uniquely designed cuff and subcutaneous DISC (Dermal Ingrowth Support Collar) to facilitate dermal tissue ingrowth at the catheter exit site.

Methods: Patients who had received a NexSite HD catheter at our center were eligible for consideration in this retrospective study. After establishing vascular access, a subcutaneous pocket was created at the catheter exit site and a small incision made in the skin above the pocket. The NexSite DISC was inserted within the pocket and the NexSite HD catheter (staggered tip design) inserted through the exit site incision and then through the DISC. The DISC and catheter cuff were then aligned so that the tissue ingrowth surface of the DISC was positioned within the pocket directly under the exit site incision, and the catheter's tissue ingrowth surface (cuff) was positioned through the skin across the exit site incision. Combined, the two tissue ingrowth surfaces facilitate dermal tissue ingrowth into the device at the catheter exit site. The catheter tunnelling and tip placement were then performed using standard interventional techniques.

Results: Twenty (20) patients (avg age of 66; 45% Male) at our center who had received NexSite HD catheters since May 2013 were considered for this study. Technical success of placement was 100% in all cases. Five (5) patients were excluded from the study: one (1) had been lost to follow up; two (2) had developed low flow rates within the first 7 days and their NexSite catheters had been exchanged with conventionally cuffed catheters (split or symmetrical tip designs); two (2) had documented evidence of a catheter related infection within the two week period prior to NexSite placement.

The fifteen (15) remaining patients were included in the analysis, with 1,715 catheter days accumulated as of May 1, 2014 (range 30-189 days). Tissue ingrowth at the exit site was observed in all cases. Of these 15 patients, six (6) had their catheters removed once their fistulas had matured, and five (5) continue to receive therapy using a NexSite HD catheter. Three (3) catheters were removed due to complications: one (1) due to an exit site infection (180 days post placement); one (1) due to a suspected CRBSI (189 days post placement); and one (1) due to skin erosion adjacent to the DISC (105 days post placement). One (1) patient died for causes unrelated to the catheter (15 days post placement). All catheter removals were accomplished by peeling the DISC out of the pocket through the exit site with 100% technical success.

Conclusions: The NexSite HD catheter is a safe and efficient tunnelled dialysis catheter design that provides a unique type of exit site management (ESM) technology. In this first in human study, NexSite HD placement and removal steps were 100% successful and the observed complication rate was low, with one (1) suspected CRBSI observed over the first 1,715 catheter days (0.6/1000 days). Additional studies across larger patient populations is warranted to determine if the use of NexSite HD can significantly decrease the rate of CRBSI relative to the use of conventional catheters. Expanding the NexSite HD product line to include split tip and symmetrical tip catheters would further enhance the value of these studies.

Author Disclosure Information: J. Ross: Consultant; Marvao Medical.

References:

1. K/DOQI Clinical Practice Guidelines, 2006 Update
2. Rabindranath et al; NDT Dec 2009;24(12) 3763 - 74