



A prospective trial on a new sutureless securement device for central venous catheters

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To the Editor,

We share our experience with a new catheter securement device called the SecurAcath[®] (Interrad Medical, Plymouth, MN, USA). It utilizes small folding subcutaneous nitinol tines that anchor an intravenous catheter at the insertion site (Figure, panels A and B). The anchor is designed to be atraumatic, and it is magnetic resonance imaging compatible. An instructional video provided by the manufacturer is available at <http://interradmedical.com/video-short-demo>.

We conducted a multicentre observational post-marketing study to evaluate the effectiveness of successful catheter securement with this device. The study was approved by the Research Ethics Board of each participating institution (listed below) and was registered at www.clinicaltrials.gov (NCT00903539).

Physicians were trained by the manufacturer on the use of the SecurAcath, and consenting patients 18 yr or older requiring a 7Fr central venous catheter (CVC) in the internal jugular vein were enrolled in the study. Seventy-four subjects were included from June 23, 2010 to January 4, 2011. The primary outcome, successful securement, was achieved in 72 (97%) of the cases. Two patients experienced catheter dislodgement, attributed to improper coupling of the two device components. These were identified within 24 hr of catheter placement. No other device-related malfunction occurred. There were no device-related adverse events, such as catheter migration within the device, difficulties with removal, cellulitis at the site, or erosion at the anchor securement site.

The immediate procedural success rate was 100%. The mean (standard deviation) time to secure the catheter was 62.5 (97.3) sec, and 91% of the devices were deployed within 2.5 min. Mean catheter indwelling time was 3.1 (5.1) days. Discomfort analogue score (scale 1-10) during device use and at removal was 0.9 (1.6) and 1.6 (2.1), respectively. Fourteen of the 15 patients with previous CVC or a peripherally inserted central catheter experience considered SecurAcath to be as or more comfortable than a sutured catheter. Six of the eight healthcare professionals questioned thought that maintenance of the device site was somewhat or much easier than with a sutured catheter, and all stated they would recommend this device to other professional colleagues.

Anesthesiologists commonly perform CVC placement, and most often this is sutured for stabilization.¹ The American Society of Anesthesiologists (ASA) believes that the literature is currently insufficient to evaluate the usefulness of sutureless stabilization; therefore, the ASA Task Force suggested that the decision should be determined on an institutional basis.¹ By contrast, multiple medical societies advocate sutureless securement devices in order to reduce the risk of infection.² It is believed that skin disruption near the catheter entry site is associated with increased risk of infection.³ Furthermore, avoidance of suturing is consistent with prevention of needlestick injury (NSI).⁴

The use of staples addresses the issue of NSI but still results in skin disruption. Adhesive-based securement systems appear to have better efficacy and safety profiles compared with sutures.^{3,5} A subset of patients, however, may be unsuitable for skin adherence because of hair growth, skin lesions, allergy to the adhesive, or diaphoresis. In addition, both adhesive-based and staple-based devices pose similar hygiene challenges during dressing changes as

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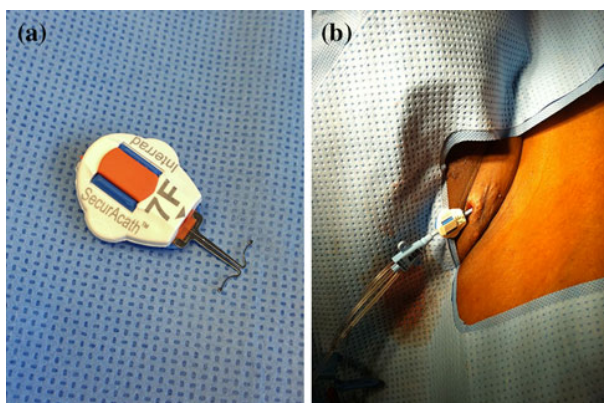


Figure Panel A: The SecurA cath[®] and its tines. Panel B: The tines are implanted subcutaneously at the catheter insertion site. (An instructional video provided by the manufacturer is available at <http://interradmedical.com/video-short-demo>)

current sutured techniques because the skin area under the flange is inaccessible. The anchor-based device presented in our study eliminates this difficulty. During dressing changes, the catheter can be lifted without sacrificing security, and the skin can be cleaned very easily.

In our view, the SecurA cath subcutaneous securement system provided safe and reliable securement of the CVC in the internal jugular vein, and it is easy to learn how to use the device. This study showed that the operator was occasionally unaware when the two device components were improperly coupled; the manufacturer has modified the device accordingly. The study was too small to confirm securement superior to sutures or to show a reduction in catheter-related infections or increased operator safety.

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Competing interests The studied device was provided by Interrad Medical Inc., Plymouth, MN, USA. All study documentation was collected, verified, and compiled by an independent research contractor.

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Details of Ethics Approval The study was approved by the Toronto General Hospital REB on June 17, 2010 (10-0279-A), Providence Health St. Paul's Hospital on September 27, 2010 (H10-01340), Health East St. Joseph's Hospital on August 23, 2010 (HE 08 12 002), and St. Luke's Hospital on May 14, 2010 (10-458). The trial was registered at www.clinicaltrials.gov under ID number NCT00903539.

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