

Clinical Assessment of the Jelco IntuitIV Safety IV Catheter™ - Salisbury Hospital's Experience with a Passive Safety Device

Case Study

AUTHORS

Laura Seiberlich, MS, Clinical Research Scientist, Smiths Medical

OBJECTIVE

A clinical study was conducted to evaluate the initial clinical performance of the Jelco IntuitIV Safety IV Catheter™. Parameters evaluated focused on clinical acceptability, risk of needlestick injury during insertion, ease of use, intuitiveness of the device design, insertion success. In addition, an overall assessment of device performance was measured after completion of study insertions.

METHODS

Ten (10) anaesthetists at Salisbury Hospital in the United Kingdom that were currently using conventional (non-safety) Jelco® peripheral intravenous (IV) catheters were consented to participate in the study and trained on the proper insertion technique of the sideport configuration of the Jelco IntuitIV Safety IV Catheter™, a passive safety device. Clinicians were provided 18 gauge (32 mm or 45 mm) or 20 gauge (32 mm) sizes with Polyurethane catheter tubing material to insert into patients indicated to receive an IV catheter in the hospital. Clinicians were instructed to use the Jelco IntuitIV Safety IV Catheter™ for 20 consecutive IV catheter insertions, if possible, considering the appropriate gauge sizes for the patients. After each use of the Jelco IntuitIV Safety IV Catheter™, clinicians answered questions documenting the device used, whether the insertion was successful, and answered usability questions about the performance of the device. After completing all 20 study insertions, clinicians were asked to answer questions about the overall performance of the Jelco IntuitIV Safety IV Catheter™.

Clinicians that are familiar with a conventional or nonsafety peripheral IV catheter can quickly adopt and be successful with the Jelco IntuitIV Safety IV Catheter™

Table 1: Clinician Demographics

Demographic	Results
Age	43.6 Years (mean) 31 Years (min) 54 Years (max)
Gender	4 Female (40%) 6 Male (60%)
Medical Credentials	Doctorate of Medicine (100%)
Medical Area Worked	10 Anesthesia (100%)
Number of Years as a Trained Professional	17.8 Years (mean) 5 Years (min) 30 Years (max)
Number of Years Inserting IV Catheters	20.6 Years (mean) 7 Years (min) 33 Years (max)
Average Number of IV Catheter Insertions per Week	21 Insertions (mean) 10 Insertions (min) 35 Insertions (max)

RESULTS

Ten anaesthetists working in the operating theatre of the hospital completed the study in an average of 20 calendar days (5 minimum, 46 maximum). Table 1 provides a description of the clinician demographics and experience inserting IV catheters.

A total of 200 Jelco IntuitIV Safety IV Catheter™ [(47) 18G x 45 mm, (16) 18G x 32 mm, (118) 20G x 32 mm, (19) unspecified 18 or 20G] venous insertions were attempted for the study. Of the 200 attempts, 186 catheters (93%) were successfully placed. Fourteen (14) or (7%) unsuccessful insertions, in total, were reported from 5 different clinicians. Nine (9) of the 14 were reportedly unsuccessful due to the patient's condition, 4 were attributed to the Jelco IntuitIV Safety IV Catheter™, and 1 did not have a reported reason for failure. Five (5) of the 14 failures were reported from one clinician that took the longest amount of time to complete the study (46 days) and reported the most uses of a non-Jelco IntuitIV Safety IV Catheter™ during the course of the study.

Clinicians were asked to rate the clinical acceptability of the device and to rate the ability of the safety mechanism to eliminate the risk of needlestick injury for each insertion. Ninety-seven percent (97%) of all insertions evaluated (189 of 195) were rated as clinically acceptable [39 (20%) Strongly Agree, 146 (75%) Agree, 4 (2%) Somewhat Agree, 4 (2%) Somewhat Disagree, 2 (1%) Disagree, 0 Strongly Disagree].

Although the risk of potential needlestick injury can never truly be completely eliminated during cannulation of a vessel, clinicians agreed that the needle retraction mechanism of the Jelco IntuitIV Safety IV Catheter™ eliminated the risk of needlestick injury in 96% (190 of 199) of all insertions evaluated [41 (21%) Strongly Agree, 122 (61%) Agree, 27 (13.5%) Somewhat Agree, 5 (2.5%) Somewhat Disagree, 4 (2%) Disagree, 0 Strongly Disagree.

A clinician's ease of using the device was measured by asking clinicians to rate levels of agreement on 10 different statements relating to the steps of IV insertion – from initially removing the needle from the sheath to securing the catheter to the patient.

For 100% of the insertions, clinicians agreed that they were able to make a connection between the catheter hub and the Luer with ease and that the catheter could be easily secured to the patient. Six (6) of the remaining 8 statements had at least 95% of the ratings between Strongly Agree and Somewhat Agree: easy to remove the needle from protector sheath, easy to orient the needle bevel up, easy to notice when the vessel had been entered, easy to feel and hear when the safety mechanism locked, and that the catheter could be flushed in a clinically acceptable manner.

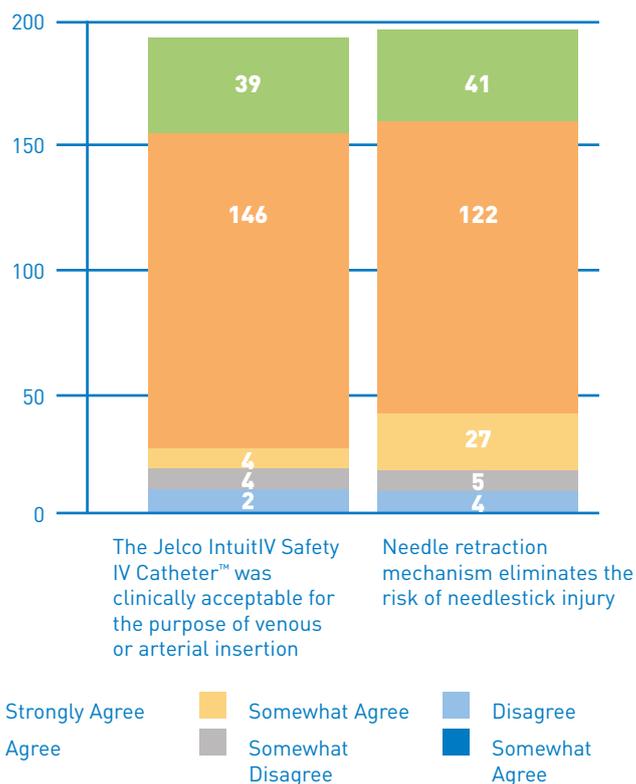
The two areas where clinicians reported slightly lower ratings were disconnecting the catheter hub from the needle assembly and withdrawing the needle. Clinicians agreed it was easy to disconnect the catheter in 88% of insertions and reported it was easy to withdraw the needle in 85% of insertions. As one clinician stated on their form, "Any cannula with additional engineering to reduce needlesticks will have an increased risk of mechanical failure over simple devices." For clinicians that had difficulty disconnecting the catheter and withdrawing the needle, most demonstrated an improvement in ratings after 10-13 uses of the device.

Nine (9) of the 10 clinicians provided an overall assessment of the Jelco IntuitIV Safety IV Catheter™ performance upon completion of the study. All 9 clinicians (100%) agreed that the Jelco IntuitIV Safety IV Catheter™ was overall clinically acceptable and that they were able to easily use the device. All clinicians agreed that the device Instructions for Use provided sufficient information to properly use the product, and 8 of the

CONCLUSION

The purpose of this study was to evaluate the clinical performance of the sideport configuration of the Jelco IntuitIV Safety IV Catheter™. As evidenced from this study, clinicians that are familiar with a conventional or nonsafety peripheral IV catheters can quickly adopt and be successful with a passive safety device. For conventional catheter users, the integration of safety features will inherently change the feel of the catheter during insertion, as demonstrated by the initial decreased ease of use ratings related to withdrawing the needle and disconnecting the catheter from the hub. However, clinicians were able to overcome the challenges of using a new device within the course of the study. All clinicians that participated in the study agreed that the Jelco IntuitIV Safety IV Catheter™ is a clinically acceptable device.

FIGURE 1: CLINICAL ACCEPTABILITY AND RISK OF NEEDLESTICK INJURY



9 clinicians (89%) agreed that the design of the Jelco Safety IV Catheter™ was very intuitive.

Despite the clinicians stating that the needle retraction or safety mechanism eliminated the risk of needlestick injury in 96% of the individual insertions, only 7 of the 9 clinicians (78%) agreed that the safety mechanism of the Jelco IntuitIV Safety IV Catheter™ was clinically acceptable. Clinicians that participated in the study favoured using conventional catheters over safety catheters, and even though they rated the product as easy to use and clinically acceptable, 8 of the 9 clinicians (89%) would also prefer to use the conventional non-safety cannula they were using prior to the study.

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Smiths Medical International
1500 Eureka Park, Lower Pemberton
Ashford Kent, TN25 4BF
Tel: +44 (0)845 850 0445
www.smiths-medical.com

Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442, USA
Tel: 1-614-210-7300 Toll-Free USA: 1-800-258-5361
www.smiths-medical.com

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