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Evaluating the Usability and Acceptability of the GRIPPER® Micro Blunt Cannula, Non-coring Safety Needle

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Objective

To assess the ease of use and acceptability of the GRIPPER® Micro safety needle in clinical use.

Materials

The new GRIPPER® Micro safety needle is a two-piece system that includes an inserter with a built-in non-coring needle attached to the safety arm, and an infusion site with a blunt cannula that remains in the port for the duration of medication delivery. Its unique design helps protect against accidental needle stick injuries. The needle is inserted into an implanted port and the inserter (sharp) is removed, leaving behind the small, low profile infusion site with blunt cannula.

Methods

Study Design

A non-randomized, observational, multi-site evaluation was performed to assess the usability and acceptability of the GRIPPER® Micro safety needle. Three clinical centers from across the United States participated in the evaluation. All sites had access to a large number of oncology patients with implanted venous access ports for medication infusion. Clinicians trained in venous port access infusion therapy performed device access and de-access. Both clinicians and patients answered a series of qualitative questions regarding the ease of use and acceptability with the device.

Patients

Potential participants were identified by clinic staff, and selected patients must have met the following criteria: 1) had an implanted venous port access system in the upper chest and was receiving medication via the port, 2) had received at least five infused therapies prior to enrollment, and 3) had ports most commonly accessed using a ¾" or 1" needle. Selected patients must not have had a history of any port issues (current or previous ports), including but not limited to site infection, inflammation, redness, or erosion.

The majority of patients were between the ages of 51 and 80 (74%). Most patients had implanted port access systems for chemotherapy (75%), and port access time for most patients was 1-72 hours (77%). The evaluation took place during February and March 2008, and a total of 93 patients (31 from each site) participated in the assessment.*

Results

Clinician and patient perception of the GRIPPER® Micro safety needle.

	During Port Access %	During Port De-Access %
Clinician perception:		
Infusion site was easy to dress/use	100	100
Port was easily accessed/ de-accessed	98	99
The inserter safety feature was easy to activate	97	Not applicable
Meets expectations for ease of use	96	99
Performs as expected	96	98
Patient appeared comfortable during portal access/de-access	95	100
Overall satisfaction	95	99
Preferred over currently used device	89	98
Patient perception:		
Device was comfortable	89	100
Satisfaction with size and comfort of device during infusion	Not applicable	100

Conclusion

Results from the present study show that the GRIPPER® Micro safety needle was easy to use and that most clinicians and patients were satisfied with the device. At least 95% of clinicians responded that the device was satisfactory, performed as expected, and met their expectations for ease of use. Also, most clinicians preferred the GRIPPER® Micro safety needle over their currently used device. Moreover, all patients stated that they were satisfied with the size and comfort of the device during infusion. The majority of patients indicated that the device was comfortable both during port access and de-access. Overall, both clinicians and patients were pleased with the performance of the GRIPPER® Micro safety needle.

*Data is on file with Smiths Medical ASD, Inc.

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