

Does a novel method of PICC insertion improve safety?

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Abstract

Background: Placing a central venous access device via the internal jugular or subclavian vein entails significant risks to both patient and healthcare worker. **Purpose:** The purpose of this randomized, prospective study was to determine whether the accelerated Seldinger technique (AST) offers significant safety advantages over the modified Seldinger technique (MST) for peripherally inserted central catheter insertion. **Materials and methods:** Patients were randomly assigned to undergo introducer sheath insertion by means of either MST or AST. Primary outcome measures included time to completion of introducer sheath insertion, estimated blood loss, and success rate. Secondary outcome measures included vessel-to-air exposure events and unprotected sharps exposure. **Discussion:** While both insertion methods proved equivalent for successful vessel cannulation, AST was significantly faster ($P = 0.0048$) and resulted in less blood loss ($P = 0.0295$) than MST. Additionally, AST resulted in significantly fewer vessel-to-air exposure events ($P < 0.0001$) and unprotected sharps exposures ($P < 0.0001$). Although this was a relatively small and unblinded study, the high degree of statistical significance of the study results suggests that, for both patients and healthcare workers, AST is faster and safer than MST for PICC peelable introducer sheath insertion.

Background

Placing a central venous access device (CVAD) via the internal jugular or subclavian vein, although often necessary and potentially lifesaving, entails significant risks.¹⁻³ Peripherally inserted central catheter (PICC) insertion into the deep veins of the upper arm obviates certain risks while introducing others. For example, pneumothorax, inadvertent carotid artery puncture, and guidewire-induced dysrhythmias are risks that can generally be avoided by placing PICCs.⁴ On the other hand, PICC placement is associated with the risk of deep vein thrombosis and pulmonary embolism.⁵⁻⁸ All these risks involve adverse patient outcomes.

Adverse outcomes to healthcare workers associated with CVAD placement include needlestick and other sharps-related injuries, blood-borne pathogen exposure, and liability for patient-related complications.⁹

Clearly, the introduction of methods and/or devices that can mitigate patient and healthcare worker risks arising from CVAD insertion warrants serious consideration.

Purpose

The purpose of this randomized prospective study was to determine whether accelerated Seldinger technique (AST) offers significant safety advantages over the modified Seldinger technique (MST) for PICC insertion.

Materials and methods

Patients referred to the vascular access team for PICC placement were randomly assigned to undergo introducer sheath insertion by means of either MST or AST. (See *Comparing techniques*.) In all but two patients, MST insertions were accomplished using the same manufacturer's MST insertion kit; the two patient exceptions underwent introducer sheath insertion using an MST kit from another manufacturer. AST insertions were accomplished using an all-in-one device for over-the-needle access with a built-in guidewire. (See *Using AST for PICC insertion*.)

Comparing techniques

- **The Seldinger technique**, invented in 1953, requires four components: needle, dilator, guidewire, and sheath (or catheter). The clinician uses each separately: first, placing the needle; next, the guidewire (removing the needle); then, the dilator over the guidewire; and finally, the sheath or catheter over the guidewire once the dilator has been removed. For the MST, the dilator and sheath are assembled together ("coaxially"), saving a step. The advantages of MST are that with a small needle, a clinician can dilate up to a large-bore sheath or catheter, which the guidewire allows to be placed in vessels with valves, stenoses, and tortuosities. The disadvantages of MST include the cumbersome use of multiple components with multiple on-off movements—risking both bloodstream and healthcare worker contamination.
- **The AST**, invented in 2007, has the same four components in an all-in-one device. The needle is placed in the vessel; then, the guidewire is advanced; finally, the dilator and sheath (or catheter) are inserted over needle and guidewire. With AST, components can't be dropped and the risk of contamination is substantially reduced. The risks of guidewire and air embolism are also reduced.

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Primary outcome measures included:

- time to completion of introducer sheath insertion
- estimated blood loss (EBL)
- success rate (meaning, successful insertion of the introducer sheath).

Secondary outcome measures included:

- vessel-to-air exposure events
- unprotected sharps exposure, such as needles or scalpels.

All data were collected during the procedure by an independent observer who hadn't been informed of the study's outcome measures. Time to completion was measured from skin penetration of the AST or MST needle to full insertion of the introducer sheath into the target vessel. (Note: Subsequent successful passage of the PICC to the superior vena cava didn't constitute an entry criterion because many unrelated variables determine this outcome.)

Blood loss was estimated by measuring the diameter of the blood spot

on gauze of uniform thickness routinely placed at the insertion site at the beginning of the procedure. Open-to-air events were witnessed and recorded as they occurred, as were sharps exposures.

Inclusion criteria for study participation were as follows:

- age 18 or older
- having a healthcare provider's order for a PICC
- being capable of providing informed consent (English speaking or via native language translator)
- not an upper extremity arteriovenous graft or native fistula near-term candidate (that is, patients must have a glomerular filtration rate [GFR] above 60 mL/min/1.73 m²)
- having a vein suitable for PICC placement identified on ultrasound.

Exclusion criteria for study participation were as follows:

- inability to hold still for procedure
- history of previous PICC in target vessel

- history of mastectomy on side of target vessel
- GFR less than 60 mL/min/1.73 m² (without nephrology clearance)
- allergy to any of the components or solutions used for PICC placement
- presence of any contraindication listed on PICC, AST, or MST kit manufacturers' instructions for use.

Results

A total of 30 patients were assigned to either the MST group (N = 16) or the AST group (N = 14). Both groups were well matched with respect to patients' age, gender, ethnicity, and the presence or absence of an underlying bleeding disorder. (For more about the baseline characteristics of patients, see supplemental digital content online and on the *Nursing2014* iPad app.)

Primary outcome parameters.

The two techniques didn't differ significantly with respect to the success rate: MST resulted in 13/16 (81.3%) successful insertions; AST resulted in 12/14 (85.7%) successful insertions.

Times to completion of sheath insertion differed significantly between the two groups. On average, MST required 4.21 minutes to complete, while the average time to completion for the AST group was 1.27 minutes ($P = 0.0048$).

EBL also differed significantly between the two groups. The average EBL associated with MST was 4.2 cm; with AST, the EBL averaged 2.4 cm ($P = 0.0295$).

Secondary outcome parameters.

Vessel-to-air exposure events differed significantly between the two groups. With MST, an average of 2.31 exposure events occurred; with AST, an average of 1.0 exposure events occurred ($P < 0.0001$).

No exposures to unprotected sharps occurred in the AST group, but exposure to unprotected sharps

Using AST for PICC insertion

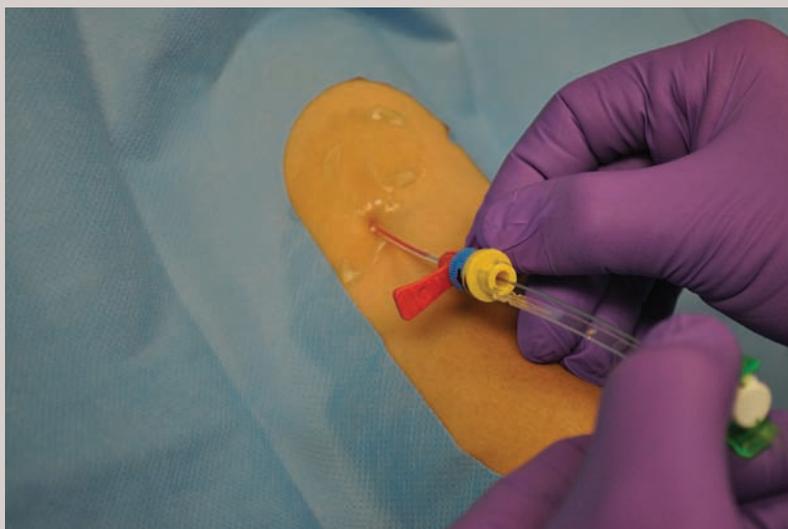


Photo shows peelable sheath being inserted over needle and guidewire using AST. Notice that no skin nick was required and no blood loss is evident. Total time for insertion is just seconds.

occurred in 93.8% of the MST group ($P < 0.0001$).

Discussion

In 1953, Dr. Sven Seldinger first described an over-wire technique for vessel cannulation.¹⁰ While an improvement over previous approaches for accessing deep vessels, this technique entailed certain risks, including lost cannulation during multiple exchanges; multiple vessel-to-air events; dropped components; lost, damaged, or embolized guidewires; excessive bleeding; soft-tissue and vessel damage; and sharps injuries.¹¹

Present-day improvements to the original technique include the coaxial mounting of dilator to sheath and improved materials and design of the various components. Despite these improvements, most of the same risks still remain.¹¹

In 2010, the FDA issued 510(k) clearance for the AST study device—which includes passive needlestick safety—allowing the claim that it's “faster, safer and simpler” than MST.¹² The FDA also allowed the claim that AST “reduces the risk of air embolism by 50%,” based on the fact that AST entails one versus two or more open-to-air events with MST.

Results of the present study confirm the FDA's findings. While both methods of insertion appear equally effective, AST proved more than three times faster with fewer than half the vessel-to-air exposure events. The risk of bloodstream contamination is mitigated by AST in two ways: reduced opportunity for microbes to enter the bloodstream during vessel-to-air events and reduced time exposure of components to the ambient microbial environment. Although the absolute time difference between the two techniques isn't extensive, averaging just 2.74 minutes, the less time components are exposed to air-

borne droplets during any insertion, the safer the procedure. Moreover, an infusion team performing, for example, eight procedures/day will save an aggregate 22 minutes/day using AST.

Additional safety benefits of AST include reduced blood loss and the elimination of unprotected sharps exposure. Both limit clinicians' exposure to blood-borne pathogens.

Patients may benefit in other ways from AST. For example, because the study device has a fenestrated needle with transparent, overlying dilator and sheath, detection of vessel entry is virtually instantaneous. This prevents back-walling (puncturing the back wall of the vein) and may reduce rates of phlebitis and thrombosis.

At New York Hospital Queens, the cost of MST kits is \$32. The AST device costs \$50. For an incremental cost of \$18 per patient (about 7% of the total cost of a PICC insertion), patients and healthcare workers can benefit from the added safety and efficiency of AST. Additional potential cost savings could result from avoiding patient complications and healthcare workers' injuries.

Although study results generally reached a high degree of statistical significance, this study has some limitations. Foremost, inserting clinicians weren't completely blinded: They were aware that the two techniques were being compared. To diminish this effect, an unbiased observer was used in all cases to collect data and the study's outcome measures were at no time disclosed to the inserting clinicians. Nevertheless, the effects of bias can't be fully ruled out. Although the sample size was sufficient to generate statistical significance, it was relatively small.

At a time when infusion teams are being pressured to prevent central line-associated bloodstream infections and increase team productivity,

AST appears to be faster and safer than MST for PICC introducer sheath insertion for both patients and for healthcare workers. ■

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