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Ultrasound-guided intravenous access in adults using SonoStik®, a novel encapsulated sterile guidewire: A prospective cohort trial

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Abstract

Purpose: We evaluated the performance of an encapsulated guidewire designed for single-handed use with ultrasound-guided vascular access (SonoStik) with Seldinger technique, as compared with conventional intravenous catheters placed under ultrasound guidance in healthy subjects.

Methods: This is a prospective cohort trial in healthy subjects in which each subject served as his/her own control by having a SonoStik ultrasound intravenous cannulation placed in one arm and a conventionally placed, standard ultrasound intravenous cannulation placed in the other arm. The basilic vein was used because it is a non-visible and non-palpable vein. Emergency department technicians with extensive experience in ultrasound-guided intravenous access performed the procedures. The first-attempt success rate of intravenous-guided intravenous by using the SonoStik was compared to the standard ultrasound intravenous cannulation in adult healthy subjects. The secondary outcomes including time of procedure, technicians' and subjects' satisfaction, and complications were compared in both arms of the study.

Results: A total of 24 volunteers with a mean age of 22.7 years were enrolled. Four emergency department technicians with extensive prior experience with ultrasound-guided intravenous access but with no prior experience using the SonoStik device performed the procedures. The first-attempt success was 83.3% with the use of SonoStik ultrasound intravenous cannulation compared to 95.8% with the standard ultrasound intravenous cannulation. There was a mean of 1.14 insertions per each successful placement in the SonoStik group compared to 1.04 insertions by using the standard catheters (mean differences = –0.1; 95% confidence interval = –0.6 to 0.4). There were no complications in either SonoStik or the standard ultrasound intravenous cannulation group. The mean time of insertion using SonoStik was slightly longer compared to standard ultrasound intravenous cannulation (143.3 vs 109.7 s).

Conclusion: This study demonstrated that emergency department technicians skilled in ultrasound-guided intravenous access could successfully place SonoStik 83.3% of the time in vessels that were unable to be palpated or visualized. Compared to standard ultrasound intravenous cannulation, the odds ratio of successful cannulation with SonoStik was 0.91 (95% confidence interval = 0.04–17.5). In all cases, the time required to successfully insert SonoStik was less than 4 min from tourniquet application to catheter advancement to hub, with a mean time of less than 2.5 min.

Keywords
Intravenous access, ultrasound, SonoStik®

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Introduction

Ultrasound (US) has been demonstrated to improve the success rate of peripheral intravenous cannulation (IV) in patients with predicted difficult access (e.g. no veins visible or palpable).[1,2] A recent randomized controlled trial involving 1189 patients found that in patients with predicted difficult access, US-guided IVs resulted in 48 more

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successful IVs per 100 attempts when compared with conventional IVs (i.e. palpation/visualization method), yet still had only an 82% success rate.[3] Even with US, US-guided IV access in this patient population has a variable success rate, from 79% to 97%.[4] Improving the first-attempt success rate creates an opportunity to improve patient satisfaction and potentially reduces time to medications and prevent diagnostic delays.[5]

As vascular access can present a significant challenge, multiple devices have been studied to aid in vascular access.[6,7] New IV catheter delivery options have the potential to further affect the success rate of US-guided IV. A recent study reviewing a new IV device with integrated guidewire that uses a guidewire delivery system showed an improved first-time insertion success rate.[8] However, these devices, and others commonly used such as arterial catheter sets,[9] often require two hands to hold the IV and advance the guidewire, making it a challenge to use with one-person US guidance technique. In this study, we evaluate the performance of a new FDA-approved vascular access device, SonoStik®, with a retractable encapsulated sterile guidewire and novel mechanism for one-handed operation and guidewire advancement. We performed the current pilot study to evaluate success rates of US IV cannulation using SonoStik compared to standard, conventionally placed, catheter-over-needle US-guided IVs in veins that were non-visible and non-palpable in the upper arms of healthy subjects and sought to identify factors involved with the technique of insertion of the catheter.

Methods

Study design

We conducted a prospective cohort study with a two-group parallel design, with each patient serving as their own control. The study was carried out by the emergency medicine physicians and staff of the emergency department (ED) of an urban, tertiary-care, academic Level 1 trauma center. The study was approved by the Institutional Review Board (IRB) and written informed consent was obtained from all ED technicians and subjects. The study design conforms to the STROBE recommendations on reporting of observational cohort data.[10]

Study population and setting

The study recruited four ED technicians and 24 subjects. The ED technicians had all been previously trained and credentialed by the hospital to place US-guided peripheral intravenous catheter.[1,11] The subjects were all healthy adults who provided informed consent prior to participating in the study and were paid a small stipend for participation. Subjects were deemed ineligible if they had a medical history of blood clotting disorders, vascular disease, immune system dysfunction, or medication with blood thinning agents.

Figure 1. The image of SonoStik®, a novel encapsulated sterile guidewire.

Study protocol

The SonoStik is an encapsulated guidewire device with a single-handed guidewire advancement mechanism and inserts into the hub of a standard IV catheter (Figure 1). This SonoStik-IV catheter unit is advanced together under US guidance until the tip of the needle is visualized inside the vein, at which point the guidewire is advanced fully in to the vein and the catheter advanced over the guidewire using a Seldinger technique. None of the ED technicians had prior experience using the SonoStik Introducer, but all had significant experience placing US IVs.

The study took place in a single-day session in February 2017 at the outpatient clinics of the Medical Faculty Associates of George Washington University. Before enrollment began, the study was explained in detail, including aims, methods, risks, and benefits, to both the group of four ED technicians and the 24 subjects, and any questions were answered prior to them providing written informed consent. Subsequently, the ED technicians received brief training including didactics and hands-on demonstration using tissue phantoms in the use of the SonoStik device. Following the brief training, the subjects were randomly assigned to an ED technician to have an US IV placed in each arm. Each subject would have a SonoStik US-guided IV placed in one arm and a standard US IV placed in the other arm, both using an 18-gauge angiocatheter. The selection of the initial arm used for IV placement and the initial technique of SonoStik versus standard US IV placement was determined through a block design that provided instructions as to initial side and technique, concealed in an opaque envelope and distributed evenly across groups. The basilic vein, typically found deeper than other veins of the forearm and antecubital fossa, was chosen in order to provide a non-palpable and non-visible target for the ED technician to place the IVs into the subjects in order to mimic as closely as possible the difficult access patient (Figure 2 and Supplementary Video 1).

For each US IV placement, the skin of the medial upper arm was sterilely prepped in the usual fashion, the

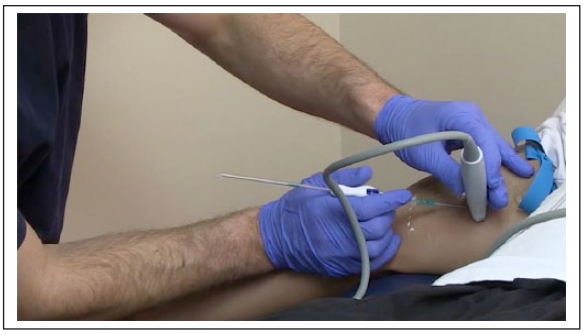
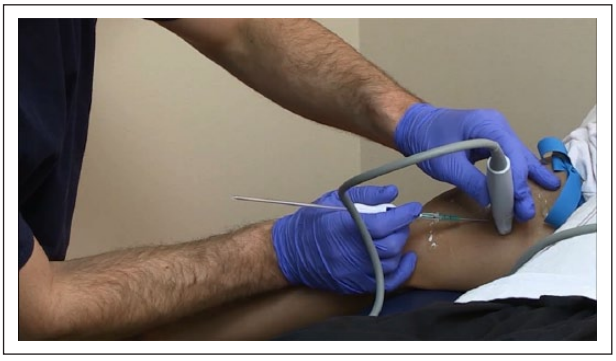


Figure 2. Image of a provider performing ultrasound-guided basilic vein cannulation using SonoStik®.



Video 1. A clip of a provider performing ultrasound-guided basilic vein cannulation in the right upper extremity using SonoStik®, a novel encapsulated sterile guidewire.

probe was covered with a sterile occlusive dressing after disinfecting the probe surface, and a tourniquet was placed on the proximal upper arm of the subject. On application of the tourniquet, a timer was started. A transverse view of the basilic vein and an out-of-plane technique was employed with both the experimental and control groups. The timer was stopped when the catheter hub had been advanced to the skin. To ensure identification of misplaced, dislodged, or infiltrated IVs, 250 mL of normal saline solution was administered to ensure successful line placement. After the 250 cc infusion was complete, the catheter was removed, pressure was placed on to the site, a sterile dressing applied, and a second catheter was attempted in the other arm using the technique not yet performed. Unsuccessful first attempt was followed by a second attempt at the same site, using the same technique and device for the completion of enrollment. No subsequent attempts were allowed per protocol to minimize volunteer discomfort.

After completion, the US IV Technician and subject provided their overall satisfaction rating on a 10-point Likert scale, as well as more open-ended feedback regarding the catheters, placement technique, ease of use, and suggestions for training improvements.

Table 1. Characteristics of volunteer subjects (n = 24) and ED technicians (n = 4).

Characteristic	Number (%)
Age (mean, years)	22.7 (range: 19–46)
Gender	
Male	13 (54%)
Female	11 (46%)
Height (mean, cm)	174.6
Weight (median, kg (IQR))	70.5 (63.4–79.5)
Body mass index	
<18.5	2 (8.7%)
18.5–24.9	15 (65%)
25–29.9	3 (13%)
>30	3 (13%)
ED technicians	
Years experience with US-guided IV	1.08
Years experience with conventional IV (mean)	2

IQR: interquartile range; ED: emergency department; US: ultrasound.

Measurements and key outcome measures

The primary outcome of this study was the first-attempt success rate of the SonoStik as compared to the standard US IV. An attempt was defined by insertion of the IV under the surface of the skin with no limit to the number of subcutaneous redirections. First-attempt success was defined as a successful IV placement with blood return and ability to infuse 250 mL of IV fluid without infiltration on first subcutaneous insertion. The secondary outcomes that were measured included the number of attempts per insertion, complication rates, the time from tourniquet application to catheter advancement, ED technicians' and volunteers' satisfaction and qualitative feedback on the SonoStik device, placement technique, ease of use, and suggestions for improving training on use of the device.

The demographic variables collected before beginning the study protocol included the subjects' demographic data (age, gender, height, weight, and body mass index (BMI)) and the IV experience of ED technicians (both US IV and standard IV) (Table 1).

Statistical analysis

Statistical analysis was performed to determine the significance of difference between US-guided IV access success rate using SonoStik (the experimental group) versus standard catheters (the control group) (Table 2). Descriptive analysis included subjects' demographics, baseline characteristics, and first-attempt insertion success as the primary endpoint. Results of the success rate were expressed by the Clopper–Pearson exact confidence interval, or null hypothesis, for p value. Secondary end points involved the number of attempts, complication rates, procedure time, and

Table 2. Comparing success rate and time of procedures between IV access procedures using SonoStik® versus standard catheters.

Variable	SonoStik® device	Standard catheter	Confidence interval
First-attempt success rate	83.3%	95.8%	(OR = 0.91; CI 0.04–17.5)
Mean number of attempts	1.14	1.04	−0.16 to −0.04
Mean procedure time (s)	143.3	109.7	−42.7 to −25.3
Overall complication rate	0	0	
Technician satisfaction	7.9/10	9.8/10	0.74 to 3.06
Volunteer subject satisfaction	8.2/10	8.9/10	−0.46 to 1.86

OR: odds ratio; CI: confidence interval.

patient satisfaction data, using the same statistical analysis process.

Results

The study included 24 healthy subjects representing 48 arms for IV placement. Four ED technicians performed all the procedures. Of the 24 subjects who completed the study, 46% were female (n = 11) and 54% were male (n = 13) with a mean age of 22.7 years. Median weight of subjects was 70.5 kg (interquartile range (IQR): 63.4–79.5) (Table 1). All subjects completed all study-related procedures.

The first-attempt success was observed among 20 subjects (83.3%) with the use of SonoStik and 23 subjects with the standard catheters (95.8%) (Table 2). Qualitative analysis of the feedback given by the ED technicians revealed that two of the four SonoStik failures resulted from looking for a flash of blood in the hub of the IV that never came through the catheter because of the guidewire in place (occluding the lumen of the needle), instead of looking for the needle tip on the US screen. The utilization of the study device was averaged 1.14 catheters per successful insertion in SonoStik group compared to 1.04 catheters using standard catheters (mean differences = –0.1; 95% CI = –0.6 to 0.4). No complications were observed.

The overall elapsed time from the tourniquet application to the flush time was 125.3 s with a trend toward a slightly longer time interval with the SonoStik-guided IV by 33.6 s as compared to the standard US IV. The mean time for SonoStik-guided IV placement was 143.3 s (122.0–164.6 s) compared to standard US IV mean time of 109.7 s (90.6–127.9 s). Therefore, from the 19 paired successes eligible for analysis, the mean time of the SonoStik took significantly longer statistically (p = 0.015; mean difference = –34; 95% CI = –42.7 to 25.3).

Discussion

In this pilot study, we sought to evaluate the feasibility of a new encapsulated sterile guidewire device to aid in placement of US IVs in non-visible and non-palpable basilic veins among healthy volunteers. The 83.3% success rate of the SonoStik-aided US IV was lower than the standard US IV in this study, but within the range of success reported in prior studies evaluating US IV placement. The procedure time was also slightly longer in the SonoStik group, although the additional 35 s required is likely not clinically significant.

A few features of the current pilot bias the study in favor of standard US IV. First, despite the protocol of using the non-visible, non-palpable basilic vein, the young healthy volunteers with relatively easy IV access elsewhere do not reflect the difficult IV access population in the ED, and although the caliber of the basilic vein was not measured, it appeared prominent in all subjects. This made the US-guided IV placement relatively easier, as reflected in the 96% success rate of US IV compared to this ED tech group's 82%–86% success rate over 605 attempts in a previously published study,[1] even with the chosen "cannot visualize, cannot palpate" scenario of the basilic vein. This may have undercut any potential advantage of the SonoStik. Second, this study represented the first 5–7 SonoStik attempts by each of the ED technicians, as compared to their previous experience of performing hundreds to thousands of standard US IVs. This pilot does not take into account any potential learning curve that may exist for a reduction in SonoStik insertion time and increase in SonoStik success rate that may come with increasing experience. Third, the tourniquet to catheter advancement time interval may have been prolonged in the SonoStik group by the need to assemble the SonoStik-IV catheter unit and pre-advance the guidewire to just before the bevel of the angiocatheter.

This group of experienced ED technicians utilizing the experimental device with encapsulated guidewire did impact the first-attempt success rate in either SonoStik or standard IVs in this healthy patient population. However, the SonoStik has potential to improve the success rate among less experienced providers and more significantly may be helpful in the truly difficult access population. We suggest that additional prospective studies among providers with various experiences

and skills, as well as in patients with a validated indicator of difficult vascular access such as those with no visible or palpable veins at all, may demonstrate the efficacy of the SonoStik. The potential next steps of this study would include a randomized controlled trial in an ED setting for patients with anticipated difficult access to measure the primary outcome of (1) success rate of SonoStik versus standard US IV placement and the secondary outcomes of (2) time from needle–catheter insertion and (3) provider and patient satisfaction and complications.

Limitations

The study was limited to a small group of healthy volunteers under controlled conditions. The small sample size of this study could potentially bias the comparison and prevent its generalizability, although in the current protocol each subject acted as his/her own control, which may have improved the reliability of the data. We exclusively used non-palpable and non-visible basilic veins as the only target to avoid variability among the access and minimizing measurement biases, although these healthy subjects are likely dissimilar to patients in previous studies with no visible or palpable veins at all. We also used a group of expert ED technicians with extensive experience in US-guided IV placement and a group of healthy subjects in which both could influence the success rate with the direction of decreased efficacy of the SonoStik.

Conclusion

This study demonstrated that ED technicians skilled in US-guided IV access could successfully place SonoStik 83.3% of the time in the vessels of healthy volunteers who were unable to be palpated or visualized. In all cases, the time required to successfully insert SonoStik was less than 4 min from tourniquet application to catheter advancement to hub, with a mean time of less than 2.5 min. Given the short training time and absence of complications in the SonoStik trials, this study demonstrated that the SonoStik is usable, safe, and fast and has the potential for use in patients with predicted difficult IV access.

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Declaration of conflicting interests

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