

Randomized, controlled clinical trial of point-of-care limited ultrasonography assistance of central venous cannulation: The Third Sonography Outcomes Assessment Program (SOAP-3) Trial*

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Context: A 2001 Agency for Healthcare Research and Quality Evidence Report on patient safety addressed point-of-care limited ultrasonography guidance for central venous cannulation and strongly recommended real-time, dynamic guidance for all central cannulas. However, on the basis of one limited study, the report dismissed static assistance, a “quick look” with ultrasound to confirm vein location before preparing the sterile field, as unhelpful.

Objective: The objective of this trial was to compare the overall success rate of central cannula placement with use of dynamic ultrasound (D), static ultrasound (S), and anatomical landmarks (LM).

Design and Setting: A concealed, randomized, controlled, clinical trial conducted from September 2003 to February 2004 in a U.S. urban teaching hospital.

Patients: Two-hundred one patients undergoing internal jugular vein central venous cannulation.

Interventions: Patients were randomly assigned to three groups: 60 to D, 72 to S, and 69 to LM. An iLook25 SonoSite was used for all imaging.

Measurements and Main Results: Cannulation success, first-

attempt success, and number of attempts were noted. Other measures were vein size and clarity of LM. Results, controlled for pretest difficulty assessment, are stated as odds improvement (95% confidence interval) over LM for D and S. D had an odds 53.5 (6.6–440) times higher for success than LM. S had an odds 3 (1.3–7) times higher for success than LM. The unadjusted success rates were 98%, 82%, and 64% for D, S, and LM. For first-attempt success, D had an odds 5.8 (2.7–13) times higher for first success than LM, and S had an odds 3.4 (1.6–7.2) times higher for first success than LM. The unadjusted first-attempt success rates were 62%, 50%, and 23% for D, S, and LM.

Conclusions: Ultrasound assistance was superior to LM techniques. D outperformed S but may require more training and personnel. All central cannula placement should be conducted with ultrasound assistance. The 2001 Agency for Healthcare Research and Quality Evidence Report dismissing static assistance was incorrect. (Crit Care Med 2005; 33:1764–1769)

KEY WORDS: ultrasonography; central venous cannulation; outcomes assessment

Establishing reliable vascular access in an emergency situation is often of critical importance. Many factors, including body habitus, volume depletion, shock, intravenous drug use, anatomical deformity, and cardiac arrest, can make obtaining vascular access in the critically ill or injured patient extremely difficult. The

introduction of *Point-of-care, Limited UltraSonography* into emergency medical practice may become an important advance for facilitating rapid and successful vascular access (1–11).

For central venous cannulation, the traditional approach has involved using anatomical landmarks. For instance, internal jugular location relies on the sternocleidomastoid muscle and clavicular landmarks. However, in many patients these landmarks may be distorted, and normal variations in the anatomical relationship of the internal jugular may prevent cannulation (12). In the emergent situation, attempting cannula placement with poor external landmarks frequently involves multiple needle passes to locate the vessel. Excessive bleeding, inadvertent arterial puncture, vessel laceration, pneumothorax, and hemothorax are

some of the potential complications of central vascular access. The incidence of complications increases when multiple attempts are required for cannulation (13–17). In patients with an underlying coagulopathy, multiple attempts can carry significant morbidity due to hemorrhage (18, 19).

An Agency for Healthcare Research and Quality Evidence Report published in 2001 listed ultrasound assistance of central cannula placement as one of the “Top 11 Highly Proven” patient safety practices that are not routinely used in patient care, and it recommended all central cannula placements be guided by real-time, dynamic ultrasound (D) (20). The report dismissed as unhelpful the use of static ultrasound assistance (S)—a quick-look visualization before the procedure to evaluate the best approach and mark the

*See also p. 1875.

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skin over the vein—on the basis of one study performed in a high-volume center with very high preexisting success rates (21). That study also included only subclavian central cannulas, which are the least amenable to ultrasound assistance.

Our trial was the third study of the Sonography Outcomes Assessment Program, a multiphase health services research project designed to accumulate evidence of the effect on patient care outcomes of point-of-care, limited ultrasonography in the emergent evaluation of common, costly, and potentially lethal clinical conditions.

For this trial, we primarily hypothesized that the ultrasound assistance of central cannula placement, both S and D, would be superior to the landmark (LM) approach for cannulation success. Secondarily, we hypothesized that ultrasound assistance, both S and D, would be superior with regard to first-attempt success rate, number of sticks, time to cannulation, and complication rate.

METHODS

Participants

This study, approved by the New York Methodist Hospital Institutional Review Board, was conducted at an urban teaching hospital during a 6-mo period from September 2003 to February 2004. The study population was enrolled when one of seven study investigators was available. The majority of subjects were from the emergency department and medical intensive care unit.

Inclusion criteria were any of the indications for central cannula placement, as determined by the attending physician caring for the patient. Exclusion criteria were any contraindications to internal jugular central cannula placement or inability to obtain or refusal of consent.

Study Sonographers and Operators

Study investigators were emergency medicine residents and attending physicians who had received a 1-hr bedside teaching session on identifying the carotid artery and internal jugular vein with an iLook25 SonoSite ultrasound machine (SonoSite, Bothell, WA) with a 7.5-MHz linear-array probe, the same equipment used on all study subjects. Subsequently, they had to demonstrate proficiency at dynamic ultrasound-guided central venous cannulation by performing the procedure a minimum of ten times. Study investigators either performed or assisted in all dynamic proce-

dures. The least experienced investigator had placed 30 cannulas at the study's outset. The most had placed >100.

Any doctor credentialed by the hospital for central cannula placement, including study investigators, performed procedures in the S and LM groups. The nonultrasound central cannulization credentialing process requires five supervised procedures per anatomical location (internal jugular, femoral, subclavian) and subjective assessment of proficiency in the procedure by a supervising physician.

Sample Size Estimate

We estimated that, given 70 patients in each group (S, D, LM), or 210 total, we would have 80% power to detect a 25% difference in success rates at a test level of 0.05.

Study Design

This was a randomized, controlled clinical trial of ultrasound assistance in central cannula placement. Randomization was performed with use of a random number table. The enrollment forms were sealed in coded opaque envelopes. After consent was obtained and immediately before the procedure, a study investigator at the bedside opened the enrollment packet, which indicated the group to which the patient had been randomized.

The following three study groups were established. *Dynamic ultrasound (D)*: for the D group, the transducer was placed in a sterile sleeve and sterile coupling gel was applied. Cannulation was under real-time ultrasound visualization in the transverse plane. *Static Ultrasound (S)*: for the static group, the transducer was used to locate the internal jugular. Visible skin indentations were made at two places along the course of the vessel, approximately 1 inch apart. The transducer was removed and the cannulation was performed with use of one mark as a locator needle skin entry point, aiming toward the second mark. "Rescue dynamic ultrasound" was available in this group. *Landmark (LM; Control)*: the traditional LM-based group had cannulation attempted without ultrasound. "Rescue dynamic ultrasound" was available in this group.

Preprocedure Likelihood of Difficulty Assessment

Clarity of Anatomical Landmarks Score. In order to control for anatomical variation of the study subjects, we developed and validated a 5-point Likert scale measuring the clinician's overall preprocedure impression of difficulty, based on the clarity of study subjects' anatomical landmarks, for internal jugular central cannula placement (1 = very clear landmarks and low probability of difficulty; 5

= very poor landmarks and high probability of difficulty).

Definitions

Successful Cannulation. Cannulation was successful if the J-wire was placed without resistance.

First-Attempt Cannulation Success. Cannulation was considered successful at the first attempt if it was achieved with the first needle pass.

Cannulation Attempt. An attempt was a single pass of the 18-gauge locator needle with no degree of withdrawal or redirection and with subsequent forward movement, whether or not a new skin puncture was made. Each successive withdrawal or redirection with subsequent forward movement was considered another attempt.

Time to Cannulation. The cannulation time, i.e., from "needle to skin to J-wire in," was measured in seconds.

Arterial Puncture. Arterial puncture involved aspiration of pulsatile arterial blood into an 18-gauge locator needle syringe.

Rescue. After five attempts or 5 mins of attempting cannulation, the patient was rescued by the dynamic technique.

Data Collection

The investigator recorded the sonographer, operator, patient demographic data, vital signs, comorbidity, indication for central cannula, and anatomy score. In the ultrasound groups, vein diameter was also recorded. After the procedure, the investigator recorded cannulation success, first-attempt success, number of attempts, time to cannulation, and complications.

Outcome Variables

Primary outcome was cannulation success. Secondary outcomes were first-attempt success, number of attempts, time to placement, and complications. Results, controlled for pretest difficulty assessment, are odds improvement (95% confidence interval) over LM for D and S.

Statistical Methods

The data analyses were performed on an intention-to-treat basis. All enrolled patients receiving internal jugular central cannulas were included in the analyses. All analyses were performed with use of R software (23).

Analyses were conducted with logistic and linear regression both to estimate the main effects and to control for possible confounders such as the score for clarity of anatomical landmarks.

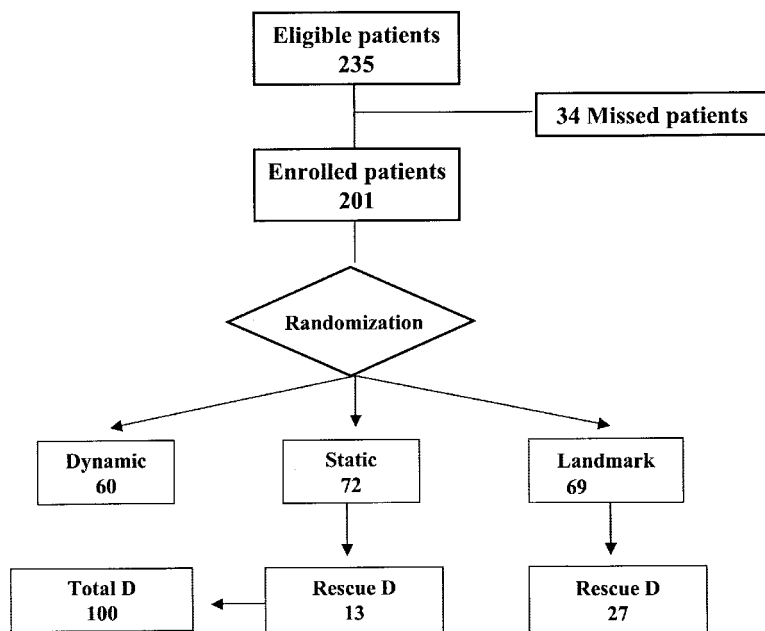


Figure 1. CONSORT participant flow chart.

RESULTS

Participant Flow

During the 6-month trial period, 235 patients underwent central cannula placement and were eligible for enrollment. Thirty-four patients were not enrolled because of the unavailability of an investigator (10) and were not called (24). No patients refused enrollment. Two-hundred one patients were enrolled and randomized: 60 to D, 72 to S, and 69 to LM. Rescue dynamic ultrasound was conducted for 13 S patients and 27 LM patients (Fig. 1). Twenty-two physicians performed the procedures.

Patient Demographics and Baseline Characteristics of the Study Population

Table 1 presents the demographic and baseline characteristics of the study population. D, S, and LM patients were compared with respect to age, gender, ethnicity, preprocedure vital signs, comorbidity, indications for central cannulation, history of central cannulation, and anatomy score. No significant differences were noted between the study groups.

Primary Study Hypothesis: Ultrasound Assistance will Enhance Cannulation Success

The unadjusted (for difficulty) success rates were 98%, 82%, and 64% for D, S,

and LM. The primary outcome of the trial was cannulation success, presented as odds improvement with 95% confidence intervals (Table 2). D and S were superior to LM. A logistic regression model was run for success, controlling for anatomical

landmark score. Group S was superior to LM, with the odds of an eventual success 3.0 (1.3–7) times greater for group S than for group LM. Group D was superior to LM, with the odds of an eventual success 53.5 (6.6–440) times greater for group D than for group LM. These odds ratio confidence intervals are wide because the success rates were near 100%.

Secondary Study Hypotheses: Ultrasound Assistance will Enhance First-Attempt Success and Reduce the Mean Number of Attempts, Time to Cannulation, and Complication Rate

First-Attempt Success. The unadjusted first-attempt success rates were 62%, 50%, and 23% for D, S, and LM. The secondary hypothesis was that both group S and D would be superior to group LM. This was indeed the case, as confirmed by a logistic regression model with first success as the outcome, with group as the factor, and controlling for the anatomical landmark score. Group S was superior to LM, with the odds of a first success 3.4 (1.6–7.2) times greater

Table 1. Patient demographic and baseline characteristics and the incidence of prior central venous cannulation in the study population

Characteristic	LM	S	D
Age, yrs, mean ± 95% CI	71 (67–75)	71 (67–75)	73 (68–76)
Gender, % female	67	57	62
Ethnicity, ^a %			
African American	25	31	27
White	60	58	58
Hispanic	6	8	12
Other	6	3	3
Systolic blood pressure, mm Hg, mean ± 95% CI	121 (113–129)	122 (114–130)	116 (109–123)
Pulse, beats/min, mean ± 95% CI	93 (88–98)	94 (89–99)	100 (94–106)
Respiratory rate, breaths/min, mean ± 95% CI	22 (20–24)	21 (19–23)	21 (19–23)
History of central cannulation, %	50	50	44

All comparisons between dynamic ultrasound (D), static ultrasound (S), and anatomical landmark (LM; control) guidance were not significant. No group-to-group variability was noted. CI, confidence interval.

^aDetermined by investigator.

Table 2. Comparison of cannulation success with dynamic ultrasound (D), static ultrasound (S), and anatomical landmark (LM) guidance

Primary Outcome	D n = 60	S n = 72	LM n = 69
Cannulation success ^a odds ratio (95% CI), compared with LM	53.5 (6.6–440)	3.0 (73–91)	—
Unadjusted success percentages	98	82	64

CI, confidence interval.

^aJ-wire successfully inserted. All comparisons were significant in multivariate regression models.

Table 3. First-attempt success, number of attempts, time to cannulation, and complications with dynamic ultrasound (D), static ultrasound (S), and anatomical landmark (LM) guidance

Secondary Outcomes	D n = 100	S n = 72	LM n = 69
Odds ratio for first-attempt success, compared with LM	3.4 (1.6–7.2)	5.8 (2.7–13)	—
Unadjusted first-attempt success percentage	62	50	23
Mean number of attempts, including 40 dynamic rescues	2.3 (1.6–3)	2.9 (2.3–3.5)	5.2 (4.1–6.3)
Mean time to cannulation, in secs, including 40 dynamic rescues	109 (47–171)	126 (89–163)	250 (184–316)
Complication rate, %	3 (0–8)	3 (0–8)	13 (5–21) ^a

Confidence intervals are in parentheses. All ultrasound (D, S) group vs. LM group comparisons were significant in multivariate regression models, except for complication rate. An attempt is a single pass of the 18-gauge locator needle, with no degree of withdrawal or redirection and with subsequent forward movement; a complication is any carotid artery puncture.

^aNot significant.

for group S than for group LM. Group D was superior to LM, with the odds of a first success 5.8 (2.7–13) times greater for group D than for group LM (Table 3).

Mean Number of Attempts. A linear regression model was run, with number of attempts as the response and controlling for the score for clarity of anatomical landmarks. Group LM had an adjusted mean number of attempts of 3.2. Group S was superior to LM, with the mean number of attempts 1.6 (0.6–2.7) less than for group LM. Group D was also superior, with mean number of attempts 1.7 (0.6–2.8) less than for group LM.

Initial Time. A linear regression model was then run with initial time as the response. Time includes only the time taken while attempting the central cannulation by the technique to which it was randomized. For failures, it includes only the time until the technique was abandoned (after either five sticks or 5 mins). It does not include rescue time. Group LM had an adjusted mean time of 130 secs. Group S was superior to group LM, with the mean number of seconds 92 (13–170) less than for group LM. Group D, however, was only marginally superior to LM, with the mean number of seconds 70 (–14–150) less than for group LM.

Total Time. Finally, a linear regression model was run with total time as the response. Total time includes rescue time. Group LM had an adjusted mean total time of 150 secs. Group S was superior to group LM, with the mean number of seconds 130 (44–210) less than for group LM. Group D was also superior to LM, with the mean number of seconds 120 (33–210) less than for group LM.

Complications. There were few com-

plications, and all were carotid artery punctures: eight in the LM group and two in each of the ultrasound groups. The differences were not significant.

Predictors of Successful Central Venous Cannulation

In a separate article, we developed and validated the score for clarity of anatomical landmarks and found it to be a good predictor of success in the LM group. This effect disappeared in the ultrasound groups of D and S, but in those groups vein size was an important predictor of success. Another article examined the effect of vein size on success and the other outcome variables.

Cannulation Failures

There were only two ultimate failures of cannulation among the 201 patients enrolled. Cannulation in one of the patients initially randomized to the LM group failed, and rescue dynamic ultrasound failed. Cannulation also failed in a patient randomized to the D group. Both patients had vein diameters of 4 mm. In both, venous blood was aspirated, but the J-wire could not be advanced. Ultimately, subclavian catheters were placed.

Of the 162 people who ultimately underwent sonography, either initially or in rescue, seven (4.3%) had anatomical abnormalities that would have precluded successful cannulation by anatomical landmarks. Five had no internal jugular vein on one side, one had transposition of the internal jugular vein and carotid artery, and one had thrombosis of one internal jugular vein. In addition, seven pa-

It appears that all central cannulations should be conducted with ultrasound assistance.

tients had veins <5 mm in diameter, which makes internal jugular central cannula placement extremely difficult.

DISCUSSION

Comments

This randomized, controlled clinical trial was conducted to evaluate the effect of assistance with point-of-care, limited ultrasonography on the success of central venous cannulation. Both static (quick look) assistance (S) and dynamic (real-time) guidance (D) were superior to the traditional landmark (LM) technique for successful internal jugular cannulation, with D being the better of the two. Ultrasound-assisted central cannulations required fewer attempts and were associated with higher first-attempt success rates and less time to complete the procedure. These data support the expanding roles of both static and dynamic ultrasound in central cannula placement.

This trial is the first to compare both static and dynamic ultrasound with use of a landmark control group and provides definitive evidence that both ultrasound-assistance approaches for central cannula placement are superior to the anatomical landmark technique. Dynamic appears to be, as expected, the best technique, but it requires more training and an extra person, which is not always possible in the emergency setting. A single-person technique can be learned (26), but it requires more training.

Static assessment of the patient's anatomy can double first-attempt success and approaches the success of dynamic guidance with regards to cannulation success, first-attempt success, and number of attempts. It requires very little training and quickly identifies obstacles to successful cannulation, such as the seven anatomical abnormalities mentioned above, and visualizes small vein sizes, which might thwart successful cannula placement. When vein sizes are <5 mm, often the contralateral vein will

Table 4. Operators, number of cannulas placed with indicated type of assistance during study, and experience levels

Operator	Landmark	Static	Dynamic	Experience Level ^a
1	0	0	1	30
2	0	0	1	50
3	0	3	0	30
4	0	1	13	30
5	1	2	1	>100
6 ^b	34	35	39	100
7	30	24	0	— ^c
8	3	4	3	50
9	1	3	2	50

^aNumber of internal jugular central cannulas placed by operator previously; ^blead author performed just over half of the procedures in the study; ^cthis is a group of 14 internal medicine and surgery residents (postgraduate years 2 and 3) with varying levels of experience.

have compensatory enlargement, which static ultrasound also quickly identifies. And if both internal jugulars are extremely narrow, as in the two study failures, subclavian catheterization may be the preferred approach. Extremely small vein sizes combined with anatomical variations represent close to 10% of patients in our study group and probably explain the occasional failures of even the most experienced practitioners when they are using only surface landmarks.

This evidence specifically refutes the dismissal of static ultrasound by the 2001 Agency for Healthcare Research and Quality Evidence Report (20). Our data show a much smaller difference between static and dynamic ultrasound with regards to cannulation success than the findings of a previous study by Nadig et al. (24), which had no control group. Regarding dynamic ultrasound, our data agree with the meta-analysis by Hind et al. (27) that two-dimensional, dynamic ultrasound increases overall and first-attempt success for internal jugular procedures and confirms the findings of recent studies by Keenan and Randolph et al (28, 29).

Our data support ultrasound assistance for all central cannula placements, with careful attention given to vein size. A protocol based on vein size may be suggested. Veins <5 mm in diameter (4.3%) may be a relative contraindication to internal jugular central cannula placement. Vein diameter between 5 and 10 mm (25%) may be a relative contraindication to static ultrasound, and in such cases patients probably should be cannulated with dynamic guidance. In veins >10 mm in diameter (71%), static assessment with three attempts, followed by dynamic rescue for failures, might be the

standard. We are currently implementing such a protocol, which we expect will limit manpower and training requirements and identify nearly all the cannulations likely to be successful with static ultrasound, thus leading to cannulation success in virtually every patient.

A second interpretation of the data might be that dynamic ultrasound should always be used when available and static ultrasound should be used only when the operator is unable to perform dynamic guidance single-handedly or when a second person is unavailable to facilitate the two-person technique.

The ultrasound groups had very low complication rates. A larger sample size might have yielded statistical significance, but we believed that continuing the study in light of the data collected would expose subjects to undue harm in the control group, which required twice as many sticks as either ultrasound group. Prior studies have shown a link between the number of attempts and the complication rate (13–16, 30).

Limitations

The study population did not include all central cannula recipients in the hospital during the study period. Our best estimate from credentialing logs is that 34 cannulations were missed, and we have no information on those procedures. Physicians tended to call study investigators more often for perceived “tough sticks.” This might have introduced a bias into the study, selecting for patients with more difficult anatomy. Study investigators, who are ultrasound proponents, could not be excluded from the group of operators because they are among the few physicians in the hospital

trained to use ultrasound. This might have introduced bias in favor of ultrasound, but there was no significant difference in success rates among investigators or between investigators and noninvestigators. Also, data were not recorded on the urgency of cannula placement, although we believe randomization adjusted for this, making any cannula equally likely to be placed by any of the three techniques. The lead author placed about half the central cannulas (Table 4 shows operators and experience levels). It is a limitation that he was not blinded to study outcomes and could have inadvertently introduced bias. However, his success rates did not vary significantly from those for the study population at large.

CONCLUSIONS

Ultrasound assistance was superior to the landmark technique. Dynamic outperformed static ultrasound, but it may require more training and personnel. It appears that all central cannulations should be conducted with ultrasound assistance. The 2001 Agency for Healthcare Research and Quality Evidence Report on patient safety dismissing static assistance was incorrect.

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