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Pulsed Doppler Ultrasonography Guidance for Catheterization of the Subclavian Vein

A Randomized Study

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Background: Catheterization of the subclavian vein may lead to severe complications. The current randomized study compared a technique of pulsed Doppler ultrasonography guidance and the standard method for subclavian vein catheterization.

Methods: Standard and Doppler ultrasonography guidance methods were performed by the same physician in 286 patients, 143 in each group. Primary end points were immediate complications (arterial puncture, pneumothorax, wrong position of catheter tip), failures, the number of subclavian vein catheterizations with immediate complication or failure, the

number of skin punctures per catheterization, and the time to placement of the guide wire. The secondary end points were the determination of predicting factors of successful cannulation in each group.

Results: Both groups were similar according to morphologic parameters of the patients. A greater number of subclavian vein catheterizations were performed on the right side using Doppler guidance (105 vs. 73, $P < 0.01$). Doppler guidance decreased complications (5.6% vs. 16.8%, $P < 0.01$), largely because of a smaller number of catheters for which the tip was defined to be in incorrect position (0.7% vs. 7.7%, $P < 0.01$). The time to catheterization was longer with Doppler guidance (300 vs. 27 s, $P < 0.001$). Failures, catheterizations of the subclavian vein with immediate complications or failure, and the total number of skin punctures per catheterization were similar in both groups. Using Doppler guidance, the presence of a good Doppler signal (124 of 143) was predictive of successful catheterization (123 successful cannulations, $P < 0.001$).

Conclusions: Doppler guidance reduces the incidence of inappropriately positioned subclavian catheters. (Key words: Monitoring; pulsed Doppler ultrasonography; subclavian vein cannulation.)

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IN critically ill patients, the subclavian vein is often catheterized for many reasons. This technique requires identification of the position of the subclavian vein according to surface landmarks. The overall complication rate (including subclavian artery puncture, pneumothorax, wrong position of the catheter tip) and the incidence of failure ranges from 0.3-20.0%.¹⁻⁴ To reduce these drawbacks, some authors proposed locating the subclavian vein by B mode or Doppler sonography.⁴⁻⁷ These methods, however, require a trained operator and expensive equipment that must be permanently available in a critical care unit. Recently, Branger *et al.* reported using a specially designed pulsed Doppler probe to locate internal jugular or subclavian veins.⁸ These authors found that this technique could decrease

the complication rate when used by a trained operator after failure of the standard method. Catheterization of the subclavian vein was attempted in only 98 patients, however, using either the standard or the Doppler guidance methods. Therefore, the aims of the current study were (1) to compare catheterization of the subclavian vein using this pulsed Doppler guidance *versus* the standard method, and (2) to determine factors that may predict successful cannulation with this new technique.

Materials and Methods

This prospective study was approved by the local ethics committee, and written informed consent was obtained from the patients or the closest family member when the patient was sedated. From January 1994 to July 1997, all patients >18 yr old requiring a central venous access by catheterization of the subclavian vein could be included. The Doppler probe was not always available in the unit, however, because it had to be sterilized after every use. Therefore, only patients requiring catheterization of the subclavian vein when both the single operator and the ultrasonic probe were available were enrolled in the study. We excluded patients <18 yr old, those with significant coagulopathy, those in whom a subclavian cannulation was previously performed or attempted, those in whom prior surgery had been performed in the area, and those in whom a central venous access was required in emergency.

Procedures for Catheterization of the Subclavian Vein

For standard insertion of the catheter (standard group), the patient was placed in a 15–20° Trendelenburg position. The side of skin puncture was decided by the physician. The ipsilateral anterior superior region of the chest was shaved and cleaned in a sterile fashion with povidone iodine. When the patient was not sedated, 1% lidocaine was injected at the infraclavicular puncture site. The subclavian vein was punctured with an 18-gauge needle, 2 cm caudal and medial to the midpoint of the clavicle.⁹ The return of venous blood into the syringe attached to the needle confirmed entry into the vein. A guide wire was passed through the needle into the vein, and the needle was removed. Then, the catheter was passed over the wire (with the use of a dilator when a double-lumen catheter was used). The guide wire was removed and the catheter

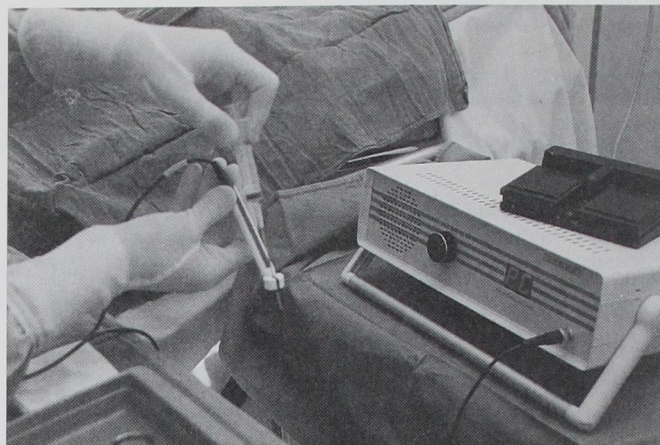


Fig. 1. The Doppler ultrasonography guidance system is composed of a probe, the Doppler system, and a two-way foot switch. On the probe (left), a radial indentation allows the coaxial insertion of the needle. A millimeter scale is engraved on the handle of the probe to check the inserted needle length during puncture (black strip on the probe). The Doppler system (right) alternatively works in high pulse repetition frequency (PC on the screen) or in normal pulsed wave mode. The use of a two-way foot switch (on the Doppler system, right) allows changing of the Doppler mode (pushing both pedals) and measurement of the depth and diameter of the vein.

connected to the perfusion system. Intravascular placement was confirmed by free reflux of blood and by chest radiography. The correct catheter position was assumed when the catheter tip was seen in the superior cava vein and was checked by another physician.

The same preparation was performed for the Doppler guidance (Doppler group). We used a specially designed pulsed Doppler probe (Vernon SA, Tours, France; fig. 1).⁸ A single, circular (15 mm in diameter), composite, 4-MHz transducer was mounted at the tip of the probe, with a 10-mm-thick backing material. A radial indentation allowed the coaxial insertion of the needle, and a millimeter scale was engraved on the handle of the probe to check the inserted needle length during puncture. The probe was connected to a 4-MHz pulsed Doppler system (Medical Biophysics Laboratory, Faculty of Medicine, Tours, France; fig. 1). This system offered a large digital display of the sample volume depth and an output of the Doppler audio signal on a loudspeaker. A high pulse repetition frequency mode was first used to locate the subclavian vein without spatial resolution. Then, the system was operated in normal pulsed wave mode to measure the depth and the diameter of the subclavian vein. The use of a two-

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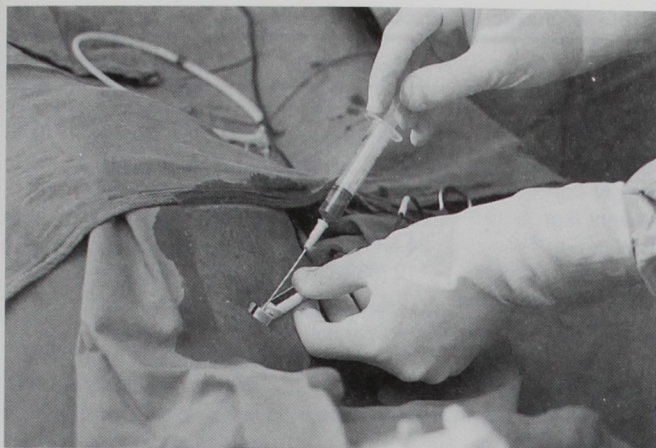


Fig. 2. After locating the subclavian vein in high pulse repetition frequency mode, the depth and diameter of the vein is determined in normal pulsed wave mode. The needle is passed into the probe indentation and introduced through the skin without exceeding the maximal depth of the vein (note the angle of the needle with the skin). During the puncture, the Doppler audio signal is listened to continuously. When the blood returns to the syringe, the guide wire is inserted.

way foot switch allowed us to change the Doppler mode by pushing both pedals and to increase or decrease the depth of the pulsed Doppler sample volume from 9 to 46 mm by pushing the right or the left foot switch, respectively. The axial spatial resolution was 1 mm. This mode permitted measurement of the depth and diameter of the subclavian vein. The probe was put on the skin at the standard landmark. Then, it was moved and angled to get the best Doppler signal. When the signal was clear, loud, and modulated by the ventilatory time, it was said to be good. Otherwise, it was said to be poor. While the Doppler signal was continuously listened to during the venipuncture, the needle was passed into the probe indentation and introduced through the skin without exceeding the maximal depth of the vein (fig. 2). Searching for the best Doppler signal significantly alters the angle of skin puncture. Using the Doppler guidance, the skin puncture was usually achieved with an angle nearer to normal than with the standard method (fig. 2). When blood returned to the syringe, the guide wire was inserted. Thereafter, the procedure was identical to the standard method.

Randomization

To avoid operator dependence, all catheterizations were performed by the same physician (J-YL). Patients

were assigned to the standard group or the Doppler guidance group using a table of random numbers.

Studied Parameters

In each patient, age, gender, height, weight, body mass index (weight [kg]/height² [m²]), underlying disease, the use of mechanical ventilation, and the side of the venipuncture were recorded. The following parameters were evaluated:

Primary end point parameters

- Incidence of successful catheterization when the catheter tip could be inserted into the superior cava vein (as verified by radiograph);
- Incidence of successful catheterization at the first needle pass;
- Incidence of catheterizations accompanied by one or more problems (failure or complication);
- Incidence of immediate complications, defined as arterial puncture, pneumothorax, or wrong position of the catheter tip (*i.e.*, placement of the catheter tip in a vein other than the superior cava vein);
- The number of separate skin punctures attempted; and
- The time to insertion. In the standard group, it was defined as the time from the first puncture attempt to placement of the guide wire. In the Doppler group, it was defined as the time from the beginning of the search for Doppler signal to the time of placement of the guide wire.

Secondary end point parameters

- Incidence of complications occurring during successful or failed catheterization;
- Quality of the Doppler venous signal (good or poor) in the Doppler group;
- Minimal depth of Doppler venous signal, defined as the depth at which the venous signal appeared when the sample volume depth was progressively increased in normal pulsed Doppler mode;
- Maximal depth of Doppler venous signal, defined as the depth at which the venous signal disappeared when the sample volume depth was progressively increased in normal pulsed Doppler mode; and
- Diameter of the subclavian vein, defined as the difference between the two previously defined depths.

Potential Effect of Training

Because the operator was not trained in Doppler guidance before the beginning of this study, we looked for a potential effect of training during the study, comparing

failure and immediate complication rates during the first and the second halves of the study.

Measurements and Statistical Analysis

The study was first performed to assess the effectiveness of Doppler guidance in improving the success rate or reducing complications. We hoped to detect a 10% reduction in complications based on published data suggesting a 15% incidence in context pattern. Therefore, a study including 276 patients was required to provide an 80% probability (power) of rejecting the null hypothesis. Studied parameters were expressed as median and 5th and 95th percentiles because their distributions were not normal. To compare the two groups, the chi-square test, Fisher's exact test, and the Kruskal-Wallis test were used. In each group, a univariate analysis was performed for each parameter to detect predicting factors of successful cannulation, failure, and immediate complication. A multivariate analysis was performed when more than one predicting factor was isolated. A probability value <0.05 was considered statistically significant.

Results

The study included 286 patients (143 patients in each group). There was no difference in age, sex ratio, height, weight, body mass index, underlying diseases, or the percent of mechanically ventilated patients between groups (table 1). The right side was more often chosen for catheterization of the subclavian vein in the Doppler group than in the standard group (105 vs. 73, $P < 0.001$). Results of catheterizations are shown in table 2. The number of successful catheterizations, successful catheterizations at first attempt, catheterizations with at least one problem, and separate skin punctures per catheterization were similar in both groups. Catheterization using Doppler guidance was more time consuming. Doppler guidance did decrease the overall rate of complications, largely because of a decrease in the number of cases of malpositioned catheter tips. The rates of complication and of wrong positions of the catheter tip were reduced in successful but not in failed catheterizations.

In the Doppler group, the venous signal was heard between 18 (range, 12–28) and 26 (range, 18–38) mm in depth. The Doppler-assessed diameter of the subclavian vein was 8 mm (range, 4–12 mm). In 124 patients,

Table 1. Characteristics of the Patients*

	Doppler Group (n = 143)	Standard Group (n = 143)	P Value
Age (yr)	67 (29–84)	68 (35–88)	NS
Sex ratio (M/F)	84/59 (59–41%)	87/56 (61–39%)	NS
Height (m)	1.67 (1.55–1.80)	1.65 (1.53–1.80)	NS
Weight (kg)	68 (48–92)	67 (49–88)	NS
BMI ($\text{kg} \cdot \text{m}^{-2}$)	24.5 (16.8–31.8)	24.6 (20–29.3)	NS
Ventilated patients	119 (83%)	116 (81%)	NS
Underlying diseases			
Abdominal surgery	46	45	NS
Sepsis	43	44	NS
Pancreatitis	21	23	NS
Pneumopathy	13	12	NS
Hemorrhage	11	11	NS
Others	9	8	NS

BMI = body mass index; NS = not significant.

* Age, height, weight, and BMI are expressed in median with 5th and 95th percentiles in parentheses. Sex ratio (M = males/F = females) is expressed in numerical values and in percentages in parentheses.

the Doppler signal was judged as good. Among them, there were 123 successful cannulations (including one case of wrong position of catheter tip) and 1 failure. In the 19 remaining patients in whom the Doppler signal was not heard or was judged as poor, there were 18 complications or failures and 1 successful catheterization. The presence of a good Doppler signal was predictive of successful catheterization ($P < 0.001$), whereas the presence of a poor Doppler signal was predictive of immediate complication. No other studied parameter predicted success or failure using the Doppler guidance. No parameter predicted the presence of a good Doppler signal. Concerning the standard group, none of the studied parameters predicted failure or immediate complication.

No training effect was found in the Doppler group. In the first 71 patients, there were nine failures and four arterial punctures (two arterial punctures occurred during two failed catheterizations). In the 72 remaining patients, there were nine failures, two pneumothoraces (occurring during failed catheterizations), one arterial puncture, and one catheter tip in the internal jugular vein.

Discussion

The current study compared a new technique of pulsed Doppler ultrasonography guidance method *ver-*

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Table 2. Characteristics of Catheterizations*

	Doppler Group (n = 143)	Standard Group (n = 143)	P Value
Primary endpoints			
Successful catheterization	124 (86.7%)	130 (90.9%)	NS
Successful catheterization at first attempt	92 (64.3%)	94 (65.7%)	NS
Catheterization with at least one problem	23 (16.1%)	33 (23.1%)	0.14
Complications	8 (5.6%)	24 (16.8%)	<0.01
Arterial puncture	5 (3.5%)	11 (7.7%)	0.12
Pneumothorax	2 (1.4%)	3 (2.1%)	NS
Wrong position of the catheter tip	1 (0.7%)	11 (7.7%)	<0.01
No. of separate skin punctures per catheterization	1 (1-3)	1 (1-4)	NS
Time to catheterization	300 (94-900)	27 (15-240)	<0.001
Secondary endpoints			
Complications in successful catheterizations	4/124 (3.2%)	20/130 (15.4%)	<0.01
Arterial puncture	3/124 (2.4%)	9/130 (6.9%)	NS
Pneumothorax	0/124 (0%)	1/130 (0.8%)	NS
Wrong position of the catheter tip	1/124 (0.8%)	11/130 (8.5%)	<0.01
Complications in failed catheterizations	4/19 (21.1%)	4/13 (30.8%)	NS
Arterial puncture	2/19 (10.5%)	2/13 (15.4%)	NS
Pneumothorax	2/19 (10.5%)	2/13 (15.4%)	NS

NS = not significant.

* Primary endpoint parameters are given after an "intention to treat analysis." Successful catheterizations, catheterizations at first attempt, catheterizations with at least one problem (failed and/or complicated catheterizations), complications (arterial puncture, pneumothorax, wrong position of the catheter tip) are expressed in numerical values and in percentages in parentheses. The number of attempts per catheterization and the time to catheterization are expressed in median with 5th and 95th percentiles in parentheses. Secondary endpoint parameters (expressed in ratio and in percentages in parentheses) are analyzed after separating failed from successful catheterizations.

the standard technique based on skin landmarks for catheterization of the subclavian vein. In the Doppler group, there was a smaller number of wrong positions of the catheter tip (11 vs. 1, $P < 0.01$). The Doppler guidance technique did not increase the overall success rate, however, and was more time consuming than the standard method. The secondary end point analysis showed that the rate of complication was reduced in successful catheterizations. This finding could be explained by the presence of a good Doppler audio signal that appeared as a predicting factor of successful catheterization without complication. Finally, training did not influence the course of the study.

The reported failure rates and immediate complications of catheterization of the subclavian vein vary according to the study, the characteristics of the patients, and the experience of physicians.¹⁻⁴ In critical care units, the incidence is between 10 and 20%. Two previous preliminary studies performed in our unit, in whom the physician performing the current study participated, showed that the rates of immediate complications and failures were similar to those reported in the standard group and that complications and failures were

independent of the operators.^{10,11} In the current study, groups were similar according to the morphologic parameters of the patients and underlying diseases, but a greater number of catheterizations were performed on the right side in the Doppler group. This could be explained simply by the fact that the operator was right handed. The statistical analysis, however, did not show that the side of the catheterization influences failures and immediate complications rates.

Ultrasonographic guidance has been available since the beginning of the 1980s. B mode sonography was first used for cannulation of the internal jugular vein. In 1987, Machi *et al.* used B mode sonography for internal jugular or subclavian vein catheterization in >100 patients.⁶ Denys *et al.* reported fewer complications with sonographic location than with the standard method for catheterization of the internal jugular vein.¹² B mode sonographic guidance allows us to locate and to see the vein during the puncture. This rather expensive and more cumbersome device is not always available in critical care units, however. Ultrasonographic guidance without echography was used more recently. Gilbert *et al.* reported a facilitation of catheterization of the inter-

nal jugular vein using a Doppler probe inserted into the needle.¹³ No study was performed for subclavian vein cannulation using this method. Recently, Mansfield *et al.* did not find any benefit with the use of ultrasonography guidance for cannulation of the subclavian vein.⁴ Their technique did not allow the real-time guidance that our technique offered. Moreover, the physicians involved in their study performed 1–62 cannulations. In the current study, all catheterizations were attempted by the same physician to avoid operator dependence.

The current study showed that Doppler guidance decreased the number of wrong positions of the catheter tip, which is classically considered as a complication.^{1–4} A wrong position of the catheter tip can result in a faulty central venous pressure reading or lead to catheter thrombosis.² The different rate of wrong position between groups could result from the different angle of incidence of the venipuncture between the two techniques. Using Doppler guidance, the best audio signal is heard theoretically when the incident ultrasonographic beam is parallel to the venous blood flow, leading the operator to point the needle along the long axis of the subclavian vein (fig. 2), hence facilitating proper wire passage and avoiding wrong position of the catheter tip. Using the standard method, the needle is tangent to the skin and pointed to the opposite shoulder. This may lead to passage of the guide wire into the internal jugular vein.

We searched for a predicting factor of successful catheterization in both groups. The presence of a good Doppler signal was the only parameter that improved the success rate with a reduction of complications. Although a good Doppler signal was not a primary end point in the current study, the success rate was >99%, with only one failure and one complication (due to wrong position of the catheter tip) in the 124 patients in whom a good Doppler signal was obtained. In contrast, the lack of a good Doppler signal led to failed and complicated catheterizations. Attempts to obtain a good signal, however, led to a substantial (tenfold) increase in the time to insertion; however, this time was defined as the time elapsed between the first attempt of central venous puncture to the placement of the guide wire. When considering the overall procedure of catheterization of the subclavian vein, including use of clothing gown and gloves, draping of the insertion site, and use of occlusive dressing, this time may be less important.

The effect of training on ultrasonography guidance for cannulation of the subclavian vein was never assessed

clearly. Gualtieri *et al.* showed that ultrasonography guidance improves the success rate of less experienced operators.¹⁴ Using real-time ultrasonography guidance, Branger *et al.* demonstrated that it improved the success rate of cannulation when the standard method failed.⁸ In the current study, the rates of failure and of immediate complications were similar in the first and second halves of the study. This suggests that training had no influence on Doppler guidance procedure and that it could be learned easily and quickly.

In clinical practice, this Doppler guidance cannot be used in emergencies because it increases the time to cannulation. In scheduled catheterization of the subclavian vein, however, our study showed that Doppler guidance increases the chances of achieving proper catheter placement. This may save patients additive catheter manipulations or added puncture attempts. The presence of a good Doppler signal seems to be predictive of successful and uncomplicated catheterization. When a good signal is heard, the depth and the diameter of the vein should be measured to avoid inserting the needle too deeply, risking complications such as pneumothorax. Therefore, this technique might be useful in patients in whom major complications could be very serious or in whom catheterization is likely to be difficult.¹⁵

Doppler guidance reduces the incidence of inappropriately positioned subclavian catheters but does not alter the incidence of other complications.

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