

Modification of Guide Wire for 22-gauge Safe Guide®

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Safe guide® is a central venous catheterization kit that serves as both pilot needle and introducer. With a single puncture, a guide wire can be introduced by inserting it through the side port of the 22-gauge needle. The advantage is that this needle can be placed within a blood vessel using no more force than is required to insert a pilot needle. However, the 0.018-inch guide wire is vulnerable to kinks and locking. Because the tip has been shaped into a sharp J-shaped angle, it can kink at the puncture site, and locking sometimes occurs when the guide wire is passed through the side port of the needle, or when the dilator is introduced. In order to resolve these issues, we modified the device by making an experimental guide wire with a gentler angle. In addition, we fortified the body of the wire without altering its thickness. We then investigated the effectiveness of our modifications. The subjects of the study were 120 patients, who required central venous catheterization. They were divided into 2 groups. The original J-type guide wire was used in one group (Group A: n = 60) and the modified guide wire in the other group (Group B: n = 60). Catheters were introduced by right internal jugular vein puncture. We observed the following: 1) incidence of back-flow appearing at withdrawal of the needle without back-flow during advancement, 2) incidence of kinking or locking of the guide wire when it was passed through the side port, 3) incidence of kinking of the guide wire at the puncture site when introducing the dilator, and 4) complications. The results were as follows: 1) back-flow appeared upon withdrawal in 3.4% of both groups; 2) kinking and locking occurred when passing the guide wire through the side port of the Safe guide® needle in 16.7% of Group A and 1.7% of Group B; 3) kinking of the guide wire occurred when introducing the dilator in 5% of Group A in contrast to 0% in Group B; 4) the only complication caused by the passing of the guide wire was accidental puncture of the common carotid artery, which occurred in 1.7% of both groups. No problems with the guide wire were noted in either group. The use of our modified guide wire decreased the incidence of kinking and locking of the guide wire when passing it through the side port. In addition, no guide wire kinking at the puncture site occurred when introducing the dilator. Issues associated with the original J-type guide wire were resolved by 1) changing the guide wire tip to a gentler angle, and 2) fortifying the guide wire by altering its composition.

Key words : Safe guide®, Modified guide wire, Flexibility

INTRODUCTION

Safe guide® is a central venous catheterization kit that serves as both pilot needle and introducer. With a single puncture, a guide wire can be introduced by inserting it through the side port of the 22-gauge needle. The advantage is that this needle can be placed within a blood vessel using no more force than is required to insert a pilot needle [8]. However, the diameter of the guide wire

included in the kit is only 0.018 inches, which is just half that of a typical 0.035-inch guide wire. As a result, kinking at the puncture site and locking (a condition where the guide wire cannot be advanced or withdrawn) can occur when passing the wire through the side port or introducing the dilator [2, 6]. We investigated whether a modified guide wire, that had been fortified without increasing its thickness, would be effective in resolving these issues.

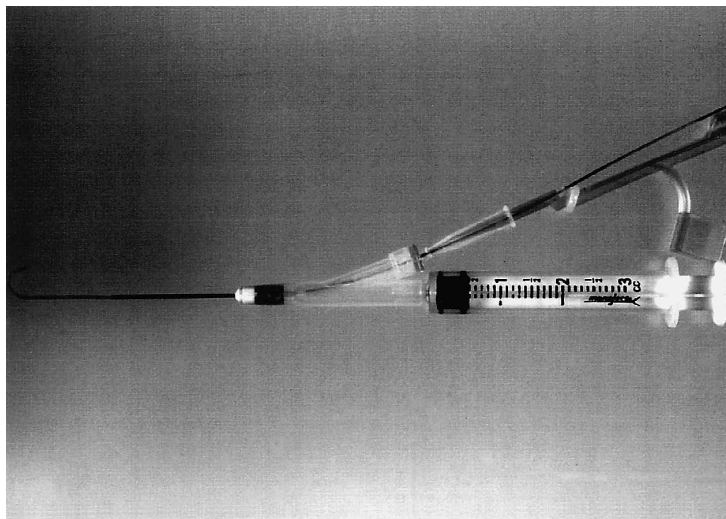


Fig. 1 Structure of Safe Guide[®]
A 0.018 mm guide wire can be introduced through a cock in the side port of the 22-gauge metal needle.

EQUIPMENT

Structure of Safe guide[®]

The 22-gauge needle of Safe guide[®] has a side port to enable the introduction of a 0.018 inch guide wire (Fig. 1).

Structure of the guide wire

In Fig. 2, the top wire is the original guide wire included in the kit. It has a stainless steel core wrapped with a stainless steel spring. The tip is J-shaped. The bottom wire is our modified guide wire. It has a nickel and titanium alloy core wrapped with tungsten. The tip has a gentle curvature of approximately 30 degrees. This structure gives the wire more resistance to kinking than the original guide wire, and also prevents extravascular exodus.

SUBJECTS AND METHODS

(1) The subjects were 120 patients who required central venous catheterization during surgery. Prior to the study, the subjects were given an explanation of the nature of the study, and informed consent was obtained. The subjects were then divided into 2 groups. The original guide wire was used in Group A ($n = 60$) and the modified wire in Group B ($n = 60$). After receiving general anesthesia and endotracheal intubation, the patients were placed in the Trendelenburg's position with their heads

angled approximately 30 degrees toward their left. A puncture was accomplished using central approach from the internal jugular vein. The 22-gauge Safe guide[®] needle was placed at an approximately 40 degree angle against the skin for puncture from the apex of the triangle composed by the clavicle, sternal and clavicular tendons of the sternocleidomastoideus. After obtaining blood back-flow, the guide wire was passed through the side port and advanced 25–30 cm. Then the Safe guide[®] needle was removed, leaving the guide wire in place. After making an incision in the skin and subcutaneous tissue at the puncture site, the dilator was introduced. Finally, a central venous catheter was introduced by passing it along the guide wire. The following events were examined to compare the original and modified wires:

- 1) Incidence of back-flow appearing at withdrawal of the needle without back-flow during advancement
- 2) Incidence of kinking or locking of the guide wire when passing the guide wire
- 3) Incidence of kinking of the guide wire at the puncture site when introducing the dilator
- 4) Complications.

Mann-Whitney's U-test was used for statistical analysis and $p < 0.05$ was considered to be significant.

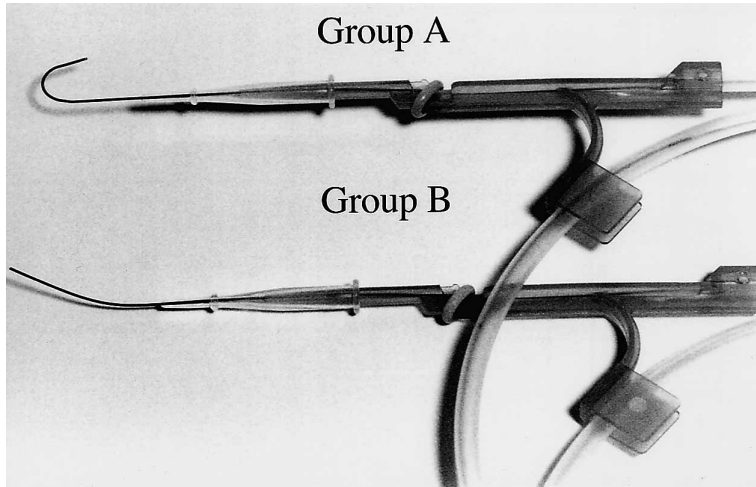


Fig. 2 Structure of Guide Wires
 The original guide wire is illustrated at the top of the figure and the modified guide wire thereunder. The modified guide wire has an angled tip with a gentler curve and is more resistant to kinking and locking than the original guide wire.

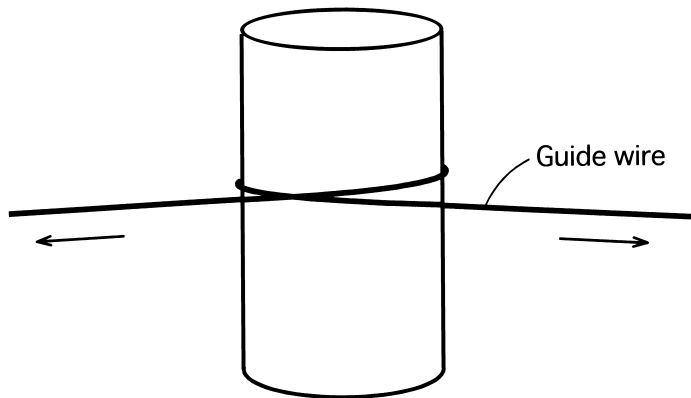


Fig. 3 Experimental Set-up for Guide Wire Kink Resistance Study
 The guide wire is wrapped completely around a column to form a complete circle. Bending of the guide wire is measured 15 seconds later. The measurement is conducted using columns with diameters of 15 cm and 10 cm.

(2) Comparison of resistance to kinking

In order to compare the incidence of kinking between Group A and Group B we examined the degree of bending in each guide wire by wrapping it around a column (360°: 1 full circle) and holding it for 15 seconds (Fig. 3). The portion of guide wire used for this test was 10 cm from the tip. This was performed with two columns; one was 10 cm and the other 15 cm in diameter.

(3) Measurement of Safe guide® bevel length and surplus bevel after passage of guide wire

“Bevel length” is the length from the bevel tip to the proximal side of the bevel (needle heel). This is measured as the distance between the bevel tip and the vertical line drawn at the needle heel when the needle is placed horizontally with the bevel orifice facing upward.

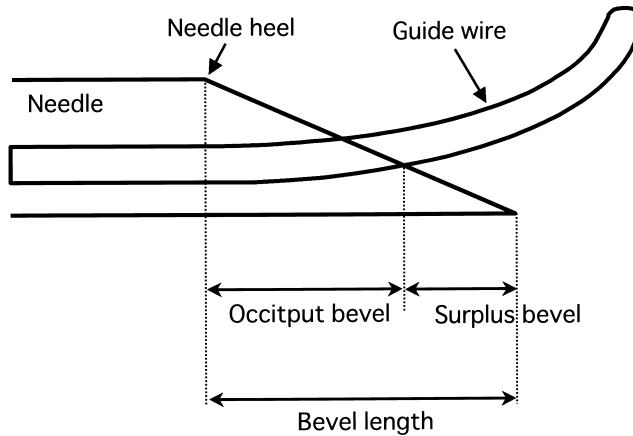


Fig. 4 Diagram of Bevel Length, Surplus Bevel and Occiput Bevel Measurements

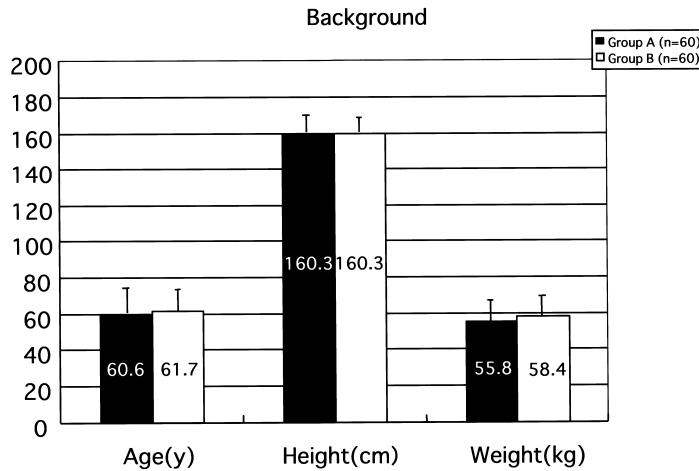


Fig. 5 Patient background

“Occiput bevel” is the length from the needle heel to the point where the guide wire exits the bevel orifice when being placed into a blood vessel. This is measured as the distance between vertical lines drawn from each of these points, when the needle is placed horizontally with the bevel orifice facing upward.

“Surplus bevel” is the remainder after subtracting the occiput bevel from the bevel length.

According to clinical observations, blood back-flow may occur when only a part of the bevel tip (surplus bevel) enters a blood vessel. The possibility of the guide wire being placed extravascularly increases as the surplus bevel increases. For both Group A

and B, Safe guide[®] bevel length and surplus bevel were measured using a stereoscopic microscope to calculate the ratio of occiput bevel lengths with both the original and modified guide wires (Fig. 4).

RESULTS

(1) Patient background

The black bar shows group A and the white bar shows group B. There are no difference between group A and group B regarding age, height and weight (Fig. 5).

(2) Clinical observations

- 1) Back-flow appeared upon withdrawal in 3.4% of both Group A and B.
- 2) Locking occurred when passing the guide wire through the side port of

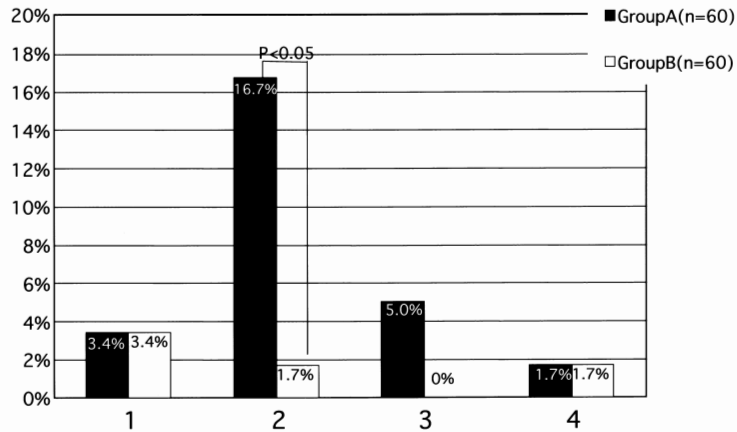


Fig. 6 Summary of Study Design

120 subjects were divided into 2 groups. Group A (n = 60): standard guide wire, Group B (n = 60): modified guide wire.

- 1) Incidence of back-flow appearing during withdrawal or advancement of the needle
- 2) Incidence of kinking or locking when passing the guide wire
- 3) Incidence of the guide wire kinking at the puncture site when introducing the dilator
- 4) Complications

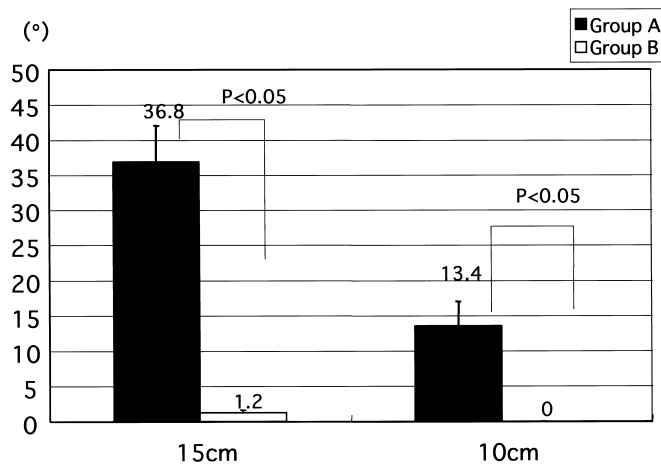


Fig. 7 Comparison of Guide Wire Kinking

the Safe guide® needle in 16.7% of Group A and 1.7% of Group B. The difference is significant.

- 3) Kinking of the guide wire occurred when introducing the dilator in 5% of Group A in contrast to 0% in Group B.
- 4) The only complication caused by passing of the guide wire was acci-

dental puncture of the common carotid artery, which occurred in 1.7% of both groups. No problems with the guide wire occurred (Fig. 6).

- (3) Comparison of resistance to kinking

The guide wires used in Group A were bent 13.4 degrees, on average, after being wrapped around a column of 15 cm in

diameter. They were bent 36.8 degrees on average after being wrapped around a column of 10 cm in diameter. In contrast, the guide wires used in Group B were bent 0 degrees and 1.2 degrees when wrapped around columns of 15 and 10 cm in diameter, respectively (Fig. 7). This indicates that the modified guide wire is more resistant to kinking.

(4) Measurement of Safe guide[®] bevel length and surplus bevel

In Fig. 8, a guide wire passing through a 22-gauge Safe guide[®] needle used in Group A is shown in the upper photograph and a one used in Group B in the lower.

The bevel length for the 22-gauge Safe guide[®] needle is 2.1 mm. The surplus bevel for the guide wire used in Group A was 0.95 mm, since the guide wire abruptly separated away from the bevel tip because the J-curve is sharp. The surplus bevel for the guide wire in Group B was only 0.8 mm because the curvature is gentle. This is 0.15 mm shorter than that of the guide wire used in Group A. The ratio of surplus bevel to full length was 45.2% and 38.1% in Group A and Group B, respectively (Fig. 9).

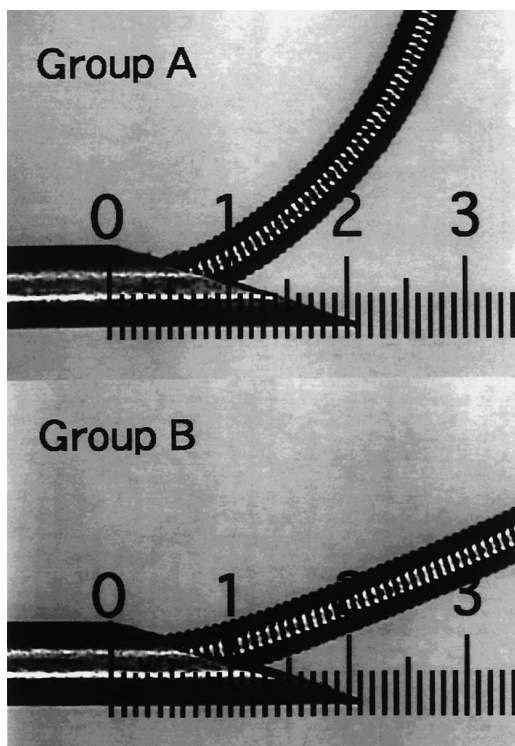


Fig. 8 Two kinds of a guide wires passing through a 22-gauge Safe guide[®] needle. Group A is shown in the upper photograph and Group B is shown in the lower.

Measurement of each bevel part

	Bevel length	Occiput bevel	Surplus bevel	$\frac{\text{Surplus bevel}}{\text{Bevel length}} \times 100$
Group A	2.1mm	1.15mm	0.95mm	45.2%
Group B	2.1mm	1.30mm	0.80mm	38.1%

Fig. 9 Measurement of Safe Guide[®] Bevel Length and Surplus Bevel According to Guide Wire

The bevel length for 22-gauge Safe guide[®] needle is 2.1 mm. The guide wire used in Group A had a sharp curvature which abruptly separated from the bevel tip, producing a 0.95 mm surplus bevel. The guide wire used in Group B had a gentler curvature, resulting in a 0.8 mm surplus bevel, which was 0.15 mm shorter than that of its counterpart in Group A. The ratio of surplus bevel to full bevel length was 45.2% and 38.1% for Group A and Group B, respectively.

DISCUSSION

We have conducted laboratory and clinical studies of central venous puncture using 22-gauge Safe guide[®] and have reported its usefulness [4, 6, 8, 9]. The issues regarding 22-gauge Safe guide[®] can be divided into 2 categories, one involving the needle and the other involving the guide wire. As for the needle, the guide wire can be introduced with a single puncture [6, 8] and compression of the vein is less than that associated with other indwelling venous catheters [8, 10, 12]. This allows it to be used safely even by beginners. However, the 0.018 inch guide wire causes a few problems. Kinking or locking of the guide wire occurred in 16.7% of the cases when introducing the guide wire through the side port after blood back-flow was confirmed. One factor may be that first-year trainees performing the catheterization lacked the ability to fix the needle tip properly. However, only approximately 50% of the cases could be salvaged when the catheterization was corrected by an instructor, suggesting the presence of a structural problem with the guide wire. When bevel length is long, blood back-flow can be obtained with the bevel only partially inserted into the vein. In such a situation, it is not possible to place the guide wire properly inside the vein. A similar situation may occur if the tip of the guide wire is formed into a sharp J-curve. The guide wire abruptly separates from the bevel tip and the surplus bevel becomes large, as illustrated in Fig. 7. Under such conditions, the guide wire cannot be introduced, despite the presence of blood back-flow. This sometimes occurs even with Safe guide[®], which has a smaller bevel surface than other needles. The bevel surplus can be reduced 0.15 mm by altering the guide wire tip to a gentler angle, making it less likely that the guide wire will be placed outside the vein. The results of our study confirm this discussion. This type of problem occurred in only one out of 60 cases (1.7%) when our modified guide wire was used, indicating that the problem can be successfully avoided by the modifications we proposed. Guide wire kinking occasionally occurs when introducing the dilator [2, 6]. In our study, this occurred in 5% of Group A. Aggressive manipulation may cause the guide wire to kink, become fixed subcuta-

neously, and as a result, prohibit withdrawal [11]. This is caused by insufficient incision of the skin and subcutaneous tissue. It can usually be resolved by slightly withdrawing the kink and placing it inside the dilator and then making an adequate incision. However, if the kink is strong, the coil wrapped around the guide wire can easily become loose, preventing the kink from being placed inside the dilator. In such cases, the puncture has to be repeated. With a 20-gauge Safe guide[®] needle, Hasegawa reported that kinking and locking of the guide wire, associated with its introduction through the side port, can be reduced and that guide wire kinking associated with the introduction of the dilator at the puncture site can be completely avoided by using a 0.025 inch guide wire with the same composition as ours [2]. The results of our kink resistance study indicate that with a modified guide wire, kinking at the puncture site can be completely avoided and that the clinical characteristics are similar to that of a 0.025 inch guide wire. Problems with guide wires occur frequently when a 0.018 inch guide wire is used for external jugular vein approach [1, 3, 5]. This is because the external jugular vein joins the subclavian vein perpendicularly, where a soft guide wire can kink inside the blood vessel. As for the subclavian approach, Saito, *et al.* [7] attempted the approach using a 22-gauge Safe guide[®]. They selected a puncture point medial to the midclavicular line. They reported that they were able to introduce a dilator but, in some cases, could not advance the catheter itself. They suggested selecting a puncture point lateral to the midclavicular line and modifying the wire material itself. The results of our study suggest that the issues related to the guide wire can be resolved in internal jugular vein puncture. However, similar studies for external jugular vein and subclavian vein puncture have yet to be conducted.

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