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Development of a safe guidewire

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Abstract
As the result of a locking phenomenon that may occur in a guidewire inside a metal puncture needle when using the Seldinger technique to insert a central venous catheter, the guidewire can break and cause an embolism. To counter this possibility we devised a guidewire with a structure that made it difficult for locking to occur and compared it to conventional guidewires. Conventional guidewires are wound lengthways with a spring. The improved version has a special multi-ply structure. A series of 100 cases were divided into two groups: group A, the conventional guidewire group; and group B, the improved guidewire group. We punctured the internal jugular vein and attempted insertion of the guidewire through the side hole of a 22-gauge metal needle. We then compared the frequency of locking and the frequency of bending of the guidewire tips that have been withdrawn. In group A, locking occurred in 72% of the cases where the guidewire was unable to be inserted, but this figure was 0% in group B. The improved guidewire has the advantage of reducing the risk of locking and of guidewire breakage.

Key words Central venous catheter · Complication · Guidewire

Complications arising from central venous catheter puncture can be divided into two main categories. The first is arterial misplacement, with hemothorax or pneumothorax due to misplacement at the time of puncture; the second is an embolism due to breaking of the catheter or guidewire device.

There is no shortage of articles discussing reports of the latter complication. They include cases where the tip has formed loops [1–3], cases where the tip has broken off [4], and cases where the guidewire has broken because of the difficulty of extracting it [5]. However, most of the reports concern post accident measures and treatment; reports examining the improvement of devices for preventing accidents before they happen are rare.

It is true that the cause of accidents in most cases is a lack of experience and the underdeveloped technique of technicians; but it is thought that there is still room for improvement in the safety features of the central venous catheter device itself. For that reason, we conducted an analysis of events that occur during insertion of central venous catheters from the standpoint of the device's structure.

In daily medical practice we use Safe Guide. Its structure consists of a 22-gauge metal needle with a side hole for inserting the guidewire; the guide wire is inserted through the lumen of the metal needle. Because the needle is so thin, there is less puncture resistance and a higher puncture success rate compared with the conventional technique [6,7]; it can also be said to be a less invasive technique. However, we have frequently encountered a guidewire locking phenomenon (where the inserted guidewire can no longer be advanced or withdrawn) that we had never experienced with conventional techniques. We also had one case where the guidewire in this type of locked state broke after being forcefully withdrawn, with part of the guidewire remaining in the blood vessel [8].

We thought that using this technique, where the guidewire is inserted through a metal needle, involves a specific risk; and as a result of investigating the cause of the guidewire locking phenomenon from the standpoint of the device's structure, we believed that the main cause of the locking phenomenon was the structure of the guidewire. Thus, we devised an improved guidewire and then compared it with conventional guidewires.

Figure 1 shows a conventional guide wire on the left and the improved guidewire on the right. The conventional guidewires consist of a stainless steel core wound lengthways by a spring made of the same material (hereafter wound lengthways). In the improved guidewire, thin wires of the same material are

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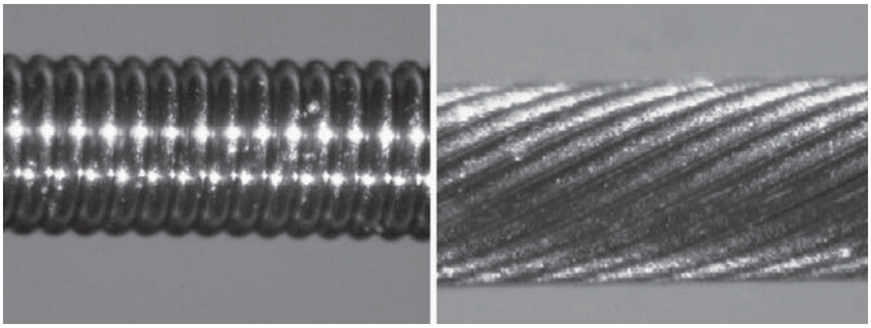

Group A
Conventional guide wire

Group B
Modified guide wire

Fig. 1. Structure of the guidewire. On the *left* is a conventional guidewire; on the *right* is an improved guidewire

plied in a straight line to form a single guidewire (hereafter multi-ply).

The subjects were 100 patients believed to require central venous catheterization. The substance of this research was explained beforehand to the subjects, and their informed consent was obtained. The patients were then divided into two groups. Group A was the conventional guidewire group ($n = 50$); and group B was the improved guidewire group ($n = 50$).

After performing intubation under general anesthesia, the neck was tilted approximately 30° to the left, and the patient was placed in a Trendelburg position. Afterward, puncture of the right internal jugular vein was attempted using a 22-gauge Safe Guide. After obtaining flashback, the guidewire was inserted through the side hole. During this process, if there was resistance when the 15-cm guide wire mark passed the yellow ring, the guidewire only was withdrawn without removing the puncture needle, and puncture was carried out again. After inserting the guidewire 25–30 cm from the side hole, the Safe Guide needle was removed, leaving the guidewire in place. Then a director was inserted. Finally, the central venous catheter was inserted using the guidewire. A comparative study was performed on the following two matters: (1) frequency of locking and (2) frequency of deformation of the guidewire tip when observed with the naked eye.

With regard to statistical processing, a chi-squared test was carried out, with a significance level of 5% or less indicating a significant difference. Using an optical microscope, we also performed a comparative study on the morphological changes of the two groups after an already used guidewire was bent 90°.

There were 7 of 50 (14%) cases in both groups A and B where the guidewire could not be inserted properly despite successful securing of the blood vessel. This is thought to have been caused by the needlepoint straying outside the blood vessel during insertion of the guidewire. The rate of locking in group A was 4 of 50 (8%) cases, which was more than half the number of cases where the guidewire could not be inserted properly. Not one case of locking was seen in group B. Bending of the guidewire tip (as seen by the naked eye) occurred in all of the cases where insertion was difficult in group A; however, this phenomenon was not seen in group B (Table 1).

Table 1. Results

Group	Frequency of locking	Frequency of deformation[a]
A (conventional guidewire)	4/50 (8%)*	0/50
	4/7 (72%)*	0/7
B (modified guidewire)	0/50	0/50
	0/7	0/7

* $P < 0.05$ vs. group B
[a] Frequency of deformation of the guidewire tip when observed with the naked eye

In Fig. 2, on the left, is an optical microscope image of group A guidewires. Deformation of the coil in several areas of the spring was detected in all seven of the guidewires that could not be inserted into the blood vessel. In the image on the right, not one guidewire in group B had deformation in the coil, indicating that the multi-ply guidewire is highly resistant to morphological changes.

Figure 3 shows the relation between the morphological changes to the bent guidewire and the puncture needle. The top row illustrates the changes to the guidewire in both groups after they are bent at 90°. The bottom row illustrates the morphological changes when each of the guidewires is bent when joined to a puncture needle. In both rows, group A is on the left and group B on the right. The elastic limit of the group A guidewire is easily exceeded when the guidewire is bent 90°. It bends easily, and the gaps between the springs increase.

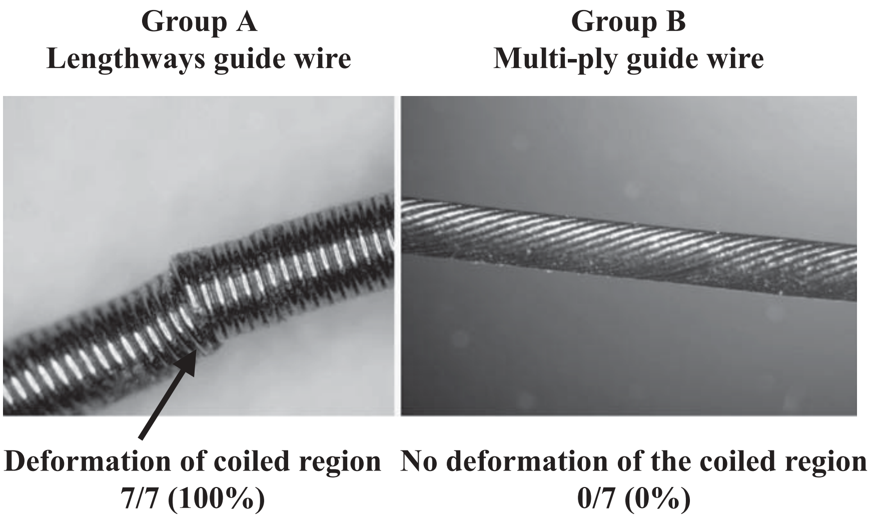

Fig. 2. Morphological changes in guidewires wound lengthways and multi-ply guidewires

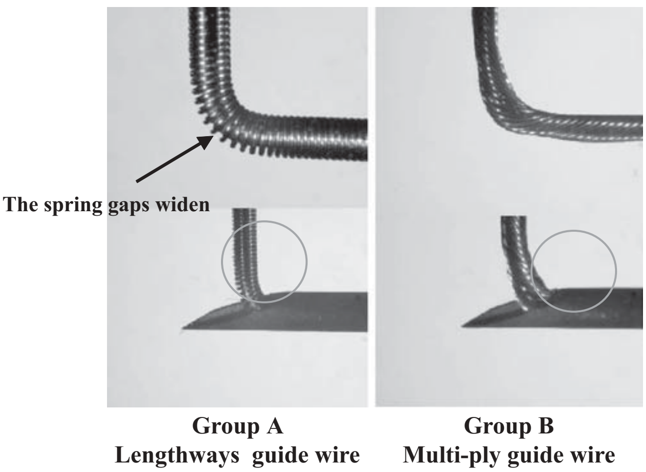

Fig. 3. Relation between the morphological changes in a bent guidewire and a puncture needle. The group A guidewire is easily bent, and the gaps between the springs increase. In contrast, the group B guidewire is difficult to bend, and the gap between the springs is small. The group A guidewire, with its expanded gaps between springs after being bent, can easily catch on the beveled portion of the puncture needle. Hence, there is a possibility that a spring may break

On the other hand, the group B guide wire does not bend easily, and it has a structure that makes it difficult for gaps to arise between the springs. As can be clearly seen in the photographs of the bottom row, the group A guidewire with enlarged gaps between springs after being bent can easily catch on the beveled part of the puncture needle and cause locking, which is thought to be the principal cause of guidewire trouble. According to the report by Domino et al. [9] there have been close to 20 reported cases of lawsuits stemming from guidewire mishaps.

Based on the results of our experiment, the main cause of locking was the affinity between the beveled surface of the metal needle and the guidewire. The most common guidewires contain a stainless steel core wound with a spring made of the same material and so have the flexibility characteristic of guidewires [10]. However, when they are bent to an extreme angle, the elastic limit of the metal is exceeded, enabling gaps to appear between the springs, which then catch on the beveled surface, causing locking.

The rate of locking when inserting conventional guidewires using a metal needle is more than half the number of cases where guidewire insertion is difficult. The principal cause of this problem is thought to be that the guidewire has become bent in the subcutaneous tissue outside the blood vessel and catches on the beveled part of the metal needle, causing locking. Furthermore, it has also been found that by forcefully withdrawing the guidewire while it is in a locked state there is a risk that the springs can break, causing the guidewire to remain in the body. When the guidewire becomes locked, it is necessary to remove the puncture needle and guidewire together and perform another puncture, resulting in the need for multiple placement of the device and increasing the risk of complications such as arterial misplacement or pneumothorax.

To minimize the risk of locking, the improved device we are currently developing has a special structure that makes it difficult for gaps in the springs to develop, so it has an advantage that even in cases where it is difficult to insert the guidewire it is not necessary to remove the entire device. One must only retract the guidewire temporarily, and the guidewire can then be safely reinserted after finely adjusting the needle point.

In summary, by using the improved guidewire, it is possible to decrease the risk of complications developing from locking or breakage compared to conventional guidewires. It also has the advantage of canceling out the need for multiple puncturing to reinsert the entire device. This improved guidewire technology is not restricted to Safe Guide but can be utilized for all guidewires that must pass through the lumen of metal needles.

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