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The Usefulness of the 22-Gauge Safe Guide® Based on Penetration Force and Pattern of Blood Regurgitation

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Abstract

The force required to penetrate a film was studied in needles used for central venous puncture. In addition, the right internal jugular vein was punctured using these needles to clinically evaluate the magnitude of venous compression associated with their usage by observing whether blood regurgitation occurred upon the advancement or withdrawal of the needles. The needles studied were a 23-G injection needle, 22- and 20-G Safe guide®, an 18-G needle and 2 types of 18-G indwelling intravenous catheters. These needles were attached to a motor propelled push-pull gauge and the changes in force (g) required to penetrate polyethylene films using these needles were observed. The difference between the penetration force of the 23-G injection needle and the 22-G Safe guide® was significant when piercing a 0.08-mm film with the penetration angle at 45°, with that of the 22-G Safe guide® being significantly smaller. However, the penetration force of the other needles was significantly greater than that of the 23-G injection needle, showing a force 2- to 4-fold greater than that of the 23-G injection needle. With the penetration angle at 30o, the penetration force of the 22-G Safe guide® was significantly greater than that of the 23-G injection needle irrespective of film thickness. Blood regurgitation occurred upon the advancement of the needle in most cases in which the 23-G injection needle and the 22-G Safe guide® were used, however, it occurred upon withdrawal of the needle in 30% of the cases in which the 20-G Safe guide® was used and in 47% of those in which the 18-G needle was used, suggesting that compression of the vein was substantial when using these needles. The results of this study indicate that the physical and clinical characteristics of the 22-G Safe guide® are similar to those of the 23-G injection needle.

Key Words: Safe guide®, Penetration force, Penetration angle

Introduction

The Safe guide® is a new central venous catheterization needle that serves as a pilot needle and introducer all in one. A guide wire can be introduced through a port on the side of the 22-gauge needle with a single puncture. The advantage is that this new needle can be placed within a blood vessel using only the amount of force required for a pilot needle. However, quantitative studies on the penetration force required for intravenous placement are limited. We measured the force required to penetrate a polyethylene film and observed the changes in the penetration force using a self-invented experimental apparatus. The penetration force of the 22-gauge Safe guide®, a slightly larger 20-gauge Safe guide®, an 18-gauge needle and 2 types of 18-gauge indwelling intravenous catheters was measured in order to com-

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pare them to that of a 23-gauge injection needle, which is commonly used as a pilot needle. Measurements were made using 0.05- and 0.08-mm polyethylene film at penetration angles of 30°and 45°. Excluding the indwelling intravenous catheters, puncture of the internal jugular vein was performed using the 4 types of needles. The magnitude of venous compression was clinically evaluated by determining whether blood regurgitation occurred upon advancement or withdrawal of the needles.

Materials

A (i) 23-gauge injection needle (Nipro), a (ii) 22-gauge Safe guide®, a (iii) 20-gauge Safe guide®, a (iv) 18-gauge needle (Arrow), and (v) 18-gauge Angiocath® and (vi) Surflow® were used in the laboratory measurement of penetration force. A i) 23-gauge injection needle (Nipro),a ii) 22-gauge Safe guide®, a iii) 20-gauge Safe guide® and a iv) 18-gauge needle were used in the clinical blood regurgitation study.

Structure of the Needles

The structures of the needles and indwelling intravenous catheters are illustrated in Fig 1. Fig 1 (upper) is a 23-gauge injection needle. The tip of the bevel surface is sharpened into the lancet type, which results in a wide and gradual bevel surface. 18-gauge needles are also sharpened into the lancet type. Fig 1 (center) is a 22-gauge Safe guide®. The bevel surface is sharpened into the K3-lancet type, which features in the non-grinding inner side of bevel. The difference between the lancet type and K3-lancet type is that only the outer side of the bevel tip is sharpened while the inner side is not. Fig 1 (lower) is an 18-gauge indwelling intravenous catheter. An inner needle sharpened into the lancet type is covered by a plastic catheter sheath.

Experimental apparatus and methods

(1) The needles were attached to the tip of a push-pull gauge propelled by a motor to measure penetration force (Fig 2). The penetration angle was adjusted first to 30°and then to 45°. The penetration speed was set at

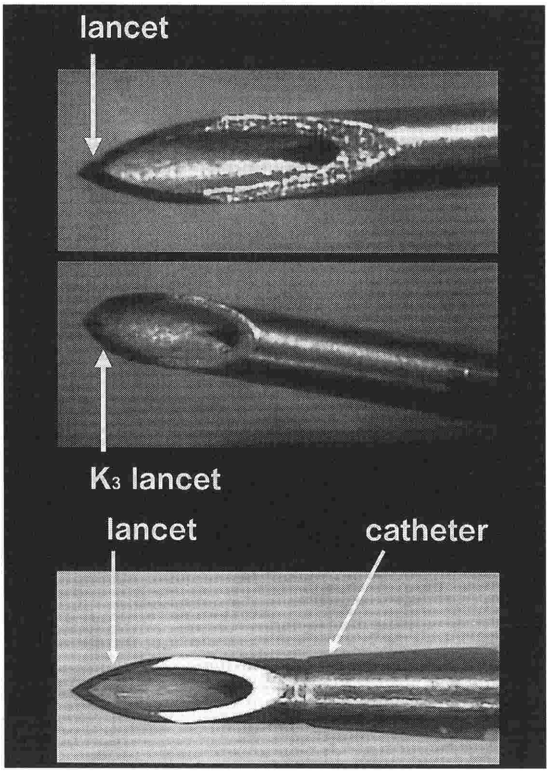

Fig. 1 Structures of needles and indwelling intravenous catheter
The upper figure is a 23-gauge injection needle. The center figure is a 22-gauge Safe guide®. The lower figure is an 18-gauge indwelling intravenous catheter.

3.3 mm/sec. The change in force (g) required to pierce both 0.05- and 0.08mm polyethylene films was observed. The change in force was indicated on a meter. Simultaneously, analog signals were sent to a computer and chart recorder for recording through an amplifier and A-D converter. The amount of movement of the push-pull gauge was also sent to the computer after transforming the information into electric signals using a potentiometer. This experimental apparatus provides information on different penetration force patterns resulting from the differences in the sharpness of needle tips and the smoothness of the catheter sheathes. The results are indicated as mean± SD. The Z-test was used for statistical comparison considering $p<0.05$ as significant.

(2) The clinical blood regurgitation study investigated

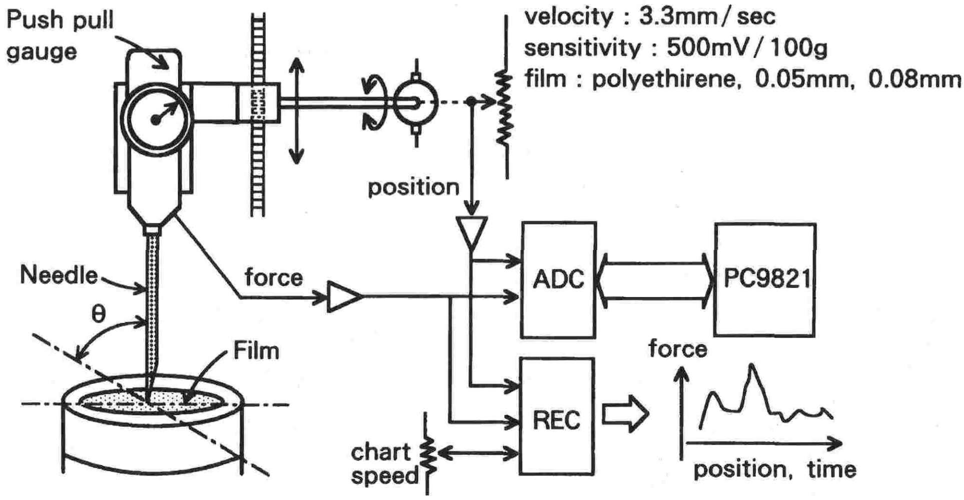

Fig. 2 Diagram of our experimental apparatus

120 surgical patients in which central venous catheterization was indicated for perioperative management. The study was explained to the patients and consent was obtained from all of the subjects prior to surgery. The right internal jugular vein was punctured with the head of the patient tilted 30°toward the left after induction of general anesthesia. The puncture was attempted approximately 45°from the triangle formed by the clavicular and sternal tendons of the sternocleidomastoid muscle. 23-gauge injection needles, 22-gauge Safe guide®, 20-gauge Safe guide® and 18-gauge needles were used in 30 patients each. An assistant judged whether blood regurgitation occurred upon advancement or withdrawal of the needle. The Student's t-test and Fisher's probability test were used for statistical analysis with $p<0.05$ considered to be significant.

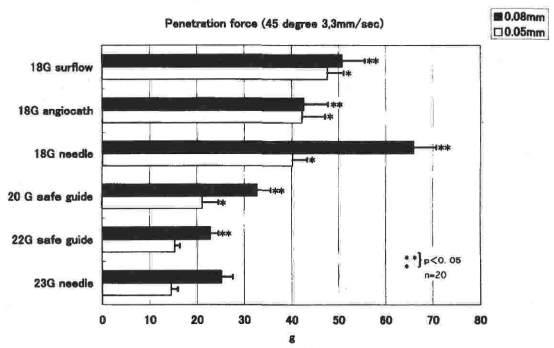

Fig. 3 Penetration force when piercing 0.05- and 0.08-mm polyethylene films at a penetration angle of 45°

The gray and black bars represent the penetration force when piercing 0.05- and 0.08-mm polyethylene films, respectively. Significant differences between values for the 23-gauge injection needle and all the other needles and catheters are indicated with single and double osterisks.

Results

(1) Comparison of penetration forces

1) Penetration force when piercing 0.05- and 0.08-mm polyethylene films at a penetration angle of 45°

The results of the penetration force study for (i) the 23-gauge injection needle, (ii) the 22-gauge Safe guide®, (iii) the 20-gauge Safe guide®, (iv) the 18-gauge needle (Arrow), and (v) the 2 types of 18-gauge indwelling intravenous catheters (Angiocath® and Surflow®) are shown in Fig 3. The point of maximum penetration force is used in the graph for the 23-gauge injection needle, and the 22- and 20-gauge Safe guide®. The point of maximum penetration force of the catheter sheath is used for the 18-gauge indwelling intravenous catheter. The gray and black bars indicate the penetration force when piercing 0.05-

and 0.08-mm polyethylene films, respectively.

Significant differences between the values for the 23-gauge injection needle and all the other needles and catheters are indicated with single and double asterisks. The maximum penetration forces of the 23-gauge injection needle were 14.5±1.4 g and 25.2 ±2.4 g when piercing a 0.05- and 0.08-mm film, respectively. Those of the 22-gauge Safe guide® were 15.3±1.1 g and 22.9±1.7g, respectively. The difference between the 23-gauge injection needle and the 22-gauge Safe guide® was not significant when piercing a 0.05-mm film but was significant when piercing a 0.08-mm film, with the penetration force of the 22-gauge Safe guide® being smaller. The maximum penetration force of the 20-gauge Safe guide®, the 18-gauge needle and the 2 types of 18-gauge indwelling intravenous catheters was significantly greater than that of the 23-gauge injection needle. The force required for penetration with the 18-gauge needle and the 2 types of 18-gauge indwelling intravenous catheters was 2 to 3 times greater than that of the 23-gauge injection needle (Fig 3).

2) Penetration forces when piercing 0.05- and 0.08-mm polyethylene films at a penetration angle of 30o

The penetration force of the 22-gauge Safe guide® was significantly greater than that of the 23-gauge injection needle regardless of film thickness. Likewise, the difference in maximum penetration force between the 23-gauge injection needle and the 20-gauge Safe guide®, the 18-gauge needle or the 2 types of 18-gauge indwelling intravenous catheters was significant with the latter being 2 to 4 times greater (Fig 4).

(2) Pattern of change in penetration force

1) Pattern of penetration force change of the 23-gauge injection needle

The pattern of penetration force change of the lancet type sharpened 23-gauge injection needle inserted at a 45° angle is illustrated in Fig 3. The horizontal axis represents time while the vertical axis represents the force required to penetrate the film (g). The penetration force increased until the needle tip passed through the film (A); it decreased slightly as the tip passed through (B), then continued increasing until the maximum diameter of the bevel passed through the film and the penetration force reached its maximum value (C). Thereafter, the penetration force decreased suddenly (Fig 5).

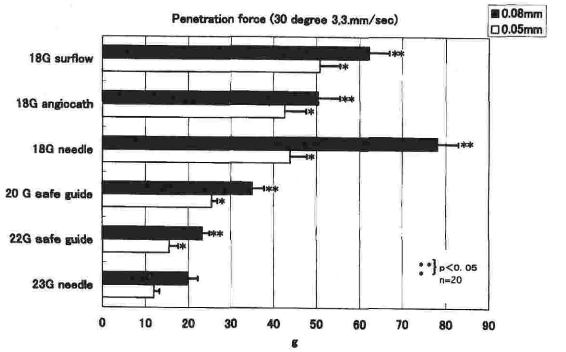

Fig. 4 Penetration forces when piercing 0.05- and 0.08-mm polyethylene films at a penetration angle of 30°

2) Pattern of penetration force change of the 22-gauge Safe guide®

The pattern of penetration force change of the K3-lancet type sharpened 22-gauge Safe guide® is illustrated in Fig 4. The penetration force abruptly reached its maximum value as the needle tip passed through the film (C) and decreased suddenly thereafter. The time to reach the peak value was shorter than that of the lancet type (Fig 6).

3) Pattern of penetration force change of the 18-gauge indwelling intravenous catheter

The pattern of penetration force change of the 18-gauge indwelling intravenous catheter with a lancet type sharpened inner needle is illustrated in Fig 7. The pattern of penetration force change of the inner needle followed that of a 23-gauge injection needle. The penetration force increased until the catheter tip breached the film (E), then it abruptly decreased until the passage of the maximum diameter of the catheter (catheter OD) where it formed another peak (F) that

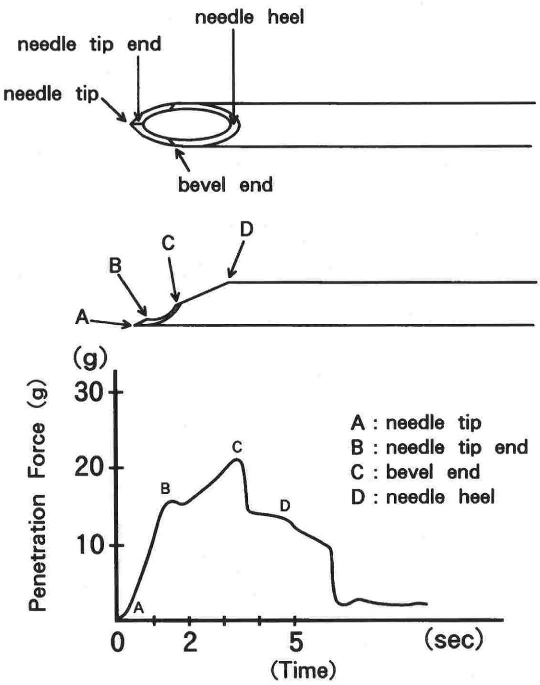

Fig. 5 Pattern of penetration force change of the 23-gauge injection needle
The horizontal axis represents time while the vertical axis represents the force required to penetrate the film (g).

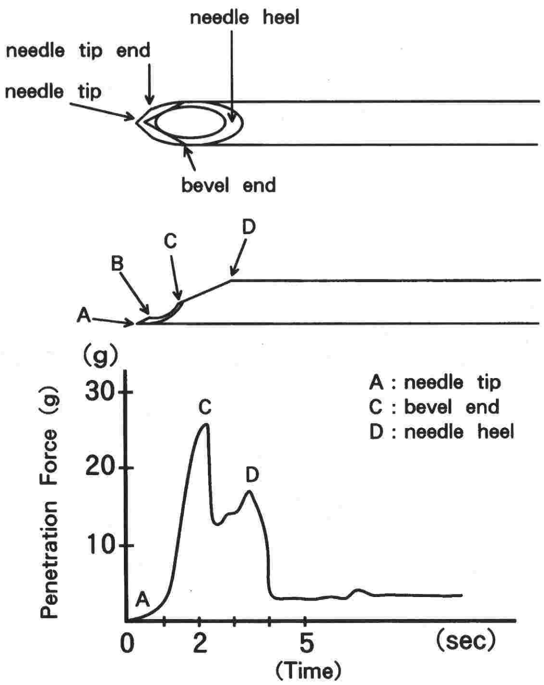

Fig. 6 Pattern of penetration force change for the 22-gauge Safe guide®

was however, smaller.(Fig 7).

(3) Comparison of blood regurgitation patterns
The blood regurgitation patterns of the needles are illustrated in Fig 8. The bars marked with oblique lines indicate the occurrence rate of blood regurgitation upon advancement of the needle whereas the white bars indicate that upon withdrawal. Blood regurgitation occurred while advancing the needle in 97% of the cases when using the 23-gauge injection needle and the 22-gauge Safe guide® , respectively. However, it occurred while withdrawing the needle in 30% and 47% of case when using the 20-gauge Safe guide® and the 18-gauge needle, respectively (Fig 8).

Discussion

The common procedure for placing a central venous catheter via the internal jugular vein is the Seldinger method. First, the position and depth of the vein is confirmed using a thin 22- or 23-gauge pilot needle attached to a syringe. After confirmation, a 16- to 18-gauge indwelling intravenous catheter is inserted and used as an introducer. A guide wire is placed into the vein through the introducer, then a dilator is inserted to dilate the puncture hole to ease feeding in the catheter. Blood regurgitation occurs while advancing the thin pilot needle. However, back-flow is obtained at a significantly deeper position or occurs, while withdrawing the needle/catheter when using an indwelling intravenous catheter with a larger caliber[1,2].

Blood regurgitation occurs while withdrawing the needle for internal jugular vein puncture in approximately half of the cases using an 18-gauge needle (Arrow)[3]. This and the results of the clinical investigation in our study suggest that the magnitude of venous wall compression depends on the size and form of the needle/catheter. Blood regurgitation occurred while advancing a 23-gauge injection needle or

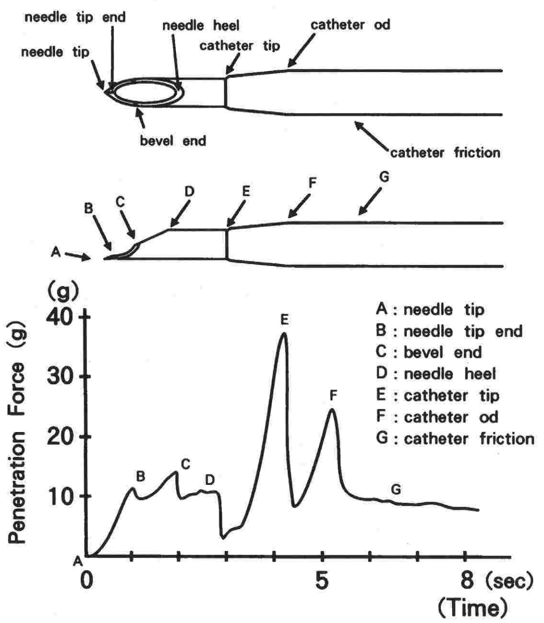

Fig. 7 Pattern of penetration force change of the 18-gauge indwelling intravenous catheter

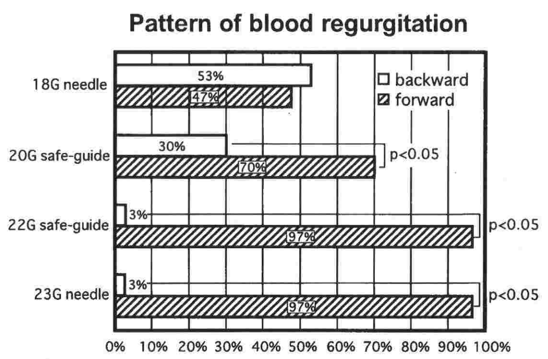

Fig. 8 Comparison of blood regurgitation patterns

The bars marked with oblique lines indicate the occurrence rate of venous regurgitation upon advancement of the needle whereas the white bars represent that upon withdrawal.

22-gauge Safe guide® in the majority of cases. In contrast, blood regurgitation occurred while withdrawing the needle in many of the cases in which a 20-gauge Safe guide® or 18-gauge needle was used. The reason for this observation is that the venous cavity is compressed because a significant amount of pressure is placed upon the anterior wall of the vein because intense force is required to penetrate the wall when using large-caliber needles. This increases the chances of the posterior wall being unintentionally penetrated as well as the anterior wall. Given that the needle is commonly advanced further, this may increase the possibility of the occurrence of complications such as accidental carotid artery puncture and pneumothorax. Recently, in an effort to avoid such complications, many studies have been carried out and proposed, including, puncture under ultrasonographic guidance [4~6,10], clarification of the anatomical position of the internal jugular vein and carotid artery[1,9], puncture while verifying venous and arterial position by ultrasonic probe[7,8], utilizing the Vasalva maneuver to dilate the internal jugular vein[1,5,12], increasing the rotation of the neck to avoid overlapping of the internal jugular vein and carotid artery[11,12] and enhancement of the needle[13,14]. None of these studies was investigated the penetration forces of the needles. Despite proper location of the puncture, the risk of a complication may increase if the penetration force of the needle being used is large. Yonei, et al. investigated the difference in transformation of the vein while using 3 types of needles with different calibers for internal jugular vein puncture under the guidance of ultrasonography[15]. The diameter of the vein was decreased from 9.4 mm to 6.1 mm, on average, that is a 3-mm compression of the anterior wall by a 22-gauge Safe guide® before entering the venous cavity. In contrast, the anterior wall of the vein was compressed by more than 6 mm when an indwelling venous catheter was inserted . It is clear that a needle requiring a small penetration force is advantageous. We went further to be the first to investigate the effects of needle structure and penetration angle on the penetration force. We instruct beginners in internal jugular vein catheterization that it is important that 1) the insertion angle to be approximately 45°, 2) the skin to be slightly stretched and 3) the puncture to be swift. These factors have been verified by our study. The results of our study indicate that the penetration force required by a 22-gauge Safe guide® is similar to that of a 23-gauge injection needle when inserted at a 45°angle. In addition, the penetration force of the

22-gauge Safe guide® was less than that for the 23-gauge injection needle when the film was thick. This suggests that a 22-gauge Safe guide® is preferable for internal jugular vein puncture given that the vein is as deep as 1 cm below the skin. Conversely, the penetration force for the 22-gauge Safe guide® was significantly greater than that for the 23-gauge injection needle when inserted at a 30° angle. This is probably dictated by the method of sharpening and the surface area of the bevel. Needles sharpened in lancet style are designed for peripheral vein insertion. This method of sharpening requires a smaller penetration force when the penetration angle is small. The larger bevel surface may lead to penetration till the posterior wall of the vein when the penetration force is great. The guide wire may be bent or hooked at the bevel when the guide wire is placed extravascularly because the inner side of the bevel is also sharpened. Given that the 22-gauge Safe guide® is sharpened into the K_3-lancet style, the possibility of the occurrence of complications such as guide wire becoming caught, etc, is decreased because the bevel surface is smaller and the inner side of the bevel is not sharpened. The required penetration force of the 18-gauge indwelling intravenous catheter is great because a large force is required for the passage of the plastic catheter sheath, resulting in the penetration force reaching 2 to 4 times of that of the 23-gauge injection needle at both 30° and 45°. In addition, the indwelling intravenous catheters, unlike the 22-gauge Safe guide® or the 23-gauge injection needle, have a plastic sheath with a variable friction index. This leads to the thickness and consistency of the skin and subcutaneous tissue determining the amount of penetration force necessary. These characteristics are not favorable for internal jugular vein puncture given that the vein runs deeply below the point of insertion.

We conclude that a 22-gauge Safe guide® used in everyday clinical practice for central venous catheterization at an insertion angle of 45° will behave similarly to a 23-gauge injection needle. However, it should be noted that the penetration force exceeds that of a 23-gauge injection needle when inserted at a 30° angle.

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