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Evaluation of dilators for central venous catheterization using an experimental model

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Abstract

Purpose. Skin incision before percutaneous central venous catheterization may cause serious hemorrhage and/or skin cicatrization. To minimize these adverse effects, we improved the shape of a dilator and coated it with lubricant to reduce insertion load.

Methods. We selected three types of dilators from different manufacturers. Each brand was widely available on the market in Japan. We redesigned one model with modified multitapering angles. Six types of dilators in total (three manufactured dilators, one manufactured dilator with lubricant, and the newly modified dilator +/− lubricant) were examined regarding load of insertion using pork muscle covered with porcine skin. Among these dilators, two manufactured dilators and the newly modified one with lubricant were also investigated regarding insertion load with or without skin incision.

Results. The minimum load of insertion was observed in the newly modified dilator with lubricant. The modified dilator attenuated the insertion load by up to 50% of the manufactured dilator, and the lubricant also reduced load by up to 16%. The insertion load of the modified dilator coated with lubricant was comparable to that of the manufactured dilators inserted with a 2-mm skin incision.

Conclusion. The lubricant-coated dilator with multitapering angles was associated with decreased insertion load and thus facilitated its insertion without skin incision.

Key words Seldinger technique · Central venous catheterization · Dilator

Introduction

A variety of central venous catheter products are on the market. Most of them adopt Seldinger technique [1] to avoid malpositioning during percutaneous central venous catheterization [2]. Because this technique allows catheters to enter into veins using relatively small gauge needles without cutdown, it is likely to be associated with minimal trauma to the surrounding tissue. Central venous catheter placement could be safely performed in patients with underlying disorders of hemostasis [3,4]. However, most of the products using this technique necessitate a skin incision to insert the dilator over the guidewire. Skin incision of a catheter insertion site before open heart surgeries may cause serious hemorrhage because of severe coagulopathy during cardiopulmonary bypass. The skin incision may also cause skin cicatrization as well. To minimize these adverse effects, we have to minimize the skin incision and push the dilator into the skin powerfully. The guidewire might be kinked and/or the dilator itself might be damaged.

We improved the shape of a dilator and coated it with lubricant to facilitate its insertion. This study compared our modified dilator with other products in respect to the load on their insertion using an experimental model.

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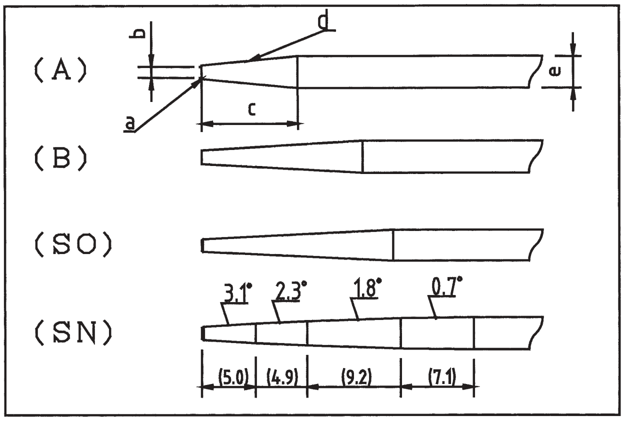
Materials and methods

Apparatus

We selected three different dilators from Arrow International (Reading, PA, USA), Becton, Dickinson (Franklin Lakes, NJ, USA), and Nippon Sherwood Medical Industries (Tokyo, Japan). We modified the Sherwood product so that we had three different types of dilator, each different from the original. We designed a tapering angle for one dilator. This newly shaped dilator (SN) has a tip as shown in Fig. 1. Methylvinylether anhydrous maleinic acid interpolymerization body $(C_7H_8O_4)_n$/acetone solution was used for lubricant and was chemically fixed over the 7-cm length of the distal part of the original and the modified Sherwood dilators.



symbol	material	a: shape of the tip	b: diameter of the tip (mm)	c: tapering length (mm)	d: tapering angle (degree)	e: diameter of the shaft (mm)
(A)	PP*	R=0.15	1.2	9.3	5	2.82
(B)	Nylon	90 ° (vertical)	1.2	15.5	2.8	2.7
(SO)	Nylon	45°	0.9	18.4	2.5	2.7
(SN)	Nylon	30°	0.95	26.2	3.1>2.3>1.8>0.7	2.77

* polypropylene R:Curvature radius

Fig. 1. Schematic representation of the dilators: (*A*) Arrow CS-17702-E (7 Fr., 20-cm double lumen), internal diameter 0.91 mm; (*B*) Becton 681300 (7 Fr., 20-cm double lumen), internal diameter 0.96 mm; (*SO*) Sherwood 1712-8WBG (12 gauge, double lumen), internal diameter 0.90 mm; (*SN*) Sherwood-shaped, internal diameter 0.95 mm

The dilators we investigated were as follow:

1. Arrow dilator (A): CS-17702-E (7-French double lumen), internal diameter 0.91 mm
2. Becton dilator (B): 681300 (7-French double lumen), internal diameter 0.96 mm
3. Sherwood original dilator without lubricant (SO−): 1712-8WBG (12-gauge double lumen), internal diameter 0.90 mm
4. Sherwood original dilator with lubricant (SO+)
5. Sherwood newly shaped dilator without lubricant (SN−): internal diameter 0.95 mm
6. Sherwood newly shaped dilator with lubricant (SN+)

We employed a static material measurement instrument [5] (AGS-1kNG; Shimadzu, Tokyo, Japan), which measures the load to move a dilator at a constant velocity. Dilators were inserted into pork muscle covered with porcine skin [6]. We prepared all samples in the same fashion to simulate human anatomy. The pork (30.0–40.3 mm thick) was prepared from the back of a female pig less than 1 year old. The swine skin (2.53–3.55 mm thick) was from the abdomen, and fat was removed.

Methods

Protocol 1

We stabbed the pork sample with an 18-gauge peripheral venous catheter (Terumo, Tokyo, Japan; catheter outer diameter, 1.25 mm; needle outer diameter, 0.90 mm) and removed the internal metal needle. A stainless steel wire (0.89 mm diameter) was put through the catheter as a guiding wire. This guiding wire corresponds to a guidewire 0.035 in. (0.889 mm) in diameter. The catheter was then removed and the dilator was inserted into the pork sample guided by the wire. Each dilator was soaked in normal saline for more than 10 s before use. We prepared six sets of pork samples and each dilator was inserted into all six samples at different insertion sites. In total, 36 measurements were conducted.

The outline of our experimental device is shown in Fig. 2. The velocity of dilator movement was fixed at 200 mm/min and the depth of insertion was set at 70 mm. The equipment consisted of a load cell, a support stand, a dilator attachment, and a guiding pin. The guiding pin was fixed both to the dilator attachment and to the support stand. The dilator was settled in the dilator attachment with the guiding pin. The sample was put on the support stand. The load cell moved vertically toward the sample on the support stand at a constant velocity of 200 mm/min. As the load cell moved, the dilator was inserted vertically into the swine skin. The guiding pin fixed to the dilator attachment and the support stand facilitated the dilator to be inserted into the swine skin vertically. The load cell measured the load on the dilator when it was penetrating the swine skin. The load was recorded on a strip chart recorder and was converted into digital data at a sampling frequency of 50 ms for computer analysis. In each measurement,

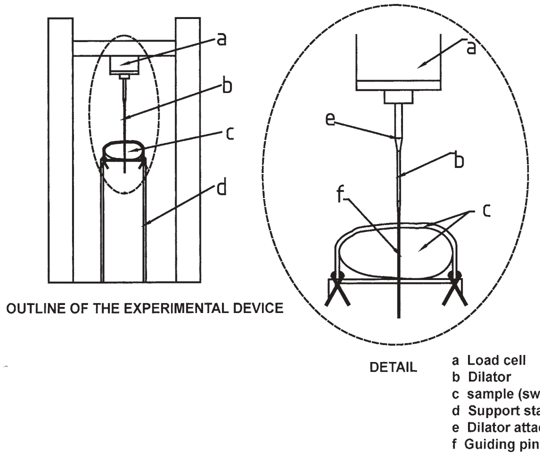


Fig. 2. Schematics of experimental settings. The equipment consists of load cell (*a*), support stand (*d*), dilator attachment (*e*), and guiding pin (*f*). The guiding pin is fixed to the dilator attachment and the support stand. The dilator (*b*) is settled in the dilator attachment with the guiding pin. The sample (*c*) is put on the support stand. The load cell moves vertically toward the sample on the support stand constantly at 200 mm/min

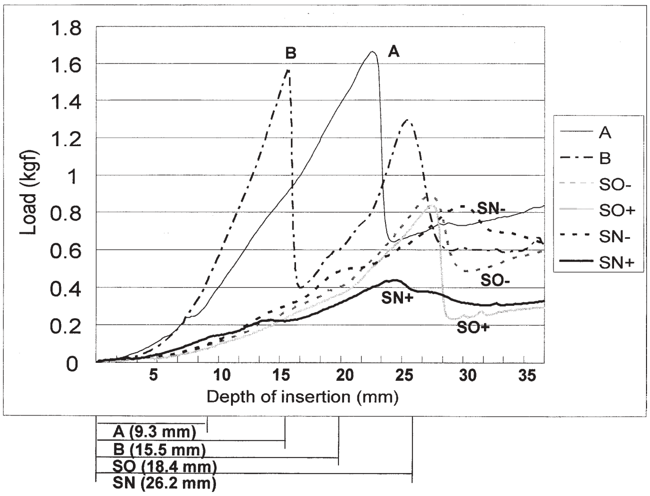


Fig. 3. Typical tracings of displacement-load curves. Tapering length of each dilator (*A*, *B*, *SO*, *SN*) is indicated at the foot of the graph. The surface of the porcine skin is set at 0 mm of displacement

we obtained displacement-load curves as shown in Fig. 3.

Protocol 2

We then selected three types of dilators (A, SO−, and SN+) from the six types of dilators examined in protocol 1 to measure the insertion load with 1-mm and 2-mm skin incisions, because a skin incision is made in most current clinical cases of central venous catheterization.

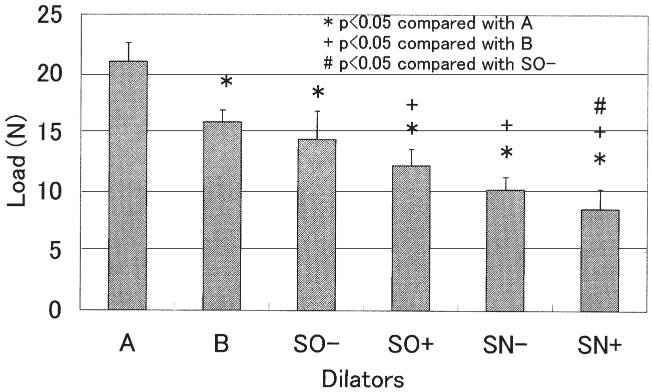


Fig. 4. Comparison of the peak load among manufactured and three types of modified dilators: the shaped dilator attenuated load by up to 50% (*SN*− vs. *A*), and the lubricant also reduced load by up to 16% (*SN*− vs. *SN*+). *Error bars* represent SE

Displacement-load curves were obtained in each measurement.

Statistical analysis

The peak loads of each dilator were compared for both measurements in protocols 1 and 2. One-way factorial analysis of variance (ANOVA) was employed for protocol 1, and a post hoc test was performed using Fisher's protected least square differences (PLSD). A P value less than 0.05 was considered significant. Two-way factorial ANOVA with contrasts was used for protocol 2. Statistical analysis was performed using Stat View (SAS Institute, Cary, NC, USA) and Super ANOVA (Abacus Concepts, Berkeley, CA, USA). Data are expressed as mean ± standard error (SE) and the unit is N.

Results

The peak loads of six dilators in protocol 1 were as follows: A, 20.97 ± 1.61; B, 15.89 ± 1.00; SO−, 14.42 ± 2.38; SO+, 12.21 ± 1.38; SN−, 10.18 ± 1.06; SN+, 8.56 ± 1.67 (Fig. 4). The peak load of dilator A was significantly larger than those of the other five dilators. Dilator B showed a significantly larger peak load value than SO+, SN−, and SN+. The peak load of SO− was also significantly larger than that of SN+.

In protocol 2, the results were as follows. Without incision: A, 21.46 ± 0.69; SO−, 14.05 ± 1.23; SN+, 9.27 ± 0.88; with 1 mm incision: A, 17.85 ± 2.07; SO−, 11.18 ± 1.31; SN+, 6.39 ± 0.47; with 2 mm incision: A, 7.83 ± 1.02; SO−, 5.83 ± 0.76; SN+, 4.48 ± 0.36 (Fig. 5). Statistical analysis revealed that both the type of dilator and the size of skin incision caused significant differences in the peak insertion loads.

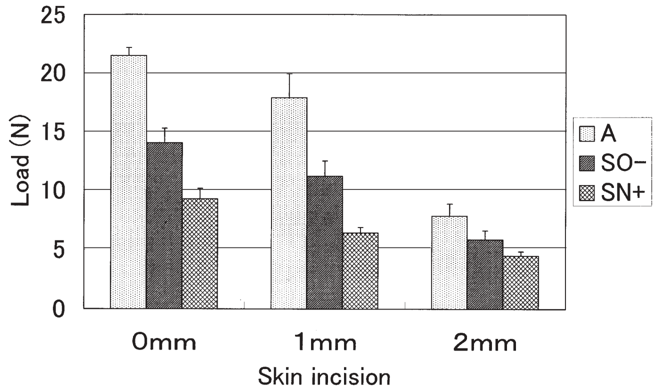


Fig. 5. Comparison of the peak load of three different types of dilators with 1-mm or 2-mm skin incision or without incision. *Error bars* represent SE

Discussion

The minimum load of insertion was observed in the multiply tapered dilator coated with lubricant. The modified dilator attenuated the insertion load by up to 50% of the manufactured dilator, and the lubricant also reduced the load by up to 16%, both of which were statistically significant. The insertion load of the multiply tapered dilator coated with lubricant was comparable to those of manufactured dilators inserted with 2 mm of skin incision.

The insertion load was influenced by the following: (1) the diameter of the dilator, (2) the shape of the tip, (3) tapering angles, (4) application of the lubricant, and (5) skin elasticity.

Diameter of the dilator

The load increases as the diameter becomes larger. As shown in Fig. 1, dilator A and B have similar tip diameters, while the diameter of the shaft is larger in dilator A than in dilator B; this might partly explain the significant difference in the peak loads between dilator A and B. There was no significant difference in insertion load between dilator B and SO− (see Fig. 4). These dilators have similar shaft diameters, but dilator B has a larger tip diameter than dilator SO (see Fig. 1). The diameter of the shaft rather than that of the tip is supposed to affect the peak load.

Shape of tip

The shape of the tip is also expected to contribute to the insertion load. The shape of the tip of dilator B is vertical. In contrast, other dilators examined in this study have round-shaped tips. Only dilator B showed two peaks of insertion load in Fig. 3. Thus, the integrated insertion load is thought to depend partly on the shape of the tip.

Tapering angles

Tapering angles are expected to contribute to the reduction of insertion load. Sharply tapered tips reduce the load on insertion of dilators. The tapering angles of A, B, and SO were 5.0°, 2.8°, and 2.5°, respectively (see Fig. 1). As shown in Fig. 4, a smaller tapering angle is associated with less peak load.

The new dilator SN is tapered differently from conventional ones. Although dilator SN has a larger tapering angle than SO, its peak insertion load was significantly lower than that of dilator SO (see Fig. 4). The stepwise reduction of the tapering angles is thought to decrease the insertion load. The tapering angles of dilator SN are gradually decreased as $3.1° > 2.3° > 1.8° > 0.7°$ from the tip to the proximal part of the dilator. We expect this multiply tapered dilator, which has a bulging shape, maintains stiffness of itself and also reduces the exponential increase of the load during insertion.

Application of lubricant

We considered application of the lubricant could also be effective to reduce the peak load. This lubricating material is approved by the Ministry of Health, Labour and Welfare of Japan and is widely used in clinical settings. It decreased the peak load on insertion by up to 16%.

Skin elasticity

The multiply tapered dilator coated with lubricant (SN+) showed the lowest peak load. There was no significant difference in the peak load between dilator SN+ without skin incision and dilator A with a 2-mm skin incision (see Fig. 5).

In clinical use, the load at dilator insertion is thought to depend mainly on the force to penetrate the skin, and the peak load should correspond to the clinician's feelings of difficulty in dilator insertion.

Swine skin has been reported to resemble human skin in terms of its property [6]. Our insertion simulation model seems to only partly reflect the clinical use of dilators, because our swine-skin model has two limitations. First, dilators are usually inserted into the vein lying beneath the skin in the clinical use. In our study the dilators penetrated the porcine skin and went into the pork muscle, which has far different structure and properties from human subcutaneous tissue and vein. Second, the dilators were moved at a constant velocity to measure the load to penetrate the porcine skin vertically in the current study, but we are not likely to insert dilators at a constant velocity or vertically in clinical practice. In spite of these limitations, we believe our model reflected the actual clinical feeling of difficulty in inserting dilators. In clinical use of manufactured dilators, we feel the largest resistance when they penetrate the skin. Moreover, even after a skin incision, we sometimes feel large resistance and add another incision to enlarge the first one. In this current study, the peak loads were observed just when the tip of the dilator penetrates the skin. The peak loads are thought to reflect the clinical feeling of difficulty in dilator insertion, even though it does not exactly simulate clinical use.

In conclusion, we found the lubricant-coated dilator with multitapering angles was fairly effective to reduce the insertion load and thus facilitate its insertion without a skin incision.

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