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Articles

Investigation of the shape of indwelling needles based on the pressure distribution inside needles using a pressure-sensing guidewire

OKU Tomoko[1], TOMI Hiroki[1], YAMAUCHI Shinobu[2], MOTOHASHI Yuka[2] and SATO Toshio[*]

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Key Words: Hemodialysis, Indwelling needle, Actual flow rate, Pressure-sensing guidewire

I. Introduction

The increased use of online hemodiafiltration as blood purification therapy in Japan means that treatment that emphasizes the efficiency of purification in terms of dialysis time and blood flow is now mainstream. Ensuring an ample rate of blood removal during hemodialysis is an issue common to all of these forms of treatment, and it is also important to maintain purification efficiency. In general, indwelling hemodialysis needles with an outer diameter of 15G to 17G are used in blood purification therapy. Considering puncture pain and deterioration of vascular access during puncture, as well as hemostasis time, an indwelling needle with a narrow diameter is desirable. With a narrow-diameter indwelling needle, however, reports have described divergence between the set blood removal rate and the actual flow rate, and this divergence reduces purification efficiency. In addition, in maintenance hemodialysis patients, not only purification efficiency, but also reduction of puncture pain and good condition of the arteriovenous fistula are important priorities. Although clinical studies of the use of a number of different local anesthetics and cryotherapy to decrease puncture pain have been reported, no study has yet reported improvements to the indwelling needle itself. “Straight type” indwelling needles currently used for hemodialysis at clinical sites induces noncontinuous widening of the blood-flow channel in the region of the needle-hub connection, leading to the occurrence of blood eddies in the connection region that are thought to narrow the actual suction inlet diameter and thereby reduce the blood removal flow rate that can be maintained. “High-flow type” needles with a funnel-shaped have therefore been marketed in recent years. The funnel configuration is said to reduce the occurrence of flow-channel discontinuity in the region of the needle-hub connection. However, few reports provide any experimental answers to issues such as the increase in the blood removal flow rate provided by funnel-shaped as opposed to straight type needles and the difference in their

* SATO Toshio: Professor, Graduate School of Engineering; Faculty of Biomedical Engineering, Toin University of Yokohama. 1614, Kurogane-cho, Aoba-ku, Yokohama 225-8503, Japan
[1] OKU Tomoko and TOMI Hiroki: Graduate School of Engineering, Toin University of Yokohama
[2] YAMAUCHI Shinobu and MOTOHASHI Yuka: Lecture, Faculty of Biomedical Engineering, Toin University of Yokohama

suction pressure.

In the present study, therefore, the differences in actual flow rates and suction pressure between commercial straight and high-flow types of indwelling needles were examined under different flow-rate settings. In addition, the pressure distribution inside straight and high-flow types of indwelling needles was measured using the pressure-sensing guidewire used to measure the intravascular pressure and determine the fractional flow reserve and, thereby, obtain experimental clarification of the reason why the high-flow type can maintain high flow rates.

II. Experimental Methods

2-1. Preparation of simulated blood

To take account of the viscosity of blood in our experiments, simulated blood was prepared by mixing 280 mL of 8% polyvinyl alcohol (PVA) solution with 1000 mL of water. The viscosity of this simulated blood was measured with a digital rotational viscometer. This was fitted with an ultra-low viscosity adaptor, and water warmed to 37 ºC was circulated through the water jacket. The chamber tube was filled with the prepared simulated blood, which was warmed to 37 ºC while viscosity measurements were carried out by changing the rotational speed of the digital viscometer (***Fig. 1***).

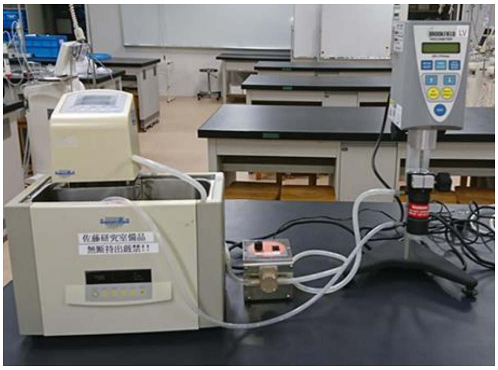


Fig. 1 Viscosity measurement

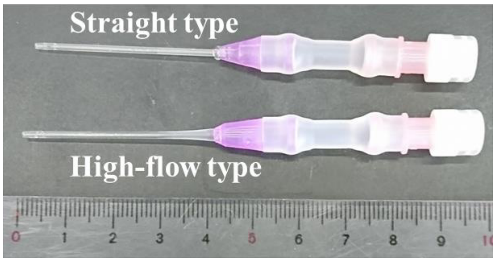


Fig. 2 Indwelling needle (17G, Covidien)

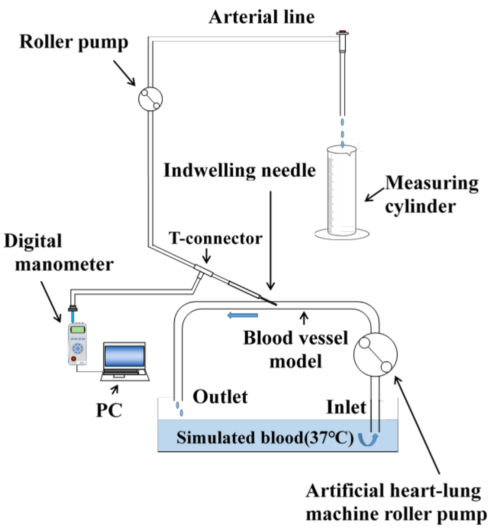


Fig. 3 Actual flow rate and removed blood pressure measurement system

2-2. Actual flow rate and removed blood pressure measurement methods

The indwelling needles used in the present study were commercial 17G (outer diameter 1.46 mm, inner diameter 1.10 mm) straight and high-flow types of indwelling needles for hemodialysis (***Fig. 2***). To investigate the effect of a difference in the outer cylinder length of the indwelling needle on the actual flow rate that can be maintained, the outer cylinders in the tip region were severed and processed to obtain lengths of 25 mm and 30 mm. A vinyl chloride tube with an inner diameter of 12 mm was used as an artificial blood vessel, and a roller pump designed for an artificial heart-lung machine was used to circulate simulated blood at a temperature of 37 °C with a flow velocity of

700 mL/min. The indwelling needle was inserted into the artificial blood vessel at an angle of 25°, placing the needle so that the tip was positioned in the center of the artificial blood vessel. A T-shaped tube was then connected to the indwelling needle, and the arterial blood circuit and a digital manometer were then attached. The arterial line from the indwelling needle was filled with simulated blood using a roller pump from a hemodialysis patient monitor, after which the pump was shut off, and the zero point of a digital manometer was calibrated with the fluid in a static state. The roller pump of a hemodialysis patient monitoring device was used to perform blood removal at set flow rates of 50 to 500 mL/min in increments of 50 mL/min. The actual flow rate was obtained from the quantity of accumulation in a graduated cylinder in 1 min. Both the actual flow rate and the blood removal pressure were measured 10 times at each set flow rate, and the mean values were calculated (***Fig. 3***).

2-3. Pressure measurement inside the indwelling needle

The pressure-sensing guidewire had an outer diameter of 0.36 mm and was equipped with an internal Wheatstone bridge circuit 3 cm from the tip. Its pressure measurement range was -30 to 300 mmHg, with an accuracy of ±2 mmHg (***Fig. 4***). As in the experiment in 2-2, the outer cylinders of an indwelling needle were processed to lengths of 25 mm and 30 mm. A vinyl chloride tube with an internal diameter of 12 mm was used as an artificial blood vessel, and a roller pump designed for an artificial heart-lung machine was used to circulate simulated blood at a temperature of 37 °C with a flow velocity of 700 mL/min. The indwelling needle connected to the hemodialysis circuit was placed in the artificial vessel. The arterial line from the indwelling needle was filled with simulated blood using a roller pump from a hemodialysis patient monitor, after which the pump was shut off. A cannula for introducing the pressure-sensing guidewire was placed in the artificial vessel pointing toward the indwelling needle. This was used to introduce the pressure-sensing guidewire into the needle hub 50 mm from the indwelling needle tip. The pressure-sensing guidewire was calibrated in still water, and a pressure reading of zero was confirmed. It was then inserted to the needle hub 50 mm internally from the indwelling needle tip, followed by measurement of the pressure at 5-mm intervals while pulling the guidewire from there toward the tip. The pressure distribution in the indwelling needle at each set flow rate was thus determined (***Fig. 5***).

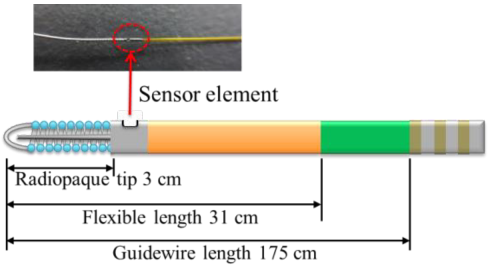


Fig. 4 Pressure-sensing guidewire (St. Jude Medhical)

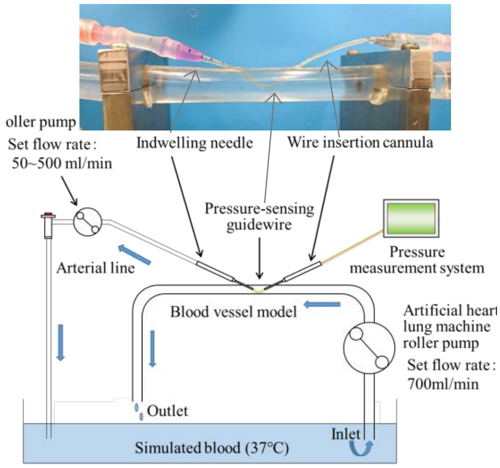


Fig. 5 Pressure measurement inside the indwelling needle

III. Results

3-1. Viscosity measurements of simulated blood

Table 1 shows the viscosity of the simulated blood prepared by mixing 280 mL of 8% PVA solution and 1000 mL of water. The value measured at 5, 10, 20, 50, 60, and 100 rotations was approximately 3.0 mPa s.

Table 1 Simulated blood viscosity

Number of rotation [RPM]	5	10	20	50	60	100
Viscosity [mPa s]	3.00	3.00	2.97	2.94	2.97	2.99

3-2. Actual flow rate and suction pressure measurements

Figure 6 shows the actual measured flow rates in the straight and high-flow indwelling needles. Comparing the actual flow rates of the straight type and the high-flow type, there was no large difference at a set flow rate up to 200 mL/min. However, at settings beyond that, the difference between each actual flow rate became larger, and it was confirmed that the high-flow type can maintain a higher flow rate. A shorter outer cylinder tends to enable maintenance of a higher actual flow rate, whereas it was found that a 30-mm high-flow type can secure the actual flow rate even though the flow path is longer than that of a 25-mm straight type. ***Figure 7*** shows the suction pressures measured in the straight and high-flow indwelling needles. The suction pressure increased in the order 25-mm high-flow < 30-mm high-flow < 25-mm straight < 30-mm straight, confirming that the suction pressure was lower in the high-flow needle. ***Figure 8*** shows the association between the actual measured flow rate and the actual measured suction pressure. The actual flow rate increased with increasing suction pressure in each type of needle, but at the same suction pressure, a higher actual flow rate was maintained in the high-flow needle, with a higher actual rate maintained when the effective length was shorter.

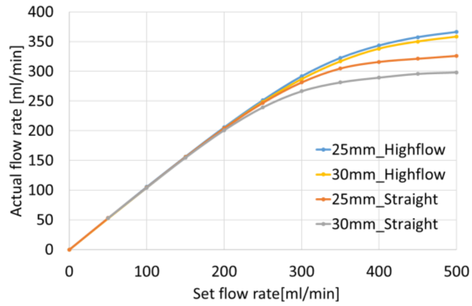


Fig. 6 Actual flow rate measurement results

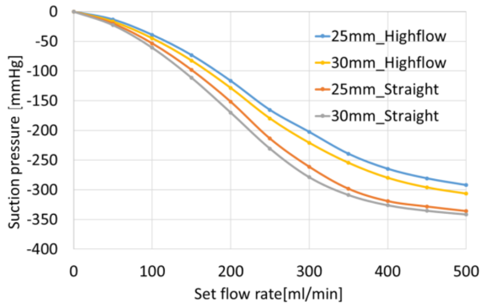


Fig. 7 Suction pressure measurement results

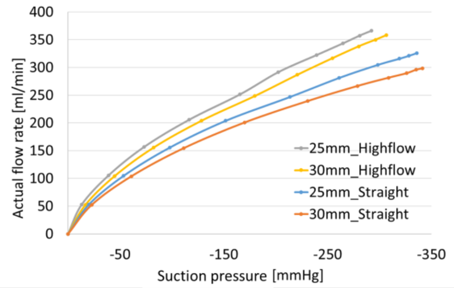
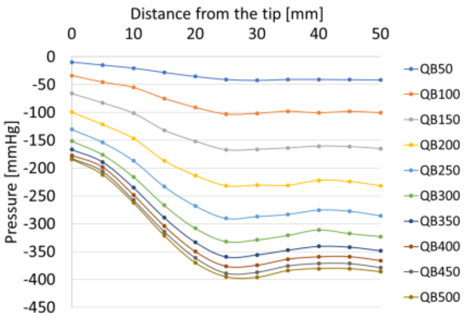


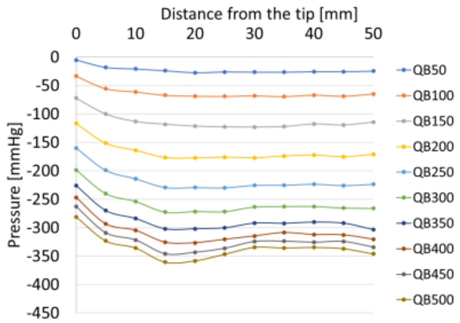
Fig. 8 The relationship between actual flow rate and suction pressure

3-3. Internal pressure measurements in the indwelling needles

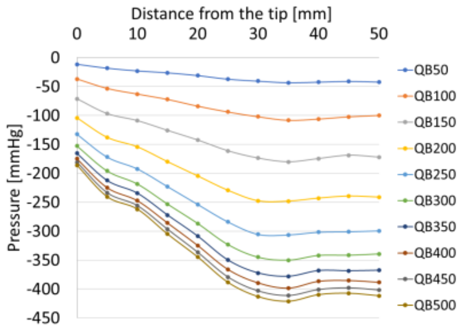
Figure 9 shows the internal pressure measured inside each of the indwelling needles. In the straight type, the increase in suction pressure with increasing distance from the needle tip was



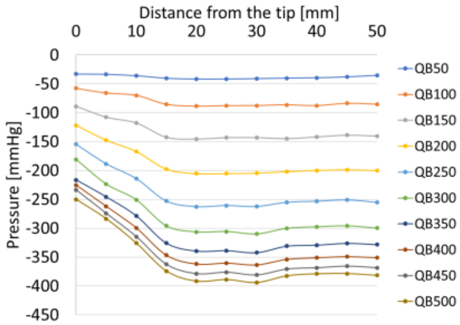
(a) 25-mm Straight type



(c) 25-mm High-flow type



(b) 30-mm Straight type



(d) 30-mm High-flow type

Fig. 9 Internal pressure results in the indwelling needles

Table 2 Error rate of actual flow rate compared to set flow rate

	Set flow rate [ml/min]	50	100	150	200	250	300	350	400	450	500
Straight 25-mm	Actual flow rate [ml/min]	53.0	140.7	155.7	203.9	246.9	281.3	304.7	315.8	321.1	325.9
	ΔQ_A [%]	+6.0	+4.7	+3.8	+2.0	-1.2	-6.2	-12.9	-21.1	-28.6	-34.8
Straight 30-mm	Actual flow rate [ml/min]	52.4	103.8	14.4	200.8	239.3	266.5	281.4	289.5	295.8	298.2
	ΔQ_A [%]	+4.9	+3.8	+2.9	+0.4	-4.3	-11.2	-19.6	-27.6	-34.3	-40.4
High- flow 25-mm	Actual flow rate [ml/min]	53.0	105.5	156.5	205.7	251.3	291.5	322.3	343.3	357.3	366.1
	ΔQ_A [%]	+6.0	+5.5	+4.3	+2.8	+0.5	-2.8	-7.9	-14.2	-20.6	-26.8
High- flow 30-mm	Actual flow rate [ml/min]	52.4	104.2	155.4	203.9	248.4	286.7	316.5	337.9	349.9	358.0
	ΔQ_A [%]	+4.8	+4.2	+3.6	+2.0	-0.6	-4.4	-9.6	-15.5	-22.2	-28.4

primarily linear, but the suction pressure was essentially constant from the root of the outer cylinder (25 mm or 30 mm from the tip) along the needle hub. With the high-flow type, in contrast, the change in suction pressure from the tip to a distance of 50 mm was smaller than with the straight needle. No large difference between the straight and high-flow types was found in the suction pressure at the tip of the indwelling needle.

IV. Discussion

4-1. Actual flow rate and flow rate error rate

If the set flow rate is designated Q and the actual flow rate Q_A, the error rate with respect to the set flow rate ΔQ_A is calculated by the following equation.

$$\Delta Q_A = \frac{Q_A - Q}{Q} \times 100\ [\%]$$

This was –34.8% to + 6.0% for the 25-mm straight indwelling needle, –40.4% to +4.9% for the 30-mm straight indwelling needle, –26.8% to +6.0% for the 25-mm high-flow indwelling needle, and –28.4% to +4.8% for the 30-mm high-flow needle. These results indicate that the discrepancy with the set flow rate was smaller for the high-flow indwelling needle, which thus has better blood-removing properties (***Table 2***). The nominal accuracy of the settings of the hemodialysis patient monitor used in this experiment is ±10%. The conditions under which it was actually within this range were 300 mL/min through the 25-mm straight indwelling needle, 250 mL/min through the 30-mm straight indwelling needle, and 350 mL/min through both the 25-mm and 30-mm high-flow indwelling needles. Accordingly, one option for maintaining the actual flow rate is to switch from a straight to a high-flow indwelling needle instead of simply changing the needle gauge.

4-2. Actual flow rate and suction pressure

Hemolysis reportedly occurs as a result of complex causes including shear rate, pressure, and temperature, and red blood cells are generally thought to be vulnerable to negative pressure. The ideal indwelling needle thus has excellent blood-removing properties at a low suction pressure. In their discussion of new dialysis puncture needles, Inagaki *et al*. reported that they resolved the issue of increased suction pressure when a 17G needle was used to reduce puncture pain and improve hemostasis and shunt condition by shortening the needle length to 25 mm. A comparison of the results from the 25-mm and 30-mm needles used in the present study also showed that suction pressure is reduced by shortening the circuit length. From the results shown in Figure 8, taking a suction pressure of –200 mmHg as an example, an actual flow rate of 290 mL/min was attained in the 25-mm high-flow needle compared with an actual flow rate of only 240 mL in the 25-mm straight needle, a difference of 50 mL/min. The fact that a better actual flow rate was attained via the high-flow needle at the same length demonstrated that the pressure is affected by the shape, as well as the length of the indwelling needle.

4-3. Internal pressure in the indwelling needle

Internal pressure measurements showed that there was a large pressure difference between the needle hub and the needle tip in the straight indwelling needles. In the high-flow needles, the pressure difference between the needle hub and the needle tip was smaller than that in the straight needles, confirming that the suction pressure was being effectively transmitted to the needle tip. Differences in the shape at the base of the indwelling needle affect the pressure distribution inside the needle, and this may also affect the amount of blood removed.

V. Conclusion

The properties of high-flow indwelling needles were investigated by measuring the actual flow rates and suction pressures of straight and high-flow 17G indwelling needles. The discrepancy between the set and actual flow rates was found to be smaller in high-flow needles compared with straight needles, and that in the former, the same flow rate was attained at a lower suction pressure. The internal pressure in the needles was also measured, and it was confirmed that it varies according to the flow-channel shape. These results suggest that, even for small-diameter indwelling needles, it may be possible to devise needles that provide an adequate flow rate with low suction pressure by designing the optimum funnel shape.

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