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Evaluation of the differences in pressure applied to the vessel wall by different types of balloon remodeling microcatheters in an experimental model

Mizuka Ikezawa[1], Takashi Izumi[1], Masahiro Nishihori[1], Tetsuya Tsukuda[1], Yosuke Tamari[1,2], Yoshio Araki[1], Kinya Yokoyama[1], Kenji Uda[1], Shunsaku Goto[1], Asuka E Kropp[1], Takafumi Otsuka[1], GQ1 Naoki Kato[1], Mizuki Nakano[1] and Ryuta Saito[1]

GQ2 **Abstract**

GQ4 **Background:** We examined compliance differences among balloon remodeling microcatheters, which have not been GQ5 established previously.

Methods: Straight and 120° angulated vascular models were created in a 3 mm diameter tube with 3 mm hole (vascular model A), a tube with a 4 mm hole (vascular model B), and a 4 mm diameter tube (vascular model C). We compared the pressure exerted when each balloon was herniated 1 or 2 mm between three compliant balloons (SHOURYU SR, TransForm C, and Scepter C) and four super-compliant balloons (HyperForm, SHOURYU HR, TransForm SC, and Scepter XC).

Results: In vascular model A, there was a significant difference in the pressure exerted by compliant balloons and super-compliant balloons in both the straight and angulated models. In the straight model (1 and 2 mm), the lowest pressure was exerted by HyperForm (super-compliant balloons group) and SHOURYU SR (compliant balloons group). The lowest pressure was exerted in the angulated model by HyperForm (super-compliant balloons group) and Scepter C (compliant balloons group). The Scepter balloon exerted higher pressure in the straight model than other balloon remodeling microcatheters but less in the angulated model. In vascular model B, the pressure decreased in all balloons compared with model A. In vascular model C, the pressure increased in all balloons compared with model A.

Conclusions: Pressure differed across balloon remodeling microcatheters. In addition, vessel shape and diameter, and hole size, affected the results. Our findings can help select balloon remodeling microcatheters.

Keywords

Balloon catheter, endovascular, intracranial aneurysm, balloon embolization

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Introduction

Balloon remodeling microcatheters (BRMCs) are mainly used for coil embolization of wide-neck cerebral aneurysms. Embolization with a BRMC (balloon-assisted coiling (BAC)) was first reported in 1997 by Moret et al.[1] as a remodeling technique, allowing for the dense coil embolization of wide-neck aneurysms. Since then, the safety and usefulness of BAC using various BRMCs have been reported.[2–6]

In BAC, BRMCs are used to cover the aneurysm neck to prevent coils from herniating into the parent vessel or stabilizing the microcatheters. In the early days of BAC, compliant balloons (CBs) were mostly used, characterized by cylindrical expansion, and used mainly for sidewall aneurysms.[4] Subsequently, super-compliant balloons (SCBs), which are more flexible and can be inflated according to the shape of the vessel wall, allowing the embolization of bifurcation aneurysms by herniating balloons, which had been difficult with CBs, were developed.

However, balloon herniation may cause vascular damage, such as dissection and rupture, due to the pressure applied to the parent vessel. While several BRMCs are available today, choosing the most CB may reduce the risk of complications. However, differences in compliance and pressure between different balloon types have not been clarified.

We sought to create various vascular models to directly compare the performance between three CB and four SCB

[1]Department of Neurosurgery, Nagoya University, Japan
[2]Department of Neurosurgery, Nagoya Medical Center, Japan

Corresponding author:
Takashi Izumi, Department of Neurosurgery, Nagoya University, 65 Tsurumai-cho, Showa-Ward, Nagoya 466-8550, Japan.
E-mail: my-yuzu@med.nagoya-u.ac.jp AQ1

types. This study aimed to determine the differences in pressure between balloons when herniated through a hole in the vessel wall. We also evaluated whether balloon pressure was affected by vessel shape (straight or angulated), hole size, and vessel diameter and sought to identify the lowest pressure balloon under different anatomical parameters.

Materials and methods

Vascular model

Six types of vascular models were prepared. A basic vascular model (vascular model A) was prepared by drilling a 3 mm hole in a silicon tube with an internal diameter of 3 mm and a wall thickness of 1 mm. This basic vascular model was used to create a straight model, and another angulated at 120° so that the hole was at the top of the greater curvature (angulated model). The balloon was herniated to a height of up to 2 mm in this experiment; therefore, if a 4 mm vascular model, which is the same as the balloon diameter, was used, the maximum inflation for each manufacturer's balloon could have been significantly exceeded, and the balloon may have ruptured. Therefore, the diameter of vascular model A was selected to be 3 mm, which is 1 mm shorter than the balloon diameter. In order to evaluate differences caused by the vessel and hole diameter, an additional silicon tube with a 3 mm internal diameter and a 4 mm diameter hole (vascular model B) and another with a 4 mm internal diameter and 3 mm diameter hole (vascular model C) were also prepared. Similar to vascular model A, vascular models B and C also created a straight model and angulated model, respectively.

Pressure measurement equipment

For the pressure measurement, an intracranial pressure (ICP) microsensor (Codman & Shurtleff Inc., Raynham, MA) was used. The ICP microsensor uses a strain gauge for the pressure measurement. The silicon diaphragm in the sensor part was bent proportionally to the pressure applied, and the microchip strain gauge converts the electronic resistance into a value corresponding to this pressure. The sensor part measures 1.2 mm in diameter and can be inserted between the vessel wall and the balloon for measurement.

Balloon catheters used in this study

In this study, BRMCs included HyperForm (4 (balloon diameter) × 7 (effective balloon length) mm; Covidien/ev3, Irvine, CA), SHOURYU SR (4 × 10 mm; Kaneka Medics, Osaka, Japan), SHOURYU HR (4 × 7 mm; Kaneka Medics), TransForm C (4 × 10 mm; Stryker Neurovascular, Fremont, CA), TransForm SC (4 × 7 mm; Stryker Neurovascular), Scepter C (4 × 10 mm; MicroVention, Inc., Tustin, CA), and Scepter XC (4 × 11 mm; MicroVention, Inc.). Five units of each catheter were prepared. Each balloon used and the recommended inflation volume is listed in Table 1.

Wall pressure measurement

The experiment was conducted in a tray with water maintained at a temperature of 37 °C. First, the pressure was measured with the balloon inflated without herniation from the hole in the vessel model. The pressure applied to the vessel wall was then measured when the effective portion of the balloon was herniated 1 mm from the hole in the vascular model. Furthermore, for vascular models A and B (straight only), the pressure when herniating to a 2 mm height was also measured. An ICP monitor was placed on the vessel wall contralateral to the side to which the balloon was herniated for the straight model and on the vessel wall on the greater curvature side for the angulated model for the pressure measurement (Figure 1). The balloon is prepared with a mixed solution of saline and contrast in the regular treatment since it is used under fluoroscopy. For this experiment, it was prepared with only saline because fluoroscopy was not used. The experiment aimed to compare the pressure among balloons, and the effect on the results caused by the absence of contrast was considered almost negligible if all balloons had the same conditions. Balloon insufflation was discontinued

Table 1. Evaluated balloon remodeling microcatheters and recommended inflation volume.

Balloon	Balloon compliant	Balloon diameter (mm)	Balloon length (mm)	Inflation volume (ml) – balloon size (mm)	Maximum inflation volume (ml) – balloon size (mm)
HyperForm	SCB	4	7	0.06–4.0	0.15 – not available
SHOURYU HR	SCB	4	7	0.07–3.9 0.08–4.1	0.12–4.6
TransForm SC	SCB	4	7	0.08–3.8 0.10–4.1	0.12–4.4
Scepter XC	SCB	4	11	0.10–3.9 0.12–4.2	0.32–5.9
SHOURYU SR	CB	4	10	0.17–4.0	0.17–4.0
TransForm C	CB	4	10	0.14–4.0	0.16–4.2
Scepter C	CB	4	10	0.16–4.0	0.32–4.9

SCB, super-compliant balloon; CB, compliant balloon.

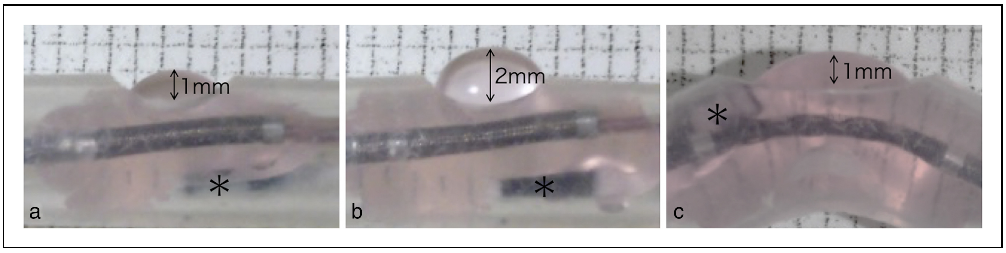

Figure 1. Each balloon was herniated 1 mm (a) and 2 mm (b) from the hole in the straight model. (c) The balloon was herniated 1 mm from the hole on the greater curvature side of the angulated model. The sensor of the intracranial pressure (ICP) monitoring system was placed in the * position.

Table 2. Median pressure of each balloon.

Balloon	Height of herniation (mm)	Vascular model A/straight (mmHg)	Vascular model A/angulated (mmHg)	Vascular model B/straight (mmHg)	Vascular model B/angulated (mmHg)	Vascular model C/straight (mmHg)	Vascular model C/angulated (mmHg)
HyperForm	0	1	1	0	0	1	2
	1	132	254	1	170	169	549
	2	258	NA	143	NA	NA	NA
SHOURYU HR	0	1	1	0	0	0	0
	1	159	354	2	224	354	All rupture
	2	335	NA	186	NA	NA	NA
TransForm SC	0	2	1	0	1	2	0
	1	235	547	2	335	344	579
	2	510	NA	267	NA	NA	NA
Scepter XC	0	3	2	0	1	2	2
	1	261	315	1	176	381	564
	2	517	NA	234	NA	NA	NA
SHOURYU SR	0	2	1	0	1	0	2
	1	240	524	166	440	487	All rupture
	2	546	NA	490	NA	NA	NA
TransForm C	0	1	1	1	1	2	1
	1	302	560	216	463	503	All rupture
	2	574	NA	510	NA	NA	NA
Scepter C	0	0	0	0	0	1	2
	1	304	374	130	251	516	579.5
	2	585	NA	437	NA	NA	NA

as soon as the desired herniation height was reached and the pressure value recorded. Furthermore, BRMCs were inflated with a microguide wire. Microguide wires used were X-pedion 10 (Micro Therapeutics, Inc., Irvine, CA) for HyperForm and CHIKAI 14 (Asahi Intech, Nagoya, Aichi, Japan) for SHOURYU SR, SHOURYU HR, TransForm C, TransForm SC, Scepter C, and Scepter XC.

Statistical analysis

In vascular model A, the pressures exerted by the different balloons on the vessel wall for both the SCB and CB groups were compared using the Kruskal−Wallis test. In case of a difference, multiple comparisons were performed between balloons using the Steel−Dwass method. Furthermore, regarding the differences in pressure between vascular models, the median value of the measured pressure of individual balloons was visualized with a line graph, and the overall pressure difference between manufacturers was evaluated. The Wilcoxon signed-rank test was performed to compare the changes in the pressure between vascular models. After that, in vascular models B and C, the differences in pressure between balloons were compared within each group using the Kruskal−Wallis test If a further difference was observed, multiple comparisons were performed between balloons using the Steel−Dwass method. A p-value <0.05 was considered significant. All statistical analyses were performed using Easy R (Saitama Medical Center, Jichii Medical University, Saitama, Japan, ver. 10.15), a statistical software package with extended R and R command functions.

Results

The median pressure of each balloon is summarized in Table 2. The values measured without herniation from the holes were close to 0 for all balloons in all vascular models.

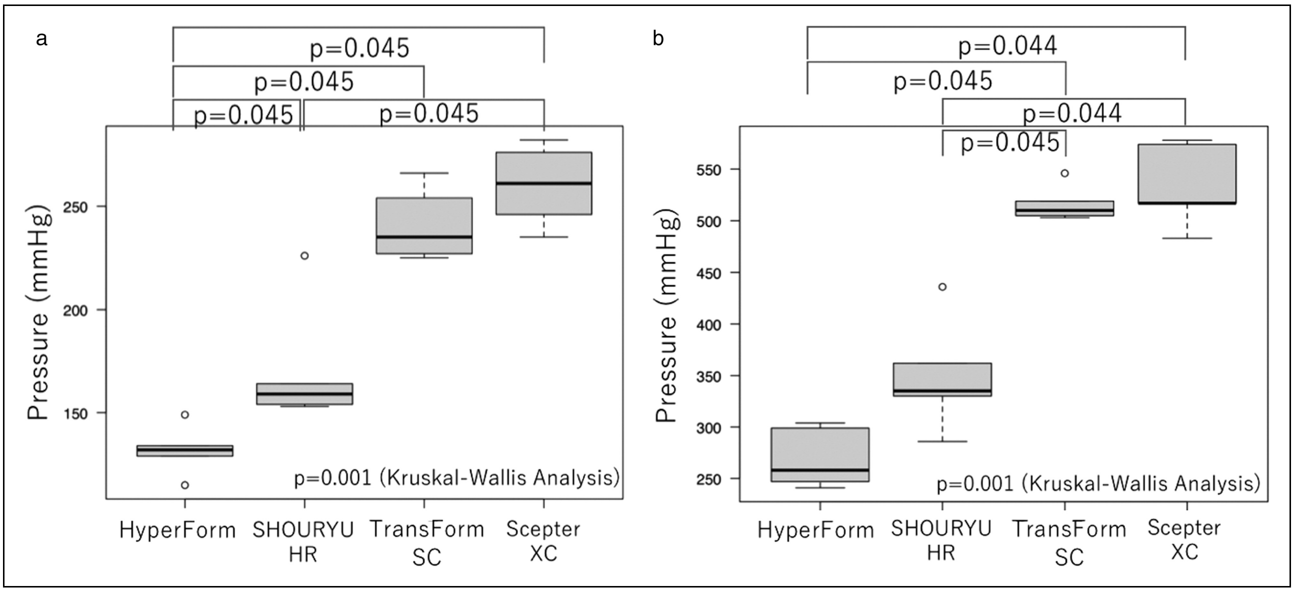

Figure 2. Box and whiskers plots representing the pressure applied to the vessel wall when each super-compliant balloon (SCB) is herniated 1 mm (a) or 2 mm (b) in a straight model.

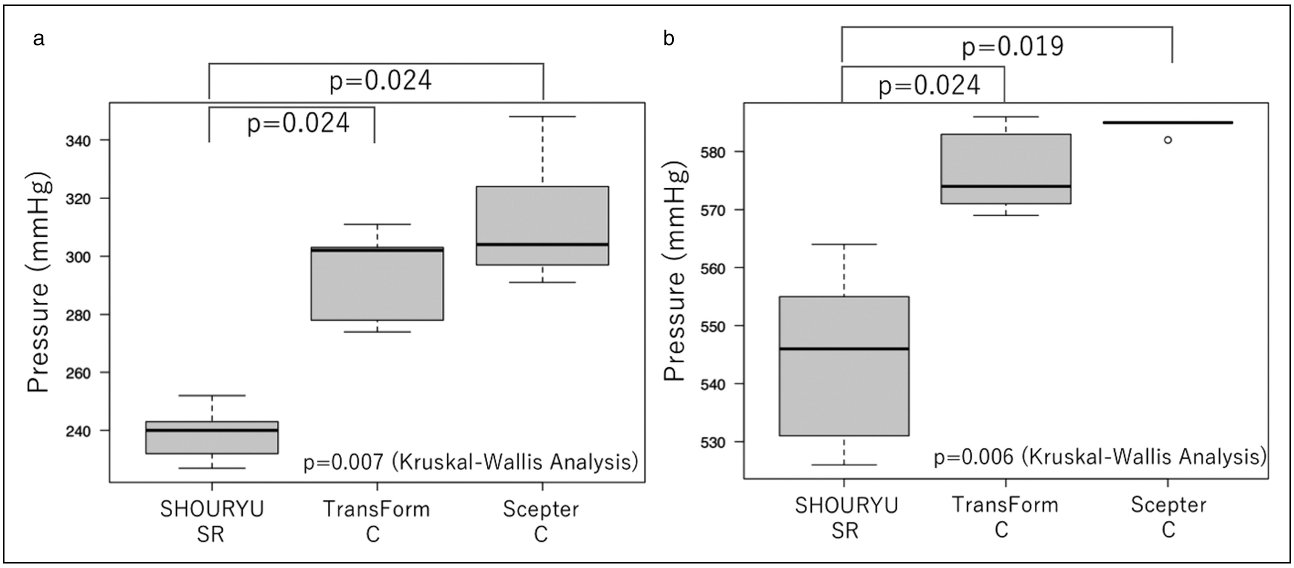

Figure 3. Box and whiskers plots representing the pressure applied to the vessel wall when each compliant balloon (CB) is herniated 1 mm (a) or 2 mm (b) in a straight model.

Pressure in vascular model A

In the straight model, multiple comparisons in the SCB group demonstrated significant variations in the pressure exerted by the different balloon catheters in both the 1 and 2 mm herniations (both $p = 0.001$). In the 1 mm herniation condition, the pressure exerted on the vessel wall by HyperForm (median: 132 mmHg) was significantly lower than that by SHOURYU HR (159 mmHg), TransForm SC (235 mmHg), and Scepter XC (261 mmHg; all $p = 0.045$). Further, the pressure exerted by SHOURYU HR was significantly lower than that by Scepter XC ($p = 0.045$). In the 2 mm herniation, the pressure exerted by HyperForm (258 mmHg) was significantly lower than that by TransForm SC (510 mmHg) and Scepter XC (517 mmHg; $p = 0.045$ and $p = 0.044$, respectively). Further, the pressure exerted by SHOURYU HR (335 mmHg) was significantly lower than that by TransForm SC and Scepter XC ($p = 0.045$ and $p = 0.044$, respectively) (Figure 2).

In the straight model, multiple comparisons in the CB group showed significant variations in the pressure exerted by the different balloon catheters in both 1 and 2 mm herniations ($p = 0.007$ and $p = 0.006$, respectively). In the 1 mm herniation, the pressure exerted by SHOURYU SR (240 mmHg) was significantly lower than that by TransForm C (302 mmHg) and Scepter C (304 mmHg; $p = 0.024$ and $p = 0.024$, respectively). In the 2 mm herniation, the pressure exerted by SHOURYU SR (546 mmHg) was significantly lower than that by TransForm C (574 mmHg) and Scepter C (585 mmHg; $p = 0.024$ and $p = 0.019$, respectively; Figure 3).

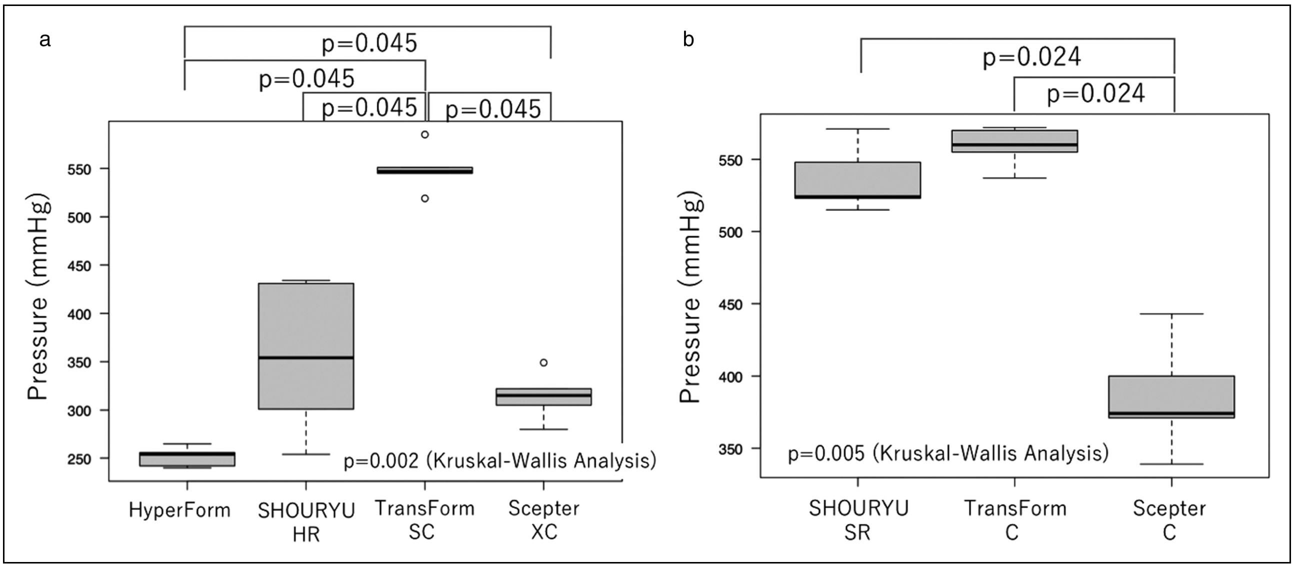

Figure 4. Box and whiskers plots representing the pressure applied to the vessel wall when each SCB (a) or CB (b) is herniated 1 mm in an angulated model.
SCB: super-compliant balloon; CB: compliant balloon.

In the angulated model, multiple comparisons in the SCB group showed significant variations in the pressure exerted by the different balloons ($p = 0.002$). The pressure exerted by HyperForm (254 mmHg) was significantly lower than that by TransForm SC (547 mmHg) and Scepter XC (315 mmHg; $p = 0.045$ and $p = 0.045$, respectively). Furthermore, the pressures exerted by SHOURYU HR (354 mmHg) and Scepter XC were significantly lower than that by TransForm SC (both $p = 0.045$). The pressures exerted by the different SCBs in the angulated model were similar to the corresponding values in the straight model in the 2 mm herniation, except for Scepter XC, which exerted a lower pressure in the angulated model than in the straight model. Multiple comparisons in the CB group also showed significant variations in the pressure exerted by the different balloons ($p = 0.005$). The pressure exerted by Scepter C (374 mmHg) was significantly lower than that by SHOURYU SR (524 mmHg) and TransForm C (560 mmHg; both $p = 0.024$). As for SCBs, the values of pressure exerted by the CBs in the angulated model were similar to the corresponding ones in the straight model in the 2 mm herniation, except for Scepter C, which exerted a lower pressure in the angulated model than in the straight model (Figure 4).

Differences in pressure between vascular models are illustrated in Figure 5 which demonstrates a line graph of the median value of the measured pressure of individual balloons. The Wilcoxon signed-rank test showed significant changes between vascular models A and B and between vascular models A and C in the straight model (1 and 2 mm herniation) and angulated model for both SCBs and CBs (all $p < 0.001$).

Pressure in vascular model B

In SCBs, the pressure in vascular model B was lower than that in vascular model A for all balloons in both the straight and the angulated models. When the straight model was herniated to 1 mm, almost no pressure was applied to the vessel wall in any balloons. When the balloons were herniated to 2 mm, multiple comparisons demonstrated significant variations in pressure between balloons ($p < 0.001$). HyperForm (143 mmHg) exerted a significantly lower pressure than SHOURYU HR (186 mmHg), TransForm SC (267 mmHg), and Scepter XC (234 mmHg; all $p = 0.045$). SHOURYU HR exerted a significantly lower pressure than TransForm SC and Scepter XC (both $p = 0.045$). Finally, Scepter XC exerted a significantly lower pressure than TransForm SC ($p = 0.045$).

The angulated model also showed variations in pressure between balloons ($p = 0.001$). HyperForm (170 mmHg) exerted a significantly lower pressure than SHOURYU HR (224 mmHg) and TransForm SC (335 mmHg) ($p = 0.045$ and $p = 0.044$, respectively). Scepter XC (176 mmHg) exerted a significantly lower pressure than SHOURYU HR and TransForm SC ($p = 0.045$ and $p = 0.044$, respectively). Finally, SHOURYU HR exerted a significantly lower pressure than TransForm SC ($p = 0.044$).

Lower pressure in vascular model B than in vascular model A was also observed in all CBs. Multiple comparisons demonstrated significant variations in pressure between balloons in all straight models herniated to 1 and 2 mm, and in the angled models ($p = 0.004$, $p = 0.009$, and $p = 0.009$, respectively). In the 1 mm herniation, Scepter C (130 mmHg) and SHOURYU SR (166 mmHg) exerted a significantly lower pressure than TransForm C (216 mmHg; $p = 0.024$ and $p = 0.043$, respectively). When herniated to 2 mm, Scepter C (437 mmHg) exerted a significantly lower pressure than SHOURYU SR (490 mmHg) and TransForm C (510 mmHg; $p = 0.040$ and $p = 0.024$, respectively). In the angled model, the pressure exerted by Scepter C (251 mmHg) was significantly lower than that by SHOURYU SR (440 mmHg) and TransForm C (463 mmHg; both $p = 0.024$).

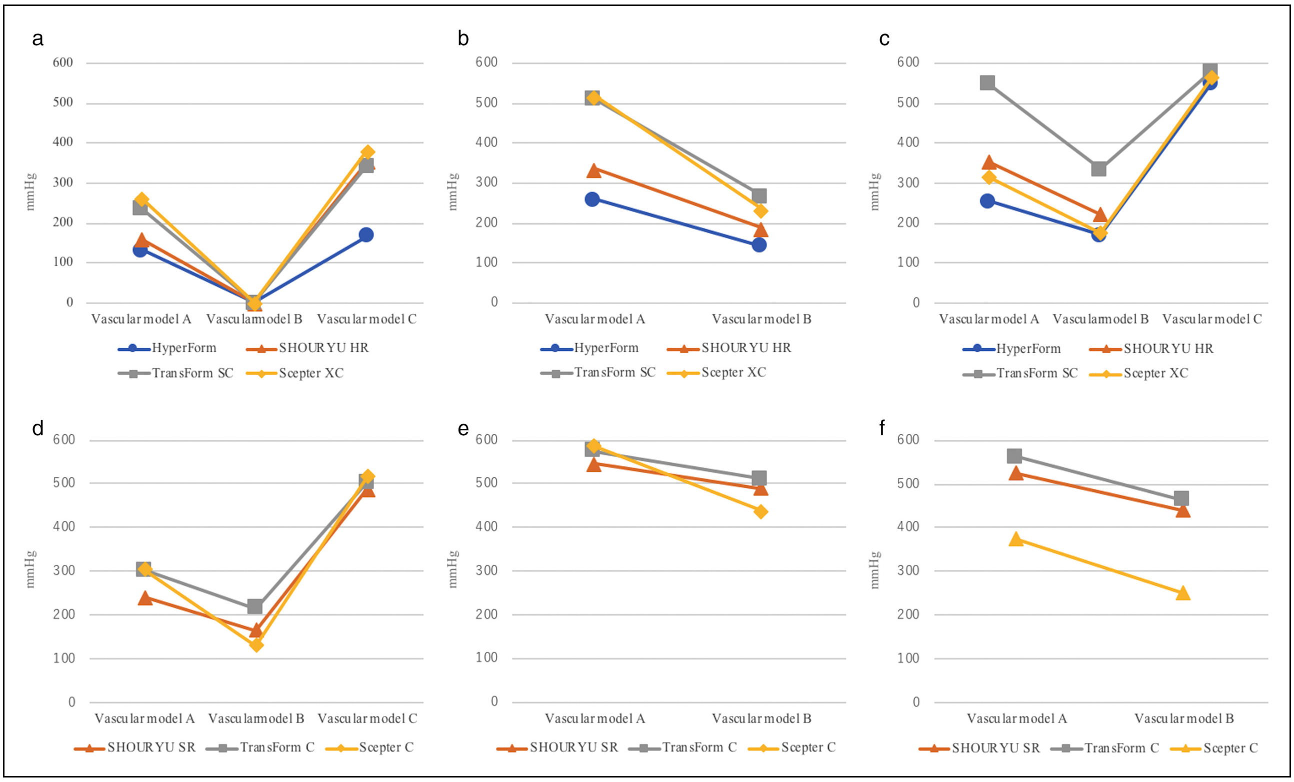

Figure 5. Plots of pressure applied to the vessel wall when each SCB is herniated 1 mm (a) or 2 mm (b) in a straight model and herniated 1 mm in an angulated model (c). Also, plots of pressure applied to the vessel wall when each CB is herniated 1 mm (d) or 2 mm (e) in a straight model and herniated 1 mm in an angulated model (f).
SCB: super-compliant balloon; CB: compliant balloon.

Pressure in vascular model C

In vascular model C, the pressure when herniated to 1 mm was higher than in vascular model A for both the SCBs and CBs. In addition, in the angulated model, all balloons ruptured in SHOURYU HR, SHOURYU SR, and TransForm C; thus, the pressure could not be measured. With Scepter C, pressure could be measured with four of the five balloons, with a median pressure of 579.5 mmHg. It was considered that the balloon rupture was associated with over inflation. The ruptured balloon required more than the maximum inflation volume.

Multiple comparisons demonstrated significant variations in pressure between balloons when the SCBs were herniated 1 mm in the straight model ($p = 0.005$). HyperForm (169 mmHg) exerted a significantly lower pressure than SHOURYU SH (354 mmHg), TransForm SC (344 mmHg), and Scepter XC (381 mmHg; all $p = 0.045$). No differences in pressure were observed in the angulated model for either SCBs and CBs.

Discussion

Complications associated with the use of BACs include thromboembolism, aneurysm rupture, perforator infarction, vascular rupture or dissection, and vasospasm.[7] Vascular rupture or dissection often accompanies balloon inflation, which frequently leads to poor prognosis and complications such as subarachnoid hemorrhage or stroke. Previous studies have found that the frequency of vascular rupture or dissection during BAC is 0.1–2%.[3–5]

A previous cadaveric study reported that an average pressure of 2.35 atm (1786 mmHg) was required for main intracranial artery rupture.[8] The maximum pressure measured in the current study was 585 mmHg. Since the experiments performed in the current study were conducted using silicon vessel models, it is impossible to directly compare the current results and values obtained in this report with those obtained from previous studies. Nevertheless, vascular rupture due to BRMC would require fairly high pressure. In addition, aneurysms and aneurysmal necks exhibit defects in the internal elastic lamina and tunica media; their structures are weaker than those of the normal cerebral arterial vessels. A case report of a patient who presented with vascular rupture when the balloon was inflated in the aneurysmal neck suggested that the fragile structure of this aneurysmal neck was relevant to the vascular rupture.[9] In the treatment of bifurcation aneurysms, the balloon is occasionally inflated beyond the diameter of the parent vessel in the aneurysmal neck to protect bifurcating vessels. In such cases, there is a risk of vascular injury due to the pressure exerted on the aneurysmal neck.

Choosing a more flexible balloon is expected to minimize vessel wall pressure, thereby reducing the risk of vascular injury. However, differences in flexibility among BRMCs have not been established. Factors associated with balloon flexibility include diameter, effective length, and material. In the current study, all BRMCs had a 4 mm diameter. However, their effective length and material were different. A study on the difference in the pressure exerted by 20 and 40 mm coronary angioplasty balloons reported a lower pressure for the longer balloon.[10] This study showed, the effective balloon length was adjusted to 7 mm for all SCBs and 10 mm for all CBs, except for Scepter XC, for which the length was set to 11 mm. However, the pressure exerted by Scepter XC was not lower than that of other SCBs, suggesting that the effective length had no particular effect. The balloon with the lowest pressure in this study was HyperForm. Since the conditions of diameter and effective length were the same as many other balloons, the material might be related to why the pressure was low. All balloons in the current study were made of different thermally reversible elastomers. We could not obtain further information on the differences in their composition and structure because this information is proprietary. However, material differences in the balloons must have a large impact on the differences observed in our present results, as the effects of the effective length and diameter were found to be small.

There is only one report comparing the differences in performance among BRMCs. Knox et al. compared three CBs, with Scepter C showing the highest compliance and improved compliance as the hole size increased.[11] This result differs from ours, which showed no significant difference in pressure between TransForm C and Scepter C in the straight model when the hole size was 3 mm (vascular models A and C). However, when the hole size was increased (vascular model B), the pressure of Scepter C was significantly lower than that of TransForm C, which was similar to that of Knox et al.; the tendency may also be similar in terms of pressure changes due to hole size. The reason for this disparity between the result of Knox et al. and the result of our vascular model A/C may be related to the different pressure measurement methods and experimental environments. Regarding the pressure measurement, Knox et al. measured the balloon's internal pressure while we directly measured the pressure applied to the vessel wall from the outside of the balloon. When the balloon is inflated, a force causes it to return to its original position. This force is included in the balloon's internal pressure and is influenced by the balloon's material and thickness. In addition, regarding the experimental environment, it is possible that the water temperature setting was different. In our study, the water temperature was 37 °C, but the report by Knox et al. did not mention this factor, and the flexibility of the thermally reversible elastomers may differ depending on the surrounding temperature.

We found that the pressure on the vessel wall when the balloon was inflated varied between the different balloons and that vessel shape and diameter, and hole size, affected the pressure. Only one similar study was previously published;[11] however, our report is the first to compare SCBs. In this experiment, the pressure applied to the vessel wall was directly measured, which more accurately reflects the damage to the vessel wall. Our results may provide a basis for choosing BRMC, especially in treating bifurcation aneurysms through balloon herniation. For example, posterior communicating artery bifurcation aneurysms and vertebral artery and posterior inferior cerebellar artery aneurysms are considered close to the straight model configuration; therefore, HyperForm or SHOURYU HR should be selected. Conversely, the angulated model more closely resembles basilar artery and middle cerebral artery bifurcation aneurysms; in such cases, the Scepter XC, HyperForm, and SHOURYU HR balloons should be considered. Since CBs were not originally designed to be used in a herniation, there may not be many situations where they can be applied; however, in aneurysms in the carotid siphon, the balloon may slightly deviate, covering the aneurysm neck firmly. Based on the results of the angulated model, selecting Scepter C may reduce the risk of vascular injury. Even if balloon herniation is not used, choosing a more flexible balloon may reduce the strain on the vessel wall and decrease the number or severity of complications. Our results also may be helpful in cases where a balloon is used in a vessel with a smaller diameter than the balloon diameter or in suspected cases of vessel fragility, such as vasculitis.

When the balloon is inflated in a curved vessel, a straightening force is applied to the vessel wall, causing the pressure on the vessel wall to be higher than in a linear vessel.[10] In the treatment of coronary angioplasty, vessel angle is considered a predictor of procedural success; if the angle >90°, there is an increased risk of vessel dissection or occlusion.[12] In the present study, the pressure exerted after 1 mm balloon herniation was higher in the angulated model than in the straight model. Furthermore, in the angulated model, the pressure was less likely to increase in Scepter C and Scepter XC than in other balloons. Observation of catheter movement during balloon inflation showed that the catheter in the balloon portion flexed and moved flexibly to the center of the vessel lumen when using the Scepter balloon, while it remained linear with less movement for other balloons (Figure 6) during balloon inflation. This difference in catheter movement may be related to the fact that only the Scepter balloon had a double lumen structure

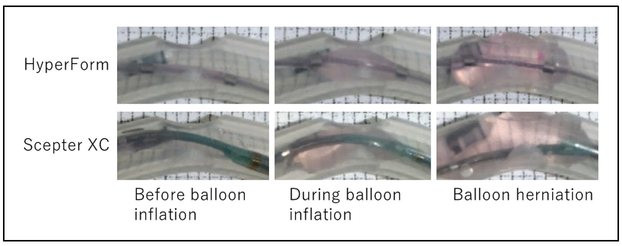

Figure 6. The difference in the movement of the catheter in the balloon portion during inflation was observed. The upper panels show the movement of HyperForm, while the lower panels show the movement of Scepter XC. Especially under observation during balloon inflation, the catheter in the balloon portion of HyperForm remained straight but bent along the vessel in the case of Scepter XC.

among all balloons. While balloons with a single lumen structure require an inflation pore in the balloon part of the catheter, balloons with a double lumen structure do not, allowing for greater flexibility of the balloon part of the catheter. The flexibility of the catheter in the balloon portion may have made the balloon inflate in accordance with the vessel shape, which allowed for an even pressure distribution to the vessel wall, thus reducing it.

The pressure applied to the vessel wall decreased for all balloons as the hole size increased. The report by Knox et al.[11] similarly shows that larger holes improve compliance and reasons that the larger the hole, the larger the range through which the balloon can pass.

In addition, when the vessel lumen size increased, the pressure in all SCBs and CBs increased. All balloons in this experiment had a 4 mm diameter. This result seems logical since a greater internal pressure must be applied to a balloon to herniate from a 4 mm vessel than from a 3 mm vessel. The pressure difference between the balloons observed in the 3 mm vessel was no longer observed in the 4 mm vessel, except when the straight model was herniated by 1 mm. There may be a difference in the balloon capacity. We suspected that the pressure difference would become less noticeable closer to the capacity limit. If herniating a vessel with a diameter equivalent to that of the balloon is needed, in terms of suppressing pressure on the vessel wall, using HyperForm for straight vessels, balloons other than SHOURYU HR for angulated vessels or for those with a larger diameter should be considered.

This study has some limitations. First, the number of balloons was limited, and balloons with different effective lengths and diameters were not evaluated. In addition, the present study was conducted in vitro, and in vivo results may differ from the current results, as there will be additional effects of vascular elasticity, bloodstream, and friction between the balloon and the vessel wall. However, considering the pressure measurement method and associated complications, it is difficult to perform this experiment in vivo. Further, in actual clinical practice, catheter guidance to the lesion, thickness of available guidewires, and the difference in lumen structure depending on the material used may also be important factors when choosing a BRMC, in addition to balloon flexibility. These conditions must be taken into consideration when choosing a BRMC.

Conclusion

The pressure exerted on the vessel differed among various BRMCs. The lowest pressure balloon in all vascular models was HyperForm. In addition, the pressure tended to rise on the greater curvature side of the angulated vessel, and the pressure was lower when the neck size was larger. Furthermore, the pressure was less likely to increase when herniated with a vessel smaller than the diameter of the balloon. The present results can assist in choosing a BRMC. However, this choice should consider various factors, of which the present results provide an evaluation of only one contributing factor.

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Authors' contribution

MI, YT and TI contributed to conception and design of study; MI and YT contributed to acquisition of data; MI, TI, MN, TT, YT, YA, KY, KU, SG, AEK, TO, NK and MN contributed to analysis and/or interpretation of data; MI contributed to drafting the manuscript; TI and RS contributed to revising the manuscript; MI, TI, MN, TT, YT, YA, KY, KU, SG, AEK, TO, NK, MN and RS contributed to approval of the version of the manuscript to be published.

Declaration of conflicting interests

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ORCID iDs

Mizuka Ikezawa https://orcid.org/0000-0001-7018-4835 GQ6
Masahiro Nishihori https://orcid.org/0000-0003-1645-0738
Shunsaku Goto https://orcid.org/0000-0003-3177-7691

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