



Clampless aortic punch system for making a large-diameter access route without side-biting clamp: a preliminary study

Ryosuke Kowatari¹ · Ikuo Fukuda¹ · Tomonori Kawamura¹ · Yasuyuki Suzuki¹

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Abstract

Although thoracic endovascular aneurysm repair (TEVAR) has been getting popularity as a less-invasive procedure, the treatment of thoracic aortic aneurysm with atherosclerotic aortic disease is still challenging. In hybrid TEVAR through the median sternotomy approach, side-biting clamp of the ascending aorta is often necessary for making an access route; however, it could cause embolic complication and aortic dissection. This study aimed to present the results of our preliminary study on the clampless aortic punch system (APS). The swine aorta was used as experimental specimen (diameter 16–20 mm). A 10-mm collagen-impregnated knitted Dacron graft was anastomosed to the aorta, and the APS was inserted into it. After piercing the aorta with the inner fish hook of the APS, the aortic wall was scooped out by an outer round cutter. Three different-angled cutters (0°, 15°, and 30°) were tested three times. The diameter of the punched-out lesion ranged from 6 to 9 mm (median 8 mm). Macroscopically, no major vessel injuries were seen 15° series, whereas minor or major vessel injuries were seen 30° and 0° series, respectively. Histological findings of 15° series confirmed the sharp edge of the stump and abrupt interruption of the elastic fiber without destruction of the normal three-layer structure of the aortic wall. This study suggests that our clampless APS could reduce the risk of stroke and aortic injury in hybrid TEVAR, and an animal study confirming its utility is now under consideration.

Keywords Aortic punch · Thoracic endovascular aneurysm repair · Clampless

Introduction

The prevalence of atherosclerotic aortic disease is increasing rapidly with societal aging. Although the treatment outcome of this disease has been improved for decades, the treatment of diffuse aortic atherosclerosis cases called “shaggy aorta” is still challenging.

As treatment for thoracic aortic aneurysm, thoracic endovascular aneurysm repair (TEVAR) has been getting popularity, because it is a less-invasive procedure than open surgery. However, TEVAR cannot be applied to the complex anatomy of the aortic arch or thoracoabdominal aorta. In this situation, a hybrid procedure which combines open

and endovascular therapy is necessary. In this procedure, the side-biting clamp is sometimes required; however, it increases the risk of embolic complication and aortic dissection. Herein, we present the results of our preliminary study of using the original aortic punch system (APS) which enables us to create a large-diameter access route without applying a side-biting clamp.

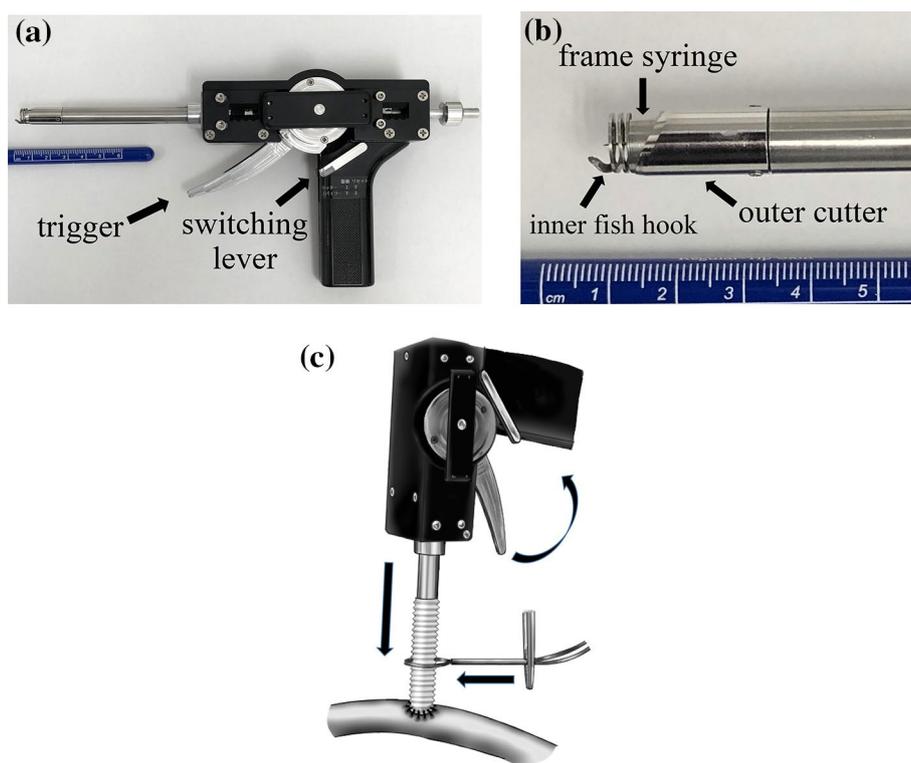
Materials and methods

The APS contains a frame syringe (FEATHER, Osaka, Japan) and two cutters: a frame syringe, an inner fish hook, and a detachable outer cutter of the 8 mm width are attached to the APS sequentially from inside (Fig. 1a, b). The inner fish hook turns clockwise and moves forward gradually by grasping the trigger repeatedly. If the switching lever is up, the outer round cutter turns counterclockwise and moves forward in the same manner. Normal and healthy descending aorta of edible young swine purchased from a hog farm

✉ Ikuo Fukuda
ikuofuku@hirosaki-u.ac.jp

¹ Department of Thoracic and Cardiovascular Surgery, Hirosaki University School of Medicine, 5 Zaifu-cho, Hirosaki, Aomori 036-8562, Japan

Fig. 1 Original aortic punch (APS). The inner fish hook turns clockwise and moves forward gradually by grasping the trigger repeatedly. If the switching lever is up, the outer round cutter turns counterclockwise and moves forward in the same manner. **a** Gross image of the device. **b** Enlarged image including the frame syringe, inner fish hook, and outer round (15° in this picture) cutter. **c** Schema which shows how to make an access route by the APS after anastomosing the graft. The APS is inserted into the anastomosed graft. The graft is snared with Teflon tape when the aortic wall is punched out to prevent saline leakage



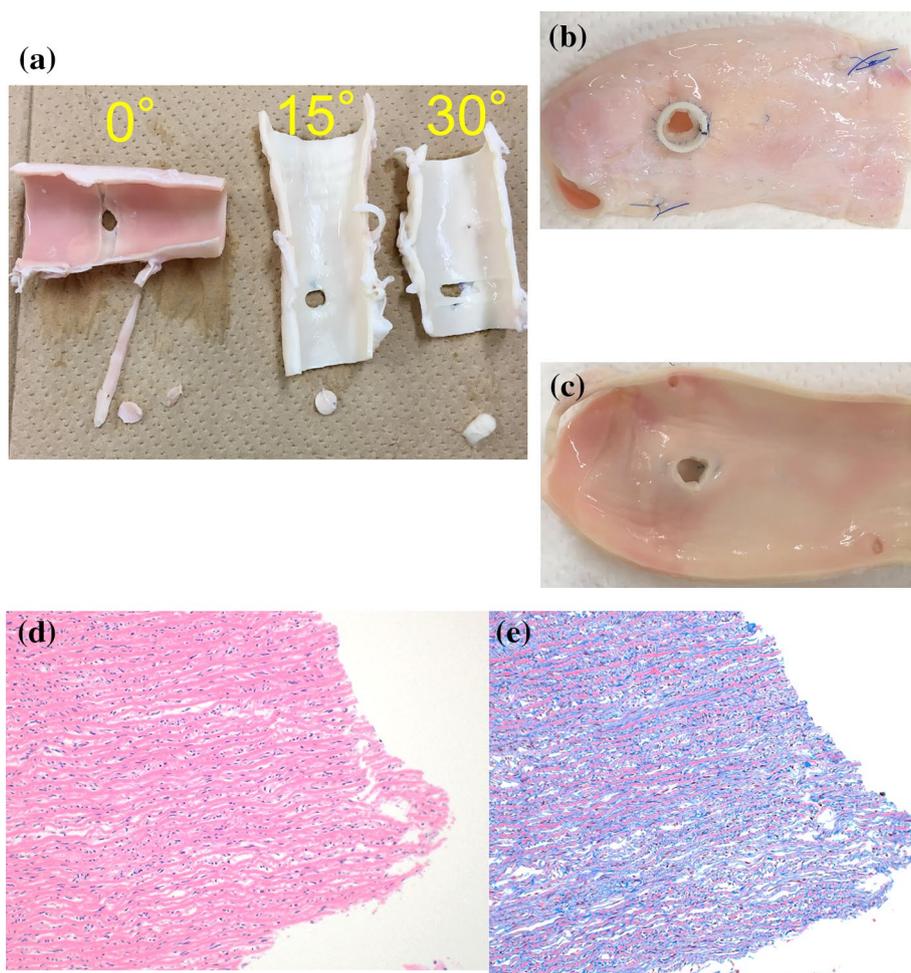
was used as the experimental specimen. After removing the periaortic connective tissue of the swine descending aorta (diameter 16–20 mm), a 10-mm collagen-impregnated knitted Dacron graft (Hemashield, Meadox Medicals, Oakland, NJ, USA) was anastomosed to the aorta using 5–0 prolene continuous suture. The aorta, of which intercostal arteries were ligated, was filled with saline under the plateau pressure of 150 mmHg by the pressurized bag. The APS was inserted into the anastomosed graft, and the graft was snared with Teflon tape to prevent saline leakage. The APS was attached to the aortic wall by pushing the frame syringe against the aorta, and by pulling up the anastomosed graft. Then, the inner fish hook was introduced into the aorta to hold the aortic wall. When the inner fish hook was inserted to about 8 mm (for 4 spiral rings), the trigger is fixed automatically. After changing the channel of the switching lever, the outer round cutter was also introduced into the aorta to punch out the aortic wall. Punched-out wall was retrieved by inner fish hook. Three different-angled outer cutters (0°, 15°, and 30°) were tested three times, respectively. Figure 1c shows a schema to make an access route by the APS after anastomosing the graft. The punched-out wall was evaluated macroscopically in each testing to verify the quality of the hole and edge and to determine the best angle of the cutter. The grafts were removed from the aorta, microscopic evaluation of the edge was performed using hematoxylin and eosin staining, and Masson staining was performed to verify the sharpness of the edge. As this study only used

commercial, edible swine aorta, the institutional board of Hirosaki University approved the study protocol. Institutional guidelines for the care and use of laboratory animals have been observed.

Results

All studies were accomplished within 30 s from inserting the aortic punch to make access routes. The side-biting clamp was not needed, and technical failure such as saline leakage from the anastomotic region was not observed. The punched-out aortic walls were successfully retrieved by the inner fish hook without leaving any pieces into the aorta. The diameter of the punched-out lesion ranged from 6 to 9 mm (median 8 mm). Only one specimen of 0° series was less than 8 mm. No major vessel injuries were seen in 15° series, although minor or major vessel injuries were seen in 30° and 0° series, respectively (Fig. 2a). The macroscopic outer and inner appearance of the aorta before removing the graft is also shown in Fig. 2b, c. In the 0° series, the entire aortic wall around the punched-out lesion was dissected focally. The pathological specimen of the punched-out aortic wall in 15° series is shown in Fig. 2d, e. Hematoxylin and eosin staining (Fig. 2d) shows the smooth and sharp edge of the stump. Masson staining (Fig. 2e) revealed abrupt interruption of the elastic fiber without destruction of the normal three-layer structure of the aortic wall. These findings of the

Fig. 2 Macroscopic and histological specimens of around the punched-out aorta. **a** Aorta and punched-out wall specimen of each angled series show no vessel injuries in 15° series. **b** Macroscopic outer appearance of the aorta before removing the graft in 15° series. **c** Macroscopic inner appearance of the aorta before removing the graft in 15° series. **d** Hematoxylin and eosin staining of 15° series ($\times 200$). **e** Masson staining of 15° series ($\times 200$)



punched-out aortic wall were the same in all parts (i.e., right, left, top, and down) of the specimen.

Discussion

These results suggest that the original APS will be useful in making a large access route on the aorta accurately and safely without side clamping.

Atheroembolism is a major concern for patients undergoing cardiovascular surgery. Although TEVAR itself is a less-invasive procedure, its instrumentation in the aorta may induce the destruction of the supple atheroma, resulting in fatal systemic atheroembolism such as cerebral infarction, blue toe syndrome, and intestinal necrosis [1]. In some situations (e.g., severe arteriosclerosis lower than the descending aorta), the ascending aorta is preferred over the femoral artery as an access route [2, 3]. In general, an access route is made after using the side-biting clamp, although the application of the side-biting clamp may induce aortic dissection and detachment of the

debris from the aortic wall [4]. To reduce the stroke risk, a clampless anastomotic device had been developed for coronary artery bypass surgery [5]. Unfortunately, this device is not available for TEVAR, since the size of the commercially available aortic punch is only around 4 mm. This APS is unique, because it can create a large, round access route without using the side-biting clamp. Only one punched-out wall of 0° series was less than 8 mm, because the aorta was not cut sharply, resulting in major aortic injuries. From these experience and macroscopic findings, we think that 0° is not suitable and 15° is the best angle for performing this procedure. Although the blunt sheath insertion method with the Seldinger technique has been reported [6], the development of a specialized system making a large-diameter access route is essential for reducing the stroke risk.

The generalizability of our results is limited. In this study, we experimented in the non-physiological situation using the descending aorta of sacrificed swine under plateau pressure. This implies that further animal studies are warranted.

Conclusion

This preliminary study shared that our clampless APS can help reduce the risk of stroke and aortic injury of antegrade TEVAR through the ascending aorta, especially in shaggy aorta cases. Animal study for confirming the utility of the APS using a 15° cutter is now under consideration.

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Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to declare.

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