A novel emboli protection cannula during cardiac surgery: In vitro results

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Objective: Intraoperative cerebral events are mainly caused by emboli generated by operative manipulation of the aorta. This study aimed to delineate the distribution profiles of emboli with 2 widely used cannulae and a third novel research cannula that simultaneously produces forward flow and backward suction to extract emboli from the distal aorta during cardiac surgery.

Methods: The current in vitro study used a silicone model of the aortic arch and branches. The main outcome measure was the distribution profile of embolic particles of different sizes to the aortic branches; 2 commercial cannulae and a third novel cannula with and without suction were used. The research cannula was examined at different suction levels and the amount of particles retrieved was measured.

Results: For the research curved-tip cannula, most of the small emboli were released into the brachiocephalic trunk in the model ($P < .05$). For the straight-tip cannula, most of the small emboli were released into the descending aorta ($P < .05$). Regarding the commercial curved-tipped cannula, most of the small emboli were released into the brachiocephalic trunk ($47.14\% \pm 4.78\%$; $P < .05$) and the medium and large emboli were predominantly released into the descending aorta. Using suction, the research cannula retrieved most of the emboli released into the aorta for all particle sizes (50%-83%; $P < .05$).

Conclusions: A straight-tip cannula may be safer in terms of cerebral embolic consequences during cardiac surgery. Furthermore, the use of the research aortic cannula may be beneficial in the cardiac surgery setting by reducing the postoperative risk for stroke. (J Thorac Cardiovasc Surg 2014;148:668-75)

The risk of neurologic injury is significant for patients undergoing cardiac surgery and is associated with increased mortality, morbidity, hospital costs, and impaired quality of life.¹ Cardiac surgery involves a wide spectrum of neurologic injuries, including ischemic stroke, occurring in 1.5% to 5.2% of patients; encephalopathy, affecting 8.4% to 32% of patients; and neurocognitive dysfunction, manifested in 20% to 30% of patients 1 month after surgery.^{2,3} Embolism is considered the main mechanism of neurologic injury.⁴

Emboli can be divided into macro and micro categories according to size. Macroemboli occlude flow in arteries 200 μ m or greater in diameter, whereas microemboli occlude flow in smaller arteries, arterioles, and capillaries.⁵ Thirty to fifty percent of perioperative strokes detected with brain imaging are caused by a cerebral macroembolism likely arising from the ascending aorta.⁶⁻⁸ Encephalopathy and

neurocognitive dysfunction are believed to result primarily from cerebral microembolisms,^{5,9} which are either gaseous or particulate in composition. Gaseous emboli can arise from an open left-sided cardiac chamber or from air entrained into the cardiopulmonary bypass (CPB) circuit.² An increased rate of embolic material released into the cerebral circulation has been detected during various aortic manipulations performed in cardiac surgery (eg, aortic crossclamp placement and removal, aortic cannulation, and side-biting clamping for proximal coronary artery anastomosis).¹⁰⁻¹²

The aim of the current study was to assess 2 commercial cannulae and a third new aortic cannula with and without suction. The novel cardiac cannula simultaneously induces forward flow and backward suction to remove solid and gaseous emboli from the distal aorta on their release during cardiac surgery.

MATERIALS AND METHODS

Description of the Commercial and Research Aortic Cannulae

The current study compared the properties of 3 different aortic cannulae; 2 commercial cannulae and the research cannula. The 2 commercial cannulae included (1) a straight-tip 24-Fr aortic cannula (DLP straight tip arterial cannula; Medtronic, Inc, Minneapolis, Minn); and (2) a curved-tip (45°) 24-Fr aortic cannula (ARS024CS; Edwards Lifesciences, Irvine, Calif). The research cannula was a curved-tip (60°) 24-Fr aortic cannula (CardioGard; BEL Bioengineering Laboratories, Cantù, Italy).

The novel research cannula comprises 2 hollow cylinders (Figure 1); the first cylinder is a standard main forward-flow tube administering

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FIGURE 1. The cannulae used in the study.

arterial blood into the aorta from the bypass machine. The second cylinder, which is attached to an existing bypass vent port, is a novel element located posterior to the main tube. Its function is to facilitate

blood and particle suction by directing the blood back to the reservoir of the bypass machine, while the evacuated emboli material is eliminated through a filter.

FIGURE 2. The silicone in vitro model of the aorta. The upper 3 exits simulate (1) the brachiocephalic trunk, (2) the left common carotid artery, and (3) the left subclavian artery. The lower exit simulates the descending aorta (DA).

FIGURE 3. A-C, Description and comparison of the amount (in milligrams) of emboli released in the various branches of the experimental model without suction, according to the size of the particles and the type of cannula (namely, [C1] straight-tip cannula, [C2] curved-tip 45° cannula, and [C3] curved-tip 60° cannula, CardioGard). The upper 3 exits simulate (1) the brachiocephalic trunk, (2) the left common carotid artery, and (3) the left subclavian artery. The lower exit simulates the descending aorta (DA). The tables represent significant differences ($P < .05$), denoted by +, between the weight of emboli filtered by the various cannulae at the various exits.

Aortic In Vitro Model

A silicone model of the aorta with its 3 arch branches was constructed (Figure 2). A fourth exit simulated the descending aorta. A 70- μ m diameter filter was placed at each exit to capture solid and gaseous embolic material. A mixed fluid composed of 80% water and 20% glycerin was used to simulate blood.

Injection Procedure

Bovine bone was ground into particles of 100 to 1000 μ m. Solid emboli material (120 mg) of 3 different sizes were injected: (1) 100 to 250 μ m in diameter in the first session; (2) 250 to 500 μ m in the second session; and (3) 500-1000 μ m in the third session. Embolic material was placed between 2 clamps in the proximal silicone aorta. Both clamps

FIGURE 3. (continued).

were released simultaneously. Flow was set to 4 L/min for nonsuction conditions and 4.5 L/min for the suction experiments. Every injection procedure was repeated 8 times. At the end of every cycle, the filters were washed and the embolic material at every exit was weighed. The research cannula was examined under different levels of suction flow (0, 0.5, 1, and 1.5 L/min).

Statistical Analysis

All analyses were conducted using the Statistical Package for the Social Sciences, Version 19 (SPSS Inc., Chicago, Ill). Data are presented as means ± standard deviation (SD). Analyses of variance and post hoc Tukey tests were used to compare the amount of emboli material retrieved at the various exits across the different particle sizes using the various cannulae.

RESULTS

Description of the Distribution Profiles of the Emboli for the Various Cannulae

For the straight-tip cannula, most of the emboli were released into the descending aorta for the small and medium particles (74.3 ± 11.0 mg, 53.6 ± 6.0 mg, respectively; *P* < .05); for the large particles, the emboli were predominantly released into the brachiocephalic trunk (52.3 ± 8.4 mg; *P* < .05). Figure 3 describes and compares the weight of the emboli released in the various branches of the experimental model without suction, according to the size of particles and type of cannula.

For the curved-tipped cannula (no. 2), most of the small particles were released into the brachiocephalic trunk (56.5 ± 5.8 mg; *P* < .05); the medium and large particles were predominantly released into the descending aorta (60.8 ± 11.2 mg, 46.1 ± 5.9 mg, respectively; *P* < .05).

The distribution profile of the research cannula was similar for all particle sizes; most emboli were released into the brachiocephalic trunk (48.1 ± 7.3 mg, 61.2 ± 14.0 mg, 51.5 ± 13.8 mg, respectively; *P* < .05).

The Research Cannula: Comparison of the Various Suction Levels

The use of the suction function of the research cannula, regardless of its intensity and for all particle sizes, enabled the retrieval of a considerable amount of emboli from the aorta. Figure 4 describes the weight of emboli released in the various branches of the experimental model with suction, according to the size of the released particles. The amount of filtered emboli significantly increased with higher suction levels, for all particle sizes: 60.1 ± 5.4 mg to 100.1 ± 6.6 mg for the small particles; 62.3 ± 4.6 mg to 95.0 ± 4.2 mg for the medium particles; and 60.0 ± 3.6 mg to 95.3 ± 5.9 mg for the large particles (*P* < .05). For each suction level, the amount of particles retrieved was comparable for the different particle sizes (*P* > .05).

Comparison of the Straight, Curved Commercial and Research (With Suction) Cannulae

Using the research cannula, the weight of emboli caught in the brachiocephalic trunk and left common carotid artery was significantly reduced under all suction conditions (*P* < .05). Figure 5 depicts the weight of emboli filtered by the brachiocephalic trunk and left common carotid artery using the various cannulae by particle

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FIGURE 4. A and B, The amount of emboli released (in milligrams) the various branches of the experimental model (curved-tip 60° cannula, CardioGard) with suction (1.5 L/min, 1.0 L/min, 0.5 L/min), according to size of particles in the novel research cannula. The amount of filtered emboli significantly increased with higher suction levels for all particle sizes ($P < .0001$). The upper 3 exits simulate (1) the brachiocephalic trunk, (2) the left common carotid artery, and (3) the left subclavian artery. The lower right exit simulates the descending aorta (DA) and the lower left exit simulates the suction function.

size: (1) for the small particles (100-250 μm) there was a significant decrease in the amount of embolic material that was caught in these exits (straight tip, highest amount; curved tip 60°, smallest amount); (2) for the medium (250-500 μm) and large (500-1000 μm) particles, a

comparable amount of embolic material was caught using the straight-tip and curved-tip 45° cannulae, and compared with each of these cannulae, the curved-tip 60° cannula captured a significantly smaller amount of emboli.

FIGURE 4. (continued).

DISCUSSION

The main finding of the current study is that the novel research aortic cannula enabled the retrieval of most of the embolic material released into the model aorta, suggesting its potential for dramatically reducing the postoperative risk for stroke.

FIGURE 5. The amount of emboli (in milligrams) filtered by the brachiocephalic trunk and left common carotid artery using the various cannulae (namely, [1] straight-tip cannula, [2] curved-tip 45° cannula, and [3] curved-tip 60° cannula, CardioGard, 1.5 L/min), according to size (100-250 μ m, 250-500 μ m, and 500-1000 μ m). Comparisons were conducted according to particle size (3 analyses of variance; $P < .0001$). Tukey post hoc comparisons. *Significant difference between the curved-tip cannula and the straight-tip cannula; NS denotes a nonsignificant difference between the curved-tip cannula and the straight-tip cannula. **Significant decrease in the weight of emboli captured using the research cannula compared with the straight-tip and the curved-tip cannulae.

Comparison of Emboli Distribution Profiles Between the Different Cannulae Without Suction

The distribution profiles of the straight, curved and the novel research cannulae may be attributed to the physical properties of the cannulae; namely, the larger the angle of the cannula tip, the greater the chances of the emboli being released into the upper part of the aorta, and specifically, the first branch. The clinical significance of this observation is that the straight-tip cannula may be associated with a reduced risk of cerebral emboli. These findings are in agreement Avrahami and colleagues¹³ who investigated numerical models of different cannula orientations, aortic anatomies, and cannula designs. Albert and colleagues¹⁴ studied the impact of the shape of aortic end-hole cannulae on stroke occurrence and concluded that straight-tip cannulae cause significantly more frequent and more severe bilateral and posterior strokes than curved-tip cannulae. Similar conclusions were presented by White and colleagues¹⁵ who compared curved-tip cannulae with standard straight-tip cannulae.

Emboli Distribution of the Novel Aortic Cannula With Suction

The novel aortic cannula enabled the retrieval of most of the embolic material released into the model aorta, in the range of 60 to 99.6 mg (50%-83%), for all particle sizes. This finding proved the theoretic efficacy of the cannula to reduce the risk of cerebral events during cardiac surgery. Avrahami and colleagues¹⁶ conducted

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FIGURE 6. A, Blood flow stagnation between the cannula and the clamp may lead to the generation of embolic material through thrombus formation. B, The novel cannula enables the elimination of blood flow stagnation and the removal of thrombotic material. Adapted with permission from Avrahami and colleagues.¹³

computerized simulations and demonstrated that compared with straight-tip and curved-tip commercial cannulae (the ones used in the current study), the novel aortic cannula was associated with a significant improvement in terms of potential risk of cerebral embolism, and similar risks for other hemodynamic complications, such as hemolysis or atheroembolism. Shani and colleagues¹⁷ investigated the novel aortic cannula in an *in vivo* model and reported that in terms of safety and hemocompatibility, the novel aortic cannula was comparable with the standard, widely used aortic cannula tested in the current study, and demonstrated a reduced risk of cerebral emboli.

The novel aortic cannula presented in the current study was developed for the purpose of reducing cerebral events after cardiac surgery, mainly by allowing the surgeon to perform the surgical procedure within safer limits of aortic manipulation, including crossclamp placement and removal as well as proximal anastomosis.

The capacity of the research cannula to retrieve emboli is enabled in several ways: (1) collection of embolic material coming behind the suction orifice and generated by manipulations of the aorta during the surgical procedure, as well as air and solid particles released from the heart after declamping of the aorta; (2) the cannula is eliminating embolic material generated in the space between the cannulation site and the aortic clamp as a result of stagnation of blood flow, as demonstrated by Avrahami and colleagues¹³ (Figure 6). This type of embolic material

is usually released into the systemic circulation after declamping of the aorta.

Several types of devices used after cannulation minimize the quantity of emboli released during cardiac surgery. First, an ultrasound-based device that is placed on the aorta during surgery is used to divert the released particles from the cerebral circulation toward the descending aorta.¹⁸ Second, a percutaneously placed device inserted into the right forelimb and deployed in the aorta¹⁹ performs a similar action of diverting particles from the cerebral circulation. Third, an intra-aortic filtration device in the aortic cannula incorporates a filter that captures particulate emboli during cardiopulmonary bypass.²⁰

In comparison with existing devices for intraoperative emboli reduction, the cannula under study is less invasive and is based on complete emboli removal rather than their deflection to the lower limbs, preventing ischemic events within the systemic circulation, including the kidneys, gastrointestinal system, and lower extremities.

Several limitations within the current study need to be addressed. First, the study did not include cycles of injected embolic material of mixed size, which may have portrayed the systemic circulation more reliably. Second, because current findings are based on an *in vitro* model, the ability to generalize to the clinical setting is limited. Third, the study was designed such that a fixed inflow was set but the suction level ranged from 0.5 to 1.5 L/min, leading to a corresponding variation in the net flow values. This technical matter may have had an effect on the distribution

profile of the embolic material in the silicone model branches, such that more embolic material was captured in the suction filter as the suction level increased; however, maintaining a constant net flow would have probably given rise to lower amounts of captured emboli. Third, the current results were achieved under clamp-release conditions, relevant to a small fraction of the surgical procedure, which is significant in terms of emboli release.

In conclusion, the current findings support the use of the novel aortic cannula in cardiac surgery for the potential reduction in the rate of cerebral events. A human, multicenter, randomized, controlled clinical trial is currently under way.

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