Gaseous and solid cerebral microembolization during proximal aortic anastomoses in off-pump coronary surgery: The effect of an aortic side-biting clamp and two clampless devices

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Objectives: Intraoperative cerebral microembolism is a cause of cerebral dysfunction after cardiac surgery, and particulate microemboli are the most damaging. Using a new-generation transcranial Doppler ultrasound, we compared the number and nature of microemboli in patients undergoing off-pump coronary artery bypass grafting during performance of proximal anastomoses with three techniques: an aortic side-biting clamp and two clampless devices (the Enclose II device [Novare Surgical Systems, Inc, Cupertino, Calif] and the Heartstring II device [Guidant Corporation, Santa Clara, Calif]) developed to obviate the need for an aortic side-biting clamp, thereby reducing the number of cerebral microemboli.

Methods: Bilateral continuous monitoring of the middle cerebral arteries was performed with a multirange, multifrequency transcranial Doppler device that both automatically rejects artifacts online and discriminates between solid and gaseous microemboli. Recordings were continuously undertaken during performance of 66 proximal aortic anastomoses in 42 patients. Thirty-five anastomoses were performed with an aortic side-biting clamp, 20 with the Enclose device, and 11 the Heartstring device.

Results: Most microemboli occurred during application/insertion and removal of each device from the ascending aorta. The median number (interquartile range) of total microemboli was 11 (6-32) during side clamping, 11 (6-15) with the Enclose device, 40 (31-48) with the Heartstring device ($P < .01$). The proportion of solid microemboli was significantly higher in the side-clamp group (23%) compared with 6% and 1% in the Enclose and Heartstring groups, respectively ($P < .01$).

Conclusions: Avoidance of aortic side clamping results in a significant reduction in the proportion of solid microemboli detected with transcranial Doppler. As solid microemboli are probably the most damaging, use of the Enclose and Heartstring devices may represent an important strategy for minimizing cerebral injury during proximal aortic anastomoses.

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Cerebral injury remains the most significant and disabling complication of coronary artery bypass grafting (CABG).¹ It occurs in two forms²: type I injury, which includes stroke, transient ischemic attack, and coma (incidence 3%-6%), and type II injury, which is more subtle and includes impairment of

Abbreviations and Acronyms

CABG	= coronary artery bypass grafting
IQR	= interquartile range
OPCAB	= off-pump coronary artery bypass grafting
TCD	= transcranial Doppler

cognitive function. The latter affects up to half of all patients soon after surgery and persists in a quarter at 6 months³ and in up to 42% at 5 years.⁴ Although macroembolization of atheromatous debris during manipulation of the diseased aorta is the main cause of stroke,⁵⁻¹⁰ intraoperative cerebral microembolization is considered to be the most important cause of postoperative neurocognitive decline.¹¹⁻¹⁴ Indeed, we¹⁵ recently added support to this hypothesis by demonstrating a correlation between the number of intraoperative cerebral microemboli and subsequent impairment of verbal memory defined by functional magnetic resonance imaging.

Using a new generation of advanced transcranial Doppler (TCD) ultrasound (Embo-Dop; DWL Elektronische Systeme, GmbH, Singen, Germany), which uses multifrequency and multirange recordings both to reject artifacts online and to discriminate between solid and gaseous microemboli, we previously confirmed that cardiopulmonary bypass and aortic manipulation (cannulation, decannulation, and application and removal of an aortic crossclamp or side-biting clamp) are the main causes of cerebral microemboli during CABG.¹⁶ While off-pump composite arterial grafts permit a true “no touch” aortic technique and may be

the most effective way to reduce the macroembolic/microembolic load to the brain,^{1,17-23} one or more proximal anastomoses to the aorta are often necessary. This has driven the development of novel anastomotic devices, to enable the surgeon to perform proximal anastomoses without an aortic side-biting clamp in a fully pressurized aorta. Although several groups have reported their clinical experience with these methods,²⁴⁻³¹ to the best of our knowledge their effects on the relative proportions of gaseous and solid microemboli have not been reported.

In the current study we compared the number and nature of cerebral microemboli in patients undergoing off-pump coronary artery bypass grafting (OPCAB) during construction of proximal aortic anastomoses using three different techniques: a conventional aortic side-biting clamp and two clampless devices, the Enclose II proximal seal system (Novare Surgical Systems, Inc, Cupertino, Calif; [Figure 1](#)) and the Heartstring II proximal seal system (Guidant Corporation, Santa Clara, Calif; [Figure 2](#)). We were particularly interested in the nature of the microemboli (solid vs gaseous) and their generation in temporal relation to application and removal of the devices.

Patients and Methods

A total of 42 patients undergoing OPCAB were prospectively recruited for the study. All patients gave informed consent, and full ethical approval was obtained from the local research ethics committee (Oxford Research Ethics Committee number C01.258). A

Figure 1. The Enclose II proximal seal system (Novare). *Foreground,* The device with uppermost extraluminal jaw with a nonexpandable wire form and intraluminal jaw with expandable membrane below; behind upper and lower knob and vented plug. *Background,* Actuator tool supplied with the kit used to open and close expandable membrane and control vertical movement of upper jaw. (Adapted from Ethicon Web site: www.novaresurgical.com).

Figure 2. The Heartstring II proximal seal system (Guidant). *Left,* The coiled device as seen after its deployment. *Right,* Aortic cutter supplied with the device. (Adapted from Guidant Web site: [www.guidant.com/products/Product templates/CS/heartstring.shtml](http://www.guidant.com/products/Product%20templates/CS/heartstring.shtml)).

Figure 3. The Enclose II proximal seal system in use. A 1 cm² area of aortic wall lies between the tightened upper and lower jaws of the device; the proximal anastomosis will be performed manually in the middle of this bloodless area without using a side-biting clamp. (Adapted from Ethicon Web site: www.novaresurgical.com).

total of 66 proximal anastomoses were performed, 35 with an aortic side-biting clamp (group S), 20 with the Enclose device (group E), and 11 with the Heartstring device (group H).

All proximal aortic anastomoses were performed in palpably³² normal aortas. Patients with symptomatic carotid disease, peripheral vascular disease, preoperative neurologic history, or atrial fibrillation were excluded. Although epiaortic scanning would also have been very useful, this is not routinely available in our center.

The operating surgeon made no choice in selection of the anastomotic device. A limited number of 11 Enclose and 11 Heartstring devices were randomly selected by two nonoperating researchers and not by the surgeon. The researchers were not involved in the perioperative evaluation or management of the study patients but were responsible for TCD measurements. Therefore, we believe that selection bias, although not completely eliminated, was effectively decreased in this study.

Surgical Technique

All operations were performed by one surgeon (D.P.T.). After midline sternotomy, one or two internal thoracic arteries were harvested in a skeletonized fashion. The radial artery, the long saphenous vein graft, or both were simultaneously harvested. Full anticoagulation was achieved with heparin. The distal anastomoses were performed first, with the aid of a suction-assisted stabilizer (Octopus; Medtronic, Inc, Minneapolis, Minn; or Guidant, Guidant Corporation) and visualization was enhanced with a surgical blower-mister (Medtronic ClearView; Medtronic, Inc).

Figure 4. The Heartstring II proximal seal system in use. The device delivered through the aortotomy and deployed creating a hemostatic seal against the inner wall of the aorta. The proximal anastomosis is performed manually without side clamping of the aortic wall. (Adapted from Guidant Web site: [www.guidant.com/products/Product templates/CS/heartstring.shtml](http://www.guidant.com/products/Product%20templates/CS/heartstring.shtml)).

After completion of the distal anastomoses, the proximal radial artery or saphenous vein graft anastomoses were performed on a disease-free segment of the aorta as assessed by gentle palpation. An anterior segment of normal aorta with a diameter of at least 1 cm, for use of the Heartstring device, and of at least 2.5 cm for the Enclose device or side-clamp was required.

Side-biting clamp. After removal of aortic adventitia, a palpably normal segment of ascending aorta was grasped with Duvall forceps and a side-biting clamp applied. The area of enclosed aorta was from 1 to 2 cm². A small (around 5 mm) linear aortotomy was performed, and the conduit was anastomosed with continuous 6-0 polypropylene (Prolene; Ethicon, Inc, Somerville, NJ). The side-biting clamp was removed after completion of the anastomosis.

Enclose device. The device was used as previously described.³³ A 14-gauge needle was introduced into the ascending aorta through a 4-0 Prolene purse-string suture. The lower jaw of the Enclose device, containing an expandable membrane (Figure 1), was then inserted and hemostasis was secured by tightening the purse-string suture. The Enclose device was then advanced toward an area of palpably normal aorta to perform the anastomosis. The nonexpandable wire-form upper jaw was lowered toward the aortic wall (with an actuator tool furnished with the kit), the membrane of the lower jaw was opened (still with the actuator tool), and an aortotomy was made in the middle of the aortic wall within the upper jaw, using an aortic punch; hemostasis was secured by the device membrane seal, which was fixed to the inner wall of the aorta (Figure 3). The anastomosis was then constructed manually in a bloodless field with continuous 6-0 Prolene polypropylene. After completion, the device was released and, if necessary, was repositioned and deployed again by rotation, without the need for complete removal, allowing a second or third anastomosis to be constructed.

TABLE 1. Perioperative patient characteristics

Characteristics	Side-biting clamp	Proximal seal systems		P value
		Enclose	Heartstring	
Proximal anastomoses, n	35	20	11	—
Patients, n	25	10	7	—
Age, y (mean $\pm$ SD)	64.3 $\pm$ 8	62.6 $\pm$ 7.5	67.4 $\pm$ 11.2	.49
Females, n (%)	7 (28)	2 (20)	1 (14)	.71
Parsonnet score (mean $\pm$ SD)	7.9 $\pm$ 7	8.5 $\pm$ 6.6	11.2 $\pm$ 8.6	.52
EuroSCORE (mean $\pm$ SD)	3.4 $\pm$ 2.1	3.4 $\pm$ 2.4	2.7 $\pm$ 2.7	.62
Diabetes, n (%)	6 (25)	5 (50)	3 (43)	.28
Hypertension, n (%)	17 (68)	7 (70)	5 (70)	.98
Smoking, n (%)	17 (68)	7 (70)	4 (57)	.83
Previous MI, n (%)	9 (36)	4 (40)	—	.14
Previous CVA/TIA, n	—	—	—	—
PVD, n	—	—	—	—
NNE Prediction Model for Strokes	3.7 $\pm$ 1.6	3.6 $\pm$ 1.6	4.3 $\pm$ 1.8	.62
Proximal anastomoses (mean $\pm$ SD)	1.4 $\pm$ 0.5	2 $\pm$ 0.6	1.6 $\pm$ 0.5	.01*
Radial artery, n (%)	11 (30)	4 (20)	2 (18)	.53
Long saphenous vein, n (%)	24 (70)	16 (80)	9 (82)	.53
No. of grafts (mean $\pm$ SD)	3.2 $\pm$ 0.7	3.5 $\pm$ 0.7	3.4 $\pm$ 0.5	.58

SD, Standard deviation; MI, myocardial infarction; CVA/TIA, cerebral vascular accident/transient ischaemic attack; PVD, peripheral vascular disease; NNE, Northern New England. *Comparison of group S versus group E.

Heartstring device. In a palpably normal segment of aorta, a proprietary aortic cutter, supplied with the Heartstring device (Figure 2), was used to create a circular aortotomy. The coiled Heartstring device was then delivered through the aortotomy, temporarily occluded by a finger, and deployed to create a hemostatic seal against the inner wall of the aorta. The anastomosis was then performed manually with continuous 6-0 Prolene polypropylene (Figure 4). In contrast to the other two techniques, a blower-mister device was used (as recommended by the manufacturer³⁴) to enhance visualization during construction of the anastomosis. After completion of the anastomosis, the device was uncoiled and withdrawn before final tightening of the suture line.

TCD Monitoring

Bilateral continuous TCD monitoring of the middle cerebral arteries was performed, as we¹⁶ have described in detail previously. This is a noninvasive technique with no known complications. All recordings were performed throughout the procedure using a multirange, multi-frequency TCD (Embo-Dop), which rejects artifacts online and automatically discriminates between solid and gaseous microemboli with a relatively high sensitivity and specificity.^{16,35,36} Russell and Brucher³⁷ recently reported that results are most reliable for embolus differentiation when, as in the current study, the Doppler signal enhancement, that is, embolus-to-blood ratio, is greater than 28 dB/ms simultaneously in 2.0-MHz and 2.5 MHz channels. Experience from “in vitro” studies^{35,36} suggests that the Embo-Dop TCD can detect with the most reliable results microemboli ranging between 2 to 3 μ m and 40 μ m in case of gaseous microemboli and between 80 μ m and 450 μ m in case of solid microemboli. Gaseous emboli larger than 40 μ m or solid emboli larger than 450 μ m passing through the sample volume are associated with overloading of the detection mechanism. Very small emboli (gaseous <2-3 μ m or solid <80 μ m) may cause such a

small increase in Doppler energy that they do not exceed the detection threshold of the instrumentation.

Statistical Analysis

Patient characteristics are presented as mean $\pm$ standard deviation. The number of microemboli is presented as median and interquartile ranges (IQRs). Statistical comparison, for normally distributed data, was performed with the Student *t* test for continuous variables and the χ^2 test or Fisher exact test for categorical variables. Inasmuch as the data for the number of microemboli were not normally distributed, the nonparametric Kruskal-Wallis test was used to compare the differences among the three groups.

Results

Perioperative patient characteristics were similar in all groups and are summarized in Table 1. Long saphenous vein and radial artery conduits were used to perform 24 (70%) and 11 (30%) proximal aortic anastomoses, respectively, in group S, 16 (80%) and 4 (20%) proximal anastomoses in group E, and 9 (82%) and 2 (18%) in group H. The number of proximal anastomoses performed per patient ranged between 1 and 3 with a median of 1.6 (66/42). Mean time for performance of the proximal anastomosis with a side-biting clamp was 6 $\pm$ 1.4 minutes, with an Enclose device, 10.4 $\pm$ 2.1 minutes, and with a Heartstring device, 10.6 $\pm$ 2.1 minutes (*P* < .05).

Microemboli

Only around 5% of all high-intensity transient signals were microemboli, with the remaining 95% being rejected as artifacts. The median number (IQR) of total microemboli

Figure 5. Median number (IQR) of total microemboli detected in the three groups. The *line* inside the box plots represent the median number of microemboli. The *upper and lower edges* of each box are respectively the first and third quartile values. The *top and bottom end* of each whisker represent the range of microemboli. *Circles* correspond to the outliers (any value that lies between 1.5 and 3 box heights from the upper or lower edge of the box). *Asterisks* correspond to the extreme values (any value that lies more than 3 box heights from the upper or lower edge of the box). S, Side-biting clamp; E, Enclose; H, Heartstring.

was 11 (6-32) during side clamping, 11 (6-15) with the Enclose device, and 40 (31-48) with the Heartstring device ($P < .01$), as shown in Figure 5. The median numbers (IQRs) of gaseous and solid microemboli are shown in Figures 6A and 6B, respectively. The proportion of solid microemboli was significantly higher in group S (23%) than in group E (6%) and group H (1%) ($P < .01$) (Table 2).

In each group the median number (IQR) of total microemboli was significantly higher during application/insertion and removal of the device compared with that occurring during performance of the anastomosis, as shown in Figure 7. However, significantly more microemboli occurred during insertion and removal of the Heartstring device than during the same maneuvers with the other two techniques. The median number of total microemboli during construction of the anastomosis using the Heartstring device was higher than in the other two groups but did not reach statistical significance ($P = .239$). The median number of gaseous and solid microemboli during the three different stages (application of the device, construction of anastomosis, and removal of the device) is shown in Figure 8. Application and removal of the side-biting clamp caused a significantly higher number of solid microemboli compared with either group E or H for the same maneuvers.

A

B

Figure 6. A, Median number (IQR) of gaseous microemboli detected in the three groups. The median number (IQR) of gaseous microemboli was significantly higher when the Heartstring device was used compared with side-biting clamp or Enclose device. See Figure 5 for right interpretation of box plots and whiskers. B, Median number (IQR) of solid microemboli detected in the three groups. The use of a side-biting clamp resulted in a significantly higher number of solid microemboli compared with the use of the two new clampless proximal seal devices. See Figure 5 for right interpretation of box plots and whiskers.

Discussion

To our knowledge, this is the first study quantifying the number of gaseous and solid cerebral microemboli, and their temporal generation, during proximal aortic anastomoses using a conventional side-biting clamp and two novel clampless proximal anastomotic devices in OPCAB. Our study demonstrated two findings: an increase in the total number of microemboli with the Heartstring device com-

TABLE 2. Median number (IQR) of total microemboli and proportion of gaseous and solid microemboli detected in the three groups

Procedure	Microemboli		
	Total median (IQR)	Gaseous (%)	Solid (%)
Side-biting clamp	11 (6-32)*	77	23†
Enclose device	11 (6-15)*	94	6†
Heartstring device	40 (31-48)*	99	1†

IQR, Interquartile range. *Comparison of the total number of microemboli between the Heartstring group and the other two groups: $P < .01$. †Comparison of the proportion of gaseous and solid microemboli in the three groups: $P < .01$.

pared with the side-biting clamp or Enclose device but a far lower proportion of solid microemboli with the clampless devices (1% in group H, 6% in group E, and 23% in group S; Table 2). This finding is important because solid microemboli are known to be the most clinically damaging and therefore use of the side-biting clamp is likely to have the greatest detrimental effect on neurocognitive function. Furthermore, considering that all our patients had palpably normal aortas, more marked changes may have been observed in patients with more severe atherosclerotic disease. Moreover, the number of microemboli detected with TCD ultrasonography only represents a very small fraction of the total systemic microembolic load. Therefore, apparently small numbers of detected microemboli cannot really be considered insignificant because small differences should in

reality be magnified several times. At last, the relationship between microembolic load and cerebral injury may not be a direct relationship.

In our study, most of the microemboli occurred during the application and removal of all three devices. Barbut and associates⁹ studied the temporal generation of microemboli in on-pump CABG during different maneuvers. They found that crossclamp and side-biting clamp removal were responsible for 58% of the total cerebral microembolic load (34% and 24%, respectively) with a far lower number of microemboli during clamp application. Inasmuch as the largest number of microemboli occurred in patients with the most severe aortic atherosclerosis, the authors concluded that the emboli detected at clamp removal may be due to dislodgment of fragments of atheromatous plaque from the aortic wall and not air bubbles or platelet clumps in the bypass equipment. In our study in the side-biting clamp group, 39% and 46% of the total microemboli were generated during clamp application and removal, respectively, and a significant proportion of these (Figure 8) were solid. These findings, detected in off-pump patients with a palpably normal aorta, add to the important conclusions from Barbut and associates' study.

We detected considerably more gaseous microemboli during application and removal of the Heartstring device than with the other two techniques. Inasmuch as several reports³⁸⁻⁴⁰ have demonstrated direct deleterious effects of gaseous microembolization on the cerebral microvasculature, such findings may represent a significant disadvantage in using the Heartstring device. Between performing and covering the fully pressurized aortotomy with a finger and delivering the coiled seal system into the lumen, the formation of gaseous microemboli may be

Figure 7. Median number (IQR) of total microemboli detected in the three groups during three different stages (applicat, application/insertion of the devices to the aortic wall; anastomo, manual construction of proximal anastomosis; removal, removal of the devices after completion of the anastomosis). See Figure 5 for right interpretation of box plots and whiskers.

Figure 8. Median number of solid and gaseous microemboli detected in the three groups during the three different stages. S, Side-biting clamp; E, Enclose; H, Heartstring.

inevitable due to turbulence. A similar but more trivial process occurs on removal of the device. In an animal model, Nollert and colleagues⁴¹ speculated that most gaseous microemboli with the Heartstring device were attributable to the use of a blower-mister when constructing the anastomosis. We have, however, clearly demonstrated that the vast majority of gaseous microemboli occur when inserting and removing the Heartstring device rather than during construction of the anastomosis and therefore cannot be attributed solely to the use of the blower-mister.

Microembolization during proximal aortic anastomosis with clampless devices has been assessed with TCD ultrasound^{33,41,42} and intra-aortic filters²⁹ by different authors. However, none of them used this new-generation multifrequency TCD or evaluated the temporal release of microemboli in terms of application of devices, construction of anastomosis, or removal of devices. The limitations inherent with traditional TCD ultrasound with its simple intensity threshold renders it unable to discriminate the nature of such microemboli. In addition, as we have previously reported (and confirmed in this current study), up to 95% of emboli may be artifacts, and this therefore has a considerable impact on the findings and conclusions of previous studies. Furthermore, the findings in some of those previous articles^{41,42} have been complicated by having a mixture of on-pump and off-pump patients.

Notwithstanding these limitations, Akpinar and coworkers³³ reported a lower microembolic load with the Enclose II device than with the use of a side-biting clamp. Compared with a side-biting clamp, the sutureless Symmetry proximal anastomotic device (St Jude Medical, Inc, St Paul, Minn) has produced conflicting results, with Scarborough and colleagues⁴² reporting a reduction in microemboli and Martens and coworkers,²⁹ using an intra-aortic filter, reporting no reduction in embolization.

With the Heartstring device and side-biting clamp, each proximal anastomosis requires repeat application and removal of the device. However, with the Enclose device it is possible to perform more than one proximal anastomosis without removing and reinserting the device; it is sufficient to manipulate the closed device to an adjacent area on the aorta. Inasmuch as the majority of microemboli occur during insertion and removal of these devices, it would be intuitive to assume that a single insertion, of the Enclose device, may result in a significant reduction in cerebral microembolic load with repeated anastomoses. However, we are concerned about the potential for dislodgment of atheromatous material from a diseased aorta when attempting to reposition the Enclose device for construction of a subsequent anastomoses.

Potential Limitations

Although lack of a rigorous randomization is a potential limitation of the present study, we believe that this is unlikely to have significantly influenced the results because two independent observers, with no direct responsibility for clinical care of the patient, randomly chose which anastomotic device was to be used. As shown in Table 1, there were no systematic differences in baseline characteristics of the patients.

Inasmuch as this is a small study, a larger sample size would have increased the statistical power of the study, especially regarding the relative proportions of gaseous and solid microemboli. Nevertheless, significant differences were still obvious between the different devices and provide a basis for future randomized controlled trials in selected patient groups (eg, high-risk patients and those with extensive atherosclerosis).

Epiaortic ultrasound is a very sensitive method for demonstrating aortic atherosclerosis but is not routinely available in our center. All the patients in our study had a palpably normal aortic wall, and the risk of embolization and stroke would be significantly greater in those patients with diseased and calcified aortic walls, particularly elderly^{5,6,43,44} and diabetic patients.^{8,45}

None of the patients had a perioperative stroke, and we did not use formal neuropsychologic assessment because the primary objective was simply to compare the degree of cerebral microembolization in the different groups. However, a strong correlation between intraoperative microembolization and postoperative neuropsychologic deficits has already been well documented,¹¹⁻¹⁵ and inasmuch as particulate microemboli are believed to be most damaging, it is intuitive that any technique able to minimize solid cerebral microembolization will reduce the risk of even subclinical injury.

The authors of the original “in vivo” validation of the Embo-Dop system reported excellent results both in automatic rejection of artifacts and in discrimination between solid and gaseous microemboli,^{35,36} reducing bias in the interpretation of high-intensity transient signals and minimizing interobserver variability. Even so, showers of emboli entering the sample volume of the insonating probes may be wrongly identified as artifacts, underestimating the true embolic burden. As showers of microemboli are less likely with an off-pump “no touch” aortic technique, the phenomenon of “undercounting” showers of microemboli may underestimate the benefits of this technique.

A recent study by Markus and Punter⁴⁶ has shown that the Embo-Dop system has a sensitivity of 50% and a specificity of 96% for detecting solid microemboli. Therefore, possibly as many as 50% of all solid microemboli may be misclassified as gaseous by the machine. If it is subsequently confirmed that an even greater proportion of microemboli are in fact solid rather than gaseous, it will only

serve to emphasize the importance of using measures that may reduce the number of solid microemboli such as OPCAB and the avoidance of any aortic manipulation and especially side-biting clamps.

Conclusions

The majority of microemboli occur during active aortic manipulation with application and removal of a side-biting clamp or insertion and removal of clampless aortic anastomotic devices. The use of such devices results in a significant reduction in the proportion of solid microemboli and may represent an important strategy for minimizing cerebral injury during proximal anastomoses, particularly in the highest risk groups.

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