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Safety and effectiveness of selective carotid angioplasty prior to cardiac surgery: a single-centre matched case–control study

Zahra Hasani[a], Rudolf W.M. Keunen[a,*], Dénes L.J. Tavy[a], Arne Mosch[a], Barry B. Mook-Kanamori[a], Sebastiaan F.T.M. De Bruijn[a], Ali M. Keyhan-Falsafi[b], Gerard J.F. Hoohenkerk[b], Gayleen Stephens[b], Eric Teeuws[b], Jan van Alphen[c], Hans van Overhagen[d], Frank E.E. Treurniet[d], Lucas van Dijk[d] and Paulien M. van Kampen[e]

[a] Department of Neurology and Clinical Neurophysiology, Haga Teaching Hospitals, The Hague, Netherlands
[b] Department of Cardiosurgery, Haga Teaching Hospitals, The Hague, Netherlands
[c] Department of Cardioanaesthesiology, Haga Teaching Hospitals, The Hague, Netherlands
[d] Department of Intervention Radiology, Haga Teaching Hospitals, The Hague, Netherlands
[e] Department of Biostatistics, Haga Teaching Hospitals, Netherlands

* Corresponding author. Department of Neurology, Haga Teaching Hospitals, Leyweg 275, 2545 CH The Hague, Netherlands. Tel: +31-70-2100000; e-mail: r.keunen@hagaziekenhuis.nl (R.W.M. Keunen).

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Abstract

OBJECTIVES: Reducing the rate of postoperative stroke after cardiac surgery remains challenging, especially in patients with occlusive cerebrovascular disease. Angioplasty in all patients with high-grade carotid artery stenosis has not been shown to be effective in reducing the post-surgical stroke rate. In this study, we present the initial results of a different approach using selective carotid angioplasty only in patients with poor intracranial collaterals.

METHODS: We conducted a single-centre study to assess the safety of this procedure. The postangioplasty complication rate of the study group was compared to that of patients who were scheduled for symptomatic carotid artery angioplasty. To determine the effectiveness of this procedure, the post-cardiac surgery complication rate of the study group was compared with that of the matched case controls.

RESULTS: Twenty-two patients were treated with selective carotid angioplasty without developing persistent major neurological complications. All patients except 1 patient subsequently underwent surgery without developing persistent major neurological disabilities. Two patients died of cardiogenic shock within 30 days.

CONCLUSIONS: Selective carotid angioplasty prior to cardiac surgery in patients with a presumed high risk of stroke was relatively safe and effective in this study group. Although this strategy does not prevent stroke in these high-risk patients, data suggest that this approach shifts the postoperative type of stroke from a severe haemodynamic stroke towards a minor embolic stroke with favourable neurological outcomes. Larger studies are needed to determine whether this strategy can effectively eliminate the occurrence of haemodynamic stroke after cardiac surgery.

Keywords: Carotid angioplasty • Cardiac surgery • Stroke prevention

INTRODUCTION

A postoperative stroke occurs in 1–5% of patients having cardiac surgery [1]. Most of these strokes are caused by cerebral emboli dislodged into the circulation from surgical vessel wall lesions and/or cardiac intravascular thrombi. Atrial fibrillation may promote this process. A minority of the postoperative strokes are related to occlusive cerebrovascular disease and/or systemic hypotension [2, 3]. These so-called haemodynamic strokes induce cerebral watershed infarcts, which often have a poor prognosis. Magnetic resonance imaging is a highly sensitive diagnostic tool for detecting watershed infarcts in the border territories between the tissues supplied by cerebral arteries. Gottesman *et al*. showed that nearly 70% of patients who had cardiac surgery experienced watershed infarcts [4]. The bilateral watershed infarcts carry a higher risk of in-hospital death and poorer neurological outcomes. Patients incurring bilateral postoperative watershed infarcts following cardiac surgery were 17.3 times more likely to die and 12.5 times more likely to be transferred to a nursing facility than to be discharged home [4].

Routine carotid artery duplex screening and subsequent angioplasty of the high-grade carotid artery stenosis has been one of the approaches used to reduce the rate of postoperative haemodynamic stroke following cardiac surgery. However, the benefits of universal carotid artery revascularization neither outweighed the costs of screening nor reduced the overall incidence of strokes [5–7]. Therefore, we explored an alternative strategy of selective angioplasty, in which only patients with poor intracranial collaterals were treated. We preferred carotid artery stenting (CAS) to carotid surgery because a meta-analysis of both procedures revealed that the incidence of major adverse events is higher in carotid surgery [8]. In particular, the incidence of post-procedural myocardial infarction was shown to be 3 times higher following carotid surgery than following stent placement. Unfortunately, there are no randomized controlled trials comparing the 2 treatment options prior to cardiac surgery.

To identify patients with poor collaterals, we conducted a transcranial Doppler (TCD) examination in each patient scheduled for cardiac surgery. To further reduce the risk of cerebral ischaemia, we monitored all patients during and after cardiac surgery with bilateral cerebral oximeter sensors. We called this proactive dual strategy the Haga Braincare Strategy (HBS). We have previously shown that the implementation of the HBS reduced the incidence of postoperative delirium by more than 50% [9]. Furthermore, in a retrospective follow-up study, implementation of HBS was shown to reduce both overall stroke incidence and severity [10]. Recently, we showed that the HBS eliminated the occurrence of haemodynamic stroke related to cardiac surgery [11]. In this study, we presented a detailed analysis of all patients treated with the HBS who we subjected to selective angioplasty between 2010 and 2016. We posed 2 questions: first, is this procedure safe, and second, is it effective in preventing strokes after cardiac surgery in this subgroup of patients with occlusive cerebrovascular disease?

METHODS

Study design and inclusion criteria

All patients scheduled for cardiac surgery between 2008 and 2016 were included if they presented with both asymptomatic carotid artery stenosis and poor collaterals (study group). Carotid artery stenosis was graded based on duplex ultrasound or computed tomography angiography (CTA) scans of the carotid arteries. North American Symptomatic Carotid Endarterectomy Trial criteria were used to define the grade of the stenosis observed on CTA scans [12]. To estimate the degree of carotid artery stenosis observed on duplex ultrasound scans, peak systolic velocity and end-diastolic velocity in both internal and distal common carotid arteries were recorded. All velocities were measured at a Doppler angle of 45–60°. An internal carotid peak systolic velocity >160 cm/s and a peak systolic velocity ratio >4 indicated >70% carotid artery stenosis.

Poor collaterals were graded based on TCD results or if TCD was not possible and a duplex scan revealed high-grade carotid artery stenosis, a CTA was used to grade the quality of the collateral circulation.All patients were examined by a neurologist before and after the angioplasty and the cardiosurgical procedure, and the number of vascular risk factors and complications was recorded.

All patients were also examined by a neurologist prior to the CAS procedure, immediately after the CAS procedure and after the cardiac surgery. All patients were examined at discharge and at 30 days following surgery. Patients who did not show clinical signs of an adverse cerebral event were not routinely subjected to a CT or a magnetic resonance imaging examination. Every periprocedural complication was documented in the electronic patient data system. Special attention was given to neurological complications including stroke, malignant cerebral hyperperfusion, new myocardial infarct and/or a systemic haemorrhage. Stroke was defined as every clinical neurological event related to cerebral ischaemia or haemorrhage lasting longer than 24 h, on Days 0–5 following the angioplasty or the cardiosurgical procedure. The National Institutes of Health Stroke Score (NIHSS) was used to determine the severity of the stroke at onset and measure recovery after 2 months. Minor, moderate, moderate to severe and severe strokes were classified as having NIHSS scores of 0–4, 5–15, 16–20 and 21–42, respectively. The NIHSS determined early after a stroke is highly predictive of hospital disposition and long-term stroke outcomes [13]. Malignant hyperperfusion was defined as an intracranial reperfusion haemorrhage occurring during the first 3 weeks following the CAS or cardiac surgery. New myocardial infarcts were defined as troponin-proven myocardial infarcts occurring after carotid angioplasty or cardiac surgery. Systemic bleeding complications were defined as any haemorrhage requiring a blood transfusion.

To estimate the safety of selective angioplasty, we compared members of the study group with all patients who were scheduled for symptomatic carotid artery angioplasty not related to cardiac surgery between 2011 and 2016 (control Group I). It would have been preferable to have a control group comprised of patients scheduled for angioplasty with asymptomatic rather than symptomatic carotid artery stenosis. However, asymptomatic carotid angioplasty is rarely performed at the Haga Hospital outside the HBS protocol. To determine the effectiveness of selective angioplasty, the members of the study group were compared with the matched case controls also subjected to cardiac surgery between June 2013 and October 2015 (control Group II, matched for gender, age and type of surgery). The complication rates of the study group were compared with those of control Group I and control Group II. All matched case controls were subjected to the same HBS and were presumed to have normal cerebral circulation based on either normal TCD values or patent carotid arteries evident on duplex scans.

Risk factors were defined as the presence of any of the following variables: smoking, diabetes mellitus, hypertension, stroke and myocardial infarction in the past. Patients who had stopped smoking less than 10 years prior to the study were scored as having smoking as a risk factor.

Definitions of poor collaterals

To determine the status of the collateral arteries, the cerebral haemodynamics at the base of the middle cerebral artery was investigated by a 2-MHz pulsed bidirectional TCD system (Delica 9-series, Delicate Manufacturer, Shenzhen, China). If the cerebral haemodynamics distal to the carotid artery stenosis revealed either a reduced pulsatility index (PI <0.8) or an asymmetrical PI value (PI on the ipsilateral side was 50% lower than the PI on the contralateral side), the collateral circulation was considered poor. Figure 1 shows an indexed TCD recording of a patient with normal middle cerebral artery blood flow velocities and PI distal to a patent internal carotid artery and contralateral reduced middle cerebral artery blood flow velocities and PI related to high-grade internal carotid artery stenosis and poor collaterals. If TCD was unfeasible, duplex scanning (Toshiba Xario, Ultrasound Imaging System, SSA-680A) of the carotid arteries was performed. If duplex scanning revealed patent carotid arteries, patients were regarded as not at risk for haemodynamic strokes. If a high-grade

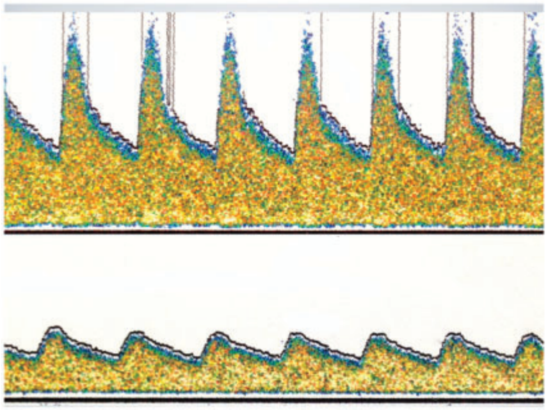

Figure 1: A transcranial Doppler examination of an index patient with normal blood flow velocities in the middle cerebral artery and pulsatility index (PI) in the upper part of the figure and reduced middle cerebral artery blood flow velocities and PI in the lower part of the figure. The reduced blood flow velocities and PI are related to stenosis of the ipsilateral internal carotid artery in combination with poor intracranial collaterals.

stenosis was determined from the duplex scanning, CTA was performed and, based on the absence or the presence of the anterior and posterior communicating arteries, patients were graded as having good or poor cerebral collaterals. Poor collaterals were defined as the absence of either the anterior or the posterior communicating artery or when both ipsilateral communicating arteries were absent.

Carotid angioplasty

Carotid angioplasty was performed with the patient under local anaesthesia. The angioplasty was always followed by placement of a stent to secure long-term patency. Stents were chosen at the discretion of the interventionist. Cerebral protection was not mandatory. Both aspirin and clopidogrel were prescribed, starting at least 2 days prior to the intervention to 3 months following the procedure. We chose not to perform carotid artery surgery in patients with unstable angina and/or overt cardiac valve dysfunction because of the high risk of periprocedural myocardial infarcts [14]. Figure 2 shows CTA images of the carotid artery prior to and following the angioplasty and stent placement.

Cardiosurgical procedures

The surgical team used uniform anaesthetic, surgical and perfusion techniques. All of the coronary artery bypass grafting (CABG) and CABG plus procedures were performed using a cardiopulmonary bypass. To ensure brain oxygenation, all patients were monitored during and following surgery with near-infrared spectroscopy (INVOS 5100; Somanetics Corporation, Troy, MI, USA). Details of the cardiovascular procedures and monitoring with near-infrared spectroscopy have been published elsewhere by Palmbergen *et al.* [9].

Data collection and statistical analysis

All data were retrospectively collected from electronic case record forms. SPSS (v 17.0) statistical software was used for statistical analysis. Categorical values were presented as numbers

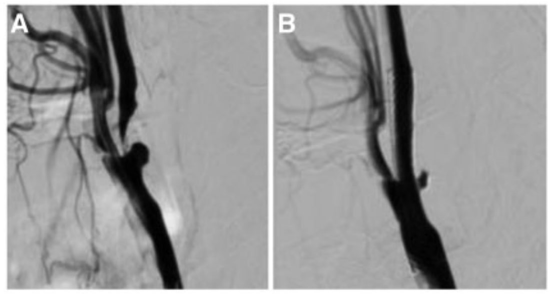

Figure 2: (**A**) High-grade internal carotid artery stenosis. (**B**) The internal carotid artery after angioplasty.

(percentages) and were analysed using the χ^2 test or the Fisher's exact test. The Fisher's exact test was used when the expected frequencies calculated from the marginal totals were (considerably) less than 5 in the cross tables (as the normal approximation of the binomial distribution will then be less appropriate). An independent *t*-test was used to compare numerical data whose distributions approximated normality. The results were considered statistically significant if the P-value was <0.05. The non-parametric Mann–Whitney *U*-test was used for data with non-normal distribution, and the results were shown as the median with the minimum and maximum values.

Protocol violations

TCD data were not stored in the electronic case record forms for 2 patients of the study group. One patient in the study group was determined not to have poor collaterals as defined by the study criteria.

Ethical aspects

All patients enrolled in the study group were informed about the HBS and selective angioplasty. We explained to each patient that an increased risk of haemodynamic stroke was present due to poor collaterals and high-grade carotid artery stenosis. We informed them that the HBS is a local protocol and not a national guideline. We clarified that the advice to have a CAS was not based on prior evidence from randomized controlled trials. Patients were informed about the complications of the CAS procedure and the potential impact of the CAS on the outcome of the cardiac surgery. Informed consent was obtained from all patients scheduled for CAS. The patients in the control groups were identified using a database for quality control of angioplasty and cardiosurgical procedures at the Haga. This research study was conducted in adherence with both the Dutch Agreement on Medical Treatment Act and the Personal Data Protection Act. The HBS study protocol and the approval of both the Haga medical authorities and the Haga scientific committee to execute this study have been archived under the file number Haga T15-065 NL.

RESULTS

Twenty-two patients were included in the study group and 39 patients were included in the control Group I. The diagnosis of poor collaterals was based on TCD criteria in 13 patients and on CTA criteria in 9 patients. In 8 of the 9 patients who were examined with CTA, neither an anterior nor a posterior communicating artery was identifiable. Table 1 lists the safety aspects of carotid angioplasty for the 22 patients in the study group compared with the 39 patients in the control Group I. The groups did not differ in age, gender and the number of vascular risk factors. As expected, the preoperative analysis showed a lower PI (0.77) in patients in the study group compared with those in the control Group I (0.77 vs 0.96); however, the difference was not statistically significant. The rates of transient ischaemic attack and strokes postangioplasty were equal for both groups; however, most of these strokes were minor (NIHSS, 2–4.5), and patients showed excellent recovery (NIHSS at 2 months, 0–1). Malignant hyperperfusion syndrome was observed in none of the study group patients compared with 1 patient in the control Group I. The latter patient experienced a severe hypertensive crisis and died the following day. One patient in the study group twice experienced a haemorrhagic shock, 6 and 14 weeks after the CAS procedure. The focus of the bleeding was intestinal angiodysplasia. She was waived from cardiac surgery and died after 18 weeks of gastrointestinal complications.

Table 2 lists the procedural efficacy of patients in the study group and in the control Group II. Most patients (73%) were scheduled for CABG. Valve replacement or valve reconstruction was performed in 27% of the patients. A third of these patients underwent a combination of valve and CABG surgery. The mean time between the angioplasty and the cardiac surgery was 8.3 days (range 2–34 days) for all except 1 patient. She was operated on after 84 days not because of a stroke but because the neurologist recommended that this particular patient needed more time to recover from the CAS prior to the surgery. Two patients in the study group (9.1%) and 4 patients in the control Group II (2.8%) experienced a stroke following cardiac surgery. The first patient of the study group experienced a moderate stroke (NIHSS 10), showing marked recovery after 2 months (NIHSS 4). The second patient from the study group experienced a minor stroke (NIHSS 3), with the CT scan revealing a minor cortical haemorrhage in the frontal lobe and a recent ischaemic stroke in the posterior lobe. He recovered completely after 2 months. Of the patients in the control Group II, 1 patient was lost to follow-up, 1 patient died of heart failure as a result of pneumosepsis and the other 2 patients showed excellent recovery (NIHSS 4 and 2). In both patients, we presumed that the cerebral ischaemia was embolic in nature because no watershed infarcts were observed on brain images. Thus, none of the patients in the study group and in the control Group II experienced a watershed infarct. The rate of myocardial ischaemia was low in both groups. The post-surgical delirium rate was equal in both groups, and none of the patients in the study group experienced malignant cerebral hyperperfusion or other non-neurological systemic complications. Two patients in the study group died within 30 days. They died of cardiogenic shock and did not experience neurological complications. Therefore, the rate of major adverse clinical events (sum of strokes, myocardial infarctions and deaths) at 30 days was 5/22 (22.7%).

DISCUSSION

The ultimate goal of the HBS is to eliminate the occurrence of both embolic and haemodynamic postoperative strokes in all patients undergoing cardiac surgery. The approach of using selective carotid angioplasty did not yield this result. Although postoperative haemodynamic strokes no longer occurred, we did observe new embolic strokes after elective CAS and cardiac surgery. Thus, if haemodynamic strokes can be avoided at the cost of embolic strokes occurring, the question becomes how clinically relevant these embolic events are for the patient. For selective carotid angioplasty to be an acceptable strategy, the embolic strokes must exhibit a low incidence and a low severity and carry a favourable prognosis. This study does not answer this question but may provide some insights in this clinical dilemma.

Table 1 lists that selective angioplasty induced a new embolic stroke in 1 of the 22 patients. Many embolic particles are released during angioplasty. Cerebral microinfarcts following

Table 1: Safety aspects of carotid angioplasty of patients with poor cerebral collaterals prior to cardiac surgery (study group) versus patients with conditions not related to cardiac surgery who were scheduled for the procedure (control Group I) at the Haga Teaching Hospitals between 2008 and 2016

Safety aspects	Study group	Control Group I	*P*-value
n	22	39	
Age (years)	70.3	73.2	NS
Male/female ratio	68:32	56:44	NS
Vascular risk factors (*n*)	2.32	1.97	NS
Prestenting haemodynamics			
Carotid artery stenosis (%)	92.5	90.0	NS
Mean BFV MCA (cm/s)	50	52	NS
Mean PI MCA, median (range)	0.77 (0.43–1.50)	0.96 (0.60–1.53)	NS
Post-stent findings			
TIA incidence, *n* (%)	1 (4.5)	3 (7.7)	NS
Stroke incidence, *n* (%)	1 (4.5)	2 (5.1)	NS
Stroke severity at onset (NIHSS), *n*	2	4.5	NS
Stroke severity at 2 months (NIHSS), *n*	0	1	NS
Malignant cerebral hyperperfusion, *n* (%)	0	1 (2.6)	NS
Stroke deaths, *n* (%)	0	1 (2.6)	NS
Myocardial ischaemia, *n*	0	0	NS
Systemic bleeding, *n* (%)	1 (4.5)	0	NS

BFV: blood flow velocities; MCA: middle cerebral artery; NIHSS: National Institutes of Health Stroke Scale; NS: non-significant; PI: pulsatility index; TIA: transient ischaemic attack.

Table 2: Effectiveness of carotid angioplasty for patients with poor cerebral collaterals prior to surgery (study group) versus age, gender and surgery matched case controls (control Group II) scheduled for cardiac surgery at the Haga Teaching Hospitals between 2008 and 2016

Efficacy aspects	Study group	Control Group II	*P*-value
n	21	142	
Mean age (years)	69.9	72.1	NS
Male/female ratio	71:29	71:29	NS
Post-surgical findings			
Stroke rate, *n* (%)	2 (9.5)	4 (2.8)	NS
Stroke severity at onset (NIHSS), *n*	6.5	5	NS
Stroke outcome at 2 months (NIHSS), *n*	2	3	NS
Stroke mortality, *n*	0	0	NS
Postoperative delirium, *n* (%)	2 (9.5)	13 (9.2)	NS
Malignant cerebral hyperperfusion, *n*	0	0	NS
Myocardial ischaemia, *n* (%)	0	3 (2.1)	NS
Systemic bleeding, *n*	0	0	NS
In-hospital deaths, *n* (%)	1 (4.8)	1 (0.7)	NS
Deaths after 30 days, *n* (%)	1 (4.8)	2 (1.4)	NS

NIHSS: National Institutes of Health Stroke Scale; NS: non-significant.

carotid angioplasty are observed frequently (up to 65%) using the sensitive technique of diffusion-weighted magnetic resonance imaging [15]. In some patients, especially those with brain atrophy and white matter hyperintensities, ischaemia is more commonly associated with clinical neurological deficits [16]. Fortunately, both patients in the study group with strokes showed a marked recovery, and the stroke rate was comparable with that in the control group. One of the patients in the study group had 2 instances of major gastrointestinal bleeding related to intestinal angiodysplasia. The use of clopidogrel after the CAS procedure contributed to this complication. In other words, the results of this study concluded that although the stroke rate of this procedure was 4.5%, outcomes following clinical strokes were good. At the same time, these patients were frail and may have had severe systemic complications.

Table 2 lists the effectiveness of angioplasty in preventing neurological damage after cardiac surgery. No haemodynamic strokes or cerebral hyperperfusion syndromes were observed in these 21 patients. However, 2 of the 21 patients experienced a presumed embolic stroke; one of these patients experienced a full recovery while the other, a nearly complete recovery. Furthermore, the rates of stroke, in-hospital mortality and mortality after 1 year were similar between the study group and the age, gender and surgery matched controls. It is evident from this cohort that angioplasty was effective in preventing moderate-to-severe neurological damage in these patients and that none of them experienced a haemodynamic stroke.

It is known from the literature that the combination of poor cerebral haemodynamics and post-stent hypertension may induce a malignant cerebral hyperperfusion syndrome, especially when uncontrolled high blood pressure occurs [17, 18]. Therefore, we took particular care to control the blood pressure during both the angioplasty and the surgical procedure. These data show that selective carotid angioplasty was safe both during carotid stenting and after a cardiosurgical procedure and that none of the patients in this cohort experienced a malignant cerebral hyperperfusion syndrome.

In this cohort, we observed that complex cardiac surgery in patients around 70 years with multiple vascular risk factors and occlusive cerebrovascular disease not only introduced a 9.5% risk of postoperative delirium but was also associated with a 9.1% mortality rate at 30 days in patients with poor cerebral haemodynamics. This observation is consistent with earlier observations in the REACH Registry, which showed that asymptomatic carotid artery stenosis was associated with high 1-year rates of both cardiovascular and cerebrovascular ischaemic events [19]. In other words, with the HBS we can potentially reduce the rate of severe haemodynamic strokes, but we cannot influence all factors that affect the outcomes (such as vessel wall stiffness, intravascular ulcers and obstructions of small- and medium-sized vessels). It should be of value to explore whether waiving cardiac surgery or opting for less invasive procedures (such as transcatheter aortic valve implantation or coronary stent placement) in patients with occlusive cerebrovascular disease would be an effective strategy, not only to reduce the rate of haemodynamic strokes after cardiac surgery but also to increase lifespan and quality of life.

Limitations

This study has a number of limitations. First, the number of patients is limited to allow for an advanced statistical analysis such as multiple regression analysis. Though more study participants are needed, we do feel that careful conclusions may be made: The absence of the occurrence of severe stroke and cerebral hyperperfusion syndrome following selective angioplasty suggests that this strategy is sufficiently safe (and the potential benefit sufficiently large) to warrant further exploration. This pilot study underlines the hypothesis that the HBS and selective angioplasty may comprise a promising strategy to reduce the burden of strokes following cardiac surgery.

The second limitation has already been discussed in the Methods section: study Group 1 is not the optimal match for the study group of patients because symptomatic patients (study Group 1) are compared with asymptomatic patients (study group). However, this second-best option provides insight into the outcome of stenting procedures at the Haga, which must be taken into account to interpret our results.

The third limitation is that it appears somewhat incorrect to use an anatomical study (CTA) as a surrogate for a haemodynamic study (TCD) in the assessment of the status of the cerebral collateral arteries. CTA, for instance, may provide an underestimation of cerebral collaterals because of lack of contrast. We have minimized this limitation using a multidetector CT and advanced imaging software, which allows high-resolution 3D visualization of the circle of Willis. Furthermore, nearly all patients in whom the collateral status was estimated by CTA showed both an absent anterior and posterior communicating artery. We believe that the absence of both communicating arteries bridge to a certain extent the gap between anatomical and dynamical flow studies.

CONCLUSION

In summary, this retrospective study shows that when selective carotid angioplasty was used in patients with high-grade stenosis and poor cerebral collaterals, they did not experience severe neurological deficits following cardiac surgery. Although the HBS does not prevent strokes in these high-risk patients, the data suggest that the procedure shifts the type of postoperative stroke from the sometimes severe haemodynamic stroke towards more likely minor embolic strokes, which have a good prognosis. However, both CAS and cardiac surgery expose these often-frail patients to an increased risk of systemic complications, which may be life-threatening. It must be emphasized that the selective CAS procedure is only one aspect of the HBS, which may have led to the reduction of the incidence of cerebral ischaemia after cardiac surgery. The other important aspect is that waiving surgery in patients with multilevel occlusive cerebrovascular disease may have contributed as well to the reduced rates of post-surgical stroke and delirium.

To date, the positive outcome of the HBS strategy has been based on the results from 3 observational studies [9–11]. The results are supported by the results from John Murkin's randomized controlled trial, which showed that cerebral oximetry enhanced the outcome of patients scheduled for cardiac surgery [20]. Based on the aforementioned studies, it seems unethical to examine the HBS in a randomized controlled trial. Therefore, we feel that a multicentre observational study before and after implementation of the HBS would be the preferred option to further establish the value of the HBS. Before implementation, we suggest monitoring the clinical events related to cerebral ischaemia for at least 1–2 years in a large number of patients. Suggested clinical end-points are stroke incidence, stroke severity (NIHSS) and delirium rate. After implementation of the HBS, the effect on neurological outcomes may be compared with the results from the treatment groups in this multicentre cohort.

Conflict of interest: Rudolf W.M. Keunen developed universal software for embolus detection by TCD, which is distributed by the SMT Medical in Germany on Delicate TCD instruments; presented stroke prevention lectures sponsored by Medtronic/Covidien; and served as an advisor for Medtronic/Covidien. All other authors declared no conflict of interest.

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