SIMULTANEOUS BILATERAL CAROTID STENTING: A SINGLE CENTRE EXPERIENCE

Yusuf Can¹, Ibrahim Kocayigit¹

ABSTRACT

Objective: To evaluate the efficiency, reliability and complications of simultaneous bilateral carotid artery stenting in patients with atherosclerotic bilateral carotid artery stenosis.

Methodology: We analyzed 14 consecutive patients who underwent simultaneous bilateral carotid stenting from September 2010 to January 2016, retrospectively. Clinical outcomes at 30 days and one year after stenting, including hyperperfusion syndrome, haemodynamic depression, minor and major stroke, myocardial infarction and death, were assessed.

Results: The patients were 43 to 73 (62.3 ± 8.8) years old, and 8 (57.1%) were male. Carotid stenting procedure success rate was 100%. Distal embolic protection devices were used in all patients. Up to 30 days after carotid artery stenting, the haemodynamic depression rate was 21.4% (3/14). There were no deaths, minor and major strokes, cases of hyperperfusion syndrome or myocardial infarctions within 30 days. One patient died of septic shock seven months after carotid artery stenting. There were no minor and major strokes or myocardial infarctions within one year.

Conclusion: The data showed that simultaneous bilateral carotid stenting is a technically feasible and reliable alternative treatment method in a selected group of patients with bilateral carotid artery disease.

Keywords: Bilateral carotid stenosis, simultaneous bilateral carotid artery stenting, atherosclerosis
INTRODUCTION

Stroke is a primary cause of long-term disability in developed countries and the third most common cause of mortality. A total of 15% to 20% of all strokes are caused by atherosclerotic carotid stenosis, and the most common location of these stenoses is the margin of the proximal internal carotid artery and carotid artery bifurcation. The incidence of bilateral carotid stenosis in patients undergoing carotid stenting (CAS) was reported to reach up to 51%. In patients at high surgical risk, CAS along with embolic protection systems also has been shown to be a proper alternative to carotid artery endarterectomy (CEA). Since, to our knowledge, there are no randomized clinical studies on those with bilateral carotid stenosis, the optimal treatment strategy is not fully known, and staged bilateral carotid stenting (BCAS) could be an alternative treatment method due to the risk of haemodynamic depression (HD) and hyperperfusion syndrome (HPS). However, there are disadvantages with staged BCAS, such as high cost, reluctance of the patient and delay of a lifesaving treatment, such as cardiac surgery. In recent years, the frequency of simultaneous BCAS has been increasing. We evaluated the short-term efficiency and reliability of simultaneous BCAS retrospectively.

METHODOLOGY

Of 240 patients at high surgical risk who underwent CAS between September 2010 and January 2016, 14 underwent simultaneous BCAS. The patients were evaluated by at least two interventional cardiologists, and those who had symptomatic >50% and asymptomatic >70% common or internal carotid artery stenosis, measured angiographically by the North American Symptomatic Carotid Endarterectomy Trial (NASCET) method, were included in the study. Patients with carotid occlusion, those in whom stenting was performed at the time of acute stroke, as well as those with disorders, such as fibromuscular dysplasia, dissection and vasculitis, that led to carotid stenosis (except for atherosclerosis) were excluded from the study. All patients had at least one comorbid condition or health problem that caused them to be regarded as at high risk for CEA, such as cardiac diseases of clinical importance, congestive heart failure (New York Heart Association [NYHA] functional class III/IV), abnormal stress test, requirement for open-heart surgery, unstable angina (Canadian Cardiovascular Society [CCS] class III/IV), left ventricular ejection fraction ≤ 30%, placement of a planned coronary artery bypass graft or valve, severe pulmonary disease, chronic obstructive pulmonary disease manifesting by forced expiratory volume (FEV) ≤ 30%, contralateral carotid occlusion or stenosis, former radical neck surgery or radiation therapy on the neck, recurrent stenosis after endarterectomy, age ≥ 75 years, surgically inaccessible lesion at or above C2 or below the clavicle, laryngeal palsy or laryngectomy, symptom onset within two weeks, neurological symptom variation (National Institutes of Health Stroke Scale [NIHSS] ≥ 4) within 48 hours from onset, arteriosclerosis obliterans, cancer, medical record of major surgery within the past year and renal problems (creatinine level > 1.5 mg/dL). Patients who experienced stroke, transient ischaemic attack and transient loss of vision within the past six months and who also had common carotid artery or internal carotid artery stenosis in the same region were evaluated as symptomatic.

All study patients underwent a complete before and after CAS neurological examination performed by an independent neurologist. To evaluate the carotid arteries, intracranial arteries and aortic arch anatomy before the procedure, the patients underwent one or more carotid Doppler ultrasonography (USG), cranial computed tomography (CT) angiography or magnetic resonance imaging (MRI) angiography examinations. Before the procedure, diffusion-weighted MRI or MRI was performed on the patients.

At least five days before the procedure, 75 mg clopidogrel and 100 mg acetyl salicylic acid were begun in all patients as antiplatelet treatment. No sedative drug was administered before the procedure so as not to influence the neurological evaluation.

All procedures were performed with the patient under local anaesthesia by placing an 8 French (Fr)
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introducer sheath into the common femoral artery. A 5F Simmons-2 catheter over a 0.035-inch hydrophilic cord was placed into the common carotid artery to allow for selective imaging of each carotid artery. The carotid arteries and cranial vessels were evaluated with at least two images, including lateral and anterior views. Following carotid angiography, an 8 Fr JR4 guiding catheter (Launcher, Medtronic, Inc., Minneapolis, MN, USA) was placed into the common carotid artery. A 5000 to 10,000 U dose of intravenous heparin was administered such that the average activated coagulation time would be approximately 250 seconds. Afterwards, a distal embolic protection filter was placed in all patients (EmboshieldNAV; Abbott, Santa Clara, CA, USA). Patients with ≥90% stenosis, or those with a lesion that did not allow passage for stenting underwent pre-dilatation with 4.0 × 20 and 5.0 × 20 mm balloons. Under the distal embolic protection filter, the procedure was performed with a self-expendable stent (XACT; Abbott Vascular, Galway, Ireland). Residual stenosis <30% was evaluated as the optimal range opening. Post-dilatation with Viatrac 14 Plus 5 × 20 balloons was performed in patients in whom no optimal opening could be ensured (Figure 1A-B, Figure 2A-B).

Figure 1: A) Selective angiogram shows a high-grade stenosis of 80% in the left internal carotid artery. B) Selective angiogram after stent deployment in the left internal carotid artery.

A

B

To avoid development of bradycardia and hypotension, 1 mg intravenous atropine was administered 30 seconds before stenting or balloon dilatation. At the end of the procedure, the cranial vessels and carotid arteries were re-evaluated through lateral and anterior images without removing the embolic protection filter with a retraction catheter. Patients who experienced deep hypotension were followed with intravenous fluid and dopamine infusion. In the wake of the treatment process, all patients were recommended dual antiplatelet therapy for six months, whereas lifelong aspirin therapy was recommended. After the procedure, all patients were monitored for 24 hours or more in the coronary intensive care unit, and neurological examinations additionally were performed. Blood pressure (BP) levels were kept between 110/80 and 130/90 mmHg.

Residual stenoses ≤30% as well as no complication experienced after CAS was considered to indicate operative success. Stroke was defined as neurological sequela lasting more than 24 hours. Minor stroke was defined as the recovery of symptoms within 30 days, whereas major stroke was defined as continuation of symptoms after 30 days. Transient ischaemic attack, on the other hand, was defined as neurological events lasting less than 24 hours, leaving no sequela.

Figure 2: A) Selective angiogram shows a high-grade stenosis of 80% in the right internal carotid artery. B) Selective angiogram after stent deployment in the right internal carotid artery. Arrows show the stent deployed into the right carotid artery in the same procedure.

Regarding the diagnosis of HPS, an ipsilateral (to the treated artery) throbbing headache with or without nausea, vomiting, or ipsilateral focal seizures, or the presence of a focal neurologic deficit without having any radiographic evidence of infarction was observed. Any symptomatic or asymptomatic hypotension (systolic BP, 90 mmHg or bradycardia, for example, heart rate, 50 beats/min) was specified as HD, without requiring any adjunctive atropine, liquid support or any vasopressor agent.

The patients were evaluated by clinical and carotid Doppler USG imaging at one and six months and one year. Restenosis was defined as stenosis ≥70%
according to NASCET criteria. In the imaging process, stenosis was evaluated initially by carotid Doppler USG and then was verified by carotid angiography. The primary endpoint was accepted as all-cause mortality, major or minor stroke, periprocedural transient ischaemic attack and periprocedural myocardial infarction as well as restenosis verified through angiography within a year.

The protocol of the study had been approved by the Ethical Committee of Sakarya University.

Data were analysed using SPSS 17.0 (SPSS, Inc., Chicago, IL, USA). Compliance of the variables with the normal distribution was determined using the Kolmogorov–Smirnov test. Continuous variables showing a normal distribution were specified as mean ± standard deviation, whereas those showing no normal distribution were specified as the median (the smallest and greatest values). Categorical data were expressed in percentages. No comparative analysis was performed, since there was no control group.

RESULTS

A total of 14 patients (8 males) undergoing bilateral BCAS were included in the study. The basic features of the patients are shown in Table 1. Average patient age was 62.3±8.8 years. Of the patients, 11 had a history of a stroke or transient ischemic attack within the past six months. One patient underwent pre-coronary bypass surgery, whereas 3 who underwent an intervention were asymptomatic. Left ventricular ejection fraction in 2 patients was <30%. Eight patients had diabetes mellitus, 11 hypertension, 7 coronary artery disease, 3 a history of smoking, 6 hyperlipidaemia and 1 renal failure. The characteristics regarding simultaneous BCAS are shown in Table 2. In all patients, a self-expendable stent and distal embolic protection device were used, and 100% angiographic operative success was achieved. Ten patients underwent a total of 15 pre-dilatations before the stenting procedure. A total of nine direct stent implantations were performed in 8 patients. Since no optimal opening could be maintained through direct stent implantation in 3 patients, post-dilatation was performed with a balloon; hence, an optimal opening was attained. During or after the procedure, HD developed in 3 patients. No neurological sequela developed in these patients who were followed with careful evaluation of tension as well as fluid and dopamine therapy.

Table 2: Procedural data of simultaneous SBCAS

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>%</th>
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<tr>
<td>Operational success</td>
<td>14</td>
<td>100</td>
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<tr>
<td>Pre-dilatation</td>
<td>15</td>
<td>53.6</td>
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<tr>
<td>Post-dilatation</td>
<td>3</td>
<td>10.7</td>
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<tr>
<td>Pre + post-dilatation</td>
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<td>3.6</td>
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<tr>
<td>No dilatation</td>
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<td>32.1</td>
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<tr>
<td>Distal protection device</td>
<td>28</td>
<td>100</td>
</tr>
<tr>
<td>9-7x40 Stent</td>
<td>16</td>
<td>57.1</td>
</tr>
<tr>
<td>8-6x40 Stent</td>
<td>12</td>
<td>42.9</td>
</tr>
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</table>

Table 1: Balloon Size Used for Predilatation and Postdilatation

<table>
<thead>
<tr>
<th>Sno.</th>
<th>Age (years)</th>
<th>Sex</th>
<th>Lesion side/ Symptom</th>
<th>Risk factors</th>
<th>Stenosis degree</th>
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<td>1</td>
<td>61</td>
<td>Male</td>
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<td>DM, HT, CAD, PAD, HL</td>
<td>RICA: 80%,</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>LICA:S</td>
<td></td>
<td>LICA: 90%</td>
</tr>
<tr>
<td>2</td>
<td>65</td>
<td>Female</td>
<td>RICA:S</td>
<td>DM, HT</td>
<td>RICA: 80%,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>LICA:A</td>
<td></td>
<td>LICA: 90%</td>
</tr>
<tr>
<td>3</td>
<td>62</td>
<td>Male</td>
<td>RICA:S</td>
<td>DM, HT, SMOKE</td>
<td>RICA: 80%,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>LICA:A</td>
<td></td>
<td>LICA: 99%</td>
</tr>
<tr>
<td>4</td>
<td>67</td>
<td>Male</td>
<td>RICA:A</td>
<td>DM, HT, CAD, HF</td>
<td>RICA: 99%,</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>LICA:S</td>
<td></td>
<td>LICA: 90%</td>
</tr>
<tr>
<td>5</td>
<td>43</td>
<td>Female</td>
<td>RICA:S</td>
<td>HT, PAD, SMOKE</td>
<td>RICA: 99%</td>
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<tr>
<td>No.</td>
<td>Age</td>
<td>Gender</td>
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<td>RICA:</td>
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<td>CAD, PAD</td>
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<tr>
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<td>RICA:</td>
<td>HT, HL</td>
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<tr>
<td>13</td>
<td>69</td>
<td>Female</td>
<td>RICA:</td>
<td>DM, HT, HL, PAH</td>
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</tr>
<tr>
<td>14</td>
<td>66</td>
<td>Male</td>
<td>RICA:</td>
<td>None</td>
<td>DM, HT, HL, PAH</td>
</tr>
</tbody>
</table>


In the present study, in which 14 simultaneous BCAS procedures were done, the rate of cardiovascular deaths, minor and major strokes and myocardial infarction at 30 days and one year was 0%, which compared favorably with the data from the recent literature. One patient (patient 3) died of septic shock seven months after carotid artery stenting.

Carotid artery stenting has been used increasingly as a minimally-invasive alternative to CEA. In patients with bilateral carotid stenosis, the complication risk during or after unilateral CAS increases. Simultaneous BCAS or a staged BCAS procedure within the same session can be performed during the patient’s hospital stay or after rehospitalisation, respectively. To our knowledge, the eligibility of BCAS was reported for the first time by Mathur in 1997. Diehm et al. found no statistically significant difference between the primary and secondary endpoints in patients who underwent staged BCAS and unilateral CAS (6.8% and 8.9%; P = 0.66). Dong et al. found no statistically significant difference in major stroke and all-cause mortality and myocardial infarction at one and six months in patients who underwent unilateral CAS and simultaneous BCAS (4.6% vs. 5.1%; P = 1.000 and 5.1% vs. 7.7%; P = 0.459, respectively). Yongkun et al. found no difference in 30-day complication rates in patients who underwent simultaneous and staged BCAS (4.8% vs. 7.7%; P = 0.633).

In a study involving 10 patients, Chen et al. reported no instance of mortality, stroke or myocardial infarction. Again, similarly, Dong et al. reported that the incidences of 30-day HPS, HD, minor stroke, major stroke, myocardial infarction and mortality in patients who underwent simultaneous BCAS were 2.6% (1/39), 28.2% (11/39), 5.1% (2/39), 0, 2.6% (1/39) and 2.6% (1/39), respectively. In our study, no minor or major stroke, myocardial infarction or mortality was observed. Therefore, we believe we have achieved better results in our study than the others. Our study suggested that simultaneous BCAS can be performed at experienced centers in a technically proper and secure fashion.
Major complications associated with CAS are cranial thromboembolic events, which may occur during or after the procedure. Such a risk has diminished a great deal thanks to the use of embolic protection devices, which also is important in terms of introducing the advantages of using a distal embolic protection device. Furthermore, we believe that no thromboembolism was observed because a distal embolic protection device was used routinely in all of our patients who underwent CAS at our clinic. Separately, we also agree that the experience of the operator who performed this procedure is quite important, and it also was emphasized particularly in the guidelines that the individual who was to perform the involved procedure must be quite experienced in his field.

HPS was first defined by Sund et al. in 1981. The rapid and partially uncontrolled cerebral flow that occurs with recovery of stenosis causes a cerebral HPS on the cerebrovascular autoregulation floor that is disrupted due to the stenosis in patients with carotid artery stenosis. Another mechanism thought to give rise to hyperfusion, on the other hand, is rebound arterial hypertension that develops post-operatively, and, hence, the hyperperfusion occurs in the wake of bradycardia and hypotension, which develop because of excitation of the baroreceptor during the course of the procedure. The risk factors for HPS were reported as severe ipsilateral stenosis, contralateral carotid stenosis, history of stroke, advanced patient age, weak collateral flow, diabetes and hypertension. In the wake of CAS, the incidence of HPS is approximately 1%, whereas the rate of intracranial haemorrhage is 0.7%, and the prognosis worsens when intracranial haemorrhage is observed. Ipsilateral cerebral oedema is observed by CT and MRI. Dong et al. reported a 2.6% incidence of HPS due to simultaneous BCAS. They found no difference in the incidence of HPS in patients who underwent unilateral CAS and simultaneous BCAS (2.1% and 2.6%; P = 0.262). Yonkun et al. found no difference in HPS in patients who underwent simultaneous and staged BCAS (4.8% and 0%; P = 0.521). A close follow-up of BP and clinical picture of the patient is of vital importance in terms of bringing BP under control and preventing or alleviating the clinical picture in this manner. In none of our patients was any HPS observed. The fact that our patients were few in number and that the mean patient age was lower than that of the other studies might have contributed to our observing no HPS at all. Apart from this, having maintained BP regulation such that systolic BPs in patients would range from 110 to 130 mmHg also may have contributed to our seeing no HPS at all.

The baroreceptors that regulate heart rate and BP regulation are found in the carotid sinus, and the most important cause of bradycardia and hypotension seen in patients who undergo CAS is excitation of the baroreceptors during placement of an intravascular stent/balloon. In the former studies, age, medical record regarding coronary artery disease, hypertension, degree of stenosis, plaque diameter, plaque calcification and increased balloon pressure were associated with HD. Dong et al. reported a 28.2% incidence of HD due to simultaneous BCAS. They found no difference in the incidence of HD in patients who underwent unilateral and simultaneous CAS (20.5% and 28.2%; P = 0.396). Yonkun et al. found no significant difference in the incidence of HD in patients who underwent simultaneous and staged BCAS (57.1% and 57.7%; P = 0.957). To prevent the development of HD, anticholinergic drugs may be administered before placing any intravascular stent/balloon. Separately, in the event of HD, fluid therapy, vasopressor agents and/or anticholinergic treatment may be administered.

We administered an anticholinergic agent to our patients before placing any intravascular stent/balloon. Although HD developed in 3 of our patients (patients 4, 8, 11), no mortality, myocardial infarction or stroke occurred in patients in whom HD had developed. Our patients with HD received fluid therapy and vasopressor treatment. HD was observed in patients whose preoperative stenosis was ≥90% and who underwent post-dilatation. The hospitalisation periods in our patients with HD were extended compared to those without HD. In our study, HD was observed on a lower level than that noted in the former studies. The reason for this could be administration of anticholinergic treatment, a younger patient population and keeping the balloon pressure used for dilatation at a lower level.

The most important restriction of our study was that it was a single-centered retrospective study with prominently few patients. The other major restriction was that, apart from the fact that we were unable to compare patients who underwent BCAS to those who underwent bilateral CEA, there also was no comparative datum pertaining to symptomatic and asymptomatic patients. Additionally, another restriction was that we could not compare unilateral CAS and BCAS, nor could we compare patients who underwent simultaneous and staged BCAS.
CONCLUSION

In conclusion, simultaneous BCAS was performed successfully at our center. The complication risk was quite low when simultaneous BCAS was performed along with the use of distal embolic protection devices at experienced centers. Simultaneous BCAS can be performed in a technically proper and reliable manner, and the short-term clinical results of simultaneous BCAS process are quite pleasing.

REFERENCES


Simultaneous Bilateral Carotid Stenting


