The Clinical Outcomes of 75 Consecutive Patients with Cervical Carotid Artery Stenosis Treated by Carotid Artery Stenting

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Objective: The purpose of this study was to analyze the clinical outcome of 75 consecutive patients with cervical carotid artery stenosis and who were treated by carotid artery stenting (CAS) only.

Methods: From February 2003 to June 2008, there were 78 stents placed in 75 symptomatic patients (mean age: 67.3 years); 69 patients had carotid stenosis ≥70%, and 6 patients had asymptomatic stenosis ≥80%. No carotid endarterectomy (CEA) was performed during the same period. The patients were clinically followed-up for a mean of 20.1 months.

Results: The procedures were technically successful in all cases. Three (3.8%) patients had procedure-related complications. During the 30-day postprocedural period, there were no restenosis or major stroke. Minor stroke was noticed in 3 (3.8%) patients and 1 (1.3%) of the 75 patients suddenly expired 2 days after discharge. There were no new neurological symptoms that developed during the clinical follow-up period. The results of our series were not inferior to those the previously published in CAS studies, and in fact they were better.

Conclusion: Our results suggest that CAS may be safe and useful for the treatment of cervical carotid artery stenosis when it is used as the first line treatment in those institutions that lack enough experience with CEA.

KEY WORDS: Carotid artery stenosis · Carotid artery stenting · Carotid endarterectomy · Stroke.
offered only CAS to all the symptomatic patients or asymptomatic patients (6 patients) with arteriographically defined carotid stenosis ≥70%.

The purpose of this study was to analyze the clinical outcome of 75 consecutive patients with cervical carotid artery stenosis and who were treated by CAS only.

MATERIALS AND METHODS

Patient population
Among the 79 patients (82 arteries) who were treated by CAS between February 2003 and June 2008, the patients who had traumatic dissection (n=4) were excluded. We treated 75 patients (78 arteries) who had carotid artery stenosis by CAS. All the patients displayed symptomatic severe carotid artery stenosis of more than 70% except 6 patients with asymptomatic carotid artery stenosis of more than 80%. No CEA was performed during the same period.

We retrospectively reviewed the 75 patients for their medical conditions, the initial presentation, the angiographic characteristics of carotid artery stenosis with the stenosis ratio, the technical success rate, the procedure-related complications and the clinical outcomes, as assessed by the 30-day morbidity and mortality. Any new neurologic deficits were scored with using the National Institutes of Health Stroke Scale (NIHSS)\(^1\). Those patients who had a new neurological event lasting longer than 24 hours with an increase in the NIHSS less than 3 and this resolved completely within 30 days were classified as having a minor stroke. A major stroke was defined as a new neurological event that lasted longer than 24 hours, with an increase in the NIHSS greater than 3\(^1\). The patients were clinically followed-up for a mean of 20.1 months (range : 2 to 52 months).

Clinical Manifestations
Table 1 summarizes the clinical and radiological characteristics of the 75 patients with severe carotid artery stenosis. Sixty (80.0%) patients were male and their mean age was 67.3 years (age range : 28 to 90 years). Twenty-two (29.3%) patients had a previous stroke and 46 (61.3%) patients initially had hemispheric symptoms, while only 5 (6.7%) had retinal symptoms. The percent ICA stenosis at the lesion side was a mean of 85.1%.

Carotid artery stenting
The patients received clopidogrel (75 mg/day) and aspirin (100 mg/day) for at least 2 weeks before CAS. The procedures were performed under local anesthesia with strict monitoring of the blood pressure. Among the 78 cases, we used an embolic protection device in the 30 more recent cases.

| Variable | No. of patients (%) |
|----------|---------------------|
| No. of patients | 75 |
| No. of CAS | 78 |
| Technical success | 78 (100) |
| 30-day morbidity and mortality | 1 (1.3) |
| Mortality rate | 1 (1.3) |
| Major stroke | 0 (0) |
| Minor stroke | 3 (3.8) |
| Myocardiac infarction | 0 (0) |
| Procedure-related complication | 3 (3.8) |
| Restenosis at 6 months | 2 (2.6) |

CAS : carotid artery stenting, PVD : peripheral vascular disease, CEA : carotid endarterectomy, ICA
DISCUSSION

CEA has been used to successfully treat extracranial carotid occlusive disease since the NASCET proved its efficacy in 1991. Although the CAVATAS trial and the SAPPHIRE trial have helped CAS become a proper treatment option for extracranial carotid artery stenosis, recent studies have overturned the trend of CAS so that CEA has again come to the forefront. CEA is now regarded as the treatment of choice for carotid stenosis, but many studies have tried to prove that CAS is not inferior to CEA.

Despite of the worldwide trend for performing CEA, our hospital has provided only CAS. Due to the small number of patients with carotid stenosis and our limited experience with CEA, we could not guarantee a reasonable outcome for CEA with periprocedural morbidity and mortality rates of 4% to 6%. In such a situation, we have offered CAS to all the symptomatic patients with carotid artery stenosis (≥70%) and to all the asymptomatic patients with carotid artery stenosis ≥80% at our institution no matter what their risk factors are, even though CAS is usually acceptable when it is offered to the patients who have the medical, angiographic, technical and neurological risk factors to perform CEA. We then compared the result of our CAS series to the results from the worldwide published studies of CAS and CEA.

CAVATAS is a large, prospective, randomized, multi-center trial that compared CEA to CAS. There was no significant difference in the risk of stroke or death related to the procedure between CEA and CAS. The rate of any stroke lasting more than 7 days or death within 30 days of the first treatment was about 10% in the CEA or CAS groups. The rate of disabling stroke or death within 30 days of the first treatment was 6% in both groups. The SAPPHIRE trial randomized 307 high-risk patients to CEA or CAS with using a distal protection device. The perioperative stroke (major stroke and minor stroke) and death rates were 7.3% for CEA versus 4.4% for CAS. The rates of myocardial infarction were 7.3% for surgery versus 2.6% for stenting. In 2001, Roubin et al. reported on the results of 604 CAS procedures in 528 patients. The reported rate of technical success was 98%; the procedure related mortality rate (including cardiac death) was 1.6%, the major stroke rate was 1%, the minor stroke rate was 4.8% and the 6-month restenosis rate was 3%. In 2004, Yadav et al. reported on the result of CAS in 159 patients. The mortality rate was 0.6% with a minor stroke rate of 3.1%, a major stroke rate of 3.1% and a 12-month restenosis rate of 0.7%.

Our results cannot be directly compared with the previously published results because of the non-randomized, single-center, retrospective nature of our study. However, our study does provide evidence that CAS was safely performed at our institution. The morbidity/mortality rate (1.3%) of our series is much better than that of the AHA/ASA guideline's recommendation, which described that 'CAS is a reasonable treatment option when performed by

**Table 3. Outcomes according to the use of protection devices**

| Variable                        | PD used (%) | PD not used (%) | Total (%) | p-value (%) |
|---------------------------------|-------------|-----------------|-----------|-------------|
| No. of cases                    | 30          | 48              | 78        |             |
| Procedure related complication  | 1 (3.3)     | 2 (4.2)         | 3 (3.8)   | 0.655       |
| Minor stroke/Death              | 0 (0)       | 3 (6.3)         | 3 (3.8)   | 0.083       |
| Major stroke/Death              | 0 (0)       | 1 (2.1)         | 1 (1.3)   | 0.433       |
| Total                           | 1 (3.3)     | 6 (12.6)        | 7 (8.9)   | 0.122       |

p-value : evaluated by Student t-test. PD : protection device.
operators with established periprocedural morbidity and mortality rates of 4% to 6%. The thirty-day morbidity/mortality rate (1.3%), the restenosis rate (2.6%), the procedure-related complications (3.8%) and myocardial infarction (0%) were similar or quite better in our series as compared to the published results (Table 4). From the comparative analysis, we carefully suggest that CAS may be regarded as a proper treatment option at our institution even though comparative analysis of these reports is made difficult by the inconsistencies in the sample populations, the lesion characteristics, the surgical or endovascular techniques and the outcome data.

The result of our CAS series were also compared to the results of the worldwide published studies of CEA (Table 5). In 1991, NASCET performed 328 CEAs in patients with carotid artery stenosis more than 70%. The mortality rate within 30 days was 0.6%, with a major stroke rate of 1.5%. The ECST reported favorable results with 1745 symptomatic carotid stenosis patients. The reported rate of 30-day morbidity and mortality was 6.6%. Yadav et al. in 2004 reported on the results of 167 CEA procedures in patients with carotid artery stenosis more than 50%. The mortality rate was 12.6% with a minor stroke rate of 4.7%, a major stroke rate of 4.2% and a 12-month restenosis rate of 4.6%.

The result of our CAS series is better for the 30-day morbidity and mortality rates, the restenosis rate and the procedure-related complications, as compared with the previously reported results of CEA (Table 5), which emphasizes the suitability of CAS as a good treatment option for carotid artery stenosis.

In 2000, Adel et al. suggested that CAS may be useful for the treatment of symptomatic cervical carotid stenosis in high-risk patients with severe medical, angiographic and neurological risk factors. Yet, without being deterred by the high-risk factors for CEA or the indications for CAS, we obtained quite good result for treating all the patients with symptomatic carotid artery stenosis with offering CAS only. It would be better to find a proper treatment option for each institution rather than performing unpracticed or unskilled CEA. Thus, CAS could be an adequate treatment option for carotid artery stenosis at our institution. Having had its safety and efficacy proven (reasonable morbidity and mortality) with the operator's increased experience, CAS may become a good option for treating carotid stenosis in high volume medical institutions.

The outcomes for treating carotid stenosis have become better according to the development of new techniques, tools and the operator's accumulated experience. As for the embolic protection device, it helped reduce the periprocedural complications, morbidity and mortality in our series while there are some reported pros and cons about its efficacy. We obtained better outcomes when the protection device was used (Table 3), but this was not statistically

| References | No. of patients | No. of CAS | Asymptomatic stenosis (%) | Technical success rates | 30-Day morbidity/mortality (%) | Mortality rate (%) | Major stroke rate (%) | Minor stroke rate (%) | Myocardial infarction (%) | Procedure-related complication (%) | Restenosis rate (%)
|-------------|----------------|------------|--------------------------|------------------------|-----------------------------|-------------------|--------------------|--------------------|-----------------------------|-----------------------------|----------------|
| Our series  | 75             | 78         | 8.0                      | 95.1                   | 100                         | 1.3               | 1.3                | 0.0                | 3.8                         | 0.0                         | 3.8            |
| Roubin      | 528            | 604        | 48.0                     | 74                     | 98                          | 2.6               | 1.6                | 1.0                | 4.8                         | 1.0                         | 2.0            |
| Yadav       | 159            | -          | >60                      | -                      | -                           | 3.7               | 0.6                | 3.1                | 3.1                         | 1.9                         | 1.9            |
| CAVATAS     | 251            | -          | >30                      | 89                     | 6.0                         | 3.0               | 4.0                | 4.0                | 0.0                         | -                           | 1.0            |
| SAPPHIRE    | 156            | -          | >50                      | -                      | 1.2                         | 0.6               | 0.6                | 3.2                | 2.6                         | -                           | -              |

Table 4. Comparison of our series of carotid artery stenting to previously published studies

| References | No. of patients | No. of CAS or CEA | Asymptomatic stenosis (%) | Technical success rates | 30-Day morbidity/mortality (%) | Mortality rate (%) | Major stroke rate (%) | Minor stroke rate (%) | Myocardial infarction (%) | Procedure-related complication (%) | Restenosis rate (%)
|-------------|----------------|-------------------|--------------------------|------------------------|-------------------|-------------------|--------------------|--------------------|-----------------------------|-----------------------------|----------------|
| Our series  | 75             | 78                | 8.0                      | 95.1                   | 100                | 1.3               | 1.3                | 0.0                | 3.8                         | 0.0                         | 3.8            |
| Yadav       | 167            | -                  | >50                      | -                      | -                  | 16.8              | 12.6               | 4.2                | 4.7                         | 7.5                         | 4.9            |
| CAVATAS     | 253            | -                  | >30                      | -                      | -                  | 6.0               | 2.0                | 4.0                | 4.0                         | 1.0                         | 17.0           |
| SAPPHIRE    | 151            | -                  | >50                      | -                      | -                  | 4.0               | 2.0                | 2.0                | 3.3                         | -                           | 3.3            |
| NASCET      | 328            | -                  | >70                      | -                      | -                  | 3.0               | 0.6                | 1.5                | 3.7                         | 0.9                         | 9.3            |
| ECST        | 1745           | -                  | All                      | -                      | -                  | 6.6               | 0.9                | 2.3                | 3.5                         | -                           | -              |

Table 5. Comparison of our series of carotid artery stenting to representative series of carotid endarterectomy

353
significant. One (4%) of the 25 patients for whom we used the embolic protection device had asymptomatic procedure-related complications, while 6 (14.6%) of the 41 patients who didn’t have the device used had procedure-related complications (4.9%), minor stroke (7.3%) and death (2.4%).

CONCLUSION

If CEA doesn’t show adequate treatment outcomes due to the lack of experience, then CAS could be the first line treatment for carotid stenosis with reasonable outcomes.

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