Results of endovascular management of carotid disease at San Juan de Dios Hospital from January 2007 to February 2010

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Abstract:

Background and aim: To determine the morbi-mortality of patients treated with endovascular stenting for Carotid Artery disease at San Juan de Dios Hospital, Costa Rica; from January 2007 to February 2010.

Methods: A retrospective observational registry of patients treated with Carotid Artery endovascular stenting was maintained at our institution over 13 months. Based on the information acquired from medical records, two subgroups were identified: symptomatic and asymptomatic. Some aspects were researched and evaluated such as risk factors, ABCD2 scale, affected cerebral territory, invasive and non-invasive lesion measurements, stent sizing and finally peri-operatory complications.

Results: 76 patients were identified in this series, 87% (n=66/76) symptomatic and 13% (n=10/76) asymptomatic. The most frequent risk factor was hypertension, followed by smoking. Underestimation by ultrasound of lesion severity was found in up to 24% (n=18/76) of patients. Predilatation was done in 55% (n=42/76) and most frequent stent sizes identified were 7x30mm or 8x30mm in 47% (n=36/76) of patients. Neurologic morbidity of asymptomatic patients was 0%, and in the symptomatic group was a 3% (2/66).

Conclusion: Endovascular therapy demonstrated to be a safe and effective as a revascularization technique; however larger patient series should be investigated for greater statistical significance.

Keywords: Endovascular procedures, Carotid Stenosis, stroke

Strokes are a major cause of mortality and permanent disability in the world, affecting not only those that experience them, but also their family and community1. Circulatory system diseases are the leading cause of death in Costa Rica, and it has been deduced that as the elderly population increases, the number of stroke cases will increase worldwide; thus, by 2030, the number of deaths due to strokes will double.2

The NIH (National Institute of Health) and the NINDS (National Institute of Neurological Disorders and Stroke)3, as well as the Spanish guidelines for the primary and secondary prevention of ictus, classify the risk factors for this disease in unmodifiable, among them, age, male gender, African-American race and hereditary factors; and modifiable, such as hypertension, diabetes mellitus, cigarette smoking, obesity, lack of physical activity, high blood cholesterol levels, sickle-cell disease, alcoholism, hormonal therapy, atrial fibrillation, carotid stenosis, left ventricular hypertrophy, hypercoagulation and prior strokes.4

Knowledge about these risk factors and the completion of massive studies on invasive treatment6-8 have allowed the implementation of primary and secondary preventive interventions that could lead to a decrease in stroke incidence. Among these, the carotid endarterectomy is considered the best therapeutic alternative9,10 for asymptomatic patients with stenosis equal or greater than 80%10, leading to a 5.9% fall in strokes at 5 years,11 and for symptomatic
patients with stenosis greater than or equal to 50\%^{5,10}, resulting in a falloff up to 13.3 to 15.6\% at 5 years.\(^5,11\)

Endovascular treatment as an option is still under research, however, there are different opinions among operators as international studies have tended to cast more doubts than clarifications. However, after the SAPPHIRE study (The Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy)\(^10\) and a Cochrane analysis of 5 randomized studies\(^4\), no significant difference was found in the complications that resulted from open or endovascular carotid surgery in patients at high surgical risk. For this reason, in 2005 the FDA\(^12\) accepted endovascular therapy for specific groups of patients.

Due to the risks involved in this type of surgery, the perioperative quality indexes required for the endarterectomy have been extrapolated. In other words, the patient should only undergo an open or endovascular revascularization procedure in centers with a perioperative morbimortality rate lower than 3\% in asymptomatic patients and lower than 6\% in symptomatic patients\(^1\). Therefore, the aim of this study is to quantify and analyze the perioperative morbimortality shown by a cohort of patients that received endovascular treatment in the Department of Vascular Medicine of the San Juan de Dios Hospital between January 2007 and February 2010.

\textbf{Materials and methods}

The medical records of patients discharged from San Juan de Dios Hospital treated with carotid revascularization therapy between January 2007 and February 2010 were reviewed. The information obtained was patient’s general data (age, sex, reason for admission), site of admission (outpatient clinic, emergency room, transfer, re-admission), stroke risk factors (hypertension, diabetes mellitus, cigarette smoking, alcoholism, atrial fibrillation, high blood cholesterol levels, carotid stenosis, hormone therapy, hypercoagulation, prior strokes), carotid artery disease (TCI or stroke) or asymptomatic, degree of carotid stenosis evidenced by ultrasound and arteriography; and finally, peri and postoperative complications. It should be noted that neurological complications were identified through NIHSS assessment performed by specialists in neurology. The hospital’s Research Ethics Committee approved the study (document 16-2010 CLOBI-HSJD).

\textbf{Results}

\textbf{Overview}

76 patients that received the mentioned treatment were identified. Out of this group, 13\% (n=10) were asymptomatic and 87\% (n=66) symptomatic. Most of them were in their 6\textsuperscript{th} decade (see figure #1) and only one patient that had suffered a previous stroke was in her twenties, she suffered from Takayasu Disease.

Out of the total of asymptomatic patients, 60\% (n=6) came to the Department of Vascular Medicine via the outpatient clinic, while 40\% (n=4) of them were transferred by other departments. None of them was admitted through the emergency service.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{Number of patients per age group treated with carotid endovascular therapy}
\end{figure}

In contrast, 64\% (n=42) of the symptomatic patients were admitted by the emergency service due to acute cerebrovascular symptomatology (stroke or TCI), 27\% (n=18) were admitted by the outpatient clinic, and 9\% (n=6) were transferred by another service.

In terms of stroke risk factors, the most frequent one in symptomatic patients is hypertension; followed by high blood cholesterol levels, cigarette smoking, prior stroke, alcoholism and diabetes mellitus; whereas, in asymptomatic patients, both hypertension and cigarette smoking have the same prevalence, followed by atrial fibrillation and dyslipidemia; there is a lower incidence of diabetes mellitus and alcoholism (see table #1). Hypercoagulation and sickle cell disease were not recorded in the medical records. However, when the patients' laboratory tests were reviewed, they showed that none of the patients suffered from said diseases. The presence of left ventricular hypertrophy was not recorded in 20 of the medical records reviewed. With respect to hormone replacement therapy, the patients' anamnesis did not record whether they had used it or not, therefore, it was not possible to determine the incidence of this risk factor.

\textbf{Severity of injury (percent stenosis)}

The preoperative ultrasound showed stenosis greater than 70\% in 100\% (n=10) of the asymptomatic patients, this concurred with the arteriographic findings.

In the symptomatic patients, the ultrasound showed a 50-70\% stenosis in 39\% (n=26) of patients and a 70-99\% one.
The most frequent stent sizes identified were the 8x30 ones, used in 31% (n=24) of the cases, followed by the 7x30 ones in 15% (n=12) of cases; the rest were not used that often. The performance of pre-dilation was recorded in 42 cases (55%) (n=42) and post-dilation was performed in all cases (n=76).

Pharmacotherapy

All patients were administered a 100 mg dose of aspirin per day, regardless of whether they were taking it. In addition, all were administered Clopidogrel premedication (a 300 mg loading dose on preoperative day), and a maintenance dose of 75 mg per day for a month after surgery.

During surgery high molecular weight heparin was administered to all patients, the mean dose was of 6000 IU (maximum 10,000 U and minimum 4000 U). Likewise, a 1 mg dose of Atropine was administered 2 minutes before handling the carotid sinus.

Complications

The asymptomatic patients did not experience complications, so the associated morbimortality was zero percent. None of them was assessed with the preoperative or postoperative NIHSS.

With regard to symptomatic patients, only two had postoperative neurologic deterioration, resulting in a 3% morbimortality (n=2/66). During the postoperative, one of the patients developed a conversion from an ischemic to a hemorrhagic stroke, which required assisted mechanical ventilation. Afterwards, the patient died due to a nosocomial pneumonia that aggravated his condition. The other one deteriorated the NIHSS from 3 to 5 because it suffered from left hemiparesis after surgery.

Discussion

Endovascular therapy for carotid artery disease is a matter of global concern. There is still no international consensus on its prescription. However, it seems prudent to determine the morbidity frequency in relation to the procedure for the sake of future decisions that impact on the welfare of our patients.

The age distribution of our patients follows the one reported by other authors in larger samples. However, the number of octogenarian patients in our sample that had good results is remarkable, despite the existence of scientific reports that claim greater morbimortality in patients older than 80 years.

A detail regarding the patient admission mechanism should be highlighted. Up to 27% of patients were admitted as a result of orders prescribed by the outpatient clinic. This does not guarantee a prompt admission of the patient.

Except for the case of very extensive ischemic events (which are readmitted at least 6 weeks later), all symptomatic
events (transient or obstructive) are emergencies that require early treatment of the carotid embolicogenic focus. This is why immediate admission, as an emergency, of patients in this condition must be required.

Sonographic screening is key to decision making in patients with carotid artery disease. However, there is no adequate correlation between the severity of the injury estimated from the ultrasound and the one found through the arteriography. It is essential to strengthen training in vascular sonographic screening of those responsible for undertaking the diagnosis studies, looking towards more real correlation; this would greatly aid the clinician in taking intelligent decisions regarding the management of these patients.

The objective measurement of the perioperative neurological condition was established with the assistance of the Neurology Department and using the NIHSS scale. 39% of patients were not assessed with this scale because it was established as a protocol only after the second half of 2008.

However, today is a useful and replicable tool that validates the results of an invasive procedure.

Furthermore, it helps establish in an objective manner the perioperative morbidity, thus aiding the clinician in the adoption of treatment decisions according to the operative risks faced by its patients when undergoing an invasive procedure. In the case of San Juan de Dios Hospital, international standards are met, something which is evidenced by a 0% morbidity in the treatment of asymptomatic patients (up to 3% is allowed) and a 3% (n=2/66) in symptomatic patients (up to 6% is allowed).

The deterioration in the NIHSS scale in 12 of the patients does not translate into adverse events for all this subgroup. This scale has a certain intra and inter-observer laxity, thus, the differences should be at least 4 points. This means that only 2 patients had a significant deterioration and were recorded as perioperative morbidity.

It is worth mentioning that one of the patients with the most morbidity had no trans or post-operative embolic injuries. However, in the immediate postoperative (during recovery), he developed a hypertensive crisis.

Despite this being a modest and initial sample of carotid endovascular therapy at San Juan de Dios Hospital, the goal is to exhibit the internaltreatment protocol and determine the perioperative morbidity. It is clear that the number of patients in this sample must be increased in order to seek greater statistical significance, however, the initial results are encouraging because they meet international standards. Moreover, they work as an objective tool to make appropriate clinical decisions.

**Table 1.** Percentage distribution of stroke risk factors in subgroups of symptomatic and asymptomatic patients treated with endovascular carotid therapy at San Juan de Dios Hospital during the period January 2007 to February 2010

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Symptomatic</th>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>76% (n = 58)</td>
<td>11% (n = 8)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>34% (n = 26)</td>
<td>3% (n = 2)</td>
</tr>
<tr>
<td>Cigarette smoking</td>
<td>53% (n = 40)</td>
<td>11% (n = 8)</td>
</tr>
<tr>
<td>Alcoholism</td>
<td>37% (n = 28)</td>
<td>3% (n = 2)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>0% (n = 0)</td>
<td>5% (n = 4)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>66% (n = 50)</td>
<td>5% (n = 4)</td>
</tr>
<tr>
<td>Left ventricular hypertrophy</td>
<td>32% (n = 24)</td>
<td>3% (n = 2)</td>
</tr>
<tr>
<td>Prior ictus</td>
<td>50% (n = 38)</td>
<td>0% (n = 0)</td>
</tr>
</tbody>
</table>

**Table 2.** Distribution of cases according to ABCD<sub>2</sub> scores in patients with transient cerebral ischemia treated with carotid endovascular therapy at the San Juan de Dios Hospital during the period January 2007 to February 2010

<table>
<thead>
<tr>
<th>Risk</th>
<th>ABCD&lt;sub&gt;2&lt;/sub&gt; scores</th>
<th>Number of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>1</td>
<td>2</td>
<td>9%</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>2</td>
<td>9%</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>6</td>
<td>27%</td>
</tr>
<tr>
<td>Moderate</td>
<td>4</td>
<td>4</td>
<td>18%</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>8</td>
<td>37%</td>
</tr>
</tbody>
</table>
References


