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ORIGINAL RESEARCH

Carotid angioplasty in diabetic patients carriers of critical carotid stenosis. Experience in a hospital in Mexico; results and six-month follow-up

Angioplastia carotídea en pacientes diabéticos portadores de estenosis carotídea crítica. Experiencia en un hospital en México; resultados y seguimiento a seis meses

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Key words:
Angioplasty, carotid stenting, stroke, diabetes mellitus, Mexico.

Palabras clave:
Angioplastia, endoprótesis carotídea, accidente isquémico, diabetes mellitus, México.

ABSTRACT

Objective: To evaluate the impact of diabetic status on outcome of patients undergoing carotid artery stenting (CAS). **Background:** Diabetes has been demonstrated to be a strong predictor of adverse outcome in patients undergoing coronary revascularization. Its significance in predicting outcome of patients undergoing carotid interventions has not been ascertained. **Methods:** This research is an observational, retrospective, comparative, descriptive study. **Results:** 279/341 patients/lesions were evaluated for carotid stenosis undergoing stenting. Non-diabetics versus diabetics were compared. Of the diabetic group, 59.5% were men, mostly hypertensive and with hypercholesterolemia. More than 40% of both groups had a prior percutaneous coronary intervention (PCI), 68.2% were asymptomatic and a half was high risk, greater comorbidity in the diabetic group with an EuroSCORE > 3, 46 vs 21.4% p = 0.000. No statistically significant difference was found in terms of major adverse cardiovascular events (MACE) at 30 days and accumulated six months in the non-diabetic group (non-DM) versus the diabetic (DM): nine patients (5.4%) versus eight (4.8%), p = 0.756 OR, 95% CI 0.857 (0.322-2.27) and 14 (8.3%) versus nine (5.3%), p = 0.249 OR, 95% CI 0.604 (0254-1435), respectively. Diabetic patients treated with carotid stent who underwent cardiovascular surgery showed a higher intrahospitalary mortality (4.6 vs 0.6%, p = 0.02). There was a higher rate of restenosis (1.9 vs 0%, p = 0.077) in non-diabetic patients. An increased incidence of TIA (transient ischemic attack) was observed in diabetic patients (8.7 vs 3.6%, p = 0.05). **Conclusion:** Diabetics undergoing CAS are more likely to have associated

RESUMEN

Objetivo: *Evaluar el impacto del estado diabético sobre el resultado de los pacientes que se someten a la colocación de stents en la arteria carótida (CAS).* ***Antecedentes:*** *Se ha demostrado que la diabetes es un fuerte predictor de resultados adversos en pacientes sometidos a revascularización coronaria. No se ha determinado su importancia para predecir el resultado de los pacientes que se someten a intervenciones carotídeas.* ***Métodos:*** *Esta investigación es un estudio observacional, retrospectivo, comparativo y descriptivo.* ***Resultados:*** *Se evaluaron 279/341 pacientes/lesiones para la estenosis carotídea sometida a colocación de stents. Se compararon los no diabéticos versus los diabéticos. Del grupo diabético, 59.5% fueron hombres, la mayoría hipertensos y con hipercolesterolemia. Más del 40% de ambos grupos tuvieron una intervención coronaria percutánea (ICP) previa, el 68.2% fueron asintomáticos y la mitad de ellos de alto riesgo, mayor comorbilidad en el grupo diabético con un EuroSCORE > 3, 46 vs 21.4% p = 0.000. No se encontraron diferencias estadísticamente significativas en cuanto a los eventos cardiovasculares adversos mayores (MACE) a los 30 días y acumulados a los seis meses en el grupo no diabético (no DM) versus diabético (DM): nueve pacientes (5.4%) versus ocho (4.8%), p = 0.756 OR; IC 95%: 0.857 (0.322-2.27) y 14 (8.3%) versus nueve (5.3%), p = 0.249 OR; IC 95%: 0.604 (0254-1435), respectivamente. Los pacientes diabéticos tratados con endoprótesis carotídea sometidos a cirugía cardiovascular mostraron una mortalidad intrahospitalaria mayor (4.6 vs 0.6%, p = 0.02). Hubo una mayor tasa de reestenosis (1.9 vs 0%, p = 0.077) en pacientes no diabéticos.*

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co-morbidities. However despite this handicap, their short term outcome after CAS is similar to that of non diabetics. Endovascular treatment of carotid stenosis may be a good alternative to surgical treatment.

Se observó una mayor incidencia de AIT (ataque isquémico transitorio) en pacientes diabéticos (8.7 vs 3.6%, p = 0.05). ***Conclusión:*** *Los diabéticos que se someten a la CAS son más propensos a tener comorbilidades asociadas. Sin embargo, a pesar de esta desventaja, su resultado a corto plazo después del CAS es similar al de los no diabéticos. El tratamiento endovascular de la estenosis carotídea puede ser una buena alternativa al tratamiento quirúrgico.*

INTRODUCTION

Diabetes is a major health problem with the numbers of diabetics increasing both in Mexico and globally. Cardiovascular disease is the leading cause of mortality and morbidity in the diabetic population.[1] When compared with non diabetics, diabetics have a worse outcome after cardiovascular therapeutic interventions.[2-4] Diabetes is a major risk factor for stroke[5] and diabetics make up 11-40% of patients undergoing carotid endarterectomy (CEA).[4] Further, diabetes appears to be a major predictor of adverse in this population.[6] Recently carotid artery stenting (CAS) has emerged as a viable alternative to CEA.[7] The impact of diabetes on outcome of patients undergoing CAS remains unknown. We accordingly evaluated the short and long term outcome of diabetic patients undergoing CAS at our institution.

Objective

This article aims to present our experience in the endovascular approach of diabetic patients with significant carotid stenosis treated at the Department of Cardiac Catheterization and Coronary Intervention in a hospital in Mexico

MATERIAL AND METHODS

Observational, retrospective, comparative and descriptive study. We included 279 patients/341 lesions with significant carotid artery stenosis; in all cases, an informed written consent was obtained before the procedure. Monitoring was conducted by clinical record in the outpatient and telephone follow-up at 30 days, 6 months. Eligible patients were considered for carotid angioplasty with stent (CAS) if any of the following high-risk variables was present: 1) age > 75, 2) bilateral disease, 3) contralateral occlusion, 4) high or low ostial lesion, 5) multivessel coronary disease associated with unstable angina, 6) left ventricular ejection fraction (LVEF) < 45%, and 7) symptomatic lesion with stenosis > 50% and/or asymptomatic injury > 70%. Patients were considered high risk when they had three or more of the aforementioned risk factors (Fx).

Technique

All patients underwent a clinical neurological evaluation and Doppler study. The vascular Doppler study was performed before each procedure by personnel accredited by the Mexican Society of Radiology. Prior to the CAS, a load of 300-600 mg clopidogrel was administered under the judgment of the operator, and 325 mg of aspirin; once the femoral arterial sheath was placed, 70 U/kg of IV heparin were applied; the arterial puncture site was femoral in the vast majority of cases; lidocaine 2% without epinephrine was used as a local anesthetic; sedation was not used in order to maintain a constant neurological condition; both blood pressure and O_2 saturation were monitored during the procedure. A description of our endovascular technique has been published previously.[8] All carotid percutaneous procedures were performed by the group of interventional cardiologys assigned to the hemodinamyc department.

Definitions in angioplasty/carotid stent

Angiographic success: stenosis postprocedure less that 30% through quantitative angiography.

Clinical success: to get a stenosis ≤ 30% without major complications (stroke, death, surgery or acute myocardial infarction) at 30 days.

Transitory ischemic attack: (hemispheric) neurological event with full recovery within 24 hours of its occurrence.

Minor cerebral vascular event: slight neurological event that causes neurological damage (≤ 3 in the National Institute Health Stroke Scale [NIHSS] scale), with recovery within 30 days.

Major cerebral vascular event: neurological injury that persists for more than 30 days and increases its severity to > 4 according the NIHSS scale.[9]

Table I. Demographic variables.

Variable	Non-diabetics 168 (49.3%)	Diabetics 173 (50.7%)	p value
Masculine gender	124 (73.8%)	103 (59.5%)	0.005*
Feminine gender	44 (26.2%)	70 (40.5%)	0.005*
Age > 75 years	42 (25%)	24 (13.9%)	0.009*
SH	135 (80%)	146 (84.4%)	0.328
Smoker	99 (58.9%)	98 (56.6%)	0.670
Hypercholesterolemia	126 (75%)	138 (79.8%)	0.292
Previous AMI	55 (32.7%)	71 (41%)	0.112
LVEF < 45%	37 (24.2%)	62 (37.3%)	0.011*
No. of diseased vessels	36 (21.4%)	25 (14.5%)	0.227
1	32 (19%)	27 (15.6%)	
2	23 (13.7%)	27 (15.6%)	
3	77 (45.8%)	94 (54.3%)	
Previous PCI	73 (43.5%)	76 (43.9%)	0.929
Previous CVE	48 (28.6%)	53 (30.6%)	0.676
Asymptomatic	112 (66.7%)	118 (68.2%)	0.761
Symptomatic	56 (33.3%)	55 (31.8%)	0.761
Low risk	97 (57.7%)	88 (50.9%)	0.203
High risk	71 (42.3%)	85 (49.1%)	0.203
Low EuroSCORE	132 (78.6%)	90 (52%)	0.000*
EuroSCORE > 3	36 (21.4%)	83 (46%)	0.000*
RIC	98 (58.3%)	99 (57.2%)	0.836
LIC	100 (59.5%)	106 (61.3%)	0.741

SH = systemic hypertension, AMI = acute myocardial infarction, PCI = percutaneous coronary intervention, CVE = cerebral vascular event, LVEF = left ventricular ejection fraction, LIC = left internal carotid, RIC = right internal carotid.
* Statistically significant.

Statistical analysis

An analysis of the study variables and their distribution with measures of central tendency and dispersion was performed. Continuous variables are presented as means with standard deviation (SD) or medians with minimum and maximum according to their distribution. Categorical variables are presented as frequencies and percentages. Continuous variables were assessed using the Kolmogórov-Smirnov test for normality and Levene's for homogeneity of variances. Subsequently, a comparative analysis of each of the variables grouped according to gender and the presence or absence of the primary and secondary endpoints was performed; the latter were also compared in subgroups of symptomatic and asymptomatic patients according to gender with the Student t test or Mann-Whitney U test —depending on the distribution of the groups— for continuous variables and chi square for categorical variables. The analysis of event-free survival was performed by Kaplan-Meier curve. All this was done with the SPSS 20.0 statistical package.

RESULTS

A total of 279/341 patients/arterial stenosis injuries who underwent carotid stenting were evaluated. Of these, 173 (50.7%) were diabetic and 168 (49.3%) were non-diabetic. In *table I*, the demographic variables analyzed and compared in both groups are shown. As for the group of diabetic patients, there were more men (59.5%) than women (40.5%). Twenty-four (13.9%) were older than 75 years and a large percentage (84.4%) had hypertension (HAS) and hypercolesterolemia (79.8%). A small percentage of these patients had a left ventricular ejection fraction < 45% (37.3%), in contrast with the number of coronary arteries affected: 54.3% had at least three diseased vessels, and 43.9% of the cases had been previously intervened for coronary angioplasty; 30.6% had a history of prior CVE and 68.2% (118 patients) were asymptomatic. In addition, about 50% were classed as «high risk» and therefore had a

high EuroSCORE. In all patients, the features of the procedure, the approach, previous carotid Doppler, use of distal protection devices, presence of thrombotic material extracted, type of stent used, and the clinical and angiographic procedural success were evaluated, among others *(Table II)*. A high percentage of diabetic patients (77.5%) were previously assessed through carotid Doppler. The procedure took place through a femoral approach in most cases (96.5%); only six of them were approached radially because of the presence of bovine bow. In most injuries (91.9%), embolic protection filters were used, obtaining atherothrombotic material in 53.2% of the cases. Closed-cell stents (Carotid WALLSTENT-Boston Scientific Corp.) were the most commonly used (73.4%), compared to open-cell stents (Precise JJ, Inc.) (26.6%). As for the features of the stent, the diameter ranged from 7.96 ± 1.078 mm and the length from 35.95 ± 6.08 mm. The percentage of stenosis was assessed using criteria of NASCET,[10] with a preprocedure stenosis percent of 79.1 ± 12.27% and postprocedure of 9.9 ± 11.07%. The reference diameter for angiography preprocedure was 6.14 ± 1.32 mm, and postprocedure, 1.34 ± 6.34 mm. Finally, in almost all patients the lesion was predilated and the stent postdilated, obtaining clinical and angiographic success in 95% of the cases. Angiographic success was considered when an arterial stenosis postprocedure was less than 30% (by quantitative angiography or QCA), and clinical success was obtained when a stenosis of less than 30% without major complications (stroke, death, surgery or AMI [acute myocardial infarction]) was achieved within 30 days of the study. Finally, the in-hospital MACE are shown in *table III*, and are detailed below. In the group of diabetic patients, a cardiovascular morbidity (fatal and non-fatal AMI) of four individuals (2.3%) and a neurologic morbidity (fatal and non-fatal stroke) of four people (2.3%) was registered. Among those diabetics who underwent cardiovascular surgery, there was a hospital mortality of 4.6%, higher compared to non-diabetics (0.6%), with p = 0.02. The diabetic versus non-diabetic patient who underwent coronary artery bypass surgery had more coronary and multivessel disease as well as previous myocardial infarction; 57.8 vs 42.2%, 57.1 vs 42.9%, and 60.5 vs 39.5% respectively p = 0.049; so also those who died have lower LVEF 44.1 + 10.1% vs 56.1 + 6.09% p = 0.002 . No cases of reangiographic stenosis occurred in the diabetic group, while the non-diabetics had a restenosis rate of 1.9%, with p = 0.077. As for the clinical six-month follow-up *(Table IV)*, cardiovascular mortality was similar in both groups p = NS; of the diabetic patients, 14 underwent cardiovascular surgery (8.8%), with an operative mortality of 1.4% at six months, without a statistically significant difference compared to non-diabetics. Finally, in terms of major clinical events, we observed a higher percentage of transient ischemic attack in the diabetic group (8.7%) compared to the non-diabetics (3.6%), with p = 0.05. There was no significant difference between the groups in terms of greater or lesser CVA (p = 0.732 and 0.329, respectively). In *figure 1* we present, through the Kaplan-Meier (KM) curve, the difference between both groups in free development of adverse events (MACE) within six months after the intervention, assessed with the Mantel-Cox curve: 94.7% for DM and 91.7% for non-DM, p = 0.249 OR (95% CI) 0.604 (0.254-1.435).

Table II. Outcomes of the procedure.

Variable	Non-diabetics 168 (49.3%)	Diabetics 173 (50.7%)	p value
Previous Doppler	133 (79.2%)	134 (77.5%)	0.823
Distal protection			0.392
Filter	158 (94%)	159 (91.9%)	
Distal balloon	3 (1.8%)	3 (1.7%)	
Proximal balloon	0 (0%)	3 (1.7%)	
Extracted thrombus	80 (47.6%)	92 (53.2%)	0.305
Access			0.552
Femoral	164 (97.6%)	167 (96.5%)	
Radial	4 (2.4%)	6 (3.5%)	
Stent type			0.395
Closed cell	130 (77.4%)	127 (73.4%)	
Open cell	38 (22.6%)	46 (26.6%)	
Predilation	167 (99.4%)	172 (99.4%)	0.983
Postdilation	161 (95.8%)	160 (92.5%)	0.188

DISCUSSION

The risk of CVA increases with age, coronary artery disease (CAD), systemic hypertension (SH), hypercholesterolemia, smoking, atrial fibrillation (AF) and other cardiac conditions (cardiomyopathies, valvular disease, congenital heart disease). Specifically, stenosis of the internal carotid artery causes up to 20% of all ischemic strokes, and atherosclerosis remains the main etiology in most cases.[11] Diabetes and other major risk factors, have also been associated with significant carotid stenosis. In a study of 1,058 patients evaluated with carotid Doppler, significant stenosis of 70 to 99% was found in 89 patients, moderate stenosis (40-69%) in 85 patients, and mild stenosis (less than 39%) in 884 patients. The risk factors considered were age, gender, alcohol consumption, smoking, CAD, hypertension and DM. Multivariate logistic regression analysis were made, where the three groups

Table III. Results and periprocedural complications (30 days).

	Non-diabetics 168 (49.3%)	Diabetics 173 (50.7%)	OR (95% CI)	p*
30-day follow-up				
MACE	9 (5.4%)	8 (4.6%)	0.057 (0.322-2.27)	0.756
CVE major, non-fatal	2 (1.2%)	2 (1.2%)	0.971 (0.0135-6.97)	0.076
AMI	4 (2.4%)	1 (0.6%)	0.238 (0.026-2.15)	0.166
Minor CVE	1 (0.6%)	3 (1.7%)	2.08 (0.303-29.7)	0.329
TIA	6 (3.6%)	15 (8.7%)	2.503 (0.970-6.77)	0.050
Cardiovascular mortality (fatal AMI)	2 (1.2%)	3 (1.7%)	1.465 (0.242-8.87)	0.676
Fatal major CVE	1 (0.6%)	2 (1.2%)	1.953 (0.175-21.8)	0.579
IH cardiovascular surgery performed	10 (6.0%)	18 (10.4%)	1.995 (0.921-1.10)	0.134
IH surgical mortality	1 (0.6%)	9 (4.6%)	8.097 (1.00-65.5)	0.020
Major CVE (fatal and non-fatal)	3 (1.8%)	4 (2.3%)	1.902 (0.287-5.90)	0.732
AMI (fatal and non-fatal)	6 (3.6%)	4 (2.3%)	0.804 (0.241-2.68)	0.722
Clinical success	163 (97.0%)	166 (96.0%)	0.727 (0.220-2.34)	0.592
Angiographic success	197 (99.4%)	173 (98.3%)	0.339 (0.035-3.26)	0.329

MACE = major adverse cardiovascular event, CVE = cerebral vascular event, AMI = acute myocardial infarction, TIA = transient ischemic attack, IH = intrahospitalary.
* Statistically significant.

Table IV. Six-month follow-up.

Six month follow-up	Non-DM: 162	DM: 158	OR (95% CI)	p
Cardiovascular mortality	2 (1.23%)	1 (0.63%)	0.483 (0.043-5.372)	0.545
Cardiovascular surgery performed	8 (4.9%)	14 (8.8%)	0.871 (0.354-2.14)	0.211
Surgical mortality	0 (0%)	2 (1.4%)	0.504 (0.454-0.561)	0.162
Doppler restenosis	4 (2.5%)	5 (3.16%)	1.220 (0.322-4.62)	0.789
Percutaneous carotid reintervention	3 (1.9%)	0 (0.0%)	0.488 (0.438-0.544)	0.077
Accumulated MACE (IH and 6 months)	14 (8.3%)	9 (5.3%)	0.604 (0.254-1.435)	0.249

Non-DM = non-diabetes mellitus, DM = diabetes mellitus, MACE = major adverse cardiovascular events, IH = intrahospitalary.

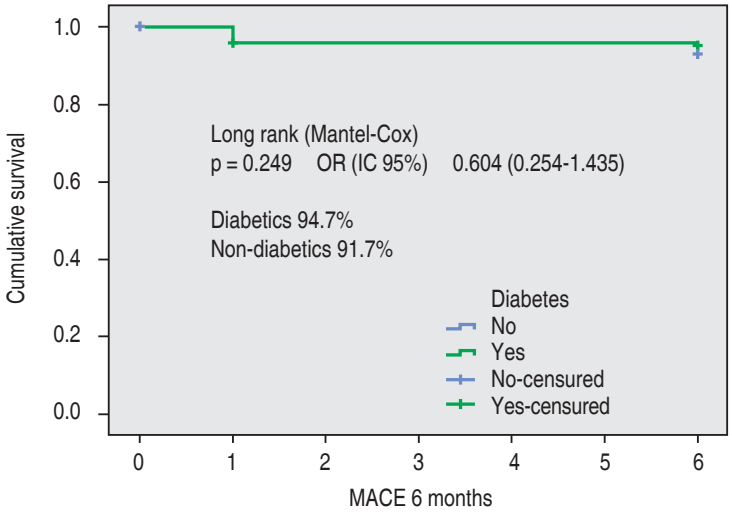

Figure 1. Freedom from major cardiovascular event (MACE).

were compared. In the significant stenosis group, the gender distribution was 34.8% female and 65.2% male, with a mean age of 64.48 ± 10.19 years. In the second and third groups, these distributions were 51.8% female and 48.2% male, with a mean age of 65.15 ± 9.66 years, and 54.30% female and 45.70% male, with a mean age of 59.56 ± 12.37 years, respectively. DM (OR = 2.77), CAD (OR = 1.67), age (OR = 1.02), and male gender (OR = 1.75) were associated with significant carotid stenosis.[12]

While the association between ischemic stroke and carotid stenosis is well established, the prevalence of asymptomatic carotid stenosis in patients with DM is uncertain. Nonetheless, De Angelis,[13] in 2003, evaluated 365 individuals through carotid Doppler: 187 non-diabetic (89 men, 98 women) and 178 diabetic (82 men, 96 women). The overall mean age was 67 ± 7.8 years; 66 ± 7.9 for non-diabetics and 67 ± 7.5 for diabetics. A percentage of 10-99% stenosis was determined in 143/365 patients (39.1%), 49/187 non-diabetics (26.2%) and 94/178 diabetics (52.8%). The differences were significant ($p < 0.001$). A significant percentage of stenosis was found in 17/143 subjects (12%); 12 of them were diabetic (70%) and five non-diabetic (30%). With these results, it was established that diabetics are three times more likely to develop significant carotid stenosis than non-diabetics (OR 3.152, 95% CI 2032-4889).

In another study by P. Lacroix in 2006, in addition to the prevalence of asymptomatic carotid atherosclerosis in a diabetic population, the presence of predictive factors for optimizing the diagnosis was evaluated. He analyzed a total of 300 diabetic subjects (166 men, 134 women) with carotid Doppler. The prevalence of carotid stenosis of 60% or more was 4.7%, and the prevalence of carotid atherosclerosis was 68.3%. Risk factors for carotid stenosis of 60% or more were the presence of diabetic retinopathy (OR = 3.62; 95% CI 1.12-11.73), ankle-brachial index (ABI) < 0.85 (OR = 3.94; 95% CI 1.21-12.84) and personal history of neurological diseases (OR = 4.54; 95% CI 1.16-17.81).[14] He then concluded that the prevalence of carotid atherosclerotic disease in diabetics is high, and that in these patients, the probability of finding a significant stenosis is higher among men with a history of CAD and an ABI < 0.85; in the latter group of patients, it is also common to find silent myocardial ischemia, which makes them candidates for close surveillance.[15]

As for the risk of a CVA in relation to the presence of symptoms in patients with carotid stenosis, it has been determined in the NASCET study that the risk of recurrent ipsilateral stroke in individuals treated conservatively is 4.4% per year for a 50-69% stenosis and 13% per year for a 70% stenosis.[16] In contrast, in asymptomatic patients with carotid stenosis of 60%, the risk of stroke is 1-2% per year. However, the risk increases to 3-4% per year in elderly patients, in those with bilateral carotid disease, in people with evidence of silent embolization in brain imaging studies, where there is a heterogeneous carotid plaque, poor collateral circulation, generalized inflammatory state or peripheral arterial disease.[17]

Among the most important data from our study, we found that 67.4% of the lesions were asymptomatic. *Table V* shows the results in major complications and death related to the procedure in both groups. We found a higher percentage of men with diabetes carriers of carotid stenosis, which concurs with what is described in the literature worldwide. Similarly, a high percentage of patients with hypertension and associated dyslipidemia was found. DM is a major risk factor for the development of

Table V. Results in the asymptomatic group at 30 days: major complications and death related with the procedure.

Follow-up 30 days	Asymptomatic non-DM: 112	Asymptomatic DM: 118	OR (95% CI)	p*
TIA	4 (3.6%)	8 (6.8%)	1.25 (0.598-2.61)	0.577
Major CVE (fatal and non-fatal)	1 (0.9%)	3 (2.5%)	0.444 (0.81-2.42)	0.270
AMI (fatal and non-fatal)	1 (0.9%)	1 (0.84%)	1.50 (0.181-12.5)	0.709

Non-DM = non-diabetes mellitus, DM = diabetes mellitus, TIA = transient ischemic attack, CVE = cerebral vascular event, AMI = acute myocardial infarction.

atherosclerotic disease. The incidence per 1,000 people/year of thromboembolic stroke increases with the level of blood glucose. As mentioned previously, the relative risk of developing a stroke associated with DM is 1.4 to 1.7 times greater. Lowering blood sugar levels and controlling blood pressure in individuals with diabetes reduces the risk of stroke by 44%.[18,19] It is worth mentioning that a high percentage of our patients were carriers of ischemic heart disease, even with prior PCI, as it was previously described by Kallikasaros,[20] who showed that carotid disease (luminal diameter stenosis > 50%) was present in 24.5% of the people with three-vessel disease and 40% of those with left main coronary artery disease. Another important thing that stands out is that half of the cases were considered high risk, which significantly increases the surgical risk, reporting a rise in complications (death, MI, higher CVD, etcetera) between 8 and 15%. Regarding the MACE, no statistically significant difference was found in-hospital and in the six-month follow-up, nor in greater or lesser risk of CVD in both groups of patients (diabetic versus non-diabetic) undergoing carotid stent.

It has already been demonstrated that carotid endarterectomy has an incidence of ipsilateral stroke in the medical branch of 11 and 5.1% in the surgical one, obtaining a reduction of 53.7% according to the ACAS (asymptomatic carotid atherosclerosis study), which was conducted on asymptomatic patients with noncritical carotid lesions; 1,662 were recruited and followed for five years.[21] In contrast, the benefit in this group of individuals considered «high risk» was demonstrated in the study SAPPHIRE (stenting and angioplasty with protection in patients at high risk for endarterectomy), which included high-risk patients; the endpoints of death/stroke/MI at 30 days in patients randomized to stenting versus carotid endarterectomy were 5.8 vs 12.6%, p = 0.047, and at 12 months, 11.9 vs 19.9%, p = 0.048, favoring endovascular therapy,[22] which is similar to our findings (2.9% of hospital mortality related to the procedure and 0.63% at six months in diabetic patients undergoing carotid stent). Only those diabetic patients treated with carotid stent who underwent cardiovascular surgery showed a higher hospital mortality (4.6%) compared with non-diabetics (0.6%), with p = 0.02. Even in non-diabetic patients, there was a higher rate of restenosis (1.8%) compared with diabetics (0%), with a p = 0.077. Finally, in diabetic patients treated with carotid stenting, compared with non-diabetics, increased incidence of cerebral transient ischemic attack (TIA) was observed (8.7 vs 3.6%, with p = 0.05).

CONCLUSIONS

According to our results, endovascular treatment of carotid stenosis can be a good alternative to surgical treatment, especially in diabetic and high-risk patients. There is still controversy regarding the choice of definitive treatment of these individuals, whether to perform an endovascular approach or take them to endarterectomy. A total of six large-scale clinical trials with more than 300 patients have been

conducted to compare stenting versus carotid endarterectomy. The CAVATAS,[23] EVA-3S,[24] ICSS[25] and SPACE[26] studies enrolled only symptomatic individuals. The SAPPHIRE and CREST[27] studies included symptomatic and asymptomatic patients at high and conventional risk for surgery, respectively. However, with the current evidence, we can conclude that the results are tipped with a tendency for endovascular therapy. A metaanalysis of 13 clinical trials where 7,484 patients were randomized, of whom 80% had symptomatic disease, showed that carotid stenting was associated with an increased risk of any type of stroke (RR 1.45; 95% CI 1.06-1.99), decreased risk of periprocedural myocardial infarction (RR 0.43; 95% CI 0.26 to 0.71), and no significant increase in mortality (RR 1.40; 95% CI 0.85-2.33).[28] Recently were published the results of the CREST trial (long-term results of stenting versus endarterectomy for carotid-artery stenosis) to 10 years. In 2,502 treated patients, there was no significant difference in the rate of the primary composite end point between the stenting group (11.8%; 95% confidence interval [CI], 9.1 to 14.8) and the endarterectomy group (9.9%; 95% CI, 7.9 to 12.2) over 10 years of follow-up (hazard ratio, 1.10; 95% CI, 0.83 to 1.44).[29] ACT I trial (randomized trial of stent versus surgery for asymptomatic carotid stenosis) compared carotid-artery stenting with embolic protection and carotid endarterectomy in patients 79 years of age or younger who had severe carotid stenosis and were asymptomatic and were not considered to be at high risk for surgical complications. This study showed that stenting was non inferior to endarterectomy with regard to the primary composite end point (event rate, 3.8 and 3.4%, respectively; $p = 0.01$ for non inferiority).[30] In our study, we observed that despite the high comorbidity of diabetic patients (higher EuroSCORE, multivessel coronary disease, LVEF < 45%, older age), endovascular treatment of carotid stenosis is a good alternative to surgical treatment, especially in the subgroup of diabetic and high-risk patients.

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