CATÉTER BALÓN CON INVERSIÓN DEL FLUJO VS. PROTECCIÓN CON FILTRO DISTAL, DURANTE LA COLOCACIÓN DE STENT CAROTÍDEO (CAS), EXPERIENCIA DE 7 AÑOS DE UN CENTRO DE REFERENCIA DEL NORORIENTE COLOMBIANO.

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Versión español:

Catéter balón con Inversión del flujo vs. protección con filtro distal, durante la colocación de STENT carotídeo (CAS), experiencia de 7 años de un centro de referencia del nororiente colombiano.

Introducción

Actualmente se estima que entre el 20 a 30% de accidentes isquémicos son secundarios a la estenosis carotídea; (1) por lo tanto, y teniendo en cuenta los avances en las opciones terapéuticas mínimamente invasivas, en los últimos años ha crecido exponencialmente el número de intervenciones endovasculares con stent para el tratamiento de esta patología (2). Gracias a este aumento en el número de intervenciones, existen criterios en cuanto a la selección de pacientes y uso de materiales que disminuyen el riesgo de complicaciones de manera significativa; entre estos, los dispositivos de protección embólica están diseñados para prevenir que fragmentos que se desprendan durante la angioplastia causen micro embolizaciones distales. (3)

Los dispositivos más usados son el filtro distal y los sistemas de balón de oclusión proximal. Los filtros son dispositivos de protección que se despliegan distal a la estenosis carotídea a tratar y atrapan residuos que eventualmente se puedan desprender de la placa, al tiempo que permiten una perfusión constante del cerebro.(4) Sin embargo, el uso de filtros implica mayor manipulación de la arteria y un paso durante la intervención.(4,5) Por otro lado, los sistemas que utilizan balones de oclusión, se basan en dispositivos que crean una situación de detención o inversión temporal del flujo en la arteria a tratar, con posterior aspiración complementaria a través del catéter antes de desinflar el balón, para evitar que partículas desprendidas durante el procedimiento embolicen distalmente(5); no obstante, este método puede ser poco tolerado por algunos pacientes, debido a la hipoperfusión cerebral transitoria que genera. (5)

A la fecha, el dispositivo más utilizado en Estados Unidos es el filtro de protección distal (6); no obstante, la evidencia actual apunta a una superioridad o no inferioridad del balòn de oclusiòn proximal (7-8).

En este estudio, se describe la experiencia institucional con el uso de dispositivos de protección embólica durante la angioplastia carotídea, comparando el uso del filtro distal y el catéter guía con balón proximal, con el fin de determinar si existe diferencia en cuanto a complicaciones, resultados adversos e independencia funcional.

Materiales y métodos:

Estudio de cohorte observacional, de corte retrospectivo, en donde se tomaron todos los pacientes con diagnóstico de estenosis carotídea en quienes se realizó angioplastia en la clínica FOSCAL y FOSCAL internacional entre el 1 de enero de 2014 al 30 de junio de 2020. Previa aprobación de comité de ética de la clínica FOSCAL/FOSCAL internacional, se revisó una base de datos anonimizada del servicio de radiología que permitiera su análisis en un software estadístico. Los resultados fueron graficados y representados a través de análisis para permitir su análisis y comprensión.

Población estudiada:
Se incluyeron pacientes adultos, con enfermedad carotídea sintomática en los últimos 12 meses mayor al 50% y/o asintomática mayor del 70%, así como los pacientes a ser sometidos a revascularización miocárdica en quienes por protocolo institucional se realiza una búsqueda activa de estenosis, tratados con angioplastia carotídea y usando algún método de protección. Se excluyeron los pacientes tratados en el momento agudo de un ACV isquémico, pacientes con oclusiones en tándem, o pacientes en quienes no se usó algún método de protección.
Posteriormente, se evaluaron las características demográficas de la población incluída, las características de la estenosis, complicaciones derivadas de la angioplastia, complicaciones relacionadas con el método de protección, el protocolo de antiagregación plaquetaria, la necesidad o no de angioplastia con balón intraStent, la escala de rankin modificado inicial y de seguimiento y hallazgos anormales del doppler de control.

<u>Técnica de angioplastia carotidea:</u>

Antiagregación y anticoagulación:
El protocolo estándar de antiagregación utilizado en nuestro servicio incluye (Aspirina 100mg y Clopidogrel 75mg) con un mínimo de cinco días previos al procedimiento, realizando Verifynow el día previo a la intervención en la mayoría de pacientes. A algunos pacientes se les dio dosis de carga de 300mg de clopidogrel dos días previos al procedimiento y en aquellos hipo respondedores se cambió el esquema a Ticagrelol y ASA. Se continuó la doble antiagregación plaquetaria durante los siguientes 3 meses.
En el caso de pacientes anticoagulados por otra causa, hubo variación en el protocolo de antiagregación plaquetaria, disminuyendo la doble antiagregación a 4 semanas o utilizando sólo un antiagregante. Durante la CAS se anticoaguló a los pacientes con 50 UI /kg de heparina no fraccionada.

Angioplastia Carotidea con Stent (CAS):
El procedimiento se realizó bajo sedación consciente o anestesia local, con monitorización hemodinámica y uso de atropina en caso de necesidad.
Se realizó un acceso arterial femoral estándar guiado por ecografía con aguja de punción y con introductor 6 u 8Fr, posteriormente con catéter diagnóstico y guía hidrofílica estándar se cateterizó la carótida común. Previo recambio de catéter diagnóstico por introductor largo(DESTINATION 6FR) o previa colocación de catéter guía con balón(FLOW GATE 8FR) en arteria carótida común, se continua según la técnica de protección utilizada.

Filtro de protección: Utilizando filtro Spider o Abbot, previamente purgados con heparina, se atraviesa la placa , se posiciona y se abre el filtro en ACI en segmento infrapetroso. Se utilizó una microguía Syncho, Tracxess o guía del filtro para pasar la placa. Sobre la guía del filtro se avanza el stent carotídeo hasta ubicarlo en posición y se libera cubriendo el extremo distal y proximal de la placa. En caso de no lograr una apertura óptima se realiza angioplastia con balón (Maverick, Viatrac, Sterling). Se recaptura el filtro previa verificación angiografía de permeabilidad y se hacen controles finales para evaluar permeabilidad de vasos intracraneales y del Stent. (Imagen 1)

Catéter guía con balón proximal: Utilizando el catéter guía Flowgate2 ubicado en la carótida común, a 2 cm de la placa, se infla temporalmente el balón en el momento de atravesar la placa

con microguia y Stent; en el momento de desplegar el Stent y en caso de angioplastia pos stent. En estos tres momentos hacemos aspiración a través del Flowgate con jeringa de 50ml o sistema de aspiración. se hacen controles finales para evaluar permeabilidad de vasos intracraneales y del Stent.

En caso no lograr adecuada estabilidad del catéter guía para atravesar la estenosis , se utiliza además del balón proximal, el filtro de protección distal para tener mayor estabilidad usando la técnica previamente descrita.

Posteriormente se retiran catéteres y se cierra la arteria femoral con sistema Perclose o Angioseal. (Imagen 2)

Se realiza evaluación neurológica antes de retirar los sistemas y del cierre arterial.

Manejo post operatorio:

Todos los pacientes fueron monitoreados durante un mínimo de 24 horas en una unidad de cuidados intermedios, con monitoreo de la tensión arterial y valoración neurológica. Posteriormente trasladados a hospitalización normal hasta su egreso.

El control clínico se realizó por consulta externa, para evaluación clínica y para evaluación de la permeabilidad del stent con Doppler carotideo.

Resultados:

Se realizaron 175 angioplastias carotídeas en el periodo comprendido entre Enero de 2014 y Junio de 2021; de estos, 17 registros fueron excluídos del análisis, 3 por no contar con historias clínicas completas, y 14 pacientes a quienes se les realizó angioplastia carotídea y trombectomía mecánica por presentar acv agudo. Por lo tanto, 158 pacientes fueron incluidos dentro del análisis estadístico; de estos, en 105 pacientes se usó filtro distal como método de protección embólico y en 50 pacientes se usó el catéter guía con balón de oclusión proximal, en 3 pacientes se usaron ambos métodos de proteccción; pero, estos no fueron incluidos en el análisis para no disminuir el poder estadìstico, y se retomaron en la discusiòn.

El promedio de edad fue de 74.2 años, con una edad mínima de 58 años y máxima de 96; el (69%) de pacientes fueron hombres, el 80,3% de los pacientes tenían como antecedente hipertensión arterial, el 38% diabetes mellitus, el 41% dislipidemia y el 17% tabaquismo. El 13% de los pacientes recibían anticoagulación previa; el 41% de pacientes intervenidos se presentaron con un sintomas neurológicos agudos, pero no tenìan alteraciones isquemicas en la resonancia magnética u oclusiòn de gran vaso, por lo cual fueron incluidos, el 31% tuvo sintomas compatibles con accidente isquémico transitorio y el 27% fueron asintomáticos. De los pacientes que se presentaron con sintomas de accidente cerebro vascular isquemico, el valor promedio de NIHSS fue de 7. En cuanto al porcentaje de estenosis, el 86% de los pacientes presentaban una estenosis severa, el 12% moderada, y sólo 1 paciente fué intervenido con estenosis leve. La mayoría de pacientes se presentaron con estenosis derecha (36%), y 52 pacientes tenían estenosis bilateral (32%). En cuanto al tipo de protección embólica, el filtro fué el más frecuentemente usado (66%), el balón fué usado en un 31% de las veces, y ambos métodos de protección fueron usados 3 veces. El stent más utilizado fué Protege (42%), seguido

de wallstent (39%), casper (15%), exact (3%) y el stent acculink fué usado una vez. Al 81% de los pacientes se les realizó angioplastia intrastent. El 21% de los pacientes tuvieron estenosis residual después del procedimiento. En lo que respecta al esquema de antiagregación, el 82% de los pacientes fueron antiagregación con aspirina y clopidogrel y el 18% con aspirina y ticagrelor.

La tabla 1 muestra las características demográficas de la muestra dependiendo del método de protección usado; no existieron diferencias estadísticamente significativas entre los grupos, con excepción del antecedente de dislipidemia.

No existieron diferencias estadísticamente significativas en cuanto al número de complicaciones relacionados con el procedimiento, el tiempo aproximado que tardó cada cirugía, o las complicaciones no relacionadas con la cirugía; así como tampoco encontramos diferencia en cuanto a la independencia funcional a los 90 días evaluado con la escala de rankin modificado. Las tablas 2 y 3 esquematizan estos resultados.

Discusión

El presente estudio sugiere que no existe diferencia entre el uso de filtro distal y balón proximal como método de protección durante la angioplastia carotidea. Estudios previos ha demostrado una ligera superioridad del balón en comparación al filtro; teniendo en cuenta que el filtro debe atravesar la placa sin protección, lo cual puede provocar que fragmentos se desprendan y causen lesiones isquémicas distales, y además permite que fragmentos con diámetros menores al tamaño de su poro atraviesen a través de él. El estudio Balloon occlusion compared to filter protection during carotid stenting (PROFI) (9) encontró una diferencia significativa en cuanto a la incidencia de nuevas lesiones isquémicas entre los dispositivos de protección (45,2 Vs 87.1% respectivamente), otro estudio publicado por Hyeck Lee et al. (10) en el que compararon los dispositivos de protección endovascular durante la angioplastia carotidea, mostró una incidencia mayor de lesiones isquemicas cerebrales nuevas en los pacientes en los que se usó filtro de protección distal en comparación del cateter balón de oclusión proximal; y aunque esta diferencia no fue estadísticamente significativa, el número de lesiones por pacientes fué significativamente superior en los pacientes en quienes se usó el filtro distal (p= 0,028). De igual manera, Stabile et al. (11) y Bijuhlic et al. (12) reportaron una eficacia superior del cateter balòn de oclusiòn proximal en comparaciòn al filtro distal en cuanto a la potección embólica, reportando además que el filtro de protección distal puede sobrecargarse con partículas durante el procedimiento, y por lo tanto permitir que se desprendan algunas durante el retiro de los sistemas.

En nuestro estudio la tasa de complicaciones globales fue de 8.2%, menores en comparación a las encontradas en pacientes que participaron en grandes ensayos clinicos de angioplastia carotidea (10% en el estudio Carotid and Vertebral Artery Transluminal Angioplasty (12) y 12.1% en el estudio WALLSTENT (Carotid stening versus endarterectomy in patients with symptomatic carotid stenosis trial(13)), y únicamente 1 paciente (0.9%) presentó síntomas neurológicos durante el procedimiento o en el postoperatorio inmediato, un valor favorable teniendo en cuenta los ensayos EVA-3S (Endarterectomy versus stening in patints with symptomatic severe carotid stenesosis) (12) y el ensayo Stent Protected Angioplasty Vs Carotid

Endarterectomy trial (15), en los cuales la tasa de alteraciones neurológicas (acv - ait) intra o postoperatorias fué del 6.8 y 9.6% respectivamente.

La incidencia de estenosis luminal intrastent durante el seguimiento fué de 6 pacientes (5.3%), Bussie et al (16) reportaron una tasa de estenosis del 15.9% en un años de seguimiento; por ende, aunque la re estenosis fué menos frecuente en nuestra institución, hace falta aumentar el tiempo de seguimiento para poder comparar estos resultados.

En cuanto a los 3 pacientes en que se usaron ambos métodos de protección, en uno de ellos, se había elegido inicialmente el filtro distal; sin embargo, este no pudo avanzar a través de la placa por lo cual se realizó una primera angioplastia con balón proximal como protección y posteriormente se ascendió el filtro, previo a la colocación del stent. En otro paciente, inicialmente se eligió el catéter guía con balón de oclusión proximal como dispositivo de protección; sin embargo, no se pudo avanzar el sistema y el stent hasta el lugar de la estenosis por acodamiento de la carótida interna que provocaba herniación del sistema hacia la carótida externa, por lo tanto se cambia de sistemas usando filtro distal como método de protección el cual se logra posicionar hasta el segmento petroso de la carótida interna para posterior ubicación de stent. En el tercer paciente, se eligió el catéter balón inicialmente; no obstante, el sistema no poseía la suficiente estabilidad para ser ascendido a través de la placa por lo cual se añade el filtro para dar más soporte y se logra ascender.

En cuanto a las 4 muertes reportadas, un paciente murió 2 años después de la intervención por choque séptico; por lo cual esta muerte no fué incluida en el análisis estadístico. De los otros 3 pacientes, 2 pertenecían al grupo en el que se usó el cateter balón guía; de estos, uno sufrió una bradicardia severa y el otro tuvo un hematoma retroperitoneal seguido de disfunción orgánica múltiple. El paciente que murió del grupo de filtro distal falleció durante una sesión de hemodialisis por deterioro clínico agudo seguido de sintomas de focalización. Se necesitan más estudios con mayores tamaños de muestra para establecer una relación entre estos desenlaces y el sistema de protección.

La principal limitación de este estudio es que arroja resultados de un único centro, además de la limitación en el tiempo de seguimiento en comparación a otros estudios similares en donde se ha evaluado la evolución de los pacientes hasta un año después. Por otro lado, el tiempo de intervención fué obtenido de los registros anestésicos, por lo cual este no representa el verdadero tiempo de la intervención pero nos permite una aproximación a este.

Conclusión

En nuestro estudio la protección con filtro distal y con catéter guía con balón para protección proximal durante la CAS no mostraron diferencias significativas en complicaciones relacionadas con el uso del método

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Versión inglés:

Proximal balloon-guided catheter with flow inversion vs. distal filter protection during the carotid stent placement, a seven years experience in a Colombian reference center.

Abstract

Background and purpose: The carotid stent placement as a therapeutic option for carotid stenosis has been increasing among years; therefore, studies are required to evaluate the security and efficacy of its materials. The purpose of this study was to evaluate the distal filter and the proximal balloon-guided catheter with flow inversion as protection devices during carotid angioplasty and stenting.

Methods: This is a retrospective, observational study of patients diagnosed with carotid stenosis treated with angioplasty between January 1, 2014, and June 30, 2020; we analyzed a radiology service database to compare the distal filter and the proximal balloon-guided catheter as protection devices during angioplasty.

Results: One hundred seventy-five angioplasties were performed, the distal filter was the most prevalent embolic protection device used (66%), patients baseline characteristics did not differ between groups with different embolic protection devices, with the exception of history of dyslipidemia ($p< 0.000$). As well, we did not find any significant differences between the groups in the device related complications, intervention time ($p=0.090$), unrelated complications ($p=0.693$) *and* functional independence at 90 days (*0.096).*

Conclusions: In our study the proximal balloon-guided catheter and the distal filter protection device as protection devices during the carotid stenting didn't show significant differences regarding complications related to the system .

Keywords: Embolic Protection Devices, Carotid Stenosis, Carotid Artery Diseases, Stroke, Endovascular Procedures.

Introduction

The percentage of ischemic accidents secondary to carotid stenosis is 20 % to 30 % (1). Interventions using endovascular stents are minimally invasive therapeutic options for treating this pathology, and the number of these interventions is growing exponentially (2). This increased number of interventions has allowed us to establish patient selection criteria and develop tools that reduce the risk of complications during the intervention. Among these tools, embolic protection devices were designed to capture debris released during angioplasty and prevent them from causing distal microembolization (3).

The most common among the embolic protection devices are the distal filter and the proximal balloon-guided catheter. Distal filters are deployed distant from the treated carotid stenosis and trap debris that may eventually detach from the plaque while allowing constant brain perfusion (4). A downside of using these distal filters is that they require additional manipulation and add a step to the intervention (4,5). The proximal balloon-guided catheter consists of devices that arrest or temporarily invert the flow in the treated artery. The particles detached during the procedure are aspirated through a catheter before deflating the balloon avoiding distal embolization (5). Despite the popularity of the proximal balloon-guided catheter, it generates transient cerebral hypoperfusion, which might not be tolerated by some patients (5)

The distal filter is the most used device in the United States (6). However, some evidence has shown that the proximal balloon-guided catheter is similar or superior (7-8). This study describes the institutional experience with the embolic protection devices used during carotid angioplasty. It compares the distal filter with the proximal balloon-guided catheter to determine whether these devices differ in complications, adverse effects, and functional independence.

Methods

This study is a retrospective, observational evaluation of patients diagnosed with carotid stenosis treated with angioplasty between January 1, 2014, and June 30, 2020, at the Fundación Oftalmológica de Santander Carlos Ardila Lulle Foscal, located in Bucaramanga, Colombia. We analyzed an anonymized database containing information from clinical records, medical consultations, and follow-up dopplers of the patients after the approval of the clinic's ethics committee. We coded the variables to analyze and organized the data in an anonymized database for further statistical analysis. Qualitative variables were described with absolute and relative frequencies including confidence intervals. The quantitative variables were described by means and standard deviation. In the bivariate analysis between groups, it was related using the student's t test for quantitative variables and Fisher's exact test for qualitative variables. A p value of statistical significance less than 0.05 was considered.

Patient cohort

The patient cohort included adult patients showing symptoms of carotid stenosis within the 12 months prior to the study and having greater than 50% stenosis. It also included asymptomatic

patients with greater than 70% stenosis and patients undergoing myocardial revascularization and active search for stenosis as indicated by the institutional protocol. All patients included had been treated with carotid angioplasty using some embolic protective device. Our evaluations excluded patients treated during acute ischemic cerebrovascular events and patients with tandem occlusions.

The variables analyzed included patients' demographic characteristics, stenosis characteristics, complications associated with the angioplasty or embolic protective device, antiplatelet protocols, whether an intraStent balloon angioplasty was necessary, the initial and follow-up modified Rankin Scale, and the abnormalities revealed by the follow-up Doppler.

Techniques of Carotid Angioplasty and Stenting

Antiplatelet and anticoagulation protocols: Most patients received our service standard antiplatelet protocol, which includes 100 mg of Aspirin and 75 mg of Clopidogrel at least five days before the procedure. The patient's platelet response was assessed one day before the procedure using Verifynow. Some patients received a 300 mg loading dose of Clopidogrel two days prior to the procedure, and the regimen was changed to Ticagrelor and ASA for hypo-responder patients. Patients were subjected to dual antiplatelet therapy for the three months following the procedure. The dual antiplatelet therapy was modified in patients prompted to anticoagulated. The therapy period was reduced to four weeks, or only one antiplatelet was used in these patients. Patients were anticoagulated with 50 IU / kg of unfractionated heparin during the carotid angioplasty with stenting (CAS).

Carotid angioplasty with stenting: Patients were under conscious sedation or local anesthesia with hemodynamic monitoring during CAS, and atropine was used when necessary. Ultrasound-guided femoral access with puncture needle and a 6Fr or 8Fr introducer was performed. The common carotid artery catheterization used a diagnostic catheter and standard hydrophilic guide. The diagnostic catheter was replaced by a long introducer (DESTINATION 6FR) or a proximal balloon-guided catheter (FLOW GATE 8FR), and CAS continued, depending on the embolic protection device used.

Distal filter: A Spider or Abbot filter was purged with heparin and led across the plaque using a_Syncho microguide, a Tracxess, or a guided filter. The distal filter was positioned and deployed in the petrous segment of the internal carotid artery (ICA). The carotid Stent was carried through the filter guide and released once in its destination, assuring the plaque's distal and proximal end coverage. A balloon angioplasty (Maverick, Viatrac, Sterling) was performed when an optimal opening was not achieved. The distal filter was recaptured following the angiography patency assessment. Finally, the intracranial vessel and Stent patency were assessed (Figure 1).

Proximal balloon-guided catheter: The balloon was located 2 cm from the plaque using a Flowgate2 guide catheter in the common carotid. The balloon was inflated on three occasions.

The first one occurred during the passage of the micro guide and Stent through the plaque, the second one during stent deployment, and the third post-Stent angioplasty. Ballon inflation coincided with suction through the Flowgate, using a 50 ml syringe or a suction system. Final controls included intracranial vessel and Stent patency assessment (Figure 2).

A distal filter was used in addition to the proximal balloon-guided catheter in cases where the stability of the guide catheter was insufficient to cross the stenosis. The addition of the distal filter was intended to increase the stability and was carried as previously described. At the end of the procedure, patients went through a neurological evaluation. Then, the catheters were removed, and the femoral artery was closed with the Perclose or Angioseal system.

Postoperative management: All patients underwent blood pressure monitoring and neurological evaluation for at least 24 hours in an intermediate care unit. Then, they were transferred to regular hospitalization until discharge. The clinical control used outpatient consultation. During these consultations, patients underwent clinical evaluation and Stent patency assessment with carotid Doppler.

Results:

One hundred seventy-five angioplasties were performed between January 2014 and June 2021. Seventeen of these records were excluded from the analysis as three of them had incomplete medical records, and 14 underwent carotid angioplasty and mechanical thrombectomy due to acute stroke. Of the remaining 158 patients, 105 had a distal filter as the embolic protective device, and 50 had a proximal balloon-guided catheter. The remaining three patients had both protection devices. These patients were also excluded from the analysis because of the small sample size and lack of statistical power. However, their cases are addressed in the discussion section of this article.

Patients had an average age of 74.2 years, with a minimum age of 58 years and a maximum of 96 years, and the percentage of males was 69.0%. Of these patients, 80.3 % had a history of hypertension, 38 % had a history of diabetes mellitus, 41 % had a history of dyslipidemia, and 17 % had a history of smoking. The percentage of patients receiving prior anticoagulation was 13 %. Regarding the symptoms, 41 % of the patients presented with acute neurological symptoms. These patients had no occlusion in the large vessel or ischemic alterations on their magnetic resonance imaging. Therefore, they were included in the analysis. Of the remaining patients, 31% had symptoms compatible with a transient ischemic attack, and 27% were asymptomatic. The mean NIHSS score was 7.2 for patients with ischemic stroke symptoms. As for the Stenosis, 86% of the patients had severe stenosis, and 12% had moderate stenosis. Only one patient had mild stenosis. Most patients (36 %) presented right coronary artery stenosis, while 52 (32 %) had bilateral stenosis.

The distal filter was the most prevalent embolic protection device used in 66 % of the patients, compared with the proximal balloon-guided catheter used in 31 %. Both embolic protection devices were used simultaneously on three occasions. Protege was the most common Stent used in 42 % of the patients. Protege was followed by Wallstent used in 39 % of the patients, Casper used in 15 %, Exact used in 3%, and the Acculink Stent was used only in one patient. The percentage of patients who underwent in-stent angioplasty was 81 %, and that of patients who had residual stenosis after the procedure was 21 %. The antiplatelet scheme included Aspirin and Clopidogrel for 82% of the patients and Aspirin and Ticagrelor for 18 %. (Table 1). Patients' characteristics did not differ between patients with different embolic protection devices, with the history of dyslipidemia being the exception (*P=>0.05)*.

The embolic protection device also did not affect the number of related and unrelated complications, the surgery time, or the functional independence at 90 days. (Table 2, Table 3)

Discussion

The present study suggests that the distal filter and the proximal balloon-guided catheter behave similarly as embolic protection devices for carotid angioplasty. However, previous evaluations have shown a slight superiority of the proximal balloon-guided catheter over the distal filter. For example, Bijuklic et al. showed that using the distal filter resulted in a higher incidence of novel ischemic lesions than the proximal balloon-guided catheter (87.1 % vs. 45.2 %) (9). Similarly, Hyeck Lee et al. found an increased number of novel ischemic lesions per patient for the distal filter ($p = 0.028$). The authors also found a higher incidence of novel ischemic lesions in patients with distal filters. However, this increased incidence was not statistically supported (10). The distal filter inferiority might come from its impossibility to stop all the detached fragments, as the filter crosses the plaque without protection. Also, the distal filter only retains fragments bigger than its pore size. On the same line, Stabile et al. (11) and Bijuhlic et al. (9) reported superior embolic protection efficacy for the proximal balloon-guided catheter than for the distal filter. These evaluations showed that the distal filter could become overloaded with particles during the procedure, which resulted in particle detachment during the removal of the systems.

We found an overall complication rate of 8.2 %. This rate is lower than those reported for patients participating in larger carotid angioplasty clinical trials (i.e., a complication rate of 10 % for the Carotid and Vertebral Artery Transluminal Angioplasty Study and 12.1 % for the WALLSTENT study) (12, 13). Only one of our patients (0.9 %) showed neurological alterations during the procedure or immediate postoperative period. This rate of intra- and postoperative neurological alterations is favorable considering those of the SPACE2 and Stent Protected Angioplasty vs. Carotid Endarterectomy trials (14, 15). These trials reported rates of intra- or postoperative neurological alterations (ACV - ait) of 6.8 % and 9.6 %, respectively.

Our intra-stent luminal stenosis incidence was 5.3 % (6 patients) during the follow-up. Bussiere et al. (16) reported a stenosis incidence of 15.9 % in the one-year follow-up. Despite restenosis being less frequent in our institution, we also considered a shorter follow-up time, with a mean in our registers of 3 months. We need to increase the follow-up time to compare these results.

Regarding the three patients with both protection devices, the distal filter was initially considered for one of them. However, the distal filter could not advance through the plaque in this patient. Then, using the proximal balloon-guided catheter as protection device angioplasty was performed, followed by distal filter and stent placement. In another patient, the proximal balloon-guided catheter was initially chosen. In this case, the system and the Stent could not advance to the stenosis site due to kinking of the internal carotid. This kinking resulted in the herniation of the system towards the external carotid. Therefore, the embolic protection device was changed, and a distal filter was used for protection. The distal filter was successfully positioned in the petrous segment of the internal carotid allowing subsequent stent placement. In the last patient, the proximal balloon-guided catheter was initially chosen. However, because of system instability the catheter could not be advanced and the distal filter was used then.

As to the four death patients reported; one patient died two years after intervention as a result of septic shock; therefore, this death was not included in the statistical analysis, three patients died during the periprocedural hospitalization, regarding these, two were from the balloon-guided catheter, of these, one patient died after a severe bradycardia followed neurologic decline; and the other one died because of a retroperitoneal haematoma followed by quick multiorganic dysfunction. The patient in the distal filter group died during a hemodialysis session because of an acute clinical and neurologic decline with focals symptoms. Further analysis with a larger sample size are needed to establish a relationship between the prevalence of these complications and the protection method used.

The principal limitations of this study are that this is a single center, retrospective and not randomized study. Also, the follow-up time was shorter in comparison to other similar studies where the clinical follow-up was performed even one year after the procedure. On the other hand, with respect to the intervention time, in our study this variable was taken from the anesthesiology records; therefore, it doesn't represent the real time of the procedure, but allows us to make an approximation to this.

Conclusion:

In our study the proximal balloon-guided catheter and the distal filter protection device as protection devices during the carotid stenting didn't show significant differences regarding complications related to the system .

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Characteristics	**Distal filter protection device (105)**	**Proximal balloon occlusion device (50)**	**p value**
Age, sex			
Mean Age (years)	74.51 +/- 7.8	74.1 +/- 8.1	0.781*
Male sex, n (%)	69 (65.7)	35 (70)	0.715+
Cardiovascular Risk Factors, n (%)			
Hypertension	87 (82.8)	37 (74)	0.205+
Diabetes Mellitus	38 (36.1)	20 (40)	0.723+
Dyslipidemia	53 (50.4)	10 (20)	0.000+
Smoking	16 (15.2)	11 (22)	0.365+
Presenting symptom, n (%)			0.15+
Asymptomatic	32 (30.4)	11 (22.4)	
TIA	32 (30.4)	16 (32.6)	
ACV	41 (39)	22 (44.9)	
Percentage of stenosis n,(%)			N/A
Low	0 (0)	1 (2)	
Moderate	10 (9.5)	10 (20)	
Severe	95 (90.4)	38 (76)	
Occlusion	0 (0)	1 (2)	
Stenosis laterality n,(%)			0.360+
Left	33 (31.43)	14 (28)	
Right	42 (40)	16 (32)	
Bilateral	30 (28.5)	50 (40)	

Intrastent angioplasty n,(%)	83 (79)	42 (84)	0.521+
Residual stenosis n,(%)	25 (23.8)	8 (16)	0.301+
Antiaggregation scheme n,(%)			N/A
ASA + Clopidogrel	97 (92.3)	30 (60)	
ASA + Ticagrelol	7 (6.6)	20 (40)	
ASA	1 (0.9)	0 (0)	
Initial mRs			
mRs 0 - 2	78 (74.2)	39 (75.4)	0.692+

* student's t test
+ Fisher's exact test

Table 2. Outcomes of patients diagnosed with carotid stenosis treated with angioplasty.

Outcome	**Distal filter protection device (105)**	**Proximal balloon oclussion device (50)**	**p value**
Mean time of intervention (minutes)	91 +/- 30	101 +/- 46	0.090*
Intraoperatory ACV, n (%)	0 (0)	0 (0)	
Intraoperatory TIA, n (%)	1 (0.9)	0 (0)	
Acute myocardial infarction, n (%)	0 (0)	0 (0)	
Intraluminal stenosis in follow up doppler, n (%)	4 (5.4)	2 (5.5)	1.00+
Protection device not related complications			0.693+
Post-operatory hypotension, n (%)	4 (3.8)	2 (4)	
Bradycardia, n (%)	4 (3.8)	0 (0)	
Puncture site hematoma, n (%)	2 (1.9)	1 (2)	
Death, n (%)	1 (0.95)	2 (4)	

* student's t test
+ Fisher's exact test

Table 3. Functional Independence (mRs) of patients diagnosed with carotid stenosis treated with angioplasty.

	Distal filter protection device (105)	**Proximal balloon occlusion device (50)**	**p value**

Functional independence before procedure (mRs 0 - 2), n (%)	78 (74.2)	39 (78)	0.692+
Functional independence after procedure (mRs 0 - 2), n (%)	97 (92.3)	41 (82)	0.096+

+ Fisher's exact test

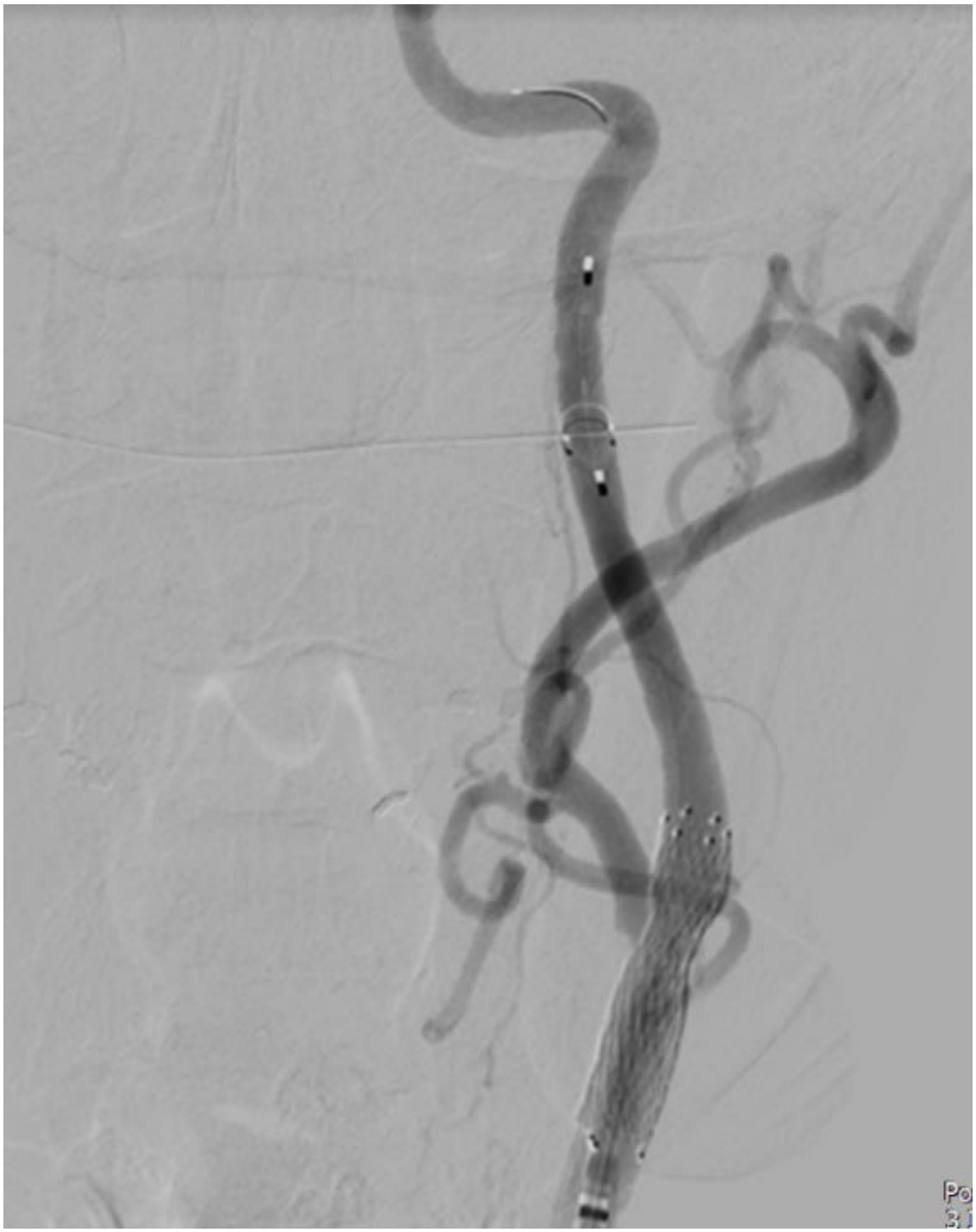

Figure 01.

Female patient with severe symptomatic stenosis. The image shows the protection filter distal to the area in which angioplasty with stent was performed.

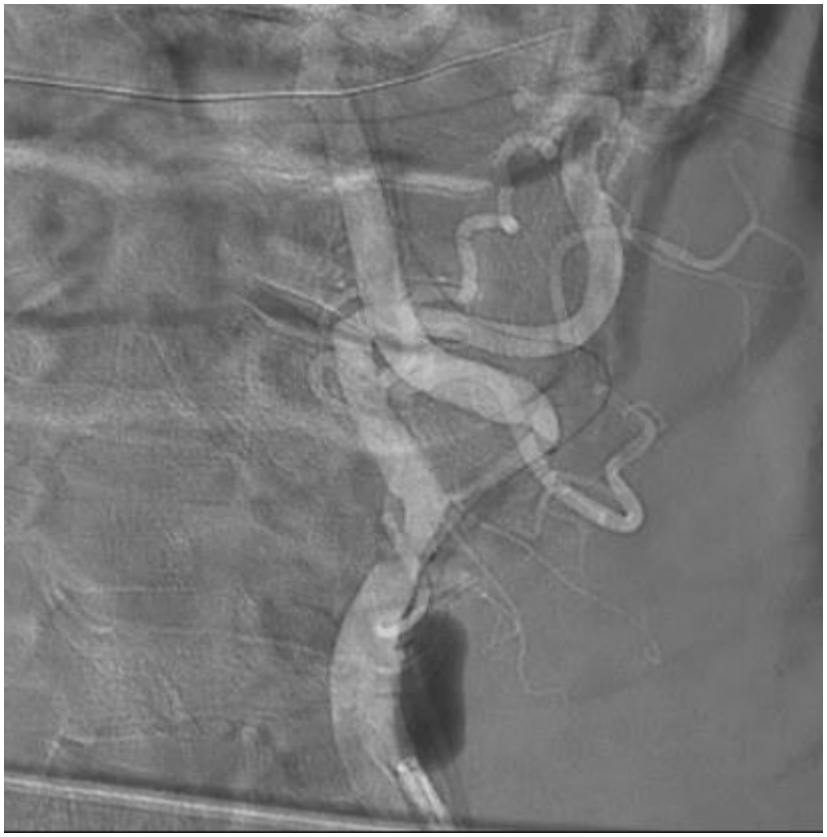

Figure 2. Patient of 54 years old with a severe carotid stenosis, the inflated balloon is observed proximal to the area of stenosis.

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