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## *Resultados funcionales tras angioplastia carotídea sin protección: un estudio descriptivo en un centro de alta complejidad en Colombia*

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**ABSTRACT**

**Introduction:** carotid artery stenting (CAS) is widely used to treat carotid stenosis. Although embolic protection devices (EPDs) are commonly employed, their benefit remains controversial. Evidence regarding unprotected CAS, particularly in South America, is limited.

**Objective:** to characterize the clinical and functional outcomes of patients undergoing unprotected carotid angioplasty at a high-complexity referral center.
**Methods:** functional status was assessed using the modified Rankin Scale (mRS) before and after the procedure. Outcomes were analyzed using descriptive statistics, chi-square tests to evaluate changes in mRS, and Kaplan-Meier analysis for hospital stay. **Results:** A total of 104 patients undergoing unprotected carotid angioplasty were included. The median age was 72.5 years, and 73.08 % were male. Most patients were symptomatic at diagnosis (88.46 %), and the most common comorbidity was hypertension (83.65 %). The median degree of carotid stenosis was 80 %, with predominantly unilateral involvement. Stents were placed in 98.08 % of patients. The median length of stay was 9 days, and the probability of remaining hospitalized at 30 days was 10.58 %. Periprocedural complications were infrequent. Functional status, assessed by the mRS, showed a statistically significant improvement after the procedure ($p = 0.005$). There was an increase in the proportion of patients who remained completely asymptomatic following the intervention.
**Conclusion:** unprotected carotid angioplasty appears to be a feasible and safe alternative, with low complication rates and significant functional improvement in selected patients.

**Keywords:** Balloon angioplasty. Carotid Stenosis. Embolic protection device. Treatment outcome. Stents.

**RESUMEN**

**Introducción:** la angioplastia carotídea (CAS, por sus siglas en inglés) se utiliza ampliamente para tratar la estenosis carotídea. Aunque los dispositivos de protección embólica (EPD) se emplean comúnmente, su beneficio sigue siendo controvertido. La evidencia sobre la CAS sin protección, particularmente en Sudamérica, es limitada.

**Objetivo:** caracterizar los desenlaces clínicos y funcionales de pacientes sometidos a angioplastia carotídea sin protección en un centro de referencia de alta complejidad.

**Métodos:** el estado funcional se evaluó mediante la escala modificada de Rankin (mRS) antes y después del procedimiento. Los desenlaces se analizaron con estadísticas descriptivas, pruebas de $\chi^2$ para evaluar los cambios en la mRS y análisis de Kaplan-Meier para la estancia hospitalaria.

**Resultados:** se incluyeron un total de 104 pacientes sometidos a angioplastia carotídea sin protección. La mediana de edad fue de 72,5 años y el 73,08 % eran hombres. La mayoría de los pacientes eran sintomáticos al momento del diagnóstico (88,46 %) y la comorbilidad más frecuente fue la hipertensión (83,65 %). El grado medio de estenosis carotídea fue del 80 %, con un compromiso predominantemente unilateral. Se colocaron *stents* en el 98,08 % de los pacientes. La mediana de estancia hospitalaria fue de 9 días y la probabilidad de permanecer hospitalizado a los 30 días fue del 10,58 %. Las complicaciones periprocedimiento fueron poco frecuentes. El estado funcional, evaluado mediante la mRS, mostró una mejoría estadísticamente significativa después del procedimiento ($p = 0,005$). Hubo un aumento en la proporción de pacientes que permanecieron completamente asintomáticos tras la intervención.

**Conclusión:** la angioplastia carotídea sin protección parece ser una alternativa factible y segura, con bajas tasas de complicaciones y una mejoría funcional significativa en pacientes seleccionados.

**Palabras claves:** Angioplastia con balón. Estenosis carotídea. Dispositivo de protección embólica. Resultado del tratamiento. *Stents*.

## INTRODUCTION

Carotid artery angioplasty is an established procedure for the treatment of carotid stenosis, used in both primary and secondary

stroke prevention. It is commonly performed in combination with stent placement, a technique known as carotid artery stenting (CAS) (1). One of the main concerns associated with this procedure is the risk of cerebral embolization, which may occur due to the dislodgement of atherosclerotic material during vascular manipulation (2). To address this issue, embolic protection devices (EPDs)—both distal and proximal—were developed (3). The choice between these devices depends largely on the patient's anatomical characteristics and the operator's preference (4).

Although the use of EPDs is generally recommended during CAS, to date, no randomized clinical trial has definitively demonstrated the superiority of protected over unprotected CAS (5). A 2017 retrospective analysis reported that carotid stenting without EPDs or post-angioplasty stents can be performed safely by experienced operators (6). In contrast, the EVA-3S trial found a significantly lower 30-day stroke risk in patients who underwent CAS with embolic protection compared to those without it (7).

Despite the availability of several retrospective and prospective studies with heterogeneous results, there is a lack of data from Colombia or other South American countries regarding the outcomes of CAS performed without EPDs. Therefore, this study aimed to characterize the clinical and functional outcomes of patients undergoing unprotected carotid angioplasty at a high-complexity referral center.

## METHODS

### Study design and population

A cross-sectional study was conducted involving patients who underwent carotid angioplasty without distal protection devices at a referral center in northeastern Colombia between September 2009 and March 2025. Initial identification of eligible patients was based on computed tomography angiography (CT) of the neck vessels and/or digital subtraction angiography (DSA), using the NASCET formula to quantify stenosis between 50 % and 99 % (8). This diagnosis was

confirmed with DSA before the angioplasty. Patients with symptomatic carotid stenosis > 50 % or asymptomatic stenosis > 70 % were included. Six patients were excluded due to a preprocedural modified Rankin Scale (mRS) (9,10) score > 4 or failure to provide informed consent for the procedure.

**Data collection**

Data were collected retrospectively by two independent investigators. To ensure data accuracy, a random 20 % sample of records was cross-verified to assess inter-rater agreement and correct discrepancies. This process ensured the reliability and consistency of the data used for analysis.

Demographic, clinical, and paraclinical variables were collected from the electronic medical records of patients who underwent endovascular treatment for intracranial arterial stenosis. The variables included age, sex, and marital status—categorized as in a relationship (married, common-law union), not in a relationship (single, separated, divorced, widowed), and not reported; health insurance regime, classified as contributory/private (contributory, private payers, prepaid health plans, foreign insurance, IPS regime), subsidized/public (subsidized), and special or exceptional regime (special and/or exceptional regime); area of residence (urban or rural), and discharge status. Admission and discharge dates were recorded to calculate hospital length of stay. Comorbidities such as hypertension, diabetes mellitus, active smoking within the last year, and a history of coronary artery disease were also included. In addition, neurological symptoms, laterality, degree of stenosis, and treatment-related complications were documented. All patients underwent baseline neuroimaging with either CT or magnetic resonance imaging.

Neurological evaluation was performed both before and after the intervention using the mRS, which assesses the degree of disability or dependence in daily activities. The mRS scores range from 0 (no

symptoms) to 6 (death), with intermediate scores reflecting increasing levels of functional impairment.

A score of 1 on the mRS indicates the presence of symptoms without significant disability, allowing the individual to carry out usual work and social activities. A score of 2 reflects slight disability, in which the patient is unable to perform all previous activities but remains capable of managing personal affairs without assistance. A score of 3 denotes moderate disability, requiring help to walk or perform certain tasks, with the need for caregiver support at least twice per week. A score of 4 corresponds to moderately severe disability, characterized by the inability to walk or attend to personal needs without daily assistance. Finally, a score of 5 indicates severe disability, with the patient being bedridden, incontinent, and dependent on continuous care (11).

**Procedural description**

All patients received acetylsalicylic acid (100 mg) and clopidogrel (75 mg) for at least five days before the procedure, or alternatively, a loading dose of 600 mg clopidogrel and 500 mg acetylsalicylic acid was administered at least 30 minutes prior to angioplasty. The procedure was performed under local anesthesia with conscious sedation provided by an anesthesiologist. Intravenous heparin (70 IU/kg) was administered at the beginning of the procedure.

All interventions were performed via femoral access, using ultrasound guidance when vascular puncture was anticipated to be challenging. An 8 Fr femoral introducer and an 8 Fr therapeutic catheter with a 0.035-inch hydrophilic guidewire were used. In patients with complex vascular anatomy, a wire exchange technique was applied. After identifying the stenotic segment, road mapping was utilized to cross the lesion with a 0.014-inch microwire (preferably Transend or Synchro, Stryker). A Wallstent (Boston Scientific) was deployed in all cases.

In lesions where the stenosis prevented stent passage, pre-dilation was performed using a 1.5-2.5 mm angioplasty balloon (Maverick), followed by post-dilation with a 5-6 mm balloon (Sterling) to achieve

approximately 90 % luminal patency. Pre- and post-procedure cerebral and cervical angiograms were performed to verify intracranial circulation and monitor the intervention. Hemostasis at the puncture site was achieved manually, two hours post-procedure, after confirming the patient's clinical stability

**Statistical analysis**

Descriptive analyses were performed to characterize the clinical and functional profiles of patients with intracranial arterial stenosis treated with endovascular intervention. Categorical variables, including comorbidities (high blood pressure, diabetes, active smoking, coronary artery disease), presence of symptoms, complications, stenosis laterality, and stent placement, were summarized using absolute and relative frequencies (percentages). The Shapiro–Wilk test was used to assess the normality of the variables age, percentage of carotid artery stenosis, and length of hospital stay. Due to non-normal distributions, these variables were reported as medians with interquartile ranges (IQR).

Functional outcomes were assessed by comparing pre- and post-procedure mRS scores, categorized as improvement, stability, or deterioration. These changes were analyzed using the chi-square test and presented in frequencies and percentages. Additionally, a Kaplan-Meier survival curve was constructed using hospital discharge date as the event to estimate length of stay and to visualize the temporal distribution of discharge in the study cohort. All analyses were performed using Stata version 16 (StataCorp, College Station, TX, USA).

**Ethical statement**

This study was approved by the Institutional Ethics Committee (approval number CEI2024-016-11). All procedures were conducted in accordance with national and international ethical standards, including the principles outlined in the Declaration of Helsinki. Additionally, the study adhered to the Colombian Personal Data Protection Law (Law

1581 of 2012), which governs the handling, processing, and protection of personal data. Informed consent was obtained from all patients participating in this study.

## RESULTS

A total of 104 patients were included, with a median age of 72.5 years (IQR: 67-77) and a predominance of males (73.08 %). Hypertension was the most common comorbidity (83.65 %), followed by diabetes mellitus (33.65 %), active smoking (29.81 %), and coronary artery disease (20.2 %). At the time of diagnosis, 88.5 % of patients were symptomatic. Most patients reported being in a relationship (60.7 %), having basic education (66.1 %), living in urban areas (85.7 %), and being affiliated with the subsidized/public health insurance regime (53.6 %). The most frequent specific diagnosis was occlusion and stenosis of the carotid artery (20.5 %).

The median degree of carotid artery stenosis was 80 % (IQR: 70–90). Stenosis was most frequently unilateral, affecting the left side in 47.1 % of cases and the right side in 41.4 %; bilateral involvement was observed in 11.5 % of patients. Stent placement was performed in 98.1 % of cases. The median length of stay was 9 days (IQR: 5–13). Complications were rare, with one case each of ischemic stroke (0.97 %), cerebral hyperperfusion syndrome (0.97 %), and hemorrhage related to hyperperfusion (0.97 %) (Table I).

**Table I.** Clinical and demographic characteristics of patients undergoing carotid angioplasty without distal protection device

| **Variable** | **Category** | ***n* = 104 (%)** |
|---|---|---|
| Sex | Female | 28 (26.92) |
| | Male | 76(73.08) |
| Age (years) | Median (IQR) | 72.5 (67-77) |
| Marital status | In a relationship | 68 (60.71) |
| | Not in a relationship | 35 (31.25) |

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| | | |
|---|---|---|
| | Not disclosed | 9 (8.04) |
| Educational level | No formal education | 9 (8.04) |
| | Basic education | 74 (66.07) |
| | Secondary technical education | 3 (2.68) |
| | Higher education | 5 (4.46) |
| | Not applicable / Not reported | 21 (18.75) |
| Area of residence | Rural | 16 (14.29) |
| | Urban | 96 (85.71) |
| Type of insurance | Contributory / Private | 46 (41.07) |
| | Subsidized / Public | 60 (53.57) |
| | Special or Exceptional | 6 (5.36) |
| Diagnosis | Occlusion and stenosis of carotid artery | 23 (20.54) |
| | Unspecified cerebral infarction | 5 (4.46) |
| | Cerebral infarction due to cerebral artery thrombosis | 4 (3.57) |
| | Sequelae of cerebral infarction | 4 (3.57) |
| | Other diagnoses | 76 (67.85) |
| Medical history | Hypertension | 87 (83.65) |
| | Diabetes | 35 (33.65) |
| | Active smoking | 31 (29.81) |
| | Coronary Disease | 22(20.19) |
| | Neurological symptoms | 92(88.46) |
| Carotid artery stenosis (%) | Median (IQR) | 80 (70-90) |
| Stenosis Laterality | Right | 43(41.35) |
| | Left | 49(47.12) |
| | Bilateral | 12(11.54) |
| Complications | Without complications | 100 (97.09) |

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| | | |
|---|---|---|
| | Stroke | 1 (0.97) |
| | Cerebral hyperperfusion syndrome | 1 (0.97) |
| | Hemorrhage due to hyperperfusion syndrome | 1 (0.97) |
| Stent | Yes | 102 (98.08) |
| Length of Hospital Stay (days) | Median (IQR) | 9 (5-13) |
| Discharge status | Death | 4 (3.57) |
| | Alive | 108 (94.73) |

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Survival analysis showed a progressive decline in the probability of remaining hospitalized over time. By day 10, 44.2 % of patients were still hospitalized (95 % CI: 34.6 %-53.5 %). This figure decreased to 17.3 % by day 21 (95 % CI: 10.8 %-25.2 %) and further declined to 10.58 % by day 30 (95 % CI: 5.6 %-17.4 %). These findings indicate that by day 30, only 10.58 % of patients remained hospitalized, while the rest had either been discharged or had died during hospitalization (Fig. 1).

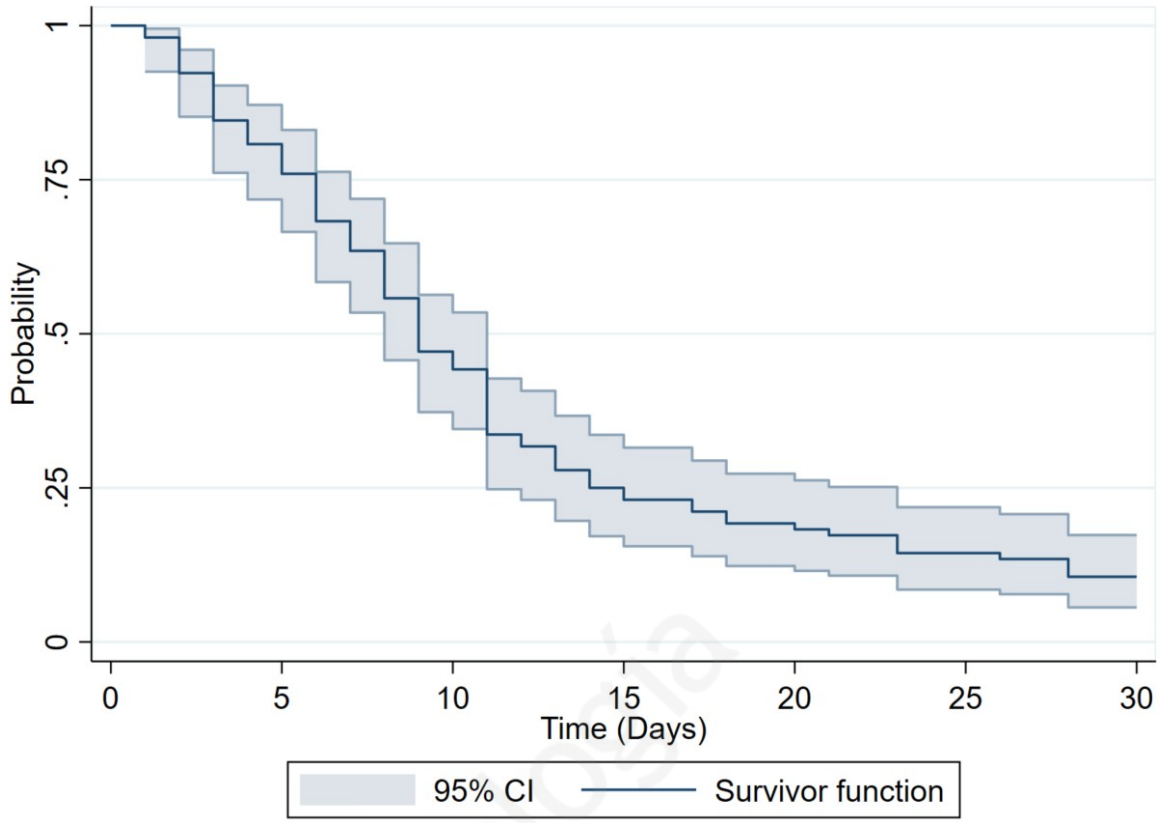



**Figure 1.** Length of stay at 30 days.

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Functional status was assessed using the modified Rankin Scale (mRS) before and after the intervention. A statistically significant improvement was observed ($p$ = 0.005). Prior to the procedure, 64.42 % ($n$ = 67) of patients were asymptomatic (mRS 0), 16.35 % ($n$ = 17) had symptoms without significant disability (mRS 1), 11.54 % ($n$ = 12) had slight disability but remained independent (mRS 2), and 7.69 % ($n$ = 8) had moderate disability requiring partial assistance (mRS 3). Following the intervention, 56.73 % ($n$ = 59) of patients achieved an mRS score of 0, and 17.30 % ($n$ = 18) had a score of 1. Scores of 2 and 3 were reported in 10.54 % ($n$ = 11) and 8.65 % ($n$ = 9) of patients, respectively. Notably, the proportion of patients with moderately severe (mRS 4) or severe disability (mRS 5) remained low, at 2.89 % ($n$

= 3 each), and only one patient (0.97 %) died following the procedure (mRS 6) (Table II).

**Table II**. Functional outcome changes measured by the modified rankin scale in patients undergoing carotid angioplasty without distal protection devices

| | | mRs Post-intervention | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | Total |
| mRS Pre-intervention | 0 | 47 (79.66) | 8 (44.44) | 4 (36.36) | 3 (33.33) | 3 (100) | 1 (33.33) | 1 (100) | 67 (64.42) |
| | 1 | 7 (11.86) | 5 (27.78) | 1 (9.09) | 3 (33.33) | - | 1 (33.33) | - | 17 (16.35) |
| | 2 | 4 (6.78) | 4 (22.22) | 3 (27.27) | - | - | 1 (33.33) | - | 12 (11.54) |
| | 3 | 1 (1.69) | 1 (5.56) | 3 (27.27) | 3 (33.33) | - | - | - | 8 (7.69) |
| | Total | 59 (56.73) | 18 (17.30) | 11 (10.57) | 9 (8.65) | 3 (2.89) | 3 (2.89) | 1 (0.97) | 104 (100) |
| | | $p$ = 0.005 | | | | | | | |

0: asymptomatic; 1: symptoms without significant disability; 2: mild disability, independent in personal affairs; 3: moderate disability, requires partial assistance and occasional caregiver support; 4: moderately severe disability, requires daily assistance; 5: severe disability, bedridden and fully dependent; 6: deceased.

## DISCUSSION

In our study of patients who underwent carotid angioplasty without distal protection, we observed a statistically significant improvement in

mRS scores following the procedure. This finding suggests that, in appropriately selected clinical scenarios, unprotected carotid angioplasty may not only be safe but also effective in enhancing neurological function (9). Although the use of distal protection devices is recommended by many clinical guidelines, their application can be limited by anatomical or technical constraints (12). Recent evidence, such as the meta-analysis by Cho et al., indicates that the absence of distal protection does not necessarily increase the risk of adverse events when patients are carefully selected and procedures are performed by experienced operators (13).

The functional improvement observed in our study aligns with prior findings documenting neurological recovery following carotid revascularization—even in the absence of protection devices (14). For example, Bonati et al. reported that both carotid endarterectomy and carotid artery stenting were associated with sustained clinical benefits, as measured by functional scales such as the modified Rankin Scale, particularly when procedures were free of periprocedural complications (15).

With regard to safety, no major neurological events or clinical signs of cerebral hyperperfusion syndrome—a serious and feared complication—were identified. While some studies have reported subclinical brain lesions detected by MRI in patients treated without protection, these findings do not consistently correlate with functional deterioration. Indeed, Rots et al. emphasize that factors such as uncontrolled hypertension, advanced age, and a history of cerebrovascular disease are more predictive of adverse outcomes than the use of distal protection per se (15,16).

These results highlight the critical importance of tailoring therapeutic strategies in carotid revascularization to the individual characteristics of each patient (6). While the use of distal protection devices is generally recommended and remains the preferred approach when anatomically and technically feasible, clinical decision-making must also consider patient-specific factors such as vascular anatomy,

comorbidities, and procedural risks. The favorable outcomes observed in our cohort suggest that, in selected patients and within a controlled clinical environment led by experienced interventional teams, unprotected carotid angioplasty may represent a safe and effective alternative (17).

Despite the strengths of our study—including the use of a well-characterized cohort from a high-complexity referral center in northwestern Colombia, consistent procedural techniques, and detailed clinical assessments—some limitations must be acknowledged. Its cross-sectional design precludes causal inference, and the absence of long-term follow-up limits our understanding of the durability of the outcomes. Future prospective, ideally randomized and multicenter studies are warranted to further assess the comparative effectiveness and safety of protected versus unprotected carotid angioplasty across diverse populations.

## CONCLUSION

Unprotected carotid angioplasty was associated with a low rate of periprocedural complications and a significant improvement in patients' functional status. These findings indicate that, in selected patients and experienced centers, this technique may represent a feasible and safe alternative.

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