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Endovascular Treatment of Ischemic Stroke in a Developing Country

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Abstract

Background: There is inequality in access to recent advancements in endovascular treatment of acute ischemic stroke (AIS), and Mexico is unusually sensitive to such inequality. **Aims:** To report the initial experience of the Mexican Endovascular Reperfusion Registry (MERR). **Methods:** The MERR is an academic, independent, prospective, multicenter, observational registry of patients treated with endovascular reperfusion techniques in Mexican hospitals. The registry includes information on demographic and clinical characteristics, diagnostic procedures, treatments, selected time metrics, and outcomes. **Results:** In all, 49 (57.1% female) patients from 8 centers were included and had the following characteristics: median National Institute of Health Stroke Scale score, 16; median Alberta Stroke Program Early CT Score score, 9; received intravenous tissue-type plasminogen activator, 49%; and treated with mechanical devices, 39 (79.6%), including 20 treated with stent retriever alone, 2 with retriever and intra-arterial thrombolysis (IAt), 10 with catheter aspiration (4 in combination with IAt), 6 with a combination of catheter aspiration and stent retriever, and 1 with IAt followed by balloon angioplasty. Recanalization (TICI 2b or better) was achieved in 69.4% of the patients. The median clot to recanalization time was 30 minutes. A modified Rankin scale $\leq$2 was achieved in 44.9% of the patients, and 68.2% of these were treated with stent retriever ($P = .011$). Procedure-related morbidity was 12.2%, 7 patients presented intracerebral hemorrhage (71.4% asymptomatic), and all-cause mortality was 6.1%. **Conclusions:** Endovascular treatment of AIS in Mexico is feasible and has an efficacy comparable to that of other countries. Still, many challenges remain, especially pertaining to high costs and difficulties in equality in access to treatment.

Keywords

stroke, endovascular treatment, epidemiology, Latin America, Mexico

Introduction

In the recent years, endovascular treatment of acute ischemic stroke (AIS) has produced extraordinary advancements in the path toward reducing AIS-related mortality and disability.[1] Nevertheless, such developments are not equally accessible to all patients, even within high-income countries.[2] For example, it has been estimated that in the United States, only 56% to 85% of the population has access to an endovascular-capable hospital that can be reached within 1 hour, and there is gross variation depending on location,[3] race, population density, and the median wealth of the individual's zip code.[4]

Due to the inherent heterogeneity derived from different degrees of social and economic development, Latin America is even more sensitive to such inequalities in access to treatment for AIS. Even data on the epidemiology of stroke in the region are scarce and much needed.[5,6] A simple search of the National Library of Medicine (as of May 2019) for the terms "endovascular treatment" and "stroke" yielded over 7000 results and showed a clear trend toward rapid growth; however, adding the term "Latin America" to the same search dropped the number of results to only 4.

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Despite the intrinsic limitations of hospital-based registries, especially in the context of a rising tendency toward the creation of well-designed multicenter randomized controlled trials (RCTs) in high-income countries, it is undeniable that the information provided by registries can still help when evaluating the efficacy of therapeutic interventions and provides data complementary to those obtained in RCTs.[7] Such information can also include other aspects of AIS care beyond efficacy, such as a glimpse of trends in the use of novel technologies, data related to the monitoring of and improvement in the quality of hospital care, to name just a few. Hence, the American Heart Association still recommends the expanded use of registries to support the prevention and management of heart disease and stroke.[8]

The primary objective of this study is to report the initial experience of the Mexican Endovascular Reperfusion Registry (MERR), a hospital-based registry of patients who received endovascular treatment for AIS in Mexico.

Methods

Mexican Endovascular Reperfusion Registry was developed by the "Asociacion Mexicana de Enfermedad Vascular Cerebral/ AMEVASC" (Mexican Association of Stroke) as an academic, independent, prospective, multicenter, observational registry meant to record data from all consecutive patients treated with endovascular reperfusion techniques in Mexican hospitals, where an interventional neurologist is available.

The registry was established in January 2019 and required over a year of working meetings before it was implemented. It is a procedure-/therapy-/encounter-based registry, and from a functional perspective, it was conceived to conduct clinical research, perform quality measurement, and provide feedback to clinicians for quality improvement. Participation was optional and open to all interventional neurologists in Mexico.

Patients entered into the database came to 2 different types of hospitals of high complexity: government-funded academic hospitals and private hospitals, both of which had the capability to provide endovascular treatment for AIS. At each institution, the interventional neurologist acted as the attending physician, and site investigator was responsible for the organization of the Stroke Team and performed the endovascular procedures.

Patients with AIS were treated according to decisions of the attending physician/site investigator, and data were collected as part of clinical routine procedures though a web-based platform accessible only to the investigator through a single-step verification process (user ID and personal password). Each investigator had access only to data from his or her own center. The steering committee of the MERR (Juan Manuel Marquez-Romero, Fernando Góngora-Rivera and Luis Manuel Murillo-Bonilla) had access to the full set of data.

To minimize variability in the registering of data across centers and investigators, the variables recorded in the MERR are based on international standards.[9,10] Additionally, a printable document containing the standardized definitions for each variable and the reference guidelines and scales used were created and made accessible to all the investigators prior to the inclusion of patients.

The MERR includes 80 variables is divided into 8 sections: (1) case identification, (2) preprocedural evaluation, (3) description of the endovascular procedure, (4) stroke intervention time intervals, (5) postprocedural evaluation, (6) complications, (7) discharge evaluation, and (8) follow-up.

The scales used in the MERR are the National Institute of Health Stroke Scale (NIHSS), the Alberta Stroke Program Early CT Score (ASPECTS), the Thrombolysis in Cerebral Infarction (TICI) Perfusion Categories, the Arterial Occlusive Lesion Scale, the American Society of Interventional and Therapeutic Neuroradiology Collateral Grading System, and the modified Rankin scale (mRs). Additionally, the MERR follows the Protocol for Recording Treatment from Interventional Stroke Therapy Outcomes proposed by Higashida et al.[9]

Ethical Considerations

This study falls into category I according to the Mexican Regulations of the General Health Law in the Matter of Research, second title, chapter I, Article 17 which regulates the institutions where this study took place. Category I studies are those based on retrospective documental techniques and methods. Therefore, ethics committee approval is not mandatory. No data that might disclose the identity of the participants were recorded.

A Brief Note on the Mexican Health-Care System

Mexico is the 10th most populated country in the world and has over 119 million inhabitants according to the 2015 census.[11] The Mexican Health System offers different benefits and coverturesdepending on the type of population: Employed workers and their families ($\sim 50\%$) have access to government-funded social insurance, while the self-employed and unemployed ($\sim 35\%$) have access to little to no health coverage, and some individuals pay for private care/insurance ($\sim 15\%$).[12]

Scope of the Present Manuscript

To test for feasibility in clinical practice, prior to the prospective implementation of the MERR, the authors decided to retrospectively capture prior cases seen in their individual practices, and these data were recovered from the clinical and angiographic records. Patients aged >18 years old with AIS were eligible for the study if they had angiographically proven occlusion (TICI: 0-1) in the internal carotid, middle cerebral (M1 or M2 segment), basilar, or vertebral artery and underwent endovascular therapy. Other inclusion criteria included a prestroke mRs ≤ 1, NIHSS score ≥ 8 and ≤ 25, ASPECTS ≥ 6, and, if eligible, treatment with intravenous tissue-type plasminogen activator (tPA) within 3 hours of stroke onset. The description of these data is the object of the current report.

Figure 1. Geographical location of centers capable of endovascular treatment for acute ischemic stroke in Mexico.

Statistical Analysis

Continuous data are expressed as the mean ± standard deviation or the median with interquartile range (IQR), whereas categorical data are presented as number and percentage. Depending on the type of data analyzed, comparisons between groups were performed with χ^2 test or the independent samples Kruskal-Wallis test, and $P < .05$ was considered significant. All statistical analyses were performed using SPSS software (SPSS Inc, Chicago, Illinois).

Results

Data from 49 patients treated at 8 different centers were registered and included in the present report. Figure 1 shows the geographical location of the centers that contributed patients and additional centers that are capable of providing endovascular treatment for AIS in Mexico.

There were 28 (57.1%) female patients in the study, and the mean age was 65.12 ± 14.6 years old. Baseline characteristics are shown in Table 1. All patients presented with moderate-to-severe neurological deficits (median NIHSS score of 16), and the most frequent stroke risk factor was hypertension (57.1%), followed by diabetes (26.5%). Atrial fibrillation was present in 18.4% (n = 9) of the patients, and 6 of these were on anticoagulants (2 on warfarin and the rest on a novel oral anticoagulant). The median INR was 1.01 (IQR, 0.22) in the anticoagulated patients and 1.03 (IQR, 0.14) in the whole sample.

All but 1 patient (who went straight to magnetic resonance imaging [MRI]) underwent a computed tomography (CT) scan (98%), and 22 (44.9%) patients underwent both CT and MRI. The median ASPECTS score was 9 (IQR, 2). Even with a median symptom onset to door time of 180 (IQR, 150) minutes, almost half (49.0%) of the patients received intravenous tPA (IV tPA). The characteristics of the procedures performed are depicted in Table 2. The most frequent type of anesthesia was general, which was used in 49% of the patients. The most common location of occlusion was the proximal middle cerebral artery (MCA, 32.7%), followed by the distal MCA (24.5%). Only 2 (4.1%) patients with posterior circulation occlusion were included. A total of 57.1% of the patients had no collateral circulation, and only 3 (6.1%) had grade 3 collaterals.

Table 1. Baseline Characteristics.

Age in years, mean (SD)	65.1 (14.6)
Female sex, n (%)	28 (57.1)
NIHSS score, median (IQR)	16 (6)
ASPECT score, median (IQR)	9 (2)
Vascular risk factors, n (%)	
Hypertension	28 (57.1)
Diabetes	13 (26.5)
Dyslipidemia	12 (24.5)
Smoking	6 (12.2)
Atrial fibrillation	9 (18.4)
Symptom-to-door time in minutes, median (IQR)	180 (150)
Intravenous tPA use, n (%)	24 (49)

Abbreviations: ASPECT, Alberta Stroke Program Early CT Score; IQR, interquartile range; NIHSS, National Institutes of Health Stroke Scale; SD, standard deviation; tPA, tissue-type plasminogen activator.

Table 2. Procedures Characteristics.

Type of anesthesia, n (%)	
General	24 (49)
Local	20 (40.8)
Monitored anesthesia care	5 (10.2)
Occlusion location, n (%)	
ICA occlusion:	
Without an intracranial embolus	5 (10.2)
With an intracranial embolus	11 (22.4)
Proximal MCA	16 (32.7)
Distal MCA	12 (24.5)
M2	3 (6.1)
Vertebrobasilar	2 (4.1)
Collaterals, n (%)	
Grade 0	28 (57.1)
Grade 1	13 (26.5)
Grade 2	2 (4.1)
Grade 3	3 (6.1)
Modality of treatment, n (%)	
Intra-arterial thrombolysis	
tPA	9 (18.4)
Tenecteplase	1 (2.0)
Disruption device	
Stent retriever	20 (40.8)
Catheter aspiration	6 (12.2)
Intra-arterial tPA + disruption device	
Stent retriever	2 (4.1)
Balloon angioplasty	1 (2.0)
Catheter aspiration	4 (8.2)
Catheter aspiration + stent retriever	6 (12.2)
Occlusion able to be traversed by a guidewire, n (%)	41 (83.7)
Occlusion able to be traversed by the catheter, n (%)	40 (81.6)
Flow improved by traversing the occlusion, n (%)	26 (53.1)

Abbreviations: ICA, internal carotid artery; MCA, middle cerebral artery; tPA, tissue-type plasminogen activator.

Regarding the modality of treatment, 17 (34.7%) patients received intra-arterial (IA) thrombolysis, and with the exception of one who received TNK, all of these patients received tPA with a median IA dose of 15 mg (IQR, 12); thus, 39 (79.6%) patients were treated with mechanical devices: 20 patients with stent retriever alone, 2 combined with tPA, 10 with catheter aspiration (4 in combination with tPA), 6 with a combination of catheter aspiration and stent retriever, and 1 with IA tPA followed by balloon angioplasty.

For purposes of this analysis, we separated the patients into 3 groups to perform comparisons of outcome measures: Group 1 was treated with stent retriever alone or with tPA, group 2 was treated with a combination of catheter aspiration and stent retrieval, and group 3 was treated with the remaining techniques. These comparisons are shown in Table 3.

The median clot to TICI 2b perfusion or better time was 30 (IQR, 15) minutes, which was achieved in 69.4% of the patients. There was a highly significant difference across treatment modalities that favored the stent retriever group. However, 42.9% of the patients in group 3 achieved TICI 2b reperfusion.

Reperfusion rates (TICI 2b or better) according to the location of the occlusion were as follows: 72.7% for T/L occlusion in the internal carotid artery (8 patients), 100% for occlusion in the internal carotid artery without intracranial thrombus (5 patients), 62.5% for a proximal M1 occlusion (10 patients), 58.3% for a distal M1 occlusion (7 patients), 66.7% for occlusion in M2 (2 patient), and 100% for basilar occlusions.

The median clot to end of procedure time was 35 (IQR, 28) minutes. Finally, the median duration of the procedures was 70 (IQR, 30) minutes. Other key time metrics are presented in Figure 2, and we found no significant differences across the groups in any of the measured time metrics.

Clinical improvement as measured by the NIHSS scale was also significantly better in the stent retriever group than in the other groups immediately and at 24 hours postprocedure but not at the 72-hour evaluation. The median time spent in the ICU was 2.5 days (IQR, 5). With regard to procedure-related adverse events, morbidity was 12.2%, and 7 patients presented with intracerebral hemorrhage (71.4% asymptomatic).

A good functional discharge outcome was defined as an mRs ≤ 2 and was achieved in 44.9% of the patients, including 68.2% of the group treated with stent ($P = .011$; Figure 3). After discharge, patients were followed as outpatients and had a median time to follow-up of 59.5 days (IQR, 58.75), at which 63.6% of the patients had a good outcome. However, 16 (32.7%) patients were lost to follow-up. The procedure-related mortality rate at discharge was 0%, and all-cause mortality was 6.1%.

Discussion

In this study of patients who underwent endovascular treatment for AIS, we achieved the goal of registering extensive data about AIS evaluation and care, procedure-related complications, and angiographic and clinical outcome measures, all of which agreed with the current recommendations.[9,10] This study also constitutes the first report of endovascular treatment for AIS in Mexico and, as far as we are aware, in Latin America.

Our results help to substantiate several facts about the current reality of stroke care in the region. The first issues are costs and limited access to specialized care. Currently, government-funded social insurance does not cover any type of endovascular treatment and only covers IV tPA partially and in a few institutions; thus, all the data included in the present report come from patients paying for private care/insurance. This finding is consistent with other reports from Hispanic populations. For example, in the study by Attenello et al, after adjusting for age, sex, population density, median wealth, and expected payer, the frequency of being admitted to hospitals that performed mechanical thrombectomy procedures at high volumes was significantly lower in ethnic minorities, including Hispanics than in those including white patients with stroke.[4] In the same study, expected payer designation of US patients with stroke was associated with the frequency of mechanical revascularization, with the procedure performed in increasing percentages (from 0.19% to 0.47%) of Medicare patients,

Table 3. Outcome Measures by Treatment Modality, Stent Retriever Versus Other Treatments.

Outcome	All	Stent Retriever, n = 22	Other Disruption Devices, n = 21	Catheter Aspiration + Stent Retriever, n = 6	*P*
TICI, n (%)					
Grade 0	7 (14.3)	2 (28.6)	5 (71.4)	0	.004[a]
Grade 2a	8 (16.3)	1 (12.5)	7 (87.5)	0	
Grade 2b	21 (42.9)	9 (42.9)	9 (42.9)	3 (14.3)	
Grade 3	13 (26.5)	10 (76.9)	0	3 (23.1)	
NIHSS, median (IQR)					
Postprocedure	10 (9)	5 (8)	10 (8)	18 (7)	.002[b]
24 hours	8 (10)	3 (6)	10 (10)	16 (5)	.012[b]
72 hours	7 (8)	2 (3)	8 (8)	10 (6)	.348[b]
Days in the ICU, Median (IQR)	2.5 (5)	4 (7)	1 (3)	10 (9)	.001[b]
Procedure-related adverse events, n (%)	6 (13.0)	3 (50.0)	1 (16.7)	2 (33.3)	.167[a]
Minor complications					
No therapy, no consequence	2 (4.3)	0	1 (50.0)	1 (50.0)	
Nominal therapy, no consequence	2 (4.3)	0	2 (100.0)	0	
Major complications					
Required minor therapy, <48 hours hospitalization	2 (4.3)	1 (50.0)	0	1 (50)	
Intracranial hemorrhage	7 (14.3)	4 (57.1)	1 (14.3)	2 (28.6)	.165[a]
Asymptomatic	5 (10.2)	3 (60.0)	1 (20.0)	1 (20.0)	
Symptomatic	2 (4.1)	1 (50.0)	0	1 (50.0)	
Discharge mRs, n (%)					.011[a]
≤2	22 (44.9)	15 (68.2)	6 (27.3)	1 (4.5)	
0	5 (10.2)	3 (60.0)	1 (20.0)	1 (20.0)	
1	8 (16.3)	4 (50.0)	4 (50)	0	
2	9 (18.4)	8 (88.9)	1 (11.1)	0	
3	11 (22.4)	2 (18.2)	7 (63.6)	2 (18.2)	
4	11 (22.4)	2 (18.2)	6 (54.5)	3 (27.3)	
5	2 (4.1)	1 (50.0)	1 (50.0)	0	
6	3 (6.1)	2 (66.7)	1 (33.3)	0	

Abbreviations: ICU, intensive care unit; IQR, interquartile range; mRs, modified Rankin scale; NIHSS, National Institute of Health Stroke Scale; TICI, Thrombolysis in Cerebral Infarction.
[a] χ^2 test.
[b] Independent samples Kruskal-Wallis test.

Medicaid patients, privately insured patients, and self-pay patients. These findings substantiate the fact that socioeconomic features are directly related to patient access to mechanical thrombectomy in the setting of AIS. Our results show that in Mexico, only a minority of people at risk (those capable of paying for private care/insurance) have access to endovascular revascularization procedures. This holds especially true for the use of stent retrievers.

In addition to the issue of cost, there is also another problem to consider, one that is perhaps particular to our country, and this is the fact that the availability of endovascular materials, namely, catheters, guidewires, and stent retrievers, to name a few, varies widely among cities and even among institutions in the same city. Access to these devices depends on a network of commercial intermediaries between international manufacturers and the end user. This supply network is scattered across the country and controls the price and inventory of different devices, which are also subject to import taxes and the ups and downs of the US dollar exchange rate. This creates yet another difficulty in providing endovascular treatment for AIS in Mexico because this limitation has the potential to impede the procedure or limit the type of devices that a treating physician can use in a determined patient. The impact of these findings on procedure and patient outcomes is uncertain and, as far as we are aware, has never been documented in the medical literature. This explains why only approximately half of our patients were treated with stent retrievers, which currently hold a higher level of evidence for efficacy[13]; despite this finding, recent efforts have aimed to match the scientific evidence for other treatment modalities, such as aspiration thrombectomy techniques. For example, the ASTER trial found no significant difference in the successful revascularization rate between aspiration thrombectomy techniques and stent retriever,[14] and Martini et al recently reported additional evidence in a "real-world" design study.[15] Catheter aspiration was the second most common procedure in our patients and achieved a 43% TICI 2b recanalization rate. Although we still favor the use of stent retrievers over other techniques, we believe that aspiration thrombectomy techniques might also constitute a very good alternative, with one of its main advantages being its potentially lower cost and consequential suitability for low-/middle-income countries such as Mexico.[16]

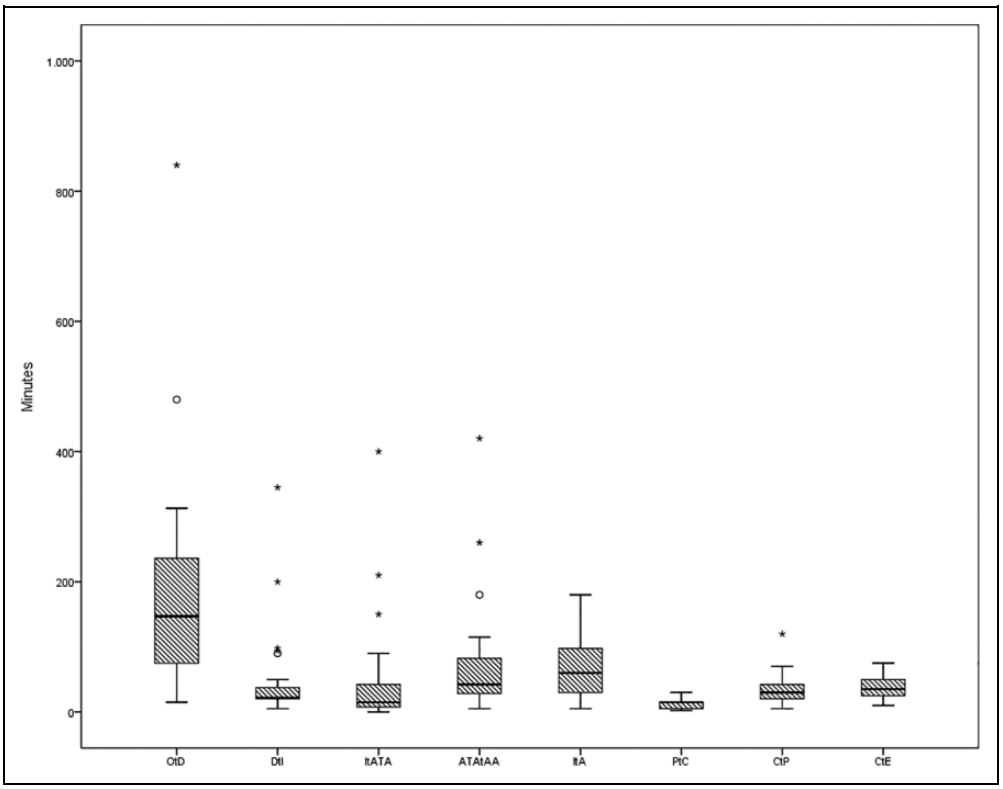

Figure 2. ATAtAA indicates endovascular team activation to arrival to angiosuite; CtE, clot to end of procedure; CtP, clot to TICI 2b perfusion; DtI, door to imaging; ItA, imaging to angiosuite; ItATA, imaging to endovascular team activation; OtD, onset to door; PtC, puncture to clot; TICI, Thrombolysis in Cerebral Infarction.

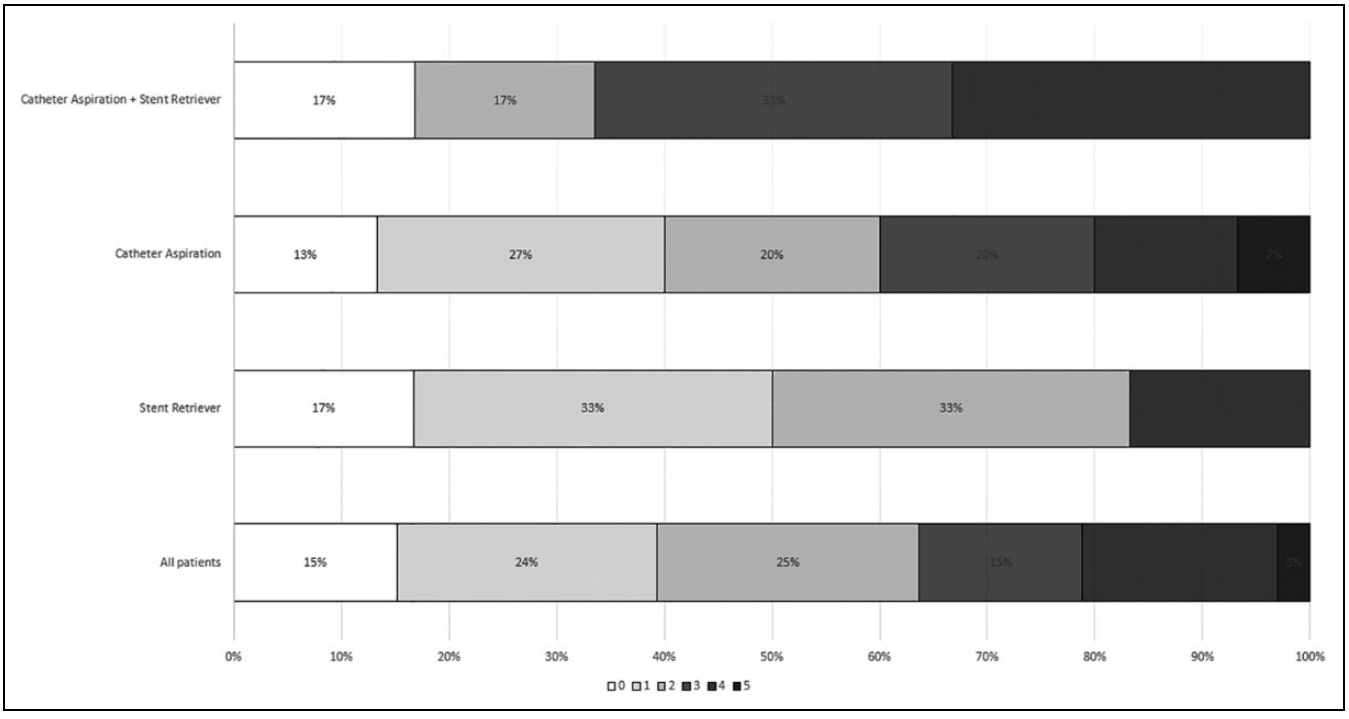

Figure 3. Clinical outcomes at follow-up by treatment group.

Concerning patient characteristics, the mean age, frequency of vascular risk factors, and NIHSS and ASPECTS scores were similar between our study and those reported in other series. The age reported in this series (65.1 ± 14.6 years) was closer to that reported in Chinese patients (63.3 ± 13.7 years old)[17] than in the US patients (69.8 ± 13.3 years old),[18] although the population in this last series was 79% Hispanic. Severity scores were also comparable between this and other series; with a median NIHSS score of 16, all our patients experienced moderate to severe stroke with results that were the same as those reported in a Pollack series[19] and 2 and 3 points below those reported in the SWIFT[20] and TREVO 2[21] trials, respectively. Additionally, in our series, the MCA was most common location of vascular occlusion (57.2%), whereas the comparable rate was 66% and 60% in the SWIFT[20] and TREVO 2[21] trials, respectively. It should be noted that all of our patients who were eligible received IV tPA, in line with current treatment recommendations[13]; nevertheless, we believe that this practice might change in the future in light of recent findings that associate the use of IV tPA in combination with endovascular treatment with higher hospitalization costs and higher rates of intracerebral hemorrhage.[18]

Regarding outcomes, we observed a high recanalization rate (69.4%), a figure well within the internationally reported rates, which range from 59% to 88%[13]; when we took into account only those cases treated with stent retriever, the recanalization success rate was 86.4% of our patients. As for the patients in group 3, their outcomes were more similar to those described in the IMS III trial,[22] in which the recanalization rate was 41%. Our symptomatic intracerebral hemorrhage rate of 4.1% was also close the average reported in prior trials.[13]

The recanalization rates found in this study also reflect clinical improvements as evidenced by the in-hospital NIHSS scores and mRS scores obtained at both discharge and follow-up. Nevertheless, we did not find that there was a substantial difference between the group treated with stent retriever and the group treated with other endovascular techniques (although this difference was statistically significant at discharge, it was not significant at follow-up).

The most important limitation of this study is the retrospective nature of the collected data. We believe that despite the fact that every effort was made to collect all data as reliably as possible from clinical files and angiographic records, we acknowledge that these efforts were not sufficient to overcome the limitation of the retrospective nature of the data. Future efforts involving the prospective collection of cases are currently being made to overcome this constraint. Additionally, the high proportion of patients who were lost to follow-up must also be addressed; unfortunately, the nature of the study population (private care/insurance patients) made it difficult to follow all the participants. In our health system, it is very common for private patients to ameliorate costs by moving to government-funded social insurance after the acute phase of an illness has passed, thus making themselves unavailable to the initial health-care team and, on some occasions, even untraceable.

Conclusion

We believe that the use of the MERR will be a great aid in the standardization of the endovascular procedures used in AIS within Mexico. Additionally, the routine measurement of desirable time metrics will likely result in continuous improvement in these metrics. Currently, our results show that in Mexico, endovascular treatment for AIS is not only feasible but also comparable in efficacy to other countries. Still, many challenges remain, especially increasing costs and difficulties associated with access to these treatments in at-risk populations.

Latin America as a whole and Mexico in particular need to close the gap in the adoption of current standards of care for AIS, such as the formation and consolidation of multidisciplinary stroke units and the expanded use of AIS therapies to achieve reperfusion, particularly endovascular techniques; moreover, such improvements need to be equally accessible to the majority of the population regardless of socioeconomic status or geographical location.

Therefore, modifications in governmental policies at the level of health system organization and the allocation of human and technological resources are critically required to secure patient access to adequate health units and to augment endovascular treatment utilization.

Declaration of Conflicting Interests

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