Endovascular therapy versus medical treatment for symptomatic intracranial artery stenosis: a meta-analysis of randomized controlled trials

Terapia endovascular versus tratamento médico para estenose arterial intracraniana sintomática: uma meta-análise de ensaios clínicos randomizados

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ABSTRACT

Background: Intracranial atherosclerotic stenosis (ICAS) is a leading cause of stroke worldwide, with a high risk of recurrence in patients with confirmed stroke and ≥ 70% stenosis. Dual antiplatelet therapy (DAPT) has proven to be more effective than monotherapy for ICAS. However, endovascular therapy (ET) has been explored for stroke prevention in ICAS patients. Therefore, we aim to perform a systematic review and meta-analysis in order to evaluate Conventional Medical Therapy (CMT) plus ET versus CMT in patients with ICAS.

Methods: We systematically searched PubMed, Embase, and Cochrane Central for randomized controlled trials (RCTs) comparing the two treatment regimens in patients with ICAS. Primary outcomes were all-cause mortality and any stroke or death within 30 days. Risk ratios (RRs) with 95% confidence intervals were calculated using a random effects model. R software (version 4.3.2) was used for statistical analyses.

Results: Five RCTs were included, comprising 1,491 patients, of whom 743 (49.8 %) received CMT plus ET. Any stroke or death within 30 days (RR = 2.73, 95% CI [1.74, 4.29], p < 0.0001, I2 = 0%) and all-cause mortality within 30 days (RR = 4.87, 95% CI [1.25, 18.96], p = 0.02, I2 = 0%) were significantly higher in patients treated with ET plus CMT compared with CMT alone.

Conclusion: This meta-analysis showed that CMT plus ET significantly increased the risk of stroke and all-cause mortality within 30 days compared with CMT alone. However, outcomes varied by technique: stenting was associated with higher early risk, whereas submaximal balloon angioplasty, as in the BASIS trial, suggested a possible long-term benefit.

Keywords: Stroke, Endovascular Procedures, Drug Therapy, Meta-Analysis.

RESUMO

Introdução: A estenose aterosclerótica intracraniana (EAIC) é uma das principais causas de AVC, com alto risco de recorrência em pacientes com AVC confirmado e estenose ≥ 70%. A terapia antiplaquetária dupla (DAPT) é mais eficaz que a monoterapia. A terapia endovascular (TE) tem sido explorada para prevenção de AVC em pacientes com EAIC. Nosso objetivo foi realizar revisão sistemática e meta-análise para avaliar TMC mais TE versus TMC isolada em pacientes com EAIC.

Métodos: Buscamos sistematicamente no PubMed, Embase e Cochrane Central ensaios clínicos randomizados (ECRs) comparando os dois esquemas de tratamento. Desfechos primários: mortalidade por todas as causas e ocorrência de AVC ou morte em até 30 dias. Razões de risco (RR) com IC 95% foram calculadas usando modelo de efeitos aleatórios. O software R (v. 4.3.2) foi utilizado.

Resultados: Cinco ECRs, com 1.491 pacientes, foram incluídos; 743 (49,8%) receberam TMC mais TE. Qualquer AVC ou morte em até 30 dias (RR = 2,73, IC 95% [1,74–4,29], p < 0,0001, I² = 0%) e mortalidade por todas as causas em 30 dias (RR = 4,87, IC 95% [1,25–18,96], p = 0,02, I² = 0%) foram significativamente maiores com TE mais TMC do que com TMC isolada.

Conclusão: TMC combinada com TE aumentou significativamente o risco de AVC e mortalidade por todas as causas em até 30 dias comparado à TMC isolada. No entanto, os resultados variaram conforme a técnica: o stent esteve associado a maior risco precoce, enquanto a angioplastia submáxima com balão, como no estudo BASIS, sugeriu possível benefício em longo prazo.

Palavras-chave: Acidente Vascular Cerebral, Procedimentos Endovasculares, Terapia com Drogas, Meta-Análise.

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Author contributions, following the CRediT taxonomy

1. Mariana Pimenta Barbosa: Conceptualization, Methodology, Formal analysis, Project administration, Writing – original draft, Writing – review & editing.
2. Gabriel Pimenta Barbosa: Data curation, Investigation, Formal analysis, Visualization, Writing – review & editing.
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4. Yan Riken Bastos Yara: Data curation, Investigation.
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INTRODUCTION

Intracranial atherosclerotic stenosis (ICAS) is a leading cause of stroke worldwide, with a particularly high prevalence among East Asian individuals and non-white populations in the United States compared to those of European descent. Among stroke patients, the risk of recurrence is highest in those with confirmed stenosis of ≥ 70%[1]. The current first-line treatment for ICAS is CMT (Conventional Medical Therapy), which typically includes aggressive control of vascular risk factors, antithrombotic therapy with DAPT (Dual antiplatelet therapy) and lifestyle modification[3]. This strategy has demonstrated superior safety and efficacy when compared to previous invasive approaches, making it the cornerstone of ICAS management, as supported by the SAMMPRIS trial.

In patients with symptomatic extracranial or intracranial large artery atherosclerosis, dual antiplatelet therapy (DAPT) has been shown to be more effective than monotherapy (MAPT) in preventing recurrent ischemic stroke without increasing bleeding risks. The optimal DAPT regimens and treatment duration for this population still need to be clarified in future studies[7]. However, recent studies have been raising the possibility of endovascular therapy (ET) plus Conventional Medical Therapy (CMT) in the prevention of stroke in patients with ICAS.

Endovascular therapy has emerged as a potential alternative or adjunctive approach for stroke prevention in high-risk patients, under the hypothesis that mechanical revascularization could provide more robust luminal restoration than pharmacological therapy alone. Despite early trials showing increased periprocedural risks, recent data from the CASSISS 2022 and BASIS 2024 trials have introduced renewed interest in whether ET combined with CMT might improve long-term outcomes in selected patients[4,10].

Therefore, we aim to perform a systematic review and meta-analysis to evaluate CMT plus ET versus CMT alone in patients with ICAS.

METHODS

This systematic review and meta-analysis was performed and reported in accordance with the Cochrane Collaboration Handbook for Systematic Review of Interventions and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Statement guidelines[11]. The prospective meta-analysis protocol was registered on PROSPERO on October 29, 2024 under protocol CRD42024603609.

Study eligibility

Inclusion in this meta-analysis was restricted to studies that met all the following eligibility criteria: (1) randomized controlled trial (RCT); (2) patients with severe intracranial stenosis, confirmed by diagnostic angiography, of a large intracranial artery supplying the territory of the target lesion; (3) studies comparing CMT plus ET with CMT alone; (4) studies available in English and full-text; and (5) studies which reported any of the clinical outcomes of interest. We excluded from this analysis studies with: (1) patients with a modified Rankin Scale score greater than 3 and intracranial stenosis less than 70%; (2) no outcome of interest, and (3) overlapping study populations.

Search strategy and data extraction

We systematically searched PubMed, Embase, and the Cochrane Central Register of Controlled Trials from inception to September 2024 using the following search terms: "Intracranial artery stenosis," "symptomatic intracranial atherosclerosis," "endovascular therapy," "stenting," "medical management," "CMT," and "medical therapy."

The references from all included studies, previous systematic reviews, and meta-analyses were also searched manually for any additional studies. Two authors independently extracted the data following predefined search criteria and quality assessment.

Endpoints

Outcomes included any stroke or death within 30 days, stroke in the same territory within 1–3 years, all-cause mortality within 30 days, and death within 1–3 years. The term "Stroke in the same territory of the qualified artery" refers to a stroke that occurs in the same area of the brain supplied by the stenosed artery under study.

Quality assessment

The Cochrane tool for assessing risk of bias in randomized trials (RoB 2) was utilized for quality assessment of randomized studies[9]. The risk of bias evaluation was performed independently by two authors (GPB and LEFC) with disagreements resolved by consensus. Publication bias was assessed with funnel-plot analysis and Egger's test.

Statistical analysis

Risk ratios (RR) with 95% confidence intervals were used to compare treatment effects for categorical endpoints. We assessed heterogeneity using the I^2 statistic and the Cochran Q test. P-values < 0.10 and I^2 > 25% were considered significant for heterogeneity. The platform used to create the forest plots was Review Manager 5.4.

RESULTS

Study selection and baseline characteristics

The initial search yielded 2,054 results. After removing duplicate records and ineligible studies, 23 studies remained and were fully reviewed based on the

inclusion criteria. Of these, a total of 5 studies were included, comprising 1,491 patients from five RCTs (Figure 1).

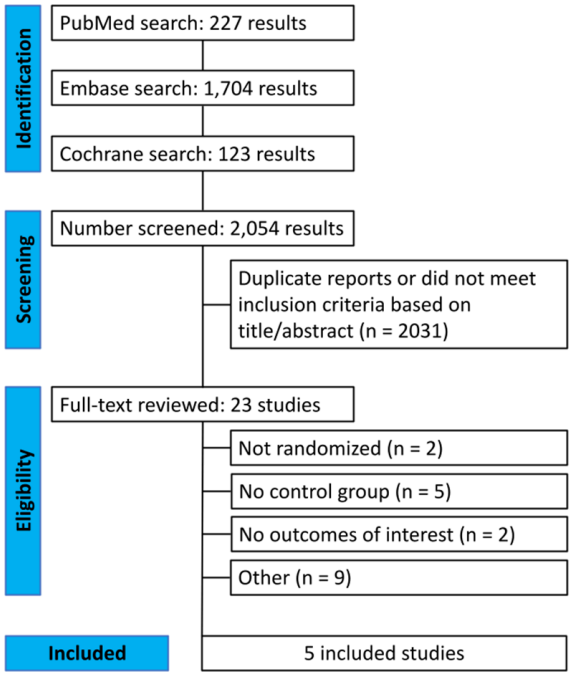

Figure 1. PRISMA flow diagram of included studies

Five RCTs were included in the meta-analysis, comprising 1491 patients (743 in the ET plus CMT group and 748 in the CMT monotherapy group)[3,4,8,10,13]. Four studies used stent and one study used balloon angioplasty without stent. Both groups received aspirin throughout the entire follow-up period and clopidogrel for the first 90 days. The mean patient age was 58.66 years. Study characteristics are reported in Table 1.

Table 1. Baseline characteristics of the included studies

	SAMMPRIS 2011 [3]	Miao 2012 [8]	VISSIT 2015 [13]	CASSISS 2022 [4]	BASIS 2024 [10]
Patients (n) ET/CMT	224/227	36/34	58/53	176/182	249/252
Male (%) ET/CMT	57/64	66.7/73.5	70.7/60.4	72.7/74.2	69.1/67.9
Mean/Median Age (Years) ET/CMT	61/59.5	53.42/49.18	61.8/61.8	56.7/55.9	58/58
HP (%) ET/CMT	89/89	63.9/44.1	84.5/81.1	66.5/68.7	72.7/73.4
DM (%) ET/CMT	47/45	22.2/14.7	43.1/37.7	32.4/24.2	32.9/34.5
HL (%) ET/CMT	87/89	27.8/38.2	50/60.4	10.2/11.5	70.7/75.8
Current smoking (%) ET/CMT	24/30	58.3/55.9	19/22.6	23.3/27.5	24.1/26.2
Stroke (%) ET/CMT	63/67	19.44/23.5	62.1/64.2	50.6/57.7	86.4/82.5
TIA (%) ET/CMT	37/33	80.55/76.47	41.4/41.5	49.4/42.3	13.7/17.5
CAD (%) ET/CMT	21/26	9.1/14.7	17.2/22.6	10.8/10.4	NA
Middle cerebral artery (%) ET/CMT	41/46	100/100	NA	36.9/43.4	57.4/61.1

SAMMPRIS: Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis, VISSIT: Vitesse Intracranial Stent Study for Ischemic Stroke Therapy; CASSISS: China Angioplasty and Stenting for Symptomatic Intracranial Severe Stenosis; BASIS: Balloon Angioplasty for Symptomatic Intracranial Artery Stenosis; ET: Endovascular therapy; CMT: Conventional medical treatment; HP: Hypertension; DM: Diabetes mellitus; HL: Hyperlipidemia; TIA: Transient ischemic attack; CAD: Coronary artery disease; NA: Not available.

Overall analysis

Any stroke or death within 30 days

Our study showed a significantly higher risk of any stroke or death within 30 days in the ET plus CMT group compared with the CMT alone group (RR = 2.73; 95% CI [1.74- 4.29]; p < 0.0001; I2 = 0%; Figure 2A).

Stroke in the same territory of qualified artery within 1–3 years

There were no statistically significant differences in the risk of stroke in the same territory of the qualified artery within 1 to 3 years with ET plus CMT compared to CMT alone (RR = 1.18; 95% CI [0.48-2.94]; p = 0.72; I^2 = 79%; Figure 2B).

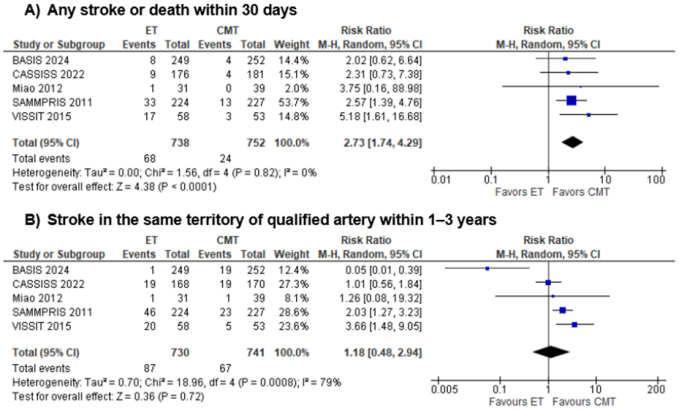

Figure 2. (A) The risk of any stroke or death within 30 days was significantly increased in the ET plus CMT group compared with the CMT group. (B) There was no significant differences between groups in the risk of stroke in the same territory of qualified artery within 1-3 years

Death within 30 days

Our study showed a significantly higher risk of death within 30 days in the ET plus CMT group compared with the CMT alone group (RR = 4.87; 95% CI [1.25-18.96]; p = 0.02; I^2 = 0%; Figure 3A).

Death within 1–3 years

There was no statistically significant difference between groups during this period. (RR = 1.50; 95% CI [0.72-3.13]; p = 0.28; I^2 = 0%; Figure 3B).

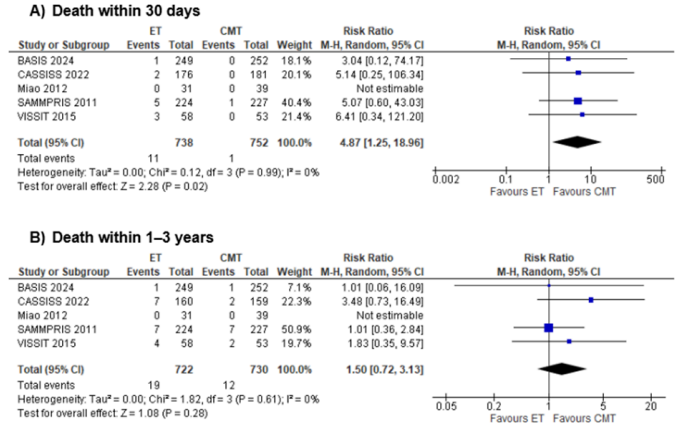

Figure 3. The risk of death within 30 days was significantly increased in the ET plus CMT group compared with the CMT group. (B) There were no significant differences between groups for the risk of death within 1-3 years.

Quality assessment

The Risk of Bias 2 (RoB 2) tool was used for quality assessment. No studies were considered at high risk of bias as described in the supplementary appendix (Table S1). Egger's test indicates no evidence of publication bias (p = 0.4445, Fig. S2 in the Supplementary Appendix). The platform used to create the bias risk charts and tables was RStudio 2024.04.0.

DISCUSSION

In this systematic review and meta-analysis of five studies, comprising a total of 1,491 patients, we compared endovascular therapy (ET) plus conventional medical therapy (CMT) against CMT alone. Our key findings demonstrated that the combination of ET and CMT significantly increased:[1] the risk of any stroke or death within 30 days and[2] all-cause mortality within 30 days. However, for long-term outcomes, specifically[3] stroke in the same territory of qualified artery within 1–3 years and[4] death within 1–3 years, no statistically significant difference could be established between the compared treatments.

Both balloon and stent angioplasty have distinct mechanisms of benefit and risk that warrant careful consideration and discussion. When it comes to risk profiles in the treatment of intracranial atherosclerotic stenosis, stenting, as evidenced by the CASSISS and SAMMPRIS trials[3,4], carries a considerable risk of severe complications within the first 30 days, including disabling stroke (2.8% in CASSISS, 8.5% in SAMMPRIS), symptomatic intracranial hemorrhage (2.3% in CASSISS, 4.5% in SAMMPRIS, with 40% of cases proving fatal), and stroke-related mortality (1.1% in CASSISS)[4,2]. In contrast, balloon angioplasty, while avoiding some of the risks inherent to stent placement, is primarily limited by arterial dissection[10], occurring in 14.5% of patients in the BASIS trial. Other procedural complications of the trial include vasospasm (1.2%), arterial occlusion (0.4%), arterial perforation (0.4%), hemorrhage (0.4%), and thrombosis (1.7%). These findings highlight the trade-offs between the two approaches, with stenting posing a higher early risk of disabling or fatal stroke, while balloon angioplasty is more prone to vascular injury during the procedure.

Despite these risks, stenting also presents notable advantages in the treatment of intracranial atherosclerotic stenosis. As demonstrated in Miao's trial[8], it reported a periprocedural complication rate of zero, suggesting a safer immediate post-procedural profile. This may be attributed to the broader clinical expertise in stent placement compared to balloon angioplasty, where the limited number of experienced clinicians could contribute to higher periprocedural complication rates and, consequently, less favorable outcomes.

The SAMMPRIS study and the BASIS study included a similar number of patients in both the control and intervention groups[3,10]. The studies showed consistent results across all outcomes, except for 'stroke in the same territory of the qualified artery within 1–3 years.' The BASIS study was the only one that demonstrated a benefit with the use of ET in this outcome. This was the only favorable result for ET across all outcomes in all the studies.

In the individual studies, only the BASIS trial demonstrated that endovascular treatment is superior to conventional medical management. This finding may be attributed to the fact that it recommended submaximal intracranial balloon angioplasty without stent implantation, a procedure that is shorter in duration compared to stent placement. Except for the BASIS study, the other studies used stenting as the endovascular approach.

This advantage is likely driven by the hemodynamic improvements provided by the procedure, which appear to outweigh its short-term procedural risks. These findings underscore a key distinction between the two techniques: while stenting may offer a lower immediate complication rate, balloon angioplasty has demonstrated superior long-term efficacy, potentially offsetting its short-term risks associated with periprocedural complications[10].

This finding opens up the possibility of revisiting more conservative approaches and less invasive treatment techniques, such as balloon angioplasty. It also provides a foundation for future research that could directly compare these approaches to optimize treatment for patients with ICAS.

If proven to be superior, the less invasive approach with submaximal balloon angioplasty could reduce the risk of complications associated with stent use, such as the occlusion of side branches and the need for additional revascularization. This could improve patient outcomes and reduce long-term costs related to complications and subsequent treatments. Furthermore, it could also open up new treatment opportunities for patients with stenosis that are difficult to manage with other approaches[10].

Recent advancements in the treatment of ICAS emphasize the critical need to balance risks and benefits in therapeutic decision-making. This diversified perspective is essential in the field of neurology, where optimizing patient outcomes depends on informed choices. The relationship between various treatment options emphasizes the complexity of managing ICAS[5]. While some interventions offer immediate procedural safety, others provide more promising long-term results. This contrast calls for a personalized approach to care, which carefully considers both short-term risks and long-term benefits.

These findings make a substantial contribution to the broader field of neurology by highlighting the necessity for treatment strategies tailored to individual patient profiles. The ongoing debate over the best therapeutic approaches reinforces the importance of continued research to refine and improve treatments for ICAS. In the end, advancing care for ICAS requires that clinicians have access to comprehensive, patient-specific data to guide

their decisions. By integrating insights from various studies into clinical practice, healthcare providers can more effectively navigate the complexities of ICAS management, ultimately improving patient outcomes over time.

The results demonstrated no clinical benefit from the addition of stenting to medical therapy for the treatment of patients with symptomatic intracranial atherosclerotic stenosis. These results reinforce the American Academy of Neurology (AAN) Practice Advisory on stroke prevention in ICAS[11], which advocates for aggressive medical therapy over stenting in patients with this condition.

LIMITATIONS

The conclusions drawn from this meta-analysis should be interpreted considering several limitations. First, we were unable to provide more robust results for subgroup analyses due to the lack of patient-level data. Second, two of the included RCTs (SAMMPRIS and VISSIT trials) were terminated prematurely, leading to a reduction in their sample size and statistical power. Third, a high degree of heterogeneity was observed in some outcomes, particularly in the analysis of stroke in the same vascular territory within 1 to 3 years, which may reduce the reliability of the pooled estimates and suggests that the included studies might have assessed slightly different phenomena or involved significantly varied populations, thereby limiting the generalizability of the results. Finally, there was procedural heterogeneity among the trials, as most used stent implantation while only one adopted submaximal balloon angioplasty without stenting, potentially influencing both efficacy and safety outcomes across studies.

CONCLUSION

In summary, ET plus CMT significantly increased the risk of any stroke or death within 30 days, death within 30 days, and early procedural complications compared with CMT alone. For long-term outcomes, no significant differences were observed overall; however, results varied according to the endovascular technique employed. Stenting was consistently associated with higher early complication rates and no clear long-term benefit, whereas submaximal intracranial balloon angioplasty, as adopted in the BASIS trial, suggested potential long-term efficacy with fewer risks. These findings indicate that not all endovascular approaches should be considered equivalent: while stenting remains burdened by early hazards, balloon angioplasty may represent a less invasive alternative with a more favorable safety profile. Therefore, further high-quality randomized trials are warranted to specifically evaluate CMT in combination with submaximal balloon angioplasty, which may provide improved patient safety and long-term outcomes in selected ICAS populations[10].

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