

## SYSTEMATIC REVIEW AND META-ANALYSIS

# CAROTID ENDARTERECTOMY VERSUS CAROTID ARTERY STENTING WITH DOUBLE-LAYER MICROMESH STENT IN CAROTID ANGIOPLASTY: NETWORK META-ANALYSIS

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## Abstract

**Introduction:** Carotid endarterectomy (CEA) remains the gold standard for carotid stenosis, but modern carotid artery stenting (CAS) with double-layer micromesh stents (e.g., CGuard, Roadsaver [RS]) offers potential reductions in peri-procedural embolic risk. However, comparative evidence between CEA and modern CAS remains limited.

**Methods:** A systematic search of PubMed, ScienceDirect, and Europe PMC (June 23, 2025) identified randomized and observational studies on symptomatic or high-grade asymptomatic carotid stenosis using terms including “double-layer stent,” “micromesh,” “Roadsaver,” “CGuard,” and “carotid endarterectomy.” Reviews, meta-analyses, and case reports were excluded. Comparisons included single-layer CAS vs. CEA, single-layer CAS vs. CGuard/RS, and indirect CEA vs. CGuard/RS. Outcomes were neurological complications and neurological death. Study quality was assessed using Cochrane RoB 2.0 and Newcastle-Ottawa Scale (NOS). A frequentist random-effects network meta-analysis was performed using MetaInsight.

**Results:** Eleven studies (7 RCTs, 4 observational; n=9483) were included. Seven had moderate RoB 2.0 risk, while three observational studies had fair quality and one study had good quality according to NOS. No significant difference was detected in neurological complications between CEA and CGuard/RS (OR 0.79; 95% CI 0.34–1.80), and neurological death was similar among CEA, CGuard/RS, and CAS. When compared with conventional CAS, CEA (OR 0.90; 95% CI 0.69–1.18) and CGuard/RS (OR 1.04; 95% CI 0.30–3.65) showed no significant differences. The direct comparison between CEA and CGuard/RS also demonstrated no significant effect (OR 0.86; 95% CI 0.24–3.11).

**Conclusions:** This study found no significant differences in stroke prevention or safety CEA and DLMS. Larger comparative studies are required to establish their relative clinical effectiveness.

**Keywords:** carotid artery stenting; carotid endarterectomy; micromesh stent; single-layer stent; stroke

**Received:** October 15<sup>th</sup>, 2025

**Accepted:** December 1<sup>st</sup>, 2025

**Published:** December 27<sup>th</sup>, 2025

## How to cite this paper:

Hailianto EN, Luvia F, Santoso KJA, Hermawan CC, Prawira JM, July J. Carotid endarterectomy versus carotid artery stenting with double-layer micromesh stent in carotid angioplasty: Network Meta-Analysis. Lumina Indones J Neurol. 2025; 1(3): 26-36

## Introduction

Ischemic stroke is one of the leading causes of morbidity and mortality worldwide, including in Indonesia. According to the World Health Organization (WHO), stroke is the second leading cause of death globally and a major cause of long-term disability. Data from the Indonesian Basic Health Research (Riskesdas) show that the prevalence of stroke in Indonesia continues to rise. In 2013, the prevalence was reported at 7 per 1,000 population, increasing to 10.9 per 1,000 in 2018. More recently, the 2023 Indonesia Health Survey (SKI) reported that 8.3 per 1,000 individuals aged over 15 years had experienced stroke. This growing prevalence highlights stroke as a serious public health problem that requires comprehensive management strategies.<sup>1</sup>

Atherosclerosis of the extracranial carotid arteries accounts for an estimated 15–20% of ischemic stroke cases. Carotid stenosis is strongly associated with an increased risk of both first-time and recurrent stroke, making carotid revascularization an important strategy for secondary prevention in patients with moderate to severe stenosis.<sup>2</sup>

The main modalities for carotid revascularization are carotid endarterectomy (CEA) and carotid artery stenting (CAS). The Indonesian Society of Cardiology (PERKI) guidelines recommend CEA for patients with asymptomatic carotid stenosis of  $\geq 60\text{--}99\%$  who are at high risk of stroke with best medical therapy (BMT) alone. CEA is also recommended for symptomatic stenosis of  $\geq 70\text{--}99\%$ , and can be considered for patients with 50–69% stenosis. Based on high-quality evidence,

CEA should ideally be performed within two weeks of the most recent ischemic event in patients with symptomatic stenosis of  $\geq 50\text{--}99\%$ . In contrast, CAS may be considered in patients under 70 years of age with symptomatic stenosis  $\geq 50\text{--}99\%$ , although the supporting evidence for this indication is more limited.<sup>3</sup>

CEA has long been considered the standard treatment, supported by strong evidence from large clinical trials such as NASCET, ECST, and CREST, which demonstrated its effectiveness in reducing long-term stroke risk. In an observational analysis, the incidence of stroke in the CEA group was 1.9%, lower than conventional CAS at 4.1%. Four-year mortality was also lower in CEA (4.7%) compared with CAS (6.4%). The mechanism of CEA is the direct removal of atherosclerotic plaque from the carotid artery, restoring lumen patency and significantly reducing the risk of embolization. CAS, on the other hand, was developed as a less invasive alternative by placing a stent to maintain vessel patency. However, its main limitation is the risk of plaque debris release which can cause peri-procedural embolization.<sup>4</sup>

To address this weakness of conventional CAS, double-layer micromesh stents (DLMS), such as Roadsaver and CGuard, were developed. These stents use a dual-layer mesh design with smaller pores, providing improved protection against plaque debris migration into the cerebral circulation. The ROADSAYER study showed that DLMS was associated with lower complication rates compared with conventional CAS. In this study, the 30-day rate of stroke or death was 2.1% in the DLMS group compared with 4.1% in the

conventional CAS group. Other outcomes also favored DLMS, including lower rates of ipsilateral stroke at 12 months (1.3% vs 3.5%), restenosis  $\geq 70\%$  (1.2% vs 4.0%), and all-cause mortality (1.9% vs 3.7%).<sup>5</sup>

CEA and DLMS represent two revascularization modalities with different protective mechanisms to prevent stroke. However, an observational study directly comparing CEA with DLMS reported no significant difference in stroke incidence, with 2.2% in the CEA group and 2.3% in the DLMS group. This finding suggests that although CEA is superior to conventional CAS, and DLMS shows improvements over earlier stent designs, current evidence is still insufficient to confirm whether CEA is superior to DLMS.<sup>6</sup>

Conventional single-layer CAS remains a widely used comparator in carotid revascularization and DLMS were developed to address its embolic limitations. Evaluating DLMS without considering conventional CAS would provide an incomplete context relative to CEA. Therefore, this study compares CEA, conventional CAS, and DLMS within a network meta-analysis framework.

## Materials and Methods

The study was conducted in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidance.

### Eligibility criteria

Studies were considered eligible if they met all of the following criteria: 1) they were randomized controlled trials, clinical trials, or observational studies; 2) they compared CEA/DLMS with single-

layer conventional CAS; and 3) Symptomatic or asymptomatic patients with significant carotid artery stenosis ( $\geq 50\%$ ) who were suitable for both CEA and/or CAS. In cases of duplicate trials, the trial with the longest follow-up period was included.

### Literature search strategy

We conducted a search across several databases, including PubMed, ScienceDirect and Europe PMC on 23 June 2025. We utilized search terms such as ("double-layer stent" OR micromesh OR "double-layered stent" OR roadsaver OR CGuard OR "carotid endarterectomy" OR CEA) AND ("single-layer stent" OR "single-layered stent" OR "wallstent" OR "stent").

### Outcome measurement

The outcomes measured were neurological death and neurological complications. Neurological death was defined as death caused by neurologic events, such as fatal stroke, intracranial hemorrhage, procedure-related cerebral embolism, and others occurring within the periprocedural or follow-up period. Neurological complications were defined as a composite of ischemic stroke and symptomatic intracranial hemorrhage (sICH).

### Data extraction

Two authors independently screened the titles and abstracts of the searched studies. After obtaining full-text studies, four authors independently extracted data for review and evaluated them based on inclusion and exclusion criteria. Another author then double-

checked the extracted data. In cases of disagreement, a fifth investigator would review data. The extracted data included baseline characteristics of the study population, primary outcome data, and other information.

### **Bias assessment**

Study quality was assessed using the Revised Cochrane Risk-of-Bias Tool for Randomized Trials (RoB 2.0) for RCTs and Newcastle-Ottawa Scale (NOS) for observational studies. The risk of bias assessment was performed by four authors. Differences in the data extraction and quality assessment processes were then discussed with other authors.

### **Statistical analysis**

We conducted a frequentist network meta-analysis using MetaInsight. We calculated treatment estimates as odds ratio (ORs) with their 95% confidence intervals (CIs). Analysis results will be presented in forest plots and effects a combination is said to be meaningful if the confidence interval does not intersect the vertical line. Inconsistency between direct and indirect evidence was assessed using a node-splitting approach to compare treatment-specific effect estimates within the network.<sup>7</sup>

## **Results**

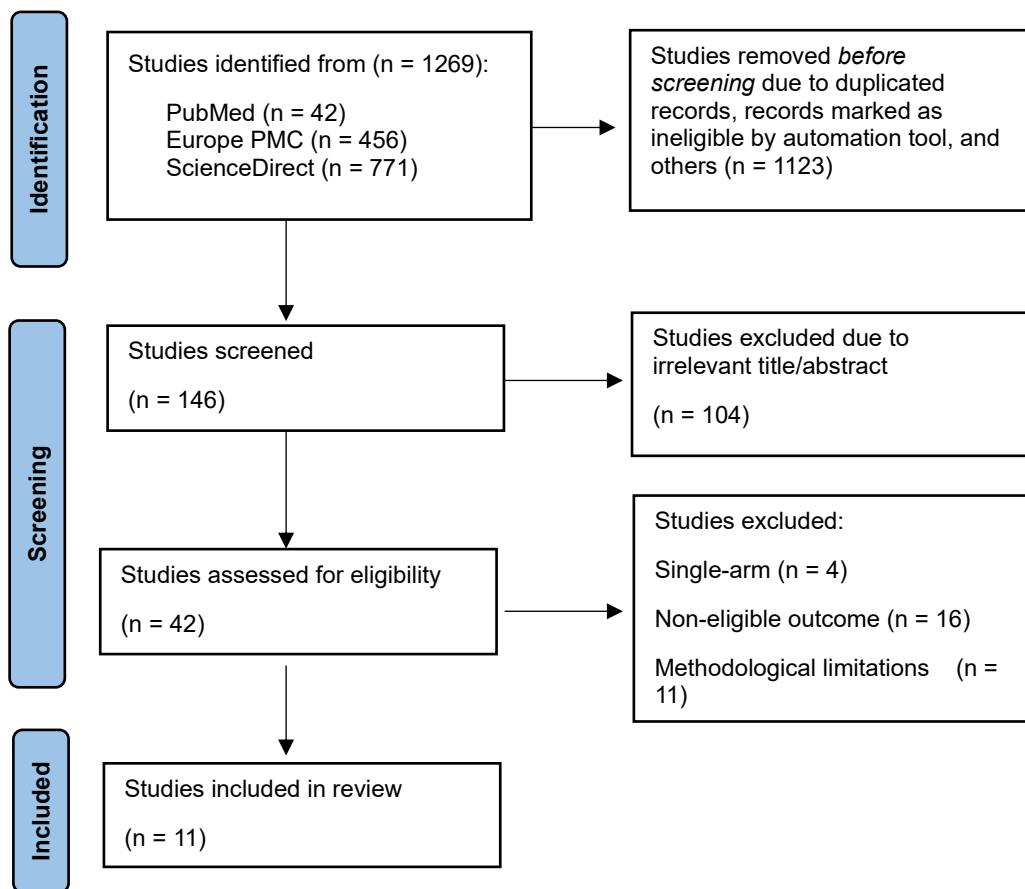
### **Search results and study characteristics**

A total of 1269 entries were identified from the preliminary database search. A total of 1227 records were removed for multiple reasons during the title and abstract screening, including duplicate and irrelevance to the analysis.

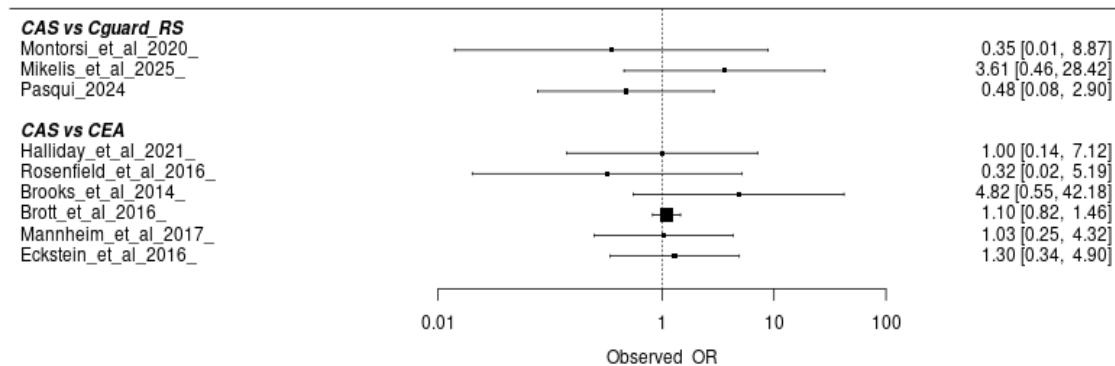
The full-texts of remaining 42 papers were meticulously examined. Subsequently, 31 papers were excluded, 4 were single-arm studies, 16 reported non-eligible outcomes, and 11 were removed due to the methodological limitations. A total of 7 randomized controlled trials and 4 observational studies involving 9,483 patients were included into the network meta-analysis. The selecting process is illustrated in Figure 1. The characteristics of the studies included are presented in Table 1. Seven studies showed moderate risk of bias. Among the observational studies, three were rated as fair quality and one as good quality (Table 2 and Table 3).

### **Neurological complications**

In the frequentist network meta-analysis (Figure 4), both carotid endarterectomy (CEA) and double-layer micromesh stenting (DLMS; CGuard/Roadsaver) were compared against conventional carotid artery stenting (CAS). The analysis demonstrated that CEA was associated with a significantly lower odds of the composite outcome compared with CAS, with an odds ratio (OR) of 0.69 (95% CI 0.55–0.87). In contrast, DLMS (CGuard/Roadsaver) showed a lower odds ratio compared with CAS (OR 0.54, 95% CI 0.25–1.21), but this result did not reach statistical significance given the wide confidence interval crossing unity. These findings suggest that while both CEA and DLMS tend to reduce adverse outcomes compared with conventional CAS, the benefit of DLMS remains uncertain due to imprecision and limited sample size, whereas CEA demonstrates a more consistent protective effect.



**Figure 1.** PRISMA flow diagram



**Figure 2.** Individual study results for neurological death

**Table 1.** Table of characteristics

Author	Country	Treat- ment	Duration	Age	Sample	Neurolo- gical complic- ation (n)	Neurological death (n)
Halliday et al. (2021) <sup>8</sup>	33 countries (multicenter)	CEA	2008–2020 (5-year follow-up)	≥70 years (50% in CAS, 51% in CEA)	3625	41	2
Rosenfield et al. (2016) <sup>9</sup>	USA	CEA	2005–2013 (5-year follow-up)	CAS: $67.7 \pm 7.0$ CEA: $67.9 \pm 6.9$	1453	5	1
Brooks et al. (2014) <sup>10</sup>	USA	CEA	1998–2002 (10-year follow-up)	N/A	189	0	1
Brott et al. (2016) <sup>11</sup>	USA and Canada	CEA	Median follow-up: 7.4 years	Mean 69.0 years ( $\pm 8.9$ SD)	2502	71	97
Mannheim et al. (2017) <sup>12</sup>	Israel	CEA	Mean follow-up of 26 months, up to 5 years	Mean age (69 $\pm$ 7 years CAS) (68 $\pm$ 8 years CEA)	136	1	4
Eckstein et al. (2016) <sup>13</sup>	Germany	CEA	2009–2014 (5 year follow up)	BMT: Mean age 68, CEA: Mean age 70 years, CAS: Mean age 69 years	513	4	4
Montorsi et al. (2020) <sup>14</sup>	Italy	DLCS	December 2016 to January 2018	70-73 $\pm$ 8-10	104	0	1
Zidan et al. (2024) <sup>15</sup>	Germany	DLCS	November 2018 to December 2022	CGuard: Mean 71.9 $\pm$ 13.0 years	86	7	N/A
				CAS: Mean 71.4 $\pm$ 12.6 years			
Abdullayev et al. (2020) <sup>16</sup>	Germany	DLCS	April 2017 to May 2018	Median 69 (IQR 61-76)	76	1	N/A
Mikelis et al. (2025) <sup>17</sup>	Lithuania	DLCS	December 2006 to September 2023	Median age 70 years (range: 45–93)	573	2	1
Pasqui et al. (2024) <sup>18</sup>	Italy	DLCS	January 2019 to January 2022	Mean 77.0 $\pm$ 7.4 years	226	0	3

**Table 2.** Newcastle-Ottawa Scale

Newcastle-Ottawa Scale					
Study	Selection	Comparability	Outcome	Quality	
Zidan et al. (2024)	4	1	1		Fair
Abdullayev et al. (2020)	4	1	1		Fair
Mikelis et al. (2025)	3	1	2		Fair
Pasqui et al. (2024)	3	1	3		Good

Study	Risk of bias domains					
	D1	D2	D3	D4	D5	Overall
Brooks et al. (2014)	+	-	+	-	+	-
Montorsi et al. (2020)	+	-	+	-	+	-
Rosenfield et al. (2016)	+	-	-	-	+	-
Halliday et al. (2021)	+	-	+	-	+	-
Brott et al. (2016)	+	+	-	+	+	-
Mannheim et al. (2017)	-	-	+	-	+	-
Eckstein et al. (2016)	+	-	+	+	-	-

Domains:  
D1: Bias arising from the randomization process.  
D2: Bias due to deviations from intended intervention.  
D3: Bias due to missing outcome data.  
D4: Bias in measurement of the outcome.  
D5: Bias in selection of the reported result.

Judgement  
- Some concerns  
+ Low

**Table 3.** Risk of Bias 2.0

When directly compared (Table 4), DLMS versus CEA yielded an OR of 0.79 (95% CI 0.34–1.80), indicating no statistically significant difference between the two modalities. These findings suggest that while both CEA and DLMS reduce the risk of neurological complications relative to conventional CAS, the comparison between CEA and DLMS remains inconclusive. Node-splitting analysis showed no evaluable inconsistency due to the absence of indirect evidence or head-to-head comparisons in the network (Table 6).

### **Neurological death**

In the frequentist network meta-analysis evaluating neurological death (Figure 5), both carotid endarterectomy (CEA) and double-layer micromesh stenting (DLMS; CGuard/ Roadsaver) were compared with conventional carotid artery stenting (CAS). CEA demonstrated a trend toward reduced neurological death compared with CAS, with an odds ratio (OR) of 0.90 (95% CI 0.69–1.18); however, this association was not statistically significant as the confidence interval

crossed unity. Similarly, DLMS showed an OR of 1.04 (95% CI 0.30–3.65) compared with CAS, indicating no measurable reduction in neurological death, with wide confidence intervals reflecting imprecision and limited evidence. Taken together, these findings suggest that neither CEA nor DLMS showed a statistically significant advantage over CAS for neurological death, though the effect estimate for CEA trended in favor of benefit, while the estimate for DLMS was neutral.

When CEA and DLMS were directly compared (Table 4), the OR was 0.86 (95% CI 0.24–3.11), suggesting no statistically significant difference between the two modalities. Taken together, these findings indicate that neither CEA nor DLMS significantly reduced neurological death compared with conventional CAS, and the direct comparison between CEA and DLMS highlights persisting uncertainty regarding their relative effectiveness for this outcome. Node-splitting analysis showed no evaluable inconsistency due to the absence of indirect evidence or head-to-head comparisons in the network (Table 7).

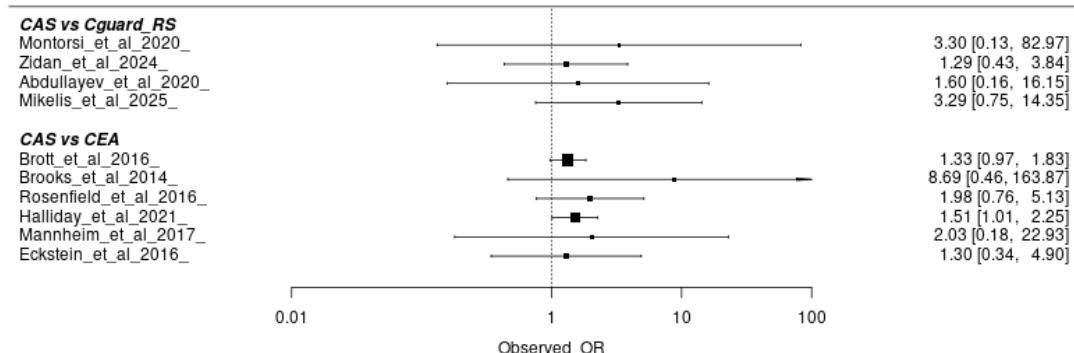


Figure 3. Individual study results for neurological complications

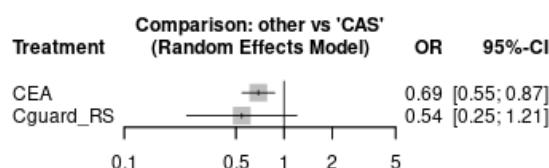


Figure 4. Forest plot of neurological complications

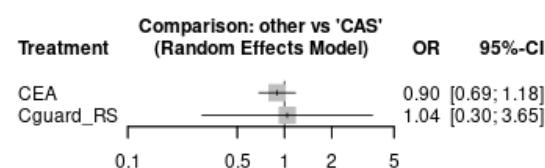


Figure 5. Forest plot of neurological death

Table 4. All comparison treatment outcome for neurological complications

Comparison	Odds Ratio (OR)	95% CI
CEA vs CAS	0.69	0.55-0.87
DLMS vs CAS	0.54	0.25-1.21
DLMS vs CEA	0.79	0.34-1.80

Table 5. All comparison treatment outcome for neurological death

Comparison	Odds Ratio (OR)	95% CI
CEA vs CAS	0.90	0.69-1.18
DLMS vs CAS	1.04	0.30-3.65
DLMS vs CEA	0.86	0.86-3.11

Table 6. All studies inconsistency for neurological complications

Comparison	Studies (n)	NMA	Direct	Indirect	Difference	95% CI	P-value
CEA:CAS	6	-0.37	-0.37	NA	NA	NA	NA
Cguard_RS:CAS	4	-0.61	-0.61	NA	NA	NA	NA
CEA:Cguard_RS	0	0.24	NA	0.24	NA	NA	NA

Table 7. All studies inconsistency for neurological death

Comparison	Studies (n)	NMA	Direct	Indirect	Difference	95% CI	P-value
CEA:CAS	6	-0.11	-0.11	NA	NA	NA	NA
Cguard_RS:CAS	3	0.04	0.04	NA	NA	NA	NA
CEA:Cguard_RS	0	-0.15	NA	-0.15	NA	NA	NA

## Discussion

In this network meta-analysis, the comparison between carotid endarterectomy (CEA) and double-layer micromesh stenting (DLMS; CGuard,

Roadsaver) showed an odds ratio favoring CEA, but the association did not reach statistical significance (OR 0.79, 95% CI 0.34–1.80 for neurological complications; OR 0.86, 95% CI 0.24–3.11 for neurological

death). These results suggest a trend toward lower adverse outcomes with CEA compared with DLMS, although the wide confidence intervals highlight imprecision and uncertainty.

The lack of statistical significance is consistent with findings from an observational study directly comparing CEA and DLMS, which also reported no significant differences in clinical outcomes. The incidence of stroke was 2.2% in the CEA group, while 2.3% occurs in the DLMS group, with comparable rates of stenosis. This parallel between network and direct observational evidence reinforces the notion that while DLMS may reduce embolic complications compared with conventional CAS, it has not yet demonstrated superiority over CEA.<sup>6</sup>

Pathophysiologically, the explanation may lie in the mechanisms of both interventions. CEA physically removes the atherosclerotic plaque, thereby eliminating the embolic source and restoring luminal patency. DLMS, in contrast, relies on its dual-layer micromesh design to prevent plaque prolapse and reduce embolization compared with conventional stents. However, recent imaging studies using optical coherence tomography (OCT) demonstrated that residual plaque prolapse (PP) and strut malapposition (SM) can still occur with new-generation stents. Specifically, PP was observed in 20% of patients treated with Roadsaver and 10% with CGuard, while SM occurred in 26% and 20%, respectively. These complications are likely related to the nature of the plaque, especially lipid-rich lesions that may prolapse despite ultra-closed mesh. Consequently, DLMS

may approximate the efficacy of CEA but does not consistently surpass it in preventing neurological complications or neurological death.<sup>19</sup>

These findings should be interpreted carefully. The comparison between CEA and DLMS had wide confidence intervals because of the small number of studies and low event counts. Most of the evidence came from observational studies, which may introduce bias and differences in procedures. The follow-up duration also varied across studies. Larger randomized trials with standardized follow-up are needed to determine whether the observed differences represent a real effect or sampling variability.

## Conclusion

This study found no significant differences in neurological complications prevention or safety between CEA and DLMS. Larger comparative studies are required to establish their relative clinical effectiveness.

## Conflict of Interest

The authors declared no conflict of interest.

## Acknowledgment

The authors declared no acknowledgment.

## Funding

No external funding was received.

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