Outcome of primary closure following carotid endarterectomy with a novel technique: An 8-year multicenter cohort study

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ABSTRACT

This study evaluated the safety and efficacy of a novel primary closure technique in carotid endarterectomy compared with traditional methods. Conducted over 8 years at three university hospitals, this study included 184 patients. Early complications (8.7%) included hematoma, transient ischemic attack, myocardial infarction, stroke, and death. Late complications involved myocardial infarction, death, transient ischemic attack, stroke, and reintervention. The 1-year follow-up showed a significant (>70%) restenosis rate of only 1.9%. The novel technique in carotid endarterectomy seems to be a safe and effective alternative to patch angioplasty, offering advantages for selected patients. Further studies are required. (J Vasc Surg Cases Innov Tech 2025;11:101662.)

Keywords: Carotid endarterectomy (CEA); Primary closure; Carotid artery disease; Stroke; Vascular surgery

Carotid endarterectomy (CEA) remains a well-established procedure for preventing strokes in patients with symptomatic carotid artery disease with stenosis >50% and in asymptomatic individuals with stenosis >70%, based on established guidelines.[1] The risk of complications after this surgery depends on creating a smooth artery surface after endarterectomy, ensuring a gradually tapered distal end point and accurately closing the artery. Although CEA with patching is widely endorsed owing to its association with improved long-term outcomes, some debate persists, particularly in specific clinical scenarios where primary closure might still be considered based on individual patient factors or surgeon preference.

After the widespread use of CEA through longitudinal arteriotomy led to high restenosis rates, patch angioplasty became the dominant standard technique.[2-6] Despite evidence supporting patch angioplasty's role in lowering restenosis, its routine application in all CEAs remains a matter of debate. Several studies have indicated that primary closure could yield results comparable with routine patch angioplasty.[7-10] Primary closure provides the advantage of eliminating graft-related complications and shortens the duration of cross-clamping compared with patch angioplasty.[11-13] The Society for Vascular Surgery implementation document for the management of extracranial cerebrovascular disease, published in 2022, recommends the use of patch angioplasty in CEA to reduce the risk of restenosis compared with primary closure. However, primary closure may be considered in selected cases with specific anatomical considerations and adequate artery diameter.[6] These factors have encouraged surgeons to suggest selective patch closure. The current study aimed to evaluate the safety and efficacy of the CEA using a novel primary closure technique.

METHODS

Study design and setting. This retrospective cohort study was conducted to explore an innovative primary closure method in endarterectomy surgeries over eight years. The study protocol was reviewed and approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences (SBMU) (IR.SBMU.MSP.REC.1397.794). Furthermore, all participants provided their written informed consent for their data to be used for research purposes. All patients who underwent CEA with this novel primary closure technique during the study period were included. We identified all patients who underwent CEA from January 1, 2009, to December 31, 2017.

Data collection. The data were collected using administrative databases from three university teaching hospitals affiliated with SBMU, Tehran, Iran. The study involved a detailed extraction of clinical data by independently trained abstractors from both inpatient and outpatient medical records. This encompassed a wide range of data, including sociodemographic characteristics; neurological, medical, and surgical histories; and findings from admission neurological examinations. For assessing the extent of stenosis in the internal carotid arteries, data were extracted from carotid contrast

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arteriography when it was performed, or from preoperative duplex ultrasound scans in other instances. In certain cases, the degree of stenosis was determined through magnetic resonance angiography.

CEA with a new technique. CEA was performed according to the following indications: symptomatic patients with carotid artery stenosis >50% and asymptomatic patients with carotid stenosis >70%. Estimated perioperative stroke and death rates were considered during patient selection. The carotid diameter was assessed preoperatively using computed tomography or magnetic resonance scans. Primary closure was performed if the carotid artery diameter was >5 mm, which is considered within the normal range for the internal carotid artery, in cases of a high carotid bifurcation or when the contralateral carotid artery was occluded. These scenarios present potential advantages for primary closure: a larger artery diameter reduces the risk of restenosis without requiring a patch, and a high carotid bifurcation allows for easier surgical access. Additionally, primary closure in cases of contralateral carotid occlusion can shorten procedural time, reducing ischemic risk in patients with limited collateral flow. After completing the standard exploration of the carotid artery, both the common and internal carotid arteries were fully mobilized. A small gauze pad was placed beneath the carotid bifurcation to gently push forward the lateral surface of the internal and common carotid arteries. The novel technique employs this gauze pad to facilitate a lateral arteriotomy, allowing for a more controlled and precise access to the artery, which may decrease the risk of complications associated with increased artery length that can occur with an anterior arteriotomy. The primary advantage of the lateral arteriotomy is to avoid complications such as twisting or kinking of the artery. It also helps to prevent distortion of the anatomy near the external carotid artery origin, which can complicate closure. Subsequently, an arteriotomy was conducted from the unaffected portion of the common carotid artery to the intact region of the internal carotid artery, precisely positioned at the farthest location directly opposite the external carotid artery. This site selection for the arteriotomy is strategic to avoid potential complications.

Performing the arteriotomy anteriorly instead of laterally could result in increased artery length after endarterectomy, increasing the risk of twisting or folding upon repair. All patients underwent routine shunting during CEA. After this procedure, an endarterectomy was conducted starting from the site of the shunt implantation. Finally, the carotid arteriotomy site was meticulously repaired using 0-7 Prolene thread, with suturing performed under magnification to ensure precision and accuracy. The Fig illustrates the differences between primary closure following CEA with a novel technique and the traditional approach.

Patient follow-up. The assessment of surgical complications in this study involved comprehensive data collection on events such as death, strokes, myocardial infarctions (MIs), and transient ischemic attacks (TIAs) occurring within 60 days after surgery and up to a year after surgery. This information was gathered from inpatient records and the surgeon's records after patient discharge. To ensure objectivity, two independent investigators, including a neurologist, individually reviewed the medical records of patients who experienced strokes or TIAs as postoperative complications. Additionally, clinical definitions for each outcome assessed include TIA, which is a temporary period of symptoms similar to those of a stroke, caused by a temporary decrease in blood supply to part of the brain, typically lasting <24 hours; MI, also known as a heart attack, which is the damage or death of heart muscle owing to a lack of blood supply, often characterized by chest pain and other symptoms; stroke, a medical emergency that occurs when the blood supply to part of the brain is interrupted or reduced, leading to brain damage; death, the cessation of all biological functions that sustain a living organism; hematoma, a localized collection of blood outside of blood vessels, often caused by injury or trauma, which can lead to swelling and pain; reintervention, any subsequent surgical procedure or intervention performed following the initial surgery; and restenosis, the renarrowing of a blood vessel after it has been treated, commonly assessed through imaging techniques to determine the degree of arterial narrowing.

Statistical analysis. The statistical analysis was performed using SPSS (version 21) statistical software. Descriptive characteristics are reported as the mean ± standard deviation or as the number of cases alongside their respective percentages.

RESULTS

Patients' demographics and clinical features. Over the 8 years, a total of 184 patients underwent CEA. The study's participant group comprised 58.7% males, with a mean age of 64.32 years (range, 43-86 years). The most prevalent comorbidities among patients included hypertension (defined as a blood pressure of >140/90 mm Hg or the need for antihypertensive drugs) (81.5%), hyperlipidemia (defined as total cholesterol values of >150 mg/dL) (48.4%), former or current smoking status (53.3%), coronary artery disease (38.6%), and diabetes mellitus (defined as the need for specific drugs to maintain metabolic control) (32.1%). Notably, 65.2% of the patients exhibited symptoms (ipsilateral TIA or stroke) within 6 months before undergoing CEA (Table I).

Operative procedures and hospitalization. The average duration of surgery was 75.6 ± 15.4 minutes, ranging from 56 to 110 minutes. Specifically, the surgery lasted <70 minutes for 43 patients (23.4%), between 70

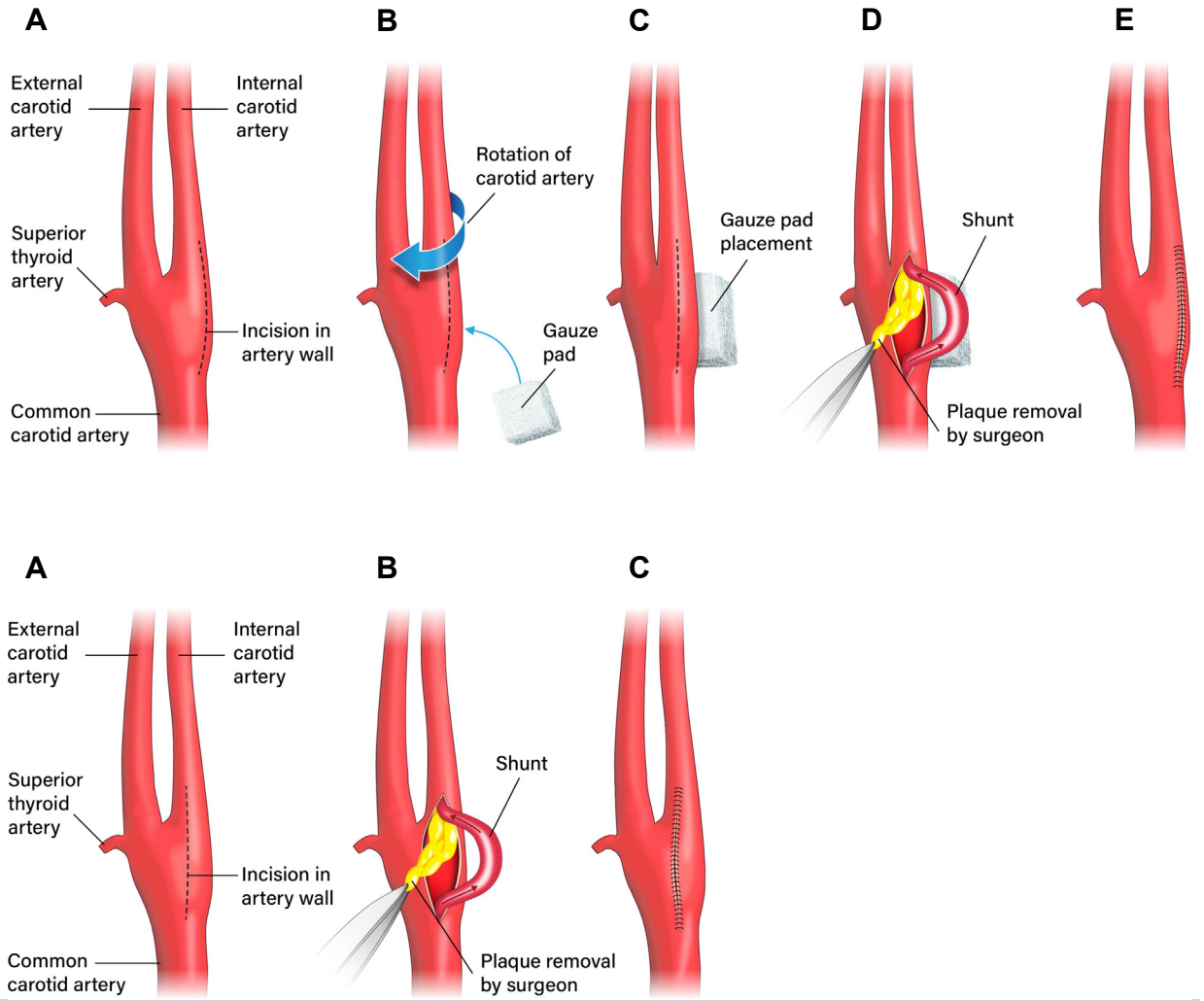

Fig. Primary closure after carotid endarterectomy (CEA) with **(I)** a novel technique vs **(II)** the traditional approach. **(A)** Incision: Precise arteriotomy made along strategic location to facilitate optimal access. **(B)** Rotation: Gentle mobilization and rotation of carotid artery for thorough exploration. **(C)** Gauze pad placement: Placement of gauze pad to aid in exposure and positioning. **(D)** Plaque removal: Methodical plaque removal to ensure clear and unobstructed flow. **(E)** Closure: After plaque removal, the artery is meticulously sutured to restore vascular integrity and ensure proper closure. **(II)** The traditional technique. **(A)** Incision: A precise arteriotomy is made along the anterior surface of the carotid artery in the standard location, allowing access for the procedure. **(B)** Plaque removal: Methodical plaque removal to ensure clear and unobstructed flow. **(C)** Closure: After plaque removal, the artery is meticulously sutured to restore vascular integrity and ensure proper closure.

and 90 minutes for 116 patients (63%), and >90 minutes for 25 patients (13.6%). Among the 184 patients included in the study, 146 (79.3%) had a hospitalization period of 1 day, 33 patients (17.9%) were hospitalized for 2 days, and 5 patients (2.7%) had a hospitalization period of >2 days (Table II). It is noteworthy that patients requiring hospitalization for >48 hours were admitted primarily for monitoring and treating other underlying medical conditions.

Early complications. Short-term complications within 60 days of the surgery were observed in 8.7% of the patients. The most common short-term complications were hematoma and ipsilateral TIA. Additionally, five patients (2.7%) experienced MI, three patients (1.6%) were diagnosed with stroke, and there were two cases (1.1%) of death attributed to MI. Thirteen patients developed a hematoma after the operation, with four requiring surgical drainage in the operating room (Table III).

Late complications. Among the cohort of 182 patients evaluated, 44% manifested long-term complications within 1 year of the operation. The most prevalent long-term complication, affecting 23 individuals (12.6%), was MI, whereas the least common was stroke, observed in 8 patients (4.3%). There were 15 reported deaths (8.2%).

Table I. Demographic and clinical characteristics of studied patients

Characteristics	Mean ± SD or No. (%)
Age, years	64.32 ± 10.91
Male sex	108 (58.7)
HTN	150 (81.5)
Hyperlipidemia	89 (48.5)
Smoking	98 (53.3)
CAD	71 (38.6)
Diabetes mellitus	59 (32.1)
Symptomatic TIA or stroke	120 (65.25)

CAD, Coronary artery disease; *HTN*, hypertension; *TIA*, transient ischemic attack.

Table II. Summary of operative procedures and hospitalization periods for studied patients

Characteristics	No. (%)
Duration of surgery, minutes	
<70	43 (23.4)
70-90	116 (63)
>90	25 (13.6)
Duration of hospital stay, days	
≤1	146 (79.3)
2	33 (18)
>2	5 (2.7)

Table III. Early postoperative complications in studied patients within 60 days after the operation

	No. (%)
TIA	6 (3.3)
MI	5 (2.7)
Stroke	3 (1.6)
Death	2 (1.1)
Hematoma	13 (7)

MI, Myocardial infarction; *TIA*, transient ischemic attack.

Table IV. Late postoperative complications in studied patients ≤1 year after the operation

	No. (%)
TIA	9 (4.9)
MI	23 (12.6)
Stroke	8 (4.3)
Death	15 (8.2)
Reintervention	4 (2.1)
Restenosis	
<50%	122 (78.7)
50%-70%	17 (10.9)
>70%	3 (1.9)

MI, Myocardial infarction; *TIA*, transient ischemic attack.

Additionally, four patients required reintervention owing to symptomatic restenosis, with three undergoing an endovascular procedure and one patient undergoing surgical treatment (Table IV).

Thorough follow-up was conducted for 1 year, focusing on postoperative restenosis. Fifteen patients (8.2%) were excluded from the study owing to death, and an additional 27 individuals (14.8%) were excluded for failing to return for follow-up. The majority of restenosis cases were found to be <50%, as determined solely by sonographic findings. Specifically, restenosis of the internal carotid artery was <50% in 122 patients (78.7%), between 50% and 70% in 17 patients (10.9%), and >70% in 3 individuals (1.9%).

DISCUSSION

Numerous research studies have substantiated the effectiveness of CEA as a strategy for preventing strokes.[11,14,15] Nevertheless, a considerable discourse persists regarding whether using patch angioplasty or opting for primary closure constitutes the most advantageous approach for minimizing the frequency of postoperative restenosis and additional complications, including stroke, TIA, MI, and mortality. The present study consisted of 184 patients undergoing CEA with a novel primary closure technique for 8 years. Overall, 8.7% of patients experienced complications within 60 days after the operation. The most common early complications were hematoma, followed by TIA, MI, stroke, and death.

During the 1-year follow-up, among the 155 patients assessed, postoperative complications were recorded in 32.3% of patients, including MI with the majority of incidences. Death, TIA, stroke, and required reintervention were the other frequent late complications, respectively. Moreover, restenosis of >70% was reported only in 1.9% of the evaluated patients. It is important to note that this assessment was conducted at 1 year, and a significant portion of patients with 50% to 70% restenosis might progress to >70% with further follow-up. This potential progression highlights a limitation of primary closure and suggests that routine use of this technique may be disadvantageous in the long term. Although our novel primary closure technique shows promise in providing advantages in short-term outcomes, such as reduced intraoperative complications and quicker recovery, it may not offer the same long-term benefits in terms of restenosis prevention as patch angioplasty.

We acknowledge that the incidence of stroke observed in our study was 4.3%, which is notably higher than contemporary data reporting an annual stroke rate of approximately 0.5%. Several factors may contribute to this discrepancy. Our patient cohort had a higher

prevalence of comorbidities and more complex medical histories, likely owing to being drawn from tertiary care centers, where patients often present with more advanced disease and multiple comorbidities. Additionally, although our study used a standardized surgical technique and experienced operators, variations in postoperative care standards in our region, as well as differences in baseline stroke risk factors, may also account for the observed higher incidence. Our study's stroke rate reflects a cumulative incidence over the follow-up period, which differs from annual rates reported in other studies. Cumulative incidence captures all stroke events over time, whereas annual rates reflect the average yearly risk. This distinction can lead to variations in perceived stroke incidence, with cumulative incidence better representing long-term risk.[16] Furthermore, the 1-year mortality rate of 8.2% in our study is higher than in some reports, likely owing to the advanced age (median, 64 years) and significant comorbidities in our patient population, including hypertension (81.5%), coronary artery disease (38.6%), and diabetes (32.1%). Studies have shown that older age and comorbidities are independent risk factors for poor postoperative outcomes, including increased mortality.[17] The need for reintervention in 2.2% of patients owing to symptomatic restenosis, though higher than in some studies, remains within the expected range for high-risk populations undergoing CEA.

Earlier research has suggested the potential benefits of using patch angioplasty to decrease restenosis frequency and subsequently lower the prolonged risk of stroke compared with primary closure.[2-5] The initial Cochrane review in 2004 highlighted a distinct advantage of patch closure over primary closure in perioperative stroke and death, as well as long-term ipsilateral stroke and restenosis.[4] A subsequent update of the Cochrane review in 2009 showed no significant difference in perioperative events, but patch closure maintained its advantage over the long term in stroke and restenosis prevention.[18] Rerkasem and Rothwell[5] further expanded on these systematic reviews by including three additional randomized controlled trials. Although the overall outcomes remained consistent, the authors noted that the two most recent trials exhibited nonsignificant trends toward a greater risk of stroke and death when using patch closure. Consequently, they concluded that further research is necessary to comprehensively assess these findings.[5,19,20]

In contrast, recent investigations suggest that selective primary closure may yield outcomes comparable with those achieved through standard patch angioplasty.[1,7-10] The decision to pursue primary closure was typically based on criteria such as carotid artery of >5 mm, a benchmark arbitrarily derived from established norms in relevant medical literature.[1,7,14,21] Additionally, primary closure was chosen in all cases aiming to minimize clamping duration and potential ischemic risk with routine shunting used during CEA. Moreover, in instances of significantly elevated carotid artery bifurcation, primary closure was favored over patch placement owing to the complexity and time-intensive nature of the latter procedure in such scenarios.[22]

A retrospective analysis of 1737 CEA cases by Avgerinos et al[1] found no significant differences in long-term restenosis or stroke rates between primary closure and patch angioplasty. The study highlighted that primary closure was associated with a significantly shorter average surgery duration (93 ± 25 minutes; $P < .001$). However, it is important to note that patients included in this analysis were selected based on specific criteria, such as carotid artery diameter and the presence of elevated carotid bifurcation. Additionally, there was a male predominance in the primary closure cases, and the presence of symptomatic disease did not significantly influence the choice of closure method.[1] Huizing et al[7] reported similar findings in a retrospective analysis of 500 patients, with no significant differences in restenosis rates at 6-week and 1-year intervals. Similarly, Maertens et al[8] documented corresponding outcomes in their retrospective review of 213 patients, where primary closure was used for carotid arteries with a diameter of >5 mm and in cases of elevated carotid bifurcation. Consistent with these findings, De Donder et al.[22] included 110 operations involving primary closure and 103 using patch angioplasty with a Dacron patch. The overall postoperative complication rate was 3.76% (1.8% after primary closure and 5.8% after patch angioplasty). After 5 years, the complication rate was 5.29% (2.0% after primary closure and 9.1% after patch angioplasty). However, there were no significant differences between the two groups ($P = .09$ and $P = .05$). Moreover, Javid[23] conducted a cross-sectional study to evaluate the postoperative comorbidity prevalence in 198 patients who underwent CEA with primary closure. Within a 1 month after the operation, comorbidities were observed in 22 patients (11.11%). The most common postoperative complications were bleeding and the need for repeat operations, occurring in 2.52% of patients. MI occurred in one patient (0.50%), and other comorbidities included infection in two patients (1.01%), stroke in four patients (2.02%), TIA in four patients (2.02%), and revision with stent placement in two patients (1.01%). Six patients (3.03%) passed away within 1 month after operation.[23] Furthermore, A recent comprehensive meta-analysis conducted by Marsman et al[9] failed to provide definitive evidence distinguishing primary closure from patch angioplasty in terms of effectiveness. This extensive study incorporated data from 12 randomized controlled trials, comprising a total of 2187 patients. Mortality and stroke rates within 30 days were comparable between both groups. Additionally, long-term mortality rates were similar in both primary closure and patch angioplasty groups. However, restenosis

incidence appeared higher in the primary closure group, though with a very low degree of certainty. Our study's findings align with the trend of higher restenosis rates associated with primary closure. For example, the cumulative incidence of ≥50% restenosis at 1 year for primary closure was reported as 26.1% and at 5 years as 37.2% in a recent study.[24] Although our novel technique using primary closure may provide advantages in terms of immediate surgical outcomes, such as fewer intraoperative complications and quicker recovery, it does not offer the same long-term restenosis prevention as patch angioplasty. Therefore, primary closure can be considered a viable option in select patients, particularly when short-term outcomes are prioritized. However, patch angioplasty remains the preferred approach for patients at higher risk of restenosis. Further research is needed to evaluate the long-term outcomes of primary closure more comprehensively.

Study limitations. A key limitation of this study is its cross-sectional design and relatively small sample size, which may affect the generalizability of the findings. Additionally, the relatively short follow-up period, limited to events within 60 days and ≤1 year after surgery, may be insufficient to capture all long-term complications and outcomes. Although we observed no long-term complications in 56% of patients within 1 year, this timeframe may not reflect the durability of outcomes fully. Extended follow-up would provide a more comprehensive understanding of potential late complications associated with the primary closure with a novel technique. Future studies should include longer follow-up periods and larger sample sizes to better evaluate the long-term efficacy and safety of the surgical technique and compare it with other methods, such as patch angioplasty. Moreover, our study did not differentiate between symptomatic and asymptomatic complications, which limits the depth of our analysis. This omission could affect the interpretation of complications and their relationship with symptomatic status. Future research should include this distinction to offer a more detailed understanding of outcomes based on symptomatic presentation. Furthermore, it is important to note that nerve injury was not included as an outcome in our analysis, which may represent a significant limitation in understanding the full spectrum of potential complications associated with the procedure. Additionally, the percentage of ipsilateral strokes in both the short and long term was not specified, because these data were not collected. Last, we did not perform a comparative analysis of the complication rates of our novel technique with those of traditional CEA methods or patch closure, because this technique was adopted exclusively as the standard approach in our hospital. Future studies involving multiple centers could facilitate such comparisons.

CONCLUSIONS

Primary arterial closure after CEA with a novel technique proves to be safe and swift in high-risk patients, such as those with a high carotid bifurcation, a carotid artery diameter of >5 mm, or contralateral carotid occlusion. Although this approach offers advantages in terms of short-term safety and procedural efficiency, it may not provide the same long-term benefits as patch angioplasty, particularly concerning the potential for restenosis progression. The current recommendations for routine patching rely on older studies, such as North American Symptomatic Carotid Endarterectomy Trial[25] and the European Carotid Surgery Trial,[26] conducted in the 1980s and 1990s. These studies, although foundational, may have methodological limitations owing to smaller sample sizes, nonstandardized techniques, and differences in perioperative management that do not align with current practices. This point underscores the need for high-quality, randomized controlled trials in contemporary cohorts of patients undergoing CEA to better compare primary closure and patch angioplasty. Our findings also highlight the necessity of careful patient selection and monitoring to mitigate the risks associated with postoperative complications in this high-risk population.

DISCLOSURES

None.

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