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Review Article

The Role of Carotid Stump Pressure in Carotid Endarterectomy: A Systematic Review and Meta-Analysis

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This review evaluates the carotid stump pressure (CSP)'s role as a single parameter at any given pressure as an indicator for selective shunting, or vice versa, in carotid endarterectomy (CEA). A systematic review of literature in MEDLINE and the Cochrane Library from 1969 to 2019 was conducted. The primary end point was set at 0 to 30-day mortality, ischemic stroke (IS), transient ischemic attack (TIA), and a secondary point at recognition of an optimal CSP pressure. The data was subjected to meta-analytics. The odds ratio (OR) was reported at 95% confidence interval (CI). This study has been registered with PROSPERO: CRD42019119851. The pooled analysis on the primary endpoint of IS demonstrated higher incidence of stroke in shunted CEAs solely based on CSP measurement alone (OR, 0.14, 95%CI: 0.08–0.24, I^2=48%, p<0.001). Sub group analysis demonstrated similar patterns at 25 mmHg (OR, 0.06, 95%CI: 0.01–0.5, p<0.01), 30 mmHg (OR, 0.07, 95%CI: 0.01–0.63, p=0.02) and 40 mmHg (OR, 0.23, 95%CI: 0.09–0.57, p<0.01). This effect on end points of mortality and TIA demonstrated no benefit in either direction. CSP, as a single criterion, is not a reliable parameter in reduction of TIA, mortality, and IS at any given pressure range.

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Introduction

Carotid endarterectomy (CEA)'s role in reducing stroke in a selective group of symptomatic and asymptomatic individuals, according to the current guidelines for extracranial internal carotid artery (ICA) stenosis, has been well established.[1–3] The indication for intraoperative shunting is inconclusive; despite suggestions for its use in 25% of cases, the recent CEA-targeted American College of Surgeons National Surgical Quality Improvement Program state that active shunting confers no benefit, even in the highest risk of clamp-induced cerebral hypo-perfusion.[4–6] In current practice, some surgeons perform selective shunting during regional anesthesia, and this is based on neurological alterations following the application of the arterial clamp.[6] However, the optimal intraoperative evaluation of cerebral hypo-perfusion during general anesthesia is debatable, and various modalities have been recommended. These include: near infrared spectroscopy (NIRS), electroencephalography (EEG), continuous transcranial Doppler ultrasonography (TCD), somatosensory evoked potential (SSEP), cerebral oximetry monitoring and carotid stump pressure (CSP) measurement.[7–9] Among them, CSP evaluation, introduced by Crawford et al. in 1960, is a technique of choice in some centers without the aforementioned adjunctive techniques.[10] However, to date, there is no conclusive evidence to support or negate CSP's role in the literature. There are numerous studies in the literature that recommend a certain CSP cut-off for selective shunting in CEAs undergoing general anesthesia. This has resulted in an ongoing debate and variable practice. Thus, this systematic review's primary objective is to evaluate the CSP's role as a single criterion for selective shunting in CEA on endpoints of transient ischemic attack (TIA), ischemic stroke (IS), and mortality. The secondary aim is to assess various CSP recommended cut-offs for selective

shunting in CEAs on similar endpoints and determine an evidence based approach for clinical practice.

Methods

Search strategy

An electronic and systematic search of literature from 1966 to December 2018 in MEDLINE, Embase, and the Cochrane Library was conducted. The following key words and/or MeSH Terms, according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA)[11] standards, were used: "Endarterectomy, carotid" [MeSH Terms] OR ("endarterectomy, carotid" [MeSH Terms] OR ("endarterectomy" [All Fields] AND "carotid" [All Fields]) OR " carotid endarterectomy" [All Fields] OR ("carotid" [All Fields] AND "endarterectomies" [All Fields]) OR "carotid endarterectomies" [All Fields]) AND (("amputation Stumps" [MeSH Terms] OR ("amputation" [All Fields] AND "Stumps" [All Fields]) OR "amputation stumps" [All Fields] OR "Stump" [All Fields]) AND ("pressure" [MeSH Terms] OR "pressure" [All Fields]) AND "humans" [MeSH Terms]. This query has been "endarterectomy, carotid [MeSH Terms] OR Carotid endarterectomies AND Stump Pressure AND Humans." All abstracts were retrieved and reviewed by two separate investigators (AK and OAA). The retrieved abstracts' references were manually evaluated for any additional articles not identified through the primary search. All articles appearing to fulfill the eligibility criteria were retrieved and studied. The data extraction was also conducted by two separate investigators (AK and OAA). This study has been registered with the International Prospective Register for Systematic Review (PROSPERO), National Institute for Health Research CRD: 42019119851.

Exclusion criteria

This systematic search was limited to the English language, adult subjects, and human studies. In addition, narrative reviews, commentaries, opinions, letters to the editors, conference abstracts, or abstracts, short case series with fewer than fifty cases (n = 50), and studies with no outcome on the defined endpoints were also excluded.

Quality assessment and analysis

To obtain an evidence based approach, articles were evaluated for their inference, bias, validity, and applicability against the tools provided by Oxford Critical Appraisal Skills Programme (CASP). Furthermore, the strength of evidence and recommendations for practice were also assessed through the National Institute for Health and Care Excellence (NICE) checklist.[12–14]

Definitions of endpoints

In order to increase the validity of this review and its replicability, all endpoints were defined according to their respective and acceptable definitions.

1. TIA was defined as a focal loss of cerebral function lasting for fewer than 24 h with a vascular identifiable cause peri-operatively till discharge.[13]
2. IS was defined as focal loss of cerebral function lasting for more than 24 h with a vascular identifiable cause peri-operatively till discharge.[13]
3. All end points of TIA, IS, mortality was defined from the time of surgery, inclusive of intraoperative time, to 30 days.
4. CSP is measured using a needle inserted into the distal common carotid artery after clamping the common carotid and external carotid artery following zero referencing of the patient arterial line in accordance to the patient's position. This technique is meant to reflect an objective measurement of the collateral cerebral circulation (systolic) thus perfusion.[10] There was no standard and/or universal range or cut-off for CSP in the recruited studies and/or that of literature.

Statistical analysis

To evaluate the proximity of individual reviewers on article selection (inclusion criterion) and data extraction, an inter-rater agreement (Cohen's kappa coefficient) was conducted. To avoid conclusion bias, a power analysis demonstrated that, for every defined endpoint in this review (mortality, TIA, IS), 90 individuals (n = 90) per event were required for a true positive outcome. The data was pooled on all endpoints of TIA, IS, and mortality events and subjected to meta-analysis using the Software Review Manager (RevMan, 5.3.5 Cochrane collaboration, Oxford, UK). Meta-analysis was conducted using a Mantel-Haenszel fixed effect model with heterogeneity ($I^2 < 25\%$) and random effect model (DerSimonian-Laird), assuming that the observed estimates of effects (events) could vary across studies with sample variability. A forest plot was created for each binary outcome of TIA, IS, and mortality long with subgroup analysis for each CSP category. The odds ratio (OR) was pooled across studies at a 95% confidence interval (CI). The degree of heterogeneity was estimated using I^2 statistics, with values ranging from 0% to 100% (low heterogeneity: 0%–25%) (moderate heterogeneity: 25%–50%) (high heterogeneity: 75%–100%). The Z-statistic was applied for the overall effect and test of significance (statistical analysis was set at $p < 0.5$).

Results

An electronic literature search produced a total of 178 studies dating back to 1971; however, the manual search

of references identified one more study dating back to 1969, thus the total hit was 179. All abstracts (179 articles) were retrieved and reviewed by two separate investigators (AK and OAA). There were n = 25 abstracts in English, but the main article was in a foreign language ([Japanese, n = 8] [Italian, n = 6] [German, n = 5] [Czech, Chinese, Portuguese, Spanish, Danish, French, n = 6]). A total of n = 43 studies were comparing CSP to other techniques, anesthesia technique in CEA (n = 36), irrelevant to topic in hand (n = 19), techniques of CEA (n = 17), shunting in CEA (n = 9) and case reports (n = 4). This resulted in full retrieval of n = 26 articles. Further evaluation demonstrated one article to be a case series of fewer than 50 cases and one with a lack of required outcomes. Thus, n = 24 articles were included in this review. Further evaluation identified one article with no specific outcome on all end points which was, thus, excluded from the statistical analysis (**Fig. 1**).

Study qualities

Of the 24 included studies, 15 were cohort studies, 7 were case series, 1 was a randomized clinical trial, and 1 was a review study. According to the CASP tool checklist, 20 studies scored the maximum marks (8/8), one study scored (7/8) and another two (6/8). The highest level of evidence in this review was level 2 and the rest at level 3. The overall data extraction was accomplished in 87% (interquartile range [IQR], 55%–100%). The inter-rater agreeability among investigators (AK and OAA) was 0.87 (kappa coefficient) (**Table 1**).

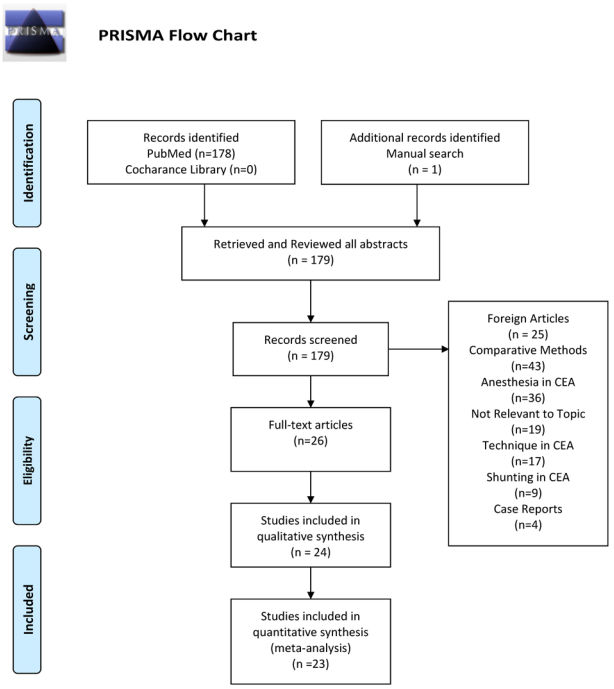

Fig. 1 PRISMA flow chart.
11. Moher D, Liberati A, Tetzlaff J, et al. PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. J Clin Epideimol 2009; **62**: 1006-12.

Study characteristics

The total population was n = 35,959 patients with n = 36,142 CEA. The eligible patients were n = 9045. There was a male predominance (60% vs. 40%) with a median age of 60.5 years (IQR, 38–95 years). The indication for the majority of CEA (89%) was extracranial ICA symptomatic disease (amaurosis fugax, TIA, and stroke). Most CEAs were performed under general anesthesia (89%). The overall median CSP value was 40 mmHg (IQR, 18–60 mmHg).

Primary outcome of all end points

The pooled effect on the primary end point of TIA, based on any given CSP value (IQR, 18–60 mmHg), demonstrated 0.08% (n = 6) (n = 7450 [not shunted]) had incidence of TIA and 0.06% of TIA ((n = 1) n = 1595 [shunted]) respectively. The test of heterogeneity I^2 was low and, despite overall a lower incidence of TIA in non-shunted (OR 0.56, 95%CI: 0.11–2.74) groups based on any given CSP, the overall test of statistics was not significant ($p > 0.05$) (**Fig. 2**).

The pooled effect on the primary end point of mortality demonstrated that, among n = 636 that were not shunted, the mortality was 0.5% vs. 1.2% (shunted group). The test of heterogeneity was I^2 was low and despite lower mortality trend (OR 0.39, 95%CI: 0.07–2.08) toward no shunting based on CSP, the overall test of statistics was not significant ($p > 0.05$) (**Fig. 3**).

The pooled effect on the primary end point of IS was 0.03% (n = 20/5487, [non-shunted]) vs. 3.5% (n = 44/1238, [shunted]). The test of heterogeneity I^2 was 48% (moderate), and the overall effect was toward no shunting based on CSP value (OR 0.14, 95%CI: 0.08–0.24) with overall significant statistical outcome ($p < 0.001$) (**Fig. 4**).

Subgroup analysis

Subgroup analysis was conducted on each category of CSP value on the IS end point.

The pooled effect in the 25 mmHg (CSP) (**Fig. 5**) demonstrated 0.06% (n = 1/1489) incidence of IS in the non-shunted group vs. 1.3% (n = 2/176) in the shunted group, favoring the non-shunted group, based on CSP of 25 mmHg (OR 0.06, 95%CI: 0.01–0.5) ($p < 0.01$). There was a similar trend in the CSP category of 30 mmHg (n = 1/325, 0.3% [non-shunted] vs. n = 5/96, 5.2% [shunted]) (OR 0.07, 95% CI: 0.01–0.63, p = 0.02) (**Fig. 6**) and 40 mmHg (n = 10/2191, 0.4% [non-shunted] vs. n = 9/401, 2.2% [shunted]) (OR

Table 1 Quality assessment of each article by Oxford Critical Appraisal Skills Programme (CASP), data availability and level of evidence (NICE)

Investigator	Study type	Clear aim	Recruitment bias	Exposure bias	Outcome measurement	Confounding factors	Follow up	Results/ Data availability	Applicability	Total score	Level of evidence
Moore et al. 1969[29]	Case series Prospective Single centre	Yes	Yes	Maybe	Clear	Not considered	Yes	100%	Yes	6/8	3
Moore et al. 1973[30]	Case series Prospective Single centre	Yes	Yes	Maybe	Clear	Not considered	Yes	100%	Yes	6/8	3
Hobson et al. 1974[31]	Case series Prospective Single centre	Yes	No	No	Clear	Considered	Yes	100%	Yes	8/8	3
Lousto et al. 1984[32]	Cohort Prospective Single centre	Yes	No	No	Clear	Considered	Yes	82%	Yes	8/8	3
Evans et al. 1985[33]	Cohort Prospective Single centre	Yes	No	No	Clear	Considered	Yes	100%	Yes	8/8	3
Hafner et al. 1988[34]	Cohort Prospective Multi centre	Yes	No	No	Clear	Considered	Yes	73%	Yes	8/8	2/3
Gnandev et al. 1989[35]	Case series Prospective Single centre	Yes	No	No	Clear	Considered	Yes	73%	Yes	8/8	3
Cherry et al. 1991[36]	Case series Retrospective Single centre	Yes	No	No	Clear	Considered	Yes	82%	Yes	8/8	3
Archie et al. 1991[37]	Cohort Prospective Multi centre	Yes	Yes	No	Clear	Considered	No	55%	Yes	7/8	3
Harada et al. 1995[38]	Case series Retrospective Single centre	Yes	No	No	Clear	Considered	Yes	100%	Yes	8/8	3
Cao et al. 1997[39]	Cohort Prospective Single centre	Yes	No	No	Clear	Considered	Yes	100%	Yes	8/8	3
Belardi et al. 2003[40]	Cohort Prospective Single centre	Yes	No	No	Clear	Considered	Yes	73%	Yes	8/8	3
Calligaro et al. 2005[41]	Cohort Prospective Single centre	Yes	No	No	Clear	Considered	Yes	100%	Yes	8/8	3
Astarci et al. 2007[42]	Cohort Retrospective Single centre	Yes	No	No	Clear	Considered	Yes	64%	Yes	8/8	3
Hans et al. 2007[43]	Cohort Prospective Single centre	Yes	No	No	Clear	Considered	Yes	73%	Yes	8/8	3
Jacob et al. 2007[44]	Cohort Retrospective Single centre	Yes	No	No	Clear	Considered	Yes	82%	Yes	8/8	2/3
Mulaudzi et al. 2009[45]	Case series Prospective Single centre	Yes	No	No	Clear	Considered	Yes	100%	Yes	8/8	3

Table 1 Continued

Investigator	Study type	Clear aim	Recruitment bias	Exposure bias	Outcome measurement	Confounding factors	Follow up	Results/ Data availability	Applicability	Total score	Level of evidence
Chiriano et al. 2010[17]	Cohort Retrospective Single centre	Yes	No	No	Clear	Considered	Yes	100%	Yes	8/8	3
AbuRahma et al. 2010[46]	Randomised Clinical trial Single centre	Yes	No	No	Clear	Considered	Yes	82%	Yes	8/8	2
Shahidi et al. 2017[47]	Cohort Prospective Single centre	Yes	No	No	Clear	Considered	Yes	82%	Yes	8/8	3
Kolkert et al. 2017[48]	Cohort Retrospective Multi centre	Yes	No	No	Clear	Considered	Yes	82%	Yes	8/8	3
Sef et al. 2018[49]	Cohort Prospective Single centre	Yes	No	No	Clear	Considered	Yes	100%	Yes	8/8	3
Wiske et al. 2018[7]	Retrospective Review	Yes	No	Not clear	No	Considered	Yes	Incomplete	No	N/A	N/A
Tyagi et al. 2018[50]	Cohort Retrospective Single centre	Yes	No	No	Clear	Considered	Yes	91%	Yes	8/8	2/3

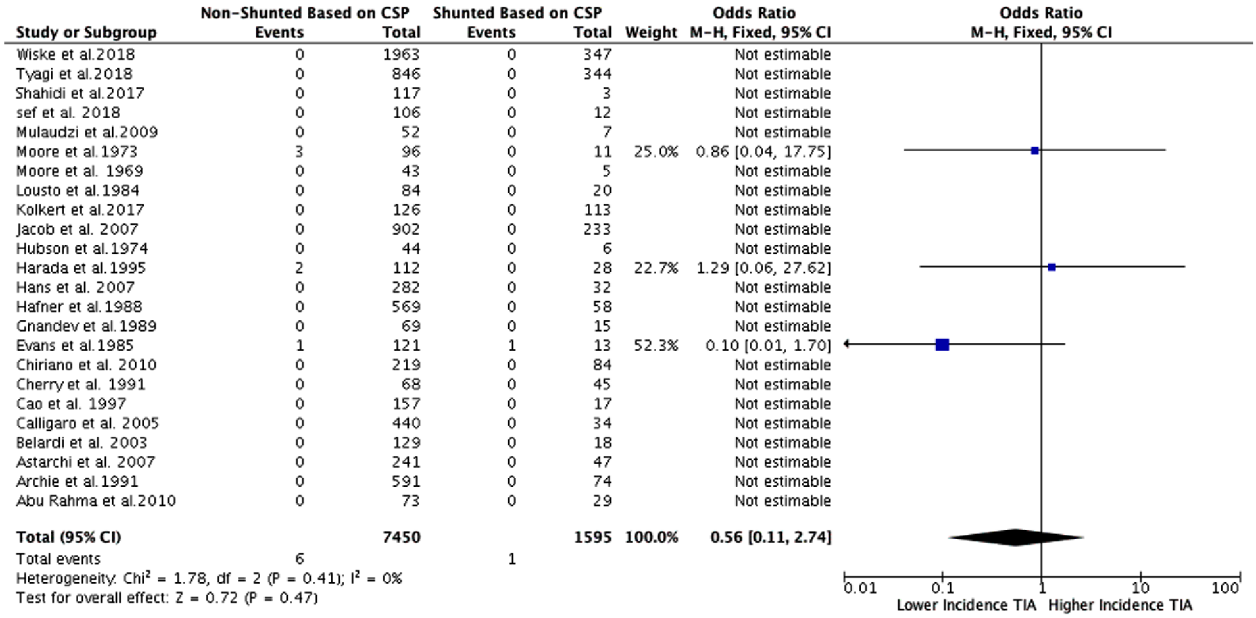

Fig. 2 Forest plot of all studies on the end point of TIA reporting odds ratio, heterogeneity and overall effect at 95%CI.

0.23, 95%CI: 0.09–0.57, p<0.01) respectively (**Fig. 7**). In the category of CSP of 50 mmHg, despite lower trends of IS toward the non-shunted group in (OR 0.90, 95%CI: 0.27–2.96), there was no statistical significance (p>0.05) (**Fig. 8**).

Discussion

This review suggests that shunting based solely on intra-operative CSP measurement at any given pressure range (IQR, 18–50 mmHg) is associated with a higher incidence of postoperative IS and is not a reliable methodology for selecting high risk cases. In addition, this technique con-

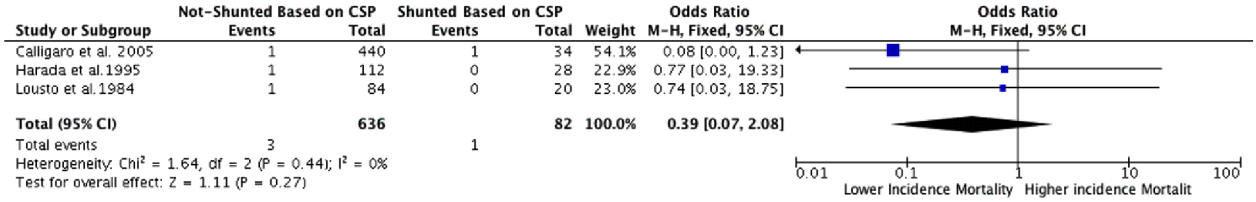

Fig. 3 Forest plot of all studies on the end point of Mortality reporting odds ratio, heterogeneity and overall effect at 95%CI.

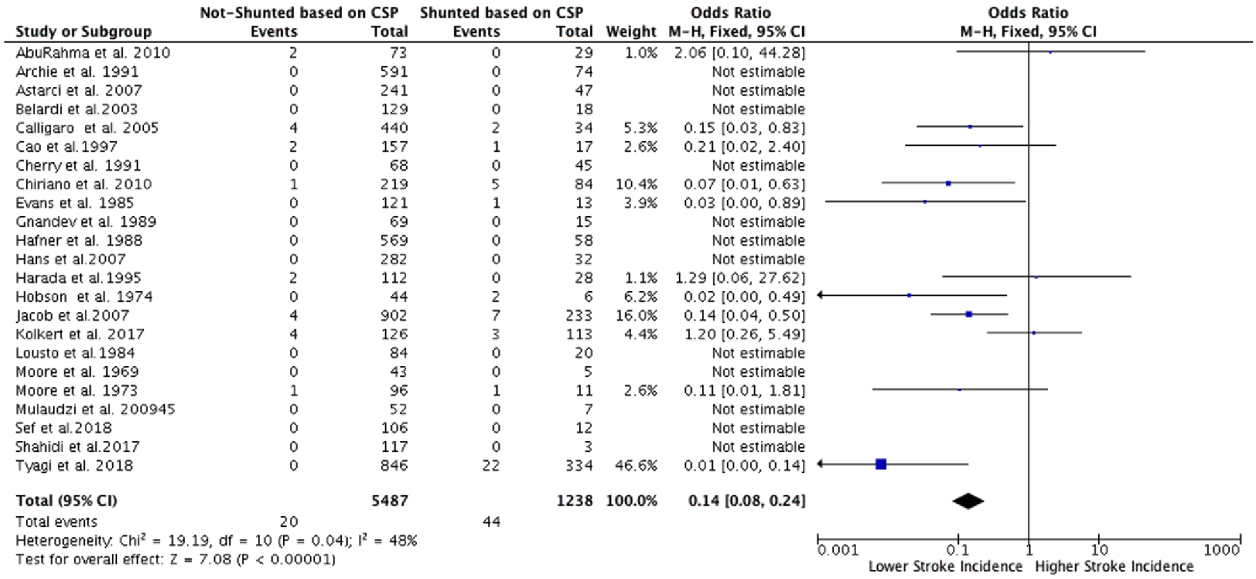

Fig. 4 Forest plot of all studies on the end point of IS reporting odds ratio, heterogeneity and overall effect at 95%CI.

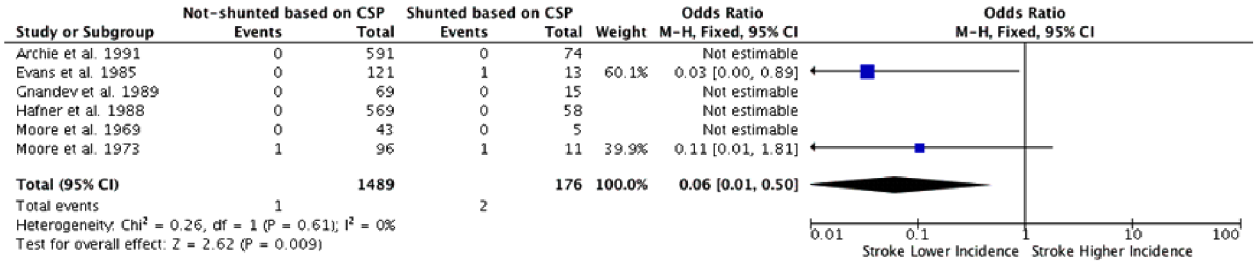

Fig. 5 Subgroup analysis on the end point of IS for 25 mmHg.

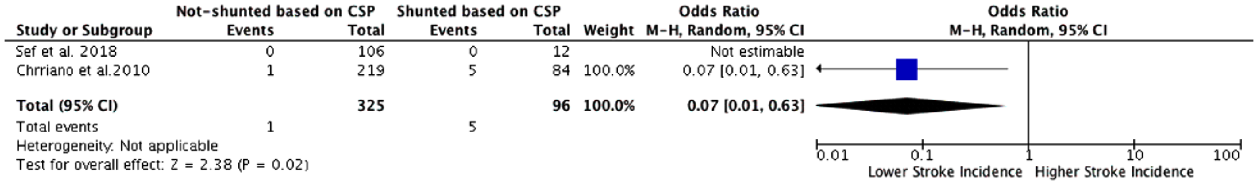

Fig. 6 Subgroup analysis on the end point of IS for 30 mmHg.

fers no benefit on reducing mortality and TIA. The type and method of shunt deployed (Bard Javid™ shunt with clamps vs. in Pruitt-Inahara held with balloon insufflation) in each article was variable and inconsistent. Critics might attribute the higher incidence of postoperative IS (shunted group) to technical downfalls like: flap creation, dissection, shunt flow, and distant embolization.[15] However, the consistency of IS (negative outcome) in different CSP categories and centres, coupled with the deployment of various shunts, refutes such provenance.

Most CEA's (89%) were undertaken for symptomatic ICA disease, and some articles dated back to the 1970s. At that time, the investigative modalities did not involve full evaluation of the Circle of Willis (complete or not),

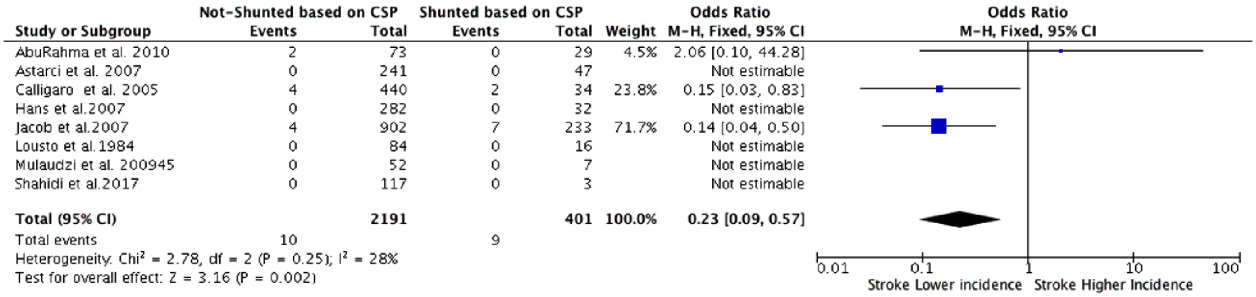

Fig. 7 Subgroup analysis on the end point of IS for 40 mmHg.

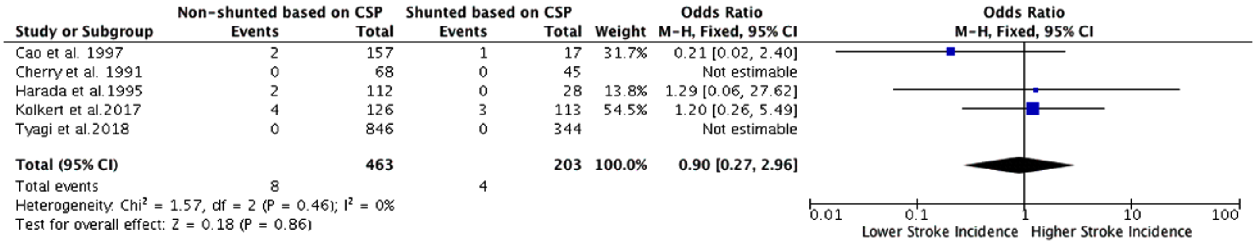

Fig. 8 Subgroup analysis on the end point of IS for 50 mmHg.

contralateral ICA stenosis, occlusion, and vertebral artery (flow and disease). This was due to a lack of current duplex expertise, computed tomography angiography and magnetic resonance imaging/angiography (MRI/A) as standard preoperative stratifications.[16] This resulted in centres having to rely on clinical acumen and basic duplex sonography assessment (operator dependent) and, at later stages, on selective subtraction unilateral angiography. One expects with advancements and availability of investigative modalities through each decade there should be a reduction in the postoperative incidence of IS (shunted group), but this sequel was not evident in the review.[16]

In this review, the investigators could not obtain individual and/or collective status of contralateral ICA stenosis, occlusion, and vertebral artery (flow and disease) in both the symptomatic (89%) and asymptomatic group despite evidential suggestions that CSP is lower in symptomatic group, contralateral ICA stenosis, or occlusion.[17–19] The contralateral ICA status (stenosis and occlusion) in the symptomatic CEAs has been a nidus of ongoing debate, and reports emphasize the importance of such status (correlation) in predicting postoperative adverse outcomes (mortality, TIA, IS).[17–19] Nonetheless, some authors abrogate such findings and conclude that the only postoperative predictor of adverse outcomes (mortality, TIA, IS) are preoperative symptomatic status, irrespective of contralateral occlusion, or shunting based on CSP.[20] Overall, there appears to be heterogeneity in the current literature with regards to either finding; furthermore, the definition of a high risk group in this category is still pending. It remains imperative that the high risk group should not be confused with high risk CEAs based solely on clinical and concomitant morbidities. This should also entail unstable and high risk plaque morphology.[21] Current evidence suggests: plaques with active inflammation, reduced collagen deposition, increased macrophage activity, large core lipid deposits, thin cap, calcification, and ulceration are categorized as unstable and high risk.[22] It appears such morphology is associated with worst outcomes in CEAs and a higher incidence of adverse cardiovascular outcomes. In recent years, there has been a notable interest in identification of biomarkers for high risk groups that include a vast array of biomarkers, such as high sensitive C-reactive proteins and lipoprotein-associated phospholipase A_2 (Lp-PLA_2).[22]

The CEA repair technique in our review was a mixture of primary closure, routine and selective patching in both groups (shunted vs. non-shunted). Given the incomplete nature of the data, no consensus with regards to the technique in each CSP category could be obtained, but all proponents seem to agree on the principle of meticulous endarterectomy and precise closure, irrespective of the closure modality. The CREST trial evaluated patch (n = 753, 70%) vs. primary closure (n = 329, 30%) on endpoints of peri-operative risk of stroke, mortality, restenosis, and myocardial infarction (MI).[23] The outcome of this review complemented previous Cochrane reviews demonstrating the superiority of patch CEA in the reduction of peri and postoperative adverse outcomes and 5 years' restenosis ratio.[23] One other aspect of CEA is related to the patch type. The use of a vein as a patch in CEA, despite a lower incidence of infection, thrombosis, and neo-intimal hyperplasia due to patch rupture/blowout, has faded away. This has been replaced with prosthetic patches (Dacron, PTFE)

and biological material (bovine). Overall, the current evidence (RCTs) infers that patch type has no impact on short and long-term neurological adverse outcomes.[16,23] The final debate over technical attributes is related to eversion (ECEA) vs. conventional (CCEA) approach for CEAs. Data from the Society for Vascular Surgery Vascular Quality Initiative (SVS-QI) showed similar outcomes on both endpoints of IS (ECEA, 0.8% vs. CCEA, 0.9%) and TIA (ECEA, 1.3% vs. CCEA, 1.2%) despite a higher ratio of shunting in CCEA (59% vs. 24%).[24]

In recent years, attention backed by evidence has been diverted toward the direct correlation of high volume centres and the surgeon's speciality to that of lower adverse outcomes in CEAs. According to the reports and systematic reviews,[25,26] high volume units and vascular surgeons attain lower peri-operative associated stroke/death rates in comparison to lower/medium centers and general surgeons. The recognition of vascular surgery as a speciality in most European and trans-Atlantic countries implies that a lower incidences of adverse outcomes such as TIA, IS, and mortality should be noted. Nonetheless, a review of articles (in this review) from the last decade, with sole focus on CSP and its role in selective shunting, suggests no alteration in adverse outcomes.

The type of anesthesia in CEAs has also been subjected to various investigations over the years. In this review, 89% of CEAs were performed under general anesthesia (GA). A Cochrane review on GA, vs. local/regional anesthesia (LA), demonstrated no significant difference on endpoints of IS (LA, 3.2% vs. GA, 3.5%) and mortality (LA, 3.6% vs. GA, 4.2%).[27] Both anesthetic types might have their own specific merit in CEAs, but focus should not be regaled from maintaining a good cerebral perfusion pressure, oxygenation, and adequate end organ perfusion. Perhaps this is another contributing factor in lower incidences of mortality and adverse outcomes (IS and TIA) in high volume centres, where vascular or procedure related anesthetic expertise is available.[28]

Strengths and limitation

To the best of our knowledge, this is the first systematic attempt to collate the evidence on the independent role of CSP measurement (as a single parameter) and decision making for shunting in CEAs. The study benefits from reproducible methodology, and an adequate data extraction thus leading to an objective inference. The outcome of this study relates to those groups of individuals that had only CSP measurement with no adjunctive modalities. The use of shunt in association with NIRS, EEG, TCD, SSEP and cerebral oximetry monitoring in carotid endarterectomy have been subjected to various reviews and debate. Routine and selective shunting could reduce postoperative stroke incidences in CEA, and the current review does not negate the role or the indication of shunting in CEA.[5–9] However, it does question CSP's use as single parameter for shunting. The investigators in this review recognize that subgroup analysis (e.g., CSP and shunt types, CSP and anesthesia type, CSP and closure technique) would have added to the study's robustness. However, the lack of uniform reporting, definitions, and data availability in the recruited literature meant this was implausible. Furthermore, the overall reported incidence of IS, TIA, and mortality are far less than other reported major series of NASCET (6%) and CREST trial (3.5%), raising the concern of under reporting. Finally, it appears that, at any given CSP pressure, high risk cases that could have ischemic stroke could not be identified; thus, the use of this technique combined with other techniques is highly advocated.

Conclusion

Selective shunting, based solely on the single criteria of CSP measurement at any defined pressure, confers no benefit, and appears to increase the incidence of IS in CEA. Furthermore, this approach does not appear to have any impact on the postoperative TIA and mortality.

Disclosure Statement

All authors have no conflict of interest.

Author Contribution

Study concept: AK
Analysis and interpretation: all authors
Data collection: AK, OAA, ES
Writing the article: all authors
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

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