

Clinical Response to Procedural Stroke Following Carotid Endarterectomy: A Delphi Consensus Study

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WHAT THIS PAPER ADDS

This study provides valuable insight into expert opinion regarding the optimal clinical management of a patient who experiences an in hospital stroke during or following CEA. Quick diagnostics should be performed initially in most phases, but re-exploration of the index carotid artery should be performed in patients who experience an ipsilateral intra-operative stroke during restoration of blood flow until the end of the CEA procedure. If diagnostics should be performed, an expedited CT brain combined with a CTA or duplex ultrasound of the carotid arteries is recommended.

Objective: No dedicated studies have been performed on the optimal management of patients with an acute stroke related to carotid intervention nor is there a solid recommendation given in the European Society for Vascular Surgery guideline. By implementation of an international expert Delphi panel, this study aimed to obtain expert consensus on the optimal management of in hospital stroke occurring during or following CEA and to provide a practical treatment decision tree.

Methods: A four round Delphi consensus study was performed including 31 experts. The aim of the first round was to investigate whether the conceptual model indicating the traditional division between intra- and post-procedural stroke in six phases was appropriate, and to identify relevant clinical responses during these six phases. In rounds 2, 3, and 4, the aim was to obtain consensus on the optimal response to stroke in each predefined setting. Consensus was reached in rounds 1, 3, and 4 when $\geq 70\%$ of experts agreed on the preferred clinical response and in round 2 based on a Likert scale when a median of 7 – 9 (most adequate response) was given, $IQR \leq 2$.

Results: The experts agreed ($> 80\%$) on the use of the conceptual model. Stroke laterality and type of anaesthesia were included in the treatment algorithm. Consensus was reached in 17 of 21 scenarios ($> 80\%$). Perform diagnostics first for a contralateral stroke in any phase, and for an ipsilateral stroke during cross clamping, or apparent stroke after leaving the operation room. For an ipsilateral stroke during the wake up phase, no formal consensus was achieved, but 65% of the experts would perform diagnostics first. A CT brain combined with a CTA or duplex ultrasound of the carotid arteries should be performed. For an ipsilateral intra-operative stroke after flow restoration, the carotid artery should be re-explored immediately (75%).

Conclusion: In patients having a stroke following carotid endarterectomy, expedited diagnostics should be performed initially in most phases. In patients who experience an ipsilateral intra-operative stroke following carotid clamp release, immediate re-exploration of the index carotid artery is recommended.

Keywords: Carotid endarterectomy, Delphi consensus study, Stroke, Treatment algorithm

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[†] See Appendix B for the members of the experts panel.

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INTRODUCTION

Peri-procedural stroke risk in symptomatic patients undergoing carotid endarterectomy (CEA) has been shown to have declined over time from 5.1% in patients who were treated before 2005 to 2.7% for patients treated after 2005.¹ Despite this decline in surgery related stroke over

time, these peri-procedural strokes still hamper the overall long term benefit of carotid revascularisation.²

The aetiology of these peri-procedural strokes is diverse, and ranges from carotid/cardio-embolism, thrombotic occlusion, haemodynamic impairment to hyperperfusion.³ Unravelling the most probable underlying pathophysiological mechanism by making a differentiation between intra-operative and post-operative stroke, has been considered a crucial step for both prevention and treatment when confronted with a procedural stroke.⁴ Unfortunately, very few data exist on the mode of action to be taken for either a stroke which occurs during surgery (intra-operative stroke) or a stroke which occurs in the recovery room or ward (post-operative stroke). Based on the European Society for Vascular Surgery (ESVS) guideline, immediate re-exploration should be performed for a stroke occurring within the first six post-operative hours (which is the same as for intra-operative stroke), whereas a stroke after six post-operative hours should be managed by emergency diagnostics.⁵ However, this advice is not based on randomised controlled trials or high quality evidence. To the best of the present authors' knowledge, no dedicated studies have been performed to achieve consensus on the optimal management of patients with an acute stroke related to carotid intervention.

Therefore, this study aimed to obtain expert consensus on the optimal management of in hospital stroke occurring during or following CEA by implementation of an international expert Delphi panel. Furthermore, based on the Delphi outcomes, the study aimed to provide a practical treatment decision tree to support clinicians who are confronted with patients who have experienced an in hospital stroke following carotid revascularisation.

METHODS

Study design

A Delphi study was performed based on components of the RAND/UCLA appropriateness method, with the aim of reaching consensus on the optimal clinical responses to in hospital stroke occurring during or following CEA.⁶ This is aligned with the quality indicators for a Delphi study

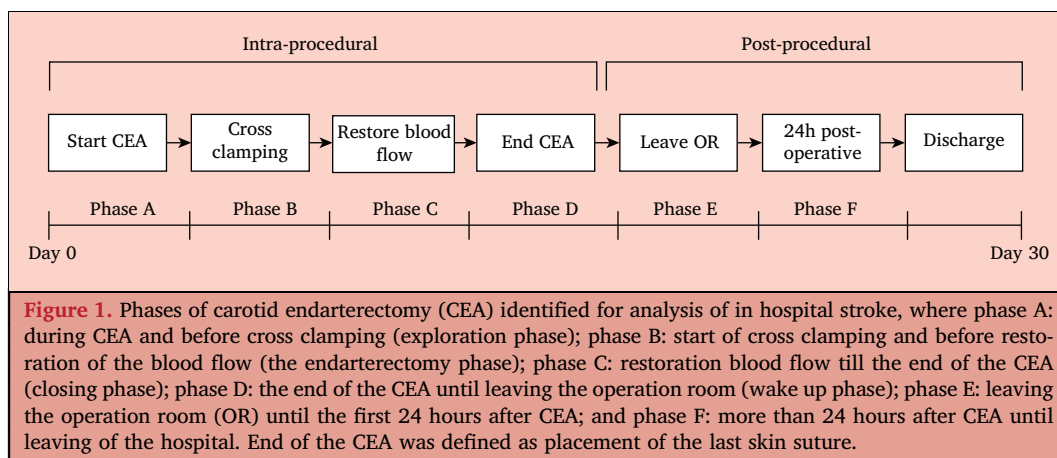
according to the guidance on Conducting and Reporting Delphi Studies (CREDES) (Supplementary Material 1) This Delphi study consisted of different rounds of prospective data collection and data analysis (see Supplementary Material 2 for the flowchart). More in depth information on the specific Delphi rounds is provided later in the Methods.

At first, a research meeting with the members of the coordinating research group was performed to identify different phases in which in hospital stroke can occur that is related to carotid surgery for atherosclerotic disease. Different phases were identified based on the experience of the research group and previous publications.^{3–5} Subsequently, a conceptual model of phases of carotid surgery was developed³ (Fig. 1). This conceptual model was discussed at a face to face meeting with members of the coordinating research team (AM, DD, JT, RB, LK, GB), and subsequently used in the first round of this Delphi consensus study.

During each round, experts were asked for their opinion regarding treatment of a 70 year old patient, with an 80% symptomatic carotid artery stenosis (minor stroke, Modified Rankin scale ≤ 2). The patient had hypertension, hypercholesterolaemia, and was treated medically according to current guidelines (including antiplatelet, statin, and anti-hypertensive therapy). Cerebral monitoring (electroencephalography [EEG] and transcranial doppler [TCD]) were performed during the operation. A standard carotid endarterectomy with selective shunting was performed. A stroke under general anaesthesia was defined as: 1) loss of flow in the ipsilateral or contralateral middle cerebral artery on TCD or 2) visual significant changes on EEG assessed by an experienced vascular laboratory physician or neurologist. A stroke under local anaesthesia was diagnosed by clinical observation and did not resolve with shunting.

Selection of experts

A panel of 20 experts is generally considered sufficient to obtain diverse representative opinions while being small enough to include recognised experts in the area of interest.⁶ Based on an expected response rate of 60%, with the



aim of including a minimum of 20 experts, 31 experts were initially invited to participate in this Delphi study.⁷

The 31 leading experts comprised a multinational panel including both stroke neurologists and vascular surgeons. Each expert had at least five years of medical and research experience in the field of cerebrovascular disease and carotid revascularisation.

Experts received an invitation to participate by email, with background information regarding this Delphi consensus study. According to Dutch law, an online questionnaire does not require ethical assessment by an Institutional Review Board. All experts were informed that participation would be on a voluntary basis and that replies would be anonymised. The central coordinating research group were also blinded to the subspecialty interests (vascular surgeon or neurologist) of the expert panel. Online informed consent was obtained before each Delphi round.

Delphi rounds

General study design. In total, four Delphi rounds were performed. Each Delphi round was discussed by the coordinating research team (AM, JT, RB, LK, GB), and subsequently adjusted to enhance validity. A free text response was available within each round, providing experts with the opportunity to elaborate or explain responses. Free text responses were taken into account by the research team and were either included in the subsequent round or included as a comment in the final algorithm.

All Delphi surveys were conducted through an online survey service, SurveyMonkey. After the email with background information, experts received an invitation to participate and complete the first round of this Delphi study within two weeks. After two weeks a reminder to complete the survey was sent by email. One week thereafter, one final reminder was sent. To provide feedback after each round, experts received an overview of the results and were asked to complete the subsequent round in a similar manner.

First round. The aims were: 1) to investigate whether the conceptual model represented in Fig. 1 was appropriate, and 2) to identify relevant clinical responses to in hospital stroke during each of the six phases outlined below (Fig. 1), and determine possible clinical stroke features and treatment characteristics which might influence this response. See [Supplementary Material 3](#) for an overview of the questions of round 1.

Subsequent rounds incorporated the consensus view of the design of this conceptual model (Fig. 1).

The conceptual model included six phases:

Phase A: during CEA and before cross clamping (exploration phase)

Phase B: start of cross clamping and before restoration of the blood flow (the endarterectomy phase)

Phase C: restoration blood flow till the end of the CEA (closing phase)

Phase D: the end of the CEA until leaving of the operation room (wake up phase)

End of the CEA defined as: placement of the last skin suture

Phase E: leaving the operation room until the first 24 hours after CEA

Phase F: more than 24 hours after CEA until leaving of the hospital.

Clinical stroke features and treatment characteristics were considered to be included if at least three experts listed the same features/characteristics. Discussing these characteristics within the research team resulted in including or excluding these characteristics in the subsequent rounds. All possible responses were included in the second round of the Delphi study.

Second round. The aim of the second round was to obtain consensus on the optimal response to stroke in each predefined setting (see section on “Endpoints” below for definitions of consensus in each round). Experts were asked to list appropriate responses to several types of stroke during the different phases in hospital. The list of responses, stroke characteristics, and different phases were based on answers given by experts in round 1. According to the RAND method,⁶ all questions were scored on a nine point Likert scale (1 = not an adequate or feasible response; 9 = the most adequate and feasible response). See [Supplementary Material 4](#) for an overview of the questions of round 2.

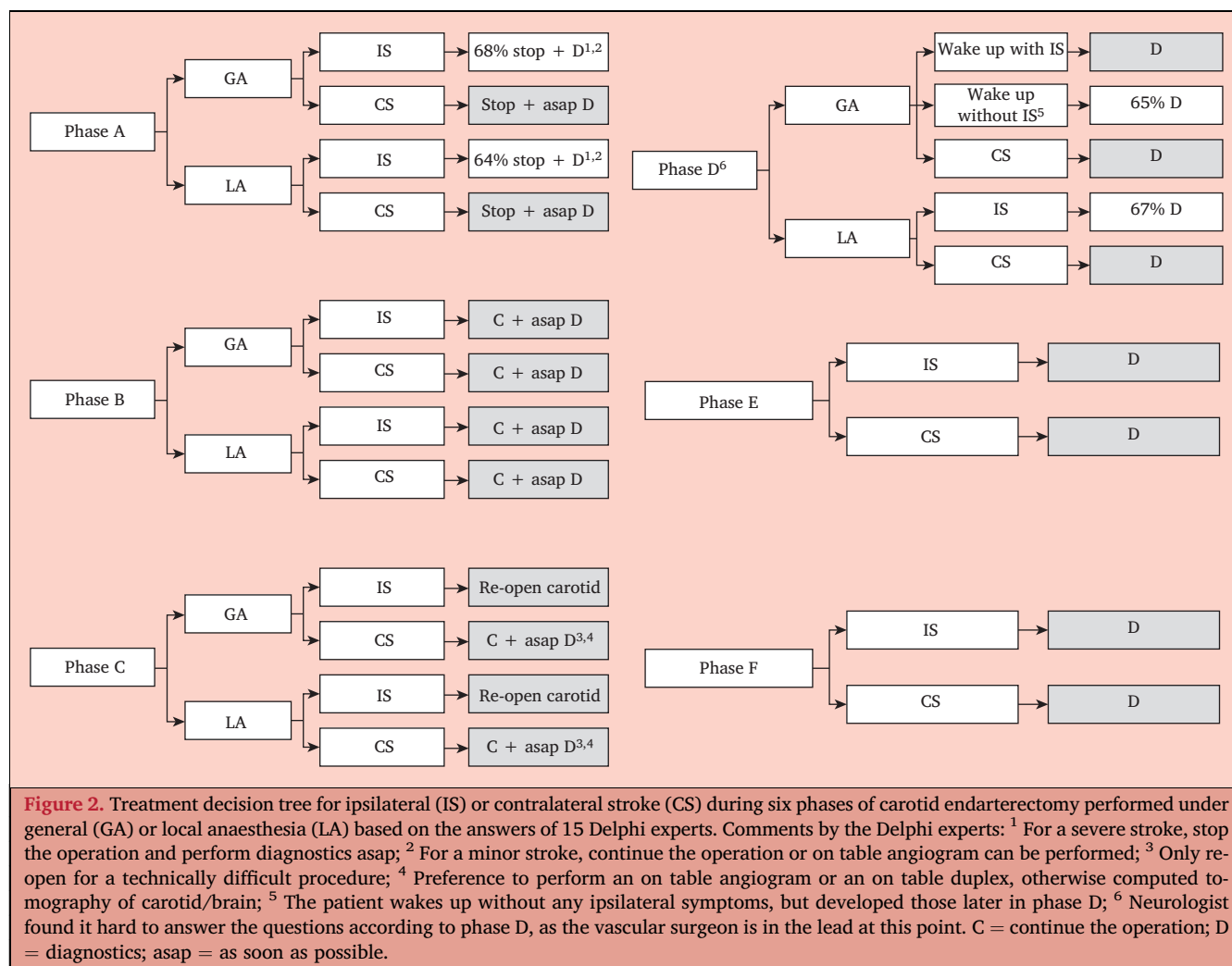
Third round. As a result of the diverse responses in round 2, the methods were adjusted for round 3 as the main goal of this Delphi consensus study was; “What would you do first?”. The second goal was: “If performing diagnostics, what kind of diagnostics would you prefer?”. Therefore, the third round consisted of multiple choice questions with the aim of obtaining further consensus on the optimal response to each stroke characteristic within each phase in hospital. Comments on the second round given by the experts were provided to all experts. See [Supplementary Material 5](#) for an overview of the questions of round 3.

Fourth round. The aim of the fourth round was to gain more insight and understanding, and to provide consensus for phase D. This round also consisted of multiple choice questions, and comments on the third round provided by the experts were fed back to all experts. See [Supplementary Material 6](#) for an overview of the questions of round 4.

Endpoints

Rounds 1, 3, and 4: Consensus was reached when $\geq 70\%$ of experts agreed on the preferred clinical response. This level of agreement was considered appropriate in previous Delphi studies and is aligned with the recommended quality indicators for a Delphi study.^{8–10}

Round 2: The nine point Likert scale based on the RAND method was used.⁶ Consensus was reached where a median of 1 – 3 (not adequate or not a feasible response) or a median of 7 – 9 (most adequate and feasible responses)



was given by the experts.¹¹ An interquartile range (IQR) was calculated to determine the level of consensus between experts. A smaller IQR represents a higher degree of consensus, with an IQR ≤ 2 considered to be consensus among experts.¹¹

Data analysis

Data were analysed using SPSS version 22 (IBM SPSS Statistics 22 for Windows). All comments were read and summarised by the first author (AM). Afterwards, this summary was reviewed by the coordinating research team to confirm its accuracy and subsequently used in the next rounds of questions. Additional meaningful statements are presented in the Results section and used in the Discussion.

RESULTS

Demographic/sample characteristics

All the demographic characteristics and expertise of the Delphi panel are shown in Table A1. In total, 31/31 (100%) invited experts agreed to participate in this study and all completed the first round. The second, third, and fourth rounds were completed by 28/31 (90%) experts.

The first Delphi round was sent out in July 2018 and the last Delphi round was completed in December 2019.

Delphi round 1

The experts agreed (> 80%) on the use of the conceptual model indicating the traditional division between intra- and post-procedural stroke (Fig. 1).

Characteristics that may influence the response were: stroke severity, stroke laterality, and type of anaesthesia. Stroke laterality, ipsilateral stroke (IS) and contralateral stroke (CS), and type of anaesthesia were included in the treatment decision tree. Stroke severity was listed at the end of each phase by asking whether the severity of the stroke may lead to a different response. Statements regarding this topic were implemented in the treatment decision tree (Fig. 2).

All possible clinical responses provided by the experts were used in round 2: neurological examination ($n = 6$), duplex ultrasound of the carotid arteries ($n = 16$), computed tomography angiography (CTA) or magnetic resonance angiography (MRA) ($n = 21$), direct re-operation ($n = 14$), endovascular treatment ($n = 8$), and medication with anticoagulant therapy ($n = 2$).

Delphi round 2

In round 2, consensus was reached for phase D (for a contralateral stroke), phase E, and phase F. In these phases the expert panel advised not to perform an urgent re-operation (median 1, IQR 1-1), but to perform urgent diagnostics (median > 7, IQR ≤ 2). Urgent diagnostics start by performing a neurological examination, followed by an urgent computed tomography (CT) scan of the brain combined with either a CTA or a duplex ultrasound of the carotid arteries afterwards.

Delphi round 3

In round 3, consensus was reached for phase A: for a contralateral stroke, stop surgery and perform diagnostics as soon as possible (80%). Consensus was reached for phase B: continue the operation and perform diagnostics as soon as possible afterwards, for contralateral stroke (75%) and ipsilateral stroke (92%), respectively. For phase C: for a contralateral stroke, continue surgery and perform diagnostics as soon as possible afterwards (87.5%), and for an ipsilateral stroke, immediately re-open the carotid (75%). A comment by the experts was made in phase C where a patient experienced a contralateral stroke. If the CEA had been technically difficult, re-opening the carotid artery could be considered. Multiple comments on how to respond in phase D for an ipsilateral stroke focused on the aspect of waking up with a stroke or not. This specific aspect was included and emphasised in the fourth round.

No consensus could be reached for phase A for an ipsilateral stroke, but multiple comments were made by the experts, which were included in the algorithm (Fig. 2, comment 1 and 2).

Delphi round 4

Consensus was reached for phase D if a patient underwent CEA under general anaesthesia and woke up with an ipsilateral stroke: Diagnostics should be performed first (71%). No consensus was reached where a patient was initially well and stable at the end of the CEA procedure, but developed a stroke later in phase D: 65% advised performing diagnostics first instead of immediate re-exploration. No consensus was reached in patients who were operated under local anaesthesia and experienced an ipsilateral stroke: 67% advised performing diagnostics first instead of immediate re-exploration. No granular analysis could be performed per expert specialty because of the blinded response.

Final conclusions

Consensus was reached in 17 of 21 scenarios (> 80%). Perform diagnostics first for a contralateral stroke. No consensus could be reached in phases A and D for an ipsilateral stroke. When diagnostic tests were advised in phase D (for a contralateral stroke), phase E, and phase F, a CT brain combined with a CTA or duplex ultrasound of the

carotid arteries should be performed. For the other phases, no further investigation on specific diagnostics test have been performed. Fig. 2 illustrates a suggested management algorithm based on the responses from the experts within each phase with additional comments added below this figure.

No further analysis could be performed to assess whether the advice differed between individual specialties because of the anonymised nature of the responses overall. However, with respect to management in the latter stage of phase D, some experts commented that they found this question challenging to answer because they were neurologists with limited personal experience of patient care during this peri-operative time period.

DISCUSSION

To the present authors' knowledge, the present Delphi study is the first expert based analysis providing insight on the most adequate and feasible clinical response to an in hospital stroke during or following CEA. A very high response rate was observed through the whole Delphi process (> 90%), with consensus achieved in 17 of 21 scenarios (> 80%). During the intra-operative phase immediate re-exploration should only be performed in phase C (restoration of the blood flow until the end of the CEA procedure) for an ipsilateral stroke. For (most) other phases, including the post-operative phases, it is recommended that immediate diagnostics should be performed initially (CT brain combined with CTA or duplex ultrasound of the carotid arteries).

These consensus recommendations for the management of post-operative stroke (phases D and E) are slightly different to those outlined in the current 2017 ESVS guideline.⁵ The experts conclude that diagnostics should be performed first, while the 2017 ESVS guideline suggested that direct re-operation should be performed for a stroke occurs that occurs within the first six post-operative hours.⁵ Most experts participating in this Delphi study described the preference to perform rapid intra-operative diagnostics, such as on table angiography/duplex, in the comments for grounding of this recommendation. In this context it is important to acknowledge that better understanding of the precise aetiology of the stroke might lead to a different response. Prior to this study, the classic paradigm assumed that the most likely cause of a post-CEA stroke (especially within the early post-operative phase) was a thrombosis of the internal carotid artery or embolism from mural thrombus in the endarterectomy zone.^{4,5} At a later stage, from the first post-operative day until day 30 it is more likely that a stroke is caused by a haemodynamic compromise, especially by hyperperfusion syndrome.⁵ Based on data from the International Carotid Stenting Study (ICSS), a trend towards both embolism from the carotid artery and a haemodynamic mechanism may be the cause of the stroke after the procedure on day 0.³ Intra-operative stroke is less common nowadays, leaving post-operative stroke as the most common timeframe.^{5,12}

This goes hand in hand with ipsilateral carotid thrombosis that is considered a less dominant mechanism over time while haemodynamic factors may be responsible for up to 50% of all post-operative strokes.^{5,12} However, this also means that only half of the patients who suffer a stroke after the procedure on day 0 would benefit from urgent surgical re-exploration.

Quite surprisingly, within the Asymptomatic Carotid Surgery Trial-1, post-stroke imaging of the carotid arteries was performed in less than half of patients, and only one third of patients with a stroke following CEA in ICSS (9 of 27) had carotid imaging carried out within 30 days.^{3,12} Twenty-five per cent of the patients participating in ACST-1 had a residual stenosis or occlusion, whereas five of nine patients (56%) with post-stroke imaging after CEA in ICSS had > 50% residual stenosis or occlusion of the revascularised carotid artery.^{3,12} Therefore, some of the patients in whom post-stroke carotid imaging was not performed might potentially have benefited from carotid re-intervention in these trials, thus further emphasising the importance of the consensus opinion in this Delphi study of requesting both brain and carotid imaging in patients with a suspected post-operative stroke. Nevertheless, it is also important to note that the cumulative five year risk of having $\geq 50\%$ moderate residual stenosis or restenosis after CEA was 29.6% in ICSS in patients for whom follow up ultrasound data were available, so most patients do have a good technical outcome post-CEA.¹³

Based on the results of this Delphi consensus study, a diagnostic and treatment decision tree is proposed to guide clinicians who are confronted with an in hospital stroke during or following CEA. This could enable more rapid and accurate diagnoses and may lead to better outcomes for patients in the absence of data from randomised controlled trials of different management strategies. It is acknowledged that several characteristics, such as severity of stroke, may influence a clinician's response. Comments on this by the experts, focused especially on phase A with an ipsilateral stroke in the pre-operative phase. In the presence of severe symptoms, diagnostics could be performed first. On the other hand, the majority of experts suggested continuing with the operation in patients with only mild symptoms, while noting that it can be very difficult to distinguish between a mild and a severe stroke early after symptom onset, especially when the patient is under general anaesthesia.

No definitive consensus could be reached for management in the latter stage of phase D where a patient underwent CEA under local anaesthesia and developed a stroke, or where the patient woke up well but developed a stroke soon thereafter. Further research is warranted to guide clinicians regarding optimal management at this stage after CEA.

Besides this, local availabilities and experience will differ worldwide. This could potentially have an effect on individual decision making. The use and availability of newer devices potentially could lead to another clinical decision

now and in the future, in particular modern devices in the operation room, for example high frequency ultrasound or on table angiography. It is conceivable that if the flow is good, as measured by intra-operative high frequency ultrasound, re-opening of the carotid artery potentially would not be the right option. The problem should be sought elsewhere, for example intracranial emboli. Therefore, this Delphi consensus study may serve as an overall guide and that further considerations can be made at all times per individual patient.

A strength of this study was that validity could be enhanced by including an expert panel of solely key international experts in the field focusing on carotid artery stenosis and stroke, working in both research and patient care. Second, a high response rate was achieved during the whole Delphi process.

The study has some limitations. There is a wide variation in methodological designs of Delphi studies. Therefore, open questions were included in the initial rounds to gain more understanding of the ratings and to check whether methodological inconsistencies were present. This resulted in a change of methodologies for rounds three and four compared with round two to include multiple choice questions instead of a Likert scale. Although the methodology changed, this is an acceptable amendment to employ in general and thus in this Delphi study. To avoid missing additional information and advice from the international experts, a comment box was also made available at the end of the questionnaire during each Delphi round. The expert panel included only vascular surgeons/vascular neurosurgeons and neurologists because they represent the main specialists who treat these patients worldwide. This study does not include information about whether management opinions differed between vascular surgeons and neurologists. This would be worth exploring in future larger studies in this area.

In conclusion, this study provides valuable insight into expert opinion regarding the optimal clinical management of a patient who experiences an in hospital stroke during or following CEA. Expedited diagnostics should be performed initially in most phases, but in patients who experience an ipsilateral intra-operative stroke during restoration of blood flow following cross clamp release until the end of the CEA procedure, re exploration of the index carotid artery is recommended. The treatment decision tree should be used as overall guidance.

ACKNOWLEDGEMENTS

We sincerely thank all the experts who participated in this Delphi study for their time and for sharing their expertise. All Delphi experts qualify for authorship based on the fact that they were involved in data collection and all critically appraised the final manuscript for important intellectual content. See [Appendix B](#) for the names of the Delphi experts.

CONFLICT OF INTEREST

None.

FUNDING

None.

APPENDIX A. SUPPLEMENTARY DATASupplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2021.05.033>.**APPENDIX B. DELPHI CONSENSUS EXPERTS PANEL**

Name	Expertise	Country	Years of experience
L.H. Bonati ¹	Neurologist	Switzerland	11 – 20
T.G. Brott ²	Neurologist	United States	>21
D. McCabe ³	Neurologist	Ireland	>21
D. Calvet ⁴	Neurologist	France	11 – 20
S.T. Engelter ⁵	Neurologist	Switzerland	11 – 20
E.C. Leira ⁶	Neurologist	United States	>21
D. Leys ⁷	Neurologist	France	>21
P.J. Nederkoorn ⁸	Neurologist	Netherlands	11 – 20
M. Paciaroni ⁹	Neurologist	Italy	11 – 20
J. Petersson ¹⁰	Neurologist	Sweden	>21
P. Ringleb ¹¹	Neurologist	Germany	>21
M. Uyttenbogaart ¹²	Neurologist	Netherlands	6 – 10
C. Weimar ¹³	Neurologist	Germany	>21
J.M. Antti Lindgren ¹⁴	Vascular neurosurgery	Finland	6 – 10
F. Bastos Goncalves ¹⁵	Vascular surgeon	Portugal	11 – 20
M. Bjorck ¹⁶	Vascular surgeon	Sweden	>21
J. Bismuth ¹⁷	Vascular surgeon	United States	11 – 20
S. Debus ¹⁸	Vascular surgeon	Germany	>21
H. Eckstein ¹⁹	Vascular surgeon	Germany	>21
P. Glovizcki ²⁰	Vascular surgeon	United States	>21
A. Halliday ²¹	Vascular surgeon	Great Britain	>21
S.K. Kakkos ²²	Vascular surgeon	Greece	11 – 20
I. Koncar ²³	Vascular surgeon	Serbia	11 – 20
A.R. Naylor ²⁴	Vascular surgeon	Great Britain	>21
D. Radak ²⁵	Vascular surgeon	Serbia	>21
M.L. Schermerhorn ²⁶	Vascular surgeon	United States	11 – 20
H. Sillesen ²⁷	Vascular surgeon	Denmark	>21
V. Tolva ²⁸	Vascular surgeon	Italy	11 – 20
M. Vega de Ceniga ²⁹	Vascular surgeon	Spain	11 – 20
F. Vermassen ³⁰	Vascular surgeon	Belgium	>21
C.J. Zeebregts ³¹	Vascular surgeon	Netherlands	11 – 20

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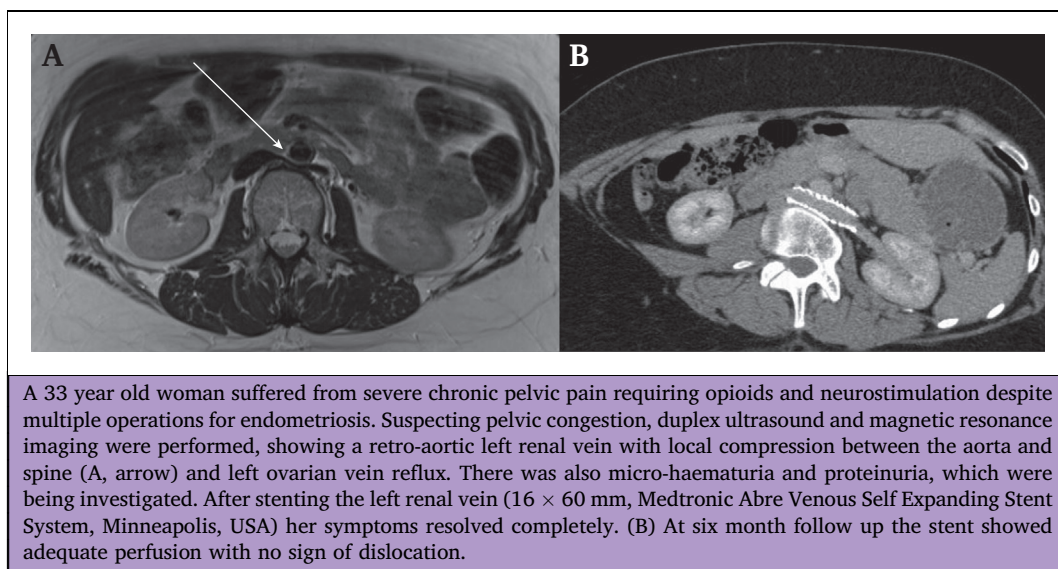
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COUP D'OEIL

Posterior Nutcracker Syndrome: Stented Vein, No More Pain

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