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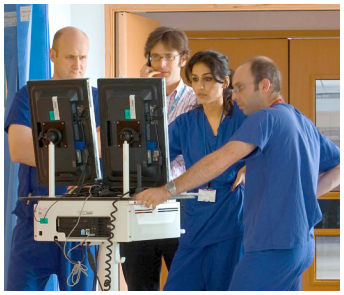

Role of physician and anaesthetic associates p 301

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Role of physician associates in the NHS

ORIGINAL RESEARCH Rapid systematic review FAST TRACK

Physician associates and anaesthetic associates in UK

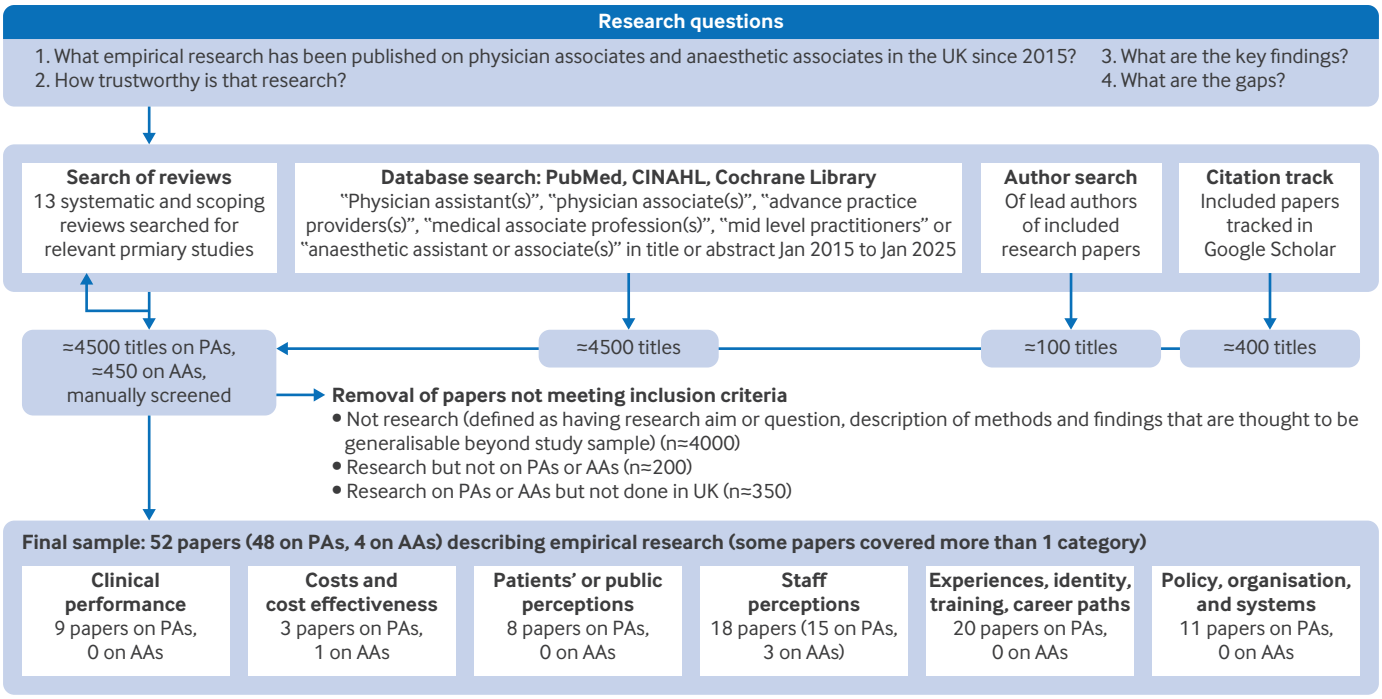
Greenhalgh T, McKee M

Cite this as: *BMJ* 2025;388:e084613
Find this at doi: 10.1136/bmj-2025-084613

Study question What can we learn from published research on the safety and efficacy of physician associates and anaesthetic associates in the UK?

Methods This was a rapid systematic review, following Cochrane guidance, of empirical UK based research on physician associate and anaesthetic associate roles published since 2015 for submission to an ongoing policy review. Studies were critically appraised using Critical Appraisal Skills Programme checklists, assessing trustworthiness, generalisability, and relevance. Two reviewers independently extracted data from studies meeting the inclusion standard and synthesised and interpreted the findings.

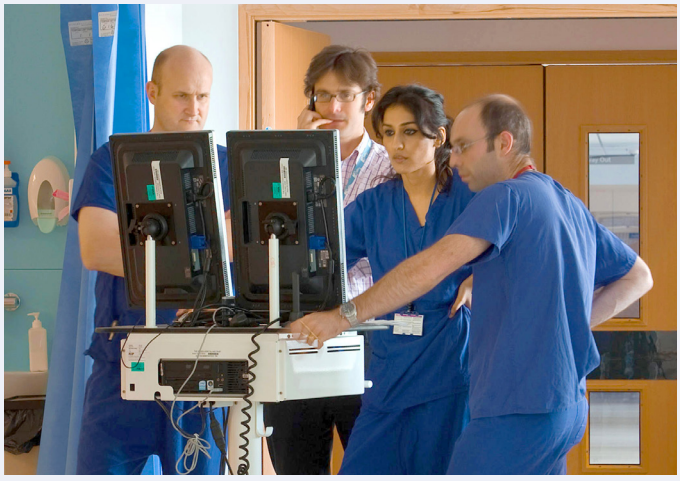
Study answer and limitations Of approximately 5000 titles, 52 papers were eligible (48 on physician associates, four on anaesthetic associates), of which 29 met the minimum inclusion standard. The evidence on the safety and efficacy of physician associates and anaesthetic associates in a UK context is sparse and of variable quality, and some is outdated. Some studies suggested that physician associates could support the work of ward based teams and work in emergency departments when appropriately deployed and supervised in low risk clinical settings, but the number of individuals and settings studied was small, and those findings should be considered preliminary. Physician associates seemed to struggle in primary care, however, because the role was more autonomous, the case mix was more diverse, decisions were more uncertain, institutional support was more limited, and supervision arrangements were more challenging. No studies examined safety incidents. No evidence shows that anaesthetic associates add value or that physician associates add value in primary care, and some evidence shows that they do not. The question of what problem these associate professionals are meant to solve remains unanswered. A limitation of the primary studies reviewed was that all were from England.



Study flowchart. AA=anaesthetic associate; PA=physician associate

COMMENTARY A lesson in how not to do workforce reform

Over recent months, a fierce and sometimes toxic debate has been taking place in the UK about the introduction of physician associates and anaesthetic associates as a new group of regulated health professionals working alongside doctors, nurses, and other health professions.[1] However, with many physician associate training programmes already well established in universities for more than a decade, with the regulation of this staff group by the General Medical Council having already started in December 2024, and with more than 3250 people having undergone training in good faith and now in physician associate or anaesthetic associate roles in the NHS, it seems rather late in the day for Royal Colleges,[2] the British Medical Association,[3] and other stakeholders to be raising fundamental concerns.


LANOWSKY/ALAMY

The government has asked Dr Gillian Leng to lead a review of physician associates (and anaesthetic associates) in England that will report later this year. It is focused on the safety of the roles, team working, and the delivery of high quality and efficient patient care.[4] Its brief excludes consideration of the training curriculums, how and by whom they are regulated, future workforce projections, and pay levels. A linked rapid review paper aimed at the Leng review examines the evidence base on the safety and effectiveness of physician associate and anaesthetic associate practice in the UK and finds it seriously wanting,[5] although it does not review the larger evidence base on similar roles internationally.

We need to do these kinds of workforce reforms much better in the future

More health workforce research needed

So how did we end up in this mess, and what should we do about it? Firstly, we have massively underinvested in research on the healthcare workforce for many years. Many unmet research needs to inform policy and practice exist, of which physician associates/anaesthetic associates are just one example.[6] We should have a large standing NHS research and development programme aimed at providing the evidence for workforce reforms such as role redesign, new and changed roles, and so on.[7] No new medical intervention would enter mainstream clinical practice on the basis of the scanty, small scale, and underpowered studies we have on physician associates and anaesthetic associates in the UK. We need much larger and more methodologically robust studies, with more effective evidence synthesis. The

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What this study adds This study challenges assumptions that physician associates and anaesthetic associates have been shown to operate safely, effectively, and cost effectively. It reveals major gaps in the evidence base and points to a need for clearer specification of their roles and further research into their appropriate place in a complex and changing workforce.

Funding, competing interests, and data sharing This review received no additional funding. The authors have expressed concern about the expansion and regulation of physician associates and called for policy to be evidence based. All papers reviewed are in the public domain.

Study registration INPLASY202520039.

National Institute for Health and Care Excellence (NICE) is the obvious national body to provide some leadership in the development of clear, research based guidance on workforce reforms, but since its controversial work on staffing levels a decade ago[8 9] it has largely steered clear of guidance on workforce matters—this needs to change.

Secondly, NHS workforce planning has been for some time prone to vague aspirations and largely uncosted future plans for workforce expansion.[10 11] Initiatives to promote new or changed roles (for example, in general practice or extended roles for nurses) have been long on rhetoric but short of clarity on what those roles actually are in terms of scope of practice, supervision and authority, legal responsibility, and their place in the wider clinical team. As a result, their implementation has often been bedevilled by ambiguity and confusion about what they were intended to achieve and what actually happened in practice.[12]

Thirdly, the statutory arrangements for regulating the health professions—with nine separate regulatory bodies and a complex web of legislation that has grown piecemeal over the past 150 years—are simply not fit for purpose. The Law Commission produced sensible proposals (and a draft bill) for a wholly new single regulatory legislative framework in 2014,[13] but successive governments have failed to enact them. In the UK, we regulate by title (controlling, for example, who can call themselves a doctor, a registered nurse, or a physiotherapist) but we largely do not define explicitly the scope of practice of health professionals—what they can and cannot do, and in what circumstances. This makes introducing new roles such as physician associates and anaesthetic associates much more difficult, as no clear statement of their scope of practice from the regulator exists.[14] Often, this is left to employers to determine, which leads to many inconsistencies and variations in practice. Physician associates have been working in the NHS for two decades and should have been properly regulated long ago.

Setting scope of practice right

It seems likely that a messy compromise will be found to resolve the debacle over physician associates and anaesthetic associates, setting out a clearer and more limited scope of practice that, for example, constrains what patients they can see, how they are supervised, and what actions they can take. The prospects for extending their role (for example, into prescribing drugs, ordering and interpreting blood tests and imaging, or undertaking some surgical procedures) now seem remote. Practically, as physician associates and anaesthetic associates have been graded at NHS band 7 (the same level as much more clinically experienced advanced nurse practitioners, and a higher salary than a foundation year 1 doctor), the economic case for expanding their numbers may not now add up.

We need to do these kinds of workforce reforms much better in the future—both for the safety of patients and for the wellbeing of staff. A new research and development programme from the National Institute for Health and Care Research focused on the workforce, an explicit role for NICE in institutionalising evidence in formal workforce guidance, and comprehensive reform to the regulation of health professions would be a good start.

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Find the full version with references at http://dx.doi.org/10.1136/bmj.r437

OPINION Trisha Greenhalgh

Systematic reviews of non-RCT evidence: building dry stone walls

To bake good cookies, start with good cookie dough. To use a different metaphor, to build a brick wall, take a large collection of bricks—all the same size and in perfect shape—and line them up neatly.

A systematic review is a review of primary research undertaken to an explicit, rigorous, and reproducible methodology. The Cochrane Handbook recommends asking a tightly focused question (usually of the format "What is the impact of intervention A on outcome B?"), finding all randomised controlled trials (RCTs) that have addressed it, extracting data on (for example) sample size, completeness of follow-up, and numbers of participants with each outcome, and summing up the findings.

The poster child of systematic review is a cumulative meta-analysis of 33 trials of streptokinase for myocardial infarction, which showed that as each study was added to a numerical synthesis, the confidence interval became progressively narrower.

But what if there are no bricks? What if RCTs are either practically impossible or unethical? Would a research ethics committee approve a trial in which half the patients on a theatre list would be randomised to an anaesthetist (a doctor with 4-6 years' training plus a postgraduate qualification) and half to an anaesthetic associate (with two years' training), with no correction for case mix? Would a patient sign the consent form?

Perhaps that is one reason why the 52 papers we identified in a search for research on physician associates (PAs) and anaesthetic associates (AAs) turned up no randomised controlled trials. Perhaps it is why every study that compared the performance of PAs or AAs with that of doctors found large differences in case mix. Quite rightly, triage processes were in place to ensure that complex patients (eg, extremes of age, with more severe or risky medical conditions, multimorbidity, or challenging social circumstances) were seen by someone with longer and more in-depth training. Also rightly, PAs and AAs in the studies were closely supervised by senior doctors.

How, then, can we reasonably compare apples (PAs or AAs seeing low complexity patients under supervision) with oranges (doctors seeing more complex patients with less supervision) in studies where nobody was randomised and there was very little (usually no) blinding of assessors?

In such circumstances, we need to accept that the "risk of bias" tools beloved by the GRADE methodologists are going to tell us only the screamingly obvious—that there are significant biases in the study designs. What those risk of bias tools won't tell us is what we should do with those biased data.

Correcting biases

For starters, we need to question how researchers attempted to correct for these biases. One team produced an elegant methodology for correcting for what they called "medical acuity." But as with any non-randomised study, the presence of unknown (and as yet unimagined) confounders cannot be excluded. The study is still comparing apples with oranges, even when you've added a fudge factor for the disproportionate hardness of apples and greater juiciness of oranges.

We need to go beyond the "single focused question" approach to examining the primary studies. Different research teams looked at the PA/AA issue in different ways, each asking a different question and studying a different primary outcome. In such situations, the primary studies are not tidy bricks, but a set of mis-shapen stones.

Ogilvie et al use the metaphor of the dry stone wall to depict how reviewers need to use narrative synthesis to weave these disparate studies together, highlight the strengths and limitations of each design and show what each study contributes (and what it fails to contribute) to the overall picture.

Whereas the conventional systematic reviewer's task is statistical (to summarise

data), the dry stone wall reviewer's task is interpretive (to make sense of those data). Both are important and provide complementary information.

Our "dry stone wall" review turned up some troubling findings, chief of which was that only a handful of primary studies had looked at any aspect of the clinical performance of PAs or AAs in a UK context.[4] Even fewer had made any attempt to correct for case mix.

Many of those studies had been undertaken in the early 2010s when the UK had a more resilient, better staffed health service and associate professionals were being deployed cautiously in low risk roles. Yet when national policy makers were interviewed, they appeared to view the evidence base on efficacy and safety as a closed case (it had, they thought, been demonstrated definitively).

The government has asked Gillian Leng to examine the evidence (including but not limited to the studies we included in our review) on the efficacy and safety of PAs and AAs. If they are expecting her to build a brick wall, they will be disappointed.

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In some cases the primary studies are not tidy bricks, but a set of mis-shapen stones

OPINION Tamara S Ritsema and Amy Donaldson-Perrott

Physician associates want their profession to have appropriate regulation and oversight

Over the past year, a firestorm of debate has been swirling around the role of physician associates (PAs) in the NHS. Many commentators have used the lack of regulation of PAs and oversight of their education as evidence that PAs are trying to hide their practice or escape the consequences of their actions. Nothing could be further from the truth.

PAs, like doctors, nurses, physiotherapists, pharmacists, and all NHS professionals, want to ensure that only highly qualified people are admitted to their profession and that there is a mechanism to manage those who are not performing to standard.

Just as all doctors do not bear responsibility for the mistakes of other doctors, nor do all PAs bear responsibility for every mistake made by another PA. Yet the government has been slow to respond to the need for regulation.

The lack of statutory regulation has meant that the PA profession took the initiative to develop the managed voluntary register for PAs in 2010. The government agreed to regulate PAs in 2018 and it has taken another six years for the agreed upon regulation to begin. PAs also welcome oversight for PA courses by the GMC, which has already performed evaluation visits. The list of approved courses will be published in spring 2025.

Advocating for oversight

Like all health professionals, PAs want good outcomes for every patient. This is why PAs have been advocating for professional regulation for more than 15 years. PAs in the UK have wanted a similar system of government oversight of their education and practice as is in place in the US, the Netherlands, and parts of Canada. Regulation of the profession would have addressed some of the issues raised in a new review by Greenhalgh and McKee, such as inappropriate ordering of radiological investigations or misrepresenting of credentials by PAs.

PAs are asking to be members of the team to provide continuity of care for patients

The lack of appropriate regulation and oversight on the part of the government does not mean that the profession itself is not fit for purpose. Indeed, as is evident in the literature on PA practice in the Netherlands and US, PAs can provide effective care when the appropriate infrastructure is in place. Like all health professionals, PAs need to be clear on their role in patient care and the wider health system.

The GMC has published helpful frameworks for PA training and practice. These outline multiple competencies for PAs, including being able to explain the PA role to others, working within the limits of their knowledge, recognising clinical risk situations, and escalating concerns about patients through appropriate channels.

The early development of the PA profession was actively supported by the Royal College of Physicians and the Royal College of General Practitioners. They helped to develop the role, as well as the curriculum, which acknowledged that PAs would work under the supervision of doctors to care for patients. PAs are not a replacement for doctors. This ideal has been lost in a turf battle played out largely over social media (an environment that rewards inflammatory posts, not reasoned discussion between parties).

PAs are not asking to take the role of the "airplane pilot" from doctors. They are asking to be members of the team to provide continuity of care for patients and to accomplish the daily jobs that need doing in clinical practice.

Like Greenhalgh and McKee, we agree that the research on PA practice is sparse. Yet this lack of evidence comes not from a lack of passion within the PA community to rigorously evaluate PA practice, but from a lack of resources to do so. Two large research groups, which do not include PAs, have been funded to evaluate the profession and feature heavily in Greenhalgh and McKee's study. One specifically evaluated PA practice in the early 2010s, and the other performed some studies of PAs in the context of an overall primary care workforce assessment.

Since the PA profession is still relatively small, the profession has not been able to fund its own health workforce research.

If the NHS wants to join other countries like the Netherlands, Canada, and the US who are successfully using PAs to increase access to care and provide continuity of care, more research funding should be provided to evaluate the implementation of them. The absence of evidence is not evidence of absence.

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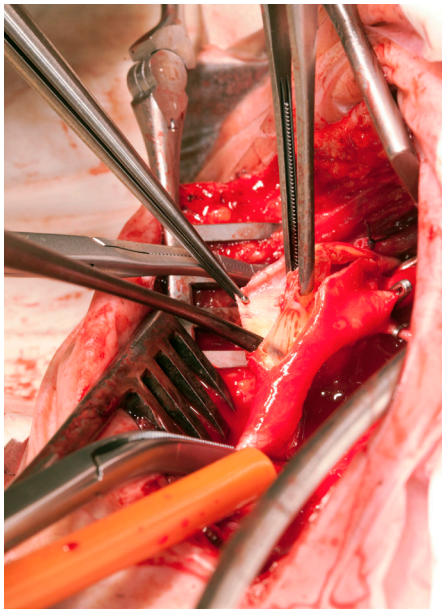
Amy Donaldson-Perrott, reader in physician associate education, University of London

Cite this as: *BMJ* 2025;388:r472

Therapeutic ultrasound during carotid endarterectomy

ORIGINAL RESEARCH Randomised controlled trial



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Sonolysis during carotid endarterectomy

Školoudík D, Hrbáč T, Kovář M, et al; on behalf of the SONOBIRDIE Trial Investigators

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Find this at doi: 10.1136/bmj-2024-082750

Study question Does sonolysis using a low intensity 2 Hz pulsed wave ultrasound beam during carotid endarterectomy reduce the incidence of ischaemic stroke, transient ischaemic attack, or death within 30 days?

Methods In this multicentre, phase 3, double blind, controlled trial, patients undergoing carotid endarterectomy were randomly assigned to receive sonolysis (n=507) or sham procedure (n=497). The primary endpoint was the composite incidence of ischaemic stroke, transient ischaemic attack, or death within 30 days. The incidence of new ischaemic lesions on follow-up brain magnetic resonance imaging was the main substudy endpoint, and incidence of intracranial bleeding was the main safety endpoint.

Study answer and limitations: A total of 1004 patients (mean age 68 years; 213 (31%) female) were enrolled in the study until the interim analysis was done. Periprocedural sonolysis significantly reduced the 30 day risk of the composite primary endpoint (including ischaemic stroke, transient ischaemic attack, and death) after carotid endarterectomy by 5.5% (11 (2.2%) *v* 38 (7.6%); risk difference −5.5%, 95% confidence interval (CI) −8.3% to −2.8%). The risk of magnetic resonance imaging detected new ischaemic lesions was also significantly lower in the sonolysis group (20/236 (8.5%) *v* 39/224 (17.4%);

COMMENTARY Intraoperative sonolysis reduces stroke complications

Ultrasonography as a diagnostic modality for the diagnosis and surveillance of carotid stenosis has been a mainstay of clinical practice for decades.[1 2] Ultrasound is non-invasive, does not use ionising radiation or contrast media, and remains low cost, making it an integral evidence based tool for patients with carotid disease.[3]

Carotid endarterectomy is the surgical therapeutic gold standard to reduce long term stroke risk in patients with severe carotid stenosis. In the linked study, investigators in the SONOBIRDIE trial have tested a new application for ultrasound: prevention of thromboembolic complications during carotid endarterectomy.[4] In a multicentre randomised trial of 1004 patients, investigators determined that intraoperative sonolysis with ultrasound at the time of carotid endarterectomy reduced the composite endpoint of transient ischaemic attack, stroke, or death within 30 days from 7.6% to 2.2%, compared with sham sonolysis. These findings represent a potentially significant innovation in the application of ultrasound from its historical diagnostic role to now also as a therapeutic intervention. Given the well documented low risk of stroke associated with asymptomatic carotid endarterectomy, the observed absolute risk reduction of 5.4% seems to represent a substantial additive advance in carotid endarterectomy care.

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Trial strengths

The trial has several strengths. As noted by the authors, use of ultrasound for sonolysis is grounded in both animal models and studies of healthy control adults, giving biological plausibility for the reduction in the risk of stroke seen in the trial. The use of sham sonolysis for the control group is a major strength of the study that enhances the internal validity of the intervention. Sham controlled interventions remain rare in surgery, because they are both costly and time intensive, but when conducted they often offer the most valid evaluation of a given intervention. In addition, outcomes in all patients were clinically adjudicated by a neurologist specialising in stroke both before and after their surgical procedure, which improves and standardises the detection of the primary outcome across the treatment groups. The addition of a magnetic resonance imaging sub-study adds corroborating imaging data to support the findings of clinical stroke risk reduction in the main study, again enhancing the internal validity of the results.

However, some persistent questions surround the study design and results and should be considered before widespread adoption of this technique. Perhaps most importantly, the risk of the primary outcome in the control group is concerning. As noted above, the risk of the composite of 30 day transient ischaemic attack, stroke, or death was 7.6% in the control arm. Post hoc analysis shows that the risk of the composite outcome was 6.9% in a control group of patients without symptoms and 8.5% in patients with symptoms. Although an 8.5% risk of this outcome in patients with symptoms might plausibly be justified, a 6.9% risk in patients with no symptoms seems high compared with societal guideline based safety benchmarks.[3 5] Specifically, this is more than double the risk of what can be expected in published randomised trials

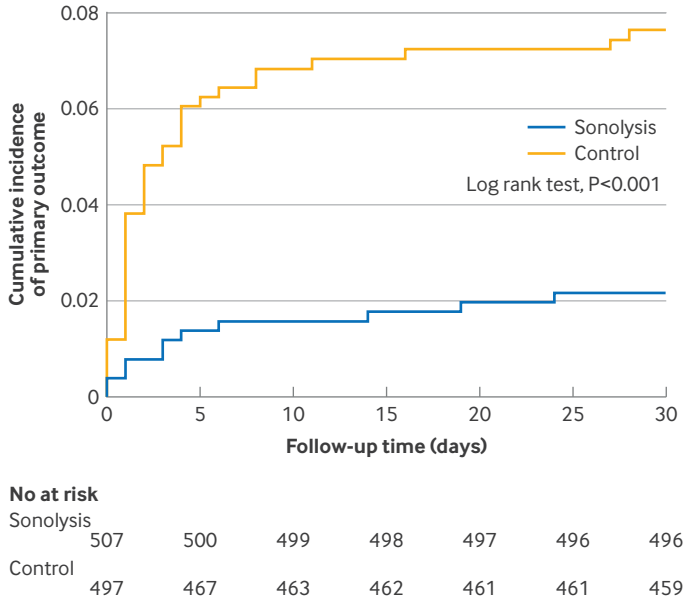
The observed absolute risk reduction of 5.4% seems to represent a substantial additive advance

risk difference −8.9%, −15% to −2.8%). A limitation of the study was that no study specific ultrasound device was used.

What this study adds Periprocedural sonolysis during carotid endarterectomy was safe for patients and significantly reduced the risk of the composite incidence of ischaemic stroke, transient ischaemic attack, or death within 30 days, as well as the risk of new brain infarction.

Funding, competing interests, and data sharing
The study was partially funded by the Czech Health Research Council. The authors have no competing interests to declare. Data will become available to interested investigators on submission of a reasonable research request by email to the corresponding author and approval by the steering committee of the trial.

Study registration Clinicaltrials.gov NCT02398734.



Cumulative incidence of primary composite outcome consisting of ischaemic stroke, transient ischemic attack, or death within 30 days

BELMONTE/BSIP/ALAMY

and large observational studies of carotid endarterectomy and remains above the threshold at which patients may fail to derive benefit from undergoing prophylactic surgery.[6-11]

Strengths and limitations

Furthermore, symptomatic carotid stenosis was not a predictor of the primary outcome in the multivariable analysis, with similar risks of the primary outcome for patients with and without symptoms alike, once stratified by the treatment arm. This would seem to be inconsistent with historical surgical outcome norms in which elevated stroke risk among patients with symptoms compared with those without symptoms is a well established phenomenon, with patients with symptoms experiencing an increased risk of perioperative stroke.[12-14] The unanticipated increased stroke risk observed in this trial among patients without symptoms, as well as the similarity in stroke risk for patients with versus without symptoms, calls into question the internal validity of the composite outcome assessment in this study.

Despite these inherent strengths and limitations, some important next steps seem to be justified. The ultrasound used in this study is non-invasive and did not seem to be associated with any safety risks. Given the low risk associated with the ultrasound, considering it for clinical use if the above questions of the internal validity of the study can be resolved may be reasonable. A formal cost effectiveness evaluation of routine use during carotid endarterectomy should be conducted, along with implications for implementation of this new treatment modality. Resolution of the above concerns, along with a cost effectiveness calculation, can then inform whether this exciting new application of an established technology can improve care for patients undergoing carotid endarterectomy.

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Find the full version with references at http://dx.doi.org/10.1136/bmj.r385

Late adverse event reporting from medical device manufacturers to the US Food and Drug Administration

Everhart AO, Karaca-Mandic P, Redberg RF, Ross JS, Dhruva SS

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Study question To what extent are adverse events reported late by manufacturers to the Food and Drug Administration's (FDA) Manufacturer And User Facility Device Experience (MAUDE) database, a central postmarket safety surveillance tool for US medical devices?

Methods In this cross sectional study, the timeliness of manufacturer reporting of initial adverse event reports submitted to the MAUDE database between 1 September 2019 and 31 December 2022 was evaluated. Differences in late reporting were evaluated as a function of medical device characteristics and recall status. The main outcome measures were time in days between the date that the manufacturer was notified of event and the date of FDA receipt of adverse event reports, proportion of reports reported late (after the required 30 day window as required by FDA regulation), and distribution of late reporting among manufacturers and medical devices.

Study answer and limitations Of 4 432 548 included reports, 71.0% of adverse events were reported within 30 days (on time), 4.5% were reported between 31 and 180 days (late), and 9.1% were after 180 days (late). 15.5% of reports had missing or invalid date data provided by the manufacturer. More than 50% of late reports were attributed to three manufacturers and 13 medical devices. A limitation of this study is that report times were measured on the basis of dates reported by manufacturers, which may have been misreported or not reported.

What this study adds Nearly a third of manufacturer reports of medical device adverse events were not demonstrably submitted to the FDA within the regulatory deadline, with most late reports submitted by a small number of manufacturers. Late adverse event reporting may prevent early detection of patient safety concerns.

Medical device report times by event type

Characteristic	Death (n=13 587)	Injury (n=1 552 268)	Malfunction (n=2 866 693)	Total (n=4 432 548)
Unique manufacturers	397	1949	2032	3028
Unique devices	2584	48 003	49 372	88 448
Report time, mean (SD)*†	54.3 (171.1)	61.7 (151.1)	99.5 (270.2)	89.6 (245.2)
Report time, median (IQR)*†	23 (13)	22 (15)	17 (20)	19 (20)
Reported within 30 days, No (%)	12 408 (91.3)	772 543 (49.8)	2 362 006 (82.4)	3 146 957 (71.0)
Reported from 31 to 180 days, No (%)	377 (2.8)	126 431 (8.1)	70 798 (2.5)	197 606 (4.5)
Reported past 180 days, No (%)	627 (4.6)	71 620 (4.6)	330 644 (11.5)	402 891 (9.1)
Missing or invalid date, No (%)	175 (1.3)	581 674 (37.5)	103 245 (3.6)	685 094 (15.5)

SD=standard deviation; IQR=interquartile range.
*Report time defined based on difference between day Food and Drug Administration reported receiving device report and day manufacturer reported becoming aware of device event.
†Mean report time and percentiles only calculated for non-missing and non-negative report times.

Funding, competing interests, and data sharing No funding declared. AOE reports prior employment by Medtronic. JSR receives research support through Yale University from the Food and Drug Administration for the Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation program (U01FD005938). For full details of competing interests, see bmj.com. Statistical code and datasets are available on Mendeley Data at https://data.mendeley.com/datasets/mydr3vdzcr/1.