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The role of interventional radiologists in acute stroke interventions: a joint statement from the Australia and New Zealand Society of Neuroradiology (ANZSNR), the Society of Neurointerventional Surgery (SNIS), the United Kingdom Neurointerventional Group (UKNG), the British Society of Neuroradiology (BSNR), and the Europe

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The Role of Interventional Radiologists in Acute Stroke Interventions: A Joint Statement from the Australia and New Zealand Society of Neuroradiology (ANZSNR), the Society of Neurointerventional Surgery (SNIS), the United Kingdom Neurointerventional Group (UKNG), the British Society of Neuroradiology (BSNR), and the European Society for Minimally Invasive, Neurological Therapy (ESMINT)

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ABBREVIATIONS

LVO = large vessel occlusion, MT = mechanical thrombectomy

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We read with interest the article by representatives of European Board of Interventional Radiology, Society of International Radiology, and International RadioSurgery Association (1). The interest of interventional radiologists in mechanical thrombectomy (MT) is welcome, but the cognitive/procedural aspects of MT must be considered along with the complex processes and resources required for service implementation. Training for *all* proceduralists must be consistent, MT proceduralists' posttraining performance must meet satisfactory benchmarks, and MT centers' outcomes must be acceptable.

Although more MT-trained physicians may ultimately be required, workforce expansion must be undertaken with diligence to ensure patient safety and cost-effective care. Assessment of the size and nature of the problem is crucial, as is evaluation of existing resources and their optimal use and calculation of what additional resources are required for current and future needs. The difficulty of delivering MT to large and/or isolated populations is acknowledged; however, there are a number of commonsense approaches to addressing these issues before expansion of the MT workforce.

Sacks makes a number of statements that must be addressed, arising from 2 assertions: MT safety/outcomes between interventional radiologists and neurointerventionists are equivalent, and more doctors and MT centers are needed to meet demand. Sacks asserts there is no evidence for differences in angiographic or clinical outcomes or procedural safety for MT done by neurointerventionists or interventional radiologists. Conversely, there is no evidence that neurointerventionists are ill-equipped to perform interventional radiologist work, but the reason for this is that trials designed to examine such differences have not been undertaken in either case.

Three of the papers cited in support of this argument predate publication of the definitive MT trials (2–6). The lack of citation of prospective, randomized, independently adjudicated publications to support this contention is notable.

Behzadi's (7) retrospective series reported mTICI-0/1/2a rates of 24.5% and complication rates of 7.4%. This is below par for a neurointerventionist in a high-volume center, as is the reported 75% TICI-2b/3 rate. High-volume centers report mTICI-2b/3 recanalization rates of >85% (2,8). The 90-day modified Rankin scale of 0–2 is quoted as 39.8%, which is comparable with the outcomes in both arms of Interventional Management of Stroke-III (9), suggesting these patients may have had similar outcomes without exposure to the additional risks of intervention.

Sacks also cites Belisle (10). Of the 83 patients, apparently <30 had MT, suggesting that most received intra-arterial fibrinolysis only, which has a different procedural safety profile to MT. It is impossible to draw conclusions regarding safety for MT between craft groups based on a 30-patient cohort. A 40-patient case series by Burkart (11) is also cited, describing a 65% TICI-2a, 2b, or 3 reperfusion rate, which is unacceptable for a trained neurointerventionist. Of note, the author included TICI-2a results as being “acceptable,” but TICI-2a reperfusion is usually considered unsuccessful MT. In fact, recent studies suggest that even TICI-2b may be insufficient in many cases (12).

Gandini (13), also cited by Sacks, in a letter responding to Fjetland (14), reported, without elaboration, a retrospective evaluation of 94 patients, claiming TICI-2b/3 reperfusion in 86%. Although superficially acceptable, no information is provided regarding the presence of large vessel occlusion (LVO), patient selection/outcomes, techniques, or complications. Both Gandini and Fjetland use Interventional Management of Stroke-III (9) and Mechanical Retrieval and Recanalization of Stroke Clots Using Embolectomy (15) as safety/efficacy benchmarks, neither of which is relevant to current practice. Sacks' citations have low evidentiary value, do not reflect current practice, and are not supported by prospective, randomized, independently evaluated studies. None reflects consecutively collected data, rendering assessment of failed access in challenging anatomy impossible. Such failure is rare for neurointerventionists. Access is often the most challenging aspect of MT and must not be underestimated as a cause of failed treatment and/or

complications. MT physicians must be capable of safe, rapid, and unassisted access to the intracranial circulation in $\geq 95\%$ of patients before certification.

The 1 prospective, randomized, controlled trial cited (which involved interventional radiologists), Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands (3), has the lowest TICI-2b/3 reperfusion rates (58.7%) and poorest clinical and safety outcomes of the MT trials. There are multiple potential reasons for this, including the expertise of the proceduralists. Nonetheless, it is scientifically unsound to infer safety equivalence or otherwise between different proceduralists in a trial not designed for that purpose.

Until such a trial has been run, it is in patients' best interests for MT to be performed by comprehensively trained neurointerventionists. This does not preclude interventional radiologists (or others) from training in MT; however, training must include all techniques required for neurointervention, many of which are needed during MT cases. There is significant risk in permitting interventional radiologists or anyone without expertise in neurointervention to set training and skills maintenance standards for MT. Assessment of such groups must be overseen by independent parties with established skills. It is well-recognized that people lacking expertise lack the metacognitive abilities to recognize that lack of expertise, and the training required to gain it. Or, “...the skills which engender competence in a particular domain are the same skills necessary to evaluate competence in that domain...” (16–18). Therefore, physicians with no inherent neurointerventional expertise must adhere to guidelines approved by neurointerventional societies, and experienced neurointerventionists must be the principal supervisors and assessors of these physicians.

Sacks advocates expanded MT physician and center numbers, arguing that patients are missing out on treatment, that MT-eligible patient numbers will increase after Clinical Mismatch in the Triage of Wake Up and Late Presenting Strokes Undergoing Neurointervention With Trevo (DAWN) (19)/Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3 (DEFUSE-3) (20); that the only way to meet MT demand is more MT physicians; and geographically isolated patients must be treated in situ. That eligible patients are currently missing out on treatment is true (21); however, “eligibility” for MT can be defined loosely as LVO, or more rigorously as a patient with LVO *and* good preexisting clinical status (modified Rankin scale <3), reasonable life-expectancy, and salvageable brain tissue.

The distinction between rigorous/nonrigorous selection is key to the low and high ends of Sacks' “10–31/100,000” patients. It is debatable whether less rigorously selected patients are in fact “missing out.” The reasons for genuinely eligible patients missing out on MT are more closely related to logistics than workforce issues, and include delayed presentation (22), inefficient triage/imaging/notification, underdeveloped stroke networks/transfer protocols, poor telemedicine/teleradiology infrastructure (23), and geographical isolation (24).

Because MT has emerged quickly as standard of care, funding for the logistical frameworks is lagging. When percutaneous coronary intervention became the standard of care, governments and clinicians collaborated (25,26) to educate health care workers, develop transfer protocols, and streamline systems of care before considering workforce expansion or developing regional centers.

The logistical framework for stroke is generally underdeveloped. Even in countries with the most advanced logistics, many patients present late to hospital for various reasons (22,27). Even in experienced centers, the triage and imaging pathway is variable, with some patients managed quickly and others receiving inadequate prioritization. When imaging is performed promptly, report turnaround time is still variable, as is the quality of reporting during business hours compared with after hours, resulting in delayed diagnosis of LVO or missed LVO.

Hospital politics and competition for funding may present additional barriers. Institutions may discourage transfers to MT centers because funding mechanisms favor retaining the patient. In the private sector, physicians may be reluctant to transfer patients if there is potential for personal financial disadvantage. This may contribute to the “silo mentality” common in some health systems. These issues could be addressed with minimal additional funding, resulting in improved access to MT in metropolitan and regional areas. Workforce analysis is essential to determine if deployment of existing neurointerventionists is optimal. Most engage in nonneurointerventional work for part of their time. Existing neurointerventionists should be encouraged to work full time, with backfilling of their nonneurointerventional roles. In Australia, this would increase the workforce by 20%–30%. This is a faster and more efficient means of increasing MT access than training or part-training nonneurointerventionists.

Sacks argues that the United States needs >300 new MT centers, but does not elaborate beyond rough estimates of patient and existing center numbers. The potential patient cohort and the capacity of existing services to expand are not examined. Sacks asserts that there are ~100,000 patients annually eligible for MT in the United States. In mature systems, numbers (after DAWN [19] and DEFUSE-3 [20]) are plateauing at 10–15 per 100,000 annually (New South Wales Agency for Clinical Innovation, personal communication, February 22, 2018). This reduces the estimated US caseload to ~50,000 annually, which is easily manageable by the existing 231 centers. Even if we assume that there are 100,000 MT-eligible patients annually, Sacks’ argument is flawed in suggesting an “average” of 200 MT per year per center and then arguing as if this were a cap on numbers achievable when calculating the number of centers and physicians required.

In fact, many centers have >4 neurointerventionists plus trainees and could absorb more cases with few additional resources, remembering that 100 procedures/year is <2 procedures weekly, easily manageable by 1 operator and most centers. Many MT centers are close to each other and

can easily be networked. It would be more efficient to employ 1–2 extra neurointerventionists and bolster the resources of one center/network than to fund and staff one new center. Even if Sacks’ annual “cap” of 200 MT per center were valid, it would require minimal investment to boost capacity to 350 MT annually per center, increasing the national MT capacity to >80,000.

Geographical isolation remains a challenge. Even after optimizing services, there will be patients without immediate access to MT. The number of such patients is key, however. The options are (a) transfer to an MT-capable center or (b) deliver MT *in situ*. Deciding which is appropriate should not occur until all logistical problems are resolved. Then, geographically isolated centers will either justify implementation of a MT service based on their numbers or not.

Sacks concurs that MT services require ≥ 4 physicians. This has implications for minimum caseloads for remote centers. Sacks cites Davis (28) and Grotta (29) to support treatment of remote patients *in situ*; however, closer inspection reveals that these authors’ views are more in line with those of the neurointerventional community. For instance, Davis states: “We agree that training standards for neurointerventionists must be rigorous,” “Outcomes relate to case volumes,” “The neurointerventionist ... must be expert, work in a multidisciplinary team...with all the backup resources and a 24/7 model,” and “...the centre [must] generate[s] sufficient volume...to maintain competency of the interventionists...” Grotta argues that to maintain individual competency: “...45 cases per year might be a reasonable estimate”; and “Appropriate training guidelines have been established by the relevant specialties and must not be shortcut.”

Forty-five MT cases per year equates to 180 MT patients for 4 physicians, implying that centers receiving <180 MT annually should adopt an outward transfer policy. A 180-MT-per-year center will also receive around 70 aneurysmal subarachnoid hemorrhage patients (30), sufficient to sustain a full neurovascular service. The neurointerventionist, however, is 1 of many stakeholders in the delivery of safe and effective MT. Before rollout of any service, there must be significant financial investment in training of ambulance staff and bypass protocols; training/education of emergency staff; training of angiography technicians and nurses; access pathways to neurosurgery and stroke neurology; training/staffing of intensive care units; training in advanced computed tomography applications; resourcing for rapid computed tomography report turnaround 24/7/365; and recurrent funding for staff to cover 24/7/365 for stroke patients.

When discussing *in situ* MT in remote areas, one must consider the more realistic scenario of centers receiving 25–30 patients annually. The funding and infrastructure required for such services is essentially the same as for a 250-MT-per-year service. Such funding would have greater impact deployed into primary prevention, education, and logistics. Given there are virtually no regional centers in developed

countries >2 hours' flight from an MT center, patient informed consent and medicolegal defence of remote centers and interventional radiologists become problematic, especially in the context of DAWN (19) and DEFUSE-3 (20). Although cited by Sacks in support of MT in remote centers, these trials imply that many patients may have time for transfer to a major center. Since their publication, focus has shifted away from time toward tissue viability as the key metric in patient selection (31).

Caution should therefore be exercised when considering large investments into low-volume services that may not actually be required.

SUMMARY

The neurointerventional societies encourage examination of the complexities of delivering MT, taking a broader view than performance of the procedure in isolation. Performing MT safely and effectively requires investment in hospital and community services, along with comprehensive neuro-interventional training. Funding bodies should prioritize resource enhancements for existing services and invest in education and logistics. Emerging evidence indicates that geographic isolation is likely to present fewer challenges than anticipated, and that remote MT centers are unlikely to be needed.

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