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EDITORIAL

Does Volume Directly Affect Outcome in Vascular Surgical Procedures?

Review of the Current Evidence

A number of recent studies have shown a link between the volume of surgery undertaken by a hospital and outcome for vascular surgical procedures.[1–10] Existence of this relationship has been known for some years, with Luft *et al.*[11] demonstrating in 1979 that there was improved mortality at hospitals performing higher volumes of high-risk operations.

More recent studies have confirmed this relationship, and in some cases have attempted to define minimum volume thresholds, above which there is a clear improvement in outcome. In two meta-analyses utilising data mainly from North America,[5,7] it was shown that better outcomes could be achieved in hospitals performing greater than 43 elective abdominal aortic aneurysm repairs (AAA) and 70 carotid endarterectomies (CEA) per annum.

One criticism of these data is that the results may not be applicable to European practice as the volumes of surgery undertaken in the USA are much higher than in most European hospitals. To address this important criticism, recent studies have been undertaken to evaluate the relationship between hospital volume and outcome in England[6,8,12] and Germany,[10] in addition to a previous Norwegian study.[9] Significant relationships were demonstrated between hospital case volume and outcome (in terms of mortality and length of hospital stay) for both elective AAA and CEA. Critical volume thresholds were estimated to be 32 AAA and 34 CEA per annum in England and, in Germany, Eckstein *et al.* found a 90% increase in the relative risk of mortality at hospitals performing fewer than 10 AAA repairs per annum when compared to those performing more than 50 AAA repairs per annum.

As well as the impact of hospital volume, there is a large body of evidence showing that higher-volume surgeons have lower operative mortality rates than lower-volume surgeons both in North America[2,13–23] and in Europe where analysis of the Finnvasc registry demonstrated a significant dependence of mortality rates on surgeon experience for elective surgery.[24] Specialist vascular surgeons also have superior results to general surgeons for both AAA[2,25,26] and CEA.[27]

The exact proportion to which hospital- and surgeon-volume affect outcome is unknown, but evidence suggests that surgeon volume is likely to account for about half the effect for large invasive procedures such as AAA, and more than this for technically-demanding procedures with less physiological disturbance, such as CEA. However, hospital volume and surgeon volume are independent predictors of mortality and there is an interaction[13,14,20] which may be due to large units, with better support services, attracting higher-volume surgeons.

Why Does This Relationship Exist?

Luft *et al.*[28] suggested that the differences seen between higher- and lower-volume hospitals could be explained by either selective referral patterns or a ''practice-makes-perfect'' hypothesis. For AAA, the effect was primarily of selective referral i.e. doctors preferentially referred patients to hospitals with pre-existing low mortality rates, which increased their volume. Hannan *et al.* [2] found evidence that both hypotheses were plausible for AAA surgery. However, in the UK and other European countries, selective referral is limited, as patients are normally referred to their local hospital. Therefore, volume-related improvements in outcome are probably based on factors other than selective referral.

Elective surgery at higher-volume hospitals significantly decreases the risk of post-operative complications,[25] particularly pulmonary,[26] and also reduces mortality.[29,30] This is not only due to intra-operative factors, but also to the pre-operative assessment by consultant anaesthetists with a vascular subspecialisation [31], and better critical care.[31–33] Furthermore, these advantages are demonstrated across many high-risk procedures[34,35] suggesting hospital infrastructure as a key component of the relationship.

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Problems with Mortality as an Outcome

In the investigation of results at the level of either the surgeon or the hospital, the validity of the outcome measure must be justified. The advantage of using in-hospital mortality is that it is easily and accurately available from routine data, as well as being a hard endpoint for major procedures. However, mortality does not take account of local discharge policies, ''near-misses'', readmission and re-intervention rates, or other procedure specific outcomes such as stroke or amputation. Furthermore, in-hospital mortality does not necessarily correlate with a patient's quality of life post surgery, or indeed the length of out-of hospital survival.[36]

Mortality can only be interpreted as an end-point where there has been appropriate adjustment for case-mix, as factors beyond volume can affect mortality. Despite this, most studies into vascular surgical procedures have still shown the presence of volume-outcome relationships after appropriate case-mix adjustment. It has variously been shown that higher-volume hospitals either have a more difficult case-mix,[6,22] or that no difference in case-mix exists between higher- and lower-volume hospitals.[10]

Administrative Data

The use of routine data in the investigation of outcomes has historically come under criticism as the data are retrospective, prone to coding errors and contain no physiological data.[37] Whether a diagnostic code represents a presenting co-morbid condition, or a peri-operative complication can be difficult to delineate, particularly in the interpretation of stroke rate and CEA.[7,12]

Aylin *et al.*[38] demonstrated that routine data could be used to create risk models with a greater predictive value for mortality than models generated from clinical databases. Different levels of risk adjustment were tested and the intermediate complexity model, adjusted for age, gender and mode of admission, held a comparable degree of accuracy to clinical databases in predicting mortality, whereas the most complex model had a greater predictive value than the best database models. These contemporary findings add validity to the use of administrative databases for outcomes analyses.

The Role of Databases and Registries

Monitoring of outcomes through mechanisms such as National Databases and registries is likely to provide helpful information, but lacks the statistical power to specifically address the issue of the competence of individual low volume practitioners or centres.[39,40] Even for larger centres the validity of such a database is likely to require a mechanism to enforce submission and verify accuracy. Where there is a lack of data, other mechanisms such as an external peer review of every death may help to ensure safe practice.

Implications

The implications of these recent studies are that the provision of vascular services should be reviewed to address the configuration of services. There is a strong case for the centralisation of both AAA and CEA services to try and achieve minimum volume thresholds. This will prevent the continued provision of care based on devolved service models, such as is present in England where 60% of elective aneurysm repairs are carried out in centres undertaking less than 20 cases per annum, which is unlikely to be consistent with best practice.[6]

Achieving this aim would probably require the formation of large referral networks for these cases. There remains doubt about the extent to which the benefits of high throughput can be achieved through networking arrangements that allow working across multiple sites and such arrangements would need to be monitored prospectively.

Previous work has suggested that it is unlikely to be feasible to centralise a single procedure, but that all the related workload of vascular surgery would need to be centralised.[41] Such reconfiguration would be a major undertaking that would require careful attention to the provision of critical care and radiology services. This would require a degree of central planning that may not be easily achieved in many health care systems that include an element of local decision making and competition between service providers.

Forward planning is all the more important with the imminent roll out of aneurysm screening programmes, as the overall benefit of such screening depends upon good operative results. It is important that the organisation of vascular services is considered ahead of the envisaged increase in elective workload[42] to minimise the operative risk to an otherwise healthy, asymptomatic screen-detected population.

Difficulties of Centralisation

Centralisation of care is not without difficulties, beyond those of local politics. It is important that

vascular specialists continue to give appropriate support to non-vascular colleagues, for example the necessity to provide an in-reach or out-reach service for the peripheral vascular and foot complications of diabetic patients, to avoid unnecessary amputations. Additionally, patients presenting to peripheral hospitals with cerebro-vascular events must be appropriately assessed and provided with a full vascular and neurological work-up in order to gain access to prompt CEA, avoiding unnecessary strokes and providing the maximum benefit from these procedures. Evidence suggests that areas without a well established local carotid surgery service have lower rates of intervention in this condition.[41]

Not only do other specialties need vascular surgical input, but also vascular units need to ensure that they are configured to gain the necessary input from other specialists, such as neurologists, diabetologists and nephrologists.

It is unlikely that services can be centralised without inevitable shifts in manpower, notably consultant surgeons.[41] The loss of surgeons from a peripheral site to a central hospital may be to the detriment of the provision of an out-of-hours general surgical rota in the peripheral hospital and must be taken into consideration in any reconfiguration of vascular services.

Another major issue is patient preference for the delivery of local services. Research evidence suggests that patients may be prepared to trade off small increases in operative risk in exchange for access to a local service.[43] This may be less important for screen-detected cases, which will be younger and fitter than the average aneurysm patient and may be more able and willing to travel for potentially improved outcomes. Many of the disadvantages of centralisation may be overcome through the provision of appropriate outreach services, maintaining local access to outpatient and investigative facilities and fostering links with local clinicians and primary care providers.

Overall economic implications of centralisation of vascular services are unlikely to be great. There may be some economies of scale through centralisation and some cost implications of differences in practice and improvements in outcome. However overall expectation is of a higher quality service at a roughly equivalent cost-per-case.[41]

Conclusion

There is clear evidence that many centres and individual clinicians are currently undertaking an insufficient number of cases to provide the best achievable outcomes from major vascular surgical procedures. Achieving sufficiently high volumes is likely to require major service reconfiguration, which would probably require an element of central planning. Each healthcare system will need to review their workload and referral patterns to delineate the most appropriate national service provision model.

The demands for local vascular support, ease of access, equity and patient preferences for local services need to be taken into account in planning services. This will require difficult trade-offs to be made between optimising clinical outcomes and providing the other desirable service attributes. The consideration of such issues should be transparent and explicit.

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