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CORRESPONDENCE

Can Registries Offer an Insight into Likely Outcomes for Newly Introduced Treatment Techniques?

The perceived usefulness of registries is that they are a pragmatic and representative tool to assess the impact of new treatments as they are introduced into practice. They give information on outcomes, learning curves and dissemination of the new technique, though the validity of the results is often viewed with suspicion because they are voluntary and observational. The results from a number of randomised controlled trials (RCTs) of Endovascular Aneurysm Repair (EVAR) are now available to compare with the outcomes contained within registries; such a comparison has been carried out by Leurs *et al.*[1]

Leurs identified patients in the EUROSTAR cohort with risk factors similar to those in the Dutch Randomised Endovascular Aneurysm Management (DREAM) trial. A group of 856 EUROSTAR patients were selected based on ASA distribution and matched to those in the DREAM trail. Outcomes from the registry and RCT are strikingly similar, supporting the case that the registry data is a valid representation of EVAR outcomes and the DREAM trial results are generalisable. Should we be surprised at this, probably not. The weaknesses of observational methods may have been overemphasised, with a number of reports now showing that as long as the methodological weaknesses are recognised and limited, either by design or analysis, observational study outcomes are as valid as more explanatory RCTs.[2–4]

Leurs *et al*'s findings strengthen the case for the use of registries to assess new techniques, and that in the case of EVAR the use of registries was worthwhile. This is important as device technology continues to develop rapidly and long-term device related complications remain problematic. Further large randomised trials for EVAR in AAA are unlikely, at least in the near future, yet the registries remain as important ongoing tools. The problem with the EVAR registries is the lack of collection of data for the comparator treatment conventional open repair, and so it is not possible to perform a true cohort study; a problem that could be addressed by establishing larger or linked databases. In the UK, the National Vascular Database collects data for both open repair and EVAR, and with appropriate information technology and web-based systems, it should be possible to ensure registry data for the UK registry of Endovascular Treatment of Aneurysms (RETA) is collected and comparator data for open repair obtained to allow comparisons in the future. Similar databases could be extended across Europe and provide a model for assessment of new techniques. Such well designed and maintained registries could produce evidence negating the need for some trials, saving time and expense, particularly if areas of uncertainty are explored using other methods such as computer modeling.

To enable this to occur requires a sound financial base to provide the appropriate infrastructure to establish, maintain and analyse registries. In the UK the National Institute for Health and Clinical Excellence recommend that EVAR cases are submitted to an existing registry,[5] yet this organization has no formal arrangements to help maintain registries. The recent announcement of the closure of the EUROSTAR registry shows that without adequate financial support, such valuable resources, and their ability to inform practice, are easily lost.

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"On the subject of multilevel modelling in vascular surgery"

We would like to thank Tang *et al.* for their comments. We advocate the idea that patient outcome is not only a function of the patient case-mix but instead predictive models should also adjust for the individual hospital-related factors (structure and process of care). This methodology is essential when there is "clustering" of patients (i.e. patients' results from the same hospital are more likely to be correlated) such as in a national setting. Multilevel models have already been used extensively in comparison studies focusing: on the Bristol enquiry (Aylin P. Lancet 2001); in colorectal cancer survival (Kee F. BMJ 1999, Tekkis PP. BMJ 2003); in gastro-oesophageal surgery (McCulloch P. BMJ 2003).

Multi-level methodology in our study, was able to rank the 24 ICUs from the development study (Hadjianastassiou VG. Br J Surg 2005) and the 2 ICUs used in the current study (the data from the smaller unit were collected prospectively and could not simply be discarded), according to the level of adjustment that needed to take place for each hospital, and it certainly did not hide differences. On the contrary, contemporary models in vascular surgery only take into account the patient case-mix and ignore this "hospital effect". We agree with Tang et al that models should only be used for the purpose they were designed for which is why we provided the evidence to warn investigators not to use POSSUM/VBHOM models in the post-operative AAA setting.

A predictive model attempts to summate into a single value ("predicted risk") the "case-mix" or the patient-related variables which have a clinical influence on outcome. Physiological data temporally closer (post-operative data) to this outcome more accurately reflect the state of the patient than data before a therapeutic intervention. Otherwise, prediction modelling would be more akin to "guessing" future events.

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