

EDITORIAL

Vascular Registries Join to Create a Common International Dataset on AAA Surgery

Introduction

The strengths and weaknesses of vascular registries and randomized controlled trials (RCTs) are a controversial issue.¹ Although well-designed RCTs provide the best scientific evidence, vascular registries are required to determine whether results from RCTs can be generally applied. They also offer the advantage of rapid feed-back, which is of particular importance when new technical developments appear frequently, as is the case with the treatment of abdominal aortic aneurysm (AAA).

Population-based regional or national vascular registries have been founded in several parts of Europe during the last two decades:² Denmark (1989), Finland (1989), Hungary (2003), Italy (2001), Northern Ireland (1995), Norway (1996), Russia -St Petersburg region (1998), Spain (2000), Sweden (1987), Switzerland (2003) and the United Kingdom (1998). There have also been attempts to create registries elsewhere in Europe, including Portugal and Poland (Krakow region).

Vascunet

Vascunet is a collaboration of predominantly European vascular registries that held its first meeting during the ESVS-meeting in Lisbon 1997. It was recognized by the ESVS Council as an official working-group of the ESVS in 2004. During the first years the aim of the collaboration was simply to share experiences in issues, such as validation techniques, evaluation of case-mix, indicators of quality assurance, computer technology (in particular on-line registration and automated analyses) and legal issues.

During the ESVS-meeting in Helsinki 2005 the important decision was taken to merge data from the registries to create a Common European Database. It was decided to restrict the project in its first phase to data on open and endovascular operations for AAA. We later discussed a possible collaboration

with the Eurostar registry. However, the major aim of the Eurostar registry is markedly different from that of the national registries: Eurostar was initiated to determine the short and long term performance of the various new endovascular devices for aortic aneurysm repair whereas the function of national registries is to monitor volume and outcome for vascular surgical procedures in relation to individual surgeons or hospitals. Vascunet thought it important to include data on both open surgery and EVAR. Moreover, the population base of the registries was believed to be fundamental and data collection and validation would be better organized locally in the region or country. This also substantially reduced the costs of the project by simply merging and analyzing existing databases.

Aims of the Collaboration

The short-term aims of our collaboration are to compare differences in case-mix, techniques used and outcomes in different European countries. The UK small aneurysm trial found a 30-day mortality of 5.8% in the early surgery group,³ whereas the “Immediate repair versus surveillance study” in the USA only had a 2.7% mortality rate in the immediate repair group.⁴ Are such clinically relevant differences explained by case-mix? Were the British patients less fit than the Americans, or are there other explanations? The Vascular Society of Great Britain and Ireland’s National Vascular Database has focused much of their attention on issues related to differences in case-mix.⁵ Most European registries include variables making correction for case-mix possible and thus allowing a meaningful comparison of outcomes.

EVAR or Open Repair?

There are major differences between European countries regarding the indications for open and endovascular repair of patients with AAA. This can be

exemplified by the figures from 2005. While in Switzerland 35%⁶ and in Sweden 30%⁷ of the elective AAA repairs were performed with EVAR, in Denmark the proportion was only 16%.⁸ In the Swedish registry it has been noted that the increase in the number of AAA-repairs is mostly endovascular, and that the patients over time are becoming older and more unfit.⁷ What effect do such changes in surgical decision-making have on short- and long-term outcome? How do they affect outcome in the entire population of patients operated on for AAA, and for those - over time ever more complex cases - who remain for open repair? With on-line registration and automated reports data is available within a very short time. The most recent Swedvasc data has indicated that the proportion of EVAR among elective AAA-repairs had increased from 30 to 45% from 2005 to 2006.⁷

Validation

The most important limitation of data emanating from registries is that they may not be as valid as in prospective controlled trials. Many registries are voluntary and therefore not all centres are submitting data. Also even in submitting centres patients may be omitted from entry to the registry, and there is evidence that such patients may have an inferior outcome than those registered.⁹⁻¹¹ It is of particular importance to perform focused validation on patients with suspected adverse events, irregularities of registration and on those who die in the perioperative period.^{10,12} Different registries have different coverage. The Vascular Society of Great Britain and Ireland's National Vascular Database reported that only approximately half of the procedures in the UK were entered into the Database, but this was mainly a result of surgeons not participating in the national initiative.¹³ The situation in Norway was different, where a validation of surgery for carotid artery stenosis showed that participating hospitals performed 89% of the procedures in the country, but 16% of the procedures performed in the participating hospitals were not reported.¹⁴ As expected, early stroke and death rates among those patients that were not reported was higher than among those reported.¹⁴ The validity of such results is greater if 50% of the hospitals include at least 90% of their patients than if all the hospitals report 50% of their activity. It should also be noted that many of the RCTs on which we base our surgical decision-making have been highly selective in their recruitment, including less than 10% of eligible patients into the trials, and often fail to report on those patients that were not randomized.

Another source of bias is if data entered into the Registry is inaccurate. Many validation techniques for the assessment have been described. The Danish registry used refilling of data-forms of randomly selected operations by both local surgeons and an external monitor, and reported excellent validity,¹⁵ the Swedvasc had similar results.^{9,10,12}

This important issue has to be addressed by each Registry, and different methods of validation are appropriate in different contexts. If other registries exist, such as the British Hospital Episode Statistics (HES),¹³ or local registries of the operating theatres and the angio-suites, they can be used for cross-matching. A great advantage of the international collaboration is that it facilitates external validation. An example is that of "Triple inspection": Registry A inspects Registry B that inspects Registry C that inspects Registry A. Future methods of external validation are under consideration within Vascunet.

The Common European Dataset on AAA Surgery

This year all participants at the ESVS-meeting in Madrid will receive "The First Vascunet report on Abdominal Aortic Aneurysm Surgery, 2007", which will also be available on the ESVS website (www.esvs.org). This pilot project was an attempt to merge data from different registries into one common database, and was restricted to AAA surgery for pragmatic reasons. Six countries have contributed: Australia, Denmark, New Zealand, Switzerland, Sweden and the United Kingdom. Data from different registries have covered different periods, dating back to 1994 for Denmark, Sweden and the UK, but only 2005 in the case of the relatively new Swiss registry. There have also been differences in the data collected by different registries: For instance, EVAR has been considerably underreported in the UK National Vascular Database as it has only recently been included in the dataset. Some countries have not reported aneurysm size and the incidence of smoking or the use of beta-blockade or statins has been variably recorded.

In all, data from 33,780 aneurysm repairs have been merged, of which 22,530 were intact and 9,522 ruptured (1728 unspecified), including 3360 endovascular repairs. Overall crude mortality was 4.2% for elective open repair and 37.6% for emergently operated or ruptured aneurysms. Various analyses have been performed comparing length of stay, risk factors and tracking trends in treatment over time. Differences in operative mortality between countries have not been reported initially because of differences between

the databases and questions regarding validation but it is hoped that such analyses may be possible in the future and will stimulate analysis and discussion, which may lead to future improvements in care.

Future Perspectives

This is the first data merge of this kind which has limitations but we believe it to be a significant step on the road to improving outcomes following vascular surgery. Vascular surgeons and specialists are highly competitive and comparison through audit allows us to strive for perfection. When merging data on case-mix, technique and outcome it is natural that the national and regional registries will adapt their variables to the common dataset, so that as much data as possible can be entered into the common database. Such adaptations have already occurred. Validity will also be strengthened as a result of external international audit. The collaboration, as well as the web-based technology, will open many doors and facilitate future multi-centre studies.

The Vascunet collaboration is growing and we anticipate national or regional participation from Finland, France, Hungary, Norway and Poland for the next year's report. In the end, nothing is impossible, it only takes more time.

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M. Björck*, C.P. Gibbons, L.P. Jensen, J. Laustsen
T. Lees, R. Moreno-Carriles, T. Tröeng, P. Wigger
The authors constitute the Steering Committee of the Vascunet, a Working-Group within the European Society for Vascular Surgery

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*Corresponding author. M. Björck, MD, PhD, Department of Surgical Sciences, University Hospital, SE-751 85 Uppsala, Sweden. E-mail address: martin@bjorck.pp.se