Editorials

Angioplasty registries: wide open for audit?

See page 1110 for the article to which this Editorial refers

Audit, like angioplasty, is easy to do badly, and hard to do really well. Procedure registers are in concept an attractive vehicle for audit, but have in the past attracted criticism for incomplete coverage of the field, selective reporting, and missing data. The recent report of the PTCA Registry of the German Community Hospitals\[1\] succeeds in avoiding these criticisms, and offers interesting insights into the actual practice of angioplasty based on a large and well defined population sample, as well as setting a standard for future studies. The register covered 65 centres which between them performed about one third of the total number of angioplasties in Germany over the period of the survey. Fifty-two thousand procedures were logged and complete data from the catheter laboratory and at discharge were obtained in over 98%. Factors contributing to this complete coverage included a simple single-sheet audit form, ‘hot pursuit’ of missing data, and regular monitoring visits from the coordinating centre.

As expected, the majority of procedures involved dilatation of a single lesion though nearly half of the patients had multivessel disease. Primary success rate was 91% in non-occluded vessels, and 66% in completely occluded vessels. ‘Severe complications’ occurred in 3% of all patients. It is interesting that only 16% of centres had cardiac surgery on site, although presumably it was available close by for the other centres. The stent implantation rate of only 2% is a reminder that these data were collected up to the end of 1994; it will be interesting in subsequent reports from the registry to see whether an increased rate of stent implantation is associated with a change in profile of complications. The amount of data which have to be analysed inevitably introduces a time lag into the reporting of registry material. However, this disadvantage is more than balanced by the ability to draw conclusions from large number of cases.

The authors of this report very reasonably comment that the process of disciplined data collection probably has in itself a positive impact on technical quality. The converse of this is, of course, that those who most need to be audited are those least likely to participate in audit. The German community hospitals registry has set a standard which other national angioplasty groups will wish to emulate; at the same time, purchasers of angioplasty, whether health authorities, insurance companies or private individuals, will wish to be assured that providers of angioplasty are active participants in a recognised and preferably nationally based registry or audit scheme. Similar schemes are in operation in the United Kingdom[2,3] but currently on a voluntary basis and with uncertain financial support. Perhaps the time has come for purchasers to appreciate that investment in quality control makes sound sense.

There is an important distinction to be drawn between audit and research. The database created by a procedure registry provides an excellent resource for focused research initiatives. We have used the U.K. catheter complications database to study left main coronary stenosis associated complications[4], and Every and colleagues have used the MITI database to study the role of primary angioplasty after myocardial infarction[5]. The cardiological community looks forward with interest to research based on the German community hospitals registry, particularly in respect of indications for angioplasty and long-term outcome. On the other hand, the temptation to make a registry over-complicated in the interest of research must be avoided. One of the major lessons we have learned from large randomized clinical trials is that the recipe for success can often be summarized as ‘simplify and add numbers’. If there is one lesson to be learned from this registry study, it is probably that the same slogan should apply to registry projects as well.

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Prosthetic aortic valves

See page 1157 for the paper to which this Editorial refers

In general, prosthetic valves in the aortic position are considered to be extremely reliable in terms of structural valve integrity and low incidence of thromboemboli. This is reflected in the study of Hokken et al. [1] describing the long-term results in 1449 patients undergoing aortic valve replacement using a mechanical prosthesis. The large patient group and the long follow-up (25 years) are appealing. As independent factors influencing long-term survival, age, gender, year of operation and concomitant operations, such as coronary artery bypass grafting, mitral valve replacement or replacement of the ascending aorta were recognized. This does not mean that these variables are the only ones to determine survival after aortic valve replacement. Most investigators found some index of cardiac function that predicted outcome; in addition pre-operative renal failure and cardiac rhythm disturbances are expected to be independent risk factors [2]. The fact that several of these risk factors are missing is not entirely surprising because the retrospective period of the study of Hokken et al. [1] is very long, with inherent inaccuracy in data collection. The fact that they found male gender predicting worse survival may be unexpected because the opposite is found in most studies dealing with survival after aortic valve surgery. However, in a recent study He et al. [3] also described male sex as an independent variable for reduced long-term survival after aortic valve replacement.

Regarding long-term survival, the type of mechanical prosthesis used for valve replacement in the aortic position seems to be irrelevant. The group from Rotterdam used the Starr–Edwards valve in the early years, followed by the Björk–Shiley valve and later the St. Jude valve. As it happens, He et al. used exactly the same types of mechanical prosthesis in their study and also found that the type of prosthesis was not correlated with long-term survival. In any case, there is no evidence that valve design should be related to survival. For example the Medtronic–Hall tilting disc is shown to be a reliable valve, while the same is true for the St. Jude valve, which is a bileaflet valve.

In a recent review, Akins [4] stated that the principal concern about mechanical valves remains their thrombogenic potential and the need for anticoagulation, essentially two sides of the same problem. Indeed, for each patient one might ask the question, at what cost of bleeding is one willing to seek no valve thrombosis and a low thromboembolic rate? Therefore Akins suggests introducing the ‘composite thromboembolism and bleeding index’. This index is calculated by adding all thromboembolic and bleeding events and dividing this by the cumulative patient-years of follow-up. However, with most mechanical valves, differences relating to incidence of thromboemboli, incidence of valve thrombosis, and anticoagulant haemorrhage are relatively small.

As Hokken et al. [1] state, a long-term study in a large group of patients undergoing aortic valve replacement illustrates changes and improvements in medical care for these patients. A clear example is the decrease in the number of patients with endocarditis in their series, which is obviously related to the use of aortic allografts in endocarditis of the aortic valve.

Aortic valve replacement using human aortic valves obtained from transplant recipient donors or from autopsy sources within 24 h of death has been performed for many years. Compared to mechanical valves or stented bioprosthesis, homografts are considered to have better haemodynamics and a zero or negligible thrombogenicity. Because of the severely restricted availability of homografts, most centres limit their use to aortic valve endocarditis and replacement of the pulmonary valve in the case of a Ross operation. Indeed, the aortic allograft seems to be much more resistant to valve endocarditis than any other prosthetic valve, so that homografts become the treatment of choice for this disease.