Non-controlled observation studies

In no. 13–14/2011 of this journal, we were introduced to the new method of catheter-based insertion of valve prostheses in the pulmonal ostium (1). The article was accompanied by two critical editorials (2, 3). The type of studies undertaken by Vegard Bruun Wyller (non-controlled observation studies) are common in medical research (4). They are similar to registry studies, they generate hypotheses and will occasionally initiate randomised studies.

Before the group launched the study, they had identified persons who had performed the procedure and discussed the problems that had been encountered and the impressions gained with respect to the benefits of the procedure. Furthermore, the authors possess long previous experience in the insertion of percutaneous valves and prostheses in other parts of the heart.

In the study, ten patients were treated and then followed over a period of 1.5 years, with good results. Stein Evensen proposes that these patients should be treated abroad (2). An EU directive on improved flow of patients across national boundaries will facilitate this. Export of patients, however, requires adequate personal communication with the treatment centre, since the diagnostics and the follow-up must take place in Norway. In my experience, such export often initiates a lot of paperwork involving complaints and discussions.

Is this an experimental treatment, a trial or an established form of treatment? Ten patients are insufficient to assess the effect of the treatment. We have successfully contacted Sweden and Denmark to obtain a larger body of material (4). Thereby, one is obliged to write a research protocol, contact the ethics committees and establish a Scandinavian data register. Should we undertake a randomised study to compare this with another established form of treatment? If so, Wyller's study is important, since it indicates a low rate of complications from percutaneous treatment of the valves.

In order to demonstrate the pre-eminence of the catheter-based treatment with the aid of a small body of material, the available alternative must be very poor. Without a randomised study, patients are likely to perceive the insertion of a percutaneous valve as less intrusive than a surgical procedure.

If a registry-based study is chosen, patients must be followed up over a number of years (4). A randomised study lasting two years will not provide sufficient answers.

Many of the initial studies of potentially beneficial forms of treatment in coronary medicine were undertaken in an identical manner as the ones done by Vegard Bruun Wyller and his collaborator. Assessing such studies will be the responsibility of the individual doctor and the department, with a particular focus on high ethical standards, of which openness and accurate data collection will be paramount.

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