E. Guerado · F. Aguiar · E. Perea-Milla

An assessment of cost-effectiveness studies in joint replacement

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At the present time there is considerable concern about financial management in orthopaedic departments. Indeed, the combination of effectiveness with cost containment (efficiency) is currently a very important challenge, as not only are health care expenses dramatically increasing, it is now also appreciated that clinical practice is not always guided by scientific evidence. Furthermore, it has become accepted that the financial situation in an orthopaedic department encourages the careful making of clinical decisions and, conversely, that well-controlled clinical practice helps to limit costs.

Many attempts have been made to reduce the costs of arthroplasty. Protocols and guidelines have been used to reduce not only the selection of implants but also the length of in-patient stay. Ideally, any paper on cost effectiveness in arthroplasty should include the real overall cost effectiveness rather than dealing with individual items such as indications, length of stay, thromboembolism prevention, etc.

The results of pre- and postoperative investigations should be included in such studies. For example, while information obtained by postoperative radiographs in total hip arthroplasty patients can be clinically important, routine postoperative knee radiographs do not appear to provide additional clinical information. In addition, the value of information obtained by radiological follow-up remains very controversial, as radiolucency at the bone/implant interface, particularly in knee replacements, is a common radiological finding even soon after surgery, and therefore is a bad predictor of implant loosening and clinical results. Moreover, the appearance of radiolu-

centy is very much related to X-ray projection and to patient positioning.

The same rings true for laboratory tests, as in many patients preoperative laboratory tests add nothing to the information derived from taking a detailed history and performing a thorough physical examination. The value of postoperative laboratory tests has still to be determined.

Antibiotic prophylaxis is another important topic, with infection and the prevention of infection being taken into account in studies of cost effectiveness. Antibiotics administered intravenously just before the skin is incised reduce the incidence of deep wound infection. Although the optimal antimicrobial agent has not yet been discovered, a short course of prophylaxis is recommended. Even so, in primary arthroplasties, as well as with revision surgery, it has been reported that there is no difference between one-dose prophylaxis and a more lengthy regime.

Well-planned strategies for preventing infection are very cost effective. They should include the deliberation of cost effectiveness as well as complications associated with the routine use of antibiotics. These include the emergence of antibiotic-resistant bacteria, supplemental antibiotic administration, antibiotic irrigation solutions, and incorporating antibiotics with acrylic bone cement or with bone grafts. There are, however, no established standards or clinical guidelines for the use of these antibiotic regimes. The use of gentamicin-impregnated cement in combination with systemic antibiotics adds an additional cost for which there are no reports of any double-blind randomised clinical research that has shown this technique to be cost effective.

Total joint arthroplasty is a major orthopaedic procedure with a high risk of postoperative thromboembolism. A regimen of postoperative prevention of deep vein thrombosis is always more cost effective than surveillance programmes with treatment after diagnosis, and also more cost effective than no prophylaxis at all. Several studies have demonstrated that prolongation of thromboprophylaxis for up to 20–35 days after elective

E. Guerado (✉) · F. Aguiar
Department of Orthopaedic and Traumatic Surgery,
Hospital Costa del Sol, University of Malaga,
29600 Marbella (Malaga), Spain
e-mail: eguerado@hcs.es
Tel.: +34-952-862748, Fax: +34-952-823219

E. Perea-Milla
Epidemiology Research Unit, Hospital Costa del Sol,
University of Malaga, Marbella (Malaga), Spain

hip replacement significantly reduces the frequency of venographically demonstrated deep vein thrombosis. However, controversies remain, as some studies suggest that the risk of developing deep venous thrombosis and pulmonary embolism may exist for as long as 3 months following hip replacement. Therefore, the cost effectiveness of such lengthy prophylaxis is unknown.

Warfarin is still very popular for preventing thromboembolism in joint replacement, although nowadays the use of a low-molecular-weight heparin (LMWH) appears to be the gold standard. LMWH offers several short- and long-term cost advantages when compared to warfarin, as it is less expensive and results in fewer complications. LMWH also has the practical advantage that it does not require anticoagulant monitoring and dose adjustment.

A new approach for the prevention of deep venous thrombosis in patients undergoing total joint replacement has just appeared with the development of desirudin. Apparently this is more cost effective following elective hip surgery when compared to unfractionated heparin, although the total cost with desirudin is 7% greater. The cost-effectiveness ratio of prophylaxis with desirudin in patients undergoing elective hip replacement gives a greater gain of life years when compared with enoxaparin. However, any conclusions on the cost effectiveness of new thromboembolism prophylaxis must be regarded with caution and in the light of clinical trials and metaanalysis. They also must be compared to physical methods for preventing thromboembolism.

Another important factor in assessing cost effectiveness in joint arthroplasty is the expense of replacing blood. Allogenic blood transfusion is the current standard, but the fear of contamination and the difficulties in obtaining blood have encouraged the search for alternative techniques. The reinfusion of blood removed by 'suction drainage' after hip and knee arthroplasty is widely used but is expensive. In most clinical situations reinfusion of red blood cells is not as cost effective as some other methods of replacement and can cost more than five times a single blood unit transfusion. Autologous transfusion is a very expensive strategy (even if there was no increased risk of bacterial infection after reinfusion), and, until there are more definitive data available on the magnitude and costs of this risk, the debate on cost effectiveness should not be closed.

Routine pathological examinations of surgical specimens removed from patients undergoing primary total hip or knee replacement due to osteoarthritis also has limited cost effectiveness, as the findings rarely alter patient management. However, although there would be considerable cost savings on a population basis if histological examination were not performed, this must be weighed against the results and costs of an incorrect diagnosis in the management of a particular patient (especially after a revision). Consequently, the debate on the value of these laboratory investigations must remain open.

Postoperative care *after* hospital discharge is one of the most important areas for cost-containment strategies.

It has been shown that "postacute" care in skilled nursing facilities is not cost effective when compared to "recovering at home," even without formal care. Better informed protocol-based decisions on where and when to discharge patients can improve the recovery of many patients and definitely save money.

The method of payment may also be very important. The use of cost-effectiveness analysis in general provides a basis for a more efficient system of reimbursement, both in private and public equity-based national health systems. However, it is important to remember that any dramatic reduction of either a diagnosis-related or a procedure-related system of reimbursement may result in a loss of care quality.

The most important aspect of cost-effectiveness outcome for patients is any change it produces in the very subjective feelings of their quality of life. At present everywhere in the world there is a strong movement toward sharing medical decisions and the assessment of results between patients and doctors. Although some instruments such as the SF-36 questionnaire are currently available to help determine quality of life, they require local validation before any attempt is made to use them to measure the outcome of joint replacement operations.

The proper design of research projects is very important. Prospective rather than retrospective studies allow the establishment of appropriate variables and well-designed statistical tests. Design of studies, assessment of results, and methodology are always problematic, as there is disagreement in the literature on evaluation of results in joint replacement. Not all indications are appropriate, and currently the best methodology to be used for assessing result remains controversial.

Survival analysis, which provides the usual basis for joint replacement studies, has been inadequately applied in some settings since dead and "lost patients at follow-up" do not come for revision surgery and therefore are usually considered as "good results." Similarly, there may not be agreement between patients and their surgeons as to the quality of the final result.

"Score questionnaires" also must be locally validated, and, although the use of mailed questionnaires is a simple and convenient system of follow-up, the validity of such replies has yet to be established.

Comparisons between groups (groups of patients, geographical areas, or hospitals) must consider the differences in the structure of the relevant populations in terms of age, gender distribution, morbidity, and any other factors that could introduce bias and consequently modify the results of a research project. These kinds of factors, known as "confounding factors," must always be considered. There are several methods to control possible confounding factors produced by different variables. The first is to ensure proper design of the study by comparing only very similar populations, and this includes matching and restriction. A second is to use statistical methods in data analysis by stratified, or by multivariate, analysis. However, these are both relatively complex tools.

Adjustment of rates or standardization is a very simple and frequently used statistical method. The principle is to use a standard population (which can be constructed by adding different strata from a population "A" plus a population "B" of, for example, age and gender). The specific age-gender rates from the standard population can be applied to (multiplied by) the correspondent population in each strata of "A" and "B." So the expected values, if population "A" and population "B" have the same profile of the standard population in terms of morbidity, surgical procedures, complications, etc., are obtained. The ratios observed and expected for "A" and for "B" (*standardized morbidity ratio*) allow comparison between them as if "A" and "B" had similar age and gender structures. By comparing these values for different populations and using one of them as a reference, it is possible to estimate the actual probability of having a specific outcome (*relative risk*). This is an approximation of the *adjusted relative risk*, a figure which gives details about increases (or decreases) of the probability (*risk*) of producing any specific outcomes in surgical procedures, i.e., infection, good or poor result, etc., and is controlled by potential confounders.

It is wise to involve an epidemiologist at an early stage in the design and indication for this sort of analysis. Appeals for grants and government support should always be reinforced by well-designed prospective studies.

While cost-containment initiatives are nowadays imperative, the quality of patient care must always remain the primary consideration in making decisions. Indeed, there are many other issues that should carefully be considered, although they have not been detailed in this article. These issues include the patient's comorbidity, type of implant, design, cementation, unilateral or bilateral one-stage procedures, primary or revision cases, peculiarities of the national health system, staff incentives, etc., which should all be studied in any cost-effectiveness joint replacement project. National databases are important tools for studying these issues, and should be able to store information on all these topics.

While it is difficult to know the current extent of "cost containment" in joint replacement surgery, it is important that funding agencies should encourage and support orthopaedic surgeons to make further studies in this important field.