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Minireview article

Development of outcome research for total joint arthroplasty

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Abstract: Total hip arthroplasty (THA) and total knee arthroplasty (TKA) are now the most common major orthopedic procedures in the world. Outcome research for patients undergoing total joint arthroplasty is now the accepted method of choice for evaluating the results of surgery. This study design incorporates the use of patient-derived data collected from patient self-administered questionnaires that will capture data on the patient's experience of pain, functional disability, and general health status. These questionnaires do not replace traditional measures of clinical endpoints, such as mortality and complication rates, but will be additions to data collection. The patient-derived data allow orthopedic surgeons to assess the impact of total joint arthroplasty on the health status of their patients. The need to collect these data is increasingly necessary with the growing demands on orthopedic surgeons to demonstrate the efficacy of total joint arthroplasty to maintain funding from both public and private funding sources. This article introduces the development of outcome research for patients undergoing total joint arthroplasty.

Key words: outcome research, total joint arthroplasty

Introduction

Total hip arthroplasty (THA) and total knee arthroplasty (TKA) are now the most common major orthopedic procedures in the world. Over 90% of knee prostheses function well for 10–12 years after surgery[4,16,17,19] and 90% of hips function well for 15–20 years.[18,21] The reporting of outcomes after THA and TKA has traditionally focused on the early clinical and technical success of the surgery and the long-term survivorship of the prosthesis. These results have focused on the state of the prosthetic device instead of on the health of the patient. Additionally, many of the earlier studies lacked unbiased and systematic reporting of results, casting doubt on the validity of the success rates reported.[8] This article introduces the concepts of outcome research and notes how this type of research is essential in orthopedics to overcome the limitations of previous clinical studies of total joint arthroplasty.

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Why do we need outcome research?

Healthcare is now moving into an "era of accountability", when it is essential for providers of health-care services, in particular doctors, to be able to demonstrate their efficacy. This expands on reporting clinical outcomes as assessed by the medical team and requires the need to collect data on the quality of care in patient terms. These data will help to evaluate the effectiveness of treatment in terms of patient outcomes as well as patient satisfaction with the outcome. Patient satisfaction with the process of care, that is, the management of the patients during their episode of care, is also essential to evaluate the effectiveness of the healthcare system.

In the area of orthopedic surgery, research journals have reported data on the results of different procedures for many years now. These articles report mainly clinical data, and it is only in the past 10 years that orthopedic units have begun to use outcome research to evaluate their clinical practice.

Limitations of previous research

In orthopedics we have traditionally reported the results of surgical treatment using criteria of success determined somewhat arbitrarily by the surgeon writing the paper, with little universal consensus on the method

of reporting results. The operating surgeon usually does the clinical measurements after total joint arthroplasty. Bias is unavoidably introduced when the operating surgeon is also assessing the outcome result.[8]

Clinical assessments of patients cover five basic topics; pain, function, range of motion, stability, and alignment. Rating systems have been developed to give weighted scores for these components of physical and functional assessment and the scores are then combined to give an aggregate score. Many different rating systems for both the hip and the knee appear in the orthopedic literature, but there are no published validation studies on these scoring systems. In a review of the TKA literature from 1972 to 1992, Drake et al.[6] found that 17% of all English-language studies used such scoring systems to summarize the outcomes of primary TKA. This review referenced 34 different scoring systems; validation studies are not available for any of these scoring systems.

Scoring systems for the hip vary in the overall score they will report on the same patient because of way the different weightings are assigned to components of the score.[3,5,11] Despite efforts to standardize clinical scoring systems for both the hip and the knee, an ideal system is not currently available. Present systems do not allow the comparison of outcomes within individual units and between orthopedic units worldwide. Any system demands inter-tester reliability; that is, all evaluators measure according to the same standards at each assessment time. This will ensure that the change in clinical scores reflects the same change in hip or knee status, regardless of who is doing the evaluation.

Traditional methods of reporting clinical outcomes include data on complication and mortality rates, and these data should be an integral part of any outcome study. Patient self-administered questionnaires will capture data on the patient's experience of pain, functional disability, and general health status. The collection of data by patient reports removes the possibility of observer bias, as the questionnaires are self-administered by the patient at each assessment. These questionnaires do not replace traditional measures of clinical endpoints, but will be additions to data collection. Health status questionnaires fall into two distinct categories — generic and disease-specific.

Health status questionnaires — generic and disease-specific

It is important to derive from the patients information that addresses areas such as psychological health and attitude toward their disability, as well as their assessment of pain and function. Numerous studies have shown that patients' assessments are at least as reproducible in these areas as those of the physician or other healthcare providers. Health status questionnaires will evaluate general health status as well as disease-specific aspects of health. Many health status questionnaires exist, but we will restrict the discussion here to the instruments we are currently using in a multinational outcome study, in which surgeons in Japan are participating. This article will discuss in detail:

1. Short Form 36 (SF-36),[22] a general health status measure developed by the Medical Outcomes Trust, and
2. WOMAC,[1] a disease-specific questionnaire developed for patients with osteoarthritis of the hip and knee by the Western Ontario and McMaster University.

The SF-36 can compare outcomes across different populations and diseases and can detect changes in general health status caused by other disease conditions. The WOMAC is more sensitive for detecting changes in hip and/or knee disability. It is recommend to use both a generic and a disease-specific questionnaire in outcome studies of joint replacement surgery.

Short Form 36 (SF-36)

The Short Form 36 is a multipurpose survey of general health status and outcomes. It assesses health concepts that are relevant to everyone's functional status and well-being, because it is not age-, disease-, or treatment-specific. Generic health measures assess health-related quality of life outcomes most directly affected by disease or treatment. The SF-36 provides a common "yardstick" to compare those patients with chronic health problems with those sampled from the general population.

The questionnaire has 38 items that patients answer, using a Likert scale. It measures physical and mental health in several contrasting ways and reports health status using eight different subscales: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. There is a validated version of the SF-36 in Japanese,[7] and it takes about 10 min for the patient to complete. The SF-36 has been proven to be a valid and reliable tool in measuring outcome after joint replacement surgery.[12,13,15]

WOMAC

The Western Ontario and McMaster Universities (WOMAC) osteoarthritis index is a disease-specific, self-administered health status measure.[2] It assesses symptoms in the areas of pain, stiffness, and function in patients with osteoarthritis of the hip and/or knee. The

index consists of 24 questions (5 on pain, 2 on stiffness, and 17 on function) and takes 5 min to complete. The questionnaire format can use either a Likert or a visual analogue scale.

The WOMAC is a valid and reliable method of assessing outcome after total joint arthroplasty. It is sufficiently sensitive to detect changes in these three dimensions over time and after total joint arthroplasty. Although a validated Japanese WOMAC is not available, a translated version of the WOMAC is currently being used as part of a multinational TKA outcome study. Validation of this translation against the SF-36 and other function questions is part of this study.[9]

Conclusion

In the past 20 years, the emphasis of medical research has broadened from technology and innovation to assessment and accountability.[20] Outcome research after total joint arthroplasty allows health-care professionals to use these data to improve the quality of care for these patients to achieve the best possible outcomes.

This article highlights the limitations of traditional clinical orthopedic research and describes the value of carrying out high-quality outcome research for patients undergoing total joint arthroplasty. This work is essential to broaden our knowledge of who does and does not benefit from these surgical procedures. In addition to guiding our patients into appropriate decisions, we would be able to demonstrate to those who pay the bill for these procedures the beneficial effects of our efforts. In most areas of orthopedics it will be difficult, if not impossible, to demonstrate financial benefit from our interventions that aim towards pain relief and patient-reported improvements in quality of life. These areas are difficult to quantify in dollar terms.[14] In an era in which healthcare systems are funding only treatments of proven benefit, outcome research is essential if we are to have the data to secure ongoing funding for total joint arthroplasty.

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