Measuring knee arthroplasty outcomes

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Abstract

Outcome measures are increasingly used by clinicians, healthcare providers and implant manufacturers for a variety of reasons. Clinical outcome studies have traditionally been used but the level of evidence presented has been variable. In recent decades joint registries have provided useful data on implant survival, but implant revision as an outcome measure has restrictions as many factors contribute to it. Patient reported outcome scores have been introduced more recently and provide important information about health gain after surgical intervention. In response to guidelines from the National Institute for Clinical Excellence, the Orthopaedic Data Evaluation Panel assesses and rates implants, and Beyond Compliance advises implant manufacturers of the level of risk of newly introduced or modified prostheses.

Keywords Beyond Compliance; clinical studies; National Joint Registry; Orthopaedic Data Evaluation Panel; outcome measures; patient reported outcome scores

Introduction

The analysis of results has become an essential part of orthopaedic practice. Outcome scores can be used to assess the effect of a disease or condition, the effect of disease treatment and its cost effectiveness of treatments. They can also be used for research purposes, teaching and peer comparison. Outcome analysis allows surgeons to make informed choices of the use of prostheses and surgical techniques based on evidence. There is increasing pressure on hospital trusts to assess their performance data and in the future clinical commissioning may depend on outcome scores for implants and treatments. Surgeons' mortality rates are openly published and available to see by the general population. Transparency is increasingly important.

There are a variety of scoring instruments available, all with advantages, limitations and varying degrees of evidence. Correct interpretation of results is essential, and combining results from different instruments may be necessary to come to the right conclusions. This article discusses clinical outcome studies, joint registries, patient reported outcome scores (PROMs), the Orthopaedic Data Evaluation Panel (ODEP) and Beyond Compliance.

Clinical outcome studies

Clinical studies are probably the most traditional of methods to investigate outcomes. Best evidence can be obtained using a randomized controlled trial or a meta-analysis of randomized studies (Level 1). In these studies patients are randomly assigned

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to a treatment or control group and are followed prospectively. Level 2 evidence consists of prospective comparative cohort studies where patients are not randomized. Meta-analysis of Level 2 studies also falls into this category. Level 3 evidence is represented by retrospective cohort studies, case control studies (presence or absence of disease or treatment) and meta-analysis of Level 3 studies. Case series are Level 4 and case reports Level 5 evidence. Level 5 evidence also includes expert opinions and personal observations.

A good study design starts with a hypothesis that investigates an anticipated association between variables (or no association, as in a null hypothesis).[1] Next, a representative study population needs to be chosen to answer the research question. Inclusion and exclusion criteria determine the characteristics of the population, and an appropriate sample size needs to be calculated to be able to reach statistical significance in outcomes. A blinded (concealed from the investigator) random allocation procedure should be used to create the different groups. Blinding when applying the intervention and measuring the outcome is essential to avoid bias. There are several outcome scores for knee arthritis, including the Oxford Knee Score (OKS), Knee Society Score (KSS), Knee Injury and Osteoarthritis Outcome Score (KOOS), Western Ontario and McMaster Universities Arthritis Index (WOMAC) and International Knee Documentation Committee (IKDC). Outcome measures need to be chosen carefully and when a scoring system is used, validation of the scoring system is essential. Finally, statistical analysis can prove or disprove the hypothesis. Other considerations are the ethical implications (Ethics Committee study approval), the need for informed consent for the study population and last but not least, patient safety.

Joint registries

In October 1975 the first national knee arthroplasty register was established in Sweden. Other countries followed suit and the British National Joint Registry (NJR) was set up by the Department of Health and Welsh Government in 2002. Since 2008, the management of the NJR has been in the hands of the Healthcare Quality Improvement Partnership (HQIP), a consortium comprising the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Northern Ireland joined in 2013 and the Isle of Man in 2015. Data on hip and knee joint replacements have been collected since April 2003, ankle joint replacements since April 2010 and elbow and shoulder joint replacements since April 2012. The NJR collects information on all hip, knee, ankle, elbow and shoulder replacement operations, using revision for any reason as an end-point. The registry monitors the performance of joint replacement implants, investigates different types of surgical methods and improves clinical standards; it benefits patients, clinicians and the orthopaedic sector as a whole. The goals of the NJR are to monitor the outcomes achieved by brand of prosthesis, hospital and surgeon. Information is published for patients and the healthcare organization in general, including clinicians, commissioning groups and implant companies. By engaging patients there is better awareness of choice. The NJR data allow for identification of best practice and presents healthcare providers with information on implant quality and cost-effectiveness. In recent years NJR data have been used to determine a national tariff for new best

practice payment in knee replacement. To-date, almost two million implants have been added to the registry.

In 2011, the National Joint Registry acquired mandatory status as a National Audit, which means that any provider carrying out hip, knee, ankle, elbow or shoulder surgery is mandated to submit 100% of eligible primary and revision procedures to the NJR. This includes NHS and private sector healthcare providers. By cross-referencing NJR data with data held in Hospital Episodes Statistics (HES) and the Patient Episode Database Wales (PEDW), accuracy of data entry can be monitored. However, errors associated with the use of HES data have been widely documented. In a paper from Jayatilaka et al. significant discrepancies were found when NJR data were compared with a surgeon's prospectively collected personal logbook.[2] Independent sector hospitals do not submit data to either HES or PEDW, so accuracy there is more difficult to monitor. NJR analysis showed that in 2013, 77% of NHS providers reported 95% or more of the joint replacements they undertook, 16% of NHS providers reported between 80% and 95% and only 7% of NHS providers reported less than 80%. A key NJR strategy is to improve data quality by monitoring data accuracy and completeness, in order to facilitate validation.

The NJR publishes results in different formats:

- The 12th Annual Report (Figure 1) was published in 2015 (www.njrcentre.org.uk), and analyzed data between 2003 and 2014. Its key conclusion was that first-time knee replacement operations continue to be hugely successful, with overall life of implants meeting national standards (95%+ lasting ten or more years). Knee brands offer comparable results and patient factors have a significant bearing on how long the implant will last, with younger patients reporting higher revision rates than their older counterparts. NJR data also highlight an interesting debate about unicompartmental knee replacements. Critics identify higher revision rates compared to total knee replacements, but proponents argue that the functional results of unicompartmental knee replacements are superior to those of total knee replacement. It is well known that approximately 20% of total knee replacements patients are unhappy with the results of surgery, but this phenomenon is not obvious in unicompartmental knee replacement patients.
- StatsOnline is an NJR facility to view and download hospital statistics regarding joint replacements. It shows number of operations submitted to the NJR, broken down by type of replacement and based on the operation date. It also shows NJR consent rate.
- ReportsOnline gives information on case total, case mix and implant usage.
- Outlier monitoring is a process where prostheses and surgical outcomes are compared to an expected revision rate. When results fall below an expected performance ('outlier'), an investigation is initiated and further action is recommended.
- Clinician feedback is only available to surgeons performing knee and hip replacements. It gives more information regarding the procedures recorded in a surgeon's name, and analyses it against hospital data and national benchmarks. It is good practice for orthopaedic departments to openly discuss surgeon-level reports in a yearly meeting.

- Management feedback provides healthcare provider management with essential indicators of their hospital's performance. It includes compliance rates of data entry, consent rates and knee outcome data (funnel plots showing revision and mortality). Revision rates for individual surgeons are reported anonymously, but can be cross-checked against surgeon-level reports (clinician feedback).

Patient reported outcome scores (PROMs)

Joint registry data provide information about revision rates only, so it was clear there was a requirement for outcome evaluation seen from a patient's perspective, about how a joint replacement operation affects their life in terms of function and quality of life. This was recognized by the Department of Health, and since April 2009 patients' health status data have been collected before and after procedures, including knee replacements. These are called patient reported outcome scores, and they aim to calculating health gains after surgical treatment. Data are collected by patients through short self-completed questionnaires pre-operatively and six months post-operatively for knee replacements. From January 2012, regular publications were released using statistical analysis. In April 2013, NHS England took over the responsibility for the national PROMs programme from the Department of Health. NHS England commissioned the Health and Social Care Information Centre (HSCIC) to collect, process and publish PROMs data, and this is now called NHS Digital. PROMs reports can be found on the NHS Digital website (www.digital.nhs.uk).

NHS Digital uses three PROMs scoring systems for knee replacement patients: the EQ-5D™ index, EQ Visual Analogue Scale (EQ VAS) and the Oxford Knee Score (OKS):

- The EQ-5D™ is a trademark of the EuroQol Group, and asks patients about their mobility, self-care, usual activities, pain/discomfort and anxiety/depression on the day of completion of the questionnaire. Each question gives five options to choose from. The EQ-5D has been validated in a patient population in six countries with patient groups suffering from a variety of chronic conditions, including arthritis.[3]
- The EQ Visual Analogue Scale asks patients how good or bad their health is, which is scored on a visual 100-point scale. Zero is the worst and 100 is the best possible health. Patients mark their score on the scale. The answer to this question is not necessarily associated with the knee replacement treatment, but more an indicator of general health.
- The Oxford Knee Score consists of 12 questions on daily activities to assess residual pain and function in knee replacement patients. It was developed at the University of Oxford in 1998 and has been validated.[4] In large scale studies it has been ranked the best disease-specific patient reported outcome score for assessing outcome after knee replacement.[5] The questions concern pain, personal hygiene restrictions as a result of knee pain, use of car or public transport, walking, getting up from a chair, limping, kneeling, night pain, (house) work interruption due to knee pain, knee instability, shopping and stairs. Each question has five options, scored from 0 to 4. A score from 0 to 19 may indicate severe knee arthritis, possibly requiring surgical intervention.