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EPIDEMIOLOGICAL STUDIES IN ORTHOPAEDICS

A BRIEF OVERVIEW

BACKGROUND

Despite rising numbers of randomised controlled trials (RCTs) being undertaken, for many research questions in trauma and orthopaedics, randomisation is often either unfeasible or inappropriate. There has been a historical natural reliance on observational studies expanding the evidence base, and these are commonly referenced both in published work and during the process of day-to-day clinical decision making. Prior to the advent of large-scale databases, institutional case series of diagnoses and interventions accounted for the vast majority of observational studies within our specialty. The advantage of these case series is the potential breadth of data collected on a clearly defined population – these can be used to pose study questions for higher quality research or in many cases may answer questions definitively in their own right. However, there is wide variation in the quality of reporting, they are often single-surgeon retrospective studies, and generalising findings can be problematic. Epidemiological studies using registries are surely then the solution, or are they?

REGISTRIES

Arthroplasty registries, designed initially to identify poorly performing implants, have led the way in terms of collecting national-level longitudinal data on individuals undergoing an orthopaedic intervention. The Swedish Arthroplasty Register is the oldest joint registry in the world and, since its creation, the number of worldwide registries has increased. The National Joint Registry of England and Wales (NJR) is the largest arthroplasty registry with over a million recorded procedures. In the UK, there are now several other orthopaedic registries including the Non-Arthroplasty Hip Register, the UK National Ligament Registry, the UK Knee Osteotomy Registry, the National Hip Fracture Database and the British Spine Registry. In addition to monitoring for failure and assessing epidemiological trends, outcomes of interventions and identification of patient- or treatment-related risk factors for poor outcomes are key analysis outputs from registry data. Expansion of data collection such as the inclusion of patient-reported outcomes measures (PROMS) provides the ability to compare success and failure on a more clinically relevant scale. Most national-level registries produce annual reports where key demographic information is published. Surgeon-level data are also increasingly becoming available, making registry outputs hugely important on a very personal level for surgeons. Specific research questions are often addressed by independent individuals or groups applying for access to the data and undertaking the necessary analysis. The strength of using epidemiological analyses in orthopaedics is the ability to examine critically the interventions we offer as a population of clinicians working within a specific healthcare system. Problems are often highlighted by registry data at an early stage which allows appropriate changes to practice to be made. Within modern healthcare systems, the need to demonstrate the cost-effectiveness of interventions is imperative and this requires comparisons to be made, not only of clinical value, but also of value for money.

COMPARABLE EPIDEMIOLOGICAL MEASURE OF INTEREST

Incidence is a commonly used measure to describe the number of new cases or occurrence of an outcome within a specific timeframe. It can be calculated using longitudinal datasets and is often used to appreciate the scale of a problem within populations. For interventions recorded in registries, incidence is quoted to describe the frequency of the primary intervention and of revision procedures. For revision procedures, in order to allow comparison between implants and registries, one way of reporting incidence is as a rate per population at risk in a given time period. The denominator is the sum of the person-time of the population at risk. For arthroplasty data, this rate is often presented in terms of 'component-years at risk'. The cumulative incidence function (CIF) has also been used as a measure of probability of failure accounting for competing risks. Prevalence is difficult to determine from registry data as it would require an estimate of the number of individuals within a population who underwent the intervention in question and are still alive. Given that many of the interventions were being performed long before the establishment of registries, this is not easy to estimate. For hip and knee arthroplasty, the concept of revision burden was introduced to provide a relatively simple

comparable measure of the steady state of arthroplasty success.[1] It is defined as the ratio of implant revisions to the total number of arthroplasties in a given period.[2] Its use has been extended to economic analysis,[3] and to describe increases in procedure numbers.[4] However, a key problem with using revision burden as a comparable measure is the magnitude of the unknowns - the size of the existing populations with a primary or revision arthroplasty. Missing data and limitations in breadth of data collected require certain assumptions to be made in order to draw useful conclusions from registries, and the findings can be inexplicable with the data available thus creating further questions without clear solutions. Comparison of outcomes between nations has in itself some significant inherent challenges, including differences in units of measurement.[5] Nonetheless, this should not prevent comparative analyses since the reasons for disparity in outcomes can be useful in implementing change; standardisation of registry analyses to allow comparability will be useful in the future. A feature of registries is the clustering of patients within hospitals which are in turn clustered within regions. Conventional regression analysis assumes that subjects are independent of one another. However, for example, subjects nested within a high-volume, well performing arthroplasty unit are likely to have outcomes that are correlated with one another, producing potential biases which need to be addressed when analysing outcomes such as probability of revision. There are a number of different approaches to what is known as multilevel modelling but their incorporation in survival analysis for orthopaedic data is far from universal. With expanding datasets, their use will become more necessary to reach appropriate conclusions.

OTHER HEALTHCARE DATABASES AND DATA LINKAGE

In the UK, the Hospital Episode Statistics (HES) records data on all hospital admissions, outpatient appointments and A & E attendances, and there are comparable (usually billing-related) datasets in other countries. The ongoing linkage of NJR with HES data forms a powerful research tool. Primary care databases, such as the Clinical Practice Research Datalink (CPRD), hold primary care data, record secondary care diagnoses and interventions for approximately 6.5 million people and are considered to be representative of the wider UK population. A number of observational studies based on orthopaedic interventions have been published using CPRD data.[6-8] Large databases have the potential to provide the volume of data necessary to perform health economic analysis, but they can rarely be used in isolation for this purpose. This is just one example where linking healthcare databases is advantageous and it is likely to become an essential part of epidemiological research. However, linkage of anonymised data is not without its own challenges in terms of maintaining data protection. Advanced machine-learning techniques, which are being used increasingly in healthcare research and development, avoid reliance on data linkage to amalgamate information from separate databases and provide output which can be translated to answer an appropriate epidemiological question.

CONCLUSION

Without doubt, the volume of observational data related to orthopaedic practice will continue to expand, both within specialty-specific as well as general healthcare databases. Alongside this expansion, data linkage and advanced analytics will provide information to improve care. It is critical that evidence is used in context, in conjunction with findings from RCTs and smaller well designed observational studies. Finally, the ability to make global comparisons of epidemiological data, while necessary, will require a greater degree of standardisation.

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