Registry data allow great progress, but must be interpreted with caution

As doctors seek more information and data to guide their decisions, registry data, large databases and big data are an increasingly attractive source of knowledge.

The registry culture has been embraced in orthopaedics (Rolfson et al, 2016). A number of large registries has sprung up worldwide, notably within the arthroplasty community (Goldberg et al, 2012).

Potential benefits

The potential for such registries and big data to provide useful information is immense. These big data sets can provide cross-sectional population-based information and allow the detection of temporal changes. They provide an easy, pragmatic means of conducting effective comparative research. Data relating to new management and treatment interventions may be thoroughly and diligently analysed in registries and big data sets without the time, ethical and logistical constraints that randomized clinical trials demand.

Information gathered from joint registries has helped change and shape arthroplasty practice worldwide. The evolving trends in the choice of bearing surface couplings in total hip arthroplasty surgery is an example. The successful use of highly cross-linked polyethylene bearings has been very clearly borne out across multiple registries (Rajpuraet al, 2014). Similarly, the failure of metal-on-metal bearings has been demonstrated (Sabah et al, 2015). Subsequently, there has been an increase in the use of ceramic femoral heads in both the UK and USA (Rajpura et al, 2014). The preference for ceramic heads may be a result of the need to obviate the potential metal ion release as a consequence of taper and trunnion wear or corrosion with metal heads. This is a concern because of the associated pain and adverse biological effects being reported in patients with metal-on-polyethylene bearing couplings (Cooper et al, 2012). Likewise, the longevity and success of the increased number of cementless hip arthroplasty procedures reported in registries worldwide has seen this emerge as an efficient and reliable alternative to cemented hip arthroplasty, with likely benefits in the second and third decade.

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The data are also agile, enabling them to be linked with other large data sets to provide information that can guide practice change, lead to more cost-effective care, and influence and shape health-care policy. In orthopaedics, registries are used to understand and guide surgeon and industry behaviour and to change practice based on any adverse findings (Dy et al, 2016). These big data sets have yet to be combined but that is an ambition that should be realized over the next decade.

Linking good quality, large databases enables investigators to answer complex questions. Database linkages studying patient-related outcomes and examining important end-points such as cancer or heart disease have been extremely useful for dispelling fears and reassuring the surgical community. For example, case reports and random clusters had suggested that the release of metal ions from metal-on-metal hip replacement may be carcinogenic and that patients with these devices may have increased risk of malignant disease. Smith et al (2012) allayed these fears using Hospital Episode Statistics data linked with the National Joint Registry. They used these linkages to conclude that compared with age- and sex-matched controls, patients who had a total hip replacement or metal-on-metal bearing had a lower incidence of cancer than the age-matched controls. Patients who had undergone resurfacing metal-on-metal procedures were less likely to get a diagnosis of any cancer and had a lower risk of death than those who had received any other bearing surface.

Drawbacks of registries

While the possibilities for meaningful, exponential change and improvement are dramatic, it is important to also understand that big data and registries have drawbacks (Goldberg et al, 2012). Sufficient time is essential to allow registries and large databases to evolve, progress and accumulate enough valid data to become palpably useful and beneficial.

The validity of the data and quality of the coding are critical to ensure that any information subsequently captured is not only accurate but efficacious (Sabah et al, 2016). The data entered may often be incomplete, particularly for adverse events. The data entry itself may also be compromised by being valid in some parts but not in others. For example, clinicians can be relatively certain that a patient's date of birth and the type of procedure entered is correct, but the side may be incorrect. The type of approach, selected venous thromboembolism prophylaxis and the patient's body mass index may also be erroneously recorded or omitted. There is also always going to be a risk of selection bias influencing outcomes.

There will undoubtedly be improvements in the validation of all these registries if surgeons engage, review their data and feedback on its accuracy. Ultimately, if such a process is mandated, the quality of data will improve markedly.

Registries also focus on a specific outcome measure: further surgical intervention (Wylde and Blom, 2011). This may be a surrogate for technically easier revision or misinterpretation of X-rays rather than poor initial surgery or defective implants. Revision rates may, therefore, be increased more as a result of the perception that the subsequent revision surgery is simpler, than the fact that it is mechanically inferior or

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that its indication is in high demand, high functioning patients. Unicompartmental knee arthroplasty is a very good example of this (Goodfellow et al, 2010). If technically well inserted into appropriately selected patients they reproduce very good function and provide high patient satisfaction levels. However, they are much easier to revise than total knee replacements and are, therefore, more vulnerable to further surgery (Thienpont, 2017).

Limitations of registry data

Registries also suffer from issues related to confounding variables (Konan and Haddad, 2013). They are basically large observational data sets and are very useful for generating hypotheses but cannot prove causation (Perry et al, 2014). As an example, we could easily infer that because more people with grey hair get cancer, that grey hair is a marker or a causative factor for carcinogenesis, whereas in reality, it is highly likely to be age, which is also linked to developing grey hair, that is a confounder or risk factor. There are many similar examples, notably the fact that patients on anti-epileptic medication are much more likely to have epileptic fits than patients who are not, and patients who see a doctor are much more likely to die than patients who do not.

Clinicians must be acutely aware of over-interpretation or misinterpretation of data and wary of the risk of confounders (Perry et al, 2014). It is paramount that when examining any large data set clinicians scrutinize the population characteristics, critically evaluate its complexity and carefully examine how all risk factors may influence outcomes and the subsequent interpretation thereof. Small data sets, data mining and over-interpretation can result in incorrect conclusions. Observational data may demonstrate a correlation but not prove causality (Konan and Haddad, 2013). Clinicians should be mindful that it is usually having the risk factors for a particular health outcome that influences the outcome, rather than any intervention that is introduced to minimize the risk. It is beholden on all who interpret large observational data sets to make sure they have considered confounding variables.

Conclusions

At this time, clinicians need to support registry data for their utility, while recognizing their limitations (Wylde and Blom, 2011; Berry, 2017). All registries need to document their data quality assurance measures and audit them regularly. All studies using these observational data sets must have clear hypotheses and be carried out in a methodologically rigorous way. Data mining could produce unsafe findings and mislead the surgical community.

The resourceful exploitation of meticulously controlled, fully supported and linked registry data, large databases and big data is the way forward. Clinicians must not only embrace this, but ensure that the data are appropriately used. **BJHM**

KEY POINTS

- Data registries have and continue to prove their worth in changing clinical practice, improving outcomes and guiding health-care policies.
- The potential for exacting even greater knowledge is exponentially more substantial with big data, linking databases and data sets that provide an easy pragmatic way to conduct effective comparative research to achieve even more significant and positive health-care improvements.
- However, the need for prolonged time, problems with inaccurate and incomplete data collection and the potential presence of confounding variables may lead to misinterpretation of data and the arrival at imprecise and erroneous conclusions.
- The onus is therefore on the clinician to harness the potential of big data and linked registries while responsibly ensuring that the data are meticulously controlled and appropriately used.

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