

58 Society Academic Meeting

Merseyside Orthopaedic Surgery Registrars

Big Data and Clinical Trials, Mr Daniel Perry.

Mr Perry outlined the sources of routine data available in medicine, and how these provide a wealth of data by which to examine both the aetiology and epidemiology of diseases, in addition to the effectiveness of interventions. Orthopaedic surgery in particular has a wealth of “Big Data” which includes the ‘National Joint Registry’, ‘The National Hip Fracture Database’ and ‘Trauma Audit and Research Network’.

Whilst big data has a wealth of opportunities, there are also pitfalls that must be recognized, anticipated and overcome. The fundamental part of big data analysis is that, on the whole, the dataset was never designed to answer the question that you wish to answer. This means that not all of the data you required may be collected, or it may be collected in a format that is not the most preferred. However, the size of datasets offer such massive opportunities, that one must consider means to overcome the challenges.

Data quality is one of the most important considerations in the analysis of big data. One must be clear why the data was collected, and how the purpose of the data collection may influence the results obtained (i.e. what bias may be introduced in the collection), i.e. financial remuneration may exist for collecting certain codes in preference to others, therefore this may result in a systematic error (i.e. bias). The data quality checks in place (i.e. audits of data quality) are important to be aware of, and to be able to describe.

Mr Perry outlined his work using General Practice data in rare childhood diseases, and how this is particularly suited to big data, owing to the rarity of diseases. Other examples included examples from Hospital Episode Statistics, and the National Hip Fracture Database. Whilst big data had amazing opportunities, the limits are also evident. With rare childhood diseases, the limits the available data is quickly appreciated, as routine data only collects a small amount of useful information. Mr Perry therefore now has a national study (the British Orthopaedic Surgery Surveillance (BOSS) Study) that prospectively collects data important to surgeons, but uses Big Data to augment data collection (i.e. to help determine where cases occur in the UK).

The ultimate goal for Big Data is to use the data as part of clinical trials. If one can consider randomizing patients between interventions within the confines of the dataset, then follow-up would simply be part of the routine data collection. This could mean that studies that were considered impossible could be delivered in a very short space of time indeed. Furthermore, the studies would be hugely efficient in terms of time, and cost. The future for Big Data in orthopaedic surgery is exciting!

Clinical Trials in Trauma Surgery – Orthopaedic Surgeons are Listening! Prof Matthew Costa.

Professor Costa outlined his recent work in trauma trials, particularly focusing on the DRAFFT trial (Percutaneous fixation with Kirschner wires versus volar locking plate fixation in adults with dorsally displaced fracture of distal radius: randomised controlled trial, BMJ 2014;349:g4807). The DRAFFT trial was the trial that has perhaps most enthused orthopaedic surgeons. DRAFFT considered whether volar plating a distal radius was preferable to K-wires, in terms of clinical and cost effectiveness. The background to the study was there had been a progressive increase in the use of locking plates for the management of these fractures, though there had been little robust evidence to support this change.

DRAFFT was a very large UK trial, taking onboard many centers that had not engaged in research before. 461 patients were enrolled, with the procedures conducted by 244 different surgeons. The results clearly demonstrated that for the patients eligible to be included into the trial, the patient functional scores were no different for either of the treatment arms at any time point. Furthermore, the only difference was the cost of the interventions, which was significantly more for the volar locking plates.

Professor Costa went onto detail how the UK trauma society has received the work with mixed feelings. Many clinicians have welcomed the findings, whilst some have felt that the results have challenged their personal beliefs. However, he demonstrated conclusive evidence, using procedural codes across the NHS, that the study significantly altered the choice of fixation across the UK. In fact, even before the trial results were evident a trend emerged whereby there was a gradual rise in k-wire fixation, and a gradual decline in plating – even at centers not engaged in the trial (i.e. it was not a direct result of the interventions occurring as part of the trial). Since the trial result has been published there has comparatively lower rate of distal radius plate fixations. Furthermore, the cost of the clinical trial was overcome in the first year alone, by the relative savings made by the decreased use of volar locking plates.

Professor Costa went onto detail the other studies ongoing in general trauma (Distal Tibial Fractures, Vac Dressings, Achilles Tendon Fixation etc), and hip fractures. He challenged the audience to consider the evidence for many of the routine treatments that we use in orthopaedic surgery, and to consider whether we truly know what is right for our patients. Orthopaedic surgery is on the cusp of a much-needed evidence revolution.