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Equipoise, ethics, and offering patients participation in studies

In general, as orthopaedic surgeons, we have a definite idea about which treatment, operation, or rehabilitation strategy we feel is best for our patient. We are rarely in 'equipoise' in the truest sense of the word. If a given patient is not in a study, it is very rare that we would offer that patient two different options, and then tell them we do not know which is best.

While most surgeons will agree in principle to being in equipoise over a specific, carefully constructed study question – for example, if a plate or nail is better for an extra-articular distal tibial fracture, or if flail chests should be plated from the off – when faced with a specific patient, nearly all will express a preference for one treatment or another. This in itself presents a problem, as surgeons are naturally cautious with study patients and will rarely 'risk' randomizing a patient in whom they have a personal treatment preference for surgery away from surgery, which could obviously happen with randomization. However, they are more likely to 'risk' randomizing a patient in whom they have a preference for nonoperative management to a surgical intervention. This, of course, tends to introduce a subtle selection bias.

The other, and often forgotten about, factor here is the patient's right to be offered, in the NHS at least, the opportunity to take part in the research study. The NHS provides for the right of patients to take part in research – and there is a good argument that 'screening out' patients based on surgical or medical preferences is in itself unethical. If a patient who fulfils the recruitment criteria for a study is not offered the opportunity to take part, there may be more lost than the satisfaction of 'helping out'. We know that patients involved in research studies are not only happier with the care that they receive, but on all measurable criteria do better than those who are not part of research.

The reason for this effect is far from clear. It could be due to the sites that take part in research being inherently better institutions. It could be because the types of surgeons prepared to undertake research are more flexible thinkers, more patient-orientated, or more meticulous about their technique. It may be due to the Hawthorne effect, or some other unknown or undescribed process. As with all things in medicine, it is likely a little of everything.

So, in the age of evidence-based medicine, we do need to get away from 'subgroup' selection from within the inclusion criteria for our studies. One of the major criticisms laid at the door of orthopaedic trialists is that everything fails to show a difference. Perhaps this is because we are excluding all those patients whom we think surgery will benefit? Even if we are not selecting out those who will do well – routinely, in large trials, only 30% of the potentially eligible patients are included – we are failing to give other patients the opportunity to have a better outcome just by taking part. I tend to side with those who would argue that it is ethically unsound not to offer our patients this opportunity.

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