Invited Editorial

To mesh or not to mesh

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We are in the midst of an increasingly acrimonious discussion regarding the use of mesh in pelvic reconstructive surgery. Modern mesh kits, aggressively marketed by biotech companies, have become widespread. At times, they are used inappropriately, and significant complications such as pain syndromes and erosion are not uncommon. While conventional alternatives such as sacropinous colpooxy and Burch colposuspension are not without their problems either, the discussion surrounding mesh use has a character never encountered before in urogynaecology. Many colleagues feel that the resolution of this conflict may be found in large randomised controlled trials such as the PROSPECT trial currently being planned in the UK. I feel that such a trial may well do more harm than good, unless certain precautions are taken. In this opinion piece I’ll try and explain why.

Key words: aetiology, female pelvic organ prolapse, imaging, levator ani, pathophysiology, pelvic floor.

Introduction

Urogynaecology in Australia and elsewhere has a major problem. The widespread marketing and indiscriminate use of modern mesh kits have caused a level of controversy not seen since the formal birth of the subspecialty in the late 80s and early 90s. A keynote lecture at last year’s International Continence Society meeting in Cairo given by Donald Ostergard, one of the doyens of the field in the USA and a previous editor of the International Urogynaecology Journal, made abundantly clear that there are colleagues who consider mesh use a sign of surgical incompetence or worse. This perception is mainly due to complications such as erosion (mesh exposure in the vagina, resulting in discharge, spotting and dyspareunia) and pain syndromes. The latter in particular are difficult to treat since we don’t understand why a small minority of women react in this way. Surgical technique or ‘mesh shrinkage’ is blamed, without any evidence to back up either explanation. I have spoken to senior colleagues who feel that mesh should be banned altogether, and that mesh users probably ought to end up in court for their endeavours. And the latter is already starting to happen all over the developed world, as many colleagues are well aware.

The standard response to any clinical controversy, in this age of ‘evidence-based medicine’ is to ask for bigger and better studies, preferably multicentre randomised controlled trials (RCT) that recruit thousands of patients and require millions of dollars, pounds or euros in public funding. It is a knee jerk response that, admittedly, often makes good sense. And of course it is a standard response to the controversy surrounding mesh. The conservatives say that large RCTs are urgently needed before they will consider mesh use at all, and the progressives demand such trials to justify what they’re doing – and what they know to be the right thing anyway.

A recent editorial and review article published in the January edition of BJOG, dealing with the growing controversy over the use of mesh in pelvic reconstructive surgery, make the point very clearly. Evidently we need to spend millions, and surely we’ll soon know how to do the right thing by our patients.

I disagree. The proposed solution to the problem, the PROSPECT trial, may well miss the point, to such an extent that the findings could become hindrance rather than help – unless we get the diagnostic work-up and inclusion criteria right. In the following lines I’ll try to explain why and how.

Any RCT is based on the premise that we’re dealing with average patients (or patients that, to all intents and purposes, can’t be shown NOT to be average). This issue should have been discussed at length after the publication of the term breech trial (TBT) in 2000. The findings of the TBT are largely irrelevant to a clinician dealing with a recognisably non-average patient. Let’s imagine Mrs Smith, a third-time mother who has had two big babies in uncomplicated four-hour labours before. She has walked in 20 min ago, is now at full dilatation, with a 37-week breech at +2, a normal trace, just getting the urge to push. In essence, Mrs Smith is much more likely to deliver vaginally than the average person recruited to the TBT, and that means the conclusions of that trial simply do not apply to her.

The point I’m trying to make here is that the largest and most powerful RCTs may well be useless for clinical

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decision-making if you can tell that your patient is well off the population mean. It is entirely rational to ignore that RCT, and hope that you’ll never have to defend your decisions against poorly informed colleagues or judges. We should focus on individual risk assessment, and that’s what clinical skills are all about. Evidence-based medicine was never meant to be an excuse for switching off our brains.

Sometimes the main problem in interpreting large RCT’s or meta-analyses lies in the fact that we don’t understand the disease we’re dealing with. David Henderson-Smart’s group published a Cochrane Review in 2007 that reported on 59 trials including 37 560 women to determine whether anti-platelet agents prevent pre-eclampsia. In their conclusions they had to say that, while there is a ‘moderate benefit’, we don’t really know why it works in some but not in others. Is this really surprising though, given that we have no idea what causes pre-eclampsia and its complications in the first place? How much sense does it make to undertake large RCTs, spending many millions on intervention trials for conditions the pathogenesis of which we don’t understand?

It’s not that different in prolapse surgery. We need to work out what we’re dealing with. That means research into pathophysiology, and proper diagnostics. The real challenge is to identify those patients most likely to fail conventional surgery, because they’re the ones most likely to benefit from any method designed to lower recurrence rates, such as mesh implants.

And we can in fact do this now. It has been shown using both MR and ultrasound that levator avulsion is a major risk factor for female pelvic organ prolapse, especially cystocele and uterine prolapse, and we have just published abstracts on two separate studies showing that patients with avulsion are two to four times more likely to recur than those without. The same has been shown on magnetic resonance imaging (personal communication, Ben Adekami, York). Excessive hiatal distensibility probably adds additional risk, independently.

The PROSPECT trial is a great opportunity to inform clinical decision-making – but only if the study design allows for a proper diagnostic work-up, at least in a subgroup of patients. Only if we identify the main predictors of recurrence, the kind of information that determines whether a patient is ‘average’ or not.

Otherwise the PROSPECT trial may become a urologyneacological TBT: something that dis-empowers clinicians, a piece of ‘evidence’ that requires us to switch off our brains. One may comment that diagnosis by MR or pelvic floor ultrasound will be impractical in many locations for the foreseeable future. But then one really doesn’t need expensive machinery to diagnose avulsion – all it needs is an educated index finger.

References