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Who needs randomised controlled trials in robotic surgery?

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It has been nearly 15 years since one of the first ever randomised controlled trials (RCT) in robotic surgery was conducted in 2002. The STAR-TRAK compared telerobotic PCNL to standard PCNL and showed that the robot was slower but more accurate than the human hand [1].

In the 24 h since the much anticipated RCT of open versus robotic assisted radical prostatectomy was published in the Lancet [2], our BJUI blog from @declangmurphy was viewed over 2500 times receiving more than 40 comments, making it one of our most read and interactive blogs ever. It is a negative trial showing no differences in early functional outcomes between the two approaches.

And it is not the only negative trial of its kind as a number of others have matured and reported recently. The RCT of open versus robotic assisted radical cystectomy and extracorporeal urinary diversion showed no differences in the two arms [3] and likewise comparison of the two approaches to cystectomy as a prelude to the RAZOR trial showed no differences in quality of life at 3 monthly time points up to a year [4]. The only RCT comparing open, laparoscopic and robotic cystectomy, the CORAL, took a long time to recruit and yet again showed no differences in 90 day complication rates between the three techniques [5].

In all likelihood, despite the level 1 evidence provided in the Lancet paper showing no superiority of the robotic over the open approach, the Brisbane study is unlikely to change the current dominance of robotic prostatectomy in those countries who can afford this technology. Why is this? Apart from the inherent limitations which the BJUI blog identifies, there are other factors to consider. In particular, as O'Brien et al observed previously in their memorable paper "Why don't Mercedes Benz publish randomised trials?" [6], there are solid reasons why surgical practice is not well suited to being tested in a traditional RCT format.

A few additional reflections are perhaps appropriate at this time-

1. Despite the best statistical input many of these and future studies are perhaps underpowered

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2. Many have argued that the RCTs have shown robotics to be as good, although not better than open surgery, even in the hands of less experienced surgeons
3. Patient reported quality of life should perhaps become the primary outcome measure because that in the end is what truly matters
4. Cost effectiveness ratios should be an important outcome measure as otherwise there is much speculation by the lay press without any hard data
5. Industry have a role to play here in keeping costs manageable, so that these ratios can become more palatable to payers
6. Surgery is more of an art than a science. The best surgeons armed with the best technology that they are comfortable with will achieve the best outcomes for their patients

While this debate will continue and influence national health care providers and decision makers, the message looks much clearer when it comes the training the next generation of robotic surgeons. A cognitive and performance based RCT using a device to simulate vesico-urethral anastomosis after robotic assisted radical prostatectomy (RARP) showed a clear advantage in favour of such structured training [7]. In this months' issue of the BJUI we present the first predictive validity of robotic simulation showing better clinical performance of RARP in patients [8]. This is a major step forward in patient safety and would reassure policy makers that investment in simulation of robotic technology rather than the traditional unstructured training is the way forward.

Most of our patients are knowledgeable, extensively research their options on Dr. Google and decide what is good for them. It is for this reason that many did not agree to randomisation in other robotic versus open surgery RCTs like LOPERA and BOLERO. Many of them continue to choose robotic surgery without necessarily paying heed to the best scientific evidence. Perhaps what patients will now do is to select the best surgeon whom they can trust, armed with their best technology to deliver their best outcomes.

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