

## First trial of robotic vs. non-robotic surgery for prostate cancer finds both achieve similar outcome at 3 months

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The first randomised controlled trial to directly compare robotic surgery with open surgery for patients with localised prostate cancer finds that robotic and open surgery achieve similar results in terms of key quality of life indicators at 3 months. The study, published in *The Lancet*, is the first stage of a 2 year trial and reports quality of life outcomes such as urinary and sexual function. Longer-term follow-up is now needed to fully assess the outcomes of both techniques, including on cancer survival.

Since the use of robot-assisted laparoscopic prostatectomy (RALP) was first reported in 2000, there has been rapid adoption of robotic surgery for men with <u>prostate cancer</u>. One million men are diagnosed with prostate cancer worldwide each year. The most common treatment for localised disease is surgery to remove the <u>prostate gland</u>, and some men experience urinary and erectile problems following surgery. For most men, the operation will get rid of the cancer cells, but for around one in three men, <u>cancer cells</u> may return some time after the operation.

In the USA, 80-85% of prostatectomies are done robotically, and although the proportion is lower in the UK and Europe, it is increasing. Robotic surgery is more expensive than open surgery (the initial cost of the robot is approximately £1.5 million) and to date, there have been no randomised controlled trials comparing robotic with open surgery.



"Surgery has long been the dominant approach for the treatment of localised prostate cancer, with many clinicians now recommending the robotic method to patients. Many clinicians claim the benefits of robotic technology lead to improved quality of life and oncological outcomes. Our randomised trial, the first of its kind, found no statistical difference in quality of life outcomes between the two groups at 12 weeks followup. Patients are now being followed-up for a total of 2 years in order to fully assess the longer-term outcomes, including on cancer survival" says lead author Professor Robert 'Frank' Gardiner, University of Queensland Centre for Clinical Research, Brisbane, Australia. "In the meantime, patients should choose an experienced surgeon they trust and with whom they have a rapport, rather than basing their decision on a specific surgical approach."

RALP uses a high magnification (x10) 3D camera that allows the surgeon to see inside the patient's abdomen through a keyhole incision. The camera is attached to one of four arms on the robot - the other three hold other surgical instruments needed during the operation. The surgeon is in the operating room but is away from the patient and controls the robotic arms to perform the operation (link to images below). Robot-assisted surgery is most commonly used for prostatectomies, but is increasingly being used in gynaecology, cardiothoracics, head and neck, and general surgery, as well as other operations in urology.

308 men with prostate cancer were included in the study, and were randomly assigned to either receive robot-assisted surgery (157) or open surgery (radical retropubic prostatectomy) (151) and who were followed up for 12 weeks after the operation. All the operations were led by two surgeons at the Royal Brisbane and Women's Hospital

The primary outcomes included urinary and sexual function at 12 weeks and there was no difference in between the two groups. There were also no differences in the number of post-operative complications. Patients



who underwent open surgery spent a longer amount of time in hospital after surgery but on average, both groups spent the same number of days away from work.

Patients who underwent open surgery lost on average three times more blood (although no transfusions were needed during the operations because blood was recycled back into the patients during the open operations). In the immediate aftermath of the surgery, patients who underwent <u>robotic surgery</u> experienced less pain doing day to day activities (at 1 week), and reported better overall physical quality of life (at 6 weeks). Although over time, the differences levelled out and became non-significant at 12 weeks.

The authors note that urinary and sexual function can continue to improve for up to 3 years after surgery, so differences in outcomes between these two groups might become apparent later on. The study is the first stage of a two year trial.

Writing in a linked Comment, Professor Ara Darzi, Imperial College London, UK says: "The clinical community waits with anticipation for the 1-year oncological outcomes; the last patient underwent surgery in March, 2015. It will be the interpretation of the longer-term functional and oncological outcomes that reveals the full implications of this study for clinical practice...Trials that show equivalence for an innovation are sometimes interpreted as supporting a return to existing practice, including rediverting the training of a generation of surgeons who might have followed the innovation's evolution. Equivalence and noninferiority should also be seen as positive, showing the innovation has preserved the intended and well established purpose of surgical intervention, such as good oncological outcomes balanced against acceptable functional sideeffects. It is these advances in applied technology, reducing the trauma of access and the invasiveness of surgery, that also provide the platform on which to develop adjunct technological innovations towards further



improving the quality and safety of <u>surgery</u>. Our challenge as a community is to demonstrate safe and cost-effective translation alongside significant health and economic impact."

**More information:** John W Yaxley et al, Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study, *The Lancet* (2016). DOI: 10.1016/S0140-6736(16)30592-X

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