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Robotics in rectal surgery - the arguments against.

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Telemanipulator robots are not new. The most commonly used platform was introduced in 1999 and has seen rapid introduction into many fields of surgery, driven by industry as well as clinicians and healthcare providers keen to be at the forefront of a new technology that offered commercial benefits. In this regard, the surgical community repeated the errors of the past, letting enthusiasm for robotics dictate its judgement, rather than good quality scientific evidence (1).

The first rectal surgery using the Intuitive DaVinci ™ system was being performed as early as 2001 and described in the literature as early as 2003 (2) and it is now widely practiced around the world. Rectal cancer surgery is one of the very few areas of robotic-assisted surgery that has been subjected to a properly conducted multi-centre randomised trial to compare robotic resection with the standard laparoscopic approach.
The questions that need addressing relate quite simply to benefit and cost; benefits or otherwise to the patient primarily, but also costs to the health system and the economy.

The operation for rectal cancer performed laparoscopically with standard instruments and that performed with robotic assistance is essentially the same with some subtle differences in the port placements to accommodate the robotic mechanism and avoid external clashing of the instrument arms. Depending on the technique, the number and size of the robotic ports is usually greater than with the standard approach. Although it is possible to perform the entirety of the surgery with the robotic platform, it is more common to perform a hybrid technique using standard laparoscopic techniques for the abdominal part of the procedure. Even in the pelvis, the approach, the planes of dissection and the method of anastomosis are identical, following standardised TME principles.

The question then is whether the computer interface between the surgeon and the instrumentation can somehow improve the surgery and achieve a more accurate dissection with better pathological specimens, less collateral injury and a higher chance of completing the surgery laparoscopically. Two elements are said to aid this – a 3D image and more dextrous wristed instruments. The high-quality 3D image is however no longer a reason to use a robot as modern passive polarising displays provide an equivalent quality image at a fraction of the price. The dexterity enhancement of wristed instrumentation is available with hand held instruments also but remain considerably inferior at the present time.
It is proposed that robotic surgery is easier and that this might particularly be the case in the difficult obese male patient with a narrow pelvis, a bulky mid-rectal tumour, following radiotherapy and with an enlarged prostate. This is of course the exact same group of patients in whom it is proposed that a trans-anal approach to the TME is beneficial.

Anecdotal reports represent the majority of published work comparing robotic and laparoscopic approaches to rectal cancer and can be summarily dismissed from the list of evidence for reasons of potential bias. Measures that might represent positive evidence include surrogate markers of better outcome (specimen quality), actual measures of outcome, such as local recurrence rate, and pelvic function and complications of anastomosis. This data is only really robust when it is large, randomised and controlled. Data registries and other non-randomised comparative studies provide a much lower form of evidence.

Attempts have been made to perform meta-analyses of the numerous small studies that have been performed and have always concluded that there is no difference in outcome. There is a suggestion that there may be a lower conversion rate in some of the meta-analyses, but these draw on the same small number of studies and are inherently influenced by case selection bias (3, 4). The clarion call was always for an RCT and this has now been performed - the EME/NIHR ROLARR trial (5, 6). This was a well-run international study that recruited to time. Only experienced laparoscopic and robotic surgeons participated, and the primary outcome measure was conversion to open surgery. The numbers in the trial were based upon predicted conversion rates in national datasets available at the time of study design. In fact, the actual rates of conversion for laparoscopic and robotic surgery were considerably less, which is testimony to the experience of the participating surgeons. The conclusion of the trial was simply that there was no statistical difference in conversion rates between the two treatment arms. A trend was observed in a sub-group analysis with less conversion in obese and male patients. But many hundreds of patients more need to have been recruited to demonstrate that this observed difference was statistically significant, which in terms of “numbers needed to treat” calls into question the clinical relevance of the finding.

Accepting that the best available evidence has demonstrated no conclusive proof of a reduced conversion rate with the robot, and that conversion is an infrequent event which ever technique is used, attention then focuses on the secondary outcome measures - pathological surrogates of oncological resection and quality of life. ROLARR demonstrated that here was no difference in pathological outcomes, patient recovery following surgery, or generic and disease-specific quality of life up to 12 months follow-up. Similar findings have recently been reported for robotic and laparoscopic APR (7).

The authors in favour of robotics state that there is a potential bias in the ROLARR trial in favour of laparoscopy because of inclusion of surgeons with greater laparoscopic experience, and quoting a robotic learning curve of 19 to 128 cases(8). Whilst laparoscopic experience was inevitably higher in the cohort overall, the median robotic experience of participating surgeon was 49 cases - well within the quoted proficiency range. The operative approach and technique for robotic and laparoscopic surgery are the same – only the instrumentation is different and the learning curve for an experienced laparoscopic proctatectomist is mostly very short. They also make the claim that the robot is more demanding requiring a longer learning curve, which is contrary to the popular argument that it makes the operation easier and less demanding.

The authors in favour of robotics also state that lower conversion rates, better outcomes and better CRM rates are inferred by many published studies, but this is not admissible evidence in favour of robotics because of the small numbers and non-randomised designs, which will inevitably introduce biases. They also quote a study that concludes that the robotic group suffered less financial difficulties, less fatigue and better emotional and social functioning - this finding from a retrospective analysis, attempting to simulate randomised techniques through propensity matching, is contrary to the findings of ROLARR and intuitively difficult to explain given that both laparoscopic and robotic operations involve the same intracorporeal operation.
The Portsmouth study that is quoted involved less than half the numbers recruited to ROLARR and allocated patients to robotic or laparoscopic without randomisation and again is subject to large potential biases. ROLARR was designed as a pragmatic study, with only the specifics of rectal dissection dictated. Other aspects of the operation were left to surgeons' usual preference, which adds greatly to the generalisability of the results i.e. ROLARR embraced usual surgical preferences and is a reflection of actual clinical practice. This contrasts to any single-centre study where the operations are performed by a limited number of surgeons and the results cannot be generalised to the wider population. This is the important fact - not what a single centre might report, but what a real-world population of experienced surgeons can achieve.

Claims of shorter lengths of stay and reduced readmission rates following robotic surgery have to be treated with a healthy dose of scepticism given the quality of the data. There is absolutely no evidence that there are fewer permanent stomas formed in robotic surgery - an outcome that is overwhelming influenced by the extent of the rectal resection, irrespective of surgical approach. As far as function is concerned, the evidence to support claims of superiority for the robot are again drawn from a limited number of small cohort studies. In contrast, ROLARR has demonstrated beyond doubt that there is no difference between robotic and laparoscopic surgery in either bladder or sexual function, and in fact the incidence of urogenital dysfunction is actually low - again an indication of the quality of surgery performed within ROLARR.

The ultimate test of any new oncological intervention is its effect on long-term disease control and survival. Here again the robot falls short of expectations: analysis of the 3-year follow-up data from ROLARR has shown no difference in local recurrence, disease-free or overall survival between robotic and laparoscopic surgery (personal communication - DG Jayne).

Notwithstanding the above, the crucial aspect when evaluating any new technology is its cost-effectiveness relative to the current standard of care at the time. The cost of robotic systems is one of the principal barriers to introduction into many health systems especially when evidence for patient benefit is lacking. All studies of cost in rectal cancer surgery confirm excess costs per patient of between $2,000 and $20,000 (9-11). The wide variation is related to different health care systems and the extent to which the purchase costs are incorporated into the calculation. However the calculation is made, the fact is that a hospital will have to spend £2 million plus the considerable cost of maintenance plus the cost of disposables in order to do this surgery. ROLARR has highlighted the extravagance of robotic surgery with greatly inflated costs, driven by longer operating times and increase

instrument costs, resulting in an incremental cost-effectiveness ratio (ICER), as compared to laparoscopic surgery, in excess of £70,000 (6) - well above the NICE willingness to pay threshold of £20,000-£30,000. During the lifetime of a robot, a hospital with proficient laparoscopic surgeons can undertake the same number of resections, with the same bed occupancy and the same outcomes without the need for any of this capital expenditure. This is a cost that the NHS in particular cannot afford and without any evidence of benefit there is a good argument to be made for disinvestment in robotics for rectal cancer. The challenge is now with industry - they have been shown what needs to be done and the moral responsibility is with them to develop systems that are at least as cost-effective as laparoscopic surgery.

The reality is that we as a profession are obsessed with techniques and novel interventions, when we all know that it is the technician that it is the most important variable in any operation. Surgeons will undoubtedly publish excellent results using the robot for a variety of reasons. By the same token, the same and indeed better results are published in series of patients operated upon using standard laparoscopic techniques and now using trans-anal surgery.

Collectively, we must learn from our past mistakes and cease bringing our profession into disrepute by adopting new and expensive technologies without rigorous evaluation. There is a place for small cohort studies, but they should not be relied upon to inform healthcare decision-making. They serve as indicators of potential improvement but should be treated with appropriate caution and interpreted accordingly when more robust data becomes available.

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