

Advice Statement

Robot-assisted surgery compared with laparoscopic resection for the treatment of rectal cancer



Advice for NHSScotland

Robot-assisted surgery should be considered for patients with rectal cancer who have a narrow pelvis, are obese (BMI \geq 30), and/or have a tumour located in the mid-to-low rectum. There is evidence of a clinical benefit in the form of reduced risk of conversion to open surgery in these patients, although relevant cost-effectiveness evidence is currently lacking. Expert opinion indicates that conventional laparoscopic options are inadequate for these patients.

Data on clinical, oncological and patient-important outcomes should be collected for all robot-assisted surgeries in patients with rectal cancer who meet the criteria outlined above.

Provision of robot-assisted surgery for rectal cancer should be concentrated within centres that currently have a robotic surgical device and are likely to receive a sufficient number of suitable patients per year to maintain surgeon proficiency.

NHSScotland is required to consider the Scottish Health Technologies Group (SHTG) advice.

Why is SHTG looking at this topic?

Da Vinci[®] robotic surgical devices are a relatively new technology which is available at four centres in NHSScotland. These devices are currently used predominantly to provide a laparoscopic prostatectomy service. To ensure the devices are optimally employed, NHSScotland is considering expanding the indications for which robot-assisted surgery is available. The topic was prioritised for inclusion on the SHTG work programme following a topic referral from NHS Greater Glasgow and Clyde to support evidence-informed use of robotic surgery capacity.

Evidence Note 85 was produced by Healthcare Improvement Scotland in response to this request.

Background

An estimated 28% to 35% of colorectal cancers are located in the rectum. In 2016 there were 1,181 new diagnoses of cancer of the rectum or rectosigmoid junction in Scotland.

The primary treatment option for patients diagnosed with rectal cancer is surgical removal of the tumour. More than 446 patients underwent surgery for rectal cancer in Scotland between 1 April 2016 and 31 March 2017 (data not available from the North of Scotland Cancer Network). In the West of Scotland 51% of these surgeries were initiated as laparoscopic procedures, while in the South and East this proportion was 64%.

Robot-assisted surgery is a potential alternative to laparoscopic surgery for patients with rectal cancer.

Clinical effectiveness

- A meta-analysis of RCTs compared robot-assisted surgery with laparoscopic surgery for the treatment of rectal cancer
 - Patients undergoing robot-assisted surgery had a statistically significant lower risk of converting to open surgery: relative risk (RR) 0.58, 95% confidence interval (CI) 0.35 to 0.97, $p=0.04$, 4 studies, 544 patients. Estimated absolute risk 75 per 1000 compared with 129 per 1000 (5.4% absolute risk reduction).
 - In analyses of only male patients, robot-assisted surgery was still associated with a statistically significant lower risk of converting to open surgery: RR 0.49, 95% CI 0.28 to 0.88, $p=0.02$, 3 studies, 342 patients. Estimated absolute risk 85 per 1000 compared with 174 per 1000 (8.9% absolute risk reduction).
 - There were no statistically significant differences in 30-day mortality, completeness of total mesorectal excision (TME), positive circumferential resection margins (CRM), mean number of lymph nodes harvested, length of hospital stay, or perioperative complications.
 - Four of the included RCTs estimated perioperative blood loss using different definitions and measures which prevented meta-analysis. None of the four RCTs reported a statistically significant difference in estimated blood loss for robot-assisted surgery compared with laparoscopic surgery.

- In a meta-analysis of 13 observational studies ($n=10,781$) converting laparoscopic surgery for rectal cancer to open surgery was associated with statistically significant longer operating time, longer length of hospital stay, higher rates of wound infection and lower tumour-free survival rates, compared with completed laparoscopic surgery.

- Logistic regression analyses within the ROLARR RCT ($n=471$) found a statistically significant increase in the odds of converting to open surgery for:

- Obese patients compared with underweight or normal weight patients: adjusted odds ratio (OR) 4.69, 95% CI 2.08 to 10.58, $p < 0.001$.
- Men compared with women: OR 2.44, 95% CI 1.05 to 5.71, $p = 0.04$.

- Two meta-analyses of observational studies reported no statistically significant difference in 3-year overall survival, and one reported no statistically significant difference in 3-year local disease recurrence, for robot-assisted surgery compared with laparoscopic surgery for rectal cancer.
- Evidence from identified RCTs was inconsistent on whether robot-assisted surgery improved postoperative urinary and sexual function compared with laparoscopic surgery.

Device safety

- The ROLARR RCT reported surgical equipment failure – of laparoscopic equipment or the robotic system including hardware and software – during eight (3.4%) robot-assisted surgeries and six (2.6%) laparoscopic procedures for rectal cancer.

Cost effectiveness

- The ROLARR RCT conducted a cost analysis based on patient resource utilisation ($n = 190$) during the initial surgery and a six month postoperative period. Capital and maintenance costs of the robotic surgical device were not included. Robot-assisted surgery had statistically significant higher total healthcare costs compared with laparoscopic surgery: mean difference £980, 95% CI £165 to £1,795, $p = 0.02$. The increased cost of robot-assisted surgery was associated with longer operating times and higher costs of surgical instruments.
- Two economic evaluations and one further cost analysis were identified but the results were not generalisable to the Scottish setting.

Patient and social aspects

A patient organisation submission from Bowel Cancer UK ([available from the Healthcare Improvement Scotland website](#)) collated information from the charity's website, case studies and a survey of patients. The following key points emerged:

- Some patients who undergo surgery for rectal cancer experience long-term side-effects that last more than six months and/or late effects which occur months after the surgery. Both long-term and late effects impact on patients' quality of life.
- Survey respondents ($n = 29$) stated that fewer treatment-related side effects, such as urinary, bowel or sexual dysfunction, were the most important potential benefit they would want from robot-assisted surgery. Only one respondent had actually had robot-assisted surgery for rectal cancer.

- If introduced, there needs to be clear guidance for patients about the potential risks and benefits of robot-assisted surgery so that they can make informed treatment choices.
- There are some misconceptions about how robot-assisted surgery works and the role of the surgeon versus the robotic device in the operating theatre.

Context (includes organisational issues)

- Robotic systems (da Vinci®, Intuitive Surgical Inc., California) are installed in four centres in Scotland: the Western General Hospital (Edinburgh), Queen Elizabeth University Hospital (Glasgow), Golden Jubilee National Hospital (Clydebank) and Aberdeen Royal Infirmary.
- The robotic systems in Edinburgh, Glasgow and Aberdeen are used 2 to 3.5 days per week to provide a robot-assisted laparoscopic prostatectomy service. Other indications for robot-assisted surgery in some centres include lung conditions, renal and bladder cancers, gynaecological indications and potentially transoral robotic surgery for selected head and neck cancers.
- A systematic review of nine studies (n=917) calculated that the mean number of robot-assisted rectal cancer surgeries required for a surgeon to be considered an expert was 39 procedures.
- Surgeons will require training and support as they transition to robot-assisted surgery and during their learning curve. Extensive training and educational materials are available from Intuitive Surgical Inc.

Further research

Robot-assisted surgery for rectal cancer is aligned with the assessment stage of the [IDEAL framework for surgical innovation](#).

- Prospective, randomised studies are needed that report long-term patient and oncological outcomes for robot-assisted surgery compared with laparoscopic surgery in patients with rectal cancer.
- Cost-effectiveness analyses applicable to the UK setting are needed to compare robot-assisted surgery with laparoscopic surgery in patients with rectal cancer.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.

It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of publication. An international evidence base is reviewed and thus its generalisability to NHSScotland should be considered by those using this advice to plan services. It is acknowledged that the evidence constitutes only one of the sources needed for decision making and planning in NHSScotland. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

SHTG Advice Statements will be considered for review if new evidence becomes available which is likely to materially change the advice. Stakeholders may submit a request, highlighting new evidence to shtg.hcis@nhs.net

Acknowledgements

SHTG would like to thank the following individuals and organisations who provided comments on the draft Advice Statement:

- Emad Aly, Consultant in General Surgery, Colorectal surgery, Haemorrhoid surgery, Laparoscopic surgery, Aberdeen Royal Infirmary
- Claire Donaghy, Bowel Cancer UK
- Julian Dunnett, Market Access Director, Da Vinci
- Clare McNaught, Consultant General and Colorectal Surgeon, Scarborough Hospital, UK and Member of the Council of the Royal College of Surgeons of Edinburgh
- Richard G Molloy, Consultant Colorectal Surgeon, Queen Elizabeth University Hospital
- Chelliah Selvasekar, Consultant General and Colorectal and Robotic Surgeon, The Christie NHS Foundation Trust

Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by the SHTG's Evidence Review Committee. However, reviewers had no role in authorship or editorial control and the views expressed are those of SHTG. Details of SHTG membership are available on the Healthcare Improvement Scotland [website](#).

Chair

Scottish Health Technologies Group



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