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Innovation in surgical technique

Safety and feasibility of a new rectoscope in rectal cancer surgery. First clinical trial



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ABSTRACT

We present a first in human clinical trial of a new rectoscope that shows, by means of transillumination, the optimal point of transection of the rectum in oncologic surgery. The device was developed together with a team of engineers and was manufactured by 3D printing. Eighteen patients with a mean age of 71 years and a mean distance from the tumor to the anal margin measured by colonoscopy of 10.4 ± 3.9 cm and by MRI of 10 ± 2.4 cm were included in the trial. Transillumination was feasible in all cases, and the use of the rectoscope was safe, as no adverse events due to its use were recorded.

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Seguridad y factibilidad de un nuevo rectoscopio en la cirugía por cáncer de recto. Primer ensayo clínico

RESUMEN

Presentamos el ensayo clínico de un nuevo rectoscopio que muestra, mediante transiluminación, el punto óptimo de transección del recto en cirugía oncológica. El dispositivo se desarrolló en colaboración con un equipo de ingenieros y fue fabricado mediante impresión 3D. Se incluyeron en el ensayo 18 pacientes con una edad media de 71 años y una distancia media del tumor al margen anal medida mediante colonoscopia de 10.4 ± 3.9 cm y mediante RMN de 10 ± 2.4 cm. La transiluminación fue factible en todos los casos durante la cirugía laparoscópica rectal, y el uso del rectoscopio fue seguro, ya que no se registraron acontecimientos adversos debidos a su utilización.

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Palabras clave:

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Introduction

In the surgical treatment of rectal cancer, a balance must be found between radicality (prevention of local recurrence) and functionality (preservation of defecatory function), since the level of the rectal anastomosis has been associated with low anterior resection syndrome and decreased quality of life of patients undergoing surgery for rectal cancer.¹

The traditional rule of 5 cm distal resection margin was questioned in the 1980s, when it was found that intramural and distal lymphatic spread of rectal tumours was uncommon beyond 1 cm from the mucosal margin of the tumour. This led to a reduction in the optimal length of the distal resection margin, allowing sphincter-sparing surgeries to be performed in patients with low rectal cancer, without compromising oncological results.^{2,3}

The NCCN® Rectal Cancer recommendations currently advise that the resection extend 4–5 cm below the distal border of the tumour to ensure adequate mesorectal excision. In rectal cancers located less than 5 cm from the anal margin, a distal margin of 1–2 cm is considered acceptable.³

In partial mesorectal resections, the selection of the rectal transection point is challenging, especially in those rectal tumours that are not visible from the abdominal approach, either because the tumour is at an early stage, the tumour is hidden by the mesorectum or due to a good response to neoadjuvant therapy.

Intraoperative rectoscopy allows measurement of the distance of the tumour from the anal margin and is often used to evaluate the distal resection margin.

In addition to intraoperative rectoscopy, different methods have been described to improve the selection of the rectal transection point, such as preoperative endoscopic staining with India ink⁴ or eversion of the distal rectal stump in low resections.⁵

The need to improve the intraoperative choice of the point of section of the rectum has been one of the drivers of the development of total mesorectal excision through a transanal approach (TaTME).⁶

Surgical technique

Device

A new rectoscope is presented with a mobile light source that transilluminates the rectal wall and makes it easier for the surgeon to visualise the transection point for the desired distal resection margin in rectal cancer surgery (Fig. 1).

This device was designed at the La Paz University Hospital, Madrid, and was developed together with the engineering team of the MaqLab of the Carlos III University, Madrid, and the engineering company UpDevices. It was manufactured by the company Tekniker 4, Eibar (Gipuzkoa), using 3D printing. This additive printing technique allows small series of devices to be manufactured in the prototyping phases, reducing the large costs involved in large-scale industrial manufacturing. The device was patented in 2017.⁷

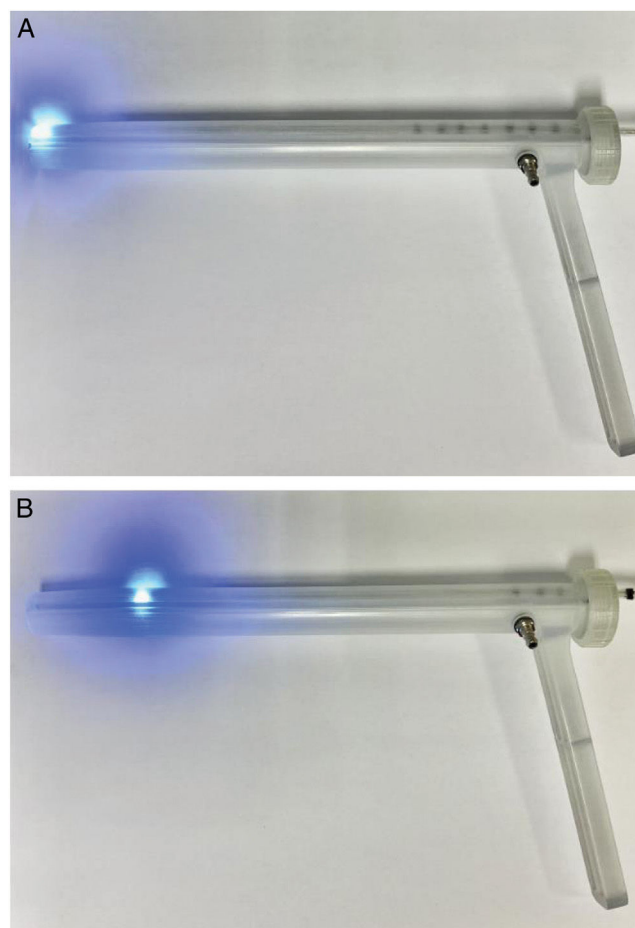


Fig. 1 – A. Rectoscope with the moving light source in initial position positioned at the distal edge of the tumour. B. Rectoscope in which the light source has been moved to the distance desired by the surgeon. The light source, visible by transillumination to the surgeon, moves distally the desired distance from the tumour in the rectoscope and corresponds to the distal section margin.

The main novelty is that this rectoscope has a mobile light source, which shows the surgeon the transection point by transillumination of the rectal wall.

Once the rectum is freed and before transection, the rectoscope is introduced by the assistant, who, using direct vision, locates the tumour and positions it at the distal edge of the tumour. In the case of patients with a good response to neoadjuvant therapy, locating the tumour or tumour scar may be difficult, although there are usually signs of regression and the rectoscope is positioned at this point.

Next, the surgeon indicates to the assistant performing the rectoscopy the desired length of the distal resection margin and the assistant moves the mobile light source to the length desired by the surgeon, without moving the rectoscope from the distal end of the tumour.

With the radial light source of the rectoscope, the rectal wall is transilluminated at the transection point, allowing the desired distal resection margin to be obtained (Fig. 2).

To improve transillumination ability through the rectum, the rectoscope is used with laparoscopic vision in ICG mode.



Fig. 2 – Transillumination of the rectoscope with light through the rectal wall. The increase in visibility conferred by the use of the ICG mode in the laparoscopy camera makes it unnecessary to reduce the laparoscopy light source to be able to objectivise the light of the rectoscope.

This enhances its usual white light which is displayed in green, eliminating the need to reduce the laparoscopy light source to better appreciate the transillumination.

This use of the ICG mode is carried out without the injection of indocyanine green to the patient, since the objective is to visualize the light of the rectoscope in green, which is achieved simply by the ICG mode, and not to evaluate the vascularisation of the tissues.⁸

Next, within the transilluminated area, we proceed to mark the point where the transillumination is maximum, since there is some dispersion of light on the rectal wall. At this point the transection is carried out, by the usual means.

Clinical trial

A prospective, single-centre study was conducted on the safety of using the rectoscope and the feasibility of rectal transillumination to mark the transection point under direct vision in rectal cancer surgery. This project was carried out thanks to a Technological Development in Health aid, granted by the Carlos III Health Institute (DTS16/00100).

After signing the informed consent, 18 patients with rectal cancer were included in the study.⁷ The study was conducted following the ethical principles of the Declaration of Helsinki (1964) and was approved by the Drug Research Ethics Committee of the La Paz University Hospital of Madrid (PI-5446). The primary objective was to evaluate the possible adverse effects associated with the use of the device. The included patients were diagnosed with rectal cancer through colonoscopy and all underwent CT and MRI for staging and measurement of the distance of the tumour from the anal verge. Postoperative complications at 30 days were recorded using the Clavien-Dindo scale.⁸

Preliminary results

The mean age of the 18 patients (13 men and 5 women) was 71.1 ± 11.5 years. The mean distance from the tumour to the anal verge measured by colonoscopy was 10.4 ± 3.9 cm and by MRI was 10 ± 2.4 cm. In all surgeries it was possible to identify

the transection point by transilluminating the device through the rectal wall. No intraoperative adverse effects related to the use of the rectoscope were observed.

Regarding postoperative complications, eight patients presented Clavien-Dindo grade I complications, five cases grade II, two cases 3A and two cases 3B.⁹ Postoperative complications were associated with the comorbidity of the operated patients and surgical complications, but none of them were related to the use of the rectoscope.

In all cases, a rectal resection was performed with a negative distal margin greater than 1 cm. An unsatisfactory mesorectal excision was reported in one patient.

Discussion

In this first clinical trial in humans, it has been shown that the use of this rectoscope is safe (there were no complications derived from its use) and feasible (transillumination of the rectum was verified in all patients, which allowed adequate selection of the point of rectal transection).

In lower rectal cancer surgery using an abdominal approach, the technical difficulty of the distal section, both in choosing the appropriate transection point and in the use of the endostapler, has led to the development of the transanal approach and the introduction of new ways of doing the colorectal anastomosis.⁶

This rectoscope provides the same functionalities as a regular rectoscope and adds the possibility of direct transillumination of the rectal wall, allowing the surgeon to visualise the transection point, under direct vision of the lower edge of the tumour.

Another possible use of this rectoscope, which has not been the subject of this trial, but has emerged in its development, is to assist in performing rectal skinning or shaving in rectal endometriosis or peritoneal carcinomatosis, since that rectal transillumination allows intraoperative appreciation of the thinning of the rectal wall.

Furthermore, in a later development, this rectoscope could be easily digitalised, with the introduction of a camera in its light that would allow the entire surgical team to see it through the screen.

Conflict of interests

The authors have no conflict of interests to declare.

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