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Prospective observational non-randomized trial protocol for surgical planner 3D image processing & reconstruction for locally advanced colon cancer

Sebastián Jerí-McFarlane[1,2,3], Álvaro García-Granero[1,2,3*], Gianluca Pellino[4,5], Noemi Torres-Marí[1], Aina Ochogavía-Seguí[1], Miguel Rodríguez-Velázquez[6], Margarita Gamundí-Cuesta[1] and Francisco Xavier González-Argenté[1,3]

Abstract

Introduction Colon cancer presents significant surgical challenges that necessitate the development of precise strategies. Standardization with complete mesocolic excision (CME) is common, but some cases require extended resections. This study investigates the use of 3D Image Processing and Reconstruction (3D-IPR) to improve diagnostic accuracy in locally advanced colon cancer (LACC) with suspected infiltration and achieve R0 surgery.

Methods Single-center, prospective, observational, comparative, non-randomized study.

•*Participants*: Patients aged > 18 years undergoing LACC surgery, as indicated by CT scans, confirmed via colonoscopy. Exclusion criteria include neoadjuvant therapy, suspected carcinomatosis on CT, and unresectable tumors.

•*Interventions*: 3D-IPR models are used for surgical planning, providing detailed tumor and surrounding structure metrics. Surgical procedures are guided by CT scans and intraoperative findings, categorized by surgical margins as R0, R1, or R2.

•*Objective*: The primary goal is to evaluate 3D-IPR's utility in achieving R0 resection in LACC with suspected infiltration. Secondary objectives include assessing preoperative surgical strategy, comparing CT reports, detecting adenopathy, and identifying vascularization and anatomical variants.

• *Outcome*: The main outcome is the diagnostic accuracy of 3D-IPR in determining tumor infiltration of neighboring structures compared to conventional CT scans, using definitive pathological reports as the gold standard.

Results

•*Recruitment and Number Analyzed*: The study aims to recruit about 20 patients annually over two years, focusing on preoperative 3D-IPR analysis and subsequent surgical procedures.

•*Outcome Parameters:* These include loco-regional and distant recurrence rates, peritoneal carcinomatosis, disease-free and overall survival, and mortality due to oncologic progression.

•*Harms*: No additional risks from CT scans, as they are mandatory for staging colon tumors. 3D-IPR is derived from these CT scans.

*Correspondence:
Álvaro García-Granero
alvarogggf@hotmail.com
Full list of author information is available at the end of the article

Discussion If successful, this study could provide an objective tool for precise tumor extension delimitation, aiding decision-making for radiologists, surgeons, and multidisciplinary teams. Enhanced staging through 3D-IPR may influence therapeutic strategies, reduce postsurgical complications, and improve the quality of life of patients with LACC.

Trial registration Trial is registered at ISRCTN registry as ISRCTN81005215. Protocol version I (Date 29/06/2023).

Keywords Innovation, Colon neoplasm, 3D Reconstruction, Colorectal surgery

Introduction

Background and rationale

Colon cancer is one of the most prevalent oncologic pathologies of the abdomen; therefore, specific surgical strategies needed to treat this pathology must be known. Currently, there is evidence of standardization of the surgical technique for colon resections using complete mesocolic excision (CME) [1–3]. However, in certain cases, such as suspected infiltration of the retroperitoneum (pre-renal fat, duodenum, etc.) or neighboring anatomical structures, the technique should be modified [4]. Thus, wider resections are performed to obtain better oncologic results, leaving neither macro nor microscopic tumors (R0) nor free surgical margins. Likewise, there is published evidence that the rates of disease-free patients increase after R0 surgery, as well as a decrease in the rates of local tumor recurrence and the risk of carcinomatosis [5].

Locally advanced colon cancer presents with greater difficulty in performing Minimally Invasive Surgeries (MIS), an increased risk of perioperative complications, and an increased risk of locoregional recurrence [4, 6–8].

On the other hand, the gold standard technique for colon cancer staging is computed tomography (CT) [9]. However, in more advanced cases in which possible or suspicious infiltration of the retroperitoneal margin or neighboring structures is observed, sensitivity and specificity decrease with a diagnostic accuracy of 60% for possible tumor infiltration [10, 11].

Colon cancer staging is performed based on the anatomopathological study of the surgical specimen: T1, T2, T3, T4, T4a, and T4b, according to the depth of invasion in each layer of the colon. CT can detect tumor invasion beyond the intestinal wall (T1/T2 vs. T3/T4), but current studies have shown great variability, with a sensitivity of 55–98% and a specificity of 33–100%. Furthermore, when comparing the diagnostic accuracy of CT with pathological anatomy in cases of T3-T4 tumors, a correct diagnosis by CT was only observed in 66%, 76%, and 54% of cases in T3, T4a, and T4b, respectively. This translates into a high percentage of patients with unknown invasion of neighboring structures [9, 11].

The diagnostic accuracy of CT for T4a and T4b tumors is fundamental for surgical planning. Prophylactic Hyperthermic Intraperitoneal Chemotherapy (HIPEC) has been proposed for T4a and T4b colon cancer, with the main objective of reducing the risk of peritoneal carcinomatosis recurrence [12, 13]. Nonetheless, the percentage of overstratification in CT scans is the main problem when performing this strategy. Recent studies suggest neoadjuvant chemotherapy for T4b tumors; however, the low diagnostic accuracy of CT in these cases challenges the practice of this approach [14].

Therefore, new methods have been proposed to improve specificity when assessing the retroperitoneal margin or infiltration of neighboring structures in colon cancer. These involve the use of three-dimensional image processing and mathematical reconstruction models to assess possible infiltrations that require a change in the surgical approach. Previous studies have already demonstrated the use of 3D-IPR to assess possible infiltrations in rectal tumors and the consequent change in surgical approach to achieve R0 surgery [2, 15–17].

Therefore, we propose the use of 3D reconstruction models to assess cases in which infiltration of neighboring structures and/or the retroperitoneal margin is suspected. This means that artificial intelligence algorithms are used on CT images to create a three-dimensional model showing different anatomical structures. In addition, this software (CELLA Medical Solutions®) can "look" more closely and with enhanced detail at possible areas of infiltration known as 3D image processing and reconstruction (3D-IPR).

This study aims to demonstrate the usefulness of 3D-IPR to obtain surgeries with R0 resection in patients with locally advanced colon cancer with suspected infiltration.

A 3D-IPR model based on mathematical algorithms from CT could improve the diagnostic accuracy of suspected tumor infiltration of the retroperitoneal margin and neighboring structures in advanced tumors of the right, transverse, and left colon. This is a novel tool to establish a correct surgical strategy to increase the percentage of R0-type resections in these types of tumors.

Objectives

The main objective of this study is to assess the usefulness of 3D-IPR to obtain surgeries with R0 resection in patients with Threatened Surgical Margin (TSM), either

by threatened retroperitoneal margin or suspected infiltration of neighboring structures in cancer of the right, transverse, and left colon.

Secondary objectives are to assess the usefulness of 3D-IPR as a preoperative surgical strategy tool, compare the diagnostic accuracy of 3D-IPR with the radiological CT report regarding the infiltration of neighboring structures and retroperitoneal margin in colon tumors with TSM, evaluate the usefulness of 3D-IPR to detect pathological or suspicious adenopathy and evaluate the use of 3D-IPR to point out the main vascularization, as well as the possible anatomical variants of the right and left colon.

Trial design

Single-center, prospective, observational, comparative, non-randomized study.

Methods: participants, interventions and outcomes

This study has been approved by the Balearic Islands research ethics committee (CE-IB) (ID: IB 5113/23 PI).

Study setting

Colorrectal Department at Hospital Universitario Son Espases, Palma de Mallorca, Spain.

Eligibility criteria

- Patients diagnosed with primary colon cancer located in the right, transverse and/or left colon by colonoscopy. Locally advanced tumors with suspected infiltration of neighboring structures and/or retroperitoneal margin or those considered as T3 or T4 (TNM staging classification), according to the radiologist's report from the extension CT.
- Over 18 years of age
- Patients who agree and sign informed consent for surgical intervention.

Exclusion criteria

- Preoperative chemotherapy or radiotherapy (neoadjuvant treatment).
- Suspicion of carcinomatosis in preoperative CT scans.
- Patients with infiltrating tumors considered unresectable, either preoperatively or intraoperatively, will be excluded, as anatomopathological analysis will not be available. This is because the only way to evaluate the diagnostic accuracy of 3D-IPR is through the pathology report, which confirms or discards the infiltration areas detected by 3D-IPR. In case of excluded patients intraoperatively, they are going to be considered as roll-out patients from the study.

Interventions

Preoperative 3D-IPR

Mathematical 3D reconstruction is extracted from the anonymized pre-operative CT, which is performed in all patients with colon neoplasms, to assess the location of the primary colon tumor and possible infiltration of neighboring or retroperitoneal structures. 3D-IPR will evaluate the same parameters exposed for the CT of the abdomen. Moreover, 3D-IPR will be based on two concepts. Firstly, preprocessing of the CT of extension using "Bias Field Correction" algorithms and anisotropic diffusion filters of the image. Secondly, medical image segmentation in the different sequences provided using a sequence of algorithms based on active contour methods, modified dynamic search, and based on atlases. Finally, the 3D surface will be reconstructed using modified "*marching cubes*" algorithms.

3D-IPR is viewed by using an online website through a user-friendly interface that requires almost no learning curve. These website can be accessed by using a login and password and can be viewed in any device (laptops, tablets o mobile phones).

All this analysis will be performed in conjunction with the 3D Reconstruction and 3D Printing Unit at the reference hospital.

Surgical procedure

The intervention will always be performed according to the radiological report from the preoperative CT scan and intraoperative findings. The assessment of tumor infiltration by the 3D reconstruction technique will not modify the surgical technique decided preoperatively based on the radiological report of the preoperative CT.

3D reconstruction is supplementary and not a replacement for the standard preoperative assessment with CT scans. However, if the 3D reconstruction identifies a surgical contraindication that the standard CT scan did not, the surgeons will not be blinded from the results of this reconstruction. The 3D reconstruction serves as an additional tool, offering more detailed spatial information. If a clinically significant contraindication is identified through this advanced technique, the surgical team will be informed, and their preoperative decisions in a multidisciplinary committee may be reassessed.

Surgical procedures will follow international guidelines with complete mesocolic excision and ligation and

division of the following structures depending on tumor location [18]:

Right side colon cancer – Right hemicolectomy: High tie of ileocolic vessels and high tie of the right branch of middle colic vessels is performed, extending the colon resection to the proximal third of the transverse colon.
Transverse colon cancer – Extended right colectomy: In cases of transverse colon cancer, literature suggests extended right colectomy in young, fit patients, while a transverse or segmental colon resection with high tie of middle colic vessels is accepted for older patients.
Splenic flexure colon cancer – Segmental colon resection vs. extended left colectomy: Both procedures are accepted. Segmental splenic flexure resection involves a high tie of the left middle colic vessels and a high tie of the left colic vessels. In the case of an extended left colectomy, apart from the high tie of the left middle colic vessels, a high tie of the inferior mesenteric artery must be performed.
Left colon cancer – Left hemicolectomy: Resection involves a high tie of the inferior mesenteric artery and the division of the inferior mesenteric vein under the inferior border of the pancreas.
Sigmoid colon cancer – Sigmoidectomy: Acceptable resection involves high tie of inferior mesenteric artery with division of inferior mesenteric vein after left colic vein division.

Extended resection must be done *en-bloc* with the surgical specimen, avoiding its fragmentation, to complete a R0 resection with free surgical margins in the pathology report.

The team decided to start this clinical trial because of the potential benefit of 3D-IPR for surgical planning in previous isolated cases. Although there have been case reports and small case studies trying to show 3D-IPR benefits, a large case series has been published before this research. There is currently a lack of prospective evidence on the use and benefits of 3D-IPR for colorectal surgical planning and its oncological outcomes for morbidity and survival rates as well as recurrence rates. It is important to state that 3D-IPR does not change the current management of colon cancer patients, as 3D-IPR can be retrieved from preoperative CT scans that are part of the usual workflow plan for these patients.

Outcomes

The present study pretends to evaluate if 3D-IPR observes more diagnostic accuracy for infiltration of colon cancer compared to conventional imaging to aid surgical planning, reduce intraoperative complications, and improve oncological outcomes. Complete mesocolic excision is the current standard of care for colon neoplasms and extended resections must be done in cases of advanced tumors with suspicious neighbor structures infiltration. This is where 3D-IPR has proven to aid colorectal surgeons in creating a surgical plan before doing the actual surgical procedure. Thus, increasing the possibility of a complete specimen resection and R0 surgery that could improve oncological outcomes in terms of lower local and distant recurrence rates [2, 19–22].

Subsequently, we will analyze the surgical specimens together with the anatomic pathology department to confirm whether CT and 3D-IPR are sensitive for the detection of infiltration in cases of colon cancer. In this way, it constitutes an important tool for general and digestive surgeons during surgical strategy planification to be able to assess whether it is necessary to extend the resection to obtain optimal oncological results.

Oncologic variables analyzed at 3 and 5 years:

- Loco-regional recurrence: intraluminal tumor growth near the suture or within the cavity near the previously operated location.
- Distant recurrence: distant metastasis outside the abdominal cavity.
- Peritoneal carcinomatosis: It will be considered carcinomatosis when there are tumor implants in at least two different areas of the abdominal cavity with an anatomopathological diagnosis of the presence of tumor cellularity. This makes it possible to differentiate it from loco-regional recurrence.
- Disease-free survival: Time from surgery to the date on which recurrence is documented.
- Overall survival: time from admission to death from any cause (includes 90-day post-operative mortality).
- Mortality due to oncologic progression.

All patients with recurrent disease should be confirmed, if possible, histologically or by radiological imaging or new surgery.

Participant timeline

Work plan

For two years, the colorectal unit will carry out the study:

- Identification of patients who are candidates for the study according to material and methods.
- Referral of the pre-operative CT scan to CELLA Medical Innovation and Technology (software owner) for the elaboration of the 3D reconstruction and assessment of tumor infiltration.

- Surgical intervention.
- Detailed microscopic study of the surgical specimen and definitive anatomopathological report.
- Incorporation of data into the prospective database.
- Remission of all microscopic images to the main investigator for storage.

During the following 6 months, the analysis of results, assessment of strategies, and communication of results will be carried out.

Coordination program of the project

- *Phase 1*. Familiarization of the whole team with the study protocol. The reference center must present a perfect coordination between four different specialties: colorectal surgery, pathological anatomy, radiology, and oncology.
- *Phase 2.* The selection of cases will follow the guidelines set out in the protocol.
- *Phase 3.* Surgical intervention of the patients.
- *Phase 4.* Analysis of the surgical specimen by pathologists. For the anatomopathological study of the cases, the guidelines set out in the protocol will be followed.
- *Phase 5.* Incorporation of results into the database. Database created especially online for this study.
- *Phase 6*. Analysis of results.
- *Phase 7*. Analysis of oncologic variables at 3 years.
- *Phase 8.* Analysis of oncologic variables at 5 years.

Sample size

As this is an innovative study in which a preoperative technique utility is going to be used and has not been analyzed yet, there is no previous bibliography. The study will be carried out in all cases that meet the inclusion and exclusion criteria established in a colorectal unit at reference hospital. It is considered that the number of patients operated in a reference colorectal unit will be around 20 patients per year with the characteristics described in the methodology.

Methods: data collection, management and analysis

Data collection methods

The colorectal unit at the reference center is currently recruiting patients. The approximate end of the recruitment will be in the 1st year of initiating recruitment. The protocol has been structured following the Standard Protocol Item: Recommendations for Interventional Trials (SPIRIT 2013) checklist [23].

This trial is registered at ISRCTN registry as ISRCTN81005215.

Data management

The information is stored in cloud servers owned by Oracle. The information is encrypted in Database (DB) so any direct access to the DB is useless unless the private key is known. No data that could be used to locate the patient such as name, surname, ID number, etc., is requested. The only data that could be used is the Clinical history ID, which is trimmed, so that the user who reports data can locate the correspondence in his/her hospital, i.e. he must have the real data written down in some place controlled only by him (such as the hospital management program itself) to be able to locate that patient.

In the event of access to the application by someone unauthorized but who has obtained a username and password with access to read patients from their own and other hospitals, the information available does not serve to "de-anonymize" the data. The accesses to the application, writings, readings, etc. are registered by the application so that any access without express authorization can be located.

Statistical methods

Qualitative variables will be expressed by sample size and percentage. Quantitative variables will be expressed by median and range.

In non-parametric univariate analysis, continuous variables will be compared by the Kruskal–Wallis test, while categorical variables will be compared by the Fisher's Exact test. A p-value < 0.05 will be considered statistically significant.

Discussion

If greater diagnostic accuracy is observed from this mathematical method of 3D-IPR with respect to infiltration of neighboring structures in locally advanced colon tumors:

- Radiologists would have an objective tool to delineate tumor extension.
- Surgeons would have an objective tool to program the type of surgical intervention with less probability of modifying it during the operative time. In addition, this 3D tool facilitates the preoperative visualization of the tumor location in a compartment where numerous anatomical structures coincide.
- This type of intervention may require the collaboration of other specialties, such as gynecology, urology, vascular surgery, traumatology, and plastic surgery. Correct surgical planification of the type of extended

resection to be performed is essential. To this end, this tool would provide the necessary data for this purpose.

- The discussion of this type of pathology in a Multidisciplinary Committee within the Colorectal Units is frequent and knowing exactly the degree of infiltration of anatomical structures facilitates decision-making.
- Selection of a better therapeutic strategy for locally advanced tumors: direct surgery, prophylactic HIPEC and neoadjuvant chemotherapy.
- The surgery of locally advanced colon tumors presents a high rate of post-surgical complications as well as an affected surgical resection margin. This tool could improve these results considerably.
- The fact that the patient is not subjected to a new diagnostic test to obtain this reconstruction is an important advantage since it is performed using a technique used by protocol to stage this oncologic pathology.

The discussion of this type of pathology in a multidisciplinary committee within a referral colorectal unit is frequent and knowing the exact degree of infiltration of anatomical structures facilitates decision-making. At the present time, there are different therapeutic lines for locally advanced colon tumors. Among them, we find direct surgery and subsequent adjuvant chemotherapy, there is also evidence of performing neoadjuvant chemotherapy and subsequent resection and finally, recent studies propose surgery with intraoperative hyperthermic peritoneal chemotherapy (HIPEC). For this reason, correct staging is essential to avoid overtreatment.

An R0 surgery decreases the risk of oncologic recurrence. This fact reduces the number of patients requiring chemotherapy treatment for this reason, long-term follow-up, the number of face-to-face consultations and complementary tests.

In this way, 3D reconstruction is a tool that could provide digital solutions for healthcare, promoting the development and use of these innovative techniques to improve the quality of life of patients. This explains the need to promote the development of these technologies, considering their security, confidentiality, and standardization, to improve the quality of life of patients.

The surgery of locally advanced colon tumors presents a rate of post-surgical complications that can be high, as well as an affected surgical resection margin. This tool could improve these results considerably. For this reason, if the results manage to change the surgical attitude, the radiology and pathological anatomy services will be informed about this observational study to carry out new clinical trials.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12893-024-02558-1.

Supplementary Material 1.

Supplementary Material 2.

Disclosure

Álvaro García-Granero works for Cella Medical Solutions. He served as technical adviser for the current manuscript. Drs. Sebastián Jerí-McFarlane, Gianluca Pellino, Noemi Torres-Marí, Aina Ochogavía-Seguí, Miguel Rodríguez-Velázquez, Margarita Gamundi-Cuesta & Francisco Xavier González Argenté have no conflict of interest or financial ties to disclose.

Dissemination policy

Dissemination of the results in the National Congress of Surgery (Asociación Española de Cirujanos), National Congress of Coloproctology (Asociación Española de Coloproctología – AECP), International Congress of European and American Coloproctology and European Congress of Endoscopic Surgery. Articles of the study will be sent to high-impact factor journals, most likely Q1 Journal Citation Reports (JCR) journals.

Authors' contributions

SJM wrote and revised the manuscript. AGG wrote and revised the manuscript. GP revised the manuscript. NTM helped writing the manuscript. AOS Revised the manuscript. MRV Wrote part of the manuscript and revised the final version. MGC Revised the manuscript. FXGA Revised the final draft.

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Availability of data and materials

The datasets generated and analyzed in the present study are available from the corresponding author upon reasonable request.

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study has been approved by the Balearic Islands research ethics committee (CE-IB) (ID: IB 5113/23 PI). Patients will be informed of the possibility of participation in the study and will need to sign an informed consent form (Human Ethics and Consent to Participate) before enrollment. Patients will be able to withdraw consent at any time without affecting their medical care they will receive. Moreover, the study will be performed in accordance with the Declaration of Helsinki. The main investigators will be responsible for adequate inclusion of patients and data recording.
All patients receive a patient information sheet for research projects (Appendix A) and signed a written informed consent (Appendix B).

Competing interests

The authors declare no competing interests.

Author details
[1]Colorectal Unit, General & Digestive Surgery Department, Hospital Universitario Son Espases, Palma, Spain. [2]Instituto de Investigación Sanitaria Illes Balears (IdISBa), Palma, Spain. [3]University of Islas Baleares, Palma, Spain. [4]Department of Advanced Medical and Surgical Sciences, Università Degli Studi Della Campania "Luigi Vanvitelli", Naples, Italy. [5]General & Digestive Surgery, Colorectal Unit, Vall D´Hebron University Hospital, Barcelona, Spain. [6]Innovation and Technology Department, Cella Medical Solutions, Murcia, Spain.

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