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3D reconstruction for the assessment of tumor infiltration in colon cancer

Submission date
26/01/2024

Recruitment status
No longer recruiting

Registration date
28/02/2024

Overall study status
Completed

Last Edited
07/02/2025

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Surgical treatment of locally advanced colon cancer (suspected infiltration of neighboring structures) requires interventions with a high rate of complications and risk of death. The most important prognostic factor for survival is to achieve surgery with infiltration-free margins, known as surgery with R0 resection. Despite imaging and technological advances, infiltrated surgical margin rates remain high for this type of tumor due to the complexity of the procedures. The preoperative surgical strategy is important in deciding how the tumor will be approached surgically and a change in surgical strategy must be made to obtain an optimal resection. If the operating surgeons could have a preoperative 3D reconstruction of the case, this would help them to have a better idea of the lesion. In this way, it could allow surgeons to prepare the surgical intervention beforehand and try to find the best surgical route for each given case. In addition, the surgeon can practice the upcoming surgery on the 3D print or visualize it on the computer to virtually walk through and experiment with the anatomical part that he or she will be facing on the operating table days later. As these are surgeries that sometimes require resection of multiple structures or extended resections, the preoperative strategy is essential to decide which organs should be removed together with the colon cancer. Preoperative simulation using 3D printing could help to get a more accurate idea of the structures involved and whether a more extensive resection is necessary. This study aims to assess whether 3D models in locally advanced colon cancer (right, transverse or left) are useful to improve the care provided to patients, improve surgical indications, and assess the anatomical variants of the blood vessels that irrigate the colon and thus try to reduce the rate of complications in this type of surgery.

Who can participate?
Patients over 18 years of age 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.

What does the study involve?
A computed tomography (CT) scan will be performed to define the colon tumor (staging) before surgery. With this CT scan, the 3D model reconstruction is performed.

In a multidisciplinary committee the CT result is used to decide which type of surgical intervention is best. The tumor is analyzed with the anatomic pathology team and compared with the 3D and CT models performed. Information will be collected for 1 year and a half.

What are the possible benefits and risks of participating?
If the operating surgeons could have a preoperative 3D reconstruction of the case, this would help them to have a better idea of the lesion. It could allow surgeons to prepare the surgical intervention beforehand and try to find the best surgical route for each given case. In addition, the surgeon can practice the upcoming surgery on the 3D print or visualize it on the computer to virtually walk through and experiment with the anatomical part that he or she will be facing on the operating table days later. As these are surgeries that sometimes require resection of multiple structures or extended resections, the preoperative strategy is essential to decide which organs should be removed together with the colon cancer. Preoperative simulation using 3D printing could help to get a more accurate idea of the structures involved and whether a more extensive resection is necessary.
The risks of this study are the same as the risks derived from the surgery itself, which the researchers want to find out whether it is possible to reduce the risks with the use of reconstruction with 3D models. There are no risks associated with CT scanning since this is a mandatory step in the staging of colon tumors and should be performed in all patients who wish to treat their disease.

Where is the study run from?
Hospital Universitario Son Espases (Spain)

When is the study starting and how long is it expected to run for?
February 2023 to June 2025

Who is funding the study?
1. Asociación Española de Coloproctología (Spain)
2. Hospital Universitario Son Espases (Spain)

Who is the main contact?
Dr Sebastián Jerí Mc Farlane, Sebastian.jeri@ssib.es

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Dr Álvaro García-Granero

ORCID ID
http://orcid.org/0000-0003-1644-1241

Contact details
Carretera de Valldemosa 79
Palma
Spain

07120
+34 (0)678411230
alvarogggf@hotmail.com

Type(s)
Public, Scientific

Contact name
Dr Sebastian Jeri

ORCID ID
http://orcid.org/0000-0003-0319-2872

Contact details
Carretera de Valldemosa 79
Palma
Spain
07120
+34 (0)691860296
Sebastian.jeri@ssib.es

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IB 5113/23 PI

Study information

Scientific Title
3D image processing and reconstruction for the assessment of tumor infiltration in colon cancer: prospective observational non-randomized trial

Acronym
3D-IPR, TUMOR INFILTRATION

Study objectives
A 3D image processing and reconstruction (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 with the aim of increasing the percentage of R0-type resection in this type of tumors.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/06/2023, Comité De Ética De La Investigación De Las Islas Baleares (C. del calçat, 2 A, 2n, Palma, 07011, Spain; +34 (0)971177378; ceic_ib@caib.es), ref: IB 5113/23 PI

Study design
Prospective observational non-randomized trial

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Medical and other records

Study type(s)
Diagnostic, Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Patients with locally advanced colon cancer and suspected infiltration in computed tomography scans

Interventions
For 2 years, the colorectal unit will carry out the study:
1. Identification of patients who are candidates for the study according to material and methods in the protocol
2. 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
3. Surgical intervention
4. Detailed microscopic study of the surgical specimen and definitive anatomopathological report
5. Incorporation of data into the prospective database

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

Intervention Type
Procedure/Surgery

Primary outcome measure
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. 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.

Secondary outcome measures
1. The usefulness of 3D-IPR as a preoperative surgical strategy tool, comparing 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:
Mathematical 3D reconstruction is extracted from the 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/retroperitoneal structures.
3D-IPR will be based on two concepts:
1.1. Preprocessing of the CT of extension using "Bias Field Correction" algorithms and anisotropic diffusion filters of the image.
1.2. 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.
After CT segmentation, 3D-IPR detects possible infiltration areas and marks them with red colouring. 3D-IPR will be compared to the anatomopathology report to confirm a complete or incomplete coincidence.
Timepoints: 2.5 years
2. The usefulness of 3D-IPR to detect pathological or suspicious adenopathy: 3D-IPR uses segmentation to detect possible lymph nodes in the mesocolon. Suspicious adenopathies located in 3D-IPR will be confirmed in the anatomopathology report to confirm a complete or incomplete coincidence. Timepoints: 2.5 years
3. The use of 3D-IPR to point out the main vascularization, as well as the possible anatomical variants of the right and left colon: 3D-IPR uses segmentation from CT and creates a 3D render of all anatomical structures. This creates a more visual representation of the abdominal vascularization and may detect possible variants. Timepoints: 2.5 years
4. Oncological variables analysis at 3 and 5 years such as:
4.1. Loco-regional recurrence: intraluminal tumor growth near the suture or within the cavity near the previously operated location.
4.2. Distant recurrence: distant metastasis outside the abdominal cavity.
4.3. Peritoneal carcinomatosis: It will be considered carcinomatosis when there are tumor implants in at least two different areas of the abdominal cavity with anatomopathological diagnosis of the presence of tumor cellularity. This makes it possible to differentiate it from loco-regional recurrence.
4.4. Disease-free survival: time from surgery to the date on which recurrence is documented
4.5. Overall survival: time from admission to death from any cause (includes 90-day post-operative mortality)
4.6. Mortality due to oncologic progression

Overall study start date
01/02/2023

Completion date
01/06/2025

Eligibility

Key inclusion criteria

1. 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.
2. Over 18 years of age
3. Patients who agree and sign informed consent for surgical intervention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
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 the 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.

Total final enrolment
21

Key exclusion criteria
1. Preoperative chemotherapy or radiotherapy (neoadjuvant treatment)
2. Suspicion of carcinomatosis in preoperative CT scan
3. Suspected distant metastasis on preoperative CT scan
4. Patients with infiltrating tumors considered unresectable (preoperatively or intraoperatively), since anatomo-pathological analysis will not be available

Date of first enrolment
30/06/2023

Date of final enrolment
01/02/2025

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario Son Espases
Carretera de Valldemosa 79
Palma
Spain
07120

Sponsor information

Organisation
Health Research Institute of the Balearic Islands

Sponsor details
Edificio S, Hospital Universitario Son Espases, Carretera de Valldemossa, 79
Palma
Spain
07120
+34 (0)871205234
idisba.calidad@ssib.es

Sponsor type
Research organisation

Website
http://www.idisba.es

ROR
https://ror.org/037xbgq12

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Asociación Española de Coloproctología

Alternative Name(s)
Spanish Association of Coloproctology, The Spanish Association of Coloproctologyl, La Asociación Española de Coloproctología, AECP

Funding Body Type

Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Spain

Funder Name
Hospital Universitario Son Espases

Results and Publications

Publication and dissemination plan
The primary goal of the dissemination plan is to share the groundbreaking research findings from this project with the broader society, including medical professionals, researchers, cancer patients, and the public. By effectively communicating their achievements, the researchers aim to raise awareness, promote understanding, and contribute to advancements in colon cancer treatment. The dissemination plan will be implemented throughout the project timeline, with ongoing activities to ensure continuous engagement and impact assessment. Regular reviews and adjustments will be made based on feedback and changing circumstances.

Active participation in national and international conferences, symposia, and workshops is planned for engaging with professionals in the field. This includes 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. To enhance scientific visibility, research findings will be submitted to prestigious medical journals with a high impact factor (most likely a Q1 Journal Citation Reports - JCR), being previously translated by an English expert. Media outreach through press releases, interviews, and social media will ensure broader visibility.

Intention to publish date
01/02/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.
The name of the repository: Cloud servers owned by Oracle (https://apex.oracle.com/pls/apex/r/estudio_colon_3d/estudiocolon3d/login_desktop)
The type of data stored: The information is encrypted so any direct access to it 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 their hospital, i.e. they must have the real data written down in some place controlled only by them (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.
The process for requesting access (if non-publicly available): The main researcher is the only one who can create a new user and password for access to the database. Users can only view records that they have uploaded, and records from other users cannot be seen or edited.
Whether consent from participants was required and obtained: Participants must sign an informed consent.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	31/10/2022	26/02/2024	No	Yes
Protocol file			26/02/2024	No	No
Protocol article		07/10/2024	08/10/2024	Yes	No
Results article		06/01/2025	07/02/2025	Yes	No