




Efficacy of robotic versus laparoscopic hepatectomy in patients with liver tumors, a systematic review protocol

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Summary

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Introduction: Liver resection remains the most effective method of treating liver tumors. Currently, the laparoscopic approach is considered the gold standard compared to the open approach; however, the emergence of robotic surgery offers a new minimally invasive approach option with apparently better results. The objective of this systematic review is to assess the benefits of robotic hepatectomy versus laparoscopic hepatectomy in the resection of liver tumors.

Methodology: This systematic review will include comparative, cohort, case-control studies with prospective or retrospective data collection. Study participants will be patients diagnosed with benign or malignant liver tumors, including children and adolescents, noncirrhotic or compensated cirrhotic, undergoing robotic hepatectomy and laparoscopic hepatectomy procedures. The primary outcome measures are: 1. Estimated blood loss during surgery, 2. Operative time, 3. Laparotomy conversion rate, 4. Intraoperative mortality rate, 5. Morbidity rate (postoperative complications), 6. Post-surgical hospital stay. Electronic searches will be conducted on PubMed, Medline, and ScienceDirect (2010 to present). The Cochrane study risk of bias assessment will be used. The mean differences (MD) and the 95 confidence intervals (CI) will be used as measures of the treatment effect. The evaluation of heterogeneity will be carried out by visual inspection of the funnel diagram. The evaluation of the quality of the evidence and 'Summary of findings' tables will be used by the GRADE test.

Keywords:

MESH: / Hepatectomy, Laparoscopy, Hepatic Neoplasms, Robotic Surgical Procedures, Treatment Results.

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Introduction

Condition Description

Liver tumors can be benign or malignant [1]. Benign tumors form a heterogeneous set of nodular liver lesions, generally developed in a healthy liver, distinguishing hepatic angiomas or hemangiomas (the most common) and focal nodular hyperplasias (FNHs), which do not have the potential to evolve towards malignancy, and they are resected if they are giant or symptomatic; on the other hand, hepatocellular adenomas, which can transform into hepatocellular cancer (they are usually hormone-dependent), for which resection is always recommended [1, 2]. Other benign liver tumors of mesenchymal origin that are known are angiomyolipoma, fibroma, leiomyoma, lipoma, and myxoma [1].

Malignant tumors are classified as primary (originating in the liver) or metastatic (spreading to the liver from an extrahepatic primary site). Primary liver cancers in turn can originate from hepatocytes, known as hepatocellular carcinomas (HCC or hepatomas), which are common in adults, while those originating from the bile ducts are known as cholangiocarcinomas (CC) and in turn are subdivided into intrahepatic, perihilar and extrahepatic or distal types [1, 3, 4].

Regardless of whether the cancer is in an early or advanced stage and despite the availability of nonsurgical treatments, liver resection remains the most effective method, especially in early stages, with solitary Child-Pugh A or B tumors, and cases with preserved portal venous pressure (hepatic venous pressure <10 mmHg) [1, 5]. The best candidates for major resections (> = 3 Couinaud segments) are noncirrhotic patients, while in cirrhotic patients with a solitary tumor, preserved liver function (Child-Pugh A; MELD <10) and absence of portal hypertension, resections are performed with small segmentectomies or enucleations [1, 6, 7].

Furthermore, the liver is a common site of metastasis, and these lesions are the most common in relation to malignant liver tumors. The most common sites of origin are the lung, breast, gastrointestinal (colon) and genitourinary tracts. Surgical indications for resection of liver metastases have gradually expanded, with liver resection being the first-line treatment for patients with resectable liver metastases, with 5-year

survival rates of 25% to 58% [1, 8]. In liver metastasis from gastrointestinal stromal tumors, liver resection is still justified in selected settings of disease progression [8].

In general, anatomic resection is better than non-anatomic resection in long-term results, considering the relatively acceptable heterogeneity, but nonanatomic resection is preferred in cases of poor liver reserve function, tumors in the margin, > 5 cm, or multiple tumors in different segments [9].

Description of the Intervention

The application of the minimally invasive approach (laparoscopic and robotic interventions) has been shown to be safe and effective for oncological and liver surgeries and is in constant development [10, 11].

In the early 2000s, the US Food and Drug Administration (FDA) approved Intuitive Surgical Inc.'s "da Vinci" surgical robot, leading robotic surgery to further improvements in the field of surgery, such as filtration of the tremor with minimally invasive fine dissection, instrument stability, three-dimensional (3D) view, and more comfort for the surgeon, with decreased conversion rates to open surgery and complications [12, 10, 13].

Thus, the surgical robot has been developed since its inception, rapidly expanding its indications for a wide variety of procedures, including very complex oncological surgeries such as esophageal gastrectomies and liver and pancreatic resections, with the advantage of being minimally invasive surgeries [12, 14].

Compared with traditional open surgery (laparotomy), less blood loss, shorter hospital stay, less postoperative pain, fewer adhesions, and faster postoperative recovery have been demonstrated with better results in the case of robotic hepatectomy for tumor resection [10, 12].

How the intervention might work

Robotic surgery shows good potential, since endowristed instruments function in a similar way to the surgeon's hands (resembling the movements of the radiocarpal joint), even with an intact abdominal wall [10], allowing minimally invasive surgery in areas that are difficult to access by conventional laparoscopy, including posterior superior segment liver resection [12], which is generally accepted as being converted to open surgery in the case of laparoscopic surgeries.

Using an optical tracking system calibrated in patients with liver tumors, robotic surgery uses image overlay navigation to locate lesions during these liver resections, with the literature suggesting that robotic imaging guidance can improve surgeon orientation, increasing the precision of tumor resection [14].

However, the technique is still under development and is limited by significant costs and by the lack of some instruments available for the laparoscopic approach, so the current evidence continues to be conflicting in relation to which is the best minimally invasive approach [10, 12].

Why it is important to do this review

There is no doubt that robotics have now become an easy portal to enter the minimally invasive surgical setting [12]; however, the paucity of universally accepted and proven data, especially in relation to long-term outcomes, motivates research on the effectiveness of robotic surgery compared to laparoscopic surgery, which is currently accepted as the gold standard for liver surgery, since it is well known that laparoscopic instruments have several technical limitations that can make it difficult to perform highly complex oncological procedures such as hepatic resection for HCC, citing among them, the straight shape of laparoscopic instruments and their lack of ability to articulate; The technique,

In this way, robotic hepatectomy becomes a useful treatment alternative that ensures patient safety, offering the possibility of minimizing skin and fascial trauma [12], reducing the risk of complications and hospitalization, and surgical recovery earlier that allows you to enjoy a better quality of life.

Likewise, it is expected to prove that the introduction of robotic surgery for liver resections could extend the indications for minimally invasive surgery [12, 14] and thus encourage the modernization and increase of robotic training and education of our physicians [15].

Aim

To assess the benefits of robotic hepatectomy versus laparoscopic hepatectomy in the resection of liver tumors.

Methods

Eligibility criteria

A systematic review and subsequent meta-analysis will be carried out to assess the benefits of robotic hepatectomy versus laparoscopic hepatectomy in the resection of liver tumors, for which we will review primary comparative studies between both procedures published from 2010 to the present. There will be no exclusion of articles by language. In addition, approved manuscripts will be accepted for publication.

Type of study

In this investigation, we will include comparative, case-control, cohort, prospective or retrospective studies of adult patients with liver tumors undergoing robotic or laparoscopic hepatectomy, reporting at least one perioperative result. We will compare the results of both procedures.

Types of participants

Patients diagnosed with benign or malignant liver tumors, including children and adolescents, noncirrhotic or compensated cirrhotic, Child-Pugh A or B classification, undergoing robotic or laparoscopic liver resection.

Studies that did not come from a reliable scientific site or that were systematic reviews, meta-analyses, letters, comments, and case reports (<5 patients) were excluded. We will exclude articles whose study group was decompensated patients with Child-Pugh C classification, portal hypertension (> 10 mmHg) or those who underwent procedures other than robotic or laparoscopic liver resection. We will also exclude studies that did not provide separate data for laparoscopic and robotic hepatectomy. If the same institute reported more than one study, only the most recent study will be included.

Types of interventions

The main categories of interventions that will be tested in this review are as follows:

- **Robotic hepatectomy:** The patient was placed in a supine position with legs apart and then in a reverse Trendelenburg position. Five ports placed along a semicircular arch in front of the epigastrium are generally used. The "da Vinci" surgical system (Intuitive

Surgical Inc, Sunnyvale, CA) will be used for robot-assisted procedures in the studies. For the procedure, a 12 mm camera port, a 12 mm operative port and 3 working 8 mm robotic ports were used. The abdominal cavity and liver were visually evaluated with a telescope 30 and laparoscopic ultrasound. The procedure has 3 stages: 1st portal dissection and vascular control; 2nd liver mobilization; and 3rd parenchymal transection. The patient cart of the robotic surgical system was placed on the patient's head for the docking phase. The first surgeon is seated at the robotic console, while an assistant surgeon stands on the right side of the patient [16].

- **Laparoscopic hepatectomy:** For tumors in the left liver, the operator and assistant camera are on the right side of the patient, and the first assistant is on the left side. Liver resection was performed with the patient in the supine position, with a reverse Trendelenburg setting of 30°. A 10-mm umbilical chamber port, a 12-mm epigastric-action port, two 5-mm ports were placed in the bilateral subcostal area, and a 30-mm flexible chamber or rigid chamber was used. Pneumoperitoneum was established through the 10 mm umbilical port and was kept below 12 mmHg to reduce the risk of air embolism. Laparoscopic ultrasound is used to localize the tumor, demonstrate satellite nodules, and mark an adequate tumor-free margin [17].

For right-sided liver resection, excluding right hemihepatectomy or right posterior section of the liver, the procedure was performed under general anesthesia with the patient positioned supine. The operator and the camera assistant stood on the left side of the patient, and the first assistant stood on the right side. One 10 mm umbilical chamber port, one 12 mm epigastric action port, and two 5 mm ports were used in the bilateral subcostal area. A flexible camera or a 30° rigid camera is used for tumors located in segments 5 and 6, and a flexible camera is used for tumors located in segments 7 and 8.

For right hemihepatectomy or right posterior liver resection, the operator stood between the patient's legs, and the first assistant and the camera assistant stood on the left side. One 10 mm umbilical chamber port, two 12 mm epigastric ports and ports acting in the right subcostal area, and two 5 mm ports in the bilateral subcostal area were used. During hemihepatectomy or right posterior section, the liver is usually fully

mobilized from the inferior vena cava, and the multiple small hepatic veins are cut and divided. The portal pedicles are dissected out of the liver parenchyma, and then the portal venous branch, the hepatic arterial branch, and the bile duct are separated. The arterial and portal venous branches were cut and divided. The superficial liver parenchyma was cut with a harmonic scalpel (such as Ethicon, Cincinnati, OH), and the deepest portion of the parenchyma was dissected with a laparoscopic cavitron ultrasonic surgical aspirator. Once the sample was completely detached, it was inserted into a protective bag and removed through the incision created by extending the umbilical port site. After careful hemostasis, fibrin glue sealant and a sealant patch were applied to the cut surface of the liver. Finally, after irrigating the surgical field, one or two silastic drains are inserted [17]. It was inserted into a protective bag and removed through the incision created by extending the umbilical port site. After careful hemostasis, fibrin glue sealant and a sealant patch were applied to the cut surface of the liver. Finally, after irrigating the surgical field, one or two silastic drains are inserted [17]. It was inserted into a protective bag and removed through the incision created by extending the umbilical port site. After careful hemostasis, fibrin glue sealant and a sealant patch were applied to the cut surface of the liver. Finally, after irrigating the surgical field, one or two silastic drains are inserted [17].

Types of outcome measures

We will include studies only if one or more of the outcomes listed below were measured or were intended to be measured.

Primary outcome measures

1. Estimated blood loss during surgery (measured in milliliters).
2. Operative time (from the skin incision to closing the abdomen).
3. Conversion rate to open surgery.
4. Intraoperative mortality rate.
5. Morbidity rate (total report of postsurgical complications).
6. Hospital stay after surgery (measured in number of days).

Secondary outcomes

1. Age of patients.
2. Sex of the patients.
3. Body mass index of the patients (kg / m2).
4. Presence or absence of liver cirrhosis by clinical diagnosis.
5. Frequency of resected liver lesions.
6. R1 resection rate.
7. Classification of resections: Right hepatectomy or hemihepatectomy (1st order), Left hepatectomy or hemihepatectomy (1st order), Left lateral section (2nd order), Right trisectomy or extended right section (2nd order), Left trisectionomy or sectionectomy Left Extended (2nd order), Subsegmentectomy (3rd order), Unspecified Segmentectomy (3rd order), Bisegmentectomy (3rd order), Mixed Segments.
8. Type of surgical resection: Major resections (> 3 segments), Minor resections.

We will also collect informed data on the American Society of Anesthesiologists (ASA) physical status classification, history of previous abdominal surgery, history of preoperative chemotherapy, intraoperative blood transfusions, classification of postsurgical complications measured with the Clavien-Dindo scale, admission to intensive care unit, mortality at 30 days, mortality at 90 days, and costs of the procedures if they have been registered.

Timing of the measurement of results

Outcome measures will be grouped into four main groups: 1. Background characteristics of the patients (age, sex, BMI, ASA, cirrhosis, previous abdominal surgery, preoperative chemotherapy); 2. Pathological parameters (histopathological diagnosis, origin of lesions, size of resected tumors, margin of resection); 3. Perioperative results (classification of resections, type of resection, mean operative time, estimated blood loss, conversion to laparotomy, intraoperative mortality, blood transfusions); 4. Postoperative results (complications, Clavien-Dindo complications, ICU admission, hospital stay, total mortality, 30-day mortality, 90-day mortality).

Search methods for the identification of studies

Electronic searches

We will search the MEDLINE Specialized Register (1946 to present) and Embase: ScienceDirect (1974 to present). No language restrictions will apply.

Table 1 Keywords chosen for a search

#1 MESH DESCRIPTOR: "LIVER NEOPLASMS, EXPERIMENTAL" OR "Liver Neoplasms" OR "LIVER NEOPL" OR "Cancer of Liver" OR "Cancer of the Liver" OR "Cancer, Hepatocellular" OR "Hepatic Cancer" OR "Hepatic Neoplasms" OR "Hepatocellular Cancer" OR "Liver Cancer" OR "Neoplasms, Hepatic" OR "Neoplasms, Liver" OR "Hepatoma" OR "Bile Ducts, Intrahepatic"
#2 MESH DESCRIPTOR: "Hepatectomy" OR "Liver Regeneration"
#3 MESH DESCRIPTOR: "Robotic Surgical Procedures" OR "Robot-Enhanced Procedures" OR "Robot-Enhanced Surgery" OR "Surgical Procedures, Robotic" OR "Robotics" OR "Remote Operations (Robotics)" OR "Soft Robotics Telerobotics"
#4 MESH DESCRIPTOR: "Laparoscopy" OR "Celloscopy" OR "Laparoscopic Assisted Surgery" OR "Laparoscopic Surgery" OR "Laparoscopic Surgical Procedure" OR "Laparoscopic Surgical Procedures" OR "Peritoneoscopy" OR "Procedure, Laparoscopic Surgical" OR "Procedures, Laparoscopic Surgical" OR "Surgery, Laparoscopic" OR "Surgical Procedure, Laparoscopic" OR "Surgical Procedures, Laparoscopic" OR "Laparoscopes"
#5 MESH DESCRIPTOR: "Treatment Outcome" OR "Clinical Effectiveness" OR "Clinical Efficacy" OR "Patient-Relevant Outcome" OR "Rehabilitation Outcome" OR "Treatment Effectiveness" OR "Treatment Efficacy" OR "Comparative Effectiveness Research"

Looking for other resources

No manual or library search resources are declared.

Data collection and analysis

Study selection

Two authors (LP and EC) will independently select the title and abstract from all search results. Full reports of potentially eligible studies will be retrieved, and study selection will be performed by the same two authors under the guidance of a standardized eligibility form. Any disagreement will be resolved by consulting a third author (SM). If eligibility is still unclear, we will contact the study authors for clarification.

Data extraction and management

Two review authors (LP and EC) will independently extract the data according to the implementation of a standardized and tested data extraction form. Disagreements will be resolved by consensus when possible, but a third review author (SM) will be consulted if a consensus cannot be reached. Data entry into Review Manager will be handled by SM (RevMan 2014).

Assessment of risk of bias in included studies

The assessment of risk of bias in the included studies will be based on the application of the Cochrane 'Risk of bias' tool (Higgins 2011a). Two review authors (LP and EC) will independently report on the following seven domains: sequence generation, allocation concealment, blinding of participants and staff, blinding of outcome assessment, data integrity of outcome, selective reporting of outcome data, and any other relevant but unreported source of bias in the above domains. A separate assessment of risk of bias will be performed for blinding domains, and incomplete outcome assessment will be performed for patient-reported (e.g., self-reported pain and function) or objectively reported (e.g., patient-reported) outcomes. Number of adverse events and recurrence rate). We will classify the risk of bias for each domain as low, unclear, or high. A third review author (SM) will be consulted in case a consensus cannot be reached.

It is difficult to blind the surgeon who performs the surgical intervention, as well as the patients who will undergo it, since they must be informed about the procedure and give their consent for it to be performed. However, there are valid ways to blind the participant.

Evidence from the assessment of successful blinding of participants is required to rate a low risk of bias in the section 'blinding of participants and staff'. Incomplete outcome assessment (due to attrition or exclusions) will be considered at high risk of bias if an intention-to-treat protocol has not been used. We will focus on the results of each procedure and make a comparison.

Treatment effect measures

For continuous outcomes (e.g., days of hospital stay), we will use mean differences (MDs) and corresponding 95% confidence intervals (CIs) to measure the outcome of the intervention. In your case, we will use the final scores instead of changing the scores. Standardized mean differences (SMDs) will be used when different measurement scales are used; we will not group the final scores and changes for DME. For dichotomous outcomes such as mortality, we will calculate odds ratios (ORs) and 95% CIs.

Unit of analysis problems

For the synthesis of the meta-analysis, the researchers will focus on the results of adult patients with liver tumors treated with the minimally invasive procedures of interest and, if there is homogeneous information, also on the complications or consequences of these procedures or the patients subjected to them.

Deal with missing data

We will attempt to contact the trial authors for missing data and information. Whenever possible, we will try to analyze available data using intention-to-treat principles. Wherever possible, we will calculate missing standard deviations (SDs) from other statistics, such as standard errors, confidence intervals, or P values, according to the methods recommended in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). We will not charge missing SDs from other sources. Whenever possible, we will perform sensitivity analyses to explore the effects of missing binary data when it exceeds 10% of the test population.

Heterogeneity assessment

Statistical heterogeneity will be assessed by visual inspection of the forest plot and by considering the χ^2 statistic at a significance level of $P < 0.05$. The level of inconsistency between trials will be defined by the I^2 statistic and will be interpreted as follows: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; and 75% to 100% considerable heterogeneity (Deeks 2011).

Assessment of reporting biases

When a sufficient number of trials (more than 10 trials) contribute to the analysis of a primary outcome, we will generate a funnel plot to explore potential small study biases. In interpreting funnel plots, we will examine the different possible reasons for funnel plot skewness, as described in section 10.4 of the Handbook (Sterne 2011). To assess results reporting bias, we will verify study protocols against published reports. Where it is evident that results stated a priori (eg in a trial protocol) have not been reported, or are reported selectively, we will note this in the 'Risk of bias' table.

Data synthesis

Where appropriate, we will pool the results of comparable groups of trials using both fixed-effect and random-effects models. Our choice of model for reporting will be guided by careful consideration of the degree of heterogeneity and whether it can be explained, in addition to other factors such as the number and size of included studies. We will use 95% CI in all parts. We will consider not pooling data where there is considerable heterogeneity ($I^2 > 75\%$) that cannot be explained by the diversity of methodological or clinical characteristics between trials. When grouping data is not appropriate, we will still present test data in analyses or tables for illustrative purposes and report them in the text.

Subgroup analysis and investigation of heterogeneity

Where data permit, we plan to perform the following subgroup analyses:

1. Average age of the intervention
2. Sex
3. Body mass index (less than 25 kg/m²; more than 25 kg/m²)
4. ASA classification
5. History of previous abdominal surgery
6. History of preoperative chemotherapy
7. Intraoperative blood transfusions
8. Presence or absence of liver cirrhosis by clinical diagnosis and Child-Pugh classification.
9. Frequency of benign and malignant liver lesions
10. R1 resection rate
11. Classification of surgical resections.
12. Type of surgical resection
13. Post-surgical complications
14. Classification of postsurgical complications measured with the Clavien-Dindo scale.
15. Admission to intensive care unit
16. Mortality at 30 days
17. Mortality at 90 days
18. Procedures costs

The above subgroups will be analyzed at the primary time points (postsurgery) for each type of intervention. We will investigate whether the subgroup results are significantly different by inspecting the overlap of CIs

and performing the test for subgroup differences available in RevMan 5.4.

Sensitivity analysis

If there are sufficient data, we will perform sensitivity analyses on various aspects of the trial and review methodology. These will include sensitivity analyses to explore:

1. The effects on primary outcomes of excluding trials with high or unclear risk of selection bias (thus restricting the analysis to studies with low risk of selection bias due to the use of adequate methods of allocation concealment);
2. The effects of excluding trials reported only in conference proceedings or other brief reports;
3. The effects on primary outcomes of comparing studies with smaller sample sizes (fewer than 50 cases in each group) versus larger ones;
4. The effects of the lack of binary data; Y
5. The choice of the statistical model to pool the data (fixed effects versus random effects).

Evidence quality assessment and 'Summary of findings' tables

We will use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the quality of the body of evidence for each outcome listed in Types of outcome measures (Schünemann 2011). The 'high' quality rating is reserved for a suite of RCT-based evidence. We can downgrade the quality rating to "moderate", "low" or "very low" based on the presence and scope of five factors: study limitations, inconsistency of effect, imprecision, indirect, and publication bias.

When there is sufficient evidence, 'Summary of findings' tables will be prepared for each comparison using the evidence available for the primary outcomes. We plan to present the results in 4 main groups consisting of baseline characteristics of the patient, pathological parameters, perioperative results, and postoperative results.

Protocol fixes

To document future amendments to this protocol, the registry plan will use the PROSPERO Guide and update it in said database.

Final results

They will be published in a summarized version in the PROSPERO protocol and sent in full to an Indexed journal for knowledge of the scientific community.

Abbreviations

ASA: American Society of Anesthesiologists Physical Status Classification; CC: Cholangiocarcinoma; DM: Differences of means; SMD: Standardized mean differences; RCT: Randomized controlled studies; FDA: US Food and Drug Administration; UFH: Focal Nodular Hyperplasia; CI: Confidence intervals; BMI: Body Mass Index; MELD: Scoring scale to measure the severity of chronic liver disease; OR: Odds ratios; SD: standard deviations; ICU: Intensive Care Unit.

Supplementary information

Supplementary materials are not declared.

Acknowledgments

Does not apply

Authors' contributions

SAMP: conception and design of the study, statistical analysis, review of this article and critical analysis of the article.

LEPC: conception and design of the study, data collection and writing of this article.

MECI: conception and design of the study, data collection and writing of this article.

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The authors financed the expenses incurred in the production of this research.

Availability of data and materials

The data sets generated and/or analyzed during the current study are not publicly available but will be available through the corresponding author upon reasonable academic request.

Declarations

Ethics committee approval and consent to participate

Not required for systematic reviews.

Publication consent

It does not apply to studies that do not publish MRI/CT/Rx images or physical examination photographs.

Conflicts of interest

The authors declare no conflicts of interest.

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