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View application from David Hakim

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Abstract

Title of Study	The National Robotic Hepatobiliary and Pancreatic Surgery Database
Abstract and methodological description	<p>Introduction:</p> <p>The National Robotic Hepatobiliary and Pancreatic Surgery Database was established in 2018 under the supervision of Professor Long R Jiao as a tool to analyse robotic HPB cases and identify ways of shortening the robotic learning curve. After initial research of current similar databases used by other surgical</p>

specialties a 'Phase 1' database was launched; accessible via www.robotichpb.com.

As robotic HPB surgery is a relatively new concept, there is little data to suggest its efficacy and adoption as part of current surgical training programs. Through the database our aim is to study robotic operative times and analyse how quickly new trainees can climb this learning curve.

Methods:

We worked with a UK-based web developer to design and implement a secure database in order to assess patient outcomes from robotic HPB surgery. The following parameters were included:

1. Patient information – sex, age at surgery, weight, Body mass index, American Association of Anaesthesiology score (a score of fitness and general health), other pre-existing health conditions. Current medications.
2. Patient hospital number and name, only visible to the patient's surgeon (With patient's informed consent).
3. Operation details: surgery date; technical details of operation performed; operative time; blood transfusion.
4. Histopathology details – The type of disease; tumour size; number of lymph nodes involved; neural and vascular invasion; resection margin status; number of lesions.
5. Complications during the surgery, blood loss during surgery, whether a keyhole operation had to be completed via a bigger cut (conversion).
6. Complications after the surgery in the first 90 days: Details of the complication and required treatment reported with checkboxes and free text and using the Clavien-Dindo classification, a widely used grading system of the severity complication from grade 1 (minor) to grade 5 (most serious).
7. 90-day Mortality: Details of any death and cause.
8. Postoperative length of stay in the intensive care unit (if applicable) and hospital.

Data is entered into the registry via a secure website by the data subjects' direct clinical care team. All data can be exported onto an Excel datasheet for statistical analysis.

The database is hosted on secure servers protected by firewalls. The database

will be managed, updated and sustained by the web developer, as well as, the HPB Robotic Registry committee made up of surgeons and researchers.

Discussion:

Laparoscopic cancer surgery has become an accepted alternative to open pancreatic and liver cancer resections in the last 10 years. Case-controlled series have demonstrated its safety and efficacy compared to open surgery. Robotically assisted laparoscopic HPB surgery offers the additional benefits of enhanced dexterity, a 3D field of view, and more intuitive instrument control. Proponents argue these advantages may lead to a reduction of conversion rate, reduced complications in terms of blood loss and anastomotic leak rate, and improved oncological outcome. The uptake of robotic HPB surgery has been limited by the high cost of robotic surgical systems. However, there are now several UK centres performing robotic HPB surgery with results comparable to open surgery. The number of cases performed is rapidly expanding with surgeon training and experience. The clinical benefit of robotic versus conventional HPB surgery remains unclear. There is pressing need to set up a collaborative network in order to compile national outcome data, pool experience, monitor safety, and improve the training of robotic HPB surgery. The proposed Registry will capture comprehensive data from every robotic HPB case performed at UK HPB centres.

-The database will help to answer the following research questions:

- Are robotically assisted HPB surgeries performed in UK safe and effective?
- What are the technical, oncological, and post-operative outcomes following robotic HPB surgery?
- Is robotically assisted HPB surgery cost-effective?

-Aims:

- To assess the safety of uptake of robotically assisted HPB surgery in the UK.
- To ensure structured training programme of robotic HPB surgeons.
- To monitor the outcomes of robotic HPB surgery over time.
- To identify specific areas of concern to focus training and improvement.
- To compare short and long-term outcomes of robotic, laparoscopic and open

operations for pancreatic and liver cancer.

- To determine the ideal surgical technique for best outcomes based on patient and cancer characteristics.
- To assess the cost-effectiveness of robotic HPB surgery and compare this with other surgical modalities.

No such database exists for robotically assisted HPB surgery in the UK. Our database will aid researchers and the robotic HPB surgical community to realise these aims for robotic HPB surgery.

In 2018, we further discussed the need for robotic HPB data collection alongside an international network of robotic HPB surgeons, through the establishment of the first International Robotic Focus Group in Geneva. This consensus meeting aimed to drive forward robotic techniques and to create a standard for quality-assuring surgery with a view to develop: training protocols, standardised techniques, research and development, and to evaluate the safety of robotic HPB operations. We aim to expand our national database into an international partnership to expedite the benefits that robotic HPB surgery can offer.

To date, this project's expenditure is primarily being spent on the maintenance and secure hosting of the database. As the project is still in 'Phase 1', we continue to make changes to the database in order to streamline the data collection process. So far, we have received positive reviews from all users and have also considered user feedback as a guide to quality improvements. We have refrained from making substantial changes to the user experience in order to minimise costs as much as possible. However, we hope that with the financial support from the prestigious 2021 Pump Priming Grant we will be able to transform our 'Phase 1' web-based database into a system accessible from any device. We aim to do this through the coding of an application that can be downloaded onto mobile devices for immediate patient data entry, and similarly, immediate recalling of previous operative data. We have continued to brainstorm with our developers and we are currently continuing with the 'Phase 1' version until funding can be sourced to expand on our current work.

Timetable

Name	Phase 1: Initial testing by a single surgeon at a single tertiary HPB unit.
Date	2018-2021

Name	Phase 2: Allow the opportunity for all eligible tertiary-HPB centres to log their robotic HPB cases in order to have more data to research.
Date	2022-Onwards

Name	Phase 3: As discussed in the 2018 International Robotic Focus Group, we hope to expand our database into an international partnership to maximise the amount of data we have for analysis.
Date	2023-Onwards

Funding

Name	Secure web hosting annual cost
Amount	250.0

Name	Annual database maintenance for miscellaneous error repairs
Amount	600.0

Name	Improvements to current Phase 1 data exports, spam prevention and multi-device compatibility. Quote from developer.
Amount	1176.0

Name	Future conversion of web-based database into a state-of-the-art mobile application accessible by both computers and mobile devices.
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Amount	7000.0
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Details of ethical approval

We received ethical approval from the NHS Health Research Authority London - City & East Research Ethics Committee in January 2019 confirming a favourable ethical opinion.

This approval is valid for 5 years and may be renewed.

Evidence is available upon request.

Institutional approval information

This project is has been approved by Imperial College London since its conception.

To date, all funding has also been approved by ICL's research departments.

Declaration

Confirm Declaration: Yes

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