

Recommendations on Robotic Hepato-Pancreato-Biliary Surgery. The Paris Jury-Based Consensus Conference

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Objective: To establish the first consensus guidelines on the safety and indications of robotics in Hepato-Pancreatic-Biliary (HPB) surgery. The secondary aim was to identify priorities for future research.

Background: HPB robotic surgery is reaching the IDEAL 2b exploration phase for innovative technology. An objective assessment endorsed by the HPB community is timely and needed.

Methods: The ROBOT4HPB conference developed consensus guidelines using the Zurich-Danish model. An impartial and multidisciplinary jury produced unbiased guidelines based on the work of 10 expert panels answering predefined key questions and considering the best-quality evidence retrieved after a systematic review. The recommendations conformed with the GRADE and SIGN50 methodologies.

Results: Sixty-four experts from 20 countries considered 285 studies, and the conference included an audience of 220 attendees. The jury (n = 10) produced recommendations or statements covering 5 sections of robotic HPB surgery: technology, training and expertise, outcome assessment, and liver and pancreatic procedures. The recommendations supported the feasibility of robotics for most HPB procedures and its potential value in extending minimally invasive indications, emphasizing, however, the importance of expertise to ensure safety. The concept of expertise was defined broadly, encompassing requirements for credentialing HPB robotics at a given center. The jury prioritized relevant questions for future trials and emphasized the need for prospective registries, including validated outcome metrics for the forthcoming assessment of HPB robotics.

Conclusions: The ROBOT4HPB consensus represents a collaborative and multidisciplinary initiative, defining state-of-the-art expertise in HPB robotics procedures. It produced the first guidelines to encourage their safe use and promotion.

Keywords: robotic surgery, minimally invasive surgery, HPB surgery, consensus, guidelines, Zurich-Danish model, hepatectomy, pancreatectomy

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This financial structure aimed to uphold the integrity and objectivity of the guideline's development process and conclusions.

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The chairmen of the consensus conference, the jury, and the panel leaders declared that they have no conflicts of interest with the robotic industry.

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Clinically introduced in the late '90s to support cardiac surgery,^{1–5} robot-assisted surgery was primarily adopted by urologists to alleviate the challenges associated with technically demanding minimal-invasive prostatectomies. Since then, the robotic approach has spread to most surgical fields, including abdominal surgery.^{6–10} Its unique and appealing features include enhanced dexterity, tremor compensation, motion scaling, three-dimensional imaging, and adjustable magnifications. While the number of available robotic platforms has recently boomed in a highly sought-after and profitable market, the DaVinci system (Intuitive Surgical) remains dominant, with over 7500 platforms accessible in 70 countries and more than 11 million procedures performed to date.¹¹ This success has arguably been based on the accumulation of evidence of its safety in a competitive health care environment, with potential advantages over both laparoscopic and open approaches. It is widely believed that robotics and its related technological developments will eventually be an irreversible surgical revolution.

Laparoscopic Hepato-Pancreatic-Biliary (HPB) surgery has achieved successful and widespread adoption, particularly for liver procedures and distal pancreatectomies.^{12–14} Its diffusion has been slowed down in the setting of advanced HPB

procedures needing a high level of expertise.^{15–18} While only a few groups have successfully adopted laparoscopy for procedures requiring complex reconstructions, robotics has helped defeat many surgeons' skepticism regarding minimally invasive HPB surgery in this setting. Studies demonstrating feasibility compared to other approaches, or even advantages, have attracted increasing interest.^{19–23} The spread of robotic HPB surgery is progressing according to the IDEAL framework for the development of surgical innovations reaching stage 2b, ie, exploration phase.^{24–26} As has been the case for other specialties adopting robotic technology, its safe diffusion and credentialing have primarily been industry-driven,²⁷ although not necessarily tailored to HPB essential requirements.²⁸ In addition, assumptions about cost-effectiveness have greatly influenced its availability and promotion in many health care systems. Thus, an independent and industry-free assessment of robotic HPB surgery has become necessary and timely.

Endorsed by all major HPB societies, the ROBOT4HPB consensus initiative has sought to generate unbiased recommendations by an independent multidisciplinary jury lacking any connections with robotic surgery or related businesses. For this purpose, the Zurich-Danish model²⁹ was chosen to assess the current status of robotic HBP surgery regarding its safety, feasibility, or benefits as it applies to its introduction in a hospital and for HPB indications. In addition, the initiative identifies areas that require attention in research and innovation.

METHODS

The Zurich–Danish Model

The process of developing the guidelines adheres to the evidence-based Zurich–Danish model.^{12,29–32} This 3-phase model, led by a local organizing committee (LOC), encompassed preparation, conference meetings, and deliberations to reach recommendations according to GRADE (Fig. 1 and Supplemental Table 1, Supplemental Digital Content 1, <http://links.lww.com/SLA/F125>). The principle of this approach is the clear distinction between the experts tasked with providing evidence, the audience participating in challenging expert opinions, and the jury responsible for formulating the final guidelines.

The preparation step was initiated in December 2021, with the LOC taking the lead in selecting ten topics and assembling a team of experts, including the panel chairs and

jury members. The primary objective of the expert panels was to address their respective questions based on a comprehensive literature review. The conference meeting was held publicly in Paris on December 7 and 8, 2023. Each panel chair delivered a 20-minute presentation with statements that directly addressed the questions and proposed a draft recommendation for each. The jury initiated the first round of questions, followed by inquiries from the audience. The jury could solicit the extent of the audience's opinion through an anonymous online voting system. Following public discussions, the jury could summon Panel chairs after daily sessions for any necessary clarifications. The jury deliberated in a closed session immediately after the conference on December 9. The final formulation of guidelines, including determining the strength and level of evidence ratings, solely fell under the jury's responsibility (Supplemental Table 1, Supplemental Digital Content 1, <http://links.lww.com/SLA/F125>).^{33–37}

Expert and Jury Recruitment

The experts were international leaders in robotic HPB surgery, selected based on their academic skills and clinical expertise. Criteria for recruitment included (1) senior authorship in relevant publications, (2) invitations extended through other recruited experts, and (3) a call for participation from patient and scientific organizations.

The Jury selection reflected the perspective of all key stakeholders, including nonrobotic HPB surgeons, hepatologists, epidemiologists, oncologists, nurses, and patient representatives, while maintaining sex and geographical balance (Supplemental Table 1, Supplemental Digital Content 1, <http://links.lww.com/SLA/F125>). Due to the partially highly technical nature of the key questions and topics addressed, the jury had to include members with significant expertise in HPB surgery and an understanding of surgical innovations and minimally invasive technologies. Members of the jury were also chosen based on their interest and experience in assessing clinical care in the setting of a consensus conference. They could not have biases or disclosures in favor of or against robotic surgery nor be involved in robotic-related research.

Key Questions and Panels

The LOC assigned each panel of experts 4 to 6 questions using the PICO framework³⁸ (Supplemental Table 2, Supplemental Digital Content 1, <http://links.lww.com/SLA/F125>). The

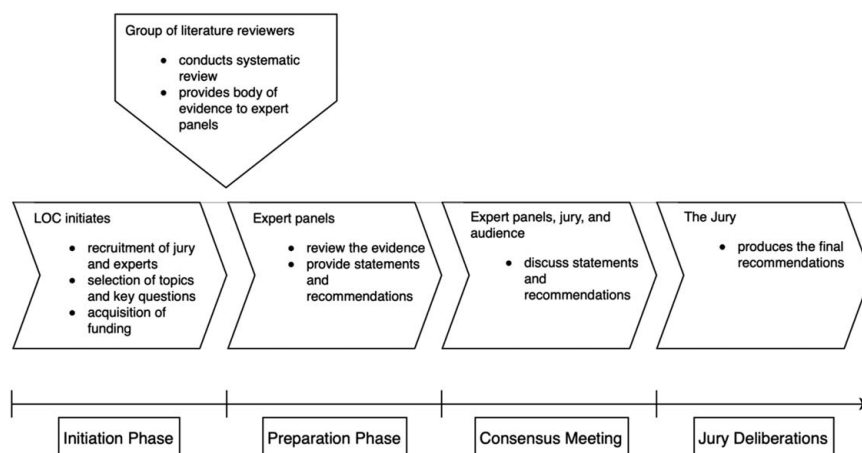


FIGURE 1. The Zurich-Danish format to develop unbiased recommendations in medico-surgical practice (modified with permission from Lesurtel et al²⁹).

questions were submitted for review among experts and the jury before the conference. Every expert was required to disclose any potential conflicts of interest. Candidates for panel chairs were excluded if they were actively serving as proctors for any robotic companies. Panels were organized as follows: panels 1 to 3 covered general topics in HPB robotic surgery, panels 4 to 7 focused on key questions related to liver robotic surgery, and panels 8 to 10 focused on key questions related to pancreatic robotic surgery.

Systematic Literature Review and Quality Evidence

Fourteen board-certified surgeons, including HPB or transplantation fellows, searched for the best available evidence addressing each question following the SIGN50 methodology³⁹ under PROSPERO (ID: CRD42023383949) covering Embase, Medline, and Cochrane databases from January 2016 to December 2022. The search included randomized trials, observational cohort studies, meta-analyses, and systematic reviews involving at least 10 patients undergoing robotic HPB surgery (excluding routine cholecystectomy procedures). The selected studies were published in English and available in full text. The supplemental methods provide details about the search process, Supplemental Digital Content 1, <http://links.lww.com/SLA/F125>.

The quality assessment of the studies (double evaluation and blinded) was conducted using SIGN50 workflow and checklists. Each study was categorized as low, acceptable, and high-quality methodologies based on SIGN50 methodology checklists.³⁹ Observational studies of low quality were considered only if no studies of better quality were available regarding a specific topic. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram illustrating the study selection process is displayed in Figure 2. The search was revised until July 2023, and the experts were provided with a summary database.

Quality of Evidence and Strength of Guidelines

The level of evidence for each recommendation or statement was evaluated using the GRADE system, based on the study design, risk of bias (ie, SIGN50 methodological assessment), precision, consistency, directness, publication bias, and magnitude of effect^{33–35} (Supplemental Table 3, Supplemental Digital Content 1, <http://links.lww.com/SLA/F125>).

Guidelines were categorized as STRONG or CONDITIONAL (ie, weak).^{36,39} This determination was based on various factors: certainty of the evidence, magnitude of the effect, consideration of resource use, feasibility, acceptability, equity, values, and preferences.^{35,37} Strong recommendations were permitted occasionally with low levels of evidence when dealing with low-quality evidence but indicating possible benefits in life-threatening situations and prioritizing patient safety (Supplemental Table 3, Supplemental Digital Content 1, <http://links.lww.com/SLA/F125>).

RECOMMENDATIONS

Overall Search and Participants

Sixty-four experts from 20 countries considered 285 studies reporting on robotic HPB surgery [pancreatotomy: 151 (53.0%), hepatectomy: 107 (37.5%), mixed HPB procedures: 11 (3.9%), living donor liver transplantation: 10 (3.5%), biliary procedures: 6 (2.1%)] (Supplemental Figure 1, Supplemental Digital Content 1, <http://links.lww.com/SLA/F125> and Supplemental Table 4, Supplemental Digital Content 1, <http://links.lww.com/SLA/F125>). Most of these studies were observational

studies (n = 172, 60.4%) and mostly considered of low quality (n = 135, 47.7%). Most studies (n = 233, 81.8%) reported on postoperative complications, while 58 (20.4%) and 30 (10.5%) other studies assessed longer-term follow-up and cost evaluation, respectively.

The audience at the conference consisted of 220 attendees: 51 (55.4%) from Europe, 18 (19.6%) from North America, 15 (16.3%) from Asia, 8 (8.7%) from South America, Africa, and Oceania. More than half (54.8%) considered themselves to have advanced robotic experience, with 71 (76.3%) and 58 (63%) having performed robotic liver and pancreatic procedures, respectively. Thirty-three (35.9%) attendees were trainees in HPB surgery. All contributors to the ROBOT4HPB Consensus Group are listed in Supplemental Table 5, Supplemental Digital Content 1, <http://links.lww.com/SLA/F125>.

The jury included 10 members, and their recommendations are presented in Table 1.

Panel 1. Robotic Technology

The Da Vinci platform (Intuitive Surgical) has been in clinical use for over 20 years and still represents the currently only available technology with reported clinical data in HPB surgery.⁴⁰ Various other surgical systems are about to emerge, of which some have already obtained marketing authorization for non-HPB procedures. Some of these offer a wide range of new features that may affect the technical considerations for surgeons, enlarging indications and possibly altering outcomes.⁴¹ Most are, however, still under development. The available platforms are presented and compared in Table 2.

The conference recognized the revolutionary capacity of the robotic approach in improving the minimally invasive capabilities of surgeons, notably for intracorporeal suturing, especially in the context of bilio-enteric anastomosis or vascular reconstruction (Table 1, Section A, Statement 1), as shown in a pooled analysis of 2 RCTs (LAEBOT3D2D and LAELAPS-3D2D trial^{42,43}) in a biotissue model.⁴⁴ Laparoscopic as well as robotic surgeons agreed that robots would likely shorten conventional laparoscopic learning curves,^{44,45} as it is offering new methods for surgical training, such as video grading of pancreatic anastomoses.⁴⁶ Altogether, it may promote the widespread adoption of minimally invasive surgery for more complex HPB procedures that are currently less widely performed with conventional laparoscopy due to inherent technical limitations requiring advanced skills (eg, pancreatoduodenectomy and advanced liver resections).^{19,47,48}

Key factors such as cost, inter-specialty competition, and industry-driven monopoly on credentialing are anticipated to generate global disparities and limit access to the robotic platform (Table 1, Section A, Statement 2).²⁷ The jury acknowledged the audience's concerns about the potential detrimental effects and medicolegal implications of approving an unequally accessible technology based largely on a low level of evidence. Thus, some guidelines were purposefully written as statements rather than recommendations, allowing for more flexibility in their application. While the conference emphasized situations where robotics may be advantageous, no situation could be recommended where robots should be unequivocally adopted instead of an open or laparoscopic approach. As patient advocates, surgeons must choose the technical approach for a given patient based on training, expertise, accessibility, cost-effectiveness, and patient-centered factors (Table 1, Section A, Recommendation 3).⁴⁹

All parties agreed that no patient-centered factors represented an absolute contraindication to the robotic approach

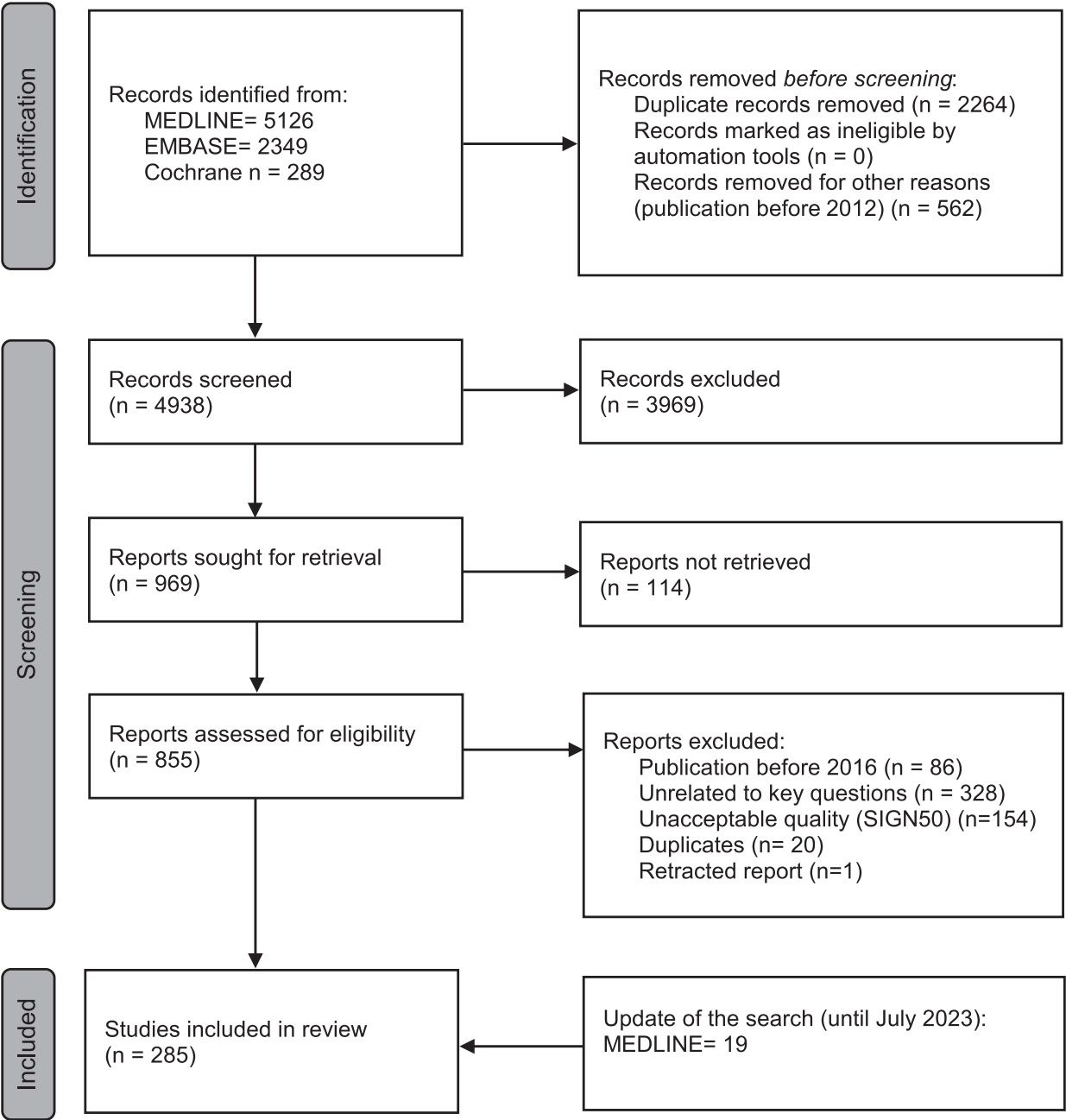


FIGURE 2. The Preferred Reporting Items for Systematic reviews and Meta-Analyses flow diagram of the ROBOT4HPB systematic review.

except for the intolerance to pneumoperitoneum (Table 1, Section B, Recommendation 4). More specifically, nine studies showed the feasibility of robotic HPB surgery in the context of advanced age,^{50–52} frailty,⁵³ increased BMI,^{54–56} visceral obesity,⁵⁷ or metabolic syndrome⁵⁸ (Table 1, Section B, Recommendation 5). However, there is a lack of data regarding HPB robotics in patients with BMI > 35 kg/m². Also, based on re-do laparoscopic liver resection series,^{59–61} it was postulated that previous abdominal surgeries should not affect the possibility of a robotic approach (Table 1, Section B, Recommendation 6); in fact, both the audience and experts

further suggested that the robotic approach may be beneficial in this situation, allowing for well-controlled and meticulous adhesiolysis.

Panel 2: Training and Expertise in Robotic HPB Surgery

The Concept of Expertise in Robotic HPB Surgery

The consensus underlines the critical role of expertise in HPB surgery as the primary prerequisite for providing adequate quality care in this exceedingly specialized domain.²⁸ The experts

TABLE 1. Final Jury Recommendations***Section A. Robotic Technology in HPB Surgery**

1. The robotic approach is advantageous for suturing during HPB minimally invasive surgeries, especially for biliary-enteric anastomoses or vascular reconstruction.

Statement: Strong, [Level of Evidence: Moderate]

2. The robotic approach is associated with higher procedural costs than the conventional laparoscopic approach.

Statement: Strong, [Level of Evidence: Moderate]

3. Surgeons should decide on the most adequate surgical approach, considering training, expertise, accessibility, cost-effectiveness, and patient-specific factors.

Recommendation: Strong†, [Level of Evidence: Low]

Section B. Contraindications for Robotic HPB Surgery

4. The patient's intolerance to the pneumoperitoneum should be considered an absolute contraindication for the robotic approach.

Recommendation: Strong†, [Level of Evidence: Very Low]

5. The patient's age or BMI should not be considered an absolute contraindication for the robotic approach.

Recommendation: Conditional, [Level of Evidence: Low]

6. Previous abdominal surgery, including redo-hepatectomy, should not be considered an absolute contraindication for the robotic approach.

Recommendation: Conditional, [Level of Evidence: Very Low]

Section C. Training and expertise in robotic HPB surgery

- Center requirements

7. A structured process, including a standardized training program, should exist at a center level for credentialing, privileging, and embarking surgeons on an HPB robotic program.

Recommendation: Strong†, [Level of Evidence: Low]

8. The standardized robotic training program is necessary and should be tailored to the procedure and the robotic surgical system and follow stepwise proficiency-based curricula.

Recommendation: Strong, [Level of Evidence: Moderate]

- Surgeons' requirements

9. The 2-surgeon technique is beneficial until the learning curve is achieved.

Statement: Strong†, [Level of Evidence: Very Low]

10. A surgeon should have open HPB expertise to embark on an HPB robotic program.

Recommendation: Strong†, [Level of Evidence: Low]

- Conversion in robotic HPB surgery

11. Standardized urgent conversion protocols and training involving the entire surgical team, including a simulation curriculum, should be required for credentialing.

Recommendation: Strong†, [Level of Evidence: Low]

Section D. Outcome assessment for Robotic HPB surgery

12. Outcome reporting in robotic HPB surgery should include standardized and validated metrics and adhere to published consensus on assessing the quality of surgical interventions.

Recommendation: Strong, [Level of Evidence: Moderate]

13. A clear distinction between urgent conversion and nonurgent conversion should be made and reported separately, along with the overall conversion rate.

Recommendation: Strong, [Level of Evidence: Moderate]

Section E. Robotic Liver Surgery

- Minor Hepatectomy (< 3 segments)

14. Compared with open, robotic anatomical and nonanatomical minor resections are associated with lower complication rates and shorter hospital stays and should be considered an acceptable approach.

Recommendation: Conditional, [Level of Evidence: Low]

TABLE 1. (Continued)

15. Compared with laparoscopy, robotic anatomical and non-anatomical minor resections should be considered acceptable minimally invasive alternatives.

Recommendation: Strong, [Level of Evidence: Moderate]

- Major Hepatectomy (≥3 segments).

16. Compared with open, robotic major liver resection performed with expertise should be considered an acceptable approach.

Recommendation: Conditional, [Level of Evidence: Low]

17. Compared with laparoscopy, robotic major liver resection performed with expertise is associated with a lower conversion rate, shorter learning curve, and similar postoperative outcomes.

Statement: Conditional, [Level of Evidence: Low]

- Complex situations

18. Compared with open, robotic liver resection performed with expertise in Child-Pugh A cirrhotic patients without clinically significant portal hypertension is feasible.

Statement: Conditional, [Level of Evidence: Low]

19. Compared with laparoscopy, the robotic approach may offer advantages in cases of liver resections involving radical portal lymphadenectomy and/or biliary reconstruction.

Statement: Conditional, [Level of Evidence: Low]

22. Compared with laparoscopy, robotic liver resection may offer advantages in advanced (as defined by laparoscopic difficulty scores) minimally invasive liver procedures.

Statement: Conditional, [Level of evidence: Low]

21. The current laparoscopic difficulty scores offer valuable guidance regarding patient selection and risk assessment.

Statement: Conditional, [Level of Evidence: Very Low]

- Robotic Donor Hepatectomy

22. Compared with open and laparoscopy, robotic donor hepatectomy performed with expertise is feasible. Although associated with prolonged operative times and warm ischemia, the robotic approach does not negatively influence recipient outcomes.

Statement: Conditional, [Level of Evidence: Very Low]

23. Compared with laparoscopy, robotic donor hepatectomy performed with expertise may offer more precision for hilum anatomic variation and bile duct division.

Statement: Conditional, [Level of Evidence: Very Low]

Section F. Robotic Pancreatic Surgery

- Distal Pancreatectomy

24. Robotic distal pancreatectomy should be considered an acceptable approach for patients with left-sided benign or premalignant neoplasms.

Recommendation: Strong, [Level of Evidence: Moderate]

25. Compared with laparoscopy, robotic distal pancreatectomy is associated with a lower conversion and failure to preserve spleen rates.

Statement: Conditional, [Level of Evidence: Low]

26. Robotic distal pancreatectomy performed with expertise should be considered an acceptable approach for patients with resectable pancreatic adenocarcinoma.

Recommendation: Conditional, [Level of Evidence: Low]

- Pancreatoduodenectomy

27. Compared with open, robotic pancreatoduodenectomy performed with expertise and in selected patients is noninferior in terms of perioperative outcomes.

Statement: Conditional, [Level of Evidence: Moderate]

TABLE 1. (Continued)

28. Robotic pancreatoduodenectomy performed with expertise should be considered an acceptable approach for selected patients with right-sided benign or premalignant neoplasms.
Recommendation: Conditional, [Level of Evidence: Moderate]
29. Compared with laparoscopy, robotic pancreatoduodenectomy performed with expertise may improve conversion and transfusion rates.
Statement: Conditional, [Level of Evidence: Very Low]
30. Robotic pancreatoduodenectomy performed with expertise could be considered an acceptable approach for selected patients with resectable pancreatic ductal adenocarcinoma.
Recommendation: Conditional, [Level of Evidence: Moderate]
- Robotic Enucleation
31. Compared with laparoscopy or open, robotic pancreatic enucleation performed with expertise for superficial benign tumors should be considered an acceptable approach.
Recommendation: Conditional, [Level of Evidence: Very Low]

*The recommendations and statements are based on clinical data from the Da Vinci platform (Intuitive Surgical).
†Strong recommendations or statements, despite the presence of low or very low levels of evidence, have been permitted in prioritizing patient safety.

and the jury unanimously agreed that the definition of expertise in robotics should not be limited to the surgeon operating the console; it should integrate the entire surgical team with allied health professionals in the operating theater. Furthermore, it should encompass the overall proficiency of HPB surgery of the facility (eg, HPB high-volume centers), with the rate of “failure to rescue” as one of the critical endpoints in HPB surgery.^{62–65}

Credentialling for Robotic HPB Surgery

Credentialing for robotic HPB surgery was one of the key points of discussion during the conference. The experts underscored the lack of evidence at large when referring to credentialling in health care.⁶⁶ The credentialling in robotics currently pertains almost exclusively to the industry’s jurisdiction, with little or no involvement by local authority.²⁷ This process is not HPB-specific and lacks tracking of progression (eg, case difficulty and long-term results). The jury recognized the need for credentialling in HPB robotic surgeons; the latter should be a systematic process certified at a center level (Table 1, Section C, Recommendation 7) rather than by industry alone.

Training Program for HPB Robotic Surgery

The experts and the Jury were unanimous that a standardized platform-specific, procedure-specific, and proficiency-specific training program^{66,67} is required to achieve credentials before starting a robotic HPB program (Table 1, Section C, Recommendation 8). As illustrated in robotic pancreatoduodenectomy, evidence shows that mentorship and proficiency-based curricula benefit newer generations (including HPB fellows) compared with first generations of surgeons; they exhibit shorter learning curves and similar, if not better, outcomes in robotics.^{68,69} The Dutch Pancreatic Cancer and the University of Pittsburgh Medical Center groups have initiated^{70–72} such training programs regarding robotic pancreatoduodenectomy (ie, LEALAPS-3⁷³). They showed the feasibility and efficacy of LEALAPS-3 multicentric implementation in real practice.^{47,73} Derived from LEALAPS-3, LEARNBOT (NTR8898) is a European training program developed by the

TABLE 2. Available Robotic Surgical Systems

System	Approval	Patient cart	Surgeon console	Controllers	Robotic arms	Degrees freedom	Camera diameter	Instrument diameter	Instrument use	Additional features
On the market										
Da Vinci Xi	FDA 2014; CE Mark 2014	Single	Closed Seated	Finger loops	4	7	8	8	10x	Multiquadrant surgery Port hopping camera Dual console
Senhance	FDA 2017 CE Mark 2016	Multiple	Open/3D glasses Seated	Laparoscopic handles	4	6	10	3–10	unlimited	Eye-tracking system Haptic feedback No port docking
Versus	CE Mark 2019	Multiple	Open/3D glasses Seated or standing	Joystick handles	5	7	10	5	NA	Haptic feedback Portable independent arms Option of standing surgeon No port docking
HUGO	CE Mark 2021	Multiple	Semiclosed/3D glasses Seated	Pistol handles	4	7	11	8	1–3x up to 54 minutes Single use	Pistol handles Medtronic devices Modularity
Avatera	CE Mark 2019	Single	Semiclosed Seated	Finger loops	4	7	10	5		Space saving
Hinotori	Japan 2020	Single	Semiclosed Seated	Finger loops	4	8	10	8	10x	Space saving No port docking
Revo-I	Korea 2019	Single	Closed	Finger loops	4	12	10	7.4	20x	Haptic feedback
Under development										
Enos	Pending	Single	Open Seated	NA	1	6	25	NA	NA	Single port Hyper redundant Multi-articulated instruments
MiroSurge	Pending	Attached to table	Open Seated	Finger loops	3 (+2 instruments)	7	10	NA	NA	Haptic feedback
Ottava	Pending	Multiple	Open Seated	Finger loops	6	NA	NA	NA	NA	

3D indicates three dimensional.

European Minimally Invasive Pancreatic Surgery (E-MIPS) group and endorsed by the European-African Hepato-Pancreato-Biliary Association (E-AHPBA), where Delphi consensus-based criteria define eligibility for training and proctoring.⁷⁴

As consensually also reported by other groups,^{75,76} such proficiency-based curricula should include stepwise training activities^{47,68,73} involving: (1) simulation/ virtual reality curriculum, (2) inanimate/biotissue curriculum, (3) video curriculum, (4) surgical curriculum, and (5) ongoing quality assurance. The surgical curriculum includes a stepwise implementation of clinical cases during which mentorship is encouraged to achieve technical proficiency.^{67,68} Thus, mentors must have established robotic expertise, often but not specifically tied to industry-based proctorship services.⁷⁴ The jury underscored that in the interest of patient safety, as in open and laparoscopic HPB surgery, there is no justification for self-taught surgeons²⁸; consequently, external mentorship is essential if none is available locally. Until the learning curve is completed, both experts and the jury concurred that the 2-surgeon robotic approach [1 at the console and 1 (at least a senior HPB resident) at the bedside] may be important to ensure patient safety⁴⁷ (Table 1, Section C, Statement 9).

Prerequisites and Learning Curves for HPB Robotic Surgery

Before embarking on HPB robotics, all surgeons must have expertise in open HPB surgery as it remains a standard and the final fallback option in case of conversion (Table 1, Section C, Recommendation 10). The need for conventional laparoscopic experience in HPB is debatable, with limited data suggesting that laparoscopic HPB experience is beneficial when starting robotic liver resection.⁷⁷ Nevertheless, the laparoscopic skillset may facilitate the robotic learning curve as minimally invasive approaches differ from open ones.^{47,78} The jury concluded that while laparoscopic experience may be advantageous, it is not mandatory when embarking on a robotic HPB training program. Gradual involvement of trainees lacking previous experience in minimally invasive surgery seems feasible in large expert robotic programs without negatively affecting outcomes.⁷⁹

Eight studies, mostly about robotic pancreatectomies,^{67,68,73,80–83} and 1 in liver resections,⁸⁴ referred to robotic learning curves, including cumulative sum (CUSUM) analyses. The expert panel and jury did not endorse an absolute numeric threshold of the number of procedures required to achieve the learning curve, as these often lack validation and are

heterogeneous.⁸⁵ This conclusion acknowledges the substantial variability impacted by generations of surgeons, the indicators used for CUSUM analysis (eg, textbook outcome⁸²), variation in health care systems, and the geographical distribution of resources, including access to robotic platforms.^{47,82,86} Strict numeric thresholds may result in misapplication, impeding this technology’s advancement.

Conversion in HPB Robotic Surgery

Robotic conversion to open surgery is an important measurable indicator in the CUSUM analysis of learning curves. Despite this, the jury questioned its imprecise use, given the lack of a clear distinction between urgent (ie, for intraoperative bleeding) versus nonurgent (ie, for technical reasons or oncologic inadequacy) conversion and the outcomes associated with each. Robotics is consistently associated with a lower conversion rate than laparoscopy. However, studies suggest that robotically converted patients may exhibit (when compared with laparoscopic converted patients) poorer postoperative outcomes (4 studies report on robotic conversion^{87–90}). More so than in laparoscopic surgery, such urgent robotic conversions may represent a logistical challenge that could impact its performance (deciding to convert and then actually converting). The jury strongly endorses converting without hesitation in critical situations to ensure safety. In this context, the jury reemphasized the importance of surgeons’ expertise in open HPB procedures as a prerequisite for HPB robotic credentialing (Table 1, Section C, Recommendation 10).

Urgent conversion in robotic surgery is likely needed in the scenario of uncontrolled bleeding when a major vasculature is injured, which is more or less associated with a risk of gas embolism and prolonged clamping/ischemic duration. While uncontrolled bleeding can result from any step in robotic pancreatic and liver surgery, several technical steps at higher risk have been identified by the experts and the Jury in Table 3. In contrast to laparoscopy, the challenge lies in the timing required to safely undock and remove the robotic platform before starting the conversion, while the first surgeon has limited direct access to ensure laparoscopic or open hemostatic maneuvers. This scenario, therefore, requires the anticipated, coordinated, and timely efforts of the entire surgical team. It cannot be improvised and necessitates regular training. Controversially, surgical teams are less exposed to conversion in robotics (compared with laparoscopy); it exposes them to a lack of experience in this setting while they progress through the learning curve and case difficulties. The jury stressed the need for granular, standardized, and team-based

TABLE 3. Robotic Surgical Steps to be at High Risk of Uncontrolled Bleeding and Urgent Conversion to Laparotomy Protocols

High-risk technical steps during liver procedures: Intrafacial hilum dissection, especially above the portal bifurcation and with peri-hilar tumor invasion. Dissection of the hepatic vein confluence. Parenchymal transection (eg, end of major hepatectomies) near the inferior vena cava and hepatic veins. Liver mobilization in cases of large bulky tumors. Vascular reconstructions.	High-risk technical steps during pancreatic procedures: Dissection/reconstruction of the superior mesenteric/portal venous axis. Splenic vessels dissection. Transection of the pancreas. Resection of the retroportal pancreatic lamina. Arterial dissection/reconstruction such as superior mesenteric artery or coeliac axis. Division of arcuate ligament for stenosis of coeliac axis.
Requirements for urgent conversion protocols: Conversion protocols should be elaborated at the center level, adjusted to local practices, and included in the center’s structured credentialing process (Table 1, Section C, Recommendations 7, 8, and 11). The entire surgical team must be engaged in conversion protocols with predefined and standardized roles. The instruments required for conversion should be standardized and available in the operative room. The preoperative checklist should include preparing conversion necessities. After each urgent conversion, the entire team should be debriefed to identify potential flaws and improve practice.	

robotic urgent conversion protocols with training (including simulation-based) to be mandatory in a center's program requirements (Table 1, Section C, Recommendation 11). They also encourage us to take advantage of nonurgent routine conversions as real-life drills for urgent conversions. Table 3 emphasizes requirements regarding urgent conversion protocols.

Panel 3: Outcome Assessment in Robotic HPB Surgery

Open and laparoscopic approaches were considered valuable comparators to robotic; however, the jury acknowledged that, at this time, the open approach must remain the gold standard in HPB surgery, especially regarding patient safety and oncological adequacy.

The use of standardized and validated metrics under recently published consensus recommendations for assessing outcomes of surgical interventions³² was strongly supported, as well as the use of definitions of liver-specific and pancreatic-specific complications endorsed by HPB societies^{91–93} (Table 1, Section D, Recommendation 12). The evidence regarding HPB robotics mostly reports on early postoperative complications during the 30 or 90-day postoperative period. Long-term follow-up reporting, specifically for oncological endpoints, must improve. Patient-centered outcomes were identified as an unmet requirement in assessing robotic HPB surgery, especially when cost-effectiveness is considered. Benchmarking observational studies are available for robotic distal pancreatectomy only.^{20,94} The reporting of patients' risk assessment in robotic series was often low, exposing likely biases related to patient population selection and heterogeneity, especially when compared with open. For these reasons, all parties agreed that, at this stage, caution is needed in interpreting favorable robotics results.^{23,95–97}

In their assessment, the Jury considered a set of critical outcomes³⁶ aligning with the recommendations for assessing outcomes of surgical interventions³² and the optimal length of postoperative follow-up to establish credible outcomes data: 3 months for liver resection^{98,99} and 6 months after pancreatic resection.^{32,100} The recommended metrics for morbidity and mortality included the Clavien–Dindo (CD) classification,¹⁰¹ Comprehensive Complication Index (CCI),¹⁰² failure to rescue,¹⁰³ comparison with “benchmark” values,¹⁰⁴ and surgical margins as well as lymph node retrieval adequacy rates in oncological contexts. Long-term results should include Disease-Free Survival (DFS) and overall survival (OS) when applicable.

The measurement of intraoperative blood loss has been subject to inconsistencies, inherent reported variations, and unclear clinically relevant effect sizes.^{105,106} Likewise, the ambiguity of the overall conversion rate as an outcome indicator should rely on more precise definitions of urgent or nonurgent conversions, as previously stated^{107,108} (Table 1, Section D, Recommendation 13). Finally, the jury conceded that the length of stay was a versatile criterion needing cautious interpretation considering local practices and various socioeconomic parameters. Consequently, the jury considered these parameters as important outcomes but not critical³⁶ when evaluating robotic value despite the fact they are currently the main measurable advantages allocated to robotics in the literature.

Robotics has notoriously been associated with greater procedural costs than the open or laparoscopic approach in almost all published reports [4 systematic reviews/meta-analyses^{109–112} and observational studies^{113–116} and 1 RCT in pancreatic surgery (EUROPA trial)¹¹⁷]. Experts contextualized these expenditures by predicting the possible rapid devolution of expenses related to emerging multiple robotic technologies and market

competitiveness.⁸⁶ The substantial expenditures on cancer medicines were also considered a reference in any comparative cost evaluation of oncological robotic technologies.¹¹⁸ As a result, the cost-effectiveness of robotic surgery was regarded as a premature outcome at this stage and felt to be outside the scope of these guidelines with the understanding that robotics has the potential to increase the use of HPB minimally invasive surgery and improve patient outcomes (Table 1, Section A, Statements 2).

Panels 4 to 7: Indications and Impact of Robotic Liver Resection

For liver procedures, the robotic approach was initially compared with the open route, with a specific emphasis on its oncological adequacy for hepatocellular carcinoma and colorectal metastasis. Subsequently, the potential advantages of the robotic approach over laparoscopic liver resections were investigated. Finally, specific challenging clinical scenarios and technical considerations were discussed.

Robotic Liver Resection Versus Open Approach

Randomized controlled trials supporting minimally invasive liver resection compared with the open route are scarce and have exclusively enrolled laparoscopic patients without robotic procedures.^{119–121} For hepatocellular carcinoma (HCC), There are 3 propensity-matched studies, including mostly Barcelona Clinic Liver Cancer Stage 0-A patients.^{23,122,123} They overall included 412 robotic HCC patients and reported R0 rates $\geq 98\%$, 3 years DFS (in 2 studies) $\geq 60\%$, and 3 years OS $\geq 75\%$. One propensity-matched study¹²⁴ includes 309 robotic patients with large HCCs (≥ 5 cm)¹²⁴ (no data on margins, 3 years DFS and OS = 33% and 62%). These studies overall support the safety (regarding short-term outcomes and oncological endpoints) of the robotic technique versus the open route for HCC. All report low morbidity in the robotic arms (in all studies,^{23,122–124} CD > 2 complications rates $\leq 6\%$). One²³ reports a decreased risk of postoperative liver failure (ISGLS grade B: 0 vs 12%; $P = 0.001$). None provide proper adjustment regarding liver functional reserve or parenchymal changes, except the Child–Pugh score, which is acknowledged to lack granularity in this setting.¹²⁵ The proportion of patients (inconsistently reported) with histologically verified cirrhosis varied from 26%¹²² to 64%.¹²⁴ One series¹²⁶ focused explicitly on margin adequacy and reports improved OS with ≥ 1 cm margins¹²⁶ ($n = 58$ robotic HCCs, median tumor size = 4 cm, margins ≥ 1 mm = 81%, margins ≥ 1 cm = 38%).

For colorectal liver metastases, 3 small-sized multicentric studies showed the safety of robotics over other approaches; 1 mainly includes patients with ≤ 2 tumors,¹²⁷ and 2 are based on a cohort of patients within “Milan criteria”.^{128,129} Another series reports satisfactory negative margin rates using robotics.¹³⁰ Beane et al trial¹³¹ randomized 171 (robotic vs open) patients having simultaneous resection of rectal cancer and liver metastasis (< 5 tumors, < 10 cm), and the primary endpoint was 30-day complication rate. It shows the superiority of the robotic approach with respect to complications (30-day complication rate: 31.4 vs 57.6%, $P = 0.014$ with 100% of R0 in the liver).

Compared with the open route, the minimal-invasive advantages repeatedly observed with laparoscopy seemed to be maintained, if not improved, with the robotic platform. Therefore, robotic surgery appears to be a valuable alternative to open surgery for minor (≤ 2 segments) (Table 1, Section E, Recommendation 14) and major (≥ 3 segments) (Table 1, Section E, Recommendation 16) liver resection in selected cases.¹³² An example of this benefit is illustrated by the reported reduced risk

of liver decompensation,²³ as recognized with laparoscopy,¹³³ compared with the open technique (Table 1, Section E, Statement 18). Satisfactory results have been reported in Child-Pugh B HCC patients²³ (n = 11 robotic Child-Pugh B HCC patients).

Robotic Liver Resection Versus Laparoscopic Approach

Significant evidence regarding the feasibility and safety of robotic liver surgery comes from studies comparing it to laparoscopy (and not to open route), leading to a new paradigm reference standard in liver surgery.^{12,13,134,135}

Indeed, the first RCT on robotic hepatectomy is the ROC'N'ROLL trial¹³⁵, which compares robotic versus laparoscopic hepatectomy. It is a single-center trial enrolling surgeons with expertise in minimally invasive hepatectomies. It randomized 81 patients undergoing hepatectomy for confirmed or suspected malignancy. The trial included 20% major resections and 60% of cases had an IWATE score ≥ 6 points. Of note, stratification was based on preoperative etiology (primary versus secondary tumors) and difficulty (IWATE score ≥ 6), but not on the extent of resection. The primary endpoint was 90-day quality of life, assessed using the role functioning scale of the European Organisation for Research and Treatment of Cancer QLQ-C30 questionnaire. Robotic patients experienced a similar mean drop of quality of life from baseline according to the QLQ-C30 (-9.0 versus -9.4 ; $p = 0.547$) compared to laparoscopic patients. Secondary endpoint analysis showed similar CCI scores (8.9 versus 15.5 , $p = 0.137$), 90-day mortality rates (3% vs. 5% ; $p < 0.99$), and R0 resection margins ($> 98\%$; $p < 0.99$). However, the authors reported a decreased risk of CD > 2 complications in the robotic arm (OR of 0.24 [95% CI, 0.07–0.84]).

The International Robotic and Laparoscopic Liver Resection Study Group Investigators conducted 9 propensity score-matched studies (ie, robotic vs laparoscopy) covering the whole spectrum of laparoscopic liver procedures:¹³⁶ these included left lateral sectionectomies,¹³⁷ antero-lateral,¹³⁸ and postero-superior resections^{139,140} and major hepatectomies¹⁴¹ (including specific reports on left¹⁴² and right¹⁹ and central hepatectomies¹⁴³). All these studies consistently established the feasibility of robotics and its advantages over laparoscopy in reducing blood loss, conversion rate, and learning curve without translation on patient postoperative outcomes (Table 1, Section E, Recommendation 15 and Statement 17). While there are no benchmark values, reported rates of conversion, severe morbidity, and 90-day mortality were 5.3%, 7.7%, and 1.5% for robotic major resections¹⁴¹ (n = 892, 56% of primary liver tumors and 25% of cirrhosis) and 2.2%, 6.1%, 0.2% for robotic postero-lateral segment resections¹⁴⁰ (n = 461, 54% of primary liver tumors and 31% of cirrhosis). These studies originate from a large, single, unique multicenter registry capturing the top-level of current expertise in robotic and laparoscopic surgery, perhaps limiting broad generalizability. One large propensity-matched study (robotic vs laparoscopy) from the International Consortium on Minimally Invasive Liver Surgery,¹⁴⁴ including a heterogeneous population with various liver procedures, shows an improved rate of textbook outcomes associated with robotic patients¹⁴⁴ (1507 robotic patients, textbook outcome after matching = 78.3% vs 71.8%, $P < 0.001$).

Experts and Jury agreed that the robot may offer benefits over laparoscopy by shortening the surgeon's learning curve and offering improved dissemination of minimally invasive liver surgery. However, whether the technology may offer valuable advantages (for the patients or the surgeons) even in the hands of expert laparoscopic liver surgeons is still to be determined.¹³⁵ Nevertheless, specific circumstances, such as vascular/biliary reconstruction (Table 1, Section E, Statement 19) and advanced (as defined by laparoscopy-based difficulty scores^{136,145,146})

minimally invasive liver procedures (Table 1, Section E, Statement 20), may be specifically suitable for robotic surgery.

Challenging Minimally Invasive Indications of Liver Resection

Two challenging clinical situations were specifically discussed because they are frequently qualified as “ideal indications” for the robotic approach: peri-hilar cholangiocarcinoma and live donor hepatectomy. While robotics is thought to provide technical advantages for hepatic hilum dissection and biliary-enteric reconstruction, only 4 small series cumulating 100 highly selected patients from expert centers provided data for peri-hilar cholangiocarcinoma patients.^{48,147–149} Xu et al study¹⁴⁸ (n = 10 robotic cases, Bismuth–Corlette Type III–IV¹⁵⁰ = 90%) showed an increased complication rate (90% vs 50%; $P < 0.05$) and decreased DFS ($P = 0.029$) compared with open surgery. The other studies support the safety of the robotic approach, notably to achieve negative margin. The quality of lymphadenectomy is documented only in the largest and most recent series⁴⁸; it includes 38 patients (Bismuth–Corlette type III–IV¹⁵⁰ = 66%), reports an R0 rate of 81% and a mean harvested nodes of 8 (± 6.6). Overall, there is a lack of robust long-term data.¹⁵¹ Thus, the safety of robotic surgery compared with the open route still needs to be demonstrated for peri-hilar cholangiocarcinoma, especially considering the wide spectrum of complex patient characteristics and risks (eg, confounding factors) associated with this indication, for which the relevance of minimally invasive approaches is continuously debated.

Live donor hepatectomies involve ideal, low-risk clinical patient and liver quality profiles.⁹⁸ One series¹⁵² and 2 propensity-matched studies^{153,154} comparing robotic with laparoscopic and open approaches demonstrate the feasibility (less bleeding and similar postoperative complications) of robotic live donor hepatectomy (n = 112 robotic full left lobes and 212 robotic full right lobes, no mortality¹⁵²; n = 35 right lobe donor hepatectomy¹⁵⁴ and n = 92 robotic right donor hepatectomies¹⁵³). Two studies even suggest that robotics is suitable for donors with hilar anatomic variations compared with laparoscopy (n = 102 robotic right donor hepatectomies¹⁵⁵ and n = 100 robotic right donor hepatectomies with extended criteria,¹⁵⁶ ie, graft weight ≥ 800 g, type B/C portal vein,¹⁵⁷ > 1 bile duct or hepatic artery to anastomose and inferior hepatic veins > 5 mm requiring reconstruction). These robotic series report improved donors' postoperative pain, recovery, and body perception.¹⁵⁸ The main drawback of robotic donor hepatectomy appears to be the increased operative time and warm ischemia,¹⁵³ likely depending on the learning curve. These studies all confirm satisfactory outcomes for recipients of these grafts. While promising, this indication is still in its early stage of development and requires broader critical evaluation^{159,160} (Table 1, Section E, Statements 22 and 23).

Technical Considerations

The lack of haptic feedback is still a limitation in robotic surgery.¹⁶¹ In the hands of expert robotic surgeons, it is somehow compensated by their optical feedback in association with the projection of both ultrasound images and preoperative renderings on the robotic screen. Studies argue that integrating haptic features may be helpful to guide the force control applied by the tool, tissue manipulation, characterization, and procedural efficiency, and may reduce cognitive overload.¹⁶² The absence of haptic feedback raises concerns about the risk of rupturing large lesions during liver surgery, especially when located in “difficult” segments requiring extended mobilization;

however, 1 propensity-matched score study¹⁶³ included 100 robotic large-tumor resections (mostly HCCs and benign tumors on noncirrhotic livers, median tumor size = 115 mm). It shows the feasibility of robotics (vs laparoscopy) with a conversion rate of 8%, CD > 2 rate of 4%, and no mortality. The jury emphasized the absence of robotic-specific technical difficulty grading systems, especially for liver surgery, while stating that current laparoscopic difficulty scoring systems remain useful, especially for risk assessment in data collection and study designs¹⁶⁴ (Table 1, Section E, Statement 21). As it was for laparoscopic liver surgery,¹² developing and validating robot-specific scoring systems, especially for liver procedures, is a high-priority research topic needed to ensure technical guidance and safety (Table 4). Finally, the lack of robotic ultrasonic cavitation or another transection device, such as the hydro jet, is currently a disadvantage, possibly highlighting a current technological benefit for open and laparoscopic techniques.

TABLE 4. Areas in Need of Innovation and Future Research Priorities

Innovations awaited by the HPB community:

- Development and validation of robot-specific difficulty scores for technical guidance, especially lacking in the context of liver procedures.
- Integrated ultrasonic surgical aspirator (for liver robotics).
- Improved liver transection sealing devices.
- Integrated augmented reality for navigation.
- Real-time AI-based surgical assistance.

Future questions for randomized trials:

- Is robotics versus laparoscopy superior in patients undergoing major liver resections (stratification regarding biliary reconstruction) for primary or secondary liver cancer?
- Is robotics versus open noninferior in patients undergoing pancreatoduodenectomy (stratification regarding neoadjuvant treatment and vascular resection) for pancreatic or peri-ampullary cancer?
- Is robotic versus laparoscopy cost-effective in patients undergoing distal pancreatectomy?
- Is robotics versus laparoscopy cost-effective in patients undergoing minor liver resection in easily accessible lesions for primary or secondary liver cancer?
- Is the uptake of an HPB robotic program effective or cost-efficient in different care systems (private vs public, with or without already implemented laparoscopy)?

Requirements for prospective real-world data collection:

- Transparency including public reporting and Web site presence.
- Transparency regarding data gathering, artificial intelligence integration, and intraoperative analytics.
- Documentation of the device characteristics: brand, generation, technical features, use of autonomous or semiautonomous options.
- Documentation of the health care structure, costs, and reimbursement schemes.
- Documentation of prior surgeons' and centers' experience and learning curves (in training/mentor, 2-surgeon technique).
- Documentation of the patient's demographics and indications with risk assessment, eg, neoadjuvant treatments, resectability, liver functional reserve, and underlying liver disease for liver resections.
- Documentation of intraoperative metrics with sufficient details (ie, transfusion rate, urgent vs nonurgent conversion).
- Documentation of postoperative and patient-centered outcomes using standardized and validated clinically relevant metrics.
- Documentation of patient follow-up while adhering to procedure-specific follow-up periods.
- Documentation of surgeons' and patients' acceptability of the device, including ergonomics and surgeon's quality of life.
- Quality control of the data, including auditing practices.

Panels 8 to 10: Indications and Impact of Robotic Pancreatic Resection

In contrast to liver procedures, which encompass several procedures associated with varying technical difficulties, pancreatic resections are often categorized in the literature into distal pancreatectomies and pancreatoduodenectomies, which each have their inherent challenges. Studies frequently focus on homogeneous populations undergoing one of these procedures. Consequently, the efficacy of the robotic approach was initially evaluated for distal pancreatectomy, with comparisons to both open and laparoscopic approaches, and subsequently for pancreatoduodenectomy, predominantly comparing it to open surgery since laparoscopic pancreatoduodenectomy is not yet widely adopted. Following this, investigations were conducted into the oncological adequacy of robotic approaches for pancreatic ductal adenocarcinoma (PDAC). Finally, the feasibility and outcomes of robotic pancreatic enucleation were assessed.

Robotic Distal Pancreatectomy Versus Open and Laparoscopic Approach

The preference for robotic distal pancreatectomy over the open route is mainly extrapolated from RCTs comparing minimally invasive (ie, predominantly laparoscopy) to open approaches such as DIPLOMA and LEOPARD.^{80,81} These trials demonstrate minimally invasive approaches (vs open route) being noninferior regarding the rate of R0 resection and improving functional recovery (ie, mobility, pain control, caloric intake, no fluids, no infection). Comparative observational studies (robotic vs laparoscopy) conducted by the E-MIPS have provided evidence supporting robotic safety (vs laparoscopy). Chen et al¹⁶⁵ (no matching) included 103 robotics patients with resectable PDACs and shows oncological adequacy (R0 = 76%, median harvested nodes = 18, 3 years OS = 43.7%). Lof et al¹⁶⁶ (propensity-matched) included 407 robotic patients (79% of benign or premalignant tumors) and shows satisfactory procedural and postoperative outcomes (conversion = 7%, spleen preservation = 81%, CD > 2 complication = 14%, 90-day mortality = 0.5%). This makes robotic a valuable minimally invasive alternative to laparoscopy with potential advantages regarding conversion and spleen preservation rates.¹⁶⁶ However, these advantages were not evident in benchmark values for spleen-preserving distal pancreatectomy (benchmark study,⁹⁴ n = 162 robotic vs 602 laparoscopic low-risk patients, spleen-preservation failure ≤ 27% vs ≤ 30%). Based on all these data, results from a pan-European registry (E-MIPS)¹⁶⁷ and on the Müller et al²⁰ benchmark study, the safety of robotic distal pancreatectomy can be considered established (n = 355 low-risk patients,²⁰ conversion ≤ 3%, clinically significant pancreatic fistula ≤ 1.8%, 90-day CD > 2 rates ≤ 26.7%, harvested nodes, and R0 margin ≥ 9 and ≥ 83%) (Table 1, Section F, Recommendation 24). Of note, in this benchmark study,²⁰ the conversion rate reported for patients operated by laparoscopy (n = 180, conversion rate = 15%) exceeded robotic benchmarks (≤ 3%) (Table 1, Section F, Statements 25). Still, its widespread advantages over laparoscopy and cost-effectiveness remain to be determined.^{167–169}

Robotic Pancreatoduodenectomy Versus Open and Laparoscopic Approach

For pancreatoduodenectomy (ie, Whipple procedure), safety concerns of the laparoscopic approach compared with open surgery were raised by the prematurely terminated LEOPARD-2 trial.¹⁸ This study has challenged the earlier

favorable results from other RCTs (PADULAP,¹⁷⁰ PLOT,¹⁷¹ and Wang et al's¹⁷²), limiting the dissemination of the laparoscopic approach. The EUROPA trial¹¹⁷ randomized 81 patients (robot vs open) for any indication, excluding borderline and locally advanced tumors, and the primary endpoint was 90-day-CCI. EUROPA concludes with the safety of the robotic approach over open pancreaticoduodenectomy (90-day CCI: 34 vs 36, $P=0.713$). It, however, demonstrates higher rates of clinically significant pancreas-specific complications (59% vs 33%; $P=0.046$) and higher overall costs (33,502 versus 21,429 euros; $P=0.011$) in the robotic arm. No advantages were observed regarding patient-reported outcome measures (including pain, quality of life, and recovery) or self-evaluation of the surgeon's mental workload. The typical advantages allocated to minimally invasive approaches regarding blood loss and length of stay are not shown. While not statistically significant, the robotic patients experienced 18% (vs 0% in the open group) of R1 resections. The Liu et al¹⁷³ trial randomized 164 patients (robot vs open) with resectable benign, premalignant, or malignant tumors, and the primary endpoint was the hospital length of stay. This trial¹⁷³ shows, in the robotic arm, a shorter length of stay (11 vs 13.5 days; median difference of 2 days; $P=0.029$), improved times to functional recovery (eg, off-bed activities and nasogastric tube removal: 2 vs 3 d; $P<0.001$) with similar CD>2 rates (22% vs 23%; $P=0.82$), pancreatic-specific complications rates, mortality (1 death in each arm), harvested nodes (median: 13 vs 13; $P=0.36$) and R0 margins (4 vs 4%; $P=0.99$).

With the EUROPA¹¹⁷ and Liu et al¹⁷³ exploratory trials, pancreatoduodenectomy becomes the procedure currently documented with the highest level of evidence in robotic HPB surgery. In addition, 7 controlled but nonrandomized studies^{22,46,79,174–178} emerging from different groups support the feasibility of robotic pancreaticoduodenectomy compared with open regarding postoperative outcomes suggesting that robotics do not negatively affect morbidity, including pancreatic fistula or hemorrhage. One propensity-matched study shows decreased transfusion and conversion rates compared with laparoscopy ($n=1158$ robotic patients, 83% with malignant tumors).¹⁷⁹ Robotic pancreatoduodenectomy seems already increasingly adopted over laparoscopic pancreaticoduodenectomy based on National Surgical Quality Improvement Program (NSQIP) data¹⁸⁰ and the E-MIPS registry¹⁷⁸ ($n=835$ robotic patients including 47% of PDACs, conversion = 9.7%, CD>2 = 46%, clinically significant pancreatic fistula = 25.4%; 30-day-mortality = 4%, R0 = 73%, harvested nodes = 16).¹⁷⁸ One population-based propensity score-matched study (de Graaf et al,¹⁸¹ Dutch Pancreatic Cancer Audit, 2014–2021, robot vs open) includes 701 robotic patients (malignancy = 73%, PDACs = 31%, neoadjuvant = 8.6%, CD>2 complications = 40%, mortality = 4%, failure to rescue = 9%, R0 = 61.5%, mean harvested nodes = 15). It stands as an example of real-world data and nationwide implementation. However, the optimal Dutch system raises skepticism regarding its generalizability in other countries.

Overall, the jury recognized the feasibility of robotic pancreatoduodenectomy in selected cases and its promising, yet still unestablished, potential in the context of emerging validated training tools,^{46,71,182} curricula and specialized difficulty scores^{47,183–185} (Table 1, Section F, Statements/Recommendations 27–29). The results of ongoing RCTs, including DIPLOMA-2 (ISRCTN27483786)¹⁷ and PORTAL (NCT04400357),¹⁸⁶ comparing minimally invasive and robotic pancreatoduodenectomy to open surgery, are awaited, while no RCTs comparing robotic versus laparoscopy are ongoing.

Robotic Surgery for PDAC

In patients with PDAC, robotic technology seems an appropriate surgical approach for both (1) right-sided PDAC (propensity-matched study,²² $n=332$ robotic PDACs; R0 = 90%, median nodes harvested = 16, 3 years OS = 24.8% and $n=380$ robotic PDACs, R0 = 91%, 3-years OS = 34.9%¹⁷⁹) (Table 1, Section F, Recommendation 30) and (2) left-sided PDAC (Müller et al;²⁰ benchmark study, $n=62$ low-risk robotic PDACs, R0 $\geq 83\%$, median nodes ≥ 9 , 3-years OS $\geq 80\%$) (Table 1, Section F, Recommendation 26). Robotic pancreatic surgery seems associated with noninferior oncologic outcomes when compared with open.^{95,165,187} The jury emphasized that appropriate expertise is necessary to fully exploit the potential of robotics for PDACs and that additional longitudinal data are still needed.⁷⁹ This is particularly true for more technically challenging scenarios, eg, patients with borderline or locally advanced tumors, where the jury addressed a note of caution regarding these indications, which were outside of the scope of most trials and studies. More research is needed to assess the impact of neoadjuvant treatments in the context of the robotic approach.^{95,96} Likewise, only a few series focused on the feasibility of the robotic approach for PDAC with vascular resection.^{167,179,188–190}

Robotic Pancreatic Enucleation

The body of evidence assessing robotic enucleation of localized pancreatic lesions remains limited to 7 retrospective single-center series on a restricted number of selected patients. This limited experience nevertheless suggests its feasibility and safety in comparison to both the open^{191–196} and laparoscopic approaches.¹⁹⁷ This has led the jury to recognize robotic enucleation as an acceptable alternative for the same indications as those used in other approaches (ie, superficial benign pancreatic tumors, tumor size <2 cm, and distance to the main pancreatic duct of at least 2 mm)¹⁹⁸ (Table 1, Section F, Recommendation 31).

RESEARCH PRIORITIES

The future assessment of robotic HPB surgery remains a major challenge that is expected to increase. The implementation of conclusive RCTs will be impacted by learning curves, commercial competition, and evolving technologies.¹⁹⁹ In addition, the conundrum regarding growing surgeons' and patients' enthusiasm for robotics and the wide acceptance of minimally invasive surgery have already compromised equipoise, especially compared with the open approach. Robotics will probably quickly pass through IDEAL phases 3 and 4, as conventional laparoscopy did for numerous advanced HPB indications. Thus, the next few years represent a crucial, brief window for designing and executing meaningful comparative controlled trials with clinical impact.

One important mission for the conference was to underscore and prioritize future research areas and needs in robotic HPB (Table 4). The jury recommended conducting exploratory trials focusing on the superiority/noninferiority of robotics in technically advanced procedures, especially in cases where conventional laparoscopy has failed to replace open surgery, eg, advanced liver resection and pancreatoduodenectomy (Table 4). Those studies should search for measurable effects on short-term and mid-term surgical outcomes.³² Conversely, there are several minimally invasive indications where conventional laparoscopy is already recognized as a positive alternative to the open route.^{12,13,200} These procedures are less demanding and function

adequately even without the use and possible expense of robotic assistance. The jury considered that pragmatic study designs with formal economic evaluations providing trial-based comparative cost-effectiveness analyses^{201,202} should be prioritized in these situations (Table 4).

Cost considerations should not be limited to direct intra-procedural/in-hospital expenses and device acquisition/maintenance alone. HPB robotic programs should be evaluated using business models that assess their profitability in advancing minimally invasive surgery. This evaluation should encompass factors such as quicker learning curves (resulting in less downtime from productivity) and improved attractiveness for the institution. In this setting, various barriers or facilitators,^{203–205} eg, governance, quality control, workforce issues (eg, 2-surgeon approach), impact on cognitive processes (eg, new theater environment), public understanding, equity of access, industry role, deskilling on other surgical domains (eg, laparoscopy), etc., will influence the implementation of HPB robotic programs (including local training and credentialing) in health care systems. These need to be further assessed using specialized tools emerging from implementation science, such as the Theoretical Domains Framework (TDF) and the Consolidated Framework for Implementation Research (CFIR)²⁰⁶ (Table 4).

The jury underscored that difficulties in conducting trials do not preclude proactive evaluation of the technology.²⁰⁷ Non-randomized observational studies will likely continue to be the primary means for assessing HPB robotic surgery, especially using benchmark methodology.¹⁰⁴ Therefore, prospective and comprehensive databases and national/international registries collecting longitudinal information from open/laparoscopic/robotic procedures are crucial, including procedure-specific and patient-specific risk information for appropriate analytical adjustment (eg, propensity score-based methods) (Table 4).²⁰⁸ They are especially needed in evaluating rare indications (eg, peri-hilar-cholangiocarcinoma, living donation, long-term outcomes (ie, oncological endpoints), and supporting the generalization of trial results.^{209,210} Such registries are also paramount for tracking the performance of new devices, the evolution of robotic technologies, and their expected impact on health care systems. The jury encourages prospective and quality data collection, seizing care practice in a naturalistic manner and based on pre-hoc definitions aiming to capture robot-specific technical endpoints and granular data regarding clinical contexts and indications in centers embarking on HPB robotic surgery (Table 4).²¹¹ Such a registry could be used as a platform for designing registry-based RCTs, possibly allowing for lesser cost, generalization, rapid enrollment, and better follow-up completeness.²¹²

Finally, the jury conveyed that future research in robotic HPB surgery must target various stakeholders⁴¹ in addition to the surgeon to inform and validate next-generation metrics and tools that could be used to assess human factors, such as procedural analytics integrating computer vision and artificial intelligence.²¹³ Gathering a substantial volume of digitized data, robotic systems are an optimal platform for future advancements in virtual patient and surgeon modeling,²¹⁴ including virtual trials using individualized computer simulation (ie, including virtual patients). This represents an emerging alternative to address typical challenges in evaluating swiftly evolving medical technologies.^{215,216}

DISCUSSION

ROBOT4HPB is the first jury-based international consensus conference evaluating robotic HPB surgery. On the basis

of the Zurich-Danish model, it aimed to provide systematic, unbiased, and industry-independent guidelines; it addressed 10 general HPB as well as specific liver or pancreatic surgery topics by comparing robotic versus laparoscopic or open approaches. This consensus conference was held at a turning point where robotic HPB surgery rapidly flows into the IDEAL phase 2b-3 of surgical technological innovation.²⁴ The main goals were to promote a template for the secure foundation of HPB robotics in clinical practice while evaluating current feasibility and potential value and identifying areas of future research and innovation.⁴¹

Through our systematic reviews, distinct trends in the evolution of robotic surgery for liver and pancreatic procedures have been observed, possibly following different IDEAL development stages. Robotic pancreatic surgery, notably pancreatoduodenectomy, is being introduced cautiously with considerable collective efforts to ensure safety in its adoption, supported by significant evidence comparing minimally invasive and open approaches. In contrast, robotic liver surgery appears to be embraced more readily, drawing upon the knowledge gained from conventional laparoscopic techniques. Overall, the consensus recognized that expertise, including training, credentialing, maintaining optimal performances at surgeon and center levels, and high-volume HPB experience are critical parameters ensuring safety. When performed in such context, these guidelines acknowledged that most HPB procedures are feasible robotically and potentially valuable to achieve technically advanced minimal-invasive benefits. The safety of robotic conversion to open surgery during HPB procedures lacks precision and validation; this has emerged as a current red flag situation requiring extreme caution and prior preparation.

Robotic surgery experts were asked to compare robotics to other HPB approaches. While the jury mostly endorsed its favorable and encouraging results, prospective data collection using validated endpoints for surgical assessment, including patient-centered and long-term outcomes, is still incomplete. Therefore, a definitive comparison to reference standards remains to be established, which precludes database and registry-driven recommendations regarding the superiority of robotics. Selected randomized trials are expected but will be challenging to design, especially considering robotics surgery's rapid and disruptive evolution. In addition, these guidelines are being implemented within a monopoly of the DaVinci (Intuitive Surgical) platform. Emerging platforms and technologies will likely affect our assessments and validations of HPB robotics in clinical practice, especially when integrating unique new functionalities and artificial intelligence with procedural analytics, augmented reality, and various autonomous/semi-autonomous features.

In the meantime, these inspiring future innovations and broadening surgeon robotic acceptance fuel the enthusiasm surrounding HPB robotics. Among the experts and the audience, most minimal-invasive surgeons who embarked on robotics acknowledged being seduced by the technology without significant evidence-based data. The drive for competition among specialized professionals and hospitals, combined with the innate curiosity of surgical experts for innovation, promotes proactive marketing strategies, although successfully maintaining a certain level of safety. Realistically, HPB robotics is “here to stay” regardless of its controlled evaluation, especially for procedures with validated minimal-invasive indications.²⁰⁷ In this setting, cost-effectiveness, accessibility, and successful uptake of robotics will constitute the main determinants of robotic diffusion, posing probable geopolitical, economic, and legal quandaries. Robotic surgical technologies and innovations inherently adhere to

market rules, and how health care systems can comply without increasing already existing care delivery inequities might become the next challenge for many societies.

The ROBOT4HPB consensus represents a unique collaborative and multidisciplinary effort involving experts, jury, and audience. The jury's impartial endorsement supports the feasibility of robotic HPB surgery while emphasizing the importance of expertise to oversee its safe promotion and development. Although it offers considerable promise for advancing minimally invasive surgery in the future, it also presents several formidable and increasing challenges regarding its ongoing assessment and implementation.

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