Title: White Paper: Robotic Cholecystectomy - New Technology but Safe Principles Still Apply

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Abstract

Background: Increasing adoption of robotic cholecystectomy (RC) has prompted debate over its cost, access, safety, and training. Given the historical lessons learned during the transition from open to laparoscopic cholecystectomy (LC), it is important that we now evaluate RC within the framework of safe cholecystectomy principles.

Methods: This white paper reviews existing literature and expert consensus on advantages and disadvantages of RC. It examines credentialing practices, safety protocols, adjunctive imaging, technological limitations, and potential global applications.

Results: RC offers enhanced visualization, improved ergonomics, and potential benefits in complex anatomy, surgeon longevity, and rural or resource-limited settings. However, challenges remain, including inconsistent credentialing, limited standardization of training, potential higher costs, and variable adherence to safe cholecystectomy principles such as the critical view of safety (CVS). Evidence on outcomes as compared to LC is mixed, and current data suggest the need for structured training, simulation, and competency-based evaluation.

Conclusion: Safe cholecystectomy principles must remain paramount in all forms of cholecystectomy. For RC adoption, there is room for improvement in standardizing training, thoughtful credentialing, and responsible integration of technology.

Abbreviations

AI: Artificial intelligence
BDI: bile duct injury
CVS: critical view of safety
LC: laparoscopic cholecystectomy
MIS: Minimally Invasive Surgery
OC: open cholecystectomy
OR: operating room
RC: robotic cholecystectomy
SAGES: Society of American Gastrointestinal and Endoscopic Surgeons

Introduction

One of the most significant advancements in modern surgical history was the advent of laparoscopic cholecystectomy (LC) in the late 1980's. Initial enthusiasm for LC over traditional open cholecystectomy (OC) stemmed from the immediate benefits of minimally invasive surgery, including decreased length of stay, reduced postoperative pain, and a quicker return to normal activity.[1] Other non-clinical factors further drove demand for LC, as explained by MacFayden et al as "pushed by the media, by patient demand, by industry, and by physician competition."[1] However, its rapid adoption soon raised concerns regarding patient safety, particularly in relation to bile duct injury (BDI) and the technical challenges posed by a steep learning curve.[2]

After the inception of LC, several studies compared morbidity, mortality, recovery, and cost over traditional OC. While LC consistently demonstrated advantages in postoperative recovery and patient satisfaction,[1] early reports found an increased incidence of BDI, especially during the initial phase of surgical adoption. This prompted a national movement for safety protocol development and underscored the importance of structured training and credentialing for laparoscopic procedures.[3,4] In 1992, *Surgical Endoscopy* published its multi-institutional LC study, organized by the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), which identified two targets for improvement: adequate surgeon training and improvement in operative skills. Through sustained advocacy and coordinated efforts, prevention of BDI during LC was addressed from residency training to national practice until rates fell below those of OC. More recently, in 2015, SAGES began a multi-society international effort to enhance a universal culture of safety around cholecystectomy to further lower the incidence of BDI.[5] However, history repeats itself. Innovation and advancements in robotics have led to a surge in robotic cholecystectomy (RC) that has, despite its technical similarity to LC, garnered intense scrutiny regarding both resource utilization and patient safety after a recent report of higher BDI rates as compared to LC.[6]

This white paper aims to address the widespread adoption of RC, revisiting the pivotal debates of the 1990s surrounding healthcare resource utilization and safe cholecystectomy principles.
The key question is: What are the benefits of RC? How does one safely adopt this technique? Do the principles of safe cholecystectomy apply differently to robotics, or is this an opportunity to renew emphasis? In this paper, we highlight key questions surrounding RC adoption and propose how to maintain a culture of safety in cholecystectomy in the burgeoning RC era. We believe this is a pivotal moment in surgical history to address and promote safe principles independent of the technology or approach used for cholecystectomy.

Body

This white paper was authored by a multidisciplinary panel of surgeon experts and committee representatives from the SAGES Safe Cholecystectomy, Robotic Surgery, and Hepatobiliary Surgery Committees. Using a structured focus group methodology, the panel delineated two primary domains: concerns vs. advantages of RC, with predefined subcategories in each, which were subsequently selected by consensus for comprehensive discussion.

What are the concerns with widespread adoption of RC?

Safety surrounding cholecystectomy is a topic uniquely positioned for international discourse. Cholecystectomy is one of the most frequently performed operations worldwide, and independent of the surgical approach, it is far from being a uniformly simple case. Acute cholecystitis, chronic inflammation, dense adhesions from prior surgery, aberrant anatomical variations (particularly in the biliary tree), obesity, and the presence of Mirizzi syndrome can transform a seemingly simple case into a challenging operation. These complexities significantly elevate the risk of complications, most notably BDI, which carries substantial morbidity and medico-legal implications. The risks also increase exponentially if the surgeon has not achieved competency in the applied surgical platform. To address this concern, we first explore credentialing and training for RC.

Credentialing and training for RC

The growing complexity of modern healthcare continues to challenge credentialing pathways. While enforcing standards can be imperfect, it is designed to ensure patient safety, provider competency, and medicolegal accountability. RC poses a unique challenge to this framework, as cholecystectomy is a core procedure for the general surgeon. The robotic platform is simply a means for execution. This raises the question, who is responsible for attesting safe use of the technology: the American Board of Surgery, national societies, industry, the hospital, or the individual surgeon?

In robotic surgery, initial exposure and training are commonly provided by the device manufacturer, most commonly, Intuitive Surgical in the United States. Completion of this training, while necessary, does not equate to procedural proficiency. Manufacturer-led instruction focuses on platform operation rather than procedure-specific skills or safety considerations. According to FDA recommendations, industry's role is to ensure safe operation of the device, not to certify clinical competence.[7] Furthermore, current robotic credentialing and privileging practices often fail to assess a surgeon's proficiency in fundamental robotic skills or case selection. For example, for RC credentialing, there is no requirement to demonstrate competency in identifying key landmarks or in managing complex biliary anatomy. There is also no set procedural volume that must be achieved with a proctor prior to being granted independent privileges to use the robot. The result is a credentialing and privileging environment that may allow underprepared surgeons to perform high-risk operations under the assumption of low complexity.

Concerns surrounding industry sponsored versus academic or society training for RC highlight a broader contextual issue - training and credentialing may be conflated but remain distinct. Credentialing is performed by the surgeon's institution and verifies qualifications and eligibility to practice, followed by privileging (authorizing) a surgeon to perform specific operations if appropriate. Training implies graduated proficiency and subsequent competency. What training should be required to perform a RC? This must be tailored to the individual, but should include industry exposure, formal training, simulation and continuing education (Figure 1). For those currently in residency training, nearly 70% of programs now incorporate formal robotic curricula, and 55% provide certification of Intuitive da Vinci robotic experience.[8] In fact, several recent national surgical society meetings have hosted panel discussions expressing concern that graduating general surgery residents may soon have more experience in robotic than laparoscopic surgery. Although that topic goes beyond the scope of this paper, it does warrant consideration of whether additional robotic training after residency is necessary for all graduates. For laparoscopic surgeons already in practice, standardized pathways for RC training remain limited. For this group, adopting new technologies into clinical practice is often random. Recognizing this challenge, SAGES issued structured guidelines for the safe adoption of emerging technologies and techniques, which also address the surgeon who has minimal prior experience with laparoscopic surgery adopting robotics.[9] The guidelines propose ways for a hospital system to approach training surgeons with different clinical backgrounds, but there is no consensus on exactly how to execute these steps. What is known is that simulation-based training can shorten learning curves and improve operative performance.[10] Robotic skills training should thus utilize simulation, with an emphasis on objective assessments prior to transitioning to clinical use. For the general surgeon, it should also include modules specific to gallbladder surgery.

Once adequate robotic training is achieved, there is a lack of published guidelines on how to then 'credential' a surgeon to perform a RC.[11] A relevant comparison in cross-credentialing however can be drawn from aviation. When transitioning to a new aircraft, skilled pilots must first complete comprehensive ground instruction, simulation-based training with failure scenarios, formal assessments, and supervised flight hours with experienced instructors.[12,13] This multi-tiered approach to competency-based credentialing prioritizes safety and standardization. A similar model for RC, especially for surgeons without prior minimally invasive experience, may improve patient outcomes and reduce preventable errors. Another consideration is enforcing a minimum procedural volume threshold after device-specific training. An example can be referenced from interventional cardiology with transcatheter aortic valve replacement (TAVR). The Centers for Medicare & Medicaid Services has established a stringent national coverage determination requiring specific institutional and proceduralist volume requirements: completion of ≥50 open-heart surgeries in the prior year and ≥20 aortic valve-related procedures over two years and must include at least two cardiac surgeons and one interventional cardiologist with ≥300 annual percutaneous coronary interventions. While procedural volume alone does not guarantee quality, it reflects a degree of technical familiarity and anatomic understanding that supports safe practice.[14] Hospitals that provide robotic surgery services may benefit from volume requirements. Each operation is known to have a learning curve to achieve safe, efficient, and high-quality outcomes. For hepatobiliary and cholecystectomy cases, it has been established that the learning curve ranges from 20 to 48 cases.[15]

In summary, each surgeon and hospital system are unique, but basic standards must be met. Knowing how to safely use robotic technology is insufficient to confer safety for cholecystectomy. Credentialing is a necessary component, but those performing RC should uphold the same culture of safety that was sanctioned during the transition to LC over three decades ago. Understanding and applying strategies to minimize the risk of biliary or vascular injury should be independent of the technology employed. Thus, this paper offers a timely opportunity to reemphasize the vital importance of prioritizing safety during *every* cholecystectomy.

Safe cholecystectomy during RC

Regardless of operative approach (open, laparoscopic, or robotic), the principles of safe cholecystectomy should be maintained. BDI during cholecystectomy can be a devastating, life-altering complication. It is often caused by anatomic misperception when dissecting out the hepatocystic triangle. BDI was a major concern during the early migration to LC from OC and several initiatives to reduce injury were undertaken in response. In 1995, the term "Critical View of Safety (CVS)" was formally introduced, which tasks the surgeon to pass an anatomic checkpoint prior to dividing any critical structures (Table 1). It includes three tenets: 1) clearing the hepatocystic triangle of fat/fibrous tissue, 2) clearing the gallbladder off the lower third of the cystic plate, and 3) identifying only two structures entering the gallbladder.[3] Promotion of the CVS seemed to reduce BDI rates during the LC era; however, variation in global technique and lack of structured training in CVS were major contributors to surgical errors across all cholecystectomy platforms.[16] This prompted a national effort by SAGES to create the Safe Cholecystectomy Task Force and the 6-step program for safe cholecystectomy that focuses on improving safety and decreasing complications associated with cholecystectomy. Notably, the 6 steps are independent of the platform or technology used for the procedure.[5] The steps include (1) Use of the CVS (2) Understand the potential for aberrant anatomy (3) Make liberal use of cholangiography or other methods to image the biliary tree intraoperatively 4) Consider an intraoperative momentary pause prior to clipping, cutting or transecting any ductal structures (5) Recognize when the dissection is approaching a zone of significant risk and halt the dissection before entering the zone. Finish the operation by a safe method other than cholecystectomy if conditions around the gallbladder are too dangerous, and (6) Get help from another surgeon when the dissection or conditions are difficult.[5] Overall, SAGES champions several strategies, including freely accessible online modules for intraoperative technique and imaging in addition to CVS documentation.[5] While important and beneficial, safety protocol success is contingent upon adoption, adherence, and continued competency.

Where does RC fit into this landscape? Unfortunately, the migration from LC to RC has not led to a reduction in BDI nor a resurgence in advocacy for safe cholecystectomy principles. In fact, one study found a higher rate of BDI in RC.[6] Anecdotal theories as to why include that the robotic platform may create a false sense of security during dissection, secondary to enhanced visualization and instrument stability. Another reason may be poor adherence to achieving the CVS: a study reviewing 50 publicly available RC videos noted that only 4 (8%) were rated as successfully achieving the CVS.[17] This is striking, as when CVS guidelines are intentionally followed, it has been shown that robotic platforms can actually aid in safer anatomical identification.[18] Are surgeons who are performing RC not aware of these safety principles, or are they deliberately omitting them? It is unclear. We recommend that robotic surgeons continue to abide by well-established safe cholecystectomy principles and not rely on technology as a substitute. Vigilance is paramount. Lack of obtaining the CVS, however, is not unique to robotics. Evidence from the last three decades suggests a broader global decline in technical discipline among minimally invasive surgery (MIS) practitioners. Multiple recent studies have shown that even experienced surgeons frequently fail to achieve or document the CVS,[6,17,19–21] with a large multicenter review reporting that documented CVS was attained in fewer than 60% of cases.[22] Surgeon self-assessment has further been shown to be insufficient to ensure compliance with CVS principles.[23] Perhaps robotic platforms are not inherently detrimental; rather, there may be a lack of consistent reinforcement of safety culture, gaps in training, and cognitive overload during MIS cholecystectomies as a whole that may lead to a failure to universally adhere to safety principles.

Ultimately, to improve outcomes for RC, renewed emphasis on mentorship, structured documentation, intraoperative pauses, continuous coaching, and video-based feedback is needed. Coaching programs, such as those developed through SAGES,[24] have shown improved CVS identification when combined with cognitive training. The possibilities of robotic systems to improve safe cholecystectomy are currently undefined, but there may be a positive tipping point if they one day seamlessly integrate additional advanced technologies or AI-powered digital tools to assist the surgeon (e.g., objectively assessing CVS achievement in real time, offering real time feedback to surgeons to promote intraoperative safety features, etc). Complications during RC may also be on the downtrend as learning curves are shortened, with more recent reports demonstrating lower rates of BDI.[25]

Biliary imaging in RC

During the time of OC, fluoroscopic intraoperative cholangiography (IOC) was commonplace to assess biliary anatomy. With the transition to LC, its routine use declined. Barriers cited included increased operative time, need for increased staff/equipment/operative space, insufficient training in technique, radiation exposure, and lack of skill in image interpretation.[26] In the current robotic era, there is a large database study showing lower utilization of IOC during RC (4.8%) versus LC (9.1%).[27] The exact reasons for this are unclear, but a likely culprit may be the technical and logistical challenges specific to robotics. This includes spatial issues requiring undocking and arm manipulation to accommodate a C-arm. Importantly, the recently published SAGES guidelines on biliary imaging during cholecystectomy recommend routine use of either IOC or intraoperative ultrasound (IUS), specifically favoring these modalities over indocyanine green (ICG) fluorescence for delineation of biliary anatomy.[28] Despite this, there remains a common misperception among surgeons that ICG fluorescence cholangiography can serve as a substitute for IOC, (whether during LC or RC). The reality is, these are complementary modalities, with their own advantages and disadvantages.

However, a lack of understanding or experience with IOC may encourage surgeons to rely more heavily on ICG imaging, which is seamlessly built into the da Vinci Intuitive Surgical RC platform when using the Firefly™ Fluorescence Imaging System with near-infrared fluorescent cholangiography (NIFC). That said, the application of ICG cholangiography for the identification of biliary anatomy has been shown in one series to be a highly effective adjunct with a rate of greater than 80% identification of the cystic duct, common hepatic duct, common bile duct, and the cystic duct-common hepatic duct confluence.[29] In the same study, which included 184 sequential RC's, there were no BDI's. Similarly, a larger series including 676 RCs using NIFC with ICG, reported no major biliary injuries with a 2% identification rate of aberrant biliary anatomy.[30] On the other hand, a large database study showed no difference in outcomes for RC with ICG compared to without ICG.[27] This latter finding may be secondary to known restrictions associated with ICG cholangiography, which are relevant regardless of whether used robotically or laparoscopically.[31] Identification of biliary anatomy is limited by obesity, as the depth of penetration is only 5-10 mm.[32] Metabolic associated fatty liver disease, formerly NASH, is present in 25-30% of Americans and is known to decrease uptake and metabolism of ICG. Similarly, severe inflammation and fibrosis of the gallbladder may limit ICG fluorescence. ICG is also not effective at identifying choledocholithiasis.[33] ICG cholangiography certainly has a role, but it should serve as an adjunctive tool to assist in identifying biliary anatomy, and not as a replacement for sound surgical technique grounded in the principles of safe cholecystectomy - achieving the CVS and performing IOC or IUS.

Hesitation to perform an IOC during RC is multifactorial and often stems from a lack of education on how to execute the maneuver. However, multiple recent papers and online video resources have revealed not only how to do it, but also how to subsequently perform a robotic transcystic common bile duct exploration (RCBDE) if choledocholithiasis is present without undocking or manipulating the arms.[34–38] These resources all note a learning curve with staff, but overall show feasibility, safety, and efficacy similar to laparoscopic CBDE and with similar advantages compared to two-stage management with LC and endoscopic retrograde cholangiopancreatography (ERCP).[36,39,40]

Peer-reviewed studies comparing operative time to perform IOC in LC vs. RC are not yet published, but anecdotal experience suggests no major difference between platforms. Beyond cholangiography, additional biliary imaging modalities such as intraoperative ultrasound have been shown to be feasible and potentially simpler than IOC to incorporate into RC, but fluoroscopy may still be required for RCBDE interventions. Increased use of intraoperative IOC and/or US has the potential to improve procedural safety during RC, but a lack of surgeon training appears to be a major barrier to implementation.

Other limitations of the robotic platform

There are some drawbacks to robotic platforms that can impact the safe execution of a cholecystectomy. Loss of haptic feedback stands as an important limitation.[41] While surgeons have learned to substitute the familiar tactile experience during LC with visual cues during RC, this limitation is an important component of the learning curve. In the interim, da Vinci Intuitive Surgical has incorporated "force feedback" to reintroduce some component of tactility. Studies on outcomes from this new technology are promising but limited. It remains unclear if computer-generated feedback will ever reach equivalent fidelity and this feature is not yet widely available. With a lack of tactile feedback, problems may arise from the inability to gauge tension or force applied to tissue. A surgeon accustomed to the direct manipulation and tactile feedback of laparoscopy may unknowingly apply inadequate or excessive force, leading to tissue trauma, some of which may not be immediately apparent. For more complex situations, the surgeon can become disoriented in the zoomed-in view, increasing the risk of iatrogenic injury from misidentification of anatomic structures. A surgeon who has not objectively overcome these limitations through training is at higher risk of complications, even during a straightforward cholecystectomy.

Another matter is the inherent issue of computer/machine reliance. Technical faults and spatial challenges with emergency undocking may pose risks to both the patient and the surgical team.[42]

Robotic surgery must be viewed as a tool, and the surgeon must still be able to offer a safe operation regardless of technical glitches. There are also logistical hurdles unique to RC not encountered with LC. Offering RC at a facility requires significant investment by the OR staff and nursing. Both the circulator and scrub technician require robotic-specific training and familiarization with the plug-in technology to prevent case delays.[43] These nurses experience their own learning curves during the adoption phase.[44] With dedicated OR teams and predictable staffing, the learning curves may be overcome relatively quickly.[45] However, in large systems without dedicated teams, the nursing learning curve may persist for some time. Off-hours (nights and weekends) nursing teams may also object to the robotic platform due to perceived difficulties and lack of resources at these times.

Lastly, resource utilization and direct cost may be higher in RC than LC.[46] Specifically, the cost of disposable items is higher in RC. Over time, surgical teams may learn how to streamline instrument usage to cut down on instrument costs, but during initial learning curves, higher utilization may be necessary for patient safety reasons. To the contrary, centers may be able to recoup costs with other benefits of the robotic platform, such as reduced conversion rate or reduced length of stay, but these are yet to be defined. Building a RC program may also increase robotic utilization across an entire system, a potential benefit to increase availability and access for other surgeons and their patients. An additional cost consideration that is often overlooked in the laparoscopic versus robotic debate is that RC may offset costs by reducing reliance on skilled assistants. The primary surgeon independently controls both the camera and operative instruments, thereby eliminating the need for a dedicated camera holder and allowing other surgeons or assistants to be deployed elsewhere. This is discussed further later in this paper. However, it is important to acknowledge that robotic cholecystectomy may not be the most appropriate 'first case' for every surgeon, given the broader safety considerations of minimally invasive cholecystectomy. The decision should be guided by the individual surgeon's experience and expertise in determining the safest and most suitable initial case.

What will be the impact of multiple robotic platforms for RC?

While much attention in RC has centered on comprehensive platforms like the da Vinci system, the rapidly evolving robotic landscape now includes numerous emerging systems,[47] with several specifically targeting cholecystectomy as an entry-level robotic procedure. First-assist platforms such as Moon Surgical's Maestro and Levita's MARS fundamentally differ in their approach - functioning as surgical assistants rather than complete operative platforms. Their reduced footprint and simplified learning curve may appeal to surgeons and administrators alike, particularly in community settings without dedicated robotics teams. However, this diversification of platforms introduces new standardization challenges for safe cholecystectomy. First-assist robots may provide enhanced visualization and stability but lack the comprehensive feature sets of fully robotic platforms, potentially creating disparate training requirements, credentialing pathways, and safety protocols across systems.

Of particular concern is that while some robotic systems have integrated ICG fluorescence and adjunct image integration capabilities, these technologies are inconsistently implemented across emerging platforms - some offering advanced visualization, others providing none. This heterogeneity may create confusion regarding the role of adjunctive imaging in biliary identification. Regardless of imaging capabilities, surgeons must remember that no technology can replace the methodical CVS and existing safe cholecystectomy principles. As these new robotic technologies gain adoption, surgical societies must develop platform-agnostic credentialing standards that emphasize the unchanging principles of safe biliary identification regardless of technological assistance level. The introduction of AI-enhanced visualization in systems like Moon Surgical's latest iteration adds yet another variable that requires rigorous assessment before implementation to ensure it supplements, rather than replaces, sound surgical judgment.

What are the advantages of RC?

<u>Surgeon longevity, ergonomics, and OR staff efficiency</u>

The Association of American Medical Colleges estimates that in 10 years the United States will face a surgeon shortage of up to 20,000 based on the aging population, residency entry/completion, and disproportionate concentration of surgeons in urban and suburban areas.[48] Robotic surgery may improve surgeon retention, surgeon longevity, and enable community surgeons to operate without the need for experienced operative assistants.

The physical stress of performing surgery has been shown to affect multisite musculoskeletal pain, fatigue, and eye strain, leading to negative downstream effects on surgeons' work, leisure, and sleep.[49] Electromyographic and perceived muscular strain studies simulating laparoscopic surgery show a high risk of muscular fatigue and risk of future injury on par with carpenters and repetitive laborers.[50] One randomized controlled trial assigned patients to robotic or laparoscopic partial colectomies and showed significantly decreased objective postural measurement scale scores amongst robotic surgeons dropping their injury risk from medium to low when compared to laparoscopic surgeons. There was no impact on operative duration nor outcomes.[45] Another bioengineering study employed randomization of surgeons to laparoscopic vs. robotic surgery while wearing monitoring technology. They demonstrated improved objective physiologic stress with robotic surgery, as well as self-reported physical stress.[51] Some robotic technology has overcome the work-related muscular fatigue by allowing the surgeon to sit, utilize a headrest, decrease grip strength, and personalize the settings. Robotic platforms, however, can introduce their own ergonomic challenges, with one systematic review citing increased neck and trapezius strain, along with forearm, fingers, and thumb, because of the robotic platform itself.[52]

In the short term, less stressful physical positions may permit more individual productivity and improved surgeon satisfaction, considering the negative effects of physical strain on leisure time and sleep. With wellness being a major issue for surgeon retention, improved physical working conditions may, in fact, help with surgeon retention.[51] In the long term, reduced physical strain has the expected benefit of prolonging surgeon longevity in their careers. However, this is all said with the caveat that the downstream effects are extrapolated, rather than data-proven, with robotic surgery still being a relatively young technology.

It should be highlighted that the ability to control the camera and all instruments by one surgeon is a major advantage of some robotic systems. This is particularly true for community surgeons, some of whom may not consistently have experienced help in the OR. Yet, as presented at the

2021 American College of Surgeons, approximately only 60 critical access hospitals (~ 4%) had robotic surgical systems.[53] This number is expected to grow. Beyond overcoming OR staffing issues, stable camera control may also contribute to more efficient dissection and reduced fatigue. After an OR staff is trained on the robot, surgeons can take responsibility for the instruments, only requiring assistance for instrument exchanges, which reduces the need for high-level support from residents, advanced practice providers, or dedicated first assistants. This is particularly useful in RC, a core procedure for community general surgeons that requires at a minimum one and often two assistants. However, it should be noted that the authorization of OR staff to introduce instruments differs from state to state with variable requirements for bedside staff to be approved in this role.

Patient populations that may benefit

Certain patient populations have been shown to benefit from the robotic platform for cholecystectomy. This includes patients with class 3 obesity (BMI $\geq$40 kg/m^2), in whom enhanced visualization and improved ergonomics can facilitate dissection within a difficult-to-access operative field that may be obscured by intra-abdominal adiposity or an oversized liver.[48] The contemporary cholecystectomy patient differs markedly from that during the transition to LC several decades ago, with approximately 40% of the population now presenting with a body mass index (BMI) greater than 30 kg/m^2.[54] Patients with severe cholecystitis or complex anatomy may also see benefits, owing to three-dimensional visualization and added dexterity from wristed instruments that can aid in safe dissection and critical anatomy identification.[25,27]

Anecdotal and theoretical populations that may benefit include patients with extensive prior abdominal surgery who require a meticulous lysis of adhesions prior to dissection of the gallbladder. In addition, patients with limited cardiopulmonary reserve better tolerate lower intra-abdominal insufflation pressure that can be achieved during RC. Further research is needed to determine exactly which patients receive substantial benefit from RC; however, it is believed that robotic technology can provide meaningful clinical advantages in select high-risk or technically challenging scenarios.

Benefits in optics and surgical training with robotics

Robotic-assisted surgery continues to gain favor across multiple surgical disciplines, with studies highlighting advantages in visual clarity, ergonomic control, and operative precision. High-definition 3D visualization, enhanced depth perception, and wristed instruments give current robotic systems a notable edge over standard 2D laparoscopy, especially in anatomically limited regions such as the pelvis or deep retroperitoneum.[55,56] Emerging AI integrations - including skill assessment modules and augmented procedural guidance - have begun to accelerate training fidelity and standardize performance metrics.[57] These features may explain evidence showing accelerated learning curves and higher scores in robotic simulation-based training and real-time AI-powered input is already making its mark in urologic procedures.[58]

In summary, robotic platforms appear to offer some technical advantages - particularly in visual fidelity, ergonomics, and training - but should be judiciously adopted based on procedural location, complexity and institutional capacity. From a safety and outcomes perspective, multiple large database reviews suggest robotic surgery is associated with similar or reduced complications and decreased conversions to open.[25,59,60] However, randomized trials such as the ROLARR study in rectal cancer failed to show a statistically significant difference in conversion rates, underscoring that this benefit may be context-specific.[61] Robotic surgery does not consistently outperform laparoscopy in terms of complication rates, operative time, or cost-effectiveness, and any procedural advantage must be weighed against resource utilization.

Discussion

Given the high global burden of benign biliary disease, universal adoption of RC (even in highly developed countries) remains impractical. This underscores the need for appropriate patient selection and continued access to other modalities. OC skills must be preserved to manage difficult anatomy or complications. At present, it is uncertain whether surgeons need to be adept in all three modalities - OC, LC, and RC - but there is still a role for LC and OC, even for those primarily trained in RC. Surgical training must ensure mastery, not just competency, through evidence-based training, simulation, and objective assessment. As technology evolves, achieving competency in safe cholecystectomy is essential prior to independent use of a robotic platform.

Drawing on aviation's stepwise licensing and TAVR's structured proctoring, we propose a platform-agnostic pathway for RC with defined gates from preparation to independent practice (Table 2). Stage 0 (prerequisites) confirms competence in laparoscopic cholecystectomy and the Safe Chole lexicon, completion of didactics on robotic system safety, energy use, and bailout strategy, plus an OR team orientation that rehearses docking, port layout, role assignments, and emergency undocking. Stage 1 (simulation proficiency) requires completion of validated virtual reality modules and dry-lab tasks focused on depth perception, camera control, precise dissection in Calot's triangle, clip application, and needle handling, with prespecified proficiency targets derived from local expert benchmarks. Stage 2 (supervised clinical adoption) consists of a minimum set of proctored cases spanning typical and difficult anatomy; proctors document readiness using a structured checklist and verify that the Critical View of Safety is achieved and recorded. A "go/no-go" decision then grants Stage 3 (independent practice) privileges restricted to case types consistent with demonstrated proficiency, with clear criteria for escalation or conversion. Minimum elements should include: (1) simulation benchmarks that are reproducible and recorded by the credentialing committee; (2) a proctored case requirement with heterogeneous case mix and standardized assessment; (3) routine video capture and independent review of CVS documentation using a simple rubric; and (4) maintenance of competence through case-volume expectations, focused continuing medical education (CME) on biliary safety and robotic technique, and periodic video-based audit within a quality program. Institutions may adopt example thresholds such as two consecutive simulation scores at or above the local expert benchmark, eight to twelve proctored cases including acute cholecystitis and obesity, and ongoing review of a small random sample of independent cases each year.

Ultimately, the growth of RC creates an opportunity to reinforce the principles of safe cholecystectomy, as outlined in the SAGES Safe Cholecystectomy 6-step framework.[5] While these guiding principles target BDI prevention, other factors such as cost, operative time, and morbidity (i.e. conversion to open) must be considered when adopting new technology.

Advocates for the robotic platform often attribute differences in complication rates to a learning curve, but as the data on this are acquired, it is our duty to ensure that complications encountered during the curve are mitigated by standardized simulation, proctoring and competency-based evaluation, and adherence to safe cholecystectomy principles. These efforts should be driven by surgeons, surgical societies, and institutions granting privileges who are ultimately responsible for patient safety.

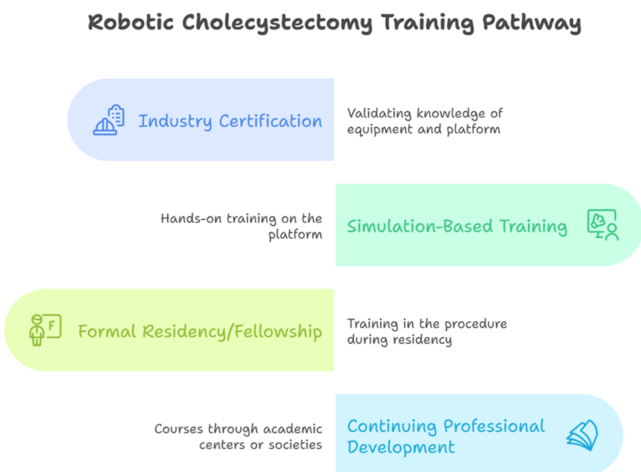
Though RC access is currently limited, its potential benefits in resource-limited regions and developing countries may exceed those in densely populated areas. Potential advantages include enhanced surgeon longevity, reduced dependence on skilled assistants, integrated proctoring or AI capabilities, and improved outcomes.[25,55,62] Achieving this accessibility, though, requires locally trained trainers, public awareness on safety, and financial investment from governing bodies. It also raises important medico-legal questions, particularly in proctored or remote surgery, regarding who is responsible for patient outcomes.

Future research on RC adoption must guide integration of advanced technologies, including AI-driven platforms developed in collaboration with industry to improve precision, enable personalized modeling, and prevent adverse outcomes. Registries should track with sufficient granularity patient, surgeon, and environmental factors that may impact outcomes. Large-scale health-services comparisons of RC to LC must be thoughtfully designed, utilizing an intention-to-treat framework to account for conversions to open, and mitigating confounding and bias, which are common limitations in analyses solely reliant on ICD and CPT administrative codes. Incorporating operative reports or surgical videos may further improve accuracy. Post-market surveillance must also be developed to uphold ethical and safety standards with transparent reporting and structured risk-mitigation strategies.

Lastly, with the rise of AI, it is conceivable that robots may one day replace surgeons altogether. Even if a robot becomes the ultimate arbitrator of surgical decision-making, safe cholecystectomy rests on the unwavering commitment and ethical duty to learn and apply the principles of safe cholecystectomy, regardless of the technique, technology, or platform.

<u>Figures</u>

Figure 1. Robotic Cholecystectomy Training Pathway*



Napkin AI was used to assist in creating the figure. All of the content is the author's own work.

Tables

Table 1. Components of the Critical View of Safety

1	Clearing the hepatocystic triangle of fat/fibrous tissue
2	Clearing the gallbladder off the lower third of the cystic plate
3	Identifying only two structures entering the gallbladder

Table 2. Proposed credentialing pathway for robotic cholecystectomy

Stage		
0	Prerequisites	• Confirm competency in laparoscopic cholecystectomy and the Safe Cholecystectomy lexicon. • Completion of didactics on robotic system safety, energy use, and bailout strategy • Complete an operating room team orientation that rehearses docking, port layout, role assignments, and emergency undocking.
1	Simulation proficiency	• Completion of validated virtual reality modules and dry-lab tasks on depth perception, camera control, precise dissection in Calot's triangle, clip application, and needle handling. • Achieve prespecified proficiency targets derived from local expert benchmarks.
2	Supervised clinical adoption	• Complete a minimum set of proctored cases spanning typical and difficult anatomy. • Proctors document readiness using a structured checklist and verify that the Critical View of Safety is achieved.
3	Independent practice	• Privileges restricted to case types consistent with demonstrated proficiency, with clear criteria for escalation or conversion.

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