French Editorial Commentary from the ACHBPT

Robotic-assisted cholecystectomy: stepping stone to expertise or vogue?

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We read with great interest the study by Kalata *et al.* published in *JAMA Surgery* comparing the safety of robotic-assisted cholecystectomy (RAC) *vs.* laparoscopic cholecystectomy (LC) (1). This nationwide cohort study from the United States includes more than one million patients who had a cholecystectomy from January 1, 2010 to December 31, 2019. An impressive 37-fold increase in the use of RAC is reported during this period. Uncannily, RAC was found to have a three times higher rate of bile duct injuries requiring surgical repair with choledochojejunostomy or hepaticojejunostomy within one year from surgery when compared to LC. Similarly, RAC in comparison to LC had a higher incidence of postoperative biliary interventions with endoscopic retrograde cholangiopancreatography and common bile duct exploration [7.4% *vs.* 6.0%; relative risk (RR) =1.25; 95% confidence interval (CI): 1.16–1.33]. In addition, an instrumental variable analysis was undertaken to investigate the causality of this result and found that RAC had two times more bile duct injuries requiring surgical reconstruction when compared to LC (0.4% *vs.* 0.2%; RR =1.88; 95% CI: 1.14–2.63). However, the overall 30-day complication rate and serious complications rate were similar. The authors concluded that due to the higher rate of bile duct injuries, the utility of RAC should be reconsidered given the existence of a safer and more economic procedure which is the LC.

This study holds a very important clinical significance and impact, while it challenges recent reports advocating safer and easier cholecystectomy procedures when using robotic surgery (2). It has several strong points such as robust methodology including a large population sample, use of well-defined inclusion and exclusion criteria and specific primary and secondary outcomes. The authors meticulously controlled potential confounders by creating multivariable logistic regression models including patient's age, race and ethnicity, sex, 29 Elixhauser comorbidities, primary diagnosis, and year as covariates. In addition, they performed instrumental variable analysis to account for potential patient selection bias (3). Last, they were able to perform sensitivity analyses to account for the effect of different factors such as hospital volume of RAC (highest *vs.* lowest quartile), clinical urgency (elective *vs.* urgent or emergent), diagnosis (cholecystitis *vs.* all other diagnoses) and patient factors (with *vs.* without obesity).

An in-depth reading of this paper elucidates some

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interesting findings. During the study period, there were 12,819 cases of bile duct injuries requiring surgical reconstruction, 80.5% of which occurred during open cholecystectomy procedures. The number of serious bile duct injuries for open cholecystectomy was 10,324 (rate of 3.8%), for LC 2,328 (rate of 0.23%) and for RAC just 167 cases (rate of 0.67%). This high rate of bile duct injuries in open cholecystectomy is more than five times greater than that of RAC and is discordant to the bile duct injury rates of another similar population study (4). Furthermore, it should be noted that this study could not identify intraoperative conversion rates and it is unknown how many LC and RAC were converted to open cholecystectomy. Intriguingly, 41.5% of the open cholecystectomies were elective and 28.8% were performed for diagnoses other than cholecystitis, indicating that they might include unaccounted converted cases. Consequently, we see that even though RAC is linked to a higher rate of serious bile duct injuries in comparison to LC, this is just the tip of an iceberg as RAC is linked to only 1.3% of the serious bile duct injuries reported in this study.

The bile duct injuries requiring surgical reconstruction for patients undergoing RAC *vs.* LC were further investigated in a sensitivity analysis. Consistently RAC had a higher relative risk for these injuries across different categories in comparison to LC. Specifically, the relative risk of RAC patients was higher in elective surgery cases, patients without a diagnosis of cholecystitis (i.e., simpler cases), non-obese patients and patients operated in hospitals with low volume of robotic surgery. Some of these findings are somewhat uncanny as it would be expected that urgent and emergent cases, and patients with acute and chronic cholecystitis would be at an increased risk of serious bile duct injuries (4). Analyzing the distribution of cholecystectomy techniques choice across time the authors deduced that the important increase in the use of RAC came by shifting simple cases from LC and not by addressing technically demanding and challenging cases. As such they support that this increased risk might be due to the use of simple cases for training of surgeons in robotic surgery. It is worth commenting that in spite of the worse outcomes concerning bile duct injuries, there was no difference in overall morbidity between the RAC and LC in the multivariate analysis. Similarly, the serious complications of the two techniques were comparable but it should be noted that the patients with serious complications were indirectly identified by having a hospital length of stay greater than the 75th percentile. Last, the instrumental variable analysis (supplemental material *eTab. 5*), which is a more appropriate method for bias control, surprisingly showed a tendency for an improved 30-day postoperative morbidity in the RCA population.

In spite of its very good design, this study has several important limitations. Primarily, it is a retrospective cohort study solely from US centers. The study population is limited to patients aged 66 to 99 years old from insurance claims of the US federal health insurance program (Medicare). Furthermore, all included patients underwent either inpatient admission for cholecystectomy or 23-hour observation, excluding patients in good health that might represent easier cases. Some data were indirectly calculated; for example, the serious complication rate was calculated by the incidence of complication with a hospital stay >75th percentile. There was important heterogeneity between the LC and RAC patient populations including the patient demographics, 29 Elixhauser comorbidities, admission type (elective *vs.* urgent or emergent) and diagnosis (cholecystitis *vs.* other diagnoses). These were controlled in the multivariate, instrumental variables and sensitivity analyses, but with a large number of covariates there is an increased risk of collinearity that may invalidate the multivariate regression models. Interestingly, patients with comorbidities that could potentially influence the difficulty of the operation such as liver disease, alcohol use disorder, metastatic cancer and non-metastatic solid tumors were systematically more prevalent in the RAC population which also had more comorbidities when compared to the LC patients. Unfortunately, the study dataset is not made available to the public as the authors were bound by a data usage agreement. Even though the analysis took into account the hospital volume of RAC, other factors such as experience, training and status of the surgeons performing the procedures were not available. Last, no technical details concerning the achievement of critical view of safety, use of indocyanine green (ICG) cholangiography or intraoperative cholangiography, or intraoperative conversion rates were analyzed.

Robotic assisted surgery aims to provide technological advantages to colleagues dealing with complex surgical procedures that are difficult to perform using minimally invasive surgery. For simple procedures such as cholecystectomy, robotic surgery is generally considered non inferior to laparoscopy (5). Conversely, emerging evidence indicates potential advantages of robotic surgery over laparoscopy in complex oncological hepato-pancreatico-biliary (HPB) procedures regarding several

outcomes (6,7). Nevertheless, the learning curve of robotic surgery expertise for complex procedures, such as distal pancreatectomy, is long with an estimated 85 cases required to reach primary textbook outcomes (8). RAC has been proposed as an entry-level operation for the training of surgeons on the robotic interface in preparation for more complex cases (9,10). Considering the findings of this study, an unrestrained use of RAC as a training procedure may lead to adverse outcomes for patients. As the use of robotic assisted surgery is soaring, more research is required focusing on the indications, patient and healthcare systems benefits and optimal surgical training of this new technology. The future will show if RAC will follow the pathway LC set against all odds several decades ago or if it will be just an expensive alternative to the current standard of treatment (10).

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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