Commentary

What's good for the goose is not always good for the gander—are conclusions from a clinical trial always universally exportable?

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Minimally invasive approaches have revolutionized how surgery is performed and as technology and instrumentation continue to improve, the use of minimally invasive surgery (MIS) will be successfully applied to more complex surgical procedures. When considering a MIS approach, the first question a surgeon must ask is whether MIS provides at least equivalence in terms of short- and long-term outcomes compared to its open counterpart. As an example, the use of MIS approach for appendectomy approaches clinical equipoise compared to the open procedure, and only when applied to certain subset of patients do we see superiority of the MIS approach (1). On the other hand, the use of robotics for thyroidectomy [using the amusingly appropriate acronym, robotic assisted thyroid surgery (RATS)] remains, at best, controversial. Although still championed by a small number of surgeons, the robotic approach converts a straightforward, low complication, open surgery, to a complex and potentially morbid MIS procedure. The disadvantages (including longer operative time, and increased cost compared to conventional open thyroidectomy, as well as potential injuries to the brachial plexus, skin flap, esophagus, and trachea) must be weighed against the effort to compensate for minor cosmetic improvements (2). For the most part however, the literature suggests that MIS for a variety of surgical procedures does provide equivalence, if not improvement over open surgery, especially in terms of postoperative pain, length of stay and return to the patient's baseline activities of daily living. Cholecystectomy is an early and prime example.

If a minimally invasive approach is deemed better than open surgery, then the next question should be which approach: laparoscopic or robotic? Similar to the open *vs.* MIS approach question, the primary factor should focus on the relative safety and equivalence of short- and long-term outcomes, including overall survival for oncologic procedures for both platforms. Secondary criteria would then include conversion rates, operative time and overall health costs. When considering a laparoscopic versus robotic approach, additional factors may also be considered. Patient factors such as tumor site, body habitus, and single versus multi-quadrant surgery may play a role in the decision making. A final and important factor in selecting an approach is the surgeon's skill set, and perhaps bias toward either approach.

The use of MIS for gastric surgery has been gaining worldwide acceptance and has been implemented using both laparoscopic and robotic platforms. In the recent paper by Kim *et al.* (3), the authors report the results of a multi-institutional non-randomized comparative study evaluating laparoscopic *vs.* robotic gastrectomy, using morbidity and mortality as the primary endpoints. Specifically, this study compared 370 protocol patients (n=185 in each per protocol group) undergoing either laparoscopic or robotic gastrectomy. Their hypothesis was that the robotic system would provide a technically superior operative environment for MIS. Evaluating this relatively large patient population, the authors report that while the results are similar in terms of morbidity and mortality, the increased operative times and overall cost were significantly higher for the robotic group. They concluded that robotic gastrectomy is not superior to laparoscopic gastrectomy. Impressively, they report a total of three conversions (two in the robotic group, one in the laparoscopic group) and a less than 2% major complication rate, which they define as a Clavien-Dindo classification of >3. They also reported a zero operative mortality rate. Considering this is a multi-institutional trial with multiple surgeons, these short-term outcomes are quite impressive and the authors should be congratulated. Obviously, they are well trained and technically adept at MIS for gastric surgery. And so, in their hands, given the increased time and cost of the robotic approach, their conclusion that robotics does not offer any benefit over a laparoscopic approach is justified.

However, is the impressive data presented in this manuscript and the authors' conclusions universally exportable to other practices and should it be applied to all patients with resectable gastric cancer? To answer this, one needs to look more closely at the study's patient population, tumor characteristics and the finally, the surgeons themselves. When carefully evaluating the patient population included in this trial, a few important issues stand out. In terms of patient factors, the mean BMI of the patients operated on was approximately 23. This BMI represents a relatively thin patient population. While MIS can be performed on the obese, there is consensus that it is technically more challenging when compared to thinner patients. As a matter of comparison, in the United States, the average BMI for a male is 28.6, with 64% of the population having a BMI >25 and 30% of the population with a BMI >30 (4). More specifically, in a series of 105 robotic gastrectomy and esophagogastrectomy in the United States, the median BMI of all patients was 26.0, with a range from 19.2–45.1 (5). In addition, since the incidence of gastric cancer is male predominant, and men tend to accrue more visceral fat, the BMI may underestimate the increased difficulty of the procedure in a heavier population (6).

When evaluating the tumor characteristics of this study, one is struck by the significant proportion of early stage disease. Of the study patients, approximately 75% of patients had tumors that invaded only up to the submucosa (T1a and b) and when T2 lesions are included, 85% of patients are represented. This is also coupled with the fact that about 85% of the tumors in this study were located in the mid-body or antrum with the vast majority of patients undergoing distal subtotal gastrectomy. Taken as an aggregate, these lesions represent the least challenging in terms of technical skill, with little perturbation of the normal gastric and surrounding anatomy. The last factor is related to the surgeon. Of the 17 surgeon who participated in this study, only eight surgeons had a robotic experience of greater than 30 cases. This is compared to their laparoscopic experience, where all surgeons had performed at least 50 gastric resections, ranging up to a very impressive 1,000 cases. This suggests a strong comfort with (and perhaps bias towards) a laparoscopic approach.

In procedures where there are significant technical skill requirements, especially for relatively less common procedures, the robotic platform appears to offer an advantage over laparoscopy in terms of learning curve and conversion rates. Examples include prostatectomy, hysterectomy and possibly rectal surgery (7-9). Therefore, it is not surprising the authors did not see any significant difference in outcome between robotic and laparoscopic surgery, since they only studied the more straightforward cases. With such low conversion rates and operative morbidity and mortality, it would take many more patients and a randomized trial to detect small differences. However, a glimpse into the superiority of the robotic platform to perform more complex dissection may be culled from the authors' lymph node dissection data. Interestingly, while the total lymph node yields were similar between both groups (approximately 33 lymph nodes per specimen), the number of patients undergoing a formal D2 lymph node dissection was significantly greater in the robotic group (53.5% *vs*. 41.1%, P=0.017). Although one cannot rule out selection bias in this comparative study, the increase in D2 dissection may be related to the advantages of robotic surgery which include a tremor filter, three-dimensional imaging, and an endowrist technology which enables the surgeon to perform delicate and complex tasks such as knot tying, suturing, and vascular or lymph node dissection.

Another way to interpret the data presented in this study is that despite the relative inexperience of the surgeons performing robotic surgery, there was the ability to achieve parity with the more experienced laparoscopic approach. Interestingly, this finding of a shorter learning curve has been documented by the same authors comparing laparoscopic and robotic gastrectomy (10). The learning curve factor becomes much more important in areas where gastric cancer is less common and the surgical experience to perform gastric resection for cancer is much less (11). For example, the incidence of gastric cancer in the North America is approximately 4 per 100,000 compared to about 23 per 100,000 in Asia (12). Arguably, for a surgeon in the West to achieve the 40–50 cases required to achieve competence to perform laparoscopic gastric resection will be difficult and he or she may be retired before that number is achieved.

To their credit, the authors do address many of the above issues in their discussion and suggest the role of robotics in gastric surgery is not fully defined. The issue of increased costs for robotics is real, regardless of the health care delivery system and that will need to be included in the final calculus of determining which approach is better for both the individual patient and the population as a whole in terms of resource utilization. The impressive results of Kim *et al*. suggest that the participating surgeons possess a technical mastery of laparoscopic gastric resection, which was facilitated by the clinical experience achieved through the large number of patients with resectable gastric cancers. The authors' conclusion that the robotic platform does not offer a superior approach compared to the laparoscopic approach is certainly true for their specific patient population and group of surgeons. However, the reader must be aware of the limitations of this study and the enthusiasm for broad application of their recommendations to perhaps more advanced/complex gastric cases or to other surgical teams should be tempered.

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Footnote

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