



Not yet IDEAL?—evidence and learning curves of minimally invasive pancreaticoduodenectomy

Felix Nickel, Caelán Max Haney, Beat-Peter Müller-Stich, Thilo Hackert

Department of General, Visceral, and Transplantation Surgery, Heidelberg University, Hospital Heidelberg, Heidelberg, Germany

Correspondence to: Felix Nickel. Department of General, Visceral, and Transplantation Surgery, Heidelberg University, Hospital Heidelberg, Heidelberg, Germany. Email: Felix.Nickel@med.uni-heidelberg.de.

Submitted Jan 18, 2020. Accepted for publication Mar 09, 2020.

doi: 10.21037/hbsn.2020.03.22

View this article at: <http://dx.doi.org/10.21037/hbsn.2020.03.22>

In response to “*What’s the next step in evaluating laparoscopic pancreaticoduodenectomy?*” (<http://hbsn.amegroups.com/article/view/29682/25710>) by Fernando Burdío, Luís Grand and Ignasi Poves.

First and foremost, we would like to express our sincere condolences on the passing of Professor Ignasi Poves. We were deeply saddened to hear of this and wish his family, friends and colleagues strength in these difficult times of grieving.

We thank Burdío *et al.* (1) for their comment on our systematic review and meta-analysis of randomized controlled trials (RCT) comparing laparoscopic pancreaticoduodenectomy (LPD) to open pancreaticoduodenectomy (OPD) (2). They provide an interesting overview of the history as well as the current status quo of LPD while describing the process from pioneers of LPD to the first monocentric RCTs (2,3) and the first multicentric RCT comparing LPD to OPD, all of which were summarized in our meta-analysis. The meta-analysis was not able to show any benefits of LPD in regard to postoperative complications or mortality. Moreover, issues of safety were raised due to high mortality in the LPD group of the multicentric trial which led to the early termination of the trial. Even more interestingly, this led to the abandonment of LPD in the trial centers thereafter.

Even so, Burdío *et al.* conclude that “*it appears that it is only a matter of time that minimally invasive (laparoscopic and/ or robotic) PD will be accepted as an adequate procedure in selected cases and selected surgeons, as has been the case in other complex procedures in the history of surgery*”.

We agree that the past has shown the adoption of minimally invasive surgery for many different surgical

procedures and now presents the gold standard especially for benign diseases such as appendectomy, cholecystectomy and bariatric procedures. However, adoption of new techniques must always be scrutinized with caution and there have always been dead ends in surgery for procedures that are difficult to establish in a safe manner and may be abandoned. On the other hand, sometimes, the new procedures only find their way into routine practice with further technical development and especially with proper training and experience of surgeons. This becomes evident when gazing into the history of laparoscopic surgery itself. Especially the adoption of laparoscopic techniques to cholecystectomy came with an initial surge of dangerous unexpected complications (4). These were the result of surgeons not being adequately prepared for the new environment and challenges such as the limited visibility and range of motion associated with laparoscopic surgery. Bile duct injury due to misconception of the prevalent anatomy had dire results especially during the initial learning curve (5).

Actions to protect patients from these mounting complications that were seen to be a result of the learning curve of laparoscopic cholecystectomy were taken by health care watchdogs. In one such example, the New York State Health Department issued guidelines in 1992 stating the ideal “*that a learning curve was not a justification for serious injuries to patients*” and mandating a minimum of 15 supervised cases presented with adequate skill before performing cases without supervision (6). Actions taken by the surgical community to prevent similar events from taking place resulted in the creation of the IDEAL guidelines (7) which provide a roadmap for safely navigating

the possibly dangerous journey of adoption of a new surgical technique. Furthermore, adhering to these guidelines provides important groundwork on which groups can base their trials on.

We do not doubt that there is a place for minimally invasive PD. However, there is still an enormous lack of evidence to adequately support this change. There is a lack of randomized long-term evidence supporting the equivalence of LPD and OPD from oncologic points-of-view. Furthermore, the scientific surgical community must see towards limiting who and where this technique should be performed because it is subject to an immense influence of both surgeon and hospital volume. Important steps toward this goal of patient safety can be certification programs and guidelines either government mandated or organized by the surgical community, such as the recent Miami Guidelines on Minimally Invasive Pancreatic Resections (8). In order to adequately support these important decisions, evidence gathered on the learning curves of these new procedures is paramount.

Regarding their comment that it may be “*very difficult to reach real conclusions from a meta-analysis of three RCTs carried out under different conditions and methods*”, we wholeheartedly agree. However, especially in the beginning of the dissemination of new surgical techniques, it seems important to keep a constant overview of the available high-quality evidence, thereby reducing the impact of singular trials and closing in on the most probable overall impact of the new surgical technique, in this case LPD. Therefore, we also look forward to the publishing of trials that are being conducted and concur that these “could help to yield some light on the real position of LPD”. Since the publishing of our meta-analysis, multiple studies have been registered. Most of these focus on short term outcomes such as postoperative complications and intraoperative blood loss, however, trials that will examine long-term outcomes have been registered as well. The estimated enrollment of these trials ranges from 36 to more than 600 patients, which will likely make these trials powerful enough to reach an adequate conclusion on the positioning of minimally invasive PD and about the necessary requirements to perform it safely.

Burdío *et al.* furthermore discuss the learning curve of LPD. As has been shown to be the case with other advanced procedures, LPD has an extensive learning curve, ranging from 10 to more than 100 procedures in surgeons with different previous experience levels and according to different definitions of the learning curve (9,10). They state that “*Extensive previous experience in laparoscopic surgery*

is advisable before starting a LPD program” and while we definitely agree with this statement, we would rather go further and advise towards extensive laparoscopic experience, extensive experience in hepatopancreaticobiliary surgery and a high hospital volume to be able to uphold an adequate number of LPDs. Some of the trials currently being conducted are already adhering to these recommendations with mandated minimum experience of 100 LPD in order to partake in the trial. Nevertheless, it has to be stated that the first 100 LPD patients in the learning curve are of critical importance and should not have to experience learning curve related morbidity and mortality either. Every possible precaution has to be taken to avoid this.

An important aspect to consider will be the route of robotic-assisted surgery that is currently being taken by many surgeons who perform minimally invasive PD. Robotic systems can potentially compensate for some of the downsides of LPD and can potentially shorten the learning curve for minimally invasive PD. This will have to be shown in adequate trials considering both surgeon related factors including experience and training as well as patient related factors for selection.

Even though we share opinions with Burdío *et al.*, we would like to emphasize the importance of caution when initiating a minimally invasive pancreatic program in order to ensure the safety of patients. There is still a lot of work to be done until minimally invasive pancreaticoduodenectomy can be seen as an equivalent choice to OPD.

Acknowledgments

Funding: Support for open access publication was provided by Baden-Württemberg Ministry of Science, Research and the Arts and by Ruprecht-Karls-Universität Heidelberg.

Footnote

Provenance and Peer Review: This article was commissioned by the editorial office of *Hepatobiliary Surgery and Nutrition*. The article did not undergo external peer review.

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/hbsn.2020.03.22>). The authors have no conflicts of interest to declare.

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.

Open Access Statement: This is an Open Access article distributed in accordance with the Creative Commons Attribution-NonCommercial-NoDerivs 4.0 International License (CC BY-NC-ND 4.0), which permits the non-commercial replication and distribution of the article with the strict proviso that no changes or edits are made and the original work is properly cited (including links to both the formal publication through the relevant DOI and the license). See: <https://creativecommons.org/licenses/by-nc-nd/4.0/>.

References

1. Burdío F, Grande L, Poves I. What's the next step in evaluating laparoscopic pancreaticoduodenectomy? *Hepatobiliary Surg Nutr* 2019;8:555-6.
2. Nickel F, Haney CM, Kowalewski KF, et al. Laparoscopic versus open pancreaticoduodenectomy: a systematic review and meta-analysis of randomized controlled trials. *Ann Surg* 2020;271:54-66.
3. Palanivelu C, Senthilnathan P, Sabnis SC, et al. Randomized clinical trial of laparoscopic versus open pancreatoduodenectomy for periampullary tumours. *Br J Surg* 2017;104:1443-50.
4. Gouma DJ, Go PM. Bile duct injury during laparoscopic and conventional cholecystectomy. *J Am Coll Surg* 1994;178:229-33.
5. Olsen D. Bile duct injuries during laparoscopic cholecystectomy. *Surg Endosc* 1997;11:133-8.
6. Altman LK. The doctor's world; When patient's life is price of learning new kind of surgery. *The New York Times Archives* 1992;Section C:3. Available online:<https://www.nytimes.com/1992/06/23/health/the-doctor-s-world-when-patient-s-life-is-price-of-learning-new-kind-of-surgery.html>
7. Hirst A, Philippou Y, Blazeby J, et al. No surgical innovation without evaluation: evolution and further development of the IDEAL framework and recommendations. *Ann Surg* 2019;269:211-20.
8. Asbun HJ, Moekotte AL, Vissers FL, et al. The miami international evidence-based guidelines on minimally invasive pancreas resection. *Ann Surg* 2020;271:1-14.
9. Wang M, Peng B, Liu J, et al. Practice patterns and perioperative outcomes of laparoscopic pancreaticoduodenectomy in China: a retrospective multicenter analysis of 1029 patients. *Ann Surg* 2019. [Epub ahead of print].
10. Kuroki T, Kitasato A, Adachi T, et al. Learning curve for laparoscopic pancreaticoduodenectomy: a single surgeon's experience with consecutive patients. *Hepatogastroenterology* 2014;61:838-41.

Cite this article as: Nickel F, Haney CM, Müller-Stich BP, Hackert T. Not yet IDEAL?—evidence and learning curves of minimally invasive pancreaticoduodenectomy. *HepatoBiliary Surg Nutr* 2020;9(6):812-814. doi: 10.21037/hbsn.2020.03.22