Robotic pancreatoduodenectomy: an ongoing exploration

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Minimally invasive surgery has become the standard of care for many abdominal surgical procedures, aiming to minimize the negative impact of surgery and enhance patient recovery. Until some years ago, pancreatoduodenectomy was lagging behind in this transformative shift. Now, five randomized trials have compared laparoscopic and open pancreatoduodenectomy (LPD; OPD).[1,2] The most recent systematic review, including four of these trials, concluded that within the hands of skilled surgeons in high-volume centres, the laparoscopic approach is feasible and as safe and efficient as the open approach.[1] One of these studies, the multicentre randomized LEOPARD-2 trial, was discontinued early because of safety concerns with LPD, likely related to the learning curve.[3] Hereafter, LPD was no longer performed in the Netherlands and the authors reported on a nationwide training program and switch to robot-assisted pancreatoduodenectomy (RPD).[4] This trend has also been observed in other countries, with the suggestion of improved outcome for the robotic approach as compared to LPD.[5] However, randomized trials comparing RPD with OPD were thus far lacking.

This wait is now over, as in this issue of *The Lancet Regional Health - Europe,* Klotz and colleagues from Heidelberg University Hospital in Germany present the EUROPA trial a single-centre stage 2b exploratory trial.[6] The authors investigated the overall 90-day morbidity rate using the Comprehensive Complication Index (CCI) in 62 patients randomised for RPD (n = 29) and OPD (n = 33). Procedures were performed by surgeons with sufficient experience (≥40 RPD or OPD). No patient blinding was performed, but biometricians were blinded to the intervention. In the modified intention-to-treat analysis, the primary outcome, 90-day CCI, was comparable between the groups (RPD: 34 ± 23 vs. OPD: 36 ± 27, p = 0.713). The conversion rate during RPD was 23%. Patient who underwent RPD had a higher rate of pancreas-specific complications (17 (58.6%) vs. 11 (33.3%); p = 0.046), with a significantly higher rate of delayed gastric emptying after RPD, compared to OPD. The trial showed no difference in functional recovery (17 vs. 13 days; p = 0.163) and length of hospital stay (17 vs. 13 days; p = 0.177). The EUROPA authors conclude that, in a high-volume centre with well-trained surgeons, both RPD and OPD are safe procedures.

The authors are to be praised for performing the first trial comparing RPD with OPD. EUROPA is a well-designed trial, performed in a very well-known high-volume centre. Despite these seemingly "optimal" conditions, none of the previously suggested benefits of RPD as compared to OPD, such as reduced intraoperative blood loss, less wound complication, shorter time to functional recovery, and shorter hospital stay were observed. However, it is crucial to acknowledge that the small sample size (n = 62) of this exploratory (IDEAL stage 2b) trial and the likely impact of the learning curve limits the ability to draw definitive conclusions on these outcomes. In randomized trials assessing the value of a new surgical intervention, finding the "sweet spot" for starting such a study is challenging. When performed too early, the intervention effects may be contaminated by the learning curve. If performed too late, after full implementation of the intervention, surgeons may feel that "equipoise" has been lost and may not be interested to join the RCT.

What was the timing of the EUROPA trial? Considering safety endpoints, the overall 90-day mortality rate of 4.8% is probably what one may expect in this population with an overrepresentation of patients with high-risk pancreatic parenchyma features (i.e. soft pancreas, narrow pancreatic duct). However, the conversion rate of 23% is most likely reflective of 'early' timing of this trial as is also acknowledged by the authors themselves. In centres who have surpassed the learning curve conversion rates are typically well below 10%.[4,7] This observation has far reaching consequences and makes it quite challenging to determine whether the observed increased rate of clinically relevant (grade B/C) pancreas-specific complications with RPD (58.6% RPD vs. 33.3% OPD) are related to the learning curve, or whether these reflect a "real" effect and thus a safety concern with RPD.

The performed cost-analysis in EUROPA showed higher costs for RPD. This may not come as a surprise, but is an in important factor for future studies. Again, one may wonder if these differences would uphold in a future IDEAL stage 3 assessment RCT in centres that have completed the learning curve of RPD. Currently, two such multicentre randomized trials on RPD vs.

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OPD are underway; in Europe the DIPLOMA-2 trial and in China the PORTAL trial.[8,9]

In conclusion, the EUROPA trial is an important contribution to the ongoing debate on the benefits of RPD vs. the traditional open approach to pancreatoduodenectomy. As we process these findings, it is clear that the integration of robot-assisted surgery into pancreatic surgery involves not just aspects of technical skill, experience, and learning curve but also considerations of cost, environmental impact, and patient experience. The EUROPA trial results underscore the importance of further IDEAL stage 3 randomized trials in centres that have completed the learning curve, to guide our understanding of the role of robot-assisted techniques within pancreatic surgery.

Contributors

Nine de Graaf drafted the manuscript. Mohammad Abu Hilal and Marc Besselink critically reviewed the manuscript and approved the final version. All authors are fully aware of this publication.

Declaration of interests

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