

8. van der Sluis PC, Ruurda JP, van der Horst S, et al. Learning curve for robot-assisted minimally invasive thoracoscopic esophagectomy: results from 312 cases. *Ann Thorac Surg.* 2018;106. <https://doi.org/10.1016/j.athoracsur.2018.01.038>.

## OPEN

## Response to the Comment on "Learning Curves of Ivor Lewis Totally Minimally Invasive Esophagectomy by Hospital and Surgeon Characteristics a Retrospective Multi-national Cohort Study"

## Reply:

We thank Prasad and Philips for their interest in our study.<sup>1</sup> We fully agree that insight into learning curve associated morbidity is important for decisions around implementation of complex new techniques and that implementation of minimally invasive esophagectomy with intrathoracic anastomosis should always be considered carefully.

In their discussion, Prasad and Philips suggest that predefined levels of acceptance should reflect average leakage rates from participating institutions. We have actually considered this during the design of our study. However, we felt this was inappropriate since average leakage rates based on historical data of participants would represent figures from the beginning of the learning curve, associated with a higher than desired incidence. In our view, the goal of implementing a new surgical technique is to improve patient outcome in comparison with the gold standard. As stated by Prasad and Philips, rates of 8% anastomotic leakage have been reported in series from high volume centers performing open esophagectomy,<sup>2</sup> which is why we chose this as a starting point in our analysis.

The second issue Prasad and Philips point out concerns the fact that in our study proctorship did not guarantee efficient learning or safe implementation. Effective proctorship in our study may have been hampered by the limited number of proctored cases and skill level, teaching methods and other capacities of the proctor, and may possibly be explained by other factors, such as differences in annual volume or TMIE experience between proctored and non-proctored surgical teams. We acknowledge proctorship is currently regarded to be one of the cornerstones of safe

implementation and we believe it can have an important role. The results of this study, however, should prompt robust research on how to design an effective proctoring program and efforts to test this program in practice with clinically relevant outcome parameters. As suggested by Prasad and Philips, this may be an important step towards improving patient safety during learning curves.

Lastly, Prasad and Philips suggest that robust assessment of individual surgeon outcomes and learning curves may facilitate targeted training to improve clinical outcomes. Although we believe this to be an excellent suggestion, we were unable to separate individual learning effects from team learning for Ivor Lewis minimally invasive esophagectomy in the present study. However, we do believe that an individual surgeon's skills are an important determinant for patient outcome and we are currently working on quality improvement studies using video data of procedures to improve individual surgeon's skills. Finally, we fully agree with Prasad and Philips that future research aimed at understanding what factors contribute to effective proctorship, fruitful fellowships and useful (hands-on) training opportunities are needed to increase patient safety.

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## REFERENCES

1. Claassen L, Hannink G, Luyer MDP, et al. Learning curves of ivor lewis totally minimally invasive esophagectomy by hospital and surgeon

characteristics: a retrospective multi-national cohort study. *Ann Surg.* 2021. doi: 10.1097/SLA.0000000000004801. Epub ahead of print. PMID: 33605581.

2. Griffin SM, Jones R, Kamarajah SK, et al. Evolution of esophagectomy for cancer over 30 years: changes in presentation, management and outcomes. *Ann Surg Oncol.* 2021;28:3011–3022.

## Comment on: "A Multicenter Randomized Controlled Trial Comparing Safety, Efficacy, and Cost-effectiveness of the Surgisis Anal Fistula Plug Versus Surgeon's Preference for Transsphincteric Fistula-in-Ano The FIAT Trial"

## To the Editor:

We write regarding the recent paper by Jayne et al.<sup>1</sup> which was recently discussed at "CRAMSURG," an online journal club based in the UK ([www.cramsurg.org](http://www.cramsurg.org)). We congratulate the authors for performing this trial comparing a new intervention (surgisis plug) against a variety of traditional practices in the treatment of trans-sphincteric fistula in ano. This is an important clinical topic where there is a dearth of good quality evidence. We would like to summarize our discussion points and raise a few questions.

1. The control arm (surgeon preference) includes patients who underwent a variety of procedures. This makes results of comparisons difficult to interpret. What does the lack of significant difference between the arms mean for the effectiveness of the surgisis plug, given the lack of a single control treatment? Given the heterogeneity of the surgeons' preference group, could it be possible that  $\geq 1$  of the included procedures is significantly superior (or inferior) to the fistula plug? Is there precedence (justification) for a trial where different treatments are included in the control arm? Was consideration given to performing a direct comparison between the fistula plug and 1 specific treatment?
2. Sample size calculations estimated that 400 patients were required to detect a small to moderate treatment effect for the primary