Comment on "The Time Has Come to Embrace Continuous Wound Infiltration via Preperitoneal Catheters as Routine Analgesic Therapy in Open Abdominal Surgery"

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accepted that the heterogeneity in volume thresholds is an important limitation of the current available literature and comparing the highest available volume threshold to the lowest available volume threshold could have attenuated the effect of volume and might contribute to the heterogeneity that we found. For this reason, we performed subgroup analyses excluding studies with extreme low-volume and high-volume thresholds and these analyses did not alter the direction or magnitude of the identified effects. Next to that, volume groups without either an upper or lower bound (eg, $\geq$100 interventions/year or $\leq$30 interventions/year) are not suitable for a meta-regression analysis. Finally, data on variables that are known to influence procedural outcomes are often not reported, precluding the possibility to use those variables as adjustment factors in a meta-regression analysis. Heterogeneity due to sampling error could be then expected, as differences in the population cannot be accounted for in the statistical analysis.

Second, we have acknowledged that the use of administrative data as data source might be inferior compared with dedicated collected hospital data. We nevertheless included such data, as it is questionable whether this reporting bias in administrative databases does apply to our study. To allow for possible underreporting of events, we focused on relative risks rather than absolute risks and did not find evidence that the problem of underreporting of adverse events was more pronounced in low-volume surgeons or hospitals compared with high-volume surgeons or hospitals, or vice versa. Furthermore, the reported event rates were consistent irrespective of the data source.

Third, the majority of the included studies in our study used retrospective data-collection. This way of collecting data might introduce more bias, as collection of variables, entry of data, and quality assurance of data were not planned ahead of time, and selection of variables might be determined by availability rather than existing evidence. For this reason, we have collected the type of data-collection as part of our risk of bias assessment. To minimize the risk of confounding bias, we meta-analyzed the unadjusted and adjusted risk estimates separately and the pooled estimates of the unadjusted risks and adjusted risks were very similar for many outcome measures. This stresses the importance of high hospital and surgeon volume in carotid revascularization. We decided not to use the individual aspects (or summation of points) of our risk of bias assessment for sensitivity analyses, because that introduces a hierarchy of one aspect of bias over others. Instead, we used generalizability (to different geographical locations, time period, and symptomatic status as the most important characteristic that influences procedural outcomes) and robustness of the volume relationship as criteria for the sensitivity analyses.

Fourth, data on operator age were not available in most studies, but we are not convinced that this is an appropriate surrogate measure for experience. Future studies assessing the relationship between aspects of quality of care (eg, operator volume or surgeon's age) and procedural outcomes should report and account for experience.

As most potential limitations noted in the correspondence were addressed in our analysis, we do not agree with the observations of Wee. The heterogeneity in volume thresholds precludes an overall judgment on the optimum volume threshold, but high operator volume and high hospital volume can nevertheless guide the process of service reconfiguration. Our findings therefore offer a sensible contribution to the debate around centralization of carotid revascularization, but further examination of volume effects within carotid revascularization is required.

MHFP and ECB contributed equally to this article and share first authorship.

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REFERENCE

1. Poorthuis MHF, Brand EC, Halliday A, et al. High operator and hospital volume are associated with a decreased risk of death and stroke after carotid revascularization: a systematic review and meta-analysis. *Ann Surg*. 2018 [Epub ahead of print].

Comment on "The Time Has Come to Embrace Continuous Wound Infiltration via Preperitoneal Catheters as Routine Analgesic Therapy in Open Abdominal Surgery"

To the Editor:

With great interest we read the randomized controlled trial (RCT) by Bell et al[1] on continuous wound infiltration via preperitoneal catheters plus patient-controlled opioid analgesia (CWI+PCA) versus epidural analgesia (EA) in patients undergoing open liver resection.

We congratulate the authors on this study and we endorse their conclusion that CWI+PCA is a valid alternative to EA, which is also supported by 2 prior RCTs and 1 meta-analysis.[2–4]

We also would like to highlight and discuss 3 issues. First, the current study found that the anesthesia time was significantly shorter with CWI+PCA compared to EA. The authors, however, did not measure the time needed for wound catheter placement, which is done by surgeons at the end of the procedure. We feel this time should be taken into account as was done in our recent trial.[3]

Second, the authors may want to clarify their sample size calculation. A sample size calculation based on length of hospital stay (mean 9.8 vs 8.8 days, standard deviation 8.2, power 80%), results in 1056 patients per study arm.[5] This is much greater than the

sample size of 40 patients per arm presented in the article. Self-evidently, we should interpret the nonsignificant difference in length of stay with extreme caution, as it may be false-negative (type-II error) result.

Third, no quality of life outcomes or patient preferences were captured in this study. We would like to stress the importance of including the patients' perspective in every aspect of our clinical care and research, especially in prospective studies like these. Therefore, we suggest that patient satisfaction or patient-reported outcomes such as the validated Overall Benefit of Analgesic Score (a combination of pain score, opioid side effects, and patient satisfaction[6]) should be added to any upcoming pain study.

In conclusion, we learn from this RCT that CWI+PCA results in adequate pain control after open liver surgery.[1] We know that CWI+PCA is more widely applicable (eg, in patients using potent anticoagulants or for converted laparoscopic or robotic surgery) and bears fewer risks and side effects (eg, no risk of epidural hematoma or abscess) than EA.[4,7] Until recently, CWI+PCA was only used as primary form of anesthesia in selected high-volume centers in the United Kingdom and USA. We fully agree with the conclusion of the authors that there is no argument indeed for routine application of EA in open liver surgery or any form of open abdominal surgery. The time has come to embrace CWI via preperitoneal catheters as routine analgesic therapy in open abdominal surgery.

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REFERENCES

1. Bell R, Ward D, Jeffery J, et al. A randomized controlled trial comparing epidural analgesia versus continuous local anesthetic infiltration via abdominal wound catheter in open liver resection. *Ann Surg*. 2018. doi: 10.1097/SLA.0000000000002988. [Epub ahead of print].
2. Hughes MJ, Harrison EM, Peel NJ, et al. Randomized clinical trial of perioperative nerve block and continuous local anaesthetic infiltration via wound catheter versus epidural analgesia in open liver resection (LIVER 2 trial). *Br J Surg*. 2015;102:1619–1628.
3. Mungroop TH, Veelo DP, Busch OR, et al. Continuous wound infiltration versus epidural analgesia after hepato-pancreato-biliary surgery (POP-UP): a randomised controlled, open-label, non-inferiority trial. *Lancet Gastroenterol Hepatol*. 2016;1:105–113.
4. Mungroop TH, Bond MJ, Lirk P, et al. Preperitoneal or subcutaneous wound catheters as alternative for epidural analgesia in abdominal surgery: a systematic review and meta-analysis. *Ann Surg*. 2018. doi: 10.1097/SLA.0000000000002817. [Epub ahead of print].
5. Power calculator for continuous outcome superiority trial. [Online]. Sealed Envelope Ltd. 2012. https://www.sealedenvelope.com/power/continuous-superiority/. Accessed August 25, 2018.
6. Lehmann N, Joshi GP, Dirkmann D, et al. Development and longitudinal validation of the overall benefit of analgesia score: a simple multi-dimensional quality assessment instrument. *Br J Anaesth*. 2010;105:511–518.
7. Liu SS, Richman JM, Thirlby RC, et al. Efficacy of continuous wound catheters delivering local anesthetic for postoperative analgesia: a quantitative and qualitative systematic review of randomized controlled trials. *J Am Coll Surg*. 2006;203:914–932.

Comment on "Mid-term Results of ACOSOG Z6051 Trial Sustain the Unresolved Debate"

To the Editor:

Controversy remains regarding the optimal surgical approach for the treatment of rectal cancer even after the publication of the follow-up oncologic outcomes of the American College of Surgeons Oncology Group (ACOSOG) Z6051 randomized controlled trial (RCT) comparing laparoscopic and open approaches for rectal cancer resection after neoadjuvant therapy.[1] The previous report of the trial was published in 2015 and focused on a main composite pathologic variable for successful resection, including the achievement of an adequate quality of the specimen (complete or nearly complete) with both clear (>1 mm) radial and distal margins.[2] You will all recall, alarms went off when the laparoscopic arm did not meet criteria for 6% noninferiority compared with the open arm. However, as the pathologic impairment for laparoscopy needs to be reflected on the follow-up for reaching any clinical significance, pending surveillance report was eagerly expected. Hence, *"the secondary and clearly more relevant outcomes"* from the ACOSOG Z6051 trial showed that laparoscopic-assisted resection of rectal cancer was not found to be significantly different to open resection of rectal cancer based on the outcomes of 2-year disease-free survival (DFS) and recurrence. As a result, yet de-emphasizing the previous concerns about the oncological safety of conventional laparoscopic surgery for rectal cancer.[2,3] The rates for DFS were 83.2% for open and 79.5% for laparoscopy, with nonsignificant differences. However, as remarked by the authors, the study was underpowered to asses such differences, and the lack of statistical difference was not an indicator of no difference existing. Furthermore, the analyses were adjusted by sex, age, surgeon, performance status, and location of tumor, but not by tumor reaction to neoadjuvant treatment (complete response 29.2% lap vs 22.5% open),[2] which is known to be crucial for the long-term behavior of the participants.[4] Moreover, recurrences are not despicable during the third year after a proctectomy preceded of neoadjuvant treatment, and this period was not here evaluated.[1] Therefore, the debate persists, and maybe is sustained, after the present publication.

Perhaps for devaluating its earliest findings and enhancing the most recent ones, Fleshman et al recognized the consequences for using a *"never-before validated composite oncologic score"* as a main outcome for reducing the number of necessary enrolled patients. Nevertheless, it is lacking a discussion involving the fact that their composite outcome also included a never-before validated mesorectal quality grading, different than the proposed by Dutch Colorectal Cancer Group (DCCG),[5] which was used at the rest of the major RCTs on the subject (ie, ALaCaRT, COLOR II, COREAN).[3,6,7] Then, ACOSOG's grades shared the names (ie,