Minimally invasive surgery for cervical cancer: Is surgeon volume a factor?

Could surgeon volume account for some of the findings of the LACC trial (which indicated better outcomes for open versus minimally invasive hysterectomy for early-stage cervical cancer)? New data say probably not.

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The role of minimally invasive surgery for early-stage cervical cancer has been the subject of heated debate since the presentation of the results of the Laparoscopic Approach to Cervical Cancer (LACC) Trial at the Society of Gynecologic Oncology Annual Meeting on Women's Cancer in 2018. This was an international, randomized, phase 3 trial comparing minimally invasive radical hysterectomy (MH) to open radical hysterectomy (OH) in the treatment of early-stage cervical cancer. The trial was closed early by the study's Data and Safety Monitoring Committee due to an imbalance of deaths between the groups, with a higher rate in the minimally invasive arm. The final results, which were largely unexpected by the medical community, showed that the disease-free survival (DFS) at 4.5 years was 86.0% in the MH arm and 96.5% in the OH arm, which was a larger difference than their noninferiority cut-off of -7.2 percentage points.[1] Results of an epidemiologic study, which used data from the Surveillance, Epidemiology, and End Results (SEER) program and the National Cancer Database, also were presented at this meeting, and they reinforced the findings of the LACC trial.[2]

The combined results have caused significant concern and confusion from the medical community regarding the clinical implication that minimally invasive surgery may be an unacceptable approach for radical hysterectomy in cervical cancer. Prior to this study, retrospective data supported similar outcomes between the two approaches.[3] Additionally, robotic surgery has made radical hysterectomy an option for those with a higher body mass index, as an open radical hysterectomy can be technically challenging in larger patients and result in a higher rate of adverse outcomes.

LACC trial questioned by US surgeons

Many in the United States have questioned the design and conclusions of the LACC trial. This trial was conducted primarily outside of North America and utilized conventional laparoscopic surgery 85% of the time as opposed to robotic surgery. Additionally, the found difference in DFS between MH and OH may have been driven more by the superior performance of the OH group (compared with historical data) than the poorly performing MH group.[4] Other criticisms have touched on the low number of overall survival events, the low bar for surgeon volume or skill assessment, and the inability to make conclusions regarding "low-risk" lesions (<2 cm, no lymphovascular space invasion, <1 cm depth of invasion).

Were requirements for surgical skill adequate? Regarding surgeon skill, the LACC trial required documentation of the perioperative outcomes from 10 laparoscopic or robotic radical hysterectomies, as well as 2 unedited videos of each surgeon participating in the study to verify their technique, which some have considered inadequate to sufficiently vet a surgeon's ability. Additionally, 14 of the 33 centers enrolled in the study accrued 71% of the patients, and concerns about the surgeon volume of the remaining 19 centers have been raised. Finally, there has been discussion about whether the variance

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in surgical approach can even be adequately assessed in a trial of this nature, as surgical skill is not a binary variable that is easily amenable to randomization. Unlike other trials, which have clear exposure and control arms, no 2 surgeries are exactly alike, and surgical technique is highly variable between surgeons, institutions, and countries.

New data evaluate for surgeon volume

In an effort to address the concerns regarding surgical approach and expertise, the recently published study by Cusimano and colleagues uses population-based data from Ontario for all women undergoing radical hysterectomy for cervical cancer over a 10-year period from 2006 through 2016.[5] The primary outcome was all-cause death, but the study also sought to address whether surgeon volume has an impact on recurrence rates for patients undergoing MH versus OH. To measure this impact the authors stratified surgeon characteristics by technique-specific volume and cervical cancer volume, splitting these volumes at the 50% percentile for low- and high-volume surgeons. They defined technique-specific volume as the number of simple and radical hysterectomies performed in the prior year using the selected approach (MH or OH). Cervical cancer volume was calculated as the number of hysterectomies of any type for cervical cancer in the previous 2 years. The technique-specific volume variable was subsequently re-categorized into tertiles, examined as a continuous variable, and analyzed at the 50th percentile for each year of the study.

Death and recurrence rates better in the OH group. The final cohort included 958 women that were relatively evenly split between MH and OH procedures. Results from their analysis show no difference in terms of all-cause death, cervical cancer–specific death, or recurrence. However, all 3 of these parameters were significantly different in favor of the OH group in women with Stage IB disease, which comprised over half of the overall cohort. Importantly, neither technique-specific volume nor cervical cancer volume had an effect on death or recurrence in Stage IB patients in any of the investigators' analyses.

Important limitations. There are several limitations to this study that have to be taken into account before drawing any conclusions. Pathologic data were obtained from the database and did not include some important details about the tumor specimens (including specifying subgroups of Stage IA and IB disease, tumor size, presence of lymphovascular space invasion, and depth of stromal invasion). All of these details have been shown to be important prognostic variables in early-stage cervical cancer. Additionally, the MH group included a predominantly laparoscopic approach with only 10% of cases performed robotically, which again brings into question the generalizability of the data.

However, despite some of these shortcomings, the study authors do make a compelling argument that surgeon volume alone does not seem to play a significant role in cancer outcomes after MH.

With surgical approaches hard to compare, turn to careful patient counseling

Definitive assessment of the impact of surgical skill and experience on cervical cancer outcomes is probably an impossible task, as even a perfectly designed trial cannot entirely account for the intricacies of a complex surgical procedure. Variations in tumor characteristics and patient anatomy that affect operative decision making are not likely to be reflected when a patient's outcome is plugged into a database. As a result, some surgeons and departments have turned to reporting personal or institutional recurrence rates for MH, which they believe may be a better representation of a patient's risk in their hands. Meanwhile, many surgeons and groups have stopped performing MH altogether, largely due to the results of the LACC trial. Irrespective of final surgical route, it is important that the risks and benefits of both minimally invasive and open approaches be adequately discussed with patients so that they can make informed decisions regarding their own medical care. ●

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