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EDITORIAL – GYNECOLOGIC ONCOLOGY

Reappraisal of Robotic Assistance in Gynecologic Oncology: The Lessons of ROBOGYN-1004

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The paper by Hotton et al. is an important contribution to the still-controversial issue of the justification of the use of robotic assistance in laparoscopic oncologic surgery.[1] This editorial is first and foremost an opportunity to commend the French ROBOGYN-1004 group for having carried out the only published randomized controlled study (RCT) comparing outcomes of the two available modalities of minimally invasive surgery (MIS) performed by gynecologic oncologists trained in both techniques—a necessary feature of any surgical trial comparing two approaches. In addition, it must be underlined that this trial has been exclusively supported by French government funding, without industry interference.

The ROBOGYN group has already reported on severe postoperative complications, up to 6 months, which was the primary outcome of the study.[2] A total of 176 and 193 patients underwent robot-assisted laparoscopic surgery (RALS) and conventional laparoscopic surgery (CLS), respectively. No difference in the rates of conversion or severe complications was found. Operative time was longer and blood loss was marginally (100 versus 50 ml) higher in the RALS arm. Quite surprisingly, this pivotal study showing nonsuperiority of robotic assistance has so far been poorly cited, most probably because its results are not in line with the current fashion.

In contrast, the ancillary trial by Hotton et al. that focused on the perspective of surgeon comfort documents a potential benefit of robotic assistance, much more reliably than the numerous statements on this matter. Indeed, this paper provides to our knowledge the only unbiased data available on this topic. The results are clearly in favor of the RALS, even in a set of patients with a comparatively low average body mass index (BMI) of 26 kg/m^2. One can even assume that the magnitude of the benefit would have been even greater in a study including a higher proportion of morbidly obese patients.

These important findings must be taken into account in an overall analysis of the benefits of robotic assistance. The results concerning the primary outcome of the Hotton et al. study, viz. the benefit for patients, are in line with earlier literature including a handful of RCTs in gynecologic surgery. A 2016 metaanalysis did not find evidence of statistically significant or clinically meaningful differences in surgical outcomes between robotic and laparoscopic hysterectomy for benign disease.[3] In 2017, Soto et al. carried out a RCT in the setting of MIS for endometriosis.[4] The authors did not find differences in average operating time, blood loss, intraoperative complications, postoperative complications, or conversion rates. A RCT in endometrial cancer patients[5] has been carried out in a relatively small number of patients (49 undergoing CLS, 50 undergoing RALS), with operative time as primary outcome. The authors found longer operative time in the laparoscopic surgery arm (170 versus 139 min) but were unable to document a difference in complication rate. Despite the observation of five conversions in the CLS group, compared with no conversion in the RALS group, all conversions in the CLS group occurred because of circumstances unrelated to the modality (adhesions, tumor dissemination, or trocar bleeding). In contrast, the only major complication, a rectovaginal fistula, occurred in the RALS group. Such a lack of benefit of robotic assistance regarding patient outcomes was also found in other surgical

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specialties in a 2018 metaanalysis.[6] Despite the higher operative cost of RALS, operative time and total complication rate were found to be significantly more favorable with CLS, with the exception of marginally lower estimated blood loss with RALS.

The ultimate outcome in oncology, i.e., survival, has yet to be investigated. In ROBOGYN-1004, no difference in disease-free or overall survival was observed after a median follow-up of 25 months.[2] However, survival was not the primary outcome of the trial, and the study was not powered to investigate oncological outcomes. In addition, the case mix of the groups included various tumor sites. Anyway, the long-term survival data of the trial are anticipated with interest. Other RCTs adequately powered to investigate a superiority of robotic assistance in survival outcomes of uterine, cervical, and possibly interval debulking surgery in selected ovarian cancers, respectively, are also badly needed.

The findings of the LACC study,[7] in which MIS, conventional or robotic, was found to result in a worse outcome compared with open surgery in the setting of radical hysterectomy, emphasize the need for level A evidence regarding oncological outcomes. The hopes that the routine use of robotic assistance might change the negative conclusion of the LACC trial are not supported by the findings of a recent metaanalysis.[8] In this metaanalysis, the survival of patients in selected studies with predominantly robotic-assisted laparoscopic surgery remained worse (hazard ratio 1.74, 95% confidence interval 1.18–2.56) compared with open surgery. One can hypothesize that CLS and RALS share the same adverse effects on the growth of tumor cells in a CO_2 atmosphere, and that the conclusions of any future trial comparing either CLS or RALS with open approach can be generalized to both modalities. Overall, these findings highlight the utmost importance of long-term, high-quality studies to guide surgical management of cancer.

Currently, we have to admit that the only demonstrated benefit of robotic assistance is not for patients but for surgeons. This demands a reassessment of the cost–benefit balance of robotic assistance as it stands today. The combination of results of the two ROBOGYN papers[1,2] suggests that comfort does not automatically improve performance. Of note, in a RCT, Kanitra et al. found that trainees with laparoscopic training performed better on a robotic simulator than trainees without laparoscopic training, that the learning curves for both modalities plateaued at similar times, and that self-reported fatigue was not different, an indication that younger colleagues can become equally proficient in both modalities, provided that they are adequately proctored.[9] Even though the physical and mental workload of surgery and the risk of developing musculoskeletal disorders are serious considerations, especially when operating on obese patients, the ergonomics of CLS can be improved by specific measures and training.[10,11]

In the specific field of gynecology, the training necessary for laparoscopic surgery should not be sacrificed in gynecologic oncology divisions. This would paradoxically end up with the curious outcome of gynecologic oncologists becoming less skilled that general gynecologists, who routinely perform not so simple laparoscopic surgeries. The current return to open surgery for radical hysterectomy and the evolution toward sentinel node only for lymph node staging in endometrial cancer may reduce the complexity of most laparoscopic procedures in gynecologic oncology and the corresponding physical and mental fatigue, making the ergonomic benefit of the robot less obvious, especially in the nonobese patient. On the other hand, robotic assistance may substantially make less tiring still-investigational highly complex procedures such as pelvic exenteration or interval surgery for ovarian cancer.

The fact is that acquiring proficiency in both CLS and RALS is today a fundamental objective, with the aim of individualizing the modality with the mindset of necessary control of healthcare costs. Going forward, the latter may be impacted by the reduction of cost of robotic platforms.

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