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Editorial Comment

Quality control in the surgical management of ovarian cancer patients

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History has shown the benefit of more, not less, radical surgery for solid malignancies. Breast surgeons have demonstrated for quite a long time that good surgical margins are associated with better local control and disease free survival. The concept of «R=O» (i.e. clear margins of safe tissue) resection in surgically resected sarcoma patients is associated with a better overall and disease free survival. Melanoma also requires good surgical margins with appropriate lymphadenectomy. There is now evidence in the colorectal literature that some patients with metastatic intra-peritoneal disease benefit from aggressive cytoreductive surgery. If ovarian cancer is considered mainly as a peritoneal disease then consider the patient benefit from aggressive surgery for pseudomyxoma peritonei.

The paper by Verleye et al.[1] is timely as debate on the management of ovarian cancer, especially advanced epithelial ovarian cancer, has become more polarised and quality of surgery is more topical and relevant in general surgical practice. Already for some oncologists the management philosophy is neoadjuvant chemotherapy for most cases of advanced ovarian cancer, whereas for others the initial primary management choice is radical surgery. Clinical experience of daily decision-making and case selection is such that many patients with advanced disease should have primary surgery, some should have neoadjuvant chemotherapy and many will be treated, outside of a study, according to local hospital guidelines. Until recently, the quality of care provided by an individual surgeon, team or institution has not been measured or scrutinised.

The authors quite appropriately distinguish the two main types of surgery undertaken for primary ovarian cancer – presumed early stage disease and advanced disease. Ovarian germ cell tumours and borderline tumours merit separate consideration. The proposals arguably apply to fallopian tube cancers and to primary peritoneal cancers. Recognising the different approaches to management, and perhaps differing surgical philosophies, the authors make the bold attempt to benchmark criteria or indicators of quality of ovarian cancer surgery. From a quite comprehensive literature search on ovarian cancer the authors have produced what they define as 'quality indicators' of ovarian cancer surgery, and in particular, process quality indicators. In essence, these refer to what is done and how well it is done and are used extensively to audit and improve clinical practice. An important benefit is that when they are adopted, valid comparisons in clinical practice and clinical outcome can be made.

In terms of establishing an evidence-base it would be helpful if the level of evidence in the publications reviewed was presented and summarised or annotated in the references. As noted by the authors there is insufficient level I evidence. Indeed, the quality indicators they have proposed represent the extent of the surgery performed and there is no account-

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ing for surgical skill, surgical morbidity and mortality in their proposals. The surgical community, while recognising the importance of competency, has yet to agree how best to assess this.

1. Presumed early stage disease (disease macroscopically confined to the pelvis)

As it is not mentioned by the authors, we underline the possibility in restricted control cases of fertility sparing surgery. Also, no mention is made of appendicectomy, which would be the standard of care for mucinous ovarian cancers. The authors recommend 'systematic pelvic and para-aortic lymphadenectomy'. Systematic should be defined as extensive and complete bilateral pelvic and para-aortic lymphadenectomy up to the origin of the gonadal vessels as there are reports of a small group of patients with contralateral pelvic and/or para-aortic nodal disease in early stage ovarian cancer.[2] Unfortunately, it is our view that it is not the practice of many surgeons to perform a systematic lymphadenectomy. Indeed, the staging guidelines for the EORTC ACTION trial (Table 4) describe 'sampling of iliac and para-aortic lymph nodes' which is consistent with clinical practice and which we would argue is not the same as 'systematic lymphadenectomy'. Meta-analyses and review of SEER data, while useful, acknowledge that many papers regrettably do not define lymphadenectomy or distinguish node sampling from lymphadenectomy or systematic lymphadenectomy. Finally, no mention is made of laparoscopic staging as this may be applicable in expert centres.

2. Advanced stage disease

Patients with advanced ovarian cancer will relapse and cure is rare. However, the evidence is that optimal primary surgery not only increases the disease free interval survival (DFI) and delays relapse but response of relapse to further chemotherapy is better in those with a longer DFI. For advanced stage disease, as the authors note, level I evidence is lacking but there is increasing evidence that the surgical goal is no visible disease. More objective decision-making may develop from results of future randomised trials but these historically have been very difficult to complete. The three questions that must be asked in any patient with advanced disease are: one, what is the surgical goal; two, is the surgical goal feasible, and three, should the patient have surgery now, or after chemotherapy? The arguments for cytoreductive surgery leaving residual disease of diameter <2 cm, <1 cm, or <5 mm are counterintuitive from a cancer biology perspective and in no other gynaecological cancer do we accept sub-optimal resection. Furthermore, the data on residual disease are open to varied interpretation as there is no standardised method of measuring the size (diameter) of residual disease, the number of deposits and the distribution. Therefore, the proposal that a detailed operative report specifically records such information is important (Table 3). Indeed, surgeons participating in future trials must be obliged to enter data onto an agreed detailed interrogative database. A computerised synoptic operative report template has been validated for rectal cancer.[3,4] This is in principle similar to the minimum dataset in use by pathologists.

The authors propose that an accepted standard for surgery should be that 50% or more of patients have complete cytoreduction, defined as no macroscopic residual disease at the end of the operation. The authors note the confusing data on lymph node dissection and sampling in advanced disease. As more than 50% of advanced ovarian cancer patients developed positive pelvic and/or para-aortic nodes then complete abdominal clearance should include pelvic and para-aortic lymphadenectomy to complete the 'completeness' of the peritoneal cavity. There is evidence that if all intra-peritoneal disease can be removed then a thorough surgical dissection of the retro-peritoneal areas removing enlarged and possibly normal sized nodes translates into survival benefit. In fact, the SCOTROC-1 trial highlights more sub-optimal surgery in UK centres and this must be of concern to UK centres. It provides, however, some evidence for supra-regional surgical centres operating on advanced stage ovarian cancer in the UK. Such centralisation, outside the UK, has been shown to benefit patients, as noted by the authors.

Clearly, surgically, everything can be performed in the abdomen. Posterior pelvic exenteration, liver resection (or transplant), vascular replacement of the liver pedicle or aorta, psoasectomy, parietectomy, etc. The question is less 'can it be done' but rather 'should it be done'? So what are the acceptable limits for extensive procedures to be carried out in the field of advanced ovarian cancer patients? If a consensus emerges that extensive procedures are only acceptable for those patients where complete cytoreduction can be achieved then we have to define criteria of resectability.

- The most simple criteria that no one can argue is the small bowel involvementAnd if so what is the acceptable residual length of small bowel?
- There are two other territories that might be considered to evaluate resection.
- Extensive retraction of peritoneal disease infiltrating supra-hepatic vessels causing fixity of the liver.
- Infiltration of the liver pedicle is more likely to be resectable in the primary surgical approach but can be difficult after relapse and/or a multiple course of chemotherapy.

An anatomical and/or 'universal' definition of resectability will give the surgeon or surgeons the possibility to select patients for a primary surgical / medical approach. We support the need to select the patient for surgical strategy regarding resectable disease. Neoadjuvant chemotherapy seems to be a logical approach for 'complete' unresectable disease and in the patient who either intra-operatively or postoperatively is unlikely to tolerate extensive surgical resection.

We suggest that another consideration for or measure of quality in ovarian cancer surgery in primary disease in a given cancer centre is the total number of advanced primary ovarian cancer cases seen per annum, the percentage operated on upfront, the percentage receiving neoadjuvant chemotherapy and, critically, a record of why the decision was made? Also, we suggest as a European consensus that ovarian cancer patients should only be managed by surgeons who either

individually or as a team will carry out safely the necessary pelvic and abdominal procedures to achieve no macroscopic disease. If we accept *a priori* the goal of 'complete' cytoreduction, i.e. 'no macroscopic disease', then the clinical team must refer the patient to the appropriate surgical team! Does neoadjuvant chemotherapy followed by debulking surgery produce similar overall survival and progression free survival outcomes compared to standard primary debulking? Unfortunately, none of the ongoing trials are considering the importance of the concept of resectability.

To come back to the issue of what constitutes quality in surgery, it is not simply the itemising of details of the technical exercise, important as this is. In surgical practice, quality of care and quality assurance of the care provided are inextricably linked. We would argue that other aspects of surgical care in ovarian cancer surgery should be considered and the proposals as they stand in Tables 2 and 3 do not go far enough. Markers or surrogate markers of quality of surgical care and/or quality assurance should include markers of serious surgical morbidity, both intra-operative and post-operative, and surgical mortality. These must be risk-adjusted. The next challenge may be to merge quality of care and quality assurance in the surgical management of primary ovarian cancer. The authors have focused on proposing process quality indicators. What they have proposed in Tables 2 and 3 are measures of what has been done surgically, not how well the surgery has been performed. This we believe to be the next challenge for the surgical community engaged in the care of ovarian cancer patients,.

We would like to congratulate the initiative of Verleye et al. who raised the need for formal benchmarking of quality control in ovarian cancer surgery. National and international organisations and oncology societies should agree on a computerised surgical template for primary ovarian cancer that records why decisions were made to operate or not to operate, the surgery undertaken, the morbidity and mortality, survival and quality of life. Each centre must be obliged to issue reports and audits. The end result of such investment would be assurances that quality of care was being delivered and patient outcome enhanced.

Conflict of interest statement

None declared.

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