Quality control in ovarian cancer surgery

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This study is a literature review of papers in the English language dealing with quality control for ovarian cancer surgery. Quality control in surgery has long been a neglected area of medicine. Initial attempts were limited to cardiac surgery, but only very recently has there been any attempt to look at quality control in ovarian cancer surgery. Investigators from Hesse, Germany were the first to document the surgical quality of patients with ovarian cancer. Subsequently, investigators in the United States and other European countries have demonstrated that patients treated by gynaecological oncologists in large-volume tertiary institutions had the best outcomes. The Gynaecological Cancer Group of the European Organisation for Research and Treatment of Cancer has developed a series of process quality indicators for ovarian cancer surgery that could be used by surgeons or units to audit and improve their practice. These and other initiatives are important, because pressure is coming from consumers, government, health care insurers and medical risk insurers for surgeons and hospitals to provide transparent patient outcome data. If the profession does not institute adequate internal regulation of the quality of ovarian cancer surgery, regulation is likely to be imposed by government.

Key words: cancer, control, ovarian, quality, review, surgery

introduction

Quality control in surgery has long been a neglected area of medicine. Traditionally, National Boards and Colleges, which are nongovernmental agencies, have been responsible for setting the training curriculum for surgeons and devising some type of exit strategy. Such a strategy may include an exit examination, a logbook of cases and/or various other requirements, including certification by a supervisor that the trainee is competent to perform the required surgery. Rarely has the trainee been required to actually perform an appropriate operation before an independent examiner.

In the case of surgery for ovarian cancer, the role of establishing training requirements and certifying competence has fallen to Boards and Colleges of Obstetricians and Gynaecologists. In 1973 the American Board of Obstetricians and Gynecologists established subspecialty Boards in Gynecologic Oncology, and since that time many other countries, including Australia, have followed suit.

Surgeons usually require a ‘Certificate of Competence’ in order to attain clinical privileges at a hospital. However, increasing health care costs, medico-legal pressures, and more widespread use of the Internet by patients and their families have placed increasing pressure on surgeons (and hospitals) to provide tangible evidence of their surgical skills and of the quality of the care that they deliver [1]. In the early 1990s, reports were published of in-hospital mortality associated with coronary artery bypass grafting [2], but only in recent years has there been any attempt to look at quality control in ovarian cancer surgery [3–6].

There is considerable debate about which measures should be used to reflect surgical quality. The most obvious way to assess the quality of surgical care is by direct ‘outcome measures’, such as morbidity and mortality rates, quality of life, and patient satisfaction. More recently, attention has been paid to ‘structural measures’, a broad group of variables that reflect the setting in which the care is being delivered, and ‘process measures’, a specific group of variables that reflect the particulars of the actual care given [1, 6].

Structural measures basically describe the hospital’s physical plant and resources. These may include such things as the number and expertise of the staff employed, access to specific technologies, access to intensive care facilities, and nurse-to-patient ratios. Of the structural measures, the number of procedures performed by either the surgeon or the hospital is most commonly used as a surrogate for surgical quality [1].

Process measures describe the specific care that the patient actually received. They have been used routinely as quality indicators for nonsurgical specialties (e.g. primary care physicians may be graded according to the proportion of appropriate patients in their practice who receive screening mammography), but are equally applicable to surgical specialties. Examples would include guidelines for surgery, type of surgery performed and the use of care pathways [1, 6].

the National Surgical Quality Improvement Program

The National Surgical Quality Improvement Program (NSQIP) in the United States, which was started in the Department of
Veteran Affairs (VA) in 1994, was the first national validated, outcome-based, risk-adjusted, peer-controlled programme for the measurement and enhancement of the quality of surgical care [7]. It followed the prospective ‘National Surgical Risk Study’ in 44 VA Hospitals in 1991, which was established in response to a congressional law that mandated that the VA Hospitals report their surgical outcomes ‘in comparison to the national average’ and ‘risk-adjusted for the severity of the patient illness’ [8].

A key element of the programme was a dedicated clinical nurse at each medical centre who prospectively collected a patient’s preoperative, intraoperative and 30-day outcome data. This nursing appointment is likely to be critical to the success of the programme. The self-reporting of surgical data and morbidity is likely to be less objective. In addition, some of the postoperative deaths will occur after discharge from hospital and may not be recorded unless there is a dedicated person calling or visiting each patient 30 days postoperatively.

Major operations performed under general, spinal or epidural anaesthesia were candidates for entry into the database. Since the inception of the programme in VA hospitals in 1991, the 30-day mortality rate after major surgery has decreased by 31% and the 30-day morbidity rate by 45% [9]. The programme has subsequently been expanded into academic and community hospitals by the American College of Surgeons.

**funding quality improvement programmes**

The quality of surgical care is important to the consumer, health insurance funds, health administrators and health professionals, as well as to the government. For the consumer, transparent documentation of surgical outcomes allows discretion in choosing a facility and a surgeon, while for hospital administrators, insurance companies and the government it should ensure cost-effectiveness of treatment [1, 6].

The prospective data collection needed for these quality improvement efforts is expensive and an important issue is who should pay for it. The two most likely sources of funding are hospitals and health care payers. Dinnick et al. merged clinical data for 1008 surgical patients from the private sector of the NSQIP to the cost-accounting database of the University of Michigan Hospital. They reported that hospitals and health care payers both suffer financial consequences from poor-quality surgical care, but the greater burden falls on health care payers [10].

**quality improvement programmes in gynaecological cancer**

German investigators were the first to document that the type of hospital and their previously reported shortcomings in the surgical treatment of ovarian and endometrial cancer in Hesse, Germany [3]. They reviewed 824 cases of ovarian cancer from 74 reporting gynaecological departments. The number of ovarian cancer operations per year ranged from 0.4 in primary care hospitals to 10.1 in centralized referral centres.

Lymphadenectomy rates in particular for patients with early-stage disease varied significantly with the type of hospital, and they concluded that the type of hospital and the experience and expertise of the surgeon were important factors in the quality of surgical treatment of ovarian cancer.

**quality of surgical staging for early ovarian cancer**

The European Organization for Research and Treatment of Cancer (EORTC) reported their Advanced Chemotherapy in Ovarian Neoplasm (ACTION) trial in 2003. The trial involved selected patients with International Federation of Obstetricians and Gynecologists (FIGO) stage I or IIa disease who were supposed to have undergone thorough surgical staging. Strict guidelines were given for staging requirements, yet only 34% of the 448 patients entered into the trial were properly staged. This inadequate staging was reflected in the outcome of the trial, with properly staged patients not benefiting from adjuvant chemotherapy, whereas patients with inadequate surgical staging had a statistically significant improvement in cancer-specific and recurrence-free survival with the addition of adjuvant chemotherapy [12].

In an attempt to understand the reasons for the inadequate staging of patients with early ovarian cancer, Timmers et al. analysed the data from the EORTC ACTION trial [13]. They reported that the common omissions were the sampling of para-aortic lymph nodes (78%), biopsy of the diaphragm (55%) and sampling of pelvic lymph nodes (52%). They suggested that these omissions reflected a lack of surgical expertise and noted that they were more likely to occur in institutions entering less than five patients. Patients from such institutions were completely staged in only 20.5% of cases. Disappointingly, even patients from institutions entering >20 patients were completely staged in only 37% of cases. The authors warned that multicentre trials recruiting patients from many institutions with small-volume contributions run the risk of inadequate adherence to the study protocol.

These randomised trial data were concordant with Surveillance, Epidemiology and End Results Program (SEER) data, which evaluated the association between lymphadenectomy and survival in 6686 women with clinical stage I ovarian cancer [14]. Lymphadenectomy significantly improved survival for patients with non-clear-cell epithelial ovarian cancer (93.3% versus 85.9%; P < 0.001) and the extent of the lymphadenectomy (0 nodes, <10 nodes and ≥10 nodes) correlated with the survival rates (87%, 91.9% and 93.8%, respectively; P < 0.001).

The Gynecological Cancer Group of the EORTC conducted a literature search to develop a series of process quality indicators for ovarian cancer surgery that could be used by surgeons or units to audit and improve their practice [15]. They identified five indicators for a staging laparotomy when the cancer was grossly confined to the pelvis [15]. The indicators were as follows:

- The percentage of patients with a suspicious ovarian mass undergoing surgery within 1 month of the decision to treat.
- The percentage of patients having a vertical incision.
- The percentage of staging operations having total abdominal hysterectomy, bilateral salpingo-oophorectomy, peritoneal cytology, infracolic omentectomy, random peritoneal
biopsies, and systematic pelvic and para-aortic lymphadenectomy if there were medium- or high-risk features.

- The percentage of surgical reports documenting the presence or absence of cyst rupture before or during surgery.
- The percentage of surgical reports documenting the presence or absence of dense adhesions, and the percentage of dense adhesions biopsied.

referral guidelines to ensure optimal surgical outcomes

Referral to tertiary hospitals that employ gynaecological oncologists is clearly an important issue if appropriate surgery for ovarian cancer is to occur. The Society of Gynecologic Oncologists and the American College of Obstetricians and Gynecologists have published recommended guidelines for the referral of patients with probable early or advanced ovarian cancer, based on five variables: age, serum CA125 concentration, physical findings, imaging results and family history of breast or ovarian cancer in a first-degree relative [16].

Im et al. reviewed 1035 patients with a pelvic mass from seven tertiary care institutions in the United States who were triaged using these criteria [17]. There were 318 (30.7%) primary ovarian, fallopian tube or peritoneal cancers, 667 (64.4%) benign masses and 50 (4.8%) secondary ovarian cancers. In premenopausal women, 70% of ovarian cancers were identified and the positive predictive value was 33.8%. In postmenopausal women, 94% of ovarian cancers were identified and the positive predictive value was 59.5%. In both groups, the negative predictive value was >90%. These guidelines tended to over-refer women with benign masses due, in part, to the strong reliance on a positive family history of breast or ovarian cancer in a first-degree relative.

We reviewed our experience with the risk of malignancy index (RMI) for the triage of patients with a pelvic mass at the Royal Hospital for Women in Sydney [18]. The RMI was derived from a multivariate logistic regression analysis incorporating three variables: the serum CA125 concentration, the menopausal status of the patient and an ultrasonic score. Each variable had been shown to be significantly and independently related to the likelihood of malignancy [19].

There were 204 patients with an isolated pelvic mass referred to the Royal Hospital for Women between January 2003 and December 2005. An RMI >200 correctly identified 70 of 77 (91%) invasive ovarian cancers. It had a sensitivity of 84%, specificity of 77%, positive predictive value of 76% and negative predictive value of 85% for the detection of both borderline and invasive ovarian tumors [18].

quality improvement programmes for advanced ovarian cancer

Investigators at the Mayo Clinic investigated the impact of the aggressiveness of the operating surgeon, as well as various clinical and surgicopathological factors, on the ability to achieve optimal cytoreduction in patients with advanced ovarian cancer [20]. Surgical aggressiveness was defined by the performance of radical procedures in more or less than 50% of patients operated. In univariate analysis, the American Society of Anesthesiology (ASA) score, ascites, carcinomatosis, diaphragmatic tumour, mesenteric involvement and the aggressiveness of the surgeon were all significantly correlated with residual disease. However, in multivariate analysis, only the ASA score, carcinomatosis and the aggressiveness of the surgeon were significant factors. Even in the subset of patients with carcinomatosis, aggressive surgeons achieved a greater incidence of optimal cytoreduction (78.6% versus 55.4%) and a significantly longer median survival (3.45 versus 2.03 years; \( P < 0.001 \)) [20].

These same investigators subsequently were the first to apply NSQIP methodology to the assessment of outcomes for ovarian cancer surgery. The study was retrospective, and involved patients with stages IIIC and IV ovarian cancer from the Mayo Clinic (1994–1998), Memorial Sloan Kettering Cancer Center (2000–2003) and Johns’ Hopkins (1997–2003). Independent variables collected included age, serum albumin and creatinine, ASA score, ascites, FIGO stage and grade, and surgical complexity. To determine the latter, individual procedures were given points (e.g. large bowel resection 2, small bowel resection 1) and complexity score groups were calculated by adding the scores of the individual procedures [21].

There were 564 consecutive patients from the three centres in the study, and significant predictors of 30-day morbidity, 3-month mortality, inability to receive planned chemotherapy and length of hospitalization were assessed. For example, the strongest predictors of 30-day morbidity were serum albumin \((P < 0.001)\), ASA score \((P = 0.008)\) and complexity of surgery \((P < 0.001)\). Age \((P = 0.002)\) and ASA score \((P = 0.001)\) independently predicted mortality. Extensive surgery is of limited value if the patient is unable to receive chemotherapy within 30 days of the operation, and ASA score \((P < 0.001)\) and surgical complexity were significant indicators of inability to receive timely chemotherapy in this study.

Observed to expected ratios for each outcome were calculated and were similar for all three institutions. The authors concluded that this system, applied nationally, could provide a meaningful mechanism to identify areas requiring quality improvement [21].

Bristow et al. used the Maryland Health Services Cost Review Commission database to evaluate the impact of surgeon and hospital case volume on short-term outcomes after surgery for ovarian cancer [4]. From 2001 to 2008, there were 1894 primary ovarian cancer operations performed by 352 surgeons at 43 different hospitals. After controlling for other factors, they found that surgery performed by a high-volume surgeon was associated with a 69% reduction in the risk of in-hospital death, while high-volume hospital care was associated with an increased likelihood of optimal cytoreduction, shorter hospital stay and lower hospital-related cost of care.

Mercado et al. examined whether surgical specialty impacted on overall survival and quality of life (as proxied by the presence of an ostomy) for patients with advanced ovarian cancer [5]. Between 1991 and 2004 they identified 31 897 such patients from the State Cancer Registries in New York, Florida, Washington and California. They determined that patients had a lower hazard of death when treated in a higher volume hospital \((P < 0.0001)\) or by a gynaecological oncologist versus
follows:

- The percentage of patients having surgery within 1 month of the decision to treat or having a documented reason for delay.
- The percentage of patients with spread of disease fully assessed for operability at the start of surgery and with the initial findings documented.
- The percentage of patients having hysterectomy, bilateral salpingo-oophorectomy and infracolic omentectomy when optimal debulking was considered feasible.
- The percentage of patients having no macroscopic residual disease.
- The percentage of patients having a pelvic and para-aortic lymphadenectomy when there was no residual intraperitoneal disease.
- The percentage of patients having documentation of the size and location of residual disease.

**conclusions**

Quality control in gynaecological cancer surgery in general and ovarian cancer surgery in particular has long been neglected by Colleges and Societies of Obstetricians and Gynaecologists. In many countries, vested interests have even resisted the move to subspecialisation in gynaecological oncology, which, in the author’s opinion, is a prerequisite for proper surgical management of gynaecological malignancies. Even in countries where subspecialisation has been officially recognised, little has been done officially to evaluate the skills and outcomes of individual surgeons. In addition, the centralisation of all ovarian cancer surgery to specialised centres with certified gynaecological oncologists has proven difficult to achieve for logistical and other reasons. Increasingly, pressure is coming from consumers, government, health care insurers and medical risk insurers for surgeons and hospitals to provide transparent patient outcome data. The onus is clearly on the profession to institute internal regulation of the quality control of ovarian cancer surgery. Several important such initiatives have been started in the past 5 years, and failure to support and expand these initiatives is likely to result in external regulation being imposed by government.

**disclosures**

The author declares that he has no conflicts of interest.

**references**