

Surgical Management of an Adnexal Mass Suspicious for Malignancy

These clinical practice guidelines have been reviewed and approved by the SOGC/GOC/SCC Policy and Practice Guidelines Committee of the Society of Obstetricians and Gynaecologists of Canada.

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Abstract

Objective: to outline the preoperative, intraoperative, and post-operative management of patients who present with a pelvic mass suspicious for malignancy.

Options: these guidelines discuss the surgical procedures involved in the adequate staging and debulking of the adnexal mass, the role of the gynaecologist and gynaecologic oncologist, and the timing of surgery in relation to the use of chemotherapy.

Outcomes: survival is the outcome of interest.

Evidence: a literature search was conducted using Medline, CancerLit, and Embase from 1960, using the terms "ovarian neoplasm," "surgery," "guidelines," "consensus," "statement."

Values: the evidence collected was reviewed by the Society of Obstetricians and Gynaecologists of Canada (SOGC)/Gynaecologic Oncologists of Canada (GOC)/Society of Canadian Colposcopists (SCC) Policy and Practice Guidelines Committee members under the leadership of the primary author and quantified using the evaluation of evidence guidelines developed by the Canadian Task Force on the Periodic Health Exam.

Benefits, harms, and costs: benefits are described in terms of three or five year survival. Harm is implied by the decreased survival benefit when suboptimal surgery is performed.

Recommendations:

1. Women with disease confined to the ovary should receive thorough surgical staging to provide the woman with maximum information to inform her decision for or against adjuvant therapy. The more localized the disease appears, the more extensive the assessment should be, including the biopsies required to confirm the clinical impression of low stage disease. (II-3 A)
2. At the initial surgery, patients with extensive abdominal disease should have an attempt at optimal debulking. (II-3 B)
3. Women with liver metastases or obvious para-aortic lymphadenopathy should be referred to a gynaecologic or medical oncologist prior to embarking on surgery to rule out a gastrointestinal primary and to allow consideration of neoadjuvant therapy. (III B)

Validation: these guidelines were reviewed and approved by the SOGC/GOC/SCC Policy and Practice Guidelines Committee.

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INTRODUCTION

Ovarian cancer is the fourth leading cause of cancer deaths in Canadian women. Each year 2,500 new ovarian cancers are diagnosed in Canada. Surgery serves two roles for the patient with an adnexal mass: diagnostic and therapeutic. The diagnostic role of surgery enables: 1) identifying the nature (benign or malignant) and location of the primary disease (ovarian, tubal, colonic); 2) if malignant, defining the areas to which the disease has spread (stage); and 3) providing information on other poor prognostic variables such as grade and histologic type. The therapeutic role of surgery provides the opportunity for optimal debulking, granting a survival advantage. (II-3 B) Surgery also has a role in symptom management, such as alleviating bowel obstruction. Although gynaecologic oncology is a recognized subspecialty, many gynaecologists and some general surgeons may find themselves involved in the decision making process with women who have an adnexal mass that is suspicious for malignancy. This guideline outlines important principles in the patient's preoperative, intraoperative, and post-operative management.

CLINICAL MANAGEMENT

A. LEVEL OF TRAINING AND INITIAL OVARIAN CANCER SURGERY

Optimal management of a woman with an adnexal mass suspicious for malignancy should include optimal surgical staging and, when possible, debulking at her initial laparotomy. The knowledge of the disease process is as important as the surgeon's skills. If doubt exists concerning optimal care, subspecialty consultation should be considered.

B. PREOPERATIVE ASSESSMENT AND MANAGEMENT

Patients presenting with a pelvic mass should have a complete history and physical examination including pelvi-rectal exam. In addition, particular attention should be paid to examination of the supraclavicular nodes. Imaging tests should include a chest X-ray and abdominal and pelvic ultrasound. The ultrasound will help to identify tumour characteristics, the presence of ascites, hydronephrosis, enlarged aortic nodes, liver metastasis or an omental cake. A CA-125 can be a useful marker of disease status, especially during adjuvant therapy. If the individual has bowel symptoms, a barium enema or colonoscopy is recommended. The CT scan is an optimal investigation providing further information on metastases. It may identify the primary disease in another organ such as the pancreas. Preoperative bowel preparation such as fleets phosphosoda 2 tabs in am and pm on days prior to surgery is recommended.

1. The mass with a intermediate index of suspicion for malignancy

Intermediate index of suspicion for ovarian cancer is suggested

by the following ultrasound findings: thick septae, multilocular, mixed or solid component, papillary excrescences.¹ In this clinical situation, the same indications for surgery as in the previous situation should be discussed with the patient. The surgical approach may be via laparotomy or laparoscopy, provided the staging procedures in section C.1 "Intraoperative Management with an Intermediate Preoperative Index of Suspicion for Malignancy" are completed and the recommendations of the SOGC Policy Statement for the Laparoscopic Management of the Adnexal Mass¹ are satisfied.

2. The mass highly suspicious for malignancy

Clinical features giving rise to a high index of suspicion for malignancy include fixation of the pelvic mass, ascites, an omental cake, enlarged nodes or bowel obstruction. When there is a high index of suspicion for malignancy, the physician should review with the patient the following indications for surgery: 1) to determine the origin of disease; 2) staging to determine the extent of disease; and 3) to debulk as much tumour as possible. Discussion of the risks of surgery should include bleeding, infection, thromboembolism, and the possibility of vascular, urologic, and digestive tract trauma. Preoperative counselling should be provided by a skilled multidisciplinary team including: a nurse to review the medical and psychological impact of disease on quality of life; a social worker to assist with personal and family counselling as well as discharge planning; a pain management team for post-operative pain management options; a physiotherapist; and a nutritionist to optimize those nutritional elements required for healing. Patients should be informed that if cancer is identified, adjuvant chemotherapy will likely be required.

A patient who presents with pelvic mass and parenchymal liver metastases, enlarged para-aortic nodes or malignant pleural effusion should be referred to a gynaecologic or medical oncologist prior to embarking on surgery. Neoadjuvant chemotherapy should be strongly considered in this situation. (III B)

C. INTRAOPERATIVE MANAGEMENT

The surgery facility should provide: on-site blood bank support, anaesthesia support capable of handling significant fluid shifts, consultation opportunities with gynaecologic oncologist/general surgeon and urologist for procedures such as pelvic and para-aortic lymphadenectomy, on-site pathology, and an intensive care unit. Surgery for ovarian cancer involves the technical ability to conduct at minimum a total abdominal hysterectomy (TAH), bilateral salpingo-oophorectomy (BSO), and omentectomy. It also involves the depth of understanding of the disease process and a willingness to interact with medical or gynaecologic oncologists to help women work through their decision making process. The ultimate goal of the health care community should be to offer the best medical and surgical care to patients with ovarian cancer for their survival advantage and quality of life.

Six guidelines have been published on the operative

management of ovarian cancer: Allen (1993),² European Organization of Research and Treatment of Cancer (EORTC) (1994),³ National Comprehensive Cancer Network (NCCN) (1995),⁴ National Institutes of Health (NIH) (1995),⁵ Society of Surgical Oncology (1997),⁶ and Society of Gynecologic Oncologists (1998).⁷ The consensus conference reports that came out of the NIH⁵ and NCCN⁴ both used the highest level of methodological rigour. Both the NIH⁵ and EORTC³ documents provide the best detailed description on the surgical management of patients. This guideline supports the general principle of intraoperative management advocated in previously published guidelines. The more localized the disease appears, the more extensive the assessment should be, including biopsies to confirm the clinical impression of low stage disease. (II-3 A) Optimal debulking provides a median survival advantage. (II B)

1. Intraoperative management with an intermediate preoperative index of suspicion for malignancy

The following staging procedures are important in a patient with an intermediate preoperative index of suspicion for malignancy. Washings or a collection of ascites should be obtained for cytologic assessment on entry into the abdomen. The following sites should be routinely inspected and palpated: right and left diaphragm; surface and parenchyma of the liver, gallbladder, stomach, spleen, right and left kidney; right and left para-colic gutter; small bowel and mesentery; appendix; ascending, transverse, descending, and rectosigmoid colon and mesentery; omentum; the lesser sac; para-aortic and pelvic nodes; ovaries, tubes, and uterus; bladder peritoneum and cul-de-sac. Surgery includes a total abdominal hysterectomy and bilateral salpingo-oophorectomy and infracolic omentectomy. In the patient who is interested in preserving fertility, a unilateral salpingo-oophorectomy is an option if the disease is low grade and confined to one ovary. Consideration should be given to a biopsy of the remaining ovary, especially if a suspicious lesion is identified. Any pelvic adhesions should be biopsied. The risk of disease when the following areas appear clinically negative are: para-aortic nodes (18%), diaphragm (7.3%), omentum (8.6%), and pelvic nodes (5.9%).⁸ Thus, if there is no visible intra-abdominal disease, biopsies should be taken of: right and left diaphragms; right and left para-colic gutters; cul-de-sac; bladder flap; small and large bowel mesentery or serosa; and pelvic and para-aortic nodes. (II-3 A)

2. Intraoperative management with a high preoperative index of suspicion for malignancy

In a patient with a high preoperative index of suspicion for malignancy, surgery should be completed through an adequate midline incision. Tumour size and distribution of disease should be documented at the beginning and end of the operation. If there is obvious intra-abdominal or retroperitoneal disease, the aim of surgery is to debulk as much intra- and retroperitoneal tumour as possible. (II-3 B) Case studies suggest that patients

who have small volume disease at the onset of surgery have the longest survival, patients with large volume disease who are debulked to less than one cm in any one site have an intermediate survival advantage (36 months), and patients left with more than one cm disease in any site have the poorest median survival (30 months).⁹ (II-2 B) In a retrospective cohort trial by Scarabelli, lymphadenectomy provided a survival advantage in patients with less than two cm intra-peritoneal disease (59% versus 22% at two years).¹⁰ Results of a European randomized trial on routine lymphadenectomy versus debulking grossly involved nodes will be available later in 2000.¹¹

D. ROLE OF THE GYNAECOLOGIST AND GYNAECOLOGIC ONCOLOGIST IN INITIAL SURGERY

Population based reviews on the surgical management of women with ovarian cancer indicate that many women are not receiving optimal care. In a 1997 review of 785 American women with ovarian cancer, Munoz¹² reported that only ten percent of women with stage 1 and 2 ovarian cancer and 50 to 70 percent of patients with stage 3 and 4 disease received staging and treatment as recommended in the NIH consensus statement. Munoz reported that the absence of full lymphadenectomy was the most common deficiency in the surgery of women with presumptive early stage disease. Survival was shown to be affected by the adequacy of the surgical procedure and by the training of the physician caring for these patients.¹² (II-3 B) In a study of 87 patients with stage 1 or 2 disease, Mayer found improved survival in women operated on by gynaecologic oncologists due to a more comprehensive staging of surgery.¹³

In contrast during 1983 and 1988, Averette and Nguyen¹⁴⁻¹⁷ reviewed the care of women in the United States with ovarian cancer, demonstrating that patients managed by a gynaecologic oncologist had the same debulking and survival rate as those cared for by a gynaecologist. However, the patient mix was different between the two groups. Fifty percent of the gynaecologic oncologist patients had advanced disease, compared to 30 percent of the gynaecologist patients. (II-3 B) Junor^{18,19} conducted a retrospective review of 1,866 Scottish women diagnosed with ovarian cancer in 1987, 1992, 1993, and 1994. This study's objective was to determine whether the level of surgical training improves survival in women with ovarian cancer. Analysis of the data revealed that gynaecologic oncologists saw women with more advanced disease, older patients, and more women with ascites. On average, gynaecologists cared for women with a better prognosis. Despite this difference in patient characteristics between the two groups, there was a 25 percent improvement in the three year survival for patients with stage 3 disease treated by the gynaecologic oncologists as compared to those treated by the gynaecologists, translating into a median prolongation survival of five months.

E. POST-OPERATIVE MANAGEMENT

A medical or gynaecologic oncologist should assess all patients with a histological diagnosis of ovarian cancer. If there has been no assessment of the upper abdomen or retroperitoneum or suboptimal debulking, a second surgery should be considered either immediately or as an interval debulking procedure. In those with metastatic disease, long-term survival can be prolonged with the use of adjuvant therapy.¹⁹ The patient should be counselled in this regard. All ovarian cancer patients should be offered follow-up as provided by their local cancer centre. The medical, psychosocial, and sexual well-being of women diagnosed for ovarian cancer should be addressed.

RECOMMENDATIONS

1. Women with disease confined to the ovary should receive thorough staging to provide the woman with maximum information to inform her decision for or against adjuvant therapy. The more localized the disease appears, the more extensive the assessment should be, including the biopsies required to confirm the clinical impression of low stage disease. (II-3 A)
2. At the initial surgery, patients with extensive abdominal disease should have an attempt at optimal debulking. (II-3 B)
3. Women with liver metastases or obvious para-aortic lymphadenopathy should be referred to a gynaecologic or medical oncologist prior to embarking on surgery to rule out gastrointestinal primary and to allow consideration of neoadjuvant chemotherapy. (III B)

CONCLUSION

Ovarian cancer affects one in 80 women and is the leading cause of death from gynaecologic cancer. There is no level A evidence for the therapeutic surgical practices that are advocated; however, as society and the medical community become more supportive of randomized trials as the basis for treatment recommendations, this information may become available. We do have sufficient information on prognostic factors in ovarian cancer and this is the basis for these surgical staging recommendations. The Canadian standard of care for any woman presenting with an adnexal mass suspicious for malignancy is staging with optimal debulking surgery at initial laparotomy.

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| TABLE 1 ¹⁹ QUALITY OF EVIDENCE ASSESSMENT | CLASSIFICATION OF RECOMMENDATIONS |
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| <p>The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam.¹⁹</p> <p>I: Evidence obtained from at least one properly randomized controlled trial.</p> <p>II-1: Evidence from well-designed controlled trials without randomization.</p> <p>II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.</p> <p>II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940's) could also be included in this category.</p> <p>III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.</p> | <p>Recommendations included in these guidelines have been adapted from the ranking method described in the Classification of Recommendations found in the Report of the Canadian Task Force on the Periodic Health Exam.¹⁹</p> <p>A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.</p> <p>B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.</p> <p>C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.</p> <p>D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.</p> <p>E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.</p> |

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