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Adnexal Masses Suspected to Be Benign Treated with Laparoscopy

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ABSTRACT

Objective: Guidelines for referring women with pelvic masses suspicious for ovarian cancer to gynecologic oncologists have been developed by the American College of Obstetrician Gynecologists (ACOG). We set out to evaluate the negative predictive value of these guidelines and to assess a modified algorithm involving minimally invasive surgery in the treatment of women with masses suspected to be benign.

Methods: 257 consecutive patients with adnexal masses of 8cm to 13cm on preoperative ultrasound examination meeting Triage Criteria set forth in ACOG Committee Opinion 280. Patients meeting the selection criteria were scheduled for operative laparoscopy, washings, adnexectomy, bagging, and colpotomy. A total of 240 patients successfully completed intended treatment (93.38%), and 234 of these did not require admission (97.5%). There was a low incidence of significant complications: 97.50% of women were successfully treated as outpatients, 97.92% of surgeries lasted <136 minutes, and 97.08% had blood loss <200mL. The negative predictive value of ACOG Committee Opinion 280 Triage Criteria as a deselector for having invasive ovarian malignancy in our population was 95.57% for premenopausal and 90.91% for postmenopausal women.

Conclusions: Laparoscopic adnexectomy, bagging, and colpotomy is a desirable goal for patients with ovarian masses in the 8cm to 13cm range meeting selection criteria affording a minimally invasive approach with attendant benefits including outpatient treatment (97.5%), few complications, low likelihood of iatrogenic rupture of the ovarian capsule (1.25%), and low necessity for reoperation after final pathology is evaluated (6.03%). Negative predictive value of ACOG Committee Opinion 280 is confirmed in a community gynecology practice and is recommended to form the basis of a new treatment algorithm for women with adnexal masses.

Key Words: Early ovarian cancer, Laparoscopy, Treatment, Minimally invasive surgery.

INTRODUCTION

Because of the relatively high incidence of adnexal masses in the female population and because most United States hospitals do not have gynecologic oncologists readily available in the operating room, we set out to test the safety of a modified algorithm for treating adnexal masses. Our proposed management algorithm assures both adherence to standard of care recommendations regarding referral of adnexal masses likely to represent ovarian cancer to gynecologic oncologists and treatment of adnexal masses felt to be benign using minimally invasive surgical techniques while carefully observing standard principals of oncologic surgery. We selected masses in this size range, because just as with larger uteri, many gynecologic surgeons view increasing size of an adnexal mass as an important deselector for laparoscopic surgery. It is our belief that the days of laparotomy in mainstream gynecology should be over. Various organizations have expressed positions on the benefits of minimally invasive surgery in hysterectomy.[1–3] We advocate the same position for ovarian masses.

Adnexal masses are relatively common, contributing to gynecologists' office volume and surgical case load. Conversely, ovarian cancer has a relatively low prevalence. Ovarian cancer has nonspecific symptoms and is usually silent in its early stages.[4] Presently, we have no reliable screening test for ovarian cancer, and we have a limited ability to detect it using current diagnostic strategies.[5,6]

Various studies have addressed the likelihood of malignancy within an ovarian mass. This likelihood ranges from 0.38% to 18.67% **(Table 1)** and is population dependent.[7–19]

Contemporary preoperative workup for an adnexal mass involves history and physical examination, labs including

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Table 1.
Likelihood of Malignancy in Adnexal Masses

Study	Patients	Malignancy	% Affected
Mage et al[7] 1990	433	9	2.08
Mecke et al[8] 1992	773	11	1.42
Nezhat et al[9] 1992	1011	4	0.40
Hulka et al[10] 1992	13793	411	2.98
Canis et al[11] 1994	757	19	2.51
Marzana et al[12] 1994	527	2	0.38
Wenzl et al[13] 1996	16601	108	0.65
Childers et al[14] 1996	138	19	13.77
Canis et al[15] 1997	230	15	6.52
Hidlebaugh et al[16] 1997	405	8	1.98
Malik et al[17] 1998	292	11	3.77
Mettler et al[18] 2001	493	8	1.62
Valentin et al[19] 2006	1066	199	18.67
Present study, 2012	257	15	5.84
Total	36776	839	2.28

Table 2.
ACOG Committee Opinion 280 Criteria For GYN Oncology Referral[44]

Premenopausal Women
CA 125 >200U/mL
Ascites
Evidence of abdominal or distant metastases
Family history first-degree relative(s) with breast or ovarian cancer
Postmenopausal Women
Elevated CA 125
Ascites
Nodular or fixed pelvic mass
Evidence of abdominal or distant metastases
Family history first-degree relative(s) with breast or ovarian cancer

CA 125, and imaging studies usually including transvaginal ultrasound. The risk of encountering an unexpected ovarian malignancy after modern preoperative screening is 0.9% to 13%.[20] Dating to Jacobs et al 1990[21] and Sassone et al 1991,[22] scoring systems have related ultrasound characteristics, CA 125, family history, and other variables in predicting the likelihood of ovarian malignancy.[23–43] By 2002, the American College of Obstetricians & Gynecologists evaluated the various predictors of ovarian malignancy and published ACOG Committee Opinion 280 setting forth criteria to refer both premenopausal and postmenopausal women for care by gynecologic oncologists.[44] These referral criteria are summarized in **Table 2**. Postmenopausal criteria include a lower CA 125 threshold or a nodular or fixed pelvic mass for referral. Importantly, only one referral criterion must be met for a patient to be referred to a gynecologic oncologist.

Two prior studies have looked at the operational characteristics of ACOG Committee Opinion 280 and how it functions in actual practice. In 2005, Im et al[45] demonstrated in a multi-center study that using criteria in ACOG Committee Opinion 280 in a referral population to identify women at high risk for ovarian cancer yielded a positive predictive value of 33.8% in premenopausal women and 59.5% in postmenopausal women. Data were not uniform from each of the 7 centers, and at some centers pelvic masses were only identified retrospectively.[45] These investigators conceded their data did not address how ACOG Committee Opinion 280 would operate in a general population.

In a more elegant study, Dearking et al in 2007[46] demonstrated in a prospectively enrolled cohort that using criteria set forth in ACOG Committee Opinion 280 in a non-referred population to identify women at elevated risk for ovarian cancer yielded a positive predictive value of 13.6% in premenopausal women and 44.9% in postmenopausal women. In their referral population applying the same selection criteria lead to a positive predictive value of 47.3% in premenopausal women and 90.5% in postmenopausal women.[46] The referral population had a demonstrably higher prevalence of disease, positively influencing assessment of the selection criteria.

By whatever method, once located, the prognosis of an ovarian tumor is determined by surgical staging, histologic subtype, and grade of tumor differentiation.[47] Overall, only approximately 25% of patients diagnosed with ovarian cancer have early ovarian cancer (EOC) or Stage 1. These patients have 5-year survival approaching 90%.[48,49] About 20% of EOC actually have microscopic metastatic disease on staging.[50] This is why thorough staging is crucial irrespective of the initial surgical perception.

The route of definitive treatment of ovarian cancer has been changing. Initially reported in 1990 by Reich et al, laparoscopic surgery for staging of ovarian cancer has become more common.[51] Laparoscopy has now become a standard treatment modality for patients with suspected benign adnexal masses.[52,53] Laparoscopy and robot-as-

sisted laparoscopy have equal efficacy in removal of adnexal masses, but masses were small with mean weight of 50 grams and size of 5.4cm (laparoscopic group) and 28 grams and size of 4.5cm (in the robotic group).[54]

Surgical treatment of adnexal masses suspected to be benign on preoperative ultrasound has also evolved over time. In each of these studies, one anesthesia was used, usually with conversion to laparotomy, if frozen section diagnosed malignancy. Definitive staging was performed at the time of initial operation by gynecologic oncologists.

Havrilesky et al[55] reported on 396 patients treated over 7 years by laparoscopy for adnexal masses thought to be benign preoperatively at a teaching center. No clear statement of criteria used to discriminate benign from malignant masses preoperatively is contained in the article. Median preoperative mass size was 5.2cm (range, 0.5 to 17): <4cm 26%, 4 to 8cm 57.4%, >8cm 16.6%. If a mass was drained within a bag, it was not counted as ruptured. Ninety-seven percent of masses were benign on pathology. Intraoperative rupture of the capsule occurred in 25% of cases. Conversion to laparotomy occurred in 25% of cases. CA 125 levels were not predictive of malignancy, but levels were not stratified based on menopausal status.

Smorgick et al[56] reported on 263 women undergoing laparoscopic adnexectomy or cystectomy between 2002 and 2006. No clear statement of criteria used preoperatively to discriminate benign from malignant masses is presented. Mean cyst size was 6.6cm. A collection bag was used if a cyst was suspected to contain irritating fluid or possible malignant cells. Of these 263 cases, 93.5% were benign. Cyst rupture occurred in 16.6% of cases, ranging from 7.4% in adnexectomy cases to 29.5% for cystectomy procedures.

Panici et al[57] reported on 60 eligible patients aged 18 to 45 years, randomized to laparoscopy or laparoscopically directed mini-laparotomy for 7-cm to 18-cm adnexal cysts. Inclusion criteria were no ultrasonographic suspicion of endometriosis or malignancy, CA 125 within normal range, BMI<29kg/m^2, ASA score 0 to 2, no previous laparotomy, and no contralateral cyst >7cm (amongst other criteria). A collection bag was used to containerize the mass if possible, during aspiration and removal. Frozen section was always performed, and the case was converted to laparotomy if definitive staging was required. Uncontrolled rupture occurred in 87% of the laparoscopy patients and in 29% of the laparoscopically assisted, mini-laparotomy patients. No data on malignancy rate was included.[57]

Sagiv et al[58] reported on 21 patients with cystic or complex adnexal masses extending at least cephalad to the umbilicus with a "low probability of malignancy" managed laparoscopically. Inclusion criteria were no suspicion of malignancy on imaging, no enlarged pelvic lymph nodes, and CA 125 <130U/mL. Masses were aspirated without containerization. If frozen section was positive for malignancy, the gynecologic oncology team immediately performed laparotomy and definitive staging. One of 21 patients had malignancy (adenocarcinoma) or 4.76%. These investigators state they could not contain spillage from such large masses, so they proceeded to laparotomy at the same setting if cancer was found.[58]

An important consideration in adnexal mass surgery is inadvertent opening of the ovarian capsule. Likelihood of cyst rupture either during laparotomic or laparoscopic removal ranges from 10.5% to 41.8% in published studies.[55,56,59–61]

Spillage affects recurrence rate for some benign lesions including mucinous cystadenoma.[62] In cases of ovarian malignancy where disease is confined to the ovary, rupture of the ovary increases the Stage to IC.

Vergote et al[63] in 2001 reported on over 1500 patients with Stage I epithelial ovarian carcinoma and found intraoperative rupture worsened disease-free survival. Various other retrospective multicenter studies support intraoperative cyst rupture as an independent predictor of disease-free survival.[64–66]

Alternatively, another group of publications[67–71] failed to demonstrate a difference in disease-free survival based on intraoperative cyst rupture. Limitations of both groups of older studies assessing long-term outcome of patients with inadvertent, intraoperative capsular rupture involve inclusion of nonstaged or incompletely staged cases, lack of consistent adjuvant treatments for women positive for malignancy, and lack of separate analysis of Stage IC cases.

In perhaps the most definitive work on this topic, Bakkum-Gamez et al[61] reported a retrospective study to specifically address outcomes related to intraoperative capsule rupture (stage IC) in treatment of Stage I epithelial cancer between 1991 and 2007. Of 161 cases meeting inclusion criteria, intraoperative capsule rupture occurred in 61 or 38%. All patients were treated in one anesthesia with definitive staging performed based on positive frozen section results. For patients whose only Stage IC qualification was intraoperative capsular rupture, there was

found to be significantly higher recurrence and mortality rates.[61]

ACOG Committee Opinion 280 sets forth the standard of care for preoperative discrimination of suspected malignant vs. suspected benign adnexal masses. But how successful is application of Committee Opinion 280 in selecting a population of women at low-risk for ovarian malignancy and how should these women be optimally treated?

Im et al[45] in 2005 showed that strict adherence to ACOG Committee Opinion 280 in a referral population yields a negative predictive value (NPV) of 92.0% for all cases of ovarian cancer in premenopausal women and an NPV of 91.1% in postmenopausal women.

Dearking et al in 2007[46] demonstrated that strict adherence to ACOG Committee Opinion 280 in a nonreferred population arising from their primary catchment area yields an NPV of 97.7% for all cases of ovarian cancer in premenopausal women and an NPV of 95.0% in postmenopausal women. In their referral population, NPV was 91.0% in premenopausal and 90.5% in postmenopausal women, or essentially identical to the Im et al data.[45] Of the women not referred based on ACOG Committee Opinion 280 who were later found to have ovarian cancer, 8 of 10 premenopausal and 11 of 14 postmenopausal women were found to have Stage I or II disease at the time of definitive surgery.

Virtually all women with adnexal masses thought to be benign are managed by general gynecologists. Some of these women are managed expectantly while others are taken directly to surgery. Regrettably, many women with adnexal masses are treated without an appropriate workup. Many gynecologists do not operate in medical centers where there is instant availability of gynecologic oncologists for intraoperative consultation and continuation of care with the patient under the same anesthesia. Because of the supposition that the adnexal mass is benign, washings are not obtained, appropriate care may not be exercised in removing the mass leading to spillage, frozen section is not ordered, and thorough examination of all peritoneal surfaces for disease is not accomplished. As a consequence, many adnexal masses are not found to be malignant until well after the procedure is concluded. Timely re-evaluation and definitive staging is required for these patients.[72–76] Lehner[74] examined reoperations before and after 17 days and found such a delay between laparoscopy and laparotomy may adversely affect the distribution of disease stage.

Definitive staging of ovarian cancer includes cytologic washings, total hysterectomy, bilateral salpingo-oophorectomy, peritoneal surface biopsies, total omentectomy, and retroperitoneal lymphadenectomy from the pelvis and paraaortic regions to the left renal vessel.[77] Laparoscopy and laparotomy have equal efficacy in both early and advanced stage ovarian cancer.[78]

Because a final pathology report returning a diagnosis of invasive ovarian cancer is often a surprise, a subsequent surgical procedure is often performed for definitive staging of disease. Frequency of upstaging in patients with EOC at initial examination is in the range of 10% to 35.7% **(Table 3)**.[72,73,79–87]

Stier et al in 1996 reported on 45 patients being re-staged by laparotomy 12 to 161 days (mean 56 days) after initial surgery. Prestaging workup showed no radiographic evidence of metastasis. Seven (15.56%) patients had their disease upstaged.[81]

Colomer et al[72] in 2006 reported on 20 patients undergoing either primary treatment or completion of staging. The interval between the initial operation and the staging procedure was 4.7 weeks (range, 2 to 11.4). Nineteen cases (95%) had successful laparoscopic surgical staging with one converted to laparotomy. In this series, 4 (20%) patients were upstaged.[72]

Nezhat et al[73] in 2009 reported on 36 patients laparoscopically staged for early-stage ovarian and fallopian tube cancers over a 12-year period. Nine were referred for

Table 3.
Frequency of Upstaging at Definitive Procedure

Study	Patients	Upstaged	% Upstaged
Pomel et al[79] 1995	10	1	10.00
Childers et al[80] 1995	14	5	35.70
Stier et al[81] 1996	45	7	15.56
Tozzi et al[83] 2004	24	5	20.80
Leblanc et al[84] 2004	44	8	18.20
Spirtos et al[85] 2005	58	6	11.00
Chi et al[86] 2005	20	2	10.00
Ghezzi et al[87] 2007	15	4	26.70
Colomer et al[72] 2008	20	4	20.00
Nezhat et al[73] 2009	36	7	19.44
Present study	9	4	44.44
Total	295	53	17.96

staging and 27 with adnexal masses. In all cases, a specimen retrieval bag was used to remove tissue. All cases were accomplished laparoscopically. Seven (19.4%) patients were upstaged.[73]

The purpose of this study is 3-fold. First, to demonstrate the safety of minimally invasive surgical treatment of 8-cm to 13-cm adnexal masses felt to be benign. Second, to confirm the negative predictive value of ACOG Committee Opinion 280 for selecting women whose adnexal masses are unlikely to be malignant in this size range. Third, based on these data, to advocate for acceptance of a new treatment algorithm prominently featuring minimally invasive surgery in the treatment of these lesions.

We propose a new treatment algorithm with initial triage based on ACOG Committee Opinion 280 **(Figure 1)**. Women having adnexal masses suspected to be malignant are immediately referred to gynecologic oncologists, while women with masses not suspected to be malignant are treated laparoscopically with careful attention to standard oncologic surgical principals. If disseminated disease is encountered at initial laparoscopy in patients felt to have benign disease, pelvic washings, biopsies of appropriate surfaces, and photo documentation is conducted. Laparoscopy is then abandoned and the patient immediately referred to gynecologic oncologists for consultation and definitive surgical staging. If after the initial laparoscopic procedure for benign disease pathology, a woman has invasive ovarian cancer, she is referred to gynecologic oncologists for definitive staging and treatment.

Following this strategy, all women having adnexal masses will receive appropriate care and optimal attention will be focused on masses not initially suspected to be malignant.

MATERIALS AND METHODS

A prospective descriptive study was conducted on patients treated by a private gynecologic surgery practice in a community hospital setting from January 1, 2004 through April 30, 2011. Two-hundred fifty-seven consecutive patients with adnexal masses of 8cm to 13cm on preoperative ultrasound examination not meeting Triage Criteria set forth in ACOG Committee Opinion 280 for referral to gynecologic oncologists were treated with operative laparoscopy, adnexectomy, bagging, and colpotomy.

Patients either arose within the practice or were referred for pelvic pain, pelvic mass, or with an incidental finding on imaging studies performed for other indications. Ultrasound examinations were performed either by the gynecologic surgeons who have extensive experience in OB/GYN ultrasound or in hospital radiology units in the case of in-patients. When imaging was performed in a hospital radiology unit, images were independently interpreted by the investigators as part of the preoperative workup.

Conventional closed laparoscopy was performed with Veress needle insufflation. An 11-mm bladed trocar is placed at the base of the umbilicus. Location and size of additional ports is dictated by the clinical situation. Washings are obtained. Inspection of all peritoneal surfaces is conducted. If disseminated frank malignancy is encountered, biopsies are performed, photo documentation is conducted, and laparoscopy is terminated. The patient is referred immediately with her records to our gynecologic oncology associates for consultation, informed consent, and definitive surgery.

If inspection demonstrates an intact ovarian capsule and no evidence of other disease, oophorectomy (172 patients) or salpingo-oophorectomy (68 patients) is performed. The ovary or the tube and ovary are dissected free as necessary, infundibulopelvic ligament divided with a bipolar energy source (most often LigaSure from Covidien, requiring 5-mm or 10-mm port or Enseal from Ethicon Endo Surgery, requiring 5-mm port). When extensive adhesions of the ovary to the pelvic sidewall are present, extra attention is used to decrease the chance of capsular rupture. A conventional retroperitoneal dissection beginning by dividing the round ligament, identifying the pelvic ureter, isolating and transecting the infundibulopelvic ligament assists in mobilizing a fixed ovary when required. When present, adhesions of the ovary to bowel are meticulously lysed and any serosal denudation of bowel is oversewn with appropriate postprocedure follow-up.

Once free, the mass is containerized within the collection system (Endo Catch from Covidien Surgery, requiring a 10-mm port or Anchor Tissue Retrieval System from Anchor Products Company, requiring either 11-mm or 13-mm port). The collection system is closed, and the introducer is removed leaving the closed bag and string within the abdominal-pelvic cavity. The string end is held with a laparoscopic grasper. A 3-puncture laparoscopy is most often required with the largest incision of either 11mm or 13mm, depending on the tissue collection system used.

Colpotomy is performed in preference to extending an abdominal incision, because the vagina is known to be more distensible than rectus fascia and allows for a larger hole without impact on the likelihood of postoperative ileus or abdominal wall hernia formation. When the uterus

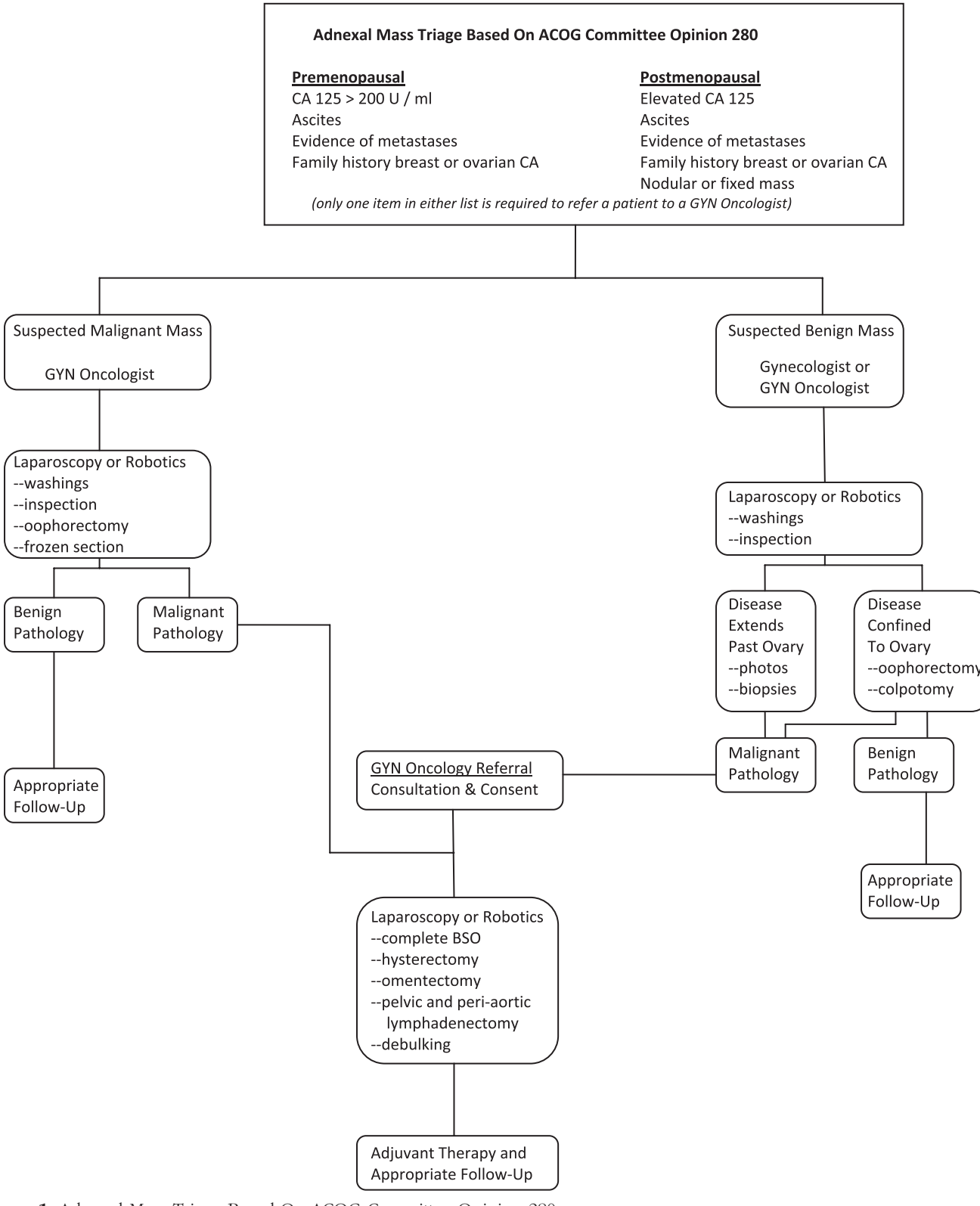

Figure 1. Adnexal Mass Triage Based On ACOG Committee Opinion 280.

is in place and the cul-de-sac is free, colpotomy is performed vaginally by elevating the posterior lip of the cervix, tenting the posterior vaginal mucosa on the midline, and transecting this tissue with Mayo scissors. When the uterus is in place and the cul-de-sac obstructed, meticulous lysis of adhesions is conducted laparoscopically to make the space accessible. Colpotomy incision can be created with electrocautery against a sponge stick inserted into the posterior vaginal fornix for additional control. When the uterus is absent, additional care is taken by performing colpotomy laparoscopically to ensure the bladder is not injured. A device (formerly a Heaney retractor handle, currently a Sacro-colpopexy Tip on the Rumi handle from Cooper Surgical) is used to distend the vaginal barrel. The bladder is filled with 300mL of sterile saline to demonstrate its location then drained. Parietal peritoneum posterior to the bladder reflection is incised with endoscopic scissors then forced caudad on the vaginal barrel with both blunt and sharp dissection. Once sufficient space is developed, a semi-circular incision is created by using the endoscopic scissors and 50 watts of cutting current at the vaginal apex.

After the colpotomy is developed, the collection system's string is passed out the colpotomy defect and into the vagina using a laparoscopic grasper manipulated by an assistant. The surgeon, positioned at the vagina, uses retractors to visualize the laparoscopic grasper and string. A Kelly clamp is used to secure the string and the laparoscopic instrument is withdrawn by the assistant. The mouth of the bag is delivered out the colpotomy defect and out the vagina. Traction is maintained on the bag both to preserve the pneumoperitoneum (laparoscopic surveillance of debulking helps ensure the bag is not perforated) and to deliver the bag once the volume of the lesion has been sufficiently decreased to allow it to pass through the colpotomy defect. This continuous caudad traction creates a seal that helps assure no fluid or tissue goes back into the peritoneal cavity. A second layer of protection from the positive pressure gradient created by the pneumoperitoneum further protects against fluid or tissue falling back into the peritoneal cavity.

In principally cystic masses, wall suction is used to aspirate fluid. In principally solid masses, ring forceps are used to disrupt the mass and withdraw it piece meal. Traction is maintained on the bag, facilitating its delivery once the volume of the lesion has been sufficiently decreased to allow it to pass through the colpotomy defect. The colpotomy is then closed in one layer encompassing both peritoneum and vaginal mucosa. Closure in all cases is performed vaginally.

New gloves are donned, and after inspection and copious irrigation, the laparoscopy is terminated. Thirty mL of 0.25% Marcaine without epinephrine is instilled to assist in postoperative analgesia. A Carter-Thomason closure system (Cooper Surgical) is used to close the fascial defect for all large ports ($\geq$10mm).[88]

Patients were assessed postprocedure and discharged home if no complications were noted and pain status was amenable to treatment with oral analgesics. Otherwise, patients were admitted for pain control and re-assessed regularly.

Patients with findings of ovarian cancer are referred immediately to our collaborating gynecologic oncologists with all required reports and intraoperative photos. Consultation, appropriate informed consent, and speedy reoperation within 7 days to 10 days follows.

RESULTS

Of 257 consecutive cases with stated inclusion criteria, 6 were found to have disseminated ovarian malignancy at the time of laparoscopy **(Table 4)**. Eleven cases were judged not to be candidates for inclusion in this study at the time of laparoscopy **(Table 5)**. A total of 240 patients successfully completed intended treatment (93.38%). Of patients successfully completing treatment, 234 did not require admission (97.5%). One patient had an inadvertent bowel injury secondary to adhesiolysis requiring reoperation during the admission. One patient developed deep vein thrombosis well after discharge. Nine patients (3.75%) required reoperation by gynecologic oncologists after final pathology was available.

Laparoscopic surgery combined with posterior colpotomy has a low incidence of significant complications. Outcome data show that by observing the principals of minimally invasive surgery, 97.50% of women were successfully treated as outpatients: 97.92% of surgeries lasted $<$136 minutes; 97.08% had blood loss $<$200mL, and there were few consequential postoperative complications.

Intraoperative rupture of the ovarian capsule was extremely uncommon in our series. Capsular rupture was noted in just 1.25% of cases.

Distribution of pathologic results is not surprising **(Table 6)**. The most common lesions were cystadenomas, endometriomas, cysts, and mature teratomas accounting for 85% of all cases. Borderline tumors accounted for 5% of lesions, while invasive ovarian malignancy represented 3.75% of the specimens.

Table 4.
Main Outcome Data

Total patients in study period (N=257)	n	Percentage (%)
Surgery ends with laparoscopy[a]	6	2.33
Failed inclusion at laparoscopy[b]	11	4.28
Total patients successfully completing	240	93.38
Duration of surgery		
≤45 minutes	52	21.67
46 to 90 minutes	145	60.42
91 to 135 minutes	38	15.83
>135 minutes	5	2.08
Age Range		
≤20 years	1	0.42
21 to 40 years	37	15.42
41 to 60 years	126	52.50
61 to 80 years	68	28.33
≥81 years	8	3.33
Menopausal Status		
Premenopausal	138	57.50
Postmenopausal	102	42.50
Blood Loss (mL)		
<100	138	57.50
101 to 200	95	39.58
201 to 300	4	1.67
301 to 400	2	0.83
>400	1	0.42
Duration of Admission		
outpatient only	234	97.50
1 hospital day	5	2.08
2 or more hospital days	2	0.84
Intraoperative Complications		
Inadvertent rupture of mass	3	1.25
Cuff cellulitis	0	0.00
Febrile morbidity	9	3.75
Injury to bowel	1	0.42
Injury to bladder	0	0.00
Injury to ureter	0	0.00
Injury to major vessels	0	0.00

Table 1 continued on next column.

Table 4. (Continued)
Main Outcome Data

Total patients in study period (N=257)	n	Percentage (%)
Postoperative Complications		
Deep vein thrombosis	1	0.42
Pulmonary embolism	0	0.00
Port site hernia	0	0.00
Vaginal dehiscence	0	0.00
Re-operation this admission	1	0.42
Death	0	0.00
Final Results		
Washings positive for malignancy	6	2.50
Re-operated later by Gyn Oncology	9	3.75

[a]Washings, directed biopsies of peritoneal surfaces and photo documentation are obtained.

[b]See Table 5.

Table 5.
Patients Not Meeting Inclusion Criteria (11 Patients)

	Patients	% Patients
Adhesions prevent laparoscopic visualization	3	27.27
Frozen pelvis	2	18.18
Fallopian tube cyst/hydrosalpinx	3	27.27
Fallopian tube cancer	1	9.09
Fibroid uterus/pedunculated myomas	1	9.09
GI malignancy	1	9.09

Reoperation, when required, occurred usually between 6 and 10 days following the initial laparoscopy (average 7.2 days, range 4 to 19 days).

Laparoscopies abandoned based on presumption of disseminated disease had significant findings at the time of definitive staging by gynecologic oncologists: Stage I-0%, Stage II-16.67%, Stage III-50%, and Stage IV-33.33% **(Table 7)**. Of the 9 cases we treated that turned out to be invasive carcinoma on final pathology, all were believed to be Stage I disease at the time of referral to gynecology oncology. No capsules had excrescences, no disease was noted elsewhere in the abdomen and pelvis, but 6 had positive washings. Definitive staging upstaged 4 of the 9 lesions or 44.44% **(Table 7)**.

Table 6.
Pathology Results

	Patients	% Patients
Ovarian cystadenoma	64	26.67
Functional cyst	47	19.58
Endometrioma	34	14.17
Simple cyst	32	13.33
Mature teratoma	27	11.25
Ovarian fibroma	5	2.08
Other benign ovarian lesions	10	4.17
Borderline ovarian tumor	12	5.00
Invasive ovarian cancer	9	3.75

Table 7.
Cancer staging from Gyn oncology

	Patients	% Patients
Invasive Ovarian Cancer On Inspection—Laparoscopy Terminated	6	
Stage I	0	0.00
Stage II	1	16.67
Stage III	3	50.00
Stage IV	2	33.33
Invasive Ovarian Cancer—Ovary Removed and Later Directed To Gyn Oncology	9	
Stage I	5	55.56
Stage II	3	33.33
Stage III	1	11.11
Stage IV	0	0.00

Finally, we examined the relationship of menopausal status and cancer Stage of all 15 patients found to have invasive ovarian malignancy **(Table 8)**. Being postmenopausal conferred a greater likelihood of having any ovarian malignancy (8/88 or 9.09%) compared with premenopausal women (7/158 or 4.43%). The negative predictive value of ACOG Committee Opinion 280 Triage Criteria as a de-selector for having invasive ovarian malignancy in our population of women with 8-cm to 13-cm lesions was 95.57% for premenopausal and 90.91% for postmenopausal women.

Table 8.
Cancer Stage Based On Menopausal Status

All Cases Of Invasive Ovarian Cancer (6 Initially excluded and 9 positive on final pathology).

	Premenopausal	Postmenopausal
Stage I	3	2
Stage II	2	2
Stage III	1	3
Stage IV	1	1
Total Patients	7/158 (4.43%)	8/88 (9.09%)
NPV ACOG 280 Triage Criteria	151/158 (95.57%)	80/88 (90.91%)

DISCUSSION

It is not reasonable to think every woman with an adnexal mass can have surgery in a center affording immediate intraoperative consultation with gynecologic oncologists or that all women with adnexal masses should be referred to gynecologic oncologists for primary treatment. In this country, many women with adnexal masses are operated on by general gynecologists, and many cases of EOC are found only on final pathology after an inadequate initial surgery.

We suggest this new, staged treatment algorithm for adnexal lesions based on the unavailability of gynecologic oncologists at most United States hospitals and the knowledge that many ovarian masses are currently treated by general obstetrician/gynecologists without observance of ACOG Committee Opinion 280 Triage Criteria, without performing washings, without ordering frozen section, and without intraoperative availability of gynecology oncology consultation. Furthermore, many masses are purposefully opened or aspirated without bagging, because surgeons do not fully consider the possibility of malignancy preoperatively.

The goal of our new algorithm is to develop a Staged process focusing additional attention on adnexal masses not thought to be malignant and improving care within this subset of patients. Because many authorities have believed that increasing ovarian mass size is an important de-selector for minimally invasive surgical candidacy, we sought to evaluate outcomes of ovarian masses in this size range including performance of ACOG Committee Opinion 280 Triage Criteria and surgical outcomes.[11,75] Laparoscopic adnexectomy, bagging, and colpotomy is a desirable goal for patients with adnexal masses meeting Triage Criteria for suspected benign lesions outlined in ACOG Committee Opinion 280 affording a minimally invasive approach with attendant benefits including outpatient treatment, decreased incidence of capsular rupture,

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few complications and low necessity for reoperation after final pathology is evaluated. Negative predictive value in our series is similar to reports in the literature,[45,46] suggesting masses in this size range are no more or less likely to be malignant than previous series not selected for size. Outcomes including inadvertent rupture rate, surgical time, blood loss, intraoperative and postoperative complication also compare favorably to previous series. We believe this study convincingly extends the size range for adnexal masses safely treated laparoscopically to the 8-cm to 13-cm range.

Colpotomy is felt to be the ideal route to retrieve significant volumes of tissue from the pelvic cavity and has many advantages over mini-laparotomy: no visible abdominal incision, less postoperative ileus, decreased postoperative pain, and more rapid return to normal activities. In the days prior to widespread availability of laparoscopy, skilled gynecologic surgeons frequently used colpotomy for ready access to the pelvis. Unlike episiotomy that can cause dyspareunia, colpotomy does not transect muscles and, therefore, has less bleeding and negligible postoperative pain. It is our practice to insert the collection bag through a laparoscopic port, because it is easier to maintain the pneumoperitoneum during manipulation of the mass and insertion into the bag. Insertion of the collection system through the colpotomy requires only an 11-mm to 13-mm colpotomy defect that would then need to be extended to ultimately deliver the bag, particularly in the case of solid lesions. Some surgeons may point out the potential disadvantages of colpotomy, including incisional infection, peritonitis, and technical complexity, particularly in patients after hysterectomy. These surgeons may instead bring the opening of the collection bag out an anterior abdominal wall incision and will likely enjoy comparable results.

The negative predictive value of ACOG Committee Opinion 280 selection criteria for encountering malignancy in suspected benign cases are set forth in **Table 9**. Data from the present study is consistent with other reports in the literature. Although reoperation is required 6.09% of the time (15 out of 246 patients), in our algorithm for women with suspected benign lesions, this risk is substantially outweighed by saving laparotomy in 93.91% of patients having benign disease, in reducing 234 of 240 patients' treatment to a single outpatient encounter, to the clear reduction in anxiety in all women not having to sign informed consent for an unduly broad range of surgical options for the first procedure (ranging from laparoscopy to laparotomy to hysterectomy and castration) and to most women not having to travel to a referral center for the initial procedure. Informed consent for this algorithm necessarily needs to highlight the possibility of 2 anesthesias in women found to have ovarian cancer on pathology and compare that to the advantages of minimally invasive surgery enjoyed by the vast number of women with benign disease avoiding laparotomy.

Table 9.
Negative predictive value of ACOG Committee Opinion 280

	Premenopausal	Postmenopausal
Im et al[45] 2005	92.00	91.10
Dearking et al[46] 2007		
Overall	93.10	91.70
Referral population	91.00	90.50
General population	97.70	95.00
Present Study	95.57	90.91

The 2-step process for women found to have ovarian cancer inherent in our proposed algorithm is not a disservice to patients. Literature does not support the necessity for definitive surgery at the time of the initial operation. If appropriate steps are followed in the first surgery, a 2-step process permits an unrushed consultation with a gynecologic oncologist in which a patient's cytology and pathology reports can be discussed, concerns for future fertility can be addressed, and informed consent for definitive surgery can be thoroughly obtained.

Observing our treatment algorithm will increase the likelihood that women meeting ACOG Committee Opinion 280 Triage Criteria will be immediately referred to gynecologic oncologists, will assure appropriate pre- and intraoperative workup of patients with ovarian masses not felt to be malignant, promote access to minimally invasive surgery for more women with ovarian masses not felt to be malignant, and allow appropriate preoperative consent for the small subset of these women actually found to have ovarian cancer at the initial surgery.

Despite the reasonableness of these suggestions, numerous reports have suggested modifying referral criteria to increase sensitivity at the direct expense of specificity in selecting patients likely to have ovarian cancer.[24,45] Changing the CA 125 cut-off to increase sensitivity of referral criteria identifying more cases of ovarian malignancy leads to more false-positives: women who are caused unnecessary anxiety, forced to travel to unfamiliar surroundings for care, and who may well be overtreated as a consequence of undergoing laparotomy in the hands

of some gynecologic oncologists, only to hear postoperatively that frozen-section pathology was benign. Even worse is the scenario where oophorectomy is performed, either laparoscopically or laparotomically, frozen section is positive leading to abdominal hysterectomy, contralateral oophorectomy, omentectomy, and thorough staging only to find out final pathology returned benign disease. A recent study demonstrated frozen section was incorrect in 12% of ovarian cancer cases.[89] Overtreatment is a real possibility in any treatment algorithm, the impact of which should not be underestimated.

To substantially increase the appropriateness of referrals to gynecologic oncologists, we will have to commensurately increase the precision of our diagnosis of ovarian cancer. This will require advent and testing of new technologies to boost diagnostic precision used in tandem with established modalities,[21–24,90] or even development of high-sensitivity and high-specificity screening tests for early stage ovarian carcinoma.[91]

Until that day arrives, we propose acceptance and testing of our new treatment algorithm for adnexal masses using ACOG Committee Opinion 280 for initial triage of patients, focusing additional care and attention on women with suspected benign lesions while encouraging minimally invasive surgical care for all affected women. This systematic approach to evaluation and treatment of adnexal masses utilizing the skills of minimally invasive surgeons and gynecologic oncologists will lead to enhanced outcomes for women with both benign and malignant disease.

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