Laparoscopic Surgery for Gynecologic Cancer

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Operative laparoscopy is an alternative to laparotomy for most gynecologic surgical procedures, but its role in gynecologic oncology has been considered only recently. Laparoscopy has been applied to gynecologic cancer with good results. Advantages include better visualization of the abdominal cavity and more rapid recovery, allowing earlier initiation of either chemotherapy or radiotherapy. Concerns include the risk for dissemination of neoplastic disease if less radical surgery is performed. With improvements in technology and advanced clinical experience, laparoscopic radical surgery can be performed with adequate tissue margins, conforming to accepted guidelines. Further, studies have shown that the yield of pelvic nodes significantly increases with experience. The danger of abdominal wall tumor implantation after laparoscopy for malignant conditions should be considered, but is infrequent. Careful techniques and the use of a laparoscopic pouch can prevent peritoneal dissemination and protect the abdominal wall. By cooperating closely, the surgical team and oncologists can offer the cancer patient optimal management with the lower morbidity and rapid recovery associated with laparoscopic surgery. However, follow-up studies are needed to determine the long-term survival following operative laparoscopy.
Laparoscopic Surgery for Gynecologic Cancer
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Despite the acceptance of most laparoscopic procedures, controversy persists about its application to the treatment of oncology patients. Several groups have clearly demonstrated the technical feasibility of this operative approach and the apparent benefits to the patient, but long-term survival rates are not available. We present the current experience with laparoscopy in gynecologic oncology, and discuss its pros and cons for patients with malignant tumors.

**ADVANTAGES OF LAPAROSCOPIC SURGERY IN GYNECOLOGIC ONCOLOGY**

The benefits for oncology patients are similar to those of other laparoscopic procedures including less postoperative pain, lower risk of wound dehiscence, early ambulation, and generally more rapid convalescence (Table 1). These benefits are especially important for patients with malignant disease who may be prone to cardiovascular and pulmonary complications, and who have a higher risk for surgical scar dehiscence. More rapid recovery may permit earlier initiation of chemotherapy or radiotherapy. The risk of adhesion formation is reduced with laparoscopic surgery. It has been suggested that adhesion formation following lymphadenectomy may be less than that following laparotomy. Other possible benefits are less blood loss, decreased fluid requirements, and less immunosuppression resulting from reduced stress and fewer blood transfusions.

**DISADVANTAGES OF LAPAROSCOPIC SURGERY IN GYNECOLOGIC ONCOLOGY**

Basic surgical principles must always be observed regardless of the approach. These include exposing the operative field, avoiding spillage of the tumor, and retrieving the specimen intact for complete pathologic analysis. At laparoscopy it may be difficult to obtain optimal retraction of the adjacent organs; intra-abdominal packing to protect the upper abdomen is not possible, and the surgeon's depth perception may be challenged by the two-dimensional vision of video (Table 2). The laparoscope does magnify pelvic and abdominal anatomy, and may enhance visualization and identification of metastatic lesions on the upper abdomen, the surfaces of the liver and diaphragm, the posterior cul-de-sac, and the posterior aspect of the broad ligaments.

A significant restriction of laparoscopy is poor tactile feedback because direct palpation is not possible. Increased tumor manipulation may result in spillage (Table 2). Laparoscopic sonography, using special probes, may help determine what structures lie beneath the visualized surface, and is an important intraoperative diagnostic tool.

**CONCERNS REGARDING LAPAROSCOPIC SURGERY FOR MALIGNANCY**

Objections to laparoscopy for cancer patients are inadequate tumor clearance and possible metastasis to trocar ports (Table 3).

Preliminary data suggest that resected tumor specimens have acceptable distal and proximal resection margins. The efficacy of laparoscopic lymphadenectomy has also been questioned. The surgeon's experience is directly related to the amount of residual lymph node tissue. The yield of laparoscopic lymphadenectomy has been shown to be satisfactory. Abdominal wall tumor implantation has been reported following laparoscopy for cancer of the ovary, stomach, gallbladder, pancreas, and colon. However, these are primarily case reports. Preliminary surveys of laparoscopy for gynecologic and colon cancer suggest that port-site recur-

<table>
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<th>Table 1. Advantages of laparoscopic surgery in cancer patients</th>
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<tr>
<td>Elimination of large abdominal incision</td>
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<tr>
<td>• less wound infection and dehiscence, more common in cancer patients</td>
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<tr>
<td>Better inspection of upper abdomen</td>
</tr>
<tr>
<td>• excellent light source and magnification</td>
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<tr>
<td>• high intra-abdominal pressure, decreasing bleeding in operative field from small blood vessels</td>
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<td>• allows observation and biopsy of diaphragm, paracolic gutter, peritoneum, omentum</td>
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<tr>
<td>Improved access to rectovaginal space</td>
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<td>Fewer adhesions</td>
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<tr>
<td>• decreased tissue manipulation and bleeding, and lower pH in CO₂</td>
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<tr>
<td>• tissues well irrigated with lactated Ringer's</td>
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<tr>
<td>Decreased postoperative pain</td>
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<td>• earlier ambulation</td>
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<td>• shorter hospitalization</td>
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<td>More rapid recovery</td>
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<td>• beneficial for older, high-risk patients</td>
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<td>• easier postoperative care</td>
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<td>• earlier initiation of postoperative chemotherapy or radiotherapy.</td>
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<table>
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<th>Table 2. Disadvantages of laparoscopic surgery in cancer patients</th>
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<tr>
<td>Optimal retraction difficult</td>
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<td>• limited exposure of the operative field</td>
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<td>No protection for upper abdomen</td>
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<td>• no intra-abdominal packing</td>
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<td>More tumor manipulation, trauma</td>
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<tr>
<td>• possibility of tumor spillage</td>
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<tr>
<td>High intra-abdominal pressure</td>
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<tr>
<td>• possible increased risk of tumor dissemination</td>
</tr>
<tr>
<td>Difficult to extract large tumors</td>
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<tr>
<td>• not suitable for large bulky tumors</td>
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<tr>
<td>Two-dimensional vision</td>
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<tr>
<td>• depth perception is altered</td>
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<tr>
<td>Direct palpation not possible</td>
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<td>• poor tactile feedback</td>
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rence is infrequent. Further, gynecologists and general surgeons have advocated placing all specimens in a laparoscopic pouch for transanal or transabdominal removal.

The complications of operative laparoscopy (Table 4) are related to the experience of the surgeon. The relatively complex procedures performed in oncologic cases should be performed only by gynecologists well trained in advanced laparoscopic surgery.

The consent form for operative laparoscopy for gynecologic malignancy should state that it is not yet the standard of care in gynecologic oncology. The patients should be informed that if malignancy is found, intraoperative spillage of tumor cells is possible and can influence prognosis. Further, a laparotomy is always a possibility, either at the time of the initial surgery or at a later date.

### CERVICAL CANCER

If a conventional workup for cervical cancer fails to reveal metastatic disease, laparoscopic management is an option. Laparoscopic pelvic and para-aortic lymphadenectomy is feasible before initiating radiotherapy. Knowledge of para-aortic nodal status can assist in planning radiation field portals. For example, in patients with uninvolved para-aortic lymph nodes, extended field radiation therapy, which may have serious complications, may be avoided. Laparoscopic lymphadenectomy may be performed in conjunction with laparoscopic radical hysterectomy in early stages of cervical cancer. The laparoscope provides easy access to the rectovaginal space. Also the vesicovaginal, paraoveseal, and pararectal spaces can be adequately developed laparoscopically because of excellent magnification provided by the camera and laparoscope, which, in turn, facilitates removal of a large portion of the vagina.

Vaginal radical hysterectomy (Schauta procedure) and laparoscopically assisted radical vaginal hysterectomy are feasible alternatives to laparotomy in treating certain stages of cervical carcinoma. Stage IA2 cervical cancer with lymphatic channel involvement, as well as Stage IB and Stage IIA disease (especially when the lesion involves the vagina) can be effectively managed by operative laparoscopy. For Stages IIB and higher, laparoscopy is useful for node dissection, which can provide additional diagnostic and therapeutic information.

Further, we believe that operative laparoscopy can be used to assist in pelvic exenteration by exploring the abdominopelvic cavity for evidence of unresectable metastatic lesions. If these lesions are discovered at laparoscopy, the patient is spared an unnecessary laparotomy.

### LAPAROSCOPIC RADICAL HYSTERECTOMY

The first laparoscopic radical hysterectomy with para-aortic and pelvic lymph node dissection was performed in June 1989. Laparoscopic radical hysterectomy and lymphadenectomy to be effective, the specimen removed must be as adequate as that removed by laparotomy. Also, the morbidity from the laparoscopic procedure must be no greater than that with conventional techniques.

We reported 7 laparoscopic radical hysterectomies and 11 laparoscopically-assisted vaginal radical hysterectomies. Laparoscopic pelvic lymphadenectomy was performed in all cases. Para-aortic lymph node dissection was performed in 3 patients with Stage IA2 disease who had lymphatic channel involvement, 7 patients with Stage IB disease, and 1 patient with Stage IIA disease. The average operative time for laparoscopic radical hysterectomy, including para-aortic and pelvic lymph node dissection, was approximately five hours (range: 4 to 8) while the average operating time for laparoscopically assisted vaginal radical hysterectomy was 163 minutes (range: 125 to 214 min). Blood loss ranged from 30 to 250 mL. The average specimen weight was 135 g (range: 120 to 155 g). On average, 3 cm of vaginal tissue and 2 cm of paracervical and paravaginal tissue were removed on each side of the specimen. Between 3 and 9 para-aortic nodes were removed (mean: 6), and between 11 and 33 pelvic lymph nodes were removed (mean: 22). The postoperative hospital stay averaged 2.1 days (range: 1 to 6). There were no major intraoperative or postoperative complications.

Minor postoperative complications included bleeding from the umbilical incision on the first postoperative day, which was controlled by a single suture applied under local anesthesia. One patient remained hospitalized for six days because of fever resulting from a urinary tract infection, which responded to medical therapy. The follow-up for all patients has included a clinical examination and a vaginal smear. There have been no signs of recurrence, the
The staging procedure plays an important role in the prognosis and planned treatment of ovarian cancer, particularly if the disease is limited to one ovary. Inadequate surgical exploration leads to suboptimal treatment. In fact, it has been reported that the incidence of positive lymph nodes can be as high as 24% in Stage I disease.34 The standard preoperative workup for ovarian cancer includes history and physical examination, Papnicolaou smear, CBC, SMA12, chest X-ray and abdominopelvic imaging. Intraoperative management includes pelvic examination under anesthesia, pelvic and upper abdominal washings, total hysterectomy with bilateral salpingo-oophorectomy, multiple peritoneal biopsies, possible appendectomy, omentectomy, and pelvic and para-aortic lymphadenectomy, all of which may be performed laparoscopically. If necessary, laparoscopic tumor debulking is performed by excising or vaporizing lesions with the CO2 laser.

For peritoneal cytology, a long suction-irrigator probe and heparinized lactated Ringer’s solution are used to obtain washings from the pelvis, both paracolic gutters and both hemidiaphragms. Peritoneal biopsies are obtained by using the CO2 laser and hydrodissection in the pelvis and abdomen. Diaphragmatic biopsies can be obtained using biopsy forceps or with hydrodissection and the CO2 laser. While visualization of the diaphragm is excellent with videolaparoscopy, an additional 5-mm trocar is occasionally necessary for direct access. During the omentectomy, the patient is brought out of the Trendelenburg and placed in a neutral position. Infracolic omentectomy is performed using sutures, bipolar electrocoagulation or a Proximate linear stapler (Ethicon Endo-Surgery, Inc.). All specimens are removed without contaminating the abdominal wall, which may be accomplished by using a laparoscopic Endopouch specimen retrieval bag (Ethicon Endo-Surgery, Inc.).

Our preliminary results include laparoscopic surgical staging of 10 women with various types of ovarian cancer and at different stages of disease. This series includes Stage IA serous cystadenoma of low malignant potential (1 patient); Stage IA, grade 1 mucinous cystadenocarcinoma (2 patients); Stage IA, grade 1 serous cystadenocarcinoma (1 patient); Stage IC clear cell adenocarcinoma (1 patient); Stage III papillary serous cystadenoma of low malignant potential (1 patient); and Stage IIIC epithelial adenocarcinoma (3 patients). In all cases, peritoneal washings, multiple biopsies, omentectomy, appendectomy, and evaluation and/or sampling of para-aortic and pelvic lymph nodes were performed laparoscopically. Laparoscopic hysterectomy and unilateral or bilateral salpingo-oophorectomy were performed in all patients except one with Stage III papillary serous cystadenoma of low malignant potential and two patients with Stage IA adenocarcinoma. All wished to preserve their child-bearing capacity. Three of the 10 women had previously undergone a total abdominal hysterectomy and bilateral salpingo-oophorectomy with incomplete initial surgery at outside institutions and were referred to us for completion of their staging and debulking surgery.

All procedures were completed laparoscopically. Three patients underwent laparoscopically assisted placement of peritoneal infusion ports. Two patients underwent chemotherapy within 48 hours of the procedure; one began chemotherapy on the day of surgery and the other on postoperative day 2. Because these patients were receiving chemotherapy, they were not discharged until postoperative days 3 and 4, respectively. A third patient who had undergone sigmoidectomy and anal fistulotomy at the time of surgery was discharged on postoperative day 2. The remaining seven patients were discharged home on postoperative day 1. Complications occurred in only two patients. One patient with Stage IIIC adenocarcinoma had an estimated blood loss of 800 mL and required a transfusion of two units of packed red blood cells intraperatively and an additional two units postoperatively. A second patient with a Stage IC clear cell adenocarcinoma had a mild corneal abrasion of her left eye, which required only overnight patching.

These patients have been followed for 1 to 36 months. Although longer follow-up is necessary, these encouraging preliminary data lead us to believe that laparoscopic staging procedures yield a more rapid recovery, allowing the patient to begin chemotherapy sooner than after a laparotomy. The impact of laparoscopic staging and debulking surgeries on patient survival, however, remains to be assessed. Although laparoscopic surgery for ovarian cancer is controversial, it can be a valuable tool in the treatment of all stages of ovarian cancer, if the patients are selected appropriately and the surgeons have adequate laparoscopic and oncologic experience.

Improved survival following intensified cytoreduction has been suggested55 and this may be a role for laparoscopic surgery. The CO2 laser has long been used to ablate endometriotic implants on the peritoneum and other intra-abdominal organs.36,37 The use of the CO2 laser has been extended to vaporizing and excising metastases of ovarian cancer in the abdomen58,59 and ovarian intestinal metastases.8,40 Observation and accessibility to the upper abdomen including the diaphragm and deep pelvis are better at laparoscopy. This improved access and observation combined with magnification may facilitate identification and treatment of metastatic lesions, and allow intensified cytoreduction with the CO2 laser.

SECOND-LOOK LAPAROSCOPY

Although the indication for second-look laparoscopy in patients with ovarian cancer after chemotherapy is debatable, it can be used safely in most cases. After the intraperitoneal placement of laparoscopic trocars, the

longest follow-up being 4.5 years. Patients who underwent laparoscopic radical hysterectomy were told to expect neurogenic bladder dysfunction, but in all cases this dysfunction gradually resolved. The incidence of intraoperative and postoperative complications at laparoscopy was lower than at laparotomy.14,33 Not only are the details of pelvic anatomy clearly visible with laparoscopy, but also the number of lymph nodes removed, the size of parametrical tissue margins, and the amount of vaginal tissue removed are equal to those achieved by laparotomy. The end results of a laparoscopic approach should be comparable to that obtained at laparotomy. The possibility of postoperative adhesion formation with this technique is lower than that with laparotomy.14,33

OVARIAN CANCER
abdominal and pelvic cavities are systematically evaluated for any gross disease. Cytologic washings are obtained from the pelvic cavity, both paracolic gutters and both hemidiaphragms, and biopsies of all suspicious lesions are performed. If no gross persistent disease is identified, several peritoneal biopsies are obtained from the pelvis and upper abdomen, including any adhesions. Any remaining portion of the omentum is also removed at this time. If pelvic or para-aortic lymphadenectomy has not been performed, it is performed at this time. Tumor debulking can be accomplished using the CO₂ laser and CUSA (Valley Lab, Boulder, CO) if the spread of tumor is not overwhelming.

Nineteen second-look laparoscopies were performed following a laparotomy for ovarian cancer. Peritoneal washings, multiple peritoneal biopsies from the upper abdomen, and pelvic and para-aortic node sampling were performed as indicated. In two patients, CUSA was used for debulking. One bowel perforation occurred which was repaired laparoscopically, and this patient was discharged home without sequelae. All patients were discharged from the hospital within 48 hours.

**ENDOMETRIAL CANCER**

The standard treatment for endometrial carcinoma is peritoneal washings, total abdominal hysterectomy, and bilateral salpingo-oophorectomy. Pelvic and para-aortic lymph node sampling should be performed in patients at high risk for nodal metastasis (Stage IB or higher and/or grade 2 or higher). Clinical staging may be incorrect in many patients with Stage I endometrial adenocarcinoma, and surgical staging is often necessary. Endometrial carcinoma can be staged laparoscopically, and most stages can be managed using this technique. An abdominal hysterectomy may be converted to either a laparoscopic hysterectomy or a laparoscopically assisted vaginal hysterectomy.

Fifteen women ranging in age from 51 to 76 years with Stage I endometrial cancer were managed at laparoscopy. In nine women, peritoneal washings, total laparoscopic hysterectomy or laparoscopically assisted vaginal hysterectomy, and bilateral salpingo-oophorectomy were performed. Lymphadenectomy was not required in these nine, but the remaining six had para-aortic and pelvic lymphadenectomy. There were no intraoperative or postoperative complications. One woman with multiple medical conditions, including early heart failure, was observed in CCU overnight and discharged from the hospital on the third postoperative day. In all cases, the lymph nodes were negative.

An additional patient was diagnosed with clinical Stage IIIb, grade 1 adenocarcinoma of the endometrium. She underwent 5005 cGy of external beam radiation therapy followed by laparoscopic hysterectomy and bilateral salpingo-oophorectomy, with placement of perineal and suburethral interstitial needle implants delivering an additional radiation dose of 3000 cGy. Because of her marked obesity, the patient was observed overnight in the ICU. She had an uneventful recovery and was discharged home on postoperative day 5 after completing her intratreaty brachytherapy and removal of the needle implants. One woman had undergone surgical staging at laparotomy revealing stage-IVB poorly differentiated endometrial adenocarcinoma. At her initial presentation to us 3 months later, she was found to have persistent tumor. For symptomatic relief, it was decided to proceed with laparoscopic tumor debulking and peritoneal infusion port placement for future dose-intensive chemotherapy. At laparoscopy, however, the abdominopelvic organs were densely adherent and agglutinated leading to an enterotomy and a cystotomy. Given the extensive nature of the pathology, a laparotomy was performed allowing for completion of the debulking procedure, adhesiolysis, and peritoneal infusion port placement. The patient was discharged in stable condition on postoperative day 7 after an uncomplicated recovery. This case illustrates that although laparoscopy can be of value in the treatment of endometrial cancer, there are still limits to its application. Large prospective controlled studies with long-term follow-up are necessary to further define the role and limitations of laparoscopy.

**TECHNIQUES**

**Radical Hysterectomy with Lymph Node Dissection**

Laparoscopic radical hysterectomy is begun by inserting the ports and inspecting the upper abdomen and pelvis. The right common iliac and para-aortic lymphadenectomy is undertaken first. To expose the para-aortic region, the patient is tilted left and placed in a deep Trendelenburg position (35 to 40 degrees). The bowel is gently directed toward the diaphragm and occasionally held in place using the grasping forceps. The ureter is identified through the peritoneum. An opening is made in the peritoneum just above the sacral promontory. Lactated Ringer's solution is injected into the retroperitoneal space. The peritoneum above this opening is grasped and incised with the CO₂ laser toward the duodenal bulb. The remaining retroperitoneum is opened in a similar fashion. The common iliac and para-aortic nodes from the surface of the veins are removed using a combination of blunt dissection, hydrodissection, and CO₂ laser. All nodes over the distal vena cava are removed, beginning at the inferior mesenteric artery and proceeding to the right common iliac artery. Larger bleeders, such as the venous perforators of the vena cava, are desiccated with bipolar electrocoagulation. The ureter is carefully identified immediately next to the vena cava, and the dissection is taken to approximately 2 to 5 cm above the aortic bifurcation. All removed tissue is carefully passed into the trocar sleeve (5-mm accessory or 10-mm infraumbilical port), avoiding direct contact between the specimen and abdominal wall. Attention is then directed toward dissecting the rectovaginal, paravesical, and pararectal spaces. An assistant performs simultaneous rectal and vaginal examination, delineating the septum. The cul-de-sac and any focal areas of endometriosis are incised, and the rectum is pushed from the posterior vaginal wall using the CO₂ laser, blunt dissection, and hydrodissection. This is taken down to 4 to 5 cm below the cervix.

The round and tubo-ovarian ligaments are dissected close to the pelvic sidewalls and transected. The peritoneum is opened, and the paravesical and pararectal spaces are dissected by blunt dissection, hydrodissection, and the CO₂ laser. This technique allows excellent skeletonization of the obliterated hypogastric artery. The uterine vessels are identified, skeletonized, and desiccated just medial to their origin and transected. They are grasped with the forceps and rotated anterior to the ureters.

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The bladder serosa is injected with lactated Ringer’s, and it is advanced using the CO₂ laser. The anterior parametrium is transected using the laser. The suction-irrigator probe may be used as a backstop to protect the ureter. The ureters are then freed from the peritoneum and skeletonized down to the bladder using the suction-irrigator probe and the laser. The utero-ovarian pedicles are coagulated with bipolar electrodesiccation and transected with the laser.

The left para-aortic nodes and common iliac nodes are removed in a fashion similar to that used on the right side. All nodes between the left ureter and aorta from the inferior mesenteric artery to the left mid-common iliac artery were excised. The remaining pelvic nodes also are removed using the CO₂ laser, blunt dissection, and hydrodissection. The removal of these nodes conforms to the guidelines established by the Gynecologic Oncology Group.

The external iliac nodes between the external iliac vein and artery and the obliterated hypogastric pedicles are carefully stripped to the deep circumflex veins. The obturator nerve is exposed bluntly, and the hypogastric and obturator nodes are removed. The obturator nerve is dissected and cleaned caudally until it leaves the pelvis. The nodal and fatty tissues between the obturator nerve and external iliac vein are identified and completely dissected. The inferior aspect of the external iliac vein is separated using blunt dissection, CO₂ laser, and hydrodissection until the internal obturator muscle and pelvic bone can be seen. Venous anastomosis between the obturator and external iliac veins was visualized under magnification and saved from trauma. Bipolar electrodesiccation was used to facilitate removal when larger vessels were encountered. Lymph nodes posterior to the obturator nerve also are excised. The lymph nodes are removed en bloc, labeled with an Endoloop ligature (Ethicon, Inc.), and placed laterally. They are removed after the vagina is opened and the hysterectomy is completed. Following the pelvic lymphadenectomy, the uterosacral ligaments and lateral parametria are coagulated with bipolar electrocoagulation and sequentially transected approximately 1.5 cm lateral to the cervix. The dissection is taken down to 2 to 5 cm below the cervix. The vagina is entered anteriorly and posteriorly using the CO₂ laser as follows. A sponge stick or right angle retractor is placed into the vagina to push the vaginal walls anteriorly and posteriorly, allowing the vagina to be incised by the CO₂ Laser from above. A sponge in the vagina prevents the escape of pneumoperitoneum.

The radical hysterectomy is completed vaginally or laparoscopically by incising the vagina 3 to 5 cm distal to the cervix. The residual cardinal ligaments are mobilized anteriorly and posteriorly, then divided from 1 to 5 cm lateral to the cervix and ligated with suture. The left angle of the vagina is sutured to the left and right anterior uterosacral ligaments. The uterus is removed transvaginally, as are the right and left lymphatic bundles. The vaginal vault is closed, and a suprapubic catheter is placed.

CONCLUSION

Laparoscopic procedures can be used for practically all types of oncologic surgery performed by the gynecologic surgeon. Numerous techniques have been proposed for laparoscopic surgery, and modifications are constantly devised. The application of laparoscopic surgery for oncology patients has been highlighted. Although some authorities believe that it should be an accepted surgical procedure, there is general agreement regarding the urgent need for randomized trials comparing laparoscopic and open surgery.

The benefits of laparoscopic surgery, including early ambulation, a decreased risk for surgical scar dehiscence and ventral hernia, are especially important for patients with malignancy. The laparoscopic approach may allow for superior intensive cytoreduction by utilizing the CO₂ laser for ablation of metastatic implants on the intestine. However, it must be remembered that laparoscopic oncologic operations require a high degree of skill and knowledge of instrumentation and techniques, and should be attempted only by experienced laparoscopists. No long-term data is available regarding the outcome of these procedures in managing malignancy. The role of laparoscopic cancer surgery will be determined only when follow-up data and survival analyses are available.

REFERENCES