The Research Advantage

When I was doing my fellowship in gynecologic oncology some 20 years ago, my senior fellow had a sign on his door that read “Publish or Perish.” He lived this motto and made me do the same during our fellowship. We even had a bibliography program to set the format called “Publish or Perish.” This was so ingrained in me that even after I left the university 12 years ago, I continue to do research and publish and present at national meetings because of him.

In this edition of Robotic Surgery Advantage, we present our most current research being performed at the Baptist Health South Florida Center for Robotic Surgery. We continue to strive to publish our work and stay at the forefront of robotic surgery research. Our robotic surgeons’ studies have been presented at several national and international meetings and some have already been accepted for publication. This research transcends other robotic surgery programs and will soon be a great addition to the Miami Cancer Institute at Baptist Health South Florida, which is scheduled to open in 2016.

It is of the utmost importance to track data and outcomes anytime you have a new tool to do surgery that allows you push the envelope to do more and more radical procedures. The question is not always: “Can it be done robotically?” But “Should it be done robotically?”

Despite the fact that we perform many advanced procedures, we always track our outcomes and make sure that we are meeting or exceeding the current standards of practice. In fact, we have published data on complications, such as vaginal cuff dehiscence, that has changed our surgical patterns for the better since we originally had a slightly higher rate of dehiscence. We will continue to monitor all of our outcomes to lead safely into our minimally invasive future.

“Publish or Perish” — thanks Mike J.

Ricardo Estape, M.D.
Medical Director
Center for Robotic Surgery

Dr. Estape is Board-certified in obstetrics and gynecology and gynecologic oncology. He received his medical degree from the University of Miami Miller School of Medicine. He completed his residency in OB/GYN and a fellowship in gynecologic oncology at the University of Miami/Jackson Memorial Medical Center. Dr. Estape is a fellow of American College of Obstetrics and Gynecology and a member of the Society of Gynecologic Oncology, American Association of Gynecologic Laparoscopists and Society of Laparoendoscopic Surgeons.
ASSESSING OUTCOMES OF ROBOTIC CHOLECYSTECTOMY

Study: Clinical Outcomes After Single-Incision Robotic Cholecystectomy: Results of a Multicenter Analysis

PRINCIPAL INVESTIGATOR:
Anthony Gonzalez, M.D.

PURPOSE OF STUDY:
The goal was to review outcomes for the procedure known as single-site cholecystectomy using the da Vinci® Single-Site Surgical System. The aim was to document and identify advantages associated with the use of the da Vinci system, in terms of outcomes to include parameters such as complication rate, total operative time and hospital length of stay.

The specific goal was to collect information from up to 300 cases done at Baptist Health South Florida, but the total cohort consisted of 500 patients from five sites nationwide. As the managing site for the study, Baptist Health South Florida compiled the data and performed the data analysis.

BACKGROUND:
Single-incision laparoscopic cholecystectomy (SILC) has become a popular procedure, but this platform still has technical limitations, and it is not recommended for “difficult” gallbladder. Recently, the da Vinci System has tried to ameliorate such technical difficulties with the creation of a single-site platform, restoring the triangulation.

Data were retrospectively collected for all patients who underwent single-incision robotic cholecystectomy (SIRC) and were compared with the same number of cases of SILC. For SIRC, there were not exclusion criteria, while for SILC all the cases considered technically “difficult” for the surgeon were generally avoided.

CONCLUSION:
SILC and SIRC are equal in terms of safety and feasibility, with a lower surgical time for SILC. In addition, SIRC can be used for acute cholecystitis or technically difficult gallbladders.

STUDY SPONSOR:
Intuitive

Dr. Gonzalez is chief of surgery at Baptist Hospital of Miami and medical director of the Weight-Loss Surgery Program at South Miami Hospital. He specializes in laparoscopic, bariatric and robotic surgery. He received his medical degree from the University of Miami Miller School of Medicine and completed his residency at University of Miami/Jackson Memorial Medical Center. He is a senior member of the American Society for Metabolic & Bariatric Surgery, Society of Laparoendoscopic Surgeons and Society of American Gastrointestinal and Endoscopic Surgeons, as well as a diplomate of the American Board of Surgery and a fellow of American College of Surgeons.
**EVALUATING ENSEAL TECHNOLOGY**

**Study: Robot-Assisted Laparoscopic Hysterectomy Using ENSEAL® Tissue Sealer: Optimizing the Minimally Invasive Hysterectomy**

**PRINCIPAL INVESTIGATOR:**
Nicholas Lambrou, M.D.

**PURPOSE OF STUDY:**
This large single-surgeon consecutive series (770 cases over a 45-month period) evaluated the use of ENSEAL vessel sealer during robotic hysterectomy for both benign and cancer surgeries.

**BACKGROUND:**
Patients were identified by electronic query from data systems including the Sovera®, ProDiver and Centricity systems. These systems integrate complete medical and surgical records, including all related documentation created during a patient’s continuum of care. Clinical and economic outcomes were derived from the extracted data. Data was exported into a customized database in the format of a limited data set for secure transfer to, and analysis by, the sponsor.

During the study period, 770 laparoscopic, robot-assisted gynecologic surgical procedures for benign and malignant indications were performed. Most were total laparoscopic hysterectomies.

**STATUS:**
Data collection is complete.

**CONCLUSION:**
The use of an advanced laparoscopic tissue-sealing device by a bedside surgical assistant led to improved operative efficiency and reliable vessel sealing during robotic hysterectomy. Procedural optimization as characterized by reductions in operative time continued to occur over a three-year period despite an increase in overall case complexity. This analysis suggests that procedural optimization may continue to occur well past previous learning-curve estimates.

**SPONSOR:**
Ethicon Endo-Surgery

“The outcomes validated excellent safety and patient outcomes by virtue of minimal EBL, minimal complications and average hospital stay of one night. It revealed continued improvements in operative efficiency over time among a high-volume surgical team compared to other published data.”

Dr. Lambrou is Board-certified in obstetrics and gynecology and gynecologic oncology. He received his medical degree from Boston University School of Medicine, did his residency at Johns Hopkins Hospital in Baltimore, Md., and completed a fellowship at University of Miami/Jackson Memorial Hospital. He is a fellow of American College of Obstetricians and Gynecologists and is a member of the Society of Gynecologic Oncology, the Howard A. Kelly Gynecologic and Obstetric Society and Alpha Omega Alpha Honor Medical Society.
ASSESSING ROBOTICS FOR GYNECOLOGIC DISORDERS

Study: Robotics Single Site Surgery in the Management of Gynecologic Disorders

PRINCIPAL INVESTIGATORS:
John Diaz, M.D., and Ricardo Estape, M.D.

PURPOSE OF STUDY:
We sought to evaluate the feasibility of robotic single-site surgery in the management of gynecologic disorders.

BACKGROUND:
A prospectively maintained database was used to identify all patients who underwent a robotic single-site surgery for gynecologic disorders at our institution. Patient demographics, operative times, pathologic findings, and perioperative complications were evaluated.

Twenty patients underwent a robotic single site procedure from May through August 2013. The median age was 46 years. The median BMI was 24.1. The following procedures were performed: total hysterectomy, 12; oophorectomy, 5; lymph node sampling, 2; ovarian cystectomy, 1; resection endometriosis, 1.

The median times are as follows: total operative time, 70 minutes; docking, 3.5 minutes; console, 41 minutes; vaginal cuff 2-layer closure, 11.5 minutes.

The median weight of uteri was 126 grams. One patient required the insertion of an additional port site. This patient had extensive endometriosis and a previous abdominal laparotomy. The median estimated blood loss was 25 mL. There were no intraoperative complications.

The following postoperative complications were observed: umbilical port site seroma, 1, and vaginal spotting 3. Two of the patients who experienced vaginal spotting were on therapeutic coumadin due to previous history of thromboembolic events. One patient required a return to the operating room for a vaginal cuff revision.

CONCLUSION:
In select women, robotic single-site surgery is feasible in the management of gynecologic disorders.

Dr. Diaz is Board-certified in obstetrics and gynecology and in gynecologic oncology. He received his medical degree from University of Miami Miller School of Medicine and completed his residency in obstetrics and gynecology at University of Miami/Jackson Memorial Medical Center. Dr. Diaz also completed a fellowship in gynecology oncology at Memorial Sloan Kettering Cancer Center in New York, where he received the Department of Surgery’s Chairman Award for Outstanding Research. Dr. Diaz is a fellow of the American College of Obstetricians and Gynecologists and a member of the Society of Gynecologic Oncology and American Society of Clinical Oncology.
EVALUATING CYTOREDUCTION
FOR RECURRENT OVARIAN CANCER

Study: Robotic and Open Cytoreductive Surgery in Combination with Hyperthermic Intraperitoneal Chemotherapy (HIPEC)

PRINCIPAL INVESTIGATORS:
John Diaz, M.D., and Ricardo Estape, M.D.

PURPOSE OF STUDY:
We aimed to evaluate the feasibility and tolerability of hyperthermic intraperitoneal chemotherapy (HIPEC) after robotic or open cytoreduction for recurrent ovarian cancer.

BACKGROUND:
In a single-institution pilot study, patients underwent optimal cytoreductive surgery in combination with HIPEC followed by consolidation chemotherapy from September 2011 to May 2013. Optimal cytoreduction was defined as no lesion > 1 cm. Adverse and oncologic outcomes were measured. Standard statistical analysis was utilized. We identified 13 patients, median age 52. The median number of chemotherapy regimens prior to HIPEC: three. A median of two platinum-containing regimens were administered prior to HIPEC. Median CA-125 at time of HIPEC was 256 U/mL. Seven patients were platinum sensitive at the time of HIPEC. Six patients underwent a robotic optimal cytoreductive surgery.

The cytotoxic agents utilized during HIPEC were: mitomycin, 6; cisplatin and paclitaxel, 4; carboplatin, 2; paclitaxel, 1. There were no intra-operative complications or adverse events attributable to HIPEC therapy. Hospital stay was a median of eight days. All patients received consolidation chemotherapy following their cytoreduction and HIPEC. At a median follow-up of four months, the progression-free survival free and overall survivals have not been reached.

CONCLUSION:
In select patients, robotic and open cytoreductive surgery in combination with HIPEC is feasible and safe. The optimal candidate and chemotherapy regimen have yet to be defined. Preliminary survival data suggests efficacy. Further investigation is warranted.

Study: Robotic Secondary Cytoreduction

PRINCIPAL INVESTIGATORS:
John Diaz, M.D., and Ricardo Estape, M.D.

PURPOSE OF STUDY:
Evaluating surgical and survival outcomes in patients with recurrent ovarian cancer undergoing robotic secondary cytoreduction.

BACKGROUND:
The review included all patients with recurrent ovarian cancer undergoing robotic secondary cytoreduction between January 2007 and December 2012 at one institution. We identified 28 patients; 93 percent were platinum sensitive. Clinicopathological and perioperative data was analyzed. Cytoreduction was defined as no gross residual disease and optimal as residual disease < 0.5 cm. Progression-free survival (PFS) and overall survival (OS) were calculated using Kaplan-Meier analysis. Complete cytoreduction was achieved in 26 patients; optimal cytoreduction in one. For all, the mean blood loss was 88 ml; and mean hospital stay 1.6 days. Postoperative complications were noted in four patients. Median follow up was 14.5 months.

Procedures ranged from robotic exploration of the abdomen and removal of tumor implants to more extensive procedures, including robotic liver wedge resection, diaphragmatic stripping and bowel resections with reanastomosis. The number of tumor sites range from a single site up to eight different sites. Two patients were noted with small volume of carcinomatosis.

The size of the tumors excised range from 0.4 cm to 10 cm. Only one patient was noted with ascites at time of surgery. All patients received chemotherapy post operatively. The median PFS was 12 months. The five-year OS rate was 78 percent.

CONCLUSION:
Robotic secondary cytoreductive surgery for recurrent ovarian carcinoma is feasible in select patients, including those with multiple sites of metastatic disease. The oncologic outcomes are comparable to traditional open techniques with the advantages of a minimally invasive surgery.
Reviewing a Case Series of Cerclage Placement

Study: Robotic-Assisted Abdominal Cerclage Placement

Principal Investigators:
John Diaz, M.D., and Ricardo Estape, M.D.

Purpose of Study:
The purpose is to present a case series of robotic cerclage on patients who were considered candidates for robotic-assisted abdominal cerclage placement.

Background:
Preterm birth remains the most common cause of perinatal morbidity and mortality to date. Cerclage placement in the uterine cervix has been evaluated in several trials for its efficacy in preventing preterm birth or second-trimester loss. As robotic-assisted laparoscopic surgery is rapidly gaining acceptance in gynecologic surgery, it has been described for placement of a transabdominal cerclage, proving to be less invasive and more effective not only as an interval procedure but also during pregnancy. Through our study, we present a case series of robotic cerclage on patients who were considered candidates for robotic-assisted abdominal cerclage placement.

We performed a retrospective review of robotic-assisted abdominal cerclages placed between 2007 and 2012. Fourteen cases were identified at our institution. Inclusion criteria included patients with prior failed vaginal cerclage, patients who desired minimally invasive surgery, patients with early pregnancy, and patients desiring interval cerclage placement prior to planned pregnancy. Exclusion criteria included patients not deemed appropriate for abdominal cerclage by evaluating physician.

The mean number of prior pregnancies per patient was approximately three. Six patients had a history of cerclage placement. Four patients were pregnant at the time of the robotic cerclage ranging from 10 – 16 weeks estimated gestational age. No major complications were identified. Mean operative time was 118 min and mean blood loss was 54.6 mL. Five patients achieved intrauterine pregnancies after cerclage placement and four of them delivered at full term without complications (by cesarean section). One patient experienced an intrauterine fetal demise at 24 weeks with subsequent development of chorioamnionitis, requiring hysterotomy.

Conclusion:
The strength of this study relies in presenting the largest case study series focused in robotic cerclage placement in both pregnant and nonpregnant patients. With increase in competency in robotic surgery emerges, robotic cerclage placement may provide an alternative means to abdominal cerclage placement. We recommend further studies be conducted, such as randomized controlled trials, in order to better assess the impact of robotic cerclage in the management of cervical insufficiency. We conclude that robotic cerclage is a safe and effective procedure with favorable obstetrical outcomes.

“We acknowledge that the population size is limited, but emphasize the significant contribution this data may provide for clinicians in practice.”
EXAMINING SURGICAL LYMPH NODE MAPPING

Study: Sentinel Lymph Node Biopsy in Endometrial and Cervical Cancer

PRINCIPAL INVESTIGATORS:
John Diaz, M.D., and Ricardo Estape, M.D.

PURPOSE OF STUDY:
To describe our first experience with a modified surgical lymph node assessment of mapping and sentinel lymph node biopsy with a minimally invasive approach.

BACKGROUND:
Sentinel lymph node (SLN) biopsy is a new surgical technique for the staging of gynecological malignancies. Since February 2013, we have utilized a modified lymph node (LN) assessment incorporating SLN mapping. In all cases, SNL mapping was performed with an intracervical injection of indocyanine green (ICG) divided into the 3- and 9-o’clock positions before laparoscopic entry. The positive SLN were identified with near-infrared (NIR) fluorescence imaging. For this analysis, we identified all cases of newly diagnosed endometrial and cervical cancer undergoing a minimally invasive staging procedure with sentinel lymph node mapping. Standard statistical analysis was performed using SPSS 20.0.

A total of 21 patients were identified from February 2013 to February 2014. The median age of diagnosis was 59. The median BMI was 31.5. Fifty-five percent of the patients had newly diagnosed endometrial cancer, 20 percent had cervical cancer and 25 percent had a diagnosis of complex hyperplasia with atypia.

Four patients had a robotic radical hysterectomy and staging procedure. A total of 25 percent underwent a robotic hysterectomy with pelvic lymph node sampling, and 40 percent had a robotic hysterectomy with pelvic and periaortic lymph node sampling. SLN mapping was successful in 19 of 20 patients. A total of 46 SLN were identified, with a median of 2 SLN per patient.

The majority of SLN were located at two main sites, external iliac and obturator. The median number of lymph nodes was 11. The median estimated blood loss was 50 mL. Three patients experienced intraoperative or postoperative complications not related to the SLN mapping. One of the patients with new diagnosis of cervical cancer had a successful SLN mapping; however, SLN failed to identify the metastatic LN, which was present in the right pelvic lymphadenectomy specimen. One patient with endometrial cancer had one metastatic SLN of three SLN mapped. The positive SLN was located in the right external iliac region, comprehensive lymphadenectomy revealed a positive periaortic LN. The final stage of the patient was IIIC2.

CONCLUSION:
SLN mapping with a minimally invasive approach is feasible in newly diagnosed gynecological malignancies. NIR fluorescence imaging with intracervical ICG injection using the robotic platform has a high bilateral SLN detection rate. SLN mapping was successful in 95 percent of the cases, comparable to larger series using robotic and conventional laparoscopic techniques.

“Sentinel lymph node mapping for gynecologic cancers is a novel technique that facilitates a more precise lymph node dissection and increased diagnostic accuracy for metastatic disease. This approach has now been approved by the new National Comprehensive Cancer Network guidelines in the surgical management of cervical and endometrial cancer.”
Stay Informed

Find previous articles about robotic surgery online. The Center’s newsletter for physicians features expert surgeons discussing the latest advancements in and benefits of robotic procedures.

To view archived issues, visit the “For Physicians” section at BaptistHealth.net/Robotics.

Surgical Abstracts

Study: Cosmesis, Patient Satisfaction and Quality of Life after da Vinci Single-Site and Multiport Laparoscopic Cholecystectomy: A Prospectively Randomized Multicenter Study

Principal Investigator:
Anthony Gonzalez, M.D.

Purpose of Study:
This study seeks to compare cholecystectomy performed with da Vinci Single-Site Instruments™ to multiport (four ports) laparoscopy.

The primary objective is to evaluate cosmesis, patient satisfaction and quality of life after robotic-assisted single-site cholecystectomy using the da Vinci Single-Site Instruments in comparison to a laparoscopic approach.

The secondary objective of this study is to assess the peri-operative clinical outcomes in the same scenario.

Status:
This study is enrolling patients undergoing minimally invasive cholecystectomy, performed by participating surgeons at their respective institutions. Baptist Health South Florida is one of three participating sites.

Sponsor:
Intuitive

“This study will determine how much the robotic single-site cholecystectomy can benefit patients cosmetically and in their quality of life as compared to the standard four-incision laparoscopic cholecystectomy. I am sure that this study will demonstrate benefits for our patients.”