

PUBLICATION INFORMATION

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MANUFACTURING DISCLOSURE: Apyx Medical manufactures and owns the J-Plasma technology discussed in this article.

INDICATIONS FOR USE & INTENDED USE DISCLOSURES

- The Renuvion Precise, Precise Open, and J-Plasma Handpieces are intended to be used with compatible electrosurgical generators for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation, and ablation of soft tissue during open surgical procedures.
- Apyx Medical wants to present to you with current scientific discourse.

RISKS:

- Risk associated with the use of the device may include: Helium embolism into the surgical site due to inadvertent introduction into the venous or arterial blood supply system, unintended burns (deep or superficial), pneumothorax, temporary or permanent nerve injury, ischemia, fibrosis, infection, pain, discomfort, gas buildup resulting in temporary and transient crepitus or pain, bleeding, hematoma, seroma, subcutaneous induration, pigmentation changes, increased healing time, and/or unsatisfactory scarring. There may be additional risks associated with the use of other devices along with Renuvion/J-Plasma and there may be an increased risk for patients who have undergone prior surgical or aesthetic procedures in the treatment area.

As with any procedure, individual results may vary. As with all energy devices there are inherent risks associated with its use, refer to the IFU for further information.

Laparoscopic Treatment of Benign and Malignant Pelvic Disorders Utilizing Helium Plasma: A Retrospective Analysis

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ABSTRACT

Objective: Assess the clinical and surgical outcomes related to the use of helium plasma, a novel energy device, in the treatment of benign and malignant pelvic conditions.

Methods: Retrospective chart review of 110 patients who underwent a laparoscopic procedure for the treatment of benign and malignant pelvic conditions treated with helium plasma from May 1, 2015 to February 15, 2017. Data collection included patient demographics, operative details, conversion rate to laparotomy, and incidence of blood transfusion, hospital readmission, and adverse events.

Results: The mean age was 50.4 ± 12.61 years, and the mean body mass index was 30.6 ± 6.95 kg/m². Medical comorbidity was noted in 52.7% of patients and 33.6% had previous pelvic or gynecologic surgery. The mean surgical time was 94.5 ± 33.68 minutes. There were no conversions to laparotomy. The mean blood loss was 107.0 ± 83.98 mL with one patient receiving a postoperative blood transfusion. There were no surgical site infections and one pelvic abscess occurred. There were no lymphedemas in patients undergoing lymph node dissection and no vaginal cuff dehiscence. The readmission rate was 0.9%. No complications were noted.

Conclusions: Helium plasma was used successfully to treat patients with benign and malignant pelvic conditions, with no reported complications or conversions to laparotomy.

Introduction

When selecting the appropriate surgical approach for an individual patient, the surgeon considers many elements that can play a role in the choice of laparotomy or laparoscopy. These elements include patient-related factors (age, body habitus, and comorbidities) and surgical factors (duration of the operation, intraoperative complications, and lymph node yield) [1]. Multiple randomized controlled trials in general surgery, urology, and gynecology have established that laparoscopic surgery is less invasive and less painful than open surgery and is associated with faster recovery and fewer complications [2,3]. Additionally, trauma markedly affects the immune system, including both the specific and nonspecific immune response [4]. Probably the most successful way to reduce surgical trauma-induced immunosuppression is to reduce the extent of trauma and may imply the use of a minimally invasive approach [5,6].

Complex gynecologic laparoscopy is an undertaking that requires careful dissection of pelvic structures. Conditions such as endometriosis, cancer, and fibroids can lead to anatomic abnormalities which can obscure important structures such as the bladder, ureters, and the serosal surfaces of the small and large intestine. In addition, previous surgery, such as Caesarean section, can lead to scarring between the uterus, adnexal structures, and the bladder. Many tools are available to facilitate laparoscopic surgery: vessel sealers, bipolar or unipolar-based cautery instruments, and ultrasonic dissectors. Some form of thermal energy is required to facilitate surgical dissections and key requirements of these instruments must include carefully controlled spread of thermal energy, ease of use, and effective tissue destruction. Existing surgical instruments can limit the surgeon's ability to negotiate around vital internal structures confidently. A concern with traditional

electrocautery is controlling the energy spread. Previous studies comparing helium plasma to other energy sources such as CO₂ laser demonstrated less or comparable lateral and depth of thermal spread for helium plasma in porcine peritoneum, bladder, and small intestine [7].

Helium plasma has been shown to be safe and effective in numerous surgical procedures where precise delivery of energy and minimal thermal spread to adjacent tissue are important, such as ablation of endometriotic cells on fallopian tubes and ovaries, and lysis of adhesions involving bowel or vital structures [8,9]. In a histology study on porcine small intestine, the helium plasma energy resulted in a depth of 0.334 mm of thermal effect compared to 1.8 mm for argon beam [7]. In further comparison, Sutton et al demonstrated that a monopolar pencil using high-frequency electrical current that is passed over the probe electrode to the tissue has a depth of reach of 4.75 mm with mean width of spread of 8.5 mm at settings of 20W/10W pure coagulation [10]. This retrospective analysis was undertaken to evaluate the impact of helium plasma on patient outcome when treating benign and malignant pelvic conditions laparoscopically.

Method

Study Patients

This retrospective analysis was based on patient data collected at a single center from May 1, 2015 to February 15, 2017 (Dignity Health California Hospital Medical Center, Los Angeles, CA). Study oversight was provided by Northridge Hospital Regional IRB #00002328 (Northridge, CA). The inclusion criterion was females aged 18-95 years who underwent a laparoscopic adhesiolysis procedure, lymph node dissection, and/or dissection of uterus and cervix for hysterectomy, for either benign or malignant pelvic conditions, using helium plasma (J-Plasma, Apyx Medical, FL) from May 1, 2015 to February 15, 2017.

Surgical Approach

Patients undergoing laparoscopic surgery in this study included patients with abnormal pelvic masses or other gynecologic cancers. Helium plasma was used for opening the retroperitoneum, dissecting the vesicouterine flap, and skeletonizing vascular structures prior to vessel sealing with another device. Helium plasma was also used for incision of the vaginal cuff and for separating the uterus/cervix from the vagina for hysterectomy. Lastly, helium plasma was used for the dissection of tissues, such as lymph nodes, from vessels. For patients with carcinomatosis or endometriosis, helium plasma was also used as-necessary for tissue ablation.

Outcomes

Patient variables collected were age, Body Mass Index (BMI), medical comorbidities, and previous pelvic or gynecologic surgery. Surgical variables included time in the operating room, total blood loss, complications, and conversion to laparotomy. Postoperative

outcome variables were assessed up to 6 weeks after the surgery and included hospital length of stay and incidence of wound infection, blood transfusion, lymphedema, abscess, vaginal cuff dehiscence, reoperation, and hospital readmission.

Results

A total of 110 women who met the inclusion criterion and underwent a laparoscopic procedure for either benign or malignant pelvic disorders were included in this retrospective analysis. Demographics and baseline characteristics of all patients are presented in Table 1. The mean age was 50.4 ± 12.61 years and 33.6% of patients had undergone previous pelvic or gynecologic surgery. The main preoperative diagnoses were ovarian neoplasm (34.5%), endometrial cancer (21.8%), and bleeding (13.6%). The procedure was well tolerated with no conversion to laparotomy, no surgical complications and a very low incidence of postoperative events (Tables 2&3).

Table 1: Demographics and Baseline Characteristics.

Characteristics	N = 110
Age (years), mean ± SD	50.4 ± 12.61
BMI (kg/m ²), mean ± SD	30.6 ± 6.95
Medical comorbidities, n (%)	58 (52.7)
Previous pelvic or gynecologic surgery, n (%)	37 (33.6)
Preoperative diagnosis, n (%)	
ascites	1 (0.9)
bleeding	15 (13.6)
BRCA (prophylactic surgery)	4 (3.6)
cervical cancer	3 (2.7)
cervical dysplasia	2 (1.8)
endometrial cancer	24 (21.8)
endometrial hyperplasia	5 (4.5)
endometriosis	3 (2.7)
fibroids	10 (9.1)
ovarian neoplasm	38 (34.5)
ovarian cancer	1 (0.9)
pelvic mass	4 (3.6)

Table 2: Surgical Operative Outcome.

Outcome	N = 110
Operating room time (minutes), mean ± SD	94.5 ± 33.68
Blood loss (mL), mean ± SD	107.0 ± 83.98
Conversion to laparotomy, n	0
Complications, n	0

Table 3: Postoperative Outcome (Up to 6 Weeks).

Outcome ^a	N = 110
Hospitalization (days), mean ± SD	1.0 ± 0.93
Blood transfusion	1 (0.9%)

Surgical site infection	0
Abscess	1 (0.9%)
Vaginal cuff dehiscence	0
Lymphedema	0
Readmission	1 (0.9%)
Reoperation	1 (0.9%)
^a Unless mentioned otherwise, data are presented as number of event and frequency, n (%)	

Discussion

This retrospective study was designed to assess the value of helium plasma, which does not use conductive currents, for reducing patient morbidity when treating benign and malignant pelvic pathology. The absence of surgical complications and conversion to laparotomy, and the very limited number of postoperative events, suggests that this device may have value for the laparoscopic surgeon. The strengths of this study are the sample size and the variability of disease treated, as patient selection was not limited by age, BMI, or the presence of malignancy. The limitation of this study is its retrospective nature, and randomized prospective trials will be necessary to validate universal acceptance of these findings and adoption of this promising new technology.

Conclusion

Helium plasma is a novel modality for the minimally invasive surgeon and was used in this study successfully for laparoscopic treatment of benign and malignant pelvic conditions, with no complications or conversion to laparotomy.

Conflict of Interest

Dr. Manuel reports grants from Apyx Medical (formerly Bovie Medical) to the Institution to cover IRB fees and study administration and personal fees as consultant during the conduct of the study and for writing the manuscript.

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Author Contribution

Dr Manuel was the study investigator and critically revised and approved the manuscript.

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