

## **Quantification of Pain Relief with Gonadal Vein Embolization for Pelvic Congestion Syndrome**

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### **Investigators**

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### **Purpose of Project**

To quantify the degree of pain relief following gonadal vein embolization.

### **Background**

Chronic pelvic pain, defined as lower abdominal or pelvic pain lasting for greater than 3-6 months, affects almost 40% of women during their lifetime.<sup>1,2</sup> Pelvic congestion syndrome (PCS) accounts for up to 30% of those with chronic pelvic pain, and is characterized by pelvic pain, dyspareunia, dysuria, and dysmenorrhea.<sup>1,2</sup> The most common underlying cause of PCS is incompetence or obstruction of the gonadal veins, resulting in painful congestion of the pelvic and perineal venous vasculature.<sup>2,3</sup>

Medical treatment is first line, and aims to suppress ovarian function and induce vasoconstriction of the venous system.<sup>1,2</sup> The most common medications used are medroxyprogesterone acetate (MPA) or the GnRH analogue goserelin, although this often necessitates estrogen replacement therapy to counteract the symptoms of ovarian suppression.<sup>1</sup> Unfortunately, efficacy and long-term pain relief from medical therapy is limited.<sup>2</sup>

Invasive options include total abdominal hysterectomy and bilateral salpingo-oophorectomy (TAH-BSO), extraperitoneal gonadal vein resection, and laparoscopic gonadal vein ligation.<sup>1,2</sup> Efficacy of TAH-BSO is poor, with 33% of patients reporting residual pain, and 20% reporting recurrent pain.<sup>1</sup> Gonadal vein resection and ligation have shown positive results, although are more invasive, and result in longer hospital stays, and have higher complication rates.<sup>2</sup>

Since its development in the early nineties, gonadal vein embolization has become the treatment of choice.<sup>1,2</sup> A number of studies have reported pain relief ranging between 47 to 94% of patients, that has been maintained through up to 36 months of follow up.<sup>2</sup> Complications are rare, and include gonadal vein perforation, coil migration, and recurrent varices.<sup>1,2</sup> The procedure involves obtaining venous access, performing venography of the gonadal veins, and subsequently embolizing one or both gonadal veins. Multiple embolic agents have been demonstrated in the literature, including liquid sclerosants (such as sodium tetradecyl sulfate, polidocanol), glue (such as n-butyl cyanoacrylate), Amplatzer plugs, and coils.<sup>1-4</sup>

Coil embolization of the gonadal veins has been shown to decrease pain in those affected by PCS, although the degree of relief has not yet been quantified.<sup>5-7</sup> This study's primary aim is to quantify the degree of pain relief with gonadal vein embolization. A patient questionnaire, called the Pelvic Congestion Symptom Score (PCSS) has been developed specifically for this project.

The PCSS is a 4-question tool used for evaluation of PCS symptoms both before and after gonadal vein embolization. It encompasses symptom frequency, severity, impact on activities, as well as happiness and quality of life, with scores ranging from 0 (asymptomatic) to 16 (disabled). Data gathered from the PCSS will help identify the degree of relief from PCS symptoms, as well as identify patients who are treatment resistant. Patients with no response or incomplete response to therapy will be further studied to identify predictors of ineffective treatment, possibly identifying patients who would benefit from more aggressive treatment.

## **Methods**

This prospective study will enroll a maximum of 30 patients 18 years of age and older who are candidates for gonadal vein embolization in the Interventional Radiology division at the University of Kansas Medical Center from October 1, 2018 to October 1, 2019. Following clinical evaluation, the patients will fill out the PCSS survey prior to their procedure. Patients will then fill out the same PCSS survey at 4 weeks, 90 days, 180 days, and 360 days following their procedure. Follow up surveys will either be performed by phone or at a relevant follow up appointment. Relevant clinical information will be obtained from patients' medical records and the Picture Archiving and Communication System (PACS), including demographics, clinical history, imaging findings, and intervention details. Secondary analysis will be performed to determine whether there are clinical or imaging factors that are predictive of a positive response to treatment, or poor response to treatment.

## **Specific Objectives**

- **Null Hypothesis:** There is no significant difference in chronic pelvic pain following gonadal vein embolization, and/or the PCSS is an invalid tool for grading symptomatic improvement following gonadal vein embolization.
- **Primary Objective:** To quantify the degree of pain relief in patients undergoing gonadal vein embolization with coils.
- **Secondary Objective:** To identify clinical or imaging factors that are predictive of a positive response to treatment, or poor response to treatment.

## **Inclusion Criteria**

- Female patients 18 years of age or older
- Meet the clinical and imaging criteria for the diagnosis of PCS and have no contraindications to coil embolization of the gonadal veins.
- Patients who are treated with coil embolization of the gonadal veins in the Interventional Radiology division between October 1, 2018 to October 1, 2019.

## **Exclusion Criteria**

- Patients less than 18 years of age.
- Patients who are found to have an underlying cause of pelvic congestion syndrome unrelated to venous congestion and insufficiency. This includes, but is not limited to, nutcracker syndrome, or a mass resulting in extrinsic compression of the gonadal veins.
- Patients who have received prior surgical therapy for PCS, including bilateral salpingo-oophorectomy (TAH-BSO), gonadal vein resection, or gonadal vein ligation.

## **Risks**

As the primary objective of this study is to quantify improvement in patient pain following gonadal vein embolization via the use of the PCSS questionnaire, there are no expected risks to be incurred by patients participating in this study.

### **Statistical Analysis**

Descriptive statistics, correlations, and multivariate linear and/or logistic regression models will be utilized to analyze the data by trained professionals in the Radiology and/or Biostatistics Departments at KUMC.

### **Data Management**

Data collection forms will be created and managed in REDCap. Patient information will be kept in password-protected databases and will be deidentified for analyses and presentations of results. All study documents will be stored on limited access KUMC protected network drives and any paper copies of source documents will be locked in the Radiology Research Office.

### **References**

1. Ignacio EA, et al. Pelvic Congestion Syndrome: Diagnosis and Treatment. *Semin Intervent Radiol* 2008; 25(4):361–368.
2. O'Brien MT, Gillespie DL. Diagnosis And Treatment Of The Pelvic Congestion Syndrome. *J Vasc Surg Venous Lymphat Disord* 2015; 3(1):96-106.
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4. Lopez AJ. Female Pelvic Vein Embolization: Indications, Techniques, and Outcomes. *Cardiovasc Intervent Radiol* 2015; 38(4):806–820.
5. Daniels JP, Champaneria R, Shah L, Gupta JK, Birch J, Moss JG. Effectiveness Of Embolization Or Sclerotherapy Of Pelvic Veins For Reducing Chronic Pelvic Pain: A Systematic Review. *J Vasc Interv Radiol* 2016; 27(10):1478-1486.
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7. Guirola JA, Sánchez-Ballester M, Sierre S, Lahuerta C, Mayoral V, De Gregorio MA. A Randomized Trial Of Endovascular Embolization Treatment In Pelvic Congestion Syndrome: Fibered Platinum Coils Versus Vascular Plugs With 1-Year Clinical Outcomes. *J Vasc Interv Radiol* 2018; 29(1):45-53.

## Table Outlines

### Table 1: Patient Characteristics

- Demographics
  - Age (mean, SD)
  - Race (n, %): White, Black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, Other / Unspecified
  - Ethnicity (n, %): Hispanic, Non-Hispanic
  - Height (mean, SD)
  - Weight (mean, SD)
  - Parity (mean, SD)
- Symptoms
  - Dyspareunia (mean, SD)
  - Dysuria (mean, SD)
  - Dysmenorrhea (mean, SD)
- Presence of Varicosities
  - Unilateral Gluteal (mean, SD)
  - Bilateral Gluteal (mean, SD)
  - Unilateral Vulvar (mean, SD)
  - Bilateral Vulvar (mean, SD)
  - Unilateral Perineal (mean, SD)
  - Bilateral Perineal (mean, SD)
  - Unilateral Upper-Inner Thigh (mean, SD)
  - Bilateral Upper-Inner Thigh (mean, SD)

### Table 2: Imaging and Intervention Characteristics

- Right Gonadal Vein Diameter (mm, SD)
- Left Gonadal Vein Diameter (mm, SD)
- Right Internal Iliac Vein Diameter (mm, SD)
- Left Internal Iliac Vein Diameter (mm, SD)
- Side of Intervention (n, %): Left, Right, Bilateral
- Number of Coils Used Per Side (n, %)

### Table 3: Pain Scores

- Pre-Intervention
  - Number of Days a Week Pelvic Pain is Experienced (mean, SD)
  - Severity of Pelvic Pain (mean, SD)
  - Limitation from Pelvic Pain (mean, SD)
  - Effect on Happiness and/or Quality of Life (mean, SD)
  - Total Score (mean, SD)
- 4 Weeks Post-Intervention
  - Number of Days a Week Pelvic Pain is Experienced (mean, SD)
  - Severity of Pelvic Pain (mean, SD)
  - Limitation from Pelvic Pain (mean, SD)
  - Effect on Happiness and/or Quality of Life (mean, SD)
  - Total Score (mean, SD)
- 90 Days Post-Intervention
  - Number of Days a Week Pelvic Pain is Experienced (mean, SD)
  - Severity of Pelvic Pain (mean, SD)
  - Limitation from Pelvic Pain (mean, SD)

- Effect on Happiness and/or Quality of Life (mean, SD)
- Total Score (mean, SD)
- 180 Days Post-Intervention
  - Number of Days a Week Pelvic Pain is Experienced (mean, SD)
  - Severity of Pelvic Pain (mean, SD)
  - Limitation from Pelvic Pain (mean, SD)
  - Effect on Happiness and/or Quality of Life (mean, SD)
  - Total Score (mean, SD)
- 360 Days Post-Intervention
  - Number of Days a Week Pelvic Pain is Experienced (mean, SD)
  - Severity of Pelvic Pain (mean, SD)
  - Limitation from Pelvic Pain (mean, SD)
  - Effect on Happiness and/or Quality of Life (mean, SD)
  - Total Score (mean, SD)

**Table 4: Primary Outcomes**

- Mean Reduction of Pain Score 4 Weeks Post-Procedure (Mean, SD)
- Mean Reduction of Pain Score 90 Days Post-Procedure (Mean, SD)
- Mean Reduction of Pain Score 180 Days Post-Procedure (Mean, SD)
- Mean Reduction of Pain Score 360 Post-Procedure (Mean, SD)