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| **Date** | 9/27/18 |
| **Title** | Are we supporting the apex during hysterectomy for pelvic organ prolapse? |
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| **Hatton #** | 17-091 |

**Purpose of Study**:

- To determine whether gynecologic surgeons at a large community hospital are already meeting the recently recommended best practice of supporting the vaginal apex at time of hysterectomy for pelvic organ prolapse.
  - **Primary Aim:** To determine the proportion of patients undergoing hysterectomy for the indication of pelvic organ prolapse having concurrent apical suspension such as: McCall's culdoplasty, Uterosacral Ligament Suspension, Sacrospinous Ligament Fixation, Abdominal Sacrocolpopexy, or Robotic Sacrocolpopexy.
  - **Secondary Aims:** Identify characteristics of surgeons not meeting the recommended best practice including their training, location of operation, operative times, concurrent procedures and estimated blood loss.

**Hypothesis or Research Question**

- We hypothesize that fewer than 10% of patients having hysterectomy for pelvic organ prolapse will not undergo concurrent apical support, being defined as McCall's Culdoplasty, Uterosacral Ligament Suspension, Sacrospinous Ligament Fixation or Robotic/Abdominal Sacrocolpopexy.

**Background**

The prevalence of pelvic organ prolapse (POP) in the United States is estimated to be between 40-50% with an anticipated increase over the next several decades[1-3]. Approximately 300,000 women undergo surgeries to repair POP in the United States every year[4]. Following pelvic reconstructive surgery, recurrence rates of symptomatic prolapse range between 6-30%[5-9]. This number has changed in recent years to favor a lower recurrence rate. This change in recurrence rate may be attributed to the efforts of pelvic surgeons in restoring proper levels of support during repairs.

Our understanding of pelvic anatomy and its support has been significantly improved over recent decades, with many researchers reporting on details and mechanics previously not understood. A landmark article by DeLancey[11] proposed a now widely accepted model

outlining the support of the pelvic organs, ordering specific aspects of support from level one to level three. This model then helped drive continued efforts in improving approaches and outcomes for reconstructive surgery.

Historically, a majority of women having pelvic reconstructive surgery would undergo anterior and posterior colporrhaphy for repair of their prolapse[12]. This was considered an appropriate standard of care. More recently, the integral relationship between loss of apical support and both anterior and posterior compartment defects has been demonstrated[13-15]. Then, in 2013, Eilber reported on the outcomes of vaginal prolapse surgery among female medicare beneficiaries[16]. They investgated a 10 year period including over 3,200 women who had undergone pelvic reconstructive surgery. They found that women having concurrent apical support procedures were significantly less likely to have recurrence of prolapse than those women who had no apical support performed.

In November 2017, the American College of Obstetricians and Gynecologists released a new practice bulletin outlining the current standard of care for the treatment of women with pelvic organ prolapse[17]. In this bulletin, they state that a hysterectomy alone is not adequate treatment for pelvic organ prolapse, and further that any woman having a hysterectomy for pelvic organ prolapse should undergo a concurrent apical suspension procedure as a standard of care. The question then arises, what proportion of our patients currently receive this standard of care?

Our purpose therefore is to investigate the proportion of patients undergoing hysterectomy for the indication of pelvic organ prolapse at a TriHealth facility who receive a concurrent apical support procedure as recommended by ACOG, which includes: McCall's Culdoplasty, Uterosacral Ligament Suspension, Sacrospinous Ligament Fixation and Robotic/Abdominal Sacrocolpopexy.

**Research Plan**

- **Study Design**
  - Retrospective Descriptive Study

- **Setting for the study**
  - A retrospective chart review will be performed on TriHealth EPIC platform of patients of TriHealth who underwent hysterectomy for pelvic organ prolapse at any of the affiliated TriHealth hospitals between October 2012 and October of 2017.

- **Participants**
  - Study population: All women 18 years of age or older, who underwent hysterectomy for pelvic organ prolapse, performed at a TriHealth facility between October 2012 and October 2017.
  - A chart review will be performed on all patients identified.

- Inclusion criteria
  - Adults 18 years of age or older
  - Underwent hysterectomy for pelvic organ prolapse, performed at a TriHealth facility between October 2012 and October 2017
- Exclusion criteria
  - Age < 18 years old
  - Pelvic Organ Prolapse was not an indication for their surgery
  - Surgery performed by a physician of Cincinnati Urogynecology Associates.
- Sample size
  - Given the retrospective nature of this study, a sample size calculation is not indicated. However, estimating the number of charts that may be available can be garnered from internal reports on department activity. Between October 2012 to October 2017, 792 hysterectomies took place at a Trihealth Facility for the indication of prolapse. Excluding those performed by a physician of the Cincinnati Urogyn Associates group, there are approximately 194 cases eligible for review. With this in mind, in order to provide for potential differences in case number during the years within the study period, we request permission to review up to 250 cases.

- **Data Collection**
  - Each chart will be reviewed and the following data will be collected or extrapolated:
    - General demographic data – name, date of birth, age, race, parity, BMI
    - Select comorbidities (connective tissue disorders, history of chronic constipation, history of chronic cough)
    - Operative details – Date of surgery, concurrent procedures performed, type of apical support, length of procedure, facility or location of procedure performed, estimated blood loss, reported intra-operative complications, primary surgeon, whether FPMRS or General OB/GYN.

- **Intervention or experimental aspect of the study**
  - No intervention will occur as part of this study.
  - There are no potential risks to the study population by any aspect of the study.

- **Statistical Analysis**
  - Given the descriptive nature of this study, limited statistical analysis will be performed. The proportion of patients who did not have concurrent apical support procedures performed will be calculated. Furthermore, the proportion of patients who had various postoperative outcomes (as defined above) will be calculated and compared to previous published literature.

**Ethical Considerations**

- **Informed consent**

- Since this is a retrospective study, waivers of Informed Consent and Authorization will be requested.

- **Privacy information**
  - Extensive efforts will be made to ensure and maintain participant confidentiality. All identifying information will be maintained in a secure area at all times. All communication between staff members regarding participant data will occur via the Subject ID number only. However, identifying information will be retained in the original/source documents.
  - The Excel spreadsheet will be stored on a password protected, encrypted TriHealth computer for ten years following study closure, and then purged.

**Cost/Budget**

- This study will incur no cost to the institution, the participants, or the investigators.

| **Estimated Period of Time to Complete Study** | |
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| **When will study begin?** | January 2018 |
| **Protocol Development Completed** | 2 weeks |
| **Admin Review Time** | 2 weeks |
| **IRB Approval** | 3 weeks |
| **Data collection** | 8 weeks |
| **Data analysis** | 2 weeks |
| **Presentation development (if applicable)** | 2 weeks |
| **Manuscript Development (if applicable)** | 4 weeks |
| **Journal submission process (if applicable)** | 4 weeks |
| **Study closure** | 2 weeks |

- **When and how will results be disseminated?**
  - The results will be disseminated at one of our division research meetings and potentially as a presentation at a national meeting.

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