**RESEARCH PROTOCOL**

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| **Date** | **5-15-19** |
| **Title** | **Utilization of the mirror during pelvic exams: Does it reduce patient vulnerability and discomfort?** |
| **Principal Investigator** | Rachel Pauls, MD |
| **Sub-Investigators** | Tiffanie Tam, MD; Austin Hill, MD; Steven D. Kleeman, MD; Catrina C. Crisp, MD MSc; Jennifer Yeung, DO; Emily Aldrich, MD |
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| **Hatton #** | **18-107** |

**IRB Review Type:** ☐ **Exempt** ☐ **Expedited** ☒ **Full Board**

**Purpose of Study**

Primary Aim:

- To determine if using a mirror during the patient's pelvic examination (MPE) decreases patients' degree of vulnerability and discomfort.

Secondary Aims:

- To assess patient degree of anxiety, sense of control, and embarrassment during pelvic exam with and without the mirror.
- To assess patient awareness of personal pelvic anatomy and diagnosis following pelvic exam with and without the mirror.
- To assess patient willingness to have mirror during each subsequent pelvic exam
- To assess patient satisfaction with their exam, with and without mirror.
- To describe any differences between patients that agree to use of the mirror for their exam compared to those who refuse the mirror.
- To determine if implementing the MPE increases average length of time of pelvic examination.

**Hypothesis or Research Question**

- We hypothesize that the MPE will decrease the level of vulnerability and discomfort experienced during the pelvic examination.

**Background**

In Obstetrics and Gynecology and its gynecologic subspecialties, the pelvic examination is routine practice for screening and diagnostic purposes. Nevertheless, due to their intimate nature, pelvic examinations may result in loss of control, embarrassment, discomfort and anxiety [1-3]. Patients that present for urogynecologic care are a unique subset of women due to their advanced age, and nature of their disorder. As such, these patients may be more likely to express anxiety and concern about their visit [3].

With the trend of hospital improvement and quality, patient centered care and experience are now a main topic of improvement. The environment in the outpatient setting is different from that of an inpatient setting however; the patient's experience is just as complex. Patients who feel emotionally comfortable are more likely to feel a greater sense of empowerment, enablement and engagement [4]. This is intertwined with patient participation and ultimately affects the patient experience [5].

The mirror pelvic exam (MPE) has been a proposed technique to decrease patient anxiety and improve comfort during an already uncomfortable examination. However, little research has focused on this modality to date. An early report from the 1970's described 90% of the patients felt more relaxed by utilization of the mirror and 76% revealed they would like a gynecologic problem demonstrated with a mirror [6]. A small study performed at California Polytechnic State University studied 15 females who underwent an MPE. Results were favorable revealing that 67% of the patients aged 18-26 years were more relaxed and had less discomfort whilst using the MPE. Additionally, it was found that 100% of the patients would like to have the mirror used in the future if they were to experience a gynecological problem and 92% would recommend this to a friend [7].

To date, there have been no trials regarding the utility of the MPE in a population with prolapse, incontinence or pelvic floor disorders. By studying this tool, we could understand better the utility of the MPE and discover if there is a specific patient population or situation in which this tool should be offered to ease patients' sense of vulnerability, pain, and anxiety.

**Research Plan**

- **Study Design**
  Prospective Two-cohort Study
- **Setting for the study**
  - All new patients to Cincinnati Urogynecology Associates, TriHealth presenting to one of four outpatient clinics (Clifton, West Chester, Kenwood, Anderson) will be eligible.
  - They will then be approached by either a research coordinator, attending physician or fellow in the exam room or in the research coordinator's office prior to the start of their visit and offered enrollment.
  - If they agree to participate they will answer a brief questionnaire about demographics, personal experience with pelvic exam, the purpose of their visit and whether they would agree to have a mirror utilized during their pelvic exam that day.
  - If they agree to have a mirror used, then they will undergo the examination with the use of a mirror during the physician examination of the pelvic area, and receive information about the anatomy being shown. No other changes will be made to the exam performed.
  - If they decline a mirror then they will undergo our standard pelvic examination.
  - All enrolled patients will then be given a questionnaire at the completion of their pelvic exam.

- **Participants**
  - Study population: All women 18 years of age to 80, who undergo pelvic exam by a physician at Cincinnati Urogynecology Associates, TriHealth will be approached for recruitment.
  - Inclusion/Exclusion criteria:
    - Inclusion
      - Adults 18 years of age to 80
      - New patients undergoing a pelvic exam performed by a physician at Cincinnati Urogynecology Associates, TriHealth
    - Exclusion
      - Existing patients
      - Unwillingness to participate in the study
      - Physical or mental impairment that would affect the subject's ability to visualize the mirror during examination or to complete questionnaires
      - Inability to understand English
  - **Sample size**
    - A sample size was calculated to be 68 patients in each arm based on the following:
      - A prior study by Seehusen D. et al, evaluated the vulnerability and discomfort level in patients who underwent a pelvic exam using stirrups or no stirrups. Because there are no prior studies that have evaluated vulnerability or discomfort using the mirror during pelvic examination, this study was used to develop a sample size [8].
      - The difference in mean VAS on level of vulnerability for two groups was selected to be 10.5 mm with SDs for 16.3 and 25.8 with/without intervention, respectively.[8]
      - Two group Satterthwaite t-test with a 0.05 two-sided significance level was used for sample size calculation.
      - The power was set at 80 %.
      - Assuming an estimated drop-out rate of 15%, the number of patient enrollment per arm was set to 80, for a total of 160 patients.

- **Data Collection**
  - Primary Outcome:

        - Patient's level of vulnerability and discomfort before and after the pelvic exam.
    - Secondary Outcomes:
        - Patient's sense of loss of control, anxiety and embarrassment during the pelvic exam.
        - Patient's level of understanding of pelvic anatomy and diagnosis after the pelvic exam.
        - Changes in the time of the examination as calculated by time performing the pelvic exam (will be performed using a timer in the room).
        - Differences in demographics and medical history between those that decline the MPE and those that consent to the MPE.
        - Patients' overall satisfaction of the entire visit.
        - Likelihood of physician referral to friends or family.
        - Patients willingness to have the MPE during future visits.
    - General demographic data and medical data
        - DOB, age, race, weight, height, BMI, religion, education level, past medical history, date of exam, duration of exam, chief complaint on initial visit, sexual activity level, outcome of visit (ie. Surgical intervention, medical intervention, none).

- **Intervention or experimental aspect of the study**
    - The patients will be addressed on their first visit in the exam room or in the research coordinator's office prior to the start of their visit. Each will be given a description of the study by a research coordinator, attending or fellow.
    - Once consent and enrolled, whether or not they refuse to have the mirror pelvic exam or not, they will be given a pre-examination questionnaire.
    - Of the patients who agree to have the mirror pelvic exam, they will then undergo routine pelvic examination by a physician with the usage of a mirror in the room. This mirror will be a roll-in mirror that is positioned in such a manner that provides the patient with adequate visualization of her female parts.
    - All physicians will be instructed on the terminology and descriptions to utilize with the exam to standardize the experience with the mirror.
    - The pelvic examination will be timed from the start of palpation of the external female genitalia and stopped at the time of last genital contact.
    - At the end of the visit, the patient will be given a questionnaire that characterizes her experience.

- **Statistical Analysis**
    - Descriptive statistics will be generated for demographic information such as age, race, BMI, Parity. Continuous variables such as level of vulnerability, pain, and anxiety on VAS will be analyzed using independent samples t-tests or Mann-Whitney U test for significant difference between groups. A multiple linear regression will be utilized for adjusting confounding variables. Categorical variables will be tested using the Fisher's exact or Pearson Chi-square tests.

**Ethical Considerations**

- **Informed consent**
  - Patients who agree to participate in the study will sign a written informed consent. They will be consented by one of the stated investigators or trained Research Nurse and they will receive a copy of the signed informed consent statements (ICS). A copy will be put in their medical file.

- **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. Source documentation will be maintained in a separate folder. When documentation has to be made available for data analysis, copies of the source (Excel spreadsheets) with only Subject ID number visible and personal information obscured will be used. 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 participant will be logged in the Excel spreadsheet and assigned a Subject ID number. Each participant will be assigned the next available Subject ID number. Once each Subject ID number has been assigned, it will not be reassigned. The Excel spreadsheet will be stored on a password protected, encrypted TriHealth computer for ten years following study closure, and then purged.

| **Estimated Period of Time to Complete Study** | |
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| **When will study begin?** | December 15th, 2018 |
| **Protocol Development Completed** | November 5th, 2018 |
| **Admin Review Time** | 2 weeks |
| **IRB Approval** | December 18,2018 |
| **Data collection** | Subjects to be enrolled starting January 1, 2019 |
| **Data analysis** | January 2020 |

- **When and how will results be disseminated?**
  - Submit for abstract presentation at national/international meeting and publication

## References

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