Pelvic organ prolapse: is there a difference in POPQ exam results based on time of day, morning or afternoon?

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OBJECTIVE: The purpose of this study was to determine if there is any difference between AM and PM POPQ exam results.

STUDY DESIGN: Prospective, IRB approved study of women presenting with pelvic organ prolapse symptoms. Initial POPQ exams were performed in the morning or afternoon; a second exam was performed within 4 weeks at the opposite time of day. Statistical analysis included Wilcoxon signed rank test, paired *t* test, Spearman correlation, and Stuart-Maxwell test.

RESULTS: The study consisted of 32 subjects. Mean age was 58.8 years, mean BMI 28.6, median parity 2.0, 75% white, 22% black, and 3% Hispanic. The POPQ exam stages were 47% stage II, 50% stage III, and 3.0% stage IV. There was no significant difference for the 9 POPQ exam measures between morning and afternoon exams. There was good agreement between AM and PM POPQ ordinal stages (Stewart Maxwell $P = 1.0$, kappa 0.76).

CONCLUSION: There is no difference between AM and PM POPQ exam results.

Key words: pelvic organ prolapse quantification exam, time of day.

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Pelvic organ prolapse is a common disease affecting between 3-9% of adult women.[1,2] Currently, we spend over 1 billion dollars annually in the United States treating it, and it is the third most common indication listed for hysterectomy in all women and the most common indication for hysterectomy in menopausal women.[3] Despite these numbers it is a poorly understood disease with many untested myths or tenets surrounding its presentation and diagnosis.

One of these tenets is that vaginal prolapse is more severe late in the day when compared to the morning, and consequently, subjects are better served by being examined in the afternoon if the full extent of the prolapse is to be demonstrated. This is secondary to the beliefs that during the course of the day, the effects of being upright, and the daily stresses and strains on the abdominal cavity bring about more pronounced prolapse. At night, the prolapse will retreat up into the vaginal canal when patients are supine and it is therefore less prominent in the morning. Many physicians base their practice patterns upon this belief and preferentially examine patients with complaints of prolapse in the afternoon. This can necessitate a second office visit prior to deciding on therapy.

Currently, pelvic organ prolapse is measured using the pelvic organ prolapse quantification system (POPQ). This exam measures 9 points in and around the vaginal canal using centimeters to give a very precise measure or outline of the pelvic organ prolapse.[4] This system has been extensively studied and has demonstrated excellent intra- and interobserver reliability. In addition, since measures of the 9 points are taken using centimeters, small differences can be detected.[5,6]

The objective of the current study was to determine if there is a significant difference in a patient's POPQ exam when measured in the morning vs the afternoon. A secondary outcome was to determine if the amount of activity (as recorded in a simple activity log) during the day of the exam influenced the outcome of the POPQ results.

Materials and Methods

This is a prospective observational study examining 32 subjects presenting to the Urogynecology Outpatient Clinics at the Medical University of South Carolina with complaints of pelvic floor dysfunction. The study was approved by the Institutional Review Board for Human Research (HR # 16114) and all subjects provided written informed consent prior to participation. All subjects presenting to the Urogynecology clinic at the Medical University of South Carolina with symptoms of pelvic organ prolapse (the complaint of a vaginal bulge which they could see or feel) were approached regarding this study. Subjects had to be greater than 18 years of age, speak and understand written English, be able to provide informed consent, and be willing to return to the urogynecology clinic for a second exam within 2-4 weeks. Subjects were excluded if they were within 6 months of delivery or surgery to correct pelvic organ prolapse. In addition, subjects who worked nights were excluded

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as this would impact their activity levels during the day and night.

Following informed consent the subjects were required to empty their bladder and were examined by author S.S. using the standard POPQ technique in the dorsal lithotomy position while performing a Valsalva or cough.[7] Subjects were asked to confirm that the prolapse noted during exam was the fullest extent of the prolapse that was bothering them. Subjects could confirm by either palpating their prolapse during the exam or using a hand held mirror to visually confirm their prolapse. It was noted on the data collection sheet whether or not the subject could or could not confirm their exam.

In order to ensure that there was good separation between a "morning" exam and an "afternoon" exam we qualified a specific time period for "morning" and "afternoon." For an exam to qualify as a morning exam it had to occur between 8:30 AM and 10:30 AM. For an exam to qualify as an "afternoon" exam it had to occur between 2:00 PM and 5:00 PM. The order of the exams was not randomized. If subjects presented in the morning for their initial exam the second exam was scheduled in the afternoon and vice versa. The urogynecology clinic has a similar number of morning and afternoon sessions and sequential subjects were recruited.

At each exam visit a simple activity log was completed during the visit that was developed by the investigators for this study. The activity log recorded the approximate number of hours the patient was standing/walking and the approximate number of hours they were sitting since awakening on the day of the exam prior to coming to the office. This was accomplished through subject recall. Patients were also asked to estimate the number of hours they were performing any unique activities (ie, exercising, walking a dog, lifting heavy materials, etc.). These data were recorded on a data sheet along with the time of the exam, basic demographic data, and the results of their POPQ exam. A second exam was performed no sooner than 2 weeks and no greater than 4 weeks following the initial exam. The second POPQ exam was performed by S.S. in an identical fashion to the initial exam with subject confirmation, prior to review of the results of the initial POPQ exam.

The characteristics of the sample population were described with simple descriptive statistics. The primary outcome for this trial was the numeric value of the individual POPQ measurement points of the vagina or cervix at the morning and afternoon exam times. The POPQ measurement is described using centimeters. The POPQ measurements are based on their relationship to the hymen. If the point remains above the hymen it is a negative number, if the individual point reaches the hymen it is zero and if it extends beyond the hymen it is a positive number. Increasing value to the POPQ points are associated with a more significant pelvic organ prolapsed, and higher overall POPQ stage. Secondary outcomes include POPQ stage and patient's report of hours spent standing and sitting prior to evaluation.

As normality was not assured in the continuous data in this trial, nonparametric statistics were utilized and central location presented as median and interquartile range. Differences in hours spent standing and sitting prior to the examination between AM and PM evaluations, and differences in individual POPQ individual measurement points between exams were tested with Wilcoxon Signed rank for paired data. The association of hours spent sitting and standing and POPQ exam results were assessed by the Spearman correlation. Finally, agreement between am and pm examination POPQ stage was performed with the Stuart-Maxwell test, a test for marginal homogeneity for multiple categories simultaneously. Kappa statistic was also used as a measure of agreement between AM and PM POPQ tests. The value of kappa defines the strength of agreement as fair (k = 0.21-0.40), moderate (k = 0.41-0.60), good (k = 0.61-0.80), and very good (k = 0.81-1.00) [1]. All tests were 2-sided with alpha $<$ .05. All analyses were performed with SAS 9.1 (SAS Institute, Inc, Cary, NC, 2002-2003).

A post hoc power calculation based on the final sample size of 32 patients (32 pairs of observations) was performed. The POPQ point Ba was determined to be the most clinically representative point for the overall POPQ stage and is a good surrogate marker for the leading edge of the prolapse. A 1 + 2 cm difference between AM and PM measurements was selected as a clinically significant difference that would favor a preference in timing of POPQ exam. Using these assumptions for paired *t* test, the sample size of 32 provided 80% power (2-sided alpha = .05) to detect this clinically significant difference between AM and PM measurements (Sample Power, SPSS, 1997; 1). As the majority of the POPQ points were not normally distributed power calculation was also tested based on the Wilcoxon Signed-Rank test. The sample size of 32 pairs of patients (32 patients with an AM and PM measurement) demonstrates 84% power to detect the same difference. Further evaluation of the estimation of the power of this study was performed using the correlation between the AM and PM point Ba. From these data, there is a high correlation between the AM and PM values (0.9, $P < .0001$). With a sample size of 30 patients, there is then 86% power to detect a correlation between the AM and PM values as low as 0.5. Overall, while the power size calculation is post-hoc, both estimates demonstrate that with the sample size of 32 pairs of subjects, this study has 78-84% power to demonstrate at least a 1 cm difference in point Ba, the minimally clinically significant difference.

RESULTS

Thirty-two sequential subjects met inclusion criteria and completed both morning and afternoon POPQ testing. Patients were primarily multiparous, white, and over half had prior hysterectomy (Table 1). Only 1 patient approached for inclusion into the study declined to participate and 1 subject did not return for follow-up citing transportation difficulties. At both AM and PM examinations, 46.9% were stage II (n = 15), 50% stage III (n = 16), and 3.1% stage IV (n = 1) (Table 3). At each individual POPQ point of measurement,