Correlation of Electronic (Web-Based and Smartphone) Administration of Measures of Pelvic Floor Dysfunction: A Randomized Controlled Trial

Cara L. Grimes, MD, MAS, Danielle D. Antosh, MD,† Sallie Oliphant, MD, MSc,‡ Ladin Yurteri-Kaplan, MD, MS,§ Shunaha Kim-Fine, MD,|| Gabriel Melamud, BS,§ Christine Heisler, MD, MS,¶ and Doreen E. Chung, MD,** for the Collaborative Research in Pelvic Surgery Consortium (CoRPS)*

Objective: We hypothesized that instruments of pelvic floor dysfunction would yield similar responses on web-based and smartphone administration compared with paper.

Methods: Subjects presenting with pelvic floor disorders were prospectively enrolled at 5 sites and invited to complete 4 validated pelvic floor disorder questionnaires (Pelvic Floor Distress Inventory 20, Pelvic Floor Impact Questionnaire 7, Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire 12, Bristol Stool Scale) on both paper and electronic formats, 2 weeks apart, with the order of administration being randomized. Participants completed the questionnaires electronically on the internet via REDCap or using the PelvicTrack App on a smartphone or tablet.

Results: Two hundred thirty-four subjects were enrolled, and 132 subjects (56%) completed both sets of questionnaires with no intervening treatment. This group was 58 (±15) years old with body mass index 28 (±6) kg/m^2 and parity 2 (1, 3) and was 77% white, 6% African American, 7% Asian, and 10% other. Presenting complaints were classified as 58% urinary, 37% prolapse, and 5% defecatory. There was no difference in overall demographic information between those who completed the second round of questionnaires and those who did not. There was no difference in age between those who chose to complete the questionnaires via REDcap and those who chose to complete the questionnaires via smartphone. Correlation coefficients between questionnaire administration range from 0.5 to 0.8. There was no significant difference in the responses for each total scale and individual scale between the first or second administration.

Conclusions: We demonstrated moderate to strong reliability between scales of pelvic floor dysfunction administered electronically compared with paper version. Our results strongly suggest that it is feasible and reliable to administer pelvic floor questionnaires in an electronic format on REDCap and on smartphones.

Key Words: electronic questionnaire, pelvic floor questionnaires, PFDI, PFIQ, PISQ, validation

(*Female Pelvic Med Reconstr Surg* 2019;00: 00–00)

From the *Department of Obstetrics and Gynecology, New York Medical College, Valhalla, NY; †Division of Urogynecology, Department of Obstetrics and Gynecology, Houston Methodist Hospital, Houston, TX; ‡Department of Obstetrics and Gynecology, University of Arkansas for Medical Sciences, Little Rock, AR; §Department of Obstetrics and Gynecology, Columbia University Medical Center, New York, NY; ||Section of Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics and Gynecology, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada; ¶Department of Obstetrics and Gynecology, University of Wisconsin, Madison, WI; and **Department of Urology, Columbia University Medical Center, New York, NY.

Correspondence: Cara L. Grimes, MD, MAS, 19 Bradhurst Ave, Suite 2700 South, Hawthorne, NY 10532. E-mail: caragrimesmd@gmail.com.

The authors have declared they have no conflicts of interest.

Presented at the Society of Gynecologic Surgeons Annual Scientific Meeting, Orlando, Florida, March 2018.

ClinicalTrials.gov identifier: NCT02724891, registered on March 31, 2016.

Supplemental digital contents are available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.fpmrs.net).

DOI: 10.1097/SPV.0000000000000713

Health questionnaires are a form of patient-reported outcomes (PROs) commonly used in health care. Health questionnaires are often used as *intake* logs, discerning and recording the symptoms and severity of a problem at the time of presentation. Unfortunately, PRO forms are often underutilized or uninterpretable in clinical practice because they are collected on paper. A recent study by Berger and Schimpf[1] demonstrated that, even in a highly educated population, completion of a paper form of pelvic floor questionnaire was low. In a study by Movsas et al,[2] using web-based surveys increased the completion rate of quality-of-life assessments from 52% to 90%. As medicine strives to incorporate technology into its systems and practices, we have to consider how to collect data electronically while ensuring that this new format is equivalent to the paper questionnaires we rely on. In a meta-analysis by Gwaltney et al,[3] 46 unique studies evaluating 278 PRO scales were reviewed, and the authors noted that the mean difference between electronic and paper scales was 0.2%, indicating equivalence. Unfortunately, none of the validated scales were measures of pelvic floor dysfunction. Within urogynecology, PRO scales such as the Pelvic Floor Distress Inventory (PFDI), Pelvic Floor Impact Questionnaire (PFIQ), Bristol Stool Scale (BSS), Bladder Diaries, and others are used ubiquitously. Their impact, however, is diminished by poor compliance and recall bias.[4,5] The move toward electronic PRO measures would be endorsed by patients (who can track and interact with their own data), physicians (who can track progress and study group outcomes), and by regulators (who want to ensure accurate and reproducible data collection). Electronic PRO tools, particularly on the patient's own device, would allow for increased rate of reporting through mobile availability, automatic time stamping of data at the actual time of questionnaire completion to prevent recall bias, and reduction in data entry mistakes and costs.[6]

In this study, we tested our hypothesis that responses on electronically administered (web-based or smartphone) validated instruments of pelvic floor dysfunction would be comparable to responses on those same instruments when administered on paper. The original studies have each been validated on paper.[7–12] The methodology of electronic validation of multiple related PRO scales has been previously used for asthma scales.[13]

The objective of this study was to correlate responses on electronically administered (web-based and smartphone) validated instruments of pelvic floor dysfunction with responses on the same paper instruments.

MATERIALS AND METHODS

This prospective validation study was performed by the Collaborative Research in Pelvic Surgery Consortium. Columbia University Medical Center served as the data coordinating center. The protocol was approved by the Collaborative Research in Pelvic Surgery Consortium Steering Committee, and institutional review board approval was obtained from each of the 5 recruiting

centers (Houston Methodist Hospital [Pro00012984], University of Wisconsin [2015-0809], Columbia University Medical Center [AAAO8451], University of Arkansas for Medical Sciences [204332], and University of Calgary [REB17–1784]). CONSORT guidelines were followed (Supplemental Digital Content 1, http://links.lww.com/FPMRS/A73).

Women 18 years or older presenting to 1 of these 5 female pelvic medicine and reconstructive surgery (FPMRS) clinics seeking care for pelvic floor disorders were eligible for this study if no intervening treatment was planned for the 2 weeks between questionnaire completion. New or returning patients were eligible. Subjects were further excluded if they did not have access to a computer/web or a smartphone, if they were not fluent in English, or if they were pregnant. Demographic measures were collected, including age, body mass index (BMI), race, ethnicity, parity, education level, and presenting chief complaint.

Participants completed 4 validated pelvic floor dysfunction instruments: PFDI Short-Form (PFDI-20), PFIQ-7, Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12), and the BSS. Subjects were allocated via 1:1 random number blocks to either an initial paper or electronic questionnaire set. The randomization scheme was generated by using the Web site Randomization.com (seed 1553). A research coordinator or study personnel generated the random allocation sequence, enrolled participants, and assigned participants to interventions. Participants who had a smartphone (iPhone platform) and agreed to download the no-cost PelvicTrack App (Virtabot, Inc, www.virtabot.com, New York, NY) completed the questionnaires on their phone. Those who did not have a smartphone or were not willing to download the app completed questionnaires via web-based administration using REDCap (www.project-redcap.org). Subjects who were randomized to initially complete the electronic forms were either directly provided or mailed paper copies of the questionnaires and a self-addressed stamped envelope, and asked to wait 2 weeks before completing and mailing the paper questionnaire. Subjects received a reminder telephone call or email based on their preferred contact method approximately 2 weeks after initial completion. The second questionnaire set was administered prior to any treatment 2 or more weeks after completion of the first questionnaire set (Fig. 1). The primary outcome analyzed was the correlation between the paper and electronic administration of each pelvic floor questionnaire.

Pelvic Floor Distress Inventory

The PFDI is a commonly used PRO scale in the field of urogynecology and in our clinics.[8] It was designed to assess symptom distress in women with pelvic floor dysfunction. The short and long forms have demonstrated high correlation ($r > 0.86$). The short form consists of 20 items divided into 3 scales: Urinary Distress Inventory, Pelvic Organ Prolapse Distress Inventory, and the Colorectal-Anal Distress Inventory.

Pelvic Floor Impact Questionnaire

The PFIQ-7 is used to assess life impact in women with pelvic disorders.[8] The short form consists of 3 scales with 7 items each and correlates highly with the long form ($r > 0.90$). The 3 scales include Urinary Impact Questionnaire, Pelvic Organ Prolapse Impact Questionnaire, and Colorectal-Anal Impact Questionnaire.

Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire

The PISQ-12 is used to assess sexual function in patients who have pelvic organ prolapse and/or urinary incontinence.[9] The short form consists of 12 items and correlates highly with the long form ($r > 0.92$).

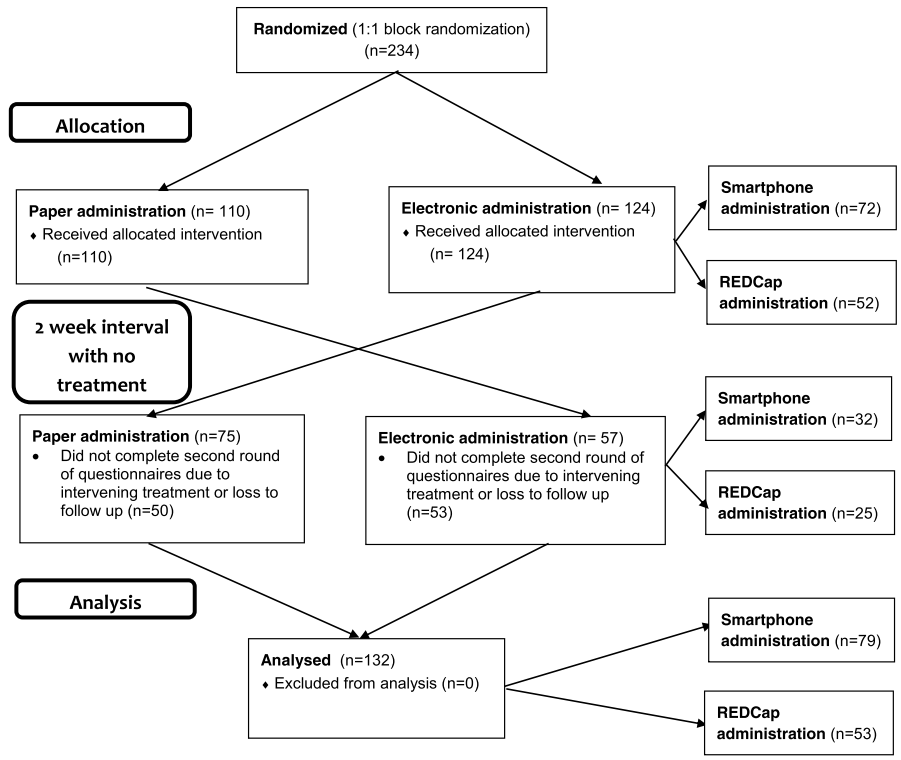

FIGURE 1. CONSORT flow diagram.

TABLE 1. Subject Demographics

Demographics	Randomized to Paper, Then Electronic (n = 110)	Randomized to Electronic, Then Paper (n = 124)	Overall	*P*
Age, y	56.1 (15.0)	57.9 (15.7)	58 (±15)	0.37*
BMI	27.6 (6.7)	28.9 (12.6)	28 (±6)	0.31*
parity	1 (1, 3)	2 (1, 3)	2 (1, 3)	0.32†
Race	77% White	72% White	77% White	0.37‡
	8% African American	14% African American	6% African American	
	7% Asian	2% Asian	7% Asian	
	7% Other	10% other	10% other	
Education level	0% Less than high school	4% Less than high school	2% Less than high school	0.112‡
	10% High school	8% High school	9% High school	
	28% Some college	22% Some college	24% Some college	
	26% College graduate	32% College graduate	29% College graduate	
	35% Graduate/professional	30% Graduate/professional	33% Graduate/professional	
	1% Unreported	4% Unreported	3% Unreported	
Presenting chief complaint	59% Urinary	56% Urinary	58% Urinary	0.250‡
	29% Prolapse	33% Prolapse	31% Prolapse	
	6% Defecatory	1% Defecatory	3% Defecatory	
	6% Other	10% Other	8% Other	

*Mean (SD), Student *t* test.

†Median (range), Mann-Whitney *U*.

‡Percentage, χ^2.

Bristol Stool Scale

The BSS was developed to classify human feces as a surrogate marker of colon transit time.[14] It is useful as a means of clinical communication and evaluating the effectiveness of treatments on "constipation" and defecatory dysfunction. Stool is divided into 7 types and represented graphically.

Prior validation metrics of the PFIQ-7 and PFDI-20 short forms compared with the long forms were used for the power calculation.[8] A sample size of 36 subjects in each arm (108 participants total) had more than 80% power to detect an effect size of 0.5 or greater with 0.05 two-sided significance. As we were recruiting when research assistants were available to recruit and targeting all new patients (before subjects had the option to elect interval treatment), our target enrollment was 216 patients to allow for a 50% dropout rate due to subjects electing interval treatment. Continuous variables were compared with paired and Student *t* test, and categorical values were analyzed with χ^2. Correlation coefficients were calculated using Pearson and Spearman tests, depending on the distribution of data. Statistical analysis was performed with SPSS (version 25, Chicago, Ill).

RESULTS

Two hundred thirty-four subjects were enrolled and randomized between August 2015 and March 2018. One hundred ten subjects completed the first administration on paper, and 124 were randomized to electronic administration, of which 72 completed the smartphone questionnaire and 52 on the web via REDCap. One hundred thirty-two subjects (56%) completed both sets of questionnaires with no intervening treatment and were analyzed. Of these, 79 completed the electronic questionnaires on the phone and 53 via REDCap (Fig. 1). Overall, subjects were 58 (±15) years old, with BMI of 28 (±6) kg/m^2 and parity 2 (1,3), and were 77% white, 6% African American, 7% Asian, and 10% other. This was a highly educated population, with 62% of subjects having graduated college or graduate school. Presenting complaints were classified as 58% urinary, 31% prolapse, 3% defecatory, and 8% other (recurrent urinary tract infections, hematuria, pelvic pain) (Table 1). There was no difference in overall demographic information between those who did and did not complete the second round of questionnaires and those who completed the electronic version of the questionnaires on the smartphone versus REDCap. There was no difference in age between those who chose to complete the electronic version via REDCap and those who chose to complete the electronic version via smartphone. In addition, there was no difference in completion rate between those who chose to do the electronic questionnaires on the phone and those who chose to do the electronic questionnaires via REDCap.

Overall mean/median scores and correlation coefficients between the paper and electronic total and subscales are shown in Table 2. Correlation coefficients range from 0.5 to 0.8. There was no significant difference in the responses for each total scale score and subscale scores for the PFDI and PFIQ between time points (first or second administration). There was no difference in total scores for each questionnaire between those who completed the questionnaires on the smartphone and those who completed the questionnaires via REDCap.

DISCUSSION

Our multicenter consortium successfully recruited and retained participants to reliably validate electronic pelvic floor dysfunction PROs. We demonstrated moderate to strong reliability between these electronic and paper questionnaires. The electronic and

TABLE 2. Questionnaire Scores and Correlation Between Paper-Based and Electronic Administration

Questionnaire	Questionnaire Score Mean (SD) or Median (25%ile, 75%ile)	Correlation Between Paper and Electronic Version (*r*, *P*)
PFDI-20		
Total score	77.5 (47.6)	0.74, <0.001*
Pelvic Organ Prolapse Distress Inventory	22.2 (18.8)	0.67, <0.001*
Colorectal-Anal Distress Inventory	16.8 (15.5)	0.66, <0.001*
Urinary Distress Inventory	32.5 (23.5)	0.77, <0.001*
PFIQ-7		
Total score	48.9 (51.7)	0.63, <0.001*
POPIQ	11.7 (18.1)	0.50, <0.001*
CRAIQ	11.3 (19.4)	0.68, <0.001*
UIQ	25.9 (24.8)	0.72, <0.001*
PISQ-12	18.1 (16.4)	0.86, <0.001*
BSS	4 (3,4)	0.58, <0.001†

*Pearson.
†Spearman.

paper versions of the PFDI-20 and PISQ were strongly correlated with *r* values of 0.74 and 0.86, respectively. The paper and electronic versions of the PFIQ-7 and BSS were moderately correlated with *r* values of 0.63 and 0.58, respectively. Our results are similar to those of 2 prior authors who demonstrated strong correlation between paper-based and electronic administration of the PISQ-12 and the PFIQ-7,[15,16] Parnell et al[15] looked at 52 women who completed both a web-based and paper-based version of the PISQ-12. They demonstrated a correlation of 0.88 between web-based and paper. Additionally, they found that women preferred the web-based administration. Sun et al[16] looked at 68 women who completed a paper and then crossed over to a WeChat version of the PFIQ-7. They demonstrated a correlation of 0.9 between formats. Additionally, they investigated completion times and subject preference for the formats and found no difference.[15] Our study is unique in that it also demonstrates correlation between paper-based and electronic administration of the PFDI-20 and BSS. Further, we specifically looked at the commonly used REDCap database and the use of smartphone to complete questionnaires. By expanding the platforms that women can complete these validated questionnaires, our hope is to have an impact of ease of use, access, completion rates, and patient satisfaction. As Berger and Schimpf[1] demonstrated, even in a highly educated population, completion of a paper form of pelvic floor questionnaire was low. Having validated questionnaires available in other formats may help us increase completion rates.

The BSS was the lowest correlated questionnaire in our study. It is possible that this is due to variations that can occur in subject's stool consistency irrelevant to the correlation of the electronic questionnaire.

There are several strengths to our study. This was a randomized multicenter study following CONSORT guidelines including 5 different FPMRS practices across the United States and Canada, which provides a representative sample of the population of women seeking care for pelvic floor disorders. A diversity of presenting pelvic floor complaints was seen. A second strength of the study was that the a priori sample size was reached. Third, we achieved a good response rate of 56% for the completion of both sets of questionnaires. Lastly, we evaluated 2 forms of electronic questionnaires: smart phone application and computer-based REDcap.

There are limitations to our study, which include the study population's mean age was 58 years, thus potentially representing a younger patient population who may be more familiar with electronic devices. It is possible that older women presenting to these clinics self-selected not to participate, creating a selection bias. However, moving forward this may not be as much of a concern as our younger, more electronically savvy patients age and move into an older cohort and close the disparity gap in electronic literacy. A prior multicenter survey of women presenting to urogynecologists revealed the majority of women desire use of the internet or social media to learn more about their pelvic floor disorders.[17]

Our data suggest that it is feasible and reliable to administer commonly used validated pelvic floor questionnaires in an electronic format via a web-based interface or on a woman's cell phone or tablet. This may allow FPMRS specialists to utilize current technology to better capture patients' responses on an up-to-date instrument that is current and to provide a more accessible and simpler interface to help improve patient satisfaction.

ACKNOWLEDGMENTS

The authors thank Jules Geynisman, MD; Heidi Brown MD, MAS; Nisha Philip; Jillian Vaughan; Carrie Derkowski; Anjali Vardhan, PharmD; and Evelyn Hecht, PT, ATC.

REFERENCES

1. Berger MB, Schimpf MO. Completion of a validated pelvic floor symptom and bother instrument in real-life practice. *Int Urogynecol J* 2018;29(12): 1841–1844.
2. Movsas B, Hunt D, Watkins-Bruner D, et al. Can electronic web-based technology improve quality of life data collection? Analysis of Radiation Therapy Oncology Group 0828. *Pract Radiat Oncol* 2014;4 (3):187–191.
3. Gwaltney CJ, Shields AL, Shiffman S. Equivalence of electronic and paper-and-pencil administration of patient-reported outcome measures: a meta-analytic review. *Value Health* 2008;11(2).
4. Wyman JF, Choi SC, Harkins SW, et al. The urinary diary in evaluation of incontinent women: a test-retest analysis. *Obstet Gynecol* 1988;71: 812–817.
5. Fischer K, Bliss DZ, Savik K. Comparison of recall and daily self-report of fecal incontinence severity. *J Wound Ostomy Continence Nurs* 2008;35(5): 515–520.
6. Coons SJ, Eremenco S, Lundy JJ, et al. Capturing patient-reported outcome (PRO) data electronically: the past, present, and promise of ePRO measurement in clinical trials. *Patient* 2015;8(4):301–309.
7. Avery K, Donovan J, Peters TJ, et al. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *NeurourolUrodyn* 2004;23(4):322–330.
8. Barber MD, Walters MD, Bump RC. Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). *Am J Obstet Gynecol* 2005;193(1):103–113.
9. Rogers RG, Coates KW, Kammerer-Doak D, et al. A short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). *Int Urogynecol J Pelvic Floor Dysfunct* 2003;14(3):164–168 discussion 168.

10. Bright E, Cotterill N, Drake M, et al. Developing and validating the international consultation on incontinence questionnaire bladder diary. *Eur Urol* 2014;66(2):294–300.
11. Srikrishna S, Robinson D, Cardozo L. Validation of the Patient Global Impression of Improvement (PGI-I) for urogenital prolapse. *Int Urogynecol J* 2010;21(5):523–528.
12. Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. *Am J Obstet Gynecol* 2003; 189(1):98–101.
13. Bushnell MA, Martin ML, Parasuraman B. Electronic versus paper questionnaires: a further comparison in persons with asthma. *J Asthma* 2003;40(7):751–762.
14. Lewis SJ, Heaton KW. Stool form scale as a useful guide to intestinal transit time. *Scand J Gastroenterol* 1997;32(9):920–924.
15. Parnell BA, Dunivan GC, Connolly A, et al. Validation of web-based administration of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12). *Int Urogynecol J* 2011;22(3):357–361.
16. Sun ZJ, Zhu L, Liang M, et al. The usability of a WeChat-based electronic questionnaire for collecting participant-reported data in female pelvic floor disorders: a comparison with the traditional paper-administered format. *Menopause* 23(8):856–862.
17. Mazloomdoost D, Kanter G, Chan RC, et al. Social networking and Internet use among pelvic floor patients: a multicenter survey. *Am J Obstet Gynecol* 2016;215(5):654.e1–654.e10.