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The Pelvic Floor Disorders Registry (PFDR): Study Design and Outcome Measures

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Abstract

Pelvic floor disorders affect up to 24% of adult women in the United States and many patients with pelvic organ prolapse (POP) choose to undergo surgical repair to improve their quality of life. Population-based projections anticipate a 35% increase in demand for pelvic floor healthcare services over the next 30 years. While a variety of surgical repair approaches and techniques are utilized, including mesh-augmentation, there is limited comparative effectiveness and safety outcome data guiding best practice. In response to adverse events associated with the use of transvaginal mesh for prolapse repairs, the Food and Drug Administration (FDA) conducted an investigation into the safety and efficacy of mesh, which resulted in new requirements for post-market surveillance studies to be performed by transvaginal mesh device manufacturers. In conjunction with device manufacturers, federal regulatory organizations and professional societies, the American Urogynecologic Society (AUGS) developed a Pelvic Floor Disorders Registry (PFDR) designed to improve the quality of care of POP surgery by serving as a data repository for the FDA-mandated studies as well as provide a resource for surgeons interested in benchmarking and outcomes data. All data elements including adverse events and surgeon characteristics were chosen within the context of the anticipated multi-functionality of the registry, and with collaboration from the multiple stakeholders. The PFDR aims to provide the opportunity to examine the outcomes from varied treatment modalities available for the treatment of pelvic organ prolapse, including surgical and non-surgical (pessary), and ultimately to improve the quality of care for women with this and other pelvic floor conditions.

Keywords: registry, urogynecology, mesh

Classification: Surgery for prolapse, mesh use in pelvic floor repair, mesh complications

Comments:

Introduction

Pelvic floor disorders (PFD) are a group of interrelated clinical conditions that include urinary incontinence (UI), sensory and emptying abnormalities of the lower urinary tract, pelvic organ prolapse (POP), fecal incontinence and defecatory dysfunction. Population data from 2008 estimated that pelvic floor disorders affect 24% of adult U.S. women and that the prevalence increases with age.¹ Approximately one in nine women will undergo surgery for UI and/or POP by age 60, increasing to one in five by age 80, with 30-40% of those women undergoing two or more surgical procedures.² As the U.S. population continues to age, current estimates predict that the need for PFD healthcare services will increase by 35% over the next 30 years.^{3,4}

Non-surgical and surgical treatment options exist for a variety of PFDs, however prospective, systematic collection of data on the safety and effectiveness of treatment options is lacking. For POP, many surgical treatments are available including transvaginal native-tissue (non-mesh) repairs, transvaginal mesh-augmented repairs and abdominal repairs (sacral colpopexy) using mesh or biologic graft which can be performed via laparotomy, or via laparoscopy with or without robotic assistance. Many Female Pelvic Medicine and Reconstructive Surgery (FPMRS) specialists incorporate multiple different surgical approaches in their practice, tailoring the specific technique to the individual patient and her unique characteristics and preferences. However, there is currently no consensus regarding which surgical approach is superior or what patient characteristics predict success or failure. Importantly, each surgery has its own risk-benefit profile.

Reinforcement of vaginal repairs with biologic or synthetic mesh has been adopted by many surgeons in the hope of improving effectiveness and durability of this approach. From 2005-2010, roughly 1/3 of all prolapse repairs utilized mesh with 75% of meshes being placed via the transvaginal approach.⁵ In response to reports of adverse events associated with transvaginal mesh for POP, the FDA conducted a systematic review of the published scientific literature to evaluate the safety and effectiveness of vaginal mesh and convened a meeting of the Obstetrics-Gynecology Devices Panel of the Medical Devices Advisory Committee.⁶⁻⁹ In a December 2011 Committee Opinion on Vaginal Placement of Synthetic Mesh for POP, the American Urogynecologic Society (AUGS) and American College of Obstetrics and Gynecology (ACOG) also issued a number of recommendations including strong support for continued audit and review of outcomes, as well as the development of a registry for surveillance for all current and future pelvic floor mesh implants.¹⁰ In January 2012, following the FDA Panel's recommendation, the FDA ordered manufacturers of transvaginal mesh products for POP to conduct post-market surveillance under Section 522 of the Federal Food, Drug and Cosmetic Act (i.e., "522 order").

To support the recommendations from AUGS and ACOG and to provide a database to track POP treatment outcomes using standardized assessments, the AUGS Pelvic Floor Disorders Registry (PFDR) was developed. The PFDR is primarily aimed at improving the quality of care of POP surgery by tracking the outcomes and providing national benchmark data for POP surgical procedures using mesh (either vaginal or abdominal) and native tissue vaginal and abdominal repairs; however, it can also assess outcomes related to non-surgical management (e.g., pessary). The PFDR data-collection platform was developed through a collaborative

process and public/private partnership with stakeholders including the FDA, NICHD, ACOG, PFDRN Advisory Panel, SUFU, AUA, and several medical device manufacturers. (Abbreviation definitions provided in Table 1.) The PFDR “structure” includes a POP treatment registry in which surgeons volunteer to enroll patients and participate at one of two levels, either the “Quality Improvement” dataset (PFDR-QI) or the “Quality & Research” dataset (PFDR-QR). The QR dataset includes all items within the QI dataset as well as additional components of interest to researchers. The overarching PFDR structure provides a means of data collection for quality improvement and for research and provides a data collection platform for industry-sponsored POP surgery clinical studies using the “Industry Supported” branch of the registry (PFDR-IS) (Table 2). A more detailed description of the PFDR structure and its levels of participation, including QI, QR and IS, are published elsewhere (Bradley et al, submitted to FPMRS). Perhaps most importantly, the PFDR structure provides a means for individual surgeons/sites to have ongoing data collection for quality measure tracking and benchmarking and, perhaps in the future, maintenance of certification (MOC) support. The aim of this report is to describe the registry design and methods, focusing on the QI and QR components of the PFDR.

Methods

The PFDR is a nation-wide, multi-center prospective cohort study that includes women undergoing treatment for POP with or without other PFD. The PFDR uses a secure, web-based platform for data collection. Overall, the PFDR is designed to collect provider and patient reported outcomes through broad participation from specialists and generalists performing surgery for prolapse. The objectives and rationale for the PFDR have been described elsewhere in more detail (Bradley C, submitted to FPMRS).

The PFDR was developed by AUGS Registry Steering and Scientific Committees, in conjunction with experts representing other professional organizations, federal agencies and private industry (listed above). Registry development was an iterative process between 2012-2015, conducted through weekly conference calls and periodic in-person meetings. Validated outcome measures were reviewed and selected by the committee and its workgroups, based on content, use in the literature, and burden to the provider (time to complete and complexity of the measure). In topic areas lacking validated instruments feasible for inclusion, the committee modified or developed new items to assess important outcomes related to treatment effectiveness, symptom-specific and generic health-related quality of life, and safety associated with both surgical and non-surgical therapy.

Registry Participation and Patient Population

Provider/site and patient participation in the PFDR is voluntary. Health care providers who treat POP will be encouraged to participate, including gynecologists, urologists, and/or FPMRS specialists (both urogynecologists and female urologists). In addition, providers in all settings, including academic, hospital or system-based, and private practice settings will be included. Each PFDR site (a self-selected group of surgeons/providers) will elect to enroll patients into either the Quality Improvement or Quality & Research level of the registry. In addition to participating in either the QI or QR studies, individual sites may also contribute to industry-sponsored (IS) studies contained within the PFDR. Sites that choose to participate in IS studies will segregate those patients from their QI/QR cohorts, as an individual patient can only participate in a single level of the PFDR registry at any one time. Once an IS study has been closed, those patients may then continue their contribution to the PFDR through either QI or

QR together with their provider. In the event that a patient-provider relationship ends, the patient will be able to continue contributing to the registry, either independently or together with a new PFDR-member provider.

The PFDR was developed specifically to allow the capture of safety and effectiveness data within the context of a pragmatic study design so as to capture diverse, “real-world” POP treatment settings. Thus, the inclusion criteria are broadly defined (Table 2) to include any woman choosing surgery or pessary treatment for POP. (It should be noted that inclusion/exclusion criteria for IS studies being performed through the PFDR are study-specific and more restrictive.) This population of the PFDR may be expanded at a later date to include patients receiving treatment for UI alone and other PFDs. All POP treatments captured in the registry will be classified using procedure definitions outlined in Table 3. Clinical data will be collected prior to initiating treatment (baseline) and post-operatively, according to the standard of care set by the participating site. PFDR-QI data collection is a quality improvement activity, which will allow individual sites to improve patient care, by providing a means of collecting, summarizing, analyzing and benchmarking their clinical outcomes. These quality improvement activities do not meet the definition of human subject’s research and, as such, do not require IRB review or patient informed consent. In contrast, PFDR-QR does include research objectives and will require IRB review and patient completion of a written informed consent document prior to enrollment.

PFDR Data Elements and Assessment Time-points

Data collection within the PFDR includes a surgeon enrollment form containing surgeon and hospital profile information (collected when a surgeon first joins the registry and updated

yearly thereafter) and baseline and follow-up patient clinical and surgical data (entered by the surgeon/site representative). Whereas the PFDR-QI is limited to surgeon-reported variables within standard follow-up schedules, the PFDR-QR also collects baseline and follow-up symptom and QOL information obtained directly from patients (see Tables 5 and 6). Office evaluation by the surgeon (or staff) including anatomic outcome assessment will occur in the early postoperative or post-treatment period (typically 4 to 12 weeks after surgery or pessary placement) and at additional scheduled postoperative visits up to 3 years post-treatment for FDA-mandated post-market surveillance studies or longer as determined by the surgeons' practice pattern. Data collected from scheduled post-treatment and non-scheduled problem-focused visits will be collected and each visit classified as 2, 6, 12, 18, 24 or 36 month (or unscheduled) visits based on visit date (as required in "522" studies), to allow comparison of outcomes at similar follow-up times. All assessments for sites participating in either the QI or QR are to be performed at the time of a routine clinical encounter, by referencing the medical record. In addition, several quality measures currently approved by CMS/NQF are included as well as POP-specific quality measures currently under review or development by the AUGS Quality Committee.

In addition to an expanded clinical dataset, the PFDR-QR automates solicitation of baseline and follow-up data from patients directly, regardless of continuity of care with the primary surgeon using a variety of validated instruments (see Table 7), which will comprise the electronic Patient Reported Outcomes (ePRO) component of the registry. Links to a secure, HIPAA compliant and web-based data entry portal will be e-mailed patients, who can enter data at home or using computer kiosks at provider offices, where available. Combined with standard

post-treatment clinical care, ePRO will provide the essential validated symptom-specific distress and impact questions important for patient-centered outcomes assessments following treatment of POP.

Definitions of Treatment Success and Failure

Patients enrolled in the PFDR are classified as having POP in the anterior, posterior and/or apical vaginal compartments based upon the anatomic criteria shown in Table 8. Providers may elect to use their preferred prolapse assessment scales in QI (including Baden-Walker), whereas the POP-Q: Pelvic Organ Prolapse Quantification system is required for QR.¹¹ These classifications are not mutually exclusive and it is expected that many patients in the registry will have POP in more than one compartment. The criteria for success following treatment of POP was selected with the guidance of the recommendations of the Committee on Pelvic Organ Prolapse Surgery, part of the 5th International Consultation on Incontinence (Paris, February 2012) and is outlined in Table 9.¹² Based on recent re-analysis of previous surgical outcome cohorts, specific attention was given to composite determination of success, incorporating anatomic, patient-reported and retreatment definitions.^{13,14}

Secondary outcome effectiveness measures used to evaluate treatments for POP include compartmental anatomic success, time to anatomic and symptomatic prolapse recurrence, changes in urinary and sexual function, patient global impression of improvement and rates of surgical intervention. Additional effectiveness and QoL outcome measures utilized in the QR focus on pain (pelvic, vaginal and vulvar) and changes in global and condition-specific QoL (see Table 7).

The PFDR safety endpoints for patients undergoing surgical intervention for POP were developed and defined in collaboration with partnering device manufacturers and the FDA and are based on endpoints required for collection by the FDA in the post-market mandated 522 studies. Safety outcomes will include the frequency of treatment-related adverse events (AE), including both intra-operative and early (≤ 12 weeks) postoperative AE, as well as long-term AE related to the index treatment for those patients managed surgically. AE outcomes will be captured both through provider and patient reporting, and each post-treatment endpoint will be classified using a modified Clavien-Dindo classification [Dindo2004]. The complete list of safety endpoints and definitions included in the PFDR QI and QR datasets can be found in Appendix A.

Data Reporting

The main findings of the PFDR will be reported in an annual PFD Registry Report and posted on the registry website. Status (e.g., enrollment statistics) and benchmarking reports will be provided periodically to participating sites and stakeholders. Registry Reports represent aggregate efficacy and safety data for the following categories of treatment: 1) Transvaginal Native Tissue; 2) Transvaginal Mesh Procedures – Permanent Synthetic; 3) Transvaginal Mesh Procedures - Biologic; 4) Sacrocolpopexy and 5) Obliterative Repairs and 6) Pessary. Within each category, data will be presented by anatomic prolapse compartment at enrollment: Anterior, Posterior, and Apical. Descriptive analyses may be performed to present qualitative and quantitative data on the population characteristics, procedures/treatments performed, and treatment outcomes. Where common data elements exist, the QI and QR data can be presented in aggregate. Participating sites have real-time access only to their own data and to

individualized benchmarking reports through the online registry portal. Data from the post-market surveillance studies will not be included in the Registry Report; the results of industry sponsored studies will be published independently and reported on the FDA website.

Discussion

Pelvic floor disorders represent an increasing public health concern and there is increasing need for systematically collected quality data upon which to develop valuable research that will then drive informed clinical decisions. Comparative effectiveness, safety data and long-term outcomes for many surgical techniques that have gained significant popularity in the past few years including sacral colpopexy using laparoscopic and robotic approaches and transvaginal mesh kits are sparse. In the current climate of reduced federal research funding and the tremendous cost associated with traditional randomized controlled trials, alternative systematic data collection methods from large datasets must be utilized.

Quality improvement strategies in healthcare hinge on coordinated efforts between individual caregivers, patients and large health systems and have recently begun to utilize a combination of government-driven incentives to promote reporting of quality information. The Physician Quality Reporting System PQRS program within the Centers for Medicare and Medicaid Services (CMS) has incorporated a registry-reporting method and the PFDR has become Qualified Clinical Data Registry (QCDR) certified which will further facilitate the collection of meaningful quality outcome measures. Development, testing, approval and implementation of individual measures unique to pelvic floor disorders are ongoing through mechanisms put in place and administered by CMS. PQRS requirements, which serve as the basis of this reporting, can change annually and will require continued adaptation. For CY 2015

reporting period, CMS is proposing that physicians report on 9 measures, two of which are cross-cutting to avoid the penalty. The further development of a QCDR as a specific mechanism of quality reporting is a new concept for CMS and the requirements are continuing to evolve, monitored closely and addressed by the PFDR Steering and Scientific Committees. The earliest expected date to begin quality reporting through the registry would be CY 2016.

On a local scale, PFDR benchmarking data will inform individual surgeons and their respective health systems of their own outcomes relative to numbers of cases, post-operative visits and immediate surgical complications. In a necessary trade-off for project feasibility, the PFDR-QI allows participating providers to engage in follow-up surveillance at their own discretion and provides a platform for maintaining surgical case logs for trainees. Those participating in the PFDR-QR will also offer long term benchmarking on delayed adverse events and treatment outcomes. This data provides opportunities for growth and the choice to offer transparency now expected by patients. It is anticipated that participation in the PFDR will assist providers in meeting their clinical care requirements of MOC.

The PFDR is a voluntary, prospective collection of baseline and longitudinal data for patients with pelvic floor disorders undergoing POP treatment and promises many benefits to patients, surgeons and researchers. The use of condition-specific validated questionnaires for patient-reported outcomes will provide an essential correlate between quality of life indicators and objective measures of treatment outcome. The PFDR will allow valuable comparative analysis of surgical and non-surgical treatments, as well as information on patient selection and surgeon-specific treatment algorithms. It will allow providers to easily track and retrieve information about their surgical volume and patient characteristics. The benchmarking feature

will allow participating surgeons to perform private, periodic self-assessment, so critical to quality improvement, especially as it relates to adverse events and rare patient events. The FPMRS research community will be able to identify modifiable and non-modifiable risk factors associated with complications and effectiveness of PFD treatments. The PFDR will capture comprehensive data including elements required by the FDA for post-marketing surveillance of transvaginal mesh use in POP. Finally, it will function as a resource for additional PFD research, whereby stakeholders and participants may propose and conduct analyses of registry data.

The PFDR is a collaborative effort of pelvic reconstructive surgeons, guiding stakeholders from multiple organizations, industry collaborators, and database development experts to create a patient-centered registry for women undergoing POP treatment. The Registry aims to provide the opportunity to examine the outcomes from varied treatment modalities available for the treatment of pelvic organ prolapse and ultimately to improve the quality of care for women with this and other pelvic floor conditions.

REFERENCES

1. Nygaard I, Barber MD, Burgio KL, et al. Prevalence of symptomatic pelvic floor disorders in US women. *JAMA* 2008;300:1311-6.
2. Wu JM MC, Conover MM, Pate V, Jonsson Funk M. Lifetime Risk of Stress Urinary Incontinence or Pelvic Organ Prolapse Surgery. *Obstet Gynecol* 2014;123:1201-6.
3. Kirby AC, Luber KM, Menefee SA. An update on the current and future demand for care of pelvic floor disorders in the United States. *Am J Obstet Gynecol* 2013;209:584 e1-5.
4. Vincent GK VV. The next four decades, the older population in the United States: 2010 to 2050. Washington (DC): US Census Bureau 2010.
5. Jonsson Funk M, Edenfield AL, Pate V, Visco AG, Weidner AC, Wu JM. Trends in use of surgical mesh for pelvic organ prolapse. *Am J Obstet Gynecol* 2013;208:79 e1-7.
6. Food and Drug Administration. Executive summary: surgical mesh for the treatment of women with pelvic organ prolapse and stress urinary incontinence.
7. Food and Drug Administration. Urogynecologic surgical mesh: update on the safety and effectiveness of transvaginal placement for pelvic organ prolapse.
8. Food and Drug Administration: Medical Devices: Urogynecologic Surgical Mesh Implants.
9. Food and Drug Administration. Safety communication: update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. 2011.
10. ACOG & AUGS Committee Opinion: Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse. 2011.
11. Bump RC, Mattiasson A, Bo K, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol* 1996;175:10-7.
12. Barber MD, Maher C. Epidemiology and outcome assessment of pelvic organ prolapse. *Int Urogynecol J* 2013;24:1783-90.
13. Barber MD, Brubaker L, Nygaard I, et al. Defining success after surgery for pelvic organ prolapse. *Obstet Gynecol* 2009;114:600-9.
14. Chmielewski L, Walters MD, Weber AM, Barber MD. Reanalysis of a randomized trial of 3 techniques of anterior colporrhaphy using clinically relevant definitions of success. *Am J Obstet Gynecol* 2011;205:69 e1-8.

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