



A longitudinal qualitative evaluation of patient perspectives of adverse events after pelvic reconstructive surgery

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Abstract

Introduction and hypothesis Patient perception of adverse events (AEs) after pelvic floor disorder surgery is incompletely understood and may differ from providers' views of AEs. Our objective is to describe patient perceptions of AEs related to pelvic floor disorder surgery and how perceptions change over time.

Methods Mixed-method study of longitudinal patient interviews and surveys. Women planning pelvic floor disorder surgery completed three one-on-one interviews: preoperatively (< 12 weeks before surgery), 6–8 weeks postoperatively, and 6 months postoperatively. Interviews explored the patient experience of surgery and their perception of AEs over time. Participants ranked self-identified AEs by severity. De-identified transcripts of audio recordings were coded and analyzed using an iterative, thematic, team-based process using NVivo software (QSR International).

Results Twenty women each completed three separate interviews for a total of 60 interviews. Their mean age was 55.3 (\pm 12.7) years, and 50% were Non-Hispanic white. Women's perceptions of AEs changed as more time passed from surgery. Women identified potential problems related to surgery such as anesthesia complications, pain, injury, catheter issues, and an unsuccessful surgery as the most concerning AEs preoperatively. Postoperatively (6–8 weeks), women expressed concern about functional outcomes (e.g., performing daily activities, symptom reduction). Late postoperatively (6 months), the majority identified unsuccessful surgery, incontinence, and sexual dysfunction as severe AEs. These findings are consistent with prior work that suggests women perceive functional outcomes as fundamental to their recovery.

Conclusions These findings contribute to a more nuanced understanding of patient-centered perspectives on AEs. Patients view poor functional outcomes as severe AEs.

Keywords Pelvic floor disorders · Surgical adverse events · Qualitative mixed method study · Functional outcomes

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Introduction

In women with pelvic floor disorders, overall patient satisfaction is linked to the patient's experience of and perspective on surgical complications [1–3]. It follows that value-based care requires focus on the patient's perspective on their surgical experience. Surgical adverse events (AEs), as defined by standard medical classifications, are uncommon and may range from 3 to 17% in pelvic floor surgery [4–6]. A frequently used scale to describe AEs is the Clavien-Dindo scale, which was created by surgical experts but did not incorporate the patient perspective [7, 8]. Similarly, The Pelvic Floor Complication Scale is a condition-specific complication scale that did not include patient perspectives in development [9]. It is likely that surgeon views of AEs differ from patients', and the limited patient-level data available were obtained from a

homogeneous population that does not represent the patient population at large [10]. Therefore, identification of the patient perception of AEs is critical, especially as the field of clinical medicine turns its attention to quality, value-based, and patient-centered care.

Definitions of successful pelvic floor disorder surgery now focus on both subjective and objective outcomes. Given that functional outcomes such as incontinence symptoms and sexual function are increasingly important to patients when determining the success of their surgery, understanding patient views of AEs following surgery is needed. We conducted prior research that found patients undergoing surgery for pelvic floor disorders view failure to achieve a successful functional outcome as an AE [11]. The prior work interviewed different women at varied time points both before and after their index surgery but did not follow the same women longitudinally over time. The primary aim of this study was to longitudinally examine how patients view surgical AEs over time and explore how such perspectives may change from the preoperative period to 6 months after surgery.

Materials and methods

This mixed-methods longitudinal study was conducted at the University of New Mexico with approval from the Human Research Review Committee (HRRC 15–129). We used a revised conceptual framework from our prior work to create a semi-structured interview guide [11]. This guide explored what concerns patients had prior to undergoing surgery for pelvic floor disorders, what they considered an adverse event, and how they obtained information about complications and risks of surgery.

All English-speaking adult women planning to have urinary incontinence and/or pelvic organ prolapse surgery were invited to participate. Each participant participated in three interviews by the same trained research coordinator. Interviews occurred preoperatively (up to 12 weeks before surgery), immediately postoperatively (6–8 weeks), and late postoperatively (6 months). Based on qualitative methodology to obtain saturation, we planned to interview 20 women over three time points, for 60 total interviews. All women underwent standard preoperative counseling prior to their surgery.

Throughout the interview, the coordinator recorded all AEs (anticipated or experienced) reported by the participant. At the end of the preoperative interview, the coordinator asked participants to group the identified AEs into categories of “not severe,” “moderately severe,” and “very severe.” Participants also received a list of AEs identified by providers from our prior work [16] to ensure that all patients were aware of what providers consider AEs as a basis for contemplation and expansion of their list as they deemed necessary. At 6–8 weeks postoperatively and 3 month postoperatively, the coordinator recorded AEs identified

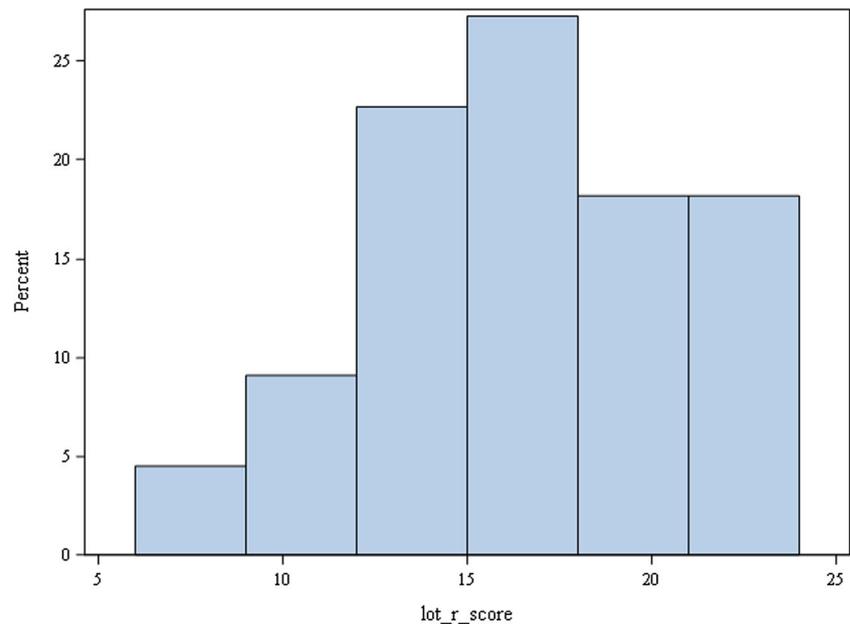
by the participant again. To stimulate reflection during the qualitative interviews, the coordinator showed participants the list they generated at their prior interview and then asked if they would change their AE ranking or add any AEs.

At each time point, participants completed a variety of questionnaires prior to the interview. At the preoperative interview, we obtained demographic information, the Pelvic Floor Distress Inventory Questionnaire-Short Form 20 (PFDI 20) [12], and the Life Orientation Test-Revised (LOT-R) [13], an assessment of optimism. The LOT-R is a continuous score ranging from 0 to 24. Standard cutoff definitions of an optimist or pessimist do not exist; however, some researchers have designated categories: low optimism (score 5.0–15.0), medium optimism (score 15.1–17.9), and high optimism (score 18.0–24.0) [14]. For the 6–8-week and 6-month postoperative interviews, participant’s completed the PFDI 20 as well as the Patient Global Impression of Improvement (PGI-I) [15], the Satisfaction with Decision Scale-Pelvic Floor Disorders (SDS-PFD), and the Decision Regret Scale-Pelvic Floor Disorders (DRS-PFD) [16]. We administered these questionnaires in order to describe the cohort’s overall symptom bother and sense of improvement.

All interviews were audio recorded and transcribed. Data collection was iterative and continued until we reached data saturation. Members of the research team with qualitative experience (GD, HRB, AS) jointly reviewed and coded transcripts until a coding template was finalized. The primary analyst (HRB) coded the remaining transcripts in NVivo (QSR International) and frequently met with the qualitative team for troubleshooting and discussion of emerging themes. Upon coding completion, we queried the NVivo database, explored cross-sectional and longitudinal relationships across themes/codes, created descriptive reports and summaries, and identified trends across groups and topics to detect differences among interviews.

Results

From October 2017 through January 2018, we recruited 20 women who underwent surgery. Each participant completed all three interviews, for a total of 60 interviews. Participants’ mean age was 55.3 (\pm 12.7) years, 50% (n = 10) were non-Hispanic white, 25% (n = 5) were Hispanic, and 25% (n = 5) were American Indian. The majority (75%) had a college degree or higher. Participants underwent a broad variety of surgeries offered for pelvic floor disorders that included both minor procedures (e.g., mid-urethral slings, sacral neuromodulation) as well as major surgeries (e.g., vaginal native tissue repairs, laparoscopic hysterectomy). Participants were evenly distributed for optimism categories (Fig. 1), and all demonstrated improvement in pelvic floor symptoms with low decisional regret after surgery (data not shown).

Fig. 1 Distribution of optimism scores of all subjects

We found that women’s perceptions of AEs changed as more time passed from surgery (Table 1). Women identified potential problems related to surgery, anesthesia complications, pain, and catheter issues as most concerning in the preoperative period. In the postoperative interview period, concerns increased around functional outcomes, such as performing routine daily activities, sexual activity, and symptom reduction. In the 6-month postoperative interview, the majority of participants identified unsuccessful surgery, incontinence, and sexual dysfunction as severe AEs (Fig. 2). These findings are consistent with our prior work that suggests women perceive these functional outcomes as fundamental to their recovery. In circumstances where these goals are not achieved, patients consider this failure as a severe AE (Table 1).

Additionally, we explored how participants felt about communication surrounding the surgery. Women spoke most about the need for more information about what happens immediately post-surgery, both in the hospital and shortly after they go home.

- “Having a list of recovery expectations, exactly what I’m supposed to do or not do, bulleted... When I do get to start driving again? When am I up taking the kids around? When do I get to lift something? Am I supposed to lay in bed the whole day or do they want me walking around the block?... Like, you should be able to get up long enough to prepare dinner by this amount of time... if you feel like this then you did too much, sit down.”

Other suggestions included more information about how long they will be in the hospital, specific instructions about medication (types, when to use, and how long to use), how much pain they will experience, how long the recovery process will take, what they will be able/unable to do at home, and emphasizing the need

for rest. Similarly, women wanted more information about what to expect long-term, including the need for another surgery and how their sex life may be affected.

Furthermore, participants expressed wishes for more visual and written information. For example, many said they would have liked to see the list of AEs that we provided in the interview, before making a decision about surgery. “If I would have seen that list before, I don’t know, I probably would have thought about it longer.” Some said they received good written information, but would have liked to get it sooner. “A lot of the information that was on my discharge paperwork, that might have been helpful to get in advance as well so you can actually read it when you’re not on drugs, and maybe have it posted up on your fridge or somewhere you’ll actually be able to find it when you need it.”

Lastly, although not the main focus of this study, many participants were confused about what the consent process was and whether they even signed a consent. When we asked about how the consenting process could be improved, many people did not recall such interactions with a healthcare provider.

- “The consenting process, what do you mean by that?”
- “I can’t remember if I signed any consents before being admitted or not.”

Discussion

We found that patients view failure to achieve anticipated functional goals as severe AEs and the AEs women identified shifted to functional outcomes over time. In addition, despite counseling, women did not remember

Table 1 Representative quotes on the focus of AEs over time

Preoperative	6 weeks	6 months
<ul style="list-style-type: none"> • Problems/complications: “So I’m just worried about that first few weeks and making sure that there is no infection...” • Anesthesia: “...The anesthesia. A little paranoid over that. Making sure that I actually wake up” • Fixing problem: “I’m afraid that it’s not going to solve any of the problems, and that I’m quickly running out of options” • Recovery: “...Making sure I’m not going too hard too fast right after surgery” • Anesthesia: “I’ve been under anesthesia a handful of times...I’ve kind of gotten sick. Queasy afterwards” • Problems/complications: “...any time you have surgery, [the chance] of nicking or damaging stuff nearby” • Recovery/support: “...Will I be back to normal in 6 weeks? Will I just be starting to function? I do not know. That’s giving me anxiety because I have to plan childcare and transportation and meals and home management and someone to cover my business, I work from home” • Pain/catheter: “I wish that I could stay a few more days in the hospital so that my pain’s a little more under control and I’m not on a catheter so when I get home I’m a little more functional” 	<ul style="list-style-type: none"> • Recovery: “I just think I would always be concerned about the healing process...The concern would be just making sure you follow your surgeon’s advice...” • Sex: “...I still do not know how the surgery will affect/improve the ability to have non-painful sex with my husband, and non-embarrassing sex” • Fixing problem: “It’s the fact that it did not work. It’s the fact that I’m still suffering from all the same symptoms” • Recovery: “...I’m afraid if I pick up too much, but I have a two-year-old that I need to pick up, and I run a business, and we lift things...” 	<ul style="list-style-type: none"> • Recovery: “I’m just good at just following the doctor’s orders and stuff they tell you all of these things and taking care of you for a reason” • Fixing problem: “I like to put a positive spin on the end of things if I can, but I hate this. I hate it so much. It really, really does impact my life negatively. It affects work, it affects everything...And it makes me very angry” • Fixing problem: “They did not tell me with already having a prolapse, how much I was at risk for another prolapse” • Sex/pain/recovery: “...Is sex always going to be painful? Is that going to improve at all? Is this burning in my abdomen going to stop? Will I ever gain my energy back?”

AEs that were discussed or that they had been discussed in the consent process. This confirms our prior work with participants from different sites across the country, which lends credibility to our principal finding. In our prior work, the majority of women were non-Hispanic white. In contrast, this study found that in an ethnic and racially diverse sample of patients, the concerns were similar. Many of the AEs that women identified in the postoperative period, such as inadequate symptom relief and sexual dysfunction, were not AEs that surgeons identify using previously created complication scales as a reference [8, 9]. This demonstrates the degree to which the surgeon and patient perspectives on AEs may be misaligned and highlights an area to improve surgeon/patient communication.

Limitations of this study include the small patient sample of 20; however, this is common for one-on-one patient interviews in qualitative work. Furthermore, this sample size achieved data saturation. Our sample was limited to a single academic medical center and only included English-speaking patients, though half the sample identified as either American Indian or Hispanic,

thereby reflecting the diverse population in New Mexico. Strengths of the study include the use of robust qualitative methodology and skilled qualitative researchers. Importantly, we were able to complete three rounds of interviews with all 20 patients.

Dindo et al. [7], in their seminal paper, wrote, “...the patient’s perspective (i.e., quality of life, pain, psychologic strain) may also be taken into account to estimate the severity of a complication. Although this perspective is obviously crucial, the perception of patients varies greatly depending on the patient’s character, the management and the information policy of the physician as well as the physical condition of the patient before and after surgery.”

Our findings support the importance of integrating the patient’s perspective about surgical complications and offer a consistent view of the experiential arc over a 6-month period of these adverse events across a diverse sample. Women undergoing surgery for pelvic floor dysfunction view functional outcomes of utmost importance. Failure to achieve successful functional outcomes, such as continued incontinence symptoms, pain, or sexual dysfunction, are viewed as adverse events by

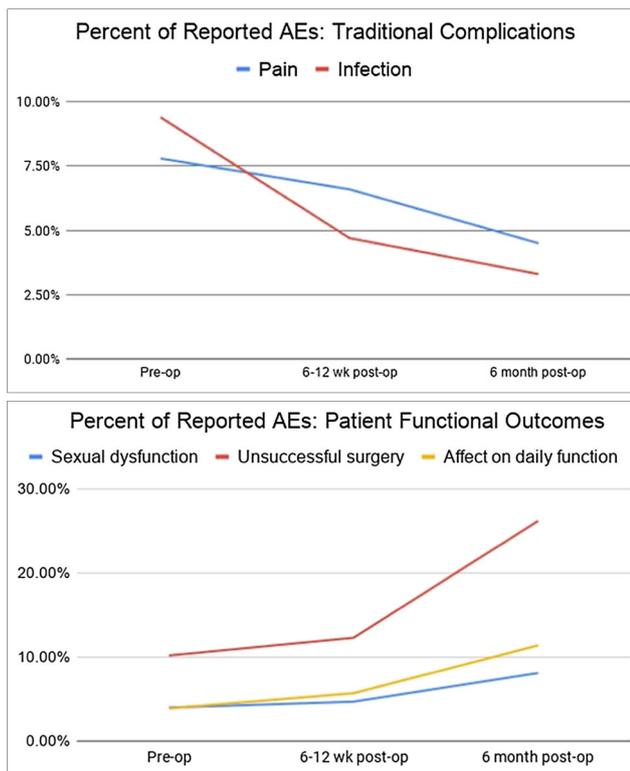


Fig. 2 Percentage of AEs ranked as severe by subjects over time separated into traditional complications and function outcomes

patients, and this finding persists and grows stronger the longer they are from surgery.

Although not the primary focus of this study, we found that patients thought they had not been informed of AEs and were confused about whether they had undergone an informed consent process. Our findings underscore the discrepancy of how surgeons view adverse events, such as with the Clavien-Dindo scale [7, 8], and how patients view adverse events. In addition, patients desire more formalized recovery expectations in both the short and long term, including information on pain, guidelines for activities of daily living, and sexual function. Furthermore, many patients requested additional written information regarding recovery as well as possible AEs. Prior work has shown that written preoperative information improved patient satisfaction in the gynecologic oncology patient population [17]. Overall this highlights the importance of appropriate counseling and expectation setting before surgery. Therefore, future research aimed at developing appropriate tools to more closely align surgical counseling with patient expectations is needed. This will only become more imperative as the medical system transitions to a greater emphasis on value-based care and patient satisfaction.

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Compliance with ethical standards

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References

1. Srikrishna S, Robinson D, Cardozo L, Cartwright R. Experiences and expectations of women with urogenital prolapse: a quantitative and qualitative exploration. *BJOG Int J Obstet Gynaecol.* 2008;115(11):1362–8.
2. Mamik MM, Rogers RG, Qualls CR, Komesu YM. Goal attainment after treatment in patients with symptomatic pelvic organ prolapse. *Am J Obstet Gynecol.* 2013;209(5):488.e1–5.
3. Lawndy SSS, Withagen MI, Kluivers KB, Vierhout ME. Between hope and fear: patient's expectations prior to pelvic organ prolapse surgery. *Int Urogynecol J.* 2011;22(9):1159–63.
4. Wei JT, Nygaard I, Richter HE, Nager CW, Barber MD, Kenton K, et al. A midurethral sling to reduce incontinence after vaginal prolapse repair. *N Engl J Med.* 2012;366(25):2358–67.
5. Visco AG, Brubaker L, Richter HE, Nygaard I, Paraiso MFR, Menefee SA, et al. Anticholinergic therapy vs. onabotulinumtoxin A for urgency urinary incontinence. *N Engl J Med.* 2012;367(19):1803–13.
6. Barber MD, Brubaker L, Burgio KL, Richter HE, Nygaard I, Weidner AC, et al. Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: the OPTIMAL randomized trial. *JAMA.* 2014;311(10):1023–34.
7. Dindo D, Demartines N, Clavien P-A. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg.* 2004;240(2):205–13.
8. Clavien PA, Barkun J, de Oliveira ML, Vauthey JN, Dindo D, Schulick RD, et al. The Clavien-Dindo classification of surgical complications: five-year experience. *Ann Surg.* 2009;250(2):187–96.
9. Gutman RE, Nygaard IE, Ye W, Rahn DD, Barber MD, Zyczynski HM, et al. The pelvic floor complication scale: a new instrument for reconstructive pelvic surgery. *Am J Obstet Gynecol.* 2013;208(1):81.e1–9.
10. Elkadry EA, Kenton KS, FitzGerald MP, Shott S, Brubaker L. Patient-selected goals: a new perspective on surgical outcome. *Am J Obstet Gynecol.* 2003;189(6):1551–7 discussion 1557-1558.
11. Dunivan GC, Sussman AL, Jelovsek JE, Sung V, Andy UU, Ballard A, et al. Gaining the patient perspective on pelvic floor disorders' surgical adverse events. *Am J Obstet Gynecol* [Internet]. 2018 [cited 2019 Jan 1]. Available from: <http://www.sciencedirect.com/science/article/pii/S0002937818309177>
12. Barber MD, Kuchibhatla MN, Pieper CF, Bump RC. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. *Am J Obstet Gynecol.* 2001;185(6):1388–95.
13. Scheier MF, Carver CS, Bridges MW. Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem):

- a reevaluation of the life orientation test. *J Pers Soc Psychol.* 1994;67(6):1063–78.
14. Wren PA, Janz NK, FitzGerald MP, Barber MD, Burgio KL, Cundiff GW, et al. Optimism in women undergoing abdominal sacrocolpopexy for pelvic organ prolapse. *J Am Coll Surg.* 2008;207(2):240–5.
 15. 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):523–8.
 16. Sung VW, Kauffman N, Raker CA, Myers DL, Clark MA. Validation of decision-making outcomes for female pelvic floor disorders. *Am J Obstet Gynecol.* 2008;198(5):575.e1–6.
 17. Angioli R, Plotti F, Capriglione S, Aloisi A, Aloisi ME, Luvero D, et al. The effects of giving patients verbal or written pre-operative information in gynecologic oncology surgery: a randomized study and the medical–legal point of view. *Eur J Obstet Gynecol Reprod Biol.* 2014;177:67–71.

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