



Validation of the Surgical Preparedness Assessment in women with pelvic floor disorders

Gabriela E. Halder^{1,2} · Rebecca G. Rogers^{2,3} · Heidi W. Brown⁴ · Kimberly S. Kenton⁵ · Eva Carlsson⁶ · Amanda White² · Lauren Caldwell² · Rachel High² · Melissa L. Constantine^{7,8}

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Abstract

Introduction and hypothesis We sought to further develop and validate the Surgical Preparedness Assessment (SPA) scale to evaluate patient preparedness for urogynecological surgery.

Methods This was a planned ancillary analysis of a randomized controlled trial (RCT) evaluating the impact of a preoperative telehealth call on patient preparedness for urogynecological surgery. Patients completed the Preoperative Preparedness Questionnaire (PPQ), the modified Preparedness for Colorectal Cancer Surgery Questionnaire (PCSQ), the Pelvic Floor Distress Inventory (PFDI-20), the Satisfaction Decision Scale (SDS), and the Decision Regret Scale (DRS). Content validity was established through expert opinion and patient cognitive interviews. Factor analysis identified item grouping into domains. Cronbach's alpha reported internal consistency. Known group validity was assessed by comparing intervention arms. External validity was evaluated by comparing intervention arms and correlations with SDS and DRS.

Results Eleven items and 3 domains met the criteria (information needs, satisfaction and pain, and catheterization). Cronbach's alpha values were acceptable for domains and ranged from 0.74 to 0.93. SPA scores did not correlate with other patient-reported outcomes. Mean SPA scores were lower among women who received a telehealth call vs those who did not (1.30 ± 0.31 vs 1.51 ± 0.44 ; $p = 0.002$).

Conclusions The content-valid SPA demonstrates high internal consistency and known group validity.

Keywords Surgery · Preparedness · Validated · Informed consent

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✉ Gabriela E. Halder
gabrielahalder@gmail.com

¹ Division of Female Pelvic Medicine and Reconstructive Surgery, Department of OBGYN, University of Texas Medical Branch, 301 University Blvd., Galveston, TX 77555, USA

² Department of Women's Health, University of Texas at Austin, Austin, TX, USA

³ Department of OBGYN, Albany Medical Center, Albany, NY, USA

⁴ Division of Female Pelvic Medicine and Reconstructive Surgery, Department of OBGYN, University of Wisconsin-Madison, Madison, WI, USA

⁵ Division of Female Pelvic Medicine and Reconstructive Surgery, Department of OBGYN, Northwestern University, Chicago, IL, USA

⁶ Sahlgrenska University Hospital, Department of Surgery, Centre for Person-centered care Gothenburg University, Gothenburg, Sweden

⁷ Division of Biostatistics, Coordinating Centers for Biometric Research, University of Minneapolis, Minneapolis, MN, USA

⁸ Evidera, Minneapolis, MI, USA

Introduction

Surgical preparedness includes optimization of patient understanding of procedural goals, risks, benefits, and expectations of the surgical recovery experience and therapeutic outcomes. Prepared patients have better reported condition-specific symptom scores, impressions of improvement, satisfaction, and lower complication rates up to 12 months postoperatively [1, 2]. A prospective trial of 79 women undergoing urogynecological surgery found that at 3 months postoperatively, prepared women were more likely to have improved Patient Global Impressions of Improvement (PGI-I) scores (68 vs 32%, $p = 0.003$), reported greater satisfaction with their surgery (77 vs 23%, $p < 0.05$), and had improved post-operative Pelvic Organ Prolapse Distress Inventory (POPDI; 0 [0–35], vs 8 [0–46], $p = 0.02$) and Urogenital Distress Inventory (UDI; 0 [0–33] vs 13 [0–67], $p = 0.02$) scores, whereas objective measures of cure did not differ by levels of preparedness [1]. Interventions to increase surgical preparedness have variable success in women with pelvic floor disorders (PFDs) [3–7].

Condition-specific tools to measure surgical preparedness have been developed for other surgical specialties [8]. Although the Preoperative Preparedness Questionnaire (PPQ) is a measure that is widely used to measure preparedness in women undergoing urogynecological surgery, it has not undergone psychometric evaluation and no other validated instruments to assess preparedness in this population exist [1]. Accurate measures of surgical preparedness are necessary to appropriately assess patient readiness for surgery as well as the quality of interventions to improve preparedness. We aimed to develop and validate a self-administered instrument to evaluate surgical preparedness in patients undergoing urogynecological surgery.

Materials and methods

Institutional review board approval was obtained prior to study initiation. This was a planned ancillary analysis of the Telephone Intervention to Increase Patient Preparedness for Surgery (TIPPS) trial [6]. Briefly, the TIPPS trial was a multicenter randomized trial assessing the impact of a preoperative telehealth call on surgical preparedness for patients undergoing surgery for pelvic organ prolapse (POP) and/or stress urinary incontinence (SUI). Enrollment was sequential and occurred at two urogynecology clinics associated with major tertiary referral teaching hospitals. Women over the age of 18 years who could read and speak English and who were scheduled to undergo surgery for SUI and/or POP were eligible for enrollment. Concomitant procedures were permitted. Exclusion criteria were inability to participate in a

telehealth call (owing to dementia, a hearing disability, etc.) or surgery scheduled within 3 days or less from the enrollment visit. Enrollment and consent were completed during preoperative in-person visits.

Data gathered at enrollment included demographic characteristics and the Pelvic Floor Distress Inventory (PFDI-20), which includes both the POPDI and the UDI. Women were followed up in clinic 4–8 weeks after surgery and completed the PFDI-20, Decision Regret Scale (DRS), and Satisfaction with Decision Scale (SDS).

Candidate items for the Surgical Preparedness Assessment (SPA) were obtained from the PPQ [1] and a modified version of the Preparedness for Colorectal Cancer Surgery Questionnaire (PCSQ) [8]. The PPQ is an 11-item questionnaire with six-point Likert-type responses developed to assess preparedness for pelvic floor surgery [1]. Although the instrument has not undergone a formal validation process it has been used in multiple studies assessing interventions to increase surgical preparedness [3–6]. The PCSQ is a 23-item questionnaire with four-point Likert-type responses developed to assess preoperative preparedness for patients undergoing surgery for colorectal cancer [8]. The measure was originally validated in Swedish and then translated into English using a translation back translation methodology [8]. We modified the PCSQ to fit our population; Questions 20 and 21 were omitted because they were specific to patients with cancer. The content validity of the modified PCSQ was assessed to determine the degree to which the content of the modified version is an adequate reflection of the preparedness construct through cognitive interviews with topic experts and women who had undergone pelvic surgery. The PPQ and PCSQ were self-administered on paper in the preoperative holding area prior to surgery.

Basic psychometric analytical tools were used to evaluate the instrument [9]. Internal dimensional validity of domains was evaluated using principle factor analysis with Varimax rotation [10]. Retention of domains was determined by application of the Kaiser–Guttman rule (eigenvalues ≥ 1.0) and overall acceptance of domain structures was based on the measure of sampling adequacy (Kaiser–Meyer–Olkin test > 0.70). Item retention was based on the standard 0.60/0.40 difference in factor loading: items with a loading value greater than 0.60 but less than 0.40 [9–13]. Internal consistency was determined using a Cronbach's alpha of greater than 0.70 as a cutoff for acceptable internal consistency [14]. Domain development was an iterative process amongst the research team to ensure that each domain was coherent and clinically useful. External measures used to evaluate construct validity were a priori identified as associated with preparedness or aspects of preparedness [1] and included the SDS [15], DRS [15], UDI [16], and POPDI

[17]. These variables were chosen because prepared women have been previously found to have greater postoperative satisfaction and improved scores on these outcome measures. Known group validity was assessed by comparing SPA values between the group that received a telehealth call vs routine counseling using Welch's *t* test. The analytical dataset used for this validation is based on a per-protocol approach on the ancillary data from the TIPPS trial [6]. We adhered to the COSMIN Study Design Checklist for Patient-Reported Outcome Measurements [18]. Based on sample size recommendations for psychometric analysis, with a rule of thumb being 10 participants per item evaluated, this $n = 132$ is sufficient for psychometric evaluation of 11 items [19].

The response scales range from 1 to 6, with lower scores indicating a greater level of preparedness. The mean value of all the answered questions is calculated for each domain. Missing values are excluded. At least 50% of the questions in the domain must have a value so that the domain can be scored. If more than 50% of the questions are missing, then a score for that domain should not be calculated. Lower scores indicate greater surgical preparedness. Only total scores should be reported.

Results

As previously reported, a total of 150 women were enrolled for the study and 132 returned a completed survey (88% response rate). A total of 60 participants received a preoperative telehealth call by a single FPMRS attending or fellow surgeon who was part of the patient's care team (Fig. 1).

The groups did not differ in baseline characteristics except that the group without additional counseling was more likely to have a history of pelvic reconstructive surgery. The mean \pm SD age of the sample was 57.9 ± 13.3 years. Ninety-two percent self-identified as white, and 27% self-identified as Hispanic, 64% had private insurance, 61% were married, and 61% had greater than a high school education. POP alone was diagnosed in 20%, SUI alone in 24%, and both POP and SUI in 56% (Table 1). A total of 28% of women underwent a sacrocolpopexy, 23% underwent a uterosacral ligament suspension, and 7% a colpocleisis [6].

Three domains meeting a priori specified criteria emerged with 11 items. The following domains emerged: information needs; satisfaction and pain; and catheterization. Factor loadings for each domain were between 0.63 and 0.88 and met the criteria as outlined in the methods (Table 2). The internal consistency for each of the domains was acceptable to excellent, with alphas between 0.74 and 0.92 (Table 2).

The mean score of the three domains comprising the SPA did not correlate with external measures including the SDS, DRS, UDI, and POPDI scores (all $p > 0.05$). Known group

validity was supported with mean total SPA scores being significantly lower among women who received a telehealth call vs women who did not (1.30 ± 0.31 vs 1.50 ± 0.44 , $p = 0.002$; Table 3).

Discussion

We validated an 11-item SPA questionnaire with three domains that has acceptable content validity, internal consistency, and known group validity. Women who received an intervention to improve preparedness achieved higher scores on the SPA than those who did not. Our measure did not correlate with other measures of surgical outcomes included in our parent study.

Measuring surgical preparedness is important because evidence suggests that prepared patients might have better subjective outcomes [1]. Evaluating surgical preparedness allows for patient and surgeon alignment in perioperative expectations and highlights aspects of surgical preparedness that require additional attention. This tool can be used to identify patients who require further counseling in certain aspects of the surgical experience.

During the informed consent process a provider reviews diagnostic findings, therapeutic options, and surgical expectations. Despite this routine and seemingly informative process, patients continue to report misalignment between preoperative expectations and postoperative experiences [20]. A key component of preoperative counseling is patient understanding. A patient's ability to understand the informed consent process is multifactorial and extends beyond health literacy [21]. In an observational study of 150 women seeking surgical treatment for PFDs, SDS scores were strongly associated with increased knowledge of the planned surgery. This study compared Informed Consent Questionnaire (ICQ-20) [22] scores between highly satisfied ($n = 70$, defined as highest possible level of satisfaction for all SDS items) and not highly satisfied ($n = 77$, defined as all other SDS scores) women and found significantly higher ICQ-20 scores amongst highly satisfied women (17.8 ± 3 vs 16.1 ± 77 , $p = 0.003$). The relationship between preoperative satisfaction and knowledge persisted even after controlling for demographic and clinical variables including education level, health literacy, race/ethnicity, age, surgeon years since completing fellowship, diagnosis, surgery category, number of visits in the past 6 months, and number of days between informed consent discussion and survey. [23].

Surgical preparedness is different than informed consent and understanding in that it also captures perceived self-efficacy. Individuals with high self-efficacy have confidence in their ability to succeed with a task or achieve a desired outcome [24]. In 100 patients who

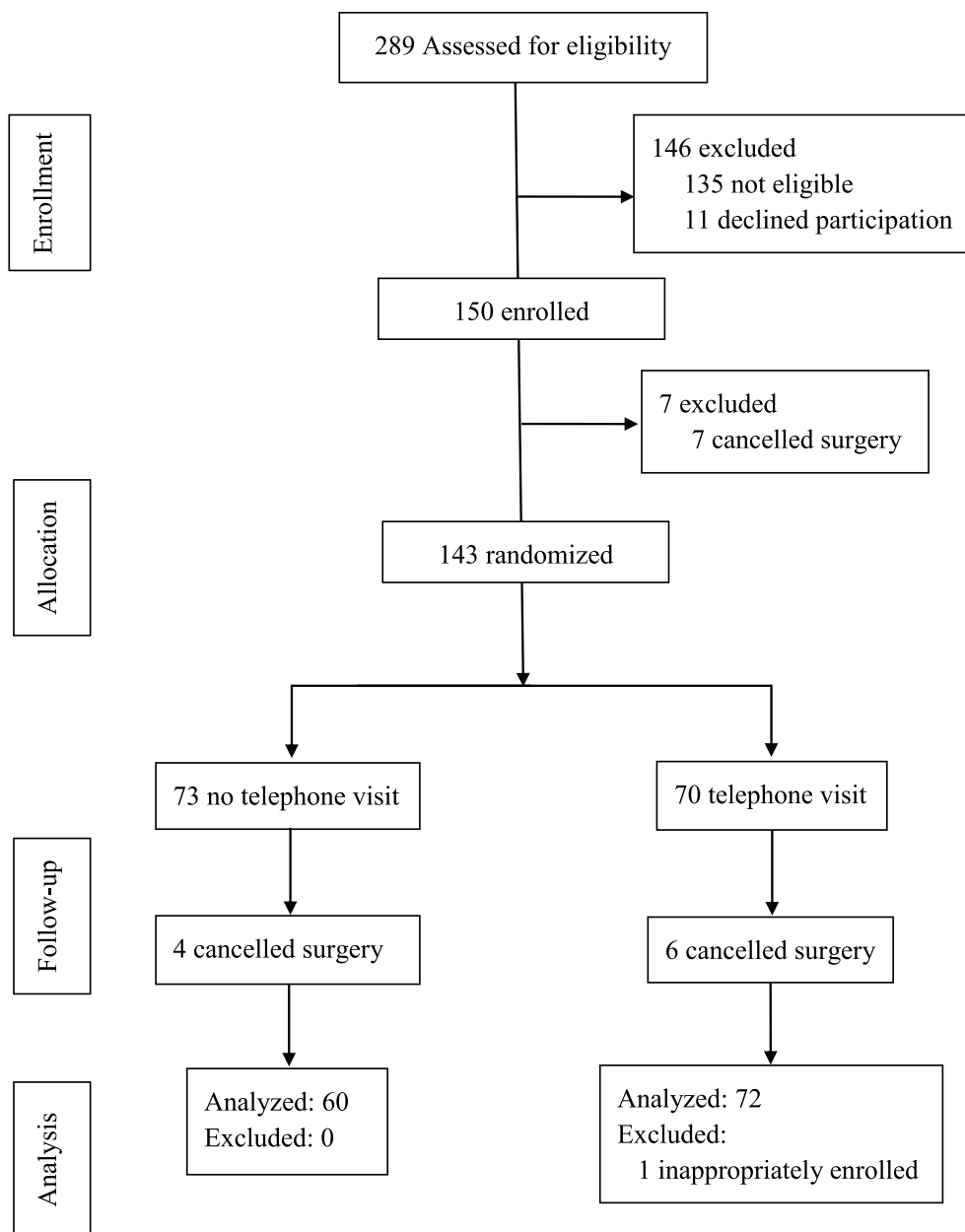


Fig. 1 Enrollment, randomization, and analysis of research participants. Patients were analyzed using a per-protocol analysis

underwent breast reconstructive surgery, higher levels of self-efficacy (as measured by the Modified Stanford Self-Efficacy Scale) were significantly related to high satisfaction with information (as measured by the information subscale of the BREAST-Q) when evaluated by multinomial logistic regression models ($\beta = 1.03$; 95% CI, 1.01 to 1.05) [25]. The SPA is a measure of both understanding and self-efficacy for women undergoing pelvic floor surgery.

Strengths of this study include the inclusion of both patients and providers in the development of our items, adequate sample size to test our items, and robust psychometric

evaluation. Factors identified through cognitive interviews reflect concepts that patients report as being most important to their surgical experience. For example, the catheterization factor reflects what patients have reported as the worst aspect of their surgical experience, even considering catheterization a complication 1 year after surgery [26]. Weaknesses include a high proportion of white patients and our inability to include patients who do not speak English. The SPA is only validated in English and validating this instrument in other languages and cultures is important. Face validity was only determined for the modified version of the PCSQ; it was not determined for the PPQ. The SPA did not

Table 1 Baseline characteristics

	Telephone call (n=60)	No tel- ephone call (n=72)	<i>p</i> value
Age (years)	56.6 ± 12.6	59.0 ± 13.9	0.30
BMI (kg/m ²)	29.6 ± 7.1	28.2 ± 6.7	0.27
Race			0.20
White	0 (0)	2 (3)	
Other	2 (3)	6 (8)	
Missing	58 (97)	64 (89)	
Ethnicity			0.98
Hispanic	16 (27)	19 (26)	
Missing	2 (3)	2 (3)	
Health insurance			0.26
Private	38 (63)	46 (64)	
Government issued	22 (37)	23 (32)	
Self-pay	0 (0)	3 (4)	
Married/partner status			0.38
Single	20 (33)	30 (42)	
Married	40 (67)	41 (57)	
Missing	0 (0)	1 (1)	
Highest level of education			0.16
High school or less than	28 (47)	23 (32)	
Greater than high school	32 (53)	48 (67)	
Missing	0 (0)	1 (1)	
Diagnosis			0.27
POP alone	16 (27)	22(31)	
UI alone	19 (32)	14 (19)	
POP and UI	25 (42)	36 (50)	
POP stage			0.48
Stage 2	24 (50)	41 (59)	
Stage 3	22 (46)	24 (35)	
Stage 4	2 (4)	4 (6)	
Prior pelvic reconstructive surgery for POP and/or SUI	6 (10)	18 (25)	0.05

Data are represented as mean ± SD or *n* (%) unless otherwise specified
BMI body mass index, *POP* pelvic organ prolapse, *UI* urinary incontinence

correlate with other commonly used measures of surgical success such as the SRS, DRS, and changes in the POPDI and UDI. This may be because we followed our patients up to only 8 weeks, and prior studies that found preparedness linked to outcomes followed patients for a longer time. In addition, our parent study did not capture other aspects of preparedness that may be an important part of the surgical

Table 2 Final factor loadings and internal consistency of factors

Domains	Factor loading
D1: Information Needs	
I understand the purpose of the planned surgery (what this surgery can accomplish)	0.88
I understand the benefits of the planned surgery (how this surgery should help me)	0.87
My doctors and nurses have spent enough time preparing me for my upcoming surgery	0.85
Overall, I feel prepared for my upcoming surgery	0.82
I understand the risks of the planned surgery (what the chances are of something not going the way my doctor and I want it to go)	0.67
I know the alternatives of the planned surgery	0.65
Cronbach's alpha	0.92
D2: Satisfaction and Pain	
I feel prepared for potential causes of pain following surgery	0.73
Overall, I am satisfied with the written information provided	0.70
My needs and wishes regarding surgery have been satisfied	0.63
Cronbach's alpha	0.74
D3: Catheterization	
I feel prepared to cope with a catheter when I am at home	0.75
I feel prepared to cope with a catheter while I am in the hospital	0.73
Cronbach's alpha	0.75

Table 3 Known group validity: SPA scores with intervention and without intervention

	Telephone intervention	Control	<i>p</i>
Total	1.30 (0.31)	1.51 (0.44)	0.002

Data are represented as mean ± SD

Welch's *t* test is used for all between-group comparison. *p* ≤ 0.05

experience, such as patient self-efficacy, physician communication, and trust in your provider.

In summary, the SPA is a more rigorously validated scale than those that are currently available to assess preoperative preparedness for women with Pelvic Floor Disorders. The SPA can be used both in clinical and research settings to assess patients' preparedness for urogynecological surgery, identify patients who may require additional preoperative counseling, and evaluate the impact of tools that are aimed at improving preoperative preparedness. More rigorous psychometric testing of the SPA is also needed.

Surgical preparedness Assessment

Information needs

Q1. I understand the **purpose** of the planned surgery (what this surgery can accomplish).

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree
- 6 Strongly disagree

Q2. I understand the **risks** of the planned surgery (what the chances are of something not going the way my doctor and I want it to go).

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree
- 6 Strongly disagree

Q3. I understand the **benefits** of the planned surgery (how this surgery should help me).

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree
- 6 Strongly disagree

Q4. I understand the **alternatives** of the planned surgery.

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree
- 6 Strongly disagree

Q5. My doctors and nurses have spent enough time preparing me for my upcoming surgery.

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree

6 Strongly disagree

Q6. Overall, **I feel prepared** for my upcoming surgery.

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree
- 6 Strongly disagree

Score D1 = (Q1 + Q2 + Q3 + Q4 + Q5 + Q6)/total number of items answered (between 3 and 6)

Note: if fewer than three items are answered, score cannot be calculated for this domain.

Satisfaction and pain

Q7. Overall, I am satisfied with the written information I received about my surgery.

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree
- 6 Strongly disagree

Q8. My needs and wishes regarding surgery have been satisfied.

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree
- 6 Strongly disagree

Q9. I feel prepared for potential causes of pain following surgery.

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree
- 6 Strongly disagree

Score D2= (Q7 + Q8 + Q9) / total number of items answered (between 2 and 3)

Note: If fewer than 2 items are answered, score cannot be calculated for this domain

Catheterization

Q10. I feel prepared to cope with a catheter after the surgery while I am **in the hospital**.

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree
- 6 Strongly disagree

Q11. I feel prepared to cope with a catheter after the surgery when I am **at home**.

- 1 Strongly agree
- 2 Agree
- 3 Somewhat agree
- 4 Somewhat disagree
- 5 Disagree
- 6 Strongly disagree

Score D3: (Q10 + Q11)/2

Total score: (D1 + D2 + D3)/3

Scoring:

The response scales range from 1 to 6 with lower scores indicating a greater level of preparedness. Using the response values associated with each response scale, determine the mean value for each of the three domains. Missing values should be excluded. At least 50% of the questions in the domain must have a value for the domain to be scored.

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Authors' contribution G.E. Halder: protocol/project development, data collection and management, data analysis, manuscript writing/editing; R.G. Rogers: protocol/project development, data collection and management, data analysis, manuscript writing/editing; H.W. Brown: data collection and management, data analysis, manuscript writing/editing; K.S. Kenton: protocol/project development, manuscript editing. E. Carlsson: protocol/project development, manuscript editing; A. White: data collection, manuscript editing; L. Caldwell: data collection, manuscript editing; R. High: manuscript writing/editing; M.L. Constantine: Protocol/project development, data collection and management, data analysis, manuscript writing/editing.

Declarations

Conflicts of interest G.E. Halder: nothing to disclose; R.G. Rogers: royalties from UpToDate, stipend and travel from the International Urogynecologic Association; H.W. Brown: nothing to disclose; K.S. Kenton: expert witness for Butler Snow/Ethicon, research funding from Axonics; E. Carlsson: nothing to disclose; A. White: Boston Scientific; L. Caldwell: nothing to disclose; R. High: nothing to disclose; M.L. Constantine: nothing to disclose.

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