Agreement between patient global impression scale of improvement, pelvic floor distress inventory and 15D in measuring the outcome of pelvic organ prolapse surgery

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Abstract
Aims: To evaluate the correlation between three commonly used patient-reported outcome measures, two generic and one condition-specific instrument, in assessing the change in health-related quality of life following pelvic organ prolapse surgery.

Methods: The generic health-related quality of life measure 15-dimensional instrument (15D), Patient Global Impression of Improvement (PGI-I), and prolapse-specific Pelvic Floor Distress Inventory (PFDI-20) were used to assess the effectiveness of pelvic organ prolapse surgery in the national FINPOP study of 3535 surgeries (83% of all pelvic organ prolapse operations) performed in Finland in 2015. Spearman correlations between PGI-I, change in 15D and its dimensions and change in PFDI-20 and its subscales over a 2-year follow-up were investigated. The proportion of concordant ratings was also studied by investigating the proportion of women rated similarly (worse/no change/better/much better) by two instruments according to validated cutoffs.

Results: Among 2248 women for whom the 2-year change in all instruments could be measured, changes in PFDI-20 and 15D and its dimensions were weak ($\rho < 0.2$ for all except excretion; $\rho = 0.39$ and sexual activity; $\rho = 0.27$). PFDI-20 change ($\rho = 0.39$) and its subscales ($\rho = 0.19-0.40$, all $P < .001$) were more strongly correlated with PGI-I. The proportion of fully concordant ratings were higher for PFDI-20 and PGI-I (50.6%) than for PFDI-20 and 15D (33.0%).

Conclusion: The weak correlations between 15D, PGI-I, and PFDI-20 observed in this study show that the quantified health gains are strongly dependent on the chosen patient-reported outcome measures. This demonstrates...
the importance of using condition-specific sensitive outcome measures in assessing the impact of surgical treatment in pelvic organ prolapse.

**KEYWORDS**
15D, Health-related Quality of Life, HRQoL, Patient Global Index of Improvement, Patient-Reported Outcome Measure, Pelvic Floor Distress Inventory, pelvic organ prolapse, pelvic reconstructive surgery, PFDI-20, PGI-I, POP, PROM, QoL, Quality of Life, surgery, urogynecology

1 | INTRODUCTION

Pelvic organ prolapse (POP), defined as the descent of vaginal wall or apex, is a common gynecological disorder affecting millions of women. The lifetime risk for surgery for POP is from 11% to 13%.\(^1\) POP symptoms, including vaginal bulge sensation and urinary and bowel symptoms may cause a significant decrease in health-related quality of life (HRQoL).\(^2\) POP can affect women's body image and cause restrictions in personal, social, and sexual activities and some women even stop these activities, which may expose them to depression.\(^3\)

Thus, the impact of POP on HRQoL is not restricted to its direct consequences, such as excretion and sexual functions.

Traditionally, the efficacy of POP surgery has been measured by anatomic outcomes, using the Pelvic Organ Prolapse Quantification (POP-Q) instrument.\(^4\) Nowadays, the role of patient's expectations and their perception of the result is being more commonly recognized. This is of particular importance when the intervention is being performed simply to improve QoL, like in POP surgery. Use of validated patient-reported outcome measures (PROMs) is increasingly common in studies evaluating the effectiveness of POP surgery.\(^5\) In particular, measuring the presence or absence of vaginal bulge symptoms, as well as patient satisfaction, and change in QoL after surgical treatment is essential.\(^6\)

As there are numerous PROMs available, it is of utmost importance to select the PROM(s) relevant to the performed procedure. The criteria for the recommendation of questionnaires is that they have been shown to be valid, reliable, and responsive to change on psychometric testing.\(^7\) However, it is unknown how consistently different validated questionnaires evaluate the changes in HRQoL after POP surgery. We\(^8\) and others\(^9\) have previously shown that POP surgery leads to improvement in both generic and disease-specific PROM measures, but it is unknown how strongly these measures are correlated, that is, whether those among whom improvement in generic HRQoL is detected are the same women who report symptom alleviation. Furthermore, as many generic instruments such as 15-dimensional instrument (15D) measure also sexual function and excretion symptoms, it is important to assess whether they capture the symptom alleviation detected by symptom-specific instruments such as Pelvic Floor Distress Inventory-20 (PFDI-20) and its subscales.

We evaluated how consistent are two generic instruments (15D and PGI-I; Patient Global Impression of Improvement), and one condition-specific HRQoL instrument (PFDI-20) in assessing the change in HRQoL following pelvic organ prolapse surgery. The specific aims of this study were to evaluate the correlation of different instruments and the proportion of concordant ratings between different instruments.

2 | MATERIALS AND METHODS

2.1 | Study design

This national prospective multicenter study was organized and funded by the Finnish Society for Gynecological Surgery. The study period was between 1 January 2015 and 31 December 2015. All Finnish hospitals performing POP surgery were invited to join the study and altogether, 41 of 45 hospitals participated. The inclusion criteria were age more than 18 years and the ability to communicate in written and oral Finnish or Swedish. The study population (n = 3515 patients, 3535 operations) covered 83% of all women operated on for POP in 2015 in Finland.

HRQoL was measured with validated instruments as described previously.\(^10\) Disease-specific symptom burden was assessed with the PFDI-20, which consists of three subscales distress caused by prolapse symptoms (Pelvic Organ Prolapse Distress Inventory, POPDI-6), difficulties of defecation (Colorectal-Anal Distress Inventory, CRADI-8), and difficulties in urination (Urinary Distress Inventory, UDI-6).\(^11\) Generic HRQoL was measured by a validated 15D, consisting of 15 dimensions (mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity).\(^12\) The 15D instrument has previously shown to
be valid in assessing the impact of pelvic floor reconstructive surgery. Patients completed these instruments at baseline, and 6 and 24 months after operation. In addition, the PGI-I was administered 6 and 24 months after the operations. PGI-I is used in several surgical fields and has also been validated in prolapse surgery.

At baseline, that data were available from 2924 (83%) of 3515 study participants. At 6 months, the change in PFDI-20 and 15D scores were available from 2522 (72%) and 2440 (69%) women, respectively. At 2 years, PFDI-20 data were available for 2337 (66%) and data on 15D for 2275 (65%) women, respectively. The data on PGI-I was available for 2525 (72%) at 6 months and 2321 (66%) participants at 2 years.

To ensure the comparability of agreements in different comparisons (ie, PFDI-20 vs 15D, PFDI-20 vs PGI-I, and 15D vs PGI-I), analyses were restricted to women who had responded to all three questionnaires at baseline and 24 months (N = 2248 main analyses). In addition, sensitivity analyses were conducted among those 2425 women who had responded to these questionnaires at baseline and 6 months to assess whether the correlations were stronger with shorter follow-up time.

2.2 Ethical approval

The study was approved by the Research Ethics Committee of the Northern Savo Hospital District on the 20th of May 2014 (reference number: 5/2014) and the study protocol was approved by the Finnish Ministry of Social Affairs and Health and institutional approval of each participating hospital. The study was also included in the ClinicalTrials.gov protocol registration system (NCT02716506) and the ethical standards for human experimentation established by the Declaration of Helsinki of 1964, revised in 2013, were followed. In addition, we obtained written informed consent from each participant.

2.3 Statistical analysis

Statistical analyses were performed with Stata MP14.0. To investigate the agreement between 15D, PFDI-20, and PGI-I, the 2-year changes in 15D and PFDI-20 were scaled to the same dimension so that negative values indicate improvement. Correlations between change in 15D, PGI-I, PFDI-20, and PFDI-20 subscales and 15D dimensions were investigated with Spearman’s method. To evaluate whether the strength of correlation was affected by the type of surgery or prolapse severity, we stratified analyses according to the surgery method and whether the prolapse of any compartment was beyond hymen. 95% Confidence interval (CI) were estimated by 1000-fold bootstrapping, in addition to correlations, we evaluated the proportion of agreeing ratings by crosstabulations.

In addition to correlations, we evaluated the proportion of agreeing ratings by crosstabulations. For this purpose, the 15D total index was categorized as “worse” (change > 0.015), “no change” (0.0149 to –0.0149), “slightly better” (–0.015 to –0.035) and “much better” (<–0.035). Change in PFDI-20 was categorized as “much better” (decrease > 45 points), “better” (decrease 23-45 points), “no change” (decrease 22.9 points-increase 22.9 points), and “worse” (increase 23 ≥ points). These threshold scores were based on previous studies defining the minimal important change (MIC) of total PFDI-20 scores. Agreement between changes in 15D and PFDI-20 was evaluated by calculating the proportion of fully concordant ratings (eg, both 15D and PFDI-20 rated as “much better”, ie, degree of improvement considered), and partially agreeing ratings (eg, 15D rated as “much better”, PFDI-20 as “much better” or “slightly better”; ie, degree of improvement ignored). For the 7-level PGI-I, we considered values 1 to 2 (very much or much better) to correspond with “much better” in PFDI-20 and 15D, and value 3 (a little better) with “slightly better”.

3 RESULTS

Of the 2248 women included in the main analyses, 1128 (50.2%) patients reported a “much better” outcome of surgery measured by PFDI-20, 1638 (72.8%) by PGI-I and 675 (30.0%) by 15D. The proportion of patients in different outcome categories are shown in Figure 1.

3.1 Correlation between PGI-I, 15D, and PFDI-20

Two-year change in the symptom-specific PFDI-20 and its subscales correlated weakly (ρ = 0.188-0.386) with changes in 15D total index and PGI-I (Table 1). The more generic instruments, PGI-I, and 15D correlated also weakly with each other (ρ = 0.275). The strength of correlation did not differ between procedure type or disease severity (Figure S1).

In general, similar results were observed with the 6-month changes, except for POPDI-6 and PGI-I which were not correlated in the 6-month data. The correlations between PFDI-20 and its subscales and specific dimensions of 15D were also modest, with both 2-year (Figure 2A) and 6-month follow-up (Figure 2B). The strongest correlations were observed between improvement in excretion and PFDI-20 and UDI-6 (ρ = 0.348-
0.395, P < .001), all other correlations were lesser than or equal to 0.3.

3.2 Agreement between ratings

When the comparability of 2-year changes was assessed, the highest agreement was observed between PFDI-20 and PGI-I. The degree of change was rated identically for 50.6% of persons. If the degree of improvement is ignored (ie, “much better” and “better” are considered to be similar ratings), the change was rated similarly by 72.8% of persons (Figure 3A). The level of agreement was approximately 5% higher with 6-month follow-up data (55.5% and 74.2%, respectively, Figure S1A). The agreement between PFDI-20 and 15D (Figure 3B) was lower, with 33.0% of women rating the change in HRQoL similarly with both instruments. If the degree of improvement was ignored, the similarity was 45.9%. The categorized HRQoL change measured by PGI-I and 15D was the same for 31.1% of persons when the degree of improvement was considered and 45.0% when it was ignored (Figure 3C). The degree of similarity was comparable, with 2% to 5% higher agreement when the 6-month changes were assessed (Figure S2B-C).

4 DISCUSSION

4.1 Principal findings

Pelvic organ prolapse surgery has been shown to improve in both generic and disease-specific patient-reported outcome measures, but the findings of this study demonstrate that the quantified health gains are dependent on the chosen patient-reported outcome measure. In our study, the three patient-reported measures (PFDI-20, 15D, and PGI-I) were only weakly correlated, and the proportion of concordant ratings between instruments varied between 31.1% and 72.8%.

4.2 Results of the study in the context of other observations

The HRQoL in relation to POP surgery has been investigated mainly using condition-specific instruments. With these instruments, pelvic floor dysfunction and quality of sexual life have been shown to improve significantly. However, the application of generic QoL instruments is valuable as it allows comparisons across different conditions and enables assessment of health gains beyond the dimensions captured by condition-specific measures. For example, with a generic instrument, the effectiveness of POP surgery can be compared with the effectiveness of procedures from different surgical fields. However, the problem with applying generic measures in POP surgery research can be that they lack sensitivity to the aspects characteristic of pelvic floor dysfunction and thus may be unable to detect clinically important improvement. Another challenge in their application, particularly in long-term outcome assessment, is

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**TABLE 1** Spearman correlations between PGI-I, and changes in 15D index, PFDI-20, and its subscales over 2 years (6 months)

| Change in 15D | PGI-I   |
|--------------|---------|
| PGI-I        | 0.275 (0.229) |
| Change in PFDI-20 | 0.363 (0.331) | 0.386 (0.316) |
| Change in POPDI-6 | 0.304 (0.181) | 0.395 (0.022, NS) |
| Change in UDI-6 | 0.281 (0.278) | 0.290 (0.258) |
| Change in CRADI-8 | 0.265 (0.233) | 0.188 (0.108) |

Note: All P < .001 unless otherwise indicated. Abbreviations: 15D, 15-dimensional instrument; CRADI-8, Colorectal-Anal Distress Inventory; PFDI-20, prolapse-specific Pelvic Floor Distress Inventory; PGI-I, Patient Global Impression of Improvement; POPDI-6, Pelvic Organ Prolapse Distress Inventory; UDI-6, Urinary Distress Inventory.
the age range of treated women. In our study, the average age was 64 years, when significant changes in general health status can occur during 2 years as ageing correlates with increasing morbidity.\(^{12}\) Thus, discomfort related to other conditions than POP explains the decreasing general HRQoL.

In our study, the overall changes in 15D were mainly explained by changes in sexual activity and excretion. This is expected, as the correction of the pelvic floor should lead to improvement in urinary and bowel symptoms. In addition, symptoms of POP greatly affect women’s body image and sexuality.\(^{18}\) Some women report that they avoid sexual activity due to a fear of discomfort or embarrassment associated with POP, or in particular with urinary or fecal incontinence during sexual activity.\(^{18}\) Although generic instruments such as 15D capture these dimensions that are strongly affected by POP, our findings on the weak correlation between these dimensions and PF DI-20 and its subscales underline the importance of using also symptom-specific outcome measures. PF DI-20 is specifically developed for assessing the symptoms, including difficulties in excretion and pelvic bulge/pressure discomfort, among women suffering from POP, and to detect the degree and change of discomfort and symptoms associated to POP, whereas 15D is intended for the general adult population, regardless of their age or sex.

Previously, Altman et al.\(^{9}\) showed that improvement in PF DI-20 was associated with improvement in 15D in a Nordic multicenter study of apical prolapse mesh surgery. The weaker correlation in our study may be explained by the differences in study populations. Women selected for transvaginal mesh surgery tend to be older, have more often advanced prolapse, and report higher scores in condition-specific questionnaires compared to women who undergo native tissue repair.\(^{20}\) We have previously shown an association between advanced apical prolapse and favorable surgery outcome with both PF DI-20 and 15D.\(^{8}\) Thus, a more homogenous population with advanced prolapse may show a better correlation of these instruments. However, the pre-operative 15D single-index mean score of 0.888 in the Altman study was similar to ours (0.889).

PGI-I has been shown to correlate well with the PROMs that are used in urinary incontinence research.\(^{21}\) The opposite findings was found in a Danish database study that showed higher satisfaction after urogynecological surgery measured by PGI-I compared with the disease-specific questionnaire (ICIQ, International Consultation on Incontinence Questionnaire score).\(^{22}\) They concluded that PGI-I score overestimates the improvement following urinary incontinence and prolapse surgery.

**FIGURE 2** Correlation between changes in 15D dimensions and PGI-I and changes in PF DI-20 and its subscales during (A) 2-year follow-up and (B) 6-month follow-up. 15D, 15-dimensional instrument; CRADI-8, Colorectal-Anal Distress Inventory; PGI-I, Patient Global Impression of Improvement; PF DI-20, prolapse-specific Pelvic Floor Distress Inventory; POPDI-6, Pelvic Organ Prolapse Distress Inventory; UDI-6, Urinary Distress Inventory.
surgery. However, the ICIQ that was used to measure the disease-specific HRQoL outcome, is a simplified tool that covers only the impact of urine incontinence and bulge symptoms.23 Many aspects of treatment response, such as de novo incontinence and persistent pain may not be reflected in the ICIQ, and it has been discussed if the PGI-I provides a more global overview of treatment success, potentially more fully encompassing the range of harms and benefits of the surgical treatment.24 The PFDI-20 covers a more holistic picture of the pelvic floor symptoms than ICIQ and thus, a comparison of the results of PGI-I and PFDI-20 provides a more realistic overview of the accuracy of the global index. In concordance with Larsen et al, our data showed “much better” outcome of surgery for PGI-I significantly more often than for PFDI-20 and the results of PGI-I and PFDI-20 were concordant in 72.8% of cases. It must be remembered though, that the PGI-I is a completely retrospective assessment, and it is affected by other aspects such as patient’s experience of the treatment and nursing. In our opinion, these two measures reflect different aspects of the outcome of surgery, and it is useful to use both measures in clinical studies. The advantage of PGI-I in clinical practice is that it is easy for the patient to fill in and it is less time consuming than the more detailed multiple HRQoL questionnaires.

The correlations were stronger, and the proportion of concordant ratings higher for PGI-I and PFDI-20 than for PGI-I and 15D. This is likely explained by the fact that PGI-I is anchored to the specific treatment being assessed (ie, POP surgery in our case). Thus, with PGI-I, the patient likely focuses on evaluation of POP related symptoms, and the bother related to them. Instead, 15D measures several domains, the majority of which are not related to pelvic floor dysfunction. PGI-I is thought to capture the global perception of the change and is typically used as an anchor when assessing the validity of

![FIGURE 3](image_url) Proportions of fully concordant (degree of improvement considered), concordant (degree of improvement ignored) and opposite ratings for (A) categorized change in PFDI-20 and PGI-I, (B) categorized change in PFDI-20 and 15D, (C) categorized change in 15D and PGI-I during two-year follow-up. 15D, 15-dimensional instrument; PGI-I, Patient Global Impression of Improvement; PFDI-20, prolapse-specific Pelvic Floor Distress Inventory.
other measures.\textsuperscript{13} One challenge of PGI-I is that as a retrospective measure it may be affected by recall bias whereas PFDI-20 measures current symptom burden and thus may be the preferable measure. However, global ratings of change are shown to provide the single best measure of significant change from the patient’s perspective.\textsuperscript{25}

4.3 | Strengths and limitations

Among the strengths of our study are the nationwide and prospective setting. To our knowledge, this is the largest study comparing different patient-reported outcome measures that are used in prolapse surgery. The participation rate was high and the baseline characteristics of the respondents at 2 years were fairly representative of the whole study population.\textsuperscript{8} One possible limitation is the definition of PFDI-20 total scores. The thresholds were obtained from two previous studies. Barber et al, defined a decrease of more than 45 points as a better outcome by studying the relationship between the change of PFDI-20 scores and subject’s global assessment of improvement among 100 patients 3 to 6 months after surgery,\textsuperscript{11} while Utomo et al performed a ROC analysis among 111 patients 6 months after surgery and thus defined that a decrease of 23 points or more indicates a clinically meaningful improvement in QoL.\textsuperscript{16} These cutoffs are based on two separate, relatively small studies and thus their robustness and generalizability to other samples are currently unknown.

5 | CONCLUSIONS

In conclusion, our findings demonstrate that the choice of outcome measurements is important and the quantified health gains are directly affected by this choice. Although the dimensions of generic instruments may appear to capture condition-specific symptoms, such as symptoms and consequences of POP, using condition-specific PROMs is essential.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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**SUPPORTING INFORMATION**

Additional supporting information may be found online in the Supporting Information section.

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