Responsiveness Comparison of the EQ-5D, PROMIS Global Health, and VR-12 Questionnaires in Knee Arthroscopy

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Background: The EuroQol 5 dimensions questionnaire (EQ-5D), Patient-Reported Outcomes Measurement Information System (PROMIS) 10 Global Health, and Veterans RAND 12-Item Health Survey (VR-12) are generic patient-reported outcome (PRO) questionnaires that assess a patient’s general health. In choosing a PRO to track general health status, it is necessary to consider which measure will be the most responsive to change after treatment. To date, no studies exist comparing responsiveness among the EQ-5D, PROMIS 10 Global Health, and the Veterans Rand 12-Item Health Survey (VR-12).

Purpose: To determine which of the generic PROs are most responsive internally and externally in the setting of knee arthroscopy.

Study Design: Cohort study (diagnosis); Level of evidence, 3.

Methods: Fifty patients who underwent knee arthroscopy were surveyed preoperatively and a mean 3.6 months postoperatively, with 90% follow-up. PROs included the EQ-5D, EQ-5D visual analog scale, PROMIS 10 Global Health (PROMIS 10) physical and mental components, VR-12 physical and mental components, and the Knee injury and Osteoarthritis Outcome Score (KOOS)–pain subscale. Internal responsiveness was evaluated by performing paired t tests on the changes in measures and calculating 2 measures of effect size: Cohen d and standardized response mean (SRM). External responsiveness was evaluated by comparing Pearson correlation measures between the disease-specific reference KOOS-pain and generic PROs.

Results: For internal responsiveness, 3 PROs showed a statistically significant improvement in score after treatment (EQ-5D: +0.10 [95% CI, 0.06-0.15], VR-12 physical: +7.2 [95% CI, 4.0-10.4], and PROMIS 10 physical: +4.4 [95% CI, 2.6-6.3]) and effect size statistics with moderate change (Cohen d and SRM, 0.5-0.8). Assessing external responsiveness, a high correlation with the disease-specific reference (KOOS-pain score) was found for EQ-5D (0.65), VR-12 physical (0.57), and PROMIS 10 physical (0.77). For both internal and external responsiveness, the EQ-5D, VR-12 physical, and PROMIS 10 physical showed significantly greater responsiveness compared with the other general PRO measures but no statistical differences among themselves.

Conclusion: There is no statistical difference in internal or external responsiveness to change among the EQ-5D, VR-12 physical, and PROMIS 10 physical instruments. In tracking longitudinal patient health, researchers and administrators have the flexibility to choose any of the general PROs among the EQ-5D, VR-12 physical, and PROMIS 10 physical. We recommend that any study tracking PROs in knee arthroscopy include 1 of these generic instruments.

Keywords: Knee; patient-reported outcomes; responsiveness
Two types of PROs exist: generic and disease specific. Generic PROs aim to assess patients’ general health status by measuring multiple domains and are valuable in comparing health across a range of disease processes. Disease-specific PROs focus on the impact of a single condition. The EuroQol 5 dimensions questionnaire (EQ-5D), Patient-Reported Outcomes Measurement Information System (PROMIS) 10 Global Health, and Veterans RAND 12-Item Health Survey (VR-12) are generic PRO questionnaires that assess and report patient general health and well-being. The EQ-5D is a preference-based measure designed to monitor health status over time and assess valuation of health status based on established population-specific indexes.\(^1\) The EQ-5D has shown applicability in randomized controlled trials, observational studies, and surveys in every medical subspecialty.\(^2\) The PROMIS 10 Global Health questionnaire (PROMIS 10) was developed by the National Institutes of Health to efficiently assess generic health-related quality of life compared with population norms.\(^3\) The VR-12 is a nonproprietary version of the 12-Item Short Form Health Survey (SF-12) that assesses health-related quality of life compared with a standardized reference population.\(^4\) Both the PROMIS 10 Global Health and VR-12 are made up of a physical and mental component scores, while the EQ-5D is split into the EQ-5D composite score and a visual analog scale (VAS).

Responsiveness to change is an important characteristic necessary in PROs. Responsiveness is made up of “internal responsiveness,” or the ability of a PRO to change over a time frame, and “external responsiveness,” or the extent that changes in a PRO over time relates to corresponding changes in a meaningful reference PRO.\(^5\) In choosing a PRO to track patient general health status on an institutional level, it is necessary to consider which measure will be the most responsive to changes. To date, no studies exist comparing the responsiveness among the PROMIS 10 Global Health, EQ-5D, and VR-12. It is difficult to choose an instrument to use in future tracking of longitudinal patient health without this information. We sought to answer which of the 3 general PROs were most responsive internally and externally in the setting of knee arthroscopy.

METHODS

Study Design and Patient Selection

A prospective observational study design was used. Fifty consecutive patients undergoing knee arthroscopy were recruited from an outpatient surgery center. Inclusion criteria included patients between the ages of 18 and 70 years undergoing any knee arthroscopic procedure. Exclusion criteria were patients who underwent a procedure that was primarily open/nonarthroscopic as well. For example, patients were excluded if they underwent a knee arthroscopy in conjunction with an open Fulkerson osteotomy. Patients were surveyed using the EQ-5D, PROMIS 10, VR-12, and the Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaires preoperatively. Patients were contacted at a minimum of 3 months postoperatively and asked to respond to the same set of PROs. Patients were compensated with a $15 gift card for participation. Study data were collected and managed using Research Electronic Data Capture (REDCap) tools. REDCap is a secure, web-based application designed to support data capture for research studies.\(^6\)

Patient-Reported Outcomes

The EQ-5D is a generic measure of health-related quality of life that assesses 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The measure is made up of 5 questions with 3 levels for each answer (no problem, some or moderate problems, and extreme problems), which creates 243 potential health states.\(^7\) The EQ-5D scores are applied to population-specific valuations of health states to result in a single index value. Based on United States population standards, scores on the EQ-5D range from –0.11 to 1, with “0” meaning dead and “1” meaning perfect health.\(^8\) Negative index values represent a state worse than dead. The EQ-5D also contains a VAS (EQ-5D VAS) that asks patients to rate their general health status on a 0 to 100 scale. The EQ-5D has shown validity, reliability, and responsiveness in diverse applications, including urinary incontinence, rheumatoid arthritis, chronic pain, and inflammatory bowel disease.\(^9\)\(^10\)\(^11\)\(^12\)\(^13\)

The PROMIS 10 is a 10-question survey that assesses generic health-related quality of life compared with population norms. PROMIS 10 gives a summary indicator of health status by assessing 5 domains: physical function, fatigue, pain, emotional distress, and social health.\(^14\) Nine of 10 questions are answered using 5-point Likert scales, and the 10th question is answered using a numerical rating scale. The PROMIS 10 does not yield an overall score but gives physical health and mental health component scores that are transformed to t score distributions with a mean of 50 and standard deviation of 10.\(^15\) PROMIS 10 physical and mental scores have shown adequate reliability and construct validity in a large 21,000-patient sample from the United States general population.\(^16\)

The VR-12 questionnaire is a nonproprietary variant of the SF-12 questionnaire meant to assess health-related quality of life. The VR-12 differs from the SF-12 in that it uses 5-point response choices, which give the VR-12 better floor and ceiling effects.\(^17\) The VR-12 includes 12 questions that do not give an overall score but yield a physical and mental component score, which are standardized to the United States population with a mean of 50 and SD of 10. The EQ-5D, EQ-5D VAS, PROMIS 10 physical, PROMIS 10 mental, VR-12 physical, and VR-12 mental were selected as general PROs in this study because of their common and widespread use in multiple settings and easy availability to researchers. Although each general PRO differs slightly in the domains measured, with pain and physical function likely being most relevant to knee arthroscopy, this study used component summary scores to evaluate their capacity to act as overall measures of health-related quality of life.

The KOOS is a questionnaire intended to quantify patients’ opinions about knee osteoarthritis and injuries that lead to posttraumatic osteoarthritis such as ligament,
meniscal, or chondral damage. The scale is made up of 42 questions measuring the following 5 subscales: pain, symptoms, activities of daily living, sports and recreation, and knee-related quality of life. Patients are asked to rate their experiences over the past week on a 5-point Likert scale. The KOOS was asked as a disease-specific reference measure to assess external responsiveness of the general PROs. The KOOS—quality of life and KOOS-pain subscales are the most responsive to change after knee surgeries, and KOOS-pain was used as the reference in the current study. The KOOS has shown validity and high reliability in all subscales in the setting of anterior cruciate ligament (ACL) reconstruction, meniscal injury, knee osteoarthritis, and cartilage lesions.

Statistical Analysis

When determining sample size comparing responsiveness between PROs, it was assumed that testing was to be done based on t statistics evaluating the correlation between PRO measures. Since little was known regarding the association between PRO measures, it was assumed that a moderate correlation of 0.5 would be important. A sample size greater than 34 patients would have had at least 90% power to detect this association. Calculations for sample size were made using G*Power1 (version 3.1), and 2-sided testing with a significance level of 5% was assumed. Fifty patients were enrolled in the current study, based on the above sample size calculations, as well as more general guidance from Terwee et al. Internal responsiveness was evaluated by performing paired t tests on the changes in measures and calculation of 2 measures of effect size: Cohen d and standardized response mean (SRM). Measures of near 0.2 represent small effect sizes, values at 0.5 represent moderate effect sizes, and values of 0.8 represent large effect size measures. To compare Cohen d and SRM measures, 95% bias-corrected bootstrap CIs for each measure and their differences were calculated. Differences were considered statistically significant if the 95% CI for the difference between measures did not cross 0. External responsiveness was evaluated by calculating Pearson correlation measures between the KOOS-pain and the other scales in the study. Comparisons of the correlations were made using the methods described by Meng et al. Comparisons of correlations used the cocor package. The internal and external responsiveness for each summary score (EQ-5D, EQ-5D VAS, PROMIS 10 physical, PROMIS 10 mental, VR-12 physical, and VR-12 mental) was compared head-to-head. Analysis was performed using R software (version 3.1). All tests were 2-sided and assumed a significance level of .05.

RESULTS

Patient Characteristics

Fifty patients who were preoperatively recruited had a mean age (±SD) of 41.0 ± 13.9 years (range, 18-69 years). The most frequent procedure was a meniscectomy, with the second most frequent being ACL reconstruction (Table 1).
Often patients had multiple procedures done during arthroscopy. Forty-five of 50 patients (90\%) were followed postoperatively at a mean of 3.6 ± 0.8 months (range, 3.0-3.3 months). Five patients were considered lost to follow-up after failure to return postoperative questionnaires with multiple contact attempts. The pre- and postoperative PRO score distributions are shown in Table 2. Interestingly, the postoperative VR-12 physical and PROMIS 10 physical scores were below the population mean.

**Internal Responsiveness**

Internal responsiveness for each PRO was assessed by testing for change between time points and the effect size statistics: Cohen $d$ and SRM (Table 3). Of the scales evaluated, the EQ-5D, VR-12 physical, PROMIS 10 physical, and KOOS-pain all showed significant changes between time points, while changes in the other scales were not statistically significant. KOOS-pain scores showed effect sizes that were large ($>0.8$), while the EQ-5D, VR-12 physical, and PROMIS 10 physical had effect sizes that were more moderate in size (0.5-0.8). The remaining scales, including the EQ-5D VAS, VR-12 mental, and PROMIS 10 mental, had very small effect sizes (<0.2), indicating little change in these measures over time.

Comparison of the difference between the Cohen $d$ and SRM effect size statistics head to head showed the EQ-5D, VR-12 physical, and PROMIS 10 physical have significantly greater internal responsiveness than the EQ-5D VAS, VR-12 mental, and PROMIS 10 mental (Tables 4 and 5). No significant differences among the EQ-5D, VR-12 physical, and PROMIS 10 physical were observed. As expected, the internal responsiveness of the KOOS-pain score was significantly greater than all the general scales considered in all comparisons.

**External Responsiveness**

External responsiveness was assessed by correlating the changes in general PRO measures with the changes in disease-specific reference (KOOS-pain). Significant positive correlations were observed for all scales with the KOOS-pain subscale (Table 6). The largest correlations with the KOOS-pain score were in the EQ-5D, PROMIS 10 physical, and VR-12 physical scales.

Differences between general PROs were assessed head to head from the differences in their correlation measures. No significant differences in external responsiveness among the EQ-5D, VR-12 physical, and PROMIS 10 physical were observed (Table 7). The EQ-5D and PROMIS 10 physical were significantly more externally responsive than the EQ-5D VAS, VR-12 mental, and PROMIS 10 mental scores. The VR-12 physical score was not significantly different from the EQ-5D VAS, VR-12 mental, and PROMIS 10 mental scores.

**DISCUSSION**

Responsiveness was compared among 3 general PRO measures in knee arthroscopy over a mean of 3.6 months, with 90\% patient follow-up. Assessing internal responsiveness, the EQ-5D, VR-12 physical, and PROMIS 10 physical scales showed a statistically significant change in score after treatment and effect size statistics with moderate change. The EQ-5D, VR-12 physical, and PROMIS 10 physical instruments showed significantly greater Cohen $d$ and SRM effect sizes compared with the other general PRO measures, but no statistical differences among themselves. Assessing external responsiveness, the EQ-5D, VR-12 physical, and PROMIS 10 physical instruments showed
high correlation with the disease-specific reference measure, KOOS-pain. Comparing external responsiveness among general PROs, the EQ-5D, VR-12 physical, and PROMIS 10 physical instruments showed no statistically significant differences among themselves and showed greater external responsiveness than the other general PROs.

To our knowledge, no literature exists comparing responsiveness among these 3 general PRO measures. It is important to determine which PRO scales are most responsive to avoid administration of redundant measures and responder burnout. Understanding which PROs are most responsive in orthopaedics will ensure gathering high-quality information. Rare literature comparing general PROs exists in non-orthopaedic settings. Only 1 study has been conducted comparing the responsiveness of the VR-12 and EQ-5D in the setting of heart failure. This study assessed change in the VR-12, EQ-5D, and other disease-specific measures over a course of 6 weeks without any specific heart failure intervention. The study provided relative rankings of the responsiveness of PROs in reference to multiple external standards. Overall, the EQ-5D and VR-12 physical were not as responsive to patient status changes as the VR-12 mental and heart failure-specific PROs. The reason for the lower responsiveness in the VR-12 physical compared with the VR-12 mental was unknown to the investigators, as heart disease is thought to cause a largely physical impact on patients. The only other comparisons between these general PROs were found with a measure closely related to the VR-12 named the SF-12. The SF-12 was shown to be more responsive to change over time than the EQ-5D in patients with depression and ankylosing spondylitis. The SF-12 was as responsive as the EQ-5D in patients with venous leg ulcers. In the current study, statistical comparison of the differences between all general PRO measures reveals 2 tiers of responsiveness: a more responsive tier including the EQ-5D, VR-12 physical, and the PROMIS 10 physical instruments and a less responsive tier including the EQ-5D VAS, VR-12 mental, and the PROMIS 10 mental instruments. Our study showed the greatest responsiveness in the PROs that pertained more to the physical domains of health, such as the EQ-5D, VR-12 physical, and the PROMIS 10 physical. These results are understandable as knee conditions cause more impairment in physical functioning than mental functioning. The VR-12 mental and PROMIS 10 mental instruments were not as responsive, which was reasonable in this patient population. The EQ-5D VAS could be too general and nonspecific to be as responsive to change as the multi-item PROs.

**TABLE 5**

| **PRO Measure** | **SRM, Estimate (95% CI)** | **vs EQ-5D VAS** | **vs VR-12 Physical** | **vs VR-12 Mental** | **vs PROMIS 10 Mental** | **Differences (95% CI)** |
|----------------|---------------------------|------------------|----------------------|-------------------|-------------------------|-------------------------|
| KOOS-pain      | 1.26 (0.99 to 1.53)       | 0.33 (0.04-0.57) | 0.30 (0.14-0.46)     | 0.34 (0.14-0.46)  | 0.37 (0.34-0.40)        | (0.28 to 0.47)          |
| EQ-5D          | 0.70 (0.52 to 0.91)       | 0.67 (0.60-0.72) | 0.64 (0.57-0.72)     | 0.61 (0.54-0.68)  | 0.63 (0.58-0.68)        | 0.15 (0.06-0.25)        |
| EQ-5D VAS      | 0.04 (-0.25 to 0.35)      | 0.37 (0.34 to 0.39) | 0.39 (0.36-0.42)    | 0.42 (0.39-0.44)  | 0.40 (0.36-0.43)        | 0.11 (0.00-0.24)        |
| VR-12 physical | 0.68 (-0.19 to 0.38)      | 0.58 (-0.38 to 0.31) | 0.60 (0.58-0.62)   | 0.62 (0.59-0.65)  | 0.63 (0.60-0.66)        | 0.05 (0.02-0.08)        |
| VR-12 mental   | 0.10 (-0.41 to 0.98)      | -0.62 (-0.95 to -0.29) | -0.64 (0.03 to 0.96) | -0.61 (0.02-0.15)  | -0.63 (0.00-0.15)        | 0.06 (0.00-0.12)        |
| PROMIS 10      | 0.72 (-0.34 to 0.37)      | -0.62 (-0.95 to -0.32) | -0.64 (0.03 to 0.96) | -0.61 (0.02-0.13)  | -0.63 (0.00-0.15)        | 0.06 (0.00-0.12)        |

**TABLE 6**

| **Variable 1** | **Variable 2** | **n** | **Correlation (95% CI)** | **P Value** |
|----------------|----------------|------|--------------------------|------------|
| Δ KOOS-pain    | Δ EQ-5D VAS    | 45   | 0.59 (0.44-0.74)         | <.001b      |
| Δ EQ-5D VAS    | Δ VR-12 physical | 44   | 0.42 (0.14-0.64)         | .004b       |
| Δ VR-12 mental | Δ VR-12 mental | 45   | 0.57 (0.33-0.74)         | <.001b      |
| Δ PROMIS 10 physical | Δ PROMIS 10 mental | 44   | 0.33 (0.04-0.57)         | .026b       |
| Δ PROMIS 10 mental | Δ PROMIS 10 mental | 45   | 0.77 (0.61-0.87)         | <.001b      |

aSignificant differences are shown in boldface (95% CI for the difference between measures does not cross 0). KOOS, Knee injury and Osteoarthritis Outcome Scale; PROMIS, Patient-Reported Outcomes Measurement Information System; SRM, standardized response mean; VAS, visual analog scale; VR-12, Veterans RAND 12-Item Health Survey.

**TABLE 6**

**External Responsiveness: Correlations With Change in KOOS-Pain Score**

| **Variable 1** | **Variable 2** | **n** | **Correlation (95% CI)** | **P Value** |
|----------------|----------------|------|--------------------------|------------|
| Δ KOOS-pain    | Δ EQ-5D VAS    | 45   | 0.59 (0.44-0.74)         | <.001b      |
| Δ EQ-5D VAS    | Δ VR-12 physical | 44   | 0.42 (0.14-0.64)         | .004b       |
| Δ VR-12 mental | Δ VR-12 mental | 45   | 0.57 (0.33-0.74)         | <.001b      |
| Δ PROMIS 10 physical | Δ PROMIS 10 mental | 44   | 0.33 (0.04-0.57)         | .026b       |
| Δ PROMIS 10 mental | Δ PROMIS 10 mental | 45   | 0.77 (0.61-0.87)         | <.001b      |

a, change from pre- to postoperative; KOOS, Knee injury and Osteoarthritis Outcome Scale; PROMIS, Patient-Reported Outcomes Measurement Information System; VAS, visual analog scale; VR-12, Veterans RAND 12-Item Health Survey.

bP < .05.
This study has multiple limitations. The minimum 3-month follow-up period may have been too soon to show the maximum improvement for some larger surgical procedures; however, we believe this intentional short-term follow-up was sufficient to evaluate responsiveness during this time frame. These results are not applicable to the pediatric population younger than 18 years. The results could have limited generalizability as these results are mainly applicable to longitudinal monitoring of general health outcomes in knee arthroscopy. Although responsiveness of PROs varies based on treatment given, we hope the trends we have discovered with the EQ-5D, VR-12 physical, and PROMIS 10 physical instruments showing equally high responsiveness will extend to other knee treatments and other treatments aimed at influencing physical function. This study used convenience sampling to enroll 50 consecutive patients undergoing knee arthroscopic surgery at an outpatient surgery center. There is potential for under- or overrepresentation of patient groups, but we believe that the study sample represents the general population of ages and most common diagnoses for patients undergoing knee arthroscopy.

CONCLUSION

The principal findings of this study demonstrate there is no statistical difference between the EQ-5D, VR-12 physical, and PROMIS 10 physical instruments in terms of internal or external responsiveness to change in knee arthroscopy. The EQ-5D, VR-12 physical, and PROMIS 10 physical instruments showed significantly greater internal and external responsiveness compared with the EQ-5D VAS, VR-12 mental, and PROMIS 10 mental scores. In tracking longitudinal patient health, researchers and administrators have the flexibility to choose any of the general PROs among the EQ-5D, VR-12 physical, and PROMIS 10 physical instruments to best capture responsiveness to change. We recommend that any study tracking PROs in knee arthroscopy include 1 of these generic instruments to best quantify health-related quality of life across disease processes. We routinely use the VR-12 physical instrument in our institution-wide outcome tracking system because it is freely available and can be quickly completed by patients. To observe the most responsiveness to change after knee arthroscopy, a disease-specific instrument such as the KOOS should be used.

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### TABLE 7

| PRO Measure | vs EQ-5D VAS | vs VR-12 Physical | vs VR-12 Mental | vs PROMIS 10 Physical | vs PROMIS 10 Mental |
|-------------|--------------|-------------------|----------------|----------------------|---------------------|
| EQ-5D       | 0.31 (0.12 to 0.83) | 0.08 (-0.22 to 0.48) | 0.32 (0.04 to 0.83) | -0.12 (-0.61 to 0.13) | 0.26 (0.003 to 0.73) |
| EQ-5D VAS   | -            | -0.19 (-0.70 to 0.16) | 0.09 (-0.19 to 0.41) | -0.32 (-0.86 to -0.09) | 0.12 (-0.18 to 0.46) |
| VR-12 physical | -        | -                | 0.24 (-0.15 to 0.75) | -0.20 (-0.77 to 0.02) | 0.18 (-0.18 to 0.65) |
| VR-12 mental | -            | -                | -0.06 (-0.30 to -0.02) | -0.12 (-0.61 to 0.13) |
| PROMIS 10 physical | -        | -                | -0.06 (-0.43 to 0.30) |
| PROMIS 10 mental | -        | -                | 0.39 (0.27 to 0.97) |

*Significant differences are shown in boldface (95% CI for the difference between measures does not cross 0). KOOS, Knee injury and Osteoarthritis Outcome Scale; PROMIS, Patient-Reported Outcomes Measurement Information System; VAS, visual analog scale; VR-12, Veterans RAND 12-Item Health Survey.*
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