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Research Article

Improvement of patient-reported outcomes measurement information system after primary anterior cruciate ligament reconstruction

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Abstract

Fifty-one patients who had been admitted to Saint Paul Hospital and Hanoi Medical University Hospital for Anterior Cruciate Ligament (ACL) reconstruction were asked to complete a detailed questionnaire at preoperative and three-month postoperative time. The questionnaire designed to evaluate the improvement of Patient-reported Outcomes Measurement Information System (PROMIS) include Physical Function (PF), Pain Interference (PI), Depression (D) and Anxiety (A) scores before surgery with those taken 3 months after primary ACL reconstruction. The improvement score of PF domain increase to 10,17 ± 8,7; PI, D, A domain decrease to 9,63 ± 7,21; 10,02 ± 6,63 and 12,51 ± 7,58 respectively. At 3-month postoperative, all of the patients had better scores and had a statistically significant difference ($p<0,05$). All patients with ACL reconstruction had substantial improvement in pain reduction and regain physical function at 3-month after surgery.

Keywords: Anterior cruciate ligament reconstruction, physical function, pain interference, depression, anxiety, patient-reported outcomes measurement information system

INTRODUCTION

A Patient-Reported Outcome (PRO) is a health outcome directly reported by the patient who experienced it. PRO measures are used to obtain self-reported information about an individual's function, such as physical, cognitive, and sexual function; symptoms such as sleep and fatigue; and perceptions such as social support and health-related quality of life. However, there are challenges to their use, including multiple measures of the same concept, widely varying quality, excessive length and complexity, and difficulty comparing findings across studies and conditions. To address these challenges, the National Institutes of Health funded the Patient-Reported Outcomes Measurement Information System (PROMIS), a web-based repository of valid and reliable PRO measures of health concepts relevant to clinicians and researchers. PROMIS is a set of measures covering different domains of physical, mental, and social health 1. There are over a thousand questions (items) of more than 50 distinct domains for adult health. They are available at www.HealthMeasures.net [1,2].

The Anterior Cruciate Ligament (ACL) is the most commonly injured of the major knee ligaments. Although the results of ACL reconstruction are often considered positive, many studies have shown different results [3,4].

PROMIS measures are considered to have greater precision compare with most conventional measures so that enhances power in a less costly way than increasing sample size. Some studies have shown the improvement of PROMIS scores before and after surgery in patients with foot and ankle abnormalities, undergoing arthroplasty reconstruction, and in patients suffer from ACL reconstruction [5-8]. In Vietnam there are not any study using PROMIS score to assess the improvement after surgery among patients who underwent ACL reconstruction so this study was conducted to the improvement of PROMIS physical function (PF), pain interference (PI), depression (D) and anxiety (A) scores before surgery with those taken 3 months after primary ACL reconstruction.

METHODS

The study was designed as a prospective cohort study. We recruited 51 patients at Saint Paul Hospital and Hanoi Medical University Hospital who were 18 years old or older and underwent primary arthroscopic ACL reconstruction with or without meniscus injury. Convenience sampling studies from April 1st to July 30th, 2019. Exclusion criteria include patient refused to join in the study, had other ligament concomitant injury and other injuries of the limb.

All patients who met inclusion were invited and explained the importance to participate in the study. Data collection was conducted at 1 day before patient's operation and after three-month postoperative, using structured questionnaires in Vietnamese. The questionnaires collected data concerning general information (demographic data and medical history) as well as PROMIS scores.

The data was collected before surgery and at 3 months after operation, patients were contacted to obtain information to assess outcomes of ACL reconstruction. Patients answered the questionnaires by verbally communicate and write. We observed the process that patients completed and explained any problems that were difficult to understand. Recheck all of patients' information; someone answered lack of information, we returned the patients' rooms or called them to add more information. Participant questionnaires were marked with ordinal numbers.

Information gathering tools include 2 parts. Demographic data include age, gender, occupation, educational level, address, phone number) and information related to surgery (date of admission, date of surgery, medical diagnosis and indication of surgery). The assessment of the outcomes of postoperative ACL reconstruction follows PROMIS short form scores. Our study has 36 questionnaires and score is based on four manifestations: physical function (PF), pain interference (PI), depression (D) and anxiety (A) scores. It probes the dimensions of physical function (12 items: 1-60), pain interference (8 items: 1-40), depression (8 items: 1-40), and anxiety (8 items: 1-40). The items of PI, D and A are scored on a scale of 1-5 (1=never, 2=rarely, 3=sometimes, 4=often, 5=always), and the items of PF are scored on a scale of 1-5 (1=Without any difficulty, 2=with a little difficulty, 3=with some difficulty, 4=with much difficulty, 5=unable to do). Of note, higher PF scores indicated increased function, higher PI, D, A scores indicate increase pain, depression, anxiety respectively.

Data was entered by excel and epidata version 3.1. All the data analysis was performed with Stata version 15.1. Data analysis involved descriptive statistics, including frequencies, percentages, mean, and standard deviation. Paired T-test, ANOVA test were used to assess differences improvement of PF, PI, D, A domain preoperative to postoperative. Statistically significance difference was defined as any p-value less than 0.05.

RESULTS

The study consisted 51 participants totally including 84,31% of male (43 participants) and 15,69% of female (8 participants). The mean age of the participants was 29,9 ± 8,01 years and ranged from 18 years old to 51 years old. Most of participants were in the 18-40 age group with 88,23%. Of the entire sample, there was 32 (62,75%) participants have an education from college to university, 13 (25,49%) participants had high school educated level, 6 (11,04%) participants just studied at primary and secondary school. There was 37 (72,55%) participants were in employment, 13 (12.1%) participants were in education at university and 1 (1,96%) participant was unemployed.

Among 51 participants diagnosis with ACL injury, there was 20 (39,22%) participants combined with meniscus tear. The most common cause of ACL injury was sports accident mostly by play football with the number of patients was 31 accounted for 60,78%; 25,49% patients suffered from traffic accident, 11,76 % patients had daily living accident due to slip down the stairs and 1,96% suffered from fell at work.

On average, patients had a statistically significant preoperative to 3-month postoperative improvement ($p<0,05$) in four domains of PROMIS scores. The Physical Function (PF) domain increased 10,17 ± 8,7 and the Pain Interference (PI), Depression (D) and Anxiety (A) decreased 9,63 ± 7,21, 10,02 ± 6,63, 12,51 ± 7,58 respectively (Table 1).

There was no statistically significant difference in PF, PI, D, A domain scores compared with male and female group (all $p>0,05$). Female group more likely to have worse score than male group in PF, PI domain at preoperative to postoperative (Table 2).

The mean score in 4 domains from preoperative to postoperative time points had no statistically significant difference by age and medical diagnosis. The study also illustrated no statistically significant difference in PROMIS improvement score when compared two groups

Table 1. Improvement of PF, PI, D, A scores preoperative to 3 months postoperative

	Preoperative mean ± SD	Posoperative mean ± SD	p value	Difference
$PF_{(T)}$	39,49 ± 8,72	49,67 ± 4,58	<0,05	10,17 ± 8,7
$PI_{(T)}$	24,82 ± 7,47	15,19 ± 4,78	<0,05	-9,63 ± 7,21
$D_{(T)}$	21,47 ± 6,31	11,45 ± 3,61	<0,05	-10,02 ± 6,63
$A_{(T)}$	26,08 ± 7,28	13,57 ± 4,80	<0,05	-12,51 ± 7,58
(T): T test; SD: Standard Deviation				

Table 2. Difference improvement of participants in PF, PI, D, A scores by sex

		Preoperative Mean ± SD	Post-operative Mean ± SD	Difference Score Mean ± SD	p value (Difference Score)
$PF_{(T)}$	Male (n=43)	40,44 ± 8,50	50,16 ± 4,24	9,72 ± 8,98	0,601
	Female (n=8)	34,37 ± 8,63	47 ± 5,68	12,63 ± 7,07	
$PI_{(T)}$	Male (n=43)	24,77 ± 7,42	15,09 ± 4,79	9,67 ± 7,32	0,697
	Female (n=8)	25,12 ± 8,22	15,75 ± 5,01	9,37 ± 8,48	
$D_{(T)}$	Male (n=43)	21,65 ± 6,31	11,44 ± 3,71	10,21 ± 6,64	0,968
	Female (n=8)	20,5 ± 6,68	11,5 ± 3,21	9 ± 6,91	
$A_{(T)}$	Male (n=43)	26,28 ± 7,35	13,23 ± 4,12	13,05 ± 7,5	0,878
	Female (n=8)	25 ± 7,29	15,37 ± 7,63	9,63 ± 7,91	
T: T test; SD: Standard Deviation					

Table 3. Difference improvement of participants in PF, PI, D, A score by educational level

		Preoperative Mean ± SD	Postoperative Mean ± SD	Difference score Mean ± SD	p value Difference score
$PF_{(T)}$	Junior level (n=19)	39,11 ± 9,15	49,37 ± 3,35	10,26 ± 9,98	0,96
	Senior level (n=32)	39,72 ± 8,41	49,84 ± 5,21	10,12 ± 8,03	
$PI_{(T)}$	Junior level (n=19)	23,63 ± 6,55	14,79 ± 4,40	8,84 ± 7,40	0,56
	Senior level (n=32)	25,53 ± 7,98	15,44 ± 5,05	10,09 ± 7,51	
$D_{(T)}$	Junior level (n=19)	22,89 ± 6,06	10,26 ± 2,51	12,63 ± 6,85	<0,05
	Senior level (n=32)	20,62 ± 6,39	12,16 ± 3,99	8,47 ± 6,08	
$A_{(T)}$	Junior level (n=19)	26,84 ± 6,01	12,63 ± 3,55	14,21 ± 6,43	0,22
	Senior level (n=32)	25,62 ± 8,0	14,12 ± 5,39	11,5 ± 8,12	
(T): T test ; SD: Standard Deviation					

of educational level: senior group (university, college) and junior group (primary school, secondary school and high school) at PF, PI, A domain (p>0,05). However, there was a significant difference in D score postoperatively (p<0,05), junior level had better improvement compared with senior level (Table 3).

DISCUSSION

The improvement score of PF domain increase to 10,17 ± 8,7; PI, D, A domain decrease to 9,63 ± 7,21; 10,02 ± 6,63 and 12,51 ± 7,58 respectively. At 3-month postoperative, all of patients had better scores and had a statistically significant difference (p<0,05). This result is likely with the study of Chen et al. [8,9], with 100 to 240 days postoperatively and the difference between preoperative and postoperative mean scores was statistically significant for PROMIS PF, PI, D score (all p<0.001). In the result of a study conducted by Papuga et al. [10], they reported the improvement of PROMIS physical function score at 10 weeks after surgery, and this improvement continues on through 52 weeks. They also concluded those individuals with the lowest PROMIS scores at baseline were indeed more likely to have poor outcomes. This finding may prove useful in developing specific surgical procedures or post-surgical interventions (bracing, physical therapy techniques, etc.) that may help to predict and mitigate the increased risk of poor outcomes.

Clinically, an ACL injury is acutely painful for the patient, but immobilization and bracing partly makes pain often recedes. The improvement in PI seen in our patients postoperatively could be due to timely clinic visits, with preoperative PROMIS scores captured in the very early post-injury phase. Furthermore, the PROMIS PI questionnaire is not designed to quantify the exact amount of pain a patient is having; instead, the score captures a patient's perceived interference in daily activities secondary to pain. Given this distinction, it is possible that some patients may feel limited in certain activities preoperatively out of fear that an activity may be painful, without actually experiencing pain, and they may answer the PROMIS questionnaire in a way that increases their PI scores preoperatively.

There is no correlation between sex as well as age group with postoperative PROMIS PF, PI, D, A improvement scores. The results were also similar with Chen et al. [8] and Ferrari et al. [11] study reflect gender, age not significantly effects the outcome of patients after ACL reconstruction.

In our study, there was a statistically significant difference in D domain scores postoperative between junior and senior group. Junior group seems to have better score improvement score at D domain that might due to they are more relax and have positive attitude about the ACL reconstruction rehabilitation so their fear at recovery process less than senior group. There was no correlation between other groups of educational level in PF, PI, A- improvement scores.

Applying PROMIS in clinical studies has some advantages when compare with other clinical scores. The first is that it is simple and easy to use for most researchers, even nurses at all levels of research and practice, so they encouraged nursing education programs should provide at least an introduction to item response theory as part of research methods coursework [12]. Secondly, PROMIS is a high-through-put PRO that has proven to be valid and accurate in multiple orthopedic patient populations and supplies item banks that offer the potential for PRO measurement that is efficient (minimizes item number without compromising reliability) flexible (enables optional use of interchangeable items), and precise (has minimal error in estimate) measurement of commonly-studied PRO [13]. Thirdly, there is clear effectiveness of cost; researchers can study on a large population with limited resources. Candidates only need to finish questionnaires, even via online forms but don't need go to the hospital. Finally, using PROMIS will allow researchers can discuss via a "common language". Lawson [14] proposed that PROMIS can be become a new tool for the clinician scientist in the future. Makhni et al. [15] also had the same opinion when applying for the upper extremity.

PROMIS, however, has also some limits but other traditional clinical scores don't have, expressed in this study. Since only patients who completed the PROMIS survey at both time points were included, our study population may have been skewed to include a higher proportion of those who were having poorer outcomes. However, given that, our second time point was 3 months postoperatively and many patients were still in the ACL rehabilitation phase during that

time and therefore more likely to appear in clinic or willing to finish all questionnaires, we hope minimal this potential bias. Although longer follow-up is desirable, as previously stated, prior work has shown that this time frame represents the phase of most rapid improvement after ACL reconstruction 10. Therefore, our data best describe this period of swift improvement directly following surgery instead of longer-term outcomes.

In our study, the sample size was relatively small, the follow-up time had restrictions during 3 months postoperatively and the study was conducted at two orthopedic departments. Therefore, it may not reflect all patients who may not be included in the study population, which is a limitation of this study. Bias may also occur when convenience sample was collected. Other limit of PROMIS is it doesn't provide clinical examinations such as physical test or scores (Lyshomlm, Tegner). But this is the novel study used PROMIS in Vietnam as far as we know, so we only focused on the improvement of some basic domains of PROMIS in patients suffered from ACL reconstruction but not compared with clinical examinations. We hope that this study will open other study of PROMIS in Vietnam.

CONCLUSION

The Physical function, pain interference, depression and anxiety scores showed significant preoperative to 3-month postoperative improvements in patients who underwent primary ACL reconstruction ($p<0,05$). The improvement score of physical function domain increases $10,17 \pm 8,7$; pain interference, depression and anxiety domains decrease $9,63 \pm 7,21$;$10,02 \pm 6,63$ and $12,51 \pm 7,58$ respectively. All have better score at 3-month postoperative.

Anterior cruciate ligament reconstruction improves significantly in-patient health and well-being at 3 months after surgery. After 3 months of operation, patients reached good physical function, limited pain interference, decreased depression and anxiety.

There was no different improvement in physical function, pain interference, depression and anxiety score between age group, sex and type of ACL injury. On the other hand, there was a statistically significant difference improvement in depression score between junior and senior group of education level. Junior group seems to have better improvement score than senior group at depression domain.

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