Pediatric Simple Knee Value: a simple patient-reported outcome measure for the knee

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Abstract

Purpose The pediatric Simple Knee Value (pedi-SKV) is an outcome score in which paediatric patients are asked 'How would you rate your knee today as a percentage of normal (0% to 100% scale with 100% being normal)?'. The primary aim of this study was to validate the pedi-SKV by measuring its correlation with validated knee function scores used most often in paediatric orthopaedics.

Methods This prospective study was conducted at a teaching hospital to evaluate the pedi-SKV's validity. A total of 44 paediatric patients (ten to 15 years old), were enrolled prior to anterior cruciate ligament reconstruction as well as 17 healthy controls. A survey form consisting of the Lysholm, International Knee Documentation Committee Pediatric Form (Pedi-IKDC) and pedi-SKV was given to subjects twice (enrolment and six months postoperatively). The criterion validity of the pedi-SKV was determined by correlating it to existing knee functional scores. Responsiveness to change was evaluated by comparing the pedi-SKV scores before and after surgery (enrolment visit and six-month postoperative visit). Discriminative ability was evaluated by comparing the pedi-SKV distribution in patients *versus* controls.

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Results There was a strong and significant correlation between the pedi-SKV and the Lysholm and Pedi-IKDC (p < 0.0001). The pedi-SKV had a good responsiveness to change (p < 0.0001 for the pedi-SKV before *versus* six months postoperatively). Like the other knee-specific functional sores (p < 0.0001), the pedi-SKV was able to distinguish between patients and controls (p < 0.0001).

Conclusion The pedi-SKV is a valid outcome measure that is strongly correlated with the Lysholm and Pedi-IKDC. This is a novel simple score that can be used by physicians in their daily practice.

Level of evidence: II

Introduction

Pre- and postoperative functional evaluations are of great importance for practitioners, either during daily practice to determine the best treatment for a patient and the effectiveness of the treatments applied, to evaluate the patient's progression or to carry out clinical studies.[1] Several functional outcome scores already exist for the knee. The most used are the Lysholm[2] and International Knee Documentation Committee Pediatric Form (Pedi-IKDC).[3-5] In the United States, physicians spend more than 785 hours per physician per year on patient-reported outcome measures (PROMs), which corresponds to a staggering $15.4 billion per year ($31 450 per year per orthopaedic surgery practice).[6]

The Single Assessment Numeric Evaluation (SANE) was published by Williams et al[7] in 1999. Patients are asked how they rate their joint on the day of the examination, as a percentage of a normal joint. This score allows healthcare professionals to save time and resources.[8] It also avoids unrelated or disconcerting questions that patients can sometimes be unable to answer.[8] The SANE has a moderate to strong correlation with the subjective IKDC and the Cincinnati Knee Rating System (CKRS) in young

adult patients undergoing anterior cruciate ligament reconstruction (ACLR) or knee arthroscopy.[8] The SANE is a general score that can be used to evaluate any joint. It was specifically validated for the shoulder joint by Gilbart and Gerber[9] under the name of the Subjective Shoulder Value (SSV). They demonstrated that its results were close to that of the Constant score. Since then, the SSV has been largely used by shoulder surgeons, rehabilitation specialists and rheumatologists, given its simplicity and speed.

Our group has validated the SANE for the knee joint, calling it the Simple Knee Value (SKV) and demonstrating its validity, reproducibility, responsiveness to change, and discriminative ability.[10] This score is simple, short and easy to understand. The SANE, CKRS, SSV, Constant and SKV are all adult scores.

According to Gao et al,[11] there is a need for studies that use PROMs validated in paediatric populations, such as the Pedi-IKDC. However, the Pedi-IKDC is limited because certain items are difficult to understand for children and measurement errors are induced by other items.[3,12] We propose to validate the 'pediatric SKV' (pedi-SKV), which could be used in all paediatric patients who have a knee injury.

Our hypothesis was that the pedi-SKV is a valid score that provides the same results as existing knee PROMs already being used in paediatric patients. The primary objective was to validate the pedi-SKV by determining its correlation with the validated knee function scores used most often in paediatric orthopaedics;[4,5] the Lysholm[2] and the Pedi-IKDC.[3] Our secondary objective was to evaluate its responsiveness to change.

Patients and methods

This was a prospective study assessing the validity of the pedi-SKV.

Patients

The study was performed between 01 August 2017 and 01 April 2019 in the Pediatric Orthopedic Unit of our teaching hospital (CHU de Toulouse). The following inclusion criteria were used: child between ten and 15 years of age who presented with an anterior cruciate ligament tear and was booked for ACLR at the paediatric orthopaedic clinic. The exclusion criteria were mental retardation or refusal by patient, parent or guardian to participate in the study. The patients were included consecutively according to those criteria.

Methods

All subjects included were given a questionnaire in paper format, which they filled out without assistance. The questionnaire comprised the Lysholm[2] and Pedi-IKDC[3] scores. The Lysholm score, which was created for the follow-up of ACLR, has eight items for a total of 100 points. The Pedi-IKDC is a subjective score of overall knee function that has 21 items for a total of 100 points. The following question was added for the pedi-SKV score: 'How would you rate your knee today as a percentage of normal (0% to 100% scale with 100% being normal)?' To ensure the pedi-SKV and benchmark tests were blinded, this question was asked before the standard functional scores so as to not bias the answer. In addition, the patients could not see the total score of the various PROMs questionnaires they had filled out. Age, sex, height and weight were recorded.

To evaluate the pedi-SKV's reliability and responsiveness, the children who were going to be operated on were asked to fill out the pedi-SKV during the six-month postoperative follow-up visit. To test the discriminative ability of the pedi-SKV, 17 control subjects between ten and 15 years of age who had no history of knee problems and who came to our clinic for a consultation about another pathology were enrolled consecutively.

Statistical analysis

The number of subjects required was calculated before starting the study. To show a correlation between the pedi-SKV and the Lysholm and Pedi-IKDC of ≥ 0.50, 44 subjects were needed (with two-tailed alpha risk set at 2.5% after Bonferroni correction for two comparisons and power of 90%).

The criterion validity of the pedi-SKV with the existing knee function scores was determined using Spearman's correlation coefficient. The significance threshold was set at 2.5%. Two time points were used: preoperative and six months postoperatively. The responsiveness to change of the pedi-SKV was analyzed by comparing the SKV at enrollment and at six months postoperatively in the patients undergoing surgical treatment using the Wilcoxon test (paired comparison). The significance threshold was set at 5%. The discriminative ability of the pedi-SKV (and the other PROMs) was analyzed by comparing the distribution of the pedi-SKV (and the other PROMs) in the patients at enrolment (initial consultation visit) and in the controls using the Mann-Whitney U test. Reported p-values for discriminative ability were two-sided and the significance threshold was set at < 5%.

Results

We enrolled 44 subjects, 28 (64%) boys and 16 (36%) girls, with a mean age of 13.8 years (sd 1.5). Their mean body mass index was 20.8 kg/m² (sd 3.1).

Validity of pedi-SKV

The distributions of the different scores at the two time points are shown in Table 1. There was a strong positive and statistically significant correlation between the pedi-SKV and the Lysholm score (Spearman coefficient = 0.62; p < 0.0001) and between the pedi-SKV and the Pedi-IKDC score (Spearman coefficient = 0.6882; p < 0.0001).

Responsiveness to change of pedi-SKV

The pedi-SKV was able to detect a change in the clinical condition (at six months postoperative *versus* preoperative) (median = 85.0 (interquartile range (IQR) 76.5 to 90.0) *versus* 65.0 (IQR 50.0 to -75.0), respectively; p < 0.0001).

Discriminative ability of pedi-SKV

Like the other PROMs (p < 0.0001), the SKV was able to distinguish between patients and controls (p < 0.0001) (Table 2).

Discussion

Our hypothesis is confirmed. The pedi-SKV is a valid outcome score, as it is highly correlated with different PROMs already being used to evaluate knee function in the context of various pathological states. Our findings are consistent with those in the literature. In their study, Gagliardi et al[13] found a median Lysholm score of 99.5 (IQR 89.0 to 100.0) and a median Pedi-IKDC of 94 (IQR 89 to 98) two years after ACLR in children ten to 18 years of age. Wilson et al[14] found a mean Pedi-IKDC of 91.2 (46.7 to 100) at 38.5 months after ACLR in 11- to 16-year-old children. In their literature review, Liechti et al[15] found the Lysholm

score ranged between 85.4 and 96.3 at 12 months minimum after meniscal repair, whether or not ACLR was done in patients who averaged 15 years of age.

There are several arguments in favour of using simple scores that are adapted to children since they often have trouble understanding and answering questionnaires developed for adults.[3,16] While several PROMs are used in paediatric orthopaedics, not many of them have been validated in children.[17] According to Taylor et al,[18] the majority of PROMs are written at a higher level of complexity than the persons intended to complete them can likely understand. It is also generally accepted that information provided by proxy respondents is not equivalent to patient self-reports and that a parent report of function cannot be substituted for the child's report.[19-22]

Only four knee-specific questionnaires are currently used in paediatric orthopaedics.[4] These are the Pedi-IKDC,[12] the Hospital for Special Surgery Pediatric Functional Activity Brief Scale (HSS Pedi-FABS)[11,23], the Knee Injury and Osteoarthritis Outcome Score for children (KOOS-Child),[24] and the Tegner score.[25] The Pedi-IKDC, which is used the most,[4] has good validity and psychometric properties:[26] good reproducibility with an intraclass correlation of 0.91, good responsiveness to change and good internal validity. However, its drawbacks[16,24,26] are the notable ceiling effect ranging from 6%[26] to 34%[27] and the fact that the youngest patients have difficulty answering items 2, 3 and 6,[12] which can induce measurement errors. Also, the length of the questionnaire can lead to loss of concentration or even fragmented completion in children when they fill it out in a context without medical supervision.[28] The HSS Pedi-FABS is a simple, reliable and valid metric to assess activity in children and adolescents ten to 18 years old, but its responsiveness to how changes in activity over time

Table 1. Median values of three different knee-specific patient-reported outcome measures at two different time points in our population of ten- to 15-year-old children with an anterior cruciate ligament tear (n = 44)

	Median preoperative score (IQR)	Median six-month postoperative score (IQR)
pedi-SKV	65.0 (50.0 to 75.0)	85.0 (76.5 to 90.0)
Lysholm	81.0 (77.5 to 87.0)	95.0 (91.0 to 100.0)
Pedi-IKDC	69.5 (63.5 to 74.5)	80.0 (76.5 to 87.5)

IQR, interquartile range; pedi-SKV, pediatric Simple Knee Value; Pedi-IKDC, International Knee Documentation Committee Pediatric Form

Table 2. Discriminative ability of the pediatric Simple Knee Value (pedi-SKV)

	Control group, n = 17	Patients, n = 44	p-value*
Median pedi-SKV (IQR)	100 (95.0 to 100.0)	65 (50.0 to 75.0)	< 0.0001
Median Lysholm (IQR)	95 (95.0 to 100.0)	81 (77.5 to 87.0)	< 0.0001
Median Pedi-IKDC (IQR)	100 (99 to 100.0)	69.5 (63.5 to 74.5)	< 0.0001

IQR, interquartile range; Pedi-IKDC, International Knee Documentation Committee Pediatric

*Mann-Whitney U test

correspond to clinical change has not been evaluated.[23] Also, parental assistance is needed for those under 13 years of age.[23] The KOOS-Child shows an adequate test-retest reliability (intraclass correlation coefficient 0.8 to 0.9; SEM 8.9 to 16.9; Smallest Detectable Change (SDC) 24.7 to 46.9), adequate content validity (> 75% relevant, except KOOS-Child subscale Activity of Daily Living (ADL)), adequate construct validity, low floor and ceiling effects (scores between 5 and 95, except KOOS-Child subscale ADL and Sport/play); however, it responsiveness is moderate (40% confirmed hypotheses).[29]

Other than being short and easy to understand, the pedi-SKV has other advantages. We think that short PROMs like the pedi-SKV will increase the participation rate. It also shows physicians where patients stand relative to their expectations. With this percentage-based assessment, patients can express the how much further they must go before their knee is normal. Thus, it captures how much patients think they can still improve. Only this type of outcome measure captures what the patient thinks 'remains' to be gained. It is then up to the practitioner to determine whether this difference can still be made up, or if the patient's expectations are not achievable. It is important to discuss patients' expectations with them in order to make a decision together about treatments,[30-32] and to increase compliance to the surgeon's recommendations.[33] The currently used knee PROMs have been translated into many languages. It is easy to imagine that the pedi-SKV could be easily translated into different languages. The introduction of new technologies to collect PROMs provides several advantages. Questionnaire delivery by automated text messaging for example allows asynchronous response and may increase compliance and reduce the labour cost of collecting PROMs.[28] We believe the format of the pedi-SKV makes it perfectly suited to this type of collection.

The current study bears certain limitations. We did not compare the pedi-SKV with other paediatric knee assessment scores such as the KOOS-Child and the HSS Pedi-FABS, since the most used scores by far in the literature for knee assessment are the Lysholm and the Pedi-IKDC.[4,5] Also, the Pedi-IKDC would be preferred both in the research context and in clinical practice, relative to the KOOS-Child.[29] We were unable to measure the reproducibility of the pedi-SKV, which is the final criteria typically used to validate a clinical score. This could be done in a future study.

Conclusion

The pedi-SKV is a valid outcome measure that is strongly correlated with the Lysholm and pedi-IKDC. This novel simple score can be used by physicians in their daily practice.

COMPLIANCE WITH ETHICAL STANDARDS

ETHICAL STATEMENT
Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by our local IRB (reference number 1-19-085/ID 5594).

Informed consent: Parents or guardians signed an informed consent form for patient's data to be used.

ICMJE CONFLICT OF INTEREST STATEMENT
None declared.

AUTHOR CONTRIBUTIONS
VM: Corresponding author, Responsible for writing manuscript.
HV: Responsible for data collection.
YD: Data collection.
AJ: Critical revision.
NR: Review of manuscript after translation.
EC: Critical revision and approval of the article.
EB: Methodology.
FA: Responsible for writing manuscript.

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