[Athletic Training]

CEU

Comparison of IKDC and SANE Outcome Measures Following Knee Injury in Active Female Patients

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Background: Knee injury among young, active female patients remains a public health issue. Clinicians are called upon to pay greater attention to patient-oriented outcomes to evaluate the impact of these injuries. Little agreement exists on which outcome measures are best, and clinicians cite several barriers to their use. Single Assessment Numerical Evaluation (SANE) may provide meaningful outcome information while lessening the time burden associated with other patient-oriented measures.

Hypothesis: The SANE and International Knee Documentation Committee (IKDC) scores would be strongly correlated in a cohort of young active female patients with knee injuries from preinjury through 1-year follow-up and that a minimal clinically important difference (MCID) could be calculated for the SANE score.

Study Design: Observational prospective cohort.

Methods: Two hundred sixty-three subjects completed SANE and IKDC at preinjury by recall, time of injury, and 3, 6, and 12 months postinjury. Pearson correlation coefficients were used to assess the association between SANE and IKDC. Repeated-measures analysis of variance was used to determine differences in SANE and IKDC over time. MCID was calculated for SANE using IKDC MCID as an anchor.

Results: Moderate to strong correlations were seen between SANE and IKDC (0.65-0.83). SANE, on average, was 2.7 (95% confidence interval, 1.5-3.9; $P < 0.00$) units greater than IKDC over all time points. MCID for the SANE was calculated as 7 for a 6-month follow-up and 19 for a 12-month follow-up.

Conclusion: SANE scores were moderately to strongly correlated to IKDC scores across all time points. Reported MCID values for the SANE should be utilized to measure meaningful changes over time for young, active female patients with knee injuries.

Clinical Relevance: Providing clinicians with patient-oriented outcome measures that can be obtained with little clinician and patient burden may allow for greater acceptance and use of outcome measures in clinical settings.

Keywords: patient-oriented outcomes; Single Assessment Numeric Evaluation (SANE); International Knee Documentation Committee (IKDC); knee injuries

Female athletes participating in sports and fitness activities demonstrate an incidence of knee injuries that is 3 to 6 times higher than males.[4,22,27] The incidence of these knee injuries in adolescents[22,27,28,32] and female young adults[1,2,10,14,15] is recognized as a pressing public health concern because of the economic impact, detrimental effects on health and well-being, and increased risk for early onset osteoarthritis.[10,12,28,35,51] Numerous clinical rating scales and patient questionnaires have been utilized to gather outcome data after knee injury or surgery.[7,25,29,36,39] These injury-specific scales can be used to measure a patient's activities and restrictions following knee injury. Recent literature[37,43,50] has called for increased attention to a whole-person health care approach in sports medicine. Athletic training researchers have advocated a whole-person approach with disablement models as a conceptual framework and clinical outcomes assessment as the measurement tools

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to enable greater integration of evidence-guided practice.[50] Patient self-report instruments, often referred to as outcome measures, allow clinicians and researchers to better understand the impact of a disease or injury on structural impairments and functional limitations from the patient's point of view. Sports medicine providers have been encouraged to measure an individual's health status[8,13] and joint function[30,31] using self-report instruments. Some of these self-report instruments specific to knee function include the International Knee Documentation Committee (IKDC) form,[20,25] Knee Injury and Osteoarthritis Outcome Score (KOOS),[40] Lysholm knee scoring scale,[29] the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC),[7] and Single Assessment Numeric Evaluation (SANE).[52,53]

Clinician-based patient outcomes assessment has traditionally focused on overall impairments (eg, strength, range of motion, and joint laxity) and time from injury to discharge to participation. While significant attention is given to understanding the incidence, mechanism, treatment options, and return to participation for knee injuries in adolescents and young women from the clinician's perspective,[5,9,18,23] few studies have attempted to document patient-oriented outcome measures following knee injury in this population.[16,17,38,40,44,45] Research on the reliability and responsiveness of these outcome measures for the knee is often performed in general orthopaedic patients 40 to 70 years of age.[7,25] Very little work has been done on the reliability and responsiveness of these instruments in young female patients,[13,39] and to our knowledge, none have compared specific outcome measures with preinjury status.

Collecting patient self-reported outcome data requires additional clinician and patient time and resources. These factors are often identified by clinicians as impediments to full implementation of an outcome measures collections program.[42] To relieve this burden, the use of single-item, self-report measures, such as the SANE, has been suggested. A SANE score requires the patient to rate their knee function on a scale of 0 to 100. The SANE score is a simplified means for collecting outcomes data, which has proven successful in studies of ankle,[21] knee,[42,53] and shoulder injuries.[52] Two previous studies correlating SANE ratings with widely used knee surveys have shown that SANE ratings can be a reliable reflection of knee symptoms after anterior cruciate ligament (ACL) reconstruction in both male and female patients.[48,53] However, correlation analysis between SANE ratings and validated knee survey scores has not been performed on subpopulations of patients with a range of knee injuries, such as active, young female patients with knee injuries. In addition, to our knowledge, there have been no reports of minimal clinically important difference (MCID) values for the SANE in active young female patients with knee injuries.

MCID was originally described as the smallest difference in score in the domain of interest a patient perceives as beneficial and would mandate a change in management.[26] The definition has varied over time and is often reported as a change that is meaningful to the patient or the smallest difference in a score that is considered to be worthwhile or important.[6] MCID holds promise for clinicians in helping to identify the threshold for clinically important improvement and can be used as an index of responsiveness to treatment.[34]

The purposes of this study were to determine the correlation between a SANE assessment and the IKDC questionnaire and to determine the MCID for the SANE score in a population of active, young female patients following knee injury from preinjury through 1-year follow-up. We hypothesized that SANE and IKDC scores would be strongly correlated and that MCID could be calculated for the SANE score.

METHODS

Study Design

The research protocol was approved by the institution's Health Sciences Minimal Risk Institutional Review Board.

Participants

Study participants consisted of a convenience sample of 263 female adolescents (age range, 13-18 years) and female young adults (age range, 19-23 years) who sustained a knee injury while participating in regular fitness or sport activities. All subjects presented or were referred to a sports medicine physician for care in 1 of 2 participating clinics: an outpatient sports medicine center or a campus-based university health service sports medicine clinic. To be eligible to participate, the potential subject must have indicated that they: (1) injured the structures of the knee to the degree that it caused them to stop participating in their activity for at least 1 day after the onset of symptoms, (2) sustained their knee injury during athletic participation or regular fitness activity (physical education classes, aerobic exercise classes, running activities), and (3) could recall the exact date they were injured. In the event that the condition was gradual in onset, the potential subject had to be able to recall the exact date they decided to seek medical treatment from an MD to continue their sport or fitness activity. All subjects were required to read and sign an informed consent form. If the subject was less than 18 years of age, her parent or guardian was also required to complete the consent form.

Instrumentation

The IKDC was developed in 1993[20] and revised in 1998.[25] The IKDC evaluation form was created to have a standardized international documentation system for knee surgery. The validity, responsiveness, and reliability of the IKDC form have been confirmed for adult and adolescent populations.[3,19,24,25,41] The IKDC subjective evaluation consists of 18 questions that stress the effects of symptoms, activities of daily living, and sports activities on the knee while also accounting for total knee function on a converted scale from 0 to 100. A score of 100 means no limitation with activities of daily living or sports activities and the absence of symptoms. The IKDC was selected for this study over other available knee self-report

Table 1. Demographic data, injury type, activity classification, and frequency

Injury Type	ACL 106 (40.3%)	AKP 82 (31.2%)	PAT 38 (14.4%)	MT 17 (6.5%)	COL 14 (5.3%)	OTH 6 (2.3%)
Activity Classification[a]	Contact 135 (51.7%)	Limited Contact 65 (24.7%)	No Contact 62 (23.6%)			
Activity frequency by classification	Basketball (63) Hockey (1) Lacrosse (1) Soccer (70)	Baseball (1) Cheer-dance (6) Gymnastics (7) In-line skate (1) Downhill ski (11) Softball (14) Ultimate Frisbee (3) Volleyball (15) Other, sport (7)	Aerobics class (1) Cross-country (7) Dancing (4) Exercise class (5) Jog/running (14) Swimming (5) Tennis (2) Track and field (15) Walking (3) Weight training (1) Other, exercise (5)			

ACL, anterior cruciate tear; AKP, anterior knee pain includes patellofemoral stress syndrome, patellar tendonopathy, fat pad impingement, Osgood Schlatter disease, medial plica irritation, and iliotibial band syndrome; PAT, patellar dislocations and subluxations; MT, meniscal tears; COL, collateral ligament sprain; OTH, other knee injuries including contusions, intra-articular loose bodies, and osteochondritis dissecans and fractures.
[a]American Academy of Pediatrics Committee on Sports Medicine and Fitness Classifications of Sport by Contact.[11]

measures of knee function based on the strength of the IKDC to allow comparison between groups with different diagnoses including ligament, meniscus, and articular cartilage injuries; patellofemoral pain; and osteoarthritis (OA).[54] While other instruments may be better choices for patients with OA,[47] the inclusion of specific questions on sports activities makes it a better choice for the targeted population.[54]

The SANE rating was introduced by Williams et al[52] as a tool to aid in the assessment of clinical outcomes by decreasing the burden of gathering outcomes data without limiting the meaningfulness of the data. The SANE is a global rating scale that is a valid and responsive tool for measuring knee function.[46,53] Despite widespread use, reliability data are limited. Reliability for the SANE has been presented for a subpopulation of female adolescents and proven reliable (n = 48, intraclass correlation coefficient [ICC] = 0.885, 95% confidence interval [CI], 0.804-0.934).[33] The SANE was selected for this study over other available single-item rating scales (eg, Global Rate of Change and Global Pain Index) based on its validity for measuring knee function.[46,53] The SANE rating is determined by the subject's written response to the following question: "On a scale of 0 to 100, how would you rate your knee's function, with 100 being normal?"[52,53]

Data Collection

Injury Diagnosis

Subjects were diagnosed during their initial clinic visit by the attending sports medicine physician. When appropriate, diagnostics (radiographs, magnetic resonance imaging, computed tomography scans) were part of the clinical evaluation. The specific diagnosis of each injury was confirmed by the research staff (2 licensed athletic trainers and 1 sports medicine physician) during a review of the subjects' medical records. In cases requiring surgery, the diagnosis was confirmed by examining the operative note provided by the surgeon. Specific knee injury diagnoses were grouped into 1 of 6 classifications (Table 1). In the event that multiple diagnoses were provided, a primary diagnosis was used for classification.

Survey Administration

Subjects completed 2 study questionnaires (IKDC and SANE) during their initial clinic visit to determine their knee function. The subjects completed the first set of questionnaires by reflecting on their knee function in the week prior to their injury (preinjury). After completing the initial questionnaires, they completed the same survey detailing their knee function since they sustained their knee injury (at diagnosis). Subsequent surveys were administered, based on the preference of the subject, through the US Postal System or electronically through the subject's e-mail address. The follow-up administration intervals included 3, 6, and 12 months postinjury, and at these time points, additional questions were included regarding factors that may affect their outcomes (physical therapy, surgery, etc).

Analyses

Pearson correlation coefficients, with 95% CIs, were calculated to assess the relationship and strength of association between

Table 2. Summary of International Knee Documentation Committee (IKDC) and Single Assessment Numerical Evaluation (SANE) measures over all time points[a]

Time Point	IKDC	SANE	*r* (95% CI)	Difference	*P* Value[b]
Preinjury	92.8 (90.7, 94.5)	93.9 (91.8, 96.0)	0.80 (0.75, 0.84)	–1.1 (–3.7, 1.5)	0.41
Baseline	47.5 (45.4, 49.6)	51.2 (49.1, 53.3)	0.70 (0.63, 0.76)	–3.7 (–6.3, –1.1)	0.01
3 mo	65.5 (63.3, 67.8)	69.1 (66.9, 71.3)	0.83 (0.78, 0.87)	–3.6 (–6.3, –0.9)	0.01
6 mo	77.9 (75.7, 80.0)	80.1 (78.0, 82.3)	0.83 (0.79, 0.86)	–2.2 (–4.9, 0.5)	0.10
12 mo	83.9 (81.7, 86.0)	86.9 (84.7, 89.0)	0.65 (0.58, 0.72)	–3.0 (–5.7, –0.3)	0.03

[a]Reported as mean (95% CI) as estimated from repeated-measures ANOVA, except for correlation coefficient.
[b]*P* value calculated from repeated-measures ANOVA for the difference.

SANE and IKDC at each of the time points. Since both SANE and IKDC are scale measures that range from 0 to 100, direct comparison of mean responses in SANE and IKDC was assessed with a repeated-measures analysis of variance (RM-ANOVA). In the RM-ANOVA, the SANE and IKDC measurements were the dependent variable, and tool (SANE or IKDC), time point, and their interaction were treated as fixed effect factors; subject was the random effect.

To calculate the MCID for SANE, we used previously calculated MCID values for the IKDC at the 6-month (6.3 units) and 12-month (16.7 units) follow-up visits.[19] We dichotomized the subjects into "improved" or "not improved" as determined by their changes from baseline in IKDC at 6 and 12 months being greater than or equal to the corresponding MCID for IKDC at each time point. We then fit 2 logistic regression models, 1 for each time point, with improved status as the dependent variable and the change from baseline of SANE as the independent variable. The MCID for SANE at each time point was then the value that maximized the sensitivity and specificity of the receiver operating characteristic (ROC) curve from the logistic model. We also calculated the area under the ROC curve (AUC) along with a 95% CI for the AUC. All analyses were conducted with R software version 2.15 (Vienna, Austria).[49]

RESULTS

Two hundred seventy-nine female patients aged 13 to 23 years (mean, 17.5 ± 1.2 years) who sustained a knee injury while participating in regular fitness or sport activities sought treatment during the study enrollment time frame. The subjects were initially examined and enrolled at 12 days (median [25th, 75th]: 7, 21) since their injury. A convenience sample of 263 of those seeking treatment (mean age, 17.5 ± 1.2 years) were enrolled (263/279, 94%). Two hundred forty-two subjects completed the 1-year follow-up (242/263, 92.0%). Specific knee injury diagnoses are presented in Table 1. All ACL tears were treated surgically. There were no isolated lateral collateral or posterior cruciate ligament sprains in this sample. Detailed characteristics of participants, injury classification, activity, and activity frequencies are provided in Table 1.

The mean differences between IKDC and SANE at each time point ranged from –1.1 at preinjury to –3.7 at baseline (Table 2). Since the interaction term showed no statistical difference ($P = 0.63$), we concluded that the differences between IKDC and SANE did not vary significantly over time. Therefore, the interaction term was removed from the model, and an RM-ANOVA model was created with only tool and time as fixed effects. SANE, on average, was 2.7 (95% CI, 1.5-3.9; $P < 0.00$) units greater than IKDC over all time points. SANE was statistically significantly higher than IKDC at baseline ($P = 0.01$) and 3 ($P = 0.01$) and 12 months ($P = 0.03$).

Pearson correlation coefficients, with 95% CI, between IKDC and SANE at each time point ranged from 0.65 at 12 months to 0.83 at both 3 and 6 months (Table 2). These correlations represent moderate to strong positive correlations between IKDC and SANE at all time points.

Using previously reported IKDC MCID values[19] as cut-off values to define improved subjects, 214 (88.4%) subjects improved in IKDC by more than 6.3 points from baseline to 6 months, and 190 (78.8%) improved by more than 16.7 points from baseline to 12 months. Those that improved in IKDC at 6 months had a significantly greater mean change in SANE from baseline to 6 months (33.6 ± 23.0) compared with those that did not improve in IKDC (–0.2 ± 23.6; $P < 0.00$). Similarly, those that improved in IKDC at 12 months had a significantly higher mean change in SANE from baseline to 12 months (42.8 ± 23.2) compared with those that did not improve in IKDC (10.6 ± 20.4; $P < 0.00$). The MCID for SANE at 6 months was 7; this corresponded with a sensitivity of 89.7% and specificity of 67.9%. The AUC (95% CI) of the corresponding ROC curve was 0.855 (0.789-0.922). The MCID for SANE at 12 months was 19; this corresponded with a sensitivity of 87.4% and specificity of 72.5%. The AUC of the ROC curve was 0.859 (0.806-0.913).

DISCUSSION

This observational prospective cohort study was performed to determine the correlation between a SANE assessment and the IKDC questionnaire and to determine the MCID for the SANE score in a population of active, young female patients following knee injury. We found moderate to strong positive correlations between the IKDC and SANE at all time points from preinjury to the 12-month follow-up.

The moderate to strong correlation values of the SANE with the IKDC for active, young female patients did not vary over a 1-year time period. This indicates that the SANE score was an excellent indicator of knee function for this group of patients, similar to previous studies that have compared a SANE rating with validated knee outcome measures for ACL injuries only.[42,48,53] Shelbourne et al[42] analyzed over 11,000 surveys from over 3000 patients who underwent ACL reconstruction in an 11-year time period and found moderate to strong correlations between SANE and IKDC scores. The SANE score was compared with results of the Lysholm score for 130 young, active patients following ACL reconstruction and a correlation of 0.75 was found.[53] Taylor et al[48] studied 34 patients with ACL injuries over a 30-year follow-up using the SANE method to correlate with Lysholm scores, KOOS pain measure, and the KOOS quality of life score and reported moderate to strong correlations for the SANE score with all measures.

A recent study[42] called for greater application of the SANE score across a range of acute and chronic knee injuries. These results confirm the usefulness of the SANE rating to evaluate overall knee function for a range of knee injuries, suggesting that this simple 1-item outcomes measure may be clinically useful in the assessment of young female patients' knee function during the first year of treatment. Its value includes ease of administration, since it is a single question. While multi-item measures may be optimal in assessing injury, they are often impractical for providers and patients alike because of time constraints for both and resource allocation (staff time and space usage). The ease of use of the SANE method may be valuable to care providers with limited resources who wish to gain a patient-oriented perspective on knee function. The use of the SANE is reserved for assessment of joint function and is only 1 component of the whole-person approach to care. Clinicians wishing to capture other dimensions of whole-person health care (eg, health-related quality of life) will need assessment tools that reach beyond function alone.

The MCID for the SANE at both 6 and 12 months is consistent with the MCID for the IKDC, with comparable sensitivity and specificity.[19] We concluded that the SANE score combined with the calculated MCID is sufficient to measure change in status for this population of active female patients with a range of knee injuries.

Clinical Relevance

Providing clinicians with patient-oriented outcome measures that can be obtained without additional clinician and patient burden may allow for greater acceptance and use of outcome measures in a range of clinical environments. While the SANE score should not replace knee outcomes measures with multiple components and established psychometric properties, it is a useful tool for environments that do not have adequate resources for traditional psychometric surveys. An additional value of the SANE score may lie in the clinical utility of using the assessment to start a conversation with the patient about their knee function. Recent literature[42] identified the SANE score as a valuable tool for facilitating provider-patient communication. The SANE score requires the patient to take into account all aspects of their knee-related activity as it relates to their own interest and needs. While this creates a personalized assessment of the patient's function, it can have limitations for clinicians in that as a global measure it does not identify specific areas of concern that may be causing underlying problems.[42] The SANE can be a quick and easy tool to help associate patient perception with other diagnostic findings (eg, physical examination, radiographs).

The moderately high sensitivity and specificity of the MCID for the SANE make it a reasonably useful tool in clinical practice. A SANE score at 6 months that is at least 7 higher than baseline and a score at 12 months that is at least 19 higher than baseline would indicate improvement in knee function that is beneficial to the patient. Because the MCID is an index of patient responsiveness to treatment,[34] knowing the MCID in addition to an overall score allows the clinician to make appropriate adjustments in the course of care. MCID values lower than the thresholds identified for the SANE may influence the clinician's treatment recommendations to facilitate more meaningful patient-oriented outcomes for young women with knee injuries. The ability to develop MCID scores for easily applied patient outcome measures, like the SANE, holds promise as we address the very real question: Are our treatment interventions providing meaningful outcomes for our patient?

Limitations

There are several limitations of this study. First, the SANE score does not provide specific information about what portion of knee function may be influencing a patient's global rating.[42] The ability to calculate MCID for the SANE using the anchor method[19] is dependent on having other psychometric measures available (eg, IKDC).

Recall bias is always a concern. Subjects were recruited from a convenience sample from 2 sports medicine clinics. As a result, subjects included in this study may have had knee injuries that they perceived to be more serious, and this may have influenced their self-reporting. Given the distribution of our injury subgroups, the patellar dislocations and subluxations, meniscal tear, collateral ligament sprain, and other knee injuries groups were underpowered.

Also, completing a survey at the time of injury diagnosis regarding their knee function for the week prior to injury may bias their assessment of knee function. Lastly, this study

focused on young women with knee injuries and may not be generalizable to other populations.

CONCLUSION

The SANE and IKDC scores were moderately to strongly correlated across all time points from preinjury to 12-month follow-up. The ability to calculate the MCID gives added meaning to the SANE score and allows for greater clinical application.

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