The single assessment numeric evaluation correlates with the western ontario rotator cuff score in non-traumatic shoulder disease

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Patient-reported outcome measures (PROMs) are essential clinical instruments used for assessing patient function and assisting in clinical decision making. The Western Ontario Rotator Cuff (WORC) index is the PROM for shoulder pathology with the most psychometric properties but is very time consuming. The Single Assessment Numeric Evaluation (SANE) method is a PROM that takes less time to answer and to analyze. The aim of the study is to evaluate the intra-class correlation between these two outcome scores in establishing shoulder function in patients with non-traumatic rotator cuff pathologies. Fifty five subjects of both genders and different ages presenting with non-traumatic shoulder pain for more than 12 weeks had a physical examination and ultrasound as well as MRI arthrogram scan findings that were consistent of a non-traumatic rotator cuff (RC) based pathology. On the same moment a WORC index and a SANE score questionnaire were filled in by the subject. The intra class correlation of both PROMs was statistically analyzed. The WORC index score and the SANE score show a moderate correlation with an Intra Class Coefficient (ICC) of r = 0.60 (95% CI:0.40-0.75). This study demonstrates a moderate correlation between the WORC index score and the SANE score in rating the disability of patients with atraumatic RC disease. The SANE score is applicable in research and clinical practice and is for the patient and the researcher an almost no time consuming PROM.

Keywords : Patient Reported Outcome Measure (PROM), WORC index, SANE score, SPONSA score, Subjective Shoulder Value (SVV).

INTRODUCTION

An outcome measure is a tool for assessing the magnitude of some longitudinal change in health state in an individual or a group. Outcome data serve many purposes: to provide evidence on the effectiveness of a treatment method, to compare different treatment methods and so to determine which treatment method is most effective and cost-beneficial. In today's healthcare environment evidence based treatment is becoming mandatory so there is an increasing application of measurement instruments in clinical practice. Valid outcome assessment tools are invaluable in supplementing clinical research and improving patient care. Clinicians and researchers use a wide variety of outcome measures. There are clinician based rating scales, radiographic based rating scales and patient reported outcomes. The clinician based outcome measures use findings acquired during clinical examination such as data of range of motion

and on strength while the radiographic based outcome measures use imaging results. These measures do not capture what is important to the patient because they do not measure the impact of the dysfunction on an individual's ability to perform activities of daily living, work and recreation[1]. There is strong evidence that patients can reliably report the impact of a condition on their health status on personally relevant outcomes[2]. So outcome measures are nowadays primarily patient based because they mirror the patient's perception of the outcome and capture information about the impact on physical, emotional and social functioning resulting from a dysfunction. They are free from eventual examiner bias.

PROMs take the form of questionnaires of a fixed number of items in which patients rate their health status using visual analogue scales. Answers are tallied to produce a summary score which will represent the impact of the dysfunction on an individual's health-related quality of life. These tools can be cumbersome

to administer in a busy clinic setting especially without administrative or research support staff. On the patient side it is also time consuming and can lead to poor patient compliance. A decreased number of questions leads to decreased PROM instrument administration time and likely improves the patient enthusiasm when filling out a questionnaire[3]. The use of a single -item, self -report measure was introduced in 1999 by Williams[4]. The Single Assessment Numeric Evaluation (SANE) is a single question assessment of the patient's perceived overall function relative to normal. This is expressed as a percentage (0%-100%) where 100% reflects normal.

The aim of the study was to evaluate the association between the WORC index a multi numbered questionnaire and the SANE score a single question questionnaire in patients with non-traumatic RC disease.

MATERIALS AND METHODS

55 subjects presenting with shoulder pain existing for more than 12 weeks without any traumatic exposure were included. All subjects had physical and radiological examination findings such as ultrasound examination and indirect MRI arthrogram that were consistent with a RC disease such as bursitis, cuff tendinopathy or a partial or complete cuff tear. Each participant received paper copies of the WORC index and the SANE score questionnaires and completed both questionnaires on the same moment independently of clinical assistance. The subjects had no difficulties understanding the use of the both scores. All stages of the study were approved by the institutional medical ethical review board and all participating subjects signed an informed consent form.

To determine the accordance between the two questionnaires, intraclass correlation (ICC) and 95% confidence interval (CF) is calculated based on 2-way mixed effects model for consistency with single measurement according to the notation of Shrout and Fleiss[5]. Interpretation will be based on the 95% confidence interval of the ICC as suggested by Koo and Li.[6] Values below 0.5 indicate poor, between 0.5 and 0.75 moderate, between 0.75 and 0.9 good and values above 0.9 excellent consistency. A scatter plot of WORC index versus SANE score will be used for visualization. A reference line is drawn to indicate identical values. Additionally a Bland-Altman plot was produced to evaluate the comparability of the two questionnaires. This plot studies the difference

between the two scores as a function of the average. Limits of agreement are constructed[7].

RESULTS

The mean WORC index is 65.84 with a SD of 15,48 and the median of the WORC index result is 67 (range 38 to 97). The mean SANE score is 59.15 with a SD of 16,60 and the median is 65 (range 24 to 85). (Table I) Calculation of the ICC between the WORC mean and the SANE mean results in a ICC of 0.60 (95%CI: 0.40-0.75)[5]. This is considered a moderate consistency[6]. On the scatter plot (Figure 1), the WORC index scores are on average somewhat higher than the SANE scores while the Bland-Altman analysis (Figure 2) shows a difference of 6.7 with limits of agreement ranging from -21.6 to 35.0.

DISCUSSION

PROMs are essential instruments for assessing the function of the shoulder and quantifying outcomes of surgical and nonsurgical management and they play a critical role in clinical and research aspects of shoulder treatment. The first step before implementation of a PROM is to carefully evaluate its psychometric properties[8]. The information retrieved from a PROM is only as useful and reliable as the quality of its measurement properties. A standardized set of criteria is the COSMIN checklist (COnsensus based Standards for the selection of health status Measurement INstruments) developed in 2010[9]. The

Table I. — Means and medians of the results of the WORC -index and the SANE score.

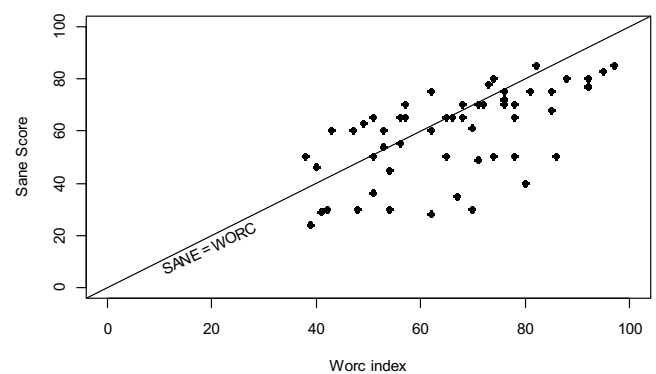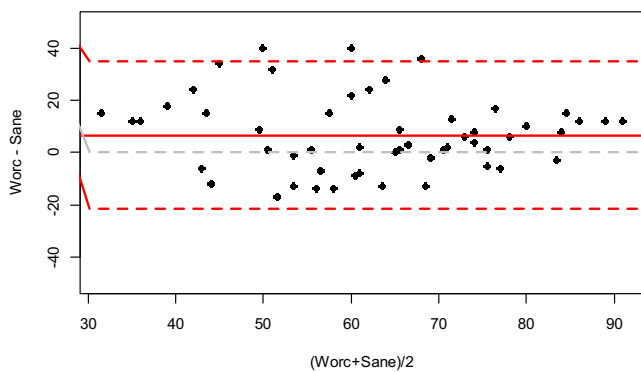|	mean	SD	median	Minimum	Maximum
Worc-index	65,84	15,48	67	38	97
Sane-score	59,15	16,60	65	24	85

Fig. 1 — Scatter plot.

Fig. 2 — Bland-Altman plot.

checklist was designed as a critical appraisal tool for evaluating the methodological quality or risk of bias of studies assessing the psychometric properties of health-related QoL outcome instruments. The COSMIN checklist consists of internal consistency, reliability, measurement error, content validity, construct validity (including structural validity and hypothesis testing) and responsiveness. Not all PROMs used have the same quality of measurements properties. The systematic review of Huang of the psychometric properties of PROMs for use in patients with RC disease the WORC index was found to have the best overall quality of psychometric properties such as internal consistency, reliability, content validity, hypothesis testing and responsiveness among all shoulder outcome measures[10]. The WORC index is a disease specific shoulder questionnaire, developed at the University of Western Ontario to measure the health quality of life in patients with RC disease[11-14]. It is a self- reported questionnaire consisting of 21 visual scales (VAS) items in 5 domains. Physical symptoms (6 items), sports and recreation (4 items), work (4 items), lifestyle (4 items) and emotions (3 items). Each item is scored on a 100 mm VAS scale. Physical symptoms up to 600 points, sports and recreation up to 400, work up to 400, lifestyle up to 400, and emotions up to 300. Summing up to a minimum total score of 0 and a maximal score of 2100. The higher the rating, the higher the negative effect on the quality of life. The score is almost always expressed as a percentage score by subtracting the total score from 2100 and dividing by 2100 and multiplying by 100 leading to total outcome ranging from 0 (worst possible) to 100 (best possible). The translation of the WORC index was validated in several languages including Dutch[15]. To fill in the questionnaire can be lengthy and time consuming. It takes about 8 minutes for the patient to fill in the questionnaire and 5 minutes for

the observer to reach the result. For the physician, given the time and administrative resources required for successful implementation concern exists whether practitioners can afford to routinely administer multi question scores. On the patient side the completion of a lengthy questionnaire is often repetitive and time consuming resulting in poor compliance. So despite the utility there is a significant limitation in the utilization of the WORC index.

A PROM consisting of 1 question is easily understood by the patient and leads to a considerable time gain for the clinician. The use of a single -item, self -report measure was introduced by Williams in 1999. The Single Assessment Numeric Evaluation (SANE) is a single question assessment of the patient's perceived overall function relative to normal This is expressed as a percentage ((0%-100%) where 100% reflects normal[4]. His study on patients after shoulder surgery reported a correlation between the ROWE and the SANE score with r = 0.77 and between the ASES score and the SANE score with r = 0.69 indicating a good correlation between the scores. From then on many studies were published to assess the correlation between different shoulder PROMs and the SANE score. Gilbart compared the SANE method which he named Subjective Shoulder Value (SSV) with the Constant Score. Correlations between both scores ranged from r = 0.61 to r = 0.80 in three different patient groups[16]. Provencher reported on the SANE and 4 others scores in patients with 10 different shoulder pathologies. In the patient group with RC tears a strong correlation between the SANE and the WOSI and between the SANE and the WORC was observed[17]. Noorani named the SANE score the Stanmore Percentage Of Normal Shoulder Assessment (SPONSA) and calculated in 55 patients with different categories of shoulder injuries the correlation between the SPONSA score and the Oxford Shoulder score with r = 0.79 and between the SPONSA score and the Constant Score with r = 0.78[18].

In a study on 262 patients who underwent surgery for RC tears and SLAP lesions the correlation between the ASES and the SANE score was r = 0.80 demonstrating a very good correlation[19]. Tigphen et al administered the SANE and ASES questionnaires at baseline and again after 3-month follow-up in patients with different shoulder diseases and different treatments. For the subjects with RC repair the correlation was r =0.84, for the subjects with shoulder replacement r = 0.80 and for physical therapy treated patients r =0.88 concluding that the

SANE is valid to assess patient outcomes across different treatments for shoulder complaints[20]. In 2019 a review identified 4 studies comparing the SANE with other shoulder PROMs. In these 4 studies the mean correlation calculated was r = 0.59[21]. Recently Lädermann reported on 253 patients treated for shoulder instability who were evaluated with both the SANE and Rowe scores. Those investigators found a high correlation of r = 0.85 between the scores with strong correlations at all time points, age groups and treatment groups[22].

The results of our investigation confirm the results of the above studies on the correlation between different shoulder PROMs and the SANE score. Our study on the correlation between the WORC index and the SANE score in patients with non-traumatic shoulder dysfunction results in a moderate correlation with an Intra Class Coefficient (ICC) of r =0.60 (95% CI:0.40-0.75).

The strengths of this study are: most studies report on the correlation between the SANE score and different PROM shoulder scores of which most of them have not all the necessary psychometric properties such as internal consistency, reliability, content validity, hypothesis testing and responsiveness. This can be noted as a possible flaw in the conclusions of these studies. In our study we correlated the SANE score with the WORC index as golden standard. The WORC index being the PROM on shoulder function with all the necessary properties. Some conclusions on correlations of other studies vary depending on different diagnosis of the shoulder dysfunction. Our cohort consists solemnly in patients with nontraumatic RC disease as proven by the radiological examinations.

CONCLUSION

We assessed in the study a moderate correlation between the WORC index score being the survey with the most psychometric properties but very time consuming and the single question SANE score with almost no time consuming for the patient and the clinician. Our study confirms earlier studies on the correlation between different PROMs on shoulder function and the SANE score. The SANE score is a simple way to assess patient perceived function relative to normal. The result suggest that the SANE method is sufficient reproducible to take decisions about changes in the QoL in patients with atraumatic RC disease.

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