

Comparison of Validity, and Responsiveness between General and Disease-Specific Quality of Life Instruments (Thai Version) in Knee Osteoarthritis

Boonsin Tangtrakulwanich MD*, Sutti Wiwatwongwana MD*,
Virasakdi Chongsuvivatwong MD, PhD**, Alan F Geater PhD**

* Department of Orthopaedic Surgery and Physical Medicine, Faculty of Medicine,
Prince of Songkla University, Hat Yai, Songkhla

** Epidemiology Unit, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla

Short-form 36 (SF-36) and Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) are common instruments for measuring quality of life (QoL) in patients with knee osteoarthritis. The goal of the present study was to compare the performance of both instruments in evaluating QoL in patients with knee osteoarthritis as diagnosed by the American College of Rheumatology (ACR) criteria. Treatment included nonsteroidal anti-inflammatory drugs and patient education for 6 weeks. Face-to-face interview by an orthopaedist was done at baseline and after treatment, including collection of demographic data and use of both SF-36 and WOMAC questionnaires. Evaluation of instrument performance included reliability, validity, and responsiveness measures. Reliability was tested by analysis of internal consistency using Cronbach's alpha at baseline and after treatment. Construct validity was computed by determining the correlation between each domain of SF-36 and WOMAC (Pearson's test). Responsiveness was compared between baseline and after treatment of both SF-36 and WOMAC in each domain using the paired t test. Fifty-two patients (8 men, 48 women) with a mean age of 58.4 years were included in the present study. About 75% of subjects had less than secondary education levels and most were from agricultural communities. Sixty-four percent had mild grade knee osteoarthritis. The internal consistency of WOMAC revealed good levels of reliability, both at baseline and after treatment, in all dimensions. The reliability of SF-36 was relatively low, especially in the role physical and bodily pain dimensions (Cronbach's alpha < 0.700). Construct validity between each dimension in SF-36 and WOMAC demonstrated coefficients ranging from -0.05 to -0.409. Both WOMAC and SF-36 showed good responsiveness when comparing scores before and after treatment in all domains. In conclusion, both the Thai version WOMAC and SF-36 were valid, reliable, and sensitive to change in evaluating QoL in Thai patients with knee osteoarthritis.

Keywords: Quality of life, Knee osteoarthritis

J Med Assoc Thai 2006; 89 (9): 1454-9

Full text. e-Journal: <http://www.medassocthai.org/journal>

Knee osteoarthritis is a chronic disease and a major health problem^(1,2). The significant burden of this disease, in terms of economic impact and quality of life (QoL) has been confirmed by various studies⁽³⁻⁵⁾. Recently, there has been a growing interest in using

QoL assessment to investigate the impact of osteoarthritis and to monitor the results of treatment⁽⁶⁻¹⁰⁾. QoL instruments are useful in patient assessment because they evaluate global effects rather than specific clinical outcomes⁽¹¹⁾. A number of QoL instruments have been developed, but the two most commonly used are the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the short-form 36 (SF-36). WOMAC is a disease-specific QoL instrument

Correspondence to : Tangtrakulwanich B, Department of Orthopaedic Surgery and Physical Medicine, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla 90110, Thailand. Fax: 074-212915, E-mail: boonsin.b@psu.ac.th

designed to evaluate hip and knee osteoarthritis, while SF-36 is an instrument for measurement of general QoL. Both instruments have been translated into a number of languages and validated in various countries; including Thailand^(12-14,17,18). There have been no previous reports, however, comparing the validity, reliability, and responsiveness of WOMAC and SF-36 for evaluation of people with knee osteoarthritis in Thailand. Since validity and reliability are the prerequisite properties of the instrument and Thai people have a different culture from Western countries, it is necessary to test these properties before putting the instruments into general use. The objective of the present study was to investigate the performance of both SF-36 and WOMAC in evaluating the QoL in Thai patients having knee osteoarthritis.

Material and Method

Patients visiting the orthopedic outpatient clinic of Songklanagarind Hospital from January to June 2005 diagnosed with knee osteoarthritis according to the American College of Rheumatology (ACR) criteria⁽¹⁵⁾ were informed and requested to participate in the present study. Face-to-face interview was done by one orthopedist. The interview covered demographic data, clinical symptoms of knee osteoarthritis and QoL questionnaire with WOMAC and SF-36. Investigation included antero-posterior and skyline views of both knees. Severity of osteoarthritis was graded by a musculoskeletal radiologist using Kellgren & Lawrence criteria⁽¹⁶⁾. All patients were treated with nonsteroidal anti-inflammatory drugs, and provided with patient education, including risk modification and knee exercises. Follow-up at 6 weeks was done to evaluate clinical response and changes in QoL. The present study was approved by the Ethics Committee of the Faculty of Medicine, Prince of Songkla University.

Measurements

The WOMAC, Thai version⁽¹⁷⁾, includes 24 items evaluating knee pain, stiffness, and physical functioning. The pain domain consists of five items asking about intensity of pain associated with activities such as walking, stair climbing, and weight bearing. The stiffness domain consisted of two items. Patients were asked about the severity of stiffness and whether it occurred in the morning and later in the day. The physical function domain consists of 17 items. Patients were asked about the severity of difficulty in performing activities such as ascending or descending stairs, walking on flat surfaces, and engaging in light domes-

tic activities. The WOMAC index in each item was rated into a five-point Likert scale.

SF-36, Thai version⁽¹⁸⁾, has 36 items in seven domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The score of each item varies from 1-2 points in physical functioning, 1-3 points in general health, and 1-6 points in bodily pain, social functioning, and mental health domains. The total score of each domain required a transformation into 100-point scales.

Statistical analysis

Analysis was performed using Stata version 7.0 software. Descriptive statistics of patients were calculated. Cronbach's alpha was analyzed for internal consistency of both SF-36 and WOMAC index at baseline and after treatment. Pearson's correlation coefficient was computed for correlation between WOMAC and SF-36 in each domain. Paired t-test was used for evaluating responsiveness by comparing baseline and post-treatment scores in each domain.

Results

Fifty-two patients (8 men, 44 women) diagnosed with knee osteoarthritis were included in the present study. Their mean age was 58.4 years. Most patients (84.6%) had less than secondary education level and 85% were from agricultural communities. Approximately half of the patients had at least one underlying disease, with hypertension being the most common. Severe involvement (grade IV according to Kellgren & Lawrence) was found in only 13.4% (Table 1).

Good levels of reliability were found in every domain of the WOMAC index (Cronbach's alpha > 0.800 at both initial (baseline), and improved at the follow-up period. In general, the reliability coefficient was found to be lower in SF-36 than in the WOMAC index, in particular in role physical and bodily pain domains (Cronbach's alpha < 0.700). The coefficient improved, however, in every domain at follow-up (after treatment) evaluation (Table 2).

There were significant correlations between pain, stiffness, and physical function domains of WOMAC index and bodily pain, vitality, and mental health domains of SF-36. Pain and physical function domains of WOMAC were also correlated with the social function domain of SF-36. In contrast, physical function, role-emotional, and role-physical domains were not correlated with any domains of the WOMAC index (Table 3).

Table 1. Participant characteristics at baseline

Characteristics (n = 52)	
• Mean age, (SD), yrs	58.4 (5.8)
• Sex (M/F)	8/44
• Educational level (%)	
-Illiterate	9 (17.3%)
-Primary school	35 (67.3%)
-Secondary school	6 (11.5%)
-Graduate or higher	2 (3.9%)
• Marital status	
-Single	1 (1.9%)
-Married	32 (61.5%)
-Divorced	17 (32.7%)
-Widowed	2 (3.9%)
• Occupation	
-Civil servant	3 (5.8%)
-Merchant	5 (9.6%)
-Agriculture	44 (84.6%)
• Having underlying disease	27 (51.9%)
• Currently smokes	18 (34.6%)
• Radiological grading, n (%)	
-Grade II	33 (63.5%)
-Grade III	12 (23.1%)
-Grade IV	7 (13.4%)

Table 2. Reliability coefficient of WOMAC and SF-36 at baseline and after treatment, (Cronbach,s alpha)

Quality of life	Internal Consistency	
	Baseline	After treatment
• SF-36 (domains)		
-Physical functioning	0.740	0.806
-Role-physical	0.632	0.643
-Bodily pain	0.636	0.676
-General health	0.881	0.887
-Vitality	0.809	0.836
-Social functioning	0.845	0.849
-Role-emotional	0.784	0.853
-Mental health	0.796	0.801
• WOMAC (domains)		
-Pain	0.820	0.808
-Stiffness	0.842	0.828
-Function	0.890	0.925

The ability to detect change in the scales, as evaluated by comparison of baseline and post-treatment scores, showed significant changes in all domains of both WOMAC and SF-36 (Table 4).

Table 3. Correlation between WOMAC and SF-36 at baseline in each dimension using Pearson's correlation coefficient, p value in parenthesis

	SF-36	Physical functioning	Role-physical	Bodily pain	General health	Vitality	Social functioning	Role-emotional	Mental Health
WOMAC									
-Pain		-0.245 (0.079)	0.068 (0.629)	0.462** (0.006)	-0.183 (0.193)	-0.384** (0.004)	-0.328* (0.017)	0.134 (0.341)	-0.395** (0.003)
-Stiffness		-0.050 (0.721)	-0.122 (0.388)	-0.285* (0.038)	-0.304* (0.031)	-0.299* (0.031)	-0.148 (0.293)	0.031 (0.825)	-0.408** (0.002)
-Physical function		-0.158 (0.271)	-0.065 (0.648)	-0.048** (0.002)	-0.262 (0.068)	-0.369** (0.007)	-0.409** (0.002)	-0.057 (0.688)	-0.320* (0.020)

* p value < 0.05, ** p value < 0.01

Table 4. Scores of WOMAC and SF-36 in each dimension before and after treatment, mean (SD)

	Before treatment	After treatment	p-value*
• SF-36 (0-100 in each dimension)#			
-Physical functioning	38.4 (21.3)	48.7 (20.5)	0.001
-Role-physical	46.8 (23.6)	51.4 (34.4)	<0.001
-Bodily pain	35.1 (15.1)	47.1 (15.5)	<0.001
-General health	53.2 (16.4)	57.0 (14.5)	0.005
-Vitality	54.3 (15.9)	57.8 (16.7)	0.022
-Social functioning	61.3 (18.4)	65.6 (17.1)	0.034
-Role-emotional	38.5 (39.8)	55.1 (37.3)	0.004
-Mental health	63.6 (16.7)	66.8 (11.2)	0.039
• WOMAC#			
-Pain (0-20)	14.9 (3.7)	12.2 (3.1)	<0.001
-Stiffness (0-8)	5.2 (2.3)	4.4 (1.8)	<0.001
-Physical function (0-68)	48.3 (10.5)	41.3 (10.9)	<0.001

* From paired t-test

Higher score in SF-36 denotes better quality of life. The reverse is true for WOMAC

Discussion

The authors found that both SF-36 and WOMAC, Thai version, have good properties for evaluating QoL in Thai patients with knee osteoarthritis. WOMAC, however showed a relatively higher reliability and responsiveness than SF-36. This result might be explained by the fact that WOMAC is a disease-specific QoL instrument, more directly related to the disease impact, while SF-36 reflects general health status. This finding is similar to the results of previous reports^(13,14,16,19). The present results confirmed the impact in terms of QoL disturbance in patients with knee osteoarthritis as demonstrated by low scores in SF-36 and high scores in WOMAC. However, when compared with results from Western countries, our patients seem to have relatively higher levels of mental health and social functioning. This might result from differences in cultural context. Elderly people in Thailand, are less active than younger people because most Thai elderly, especially in rural areas, live as part of the extended family and are usually supported and helped in their daily activities by relatives; hence, the need for heavy physical activity is less intense compared with elderly in Western countries.

The WOMAC scale has two formats; the visual analogue scale (VAS) and the categorical (Likert scale). In the present study, the authors used the categorical format, which is quite feasible and easier to complete. However, Villanueva et al (14) demonstrated that pain and physical function have a slightly better performance in VAS format while stiffness has a slightly

better performance in categorical format. In contrast, the present results demonstrated that physical function domain had the highest level of reliability.

The responsiveness of the mental health domain of SF-36 is relatively low when compared with other domains. This might be associated with low levels of mental disturbance among patients in the present study. This might result from elderly patients in Thailand not worrying much about their problem, and accepting knee osteoarthritis as a part of life.

The limitations of the present study are, firstly, the number of patients is limited, which may explain the insignificant correlation between all domains of SF-36 and WOMAC. Secondly, the authors used face-to-face interviews instead of self-administered questionnaires, as recommended in the standard guidelines, which may partly affect the validity of the results because most of the patients in the present study are elderly people with low educational status. Although both SF-36 and WOMAC (Thai version) were tested for their validity and reliability before, they have not been compared and tested in patients with knee osteoarthritis like the present study.

From these results, the authors can speculate that the decision whether to use WOMAC or SF-36 should primarily depend on the main objective of the study. If the aim is to monitor clinical responses, such as in a clinical trial, WOMAC would be more appropriate. In contrast, if the objective of the study is to identify or compare the burden of disease, SF-36 would be appropriate since the results can be compared with

other diseases. However, both instruments can be used simultaneously to evaluate the impact in the different dimensions of QoL.

In conclusion, the authors demonstrated that both SF-36 and WOMAC, Thai version, have good evaluative and discriminative properties for assessing QoL in patients with knee osteoarthritis

Acknowledgements

The present study was a part of the thesis of the first author to fulfill the requirement of the Ph.D. degree on Epidemiology at Prince of Songkla University. The generous financial support by the Faculty of Medicine, Prince of Songkla University and the Royal Golden Jubilee Ph.D. Program of the Thailand Research Fund is gratefully acknowledged.

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การเปรียบเทียบ Validity และ Responsiveness ของแบบสอบถามคุณภาพชีวิต ในผู้ป่วยโรคข้อ เข่าเสื่อมไทย

บุญสิน ตั้งตระกูลวนิช, สุทธิ วิวัฒน์วงศ์วนา, วีระศักดิ์ จงสู่วิวัฒน์วงศ์, อลัน กีเตอร์

แบบสอบถาม Short-Form 36 (SF-36) และ Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) เป็นแบบสอบถามที่นิยมใช้สำหรับวัดคุณภาพชีวิตในผู้ป่วยข้อเข่าเสื่อม จุดประสงค์ของการศึกษาครั้งนี้เพื่อเปรียบเทียบคุณสมบัติของแบบสอบถามทั้งสองฉบับแปลเป็นไทยในผู้ป่วยโรคข้อเข่าเสื่อมในคนไทย โดยการวินิจฉัยโรคใช้ตามเกณฑ์ของ American College of Rheumatology (ACR) ผู้ป่วยที่เข้าร่วมการศึกษาได้รับการรักษาเป็นเวลา 6 อาทิตย์ด้วยยาต้านอักเสบชนิดไม่ใช้สเตอรอยด์ และการให้ความรู้ ผู้ป่วยได้รับการสัมภาษณ์ 2 ครั้งก่อนและหลังการรักษา ในเรื่องข้อมูลพื้นฐานและข้อมูล SF-36 และ WOMAC คุณสมบัติของแบบสอบถามที่ศึกษาได้แก่ reliability, validity และ responsiveness reliability ทดสอบโดยใช้ Cronbach's alpha validity ตรวจสอบหาความสัมพันธ์ระหว่างแต่ละ domain ของ SF-36 และ WOMAC (Pearson's test) ใช้ responsiveness ศึกษาเปรียบเทียบค่า SF-36 และ WOMAC ก่อนและหลังการรักษา (paired t test) ผลการศึกษามีผู้ป่วยโรคข้อเข่าเสื่อมทั้งสิ้น 50 คน (ชาย 4 หญิง 48) อายุเฉลี่ย 58.4 ปี ร้อยละ 75 ของผู้ป่วยมีการศึกษาต่ำกว่าระดับมัธยมศึกษา ร้อยละ 60 มีความรุนแรงของโรคข้อเข่าเสื่อมอยู่ในระดับน้อย พบว่าค่า reliability ของ WOMAC อยู่ในเกณฑ์ดี ทั้งก่อนและหลังการรักษาในทุก domain ขณะที่ SF-36 มี reliability ต่ำกว่าโดยเฉพาะในด้าน role physical และ bodily pain (Cronbach's alpha น้อยกว่า 0.700) construct validity ระหว่าง SF-36 และ WOMAC มีค่า coefficient ระหว่าง -0.05 กับ -0.409 ทั้ง SF-36 และ WOMAC มีค่า responsiveness ที่ดี โดยสรุปแบบสอบถามคุณภาพชีวิต SF-36 และ WOMAC ฉบับแปลเป็นไทยเป็นแบบสอบถามที่ดี สามารถใช้วัดคุณภาพชีวิตผู้ป่วยข้อเข่าเสื่อมในคนไทยได้
