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Validation study of the Forgotten Joint Score-12 as a universal patient-reported outcome measure

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Corresponding Author:	Tomonori Baba, M.D., Ph.D. JAPAN
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	
Corresponding Author's Secondary Institution:	
First Author:	Mikio Matsumoto, MD
First Author Secondary Information:	
Order of Authors:	Mikio Matsumoto, MD
	Tomonori Baba, M.D., Ph.D.
	Yasuhiro Homma, MD.,PhD.
	Hideo Kobayashi, MD.
	Hironori Ochi, MD.
	Takahito Yuasa, MD.,PhD
	Henrik Behrend, MD.
	Kazuo Kaneko, Prof.
Order of Authors Secondary Information:	
Funding Information:	
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	useful in Japan.
Suggested Reviewers:	Kentaro Futamura kenshin@friend.ocn.ne.jp
	Karlmeinrad Giesinger karlmeinrad.giesinger@kssg.ch He is a specialist in this field.

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Validation study of the Forgotten Joint Score-12 as a universal patient-reported outcome measure

Mikio Matsumoto[1], Tomonori Baba[1], Yasuhiro Homma[1], Hideo Kobayashi[1], Hironori Ochi[1], Takahito Yuasa[1], Henrik Behrend[2], and Kazuo Kaneko[1]

1. Department of Orthopedic Surgery, Juntendo University School of Medicine, Tokyo, Japan

2. Department of Orthopaedic Surgery, Kantonsspital St.Gallen , St. Gallen, Switzerland

Address correspondence to: Tomonori Baba

Department of Orthopedic Surgery, Juntendo University School of Medicine.

2-1-1 Hongo, Bunkyo-ku, Tokyo, Japan

E-mail: tobaba@juntendo.ac.jp Tel: +3-3813-3111 Fax: +3-3813-3428

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Abstract

Purpose: The Forgotten Joint Score-12 (FJS-12) is for patients to forget their artificial joint, is reportedly a useful patient-reported outcome tool for artificial joints. The purpose of this study was to determine whether the FJS-12 is as useful as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) or the Japanese Orthopaedic Association Hip Disease Evaluation Questionnaire (JHEQ) in Japan.

Methods: All patients who visited our hospital's hip joint specialists following unilateral THA from August 2013 to July 2014 were evaluated. Medical staff members other than physicians administered three questionnaires. Items evaluated were (1) the reliability of the FJS-12 and (2) correlations between the FJS-12 score and the total and subscale scores of the WOMAC or JHEQ.

Results: Of 130 patients, 22 were excluded. Cronbach's α coefficient was 0.97 for the FJS-12. The FJS-12 showed a significantly lower score than the WOMAC or JHEQ ($p < 0.01$). The FJS-12 score was moderately correlated with the total WOMAC score ($r = 0.522$) and its subscale scores for "stiffness" ($r = 0.401$) and "function" ($r = 0.539$) and was weakly correlated with the score for "pain" ($r = 0.289$). The FJS-12 score was favorably correlated with the total JHEQ score ($r = 0.686$) and its subscale scores ($r = 0.530$~0.643).

Conclusion: The FJS-12 was correlated with and showed reliability similar to that of the JHEQ and WOMAC. The FJS-12, which is not affected by culture or lifestyle, may be useful in Japan.

Keywords

Forgotten Joint Score-12, patient-reported outcome, Total hip arthroplasty, WOMAC score, JHEQ score

Introduction

Total hip arthroplasty (THA) is recognized as an excellent surgical technique that produces the most stable results for osteoarthritis of the hip, rheumatoid arthritis, and osteonecrosis of the femoral head [1-4]. Among postoperative evaluation methods for THA, clinician-reported outcomes (CROs) such as the Harris Hip Score are affected by biases including intraobserver and interobserver variability and differences in patients' understanding of the questions asked [5]. Therefore, patient-reported outcomes (PROs) have attracted attention for more accurate evaluation of patients' quality of life. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [6], which is the most commonly used among various PRO tools, is based on the lifestyle of people in Western countries. Various studies have reported the usefulness of the Japanese Orthopaedic Association Hip Disease Evaluation Questionnaire (JHEQ), which takes the Japanese lifestyle into consideration [5, 7]. However, because the JHEQ is specific to the Japanese culture and lifestyle, international comparison of its clinical results is impossible.

The Forgotten Joint Score-12 (FJS-12), which is based on the concept that the ultimate goal of THA is for patients to forget their artificial joint, is reportedly a useful PRO tool specific to artificial joints [8, 9]. Evaluation using the FJS-12 is based on one factor, namely "awareness," unlike evaluation using the WOMAC, which is based on multiple factors such as pain, stiffness, and difficulty of activities of daily

living in various actions and behaviors. We hypothesized that the FJS-12 is applicable as a clinical evaluation tool similar to the WOMAC and JHEQ. The purpose of this study was to determine whether the FJS-12 is as useful as the WOMAC or JHEQ in Japan.

Materials and Methods

Translation

A Japanese version of the FJS-12 was developed using translation/back-translation [10]. We translated the English version of the FJS-12, and a native speaker and four hip joint specialists evaluated the translation and developed a preliminary Japanese version of the FJS-12. The English version and preliminary Japanese version were evaluated using the translation/back-translation method, and a formal Japanese version of the FJS-12 was established.

Patients

This study involved all patients who visited hip joint specialists of our hospital following unilateral THA from August 2013 to July 2014. Medical staff members other than physicians administered three

questionnaires (FJS-12, WOMAC, and JHEQ) at a time to the patients and obtained responses. Patients who did not cooperate, could not write by themselves, had dementia, or provided incomplete answers were excluded.

FJS-12

The FJS-12 is a PRO tool specific to clinical evaluation after arthroplasty. It is a self-administered questionnaire used to assess the degree of patients' awareness of their artificial joint using a 5-grade Likert scale. The FJS-12 comprises 12 questions regarding whether patients are aware of having undergone arthroplasty during activities of daily living (such as being in bed at night, climbing stairs, and taking a bath) and relatively difficult movements such as housework, standing for long periods of time, and sports irrespective of pain, range of motion, or leg-length discrepancy. The scoring method of FJS-12 is as follows: 0, never; 1, almost never; 2, seldom; 3, sometimes; and 4, mostly. The mean value for the 12 items is multiplied by 25, and the obtained value is subtracted from 100. The final score range is 0 (worst) to 100 (best) [8, 9].

WOMAC

The WOMAC is a PRO tool first reported by Bellamy and Buchanan in 1986 for evaluation of the lower limbs, particularly the hip and knee joints, and it has frequently been used worldwide. This questionnaire comprises 24 questions in 3 subscales (pain, stiffness, and function). A Japanese version was also developed, and its validity, reliability, feasibility, and responsiveness have been confirmed. The total score range is 0 (best) to 96 (worst) [6, 11-13].

JHEQ

The JHEQ is a PRO tool first reported in 2012 by Matsumoto et al. [5] for evaluation of the hip joint. This self-administered questionnaire uses a 5-point Likert scale and comprises 24 questions in 3 scales (pain on a visual analog scale, movement, and mental; 8 questions in each subscale). The JHEQ reflects the Japanese lifestyle (such as rising from a tatami mat and using the traditional Japanese-style toilet) [5, 7]. The total score range is 0 (worst) to 84 (best).

Statistical analysis

Cronbach's α coefficient was used to evaluate the internal consistency of the FJS-12. An α of >0.8 was considered to indicate acceptable reliability [14]. The highest scores indicating the best results for the

WOMAC and JHEQ are 0 and 84, respectively. Therefore, the lowest and highest scores for each questionnaire were converted to 0 and 100, respectively (Table 1). The evaluation items were (1) the reliability of the FJS-12 and (2) correlations between the FJS12 score and the total and subscale scores of the WOMAC or JHEQ. Statistical analysis was performed using SPSS software. Student's t-test was performed to evaluate differences among the questionnaires, and $p < 0.05$ was regarded as statistically significant. Correlations between the FJS score and the total and subscale scores of the other questionnaires were analyzed using Pearson's product-moment correlation coefficient. In all validity analyses, the coefficient values were characterized as follows: 0.00–0.19 = poor, if any; 0.20–0.39 = fair; 0.40–0.59 = moderate; 0.60–0.79 = good; and 0.80–1.00 = high/strong [15, 16]. The ceiling and floor effects of a scale are described as the percentages of patients showing the best or worst possible score on the scale, respectively.

Results

Of the 130 patients, 22 were excluded. The remaining 108 patients comprised 20 men and 88 women (Table 2). Their mean age was 65.7 years (range, 25–88 years), and the mean time since surgery was 29.5 months (range, 1–180 months). The underlying disease was osteoarthritis in 91 patients, rheumatoid arthritis in 3, and osteonecrosis of the femoral head in 14. The posterior approach was used in 65 patients

and the anterior approach in 43. Cronbach's α coefficient, representing internal consistency, was 0.97 for the FJS-12. The FJS-12 score and the total and subscale scores of the other questionnaires are shown in Table 3 and Figure 1. The mean score was 53.6 ± 25.3 for the FJS-12, 82.1 ± 16.0 for the WOMAC, and 63.8 ± 19.7 for the JHEQ; the FJS-12 showed a significantly higher score and standard deviation than the WOMAC or JHEQ ($p < 0.01$). The correlation coefficients between the FJS-12 and WOMAC or JHEQ are shown in Table 4. The FJS-12 score was moderately correlated with the total WOMAC score ($r = 0.522$) and its subscale scores for "stiffness" ($r = 0.401$) and "function" ($r = 0.539$) and weakly with the score for "pain" ($r = 0.289$). The FJS-12 score was favorably correlated with the total JHEQ score ($r = 0.686$) and its subscale score for "movement" ($r = 0.643$) and moderately correlated with the scores for "pain" ($r = 0.550$) and "mental" ($r = 0.530$). Evaluation of patients with unilateral disease based on plain X-ray images showed a moderate correlation between the FJS-12 score and the WOMAC subscale score for "pain" ($r = 0.493$). The correlation coefficients between the FJS-12 score and the scores for the other items were also high in these patients compared with all patients (Table 5). The ceiling effect was higher for the WOMAC (7.4%) than for the FJS-12 (3.7%) and JHEQ (2.8%). No subscales were lower than the FJS-12. One patient showed a floor effect for the JHEQ "mental" scale (0.9%).

Discussion

Various tools are used for the postoperative evaluation of patients who have undergone THA, such as the Harris Hip Score, which is the most widely used CRO [17-19]; the Merle d'Aubigné and Postel Hip Score used in Europe [20], particularly in France; and the Japanese Orthopaedic Association Hip Score in Japan [21]. However, even when the score obtained by physicians' evaluations is the same, the satisfaction level differs among patients. A difference between CROs and PROs has been previously reported [22, 23]. PROs, which have attracted attention in recent years, reflect patients' self-assessed satisfaction level and provide an accurate evaluation of quality of life [5]. Use of the WOMAC is based on the Western lifestyle; thus, accurate evaluation of patients living in Japanese culture is difficult using the WOMAC. However, the JHEQ, which was developed to overcome the disadvantages of the WOMAC, does not allow for international comparison. Therefore, we focused on the FJS-12. The main characteristic of the FJS-12 that is not observed in other tools is that discrimination among "good," "very good, " and "excellent" is possible using relatively abstract questions to ask whether patients are aware of their artificial joint during activities of daily living. We considered that a more accurate evaluation of patients' complaints will be possible if the FJS-12 can also be used in Japan. Behrend et al. [8] evaluated patients after THA or total knee arthroplasty and reported that the FJS-12 has a low ceiling effect and high internal consistency (Cronbach $\alpha = 0.95$). In this study, the Cronbach α coefficient of the Japanese version of the FJS-12 was very high (0.97), showing its high reliability.

Because the reliability of the Japanese version of the FJS-12 was high, its correlations with other PRO

tools were evaluated. The FJS-12 showed a favorable correlation with the total JHEQ score and moderate or better correlations with all of its subscale scores (“pain,” “movement,” and “mental”). This may have been due to the FJS-12 question “Are you aware of your artificial joint?” This “awareness” includes the presence of pain and difficulty in climbing stairs. The awareness overrides those varieties of complaints.

The correlation between the FJS-12 and WOMAC was slightly weaker than that between the FJS-12 and JHEQ. In particular, the correlation between the FJS-12 score and the WOMAC score for “pain” was fair. For the “pain” scale in both the WOMAC and JHEQ, patients are asked about pain during simple activities of daily living. Questions about pain are answered separately for the left and right sides in the JHEQ, but not separately in the WOMAC. Therefore, there is a possibility that the answers given by patients with bilateral disease may have been about pain on the nonoperated side. Indeed, in patients with unilateral disease, the correlation increased, which supports this possibility. The FJS-12 was correlated with both the JHEQ, which is based on the Japanese lifestyle, and the WOMAC, which is the most widely used scale. Thus, the FJS-12 can also be used in Japan irrespective of lifestyle and may allow for international comparison.

Although the FJS-12 was correlated with the JHEQ and WOMAC, its score was significantly lower. This may have been because the FJS-12 does not comprise obvious questions, as are used in the JHEQ and WOMAC, and when patients become aware of their artificial joint due to pain, stiffness, mental factors, or walking ability, the score does not increase. Therefore, slight changes tend to increase

differences in the score, which is considered to reflect differences not only between “good” and “bad” but also among “good,” “very good,” and “excellent” outcomes. Because the questions in the FJS-12 assess the level of patients’ awareness of their artificial joint, even changes of which patients are only negligibly aware may tend to be reflected in the score. Physicians may be able to notice these changes based on changes in the score. Joint awareness could be seen as “overriding” those symptoms, possibly making it a parameter at a higher/different level.

The FJS-12 contains 12 questions, but the JHEQ contains 20 (plus the visual analog scale) and the WOMAC contains 24. Although the answer time is not always proportional to the number of questions, the FJS-12 comprises questions about patients’ awareness of their artificial joint and may thus be relatively straightforward, reducing the burden on patients.

In general, the ceiling effect decreases as the number of questions increases. However, the data showed a lower ceiling effect in the FJS-12 and JHEQ, despite the FJS-12 having only 12 questions (in contrast to the 24 questions of the WOMAC). Our study in Japan was similar to that performed by Behrend et al. [8].

A limitation of this study was the small number of patients. However, complete and accurate data for many questions of the three questionnaires was obtained. In addition, the number of patients in many similar previous studies was similar or lower than that in this study [12, 24, 25]. Because the purpose of this study was to compare the usefulness of the FJS-12 with that of other PRO tools, no comparison with CROs was performed. However, as previous studies showed, dissociation between CROs and PROs

sometimes occurs [23]. Therefore, we consider that the absence of comparison between the FJS-12 score and CROs did not directly affect the results of this study.

In conclusion, the FJS-12 was correlated with the JHEQ and WOMAC, and its reliability was similar to that of these tools. The FJS-12 showed a lower mean score than the WOMAC or JHEQ and tended to show greater dispersion and more marked differences among patients. The FJS-12, which is not affected by culture or lifestyle, may also be useful in Japan.

Conflict of interest: The authors declare that they have no conflict of interest.

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Figure legend

Figure 1 Mean total score of each questionnaire (* $p<0.01$)

Table 1 Outline of each questionnaire

Table 2 Demographic characteristics

Table 3 Total and subscale scores of each PRO

Table 4 Correlations between FJS-12 score and total or subscale scores of JHEQ and WOMAC

Table 5 Correlations between FJS-12 score and total or subscale scores of JHEQ and WOMAC in patients with unilateral disease

Figure 1

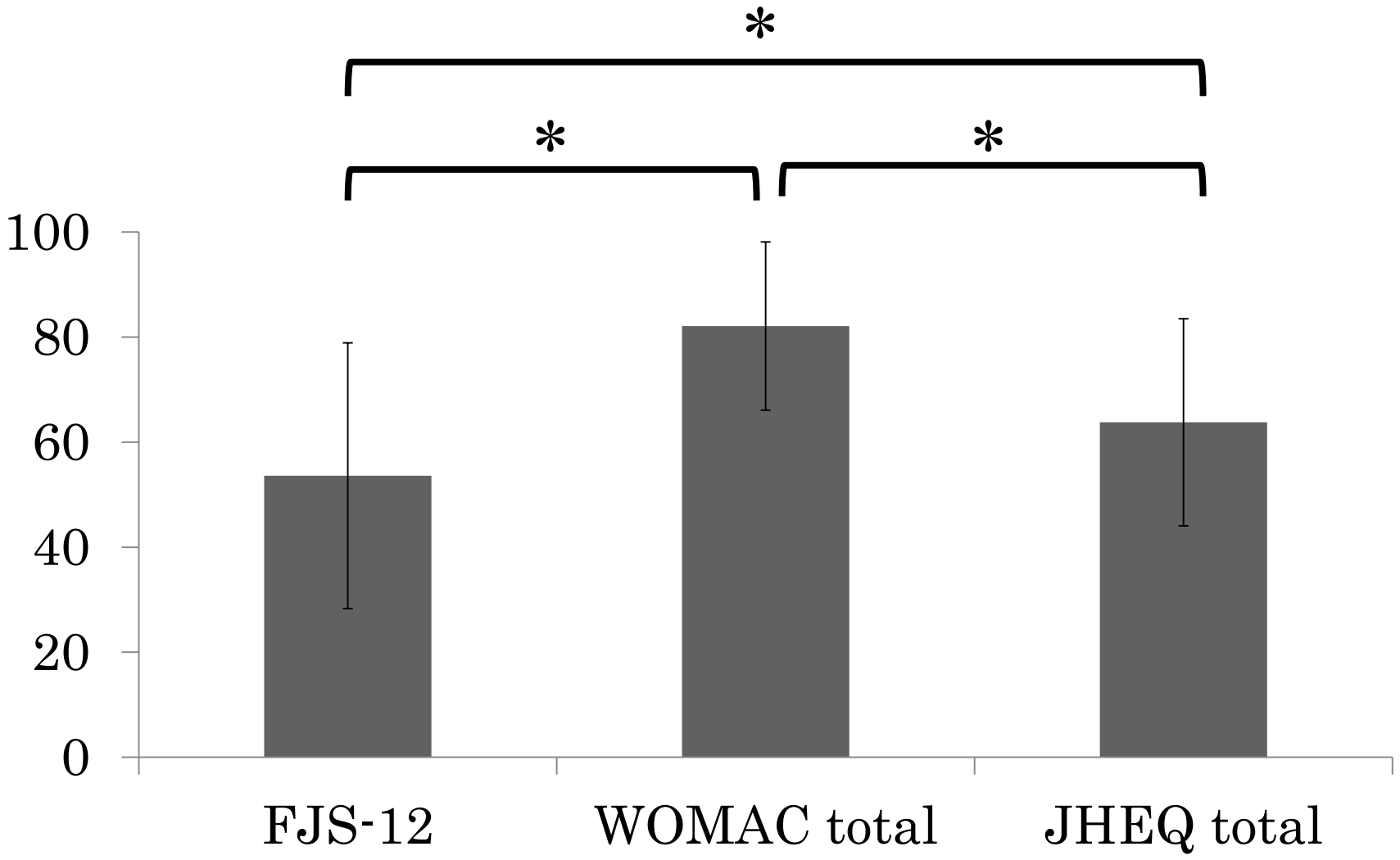

Table 1

	JHEQ	WOMAC	FJS-12
Subscales	Pain, ADL, mental	Pain, stiffness, function	Awareness of prosthesis
Number of questions	20 (+VAS)	24	12
Best score	84	0	100

Table 2

Characteristics	Mean ± SD or n (%)
Sex	
Male	20 (18.5)
Female	88 (81.5)
Age (years)	65.7 ± 11.6
Time since surgery (months)	29.5 ± 38.7
Disease	
OA	90 (83.3)
RA	15 (13.9)
ON	3 (2.8)
Approach	
Posterior	65 (60.2)
Anterior	43 (39.8)
Side	
Right	61 (56.5)
Left	47 (43.5)

Table 3

		score ± SD
FJS-12		**53.6 ± 25.3**
JHEQ	Total	**63.8 ± 19.7**
	Pain	26.5 ± 6.48
	Movement	14.8 ± 8.63
	Mental	20.7 ± 8.77
WOMAC	Total	**82.1 ± 16.0**
	Pain	18.3 ± 3.18
	Stiffness	7.07 ± 1.42
	Function	56.7 ± 12.7

Table 4

	FJS-12	JHEQ Total	Pain	ADL	Mental
FJS-12	–	0.686	0.550	0.643	0.530
WOMAC Total	0.522	0.693	0.469	0.687	0.546
Pain	0.289	0.553	0.498	0.438	0.479
Stiffness	0.401	0.513	0.459	0.491	0.345
Function	0.539	0.674	0.413	0.698	0.527

All scores $p < 0.01$

Table 5

	FJS-12
WOMAC Total	0.559
Pain	0.493
Stiffness	0.456
Mental	0.531
JHEQ Total	0.738
Pain	0.503
Movement	0.661
Mental	0.692