1 Abstract

- 2 **Background:** Low back pain is a common health problem encountered by various populations among countries.
- 3 This prospective study aimed to translate and cross-culturally adapt the Japanese Orthopaedic Association Back
- 4 Pain Evaluation Questionnaire (JOABPEQ) into Traditional Chinese and to assess its validity, reliability and
- 5 sensitivity in Chinese patients experiencing low back pain.
- 6 Methods: Double forward and single back translation of the JOABPEQ was performed with cross-cultural
- 7 adaptation. By convenience sampling, the final version of the translated JOABPEQ was administered to Chinese
- 8 patients attending a specialty outpatient clinic with a history of back pain, followed by the traditional Chinese
- 9 versions of Oswestry Disability Index (ODI) and Short Form-12 version 2 (SF-12v2). Construct validity of the
- domains were assessed using Spearman's correlation test. Internal consistency was assessed by Cronbach's alpha
- 11 (α). Sensitivity of the adapted JOABPEQ was determined by known group comparisons.
- 12 **Results:** A total of 100 patients were recruited. The translated JOABPEQ demonstrated excellent overall internal
- consistency (a: 0.912); and good internal consistency for the domains of Lumbar Function, Walking Ability, Social
- Life Function and Mental Health (α: 0.811, 0.808, 0.788, and 0.827 respectively). Scores of all domains of the
- translated JOABPEQ had significant correlations (p<0.01) with ODI at all domains, as well as with almost all
- domains of SF-12v2 (p<0.01-0.05). The translated JOABPEQ was sensitive in detecting differences in patients
- with/without a history of previous spine surgery, and also between patients with acute/acute on chronic versus
- 18 chronic pain in specific domains.
- 19 **Conclusions:** The Traditional Chinese version of JOABPEQ has satisfactory psychometric properties in general,
- 20 including adequate clinical and construct validity, and internal consistency in assessing Southern-Chinese patients
- 21 with low back pain. It is demonstrated as a sensitive outcome measure. The translated JOABPEQ is verified for its

 $1 \qquad \hbox{use in the local clinical setting for patient assessment and future research.}$

Introduction

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According to the World Health Organization (WHO), Low Back Pain (LBP) is the most disabling disease worldwide.[1] LBP is also the most common type of pain reported by adults in the United States,[2] and can affect one-third of the UK adult population each year.[3] Moreover, in Japan, the lifetime LBP prevalence was found to be 83%.[4] When LBP becomes chronic, it becomes one of the main reasons to seek health care services.[5, 6] LBP is complex with many etiologies and is often a mixture of various presentations and associated conditions including spinal stenosis, spondylolysis, disc degeneration and herniation, and spondylolisthesis. As a result, symptomatology not only manifests as back pain but also accompanying neurological symptoms such as lower limb numbness. Due to the variable nature of this disease, it is desirable to have a LBP-specific, single measure incorporating these multidimensional aspects, in order to facilitate communication between medical practitioners. The Japan Orthopaedic Association (JOA) has introduced the JOA score rating system as a specific measure for LBP in 1986.[7] However, it has shortcomings due to lack of patient-orientated measures as the patient's perspective is an essential component in the evaluation of treatment outcomes and medical decision making.[8] The Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOABPEQ) is then developed as a patient-perceived outcome measure for patients with LBP, which includes the original physical components related to the disease, and also psychological problems resulting from dysfunctions and disabilities.[9-11] It has been tested for its reliability and validity in the use for LBP patients in Japan, Thailand, Iraq and Turkey. [10, 12-14] Due to the differences in culture and geographic location, it is desirable for the JOABPEQ to be translated to a Chinese version for local adaptation. This will ensure that this patient-orientated disease-specific instrument can elicit appropriate information about the severity of LBP along with quality of life (QoL). By ascertaining the psychometric properties of the translated JOABPEQ, healthcare professionals can utilize this standardized and

- 1 region-specific assessment tool to communicate progress of a patient's status through its natural course or after an
- 2 intervention. As such, the aim of study is to translate the JOABPEQ questionnaire into Chinese whilst maintaining
- 3 the characteristics of the original property of JOABPEQ to facilitate the assessment of the patient-perceived/
- 4 reported function and QoL of LBP patients.

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Materials and Methods

Subjects and Setting

8 A convenience sampling of Chinese patients attending a specialty back pain outpatient clinic during the

months between April 2016 and November 2016 was performed. Exclusion criteria included patients of

non-Chinese ethnicity, illiterate or could not understand traditional Chinese characters or speak Cantonese. Ethics

approval was obtained from the institutional review board.

Demographic and clinical data at the time of visit were collected. Clinical data included

clinician-documented episodes of LBP being acute (< 6 weeks duration), chronic (≥12 weeks' duration) or acute

on chronic (acute episode or deterioration of pain requiring hospitalization or an emergency visit), as well as only

back pain or with radiating leg pain and numbness.[15] Also, radiographic diagnoses by attending orthopedic

surgeons including spinal deformities (scoliosis, spondylolisthesis), disc degeneration, and lumbar spondylosis

(degeneration with osteophytes) were extracted. Histories of any previous spine surgery, any previous trauma

relating to spine or accidental fall were recorded. Clinicians who attended these subjects for consultation visit have

no prior knowledge of this study.

Subjects who consented were invited to fill in the translated JOABPEQ (Traditional Chinese – Hong Kong).

Upon completion, the patients were also asked to complete the Traditional Chinese (Hong Kong) version of the

- 1 Oswestry Disability Index (ODI) and the Short term 12-item Health Survey version 2 (SF-12v2) questionnaires.
- We aimed for 100 patients as according to Terwee et al[16], a sample size of 100 is considered adequate for
- 3 psychometric factor analyses of health status questionnaires.

5 Translation and Cross-culture Adaptation

The original version of JOABPEQ was translated into traditional Chinese (Hong Kong) following one of the internationally accepted translation techniques,[17] which consisted of double forward translation and single back translation. The translations were performed by independent professional translators, who were native speakers of Cantonese and understand local terms in traditional Chinese used in Hong Kong. After the first forward translation, the translated traditional Chinese version of JOABPEQ was reviewed by a panel of local health-related professionals (consisting of at least one spine specialist). It was then back-translated into English by a professional translator who had no prior knowledge of the original questionnaire. The final forward translation was carried out by an independent translator. The final version of the translated and culturally-adapted JOABPEQ in traditional Chinese (Hong Kong) was finalized and approved by the review panel. (Appendix 1)

16 Study Instruments

Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOABPEQ)

The JOABPEQ was developed specifically to evaluate LBP, and is based mainly on recognizing problems with activities of daily living.[18] It contains 25 questionnaires which are categorized into five factors. By using the measurement scale, each factor is then scored up to 100 points and to be evaluated separately. Also, at the end of the questionnaire, visual analogue scale (VAS) is used to ask patients to rate the degree of their low back pain, pain

- 1 in buttock(s) and lower limb(s), and numbness in buttock(s) and lower limb(s) during the recent past week. A bar
- 2 is marked with 0 as 'no pain (numbness) at all' and 10 as 'the most intense pain (numbness) imaginable'. In
- addition, there was a five-point Likert scale introduced in this study immediately upon completion of the translated
- 4 JOABPEQ. This was to facilitate patients to rate the clarity and understanding the translated JOABPEQ, from 1 to
- 5 5, representing Strongly Agree, Agree, Neither agree/disagree, Disagree, Strongly Disagree.

Oswestry Disability Index Questionnaire (ODI)

The ODI is an index derived from the Oswestry Low Back Pain Disability Questionnaire,[19] which is a self-administered outcome measure designed to assess limitations of various activities of daily living,[20] It is considered the 'gold standard' of low back functional outcome tools, and is used to measure patient's permanent functional disability,[21] The questionnaire is divided into ten sections, of which each is scored on a 0–5 scale, with increasing level of disability. The index is calculated by dividing the summed score by the total possible score, which is then multiplied by 100 and expressed as a percentage. If the ODI ranges from 21% to 40%, it represents that the patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. If the ODI is between 41% and 60%, pain remains the main problem and activities of daily living are affected. If the ODI reaches 61% to 80%, it represents the back pain impinges on all aspects of the patient's life. Validity of ODI for use in Hong Kong Chinese population has been reported,[22]

Short Form 12 – version 2 (SF-12v2)

The SF-12v2 Health Survey is a shorter version of the SF-36v2 Health Survey. It is a generic, health-related

- 1 QoL measure that assesses the functional health and well-being from the patient's perception. It consists of twelve
- 2 questions, designated into eight domains from which the two composite scores of mental and physical health are
- derived. SF-12v2 was found to be a valid, sensitive and reliable substitute of the SF-36v2 for the Chinese in Hong
- 4 Kong.[23]

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- 6 Statistical Analysis
- Descriptive statistics including mean \pm standard deviation (SD), and percentage of the study population were
- 8 calculated. The construct validity of the JOABPEQ domain was assessed using Spearman's correlation test against
- 9 the SF-12v2 domain scores holding similar constructs.
- The internal consistency reliability was assessed by Cronbach's alpha using a value >0.7 to indicate adequate
- internal consistency. The sensitivity of the JOABPEQ was determined by performing known group comparisons
- by independent t-test and analysis of variance, where appropriate. Comparisons of known clinical groups were
- among patients who had a history of previous spine surgery, a history of trauma relating to the spine or accidental
- 14 fall, a diagnosis of spinal deformities (scoliosis, spondylolisthesis), disc degeneration, lumbar spondylosis/
- degeneration with osteophytes, as well as examining patients with acute or chronic or acute on chronic LBP, and
- location of pain (back only versus back and leg pain±numbness).
- Data analyses were conducted using SPSS Windows 23.0 (IBM SPSS Inc., Chicago, IL, USA) and STATA
- version 13.0 (StataCorp LP. College Station, Texas, U.S.). P-value<0.05 was statistically significant.

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Results

A total of 100 patients were recruited, with 57% being females and 43% being males. The mean age of the

studied population was 57.0±12.5 years. The clinical characteristics of patients are presented in Table 1. The

2 descriptive statistics of JOABPEQ and the VAS scores for low back pain, pain in buttock(s) and lower limb(s), and

3 numbness in buttock(s) and lower limb(s), ODI and SF-12v2 subscale and summary score can be found in Table 2.

4 There were 83% of patients who agreed or strongly agreed that the translated questionnaire was clear and

understandable, with 17% had neither agree nor disagree, and none disagreed. This is presented together with the

frequency distribution of responses of JOABPEQ in Table 3.

Psychometric testing of the translated JOABPEQ (Traditional Chinese – Hong Kong) demonstrated an excellent overall internal consistency with Cronbach's alpha of 0.912. (Table 4) Internal consistency was demonstrated to be good for the domains of Lumbar Function, Walking Ability, Social Life Function and Mental Health (Cronbach's α: 0.811, 0.808, 0.788, 0.827 respectively) but inadequate for the Low Back Pain domain (Cronbach's α: 0.531). There were significant correlations (p<0.01-0.05) between all domains of the translated JOABPEQ with all domains of SF-12v2, except for General Health and Vitality. In addition, the translated JOABPEQ also correlated significantly (p<0.01) with the ODI at all domains as well as its VAS scores for low back pain, pain in buttock(s) and lower limb(s), and numbness in buttock(s) and lower limb(s).

Testing of sensitivity of the translated instrument was performed and results are detailed in Table 5.

JOABPEQ was sensitive in detecting differences in patients who had a history of previous spine surgery as compared to those without, in the domains of Low Back Pain and Walking Ability. The JOABPEQ was also sensitive to differences between patients with acute/acute on chronic versus chronic pain patients with its Low Back Pain domain.

Discussion

LBP is not only a major cause but one of the commonest causes of disability, and affects most people in a society at some point in their lives.[1] Presentations to the emergency department are not uncommon and consume significant healthcare resources.[24-26] An appropriate outcome assessment should not be merely a tool for communication between clinicians regarding the physical assessments, but needs to contain patient-perceived components which is a more meaningful interpretation of how LBP affects QoL. For instance, low back and leg pain are the chief complaints of herniated discs and spinal stenosis causing nerve compression. Management is not only targeting at elimination of pain and numbness, but also focus on the impairment and effects on QoL.[27] The extent of how QoL is being affected by LBP should be elicited by an appropriate outcome measure.

JOABPEQ is an outcome measure of choice as it is developed specifically for LBP, and it makes possible a comprehensive representation of patients' status by incorporating both the objective clinical assessment by clinician as well as subjective rating by patients. The translated JOABPEQ demonstrated an excellent overall and good internal consistency for the domains of Lumbar Function, Walking Ability, Social Life Function and Mental Health, except for the Low Back Pain domain. This can be largely accounted by the profile of the studied population, which consists of 14% of chronic LBP patients who were not experiencing any current pain but requiring regular outpatient clinic follow-ups. This is suggested by the lack of significant correlation of the VAS score of current LBP with the Low Back Pain domain. Additionally, 78% of the patients were chronic LBP patients, who might not necessarily be experiencing constant ache, lying down more than usual or cannot sleep well as questioned by the items contributing to the Low Back Pain domain. Definitely this factor will need further detailed investigation with larger sample size at multiple clinics.

As compared to the both Thai, Iran, and Turkish JOABPEQ studies[12-14], our translated JOABPEQ had satisfactory reliability and comparable internal consistency in all the domains Lumbar Function, Walking Ability,

Back Pain domain (Cronbach's α: 0.531). The Traditional Chinese version of the JOABPEQ was found to correlate significantly (p<0.01) with the scores in VAS for low back pain, pain in buttock(s) and lower limb(s), and numbness in buttock(s) and lower limb(s). The Low Back Pain and Walking Ability domains supported the

Social Life Function and Mental Health (Cronbach's a: 0.811, 0.808, 0.788, 0.827 respectively) except the Low

sensitivity of the JOABPEQ subscale scores to the difference among patients with/without a history of previous

spine surgery. In addition, our translated JOABPEQ is also significantly correlated to ODI (at all domains) and

SF12v2 (all domains except General Health Perception). Hence despite a different study approach, our findings are

comparable, with additional findings unique to this local back pain population.

As JOABPEQ is partly derived from the Roland Morris Questionnaire and the medical outcome study 36-Item Short-Form Health Survey (SF-36),[9] it is thus important to examine the ability of the adapted JOABPEQ version in correlating with a generic QoL measure. The translated JOABPEQ had all its domain significantly and strongly correlated with the ODI as well as the SF-12v2 in all aspects, except for correlation of General Health and Vitality with the Low Back Pain domain. It is suggested that adequate properties of QoL measure have been maintained in the translated JOABPEQ, which is capable of reflecting any relationship between LBP and the patients' limitations of daily activities, functional health and general well-being.

Moreover, the translated JOABPEQ is sensitive in detecting any differences in scores between patients with and without a history of spine surgery by the domain of Low Back Pain and Walking Ability. It is crucial that the JOABPEQ can differentiate these groups of patients especially at baseline assessment to claim that it is receptive to any changes after surgery. Apart from contributing to a valid comparison between preoperative and postoperative status, this sensitivity is also needed in capturing further improvement rate postoperatively. If the Low Back Pain and the Walking Ability domain scores of JOABPEQ are sensitive to differences between those who have or never

1 had any spine surgery, then these domains aid in assessing any further improvement during post-operative care or

2 rehabilitation stage when the scores have already taken the occurrence of surgery into account. Also, the Low Back

Pain domain is sensitive to changes of scores between acute and chronic LBP patients. It is essential to display such

sensitivity when patients present with an acute onset of pain, or even more clinically useful when chronic patients

present with acute episodes of pain, or deteriorated/increased of severity of pain during a rather stable condition.

6 The main limitation of this study is that this validation of JOABPEQ was carried out only in a single center. Further

studies are needed with larger population size and preferably be conducted at multiple centers. Also, it is necessary

to further investigate the responsiveness of the translated JOABPEQ for patients at several time points with certain

intervention such as preoperatively versus postoperatively. In addition, JOABPEQ scores were reported to be

different depending on age, sex and disease type based on individual patient data.[28] If reference values of

JOABPEQ are not established, clinicians cannot assess the exact status of a patient at a single time point. Hence,

future possibility of defining reference values for the local population, or for patients in China as a whole should be

considered.

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The Traditional Chinese version of JOABPEQ has satisfactory psychometric properties in general, including adequate clinical and construct validity, and internal consistency in assessing Chinese patients with LBP. It is also demonstrated as a sensitive outcome measure to be used in the local clinical setting. With its strong correlation with the generic measures, the translated JOABPEQ allows the reflection of not only the severity of LBP, but a valid representation of the impact of symptoms on patients' QoL, and their perceived improvement through time. This make feasible a closer examination of the cost-effectiveness of differential treatment options of LBP in the future, in the hope to maximize the use of healthcare resources.

- **Conflict of interest:** No funding received for this work from any organizations
- **Ethics Approval:** HKU/HA HKW Institutional Review Board

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