

## Policy Forum



## Evaluation of the Sensitivity and Specificity of the New Clinical Diagnostic and Classification Criteria for Kashin-Beck Disease, an Endemic Osteoarthritis, in China\*

YU Fang Fang<sup>1,^</sup>, PING Zhi Guang<sup>2,^</sup>, YAO Chong<sup>1</sup>, WANG Zhi Wen<sup>3</sup>, WANG Fu Qi<sup>3</sup>, and GUO Xiong<sup>1,#</sup>

This study aimed to evaluate the sensitivity and specificity of the new clinical diagnostic and classification criteria for Kashin-Beck disease (KBD) using six clinical markers: flexion of the distal part of fingers, deformed fingers, enlarged finger joints, shortened fingers, squat down, and dwarfism. One-third of the total population in Linyou County was sampled by stratified random sampling. The survey included baseline characteristics and clinical diagnoses, and the sensitivity and specificity of the new criteria was evaluated. We identified 3,459 KBD patients, of which 69 had early stage KBD, 1,952 had stage I, 1,132 had stage II, and 306 had stage III. A screening test classified enlarged finger joints as stage I KBD, with a sensitivity and specificity of 0.978 and 0.045, respectively. Shortened fingers were classified as stage II KBD, with a sensitivity and specificity of 0.969 and 0.844, respectively, and dwarfism was classified as stage III KBD with a sensitivity and specificity of 0.951 and 0.992, respectively. Serial screening test revealed that the new clinical classification of KBD classified stages I, II, and III KBD with sensitivities of 0.949, 0.945, and 0.925 and specificities of 0.967, 0.970, and 0.993, respectively. The screening tests revealed that enlarged finger joints, shortened fingers, and dwarfism were appropriate markers for the clinical diagnosis and classification of KBD with high sensitivity and specificity.

Kashin-Beck disease (KBD) is an endemic, chronic, and degenerative form of osteoarthritis, characterized by deformity and disability<sup>[1-3]</sup>. KBD occurs most commonly in children aged 5-15 years and is characterized by the degeneration and

necrosis of epiphyseal plate cartilage as well as articular cartilage at several other locations in the developing skeleton. The clinical syndrome includes joint pain and enlargement, restricted movement, short fingers, and dwarfism. Severe patients experience a loss of capacity for physical labor in adulthood and lifelong disability<sup>[4-5]</sup>. A previous study has described 20 clinical symptoms and four radiological signs in various joints of 2,560 KBD patients from endemic and non-endemic areas in China<sup>[6]</sup>. It has been suggested that the symptoms should be classified into the following five groups, representing the manifestations of KBD: flexion of the distal joint of fingers or deformed fingers, arthritic pain in the knee and ankle joints, enlargement of small- and middle-sized joints, limited motion in affected joints with deformity, and retarded growth<sup>[7-10]</sup>.

Appropriate diagnostic criteria are important for the surveillance, prevention, control, and elimination of KBD. In 1995, the National Health and Family Planning Commission of the People's Republic of China promulgated and implemented 'Diagnosis Criteria for Kashin-Beck Disease (GB16003-1995)<sup>[11]</sup>. These criteria were developed by the Ministry of Health based on KBD research data collected since 1956, diagnostic criteria of KBD research consortium (three northeast provinces) since 1972, diagnostic criteria of the central endemic disease office since 1983, and the Yongshou study group of clinical diagnosis and X-ray diagnostic criteria since 1984<sup>[12]</sup>. These criteria (GB16003-1995) have been employed for surveillance, therapy, and research for 15 years. In 2010, the National Health and Family Planning Commission of the People's Republic of China

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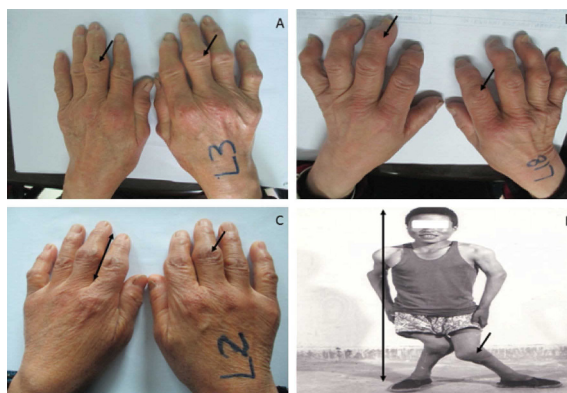
1. Institute of Endemic Diseases, School of Public Health of Health Science Center, Xi'an Jiaotong University, Key Laboratory of Trace Elements and Endemic Diseases, National Health and Family Planning Commission, Xi'an 710061, Shaanxi, China; 2. Department of Health Statistics, College of Public Health, Zhengzhou University, Zhengzhou 45001, Henan, China; 3. The Centers for Disease Control of Linyou country, Linyou 721500, Shaanxi, China

promulgated and implemented new ‘Diagnostic Criteria for Kashin-Beck Disease (WS/T207-2010)’<sup>[13]</sup>. This new criteria integrated and revised both ‘Diagnostic Criteria for Kashin- Beck Disease (GB16003-1995)’<sup>[14]</sup> and ‘X-ray classification indexing for Kashin-Beck disease (WS/T207-2001)’ (Table 1). The new diagnosis criteria (WS/T207-2010) were convenient and simple for epidemiological surveillance and had extensive clinical applications.

This study aimed to evaluate the sensitivity and specificity of the new clinical diagnostic and classification criteria for KBD compared with those of the old criteria (GB16003-1995). We sampled 3,459 KBD patients in Yongshou County using the new ‘Diagnostic Criteria for Kashin-Beck Disease (GB16003-1995)’ in 2002. Subsequently, we performed a screening test for six clinical symptoms in this population ( $n = 25,304$ ) using the new ‘Diagnostic Criteria for Kashin-Beck Disease (WS/T207-2010)’ to determine its sensitivity and specificity.

**Sample** This study was conducted in 110 villages in Linyou County in 2002. Stratified random sampling was performed according to the prevalence of KBD in the villages. The 110 villages in Linyou County were divided into three groups: 13 low-prevalence villages (< 10%), 42 medium-prevalence villages (10%-20%), and 55 high-prevalence villages (> 20%). One-third of the villages in each group were sampled: 36 villages, including four low-prevalence villages, 14 medium-prevalence villages, and 18 high-prevalence villages. In total, 25,304 individuals were surveyed, and all participants provided written informed consent according to the Declaration of Helsinki. Ethical approval on the research was obtained from the Xi’an Jiaotong University.

**Questionnaires** We surveyed baseline characteristics and clinical diagnosis in accordance with the research objective. Baseline characteristics included name, sex, age, ethnicity, occupation, and age at the incidence. Clinical diagnosis included flexion of the distal part of fingers, deformed fingers, enlarged finger joints, shortened fingers, squat down, and dwarfism (Figure 1). We first identified 3,459 KBD patients using the old ‘Diagnostic Criteria for Kashin-Beck Disease (GB16003-1995)’. Subsequently, we performed a screening test using the new ‘Diagnostic Criteria for Kashin-Beck Disease (WS/T207-2010)’ (Table 1), and evaluated the sensitivity and specificity of the new criteria.



**Figure 1.** The KBD patients were classified as stages I, II, or III KBD using the new diagnostic criteria for Kashin-Beck disease (WS/T207-2010). Stage I KBD is depicted in A (enlarged finger joints) and B (enlarged finger joints and flexion of the distal part of fingers), stage II KBD is depicted in C (shortened fingers and enlarged finger joints), and stage III KBD is depicted in D (dwarfism).

**Table 1.** The Two Different Diagnostic Criteria of Kashin-Beck Disease

Criterion	KBD	Endemic Areas, Clinical Symptoms, and X-ray Signs
GB16003-1995 (gold criterion)	Early stage	Mild limited and pain in hand, wrist, knee and ankle joint, multiple symmetric flexion of distal part of fingers, metaphyseal lesions in phalanges
	I stage	Multiple symmetric enlarged finger joints, restricted stretch, mild muscle atrophy and clinical symptoms of early stage, metaphyseal or epiphyseal lesions in phalanges
	II stage	Shortened fingers and clinical symptoms of first stage, early closure of epiphysial plate in phalanges
	III stage	Dwarfism and clinical symptoms of second stage, aggravated metaphyseal lesions in phalanges
WS/T207-2010 (new criterion)	I stage	Enlarged finger joints, limited and pain in the joints of the limbs
	II stage	Shortened fingers and clinical symptoms of first stage
	III stage	Dwarfism and clinical symptoms of second stage

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