Development and Validation of a New Clinical Risk Index for Prediction of Osteoporosis in Thai Women

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The objective of this study was to develop and validate a new simple tool for identifying Thai women who are at high risk of having osteoporosis. A total of 322 women, aged ≥ 45 years, were randomly divided into two cohorts: a development (n = 130) and a validation cohort (n = 192). Femoral neck and lumbar spine BMD were measured by LUNAR DPX-IQ densitometer. The prevalence of osteoporosis (defined by BMD T-scores ≤ -2.5) was 33 per cent by either femoral neck or lumbar spine BMD. Khon Kaen Osteoporosis Study (KKOS), scoring based on age and weight was calculated and applied to the development cohort. Individuals with KKOS score ≤ -1 were defined as "high risk"; otherwise a "low risk" was defined. In the validation cohort, the sensitivity and specificity of KKOS was 70 and 73 per cent, respectively. Furthermore, if the high risk individuals identified by KKOS are to be treated, and if the treatment reduces fracture incidence by 50 per cent and assuming that treatment cost is 10 bahts per day, then the cost to prevent one fracture is estimated to be 466,695 bahts per year. These data suggest that although age and body weight can be used to identify Thai women who are at high risk of having osteoporosis, its application to the general population requires further research to arrive at the optimal cost-benefit for the community.

Keywords : *Clinical Risk Index, Osteoporosis, Fracture, Asia, Thailand*

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Osteoporosis and its ultimate consequence of low traumatic fracture in postmenopausal women represent one of the major public health problems in Western countries[1,2]. However, it is also increasingly becoming a major problem in Asian countries[3,4], due to the rapid ageing of the population[5]. It is projected that by the end of this century, 50 per cent of all hip fractures in the world will occur in Asia[6]. Effort of prevention of osteoporotic fractures by early identification of high risk subjects is likely the most cost-effective approach in Asia.

Bone mineral density (BMD) measured by dual energy x-ray absorptiometry (DXA) is regarded as the standard method for BMD assessment and fracture prediction[1]. However, in some developing countries, DXA is not widely available and the cost of measurement is high. It is reasonable to use the clinical risk indices for identifying subjects with low BMD or high risk fracture individuals.

Bone mineral density is highly related to age and body weight. Indeed, the two factors collectively account for 40 to 60 per cent variance of BMD in the population[7-12]. Some studies have suggested that these two factors were sensitive and specific enough to merit a large-scale identification of low BMD[13,14]. The Osteoporosis Self-Assessment Tools for Asians (OSTA) which is largely derived from age and body weight has been found to be a good and simple tool for the identification of women with osteoporosis risk[15]. However, the sample in which OSTA was developed largely came from the Chinese population, among whom lifestyles and behavioral factors are likely different from other developing populations such as Thai.

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The present study was designed to develop and validate a new simple tool for Thai women, and evaluate its utility in terms of economic costs and fracture prediction.

Material and Method

Setting and Subjects

This study was designed as a cross-sectional investigation in Muang district, Khon Kaen province, Thailand. All women were of Thai background, with the majority of them being farmers and house workers. The sampling frame consisted of 14 hamlets in 2 villages (9 hamlets from the first village and 5 hamlets from the second village). Subjects were randomly selected by an administrator of a sub-district. Three hundred and thirty-two letters were sent out, and the response rate was 100 per cent (no subjects refused to join the study).

Subjects were excluded from analysis if they had a history of metabolic bone disorders (other than postmenopausal bone loss), presence of cancer(s) with known metastasis to bone, menopause before the age of 40 years, at least one ovary removed, a history of taking medications affecting calcium and bone metabolism such as steroids, thyroid hormone, bisphosphonates, fluoride or calcitonin. Of the 332 women invited, 10 were excluded because they did not meet the study's criteria, leaving 322 women in the study. This study was approved by the Ethics Committee of Khon Kaen University and informed consent was obtained from all subjects. The study was conducted in accordance with the Helsinski Declaration in 1975 and as revised in 1983.

Measurements

Subjects were invited to meet with a trained research nurse who completed a questionnaire and an informed consent form. Body weight (including light indoor clothing) was measured using an electronic balance scale (accuracy 0.1 kg) and standing height (without shoes) with a standiometer (nearest 0.1 cm). Bone mineral density (g/cm^2) was measured at the lumbar spine and femoral neck by DXA using a LUNAR DPX-IQ densitometer (LUNAR Corporation, Madison, WI, USA). The radiation dose with this method is < 1 μGy. The coefficient of variation of BMD for normal subjects in Srinagarind Hospital was 1.5 per cent for the lumbar spine and 1.3 per cent for the femoral neck. *T*-scores were calculated using local population peak young mean value (mean $\pm$ SD: 0.94 ± 0.14 g/cm^2 for femoral neck, 1.15 ± 0.11 g/cm^2 for lumbar spine).

Development and Validation of Khon Kaen Osteoporosis Study (KKOS) score

A new Thai-specific osteoporosis score (called KKOS) was developed and validated. The entire sample (n = 322) was randomly divided into two cohorts according to the ratio 2:3; development cohort (n = 130) and validation cohort (n = 192). In the development cohort, logistic regression was used to evaluate the association between age and weight and BMD-based osteoporosis diagnosis. In this model, the relationships between age and weight and osteoporosis were expressed in odds ratio, the KKOS score was derived as the sum of odds ratios (by rounding the odds ratio to the nearest integer). In addition, receiver operating characteristic (ROC) curves were constructed for the KKOS score system. A cut-off score with the highest discriminatory power was derived from the ROC curves.

In the validation cohort, each subject was classified as "osteoporosis" if her BMD *T*-score was equal to or less than -2.5; otherwise the subject was classified as "non-osteoporosis". The KKOS score was then calculated and classified into 2 groups (high and low risk) based on the cut-off score. The concordance between the KKOS classification and the actual BMD-based classification can be summarized by a 2x2 table, from which sensitivity, specificity, and positive predictive value (PPV) were derived. Sensitivity is defined as the proportion of osteoporotic individuals who are identified as "high risk" by the KKOS score. Specificity is the proportion of non-osteoporosis individuals who are identified by the KKOS score as "low risk". PPV is the probability that an individual with a "high risk" diagnosis indeed is osteoporotic. All statistical analyses were performed using the SAS statistical analysis system[16]. A *p* value of less than 0.05 was considered statistically significant.

Evaluation of costs

The utility of the KKOS score was further evaluated in relation to costs and fracture prevention. Using the KKOS score classification (high and low risk), the prevalence of osteoporosis by KKOS score was calculated in the population. In this evaluation, the cost of treatment was assumed to be 10 bahts per day (hormone replacement therapy and calcium supplementation) or 50 bahts per day (anti-resorptive agent and calcium supplementation), and the cost of BMD measurement was 600 bahts per subject. Furthermore, it was assumed that treatment would reduce the fracture incidence by 50 per cent[17].

Table 1. Characteristics of study subjects

Variable	Development group	Validation group	*p* value
Number of subjects	130	192	
Age (y)	59.6 ± 9.1	60.5 ± 9.8	0.41
Weight (kg)	57.0 ± 10.3	55.7 ± 9.8	0.25
Height (cm)	152.9 ± 5.6	152.5 ± 5.5	0.49
Body mass index (kg/m^2)	24.4 ± 4.2	23.9 ± 3.7	0.27
Femoral neck BMD (g/cm^2)	0.77 ± 0.15	0.77 ± 0.16	0.85
Lumbar spine BMD (g/cm^2)	0.97 ± 0.20	0.95 ± 0.20	0.36
Prevalence of osteoporosis (%; 95% CI)			
Femoral neck (FN)	10.2 (5.0-15.4)	11.6 (7.1-16.1)	
Lumbar spine (LS)	31.3 (23.3-39.3)	32.3 (25.7-38.9)	
Either FN or LS	32.8 (24.7-40.9)	33.3 (26.6-40.0)	

Values are mean ± standard deviation, otherwise is specified

In the model, the average cost of preventing a fracture can be shown to be a function of 3 parameters as follows; (1) prevalence of high risk KKOS scores (p_1) and low risk scores (p_2), (2) PPV of the high risk scores (k_1) and low risk scores (k_2), and (3) the incidence of fracture. In a population of N subjects, the risk score can identify k_1p_1N, k_2p_2N osteoporotic and $(1\text{-}k_1)p_1N$, $(1\text{-}k_2)p_2N$ non-osteoporotic in high and low risk group, respectively.

If BMD is measured in individuals with high risk scores and if treatment is considered for those with BMD *T*-scores ≤-2.5, then the costs of BMD measurements and treatment can be shown to be $p_1N(C+Tk_1)$ where C is the cost of BMD measurement and T is the cost of treatment. Now, assuming that the annual incidence of fractures in the osteoporotic group is I per cent, and with a relative risk R, the annual incidence of fractures in the non-osteoporotic group is I/R. However, treating the k_1p_1N high risk individuals can prevent $0.5Ik_1p_1N$ fractures. Therefore, the cost of BMD screening and treatment to prevent one fracture is $2(C+Tk_1)/(Ik_1)$ per year.

In the analysis, several scenarios were considered according to prevalence and PPV of KKOS scores, the incidence of fracture of individuals with osteoporosis and also the cost of drug treatment.

Results

There was no significant difference in age, body weight, height, body mass index, and bone mineral density between the development and validation groups (Table 1).

The prevalence of osteoporosis in the entire sample was 11 per cent by femoral neck BMD and 32 per cent by lumbar spine BMD. When two BMD measures were considered, the prevalence was 33 per cent. The prevalence of osteoporosis increased with advancing age, such as by the age of 60 years or above, 51 per cent of individuals had osteoporosis which was more pronounced at the lumbar spine than femoral neck. However, there was no significant difference in the prevalence of osteoporosis between the development and validation cohorts (Table 1).

Development of KKOS

In the development cohort, each 5 years increase in age and each 5 kg decrease in weight was associated with 1.6-fold (95%CI: 1.2-2.0) and 2.0-fold (95%CI: 1.5-2.8) increase in the risk of osteoporosis, respectively. The scoring based on age and weight is shown in Table 2. The range of KKOS score was between 19.5 to -21.5. The cut-off score of -1 was found to have the highest discriminatory power.

Table 2. KKOS scoring system

Age (y)	Score	Weight (kg)	Score
< 45	+ 7.5	< 30	- 14
45-49	+ 6.0	30-34	- 12
50-54	+ 4.5	35-39	- 10
55-59	+ 3.0	40-44	- 8
60-64	+ 1.5	45-49	- 6
65-69	0	50-54	- 4
70-74	- 1.5	55-59	- 2
75-79	- 3.0	60-64	0
80-84	- 4.5	65-69	+ 2
85-89	- 6.0	70-74	+ 4
> 90	- 7.5	75-79	+ 6
		80-84	+ 8
		85-89	+ 10
		> 90	+ 12

Subsequently, individuals with KKOS score being ≤ -1 were defined as "high risk", on the other hand, individuals with KKOS score being > -1 were defined as "low risk". For identifying women with osteoporosis, the sensitivity and specificity were 75 and 80 per cent, respectively. The KKOS score system yielded an area under curve (AUC) of 0.85 (Fig. 1).

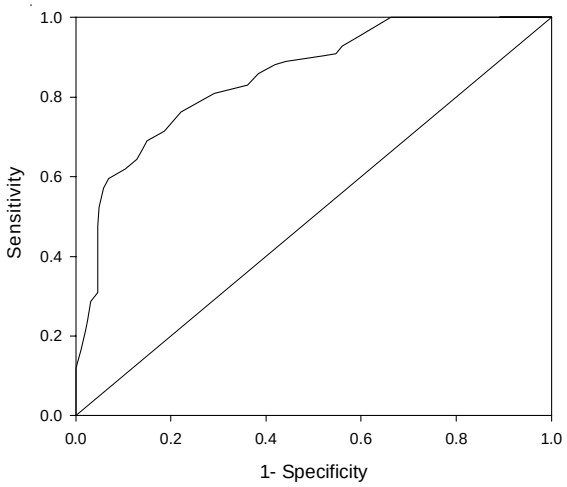

Fig. 1 Receiver operating characteristic (ROC) curve of KKOS score in the identification of low BMD women (*T*-scores ≤ -2.5)

Validation of KKOS

When applied to the validation cohort, the sensitivity of KKOS was 70 per cent and the specificity was 73 per cent. However, there was a significant variation in the diagnostic measures with age. For instance, in the younger group (45-60 years), the sensitivity was 50 per cent, but the specificity was higher (89 per cent). On the other hand, among those aged 60+ years, the specificity was 44 per cent compared with the sensitivity of 78 per cent. There was no significant difference between the two age groups with respect to the AUC statistics (ranging between 0.72 and 0.74, Table 3). Based on the logistic regression model, the probability of having osteoporosis was calculated for each age and weight group and was classified into three subgroups depending on the probability of having osteoporosis, if individuals with the probability ≥ 80 per cent was defined as "high risk", while individuals with the probability ≤ 20 per cent was defined as "low risk" and the rests (21-79 per cent) was defined as "intermediate risk" (Table 4).

Impact on fracture and cost

In the entire cohort, 41 per cent of individuals were considered "high risk" (KKOS ≤ -1). The prevalence of osteoporosis at femoral neck or lumbar spine in the high risk individuals was 59 per cent, which was almost 4-fold higher than that in low risk individuals (15 per cent). Assuming that the annual incidence of fracture among osteoporotic and non-osteoporotic Thai women is 2 and 1 per cent, respectively; and if the high risk individuals (KKOS ≤ -1) who have osteoporosis (*T*-scores ≤ -2.5) are treated, and under the assumption that the treatment can reduce fracture incidence by 50 per cent, then the cost of preventing one fracture is estimated to be 466,695 bahts per year. Most of the cost is due to treatment (~80 per cent) as BMD cost is modest (~20 per cent).

For a given incidence of fracture and prevalence of high risk individuals, the cost of preventing one fracture decreased as the PPV increased, however the effect is modest. For example, under the same assumption as above for a PPV of

Table 3. KKOS score in validation cohort

	KKOS score	Either FN or LS *T*-scores ≤ -2.5		FN *T*-scores ≤ -2.5		LS *T*-scores ≤ -2.5	
		Yes	No	Yes	No	Yes	No
All	≤ -1	44	34	19	59	43	35
	> -1	19	92	3	108	18	93
Age 45-60 (y)	≤ -1	9	9	1	17	9	9
	> -1	9	72	1	80	9	72
Age 60+ (y)	≤ -1	35	25	18	42	34	26
	> -1	10	20	2	28	9	21

KKOS, Khon Kaen Osteoporosis Study
FN, femoral neck; LS, lumbar spine

Table 4. Probability (%) of having osteoporosis for a given age and body weight

Weight (kg)	Age (y)										
	< 45	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85-89	> 90
< 30	58.7	67.4	75.0	***81.3***	***86.3***	***90.2***	***93.0***	***95.1***	***96.6***	***97.6***	***98.3***
30-34	47.5	56.8	65.6	73.5	***80.1***	***85.4***	***89.5***	***92.5***	***94.7***	***96.3***	***97.4***
35-39	36.6	45.6	54.9	63.8	71.9	78.8	***84.4***	***88.7***	***91.9***	***94.3***	***96.0***
40-44	26.9	34.8	43.6	52.9	62.0	70.3	77.5	***83.3***	***87.9***	***91.3***	***93.9***
45-49	**19.0**	25.4	33.0	41.7	51.0	60.2	68.7	76.1	***82.2***	***87.0***	***90.7***
50-54	**13.0**	**17.8**	23.9	31.3	39.8	49.0	58.3	67.0	74.6	***81.0***	***86.1***
55-59	**8.7**	**12.1**	**16.7**	22.5	29.7	38.0	47.1	56.4	65.2	73.1	***80.0***
60-64	**5.7**	**8.1**	**11.3**	**15.6**	21.2	28.1	36.2	45.1	54.4	63.4	71.6
65-69	**3.7**	**5.3**	**7.5**	**10.5**	**14.6**	**19.9**	26.5	34.4	43.2	52.5	61.6
70-74	**2.4**	**3.4**	**4.9**	**7.0**	**9.8**	**13.7**	**18.7**	25.0	32.6	41.3	50.5
75-79	**1.5**	**2.2**	**3.2**	**4.6**	**6.5**	**9.2**	**12.8**	**17.5**	23.6	30.9	39.4
80-84	**1.0**	**1.4**	**2.1**	**3.0**	**4.2**	**6.0**	**8.5**	**11.9**	**16.4**	22.2	29.3
85-89	**0.6**	**0.9**	**1.3**	**1.9**	**2.7**	**3.9**	**5.6**	**7.9**	**11.1**	**15.4**	20.9
> 90	**0.4**	**0.6**	**0.8**	**1.2**	**1.8**	**2.5**	**3.6**	**5.2**	**7.4**	**10.4**	**14.4**

Bold and italic figures: “high risk”, bold figures: “low risk”, normal figures: “intermediate risk”

80 per cent, the cost is 440,000 bahts per year, a reduction of 26,695 bahts compared to the cost associated with a PPV of 59 per cent (Table 5).

Discussion

Bone mineral density measured by DXA is widely recognized as the most robust predictor of future osteoporotic fracture, and is considered a surrogate measure of osteoporosis[1]. However, mass screening using DXA scanning is not recommended without some selection of the target population[18]. Moreover, in developing countries, DXA scanner is not widely available and the cost of BMD measurement is expensive. Hence, effort to use clinical risk indices to identify subjects likely to have low BMD is regarded as an attractive and cost-effective approach to the prevention of osteoporosis.

In this present study, the authors found that a simple assessment using 2 factors (age and body weight) that can identify women who have an increased risk of osteoporosis (low bone mineral density). The KKOS score had a high sensitivity (70 per cent) and specificity (73 per cent) for identifying individuals with a high risk of osteoporosis at the femoral neck or lumbar spine. When the KKOS score was compared with the OSTA score in he validation

Table 5. The costs for preventing one fracture case in Thai population based on KKOS score

Scenario	Prevalence of KKOS score in the population		Positive predictive value of KKOS score		Incidence of fracture in osteoporosis* (%)	Cost of drug treatment** (Bahts per day)	Cost to prevent one fracture (Bahts per year)		
	High risk	Low risk	High risk	Low risk			BMD	Treatment	Total
1	0.41	0.59	0.59	0.15	2	10	101,695	365,000	466,695
2	0.41	0.59	0.80	0.15	2	10	75,000	365,000	440,000
3	0.41	0.59	0.45	0.15	2	10	133,333	365,000	498,333
4	0.41	0.59	0.59	0.15	3	10	67,797	243,333	311,130
5	0.41	0.59	0.59	0.15	5	10	40,678	146,000	186,678
6	0.41	0.59	0.59	0.15	2	50	101,695	1,825,000	1,926,695
7	0.41	0.59	0.59	0.15	3	50	67,797	1,216,667	1,284,464
8	0.41	0.59	0.45	0.15	3	50	133,333	1,825,000	1,958,333

* Assuming the incidence of fractures in women with osteoporosis is 2 per cent (or 3, 5 per cent) per year compared with 1 per cent in non-osteoporotic women, ** Estimated cost of drug treatment for HRT with calcium supplementation was 10 Bahts per day and Anti-resorptive agent with calcium supplementation was 50 Bahts per day, Note: the 1st scenario was derived from the present study, BMD; bone mineral density

cohort, the specificity of KKOS was higher (73 vs 63.5 per cent) with comparable sensitivity and PPV.

Data from the present study showed that weight less than 55 kg was the best indicator of osteoporosis. Of women whose weight was less than 55 kg, 52 per cent had BMD *T*-scores $\leq$ -2.5, compared with 8.3 per cent in those who were 65 kg or heavier. Apart from weight, age was also an important determinant of osteoporosis. Approximately, 50 per cent of women aged $\geq$ 60 years had osteoporosis, compared with 11 per cent in women aged < 50 years. However, the authors also found that the PPV of KKOS was modest, suggesting its use for an individual is not warranted because of the high false positive rate.

The ultimate aim of identifying individuals with osteoporosis is to prevent fracture by intervention. The KKOS as well as other instruments were designed to identify low-BMD individuals. However, not all fractures result from low BMD[19]. Indeed, assuming that the annual incidence rates of fracture in the osteoporosis and non-osteoporosis group are 2 and 1 per cent, respectively, then the instrument can only identify 73 per cent osteoporosis and osteoporotic fracture cases correctly and if the identified individuals are to be treated, then the cost to prevent one fracture case in the population is high (466,695 bahts per year). However, if all individuals aged 45 or above, are to have BMD measurement and treatment is considered for those with osteoporotic BMD, then the cost for preventing one fracture is higher (605,000 bahts per year) than KKOS-based approach.

The present findings must be interpreted in the context of a number of potential strengths and weaknesses. Despite the subjects in this study being randomly selected, well characterized and a large sample; however, the study subjects were Thai, among whom, body size, lifestyles, and environmental factors are different from other populations. Thus, care should be taken when extrapolating these results to other populations. The measurement error of BMD could result in misclassification of osteoporosis[20,21] and body weight was measured at a single time point which may not reflect the true long-term weight of a subject. These two sources of measurement errors albeit inevitable, could have affected the result. However, such a limitation is present in any study of this type. Furthermore, the average cost in the present study was calculated and estimated using the actual cost in Thailand. Therefore, it may not be extrapolated to other countries with different health care systems.

In conclusion, the authors have developed a Thai-specific clinical risk score, KKOS based on age and body weight for assessment of osteoporosis risk. The score is sensitive and specific, but had modest positive predictive value. However, its use in the general population requires further research and evaluation to arrive at an optimal cost-benefit for the community at large.

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การพัฒนาและทดสอบดัชนีชี้วัดความเสี่ยงทางคลินิกในการทำนายการเกิดโรคกระดูกพรุนในหญิงไทย

ฉัตรเลิศ พงษ์ไชยกุล, เหงี่ยน เหงี่ยน, ชูวงศ์ พงษ์ไชยกุล, ทวน เหงี่ยน

การศึกษานี้มีวัตถุประสงค์เพื่อพัฒนาและทดสอบเครื่องมือชนิดใหม่ในการทำนายความเสี่ยงในการเกิดโรคกระดูกพรุนสำหรับหญิงไทย มีผู้เข้าร่วมการศึกษาทั้งสิ้นจำนวน 322 คน อายุตั้งแต่ 45 ปีขึ้นไป ได้แบ่งผู้เข้าร่วมการศึกษาออกเป็น 2 กลุ่มโดยวิธีการสุ่ม กลุ่มแรก (กลุ่มพัฒนา) จำนวน 130 คนและกลุ่มที่สอง (กลุ่มทดสอบ) จำนวน 192 คน โดยทำการตรวจวัดความหนาแน่นของกระดูกที่บริเวณกระดูกสะโพกและกระดูกสันหลังระดับเอวด้วยเครื่อง Lunar DPX-IQ ผลการศึกษาพบว่าความชุกของโรคกระดูกพรุนคิดเป็นร้อยละ 33 ที่บริเวณกระดูกสะโพก หรือกระดูกสันหลังระดับเอว การศึกษานี้ได้สร้างเครื่องมือชื่อว่า KKOS จากกลุ่มพัฒนาโดยใช้ค่าคะแนนรวมซึ่งคำนวณทางสถิติจากอายุและน้ำหนัก พบว่าเมื่อค่าคะแนนรวมมีค่าน้อยกว่าหรือเท่ากับ -1 จัดเป็นกลุ่มที่มีความเสี่ยงสูง และถ้าค่าคะแนนรวมมีค่ามากกว่า -1 จัดเป็นกลุ่มที่มีความเสี่ยงต่ำในการเกิดโรคกระดูกพรุน เมื่อนำเครื่องมือนี้ไปใช้ในกลุ่มทดสอบพบว่ามีความไวร้อยละ 70 และมีความจำเพาะร้อยละ 73 นอกจากนี้การนำเครื่องมือนี้ไปใช้ในระดับประชากร โดยกำหนดให้ผู้ที่ความเสี่ยงสูงในการเกิดโรคกระดูกพรุนจากเครื่องมือได้รับการรักษา ซึ่งผลการรักษาสามารถลดอุบัติการณ์ของการเกิดกระดูกหักได้ร้อยละ 50 และคิดค่ารักษา 10 บาทต่อวัน พบว่าค่าใช้จ่ายในการป้องกันการเกิดกระดูกหัก 1 ครั้งคิดเป็นจำนวนเงิน 466,695 บาทต่อปี

โดยสรุปการศึกษานี้ได้พัฒนาเครื่องมือจากอายุและน้ำหนักเพื่อทำนายความเสี่ยงในการเกิดโรคกระดูกพรุนสำหรับหญิงไทย อย่างไรก็ตามเครื่องมือนี้ยังต้องการการทดสอบจากการศึกษาอื่นเพื่อนำไปใช้ให้เกิดความคุ้มค่าในเชิงเศรษฐศาสตร์สำหรับชุมชน