

**Comparison of quality of life
according to relevant factors of
osteoporotic vertebral fracture in
postmenopausal females.
– A multicenter study –**

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– A multicenter study –**

Directed by Professor **Seong-Hwan, Moon**

The Master's Thesis
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of Master of Medical Science

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<TABLE OF CONTENTS>

ABSTRACT	1
I. INTRODUCTION	3
II. MATERIALS AND METHODS	5
1. MATERIALS	5
2. METHODS	7
III. RESULTS	10
IV. DISCUSSION	18
V. CONCLUSION	21
REFERENCES	22
ABSTRACT(IN KOREAN)	24

LIST OF FIGURES

Figure 1. EQ-5D and Fracture	12
Figure 2. EQ-5D index by age	16

LIST OF TABLES

Table 1. EQ-5D characteristics of patients with fracture	13
Table 2. Correlation between appearance of osteoporotic vertebral fracture and EQ-5D	15
Table 3. EQ-5D index by osteoporosis treatment	17

ABSTRACT

Comparison of quality of life according to relevant factors of osteoporotic vertebral fracture in postmenopausal females. – A multicenter study –

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The World Health Organization defines osteoporosis as a skeletal disease characterized by bone quantity decrease and substructure disorder, which results in a higher possibility of bone fracture. The most frequent clinical aspect of osteoporosis is vertebral fracture, of which pain and after effects usually change the way of life. The medical expenses of these patients are increasing annually. It is reported that vertebral compression fractures accompanying osteoporosis happen among 25% of females over 70, and 50% of females over 80. Furthermore, vertebral compression fracture can cause vertebral body deformity or increase the angle of vertebral kyphosis drastically; such effects can cause continuous pain, as well as serious inconvenience and disability.

In this nationwide, observational, and cross-sectional epidemiology study in Korea, we continuously recruited postmenopausal females between 50 and 80 years old who visited any of 62 orthopaedic offices at university, general, and

private hospitals. We analyzed and compared the quality of life (EQ-5D index) according to fracture, the number of fractured vertebral bodies, history of falls, and bone density. The average age of the subjects was 63.2, and the average age at the time of menopause was 48.8. The average age of the subjects with a fracture was 65.8 and their EQ-5D index was 0.787; for subjects, without fracture, the average age was 61.3, and the EQ-5D index was 0.825. The EQ-5D index of the patients with fracture yet without fracture history was 0.805, while that of the patients with a history was 0.750. Also, depending on the number of fractures, the EQ-5D index was 0.825, 0.793, 0.807, 0.760, and 0.778 for no fracture, one, two, three, and four fractures, respectively.

The EQ-5D index decreased with age after menopause, the number of fractured vertebral bodies, and an increase in the number of falls. Through early diagnosis and treatment of postmenopausal osteoporosis, we expected a decrease in the number of vertebral fractures and an increase in the quality of life.

Key words : osteoporotic vertebral fracture, quality of life , EQ-5D

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I. INTRODUCTION

The World Health Organization defines osteoporosis as a skeletal disease characterized by bone quantity decrease and substructure disorder, which results in a high possibility of bone fracture. The most frequent clinical aspect of osteoporosis is vertebral fracture and the pain and after effects of fracture usually changes the way of life; additionally, the medical expenses of these patients are increasing annually.¹

It is reported that vertebral compression fracture following osteoporosis occurs among 25% of women over 70 years of age, and 50% of women over 80years of age. Furthermore, vertebral compression fracture can cause vertebral body deformity or increase the angle of vertebral kyphosis drastically, which influences the quality of life due to continuous pain and serious inconvenience.² Generally, osteoporotic vertebral fractures increase

mortality and disability rates, and similarly, asymptomatic osteoporotic vertebral fracture can increase both of these rates when diagnosis or treatment is overlooked or delayed.³ However, 50% of osteoporotic vertebral fractures can be symptomless clinically, and when osteoporotic fracture is slight, its diagnosis is difficult.^{1,2} Naturally, there exist some differences among races and countries,⁴ and the danger of fracture due to osteoporosis is believed to be lower in Korea compared to other countries.^{5,6} However, according to the recent Korean national nutrition survey in 2008, the rate of osteoporosis among postmenopausal females was 32.6%, and the probability that women over 50years of age would experience osteoporosis was 29.9%. Therefore, considering the rapid aging of Korea, fractures due to osteoporosis should not be overlooked. However, in spite of such high statistical numbers, the aspects of osteoporotic vertebral fracture and its influence on quality of life caused by relevant factors have not been thoroughly studied.

In this paper, through a multicenter study, we compared the quality of life according to aspects of osteoporotic vertebral fracture and other relevant factors among almost 1,300 postmenopausal females over 50years of age. More specifically, the list of compared items included existence of fracture, the number of fractured vertebral bodies, tenderness, age, intake of osteoporosis medication, history of falls, and bone density.

II. MATERIALS AND METHODS

Materials

In this nationwide observational cross-sectional epidemiology study in Korea, we recruited postmenopausal females between 50 and 80years of age who visited any of 62 orthopaedic offices at university, general, and private hospitals between November 2010 and February 2011. According to previous studies in Europe or the USA, 18%-26% of postmenopausal females experienced vertebral fracture; therefore, we assumed the prevalence of osteoporotic vertebral fracture to be 26%.⁷ With 5% precision and 95% confidence level, the target number of subjects in this study was 1,183. The resulting subjects were 1,281 postmenopausal females between 50 and 80years of age. In order to compensate for regional differences, we identified the regional distribution of women over 50years of age in Korea using data from the Korean National Statistical Office from 2005 and subdivided the subjects proportionally into four regions, Seoul/Gyeonggi-do, Chungcheong-do, Jeolla-do, and Gyeongsang-do.

We followed the Helsinki declaration in that the subjects in accordance with the criteria above signed consent forms before participation. We also collected data by interviewing the subjects and searching their medical reports, and we asked the subjects themselves to fill in quality of life questionnaires.

Additionally, osteoporotic vertebral fracture, which was the first evaluation variable, was determined by orthopaedic surgeons.

The subjects included patients who visited an orthopaedic office and who had received diagnosis of menopause by a doctor. We defined menopausal females as those whose last menstruation was 12 months prior to visiting the orthopaedic office. Exclusion criteria were (1) subjects who were not diagnosed with menopause by a doctor, (2) those over 80 years of age, (3) those who had suffered high energy trauma (e.g. car or falling accident) within three months of data collection, (4) those who had suffered non-vertebral fracture within six months of research registration, (5) those who lacked cognitive ability in our discretion enough to have difficulty understanding the contents of the questionnaires, (6) those who had fracture or instrumentation between lumbar 1 and 4 such that the normal identification of more than two segments was impossible, and (7) those with femur fracture or instrumentation such that BMD evaluation in the bilateral femur was impossible.

Methods

1. Demographic information and medical history

Using a questionnaire, we surveyed the patients' age (date of birth), height, weight, length of menopause, maternal history of osteoporosis, living environment, smoking status, and average drinking quantity. Furthermore, we identified accompanying diseases such as spinal disease and Parkinson`s disease, the latter of which causes hypertension, diabetes mellitus, hypercholesterolemia, osteoporosis, rheumatoid arthritis, hyperthyroidism, hyperparathyroidism, severe osteoarthritis of the knee joint, foot disease and claudication. Uncured cataracts were recorded. Finally, the history of falls, trauma, and back pain within the recent year was requested and if there was a history of fracture, the location, cause, and treatment of the fracture were identified.

2. Bone mineral density (BMD)

We measured the BMD of the lumbar spine, femur neck, and total hip using dual energy X-ray absorptiometry.(DXA) If measured within three months, we used the existing measurements. We strictly followed the manual of each bone

density measurement machine. We evaluated BMD according to patient age and distribution of the lumbar spine, femur neck, and total hip, using T-scores to divide patients into a normal group ($T \geq -1.0$), osteopenia group ($-2.5 < T < -1.0$), osteoporosis group ($T \leq -2.5$). Lastly, the correlation between bone mass index (BMI) and BMD was also analyzed.

3. Plain radiography

We diagnosed vertebral fracture by taking standing anteroposterior and standing lateral radiographs of the thoracic and lumbar spine. If radiographs had been taken within three months prior to examination, we used those instead. Orthopaedics specialists at each hospital evaluated vertebral fractures using modification levels according to a semiquantitative evaluation method.⁸ They also checked symptoms.(e.g.tenderness)

We compared vertebral compression fracture among the normal group, osteopenia group, and osteoporosis group, and also compared the BMDs of the L -spine, femur neck, and total hip of patients with osteoporotic vertebral fracture to those of patients without fracture. We compared BMD among symptomatic and asymptomatic patients of vertebral fracture and those without vertebral fracture.

4. EQ-5D

We used the EuroQol (EQ-5D) questionnaire to evaluate quality of life. We excluded two subjects whose cognitive ability was not sufficient enough to fill out the questionnaire. We calculated each patient's utility index from the questionnaire results, using the model suggested in by Lee et al.⁹ Items in EQ-5D are mobility, self-care, usual activities, pain or discomfort, and anxiety or depression, and each item is subdivided into three levels (Lv.1: no problems, Lv.2: some problems, Lv.3: severe problems). For each item of EQ-5D, we analyzed the correlation of quality of life with aspects and relevant factors of osteoporotic vertebral fracture.

5. Statistical analysis

In the descriptive analysis of baseline characteristics, the numerical data were expressed as mean \pm standard deviations. Statistical analysis was performed using a one-way analysis of variance, *t*-test, or ANOVA test, if applicable. A probability value of less than 0.05 was accepted as the level of statistical significance.

III. RESULTS

1. Demographic information

In this study, participants included 1,281 postmenopausal females between 50 and 80 years old who visited any of 62 orthopaedic offices at university, general, and private hospitals. Among them, 25 corresponded to exclusion criteria and one whose fracture was not diagnosed was also excluded; therefore, the total number of subjects in this study was 1255. The distribution of age was as follows: 36.4% were 50-59 years old, 39.5% were 60-69 years old, and 24.1% were 70-79 years old. The average age was $63.2 (\pm 7.7)$ years. The average height was $155.3 (\pm 5.3)$ cm, the average weight was $57.4 (\pm 8.3)$ kg, and the average BMI was $23.8 (\pm 3.2)$ kg/m². The average age of menopause was $48.8 (\pm 5.2)$, and at the time of this study, the average period since menopause was $14.5 (\pm 9.0)$ years.

2. Correlation between EQ-5D Index and osteoporotic vertebral fracture.

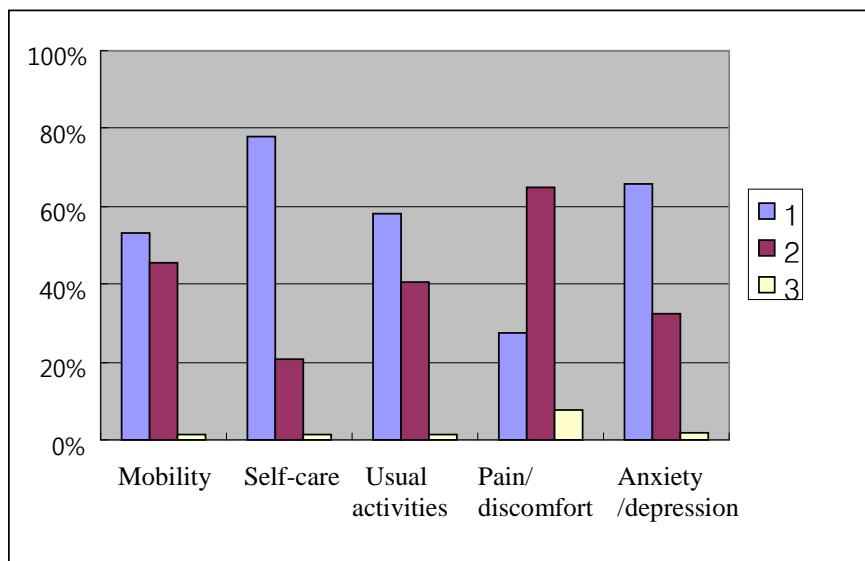
The quality of life was evaluated using the EuroQol (EQ-5D) questionnaire and we excluded two subjects who lacked the required cognitive ability to complete the survey. The number of patients with osteoporotic vertebral compression

fracture was 533 and their mean EQ-5D index was 0.787. The remaining 712 patients without fracture a mean EQ-5D index of 0.825 ($p < 0.0001$). We found that the EQ-5D index, which quantifies quality of life, was substantially lower in patients with fracture than in those without fracture, and this difference was statistically significant. However, 206 patients had an asymptomatic or overlooked osteoporotic vertebral compression fracture and their mean EQ-5D index was 0.801, which was not statistically different ($p=0.4303$) from the mean EQ-5D index (0.810) of the other 1039 subjects in this study who did not have such fractures. The 257 patients who suffered osteoporotic vertebral compression fracture within three months of the study had mean EQ-5D index of 0.781, while the other 988 patients' mean index was 0.816 ($p = 0.0006$). We found that the patients with recent fractures had a statistically lower mean EQ-5D index. That is, those with osteoporotic vertebral fracture and those with fractures that occurred within three months had a significantly lower quality of life index. However, asymptomatic osteoporotic vertebral fracture did not show any correlation with the quality of life index.

The items in the EQ-5D questionnaire are mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. The level 1 group in pain or discomfort accounted for as noticeably lower proportion of subjects compared to the level 2 and 3 groups. Similarly, in the EQ-5D graphs based on fracture, the pain or discomfort shows a significantly lower percentage of level 1 results compared to those of level 2 and 3. Below are the graphs showing the

level distribution of each item in the EQ-5D and the difference according to the existence of vertebral compression fracture (Figure1).

A.



B.

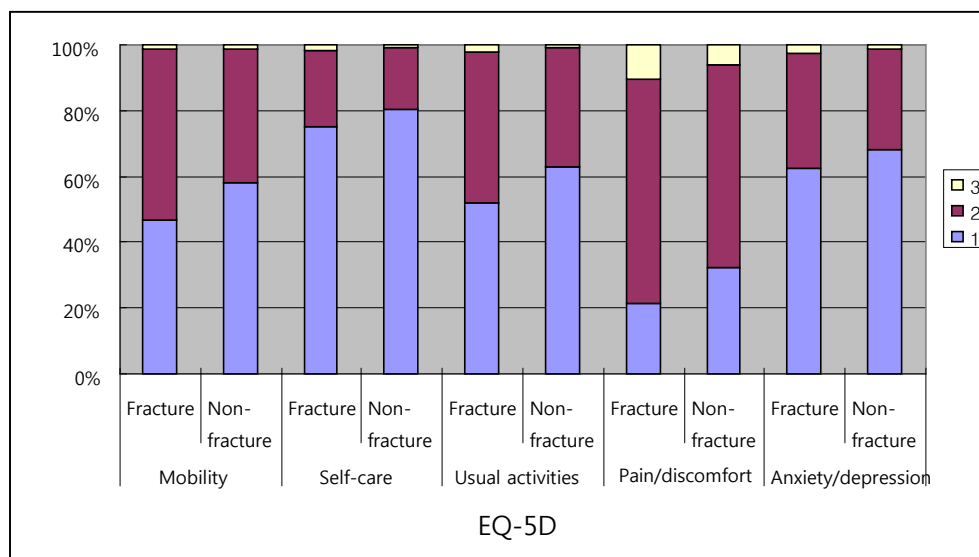


Figure1. EQ-5D and Fracture. (A) The level distribution of each item in EQ-5D. (B) The difference according to the existence of vertebral compression fracture.

In mobility, there were 662 patients in the level 1 group, 567 in the level 2 group, and 16 in the level 3 group. In level 1 group, 163 patients (24.6%) had symptoms (i.e. tenderness), 250 patients (37.8%) had modification level 1, 2, or 3, and 114 patients (17.2%) had both. (Table 1)

Table 1. EQ-5D characteristics of patients with fracture * T-test

Item		N	Tenderness n(%)	1-3 grade deformity n(%)	1-3 grade deformity & tenderness n(%)	Number of fractures [mean]
Mobility	No problem	662	163 (24.6)	250 (37.8)	114 (17.2)	1.26
	Some problems	567	175 (30.9)	276 (48.7)	139 (24.5)	1.72
	Severe problems	16	5 (31.3)	7 (43.8)	4 (25.0)	1.31
Self-care	No problem	972	271 (27.9)	400 (41.2)	197 (20.3)	1.41
	Some problems	258	66 (25.6)	123 (47.7)	54 (20.9)	1.68
	Severe problems	15	6 (40.0)	10 (66.7)	6 (40.0)	2.27
Usual activities	No problem	724	180 (24.9)	277 (38.3)	128 (17.7)	1.29
	Some problems	503	155 (30.8)	245 (48.7)	123 (24.5)	1.70
	Severe problems	18	8 (44.4)	11 (61.1)	6 (33.3)	2.56
Pain or discomfort	No problem	344	75 (21.8)	115 (33.4)	50 (14.5)	1.05
	Some problems	803	234 (29.1)	362 (45.1)	180 (22.4)	1.56
	Severe problems	98	34 (34.7)	56 (57.1)	27 (27.6)	2.21
Anxiety or depression	No problem	818	219 (26.8)	332 (40.6)	166 (20.3)	1.39
	Some problems	403	112 (27.8)	187 (46.4)	81 (20.1)	1.59
	Severe problems	24	12 (50.0)	14 (58.3)	10 (41.7)	2.46
p-value*			0.0073	<0.0001	0.0006	r=-0.1419

The average number of fractures was 1.26 in the mobility level 1 group. In contrast, in mobility level 2 and 3 groups, there were respectively 175(30.9%)

and 5(31.3%) patients with symptoms (tenderness), 276(48.7%) and 7(43.6%) patients with modification level 1, 2, or 3, and 139(24.5%) and 4(25%) patients with both. The average number of fractures was 1.72 in level 2 and 1.31, in level 3. Across the different items of the EQ-5D, the pain or discomfort item had a particularly low number of level 1 patients compared to level 2 and 3 patients.

3. Correlation between appearance of osteoporotic vertebral fracture and EQ-5D

Comparing the mean EQ-5D index according to the number of vertebral compression fractures, we found that the index was 0.825 in the group without fractures, 0.793 for one fracture, 0.807 for two, 0.760 for 3, and 0.778 for 4 or more. We recognized that there was a statistically significant tendency for the mean EQ-5D index to decrease as the number of fractures increased. Similarly, BMD also decreased as the number of fracture increased. The number of fractures also increased with a history of fall (Table 2).

Among the patients with vertebral compression fracture, the mean EQ-5D index of the group with symptoms (i.e. tenderness) was 0.781, while that of the group without symptoms was 0.793. That is, there was no significant relationship between quality of life and tenderness.

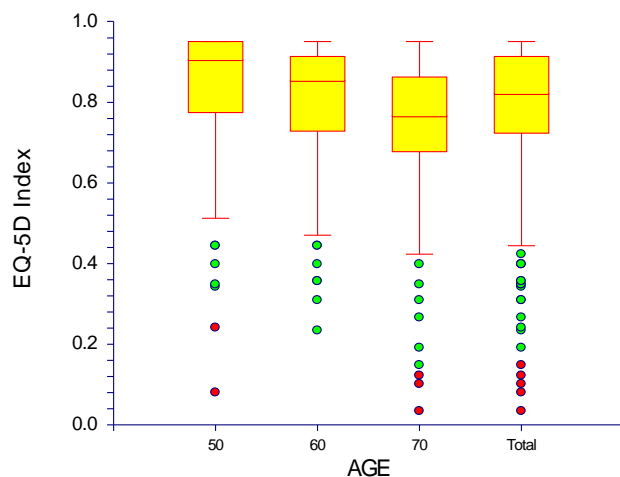
Table2. Correlation between appearance of osteoporotic vertebral fracture and EQ-5D (*p-value by ANOVA*)

	Non-fracture	1 fracture	2 fractures	3 fractures	≥4 fractures	p-value
History of falls	10.40%	14.40%	12.60%	13.90%	20.90%	0.0033
BMD (L-spine)	0.899 [0.176]	0.815 [0.179]	0.820 [0.191]	0.821 [0.179]	0.802 [0.198]	<0.0001
BMD (Femur)	0.749 [0.185]	0.673 [0.234]	0.679 [0.191]	0.663 [0.189]	0.643 [0.178]	<0.0001
BMD (Total hip)	0.805 [0.199]	0.733 [0.160]	0.733 [0.164]	0.750 [0.157]	0.697 [0.175]	<0.0001
EQ-5D	0.825 [0.139]	0.793 [0.139]	0.807 [0.162]	0.760 [0.183]	0.778 [0.143]	<0.0001

4. Correlation between the relevant factors of osteoporotic vertebral fracture and EQ-5D index

EQ-5D indexes according to age, which is one of the relevant factors of osteoporotic vertebral fracture, showed that the older the subject was, the lower the EQ-5D index. We concluded that age and quality of life were correlated. In EQ-5D graphs of different age groups, the pain or discomfort item showed a significantly lower number of people in the level 1 group than in level 2 and 3(Figure2).

A.



B.

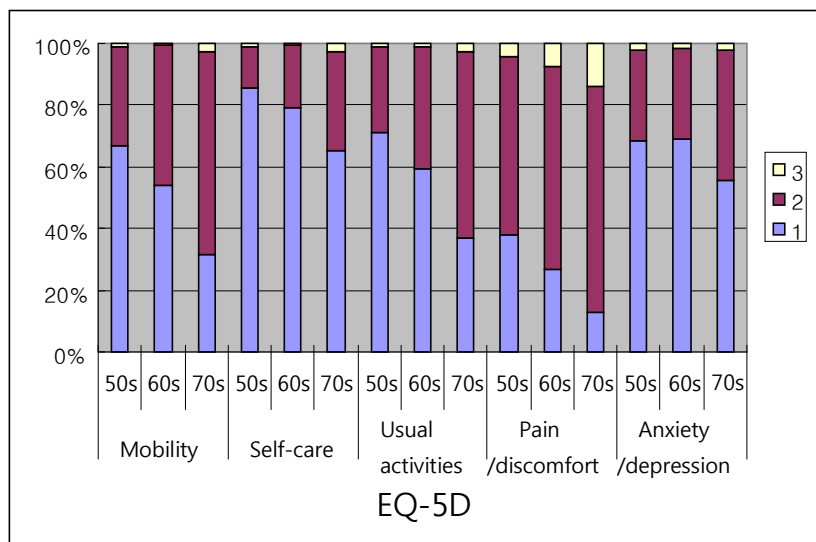


Figure2. EQ-5D index by age : A: Box plot

(ANOVA p -value <0.0001):With increasing age, the EQ-5D index significantly decreased. B: The level distribution of each item in EQ-5D by age.

Chisquare test: $p<0.0001$ (Mobility), $p<0.0001$ (Self-care), $p<0.0001$ (Usual activities), $p<0.0001$ (Pain or discomfort), $p=0.0011$ (Anxiety or depression)

Osteoporosis treatment, another relevant factor of osteoporotic vertebral fracture, showed no statistical relevance to the EQ-5D index. Among the 344 patients who received osteoporosis treatment, 291 took bisphosphonate, 77 took calcium, and 41 took vitamin D. The different medicines taken showed no differences in the EQ-5D index (Table3).

Table 3. EQ-5D index by osteoporosis treatment ($p=0.9369$, from *T-test*)

	None	Treatment			
		Total	Bisphosphonate	Calcium	Vitamin D
N	901	344	291	77	41
Mean[SD]	0.808[0.146]	0.809[0.146]	0.803[0.150]	0.791[0.144]	0.838[0.108]
Median	0.824	0.819	0.817	0.817	0.870
Min, Max	-0.056, 0.950	-0.056, 0.950	-0.056, 0.950	0.309, 0.950	0.513, 0.950

Patients with diseases affecting walking capability, such as severe osteoarthritis, foot disease, spine disease, and Parkinson's disease, showed a higher degree of risk of falls (19.40%), compared to 11.50% for patients without such diseases (t-test, p-value = 0.0028). Additionally, the EQ-5D index was lower in patients with such diseases (0.735) compared to those without (0.823) (t-test, p-value<0.0001). That is, the quality of life index was lower in the group with diseases affecting walking capability in a statistically meaningful way.

IV. DISCUSSION

This study is the first nationwide, observational, cross-sectional epidemiology study in Korea to analyze the influence of appearance and relevant factors of vertebral compression fracture on quality of life among postmenopausal females using the EQ-5D questionnaire. One characteristic of this study was that, using data from the Korean National Statistical Office for nationwide cross-sectional study, we divided Korea into four regions and recruited the subjects of each region in accordance with the population proportion of females over 50 in the region, thereby decreasing the regional bias. Another characteristic was that we recruited 1281 patients from 62 hospitals all around Korea during the same period of time, allowing us to identify the nationwide characteristics of osteoporotic vertebral compression fracture in Korean postmenopausal females. However, there exists a limitation in that our subjects included only those who visited orthopaedic offices; thus it is hard to say that our study reflects the quality of life of the entire postmenopausal female populations in Korea.

As a criterion for evaluating quality of life, the EQ-5D is a useful measure, and we identified that an increase in the number of osteoporotic vertebral compression fractures lowered the quality of life, correspondings to other previous studies.^{10,11} Lips, et al. reported that if other fractures such as hip fracture accompany vertebral compression fractures, the quality of life index

decreases further.¹⁰ In this study, older patients were also found to have a lower EQ-5D index, a finding that similarly agrees previous studies.¹¹

Although in our research we were not able to identify any correlation between osteoporosis treatment and EQ-5D index, there exists a study in Japan demonstrating that patients show a higher quality of life index after taking elcatonin together with calcium than before treatment.¹² The difference in our research may originate from the fact that we evaluated the EQ-5D index simply by asking whether the patient was receiving osteoporosis treatment, instead of comparing indices before and after such treatment. A large scale study making such comparisons in postmenopausal females is recommended with a fixed follow-up period.

However, it is reported in Europe that postmenopausal females show a similarly low quality of life index after taking teriparatide as an osteoporosis treatment, compared to before the treatment. Also, 69% reported that mobility was restricted. Furthermore, 91% reported chronic, intermittent back pain and severe back pain was also frequent.¹³

Limitation

There are several limitations in our study.

First, although we used the data from the Korean National Statistical Office to perform a nationwide cross-sectional study and divided the recruited postmenopausal females over 50 into four regions with appropriate proportions, we did not take into consideration the regional differences of health characteristics and the proximity and convenience of orthopaedic offices; therefore, it is hard to say that we completely removed all possibilities of regional bias. Additionally, from the previous studies indicating that different conditions across regions can influence quality of life, we feel that our analysis of the quality of life in each region could have been more precise.¹¹ That is, for better evaluation we will need to perform multiple tests (e.g. model optimism) in order to decrease the influence of interaction factors; however in this study, such testing was not conducted.

Second, there exists a limitation in the EQ-5D index for older ages. The decrease in quality of life for older patients may not necessarily be due to vertebral fracture, and other diseases or socioeconomic factors can be influential. That is, there is a significant ceiling effect.¹⁴

Third, the length of time during which subjects were recruited in this study was only 4 months. With this short sampling of patients visiting orthopaedic offices, it is hard to determine the relationship between quality of life and vertebral compression fractures in postmenopausal females.

V. CONCLUSION

Osteoporotic vertebral fractures that occurred within the three months of evaluation were found to decrease the quality of life index significantly. However, asymptomatic osteoporotic vertebral fracture showed no correlation with the quality of life index. In the distribution of each item of the EQ-5D according to the existence of vertebral compression fracture, pain or discomfort showed the greatest difference. As the number of fractures increased, the mean EQ-5D index decreased. Similarly, BMI decreased as the number of fracture increased, and the number of fractures increased when the history of falls increased. However, there appeared to be no significant influence of tenderness on quality of life.

The older group showed a lower EQ-5D index; therefore, there seems to be a significant relevance between age and quality of life. However, there was no correlation between EQ-5D index and osteoporosis treatment, including different types of medicine. Lastly, the patients with diseases affecting walking capability showed a statistically lower quality of life index. We expect that our study of the relationship between quality of life and the appearance and relevant factors of osteoporotic vertebral fracture among Korean postmenopausal females can be beneficial for predicting and improving quality of life.

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ABSTRACT(IN KOREAN)

폐경 후 여성에서의 골다공증성 척추 골절과 관련된 인자에 따른 삶의 질 비교 - 다 기관 연구 -

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골다공증은 세계보건기구(WHO)에서 골량의 감소와, 미세구조 이상을 특징으로 하는 골격계 질환으로, 결과적으로 뼈가 약해져서 부러지기 쉬운 상태가 되는 질환으로 정의하고 있다. 이런 골다공증의 가장 주된 임상양상으로 척추 골절이 나타나며 골절로 인한 통증 및 후유증으로 생활방식의 변화가 오게 되며 이들 환자를 치료하기 위한 의료경비도 매년 증가 하고 있다. 골다공증에 동반된 척추 압박 골절은 70세 이상의 전체 여성 중 25%, 80세 이상 여성에서는 50%에서 발생하는 것으로 알려져 있다. 또한 척추 압박 골절로 인해 척추체 변형이 발생하거나 척추 후만 각의 과도한 증가로 인해 지속적인 통증 및 심각한 불편함과 장애를 초래할 수 있다.

본 연구는 전국적, 관찰적, 단면적 조사로서, 총 62개의 종합병원

및 병의원 정형외과 외래에 내원한 50세에서 80세까지의 폐경 후 여성을 연속적으로 모집하였다. 특히 나이, 골절의 유무와 골절된 척추체의 개수, 낙상 기왕력, 골밀도 등에 따라 삶의 질(EQ-5D index)을 비교 분석하였다. 평균 환자의 연령은 63.2세, 평균 폐경 연령은 48.8세 이었고, 골절의 유무에 따른 평균 나이는 65.8세, 61.3세 이었고, 삶의 질은 각각 0.787, 0.825 였다. 골절이 있으면서 골절 기왕력이 없는 환자의 삶의 질은 0.805, 골절 기왕력이 있는 환자에서는 0.750 이었다. 또한 척추 골절의 개수에 따른 삶의 질은 골절이 없는 경우는 0.825, 골절이 1개인 경우는 0.793, 골절이 2개인 경우는 0.807, 골절이 3개인 경우는 0.760, 골절이 4개 이상인 경우는 0.778 로 나타났다.

폐경 후 나이, 골절, 골절된 척추체의 개수, 낙상 기왕력이 증가할수록 삶의 질(EQ-5D index)지수는 낮았다. 폐경후 골다공증의 조기진단과 치료를 통해 척추골절의 감소와 삶의 질 증가를 기대할 수 있다.