OSTEOPOROSIS AND BONE DISEASES

# SPINAL DEFORMITY INDEX AND QUALITY OF LIFE OF PATIENTS WITH A DENSITOMETRIC DIAGNOSIS OF OSTEOPOROSIS

ÍNDICE DE DEFORMIDADE ESPINAL E QUALIDADE DE VIDA DE PACIENTES COM DIAGNÓSTICO DENSITOMÉTRICO DE OSTEOPOROSE

ÍNDICE DE DEFORMIDAD ESPINAL Y CALIDAD DE VIDA DE PACIENTES CON DIAGNÓSTICO DENSITOMÉTRICO DE OSTEOPOROSIS

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## ABSTRACT

Objective: To evaluate the existence of a possible significant correlation between the quality of life of outpatients with osteoporosis and the Spinal Deformity Index (SDI), a radiographic method for semiquantitative assessment of the spine that enables the identification of prevalent and incident fractures. Methods: A cross-sectional observational study carried out with female patients, Caucasians, over 50 years of age, with a densitometric diagnosis of osteoporosis and in an outpatient follow-up, who were submitted to the Oswestry Disability Index (ODI) and SF-36 questionnaires to measure the direct and indirect damage of vertebral fragility fractures on quality of life. The scores obtained in these questionnaires were correlated with the SDI scores, calculated from the radiographs of the lumbar and thoracic spine. Results: 48 patients completed the study, with a mean age of  $69.6\pm6.7$  years, mean body mass index (BMI) of  $25.4\pm3.4$  kg/m<sup>2</sup>, mean ODI of  $25.1\pm17.9\%$ , mean SF-36 of  $428.7\pm192.4$  and mean SDI of  $4.3\pm3$ . For the statistical analysis, Spearman's coefficient was used ( $p \le 0.05$ ). Conclusion: There is no statistically significant correlation between the SDI and the scores obtained on the ODI and SF-36 quality of life questionnaires. *Level of evidence: III. Study of non-consecutive patients, without gold standard, applied uniformly.* 

Keywords: Spinal Fracture; Quality of Life; Osteoporosis.

## RESUMO

Objetivo: Avaliar a existência de uma possível correlação significativa entre a qualidade de vida de pacientes ambulatoriais com osteoporose e o Spinal Deformity Index (SDI, Índice de Deformidade Espinal), método radiográfico de avaliação semiquantitativa da coluna vertebral que permite identificar fraturas prevalentes e incidentes. Métodos: Estudo observacional transversal realizado com pacientes do sexo feminino, caucasianas, com mais de 50 anos de idade, diagnóstico densitométrico de osteoporose e em seguimento ambulatorial, as quais foram submetidas aos questionários Oswestry Disability Index (ODI) e SF-36 para dimensionar o dano direto e indireto das fraturas por fragilidade vertebral na qualidade de vida. A pontuação obtida nestes questionários foi correlacionada com os escores do SDI, calculados a partir das radiografias da coluna vertebral lombar e torácica. Resultados: Concluíram o estudo 48 pacientes, com média de idade de 69,6 ± 6,7 anos, índice de massa corporal (IMC) médio de 25,4 ± 3,4 kg/m<sup>2</sup>, ODI médio de 25,1 ± 17,9%, SF-36 médio de 428,7 ± 192,4 e SDI médio de 4,3 ± 3. Para a análise estatística empregou-se o coeficiente de Spearman ( $p \le 0,05$ ). Conclusões: Não há correlação estatística significativa entre o SDI e a pontuação obtida nos questionários de qualidade de vida ODI e SF-36. **Nível de evidência: III; Estudo de pacientes não consecutivos, sem padrão ouro, aplicados uniformemente**.

Descritores: Fraturas Vertebrais; Qualidade de Vida; Osteoporose.

# RESUMEN

Objetivo: Evaluar la existencia de una posible correlación significativa entre la calidad de vida de los pacientes ambulatorios con osteoporosis y el Spinal Deformity Index (SDI, Índice de Deformidad Espinal), un método radiográfico de evaluación semicuantitativa de la columna vertebral que permite identificar fracturas prevalentes e incidentes. Métodos: Estudio observacional transversal realizado con pacientes del sexo femenino, caucásicas, mayores de 50 años, con diagnóstico densitométrico de osteoporosis y en seguimiento ambulatorio, a las que se les aplicaron los cuestionarios Oswestry Disability Index (ODI) y SF-36 para medir el daño directo e indirecto de las fracturas por fragilidad vertebral en la calidad de vida. Las puntuaciones obtenidas en estos cuestionarios se correlacionaron con las puntuaciones del SDI, calculadas a partir de las radiografías de la columna lumbar y torácica. Resultados: Un total de 48 pacientes completaron el estudio, con una edad promedio de 69,6 ± 6,7 años, índice de masa corporal (IMC) promedio de 25,4 ± 3,4 kg / m2, ODI promedio de 25,1 ± 17,9%, SF-36 promedio de 428,7 ± 192,4 y un SDI promedio de 4,3 ± 3. Para el análisis estadístico se utilizó el coeficiente de Spearman (p ≤ 0,05). Conclusiones: No existe una correlación estadísticamente significativa entre el SDI y la puntuación obtenida en los cuestionarios de calidad de vida ODI y SF-36. **Nivel de evidencia: III; Estudio de pacientes no consecutivos, sin padrón oro, aplicados uniformemente.** 

Descriptores: Fracturas de la Columna Vertebral; Calidad de Vida; Osteoporosis.

Study conducted at Osteoporosis and Spinal Diseases Outpatient Clinics of Hospital das Clinicas da Universidade Estadual de Campinas, supervised by the Rheumatology, Orthopedics and Traumatology Department (Spinal Surgery Discipline). Campinas, SP, Brazil.

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#### INTRODUCTION

Osteoporosis is a global public health problem that affects large portions of the population, especially in connection with population aging. It is a systemic multifactorial osteometabolic disease characterized by decreased bone mineral density (BMD) and changes in bone microarchitecture, with a consequent increase in fragility and susceptibility to fractures.<sup>1</sup> Vertebral fractures represent almost half of all osteoporotic fractures and are at least twice as frequent as hip fractures.<sup>2</sup> In Brazil, in the population over 65 years of age, the prevalence of these fractures due to fragility is as high as 27.5% among women and 31.8% among men.<sup>3</sup> However, given that many vertebral fractures are asymptomatic, the problem is more severe than these figures indicate.<sup>1.4</sup>

Fractures of the vertebral bodies are one of the main characteristics of osteoporosis.<sup>5,6</sup> The presence of one vertebral fracture leads to a five-fold risk of another vertebral fracture and a two-fold risk of a non-vertebral fracture. Therefore, vertebral fractures have greater capacity than BMD or bone remodeling markers to predict the risk of subsequent fractures.

In parallel, the risk of new fractures increases with the number and severity of previous vertebral fractures. Therefore, it may be more appropriate, when assessing the future risk of fractures, to consider each of the vertebrae individually, as a quantitative parameter (number of fractured vertebrae), rather than the spine as a whole, as a qualitative parameter (the presence or absence of vertebral spine fracture).

Thoracic and lumbar fractures due to fragility are peculiar, since, unlike cervical or limb fractures, they are underdiagnosed in up to 75% of cases, whether because they go unrecognized due to the fact that they are asymptomatic, or because they present only a few, generally nonspecific symptoms. In addition, the fact that, even when diagnosed, these fractures are rarely documented in medical records and, when diagnosed, rarely become an opportunity for intervention and treatment for osteoporosis. That said, many standardized tools and approaches have been developed with the aim of providing immediate, accurate and unambiguous diagnosis of vertebral fractures.<sup>7,8</sup>

Osteoporosis leads to a significant decrease in quality of life and an increase in morbidity and mortality. This is mainly due to the consequences of fractures, particularly spinal fractures. Pain, deformity, weight loss, loss of ability to walk, inactivity, pulmonary dysfunction and gastroesophageal reflux are observed. As a result, there is a decrease in functionality, less capacity for self-care, reduced independence, cognitive deterioration, and esthetic impairment that, in turn, lead to social isolation, low self-esteem and depression.<sup>9</sup> General and specific tools of the patient's health status can be used to evaluate the repercussions of fractures due to bone fragility.<sup>10</sup>

The mortality associated with osteoporotic spinal fractures is still very high, reaching 20% in one year and 50% in three years. Deaths are caused by the fractures themselves and also by their repercussions, from hospital admission and prolonged immobilization to complications such as infections and thromboembolic events.<sup>11,12</sup>

Currently, the diagnosis of osteoporosis is based on BMD, measured by dual energy X-ray absorptiometry. In 1994, based on epidemiological studies, the World Health Organization defined a cutoff value for the diagnosis of osteoporosis as a score of BMD greater than or equal to 2.5 standard deviations below the mean T-score.<sup>4,11</sup> However, the impact of osteoporosis on morbidity and mortality is mainly attributed to the presence of fractures due to fragility. While on the one hand, vertebral fractures may occur even with a BMD above the osteoporotic range; on the other, after the occurrence of a vertebral fracture, the risk of a subsequent fracture is greater regardless of BMD. In view of this, for many specialists, the presence of fractures due to fragility is sufficient for the diagnosis of osteoporosis.<sup>4</sup>

The spinal deformity index (SDI) described by Genant, Minne et al. is a semi-quantitative radiographic evaluation tool that expresses the impact caused by osteoporosis on the spine in a single measure. For each vertebra, a score is assigned according to the percentage loss of vertebral body height: Absence of deformity (<20% compression – SQ = 0), mild deformity (20 to 25% compression – SQ = 1), moderate (25 to 40% compression – SQ = 2) or severe (> 40% compression – SQ = 3). Fracture is diagnosed by a reduction of at least 20% of vertebral body height. <sup>13,14</sup>

The SDI is the result of the sum of the score attributed to each of the vertebrae from T4 to L4. Thus, a patient without vertebral fracture would have an SDI = 0 and a patient with a mild fracture and a severe one would have an SDI = 1 + 3 = 4. This method allows the identification of prevalent fractures in an initial visit and incidents in a serial assessment.<sup>8,13,14</sup>

There have been many studies on the description of vertebral fractures by semiquantitative visual and quantitative morphometric approaches.<sup>13,15</sup> In this respect, Genant et al. demonstrated that the SDI is an accurate and reproducible method for the evaluation of prevalent and incident osteoporotic vertebral fractures.<sup>13,16</sup>

#### **METHODS**

This study was approved by the Research Ethics Review Board of Universidade Estadual de Campinas under CAAE registration no. 32912214.1.0000.5404.

The research subjects were informed that their participation would be voluntary and that refusal or withdrawal at any time would not harm the health care they received. The exclusion criteria were: male patients or patients under 50 years of age or non-Caucasians; patients submitted to some previous surgical procedure to the spine; patients with congenital deformities of the spine; patients who did not agree to collaborate with research by not signing the Informed Consent Form (ICF).

A cross-sectional observational study was carried out with 48 female Caucasian patients over 50 years of age, with a densitometric diagnosis of osteoporosis and in outpatient follow-up at the Osteoporosis and Spinal Diseases Outpatient Clinics (*Ambulatórios de Osteoporose e de Patologias da Coluna Vertebra*) of the Hospital das Clinicas da Universidade Estadual de Campinas (HC -Unicamp).

The outpatient schedule was considered, with clinical assessment and the application of quality-of-life questionnaires by the research doctors during the routine outpatient follow-up appointment for the diagnosis of osteoporosis.

Anthropometric data and information on comorbidities and continuous use of medications were collected. The BMI was calculated based on the weight, in kilograms, divided by the square of the height, in meters. Any additional information needed was obtained from the medical records in the Medical Archive Service (*Serviço de Arquivo Médico* - SAME) and in the University Hospital Management App (AGHUse).

Both quality-of-life questionnaires, the Oswestry Disability Index (ODI) and the SF-36, were validated in Brazil. The questionnaires are quick and easy to apply, and the average response time for each is approximately ten minutes.<sup>17,18</sup>

The ODI is used for the functional assessment of the patient and consists of ten questions, each with six statements, with score ranging from zero to five. The first question evaluates the intensity of pain and the other nine, the effect of pain on activities of daily living such as: Personal care (washing and dressing), lifting weights, walking, sitting, standing, and sleeping, as well as its effects on the sex life, social life and traveling. The total value is divided by the number of questions answered and multiplied by five. The result of this division is multiplied by 100. The final score is given as a percentage ([Total score  $\div$  (number of questions answered x 5)] x 100) % and ranges from 0 to 100%; the higher the score, the more severe the disability. The cut-off points are: 0-20% – minimum disability, 21-40% – moderate disability, 41-60% – severe disability, 61-80% – crippled and 81-100% – bed-bound.<sup>17</sup>

The SF-36 is a multidimensional instrument comprised of thirty--six items, which assess two basic components: physical and mental. The physical comprises the following domains: functional capacity, with 10 questions (performing daily activities, such as ability to care for oneself, wash and dress, and climb stairs); physical aspects with four issues (impact of physical health on the performance of daily and/or professional activities); pain, with two questions (level of pain and impact on the performance of daily and/or professional activities) and the general state of health, with five questions (subjective perception of general state of health). The mental aspect, meanwhile, addresses: vitality, with four questions (subjective perception of state of health); social aspects, with two questions (effects of physical health condition on social activities); emotional aspects, with three questions (effects of emotional conditions on the performance of daily and/or professional activities) and mental health, with five questions (mood and well-being scale). The final score for each domain varies from 0 to 100; the lower the value, the poorer the patient's overall state of health and quality of life.<sup>18</sup>

The imaging propaedeutics was performed by qualified professionals in the specific sectors for this purpose, at HC-Unicamp. X-rays of the thoracic and lumbar spine were requested, in the anteroposterior and profile views, in different films, and the SDI was calculated based on these images. Bone densitometry was also requested.

The clinical and imaging data obtained were tabulated and used in a way that ensured the secrecy, privacy and confidentiality of the research subjects. There was no interference in the evaluation, conduct or follow-up of patients.

The Spearman coefficient and the software program Jamovi version 1.8 were used for the statistical analysis. The level of rejection for the null hypothesis was considered as equal to or less than 0.05.<sup>19,20</sup>

#### RESULTS

A total of 48 female, Caucasian patients aged over 50 years, with a densitometric diagnosis of osteoporosis and in outpatient follow-up at the Osteoporosis and Spinal Diseases Outpatient Clinics of the HC-Unicamp, were evaluated. The mean age of the patients was  $69.6\pm6.7$  years, the lowest being 58 years and the highest 85 years. The mean body mass index (BMI) was  $25.4\pm3.4$  kg/m<sup>2</sup>, with a variation of 17.8 kg/m<sup>2</sup> to 33kg/m<sup>2</sup>. (Table 1)

The mean BMD in the femoral neck was  $-1.9\pm0.8$  standard deviations in the T-score, with a minimum of -3.8 and a maximum of 0.2. The mean BMD in the lumbar spine was  $-2.6\pm1$  standard deviations in the T-score, with a minimum value of -5.0 and a maximum of 1.1. (Table 1)

We applied two quality-of-life questionnaires: the ODI and SF-36, each of whose domains are considered separately: Functional capacity, Limitation by physical aspects, Pain, general state of health, Vitality, Social aspects, Emotional aspects and Mental Health. It was observed that the patients obtained a mean final score of 428.7±192.4 in the SF-36 and 25.1±17.9% in the ODI. (Table 2) In other words, it was evident that the patients presented moderate quality of life and a moderate degree of disability in both scores.

X-rays of the thoracic and lumbar spine, in the anteroposterior and profile views, were used to calculate the SDI, which had a mean of  $4.3\pm3$ . (Table 3)

Spearman's coefficient was used to determine the existence of a possible significant correlation between the variables: on one hand, the SDI score and, on the other, the BMI, the ODI and the SF-36, together with each of their domains. (Table 4)

There was no statistically significant correlation between the SDI score and the scores obtained in the ODI and SF-36 quality-of-life questionnaires, even when each of their domains were considered

Table 1. Demographic data.

N = 48	Minimum	Maximum	Mean	Standard Deviation
Age (years)	58	85	69.6	±6,7
BMI (kg/m2)	17.8	33	25.4	±3,4
T-score BMD pelvis	-3.8	0.2	-1.9	±0,8
T-score BMD spine	-5.0	1.1	-2.6	±1

separately. On the other hand, the BMI showed a positive correlation of 0.37 ( $p = 1x10^{-2}$ ) with the SDI, though it should be emphasized that this is a weak correlation.

Considering the subgroups with SDI of less than 4 (n=21), between 4 and 7 (n=17) and greater than 7 (n=10), there was also no statistically significant correlation between the SDI score and the scores obtained in the ODI and SF-36 quality of life questionnaires. One exception was the BMI of patients with SDI less than 4. (Tables 5, 6, and 7)

#### DISCUSSION

Vertebral fractures are strong indicators of a deterioration in the quality of life of patients with osteoporosis, but are commonly

Table 2. Final scores in the SF-36 and ODI guality-of-life guestionnaires.

Minimum	Maximum	Mean	Standard Deviation
44	773	428.7	±192.4
0	100	54.3	±33.5
0	100	47.4	±46.5
0	100	19.1	±20.6
10	87	57.7	±20.3
5	100	63.9	±22.2
0	100	65.8	±29.6
0	100	55.1	±47
20	100	65.4	±20.6
2	62	25.1	±17.9
	44 0 0 10 5 0 0 20	44         773           0         100           0         100           0         100           0         100           0         100           0         100           0         100           0         100           0         100           0         100           0         100           0         100           0         100           0         100           20         100	44         773         428.7           0         100         54.3           0         100         47.4           0         100         19.1           10         87         57.7           5         100         63.9           0         100         55.1           20         100         55.4

Table 3. Final score in the SDI.

	Minimum (n = 0)	Maximum (n = 39)	Mean	Standard Deviation
SDI	0	11	4.3	±3

Table 4. Correlation between SDI and BMI, SF-36, ODI.

SDI and Correlated variable	Spearman correlation coefficient	p *p≤0.05
BMI (kg/m <sup>2</sup> )	0.370	0.01*
SF-36	-0.040	0.80
SF-36 –Functional capacity	-0.050	0.72
SF-36 – Limitation by physical aspects	0.001	-0.10
SF-36 – Pain	-0.030	0.84
SF-36 – General state of health	-0.127	0.14
SF-36 – Vitality	0.073	0.62
SF-36 – Social aspects	-0.080	0.59
SF-36 – Emotional aspects	-0.034	-0.04
SF-36 – Mental Health	0.079	-0.59
ODI (%)	0.067	0.65

Table 5. Correlation between SDI < 4 and BMI, SF-36, ODI.

SDI < 4 and Correlated variable	Spearman's Coefficient	p *p≤0.05
BMI (kg/m <sup>2</sup> )	0.665	0.001*
SF-36	-0.376	0.093
ODI (%)	0.283	0.213

Table 6. Correlation between SDI between 4 and 7 and BMI, SF-36, ODI.

SDI between 4 and 7 and Correlated variable	Spearman's Coefficient	p *p≤0.05
BMI (kg/m <sup>2</sup> )	-0.258	0.318
SF-36	-0.292	0.256
ODI (%)	0.440	0.077

Table 7. Correlation	n between SDI>7	7 and BMI,	SF-36,	ODI.
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SDI > 7 and Correlated variable	Spearman's Coefficient	p * p≤0.05
BMI (kg/m <sup>2</sup> )	-0.528	0.117
SF-36	-0.155	0.670
ODI (%)	0.334	0.345

underdiagnosed.<sup>7-9</sup> The presence of fractures due to fragility, however, implies a significantly increased risk of another, subsequent fracture, adding even greater morbidity and mortality to the disease.<sup>2</sup> On the other hand, there is a growing need for management strategies to be seen from an economic perspective of cost-usefulness as a measure of cost-effectiveness.<sup>1</sup> In this context, the SDI is a significant radiographic tool for the diagnosis of incident vertebral fractures, as it is easy to use, widely accessible, and low cost.<sup>13,16</sup>

Early diagnosis, timely treatment, a multidisciplinary approach and continuing education are prerequisites for the proper management of osteoporosis. Thus, quality-of-life questionnaires are important tools to outline an overview of the biopsychosocial impacts of the disease and guide the relevant interventions throughout the follow-up of these patients.<sup>2,10</sup>

In this study, the patients' mean final score was  $428.7 \pm 192.4$  in the SF-36, i.e., an intermediate quality of life. Similarly, their average score was  $25.1 \pm 17.9\%$  in the ODI, suggesting moderate disability. These results allow us to infer that patients with a diagnosis of osteoporosis, who maintain adequate follow-up, tend to have better quality-of-life indices.

The literature states that older patients diagnosed with osteoporosis tend to have poor quality-of-life indices.<sup>2,6</sup> In this regard, it should be noted that this study includes a relatively small number of patients over 80 years of age.

Analyzing each of the SF-36 domains, "Pain", with a final score

of  $19.1\pm20.6$ , was below the other domains, in which the mean scores were  $65.8\pm29.6$  to  $47.4\pm46.5$ . It is noted that pain is the most determining factor in the reduction of the quality of life of these patients, when compared to the other aspects investigated through this questionnaire. On the other hand, considering that the final score of each domain varies from 0 to 100, and that the lower the value, the poorer the overall state of health of the patient, it is warned that pain control is indispensable for improving the quality of life indices.

We expected to demonstrate that when applying the quality-oflife instruments, the results would be poorer the higher the score in the SDI, denoting not only greater bone fragility but also greater morbidity. However, there was no statistically significant correlation between the SDI score and the score obtained in the quality-of-life questionnaires, ODI and SF-36, even when each of its domains was considered separately.

Low BMI is a well-documented risk factor for osteoporotic fractures, while high BMI appears to be a protective factor.<sup>21</sup> Therefore, the hypothesis was proposed that BMI is negatively correlated with the SDI, whose score is higher as the percentage of height loss of the vertebral body increases. However, in this study, BMI presented a positive, albeit weak correlation with the SDI, of 0.37 ( $p = 1x10^{-2}$ ). The same was found for SDI subgroup<4, probably because the significance of BMI as a risk factor varies according to BMI level, being higher in BMI<22kg/m<sup>2</sup>.<sup>21</sup>

#### CONCLUSION

There is no statistically significant correlation between the SDI and the score obtained in the quality-of-life questionnaire, ODI and SF-36.

All authors declare no potential conflict of interest related to this article.

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