

Evaluation of satisfaction and preference in patients with osteoporosis receiving Denosumab

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Abstract

Objective: Satisfaction and preference properties differ in osteoporosis treatment agents. In our study we aimed to evaluate these properties in patients receiving denosumab treatment.

Material and methods: Thirty female patients who had denosumab injections were included in our study. Demographic and general characteristics were recorded.

General patient satisfaction, patient satisfaction of the drug and its effect on quality of life was evaluated on a Likert scale. Patients' preference was evaluated with asking the reasons of switches to denosumab.

Results: The mean age of patients was 59.30 ± 12.86 years. Of the patients 30 (% 100.0) wanted to continue the same therapy, 25 (%83.3) patients stated that managing this treatment is extremely easy. 25 (% 83.3) patients stated that it was extremely well-suited with lifestyle. 25 (% 83.3) patients were extremely convenient to take medication. 25 (% 83.3) patients have extremely willed to continue to use the medication. Of 30 patients, 30 (% 100) have been switched to denosumab due to physician recommendation. Physician recommended have been done to these patients due to ineffectivity of previous osteoporosis treatments or due to side effects of previous osteoporosis treatments. 22 (%73.33) of these patients have been switched to denosumab due to ineffectivity of previous osteoporosis treatments. About 8 (%26.66) patients have been switched to denosumab due to side effects of previous osteoporosis treatments.

Conclusion: Denosumab treatment in osteoporosis is a convenient and well-tolerated therapeutic modality.

Key words: denosumab, osteoporosis, satisfaction, preference

Introduction

Osteoporosis (OP) is a skeletal disease characterized by low bone mass [1]. It has been reported that more than 200 million people are suffering from OP [2]. Risk factors defined in OP are major modifiable and non-modifiable risk factors [3]. OP is defined as a bone mineral density (BMD) with 2.5 standard deviations (SD) or more below the average value for young healthy women (a T-score of < -2.5 SD) [4].

Management of OP includes pharmacological and non-pharmacological treatments [5]. Modifying lifestyle, calcium and vitamin D intake and exercise are the main non-pharmacological treatments of OP. Other non-pharmacological treatments are adequate protein intake, treatment of risk factors for falls, and limiting the consumption of coffee, alcohol and tobacco [6]. Pharmacological treatments of OP are oral bisphosphonates (alendronate, risedronate, ibandronate, etc), hormone

replacement therapies, raloxifen, teriparatide, strontium ranelate, intravenous bisphosphonates and denosumab [7].

Denosumab is a fully human antibody which is composed against receptor activator of nuclear factor kappa-B ligand (RANKL). It specifically binds to RANKL, prevents its interaction with receptor activator of nuclear factor kappa-B (RANK) and inhibits bone resorption [8]. Denosumab is approved for: OP treatment in postmenopausal women and men, in glucocorticoid-induced OP, in men who are receiving androgen-deprivation therapy for non-metastatic prostate cancer; and in women who are receiving adjuvant aromatase inhibitor therapy for breast cancer [9].

The success of OP treatment depends on satisfaction and preference of the patients [10]. Satisfaction and preference in patients receiving denosumab versus to bisphosphonates has been assessed in many studies before

[11-13]. In our study we assessed satisfaction and preference in patients receiving denosumab. We evaluated the factors which affect denosumab treatment choosing.

Material and methods

Our study is a descriptive study. It was carried out at Department of Physical Medicine and Rehabilitation, Division of Rheumatology, Aydın, Turkey from January 2017 to June 2017. Thirty female patients who had denosumab injections were included in our study. Informed consent was obtained from the patients. The inclusion criteria for our study were patients with an age between 50-90 years and diagnosed as primary OP. Exclusion criteria for our study were patients diagnosed as secondary OP. We recorded gender, age (at the diagnosis of OP and onset of menopause), previously OP therapies, number of denosumab injections, and patients' satisfaction to the research form. General patient satisfaction, patient satisfaction of the drug and its effect on quality of life was evaluated on a Likert scale. Patients' preference was evaluated with asking the reasons of switches to denosumab.

Statistical analyses

The analysis of the data was performed with SPSS 19.0 for Windows (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp.). Descriptive statistics for quantitative variables were given as mean±standard deviation for normally distributed variables and as median (25th-75th percentile) for non-normally distributed variables. X2 test or Chi-square test was used for comparison of the categorical data. The Kolmogorov-Smirnov test was used to determine whether the quantitative variables were normally distributed or not. For normally distributed variables ANOVA, for non-normally distributed variables Kruskal-Wallis test was used. Statistical significance was set at $p < 0.05$.

Results

The mean age of patients was 59.30 ± 12.86 years, mean age of menopause was 44.42 ± 5.75 years and mean age of OP diagnosis was 50.60 ± 11.25 years, respectively (Table 1). The mean number of denosumab injections was 2.00 ± 1.17 (Table 1). Of 30 patients 11 (%36.66) had history of using weekly bisphosphonate previous year. 11 (%36.66) had history of monthly bisphosphonate previous year. 1 (%3.33) patient had history of intravenous ibandronate previous year. 1 (%3.33) patient had history of intravenous zoledronic acid, 6 (%20) patient were not receiving any treatment previous year. The mean number of denosumab injections was 2.00 ± 1.17 (Table 1). Of the patients 30 (%100.0) wanted to continue the same therapy. 25 (%83.3) patients stated that managing this treatment is extremely easy. 25 (%83.3) patients stated that it was extremely well-suited with lifestyle. 25 (%83.3) patients were extremely convenient to take medication. 25 (%83.3) patients have extremely willed to continue to use the medication. Of 30 patients, 30 (%100) have been switched to denosumab due to physician recommendation. Physician recommended have been done to these patients due to ineffectivity of previous OP treatments or due to side effects of previous OP treatments. 22 (%73.33) of these patients have been switched to denosumab due to ineffectivity of previous OP treatments. About 8 (%26.66) patients have been switched to denosumab due to side effects of previous OP treatments. Of 30 patients, 30 (%100) were satisfied with this treatment (Table 2).

Table 1

The 10 most cited manuscripts in mushroom poisoning literature

| | |
|--|--------------|
| Age (years) | 59.30±12.86 |
| Sex (M/F) | 0/30 |
| Education status | |
| •Illiterate | 3 (%10) |
| •Primary school | 18 (%60) |
| •Middle school | 1 (%3.33) |
| •High school | 3 (%10) |
| •University | 5 (%16.66) |
| BMI (kg/m2) | 26.94±4.63 |
| Menopause age(years) | 44.42±5.75 |
| Diagnosis of osteoporosis age(years) | 50.60±11.25 |
| Previous osteoporosis medication | |
| • Weekly bisphosphonate (n) | 11 (% 36.66) |
| • Monthly bisphosphonate (n) | 11 (% 36.66) |
| • I.V. convenient ibandronate (n) | 1 (% 3.33) |
| • I.V. convenient ZA (n) | 1 (%3.33) |
| • Calcitonin (n) | 0 |
| • Strontium ranelate (n) | 0 |
| • HRT (n) | 0 |
| • Not receiving treatment | 6 (%20) |
| Number of denosumab injections | 2.00±1.17 |
| M/F: Male/Female; BMI: Body Mass Index; I.V: Intravenous; HRT: Hormon replacement treatment; ZA: Zoledronic acid | |

Table 2

Therapy preference and satisfaction

| Questions n (%) | Denosumab (n=30) |
|--|------------------|
| Remain on same therapy or change? | |
| • Remain on same therapy | 30 (%100) |
| • Change to alternative treatment | 0 (% 0) |
| Easy to manage medication? | |
| • Not at all | 0 (% 0) |
| • Somewhat | 0 (% 0) |
| • Very | 5 (%16.7) |
| • Extremely | 25 (%83.3) |
| • Missing | 0 (% 0) |
| Medication fits with lifestyle? | |
| • Not at all | 0 (% 0) |
| • Somewhat | 0 (% 0) |
| • Very | 5 (%16.7) |
| • Extremely | 25 (%83.3) |
| • Missing | 0 (% 0) |
| Convenient to take medication? | |
| • Not at all | 0 (% 0) |
| • Somewhat | 0 (% 0) |
| • Very | 5 (%16.7) |
| • Extremely | 25 (%83.3) |
| • Missing | 0 (% 0) |
| Willing to continue to use medication? | |
| • Not at all | 0 (% 0) |
| • Somewhat | 0 (% 0) |
| • Very | 5 (%16.7) |
| • Extremely | 25 (%83.3) |
| • Missing | 0 (% 0) |
| Reasons of switches to denosumab | |
| • Physician recommend | |
| • Ineffectivity of previous osteoporosis drugs | |
| • Side effects of previous osteoporosis drugs | 30 (%100) |
| • Forgetting the use of osteoporosis drugs | 22 (% 73.33) |
| • Forgetting the use of osteoporosis drugs | 8 (% 26.66) |
| • Missing | 0 (% 0) |
| Number of patients satisfied | 30 (%100) |

Discussion

In this study all patients were satisfied with denosumab treatment. All the patients received denosumab treatment due to ineffectivity of the previous OP treatments or due to side effects of previous OP treatments.

Satisfaction and preference are substantial in patients with receiving OP treatments. Morizio et al.'s [11] study had synthesized data of four studies, about patient preference, three studies about persistence and compliance and/or adherence, twelve articles and 3 abstracts about cost-effectiveness of denosumab. As a result of these data positive outcomes for preference and satisfaction, and also improved persistence and compliance rates were found with denosumab treatment compared with oral bisphosphonates. Sheedy et al. [12] investigated the efficacy and tolerability of zoledronic acid (ZA) and denosumab. Their study included 107 patients. Of 107 patients 51 patients were using denosumab, 56 patients were using ZA. They have recorded data about bone mineral density (BMD) changes, bone turnover markers, and questionnaire results which included the efficacy, tolerability and treatment cost of ZA and denosumab.

They evaluated patient' satisfaction with a five point scale. One point was representing 'very unsatisfied' and five point was representing 'very satisfied'. As a result of their study denosumab group had a higher mean increase in spine BMD. ZA group had higher incidence of flu-like symptoms. Both of study groups were statistically similar in terms of patient satisfaction. They found that patient satisfaction is similar in both patients receiving ZA and denosumab. Kendler et al.'s [13] study was a multicenter, randomized, open-label, 2-year, crossover study. Their study included 250 postmenopausal women with low BMD. All patients were randomized to 12 months with subcutaneous denosumab 60 mg every 6 months or oral alendronate 70 mg once weekly. Later the patients were crossed over to other treatment. Treatment adherence at 12 months was 95/124 (%76.6) for alendronate and 110/126 (%87.3) for denosumab. As a result of their study, significantly greater treatment adherence was obtained with denosumab treatment every 6 months than oral alendronate treatment once weekly.

Kendler et al. [14] compared subsequent osteoporotic fracture rates between denosumab-treated subjects during FREEDOM or the Extension and placebo-treated subjects in FREEDOM. Their results showed that denosumab decreases the risk of subsequent fracture. Dempster et al. [15] investigated the effects of 10 years of denosumab on bone histology, remodeling, and matrix mineralization. Their study included 92 women with postmenopausal OP. As a result of their study ten-year denosumab biopsies showed normal histology, normal bone structure and reduced bone remodeling. The degree of mineralization of bone was increased and mineralization heterogeneity was reduced in the denosumab years 2/3 group vs placebo. The changes in mineralization variables progressed from years 2/3 to year 5 of denosumab [15].

In this study we aimed to evaluate satisfaction and preference in patients receiving denosumab treatment. These properties should be considered because of they determine the continuation of the treatment. Previous studies [12-13] have evaluated only patient satisfaction or only preference. Morizio et al.'s [11] study was designed to be a synthesized data of some studies, articles and abstracts. We evaluated both satisfaction and preference. Our study supported that denosumab treatment in OP is a convenient and well-tolerated treatment.

The limitations of the study

The limitation of our study was that we evaluated satisfaction, preference and side-effects in a small number of patients receiving denosumab treatment. The other limitation of our study was that we did not record the density of patients' after denosumab treatment.

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