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Efficacy and Safety of Once-Monthly Ibandronate Treatment in Patients with Low Bone Mineral Density – ESTHER Study: 24 Months of Follow-Up

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SUMMARY
Introduction Osteoporosis is a major health and economic problem worldwide. The use of new drugs, such as ibandronate, is aimed at improving treatment of osteoporosis and currently poor compliance with BP therapy.
Objective To investigate efficacy and safety of ibandronate applied monthly, orally, in women with low bone mineral density (BMD).
Methods The prospective study was conducted in 34 centers in Serbia and included 77 women treated for 24 months with monthly ibandronate. The efficacy of treatment was assessed by change in bone mass values obtained by BMD measurement at the end of 24 months follow-up versus baseline and 12-months follow-up values. Compliance and safety, i.e. adverse effects (AE) were recorded.
Results Participants were postmenopausal (96%), osteoporotic (79.7%) females, diagnosed by lumbar spine DXA measurement (81%), with history of prior BP therapy in 33.8% women. The physical activity level significantly increased to the substantial level of activity (5.2% vs. 21.3%, p=0.003) during the study. After 12 and 24 months of treatment, BMD values significantly increased (p=0.002 and p<0.001). BP experienced patients improved more than BP naïve patients at both time points (p=0.012 and p=0.027, respectively). During the second 12 months of treatment the adherence was 96%; AE were recorded as mild gastrointestinal disturbances in 3.9%.
Conclusion Treatment by using ibandronate once monthly for 24 months was generally well tolerated and led to a significant increase in BMD in women with low BMD.
Keywords: osteoporosis; bone mineral density; bisphosphonates; ibandronat

INTRODUCTION

Osteoporosis is a common, debilitating disease. The lifetime risk of any fracture occurring in women from the age of 50 years exceeds 40% [1]. The lifetime risk of hip fracture is greater than the combined lifetime risks of breast, endometrial and ovarian cancers. Postmenopausal osteoporosis is also likely to become more common in the decades ahead as the life expectancy of the population increases. The personal and economic burden of postmenopausal osteoporosis is related to osteoporotic fractures, which are a significant public health problem resulting in substantial morbidity and mortality. Within the first year of post-hip fracture, 80% of patients are unable to carry out at least one independent activity in daily living and the associated mortality rate is 20%. Vertebral fractures also cause significant complications including back pain, height loss, kyphosis, loss of self esteem and death [2]. Osteoporosis can be undetected until a fracture occurs; therefore timely and effective diagnosis and treatment are the main goal in the management of this health problem. Treatment of osteoporosis is a challenging task for public healthcare and physicians taking into account the data that the majority of postmenopausal osteoporosis patients remain untreated and that even treatment compliant patients experience new vertebral or nonvertebral fractures during therapy with a rate of 9.5% per year [3]. Also, just 6% of previously untreated patients hospitalized for hip fracture are prescribed antiosteoporotic therapy, while only 41% of patients persist with treatment after 12 months [4].

Only a long-term compliance with the prescribed medication can improve bone mineral density (BMD), bone strength and reduce the risk of fracture [5]. It is widely accepted that osteoporosis treatment is monitored by BMD measurements in 1 to 2-year intervals, and if the drug mode of action is antiresorptive, monitoring should be also done for resorption markers, such as N or C telopeptide fragments of collagen type I. Increase of lumbar spine BMD by more than 3-6% indicates treatment success [6]. Bisphosphonates (BP) are stable pyrophosphate analogs with P-C-P bond (so far non-degradable bond) with a strong affinity for bone apatite, acting in the inhibition of osteoclasts activity and recruitment. Nitrogen containing BP interfere with mevalonate pathway, additionally inhibiting bone resorption. The oral bioavailability of BP are low, 1-3% of ingested dose and approximately 50% of absorbed BP is excreted in urine. However, they have

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a long half-life. [7]. BP are considered a first line therapy for the treatment of postmenopausal osteoporosis [8]. A cost–effectiveness analysis has indicated that BP increase treatment costs by 21%, but decrease the number of fractures by 35%, with the additional offset of the cost of therapy by other cost savings if treatment is targeted at high-risk women [9]. Importantly, when all available antiosteoporotic treatment options are considered, BP combine effectiveness, tolerability and patient comfort.

Ibandronate is nitrogen containing third generation BP, ten times more potent than alendronate. Owing to both biocompound and potency, it was possible for the first time to synthesize an oral medication to be taken once a month for the treatment of osteoporosis [10]. Ibandronate has been studied extensively for prevention and treatment of postmenopausal osteoporosis [11, 12].

OBJECTIVE

The aim of this trial was to investigate efficacy of once-monthly ibandronate treatment in patients with low BMD and to evaluate safety of this treatment in everyday clinical practice.

METHODS

Study design

The ESTHER Study (Efficacy and Safety of 12 months Bonviva THERapy) was a prospective multi–center observational study with one year follow-up, with the aim to evaluate efficacy and safety of ibandronate once a month. The studied population comprised 77 female patients with reduced BMD in everyday clinical practice in Serbia. Thirty-four centers participated in the ESTHER study. Prior to the enrolment, all patients gave informed consent for the participation and use of their personal data in this trial, as well as for the presentation of obtained study results to medical professionals. This study was extended to 2 years, comprising ESTHER 24-months follow-up.

Inclusion criteria for ESTHER trial were the same as for a routine drug prescription according to the summary of product characteristics: patients with decreased BMD and increased fracture risk, when antiresorptive treatment was indicated. Exclusion criteria were: males and osteoporosis due to prior metabolic or malignant diseases. Evaluation of efficacy included changes in T-score values after 24 months of treatment compared with baseline and 12-month data, and the incidence of low-energy fractures during the treatment period. The patients self-reported adverse events (AE) providing the information about safety issues. During the treatment period, the patients kept a diary about ibandronate use as well as on adverse reactions. During regular out-patients visits, the diaries were checked by investigators and in case of AE, type and grade of AE was specified and the reason for discontinuation, if any. The same setting was continued in the ESTHER 24-month follow-up. Women who completed the first year of ESTHER follow-up were eligible for participation in the extension study.

Treatment protocol

The patients received 150 mg ibandronate tablets once a month, in combination with daily 500 mg calcium supplement and 400 IU of vitamin D. No restrictions were set in relation to previous osteoporosis treatment.

The following data were recorded:

I. Demographics

Age, reproductive status (generative period or menopause, use of hormone replacement therapy), educational level (lower than primary, primary, secondary and university education).

II. Osteoporosis risk factors

Physical activity was divided in three levels for assessment: significant (defined as fitness exercise 3 times per week or as any other type of physical work), moderate (daily walks of 1 hour outdoors), low (less than 1 hour of walking outdoors or absence of physical exercise). Presence of fragility fracture during lifetime was recorded (fracture caused by minimal trauma or fall during sitting or standing position), family medical history of hip fracture in parents and close relatives, low body mass index (≤18), smoking habits, use of oral corticosteroids longer than 3 months. Data on significant diseases during the last 6 years which could affect bones were also recorded (rheumatoid arthritis, connective tissue diseases and hyperthyroidism).

III. Osteoporosis diagnosis

The same method was applied as in ESTHER; the diagnosis of osteoporosis was established according to the WHO definition [13] based on: a) dual energy X ray absorptiometry (DXA) of the spine and/or hip within 3 months of starting the treatment; b) and/or based on the presence of vertebral fractures; c) and/or skeletal X-ray findings. Treatment decision was based on the presence of osteoporotic fracture risk and results of DXA testing. The type of DXA device and the site of each measurement were recorded. The 12- and 24-month DXA measurements were performed by the same device and at the same site as the baseline. T-score values were recorded [14].

IV. Previous osteoporosis treatment

Previous osteoporosis treatment was recorded in ESTHER: type of supplemental treatment – calcium and vitamin D, type of previous BP use (oral BP daily, weekly, parenteral BP), as well as the duration of previous treatment.

At the end of 24-months of follow-up, DXA scan was repeated in those patients who had a previous scan, and T-score values were recorded again. The 24-month data regarding the incidence of new fragility fractures, type of fracture and time to fracture, AE as well as the type of AE, were recorded and analyzed. Statistical analysis of bone density change was also conducted.

Statistical analysis

Numerical values (age and T-scores) were presented as average, with standard deviation and range as measures of variability. Categorical values were presented as absolute frequencies and percentages. Incidence of AE during 2 years of follow-up was analyzed by the Cochran's Q test. The Student's t-test for paired samples was used for analyzing changes in T-score values from the baseline, after 12 months and 24 months. Analysis of significance of the difference in T-score from the baseline and 12-month values to 24-month follow-up data in relation to the incidence of prior BP treatment was conducted by analysis of variance for repeated measurements. The rate of missing data for any of the studied features did not exceed 10%.

RESULTS

The extension of ESTHER study comprised 77 female patients. The average age was 62.92±10.8 years (30-85). The other demographic data including reproductive status, educational profile, level of physical activity and presence of additional risk factors for low BMD (except menopause), are shown in Table 1.

When assessing BMD it was found that 74 (96%) underwent DXA testing and among them 15 (19.5%) women had osteopenic finding, while the remaining 59 (76.6%) had the osteoporotic level of BMD. The complete DXA evaluation of the hip and spine was made in 63 (81.8%) of patients. Osteoporosis diagnosis was established by radiological finding of osteoporosis in 6 (7.8%) patients, and by the presence of vertebral fractures in 10 (13%) patients. The diagnosis was established by one method in 61 (79%) patients.

Among all patient included in the ESTHER study with 24 months of follow-up, 21 patients (27.2%) had a co-morbidity which can affect bone metabolism in the preceding 6 years (e.g. chronic arthritis, connective tissue disease, hyperthyroidism). When assessing the presence of clinical risk factors we identified family history of fractures in 29 (37.7%) patients, early menopause in 16 (21.9%), while 17 (22.1%) were smokers, another 13 (16.9%) had fragility fractures and 4 (5.2%) used corticosteroids. The presence of major risk factors for osteoporosis in patients with low BMD is shown in Table 2.

Physical activity habits were assessed at the baseline and after additional 12 months of treatment in the ESTHER study with 24 months of follow-up. It was found that the level of physical activity was significantly increased, especially in patients with significant physical activity, from 5.2% at baseline up to 20.8% at the end of the follow-up (Z=2.137; p=0.033). Most of patients changed their physical activity from moderate to significant (Graph 1).

In the majority of patients (58.4%), ibandronate treatment was the first BP treatment for osteoporosis. Thirty-two patients (41.5%) were experienced in BP osteoporosis treatment. Daily BP was most frequent in 16 patients, while 14 patients received weekly BP prior to the enrollment into ESTHER study. Two patients (2.6%) had received parenteral BP. Forty-two patients (54.5%) had received supplemental calcium and vitamin D treatment before the study, while three (3.89%) of the patients had received neither supplements nor any other treatment (Table 3).

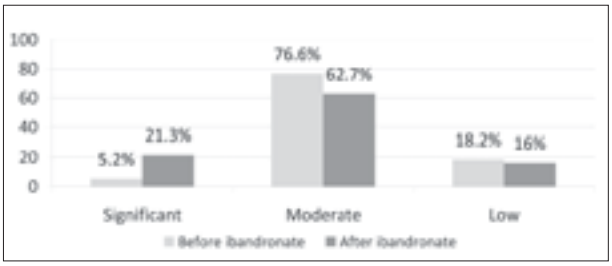
Efficacy assessment comprised bone density change of lumbar spine, i.e. 96% of patients were assessed at this point twice: at the baseline and after 12 and 24 months of

Table 1. Demographic data of patients with low bone mineral density treated with ibandronate during follow-up period of 24 months

Parameter		Number of patients (%)
Reproductive state	Generative period	2 (2.6)
	Menopause	75 (97.4)
Educational profile	Lower than primary school	1 (1.3)
	Primary school	9 (11.7)
	Secondary school	35 (45.5)
	University education	32 (41.6)
Physical activity	Substantial	16 (20.8)
	Moderate	47 (61)
	Low	12 (15.6)
	Unknown	2 (2.6)
Risk factors (except menopausal status)	None	15 (19.5)
	One	49 (63.6)
	Two	11 (14.3)
	Three or more	2 (2.6)

Table 2. Presence of major risk factors for osteoporosis in patients with low bone mineral density treated with ibandronate during 24 months of follow-up

Risk factor	%
Relevant diseases affecting bone mass	27.2
Smoking	22.1
Low body weight	18.2
Fractures in adulthood	16.9
Family history of fractures	37.7
Corticosteroid use	5.2
Early menopause	21.9



Graph 1. Change in physical activity levels (between baseline and at the end of follow-up) in patients with low bone mineral density treated with ibandronate during 24 months of follow-up

Table 3. Previous osteoporosis treatment in patients with low bone mineral density treated with ibandronate during 24 months of follow-up

Parameter	Number of patients (%)
Calcium and vitamin D supplementation	42 (54.5)
Daily BP	16 (20.8)
Weekly BP	14 (18.2)
Parenteral BP	2 (2.6)
No supplementation or treatment	3 (3.89)

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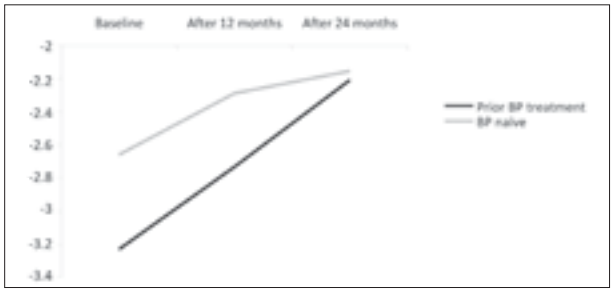
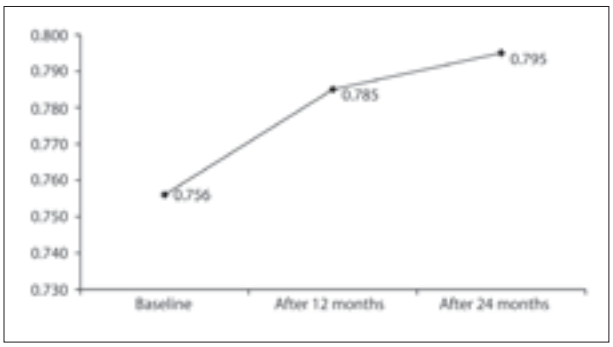


Graph 2. T-score changes in patients with low bone mineral density treated with ibandronate during 24 months of follow-up

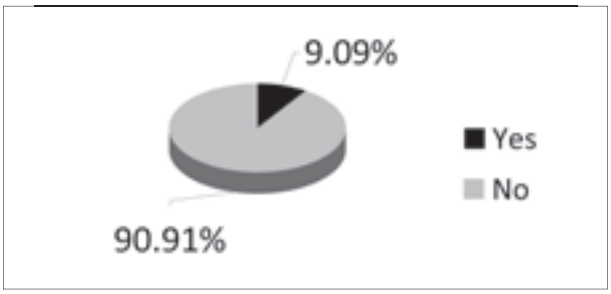


Graph 3. BMD changes in patients during 24 months follow up

follow-up. The average T-score at baseline was -2.83±0.825 SD, while at 12 and 24 months of follow-up it increased to -2.4±0.799 SD and -2.15±0.941 SD, respectively. Statistical analysis of the T-score change reached the level of high significance in both time points, between the baseline and 24 months, as well as between 12 months and 24 months of follow-up, $p<0.001$ and $p<0.002$, respectively (Graph 2). In regard to BMD, its values changed also during the observational period. Average baseline values increased from 0.756 g/cm^2 to 0.785 g/cm^2 and 0.795 g/cm^2 at 12 and 24 months follow-up measurements, respectively (Graph 3).

Further efficacy analysis was based on BMD change in two different patient subgroups, BP experienced and BP naïve patients. T-score values were increased in both subgroups. The average baseline T-score in BP experienced patients was -3.23±0.79 SD, reaching -2.7±0.713 SD at 12 months and finally -2.21±1.2 SD after 24 months of follow-up, while BMD values changed from 0.699 g/cm^2 to 0.748 g/cm^2 and 0.807 g/cm^2. In BP naïve patients the baseline T-score rated -2.66±0.799 SD reaching -2.29±0.799 SD and -2.15±0.825 SD after 12 and 24 months, respectively. If expressed in BMD values, from average baseline values of 0.738 g/cm^2 baseline reached 0.750 g/cm^2 and 0.795 g/cm^2 during follow-up period of 12 and 24 months. Differences in BMD values, in both of the two different patient populations were significant at both time points: from baseline to 24 months ($p=0.012$) and from 12 to 24 months of follow-up ($p=0.027$).

None of the patients had fractures during 24 months of treatment, while AE were recorded in 3 patients (3.9%) during 12 to 24 months of follow-up. During the overall treatment (from baseline to 24 months), 7 patients (9.1%) reported AE. All reported AE involved gastrointestinal complaints (Graph 4).



Graph 4. AE reported by patients with low bone mineral density treated with ibandronate during 24 months of follow-up

At the end of follow-up, 72 patients (94.8%) maintained ibandronate treatment, while 5.19% discontinued it. No other reasons for discontinuation were reported, except for treatment costs.

DISCUSSION

Since the mid-eighties, management of osteoporosis has dramatically changed, from treatments that were either lacking anti-fracture efficacy (i.e. etidronate, calcitonin) or were linked to increased morbidity (i.e. estrogens). Nowadays, consistent evidence has demonstrated that BP significantly reduce the risk of new fractures in women with postmenopausal osteoporosis, including new ones, such as ibandronate [10]. Accordingly, in the ESTHER study, we aimed at testing the efficacy and safety of ibandronate once monthly in everyday practice in Serbia over 24 months of follow-up.

Ibandronate treatment was started in osteoporotic patients (79.7%) as it is in many other clinical trial settings, as well as in real life studies [14, 15], based on the assumption that osteoporosis patients will benefit most from this treatment. Some meta analyses that include more than 8700 patients, showed that 2 years of follow-up including good compliance (as annual cumulative dose – ACE of more than 10.8 mg of ibandronate) was associated with significant reductions in all clinical fractures compared to placebo with HR of 0.7, RRR 30%. Also some of osteopenic patients (20.2%) were enrolled even in the reproductive age (2.6%), but with significant fracture risk factors. The drug was mostly prescribed to educated patients (over 70% patients had secondary school and university degrees). Obviously, they were aware of both the risks associated with osteoporosis as a disease and the importance of treatment compliance. The reported level of physical activity was low before the study, but significantly increased during treatment (5.2% vs. 21.3%; $p=0.033$) showing that patients who complied with treatment, complied also with the life style advice they received.

Risk factors for osteoporosis in addition to menopause were present in about 70% of patients, given as fragility fractures, family history of hip fractures, corticosteroid use, smoking and presence of diseases that affect bone density adversely (Table 2). Presence of more risk factors makes treatment more reasonable. Some of the studies of bone quality changes have revealed that ibandronate once monthly improves vertebral, peripheral and trabecular

strength and anterior-posterior bending stiffness compared to placebo, by 7.1%, 7.8%, 5.6% and 6.3%, respectively, along with femoral narrow neck cross-sectional area by -3.6% and outer diameter by -2.2%, which can lead to further gain in fracture risk reduction [16].

Large majority of the patients were diagnosed with DXA testing (81.8%, i.e. 96%), on both central skeletal sites, which is the golden standard in our routine medical practice. Unfortunately, some of 16.9% of patients already had a history of fragility fracture at the time of diagnosis.

Highly significant increase in BMD (measured with T-score change) occurred during 24 months of treatment despite the fact that 27.27% of patients in our treatment group had other clinically significant co-morbidities which could worsen the postmenopausal bone loss. This can be explained by the fact that most investigators were rheumatologists who recruited postmenopausal patients from their pool of rheumatology clinical practice. The findings of continuous gain of BMD are in accordance with previously reported results from randomized controlled trials and meta-analyses [11].

Results of our study showed that both BP naïve and BP experienced patients continued to gain BMD during 24 months of treatment with monthly ibandronate. The improvement was even better in the BP experienced subgroup, significantly better than in BP naïve patients, from baseline to 24 months and from 12 to 24 months time points. This finding cannot be explained by the "nonresponding" patient concept, or by any other reason for weaker effect in BP naive patients. It was expected that patients receiving ibandronate for 24 months would further improve BMD, and this is exactly what we recorded. The BMD was statistically highly significantly improved between 12 and 24 months of follow-up ($p=0.002$), but when the analyzed patients were divided in two subgroups, BP experienced vs. BP naïve, both subgroups increased BMD, but the improvement was not significant in the BP naïve subgroup. The similar subgroups increased BMD significantly ($p<0.0001$), but the difference between the increase of the compared groups was not significant ($p>0.05$) during 12 months follow-up, as it was shown in the ESTHER study [14]. In our study, during 12 to 24 months of follow-up, BP experienced patients had a significantly greater increase than the BP naïve ones ($p=0.027$).

Low incidence of AE occurred in 3.9% of patients, mostly as mild gastrointestinal disturbances, during 12 and 24 months of follow-up. These AE are expected, as studies so far have illustrated that the incidence of AE with intermittent ibandronate is similar to placebo [11].

The possibility of intermittent use of BP is important both for improving suboptimal persistence and compliance, as well as for maintaining the integrity of upper gastrointestinal tract health [11].

We observed that adherence to treatment was excellent in 94% of patients, which is better than previously shown in clinical trials. It is also superior when we compare the compliance to monthly ibandronate treatment (improved up to 51%) to weekly or daily administration of oral BP (less than 30%) [15]. Discontinuation of treatment was due to cost of treatment in 5.1%, meaning that every effort of health care professionals should be made so that effective and well tolerated medication can be reimbursed. Since treatment compliance is a major determinant of the final outcome of drug management, for patients who are starting the ibandronate treatment this does not seem to be a problem.

CONCLUSION

Significant increase in BMD is achieved after 24 months of treatment with once-monthly oral ibandronate, with significant increase in BP experienced patients and with low BMD. Treatment was safe, without any early treatment discontinuation and without reports of any new fractures.

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Ефикасност и сигурност лечења болесница са смањеном минералном густином кости једномесечном дозом ибандроната – студија *ESTHER*: клиничко праћење током 24 месеца

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КРАТАК САДРЖАЈ

Увод Остеопороза је један од главних здравствених и економских проблема у свету. Употребом нових лекова, као што је ибандронат, покушава се да унапреде лечење особа оболелих од остеопорозе и слаба привржености бисфосфонатној терапији.

Циљ рада Циљ рада је био да се испитају ефикасност и сигурност ибандроната примењеног једном месечно код жена са смањеном минералном густином кости.

Методе рада Проспективна студија је изведена у 34 центра у Србији, а обухватила је 77 жена лечених током 24 месеца једномесечном дозом ибандроната. Ефикасност лечења је процењена променом вредности коштане масе које су добијене дензитометријским мерењем на крају периода клиничког праћења у односу на базичне и вредности после 12 месеци лечења. Забележени су подношљивост, сигурност и нежељена дејства.

Резултати Испитане су жене у постменопаузи (96%) и са остеопорозом (79,7%), дијагностикованом мерењем густине кости лумбалног дела кичме (81%), од којих је 33,8% претходно лечено бисфосфонатима. Ниво физичке активности испитаница је био знатно повећан током лечења (5,2% према 21,3%; p=0,003). Након 12 месеци и 24 месеца лечења значајно се повећала минерална густина кости (p=0,002 и p<0,001). Код болесница које су претходно биле на бисфосфонатној терапији установљен је већи пораст у односу на болеснице које ову терапију нису примале у оба периода посматрања (p=0,012 и p=0,027). Током клиничког праћења од 12 до 24 месеца привржености лечењу је била 96%, док су се нежељена дејства јавила код 3,9% у виду благих гастроинтестиналних сметњи.

Закључак Лечење једномесечном дозом ибандроната током 24 месеца болеснице су добро подносиле, а дошло је и до значајног повећања густине кости код ових жена.

Кључне речи: остеопороза; минерална густина кости; бисфосфонати; ибандронат

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