PHARMACOTHERAPY COSTS OF OSTEOPOROSIS AND RELATED FRACTURES IN BULGARIA

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Summary. The objective of the study is to investigate and calculate the direct medical costs of osteoporosis, the indirect ones, as well as the family costs in Bulgaria. A top down retrospective cost study has been developed. Epidemiology data for osteoporosis has been derived from two published reports. The information on the prices of medicines, patient co-payment, level of reimbursement, hospitalization cost and average hospital stay is based on the official national sources. Official information provided by the National Health Insurance Fund is that in 2009 only 2,143,046 BGN for 5,950 treated patients were paid. The annual cost of femoral fractures should be 8 million BGN, and 800,000 BGN for rehabilitation. The rest of the fractures are mild and account for 26,950,000 BGN. The average disability loses account for approximately 23,105,472 BGN. The direct medical cost exhibits the proportion of 2 million for medicines to 36 million BGN for treatment of fractures. The major conclusions from our analysis are that the patients with osteoporosis in Bulgaria are not adequately treated in terms of reimbursement coverage and patients carry the greater part of financial and social burden.

Key words: *cost study, pharmacotherapy, osteoporosis, health policy, medicines policy*

INTRODUCTION

Osteoporosis is a chronic condition characterised by bone fragility resulting in bone fracture. Bone fracture is associated with pain and decreased quality of life. Osteoporosis affects 1 in every 8 persons over of age. One in every 3 women and one in every 5 men over the age of 50 years develop osteoporosis and will suffer fracture in their lifetime. Fragility fracture is the clinically apparent and relevant outcome in osteoporosis. In Europe every 30 seconds one person experiences fracture, but there is no clear evidence of the pro-

portion of osteoporotic ones [5, 16]. The risk of a subsequent fracture in the same year increases fivefold, when women have already had vertebral fracture due to osteoporosis. Fractures increase the health care cost of patients with osteoporosis. When the risk of fractures increases over 40 per cent, the cost doubles [15]. It is estimated that there are 180,000 osteoporosis-related symptomatic fractures annually in England and Wales. Of these, 70,000 are hip fractures, 25,000 are clinical vertebral fractures and 41,000 are wrist fractures [17].

The economic burden of osteoporosis is tremendous. Burge et al. estimated the cost of osteoporotic fractures as $ 19 billion in the USA in 2005 year [4]. Out of them 56 per cent are hospitalization cost due to fractures, and 37 per cent are covered by the health insurance institutions.

The health economic analysis shows that in 2010 year the costs of osteoporosis in Europe will double to 40 million Euro in comparison to 2000 year. It is expected that fracture expenditure be 80 milliard Euro till 2050 year when the proportion of fractures of women and men will be 2 to 1 [6, 19]. According to the type of care health care costs are distributed to 42 per cent for medical cares, 26 per cent - for medicines, 24.7 per cent – for visiting the GP, 5.8 per cent - for additional insurance. The indirect costs of fracture disability are almost equal to the direct health care costs, and in some countries they are twice as much.

The direct unit costs associated with non-vertebral osteoporotic fractures in five European countries (France, Italy, Spain, UK, Belgium) range for hip fractures between 8,346 Euro and 9,907 Euro; for others – between 890 and 3,262 Euro [2]. The average cost for hospitalization of women is 5,548 euro and for the men 6,834 Euro. The interest in cost of illness studies in Bulgaria has been increasing recently, but there is no cost study of osteoporosis therapy [13]. The overall world economic burden of osteoporosis and the lack of studies on health care costs in relation to this chronic disease in Bulgaria stimulate our interest in the topic.

The objective of the study is to investigate and calculate the direct medical costs of osteoporosis, the indirect ones as well as the family costs in Bulgaria.

The point of view is that of the health insurance fund, society, and the patients with a time horizon of one year.

MATERIALS AND METHODS

A top down retrospective cost study has been developed.

First, an interview with the chairman of the Association of osteoporotic patients in Bulgaria focusing on cost drivers was taken. The interview comprises of open ended questions on the reimbursed medicines, co-payment contribution, coverage of hospitalization and rehabilitation after fractures, and medical devices. The answers were used to create a cost-structure model.

Epidemiology data for osteoporosis in Bulgaria has been derived from two published reports [1, 3]. The information on the prices of medicines, patient co-pay-

ment, level of reimbursement, hospitalization cost, average hospital stay is based on the official national sources or normative and administrative acts as presented in Table 1. The population and average income data has also been obtained from the official statistical sources – Table 1. [7-12, 14, 18].

Table 1. Sources of information

Variable	Source of information
Epidemiology	[10] , [11]
Reimbursed medicines, prices and co payment	Positive drug list [12]
Expenditures for reimbursed medicines	Database of the health insurance fund [13]
Hospital charges for fractures and rehabilitation procedures	National framework contract [14]
Population	National Statistical Institute [15]
Hospital stay	National Health Information Institute [16]
Income	National Social Insurance Fund [17]

The direct medical costs are calculated as a sum of the yearly cost of pharmacotherapy, cost of fractures, and rehabilitation costs. The yearly cost of pharmacotherapy is provided by the National Health Insurance Fund (NHIF). Cost of fractures is calculated by multiplying the epidemiology information from the published studies by the NHIF charges for fracture. The rehabilitation cost is calculated by multiplying the cost for 10 days rehabilitation by the number of patients. There are 2 negotiated charges in case of fracture in the National framework contract and these are 2,035 BGN for femoral fracture, and 385 BGN (Bulgarian Levs, National currency) for any other fracture. In addition, 10 days of rehabilitation procedures are paid 20 BGN per day [14].

The indirect cost of productivity losses and premature death was calculated by multiplying the average number of days lost due to the event (hospital stay, or mortality statistics) by the lowest monthly or yearly income per capita based on information on the population structure and payment [17].

Out of the cost contributed by the patients, only the cost for co-payment for medicines was calculated.

The exchange rate for 2009 is 1,956 BGN (Bulgarian levs, national currency) equal to 1 Euro.

RESULTS

Epidemiology information about osteoporosis in Bulgaria

Two main national reports on osteoporosis and related fractures in the country were found. According to the expert opinion of the Bulgarian endocrinologist

society, published in 2004, 92,000 women had at least one osteoporotic vertebral fracture, over 4,000 of them had femoral fractures every year and 800 would die due to complications within one year [10].

The second study was presented by the Expert Group of "National Program for Osteoporosis Limitting". This is a prospective study of 426,000 women with osteoporosis over 50 years of age during the 2005-2010 period. The number of femoral fractures reported in the study is 30,436 (1, 9% of 1,601,919 being the total number of women over 50 years of age, according to demographic statistics), of vertebrale – 36,844 (2, 3%), of the wrist – 145,774 (9, 1%). The absolute risk of fracture within ten years calculated in the study reaches >3 per cent for the people over 65 years of age, and more than 20 percent - over 70 [11].

The hospital stay after femoral neck fracture is 30-35 days [16].

The huge difference in the number of fractures in the two studies is probably due to the fact that the first one is an expert opinion focusing on the age group over 60 years of age, while the second one is a prospective study focusing on the age group over 50 years of age. Both studies could be considered as a basis for establishment of the lower and upper boundaries of osteoporosis cost.

Cost structure model

The interview with the Chairman of the Patients' Osteoporosis Association led to the creation of the following cost structure model – Fig. 1.

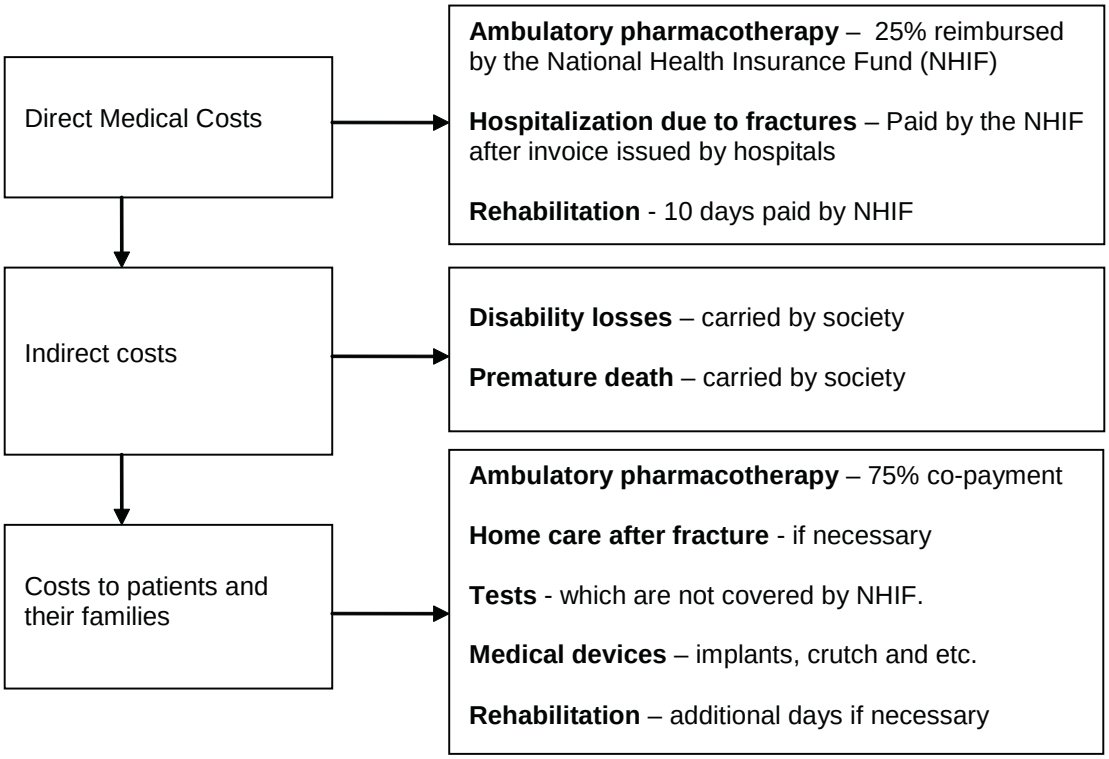

Fig. 1. Costs structure model for osteoporosis therapy in Bulgaria

Three main groups of costs were derived from the interview and included in the model. Direct medical costs are assigned to medicines, fracture therapy and rehabilitation. The National Health Insurance Fund reimburses 25 per cent of the medicines for osteoporosis therapy, which are included in the national positive drug list. It also pays the previously negotiated hospital charges for different types of fractures, as well as 10 days of rehabilitation procedures following every fracture.

The patients and their families pay 75 per cent of the cost of medication therapy, home care if necessary, clinical tests for bone density evaluation, medical devices, and additional rehabilitation procedures if necessary.

The indirect costs to society are determined by the days off work due to disability (30-35 day) and premature death.

Cost calculations

Cost of pharmacotherapy

The medicinal products that are included in the positive drug list and reimbursed for osteoporosis therapy are presented in Table 2 [10]. There are 7 INN (International Nonproprietary Name) of medicines reimbursed. Out of them 2 have 3 competitors each (risendronate and alfacalcitriol), and one is provided in two dosage forms (ibandronate).

Table 2. Annual treatment costs for one patient with reimbursement alternatives in 2009 year

INN	DDD	Monthly cost per DDD (BGN)	Annual cost per DDD per day (BGN)	Reimbursement Level	Patient co-payment
Alendronic acid tabl	10 mg	23.88	279.36	69.84	209.52
Ibandronic acid tabl	5 mg	64.62	775.44	193.86	581.58
Ibandronic acid inj	5 mg	221,18	884,72	221,18	663.52
Risedronate sodium tabl	5 mg	29.98	359.76	89.94	269.82
		30.01	360.12	90.03	270.09
		69.34	832.08	208.02	624.06
Alendronate /Colecalciferol tabl	10 tabl	47.7	572.40	143.10	429.30
Zoledronic acid inj	5 mg	806.84	806.84	201.71	605.13
Strontium ranelat tabl	2 g	89.63	1075.56	268.89	806.67
Alfacalcidol tabl	1 mcg	14.24	170.88	42.72	128.16
		9.74	116.88	29.22	87.66
		21.28	255.36	63.84	191.52

INN – International Nonproprietary Name
DDD – Defined Daily Dose
BGN – Bulgarian Leva (national currency)

If every patient receives one defined daily dose (DDD) per day the annual cost of pharmacotherapy per patient ranges between 116.88 BGN and 1075.56 BGN at pharmacy prices. The reimbursement level is within the range of 29.22 BGN to 268.89 BGN.

If all 426,000 women with osteoporosis will take the cheapest medicine (Alendronic acid) then the theoretical total costs for pharmacotherapy should be 72,539,280 BGN. According to the existing reimbursement level of 25 per cent the costs for the National Health Insurance Fund will be 18,134,820 BGN.

In 2009 only 5,950 patients who received pharmacotherapy are included in the database of the National Health Insurance Fund on the average (the number of patients varies between 3,952 and 7,064 people during different months). These are just 10 per cent of the patients with osteoporosis diagnosed by the Bulgarian Expert Group. Official information provided by the National Health Insurance Fund is that in 2009 only 2,143,046 BGN for 5,950 treated patients were paid.

The rest of the diagnosed patients are either not suitable for reimbursement, or use medicines which are not included in the positive drug list.

Cost of fractures

Because no separate information on the reasons for fractures is available, we calculated the cost of osteoporosis fractures based on the health insurance charges and epidemiology data for their prevalence. It is accepted that 50 per cent of the women and 25 per cent of the men over the age of 60 years will have at least one fracture due to osteoporotic bone damages in their lifetime.

In Bulgaria the total number of population over age 60 is 1,835,749, of which 771,858 men and 1,063,890 women. Out of them 1,110,839 will have at least one fracture in their lifetime (917,875 in the women and 192,964 in the men). When remaining lifespan is 15 years on the average, the annual number of fractures is 74,056 and over 4,000 are on the femoral neck.

Thus the annual cost of femoral fractures should be 8,140,000 BGN (4,000 x 2,035 BGN). The cost of rehabilitation of those patients is paid by the National Health Insurance Fund and should be 800,000 BGN (4,000 x 10 x 20 BGN).

If we accept that the rest of the fractures are mild and are paid applying the smallest charge of 385 BGN, their cost should be 26,950,000 BGN (70,000 x 385 BGN).

Indirect costs

The average disability losses of 74,056 patients for a month in plaster will be 23,105,472 BGN (312 BGN is the lowest monthly income). The real costs are higher because those for the recovering period are higher and incomes differ.

If the patient is paid at least 10 days for rehabilitation at 20 BGN per procedure, a further 14,811,200 BGN costs will be generated.

The loss of premature death will be at least 30,000,000 BGN. (800 persons x 10 years remaining life x 3,750 BGN lowest annual income).

On the basis of these approximate calculations it is possible to present the structure of total annual costs for osteoporosis in Bulgaria – Table 3.

Table 3. Structure of total osteoporosis costs in Bulgaria in 2009

Type of costs	Main point	Costs	Total costs
Direct medical costs	– medicines – fractures – rehabilitation	2 143 046 35 090 000 800 000	**38 033 046**
Indirect costs	– productivity losses – losses of premature death	23 105 472 30 000 000	**53 105 472**
Costs to patients and their families	– medicines – rehabilitation – home cares – medical devices – additional tests	6 429 138 n.a. n.a. n.a. n.a.	**6 429 138**

DISCUSSION

Although the calculations are illustrative and provide information only about the minimum costs that the society, the National Health Insurance Fund, and the patients with osteoporosis have to cover, they provide useful information about the costs structure. The costs structure follows the world tendencies with main driver's hospitalization due to fractures for medical cost. It is also clear that the patients with osteoporosis in Bulgaria are not properly treated in terms of unified coverage, the treatment is sub-financed, and patients carry the heavier burden.

There is a lack of prevention programs at a national level and not all patients are treated. On the other hand the National Health Insurance Fund has paid for all fractures and thus it is not clear what the savings in case of a prevention program could be. The present ratio between resources paid for medicines and for fractures from the National Health Insurance Fund is 2 million to 36 million BGN. It is obvious that the medicines are not the greater part of the cost. A better preventive program focusing on increasing the amount of medicines reimbursement could lead to the decrease of fractures expenditure.

We have not calculated the possible decrease in the expenditures due to better pharmacotherapy. Studies indicate that proper pharmacotherapy could decrease the relative risk of fractures to 62-35 per cent [18]. There are serious doubts that the current low level of reimbursement is one of the major obstacles for better patients' compliance with the pharmacotherapy [19].

In the future it is expected that the costs of osteoporosis will increase and this tendency is also applicable to Bulgaria. Thus it is necessary to point out that the reimbursement policy should be changed and patients should receive higher level of reimbursement.

It should also be noted that we have not calculated all costs carried by the patients. Except the co - payment for medicines they cover expenditures for home care, additional rehabilitation procedures, tests, and medical devices. Thus, resources which are paid by the patients could become equal to those paid by National Health Insurance Fund. In this case the logical question is why those persons are obligatorily health insured and how they benefit from that.

CONCLUSION

The major conclusions from our analysis are that the patients with osteoporosis in Bulgaria are not adequately treated in terms of reimbursement coverage, the treatment is not financed well enough and patients carry the greater part of osteoporosis financial and social burden.

The direct medical cost shows a ratio of 2 million for medicines to 36 million BGN for treatment of fractures. Therefore appropriate medication therapy is essential to reduce the cost of fractures treatment.

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