

Resource Utilization in Postmenopausal Osteoporosis Without Incident Fractures

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ABSTRACT. Objective. To evaluate the annual utilization and cost incurred by postmenopausal women with osteoporosis in a public tertiary healthcare facility.

Methods. One hundred consecutive patients with postmenopausal osteoporosis were selected from the Universidade Federal de São Paulo (UNIFESP), Brazil. The socioeconomic and clinical characteristics, quality of life, and resource utilization and costs in the last year were assessed using 3 questionnaires. Each resource used had its unitary cost based on the Public Healthcare System Table of Fees (1998).

Results. The mean age was 66 years and the monthly family income was US\$ 456 (1998). There was a mean of 7 visits/patient/year. Seventy-seven percent of the patients used calcium and 38% used estrogens. There were no incident fractures during the study. The mean total annual cost for osteoporosis treatment, considering the societal perspective, was US\$ 775 (1998) per patient/year.

Conclusion. The costs of all treatment drugs related and not related to osteoporosis represented 9% of the monthly household income. Among some drugs used, many are lacking evidence of effectiveness, such as shark cartilage. The costs related to transportation were significant, representing 21% of the total directly spent by the patients. Further studies are necessary to rationally drive treatment, based on the best cost-effectiveness strategies of osteoporosis management. (J Rheumatol 2004;31:938–42)

Key Indexing Terms:

COSTS

OSTEOPOROSIS

RESOURCE UTILIZATION

Osteoporosis is a disease characterized by low bone mass and deterioration of the micro architecture of the bone tissue. As a consequence there is an increase in bone fragility and an increased susceptibility to fractures¹.

The resource utilization in the treatment of osteoporosis is significant, resulting in 432,000 hospitalizations, 3.4 million visits (outpatient physician, outpatient hospital, and emergency room examinations), and 180,000 nursing home stays in the USA in 1995. The costs of these resources were estimated at US\$ 13.8 billion².

In Brazil there are no data related to resource utilization and costs of postmenopausal osteoporosis. We evaluated the annual utilization and annual cost incurred by postmenopausal women with osteoporosis in a tertiary healthcare facility of the Public Health Care System.

MATERIALS AND METHODS

Patients. One hundred patients were consecutively selected from the out-

patient clinic at the Universidade Federal de São Paulo (UNIFESP) between April 1997 and August 1998.

The inclusion criteria were as follows: women with diagnosis of postmenopausal osteoporosis (WHO 1994) for at least one year, at least one year of followup at the outpatient clinic, agreement to participate, and minimal conditions of verbal expression to answer the questionnaires. The exclusion criteria were as follows: secondary osteoporosis, cerebrovascular diseases, dementia, nephrolithiasis, use of phenytoin, diphenylhydantoin, corticosteroids, heparin, immunosuppressants, and lack of medical records.

Data collection. The data were collected through individual interviews using 3 questionnaires. Questionnaire 1 was employed in a face-to-face interview to evaluate the socioeconomic and clinic data. It was used also to collect data related to absenteeism in the last 12 months.

The resources used at UNIFESP or other facilities were computed. We focused on the number of outpatient visits, hospitalizations, surgical procedures, laboratory tests, diagnostic procedures, medication, and complementary and alternative medicine. We also assessed the utilization of orthosis, auxiliary devices, transportation, expenditures with auxiliary workers, adaptations in the workplace and at home, and resources used with co-morbidities such as emergency visits and laboratory tests.

Questionnaire 2, the Medical Outcome Study Short Form-36 (SF-36), was used in face-to-face interviews to assess the quality of life of the postmenopausal patients with osteoporosis.

Questionnaire 3 was used to extract data from the medical records. The clinical data and medical resources not mentioned by patients were collected.

Cost analysis. Every resource used had its cost defined in Real (R\$) and converted in 1998 US dollars (1 R\$ = US\$ 0.85). The results were obtained by multiplying the unitary cost of the resource by the number of times it was used in the last year.

We considered all costs related to outpatient visits, laboratory examinations, treatments, surgical procedures, hospitalizations, orthosis, auxiliary devices, and adaptations (home, work, or transportation). The costs related

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to hiring people for domestic tasks as a consequence of the disease were also calculated. The costs of medications were based on a Regional Pharmacy Index (August, 1998). The cost of etidronate, calcium carbonate, shark cartilage, and calciferol were based on pharmacy table calculations.

The unit costs of the medical resources were based on the National Public Healthcare System Table of Fees (1998). The costs related to transportation were based on the Regional Agency of Transportation.

Indirect costs were calculated based on the patients who were working in the last year. We considered the costs related to workdays lost in consequence of the disease. The mean monthly income was divided by 30 (days) and multiplied by the number of days lost.

Statistical analysis. Descriptive statistics were used to characterize the postmenopausal osteoporosis women. The demographics, clinical characteristics, as well as the resource utilization and costs were presented as means, standard deviations, and proportions.

Ethical aspects. The study was analyzed and approved by the Ethical Committee of the UNIFESP. All patients gave verbal informed consent.

RESULTS

One hundred women with postmenopausal osteoporosis were studied. The majority were white (95%) and the mean age was 66 years (range 41–84). The mean monthly household income was US\$ 456. Seventy-nine percent of the patients were not working during the study period. Forty-two percent had at least one fracture related to osteoporosis. The most prevalent fracture sites were the hip, vertebrae, and wrist (30 fractures), and 25 in other sites (Table 1).

The SF-36 measures quality of life using a scale where 0 is the worst score and 100 the best. Most patients were in an intermediate range. The physical aspects showed the lowest scores (50) and the social aspects the highest (67). We note that the figures are significant, representing a poor quality of life (Table 1). Ninety-six percent of the patients had at least one comorbidity, the most common were osteoarthritis (44%), hypertension (40%), and fibromyalgia (37%).

The medical visits related to osteoporosis ($n = 327$) represented 22% of the total medical visits in the period.

Table 1. Clinical characteristics of 100 outpatients with postmenopausal osteoporosis followed up at the UNIFESP osteoporosis outpatient clinic during a one year period.

Characteristics	Mean (SD)
Disease duration, yrs	4.41 (3.27)
Time since menopause, yrs	18.79 (10.22)
Fractures*, n	55
SF-36 Questionnaire	
Functional capacity	58.71 (24.00)
Physical aspects	49.64 (40.04)
Pain	58.01 (22.80)
General health status	66.15 (22.86)
Vitality	53.21 (22.36)
Social aspects	67.39 (25.74)
Emotional aspects	51.90 (42.71)
Mental health	56.89 (24.76)

* Previous fractures (hip, vertebral, and wrist, $n = 30$; other sites, $n = 25$).
UNIFESP: Universidade Federal de Sao Paulo.

The number of visits to physiotherapist was significant ($n = 696$), the most used healthcare service (Table 2).

The most frequently ordered lab exams were related to the bone mineral metabolism. A mean of 1.88 calcium tests and 1.79 alkaline phosphatase tests were ordered per patient per year. The mean number of bone mineral densitometry test performed was 0.85 per patient per year (Table 3).

For the associated diseases, electrocardiogram, glycemia challenge, and mammography were the most frequently ordered subsidiary examinations/procedures (Table 4).

A large percentage of patients used calcium (77%) and D vitamin (47%); estrogens were used by 38% of patients. It was noteworthy that 15% of patients used shark cartilage for the treatment of osteoporosis, a figure higher than alendronate (12%), fluoride (11%), and etidronate (10%). Shark cartilage was used by a significant group of patients, despite the lack of scientific evidence of efficacy (Table 5).

The drugs most used for comorbidities were analgesics (54%), diuretics (36%), and antidepressants (34%), in line with the most common comorbidities in the sample (Table 6).

Assistive devices were used by only 24 patients (special shoes: $n = 16$ and canes: $n = 8$) in spite of their low cost and important auxiliary function.

The most commonly used mode of transportation was bus, for visits and laboratory tests, related to treatment of

Table 2. Number of outpatient visits attended by 100 outpatients with postmenopausal osteoporosis followed up at the UNIFESP osteoporosis outpatient clinic during a one year period.

Specialty	n	Mean (per patient/year)
Cardiology	103	1.03
Gynecology	97	0.97
Ophthalmology	37	0.37
Geriatrics	32	0.32
Other	170	1.7
Rheumatology (osteoporosis)	327	3.27
Physiotherapy	696	6.96
Total	1462	14.62

Table 3. Laboratory tests ordered for osteoporosis management related to the 100 outpatients with postmenopausal osteoporosis followed up at the UNIFESP osteoporosis outpatient clinic during a one year period.

Test	n	Mean/Patient/Yr
Calcium	188	1.88
Alkaline phosphatase	179	1.79
Phosphorus (24 h urine)	175	1.75
Calcium (24 h urine)	147	1.47
Creatinine	123	1.23
Hemogram	112	1.12
Lipidogram	109	1.09
Bone densitometry	85	0.85
Creatinine (24 h urine)	81	0.81
Glycemia	75	0.75

Table 4. Laboratory and subsidiary tests ordered for management of associated diseases in 100 outpatients with postmenopausal osteoporosis followed up at the UNIFESP osteoporosis outpatient clinic during a one year period.

Test	n	Mean/Patient/Yr
Electrocardiogram	30	0.3
Glycemia	27	0.27
Mammography	24	0.24
Cervical smear	22	0.22
Lipidogram	21	0.21
Creatinine	20	0.2
Potassium	16	0.16
Sodium	16	0.16
Transaminases	13	0.13
Echocardiogram	11	0.11

Table 5. Drugs used for osteoporosis treatment for 100 outpatients with postmenopausal osteoporosis followed up at the UNIFESP osteoporosis outpatient clinic during a one year period.

Drug	Utilization, %
Calcium	77
Vitamin D	47
Estrogens	38
Nandrolone decanoate	22
Shark cartilage	15
Alendronate	12
Etidronate	10
Fluoride	11

Table 6. Drugs used for treatment of the associated diseases related in 100 outpatients with postmenopausal osteoporosis followed up at the UNIFESP osteoporosis outpatient clinic during a one year period.

Drug	Utilization, %
Analgesics	54
Diuretics	36
Antidepressives	34
Vasodilators	27
Nonsteroidal antiinflammatories	23
ACE inhibitors	20
Other antihypertensives	6
Benzodiazepines	6

ACE: angiotensin converting enzyme.

osteoporosis and associated diseases. The total number of annual trips was 7708. It is an important issue, because our results showed that 21% of the direct costs were directly spent by the patients on transportation. The mean cost of medications for postmenopausal osteoporosis was US\$ 300 and for comorbidities was US\$ 185.47 per patient per year. The mean direct medical cost was US\$ 640 per patient per year. The mean direct non-medical costs was US\$ 134.9. The mean total direct cost was US\$ 774.9 per patient per year.

There were 21 patients working, 14 patients lost a mean of 11 working days in the previous year. The mean indirect cost related to these patients was US\$ 64.80. There were 20 caregivers who lost a mean of 20 working days in the previous year, representing indirect costs of US\$ 68.37 per caregiver per year.

DISCUSSION

Osteoporosis is a disease that has increased public awareness recently because the population is ageing and the life-time risk is also increasing³. In Brazil it is estimated that the elderly population (65 years and above) will increase from 5.1% in 2000 to 14.2% in 2050⁴.

In our study, the mean age was 66 years. The additional life expectancy for this group is 16 years, a period where the incidence of osteoporosis fractures increases exponentially, especially hip fractures^{5,6}. Almost half of these patients had at least one previous fracture and would be considered a group at high risk to suffer another fracture. As a consequence, the sample represented a group in which preventive and therapeutic measures should be highly prescribed.

Another aspect that could contribute to a worse prognosis in this group of patients is that 96% had at least one comorbidity and 72% had 2 or more associated diseases. The most common comorbidities were hypertension, osteoarthritis, and fibromyalgia. The association of these diseases could contribute to the poor quality of life, especially in the physical aspects.

Daily activities were limited as a consequence of osteoporosis. Cooper, *et al* showed that one year after the fracture, 40% of the patients were not able to walk without help and 60% had difficulty in performing at least one activity like dressing, having a shower, or cooking⁷.

In our study, 32% of the patients had some limitations in daily activities, but only 5 patients had contracted someone to help. The reason for this low rate could be the low income.

One study showed that the proportion of women living alone in Brazil is increasing; approximately 15% of the women 65 years of age and older were living alone, and 60% of them earn less than the minimum wage⁵. These numbers should be used to drive policy strategies to apply more cost effective strategies in the management of osteoporosis, in order to increase patient access.

In our study, the mean number of outpatient visits was 7 per patient per year; among these, 3 were for the treatment of osteoporosis, and 4 for associated diseases. These results are similar to that found in the USA between 1984 and 1986, where patients with musculoskeletal diseases and without comorbidities had on average 4.5 visits per year. Those with comorbidities had on average 9.6 visits per year⁸.

The most frequently ordered laboratory tests were related to bone metabolism. The mean number of bone densitometries (BD) ordered per patient per year was 0.85.

In a German study by Krappweis, *et al* during a one-year period, 120 patients with osteoporosis had a mean of 0.511 BD⁹. Our results show that the number of BD was greater than that suggested by guidelines for the early detection of osteoporosis and prediction of fracture risk¹⁰. It could be justified by the fact that the UNIFESP is a school of medicine and many scientific protocols are running simultaneously. In addition, our medical records are not computerized and sometimes results of the examinations become lost and have to be reordered.

Considering the examinations for the associated diseases, mammography was one of the most ordered subsidiary examinations/procedures, however, the number (0.24/patient/year) was lower than that recommended by international guidelines (one exam/year) for women 40 years and older¹¹.

A majority of our patients (77%) used calcium, 47% used vitamin D, and 38% used estrogens during some period of the study. The patients bought all the drugs. The fact that calcium is the most common non-hormone replacement therapy drug used for the treatment of osteoporosis is consistent with the international trend¹². The monthly cost of calcium consumption was US\$ 15.60 and for the vitamin D was US\$ 16.50 (1998).

Thirty-eight percent of the patients had used estrogens. It is suggested that estrogens represent a good cost effective treatment for osteoporosis, but we know that the compliance is low¹³.

A significant number of patients (15%) used shark cartilage. This fact is a surprise because its cost was around US\$ 12 per month and its efficacy lacks scientific evidence. Drugs with scientific evidence of effectiveness such as alendronate or etidronate were used by few patients (22%); their costs were US\$ 47 and US\$ 10, respectively. The shark cartilage was presumably not ordered by a physician, so we can assume the high usage was due to the marketing power of the media, because patients tried many drugs without scientific evidence and did not use others that have been shown to be more effective. The prevalence of complementary and alternative medicine (CAM) users is increasing in recent years. In the USA, the use of CAM during the previous year increased from 33.8% in 1990 to 42.1% in 1997. CAM was used most for chronic conditions, including back problems, anxiety, depression, and headaches¹⁴.

Salicylic acid was the most prescribed drug for the associated diseases, followed by diuretics and anti-hypertensives. The monthly cost of salicylic acid was US\$ 6.15.

Patients spent around 5% of their monthly income on drugs for osteoporosis. Adding the costs of the drugs for associated diseases, the number rises to 9% of their monthly household income.

Data from a regional survey in Sao Paulo-Brazil showed that 3.96% of the monthly income was spent on medications among those who earned between 3 and 5 national

minimum wage in 1991¹⁵. The mean monthly household income in our study was US\$ 456, but the expenditure for drugs was twice the figure cited in the study above. One possible explanation is that our study patients had access to a tertiary health care system, so they had many diseases diagnosed and as a consequence, had a high number of prescriptions. Another explanation could be that our sample had a large number of patients with more comorbidities than those of the population-based survey.

The proportions of expenditures with the resources used and paid directly by patients were: 78% on drugs (62% for osteoporosis and 16% for associated diseases), 21% on transportation, and 1% on equipment and other services. In the Krappweis study, 65% was spent on drugs for osteoporosis, a figure similar to ours⁹.

According to the society perspective, the costs were US\$ 775 per patient per year; among these, 82% was spent on medical-hospital resources, and 18% on non-medical-hospital resources. The highest burden of the disease was the cost of drugs bought by the patients. The indirect costs represented a small part of the total costs, because 79% of the sample were not working.

It is noteworthy that although osteoporosis has a great burden on clinical and economic aspects, patient awareness of the disease seems to be low even in some developed countries¹⁶.

However, some studies show that even physicians have low awareness of the treatment of osteoporosis. In Ontario, Canada, one study showed that 46% of the physicians who attended patients in longterm care units did not routinely assess osteoporosis in their practice, and 27% did not treat osteoporosis routinely. The reasons for that behavior could be the cost of therapy, patient or family reluctance to accept therapy, and time and cost of diagnosis. The costs should not be the principal argument to not treat osteoporosis because etidronate is covered by the Ontario provincial formulary and the calcium 1 g/day and vitamin D 1000 UI/day costs only \$30 yearly¹⁷.

Another study in Canada showed that less than 20% of the patients who had had a fragility-type fracture had undergone investigation and adequate treatment of osteoporosis at 1 year's followup¹⁸.

Torgerson, *et al* in the UK, studying 300 women 50 years old and over, with a least one vertebral fracture, showed that only 39% had been prescribed one drug for osteoporosis¹⁹.

The National Osteoporosis Risk Assessment Program (NORA) showed that among patients who fulfilled the criteria for both diagnosis and treatment of osteoporosis, only 32% were using calcium and vitamin D and 34% were using other drugs for osteoporosis²⁰.

Our study shows that patients with osteoporosis had associated diseases and that the costs of drugs were significant, possibly acting as a barrier to compliance with doctors' prescriptions. Some alternative measures should be consid-

ered to overcome the costs of the drugs, like a calcium-enriched diet.

Another point to be considered is that few patients used auxiliary devices (canes, special shoes) to prevent falls. The cost of these devices is not significant and they could be good preventive measures.

Our study had some limitations: for instance, it was retrospective, so some information could be missing in the medical charts, and the patients could present recall bias. The sample was consecutively selected for logistic convenience. It would have been better if a random sample were used to prevent selection bias. We studied women over a one-year period, so we did not have a long enough followup to detect incident fractures. Studies with longer followup periods evaluating women and men should be done to improve the data related to resources used by patients with osteoporosis.

In conclusion, despite the foregoing limitations, our study is the first evaluating resources used and costs of osteoporosis in our country, and we observed that costs in the outpatient clinic were significant.

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