Estimating the cost per avoided hip fracture by osteoporosis treatment in Italy
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of calcitonin and a screening programme involving bone mass measurement to select a high risk subpopulation in the treatment of osteoporosis and the prevention of osteoporosis-induced hip fractures.

Type of intervention
Treatment, screening, and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Women over 50 years of age and women with fractures of the proximal femur.

Setting
Hospital and community. The economic study was carried out in Italy.

Dates to which data relate
The effectiveness data were obtained from the Mediterranean Osteoporosis Study (MEDOS) published in 1992. 1995 cost data were used and the price year was 1995.

Source of effectiveness data
Effectiveness data were derived from a single study and assumptions made by the authors.

Link between effectiveness and cost data
The costing was retrospectively undertaken based on the incidence of hip fracture in Italian women and not on the same patient sample as that used in the effectiveness analysis.

Study sample
A retrospective power calculation showed a power of greater than 80% for the study in terms of the number of women taking oestrogens (and calcitonin and calcium). A total of 2,086 women (80%) with hip fractures (mean age 78 years), who were participating in the MEDOS study, were interviewed. The corresponding number of controls interviewed was 3,632 (84%) (mean age 78 years).

Study design
MEDOS was a retrospective, population-based, case-control study, carried out in 14 centres in six countries in southern
Europe. Interviews with women with hip fracture were performed within 14 days of fracture. The loss to follow-up (those who could not be interviewed) was 20% in the case group and 16% in the control group.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness was treatment completers only. The primary health outcome used was reduction (relative risk with intervention) in incidence rate of hip fractures. Logistic regression models were used to adjust for the effects of confounding variables.

**Effectiveness results**
The adjusted relative risk of hip fracture according to exposure to drugs affecting bone metabolism were as follows:

- calcium preparations, 0.75 (95% CI: 0.60 - 0.94), p=0.01;
- anabolic steroids, 0.60 (95% CI: 0.29 - 1.22);
- fluoride, 1.31 (95% CI: 0.75 - 2.29);
- vitamin D compounds, 0.83 (95% CI: 0.60 - 1.15);
- calcitonins, 0.69 (95% CI: 0.51 - 0.92), p=0.015; and
- oestrogens, 0.55 (95% CI: 0.36 - 0.85), p=0.01.

**Clinical conclusions**
Oestrogen, calcium, and calcitonins significantly decrease the risk of hip fracture. Short term intervention late in the natural course of osteoporosis may have significant effects on the incidence of hip fracture.

**Methods used to derive estimates of effectiveness**
Assumptions about effectiveness were also made by the authors.

**Estimates of effectiveness and key assumptions**
All the drugs were assumed to be equally effective.

**Measure of benefits used in the economic analysis**
The benefit measure was reduction in the relative risk of fracture after one year of treatment.

**Direct costs**
Costs were not discounted given the short (1 year) treatment period of the study. The quantities of resource use were not fully reported separately from the costs. Costs included hospitalisation, physician time, drug acquisition costs, laboratory, screening, counselling, ancillary services, rehabilitation and custodial costs incurred during a 1-year treatment period. The cost of screening with dual energy X-ray absorptiometry was included in the treatment of a selective high risk subpopulation. The costs associated with extended life and side effects were excluded because they were assumed to be common to all strategies. The cost figures were obtained from Italian expenditure figures. The drug acquisition costs corresponded to Italian prices in July 1995. The price year was 1995.

**Indirect Costs**
Not considered.
Currency
US dollars ($). The exchange rate used for conversion (at July 1995) was US$1 = 1,639 Italian Lira.

Sensitivity analysis
A threshold analysis was performed to identify the cut-off annual cost of treatment according to which screening could save resources. The threshold value for the relative risk of the calcitonin therapy to make the unselective HRT cost-neutral was also reported.

Estimated benefits used in the economic analysis
The relative risk of fracture after 1-year was 0.69 for the use of calcitonins. All the drugs studied were assumed to be equally effective.

Cost results
The total cost per patient associated with each strategy was not reported. The items reported were as follows: 360 doses of salmon calcitonin 100 IU given intranasally, $1,907; rehabilitation and custodial costs of one hip fracture, $82,508; screening with dual energy X-ray absorptiometry, $61.

Synthesis of costs and benefits
The net cost per avoided hip fracture was the cost-effectiveness measure used in the economic analysis. The cost-effectiveness value for one year of calcitonin therapy for unselective treatment was $2,367,987. This decreased to $838,120 (-65%) for selective treatment. HRT with conjugated estrogens had cost-effectiveness values of $19,007 for unselective and $55,736 for selective treatments. HRT with oral ethinylestradiol had corresponding figures of $6,157 and $51,456. HRT with estradiol had figures of $96,107 (unselective) and $81,416 (selective). The cost-effectiveness value for other strategies under unselective treatment ranged from $135,942 to $904,372, and, for selective treatment from $94,684 to $488,444. The threshold analysis demonstrated that, when the annual cost of a treatment was higher than $91, screening would save resources. When it was lower than $91, screening would produce an increase in the cost-effectiveness ratio. The threshold value for the relative risk associated with the calcitonin therapy was 0.50 to make the unselective HRT cost-neutral.

Authors’ conclusions
The use of calcitonin to prevent hip fractures in Italian women over 50 years of age is extremely expensive.

CRD COMMENTARY - Selection of comparators
The comparators chosen were osteoporosis drugs licensed in Italy, which were reported to be likely to be prescribed to reduce fracture risk, at the time of the study. You, as a database user, should consider whether these are widely used health technologies in your own setting.

Validity of estimate of measure of benefit
The retrospective nature of the study design may have introduced bias into the study results. The authors noted that the time period covered by the study may have been too short for assessing all the relevant benefits associated with the intervention. The authors assumed equal efficacy for all strategies involved.

Validity of estimate of costs
The resource use quantities were not fully reported separately from costs and insufficient details of methods of cost estimation were reported. The costs associated with side-effects were excluded, as were those associated with extended life, since they were assumed to be common to all strategies.
Other issues
The conclusions reached by the authors may not be fully justified, given the uncertainties in the data. The issue of generalisability to other settings or countries was not addressed. However, appropriate comparisons were made with other studies.

Implications of the study
Cost-effectiveness screening guidelines can not be explicitly established until further data addressing the association between bone mass measurements in the hip and hip fracture risks are available.

Bibliographic details

PubMedID
9147350

Indexing Status
Subject indexing assigned by NLM

MeSH
Aged; Calcitonin /administration & dosage /economics; Cost-Benefit Analysis; Estrogen Replacement Therapy /economics; Female; Hip Fractures /economics /prevention & control; Humans; Italy; Male; Mass Screening /economics; Middle Aged; Osteoporosis, Postmenopausal /economics /prevention & control; Risk Factors

AccessionNumber
21997000649

Date bibliographic record published
30/11/2000

Date abstract record published
30/11/2000