Cost-effectiveness of first-line treatment for osteoporosis when the drug goes generic

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Purpose

Current Norwegian guidelines recommend that only women at high risk of fracture (i.e. previous fracture and a T-score less than -1.6 or T-score ≤ -2.5 without fracture) should receive alendronate. The purpose of this study was to guide revision of osteoporosis guidelines to account for price reductions because alendronate went generic in 2006.

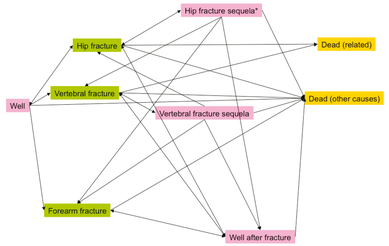
Table 1. Summary

Research question	For which groups of women can treatment with alendronate be considered cost-effective in the prevention of osteoporosis related fractures?
Treatment	Alendronate 70 mg in combination with calcium and vitamin D
Comparator	Calcium and vitamin D
Perspective	Societal
Patient groups	Women aged 55, 65 and 75 with T-scores -2.5, -2.0, -1.5 without previous fracture (T-score -2.0 also with pervious fracture)
Willingness to pay	NOK 500 000= $ 85 470
Evidence of effectiveness	Meta-analyses of randomised controlled trials (RCTs)
Duration of treatment	Five years
Time horizon	Life-long
Discount rate	4%
Sensitivity analyses	One way and probabilistic

Methods

We developed a Markov cohort model with the events hip fracture, vertebral fracture and wrist fracture and four sequelae states; vertebral fracture sequel and mild, moderate and severe hip. We analysed women aged 55, 65 and 75 with T-score of -1.5, -2.0 and -2.5 without fracture and with T-score -2 with fracture. We modelled five years of treatment with

Figure 1. Modelstructure



*Hip fracture sequela is divided into; mild, moderate and severe

vitamin D and calcium alone versus vitamin D and calcium plus 70 mg alendronate weekly. The cohorts were followed until death or 100 years of age.

Unit prices were based on Norwegian tariffs and resource consumption on published literature and expert opinions. Quality of life population norms and multipliers were gathered from published literature.

Efficacy data were based on a Cochrane meta-analysis, subdivided to fit our groups. Costs and QALYs were discounted with 4%.

We performed a series of one way sensitivity analyses and also a probabilistic sensitivity analyses with 10 000 iterations.

Results

Assuming a willingness to pay per QALY of US 85,470 (NOK 500,000), alendronate is a cost-effective strategy for all groups aged 65 and older. The ICER decreases with age and T-score and also with increasing risk within the same age group. The ICER's in the base case varies from a cost of $911 000 per QALY for the women at the lowest risk of fractures to a cost saving of $ 115 000 per QALY for those at highest risk. The incremental QALY gain ranged from 0.0007 for women aged 55 with a T-score of -1.5 to 0.0589 for women aged 75 with a T-score of -2.0 and a previous fracture.

In figure 2 we plotted the ICER's of women with a T-score equal to -2 with and without a previous fracture against the price of alendronate over time. The figure show that, according to our model, alendronate was cost-effective before the introduction of generic competition for women aged 65 with a previous fracture. The reduction in price has lead to treatment of women aged 65 without a previous fracture to also being cost-effective.

Figure 2. ICERs vs. price over time

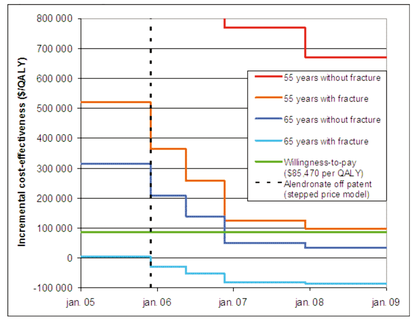


Figure 3. ICE Scatterplot for 55, 2.0, 1
Alendronate in combination with calcium and vit. D vs. calcium and vit. D

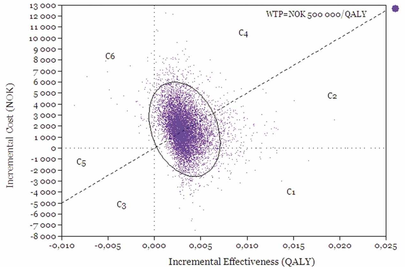


Table 2. Ruesults from of the Monte Carlo simulations; distribution of ICERs in the Cost-Effectiveness Plane.

			T-score:	1.5	2	2.5	2	1.5	2	2.5	2
			Previous fracture:	0	0	0	1	0	0	0	1
Component	Incr. Eff.	Incr. Cost	ICER	Percentage of ICERs at age 55				Percentage of ICERs at age 65			
C1	IE>0	IC<0	Superior	0 %	1 %	10 %	15 %	37 %	48 %	56 %	88 %
C2	IE>0	IC>0	<WTP	1 %	4 %	19 %	35 %	19 %	15 %	10 %	5 %
C3	IE<0	IC<0	>WTP	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
C4	IE>0	IC>0	>WTP	79 %	77 %	46 %	49 %	28 %	21 %	14 %	5 %
C5	IE<0	IC<0	<WTP	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
C6	IE<0	IC>0	Inferior	19 %	17 %	25 %	1 %	15 %	15 %	20 %	2 %
Σ C1-C3	Percentage alendronate cost-effective:			1 %	5 %	29 %	50 %	56 %	64 %	66 %	94 %

*WTP=$85,470 = NOK 500,000

The one-way sensitivity analyses indicate that the results were most sensitive to the price of alendronate, number of BMD measurements at treatment initiation, efficacy of alendronate on hip fractures, probability of post hip fracture rehabilitation in a nursing home, number of GP visits and duration of treatment.

Plotting the iterations of the Monte Carlo simulations in the cost-effectiveness plane, the probability of alendronate being a cost effective strategy varied from 1% for women aged 55 with a T-score of -1.5 to 95 % for women aged 75, T-score equal to -2.5 and a previous fracture, see table 1.

Conclusions

With current price levels, five year treatment with alendronate is likely to be cost-effective in all women 65 years and older with T-scores equal to or less than -1.5.

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