Budget impact of FVIII concentrates taking into account the incidence of de novo inhibitor formation in PTPs: a breakeven analysis applied to ADVATE© in the Italian context.

Giuseppe Turchetti (Scuola Superiore Sant'Anna, Pisa), Francesco Fusco (Scuola Superiore Sant'Anna, Pisa), Paolo A. Cortesi (University of Milan-Bicocca)

Objective:

The objective is to identify the number of previously treated patients (PTPs) affected by haemophilia A who, developing anti-FVIII inhibitor using an hypothetical FVIII (FVIII "x"), could lead to a breakeven of the cost with respect to the treatment with ADVATE©.

Methods:

We perform a breakeven point analysis, developing a model. The breakeven point in the model represents the number of patients who should develop inhibitors using FVIII "x" in order to get a budget impact equal to the treatment with ADVATE©, in a population of 348 patients.

Model:

Population: we simulate to treat 348 PTPs affected by severe/moderate haemophilia (FVIII≤2%), following the characteristics of the population of Oldenburg[1]. Assumptions: population age≥12y, weight 70Kg[2]; 5 years time horizon, 3% discount rate; for patients treated with ADVATE© we assume 0,29% probability to develop anti-FVIII inhibitor[1]. We compare 2 scenarios: all patients treated with ADVATE© and all patients treated with FVIII "x", assuming that in both scenarios 50% patients follows an on-demand regime (ADVATE© or FVIII "x": 34,5 IU/Kg[3]; bleeding events: 1,5/month[4]) and 50% a prophylaxis regime (ADVATE© or FVIII "x": 32,5 IU/Kg, 3 infusions/week). To patients developing inhibitor, a 2 years immune tolerance induction therapy is applied[5]. Adopted cost per IU is: for ADVATE© 0,75 €, for FVIII "x" 0,69€[6]. We calculate the following costs: a) treatment with ADVATE©; b) treatment of patients who develop inhibitor with ADVATE©; c) treatment with FVIII "x"; d) treatment of patients who develop inhibitor with FVIII "x". The model also estimates a breakeven curve showing the cost gap between the 2 treatments varying the number of patients developing inhibitor with FVIII "x". A sensitivity analysis is performed.

Results:

We estimate that - in order to reach an equal expense between ADVATE© and another FVIII "x" - the number of patients who should develop inhibitor using a FVIII "x" is 4,44.

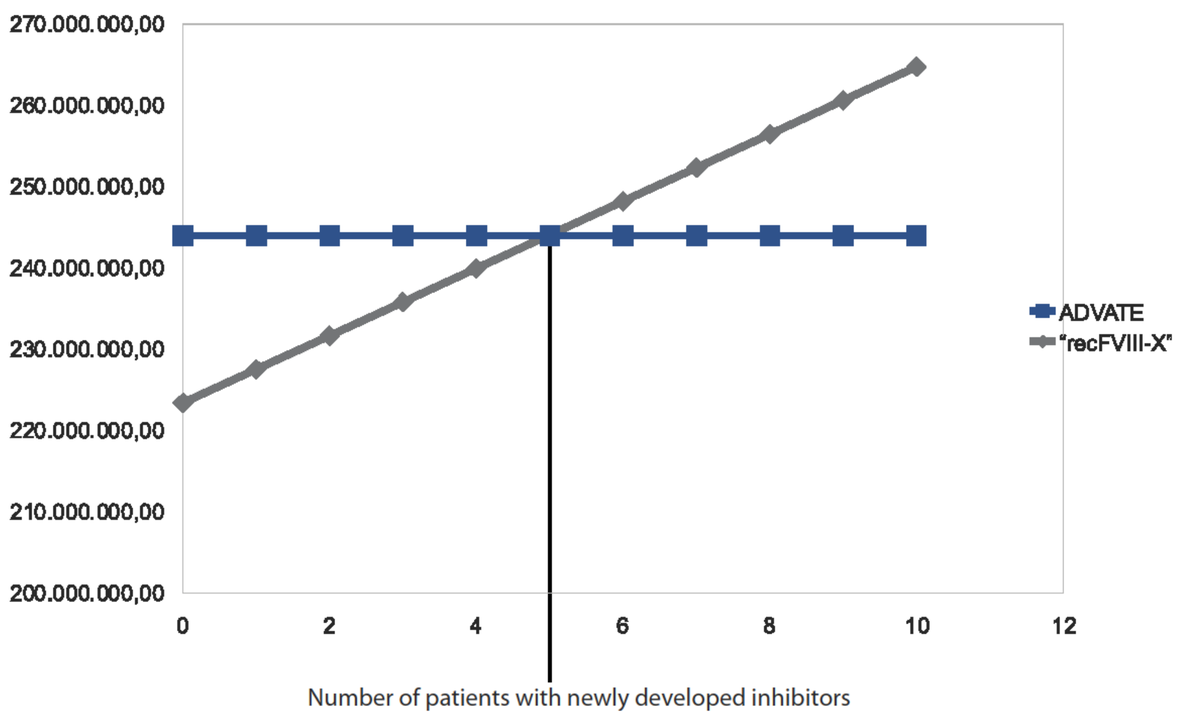

Figure 1. Breakeven curve. The grey line indicates the cost variation of treatment with recFVIII-X as the number of patients with inhibitors increase. The cost of ADVATE© 's treatment is indicated in blue. The line is unvaried since the model assumes that the number of patients that develop inhibitors is always 1.01. The point where the two lines cross indicates breakeven point and the costs are referring to 348 patients treated for 5 years.

Conclusion:

The results of the paper could have important health economic, budget impact, and health policy implications.

References:

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