

Cost-effectiveness of ferric carboxymaltose in the treatment of iron deficiency anemia in patients with inflammatory bowel disease

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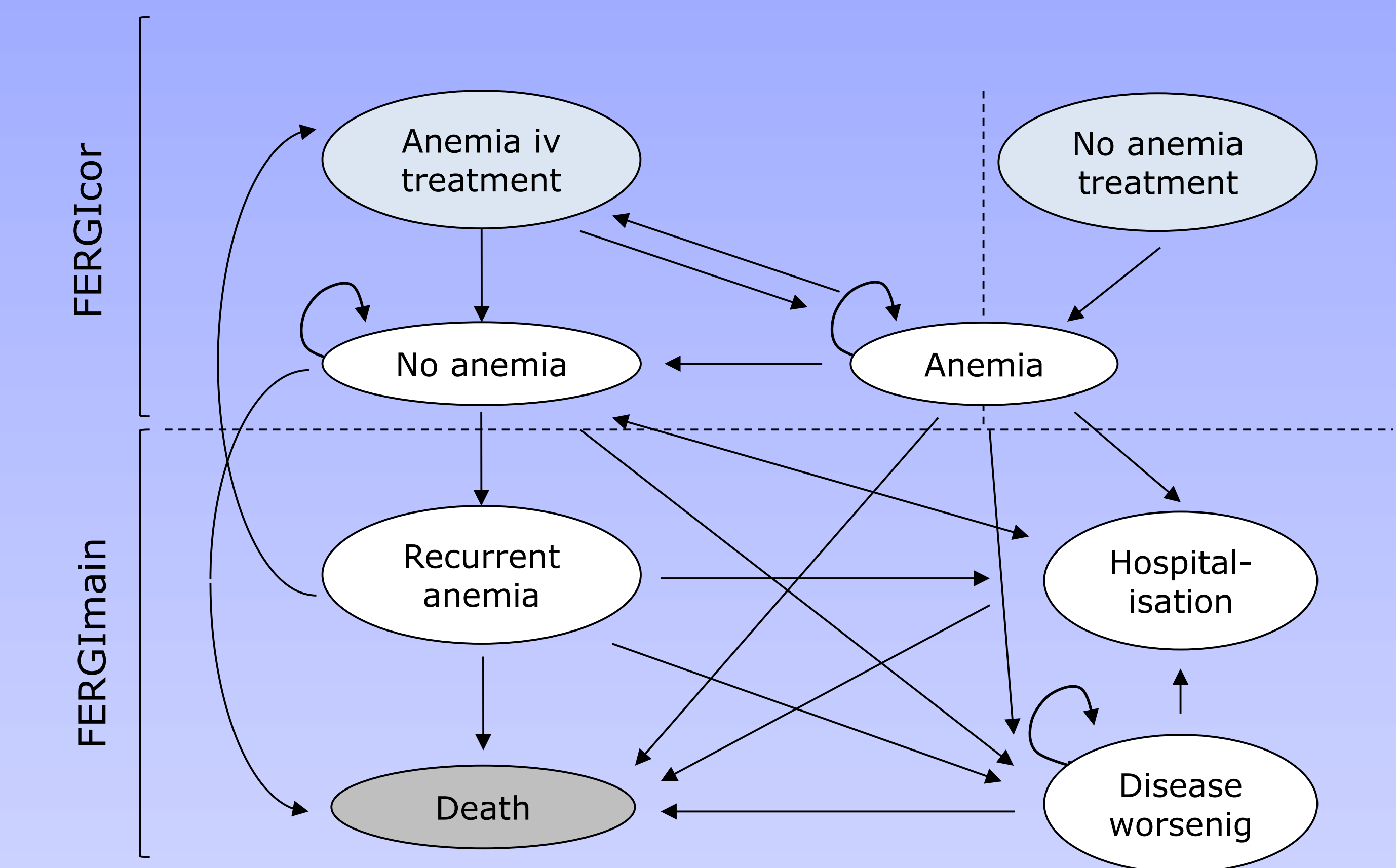
Objectives

Anemia is the most common systemic complication and extra-intestinal manifestation of inflammatory bowel disease (IBD). Anemia imposes a significant disease burden for IBD patients with enormous impact on their outcome. Two pivotal studies (FERGIcor and FERGImain) showed clinical meaningful results of ferric carboxymaltose (FCM), an i.v. iron, regarding to Hb increase 2 g/dL and prolonged time to recurrence of anemia. The purpose of this economic evaluation was to evaluate the cost-effectiveness of FCM versus Iron-Sucrose (IS) and no-treatment in IBD patients with iron deficiency anemia (IDA).

Methods

We developed a Markov-Model to simulate the treatment pathway of IDA in IBD patients. Patients with mild to moderate IBD and IDA run into the model and receive different strategies of iron-deficiency management (FCM, IS or no-treatment). The model includes 6 states (treatment success, recurrent anemia, hospitalization, disease worsening and death) based on RCT-data of FERGICor and FERGImain. The cohort definition was adapted from the FERGICor study. Monte Carlo simulation accounted for uncertainty. Direct costs were retrieved from published sources for 2016 and were expressed in Euro from the payer’s perspective. QALYs and total costs were projected over a 5-year time-horizon and discounted at 5% p.a.

Fig. 1: Model Design



Source: own developed

Clinical Data

Transition probabilities for movement between states were estimated from the RCT-data of FERGICor and FERGImain. Primary end point of FERGICor was Hb response (Hb increase ≥ 2 g/dL) and secondary end points included anemia resolution and iron status normalization by week 12, which were used for modelling the first 12 weeks (1st Markov-cycle). Patients who were nonanaemic after the FERGICor trial were randomised to placebo or ferric carboxymaltose containing 500 mg iron. Iron and haematological status were assessed every 2 months for 8 months. This two month cycles also were incorporated for the Makov process. The primary endpoint was time to recurrence of anaemia, defined as haemoglobin <12 g/dL (women) or <13 (men) g/dL. For the secondary endpoint, iron parameters, the adjusted mean change in ferritin from baseline to 8 months was significantly improved by FCM use ($P < .001$), as was transferrin saturation ($P = .022$).

Resource Use and Costs

Data on the resource use of the included iron deficiency anemia and IBD was collected in two steps. First, the medical resources were derived by literature (clinical trials FERGICor and FERGImain cohort studies including patients with IBD; Gutzwiller et al. 2012). In a second step this literature review was transferred to the Austrian setting.

The following direct medical costs (2016 €) were included:

- Medication costs: dosage equivalents of FCM and IS were calculated based on FERGICor and FERGImain.
- Outpatient costs: GP consultations, i.v. administration and monitoring (blood count).
- Inpatients costs: hospitalization due to iron deficiency anemia were calculated based on FERGImain and Gutzwiller et al. 2012.

Austrian costs were derived from a number of publicly available sources like the DRG catalogue (LKF), official price lists for the Austrian Health insurances funds and the Austrian official drug price list (Warenverzeichnis). When necessary, prices were adjusted to 2016 prices using the consumer price index.

Results

Over a 5-year timeframe, costs and outcomes associated with FCM would amount to 3,630 € and 3.22 QALYs. Costs associated with IS are 3,144 € and 3.18 QALYs. The incremental-cost-utility-ratio (ICUR) amounts to 11,780 €. Costs and outcomes associated with no-treatment are 3,227 € and 2.97 QALYs. The ICUR amounts to 1,585 €.

Tab. 1: Results, 2016

Strategy	Cost per patient (€)	Cost difference	QALYs per patient	QALY difference	ICER
FCM	3,630		3.22		
IS	3,144	487	3.18	0,041	11,780
No treatment	3,227	403	2.97	0,254	1,585

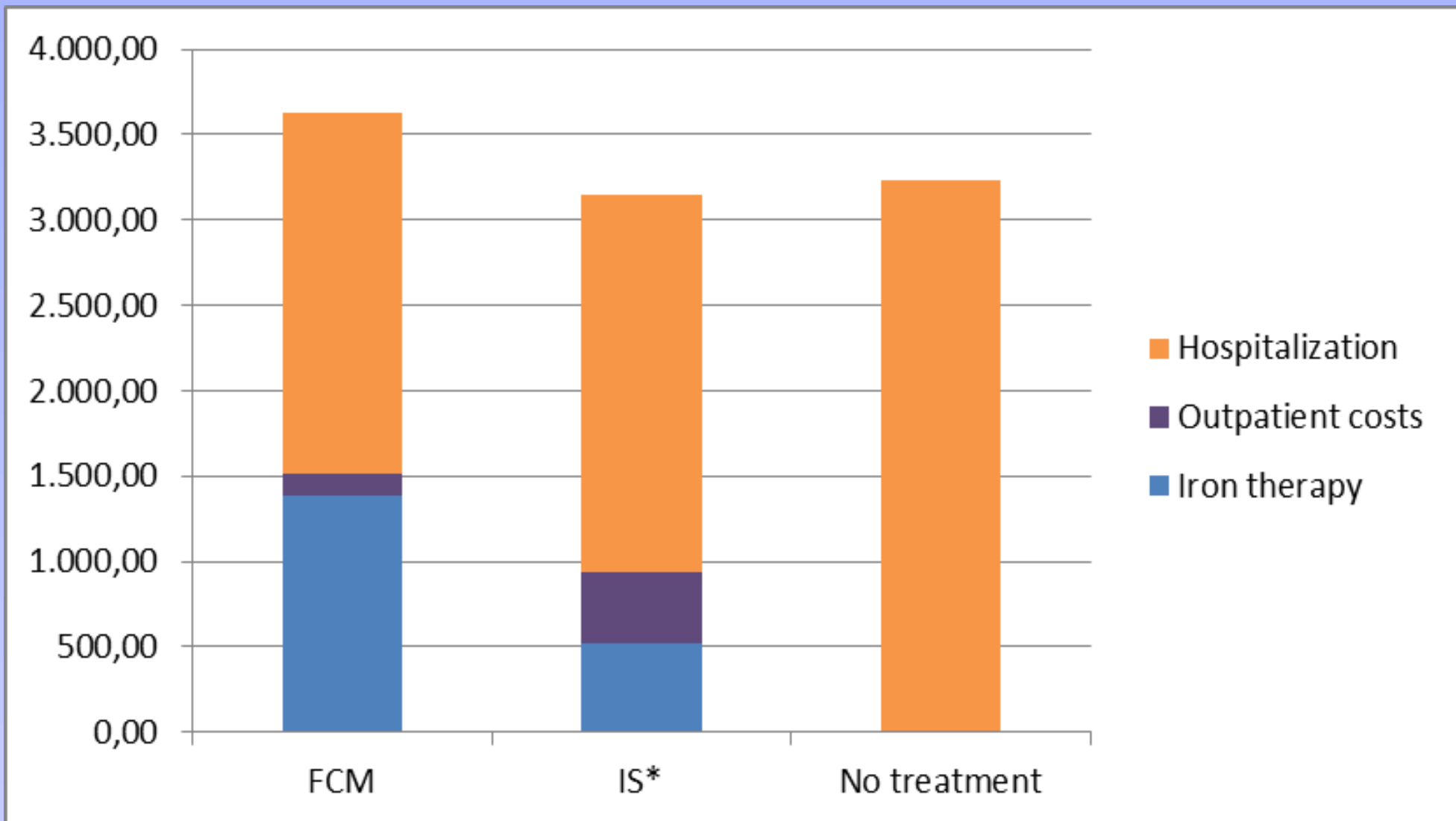
Source: own calculations

ICER = incremental cost effectiveness ratio

At the study endpoint 22.95% of patients are anemic in the FCM-group, 32.23% in the IS-group and 99.86% in the group without treatment. As a consequents the additional costs per anemia saved with FCM vs. IS amount to 5,244.85 €; additional costs vs. no treatment are 523.86 €.

Fig. 2 shows the disaggregated costs of considered comparators. The analysis shows that iron deficiency therapy leads to lower outpatient and hospitalization costs. Iron treatment costs are partly offset.

Fig 2: Breakdown of total costs per per patient , 2016



*Iron-Sucrose

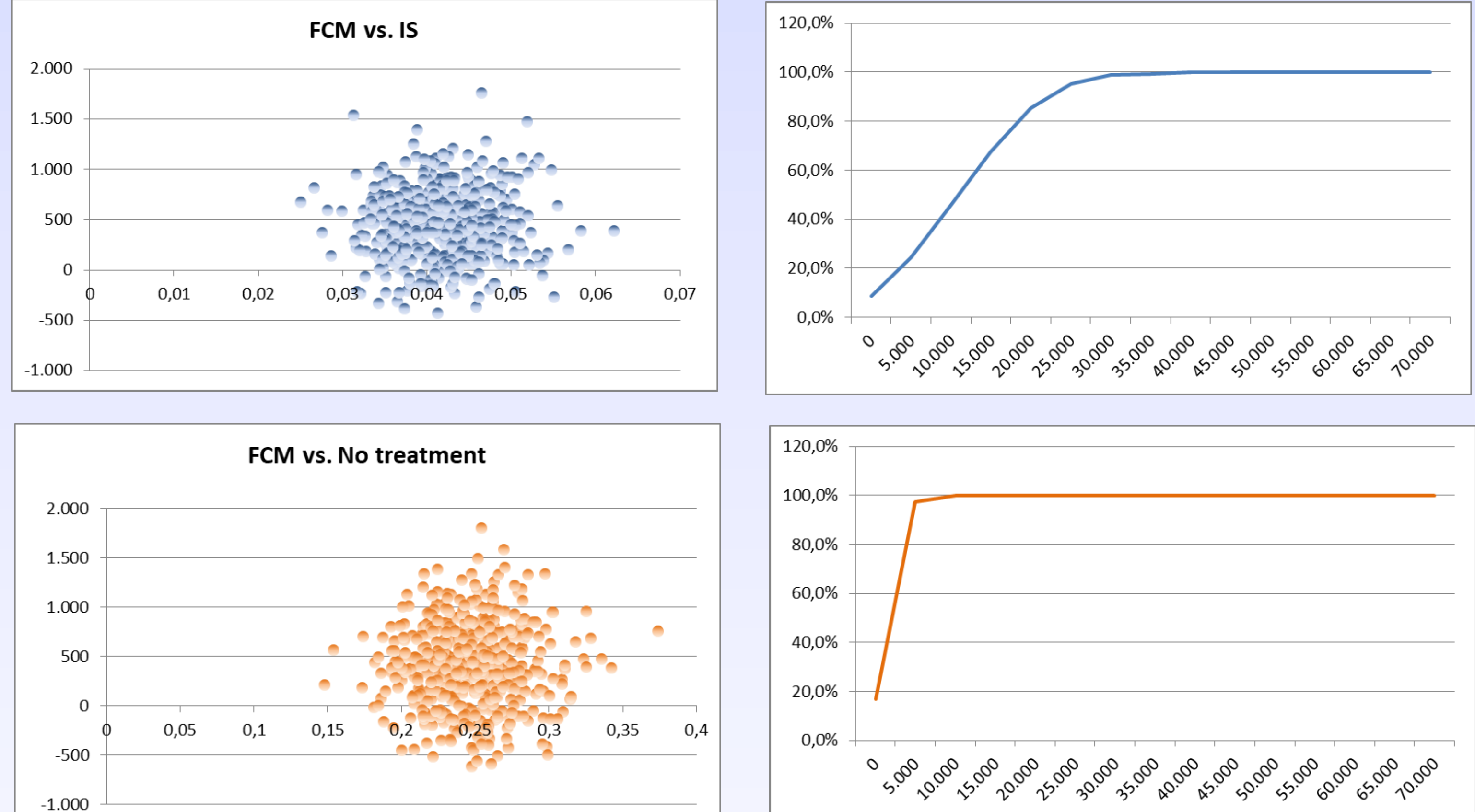
Source: own calculations

Patients with IS treatment face a quality of life reduction of 0.5 month in perfect health compared to FCM within 5 years; with no treatment 3 month in perfect health are foregone.

Sensitivity Analysis

Uncertainty is addressed in the model using probabilistic sensitivity analysis. Statistical distributions were assigned to key model parameters to examine second-order uncertainty in the estimation of the parameter. Uncertainty was propagated through the model using Monte Carlo simulation, drawing parameter values at random 500 times from the particular distributions.

Fig. 3: Probabilistic sensitivity analysis



Source: own calculations

Conclusion

IDA treatment with FCM compared with IS or no-treatment is clearly below the CE threshold of €22,200-€33,300/QALY typically used by the UK NICE and hence can be considered as a cost-effective treatment strategy.

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Additional Literature with the author