

Economic Impact of Once-daily MeltDose Extended-Release Tacrolimus (LCP-TAC) in Patients with Kidney or Liver Transplantation in Spain

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Background

- Tacrolimus is an immunosuppression drug widely used for prevention of allograft rejection in kidney and liver transplantations.
- In Spain there are currently three available formulations: immediate-release tacrolimus (IR-Tac); prolonged-release tacrolimus (PR-Tac); and extended-release tacrolimus (LCP-Tac).
- LCP-Tac is a novel formulation for tacrolimus, differentiated by using the MeltDose® technology which was designed to enhance the bioavailability of drugs with low water solubility. LCP-Tac has a pharmacokinetic profile that achieves peak levels (C_{max}) lower than other tacrolimus, with a longer time to peak (T_{max}) (Figure 1) (1). For this reason, **the required daily drug dose (DDD) is lower than that of the rest of tacrolimus** (1).

Objectives

- The aim of this study was to estimate the economic impact of the use LCP-Tac compared with PR-Tac and IR-Tac in patients with new kidney or liver transplantation in Spain.

Methods

An economic impact analysis was carried out from the Spanish National Health System (SNHS) perspective, with a time horizon of 1 year.

- A total of new 3,423 and 1,227 kidney and liver transplants, respectively, were identified in 2019 in Spain (2). The number of transplants in 2020 was not considered due to Covid-19.
- Only drug cost were included considered the list price. A 36% and 30% reduction DDD when switching from PR-Tac or IR-Tac to LCP-Tac respectively (1).

Methods

- Two scenarios were compared, a current scenario assuming a market share of 12.34%, 60.32% and 27.34% for LCP-Tac, PR-Tac and IR-Tac respectively, and an alternative scenario in which 100% of these new transplanted patients would be treated with LCP-Tac.
- The robustness of the model was verified by sensitivity analysis with the retail price drug plus value added tax (VAT).

Figure 1. Normalized tacrolimus pharmacokinetic profile.

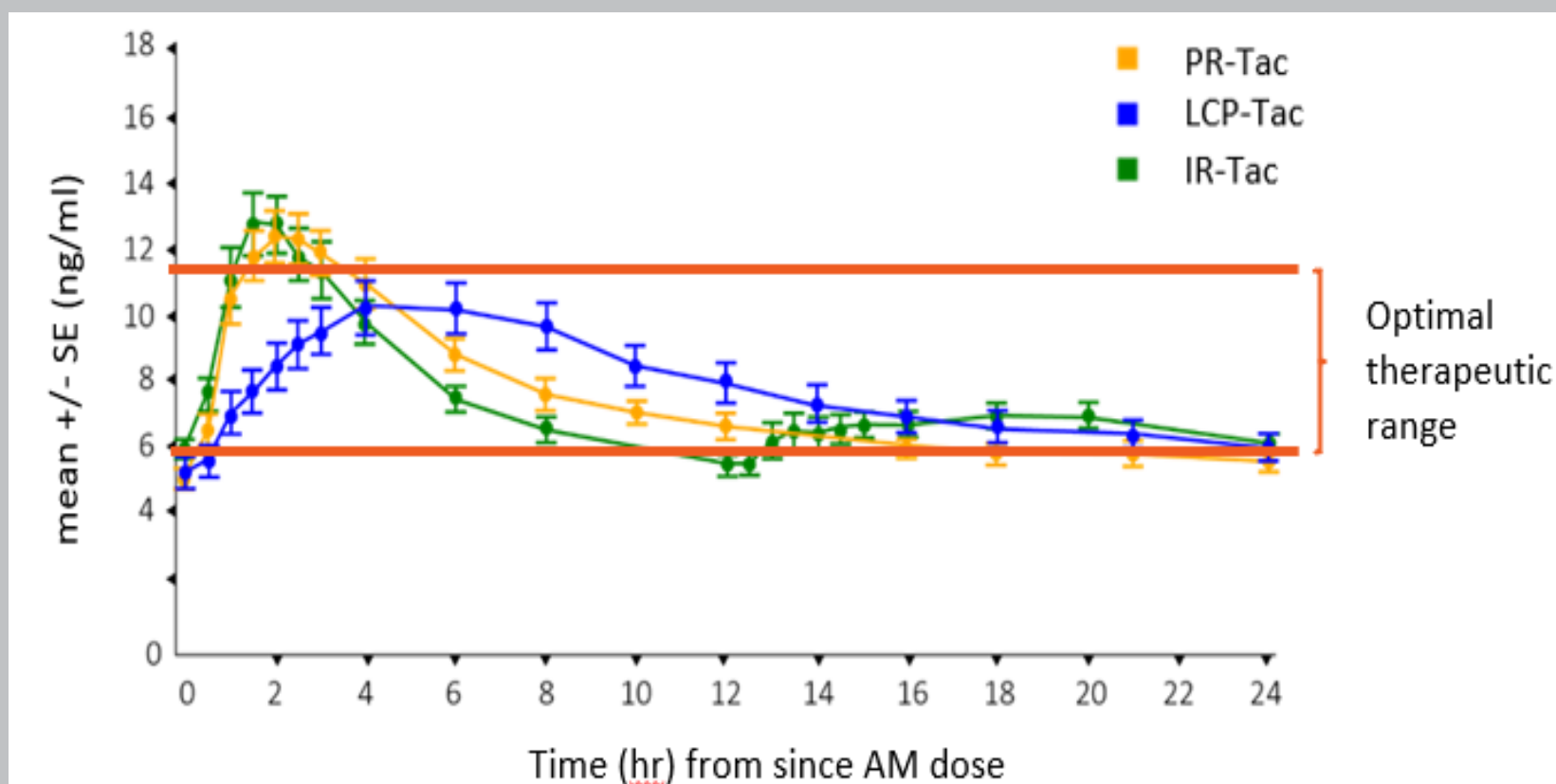


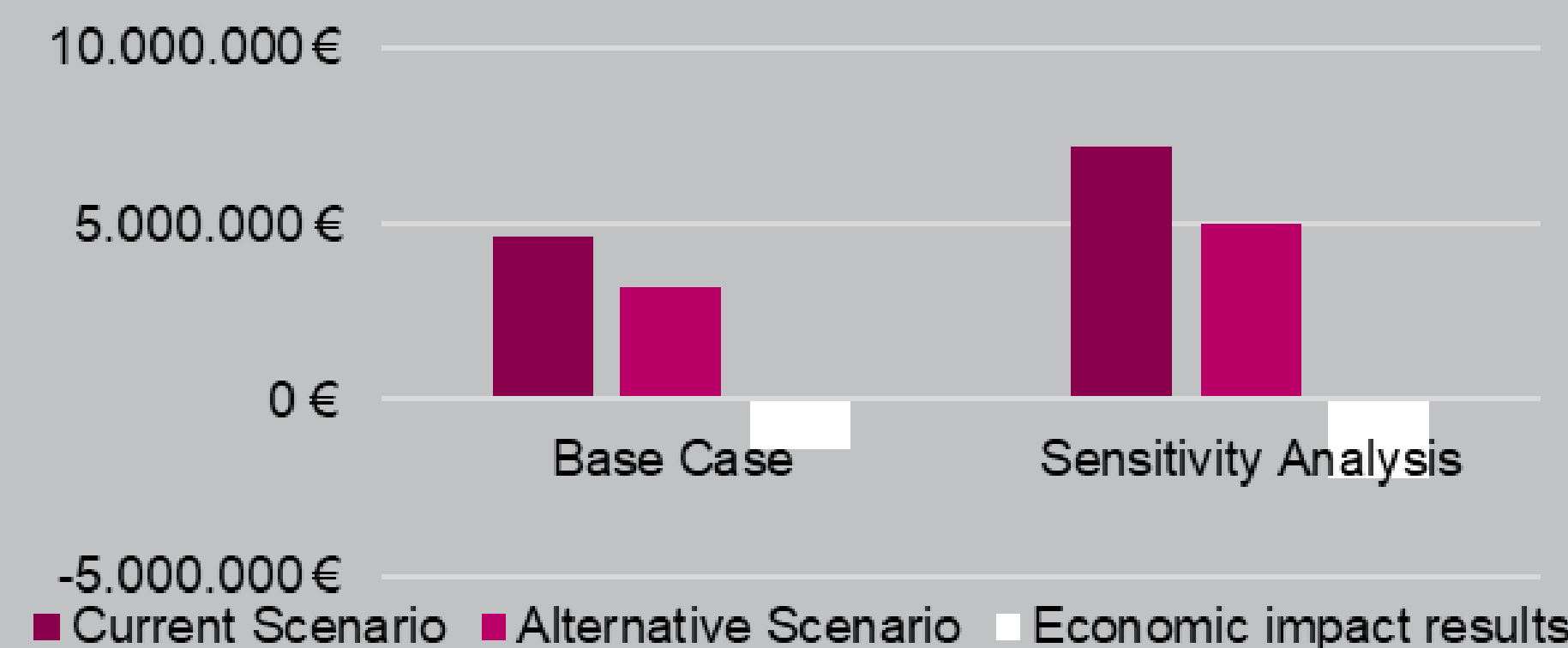
Table 1. Patients, doses and cost per day for both scenarios.

	Patients	Dose	Cost/day
Current scenario			
PR-Tac	2,804	3.78	€ 2.90
IR-Tac	1,271	3.5	€ 2.69
LCP-Tac	573	2.45	€ 1.88
Alternative scenario			
PR-Tac	0	3.78	€ 2.90
IR-Tac	0	3.5	€ 2.69
LCP-Tac	4,650	2.45	€ 1.88

Results

- The cost treatment per day was € 1.88 for LCP-Tac, € 2.90 for PR-Tac and € 2.69 for IR-Tac (Table 1). Use of LCP-Tac is cost saving for the SNHS more than even generic drugs of PR-Tac and IR-Tac, as the results shows.
- Economic impact results are shown in Figure 2. In the current scenario, the annual cost was € 4,611,676.07 and in the alternative scenarios was € 3,193,545.60. Use LCP-Tac, instead of PR-Tac and IR-Tac in naïve patients with kidney or liver transplantation in Spain would saving of 30.8% (€ 1,418,130.47) for the SNHS. The sensitivity analysis shows a saving for the SNHS of € 2,212,391.23 (30.7%).

Figure 2. Economic impact model results



Conclusions

- Based on pharmacokinetic study of LCD-Tac compared with IR-Tac and PR-Tac, a better bioavailability of LCD-Tac that lead to a decrease in its DDD would be considerable cost saving for the SNHS in the treatment of new kidney or liver transplanted patients for prevention of allograft rejection.