Cost-Effectiveness of the Personalisation of Immunosuppressive Therapy in Kidney **Transplantation By Means of an in Vitro Diagnostic Test (IMMUNOBIOGRAM®) in Spain**

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INTRODUCTION & AIM

Immunobiogram (IMBG) is a novel vitro in diagnostic bioassay that provides pharmacodynamic information on each patient's sensitivity to individual immunosuppressive drugs (IMS) in renal transplant (RT) patients:

METHODS

The evolution of a cohort of patients with RT > 1 year (time horizon = 5 years) was simulated using a second-order Monte Carlo model for 2 scenarios:

graft failure in patients with high immunological risk (HR) (Figure 1)

adverse events (AEs) in stable patients (non-HR) (Figure 2)

- tacrolimus (TAC),
- mycophenolic acid (MPA),
- sirolimus (SIR),
- everolimus (EVER)
- and corticosteroids (MTP).

The **AIM** was to estimate the cost-effectiveness of the use of IMBG for the Spanish National Health System (NHS).



Figure 1. Estimated impact of IMBG on renal graft failure in patients at high risk of rejection.

Figure 2. Estimated impact of IMBG on the adverse events of IMS therapy on patients without high risk of rejection.

The transition probabilities were obtained from a clinical study with IMBG and a systematic review (1-4). The cost associated with graft failure (dialysis, re-RT), IMS and AEs management were obtained from Spanish sources updated to 2023 (4). The loss of utilities associated with graft rejection was obtained from the literature (5).



COSTS IMPACT

Immunosuppression adjustment, according to IMBG, could contribute to a risk reduction of graft failure with a saving per HR patient of €22,664 (95% CI €19,502-25,779) (100% saving probability)

The expected reduction in AEs rate would generate savings per non-HR patient of €537 (95% CI €-484;1,808) (80.6% saving probability).

Considering both subject populations (HR and non-HR) the savings per patient would amount to €8,281 (95% CI €6,511-10,198) with a probability of savings of 100%.
Table 1. Costs impact results, per patient (NHS perspective).

GRAFT FAILURE				IMS DOSE ADJUSTMENTS & ADVERSE EVENTS				TOTAL			
Item	WITH IMBG	W/o IMBG	Difference	Item	WITH IMBG	W/o IMBG	Difference	Item	WITH IMBG	W/o IMBG	Difference
Mean	22,604 €	45,267€	-22,664 €	Mean	24,990 €	25,527€	-537 €	Mean	24,155€	32,436€	-8,281 €
SD	8,341 €	9,836€		SD	6,409 €	6,891 €		SD	7,085€	7,922 €	
LL 95%CI	8,997€	28,499€	-19,502€	LL 95%CI	14,354 €	13,869€	484 €	LL 95%CI	12,479€	18,990€	-6,511€
UL 95%CI	40,496€	66,275 €	-25,779€	UL 95%CI	39,031 €	40,839 €	-1,808 €	UL 95%CI	39,544 €	49,742 €	-10,198 €
Saving probability:			100.0%	Saving probability: 80.6%			Saving probability: 100.0%				

LIFE YEARS AND QALYS

Table 2. Life years and QALYs gained with IMBG, per patient.

Item		Life years	QALYs			
	Life years lost WITHOUT IMBG	Life years lost WITH IMBG	Life years gained WITH IMBG	QALYs lost WITHOUT IMBG	QALYs lost WITH IMBG	QALYs gained WITH
						IMBG
Mean	1.1301	0.6215	0.5085	0.0471	0.0259	0.0212
SD	0.2275	0.1252	-	0.0136	0.0075	-
LL 95%CI	0.7568	0.4167	0.3401	0.0260	0.0143	0.0117
UL 95%CI	1.6264	0.8953	0.7310	0.0779	0.0429	0.0350

- Compared with the option of not using IMBG, 0.0212 (95% CI 0.0117-0.0350) quality-adjusted life years (QALY) would be gained in each patient evaluated with IMBG.
- The probability that IMBG is a cost-effective option (for a willingness) to pay of €25,000 per QALY gained) compared to the non-IMBG choice would be 85.4%.

Abbreviations: IMBG: Immunobiogram; SD: standard deviation LL: lower limit; QALYs: quality-adjusted life years; US: upper limit; 95% CI: 95% confidence interval

• If the risk of rejection is 18.6% according to ERA-EDTA at 5 years (3), it would have to be reduced to less than 18.2% for IMBG to be cost-effective.

CONCLUSION

According to the model, IMBG could contribute to a risk reduction of graft failure and AEs related with IMS, with gain in years of life and QALYs, as well as with considerable savings for the NHS. IMBG could be a cost-effective option from the NHS perspective compared to the alternative without IMBG in kidney transplantation.

REFERENCES

(1) Foucher Y et al. A clinical scoring system highly predictive of long-term kidney graft survival. Kidney Int. 2010; 78:1288-94. (2) Portoles JM et al. The Immunobiogram, a novel in vitro assay to evaluate treatment resistance in patients receiving immunosuppressive therapy. Frontiers in immunology 2021; 11:3483.

(3) ERA Registry Annual Report 2021. Amsterdam UMC, location AMC, Department of Medical Informatics, Amsterdam, the Netherlands, 2023.

(4) Jimenez C et al. Economic evaluation of the personalization of immunosuppressive therapy in kidney transplantation by means of an in vitro diagnostic test (Immunobiogram®) in Spain. Rev Esp Eco Salud 2022; 17(1):23-34.

(5) Lee AJ, et al. Characterisation and comparison of health-related quality of life for patients with renal failure. Curr Med Res Opin. 2005; 21:1777-83.

