

THE COST OF PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS WHO DEVELOP NEUTRALIZING ANTIBODIES WHILE TREATED WITH INTERFERON BETA

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Objective: Relapsing Remitting Multiple Sclerosis (RRMS) patients treated with interferon beta (IFN β) can develop neutralizing antibodies (NABs) that reduce treatment efficacy. The aim of this study was to estimate the cost of RRMS patients who develop NABs.

Materials and methods: The study was based on a mixed method, based partly on real-world data on 546 RRMS patients treated with IFN β from a previous observational study [1], and partly from the review of cost studies in the published literature. Reverting and fluctuating patients were not considered in this evaluation. EDSS level (measured at 6-30 months) and average relapse rates were analysed in a subgroup of nearest-neighbor (NN) matched subjects (67 NAb+ and 59 NAb- patients; matching covariates: gender, age at the beginning of IFN β , baseline EDSS and disease activity) [Table 1]. Routine management costs and relapse costs were obtained from the literature [2,3]. The perspective was the Italian National Healthcare Service (NHS) and the Italian Society.

Table 1.

Baseline demographical and clinical characteristics of the cohort. Values expressed as mean (\pm SD) and percentage (%)

	NN-matched cohort	
	NAb-	Nab+
N	59	67
Male sex	17 (28.8%)	17 (25%)
Age at IFNβ	34.9 (\pm 7.3)	35.8 (\pm 8.1)
EDSS score	2.4 (\pm 0.7)	2.4 (\pm 0.7)
Relapses in 2 prev. yrs	2.0 (\pm 1.0)	2.1 (\pm 1.0)
Follow-up, yrs	5.9 (\pm 2.3)	5.2 (\pm 2.5)

Results: The mean (\pm SD) number of relapses per year was 0.61 (\pm 0.48) in NAb+ patients vs. 0.28 (\pm 0.32) in NAb- patients. At month 30, 37.1% and 22.4% of NAb+ and NAb- patients had EDSS score 4. The annual societal cost per patient was estimated in €33,890 for the NAb+ (direct cost €15,428), and €30,790 (direct cost €14,317) for the NAb-. The increase of the total annual costs specifically due to the NAb+ status was €3,100 from the Italian societal perspective and €1,111 from the Italian NHS perspective [Table 2].

Table 2 - Estimate of the annual total costs for the NAb- and NAb+ patients

	NAb-	NAb+	Increase for NAb+
Direct healthcare costs (except DMDs) + direct non healthcare costs (walking aids and wheelchair)	4,410 €	4,761 €	351 €
Cost of IFN- β	9,245 €	9,245 €	-
Direct cost of relapses	662 €	1,422 €	760 €
Total direct healthcare costs + direct non healthcare costs (walking aids and wheelchair)	14,317 €	15,428 €	1,111 €
Indirect costs + direct non healthcare costs (except walking aids and wheelchair)	15,802 €	17,021 €	1,219 €
Indirect cost of relapses	671 €	1,441 €	770 €
Total indirect costs + direct non healthcare (except walking aids and wheelchair)	16,473 €	18,462 €	1,989 €
Total social costs	30,790 €	33,890 €	3,100 €

Conclusions: The results of this economic evaluation suggest the association between NAb+ status and increased costs for the management of RRMS. These results may have implications in clinical decisions for patients with RRMS. Further pharmacoeconomics research will be needed to confirm these first results.

1. Paolicelli et al. J Neurol. 2013 Jun; 260(6):1562-1568

2. Ponzio et al. Neurol Sci. 2014 Aug 11

3. Kobelt et al. Eur J Health Econ. 2006 Sep; 7 Suppl 2:S45-54