

Budget Impact Analysis of a Natalizumab extended interval dosing regime



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INTRODUCTION

Natalizumab is a monoclonal antibody which targets an integrin receptor expressed in the surface of mononuclear cells: this mechanism can stop the immune reaction evoked during multiple sclerosis' acute attacks, typical of multiple sclerosis relapsing remitting form (RRMS), but could weaken immunosurveillance. This could lead to an increased risk of developing progressive multifocal leukoencephalopathy (PML), a condition more severe than RRMS itself. Many studies demonstrated the efficacy and safety of natalizumab administered on an extended interval dosing (EID): 300mg every 6 weeks instead of every 4, standard interval dosing (SID). This schedule is considered safer because of the lower risk of developing PML and same efficacious.

AIM AND OBJECTIVES

The aim of this study is to compare the costs of SID and EID administration of natalizumab and estimate the savings associated to the EID.

MATERIALS AND METHODS

The analysis was carried out adopting a 3 years time horizon, the hospital perspective (corresponding to NHS) and considering only direct costs of drug's purchase. The population corresponded to patients who were diagnosed MS and already treated with SID regime at our hospital. The model used was based on real clinical data: patients selected from September 2016 to September 2019.

RESULTS

The annual cost considered 12 infusions for SID and 8 for EID of natalizumab according to the actual regional public tender which is mandatory (no possibility of further paybacks or discounts, neither planning of changes to the purchase agreement in the next 3 years).

As shown in figure 1, three different scenarios were considered: 75, 85 and 95% of patients on EID regime and the remaining on SID, based on the clinical judgment that almost all patients could benefit from an EID regime, but the possibility should also be foreseen that someone couldn't wait more than 4 weeks between infusions.

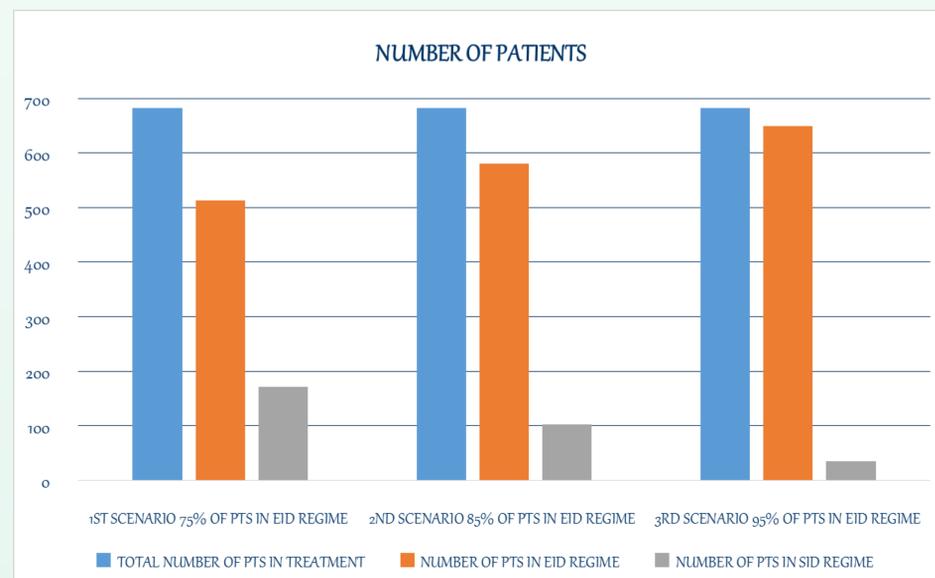


figure 1

In the first scenario there were 512 patients in EID and 171 in SID that correspond to a total cost of €10,490,101 which would be €13,986,802 if all patients were in SID. Treating 75% of patients with EID could reach a saving of €3,496,700.

The second scenario (581 vs 102) generates a cost of €10,023,875 and a saving of €3,962,927, and the third one (649 vs 34) a total amount of €9,557,648 that lets save €4,429,154. These results are shown in the figure 2.

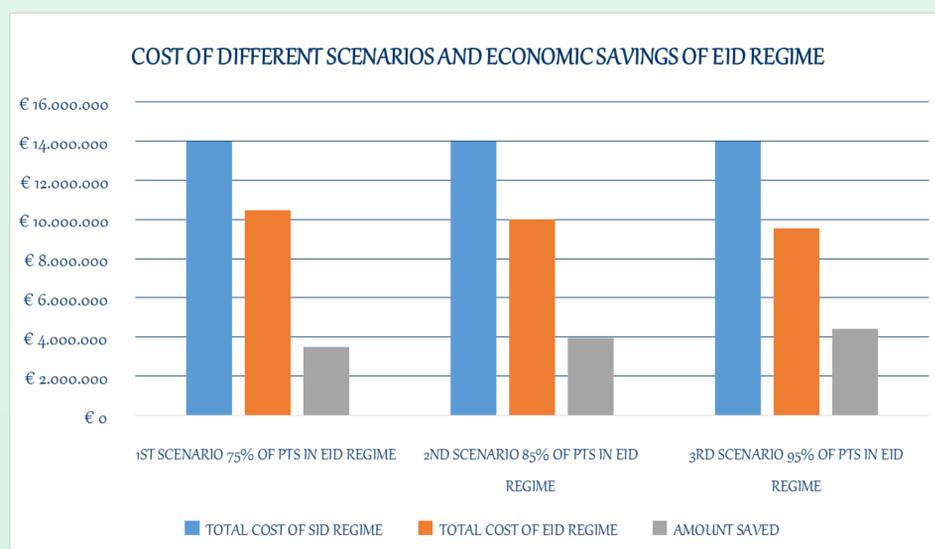


figure 2

CONCLUSION AND RELEVANCE

The analysis underlines the huge wealth saving of direct costs if most patients would be infused every 6 weeks instead of every 4 weeks. This also corresponds to a lower administration related costs (indirect ones) that we could calculate in a future analysis. We consider sharing these results with the stakeholders.

