

## BETAFERON IN THE TREATMENT OF MULTIPLE SCLEROSIS

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**SUMMARY** – The aim of the study was to analyze the usefulness and side effects of treatment with interferon beta 1B (Betaferon) in patients with the relapsing-remitting form of multiple sclerosis (RRMS). The study included 32 RRMS patients that had completed two-year therapy with interferon beta 1B or were still receiving this therapy. Every six months, patients were clinically evaluated and scored by the Expanded Disability Status Scale (EDSS). Two-year therapy was completed by 11 (34.3%) of 32 RRMS patients. Relapse was verified in 4 (36.36%) patients. The mean EDSS score was  $2.45 \pm 1.03$  at the beginning of therapy and  $2.54 \pm 0.98$  after two-year therapy; the difference was not statistically significant. In 2 (6.25%) patients on therapy for 18 months there was no relapse, and the mean EDSS was  $1.75 \pm 0.35$  (both at therapy introduction and at 18 months). Five (15.62%) patients were on therapy for one year. The mean EDSS was  $1.6 \pm 1.08$  at the beginning of therapy and  $1.5 \pm 0.70$  at one year. One patient experienced relapse. Two patients were on therapy for six months. They had no relapses with the same EDSS at six months as at therapy introduction (2.0). At the beginning of 2008, another 12 patients started therapy with interferon beta 1B. In conclusion, our experience with two-year interferon beta-1B therapy for RRMS is favorable, with a relatively low rate of relapses (36.36%) and without significant worsening on EDSS. The medication side effects were mild and transient.

**Key words:** *Multiple sclerosis – drug therapy; Interferon-beta – therapeutic use; Interferon-beta – adverse effects*

### Introduction

Multiple sclerosis (MS) was described and defined by Charcot in 1868, however, therapy has remained a great challenge ever since. Research into the causes and treatments of MS has expanded our knowledge of the disease, promising better management of MS patients in the future<sup>1</sup>. The aim of the study was to analyze our results on the usefulness and side effects of interferon beta 1B (Betaferon) treatment of patients with the relapsing-remitting form of MS (RRMS).

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### Patients and Methods

The study included 32 RRMS patients treated at University Department of Neurology, Tuzla University Clinical Center, that had completed two-year therapy with interferon beta 1B or were still receiving this therapy. All patients were admitted to the Department at the beginning of therapy or during relapse. Every six months, patients were clinically evaluated and scored by the Expanded Disability Status Scale (EDSS). Standard statistical tests, mean and t-test were used. Statistical significance was set at  $P < 0.05$ .

### Results

The mean patient age was  $30.78 \pm 8.99$  years and the mean disease duration before therapy introduction

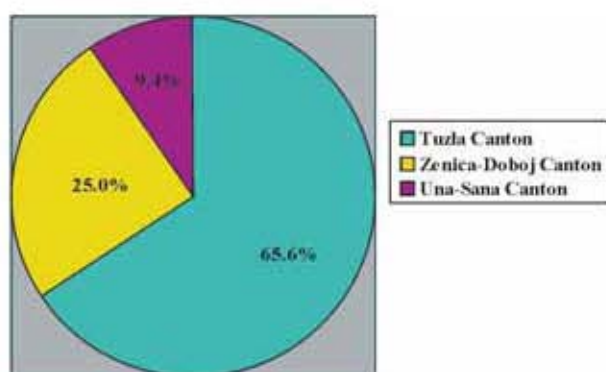


Fig. 1. Distribution of multiple sclerosis patients according to cantonal residence.

2.78±2.33 years. Most patients were Tuzla Canton residents (21; 65.6%), 8 (25%) were from Zenica-Doboj Canton and 3 (9.4%) from Una-Sana Canton (Fig. 1). Two-year therapy was completed by 11 (34.3%) patients. Relapse was verified in 4 (36.36%) patients. The mean EDSS score was 2.45±1.03 at the beginning of therapy and 2.54±0.98 at two-year therapy; the difference was not statistically significant (Fig. 2). Two (6.25%) patients that were on therapy for 18 months had no relapse and the mean EDSS was 1.75±0.35 (both at the beginning and at 18 months of therapy).

Five (15.62%) patients were on therapy for one year. Their mean EDSS was 1.6±1.08 at the beginning and 1.5±0.70 at one year of therapy. One patient experienced relapse. Two patients were on therapy for six months. They had no relapses, and their mean EDSS was the same (2.0) at the beginning and after six months of therapy. At the beginning of 2008, another 12 patients started therapy with interferon beta a1B.

The most common side effects were elevation of body temperature, redness at the site of needle insertion and muscle pain (Fig. 3).

### Discussion

Although disease relapse was verified in 36% of patients during two-year therapy with interferon beta 1B, there was no statistically significant worsening on EDSS. Previous studies have reported similar results<sup>2</sup>. Some authors found prolonged therapy with interferon β (IFN-β) to frequently lead to the development of anti-IFN-β binding antibodies (BAbs), which is associated with reduced clinical efficacy of therapy<sup>3-6</sup>. We could not analyze the level of BAbs and the risk of a new relapse in IFN-β treated patients.

The medication side effects were temporary and mild. The most common side effects were elevation of

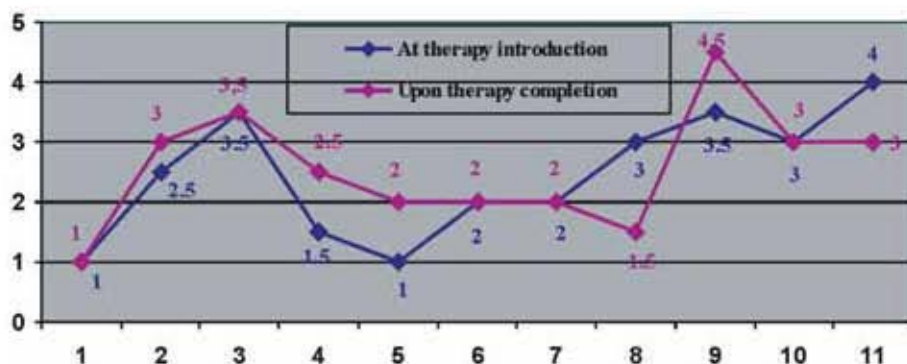


Fig. 2. Expanded Disability Status Scale (EDSS) before and after betaferon therapy.

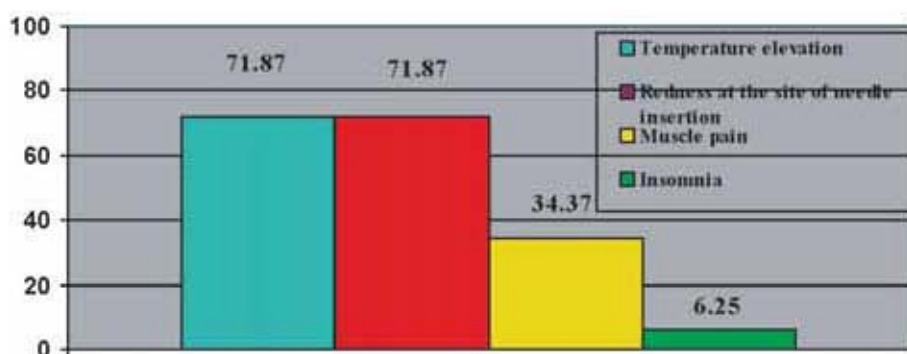


Fig. 3. Distribution of medication side effects.



body temperature, redness at the site of needle insertion and muscle pain. In our series of IFN- $\beta$  treated patients, there was no case of elevated aminotransferase levels and severe hepatic injury<sup>7</sup>.

## Conclusion

Our experiences with two-year interferon beta-1B treatment for RRMS at Tuzla Department of Neurology are favorable. Our patients had a relatively low rate of relapses, without significant worsening of EDSS. The medication side effects were temporary and mild.

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## Sažetak

### BETAFERON U LIJEČENJU MULTIPLE SKLEROZE

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Cilj studije bio je analizirati korist i nuspojave liječenja bolesnika s relapsno-remisijskim oblikom multiple skleroze (RRMS) interferonom beta 1B (Betaferon). U studiju je bilo uključeno 32 bolesnika s RRMS koji su završili dvogodišnju terapiju interferonom beta 1B ili su ovu terapiju još uvijek primali. Svakih šest mjeseci provodila se klinička procjena bolesnika i procjena prema ljestvici EDSS (*Expanded Disability Status Scale*). Dvogodišnju terapiju završilo je 20 (62,50%) od 32 bolesnika. Recidiv je dokazan u 8 (40,00%) bolesnika. Prosječan rezultat na ljestvici EDSS bio je  $2,17 \pm 0,99$  na početku liječenja i  $2,40 \pm 1,15$  nakon dvije godine terapije; razlika nije bila statistički značajna. Jedanaestoro (34,37%) bolesnika bilo je na terapiji jednu godinu. Kod njih je prosječan rezultat na ljestvici EDSS bio  $1,54 \pm 0,65$  na početku terapije i  $1,45 \pm 0,65$  nakon jedne godine liječenja. Recidiv je zabilježen u dvoje (18,18%) bolesnika, dok je jedan bolesnik prekinuo liječenje nakon šest mjeseci. Naša iskustva s dvogodišnjim liječenjem RRMS interferonom beta 1B su povoljna. Bolesnici su imali relativno mali broj recidiva (40%) bez znatnijeg pogoršanja na ljestvici EDSS. Nuspojave lijeka bile su prolazne i blage naravi.

Ključne riječi: *Multipla skleroza – terapija lijekovima; Interferon-beta – terapijska primjena; Interferon-beta – štetni učinci*