Study design and methods

• Data from 1343 patients (26.9% male, 71.0% female) from 76 sites were evaluated.
• Mean duration from first MS diagnosis until start of a specific MS-treatment was 30.8 (0.0 – 475.5) months.
• Only 0.7% of patients experienced severe adverse events; without causal relation to the MS-treatment.

Results

Previous MS-treatments before enrolment

- Approximately 60% of the patients stopped previous MS-treatment (range: 0.0% – 65.9%, depending on the treatment).
- Evaluation of previous treatment with SC Interferon beta 1a was stopped by 61.3% of the patients.
- Mean observation time from beginning of current treatment to visit 1 was 6.7 months (all treatments).

Reasons for stopping previous MS treatment were documented (all treatments).

- Additional reasons: (31.7% patients) with 23.4% other side effects (22.1%); skin reactions (18.3%); other reasons (13.3%;)
- The frequency of the reasons were a frequent cause for stopping previous treatment with Glatirameracetate and Interferon beta 1b (36.9% and 21.4%); with IM Interferon beta 1a only 3.8%.

Table 1: Reasons for stopping previous MS treatment (%) (approx. 40 – 50% of patients were affected [all treatments]).

<table>
<thead>
<tr>
<th>Reason</th>
<th>IM IFNb 1a</th>
<th>IM IFNb 1a 22 µg</th>
<th>SC IFNb 1a 22 µg</th>
<th>SC IFNb 1a 44 µg</th>
<th>SC IFNb 1b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional reasons</td>
<td>23.1%</td>
<td>27.0%</td>
<td>29.8%</td>
<td>26.2%</td>
<td>27.8%</td>
</tr>
<tr>
<td>Other side effects</td>
<td>18.9%</td>
<td>27.5%</td>
<td>28.0%</td>
<td>28.9%</td>
<td>31.7%</td>
</tr>
<tr>
<td>Skin reactions</td>
<td>16.7%</td>
<td>14.2%</td>
<td>13.7%</td>
<td>13.1%</td>
<td>15.7%</td>
</tr>
<tr>
<td>Other reasons</td>
<td>15.5%</td>
<td>19.7%</td>
<td>16.0%</td>
<td>18.9%</td>
<td>15.7%</td>
</tr>
</tbody>
</table>

Conclusions

- The results of this observation in real life setting underline the good efficacy and safety of DMTs - despite EDS1 and reduction of relapse rate.
- Relapse-free periods were significantly longer under IM IFNb 1a treatment compared to SC IFNb 1a and 1b, respectively.
- Patients treated with Interferon beta 1a experienced fewer injection site reactions.
- Skin reactions were a frequent cause for stopping previous treatment with Glatirameracetate and Interferon beta 1b.
- Particularly, skin reactions were a frequent cause for stopping previous treatment with Glatirameracetate and Interferon beta 1b.

Disclosure

- MM received lecture fees and travel grants from the following companies: Bayer HealthCare AG, Berlin-Chemie AG, Biogen Idec GmbH, Merck KGaA, Novartis Pharma GmbH, Pﬁ zer Pharma GmbH, Sanofi-Aventis, Teva.
- TG: Honoraria, research support, speaking honoraria and travel support were received by Biogen Idec GmbH.

References

[1] Martin Marziniak, MD, Department of Neurology and Department of Infl ammatory Diseases of the Nervous System and Neurooncology, University of Münster, Germany. 28th Congress of the European Committee for Treatment and Research in Multiple Sclerosis, Lyon, France

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INTRODUCTION

Efficacy and safety of the disease modifying treatments (DMT), interferon (IFN) beta and glatiramer acetate, have been demonstrated in clinical trials and follow-up studies in the treatment of monitoring multiple sclerosis (MS). However, the pattern of application makes as well as understandable effects of the treatment, e.g. local injection site reactions, can negatively affect the Quality of Life (QoL) and has a negative impact on treatment compliance. A clinical study evaluating the available DMTs in a real-life setting is in a high number of patients of major interest.

Efficacy

- Mean EDS1 was stable for all treatments within the observational period (range: 1.4 – 2.4 [total: 2.3, 95% CI: 2.1 – 2.4].

Safety and tolerability

- Patients treated with Interferon beta 1a within the observational period (visit 1: 11.5% was normally reduced compared to the 12 month period previous to the enrolment visit (11.5% [90% CI: 9.3% – 13.7%] EDS0; 13.6% [95% CI: 11.3% – 15.9%] EDS1), with consistent reduction in the observational period and with complete observation.

- There were no significant differences between current MS-treatments.

RESULTS

Demographics and disease characteristics

- Data from 1343 patients (26.9% male, 71.0% female) were evaluated (n = 1343).
- Mean duration between beginning of current MS-treatment and visit 1 was 45.7 months (all treatments).
- Particularly skin reactions were a frequent cause for stopping previous treatment with Glatirameracetate and Interferon beta 1b (36.9% and 21.4%).
- Patients treated with IM Interferon beta 1a experienced fewer injection site reactions.

Data from 1343 patients in 76 sites were evaluated (26.9% male, 71.0% female).

• Mean duration from first MS diagnosis until start of a specific MS-treatment was 30.8 (0.0 – 475.5) months.
• Only 0.7% of patients experienced severe adverse events; without causal relation to the MS-treatment.

Table 1: Reasons for stopping previous MS treatment (%) (approx. 40 – 50% of patients were affected [all treatments]).

- Approximately 50% of the patients stopped previous MS-treatment (range: 0.0% – 65.9%, depending on the treatment).
- Previous treatment with IM Interferon beta 1a showed a significantly better skin tolerability than the SC applied MS-treatments:
- Particularly, skin reactions were a frequent cause for stopping previous treatment with Glatirameracetate and Interferon beta 1b (36.9% and 21.4%).
- Patients treated with IM Interferon beta 1a experienced fewer injection site reactions.

Current MS-treatment

- 31% of recalled patients (71.0%) did not change MS-treatment within the observational period.
- Efficacy and safety of the DMTs were evaluated: interferon beta 1a, glatiramer acetate (Glatirameracetate 1a 22 µg, 44 µg; Interferon beta 1a 22 µg, 44 µg).

Figure 6: Patients with skin reactions of patients with consistent medication over all visits within the observational period (n = 1343)

Figure 7: Patients with indications of skin (patients with skin reactions and the same treatment over all visits, n = 401 [17.4%] at visit 1, 15.5% at visit 5).

Figure 5: Patients with skin reactions of patients with consistent medication over all visits within the observational period (n = 401 [17.4%] at visit 1, 15.5% at visit 5).

Safety and tolerability

- Relapse-free periods were significantly longer under IM IFNb 1a treatment compared to SC IFNb 1a and 1b, respectively.
- Particularly, skin reactions were a frequent cause for stopping previous treatment with Glatirameracetate and Interferon beta 1b (36.9% and 21.4%).
- Patients treated with IM Interferon beta 1a experienced fewer injection site reactions.

DISCLOSURE

- MM received lecture fees and travel grants from the following companies: Bayer HealthCare AG, Berlin-Chemie AG, Biogen Idec GmbH, Merck KGaA, Novartis Pharma GmbH, Pﬁ zer Pharma GmbH, Sanofi-Aventis, Teva.
- TG: Honoraria, research support, speaking honoraria and travel support were received by Biogen Idec GmbH.

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SAVE THE DATE

28th Congress of the European Committee for Treatment and Research in Multiple Sclerosis

10 – 13 October 2012, Lyon, France

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AVONEX® Assessment in Multiple Sclerosis-Therapy (ASSET) – an observational study in 1354 patients

OBJECTIVES

- To prospectively assess treatment efficacy, safety and tolerability both in a particular focus on skin tolerability as well as the patients‘ QoL under a stable parenteral DMT.

STUDY DESIGN AND METHODS

- Patients with MS attending treatment visits at an approved DMT (Interferon beta 1a, Interferon beta 1b, SC Glatirameracetate) were evaluated.
- Course of disease (EDS0 and EDS1), injection site reactions, overall tolerability, general health status and QoL were documented every 2 months.
- Primary endpoint: efficacy of the different DMTs (relapse activity); secondary endpoints: disability progression (EDSS), MRI findings, tolerability, overall health status and QoL.

Figure 1: Efficacy and safety of the disease modifying treatments (DMT), interferon (IFN) beta and glatiramer acetate, have been demonstrated in pivotal clinical trials and follow-up studies in the treatment of monitoring multiple sclerosis (MS). However, the pattern of application makes as well as understandable effects of the treatment, e.g. local injection site reactions, can negatively affect the Quality of Life (QoL) and has a negative impact on treatment compliance. A clinical study evaluating the available DMTs in a real-life setting is in a high number of patients of major interest.

Figure 2: Efficacy and safety of the disease modifying treatments (DMT), interferon (IFN) beta and glatiramer acetate, have been demonstrated in pivotal clinical trials and follow-up studies in the treatment of monitoring multiple sclerosis (MS). However, the pattern of application makes as well as understandable effects of the treatment, e.g. local injection site reactions, can negatively affect the Quality of Life (QoL) and has a negative impact on treatment compliance. A clinical study evaluating the available DMTs in a real-life setting is in a high number of patients of major interest.

Figure 3: Efficacy and safety of the disease modifying treatments (DMT), interferon (IFN) beta and glatiramer acetate, have been demonstrated in pivotal clinical trials and follow-up studies in the treatment of monitoring multiple sclerosis (MS). However, the pattern of application makes as well as understandable effects of the treatment, e.g. local injection site reactions, can negatively affect the Quality of Life (QoL) and has a negative impact on treatment compliance. A clinical study evaluating the available DMTs in a real-life setting is in a high number of patients of major interest.

Figure 4: Efficacy and safety of the disease modifying treatments (DMT), interferon (IFN) beta and glatiramer acetate, have been demonstrated in pivotal clinical trials and follow-up studies in the treatment of monitoring multiple sclerosis (MS). However, the pattern of application makes as well as understandable effects of the treatment, e.g. local injection site reactions, can negatively affect the Quality of Life (QoL) and has a negative impact on treatment compliance. A clinical study evaluating the available DMTs in a real-life setting is in a high number of patients of major interest.