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ORIGINAL RESEARCH

Patient Satisfaction with the New Interferon Beta-1b Autoinjector (BETACONNECT™)

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ABSTRACT

Introduction: Multiple sclerosis (MS) typically requires life-long management with disease-modifying therapies (DMTs). Many DMTs require regular self-injection, and can be associated with injection site reactions, pain, and needle/injection phobia—but these can be addressed by improvements in autoinjector design. The aim of this study was to investigate patient satisfaction and preference for BETACONNECT™ (Bayer Pharma AG), a novel interferon beta-1b autoinjector.

Methods: Patients in Germany performing self-injections using BETACONNECT took part in the study. Data were collected through an online 15-min structured survey. Participants rated their experience with BETACONNECT on a 6-point scale and those satisfied with BETACONNECT were asked to describe the reason using a free-text box.

Results: One-hundred and eighteen patients with MS completed the survey. Ninety percent preferred BETACONNECT to their previous injection method (only 4% previously used manual injections, so most had previously used other autoinjectors). Ninety-two percent were very confident/confident in their ability to perform an injection using BETACONNECT. The most common free-text responses to "Why are you satisfied with the BETACONNECT™ autoinjector?" were ease of use (46%), less irritation/pain at the injection site (33%), and smoother injections (24%). Features considered most useful were automated injections (98%), adjustable injection speed (98%), and adjustable injection depth (98%). Ninety-seven percent thought it was easy to know when an injection was complete and 95% agreed/strongly agreed it was easy to learn to use the autoinjector. Seventy-three percent agreed that

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the quietness and effortlessness of the BETACONNECT reduced their level of injection anxiety, 92% that its size and shape makes it easy to handle during injections, and 67% that it decreases injection site pain. Eighty percent of those using the reminder function thought they were less likely to miss an injection.

Conclusion: Patients with MS self-injecting interferon beta-1b expressed a high level of satisfaction and preference for BETACONNECT. Thus, BETACONNECT represents a valid option to improve patients' overall injection experience.

Funding: Bayer HealthCare Pharmaceuticals.

Keywords: Beta-interferons; Disease-modifying therapies; Electronic autoinjector; Patient survey; Relapsing–remitting multiple sclerosis

INTRODUCTION

Multiple sclerosis (MS) is a chronic and debilitating autoimmune disease affecting the central nervous system, with a worldwide prevalence of approximately 33 cases per 100,000 individuals [1]. Typically, the first manifestation of MS occurs when patients are in their 20 or 30 s, and it is normal to live with MS for about 30 or 40 years [2, 3]. Medication for MS usually includes long-term management with disease-modifying therapies (DMTs) such as interferon beta-1b, which can alter the pathological immune responses associated with MS, prevent relapses, and slow disease progression [4].

Other than the development of new treatments, improving the management of MS can focus on a number of factors, including the delivery systems of existing drug therapies. Many of the currently approved DMTs require patients to perform regular self-injections, which can be associated with injection site reactions, pain, and needle phobia or other injection anxieties. However, the use and ongoing development of autoinjectors have the potential to reduce the incidence of injection site reactions [5, 6], reduce needle phobia and patients' anxiety about self-administered injections [7], and increase adherence [8]. This is supported by new autoinjector designs that could make the injection process easier, particularly for patients with visual, dexterity or cognitive problems (for example, by incorporating electronic reminders to overcome forgetfulness) [5, 6, 9].

A variety of injection devices for many DMTs have been developed and evaluated with respect to patient satisfaction [10–15]. However, the new fully electronic BETACONNECT™ (Bayer Pharma AG) autoinjector evaluated in the current study encompasses many advances in autoinjector design and technology as outlined in the following section, which may further enhance patient comfort, satisfaction and adherence, and is hoped to further improve management of MS. Thus, the aim of the current study was to investigate patient satisfaction and preference for this new interferon beta-1b autoinjector. We hypothesized that patients would be more satisfied with the BETACONNECT autoinjector in comparison with other methods they used previously to inject interferon beta-1b. We also aimed to investigate the reasons underlying patient satisfaction.

METHODS

BETACONNECT™ Autoinjector

The BETACONNECT autoinjector (Fig. 1) is fully electronic and offers many improvements over older mechanical devices used for the delivery of other MS therapies. It has an intuitive user

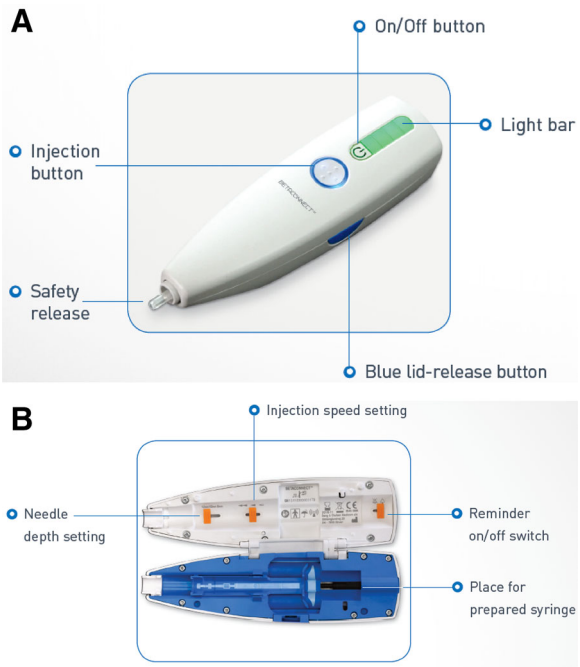

Fig. 1 The BETACONNECT™ electronic autoinjector. **a** The ergonomic design makes the device easy to handle and allows one-handed injections, with the needle hidden during the entire injection process, and audible and visible indicators of battery status, safety release, and dose reminder functions. **b** The syringe for interferon beta-1b release is placed within the autoinjector, and the interior features injection setting controls

interface and ergonomic design making it easy to handle and allowing one-handed injections. It features adjustable injection speed and depth to allow individual injection settings, and a low-force safety release to ensure the device is positioned correctly at the time of the injection. The BETACONNECT autoinjector's electronic injection is nearly silent and features four-phase injection technology: (1) automatic needle insertion; (2) delivery of the medication; (3) dwell time, when the needle remains in the skin momentarily, reducing the risk of an injection site reactions; and (4) automatic needle retraction. The autoinjector then provides both optical and audible signals of injection completion. It also features audible and visible indicators of battery status and a dose reminder function. Finally, this novel device automatically records data such as injection date and time, injection depth, injection speed, and injection volume as patients perform injections. It also offers the possibility to share data with healthcare providers via an app called myBETAapp™ (Bayer Pharma AG) and the Navigator, a dashboard monitoring application, to enhance communication between patients and healthcare professionals. Table 1 shows some of the key characteristics of the BETACONNECT autoinjector [12, 16–21].

Participants

Patients using BETACONNECT in Germany were invited to participate in the survey, through either invitations sent by mail or invitation cards distributed by BETAPLUS® nurses (Bayer-sponsored nurses who train patients with MS and help them to manage their disease). Participation required use of BETACONNECT for at least 2 weeks, use of interferon beta-1b for at least 6 months, and performance of self-injections the majority of the time. All patients were aged 18 years or older and had been diagnosed with MS more than 6 months ago.

Survey Instruments and Data Collection

Data were collected through an online 15-min structured survey. Participants rated the usefulness of features offered by BETACONNECT on a 6-point scale which ranged from 1 (very useless) to 6 (very useful), with results presented as the percentage of those who rated each feature "useful" or "very useful" (rating of 5 or 6). Respondents were able to skip questions for features they were unaware of and/or did not have enough experience with to provide a response. Participants also rated

Table 1 Key characteristics of the BETACONNECT™ autoinjector [12, 16–21]

Feature	Main rationale/benefit
Ergonomic design	Allows ease of handling and one-handed operation: useful for patients with reduced manual dexterity (about 79% of patients with MS) [16] or short "thumb reach" (particularly a problem for some women) [17]
Intuitive user interface	Simplicity and ease of use are considered important features by patients with MS [12]. May be helpful as about 65% of patients with MS have cognitive impairment which can accrue in all MS sub-types [18]
Safety release	Important owing to reduced manual dexterity in the majority of patients with MS (as noted above)
Automatic needle insertion/retraction and needle hidden at all times	Avoidance of needle phobia and reduce the risk of inadvertent needle-stick injury [19]
End-of-dose indicators (visible and audible)	Considered important by patients with MS [12]
Adjustable injection speed and depth	Regarded as important features, and lack of control of injection process including speed and depth given as a reason for not using an injection device [12]
Injection reminder	Forgetting to take medications for MS is the most common reason for non-adherence to MS drug therapy [20, 21]

MS multiple sclerosis

BETACONNECT on its intuitiveness, ease of use, and its effect on their injection experience. Ratings were provided on a 6-point scale ranging from 1 (strongly disagree) to 6 (strongly agree), with results presented as the percentage of those who "agreed" or "strongly agreed" (rating of 5 or 6). Participants satisfied with BETACONNECT were asked to describe the reason why they are satisfied with the autoinjector in an open-ended free-text box. The open-ended free-text box allowed participants to describe their feelings about the device completely unaided, reducing the potential influence of the survey design. The answers provided were coded by frequency that they were mentioned. Patients were also asked to rate the ease of performing injections (rating from very difficult to very easy) and how confident they were in performing an injection with the BETACONNECT (rating from very unconfident to very confident). The survey was created and managed by an independent market research company, and funded by Bayer HealthCare Pharmaceuticals, Inc., Whippany, NJ, USA. Respondents were offered a gift card valued at €10 for their participation.

All procedures followed were in accordance with the 1964 Declaration of Helsinki and its subsequent revisions. Informed consent was obtained from all patients included in the study. This article describes a non-interventional study, and so does not involve any new studies of human or animal subjects performed by any of the authors.

RESULTS

Demographic Characteristics

A total of 118 respondents with MS agreed to participate, and completed the survey. The demographic characteristics of survey

participants are shown in Table 2. Nearly three-quarters (72%) of respondents were female, average age was 47.2 years, and the majority (69%) had been using the autoinjector for more than 1 month. Before using BETACONNECT, the majority of participants had been administering interferon beta-1b using a different autoinjector (BETACOMFORT® 56%, BETAJECT COMFORT® 39%, BETAJECT LITE® 14%; all Bayer Pharma AG) or manual injection with a syringe (4%).

Table 2 Demographic characteristics of survey participants ($n = 118$), including previous injection method(s)

Characteristic	Number (%)
Females	85 (72%)
Age	
<36 years	13 (11%)
36–45 years	18 (15%)
46–55 years	35 (30%)
56–65 years	24 (20%)
≥60 years	1 (1%)
Previous injection method(s)[a]	
BETACOMFORT®	66 (56%)
BETAJECT® Comfort	46 (39%)
BETAJECT® Lite	16 (14%)
Manual, no autoinjector	5 (4%)
No answer	4 (3%)
Length of time using BETACONNECT™	
<1 month	37 (31%)
>1 month	81 (69%)
No answer	0 (0%)

[a] Multiple selections were allowed to cover any previous injection method the patient had used, thus these percentages total more than 100%

Overall Perceptions of BETACONNECT™

The overall ratings for the autoinjector were very positive, with 90% of respondents stating that they preferred BETACONNECT to their previous injection method and 92% reporting that they were very confident or confident in their ability to perform an injection using the BETACONNECT autoinjector (Fig. 2). A total of 85 patients who were satisfied or very satisfied with the BETACONNECT device, responded to the open-ended question "Why are you satisfied with the BETACONNECT™ autoinjector?" The most common reasons given were its ease of use (46%), less irritation/pain at the injection site (33%), and smoother injections (24%; Fig. 3). Patients also appreciated the reminder function (13%), ability to personalize the injection speed and depth (12%), ease of handling (9%), and quieter injections (6%).

The features of BETACONNECT that were rated as most useful (i.e., rated "useful" or "highly useful") are shown in Fig. 4. Features considered as most useful (by 98% of survey responders in each instance) were automated injections, adjustable injection speed, and adjustable injection depth. Features that help guide the injection process such as the self-check function (which communicates that the autoinjector is functioning and ready for use) and the end-of-dose indicator (signified acoustically and visually) were also rated as "useful" or "very useful" by more than 9 in 10 respondents using these features.

Ease of Use

Responses related to the intuitiveness and ease of use of the autoinjector were also favorable: 97% thought it was easy to know when an injection was complete and 95% agreed/strongly agreed it was easy to learn to use the

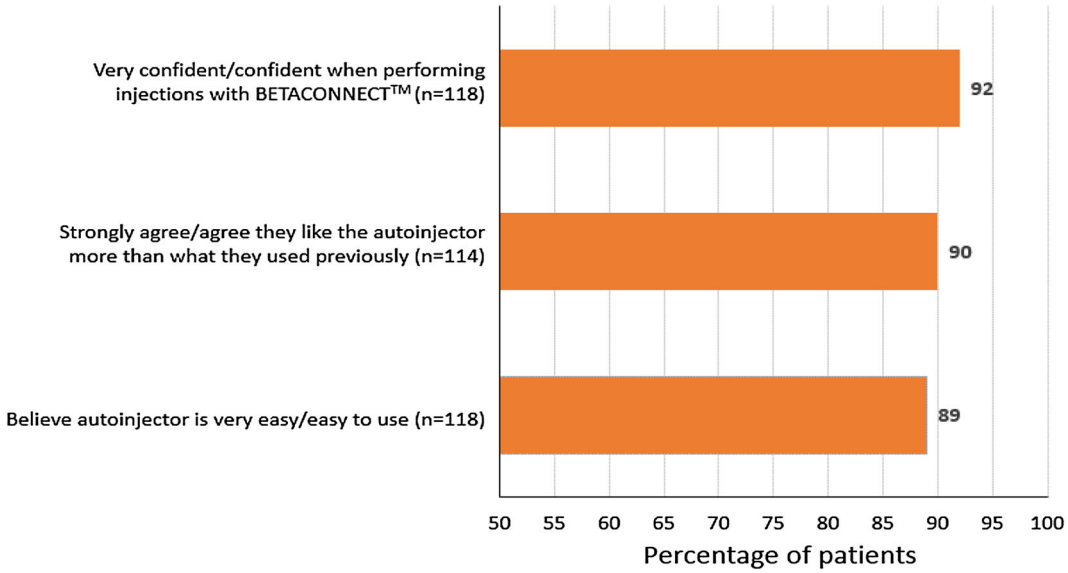

Fig. 2 Overall impressions of the BETACONNECT™ autoinjector. *Base*: total respondents, excluding those who answered "don't know"

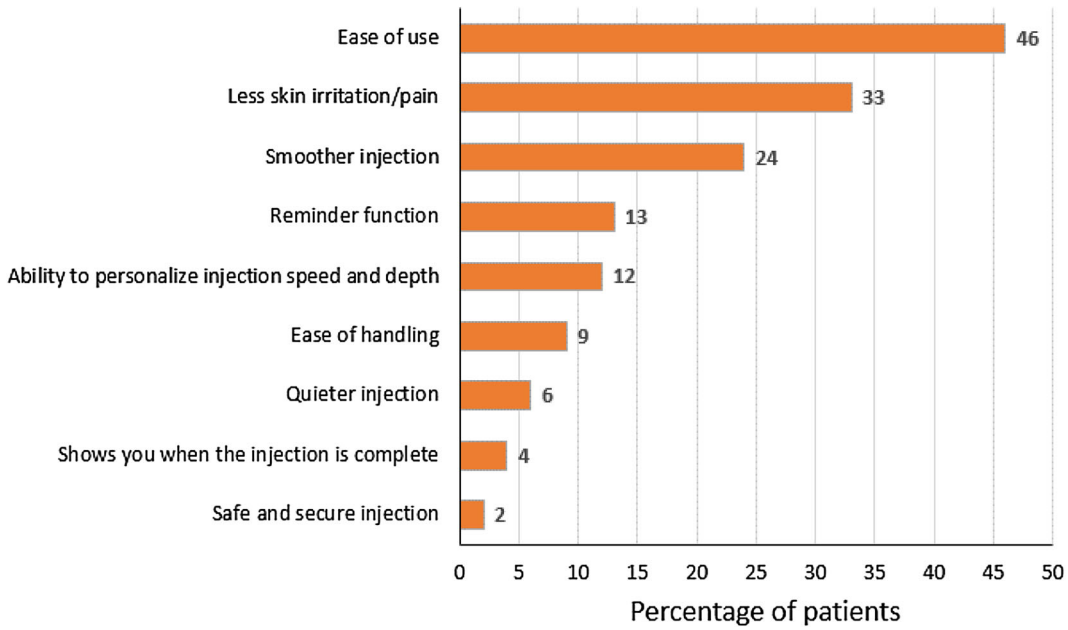

Fig. 3 Primary reasons for satisfaction with BETACONNECT™ (unaided responses to open-ended questions, $n = 85$). *Base*: respondents satisfied with BETACONNECT™ and who answered: "Why are you satisfied with the BETACONNECT™ autoinjector?"

autoinjector (Fig. 5). Likewise, 94% agreed/strongly agreed that the lights and buttons are self-explanatory, and 91% that the light bar makes it easy to monitor the progress of an injection. Among those aware of the contact sensor ($n = 110$), 85% agreed/strongly agreed it

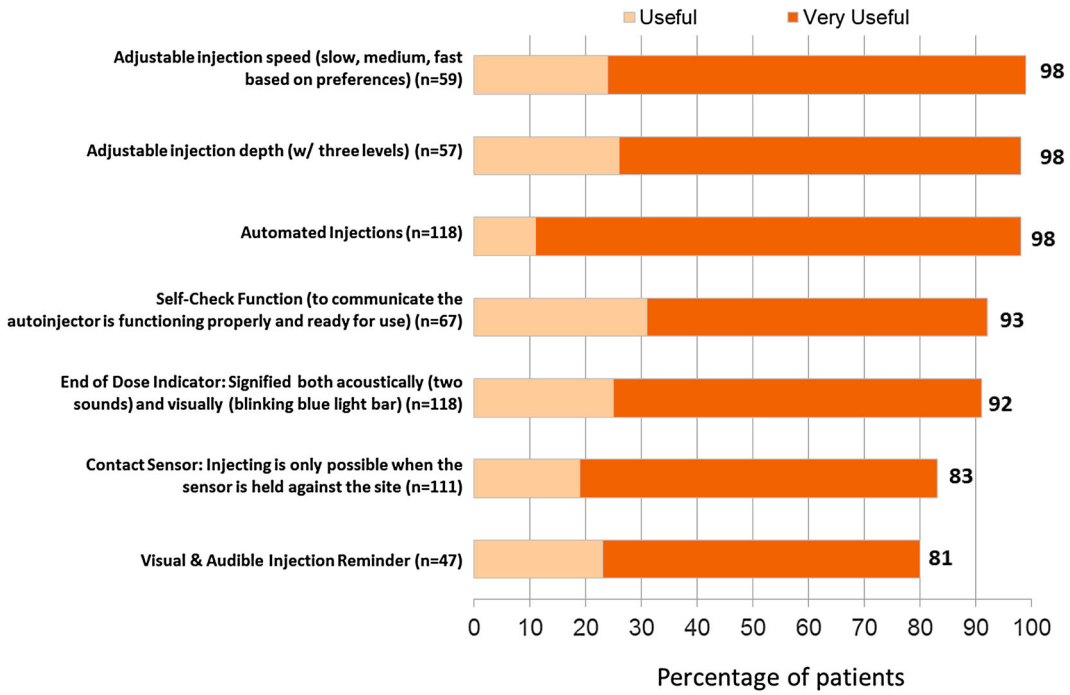

Fig. 4 Usefulness of BETACONNECT™ features. *Base*: respondents aware of/using feature and who did not answer "don't know"

reduces the chance of starting an injection by accident.

Effect of BETACONNECT on the Patient Experience

Participants using the various features of BETACONNECT largely agreed they had a beneficial effect on their injection experience (Fig. 6). Among those personalizing their injection depth ($n = 57$) and speed ($n = 59$), 88% and 81%, respectively, thought that these features make injecting more comfortable. Moreover, 73% agreed that the quietness and effortlessness of the BETACONNECT autoinjector reduced their level of anxiety about injecting. BETACONNECT also received positive ratings regarding its ease of handling: 92% agreed that the size and shape of BETACONNECT makes it easy to handle during injections and 68% thought that BETACONNECT makes it easier to reach injection sites. Moreover, 67% agreed that the autoinjector decreases the level of injection site pain. These results also suggest that BETACONNECT may help improve compliance, as 80% of those using the reminder function thought they were less likely to miss an injection.

DISCUSSION

Interferon beta-1b is an injectable DMT with an established and favorable long-term safety and efficacy profile for patients with MS [22–24]. In addition, administration of DMTs using an autoinjector can reduce the number of adverse events such as injection site reactions, increase adherence to treatment, and improve patients' quality of life [6, 8, 25]. Whilst it is known that the use of an autoinjector is generally superior to manual injection for administering DMTs [6],

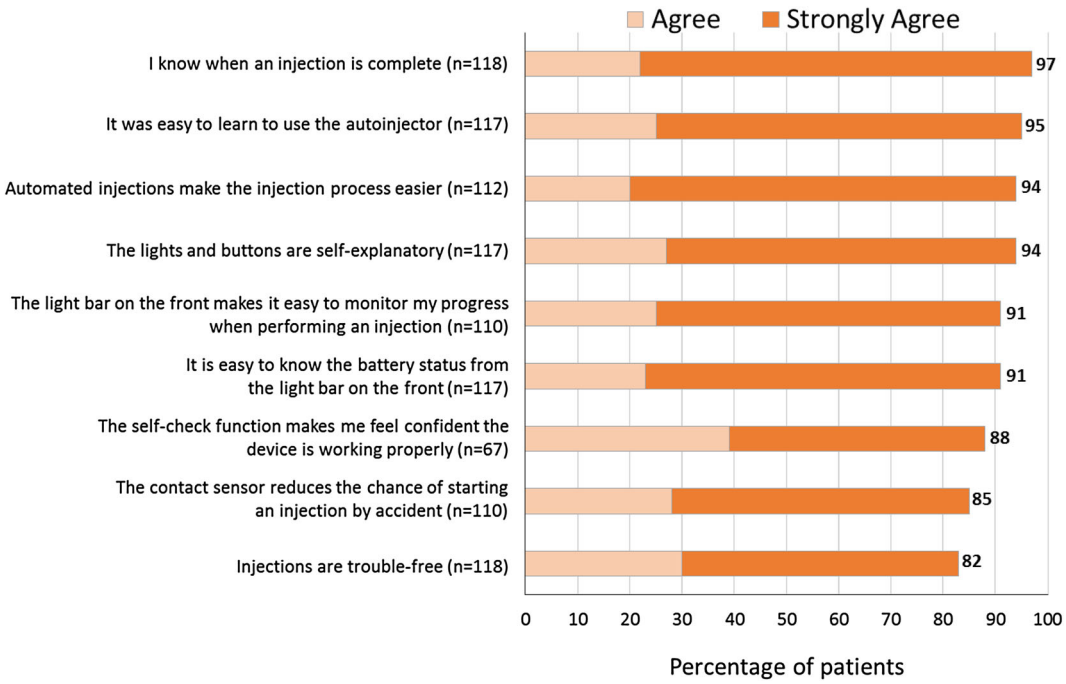

Fig. 5 Intuitiveness and ease of use of the autoinjector. *Base*: respondents aware of/using feature and who did not answer "don't know"

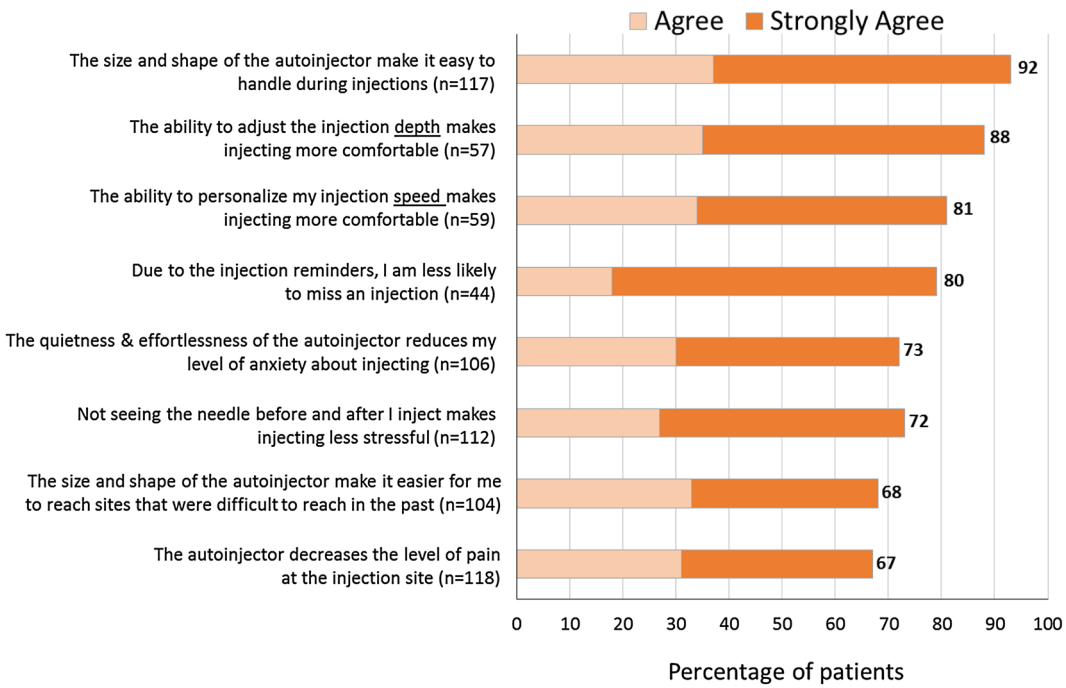

Fig. 6 Effect of BETACONNECT™ on the patient experience. *Base*: respondents aware of/using feature and who did not answer "don't know"

ongoing improvements in autoinjector design represent additional opportunities to improve interferon beta-1b therapy. Two of the problems associated with most mechanical autoinjectors are the noise of operation and that the needle is not hidden after the injection process [19]. These issues may contribute to needle/injection phobia, and in fact a survey of patients with MS reported that among those using mechanical autoinjectors, most users (54%) were unsatisfied or only moderately satisfied with their device [14]. As such, there is considerable scope to improve patients' injection experience, with many of these needs being met by the development of autoinjectors such as BETACONNECT. BETACONNECT features a fully electronic silent injection process and a needle that is hidden before, during, and after injection. Nevertheless, it is particularly important to measure patient satisfaction with new autoinjectors, such as BETACONNECT, as increased treatment satisfaction is associated with better adherence, as shown by numerous studies covering a wide range of medical conditions and treatments, including MS [21, 26]. For patients with MS, satisfaction with treatment (odds ratio [OR] 1.54; 95% CI 1.20–1.98; $P = 0.0007$) and ease of injection (OR 1.47; 95% CI 1.15–1.87; $P = 0.002$) were independent predictors of DMT adherence [21].

A patient satisfaction survey has recently been reported by Weller et al. [27] and forms the precursor to the current report. Weller et al. [27] surveyed the use of the BETACONNECT autoinjector in 1365 patients using a 13-question structured paper survey to gauge overall satisfaction with the device and the relative importance of its features. They found that 88% felt that the autoinjector was good or very good, 92% that it was helpful or very helpful, and 89% of respondents would most likely/probably recommend its use [27]. The current survey was conducted to further validate patient satisfaction with the BETACONNECT autoinjector and also to gain a much deeper understanding of the autoinjector's effect on patients' injection experience. Though only 118 patients completed the current survey, it was longer (lasting 15 min), and more questions were answered and in greater depth, for example, using an open-ended question on reasons for satisfaction with BETACONNECT. It is known that quantitative patient satisfaction surveys benefit by supplementation with open response fields that allow patients to add free-text comments [28]. Free-text comments allow patients to think freely and communicate their opinions openly, and so may reflect something closer to an accurate patient experience than a reliance on structured questions and answers alone. Potential weaknesses of the current study are that it was performed in an uncontrolled setting and without a longitudinal follow-up, and had a relatively small sample size.

The overall results from the current survey show a preference for BETACONNECT over the previous device or method of injection and suggest that using the BETACONNECT autoinjector may increase satisfaction with treatment among patients on interferon beta-1b therapy. General impressions of using the BETACONNECT injector in the current survey were extremely favorable. These results are also in line with another study where "overall convenience" was cited by patients with MS as the most common benefit of using another autoinjector [29], whereas in other surveys better control of needle depth and injection speed was the most common response given as a desirable feature of autoinjectors for MS therapies [12, 14]. It is interesting to note that less skin irritation/pain and smoother injection were the second and

third most common reasons given to be satisfied with BETACONNECT. This may reflect new BETACONNECT features such as its four-phase injection technology to help reduce the risk of an injection site reaction and its smooth fully electronic (rather than mechanical) operation.

CONCLUSIONS

Results from this study confirm the positive impact of the new BETACONNECT autoinjector and the relevance of its features in reducing injection site pain, promoting comfort, smooth injections, and ease of use, including improved ability to reach injection sites. As such, BETACONNECT represents a valid option for people that require interferon beta-1b injections for the improvement of their overall injection experience. More studies are currently underway to evaluate BETACONNECT with regard to patient adherence and persistence.

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Compliance with ethics guidelines. All procedures followed were in accordance with the 1964 Declaration of Helsinki and its subsequent revisions. Informed consent was obtained from all patients included in the study. This article describes a non-interventional study, and so does not involve any new studies of human or animal subjects performed by any of the authors.

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