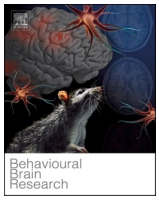
Behavioural Brain Research 479 (2025) 115361

Contents lists available at ScienceDirect

Behavioural Brain Research

journal homepage: www.elsevier.com/locate/bbr



Research article

Four weeks standard vs. one week accelerated intermittent Theta Burst Stimulation for the treatment of depression – A retrospective analysis

Katharina Dragon [a,*], Carina Janthur [b], Tobias Hebel [a], Mohamed A. Abdelnaim [a], Andreas Reißmann [a], Berthold Langguth [a], Martin Schecklmann [a]

[a] Department of Psychiatry and Psychotherapy, University of Regensburg, Regensburg, Germany
[b] University Medical Center, University of Regensburg, Regensburg, Germany

ARTICLE INFO

Keywords:
Major depressive disorder
(Accelerated) intermittent theta burst stimulation (aiTBS)
Transcranial magnetic stimulation (TMS)

ABSTRACT

Introduction: Intermittent Theta Burst Stimulation (iTBS), a specific form of repetitive transcranial magnetic stimulation (rTMS) is increasingly used for treating affective disorders. Accelerated iTBS protocols (aiTBS) with shorter treatment duration may lead to equal but faster response rates compared to standard protocols.
Methods: Here, we retrospectively analyzed the records of 66 rTMS in- and out-patients with major depressive disorder in a tertiary care hospital between April 2023 and September 2023. All patients received left prefrontal iTBS with 1200 pulses, either one session/workday over 4 weeks ($n = 34$) or left prefrontal aiTBS on five sessions/workday for one week ($n = 32$). Depressive symptoms were assessed with the 21-item Hamilton Depression Rating Scale (HAMD-21) and the Major Depression Inventory (MDI) before and at the end of the respective treatment.
Results: With both treatments, iTBS and aiTBS, the severity of depression improved significantly according to HAMD-21 and MDI. Response rates for iTBS were 38 % (HAMD-21) and 35 % (MDI), for aiTBS 19 % (HAMD-21) and 16 % (MDI), respectively. Remission rates showed a similar pattern. Effect sizes for group differences were small to medium. No serious adverse events occurred in any group. Tolerability was lower in aiTBS. Overall satisfaction was low for aiTBS on a qualitative and subjective level.
Conclusion: aiTBS with 1200 pulses and five daily sessions lead to amelioration of symptoms within one week. But benefit, satisfaction, tolerability was slightly lower in contrast to four weeks of iTBS. For everyday clinical practice, aiTBS protocols can be considered after weighing up the logistical disadvantages, such as possible longer waiting time for new patients that want to start a therapy with TMS. Future studies should explore the optimal dosage regime (number of sessions per day, number of pulses per session) for fast and effective symptom reduction.

1. Introduction

Depression is one of the most prevalent health disorder worldwide, with a lifetime risk of developing a depressive episode reaching 15–18 % [1-3]. Major depressive disorder (MDD) was expected to be the leading cause of overall global burden of disease by the year 2023, which lead to an urgent need of fast and effective treatment options [4,5]. Repetitive transcranial magnetic stimulation (rTMS) is a non-invasive and evidence-based treatment option for people suffering from treatment resistant MDD, when stimulating the left dorsolateral prefrontal cortex (DLPFC) [6]. However, with a treatment duration of 4–6 weeks with once-daily stimulation sessions rTMS requires time and resources, which limit its applicability [7].

Intermittent theta-burst stimulation (iTBS), a patterned form of rTMS that uses 50 Hz triplets repeated at 200 ms (theta/5 Hz)-intervals, [8,9] has significantly shortened the duration of one treatment session to 3 min and has shown similar antidepressant efficacy as compared to high frequency rTMS, where on sessions lasts about 25 min [10]. Hence, to further optimize TMS treatment efficacy, accelerated iTBS protocols (aiTBS) with multiple sessions per day have been proposed [11]. Instead of spreading the stimulation sessions over several weeks, a similar number of sessions and pulses is administered within just a few days [12]. Neurophysiologic studies have shown that aiTBS can induce larger effects on cortical excitability and synaptic strengthening [13,14].

* Correspondence to: Department of Psychiatry and Psychotherapy, University of Regensburg, Universitätsstraße 84, Regensburg 93053, Germany.
E-mail address: katharina.dragon@medbo.de (K. Dragon).

https://doi.org/10.1016/j.bbr.2024.115361
Received 10 April 2024; Received in revised form 21 November 2024; Accepted 26 November 2024
Available online 27 November 2024

Regarding the clinical outcome, preliminary data suggest that aiTBS protocols are safe, well tolerated, and have a rapid onset of antidepressant effects (after 2–3 days) in patients with MDD, resulting in improved cost effectiveness [4].

In this retrospective analysis, we aimed to analyze the efficacy of iTBS compared to aiTBS in treating major depressive disorder. Clinical data consisted of a clinical interview in the sense of an external rating (HAMD-21) as well as a self-assessment questionnaire (MDI) before and after treatment (see below for further details). Additionally, we analyzed the usability, tolerability as well as the preference of our clinicians for one of the two used protocols. Regarding the clinical outcome, we hypothesized that improvement in depressive symptoms would occur regardless of the type of protocol (iTBS or aiTBS) and that both protocols would be tolerable [4]. Nevertheless, in light of the fact that each protocol can pose different challenges for everyday clinical practice, we exploratively investigated advantages and disadvantages for iTBS and aiTBS on a logistical as well as clinical level.

2. Methods and materials

This study is based on a retrospective review of the clinical records of 106 patients with uni- or bipolar depression who were treated with repetitive transcranial magnetic stimulation (rTMS) at a large, tertiary psychiatric hospital (Regensburg, Germany) between April 2023 and September 2023. This analysis was approved by the local ethics committee of the University of Regensburg (22-2958-104). All in- and outpatients referred to the TMS unit were interviewed by a psychiatrist or a clinical psychologist with experience in brain stimulation to evaluate the indication and contraindications of TMS-treatment. All patients provided written informed consents for TMS treatment and for data collection and analysis. Due to the fact that this is a retrospective analysis of records of everyday clinical practice, patients were not prospectively randomized to one of the treatments. Also, neither protocol included a sham condition to test for placebo effects.

Depressive symptoms were assessed with the Hamilton depression rating scale (HAMD-21; [15]) and the major depression inventory (MDI; [16]) before the beginning and after the end of rTMS treatment. Treatments were given and supervised by experienced psychiatric nurses or physician assistants. In the period from April to June 2023, patients were treated with aiTBS (5 stimulation sessions per day for 5 days, starting in the morning with approximately 40 min interval between sessions; overall 25 sessions) [4]. From July to September 2023 patients were treated with a standard protocol, i.e. four weeks of iTBS with one daily session/workday. All patients were treated over the left dorsolateral prefrontal cortex. Each treatment was performed with a MagVenture system (MagVenture Inc., USA) using a figure-of-8 coil aiming for a target treatment intensity of 120 % resting motor threshold (RMT). Because of local discomfort, stimulation intensity had to be lowered for some patients in some sessions to an intensity which could be tolerated. Each iTBS session consisted of 1200 pulses which had delivered good antidepressant effects in previous literature (e.g. [17]).

Only patients with complete HAMD-21 and MDI questionnaires before and after treatment were included in the analyses. Additionally, only patients with at least 15 treatment sessions in the iTBS condition (75 % of the intended treatment) were included into the analysis. In the interests of comparability, also only patients with at least 15 sessions in the aiTBS condition were included into further analyses. Further, we included only patients with an average stimulation intensity of at least 110 % RMT. The number of analyzed patients and reasons for exclusion can be found in the CONSORT Flow Diagram (Fig. 1).

All statistical analyses were conducted with SPSS version 28.0 (IBM SPSS, Chicago, IL). Due to the use of two depression measurements, threshold level of significance was adjusted for multiple comparisons by Bonferroni's correction ($p = 0.025$). For effect sizes we used Cohen's d [18](partial η^2 or the phi-coefficient (φ). By convention (Cohen, 1988), effect sizes are divided in small ($d = 0.2$; partial $\eta^2 = 0.01$; $\varphi = 0.1$), medium ($d = 0.5$; partial $\eta^2 = 0.06$; $\varphi = 0.3$), and large effects ($d = 0.8$; partial $\eta^2 = 0.14$; $\varphi = 0.5$). Response was defined as $\geq$ 50 % reduction in the combined mean score on the MDI and HAMD from baseline to end of treatment. Remission rates were defined as a maximum total value of 20 points in the MDI and a maximum value of 10 in the HAMD-21 respectively. Both depression questionnaires as well as responder- and remission rates were defined as primary outcome measures. For the analysis of the course of the depressive symptoms, we calculated two mixed analyses of variance (ANOVA) with time as within factor (2 levels: before and after treatment) and group as between factor (2 levels: iTBS and aiTBS). In case of a significant interaction, a post-hoc t-test was performed. Group differences were calculated by chi-square tests of independence or Student t-tests.

Side effects were quantified by the number of patients reporting a side effect in at least one of the TMS sessions. Assessments were done at baseline (up to 7 days before start of rTMS treatment or) and after treatment (up to 4 days after the last rTMS session) which means that the interval between the two assessments differed between the two groups (1 week vs. 4 weeks). All demographic and clinical characteristics of the enclosed patients are provided in Table 1.

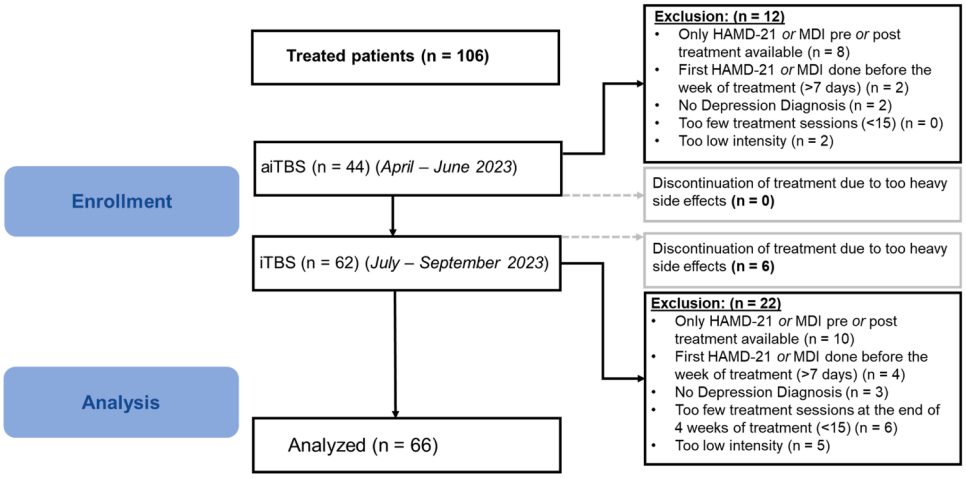


Fig. 1. CONSORT flow diagram. Flow-chart showing total number of treated patients, exclusion and participation throughout the chosen time frame. *Important note:* Some patients have been excluded for more than one reason.

Table 1
Demographic and clinical data of the present sample.

	iTBS (n = 34)	aiTBS (n = 32)	Statistics for group comparisons
General variables			
sex: m/f	9/25	14/18	$\chi^2 = 2.19$, df = 1, $p = .141$; $\varphi = 0.181$
age: $\bar{x}$ (SD)	49.74 (17.34)	45.50 (16.56)	t(64) = 1.014, $p = .315$, $d = .25$
age: range	20 – 84	20–85	
In-/Outpatient: *n*	26/8	30/2	$\chi^2 = 3.83$, df = 1, $p = .050$; $\varphi = 0.241$
Type of Depression (ICD-10)			
Unipolar/bipolar Depression (F3): *n*	33/1	31/1	$\chi^2 = 0.002$, df = 1, $p = .965$; $\varphi = 0.005$
Comorbid Diagnoses (ICD-10)			
Neurotic, anxiety and somatoform disorder (F4): *n*	5	10	$\chi^2 = 2.57$, df = 1, $p = .109$; $\varphi = 0.197$
Personality disorder (F6): *n*	3	4	$\chi^2 = .24$, df = 1, $p = .628$; $\varphi = 0.060$
Other psychiatric diagnoses (F1, F2, F8 and F9): *n*	5	4	$\chi^2 = .10$, df = 1, $p = .757$; $\varphi = -.038$
TMS variables			
no. of weeks	4	1	
percentage of sessions completed (%)	93.40 (7.55)	91.12 (10.44)	t(64) = .759, $p < .451$, $d = .19$
Resting motor threshold (%): $\bar{x}$ (SD)	46.12 (9.41)	43.47 (8.75)	t(64) = 1.182, $p = .241$, $d = .29$
Intensity of treatment (%): $\bar{x}$ (SD)	52.47 (8.02)	50.34 (8.07)	t(64) = 1.074, $p.287$, $d = .26$

3. Results

3.1. Efficacy

Response rates for standard iTBS were 38 % (HAMD-21) and 35 % (MDI), for aiTBS 19 % (HAMD-21) and 16 % (MDI), respectively. Remission rates for standard iTBS were 29 % (HAMD-21) and 44 % (MDI), for aiTBS 16 % (HAMD-21) and 25 % (MDI), respectively. This difference did not reach significance with a small effect size (see Table 2 for details).

Table 2
Mean questionnaire scores (baseline and end of treatment) with response and remission rates.

	iTBS (n = 34)	aiTBS (n = 32)	Statistics for group comparisons
HAMD-21			
Scores at baseline: $\bar{x}$ (SD)	19.30 (5.30)	22.00 (6.80)	t(64) = − 1.861, $p = .067$, $d = .46$
Scores at end of treatment: $\bar{x}$ (SD)	12.90 (5.82)	16.76 (7.23)	t(64) = − 2.393, $p = .020$, $d = .59$
response (yes/no)	13/21	6/26	$\chi^2 = 3.05$, df = 1, $p = .081$;
response rate	38 %	19 %	$\varphi = 0.215$
remission (yes/no)	10/24	4/28	$\chi^2 = 2.82$, df = 1, $p = .093$
remission rate	29 %	13 %	$\varphi, = 0.207$
MDI			
Scores at baseline: $\bar{x}$ (SD)	33.65 (8.18)	34.34 (10.20)	t(64) = − .307, $p = .380$, $d = .08$
Scores at end of treatment: $\bar{x}$ (SD)	20.53 (10.01)	28.38 (11.62)	t(64) = − 2.947, $p = .004$, $d = .73$
response (yes/no)	12/22	5/27	$\chi^2 = 3.34$, df = 1, $p = .068$;
response rate	35 %	16 %	$\varphi = 0.225$
remission (yes/no)	15/19	8/24	$\chi^2 = 2.65$, df = 1, $p = .103$;
remission rate	44 %	25 %	$\varphi = 0.201$

Notes. HAMD-21: Hamilton Depression Scale 21 items. MDI: Major Depression Inventory.

Fig. 2 provides changes in depressive symptoms over the course of the treatment for each subject. A mixed ANOVA regarding the HAMD-21 data revealed a significant effect of time ($F(1,64) = 40.59$, $p < .001$, partial $\eta^2 = .388$). There was no significant interaction between time and group ($F(1,64) = 0.35$, $p = .558$, partial $\eta^2 = .005$) (see Fig. 2). Further, a mixed ANOVA regarding the MDI data also revealed a significant effect of time ($F(1,64) = 63.48$, $p < .001$, partial $\eta^2 = .498$). A significant interaction was found between time and group ($F(1,64) = 8.92$, $p = .004$, partial $\eta^2 = .122$). A subsequent post-hoc t-test with a new variable (difference: post treatment – pre treatment) regarding between subjects effects revealed that the mean difference in the aiTBS condition was significantly lower ($\bar{x} = -6.13$, SD = 9.00) than in the iTBS protocol ($\bar{x} = -12.63$, SD = 10.46) ($t(61) = -2.64$, $p = .011$, $d = 9.77$) (see Fig. 3).

3.2. Tolerability

Six out of 62 patients that were treated with the four-week iTBS protocol could not be included in the analysis because they discontinued treatment early due to side effects: 4 patients discontinued treatment due to heavy headaches, one patient discontinued treatment due to dizziness and one patient discontinued treatment due to unmanageable fatigue. In the aiTBS group, no patient discontinued treatment prematurely due to side effects.

Otherwise, no serious side effects occurred for patients that finished the respective treatment. The following side effects were registered: Regarding the iTBS group, 5/34 patients indicated mild headaches, and 2/34 patients reported dizziness. Concerning the aiTBS condition, 11/32 patients reported mild headaches, 2/32 local pain, 1/32 mild dizziness and 1/32 patients reported tiredness after treatment. A chi-square test was used to compare the two treatment groups and the occurrence of any side effects (5 patients with side effects in the iTBS group and 15 patients in the aiTBS group). Results show a significant association between treatment group and side effects ($\chi^2(1) = 8.08$, $p = .004$, $\varphi = -0.350$).

3.3. Feasibility

Qualitative feedback from physicians, patients, raters and handlers was characterized by reservation and skepticism towards aiTBS. Non-standardized interviews with the clinicians revealed that they had a negative clinical impression of the effectiveness of the treatment. From a practical perspective, approximately the same number of patients can be treated with iTBS or aiTBS within four weeks - for iTBS all patients in parallel, for aiTBS sub-groups of patients week by week. However this also implied, that treatment start was delayed for many patients in the aiTBS group. This inherent waiting time led to complaints from the patients and the hospital occupancy management. Furthermore, we observed with iTBS more flexibility. If one patient quit the treatment the next patient could start in the week thereafter (treatment start is always on Mondays) for iTBS. For aiTBS this empty time slot in this week could not be filled up easily and led to high organizational efforts for the team. If the time slot for treatment could not be filled up waiting time increased overall. In addition, the expectations for aiTBS were high, whereas the effectiveness was rated rather low which was in accordance to the statistical analyses.

As an advantage of aiTBS, it should be noted that our clinicians felt more comfortable treating the same patients repeatedly over the course of one week than treating several different patients (iTBS). Nevertheless, they noted that the relationship to the patients wasn't as deep as in the iTBS protocol, where they were in contact with the patients over a longer period of time.

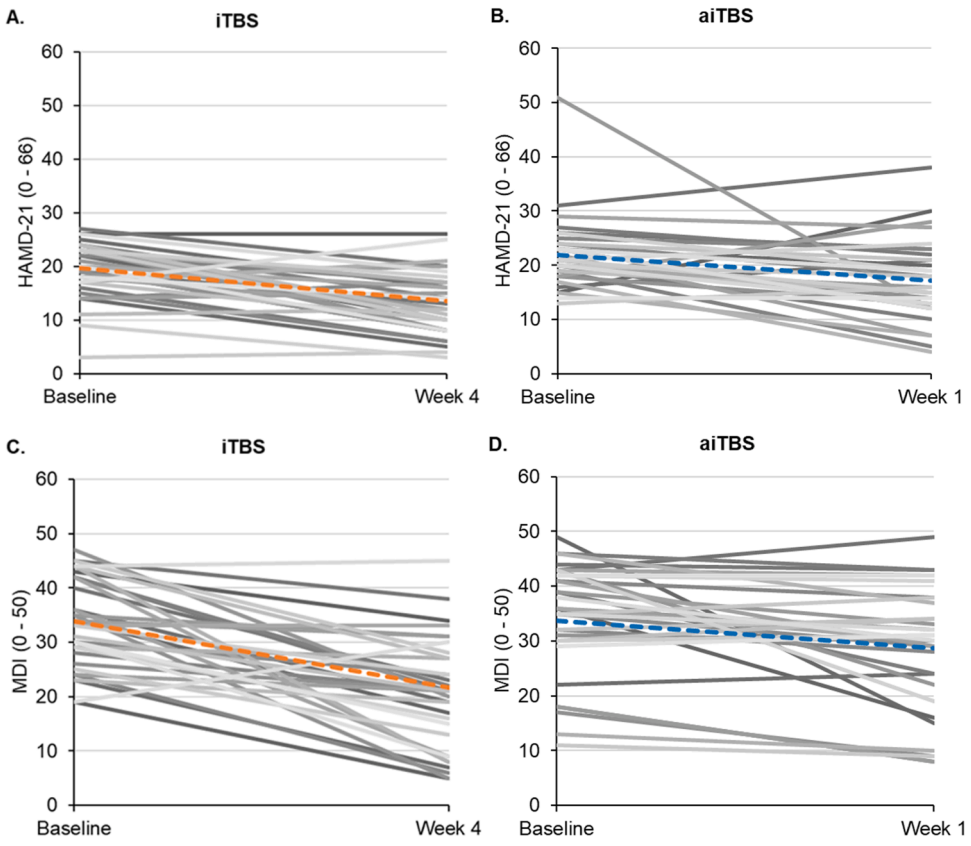


Fig. 2. Course of the depression scores for each patient as well as the mean course for the iTBS condition (orange) and aiTBS condition (blue): the Hamilton depression rating scale (HAMD-21) for (**A.**) the iTBS condition and (**B.**) the aiTBS condition and the Major Depression Inventory for (**C.**) the iTBS condition and (**D.**) the aiTBS condition. SDs are not plotted for presentational purposes.

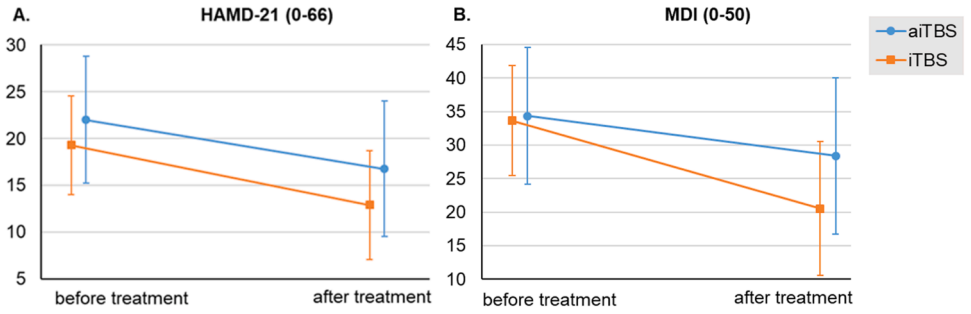


Fig. 3. Mean scores and SDs for aiTBS (blue) and iTBS (orange) before and after treatment for (**A.**) Hamilton Depression Rating Scale and (**B.**) Major Depression Inventory.

4. Discussion

The aim of the present retrospective analysis was to investigate the effectiveness, tolerability and usability of an aiTBS protocol (5 stimulations per day for one week) in comparison to a standard iTBS protocol (1 stimulation per day for 4 weeks) (April–September 2023) in a tertiary care hospital in Germany.

In our analysis, we found that patients improved with the aiTBS treatment, but amelioration of depressive symptoms tended to be smaller with aiTBS as compared to standard iTBS. In detail MDI scores improved significantly less with aiTBS as compared to standard iTBS, whereas no such difference was found in the HAMD scores. Response and remission rates showed a similar trend but the differences did not reach significance levels. Our result regarding significant reductions of the depression symptoms is in line with the current literature for the iTBS condition [19] and aiTBS condition [20,21]. The result of a slightly lower effectiveness of aiTBS treatment goes in line with the clinical impression of staff members. Thus our data suggest, that the treatment effect cannot be accelerated simply just by compressing the treatment sessions. Considering that rTMS exerts its clinical effects by inducing neuroplastic alterations, which require a certain time to develop, one could speculate, that such delayed effects might be particularly pronounced after the accelerated paradigm. Nevertheless, a study by Baeken et al. [22] found that only four days of active aiTBS induces grey matter volume (GMV) increases in areas of the brain well documented to be involved in the pathophysiology of treatment resistant depression. Accordingly, although it appears that similar neuroplastic processes occur regardless of the protocol, another important point that can affect neuronal excitability must be emphasized: our retrospective analysis did not take medication use into account. Benzodiazepines have been shown to have a dampening effect on the effectiveness of TMS [23]. It cannot be excluded that in the aiTBS group, that had more patients with a

comorbid anxiety diagnosis (ICD-10: F4), there were some patients with confounding medicine intake. On the other side, medication changes or effects of additional treatment are more likely over the course of four weeks than over the course of 5 days. In future studies, a systematized record of ongoing medication should be considered. Further, the studies by Cole et al. [24,25] included only patients whose primary diagnosis was depression. In our retrospective analysis, it cannot be ruled out that the enrolled inpatients primarily suffered from another symptom from the F4 spectrum, e.g. PTSD, which would also explain the lower effects in the aiTBS group than in the iTBS one. Additionally, we are well aware that the present analysis might be biased by the difference of assessment time points.

Regarding the response- and remission-rates in the iTBS protocol, our results go in line with the findings of an exploratory meta-analysis by [26], who found 35.5 % responder- and 18.6 % remission-rates after daily theta-burst stimulation. In terms of the aiTBS data, our findings also go in line with previous literature, e.g. the investigation by Duprat et al. [20] who found 18 % responders (HAMD-17) after one week of treatment with a four-day aiTBS protocol. It is important to note, that the authors found a further rise in the response rate up to 38 % after follow-up assessments after 4 weeks, highlighting again the need for follow-up data to detect possible delayed responses.

Even though we found an association between treatment group and side effects (more side effects for aiTBS), we registered no serious adverse effects and only few minor side effects (mild headaches, dizziness, mild pain sensations and tiredness) in both groups confirming that an aiTBS protocol is also a safe antidepressant treatment option [4,20]. The fact that we recorded more side effects in the aiTBS condition could have been confounded by the fact that we analyzed more in- than outpatients. The inpatients might have had potentially more complex clinical symptoms that required inpatient admission with what they may not have been able to cope with an intensified treatment. Although more side effects occurred in the aiTBS condition, no patient discontinued the accelerated treatment for this reason. The lack of dropout rate is comparable to the results of the SAINT protocol by Cole et al. [24,25], who even administered twice as many sessions per day. In contrast, more non-adherence was recorded in the iTBS group, where some patients discontinued treatment e.g. after just 3–5 sessions due to intolerable side effects. Ultimately, this might speak in favor of faster treatment with aiTBS, in which presumably more side effects are accepted because of the shorter treatment duration per se. Future studies should take this into account in randomized trials. A high number of patients as reported in meta-analyses will finally show if side effects are really comparable between iTBS and aiTBS protocols.

With respect to the usability of an aiTBS protocol, we registered difficulties regarding logistical aspects such as longer waiting lists (compared to the standard iTBS protocol) and consequent complaints from the patients and the hospital, a more superficial relationship between the clinicians and patients, time-consuming planning for our clinicians, and a rather low rated effectiveness. Furthermore, clinicians had a better clinical impression of the treated patients after the longer protocol leaving the question open whether the amount of interaction with the patients, respectively the elapsed time influences an expected outcome. Clinicians and patients were overall in high anticipation of very good outcomes after the novel form of treatment with just one week.

Limitations: First, our data have to be interpreted cautiously, as patients were not randomized to the two treatments and as this retrospective analysis did not include a sham control group. Previous sham-controlled studies investigating aiTBS protocols have shown improvements in both, active and sham conditions [22]. Here, the allocation of patients to one of the two treatment protocols was based on logistical aspects (e.g. long access routes for some patients living far away from the clinic). Further, this retrospective analysis lacks of standardized interviews regarding preference of the protocol for both, clinician and patient. The use of a standardized questionnaire would also have made it possible to make statements about the preferences of protocol regarding different age groups or treatment setting. The selection bias present in the analysis (patients were only included if they had at least 15 treatment sessions in either group) presumably led to the small effect sizes found. Previous controlled investigations have found larger effects, e.g. in the SAINT-protocol by Cole et al. [24,25]. Further, due to the lack of follow-up data, we cannot exclude, that there might be delayed clinical effects, occurring after end of treatment.

Clinical implications: In conclusion, this retrospective analysis indicates that aiTBS protocols may be one alternative to standard treatment over weeks in the future, with several open issues yet to be resolved. Future studies will need to include a standardized examination of e.g. an expectation attitude before or spontaneous feedback from the clinician after the respective treatment for identifying possible interference variables. Just as a side notice we applied 1200 pulses per session and five sessions per day. It is an open issue how much pulses or how many sessions are most effective and if there is an interaction of number of daily sessions and pulse number per session.

CRediT authorship contribution statement

Katharina Dragon: Writing – original draft, Visualization, Formal analysis. **Carina Janthur:** Writing – review & editing, Visualization, Formal analysis. **Tobias Hebel:** Writing – review & editing, Investigation. **Martin Schecklmann:** Writing – review & editing, Supervision, Project administration, Investigation, Conceptualization. **Mohamed A. Abdelnaim:** Writing – review & editing, Investigation. **Andreas Reissmann:** Writing – review & editing. **Berthold Langguth:** Writing – review & editing, Supervision, Project administration, Investigation, Conceptualization.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships.

Data availability

Data will be made available on request.

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