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A survey of patient acceptability of repetitive transcranial magnetic stimulation (TMS) during pregnancy

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Abstract

Objective—Given the data that depression is common during pregnancy and that pregnant women prefer non-medication treatment options, we hypothesize repetitive transcranial magnetic stimulation (TMS) may be a treatment option. Given the novelty of TMS, we sought to assess whether patient acceptability would be a barrier to enrolling pregnant women in TMS studies.

Methods—In Study 1, 500 pregnant women were surveyed in an outpatient, urban obstetrics clinic using the Edinburgh Depression Rating Scale (EPDS) and a treatment acceptability survey. In Study 2, 51 women were surveyed with the EPDS and acceptability survey using an informational video to increase participant knowledge about TMS.

Results—Approximately 25% of participants had an EPDS score of ≥ 12 in both studies. Psychotherapy was identified as the most acceptable treatment option. TMS was considered an unacceptable treatment option to virtually all women before the informational video. After the video, 15.7% considered TMS an acceptable treatment option.

Conclusion—Psychotherapy is the most acceptable treatment option for depression to pregnant women. Increasing participant knowledge about TMS increased its acceptability significantly. Large-scale multi-center trials are needed for confirmation of these results.

Keywords

Depression; Pregnancy; Transcranial magnetic stimulation; Treatment; Acceptability

1. Introduction

The American Psychiatric Association (APA) and the American College of Obstetricians and Gynecologists (ACOG) recently convened experts in the field of reproductive psychiatry to review the evidence regarding the management of depression during pregnancy (Yonkers et

al., 2009). The expert panel published consensus treatment guidelines focusing on recommendations regarding psychotherapy and anti-depressant medications. For moderate to severe major depression during pregnancy, the guidelines recommend initiating or continuing antidepressants. Despite the relatively low risk to the fetus of maternal antidepressant treatment, some women may choose to avoid or discontinue psychotropic medication (Goodman, 2009). Others may experience significant depressive symptoms despite adequate medication doses (Cohen et al., 2006).

One potential treatment alternative to antidepressants for pregnant women with moderate to severe depression is repetitive transcranial magnetic stimulation (TMS). TMS is a Food and Drug Administration (FDA) approved device for the treatment of depression in adults who have failed one antidepressant trial. TMS non-invasively delivers focused magnetic pulses to the surface of the brain causing local neuronal depolarization. TMS has few side effects and is not associated with any cognitive impairment (Janicak et al., 2008). Both left high frequency (HFL) TMS and right low frequency (LFR) TMS of the dorsolateral prefrontal cortex (DLPFC) have been shown to be more effective than placebo in patients with depression (Daskalakis et al., 2008).

The non-pharmacologic nature of TMS eliminates concerns about fetal exposure to the potential risks of psychotropic medications, however the absolute number of pregnancies exposed to TMS remains small and the true risks unknown. There are currently 6 published case reports of TMS for the treatment of major depression during pregnancy (Klirova et al., 2008; Zhang and Hu, 2009; Nahas et al., 1999). In all cases, TMS was safe and effective for the treatment of depression during pregnancy, although there is no long-term data published on children born to mothers exposed to TMS. While data from these case reports are promising, TMS needs to be tested more extensively in pregnant women in order to examine whether pregnancy alters its efficacy and to confirm safety. However, more large-scale research addressing this question depends upon the extent to which TMS is acceptable to pregnant women as a potential treatment option. To this end, we sought to examine pregnant women's attitudes towards various depression treatment options, including TMS. This study was conducted in two phases. In the first phase (Study 1), we assessed the acceptability of TMS in a cohort of pregnant women using a simple questionnaire. In the second phase (Study 2), we assessed whether an informational video we developed regarding TMS would improve acceptability to pregnant women.

2. Methods

In Study 1, 500 consecutive women, 18 years or older, presenting for their initial prenatal visit from November 2008 to April 2009, were asked to complete a paper and pencil treatment acceptability survey (Table 1) and the Edinburgh Postnatal Depression Scale (EPDS) (Cox et al., 1996) to assess severity of present symptoms of depression as the presence of depression was thought to be a potential contributor to acceptability of various treatments. The questionnaire included in Study 1 and Study 2 was developed based upon a previous survey used to determine the acceptability of implantable antipsychotic medication among patients with psychosis (Dankert et al., 2008). Except for age 18, there were no exclusion criteria. Surveys were included with the obstetrics service's standard paperwork

for the first prenatal visit. The acceptability survey included a brief description of TMS, as TMS is a relatively novel treatment modality.

The study population was derived from an urban, hospital-based clinic at the University of Pennsylvania in which the majority of patients are insured by Medicaid. Prior to initiation, this study was approved by the University of Pennsylvania Institutional Review Board and all subjects were given a written information sheet describing the study and indicating the voluntary nature of the questionnaires. The primary outcome variable was whether the patient would indicate that they would accept TMS as a treatment during pregnancy if they were depressed or to become depressed during the course of the index pregnancy (Table 1, Question 5). Secondary outcomes include whether the subject would consider talk therapy or pharmacotherapy, acceptable frequency of treatment, and patient-identified barriers to treatment.

After analyzing the results of Study 1 (see Results section), an informational video was made to inform patients further about TMS. In Study 2, an additional 51 women were recruited in August 2009 and consented by a research assistant who was present in the obstetrics service on the day of the patient's first prenatal visit. Subjects completed a slightly modified version of the acceptability survey to include questions about perceived safety of various treatments and the EPDS prior to viewing an informational video regarding TMS in the treatment of depression during pregnancy. Subjects completed the acceptability survey again after viewing the video. The research assistant remained with the subject as they watched the video and completed the surveys, but did not provide additional information regarding TMS. The 4-minute video consisted of an actual physician (DK) and an actor patient discussing TMS, a true patient receiving TMS and a true patient providing a testimonial regarding her experience with TMS. No financial incentive was given for filling out the surveys in either study. Surveys were coded with a study identifier to protect respondent privacy and entered into a secure database. Descriptive characteristics were calculated for subject demographics and independent-samples t-tests were conducted to compare demographic characteristics of the two samples. The acceptability of each treatment was treated as a dichotomous variable (Yes/No), and t-tests were conducted to assess whether there were differences in the acceptability of the different types of treatment within and between studies. A series of binary logistic regressions was conducted to assess the relations between subject characteristics (age, race, EPDS scores, gestational age) and the acceptability of the different treatment approaches. Separate regressions were conducted for each predictor–outcome pair.

3. Results

3.1. Study 1

In Study 1, 500 women were given the survey. The response rate was 94% (30 refusals). Of the remaining 470 subjects, 8 were excluded because they were under the age of 18, and complete data was available for 460 women (92% of total surveys distributed). The mean age of the sample was 24.84 years (*SD* 5.57) and mean gestational age was 17.12 weeks (*SD* 8.09). The mean EPDS score was 8.19 (*SD* 5.89) with 37.2% of the subjects reporting an

EPDS score of 10 and 24.9% reporting an EPDS score of 12. The demographic characteristics of the study population are reported in Table 2.

Subjects first indicated whether they would consider a particular type of treatment prior to any description of TMS (Table 1, Question 1). The percentage of subjects indicating that they would consider each type of treatment is presented in Fig. 1. There was a significant difference in the level of preferences for the optional treatments described in Fig. 1; the acceptability of each treatment type differed significantly from the acceptability of every other treatment type; all $t_s(459) > 3.26$, all $p_s < 0.001$. For example, not only was talk therapy the most acceptable treatment type; this preference was significantly higher than for the next most preferred treatment which was no treatment. 43% of subjects indicated that they would consider talk therapy, 5.4% would consider medication, 0.2% would consider magnet therapy, 30.4% would not consider any treatment, and 16.7% did not know what type of treatments they would consider.

After a brief written description of TMS, subjects were asked a question to test whether they understood what they read and then were asked if they would consider TMS as a treatment option. While the acceptability of TMS was also assessed prior to the provision of information regarding TMS, due to the very low percentage of subjects indicating that they would consider magnet treatment on this question (Study 1:0.2%, Study 2:0%), all analyses concerning the acceptability of TMS address subjects' willingness to consider TMS after this information was provided (Table 1, Question 5). Subjects were significantly more likely to indicate that they would not consider TMS (50.9%) or were not sure (25.2%) than to indicate that they would accept TMS (9.3%) as a treatment option ($t(459)=-7.61$, $t(459)=-6.90$, respectively, both p values < 0.001). There was not a significant difference in the proportion of women who indicated that they would not consider TMS compared to those who indicated that they were not sure ($t(459)= 0.71$, $p > 0.05$). Of the 363 women who provided an answer to the fact-check question, 73.8% answered correctly.

As TMS requires daily treatment and psychotherapy weekly treatment, we also assessed the acceptability of treatment frequency. The survey asked subjects to indicate the frequency with which they would be willing to attend treatment. The cumulative percentage of subjects indicating that a given treatment frequency was acceptable are presented in Fig. 2. Most subjects (48%) indicated that there was no limit to the frequency with which they would be willing to attend treatment; an additional 26% reported that they would be willing to attend treatment once per week and 20% would be willing to attend treatment once per month. When specifically asked whether they would consider a treatment that required daily visits for a four-week period of time (as per most TMS protocols), 16% of subjects indicated that they would consider this treatment frequency, 44% of subjects indicated that they would not consider this treatment frequency, and 40% were unsure.

Predictors of treatment acceptability were assessed using binary logistic regression (see Table 3). The only significant predictor of the acceptability of talk therapy was EPDS score; higher levels of depressive symptoms were associated with increased acceptability of this treatment type (OR=1.03, 95% CI 1.00–1.10). Both age and depressive symptoms were significant predictors of the acceptability of medication treatment; older subjects (OR=1.17,

95% CI 1.05–1.19) and subjects with higher levels of depressive symptoms (OR=1.19, 95% CI 1.12–1.27) were more likely to indicate that they would consider treatment with medication. Accuracy in response to the fact-check question was the only significant predictor of the acceptability of TMS; subjects who correctly responded to the fact-check question were more likely to indicate that they would consider this treatment option (OR=1.67, 95% CI 1.04–2.69).

The most common barriers to treatment reported by subjects are presented in Table 4. Difficulty arranging transportation for treatment, a belief that symptoms would improve without intervention, and difficulty accommodating work schedules were the most commonly reported barriers for treatment.

3.2. Study 2

In Study 2, 51 women were given the survey and shown the informational video. The response rate in Study 2 was 100%. The mean age of the sample was 24.39 years (*SD* 5.88) and mean gestational age was 16.82 weeks (*SD* 8.25). The mean EPDS score was 7.84 (*SD* 6.95) with 39.2% of the subjects reporting an EPDS score of 10 and 29.4% reporting an EPDS score of 12. In Study 2, we also asked if women had received prior mental health treatment; 18% reported that they had. There were no significant differences between the two samples with respect to age ($t(509)=0.54, p=0.59$), gestational age ($t(509)=0.25, p=0.30$), EPDS scores ($t(509)=0.40, p=0.35$), or ethnicity ($\chi^2(2)=2.70, p=0.26$).

Subjects indicated whether they would consider each treatment type both before and after watching the informational video. As in Study 1, before viewing the informational video, there were significant differences among the treatments; the acceptability of each treatment type differed significantly from the acceptability of every other treatment type, with the exception of no treatment versus don't know, which did not differ significantly from one another ($t(50)=0.69, p=0.50$), and medication versus magnet treatment, which no subjects indicated they would consider. Most subjects (64.7%) indicated that they would consider talk therapy, 0% would consider medication, 0% would consider magnet therapy, 21.6% would not consider any treatment, and 15.7% did not know what type of treatments they would consider. After viewing the informational video, 80.4% of subjects indicated that they would consider talk therapy, 5.9% would consider medication, 15.7% indicated that they would consider magnet therapy, 9.8% would not consider any treatment, and 0% did not know what type of treatments they would consider. McNemar's test indicated that there was not a significant difference in subjects' willingness to consider talk therapy after watching the video ($p > 0.05$). Subjects were less likely to indicate that they would not consider any treatment option after watching the video ($p < 0.05$).

Subjects were also specifically asked to indicate whether they would consider magnet treatment after reading a brief written description of the treatment and answering a fact-check question. Before watching the informational video, 13.7% of subjects indicated that they would consider magnet treatment, 70.6% would not, and 15.7% were not sure (Fig. 3). 77.1% of subjects correctly answered the fact-check question. After watching the informational video, 13.7% of subjects indicated that they would consider magnet treatment, 52.9% would not, and 33.3% were not sure (Fig. 3). 93.6% of subjects correctly answered

the fact-check question. The acceptability of TMS changed significantly following the informational video ($p < 0.05$). Using McNemar's test, a significant difference was found in the rates at which subjects reported that they would definitely or possibly consider magnet treatment after watching the video (47.0%) than before (29.4%).

In Study 2, subjects were also asked to rate the degree to which they perceived each treatment to be safe. Subjects' ratings of the perceived safety of each type of treatment before and after the informational video are presented in Fig. 4. In order to compare the perceived safety of the treatments before and after the informational video, subjects' ratings were converted to a 4-point scale. There was no significant change in subjects' confidence in the safety of medication (Before: $M=1.80$, $SD=0.96$, After: $M=1.68$, $SD=0.96$, $t(49)=0.63$, $p > 0.05$) or talk therapy (Before: $M=3.88$, $SD=0.48$, After: $M=3.94$, $SD=0.24$, $t(49)=-0.90$, $p > 0.05$) following the video. There was a slight increase in subjects' confidence in the safety of magnet treatment after watching the video (Before: $M=1.88$, $SD=0.98$, After: $M=2.14$, $SD=0.95$). This difference approached significance, $t(49)=-1.91$, $p=0.063$, with an effect size in the moderate range, $d=0.27$.

4. Discussion

To our knowledge, this is the first study examining the acceptability of TMS as a treatment option for depressed, pregnant women. Approximately 25% of our sample would have met criteria for major depressive disorder based on the EPDS scores. This is similar to depression rates previously reported using patient-rated, screening instruments in obstetric clinics (Marcus et al., 2003) but higher than the prevalence reported when clinician-rated standardized interviews are utilized (Uguz et al., 2010). Our sample was a low income, urban population likely increasing the exposure to risk factors for depression in pregnancy (Lancaster et al., 2010).

Virtually no women would consider TMS as an acceptable treatment when given a list of possible treatments for depression during pregnancy. However, when women are given more information about TMS, its acceptability increased. In Study 2, 15.7% of subjects reported they would consider TMS after watching the video compared to none before the video. The informational video also decreased the number of women who would not consider TMS and increased the number of women who would possibly consider it. The video did not affect the number of women who definitely accepted TMS as a treatment option. Although baseline knowledge about TMS in pregnant women is limited, when given fairly brief information, pregnant women are willing to consider it as a treatment.

Our data indicate that psychotherapy is very acceptable to most pregnant women and as per the APA/ACOG guidelines (Yonkers et al., 2009) regarding the treatment of depression during pregnancy should be a first-line treatment option. However, for women who do not respond to psychotherapy, TMS is a potential non-pharmacologic treatment for depression during pregnancy. TMS was recently FDA approved in October 2008 and, knowledge regarding its safety and efficacy was not wide spread among our population of pregnant women. Although academic centers may have TMS devices, access to these centers is limited and specific training is required to dose and perform TMS. The general mental

health practitioner is unlikely to have access to or the training to use the device. Our informational video was developed to bridge this lack of knowledge regarding TMS. Another potential acceptability issue would be the time burden associated with receiving TMS treatments. Most treatment protocols require treatment daily for at least 20 sessions. Despite this time burden, pregnant women may be a good target population for this treatment and our findings suggest that education regarding the nature of the procedure is likely to enhance its acceptability to patients. In our sample (Study 1), an unexpectedly high proportion of subjects (50%) were agreeable to daily treatment for 4 weeks. TMS has a low burden of side effects but is time intensive. It was surprising to see how many women did not view this level of time commitment as a barrier.

In our study both attitudinal and structural barriers regarding mental health treatment were identified. O'Mahen and Flynn (2008) surveyed an urban population similar to ours and found that only 12% of depressed, pregnant women were receiving formal psychiatric treatment (O'Mahen and Flynn, 2008). In their sample women were more likely to have confidence in psychotherapy than antidepressants and African American women expressed less confidence in antidepressants compared to white women. Women were most likely to report insurance, inability to pay, transportation and inadequate childcare as barriers to care. In the largest sample to date ($n = 509$), only 33% of pregnant women reported that antidepressants were an acceptable treatment option during pregnancy (Goodman, 2009). Time, stigma and child care were the 3 top-rated barriers to help-seeking in this population. In another study, only 23% of pregnant women surveyed reported antidepressants were an acceptable treatment during pregnancy but race was not predictive of treatment preference (Sleath et al., 2005). Women with moderate to severe depression were more likely to report antidepressants as acceptable compared to women with mild depression in contrast to the Goodman study which found lower depression scores and prior medication use predicted acceptability of antidepressants. In Study 1, we evaluated predictors of treatment acceptability. Increased EPDS scores were associated with increased acceptability of psychotherapy and medication. In addition increased age was associated with increased acceptability of medications. The only factor associated with the acceptability of TMS was correctly answering the fact-check question, suggesting that improving knowledge about TMS improves acceptability. It was surprising that given that increased EPDS scores were only associated with increased acceptability of other treatments but not TMS. We hypothesize that it is such a novel treatment that this outweighed any potential impact of other predictive factors.

4.1. Conclusion

Depressive symptoms during pregnancy are common with approximately 25% of our general obstetrics clinic reporting significant symptoms which would likely meet criteria for a major depressive episode. In our sample as in other samples, psychotherapy was the most acceptable treatment option. We examined the acceptability of a novel, non-pharmacologic treatment, TMS. With increased knowledge about TMS, pregnant women are willing to consider it as a treatment for depression.

4.2. Limitations

We were not able to determine what about the informational video improved patient acceptability. It is possible that other educational tools would have been just as effective. In addition, we did not use this sample to enroll patients in a TMS clinical trial so that we did not test how many patients reporting acceptability would actually go on to treatment. Because of time constraints, depression symptoms were only evaluated using a self-report instrument and were not confirmed with a clinical interview. This would have enhanced our understanding of how depression impacts treatment acceptability. Lastly, we only tested our hypothesis in a single sample and our results would benefit from confirmation in a larger scale, multi-center study.

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Fig. 1.
Percent of subjects indicating they would consider each treatment option.

Fig. 2.
Acceptability of rTMS treatment.

Fig. 3.
Acceptable treatment frequency (cumulative percentage).

Fig. 4.
Perceived safety of treatment options.

Table 1

Acceptability questionnaire.

Date _____

Race: ☐ Caucasian ☐ Black ☐ Hispanic ☐ Native American ☐ Other

Last menstrual period _____

Your age _____

Are you pregnant? (circle one)

YES NO

These questions are being asked as part of a research study. Your treatment will not be based on your answers which are confidential. Please take the time to fill this out. Circle your answer to each question.

1. If you needed mental health treatment during pregnancy, which would you choose (circle many as you want)?

Talk therapy Medication Magnet treatment None Don't know

2. If you needed mental health treatment during pregnancy, how often would you be willing to see a mental health professional (check one only)?

Once a day Once a week Once a month As often as I needed to

3. If you could get a medication-free treatment, would you be willing to be seen by a mental health professional every day for 4 weeks?

Yes No Not sure

4. Magnet treatment is a study treatment for depression that can be used instead of medications. A strong magnet is put on your head for a short time every day for 4 weeks. This has to be done at a doctor's office. Bad effects are unusual but can include pain, hearing loss and seizures.

PLEASE ANSWER THE FOLLOWING QUESTION:

Magnet treatment for depression involves having a device put on my head for a short time everyday for 4 weeks. (Circle one)

True False

5. If you were depressed during your pregnancy, would you consider magnet treatment as a possible option?

Yes No Not sure

If you checked no, please write why you would not consider magnet treatment as a possible option for you

6. If you needed mental health treatment during your pregnancy, what would stop you from getting help? (check as many as you want)

___ No transportation

___ No insurance

___ I do not believe that treatment will/would help me

___ Not enough money

___ No childcare

___ Work schedule

___ I do not trust mental health system

___ No family/partner support

___ I hope that I will/would feel better on my own

___ I would worry that my mental health problems will be reported to DHS (Child Protective Services)

Table 2

Demographic characteristics of samples.

Variable	Study 1			Study 2		
	n	Range	<i>M</i> (<i>SD</i>)	n	Range	<i>M</i> (<i>SD</i>)
Age	460	18–44	24.84 (5.57)	51	18–41	24.39 (5.88)
Weeks pregnant	460	1–40	17.12 (8.09)	51	2–37	16.82 (8.25)
EPDS	460	0–27	8.19 (5.89)	51	0–28	7.84 (6.95)
	n	%		n	%	
Ethnicity	460			51		
Black		79.3			70.6	
Caucasian		4.2			5.9	
Hispanic		4.2			1.96	
Other		12.2			21.57	
Previous mental health treatment		Not assessed		51	18	

Table 3

Odd ratios of factors associated with the acceptability of treatment options.

Outcome predictor	OR (sig)	95% CI
<i>Talk therapy</i>		
Age	0.98 <i>ns</i>	0.95–1.02
EPDS	1.03 *	1.00–1.10
Ethnicity		
Caucasian	1.12 <i>ns</i>	0.39–3.24
Black	1.45 <i>ns</i>	0.78–2.71
Hispanic	1.66 <i>ns</i>	0.59–4.69
Weeks pregnant	1.01 <i>ns</i>	0.98–1.03
<i>Medication</i>		
Age	1.17 **	1.05–1.19
EPDS	1.19 ***	1.12–1.27
Ethnicity		
Caucasian	1.58	0.24–10.22
Black	0.86	0.25–3.09
Hispanic	0.00	0.00
Weeks pregnant	1.03	0.98–1.08
<i>Magnet</i>		
Fact-check accuracy	1.67 *	1.04–2.69
Age	0.99	0.96–1.03
EPDS	1.01	0.97–1.05
Ethnicity		
Caucasian	1.20	0.38–3.79
Black	0.97	0.48–1.98
Hispanic	1.67	0.54–5.14
Weeks pregnant	1.00	0.98–1.02

* $p < 0.05$,

** $p < 0.01$,

*** $p < 0.001$.

Table 4

Barriers to treatment (%).

Barrier	Study 1	Study 2
Transportation	21.1	21.6
Hope will feel better on own	17.0	23.5
Work schedule	14.1	13.7
No money	10.4	7.8
Childcare	7.8	3.9
Don't believe treatment will help	7.8	5.9
Insurance	7.8	7.8
Dept health services *	5.9	9.8
Don't trust mental health system	3.9	9.8
No support	2.2	3.9

* Worried that child protective services would be called.