

<b>Authorising Committee:</b>	Board
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<b>Document Code:</b>	<b>PS 79 PPC Repetitive Transcranial Magnetic Stimulation</b>

## 1. Introduction

Repetitive Transcranial Magnetic Stimulation (rTMS) is a therapeutic, medical procedure for the treatment of psychiatric disorders, such as major depression. There is robust evidence base for its therapeutic effectiveness in major depressive disorders. rTMS is emerging into general psychiatric practice in Australia and New Zealand but is currently only available in certain academic and tertiary medical centres.

## 2. What is TMS?

rTMS involves the focal application of magnetic energy to the cerebral cortex, inducing small electrical currents with the aim of altering brain function for therapeutic purposes. The treatment does not involve seizure induction or loss of consciousness. The patient is completely alert during the procedure and an anaesthetic is not required. rTMS is usually administered multiple times a week for four to six weeks, though the optimal treatment schedule is still being refined. Maintenance rTMS - further treatments given after the acute course to prevent relapse - may be a useful strategy, but is yet to be thoroughly investigated.

## 3. Evidence of efficacy

### *Depression*

- 3.1. An evidence base of over 30 randomised controlled trials involving a placebo-control (sham stimulation) has demonstrated that rTMS has efficacy in the treatment of depression (effect size from a recent meta-analysis of the active-sham comparison was 0.55) (Slotema et al, 2010). Thus, rTMS should be considered an effective treatment for depression.
- 3.2. Those referred for rTMS for management of a severe depressive episode have generally inadequately responded to initial medication trials and focused psychological therapy sessions (defined as treatment resistant depression). Those with treatment resistant depression who respond to rTMS treatment (of the order of 50% of patients) will subsequently experience a lower burden of disease both subjectively and functionally. Over the past several years, the evidence for efficacy has been compelling for this population group, with a shift towards consistently positive findings following refined treatment parameters.

### *Schizophrenia*

- 3.3. The evidence base for the use of rTMS in schizophrenia is less substantive than that for depression. Clinical trials have examined the use of rTMS to treat symptoms of schizophrenia, particularly auditory hallucinations, and also negative symptoms (including cognition). Randomised controlled trials involving a placebo control comparison, have found rTMS to have beneficial effects in reducing the severity and/or frequency of auditory hallucinations. A recent meta-analysis and review of these studies concluded there is evidence of efficacy for rTMS as a treatment for auditory hallucinations (Matheson et al. 2010).
- 3.4. A full review of evidence can be accessed through the suggested further reading at the end of this statement.

## 4. rTMS use with other treatments

- 4.1. Treatment with rTMS can occur in combination with psychological therapies or medications. This depends on the care needs and symptom profile of the particular patient. Studies have compared rTMS and ECT in major depressive disorders. A meta-analysis of this limited evidence found rTMS was not as effective as electroconvulsive therapy, and rTMS should not be seen as a replacement for ECT (Slotema et al 2010). Currently there is no evidence to support the use of rTMS and ECT concurrently. The treatments should be seen as complementary with partial overlap in the patient populations treated, e.g. some patients whose depression does not warrant treatment with ECT may be appropriately treated with rTMS.

## 5. Clinical indications

### *Major Depression*

- 5.1. rTMS should be offered in psychiatric clinical settings with appropriate protocols, training and equipment to appropriately selected patients with major depression

### *Refractory hallucinations in schizophrenia*

- 5.2. rTMS may be offered on a restricted basis to carefully selected patients with schizophrenia who have auditory hallucinations that have not improved with adequate trials of antipsychotic medications. This should only be performed in tertiary referral centres with appropriate expertise.

### *Other psychiatric disorders*

- 5.3. Until further data are available, rTMS should only be used for the treatment of other psychiatric disorders within a research protocol which has had formal ethical review and approval .

## 6. Patient selection

- 6.1. The screening and selection of appropriate patients is essential and should be conducted by a psychiatrist with appropriate training and expertise in rTMS.
- 6.2. There is little safety data on the use of rTMS in pregnant women. The use of rTMS in this group requires a careful assessment of the patient's situation and detailed informed consent. Careful discussion of known and potential risks of rTMS compared to alternative modalities of treatment is needed. Outcomes in this group should be closely monitored and where possible employed to better inform an empirical evidence base in this group
- 6.3. There is little safety and efficacy data on the use of rTMS in children and adolescents. rTMS should only be given to those aged under 16 within an approved research protocol. The use of rTMS in older adolescents requires a careful assessment of the patient's situation, their family situation, their developmental stage and maturity, their capacity to provide informed consent and disclosure of known and potential risks. The opinion of a specialist child and adolescent psychiatrist should be sought. Outcomes in this group should be closely monitored and where possible employed to better inform an empirical evidence base in this group
- 6.4. Informed consent is essential for all patients considering rTMS. Enough information and time should be provided for patients to make an informed decision along with families and caregivers. The consent process must be undertaken by a psychiatrist with knowledge and expertise in rTMS therapy, and should detail alternative treatment considerations, the possible benefits of rTMS, and possible adverse effects.

## **7. rTMS administration and adverse effects**

- 7.1. rTMS should be prescribed by a psychiatrist.
- 7.2. rTMS should be administered by a medical practitioner or an appropriately trained mental health clinician under the supervision of a psychiatrist.
- 7.3. Patients should be monitored during a course of TMS, and this should include their progress and any side effects.
- 7.4. Potential adverse effects of rTMS include scalp pain and facial muscle twitching during stimulation, headache, induction of mania, hearing impairment (if ear protection is not used), and induction of a generalised seizure.
- 7.5. The research to date indicates that TMS is relatively safe when patients are carefully screened for relevant exclusions, including seizure risk, and treatment is given within recommended safety parameters and evidence based guidelines. With appropriate screening, the overall risks are low.
- 7.6. Clinical trials have found no cognitive impairment when rTMS is given within recommended parameters.

## **8. Credentialing and training**

- 8.1. Each institution that conducts clinical rTMS treatment should have in place formal policies and procedures which govern the prescription and use of rTMS, qualifications, training and credentialing of clinicians involved, treatment protocols, process for monitoring outcomes – efficacy and adverse events – and clinical indicators, as well as the appropriate maintenance of rTMS machines and ancillary equipment.
- 8.2. The psychiatrist should have appropriate expertise and be credentialed by his/her institution for the rTMS treatment. There should be continuing professional education to ensure the psychiatrist is kept updated on treatment advances.
- 8.3. Each institution that conducts clinical rTMS treatment should have a process for ensuring the adequate training of rTMS practitioners and a process of credentialing, such that practitioners have appropriate levels of both theoretical knowledge and practical experience. All personnel who administer rTMS should be properly trained in the theory, technique and safe operation of rTMS.
- 8.4. All personnel who administer rTMS should be properly trained in the identification, assessment and early management of unexpected complications from rTMS, including seizures. Appropriate facilities to manage any complications from rTMS, including seizures, should be available.
- 8.5. All personnel who administer rTMS should also have appropriate mental health expertise and supervision.
- 8.6. Each institution should have a formal time period for re-credentialing of personnel involved with rTMS.

## **9. Future directions**

- 9.1. The College promotes ongoing research into rTMS. Further optimisation of treatment protocols, utility in different patients groups, and efficacy for other psychiatric conditions are important foci of ongoing research.
- 9.2. A considerable percentage of efficacy trials conducted for the use of rTMS have included subsets of patients with bipolar depression although few studies have targeted this group in stand-alone trial. In trials conducted to date patients with bipolar disorder have shown similar response rates to rTMS as patients with non bipolar depression. Further trials in this area should increase understanding of the use of rTMS for bipolar depression.

9.3. rTMS should be available in private and public medical settings and should be accessible and, where appropriate, offered as a potential therapeutic option for the treatment of major depression.

9.4. Transcranial Direct Current Stimulation (tDCS), another innovative brain stimulation treatment that does not involve seizure induction, has shown promise in recent trials for the treatment of depression. Until further data is available, it should only be given within approved research protocols.

## Further Reading

Fitzgerald PB, Daskalakis ZJ. A practical guide to the use of repetitive transcranial magnetic stimulation in the treatment of depression. *Brain Stimulation* 2012; 5: 287-296.

Fitzgerald PB, Daskalakis ZJ. The effects of repetitive transcranial magnetic stimulation in the treatment of depression. *Expert Rev. Med. Devices* 2011; 8: 85–95.

George MS, Lisanby SH, Avery D et al. Daily left prefrontal transcranial magnetic stimulation therapy for major depressive disorder. *Archives of General Psychiatry* 2010;67:507-516.

Loo CK, McFarquhar TF, Mitchell PB. A review of the safety of repetitive transcranial magnetic stimulation as a clinical treatment for depression. *International Journal of Neuropsychopharmacology* 2008; 11: 131–147.

Loo CK, Mitchell PB. A review of the efficacy of transcranial magnetic stimulation (TMS) treatment for depression, and current and future strategies to optimize efficacy. *Journal of Affective Disorders* 2005; 88: 255–267.

Matheson SL, Green MJ, Loo C et al. Quality assessment and comparison of evidence for electroconvulsive therapy and repetitive transcranial magnetic stimulation for schizophrenia: A systematic meta-review. *Schizophrenia Research* 2010; 118: 201-210.

O'Reardon JP, Solvason HB, Janicak PG, et al. Efficacy and safety of transcranial magnetic stimulation in the acute treatment of major depression: a multisite randomized controlled trial. *Biological Psychiatry* 2007; 62: 1208–1216.

Slotema CW, Blom JD, Hoek HW et al. Should we expand the psychiatric toolbox to include repetitive transcranial magnetic stimulation (rTMS)? A meta-analysis of the efficacy of rTMS in psychiatric disorders. *Journal of Clinical Psychiatry* 2010; 71: 873-884.

Royal Australian and New Zealand College of Psychiatrists. Consultation Decision Analytical Protocol to guide the assessment of repetitive Transcranial Magnetic Stimulation as a treatment for major depression. Submission to the Therapeutic Good Administration Protocol Advisory Subcommittee 2012.

## REVISION RECORD

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