

Funding for Transcranial Magnetic Stimulation

Paul B Fitzgerald^{1,2} & Saxby Pridmore^{3,4}

1. Professor of Psychiatry, Epworth Healthcare, Melbourne, Australia
2. Director, Therapeutic Brain Stimulation, Monash University Central Clinical School and The Alfred
3. Medical School, University of Tasmania, Hobart, Australia
4. Saint Helen's Private Hospital, Hobart

Corresponding author: Prof. Pridmore, Email: s.pridmore@utas.edu.au

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Major depressive disorder (MDD) is common, painful and disabling; in addition to patients, work colleagues, friends and family are negatively impacted. The currently available antidepressant drugs are not always useful – all achieve remission in only a proportion of cases, and none universally prevent relapse. They have troublesome side-effects (which may precipitate discontinuation), and are often used in suicidal behaviour.

Transcranial magnetic stimulation (TMS) was first demonstrated to be potentially safe and effective in the management of treatment resistant (tr)MDD, more than 20 years ago (Pascual-Leone, 1996). Its efficacy and excellent tolerability/safety profile has been confirmed by dozens of large clinical trials and meta-analyses (Lefaucheur et al, 2014).

TMS is achieved by placing an electromagnet on the scalp/hair and generating fluctuating magnetic fields, which pass through the skull and produce small electric fields in the adjacent cortex. The administration of a session of TMS is relatively safe, but not completely without risk. Headache, mood elevation and seizure are among possible adverse events, although drop-out rates in clinical trials have been low and serious adverse events are rare. It is frequently administered by a non-medically trained (but otherwise certificated) TMS Operators under psychiatric supervision. A series of TMS treatment protocols have been evaluated in patients with trMDD: the most well-established is the application of high frequency (usually 10Hz) stimulation trains to the left dorsolateral prefrontal cortex (DLPFC). There is also consistent evidence supporting the use of 1Hz TMS applied to the right DLPFC.

There are more than half a dozen manufacturers of TMS apparatus, and their recent models have similar outputs. At the current time, 'approval/acceptance of TMS' refers not to a model, supplied a particular manufacturer, but to the treatment of a certain disorder, using a certain stimulation protocol.

Throughout the world (including New Zealand, Australia, UK and US) TMS is available in occasional public, but most private psychiatric facilities. However, government authorities are yet to fully support TMS for trMDD by providing a publicly funded rebate for treatment. In Australia, for example, we are awaiting a TMS specific 'Medicare Item Number' – which we believe is justified and necessary.

Approval/acceptance of TMS for the treatment of trMDD can be viewed at three levels, 1) academic/professional bodies, 2) national health authorities, and 3) insurance companies.

Academic/professional bodies approving/accepting this TMS treatment include the Australian and New Zealand College of Psychiatrists (Practice and Partnerships Committee, 2014), the Clinical TMS Society (USA based), International Neuromodulation Society (Chapters around the world), Mayo Clinic (Minnesota), Johns Hopkins (Maryland), North Metropolitan Health Service Mental Health Neurophysiology Service (Western Australia), Metro South Addiction and Mental Health (Queensland), and many private hospital-university collaborations including those involving the Melbourne and Adelaide Clinics.

National health authorities which approve the use of TMS include the Food and Drug Administration (FDA) of the USA (Horvath et al, 2011), Canada Health (Health Quality Ontario, 2016) and the National Institute for Health and Care Excellence (NICE) which informs practice in England, Wales, Scotland and Northern Ireland.

There is limited public information available regarding the coverage by insurance companies around the world. However, in the USA, a considerable proportion of insurance companies provide coverage for outpatient TMS treatment.

A designated publicly funded rebate is required, to support the medical practitioners prescribing and supervising TMS treatment of trMDD, and the TMS Operators to deliver the stimulation.

The cost of providing TMS treatment is considerable. A standard machine costs around AUD 50 000, and a suitable patient chair, around AUD 5 000. A psychiatrist needs to be involved. A properly trained operator must be in constant attendance. A typical course consists of 20-30 treatments, over a four to six-week period. Except for those able to access one of the few public TMS services, TMS is available through private outpatient services, for those are able to pay from their own resources, in the region of AUD 170-300 per treatment (up to AUD 6 000 per course). This, naturally, applies to few patients.

There is another route to TMS treatment available to privately insured patients. Private psychiatric hospitals often have an inpatient TMS service, with the cost of treatment borne by the hospitals (drawn from insurance company contributions to the cost of hospitalization). The relapsing insured patient either waits for sufficient deterioration to justify hospitalization, or pursues hospitalization (and the associated inconvenience) before it is necessary: both options are undesirable.

The equitable availability of outpatient TMS requires the granting of a government funded rebate, to support this treatment. The role of the psychiatrist begins with specialist knowledge of this disorder, and the knowledge and experience to make the diagnosis. In the case of trMDD there is the need for knowledge of the other forms of treatment, so that resistance can be recognized and confirmed. The psychiatrist working with TMS treatment must have a complete knowledge of the treatment protocols, and must select the dosage and the appropriate stimulation parameters for the particular patient. Psychiatric knowledge and experience is also required for the proper monitoring of patient progress, for the management of side-effects and other problems, and for determining the optimum subsequent management of the patient. TMS Operators are generally experienced psychiatric nurses and recognized standards require one such professionals to be present with each patient, throughout treatment.

Electroconvulsive therapy (ECT) is regarded as the 'gold standard', being the strongest available antidepressant therapy. However, there is no significant difference in the efficiency between TMS and ECT (Chen et al (2017), and the cost of ECT is higher (Magnezi et al, 2016). There have been calls for the wide availability of TMS for many years (Slotema et al, 2010; Magnezi et al, 2016). TMS has fewer side effects than ECT. As much, if not more is known of its biological effects than electroconvulsive therapy (ECT) (Huang et al, 2017).

TMS has proven highly effective in research settings, and private practice outpatients, when a source of funding can be found (Galletly et al, 2015). The 2017 International Brain Stimulation Conference (Barcelona) was attended by almost 1000 scholars, from more than 40 nations. The time has come for governments to implement rebates for TMS, as they do for ECT; this is justified from both scientific and humane perspectives.

References

- Chen J, Zhao L, Liu Y, Fan S, Xie P. (2017) Comparative efficacy and acceptability of electroconvulsive therapy versus repetitive transcranial magnetic stimulation for major depression: a systematic review and multiple-treatments meta-analysis. *Behaviour and Brain Research* 320:30-36.
- Galletly C, Clarke P, Carnell B, Gill S. (2014) A clinical repetitive transcranial magnetic stimulation service: 6 years on. *Australian and New Zealand Journal of Psychiatry* 49: 1040-1047.
- Health Quality Ontario (2016) Repetitive Transcranial magnetic stimulation for treatment resistant depression: an economic analysis. *Ontario Health Technologies Assessment Series* 16;1-51.
- Horvath J, Perez J, Farrow L, et al. (2011) Transcranial magnetic stimulation: a historical evaluation and future prognosis of therapeutically relevant ethical concerns. *Journal Medical Ethics* 37:137e143.
- Huang Y-J, Lane H-Y, Lin C-H. (2017) New treatment strategies of depression: based on mechanisms related to neuroplasticity. *Neural Plasticity* Published online 2017 Apr 11. doi 10.1155/2017/4605971.
- Lefaucheur J, Andre-Obadia N, Antal A, et al. (2014) Evidence-based guidelines on the therapeutic use of repetitive transcranial magnetic stimulation. *Clinical Neurophysiology* 125:2150-2206.
- Magnezi R, Aminov E, Shmuel D, Dreifuss M, Dannon P. (2016) Comparison between neurostimulation techniques repetitive transcranial magnetic stimulation vs electroconvulsive therapy for the treatment of resistant depression: patient preference and cost-effectiveness. *Patient Preference Adherence* 10;1481-1487.
- Pascual-Leone A, Rubio B, Pallardó F, et al. (1996) Rapid-rate transcranial magnetic stimulation of left dorsolateral prefrontal cortex in drug-resistant depression. *Lancet* 348(9022):233-237.
- Practice and Partnerships Committee (07 January 2014) PS 79 PPC Repetitive Transcranial Magnetic Stimulation. Royal Australian and New Zealand College of Psychiatrists. [https://www.ranzcp.org/News-policy/News-archive/Repetitive-Transcranial-Magnetic-Stimulation-\(rTMS.aspx](https://www.ranzcp.org/News-policy/News-archive/Repetitive-Transcranial-Magnetic-Stimulation-(rTMS.aspx) (Accessed, 20 March 2017)
- Slotema C, Blom J, Hoek H, Sommer I. (2010) Should we expand the toolbox of psychiatric treatment methods to include repetitive transcranial magnetic stimulation (TMS)? A

meta-analysis of the efficacy of rTMS in psychiatric disorders. *Journal of Clinical Psychiatry* 71:873-884.