Equipment and rTMS Programme Set-Up 11

11.1 TMS Equipment

There are currently a progressively increasing number of TMS equipment manufacturers. However, the accessibility of equipment for the provision of rTMS treatment will vary greatly country by country, limited by local regulatory approval and the availability of local distribution.

Beyond these obvious practical issues, a number of factors should be taken into account when selecting TMS equipment for clinical application. One of the most important is the capacity of stimulators to provide stimulation in the manner required for particular treatment protocols. There is variation across stimulation devices in the ranges of frequencies and intensities able to be provided, especially at stimulation frequencies greater than 20 Hz. A common and critical consideration is whether the coil being utilised for stimulation will provide an adequate number of pulses without overheating. There is considerable variation in the systems used to provide long periods of stimulation without coil overheating across device manufacturers. These include the development of iron core coils, the integration of fluid cooling systems and fan-based cooling systems. Prior to the selection of a stimulator and coil, potential users should ensure that a sufficient number of pulses at high intensity can be provided for each individual treatment session but also that individual treatment sessions can be provided consecutively with only short between patient intervals if required.

It is also important to confirm that the system is provided with adequate accessories to ensure the smooth operation of treatment sessions. Coil stands and localisation positioning systems vary substantially across equipment manufacturers and should be evaluated prior to equipment purchase. The software system to control stimulation protocols should also be evaluated: these are progressively improving but some systems are not very end user-friendly.

A final but critical consideration is the availability of timely on-site equipment support. rTMS equipment is technically complex and utilises high electrical voltages. As such, equipment malfunction should be expected to occur occasionally and local technical staff may not be qualified to service and repair equipment. As most equipment is quite heavy and bulky, shipping back to a device manufacturer for

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repair can be expensive, slow and problematic. In establishing a clinical service, thought may be given to ensuring the availability of backup equipment to prevent the interruption of clinical programmes should equipment fail. It seems sensible and financially viable to ensure the local availability of backup coils; however, resourcing local backup stimulators may well be more problematic. Questions should be asked of distributors as to whether replacement devices on loan are available during equipment repair.

The following is a brief description of a number of currently available TMS devices and manufacturers:

11.1.1 MagVenture

MagPro TMS stimulators have been produced since the early 1990s by Tonica Elektronik in Denmark and over time sold under the brands of Dantec, Medtronic and currently MagVenture. Several MagPro devices are currently available, servicing both clinical and research TMS communities. For the treatment of depression, the most commonly utilised devices are likely to be the MagPro R30 and the MagPro R100. These machines are very similar in design and utilise the same stimulation coils. The main difference is the frequency/intensity at which stimulation can be provided: The MagPro R30 is effectively limited to below 30 Hz, whilst the MagPro R100 can provide stimulation at up to 100 Hz. In the routine treatment of depression utilising protocols in the 1–20 Hz range, this difference is insignificant and a MagPro R30 is likely to suffice. If there is a need for more experimental protocols, for example, considering theta burst and higher stimulation intensities, a R100 device may be considered appropriate.

The MagPro R30 device is relatively compact and is sold with optional accessories including a coil stand, stimulator trolley and device for displaying EMG data during the assessment of resting motor thresholds. There are a number of coils available. The most useful coil for clinical applications is a ‘dynamically’ cooled figure-of-eight coil, which is sold with a separate fluid-based cooling system. In our experience, this allows long stimulation protocols without any substantial coil overheating during or between closely spaced patient sessions. The MagPro systems have been CE approved in Europe for ‘treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from two prior antidepressant medications, at or above the minimal effective dose and duration in the current episode’.

11.1.2 Magstim

Magstim has also been selling TMS systems for many years for a variety of research and clinical applications. There are several Magstim systems available that are suitable for clinical use. These include the Magstim Rapid2, the Super Rapid and Super Rapid Plus. These three units essentially vary only in the stimulation frequencies

and intensities that are able to be applied during stimulation protocols. A choice between these devices, like the choice between the MagPro R30 and R100, will be predominately driven by user needs. A series of different coil types are available for the Magstim systems. These include a cooled coil using a fan mounted close to the coil itself. Coil stands and other accessories are also available.

11.1.3 Neuronetics

Neuronetics is an American company that has developed and commercialised the NeuroStar TMS treatment system, which has been commercially available in the USA since 2008. The system was approved by the FDA for the treatment of major depressive disorder in patients who had failed to receive benefit from antidepressant therapy based on a large multisite trial conducted across a number of countries. The device is sold as an integrated system with stimulator, coil, coil positioning system and software for assisting in estimation of the motor threshold. The commercial devices can only operate with a single use disposable 'SenStar' device in place, which is proposed to ensure adequate coil functioning and localisation. There is a significant cost for each of these devices, and they cannot be reused across treatment sessions even within an individual patient's course.

11.1.4 Other

Brainsway is an Israeli company that is in the process of commercialising a system for deep TMS using a proprietary 'H-coil'. In April 2012, the company announced positive results from a clinical trial evaluating deep TMS treatment of 233 patients across 14 sites. CE marks for marketing and sale of deep TMS systems in Europe have been granted for a number of psychiatric indications including major depression and bipolar disorder.

Nexstim is a Finnish company that manufacturers a TMS device that is predominately marketed for use in neurosurgical planning due to its integration with neuroimaging capacity. Cervel Neurotech is a venture capital-backed start-up company that is currently attempting to develop a system for deeper rTMS stimulation for clinical applications. Several other TMS manufacturers are producing devices in other countries, for example, in China and Russia.

11.2 Treatment Programme Establishment

There are potentially a number of models for the provision of an rTMS clinical service, and the appropriateness of these to local clinical and organisational needs should be considered. It is possible that rTMS could be provided within the office-based practice of an individual psychiatrist or small group of clinicians. However, this type of approach may prove problematic if insufficient patients are regularly in

treatment to justify the employment of an individual to actually provide treatment. Alternatively, rTMS treatment centres may be established on a local or regional basis, receiving referrals from a network of referring doctors and providing rTMS treatment only. This model may provide a more sensible concentration of expertise, but issues relating to the separation of rTMS from other forms of clinical care will need to be managed.

The set-up of TMS programmes will by necessity have to follow the local regulatory frameworks, including for the credentialing of TMS clinic staff. Issues to be considered and clearly articulated include the establishment of referral pathways and processes for routine and emergency clinical review. The degree to which the provision of treatment with TMS is integrated with the referred patient's overall treatment programme is something that can be established on a patient-to-patient basis but should be at least in part determined by local policy. For example, when a patient is referred to a TMS clinical programme, a clinician within the programme, preferably a psychiatrist, will need to make ongoing decisions about TMS provision: for example, whether a sufficiently adequate course has been tried, should stimulation parameters change, when treatment should stop and whether maintenance treatment should be considered.

However, simultaneously, decisions may need to be made in regard to altering other forms of treatment such as antidepressant or other medication. Regardless of whether these decisions are made by the TMS programme psychiatrist or the patient's original treating psychiatrist, communication is essential to ensure that problems do not eventuate. For example, motor threshold may need to be reassessed if medications are changed. In establishing a TMS programme, thought should be given to establishing protocols to determine how these relationships are managed. In addition, it should be clear to the patient who is responsible for routine review of their mental state and for responding to psychiatric emergency such as an escalation of suicidal ideation.

In addition, formal protocols should be developed for emergency responses during rTMS provision. These will include a seizure response protocol and a protocol for response to other forms of loss of consciousness such as syncope. Documentation is required for the prescription of rTMS treatment and recording of all aspects of stimulation provided (see examples in the following chapter).

11.3 Patient Information and Consent

As with all significant medical procedures, patients should be provided with sufficient verbal and written information as to the nature of rTMS treatment, its risks and its potential benefits to allow them to provide informed consent. This information should include a discussion of the short-term nature of the research trials from which rTMS treatment has evolved, the potential risk of seizure induction

and the possibility of side effects such as treatment-related discomfort, pain and headache. Patients should be informed in advance of the need to disclose any changes in medical status or medication treatment and drug or alcohol consumption during the course of rTMS therapy. Ideally they should also be informed as to the processes for emergency responses during the course of rTMS treatment and the roles of clinicians with whom they will have contact.