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Troubleshooting Complications of Intrathecal Baclofen Therapy

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Abstract

Intrathecal baclofen (ITB) is a well-recognised treatment for severe spasticity refractory to oral medications. However it is known to have a significant complication rate with serious potentially fatal consequences of baclofen overdose or withdrawal. It is therefore essential that patients receiving ITB therapy are managed by responsive, accessible multidisciplinary services with a systematic and timely approach to troubleshooting complications when they occur. A troubleshooting algorithm is presented here to facilitate prompt and effective investigations and treatment; this tool can be adapted by individual services to suit their own particular patient cohort and healthcare setting.

Keywords: Intrathecal baclofen; Troubleshooting; Algorithm; Complications; Spasticity

Introduction

Intrathecal baclofen (ITB) was first used in 1985 for spinal cord injury [1] and has since been shown to be an effective treatment in the management of severe spasticity of either cerebral or spinal origin [2-5] and in monophasic or progressive conditions [6,7].

In long-term follow-up studies, the benefit has proved to be sustainable over time [8-11], with many individuals demonstrating high levels of satisfaction and continuing to benefit following a pump replacement once the battery life of the original pump has been depleted.

Use of intrathecal baclofen requires a coordinated approach by an experienced multidisciplinary team including a neurologist or rehabilitation physician, neurosurgeon, physiotherapists, nurses, and occupational therapists. The process involves careful patient selection, detailed assessment including a trial of ITB, implantation and importantly both responsive and accessible follow up as ITB therapy is not without risk of complications. Whenever complications are suspected investigation and treatment should be instigated promptly and in a systematic way [1].

Complication rates of ITB therapy vary between published studies depending on their definition of adverse events, the population studied and the follow up period, rates are however not insignificant and range between 4 and 25%. Complications can be considered as mechanical (ie a hardware issue with the pump or catheter), infection related, drug or procedure related (for example baclofen overdose or deep vein thrombosis). Mechanical complications are the most frequently observed; these usually involve catheter malfunction (disconnection, kinks, breaks or displacement) [13-15]. Pump dysfunction is rare with the use of baclofen but corrosion of the internal tubing causing a motor stall can occur particularly if pumps are used off label with drug mixtures [16]. Data reported from Medtronic through their Implantable Systems Performance Registry on 7,459 patients with pumps (21.6% for intractable spasticity) revealed a total of 1,393 product performance events in 982 patients enrolled (13.17%), 75.7% of these were related to catheter malfunction [17].

Investigation of potential system malfunction

If there is any suspicion of ITB system dysfunction (symptoms of over or under dosage or failure to gain control of spasticity on escalating dosages) it is important to investigate promptly to avoid potentially fatal withdrawal syndromes. There is no agreed consensus on the process used for investigation; previously published algorithms have looked at different aspects including troubleshooting in the outpatient setting, managing ITB withdrawal and overdose as well as extensive investigations of the pump system [18-20].

We present our troubleshooting algorithm illustrated in Figure 1 which is based on the author's own experience of ITB practice and takes a pragmatic approach ensuring investigation is sufficient to ensure confidence in the need for surgical intervention but also prevents delay in diagnosing mechanical complications. The National Hospital for Neurology and Neurosurgery, University College London Hospitals has been utilising ITB since 1994 (currently 155 patients under ITB pump follow up). The choice of particular investigations and the order they are used will of course be influenced by investigation availability and the particular nuances of the patient concerned. Other investigations not included in our algorithm, such as magnetic resonance imaging (MRI) or radio-isotope scintigraphy [21], are available however on a pragmatic note the demonstration of a non-functioning catheter requires surgical replacement and there is therefore often no need to proceed to extensive investigation and imaging.

The first stage of investigation when suspecting ITB system malfunction is to take a careful history exploring the presence of, and addressing, any noxious stimulus (for example infection, concomitant medication effects, pressure sores, bladder and bowel dysfunction, undiagnosed fractures or deep vein thrombosis and importantly progression/remission of underlying neurological disorder). It is also important to explore whether there are any precipitants to ITB treatment failure such as recent falls, MRI, or rarer causes of pump malfunction such as high dose radiation, SCUBA diving, use of

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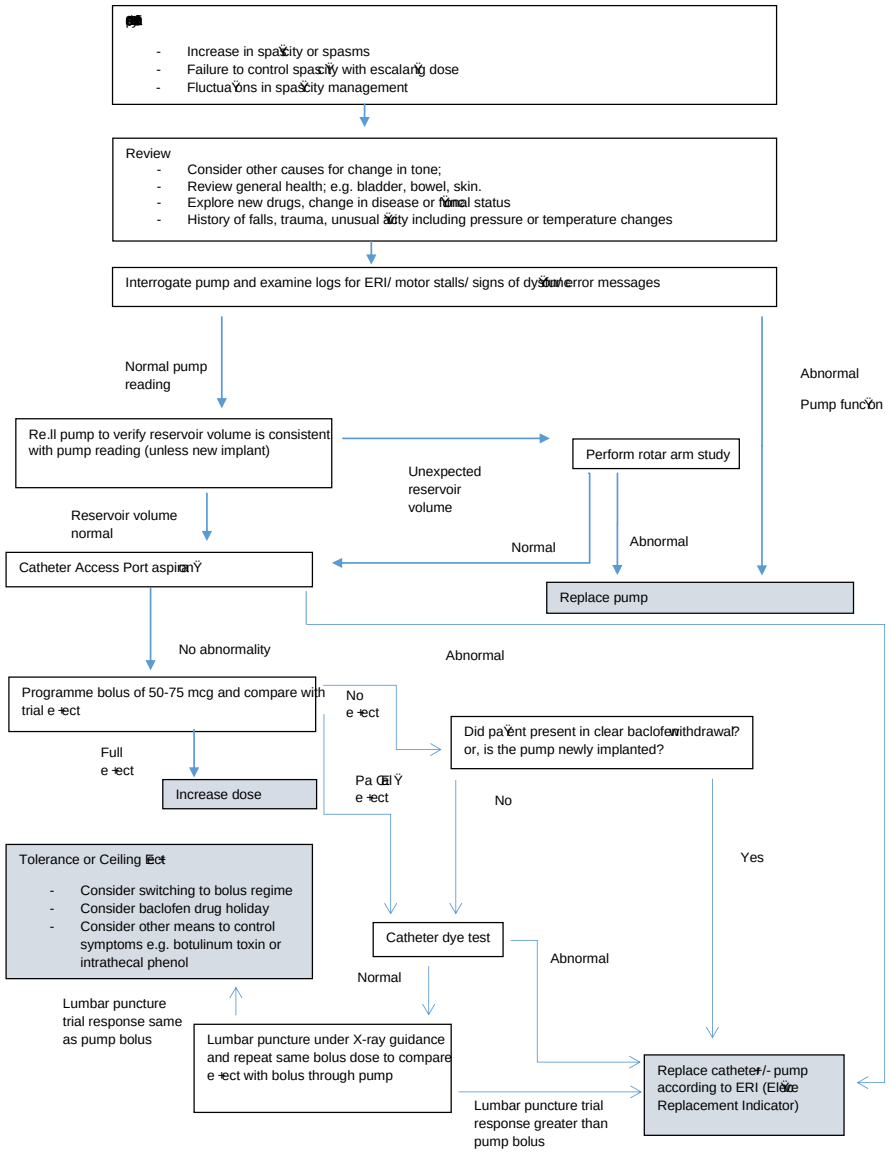

Figure 1: Algorithm for ITB troubleshooting. Adapted from Stevenson VL. Intrathecal baclofen and phenol: Spasticity Management, A Practical Multidisciplinary Guide. 2nd ed. Taylor and Francis. 2016; 129-160 [12].

hyperbaric oxygen chambers or vibration plates [12].

If these factors are excluded or managed and spasticity remains problematic then it is vital to proceed swi ly to pump system investigation.

3XPS LQWHUURJDWLRQ DQG UHVHUYRLU YROXPH YHUL FDWLRQ

Electronic pumps have alarms to alert if any problems are occurring although these can sometimes be overlooked by patients or their carers. Whether or not an alarm is sounding, the electronic pump status can be checked by reading the pump with the programmer; this will identify the nature of any pump problem. In addition, an ongoing regular check for pump e ciency can be made when the reservoir is re lled. e actual volume of baclofen removed from the reservoir can be checked against the expected amount: more or less than the expected volume (outside of accepted tolerances of ~15%) could indicate an over- or under-infusing pump.

Bolus dose testing

e pump can be programmed to deliver a bolus equivalent to a trial test dose (usually 50-75 mcg) over a few minutes. Hence the original ITB trial can be reproduced and outcome measures assessed at 4 hours. If the system is functioning the e ect should mimic the trial, particularly if this is used in the early post-implantation period to assess for surgical problems at implantation. If loss of baclofen e ect occurs several years a er implantation or the e ect of a programmed bolus is partial it is sometimes useful to perform a bolus via lumbar puncture (taking care not to puncture the catheter; X-ray or ultrasound can be useful for this) at the same dose as the pump programmed bolus to compare the response. A di erence in e ect implies a catheter leak necessitating surgical replacement of the catheter, where as an equal e ect suggests either a ceiling e ect (no additional bene t on escalating doses) or rarely the development of baclofen tolerance (the e ect ameliorating over time).

vaccine design.

Conoclusion

is study indicated that the VP4 gene of the isolate belonged to genoty pe P[7], while the VP7 gene belonged to the genotype G[5]. e experimental infection model showed that the new isolate is pathogenic str ain. is experimental infection model has established a foundation for further studies on vaccine development.

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