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SHORT COMMUNICATION

USE OF BOTULINUM TOXIN TYPE A IN MANAGEMENT OF ADULT SPASTICITY – A EUROPEAN CONSENSUS STATEMENT

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INTRODUCTION

There has been a considerable increase over the last few years in the use of botulinum toxin type A in the treatment of adults with spasticity. It is considered the pharmacological treatment of first choice in focal spasticity. Botox® currently has a licence for post-stroke wrist and hand spasticity in all European countries (except the Netherlands), but this is extended in France and Switzerland for upper limb spasticity. Dysport® has a licence in France and Spain for upper limb spasticity and in Italy for upper and lower limb spasticity. Clinical standards of care are also being developed in neurological rehabilitation and nowhere is this more relevant than in spasticity treatment. Botulinum toxin is perceived as an expensive treatment in an area of medicine, where there have not traditionally been cost-pressures on pharmacy budgets. It has come to the awareness of health providers at the same time as other relatively expensive new treatments and technologies in restorative neurology and rehabilitation. While the drug is considered to be of good value in its benefits to patient management, its safety record and its duration of action over 12–16 weeks, it falls upon clinicians to utilize the treatment as efficaciously as possible.

Clinical guidelines for the use of botulinum toxin type A in the management of adults with spasticity have thus been produced in the UK (1), which have looked at the current evidence for its indications and use and, where this is not available, have drawn a consensus of opinion from the expert panel of clinicians in rehabilitation medicine, neurology, physiotherapy and occupational therapy. They have been adopted by the Royal College of Physicians of London Clinical Effectiveness & Evaluation Unit (2, 3) as a guidance to good practice and will eventually be submitted for further evaluation for use in the UK National Health Service. Similarly a series of articles appeared in a supplement to *Muscle & Nerve* in 1997 (4) giving good information on the state of the art at that time in spasticity management and they were used to influence clinical practice in North America and across the world. Because of the differences in the health systems across Europe, such a document is more difficult to produce, as aspects that are relevant in one country may not be relevant another. As a result, any guidelines to fit all the countries of Europe would be so basic, that they would not say very much and would not influence clinical practice.

With this in mind, a working party of doctors known for their expertise in using botulinum toxin assembled to create a set of statements highlighting best practice, which could be applied across all European countries. Again, the panel looked at the evidence base to agree the statements below and, where there was none, the members agreed on best practice, as applied to their own countries and health systems. What has thus been produced are simple practical statements that can be used in each European state and which will help clinicians from all professions and medical fields ultimately to develop standards of care though clinical guidelines in the future. It is not intended as a work of scientific merit and does not go into the mechanisms of spasticity or of the underlying disorders contributing to the impairment.

The panel looked primarily at the evidence base for botulinum toxin type A, as most clinical trials have been conducted with that sero-type. The evidence base therefore cannot necessarily be extrapolated to other formulations and the panel did not feel qualified to do so.

EUROPEAN CONSENSUS STATEMENT

Introduction

Spasticity commonly follows damage to the central nervous system (brain and spinal cord) and presents in conditions such as stroke, brain and spinal injury of traumatic and non-traumatic causes, multiple sclerosis, cerebral palsy and in a variety of ways depending on the size, location and age of the lesion. It is an involuntary muscle overactivity, which may have several harmful effects such as pain, deformity and impaired function.

Botulinum toxin type A is a highly effective treatment in the management of spasticity and has an innovative role where the clinical goals are focal. There is now considerable well-

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documented experience of its use and knowledge of its indications, effects and safety in clinical practice.

Recommendations

- Spasticity management is a multi-disciplinary activity and should only be undertaken where appropriate personnel and facilities are available.
- Before using botulinum toxin type A (BTX-A), the team must ensure that an appropriate rehabilitation management programme is in place and available post-injection. This has not been defined, but one that is specifically designed to assist the patient meeting the treatment goals.
- Patients should be selected for BTX-A treatment depending on the pattern of their spasticity, the dynamic spastic component, clearly identified goals of treatment and their ability to meet those goals.
- Prior to treatment, patients and their families and carers should be given appropriate information and should agree with the treatment goals.
- Targeted intramuscular injections of BTX-A must only be given by clinicians with experience in diagnosis and management of spasticity, which includes appropriate knowledge of functional anatomy, and clinical dosing regimens.
- Following an injection of BTX-A it is possible to achieve an optimal clinical benefit only with a programme of exercise, muscle stretch and/or splinting.
- BTX-A is currently commercially available as BOTOX® (Allergan) and Dysport® (Ipsen). These 2 preparations are different and 1 unit of BOTOX® is not the same as 1 dose of Dysport®. A proven dose ratio has not been established.
- The clinical team should formally evaluate the outcome of treatment, which requires a set of measurements before and after the injection of BTX-A.
- Whilst the management of spasticity is a long-term process, a defined period of BTX-A treatment can facilitate patients and carers achieving their goals.

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