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Cutaneous cooling to manage botulinum toxin injection-associated pain in patients with facial palsy: A randomised controlled trial☆

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KEYWORDS
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Summary *Introduction:* Botulinum toxin injections are an effective, well-established treatment to manage synkinesis secondary to chronic facial palsy, but they entail painful injections at multiple sites on the face up to four times per year. Cutaneous cooling has long been recognised to provide an analgesic effect for cutaneous procedures, but evidence to date has been anecdotal or weak. This randomised controlled trial aims to assess the analgesic efficacy of cutaneous cooling using a cold gel pack versus a room-temperature Control.
Material and methods: The analgesic efficacy of a 1-min application of a Treatment cold (3 −5 °C) gel pack versus a Control (room-temperature (20 °C)) gel pack prior to botulinum toxin injection into the platysma was assessed via visual analogue scale (VAS) ratings of pain before, during and after the procedure.
Results: Thirty-five patients received both trial arms during two separate clinic appointments. Cold gel packs provided a statistically significant reduction in pain compared with a room-temperature Control (from 26.4- to 10.2-mm VAS improvement ($p < 0.001$)), with no variance noted secondary to age, the hemi-facial side injected or the order in which the Treatment or Control gel packs were applied.

☆ **Summary**: Cutaneous cooling prior to botulinum toxin injection to treat facial palsy synkinesis is proven to provide an effective analgesic effect.

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Conclusion: Cryoanalgesia using a fridge-cooled gel pack provides an effective, safe and cheap method for reducing pain at the botulinum toxin injection site in patients with facial palsy.

Introduction

Chronic facial palsy (FP) is associated with a number of significantly debilitating functional and aesthetic deficits, which often have detrimental effects on patients' quality of life.[1] Facial synkineses, simultaneous abnormal involuntary muscular contractions with voluntary facial muscle contractions, are common sequelae of chronic FP, resulting in painful increased resting facial muscle tone, facial asymmetry and poor oral and ocular competence/control. The role of botulinum toxin (BT) injections in the treatment of FP synkinesis is well established, with both subjective and objective improvements in facial muscle tone, muscular control and facial symmetry observed,[2–10] along with significant improvements in patients' quality of life.[11] While demonstrably effective, the pain and injection-related anxiety surrounding BT injections can be a deterrent to subsequent treatment compliance. Any analgesic adjuncts that can reduce injection-related pain or discomfort are likely to improve long-term treatment adherence.

A variety of methods have been described to reduce the pain associated with BT injections, including modifications to the reconstituting solution[12,13]; topical local anaesthesia[14–16]; and cutaneous cooling using a topical refrigerant spray, cold gel pack or ice.[17–19] Cryoanalgesia is a long-standing technique for pain reduction. Refrigeration analgesia was first recorded in 1807 for surgical use by Baron Larrey, Napoleon's surgeon, who undertook battlefield amputations of frozen limbs during the Battle of Eylau, Poland. Since then, it has become commonplace within the anaesthetic options available to dermatological surgeons. However, a randomised controlled trial demonstrating its comparative efficacy has never been documented. While more modern anaesthetic techniques, for example, topical local anaesthetics (e.g., EMLA) or cooling with ethyl chloride spray, may be effective, certain disadvantages limit their use: comparatively higher cost, prolonged application time prior to anaesthetic efficacy, risk of local skin irritation and potential for allergic reactions. Cryoanalgesia using cold gel packs provides a cheaper, easier and safer option for simple dermatological procedures.

The aim of this study was to determine whether cutaneous cooling using a cold gel pack (3–5 °C) for 1 min prior to BT injection significantly reduces injection pain as compared with a room-temperature (20 °C) Control gel pack.

Material and methods

Participants

This study was conducted in accordance with the ethical principles of Good Clinical Practice and the Declaration of Helsinki (June 1964 and subsequent amendments). Ethical approval for the study was granted by the National Research Ethics Service committee, London, UK (REC reference: 11/LO/0806), and site-specific approval was given by the Queen Victoria Hospital (QVH) National Health Service (NHS) Foundation Trust Research and Development committee.

Forty-one FP patients who were already receiving BT injections as part of their routine treatment for chronic synkinesis secondary to FP were recruited from within the specialist multidisciplinary Facial Palsy Clinic at QVH. Patients acted as their own control. After being recruited, the subjects were randomised into two groups, 'Treatment first' and 'Control first'. This determined whether they applied the cold (3–5 °C) gel pack (Treatment) or room-temperature (20 °C) gel pack (Control) prior to BT injection into the platysma muscle at the first appointment. Each subject underwent the alternate treatment at his or her subsequent BT injection appointment. This method allowed for the highly subjective nature of pain descriptions, which can vary significantly between patients.

Procedure

All patients provided written informed consent for trial participation. A gel pack (either cold (3–5 °C) (Treatment) or room temperature (20 °C) (Control)) was applied to the patient's skin over the platysma muscle for 1 min (Figure 1). Then the pack was removed and the BT injection was immediately administered into the platysma. Five measurements of pain experienced at different stages of the procedure were taken using 100-mm visual analogue scales (VASs). Patients completed the assessment immediately following the BT injection, indicating the extent of pain experienced: pre-intervention, post-intervention, at needle insertion, during the BT injection and the overall discomfort from the procedure (Figure 2).

BT type A (Botox®, Allergan Ltd., Marlow, UK) was used in this trial and reconstituted with normal saline (sodium chloride 0.9%, Fresenius Kabi Ltd., Bad Homburg, Germany). BT was injected using a 29-gauge insulin needle and