Functional electrical stimulation cycling has no clear effect on urine output, lower limb swelling, and spasticity in people with spinal cord injury: a randomised cross-over trial

Keira E Ralston[1,2], Lisa A Harvey[2,3], Julia Batty[1], Bonsan B Lee[1,4], Marsha Ben[3], Rita Cusmiani[3] and Jacqueline Bennett[1]

[1]Prince of Wales Spinal Injury Unit, Prince of Wales Hospital, [2]Rehabilitation Studies Unit, Sydney School of Medicine/Northern, University of Sydney, [3]Royal Rehabilitation Centre Sydney, [4]Neuroscience Research Australia (NeuRA) Sydney, Australia

Question: Does functional electrical stimulation (FES) cycling increase urine output and decrease lower limb swelling and spasticity in people with recent spinal cord injury? **Design**: Randomised cross-over trial. **Participants**: Fourteen participants with a recent motor complete spinal cord injury were consecutively recruited from two spinal cord injury units in Sydney. **Intervention**: Participants were randomised to an experimental phase followed by a control phase or vice versa, with a 1-week washout period in between. The experimental phase involved FES cycling four times a week for two weeks and the control phase involved standard rehabilitation for two weeks. Assessments by a blinded assessor occurred at the beginning and end of each phase. Allocation was concealed and an intention-to-treat analysis was performed. **Outcome measures**: The primary outcome was urine output (mL/hr) and the secondary outcomes were lower limb circumference, and spasticity using the Ashworth Scale, and the Patient Reported Impact of Spasticity Measure (PRISM). In addition, participants were asked open-ended questions to explore their perceptions about treatment effectiveness. **Results**: All participants completed the study. The mean between-group difference (95% CI) for urine output was 82 mL/hr (–35 to 199). The mean between-group differences (95% CI) for lower limb swelling, spasticity (Ashworth), and PRISM were –0.1 cm (–1.5 to 1.2), –1.9 points (–4.9 to 1.2) and –5 points (–13 to 2), respectively. All point estimates of treatment effects favoured FES cycling. Participants reported many benefits from FES cycling. **Conclusion**: There were no clear effects of FES cycling on urine output, swelling and spasticity even though all point estimates of treatment effects favoured FES cycling and participants perceived therapeutic effects. **Trial registration**: ACTRN12611000923965. **[Ralston KE, Harvey LA, Batty J, Lee BB, Ben M, Cusmiani R, Bennett J (2013) Functional electrical stimulation cycling has no clear effect on urine output, lower limb swelling, and spasticity in people with spinal cord injury: a randomised cross-over trial. *Journal of Physiotherapy* 59: 237–243]**

Key words: Spinal cord injury, Functional electrical stimulation cycling, Physical therapy

Introduction

Functional electrical stimulation (FES) cycling is commonly prescribed for people with spinal cord injury for a variety of reasons (Carlson et al 2009, Hicks et al 2011). Some of the proposed benefits of FES cycling include increased urine output, decreased lower limb swelling and decreased spasticity (Elokda et al 2000, Faghri and Yount 2002, Krause et al 2008, Sampson et al 2000, Skold et al 2002, van der Salm et al 2006). It is important to investigate the therapeutic effects of FES cycling on these variables because: increased urine output is associated with a reduced incidence of urinary tract infection (Wilde and Carrigan 2003); decreased lower limb swelling makes it easier for people with spinal cord injury to lift their legs and reduces incidence of pressure ulcers (Consortium for Spinal Cord Medicine Clinical Practice Guidelines 2001); and decreased spasticity has various functional and health benefits (Adams and Hicks 2005).

Anecdotal evidence suggests that FES cycling affects renal function causing an increase in urine output and decrease in lower limb swelling (Man et al 2003). It is hypothesised that the cyclic muscle contractions associated with FES cycling compress the lower limb vasculature thereby improving venous return and decreasing lower limb swelling (Elokda et al 2000, Faghri and Yount 2002, Man et al 2003, Sampson et al 2000). It is also claimed that the increased venous return associated with FES cycling stretches the myocardium of the right atrium stimulating the expression of atrial natriuretic peptide. This peptide is known to have an excitatory effect on the kidneys, which increases urine excretion (Dunn and Donnelly 2007) and

What is already known on this topic: Functional electrical stimulation of paralysed legs in people with spinal cord injury increases venous return which may increase urine output and decrease lower limb swelling. Functional electrical stimulation may also have short-term effects on spasticity.

What this study adds: This study provides unbiased point estimates of the effect of functional electrical stimulation on urine output, venous return and spasticity. These estimates indicate that our current confidence in the effectiveness of functional electrical stimulation on these outcomes is not yet justified.

potentially decreases lower limb swelling. However, it is not known whether FES cycling is a sufficiently potent stimulus to influence urine output or lower limb swelling. This has not been tested in a randomised controlled trial.

FES cycling is also advocated as a way to reduce spasticity (Elbasiouny et al 2010, Krause et al 2008, Skold et al 2002, van der Salm et al 2006). Various theories exist on how this may occur. One theory is that repeated electrical stimulation (ES)-evoked contractions lead to muscle fatigue (Skold et al 2002). Another hypothesis is that the excitation of the cutaneous afferents decreases the excitability of the propriospinal interneurons and motoneurons (Elbasiouny et al 2010), while others argue that ES applied to antagonistic muscles augments reciprocal inhibition of agonistic spastic muscles (van der Salm et al 2006). However, similar to the beliefs about FES cycling on urine output and lower limb swelling, it is not yet clear whether FES cycling affects spasticity. There are some studies indicating an immediate dampening of spasticity from one-off episodes of ES but these studies are vulnerable to bias and do not provide convincing evidence of the effects of FES cycling on spasticity (Krause et al 2008, Skold et al 2002, van der Salm et al 2006). Therefore, the research question for this study was:

> Does a two-week FES cycling program increase urine output and decrease lower limb swelling and spasticity in people with recent spinal cord injury?

Method

Design

A 5-week cross-over randomised trial was undertaken, where participants received both experimental and control phases. Each participant underwent the 2-week control phase and the 2-week experimental phase. During the experimental phase, participants received FES cycling for 2 weeks. During the control phase, participants did not receive any FES cycling. The order of the two phases was randomised with a 1-week washout period in between. Participants continued to receive other usual care throughout the trial.

A blocked randomisation allocation schedule was computer-generated by an independent person to ensure equal numbers of participants commenced with the FES cycling phase and control phase (Schulz et al 2010). Each participant's allocation was placed in a sealed, opaque and sequentially numbered envelope and kept at an off-site location. Once a participant passed the initial screening process, an independent person was contacted, an envelope opened and allocation revealed. The participant was deemed to have entered the trial at this point.

Participants

Fourteen participants with an upper motor neuron lesion following recent spinal cord injury were consecutively recruited from two Sydney spinal cord injury units over an 18-month period commencing July 2011. Participants were included if they: had sustained a spinal cord injury (traumatic or non-traumatic) within the preceding six months; were currently receiving inpatient rehabilitation; were over 16 years of age; were diagnosed with an American Spinal Cord Injury Association Impairment Scale (AIS) of A, B or C with less than 5/50 lower limb strength according to the International Standards for Neurological Classification of Spinal Cord Injury; and could tolerate FES cycling for at least 20 minutes within a one-hour period. Participants were excluded if: they had participated in a FES cycling program in the preceding two weeks; ES was medically contraindicated; or they had a limited ability to comply. All participants were deemed medically fit to participate by their treating medical consultant.

Intervention

Participants in the experimental phase received a progressive, individualised FES cycling program performed four times a week for two weeks. The aim was to provide participants with 30 to 45 minutes of FES driven leg cycling within a one-hour session with the option of participants building up to this time from 20 minutes. However, all participants tolerated at least 30 minutes from the start. Three muscle groups were stimulated for each leg; quadriceps, hamstrings, and gluteals. Electrodes were placed over two points on each muscle to provide a maximal contraction. One participant did not tolerate stimulation of the quadriceps; therefore the gastrocnemius was stimulated instead. FES cycling was performed using a leg FES cycling system[a], with participants seated in their wheelchairs. A FES protocol based on that recommended by others (Krause et al 2008) was used with the following parameters: frequency 33Hz, wavelength 350λ and stimulation amplitude of up to 140mA according to participants' tolerance to ES. Resistance was set at the highest level that still enabled participants to cycle for at least 30 minutes. The initial sessions for each participant were supervised on a one-to-one basis by a physiotherapist with at least four years of experience in the management of spinal cord injury. Later sessions for participants were sometimes supervised by a physiotherapist aide working under the guidance of a physiotherapist.

The usual care that was provided during both intervention phases of the study consisted of standard inpatient physiotherapy and occupational therapy that is typically provided to patients during their initial rehabilitation following spinal cord injury. This includes interventions directed at impairments such as poor strength, restricted joint mobility, limited fitness, reduced dexterity, and pain. It also includes a strong focus on training of functional skills such as dressing, walking, transferring, using the hands, and pushing a wheelchair.

Outcome measures

All assessments were conducted at the beginning (baseline) and end of each two-week phase by trained assessors who were blinded to group allocation. The success of blinding was determined by asking assessors at the completion of each participant's last assessment whether they had been unblinded.

The primary outcome was urine output. Secondary outcomes were lower limb swelling measured as lower leg circumference, and spasticity measured using the Ashworth Scale and the Patient Reported Impact of Spasticity Measure (PRISM). An additional secondary outcome measure, Global Impression of Change, was collected at the completion of the trial.

Baseline urine output was measured prior to the commencement of each trial phase with the participant sitting quietly and avoiding any activity. Urine output was again measured at the end of both experimental and control phases, however at the end of experimental phase urine output was measured while participants simultaneously

