Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration

ISSN: 2167-8421 (Print) 2167-9223 (Online) Journal homepage: http://www.tandfonline.com/loi/iafd20

ALSUntangled 39: Acuscope (micro-Amp electrical muscle stimulation)

The ALSUntangled Group

To cite this article: The ALSUntangled Group (2017): ALSUntangled 39: Acuscope (micro-Amp electrical muscle stimulation), Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration, DOI: 10.1080/03007995.2017.1285468

To link to this article: http://dx.doi.org/10.1080/03007995.2017.1285468

Published online: 06 Mar 2017.

Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration, 2017; 1–4

Taylor & Francis
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RESEARCH ARTICLE

ALSUntangled 39: Acuscope (micro-Amp electrical muscle stimulation)*

THE ALSUNTANGLED GROUP

ALSUntangled reviews alternative and off-label treatments (AOTs) for people with ALS (PALS). Here we evaluate Acuscope therapy for ALS in response to 395 requests (1). As with all our previous reviews, this paper will focus on the specific possibility that Acuscope treatment might slow, stop or reverse ALS progression. Reviews on potential symptomatic benefits (such as improved pain or energy levels) are outside the scope of our programme.

Overview

Acuscope, also known as Electro-Acuscope, is a device that can deliver very low amplitude (micro-Amp) electrical stimulation to muscle. The amplitude delivered is too low to produce a muscle twitch. It has FDA approval on the basis of it being 'substantially equivalent' to earlier-approved electrical nerve stimulators for pain relief (2). Acuscope and other 'micro-current therapy machines' are advertised to treat a wide variety of medical conditions in animals and humans, ranging from musculoskeletal pain, to aging, to neurological disorders (3–5). One website reports that Acuscope slowed disease progression in a person with ALS (6), and one Tweet reports that it allowed a person with ALS to get back to riding horses (7).

Our PubMed search revealed few publications about Acuscope in the scientific literature; these are limited to a case series in which it was used to treat neck and shoulder pain (8), comments about this case series (9,10), and an editorial on its use for skin ulcers (11). There is a much larger literature describing the use of Functional Electrical Stimulation (FES) of muscle, whereby currents in the milli-Amp range are used to produce muscle twitches (ex. 12–14). Acuscope and FES may have very different mechanisms (see next section), and will thus be separately reviewed.

Mechanism

Proponents of Acuscope claim that it 'reads and treats the body along the linear pathways of current flow – nerves, meridians, and dermatomes – often following acupuncture meridian lines. The Acuscope delivers an electrical current at a millionth of amperage and lower (trillionth) at the cellular level to open the ion-sensitive gates, allowing entrance of substances such as calcium ions which turn on the repair mechanisms within those cells. Once the cell membranes open up, nutrients can easily flow in and waste products/toxins flow out' (15). In one study, application of micro-Amp current to isolated rat skin did alter membrane transport, protein synthesis and ATP generation (16). Since patients with ALS may have abnormal motor neuron or muscle membrane transport/trafficking (17), protein synthesis and degradation (18) and ATP generation (19), such effects could theoretically be useful. However, there are some significant problems with these proposed mechanisms. First, as we pointed out in our review of

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ISSN 2167-8421 print/ISSN 2167-9223 online
DOI: 10.1080/03007995.2017.1285468

Table 1. TOE grades for Acuscope in ALS.

	Grade	Explanation
Mechanism	D	Acuscope can act on a biological mechanism in isolated rat skin, but it is not clear that this is relevant in ALS
Pre-Clinical	U	No studies of Acuscope in pre-clinical ALS models
Cases	F	The only PALS we could find felt better on Acuscope but had faster ALSFRS-R progression on this treatment
Trials	U	No clinical trials of Acuscope in PALS
Risks	B	More than 0% but less than 10% of exposed patients experienced harms (no hospitalisations or deaths)

acupuncture, there is no good evidence for the concept of meridians (20). Secondly, it is not clear that experiments on isolated rat skin would translate to cells involved in human ALS, such as motor neurons. Thirdly, excess intracellular calcium may be part of the reason motor neurons die in ALS (21); if so, treatments that increase intracellular calcium further might be detrimental. Finally, some studies show that people with ALS have an increased metabolism (22), and that a higher resting energy expenditure correlates with faster disease progression (23). It is therefore possible that increasing ATP production might accelerate ALS progression. Based on all this, ALSUntangled assigns a TOE 'Mechanism' Grade of D (Table 1).

The rat skin study described above showed that effects on protein synthesis and ATP generation were only seen with very low amplitude electrical stimulation; stimulation above 1000 micro-Amps had no beneficial effect (16). This suggests that micro-Amp (ex. Acuscope) and milli-Amp muscle stimulation (ex. FES) might trigger totally different pathways and potential mechanisms.

Pre-clinical models

We found no trials of Acuscope in recognised ALS pre-clinical models. Based on this, ALSUntangled assigns a TOE 'Pre-Clinical' Grade of U (Figure 1).

Data in PALS

Cases

ALSUntangled located the person referred to in the website described above (6), and confirmed this to be the same person referred to in the Tweet described above (7). She and her daughter (who offers Acuscope treatment in her practice (6)) kindly sent medical records and answered questions about her experience via email. She had a subacute onset of mild dysarthria after oral surgery in October 2010, at age 50 years. Her symptoms improved, and then returned in February 2012, after a second oral surgery. Since then, she has had very slowly progressive dysarthria, dysphagia, dyspnoea and limb weakness, along with pseudobulbar affect. Neurological exams have shown upper motor neuron signs in bulbar, cervical and lumbar regions, but no lower motor neuron signs. Her cognition and sensation have been preserved. Work-up has included MRI scans of her brain, cervical and thoracic spine, which did not reveal any pathology that might account for her presenting complaints and exam findings. EMG studies of the tongue, thoracic paraspinals and all four limbs on multiple occasions have been normal. CSF, and blood tests for B12, ACE, Sjogren's, ANA, double-stranded DNA, HTLV, Lyme, acetylcholine receptor antibodies have been unremarkable. She was initially suspected to have the pseudobulbar palsy form of ALS, but this diagnosis has now been changed to primary lateral sclerosis (PLS). Her progression has been overall very slow. Her treatments have included riluzole, baclofen, Nuedexta® and medical marijuana. Acuscope treatment was started in the first half of 2013. Subjectively, she and her family have noted improvements in energy, speaking and swallowing on this regime. Available objective outcome measures before and during Acuscope treatment include ALSFRS-R, FVC, manual muscle testing and weight (Table 2). Assuming disease onset was February 2012, ALSFRS-R progression measured by her clinic was 0.76 points per month before, and 0.08 points per month during, Acuscope treatment; in other words, progression was slightly slower during treatment. Since the progression of motor neuron diseases can vary spontaneously in a given person over time (24), there is no way to confirm that this difference was because of the Acuscope treatment. We do not see improvements in the progression rates of any other objective outcomes that correlate with treatment. On the other hand, her breathing deterioration (percent predicted FVC) appeared to occur faster during Acuscope treatment. It is not clear whether apparent treatment responses in a person with PLS predict what will happen in PALS.

A second person who tried Acuscope for their ALS spontaneously emailed us earlier this year, asking us to review her response to this treatment. She kindly sent records and answered questions via email. She had gradual onset of lower extremity weakness in August 2014, at the age of 52 years. This progressed and eventually spread to the upper extremities. Neurological exams have shown upper and lower motor neuron signs in both arms and both legs. Cognition and sensation have been spared. Work-up has included imaging of the brain and spine, which failed to show any alternative

Table 2. Outcome measures from a person with motor neuron disease (likely PLS), before and during (*) acuscope treatment.

	2/12	7/12	10/12	11/12	3/13	7/13*	1/14*	9/14*	1/15*	1/16*	7/16*
ALSFRS-R	48 (assumed)					35	33	34	31	33	33
FVC (% Predicted)					99%	128%	123%		85%	86%	79%
Weight (lbs.)				163	171	167	180	180	170		
Speech				"Slowed, with some slurring"	Slowed, with some slurring"	"Slowed, with some slurring"	"Mildly slow and slurred"	"Mildly slow and slurred"	"Mildly slow and slurred"		
Power (R/L)											
Deltoids				5/5	5/5	5/5	5/5	5/5	5/5		
Biceps				5/5	5/5	5/5	5/5	5/5	5/5		
Triceps				5/5	5/5	5/5	5/5	5/5	5/5		
Wrist Extension				5/5	5/5	5/5	5/5	5/5	5/5		
Wrist Flexion				5/5	5/5	5/5	5/5	5/5	5/5		
APB				5/5	5/5	5/5	5/5	5/5	5/5		
ADM				4/4	4/4	4/4	4/4	4/4	4/4		
Iliopsoas				5/5	5/5	5/5	5/5	5/5	5/5		
Quadriceps				4/4	4/4	4/4	4/4	4/4	4/4		
Hamstrings				4/4	4/4	4/4	4/4	4/4	4/4		
Tibialis Anterior				5/5	5/5	5/5	5/5	5/5	5/5		

explanation for her clinical presentation. NCS/EMG studies have confirmed a widespread lower motor neuron disease. CSF studies were unremarkable. Her progression has also been overall slow. Her treatments included riluzole, Lunasin and a paleo diet. Acuscope treatment was started in April 2016. Subjectively, she has noted improvements in energy, balance and gait. Objectively, ALSFRS-R progression measured by her clinic was 0.25 points per month before, and 0.5 points per month during, Acuscope treatment; in other words, progression was slightly faster during treatment. No PALS on PatientsLikeMe or ALSTDI reported using Acuscope for their ALS. A Google search identified no additional cases. Based on the objective data in the one PALS we could find using Acuscope, ALSUntangled assigns a 'Cases' score of F.

Trials

ALSUntangled found no trials of Acuscope in PALS. Based on this, we assign a TOE 'Trials' Grade of U (Table 1).

There has been a trial of Acuscope in patients with another motor neuron disease: post-polio syndrome (PPS) (25). Twelve people from a PPS support group were treated with Acuscope and their 'percent improvement' was measured over at least two years. All participants noted some improvement, and eight out of 12 rated this to be '100%'. There are many problems with this study. The inclusion and exclusion criteria, including diagnoses of PPS, were vague. The sample size was small, outcomes were subjective, and there was no randomisation or blinding. To our knowledge, this study has never been replicated.

Risks, dosing and costs

Side-effects from Acuscope treatment are described on the internet as rare; one website states that there can be "an immediate detox or atypical reaction for a small percentage of people. This may include diarrhoea, night sweats, headaches, nausea, flu-like symptoms, or increase in pain, etc." (26). According to one Acuscope practitioner, this reaction occurs less than 5% of the time (27). Based on this information, ALSUntangled assigns a TOE 'Risks' Grade of B. However, we caution readers that we found no large case series in which systematic monitoring for side-effects occurred.

There is no standard dosing regimen of Acuscope for ALS found in the literature or on the internet. Depending on how it is dosed (which muscles, for how long, etc.), Acuscope therapy sessions may cost $80–250 per session (26). Several sessions per week are often used, meaning costs could potentially total $1000 or more per month.

Conclusions

Acuscope appears reasonably safe, but it is not clear that it has a mechanism of action that would be useful to PALS. One person with PLS experienced slightly slower ALSFRS-R measurements while using Acuscope than she did before starting it, but a PALS had slightly faster ALSFRS-R progression during treatment. Since the natural history of motor neuron disease progression can vary spontaneously, it is not clear that either of these slight changes in progression were related to the treatment. Given these limitations, at this time we cannot endorse the use of Acuscope to slow, stop or reverse ALS progression.

Disclosure statement

ALSUntangled is sponsored by the ALS Association and the Motor Neurone Disease Association. The patients mentioned in this paper provided signed authorizations.

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