Functional electrical stimulation in the treatment of patients with chronic heart failure: a meta-analysis of randomized controlled trials

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CRD summary
This review concluded that functional electrical stimulation may be an alternative therapy for people with chronic heart failure who were unable to perform conventional aerobic exercise. Data came from small studies of low methodological quality. Further research was needed. Given the available data and as they included a need for further research, the conclusions are suitably conservative.

Authors' objectives
To assess the effects of functional electrical stimulation in people with chronic heart failure.

Searching
MEDLINE, LILACS, PEDro and The Cochrane Library were searched from inception to January 2009. Search terms were reported. No language restrictions were applied.

Study selection
Randomised controlled trials (RCTs) that assessed the effects of functional electrical stimulation (FES) in people with chronic heart failure (New York Heart Association Class II, III or IV) were eligible for inclusion. Studies needed to have a follow-up of at least five weeks. The comparator could be conventional aerobic exercise training or control (same regime as the treatment group, but where the intensity of stimulation did not lead to visible or palpable contractions). Application of FES had to be in the quadriceps femoral muscle. Study objectives had to include assessments of peak oxygen consumption ($V_O^2$), six-minute walk test or muscle strength. Studies that failed to provide a reliable definition of chronic heart failure were excluded.

Most participants were men. Mean age ranged from 53 years to 63 years. All participants were on optimal medical therapy for heart failure. FES treatment programmes ranged from 30 to 240 minutes daily (five to seven days per week) for 25 days to 10 weeks.

Reviewers made an initial selection of studies that could possibly be eligible. Full texts were evaluated by two reviewers independently. Disagreements were resolved by consensus.

Assessment of study quality
Quality was assessed independently by two reviewers using items such as concealment of allocation, intention-to-treat analysis, baseline comparability, outcomes assessment blinding and description of losses to follow-up and exclusions. Quality was summarised using PEDro and Jadad scales.

Data extraction
Data were extracted to enable calculation of mean changes between baseline and end of treatment, and subsequent mean differences in changes, between treatment and comparison groups.

Two reviewers independently extracted data. Authors were contacted for further information.

Methods of synthesis
Pooled weighted mean differences (WMD) were calculated using a fixed-effect model. Heterogeneity was assessed using Cochran’s Q test and $I^2$ statistic. Where insufficient data were available, narrative results were provided. Sensitivity analyses were undertaken based on quality factors. Analysis was redone using a random-effects model.

Results of the review
Seven RCTs (224 participants) were included. Study size ranged from 24 to 46 participants. Five trials (168 participants) used conventional aerobic exercise as comparator and two trials (56 participants) used a control treatment.

The quality of most studies was poor: on the Jadad scale one scored 3, four scored 2 and two scored 1 (out of a maximum of five); on the PEDro score two studies scored 6, two scored 5, two scored 4 and one scored 2 (out of a maximum of 10).

Compared to conventional aerobic exercise, FES was associated with less favourable change in peak VO$_2$ (-0.74mL/kg per minute, 95% CI -1.38 to -0.10, $I^2$=0%; five trials). There was no difference in muscle strength (two trials). A small increase in six-minute walk test was neither statistically nor clinically significant ($I^2$=41%, five trials).

Compared to control treatment, FES was associated with an increase in VO$_2$ (2.78mL/kg per minute, 95% CI 1.44 to 4.13, $I^2$=52%; two trials). Two trials reported that there was a statistically significant change in the six-minute walk test with FES, but not with the control treatments. No data were available for muscle strength.

The overall low quality of trials precluded planned sensitivity analyses. Use of random-effects models gave results similar to those in the main analyses (data not presented).

**Authors’ conclusions**

FES may be an alternative to conventional aerobic exercise training for those people who are unable to perform these types of exercise; data came from small studies of low methodological quality and further research is needed.

**CRD commentary**

The aims of this review were clearly stated in terms of the inclusion criteria. The search covered a number of relevant sources. There were no language restrictions, which reduced the risk of language bias. It was unclear whether non-published trials were eligible, and it may be that publication bias affected the review. The methods of study selection, data extraction and quality assessment aimed at reducing reviewer error or bias. The quality of included studies was assessed. The methods of synthesis appeared appropriate. Heterogeneity was assessed, but evident heterogeneity in some outcomes was not investigated.

As the authors commented, available data came from small studies of generally low quality. Their conclusions, which include a need for further research, are suitably conservative.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Review:** The authors stated that further research was needed into the effects of functional electrical stimulation in people with chronic heart failure. RCTs should be methodologically sound, include a large number of participants and use long treatment periods and follow-up for clinical outcomes.

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