Shoulder Pacemaker Treatment for Functional Posterior Shoulder Instability: A Multicentric, Prospective, Randomized Controlled Trial

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INTRODUCTION:

Functional posterior shoulder instability (FPSI) is a severe type of instability mostly affecting teenagers and young adults that leads to loss of function, pain, and stigmatization among peers. Even though physiotherapy is the gold standard treatment, it is often not successful leading to salvage surgical stabilization attempts with uncertain outcomes. An experimental nonsurgical treatment protocol based on electrical muscle stimulation (EMS) called the Shoulder Pacemaker concept showed very promising early results in the treatment of FPSI and has been promoted by different experts via impressive videos of successfully treated patients at congresses and on social media. However, as with most new inventions and techniques in orthopaedics, the initial reports tend to be positive and subsequently over time increasing evidence challenges their benefit.

The goal of this study was to evaluate the effectiveness and general applicability of this promising but yet-unproven treatment option for a largely unresolved clinical problem in a multi-centric, randomized controlled trial with independent data analysis and quality control by independent study supervision. The hypothesis of this study was that the Shoulder Pacemaker treatment leads to better outcome than the current gold standard of treatment in patients suffering from FPSI.

METHODS:

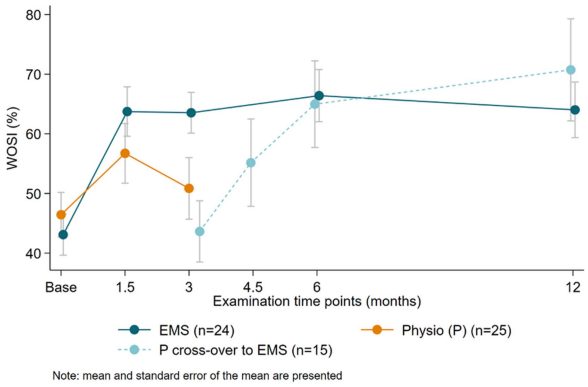
This multicentric randomized controlled trial involved 5 national shoulder centers as study sites, independent data storage and analysis outside of the country, and an independent international study advisory board. Fifty-nine patients with a functional posterior shoulder instability (Type B1 according to the ABC classification) were randomly allocated in a 1:1 ratio either to a 6-weeks physiotherapy (PT) protocol including exercises determined in prior Delphi survey or the same protocol supervised by the same physiotherapists with simultaneous Shoulder Pacemaker stimulation (SPM-PT). No physiotherapist had received a prior dedicated training for the Shoulder Pacemaker. Baseline scores, as well as outcome scores at 6 weeks, 3 months, 6 months, and 12 months after the intervention were obtained. The 3-months Western Ontario Shoulder Instability Index (WOSI) was defined as main outcome measurement with a minimally clinically important difference of 10.4%. If treatment was unsatisfactory for the patients, crossover to the other treatment group was allowed after the 3 months follow up. Prior to the beginning of the trial, the study design was registered online, a power-analysis was performed, and ethical committee approval was obtained.

RESULTS:

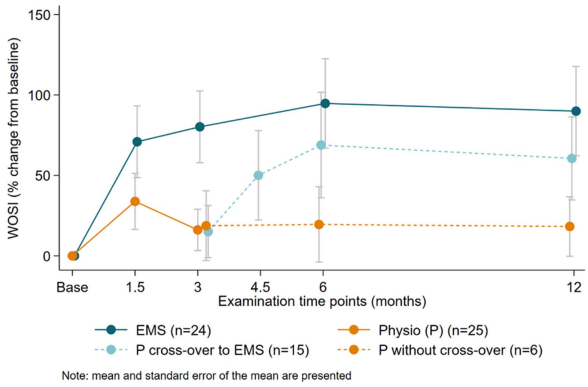
Both groups showed comparable baseline characteristics and adherence to treatment protocols. The SPM-PT group showed a significantly better outcome compared to the PT group in terms of the 3-month WOSI Score (64 ± 16% vs. 51 ± 24%; p=0.047). Two thirds of the patients from the PT group crossed over to the SPM PT group due to dissatisfaction after the 3-month follow up and showed a significant increase in their WOSI Score from 49 ± 18% to 65 ± 24% (p=0.041) at the 6-months follow up and beyond. (Fig. 1) The improvement compared to baseline was significant in the SPM PT group (p<0.001) and there was no significant improvement in the PT group (p=0.281). (Fig. 2) Better treatment response to EMS was observed in patients with worse baseline WOSI scores (p=0.001). Patients in the SPM-PT group reported a subjective improvement of their symptoms in 95% of the cases, while patients in the PT group reported an improvement in 63% of the cases (p=0.011). No serious adverse events were recorded in either treatment group.

DISCUSSION AND CONCLUSION:

The current study shows that Shoulder Pacemaker-enhanced physiotherapy leads to statistically significant and clinically relevant improvement of outcomes in the treatment of functional posterior shoulder instability compared to conventional physiotherapy alone. Even patients with prior unsatisfactory results after conventional physiotherapy show a significant benefit after secondary Shoulder Pacemaker enhanced physiotherapy.



Note: mean and standard error of the mean are presented



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