Effectiveness and Safety of Home-Based Muscle Electrical Stimulator in Brachial Plexus Injury Patients

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Objective: *To evaluate the effectiveness and safety of home-based muscle electrical stimulation system in brachial plexus injury patients.*

Material and Method: *Forty brachial plexus injury patients underwent muscle electrical stimulation using a custom designed electrical stimulator. Effectiveness of the system, visual analog pain score, skin temperature, superficial skin condition, overall patient satisfaction, and location of treatment preference were evaluated after the intervention. A follow-up telephone call was used to evaluate late-onset complications.*

Results: *Thirty-three men and seven women with an average age of 32 years were enrolled in the present study. According to our predefined definitions, 39 of 40 stimulation sessions were successfully completed, which resulted in a total system effectiveness of 97.5%. All patients tolerated the stimulation well. The average visual analog pain score was significantly decreased from 4 to 3 after the stimulation. There were no adverse incidents reported. The average patient satisfaction score was 7.8 out of 10. Thirty-five of 40 patients (88%) preferred to use home-based electrical stimulation vs. hospital-based treatment.*

Conclusion: *The custom designed muscle electrical stimulator used in this study has demonstrated adequate effectiveness and safety for clinical home use for brachial plexus injury patients.*

Keywords: *Brachial plexus injury, Muscle electrical stimulation, Physical therapy*

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Brachial plexus injury (BPI) is one of the most devastating peripheral nerve injuries in the upper extremities[1,2]. Patients typically lose both sensation and motor power of the affected limb and may experience disabling neuropathic pain. Advances in peripheral nerve surgery have significantly improved the outcomes of brachial plexus treatment. However, many patients still suffer from a substantial degree of disability, which can permanently change their life style, occupation, and income.

Over 70% of BPI injuries have been found to occur in motorcycle accidents. Typical lesions contain multiple cervical nerve root avulsions, in which spontaneous recovery rarely occurs[3]. Multiple nerve reconstructive surgeries are often required. The ultimate goal of treatment, although difficult to achieve, is a return to pre-injury functional status. Timing of surgery is one of the most important factors towards achieving a satisfactory result. As soon as the brachial plexus is injured the denervated muscles undergo the development of denervation atrophy; thus rendering them refractory to reinnervation. Studies have shown that recoverable muscle force will decrease by at least 30-50%, if the nerve repair is delayed for a month or longer[4]. Nerve reconstruction surgery should be performed within 6 to 9 months after injury, before irreversible motor end plate degeneration occurs[5,6]. The recovery of motor function can be delayed for up to 1-2 years after surgery, depending on the nerve reconstruction method[7-9].

Typical elapsed time after injury until reinnervated muscles regain function can take years. Proper physical therapy is mandatory during this period in order to maintain passive range of motion (ROM) and muscle condition. Physical therapy for denervated muscle consists of passive range of motion exercise and neuromuscular electrical stimulation (ES)[10,11]. Motor and sensory reeducation, as well as

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strengthening exercise, will be assigned after reinnervation has been observed.

Patient therapy programs should be setup and conducted under the guidance of specialized hand and occupational therapy professionals. However most of our patients come from a low socioeconomic status. Even though public therapy services are literally free of charge, these now lower income patients may still not be able to afford the transportation costs of accessing these services. In order to encourage adherence to the assigned therapy program, our home-based neuromuscular electrical stimulator was designed and produced for use, specifically by this segment of BPI patients.

The objective of the present study is to evaluate the effectiveness and safety of our prototype home-based ES system on BPI patients. Particular emphasis is also placed on the monitoring of adverse effects that may occur during stimulation, as well as patient preference regarding and satisfaction of the therapy program.

Material and Method

Subject

Subject participants were recruited between November 2011 and June 2012 from BPI patients treated at our institute. The inclusion criteria included adult BPI patients, aged 18 years or more, no recovery of the biceps brachii muscle, no communication problems, no associated injury that may preclude the test evaluation, and no contraindication for ES.

The ethics committee at our institute approved this study. The study was conducted according to Good Clinical Practice guidelines and the Declaration of Helsinki, with respect to informed consent.

Study design and intervention (Fig. 1)

This prospective, single-group, non-randomized clinical study was designed to evaluate the clinical effectiveness of our home-based ES system. All of the BPI patients that were eligible for this study and who had given their consent were evaluated for socioeconomic background, level of BPI lesion, status of motor and sensory functions, and visual analog pain score. Skin temperature was measured at the marked area for electrode placement before and after the stimulation by Thermal Infrared Imaging camera (Fluke TiR1, Fluke Corporation, Washington, USA) (Fig. 2).

All of the electrical stimulators used in the present study were tested and calibrated by a certified biomedical instrument calibration laboratory. Electrical parameters, including pulse interval, pulse width, waveform, resistance, voltage, and current were measured with digital multimeter and oscilloscope

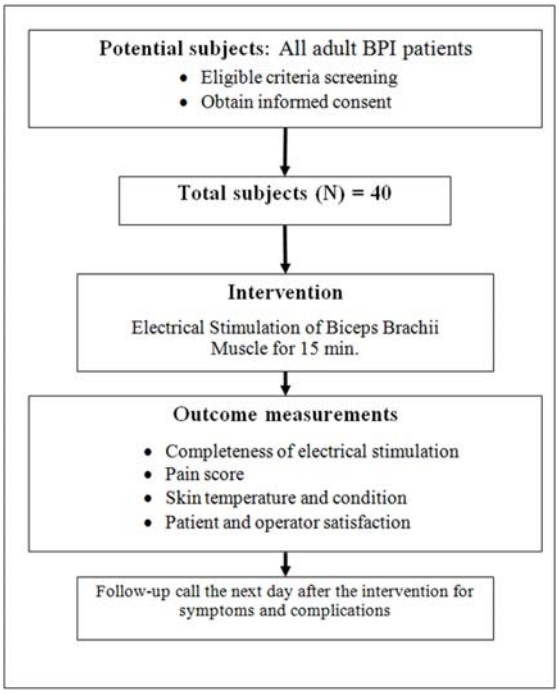

Fig. 1 Study scheme

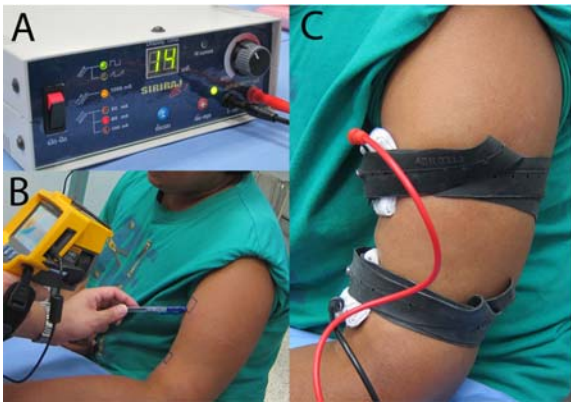

Fig. 2 A) The muscle electrical stimulator (Model Siriraj ES1) front panel shows the functions that can be controlled by the patient, including on/off switch, electrical intensity setting, and timer for stimulation. The other parameters have to be adjusted by a clinician in order to protect the patient from improper use. B) The measurement of skin temperature by a thermal infrared imaging camera. C) The placement of stimulation electrodes over a predefined area.

under a controlled environment.

The ES of the biceps brachii muscle was stimulated for 15 minutes. The stimulation parameters included monophasic triangular wave form, pulse width 80 milli second, pulse interval 1 sec, and an adjustment in electrical intensity (0-100 mA) to the minimal level that produced maximal visible biceps contraction.

Outcome measurements

The effectiveness of the ES system was measured by the completeness of the stimulation for 15 minutes, while maintaining maximal visible biceps brachii muscle contraction by assigned electrical intensity.

Visual analog pain score (VAS) was evaluated immediately before and after the electrical stimulation. Skin maximal temperature in the marked area for the stimulation electrodes was measured immediately before and after the stimulation by thermal infrared imaging camera. Skin condition under the stimulated electrode was evaluated by two physicians immediately after the ES. Overall patient satisfaction and treatment location preference for the ES system were evaluated with the use of a questionnaire. Evaluation of late-onset abnormal symptoms and complications was performed by follow-up phone call on the day after the intervention.

Statistics

The sample size was calculated based on the acceptable expected clinical effectiveness of the ES system as being 90%. Assuming a dropout rate of 10%, 40 patients were required to prove the hypothesis with a 95% confidence level and a power of 90% using a two-sided significance test.

The Wilcoxon signed-rank test was used to assess the difference between pre- and post-intervention VAS and skin temperature. Significance was set at an alpha level of 0.05 with associated 95% confidence intervals.

Results

Patient demographic data is shown in Table 1. There were 33 men and 7 women in this study. The mean age was 32 years (range: 18-73). Thirty-three patients had total brachial plexus lesion (5^{th} cervical-1^{st} thoracic nerve roots) and 7 patients had upper brachial plexus lesion (5^{th}-6^{th}/7^{th} cervical nerve roots). Eighty percent of patients (32/40) were injured on their dominant arm. At the time of electrical stimulation, 21 patients had not undergone any brachial plexus operations; 19 patients were enrolled during a postoperative visit, if there was no recovery of the biceps muscle. The mean duration between the initial injury and the index operation was 6 months (range: 3-14).

Table 1. Patient demographic data

Total patients	40
Mean age at the enrollment (years)	32 (18-73)
Gender (male: female)	4.7:1 (33:7)
Dominant arm injury (%)	32 (80)
Preoperative: postoperative patients	21:19
Mean time between injury and operation (mo.)	6 (3-14)
Total: upper brachial plexus lesions	33:7
Occupation (%)	
Wage labor	9 (22.5)
Farmer	8 (20)
Office worker	5 (12.5)
Student	4 (10)
Merchant	3 (7.5)
Manual worker	3 (7.5)
Unemployed	3 (7.5)
Security guard	2 (5)
Mechanic	2 (5)
Chef	1 (2.5)
Previous experience with electrical stimulation	
At hospital facility	17 (42.5)
At home	4 (10)
Never	19 (47.5)

The measurement and questionnaire results are shown in Table 2. The effectiveness of this ES system according to predefined definition was 97.5% (39 of 40 stimulations). One incidence of spontaneous machine shut down shortly after being turned on was reported. After disconnecting the power cord and resetting the machine, the ES system was able to normally resume work and finish the stimulation. The authors sent this prototype machine back to the calibration laboratory, but no significant issue was found. All of the patients well tolerated the stimulation for the assigned time of 15 minutes. Mean VAS was significantly decreased from 4.0 ± 2.6 at pre-stimulation to 3.0 ± 2.5 at post-stimulation ($p<0.01$). Average maximal skin temperature under the stimulated electrodes was significantly decreased from 32.8 ± 1.3°C to 30.8 ± 1.8°C ($p<0.01$) for the proximal electrode and from 32.3 ± 1.5°C to 30.9 ± 1.9°C ($p<0.01$) for distal electrode. There were no adverse incidents reported, either immediately after the stimulation or the day after the intervention. The

Table 2. Measurement and questionnaire results

	Pre-ES	Post-ES	*p*-value
Visual analog pain scale (0-10)	4.0±2.6	3.0±2.5	< 0.01 *
Maximal skin temperature under electrodes			
Proximal electrode (°C)	32.8±1.3	30.8±1.8	< 0.01 *
Distal electrode (°C)	32.3±1.5	30.9±1.9	< 0.01 *
Skin condition after ES (%)			
Normal		11 (27.5)	
Hyperemia		29 (72.5)	
Patient satisfaction scale (0-10)		7.8±1.5	
Patient preference for ES (%)			
At hospital facility		5 (12.5)	
At home		35 (87.5)	
Expected price for home ES system (%)			
<2,000 baht (65 USD)**		4 (12.5)	
2,000-3,000 baht (65-100 USD)		15 (37.5)	
3,000-5,000 baht (100-165 USD)		18 (45)	
>5,000 baht (165 USD)		3 (7.5)	

Values are given as means and standard deviation, ES = electrical stimulation, * significance (p<0.05), ** approximate number from the exchange rate of 30 baht = 1 USD

mean patient satisfaction score (0-10) with this ES system was 7.8±1.5. Thirty-five of 40 patients (88%) preferred home-based electrical stimulation to hospital-based treatment.

Discussion

Advances in peripheral nerve surgery have significantly changed the outcomes of brachial plexus treatment. The authors can now expect good to excellent functional results in patients with upper arm BPI[8,12]. Although there remains considerable disabilities relating to total arm BPI, today's outcomes following reconstructive surgery have improved to a degree that motor recovery can be expected in most of the patients[13].

Regardless of reinnervation procedure, all brachial plexus surgery requires substantial time before any functional recovery occurs. Rehabilitation is mandatory to maintain the condition of the denervated limb. The goals of a physical therapy program consist of maintaining and increasing range of motion, retarding the rate of muscle atrophy, and re-educating motor and sensory functions after reinnervation is verified[10].

In the present study, almost 50% of patients never received a proper therapy program before being referred to our facility, although these patients were usually prescribed a therapy program. However, often as a result of the stress associated with injury, disability, and loss of income, ongoing trips to rehabilitation became unachievable. This project was initiated by the senior author in order to encourage and facilitate accessibility to proper rehabilitation for these patients. The authors designed and produced the home-based ES system with the objective that it's easy-to-use, as effective as a hospital-based device, has enough clinician-adjustable parameters, protects the patient from improper use, and is affordable according to the demographic sector in which most of these patients fall.

The present study demonstrates that this system is effective for clinical treatment. Patients tolerated the system well and indicated that they were very satisfied with the system. The price range was also affordable for most patients. Almost 90% of the patients preferred the home-based rehabilitation program. The significant decreasing of the VAS, although not a stated objective of the ES, may be assumed to be as a result of the same mechanism as transcutaneous electrical nerve stimulation (TENS), in which low voltage current overrides pain message transmission[14].

Hyperemia was a common finding that was caused by an increase in local blood flow after electrical stimulation (Fig. 3). The monitoring of surface skin temperature under the electrodes didn't show an increase in temperature after a 15-minute ES session. A conductive electrolyte jelly and improper use of electrodes can cause irritant contact dermatitis and

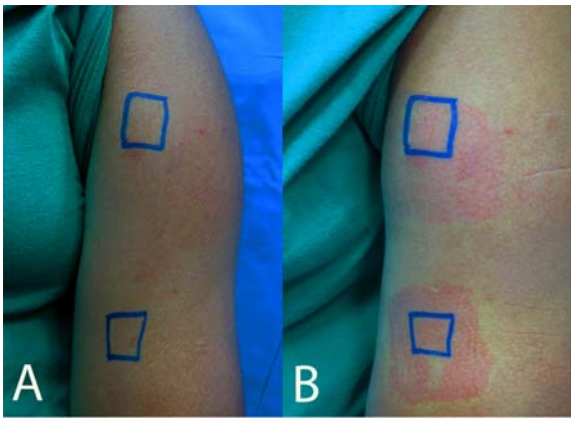

Fig. 3 The pictures show skin condition under the stimulated electrodes before A) and after B) electrical stimulation. Hyperemia of the skin under the electrodes was commonly found after the stimulation.

punctate burn[15]. In limited instances, we observed some BPI patients who experienced chronic burning wounds and scars from improper use of their ES systems. As a result, we designed our system which only allows patients to turn the unit on and off, adjust the intensity, and set the session timer. The other electrical parameters must be preset and adjusted by the therapist. These functions aim to protect them from prolonged or excessive stimulation. Since these patients have abnormal sensation and often feel better from muscle contraction during the ES.

Conclusion

This ES system can provide effective and safe neuromuscular electrical stimulation for BPI patients. Although electrical stimulation is considered a common treatment for use in peripheral nerve injury patients, further clinical trials are needed to prove its real benefit in the prevention of disuse atrophy. The home-based ES system was preferred by most of the patients in this study, however a long-term study should be undertaken to better compare it with the hospital-based system.

Funding

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Ethical approval

This research protocol was approved by the Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.

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Potential conflicts of interest

None.

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การทดสอบประสิทธิผลและความปลอดภัยของเครื่องกระตุ้นกล้ามเนื้อด้วยไฟฟ้าประเภทที่ผลิตขึ้นเพื่อนำกลับไปใช้ที่บ้านในผู้ป่วยบาดเจ็บข่ายประสาทของแขน

รุ่งศักดิ์ ลิ่มทองแท่ง, ภานุมาศ หมื่นน้อย, เหรียญพร ผู้เจริญชนะชัย, ต่อพล วัฒนา, สายชล ว่องตระกูล, ภานุพันธ์ ทรงเจริญ

วัตถุประสงค์: *เพื่อศึกษาถึงประสิทธิผลและความปลอดภัยของการใช้เครื่องกระตุ้นกล้ามเนื้อด้วยไฟฟ้าประเภทที่ผลิตขึ้น เพื่อนำกลับไปใช้เองที่บ้านสำหรับผู้ป่วยบาดเจ็บข่ายประสาทของแขน*

วัสดุและวิธีการ: *ผู้ป่วยบาดเจ็บข่ายประสาทของแขนจำนวน 40 ราย ได้เข้าร่วมในการศึกษานี้โดยทุกคนจะได้รับการกระตุ้นไฟฟ้าของกล้ามเนื้อด้วยเครื่องกระตุ้นกล้ามเนื้อด้วยไฟฟ้าที่ผลิตขึ้นโดยคณะของผู้นิพนธ์ การวัดผลการศึกษาทำโดยการบันทึกผลสำเร็จของการกระตุ้นไฟฟ้า อาการปวดค่าอุณหภูมิของผิวหนังบริเวณที่ถูกกระตุ้น สภาพของผิวหนังบริเวณที่ถูกกระตุ้นความพึงพอใจ และประเภทของการกระตุ้นไฟฟ้าที่ผู้ป่วยต้องการ จากนั้นผู้ช่วยวิจัยจะโทรศัพท์เพื่อสอบถามอาการของผู้ป่วยในวันรุ่งขึ้นหลังจากการกระตุ้นไฟฟ้า*

ผลการศึกษา: *ผู้ป่วยชาย 33 ราย และผู้ป่วยหญิง 7 ราย (อายุเฉลี่ย 32 ปี) ได้เข้าร่วมในการศึกษาผลการศึกษา พบว่าประสิทธิผลของเครื่องกระตุ้นไฟฟ้าชนิดนี้เท่ากับร้อยละ 97.5 ผู้ป่วยทุกคนสามารถทนการกระตุ้นไฟฟ้าได้จนครบระยะเวลาที่กำหนด ค่าเฉลี่ยของระดับความปวดลดลงจาก 4 เป็น 3 คะแนน หลังจากการกระตุ้นไฟฟ้า ไม่พบผลไม่พึงประสงค์เกิดขึ้นกับผู้ป่วยในการทดสอบ ค่าเฉลี่ยความพึงพอใจของผู้ป่วยเท่ากับ 7.8 คะแนนร้อยละ 88 ของผู้ป่วยรู้สึกพอใจที่จะใช้การกระตุ้นกล้ามเนื้อด้วยไฟฟ้าเองที่บ้าน*

สรุป: *เครื่องกระตุ้นกล้ามเนื้อด้วยไฟฟ้าที่ผลิตขึ้นโดยคณะของผู้นิพนธ์มีประสิทธิผลและความปลอดภัย เพียงพอที่จะนำไปใช้ในทางคลินิกสำหรับผู้ป่วยบาดเจ็บข่ายประสาทของแขน*