Original Article

wiener klinische wochenschrift
the middle european journal of medicine
Printed in Austria

Wien Klin Wochenschr (2003) 115/19–20: 710–714

Safety of a combined strength and endurance training using neuromuscular electrical stimulation of thighs muscles in patients with heart failure and bipolar sensing cardiac pacemakers

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Sicherheit eines kombinierten Kraft- und Ausdauertrainings durch neuromuskuläre Elektrostimulation der Oberschenkelmuskulatur bei Patienten mit Herzinsuffizienz und bipolaren Herzschrittmachern

Zusammenfassung. Für Patienten mit schwerer chronischer Herzinsuffizienz ist Ausdauer- und Krafttraining durch neuromuskuläre Elektrostimulation (NMES) eine effektive und nicht belastende Alternative zum aktiven Training. Wegen möglicher elektromagnetischer Interferenz werden Herzschrittmacherpatienten häufig von einer NMES-Behandlung ausgeschlossen. Ziel dieser Pilotstudie war die Untersuchung der Sicherheit eines kombinierten NMES-Ausdauer- und Krafttrainingsprotokolles für Patienten mit Herzschrittmachern.

In die Studie wurden sieben Patienten mit schwerer chronischer Herzinsuffizienz und implantierten Herzschrittmachern mit bipolar wahrnehmenden Elektroden eingeschlossen und ein ärztlich supervidiertes kombiniertes Ausdauer- und Krafttraining mittels NMES unter Pulsmonitoring durchgeführt. Das NMES-Protokoll bestand aus biphasischen, symmetrischen Rechteckimpulsen mit unterschiedlichen Frequenzen von 8 Hz bis 50 Hz, Impulsdauern bis 60 s (8 Hz), 4 s (15 Hz), 4 s (30 Hz) und 6 s (50 Hz), sowie Amplituden bis ± 100 mA (alle Frequenzen). Die Stromapplikation erfolgte über Oberflächenelektroden (8 x 13 cm) im Bereich der Streck- und Beugemuskulatur beider Oberschenkel.

Eine akute elektromagnetische Interferenz trat im Verlauf eines Sicherheitschecks (Telemetriemonitoring) vor Beginn der NMES-Therapie bei keinem der Patienten auf. Den 7 Patienten wurden während jeweils 20 NMES-Therapie-Einheiten komplikationslos bei insgesamt 23.380 Einschaltphasen $2.194{,}08 \times 10^3$ Stimuli appliziert. Es wurden keine Änderungen der simultan registrierten Herzfrequenz detektiert und keine Fehlfunktion des Schrittmachers festgestellt.

Die Durchführung eines kombinierten NMES-Ausdauer- und Krafttrainingsprogrammes der Oberschenkelmuskulatur erscheint bei Patienten mit Herzinsuffizienz und implantierten bipolaren Herzschrittmachern unter Berücksichtigung der beschriebenen Elektrodenlagen und Parametergrenzen sicher.

Schlüsselwörter: Neuromuskuläre Elektrostimulation, Kraft, Ausdauer, schwere chronische Herzinsuffizienz, Herzschrittmacher.

Summary. Neuromuscular electrical stimulation (NMES) is an effective and non-strenuous therapy to enhance the strength and endurance capacity of the skeletal muscles in patients with severe chronic heart failure. NMES in patients with pacemakers is controversial because potential electromagnetic interference may result in pacemaker malfunction. Therefore, such patients are in general excluded from NMES. The aim of this pilot study was to evaluate the safety of a combined NMES protocol to increase strength and endurance capacity of the skeletal muscles in patients with heart failure and implanted pacemakers.

Seven patients with chronic heart failure and implanted cardiac pacemakers with bipolar sensing leads received NMES treatment of thigh muscles, using a combined protocol comprising biphasic, symmetric, rectangular constant current impulses at different frequencies (8–50 Hz), pulse width up to 60 s (8 Hz), 4 s (15 Hz), 4 s (30 Hz), and 6 s (50 Hz), and amplitudes up to ± 100 mA (all frequencies) applied to both knee extensor and flexor muscles via surface electrodes (8 x 13 cm each).

Acute electromagnetic interference during a safety procedure (telemetric monitoring) before therapeutic NMES application was not observed in any of the patients. The 7 patients received during 20 therapeutic NMES sessions a total of 23,380 on-phases, comprising

2194.08 x 10^3 biphasic electrical pulses, without adverse events. Heart rate monitoring during stimulation and pacemaker interrogation revealed no abnormalities.

NMES treatment of thigh muscles using a combined NMES protocol to enhance strength and endurance capacity appears to be safe in patients with heart failure and implanted pacemakers with bipolar sensing, as far as the described electrode configuration and parameter range is applied.

Key words: Neuromuscular electrical stimulation, strength, endurance, severe chronic heart failure, pacemaker.

Background

In addition to dyspnea and edema, patients with severe chronic heart failure frequently present with marked muscular weakness and/or atrophy and a reduced endurance capacity of the skeletal musculature [1–4]. Deficits in the basic motor properties of strength and endurance can be successfully treated by medical training therapy in a large number of patients [4, 5]. However, active training may be too strenuous for patients with severe chronic heart failure [3, 6].

Physical-medical electrotherapies have a wide range of indications [7–10]. In clinical studies it was found that neuromuscular electrical stimulation (NMES) of the thigh muscles is a well tolerated, effective and clinically relevant alternative to active strength and endurance training [10–13].

The question whether electronic implants are disturbed by potential electromagnetic interferences, in particular cellular phones, burglar alarms, metal detectors, magnetic resonance tomography devices, defibrillators and physical-medical electrotherapy devices is a relevant and extensively discussed subject [14–32].

The application of NMES in patients with implanted cardiac pacemakers is frequently avoided because of potential electromagnetic interference resulting in disturbed pacemaker function [17]. As many patients with severe chronic heart failure have a pacemaker because of cardiac bradyarrhythmia, a relatively large group of patients is excluded from the effective and non-strenuous NMES strength and endurance training in the thigh musculature.

The goal of the present pilot study was to test the safety of a combined NMES strength and endurance protocol during stimulation of the thigh muscles in patients with implanted pacemakers with bipolar sensing, and to document its applicability.

Patients and methods

Safety trials to register hazardous events in implant-bearing patients require large numbers of cases [20]. Since different electrodes and diverse pacemaker algorithms and also differing electrode positions in cases of respiratory excursion (elevation of the diaphragm) cause individual differences to persist, the present investigation was conducted as a pilot study in seven pacemaker patients who received a large number of stimuli and stimulation trains with various frequencies in a series of 20 therapeutic NMES sessions.

Seven patients (male/female ratio 6:1; 60 ± 14 years; six were intermittently pacemaker-dependent and one was pacemaker-dependent) with severe chronic heart failure and implanted pacemakers with bipolar sensing leads were included in this pilot study after they had been informed and had given their consent to participate in the investigation (Table 1). NMES of the thigh muscles was indicated due to their marked deconditioning and greatly reduced strength and endurance of the skeletal musculature and the advanced stage of their basic disease that excluded the alternative of voluntary exercising.

NMES at the thigh flexor muscles and thigh extensor muscles was conducted using a portable electrotherapy device (Compex 2, Compex SA, Ecublens, Switzerland). The NMES protocol consisted of biphasic symmetrical rectangular impulses with a pulse width of 250 µs and frequencies of 8 Hz (warm-up and cool-down), 15 Hz (endurance), 30 Hz (strength 1) and 50 Hz (strength 2). The on-phases (burst duration) varied depending on the frequency (8 Hz = 60 s, 15 Hz = 4 s, 30 Hz = 4 s and 50 Hz = 6 s). The current was applied through adhesive electrodes (8 x 13 cm, ValueTrode, AXELGAARD Manufacturing) attached to the skin surface; the distance between the bipolar electrode tip of the pacemaker and the nearest surface electrode was at least 40 cm.

Table 1. Patients and pacemakers (all bipolar)

	Gender	Age	Pacemaker (manufacturer, model)	Mode	Leads (manufacturer, model)	Duration of implantation
Pat 1	male	72	Medtronic, KAPPA SR 701	VVIR	V: Pacesetter 1452 T	6 months
Pat 2	male	34	Intermedics S.A. Relay, 294-03 VS-1	VVIR	A: Medtronic 4058 M; V: Medtronic 4024	74 months
Pat 3	male	58	Intermedics, 292-03 Dash	VVIR	V: Pacesetter 1403 T	72 months
Pat 4	male	52	ELA Medical, Talent DR 213	DDDR	A: Medtronic 4068; V: Pacesetter 1452 T	24 months
Pat 5	male	66	ELA Medical, Talent SR 113	VVIR	V: Pacesetter 1452 T	10 months
Pat 6	female	76	Vitatron, Selection DR	DDDR	A: Medtronic 4068 T; V: Pacesetter 1452 T	25 months
Pat 7	male	63	Medtronic Thera SR	VVIR	V: Pacesetter 1452 T	68 months

A right atrial lead; *V* right ventricular lead.

Table 2. Number of applied biphasic impulses and on-phases in all (seven) patients

Frequency	Number of impulses	Number of bursts
8 Hz	26880	560
15 Hz	1050000	17500
30 Hz	319200	2660
50 Hz	798000	2660
All frequencies	2194080	23380

Safety procedure: To test for potential acute electromagnetic interference in the intermittently pacemaker-dependent patients, pacemaker function was monitored during intrinsic cardiac rhythm with pacemaker intervention rate programmed first below intrinsic heart rate and later above the intrinsic heart rate whilst applying NMES following the protocol described above under permanent additional heart rate ECG monitoring. The nominal sensing settings were not changed for this test. In the pacemaker dependent patient all pacemaker settings were kept unchanged-during the entire NMES application period.

Therapeutic NMES sessions: After acute individual risk interference had been ruled out, each patient received a NMES therapy series consisting of twenty 40-minute sessions with application of the combined NMES strength and endurance training of the thigh musculature according to the protocol described above. At the beginning, the amplitude of the applied electrical current was adjusted to the patient's maximum subjective sensible tolerance [13]. During the therapy series this tolerance level adapted to higher values and finally a maximum amplitude of ± 100 mA (all frequencies) was applied in all patients. During these therapeutic NMES sessions the patients' pulse rate was constantly monitored with a pulse watch (Polar® "Tempo") and the therapy was performed in the presence of technical medical personnel and under the supervision of a physician at the University Department of Physical Medicine and Rehabilitation at the Vienna University Medical School, but without pacemaker telemetry monitoring.

Results

No acute interference of pacemaker function related to NMES treatment was observed during the safety procedure tests, neither in intermittently pacemaker-dependent patients in both sub-threshold and supra-threshold mode nor in the pacemaker dependent patient with unchanged clinical pacemaker setup.

In the course of the combined NMES strength and endurance training protocol (therapeutic NMES sessions), the 7 patients underwent 20 sessions each with a total of 23,380 on-phases (stimulation bursts) of different duration, comprising as many as 2194.08×10^3 biphasic stimuli of varying frequencies (Table 2). The NMES applications were uneventful. No adverse events in the subjective or clinical condition of the patient were registered during or after the treatment units. Pulse monitoring revealed no clinically relevant changes in heart rate. Pacemaker controls after the series of 20 applications showed no technical abnormities neither in the functional circuit and the program nor in the electrode properties.

Discussion

A pacemaker system's response to interference depends on a number of variables including, but not limited to, the nature and strength of the interfering signal, the proximity of the patient/pacemaker/electrode to the source of interference, and the pacemaker's design as this relates to the signal, including the degree of shielding as well as its sensing and polarity characteristics. Most pacemaker circuitry uses filters to attenuate electromagnetic signals in a frequency spectrum higher or lower than the normal ECG range. Unfortunately filtering alone is not sufficient for suppressing all interference, as many drop-ins contain frequencies that overlap the ECG. Therefore modern pacemakers provide more complex algorithms to compare the transient shape and magnitude of the recorded signal with an expected ECG. Due to this advanced signal conditioning the artefacts from electrical stimulation at the extremities seem to have a higher probability to be misinterpreted as cardiac signals than those applied closer to the pacemaker site and inducing artefacts with much higher amplitude. The latter are neglected by many pacemakers, whereas the peripheral application may deliver artefacts in a similar frequency range and arriving in a similar amplitude range as the recorded ECG.

The range of responses from the pacemaker system to electromagnetic interference is wide and largely depends on the interference signal characteristics. Possible pacemaker responses to interference include a single beat inhibition (where the pacemaker may not pace the heart for a single cardiac cycle), total inhibition (where the pacemaker ceases to pace the heart), noise reversion/asynchronous pacing (where the pacemaker paces the heart at a fixed rate), rate increase, or erratic pacing rate. These responses are almost always temporary and only occur as long as the source of interference is active and within a critical distance to the pacemaker. In extreme cases, where the interference is of a sufficiently high magnitude, it is possible for the pacemaker circuitry to be damaged, leading to a continued abnormal pacing behavior [16, 17, 29, 30].

In our study NMES was applied to seven patients with severe chronic heart failure and implanted pacemakers with bipolar sensing leads (Table 1) during a NMES safety procedure followed by twenty 40-minute therapy sessions through adhesive electrodes (8×13 cm). The distance between the bipolar sensing electrode tip of the pacemaker and the next adhesive electrode of the stimulation device was at least 40 cm, following the protocol described above. During the individual primary testing (safety procedure), in no patient any interference of pacemaker function such as inhibition, acute pacing frequency changes or switching to an asynchronous mode were observed in conjunction with NMES. The application of more than of 2×10^6 impulses and more than 23,000 stimulation bursts in seven patients during long-term application (NMES therapy sessions) was uneventful. No functional interference occurred in the tested pacemaker models and operation modes throughout the whole study, though stimulation frequency and intensity were varied in a wide range.

In principle electromagnetic interference secondary to NMES may inhibit the pacemaker output (VVIR, DDDR).

If this inhibition causes a heart rate pause of more than 3 seconds, negative clinical symptoms are likely to occur [33]. These facts recommend to choose a shorter burst duration than 3 s for the NMES. Rate responsive pacemakers (DDDR) may develop a high pacing rate during sensing of NMES artifacts. Another possible interference in conjunction with NMES is the potential switching of the pacemaker to the asynchronous mode. None of these problems occurred in our study. Obviously the stimulation artifacts sensed by the pacemakers remained sub threshold throughout the whole treatment in the chosen technical setup. Technical advancements, in particular improved filter functions and algorithms, have made modern pacemakers much more resistant to electromagnetic interference than older models [16, 17, 29, 30]. Interferences are less likely when bipolar sensing electrodes are used, and if the distance between sensing electrode and surface stimulation electrodes is as big as given in applications at the lower extremity [16, 17, 29, 30].

The results of this pilot study show that, after exclusion of an individual risk by an acute testing procedure, application of NMES under medical supervision and, if possible, permanent ECG monitoring, and given sufficient patient compliance, a NMES based combined strength and endurance training of the thigh muscles seems to be a safe procedure. For deconditioned heart failure patients with an implanted pacemaker, the combined NMES strength and endurance training protocol is a non-strenuous alternative – in many cases the only one – to strenuous active exercise.

References

1. Mancini DM, Walter G, Reichek N, Lenkinski R, McCully KK, Mullen JL, et al (1992) Contribution of skeletal muscle atrophy to exercise intolerance and altered muscle metabolism in heart failure. Circulation 85: 1364–1373
2. Schaufelberger M, Eriksson BO, Lonn L, Rundqvist B, Sunnerhagen KS, Swedberg K (2001) Skeletal muscle characteristics, muscle strength and thigh muscle area in patients before and after cardiac transplantation. Eur J Heart Fail 3: 59–67
3. Sullivan MJ, Hawthorne MH (1995) Exercise tolerance in patients with chronic heart failure. Prog Cardiovasc Dis 38: 1–22
4. Quittan M, Sturm B, Wiesinger GF, Fialka-Moser V, Pacher R, Rödler S (1999) Skeletal muscle strength following orthotopic heart transplantation. Wien Klin Wochenschr 111: 476–483
5. Schnizer W (1993) Therapeutic muscle training. Wien Klin Wochenschr 105: 232–238
6. Ernst E (1989) Effects of physical activity on the cardiovascular system and risk factors. Phys Med Kurortmed 21: 54–58
7. Jenkner FL (1977) The treatment of intractable pain by transdermal electrostimulation. Wien Klin Wochenschr 89: 126–131
8. Hertz H, Bochdansky T, Scharf W (1984) Electrotherapy of pain relief using the Tenzcare stimulator. A clinicoexperimental study. Wien Klin Wochenschr 96: 585–588
9. Hein L, Ammer K, Rathkolb O, Krcevsky N (1987) Physical treatment of herpetic diseases. Report of a pilot study with low-frequency electrotherapy. Wien Klin Wochenschr 99: 149–153
10. Quittan M, Sochor A, Wiesinger GF, Kollmitzer J, Sturm B, Pacher R, et al (1999) Strength improvement of knee extensor muscles in patients with chronic heart failure by neuromuscular electrical stimulation. Artif Organs 23: 432–435
11. Quittan M, Wiesinger GF, Sturm B, Puig S, Mayr W, Sochor A, et al (2001) Improvement of thigh muscles by neuromuscular stimulation in patients with refractory heart failure. Am J Phys Med Rehabil 80: 206–214
12. Quittan M, Nuhr MJ, Hülsmann M, Crevenna R, Pacher R (2001) Chronic low frequency electrical stimulation of thigh muscles increases aerobic capacity in patients with sewere chronic heart failure. Circulation 104 [Suppl]: 2143
13. Crevenna R, Posch M, Sochor A, Keilani M, Wiesinger G, Nuhr M, et al (2002) Optimizing neuromuscular electrical stimulation-a comparative study of three different currents. Wien Klin Wochenschr 114: 400–404
14. Barbaro V, Bartolini P, Donato A, Militello C (1999) Electromagnetic interference of analogue cellular telephones with pacemakers: In vitro and in vivo studies. Pacing Clin Electrophysiol 22: 626–634
15. Burck G, Hentschel R, Wiedemann D, Henßge R (1988) Beeinflussung von Herzschrittmachern der MCP- und LCP-Serie durch Elektrodiagnostik- und Elektrotherapieverfahren. Z Ges Inn Med 43: 572–577
16. Crevenna R, Quittan M, Wiesinger GF, Nuhr MJ, Nicolakis P, Fialka-Moser V (2001) Elektrostimulationstherapie bei Patienten mit Herzschrittmachern. Phys Rehab Kur Med 11: 159–164
17. Crevenna R, Nuhr M, Wiesinger G, Hülsmann M, Mayr W, Pacher R, et al (2001) Langzeitbehandlung mit neuromuskulärer Elektrostimulation bei Herztransplantationskandidaten mit implantierten Herzschrittmachern. Phys Rehab Kur Med 12: 212–215
18. Csermely M, Rusznyák P, Szabó J (1989) Die Wirkung der Elektrostimulation auf den Pacemaker. Z Physiotherapie 41: 301–303
19. Geppert A, Rauscher F (2001) Pacemaker dysfunction in daily clinical practice. Wien Klin Wochenschr 113: 15–26
20. Irnich W, Batz L, Müller R, Tobisch R (1996) Electromagnetic interference of pacemakers by mobile phones. Pacing Clin Electrophysiol 19: 1431–1446
21. Irnich W (1999) Störbeeinflussung von Implantaten. Elektrostimulation und Elektrotherapie 1: 42 (Abstract)
22. Jacob C, Volkmann H, Ziegenhahn C, Uhlemann C (1990) Störbeeinflussung von implantierten Herzschrittmacher durch apparative Physiotherapie. Z Ärztl Fortbild 84: 443–447
23. Jones SL (1976) Electromagnetic field interference and cardiac pacemakers. Phys Ther 56: 1013–1018
24. Kainz W, Neubauer G, Alesch F, Schmid G, Jahn O (2001) Electromagnetic compatibility of electronic implants-review of the literature. Wien Klin Wochenschr 113: 903–914
25. McIvor ME, Reddinger J, Floden E, Sheppard RC (1998) Study of pacemaker and implantable cardiverter defibrillator triggering by electronic article surveillance devices (SPICED TEAS). Pacing Clin Electrophysiol 21: 1847–1861
26. Mugica J, Henry L, Podeur H (2000) Study of interactions between permanent pacemakers and electronic antiheft surveillance systems. Pacing Clin Electrophysiol 23: 333–337
27. Naegeli B, Osswald S, Deola M, Burkart F (1996) Intermittent pacemaker dysfunction caused by digital mobile phones. J Am Coll Cardiol 27: 1471–1477

28. Toivonen L, Valjus J, Hongisto M, Mesto R (1991) The influence of elevated 50 Hz electric and magnetic fields on implanted cardiac pacemakers: the role of lead configuration and programming of the sensitivity. Pacing Clin Electrophysiol 14: 2114–2122
29. Wiesinger GF, Crevenna R, Nuhr MJ, Hülsmann M, Fialka-Moser V, Quittan M (2001) Neuromuscular electrical stimulation as treatment of skeletal muscle weakness in heart transplant candidates with cardiac pacemakers. Arch Phys Med Rehabil 82: 1476–1477
30. Wilke A, Kruse T, Funck R, Maisch B (1997) Störbeeinflussung von Herzschrittmachern. Dtsch Med Wochenschr 122: 517–522
31. Wilke A, Kruse T, Hesse H, Funck R (1998) Interactions between pacemakers and security systems. Pacing Clin Electrophysiol 21: 1784–1788
32. Wilke A, Müller H, Noll B, Maisch B (1999) Häufigkeit von elektromagnetischen Herzschrittmacher – Störbeeinflussungen im Alltag aus der Sicht der Patienten. Herzschrittmacher 19: 109–115
33. Gregeratos G, Cheitlin MD, Conill A, Epstein AE, Fellows C, Ferguson TB Jr, et al (1998) ACC/AHA guidelines for implantation of cardiac pacemakers and antiarrhythmia devices: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Pacemaker Implantation). J Am Coll Cardiol 31: 1175–1209

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(Received November 11, 2002, accepted after revision September 4, 2003)