

ORIGINAL ARTICLE

Neuromuscular Electrical Stimulation on Hemodynamic and Respiratory Response in Patients Submitted to Cardiac Surgery: Pilot Randomized Clinical Trial

Telma Cristina Fontes Cerqueira,¹ Manoel Luiz de Cerqueira Neto,² Auristela Julia Guilhermino Carvalho,² Gécica Uruga Oliveira,² Amaro Afrânio de Araújo Filho,³ Vitor Oliveira Carvalho,² Lucas de Assis Pereira Cacau,³ Walderi Monteiro da Silva Júnior,² José Teles de Mendonça,² Valter Joviniiano de Santana Filho²

Universidade Federal de Sergipe (UFS),¹ Lagarto, SE - Brazil

Universidade Federal de Sergipe (UFS),² São Cristóvão, SE - Brazil

Universidade Tiradentes (UNIT),³ Aracaju, SE - Brazil

Abstract

Background: Neuromuscular electrical stimulation seems to be a promising option to intensify the rehabilitation and improve the exercise capacity of patients in the immediate postoperative period of cardiac surgery.

Objective: This study aimed to evaluate the hemodynamic (heart rate, systolic blood pressure, diastolic blood pressure, and mean blood pressure) and respiratory (respiratory rate and oxygen saturation) responses to neuromuscular electrical stimulation in the immediate postoperative period in patients submitted to cardiac surgery and to verify its feasibility and safety.

Methods: This is a pilot randomized controlled trial, wherein critical patients in the immediate postoperative period of cardiac surgery were randomly assigned to a control group, using sham neuromuscular electrical stimulation, or an experimental group, submitted to neuromuscular electrical stimulation sessions (FES), for 60 min, with a 50-Hz frequency, 200- μ s pulse duration, time on: 3 s, and time off: 9 s. Data distribution was evaluated by the Shapiro-Wilk test. The analysis of variance was used and a p-value < 0.05 was considered significant.

Results: Thirty patients were included in the study. The neuromuscular electrical stimulation was applied within the first 23.13 ± 5.24 h after cardiac surgery, and no changes were found regarding the hemodynamic and respiratory variables between the patients who underwent neuromuscular electrical stimulation, and those in the control group.

Conclusions: In the present study, neuromuscular electrical stimulation did not promote changes in hemodynamic and respiratory responses of patients in the immediate postoperative period of cardiac surgery. (Int J Cardiovasc Sci. 2019; [online].ahead print, PP.0-0)

Keywords: Thoracic Surgery; Cardiac Rehabilitation; Electric Stimulation Therapy; Diagnosis of Health Situation; Heart Rate; Blood Pressure; Oxygen Level.

Introduction

Although cardiac surgery is an effective option and a safe procedure that increase quality of life and survival in patients with heart failure, it is still a complex procedure with many possible complications.^{1,3} Muscle proteolysis has been known to accelerate within 48 h after cardiovascular surgery,² when patients are under significant mobilization restrictions, and use of

mechanical ventilation, vasoactive drugs, sedatives, and analgesics, and the presence of catheters, thoracic, and mediastinal drains. In this context, the rehabilitation of patients after cardiac surgery becomes a challenge in the intensive care unit (ICU).¹⁻³

Early mobilization and physical exercise have been considered as fundamental components in the rehabilitation of patients in the postoperative period of cardiac surgery.^{4,5} The functional status is

Mailing Address: Prof. Telma Cristina Fontes Cerqueira

Universidade Federal de Sergipe - Campus Universitário Prof Antônio Garcia Filho - Gov. Marcelo Deda, 13. Postal Code: 49400-000, Centro, Lagarto, Sergipe - Brazil
E-mail: telmac@gmail.com

known as being prognostic in patients submitted to cardiac surgery at hospital discharge.⁶ In this context, neuromuscular electrical stimulation (NMES) seems to be a promising option to intensify the rehabilitation of patients in the immediate postoperative period of cardiac surgery.⁷

Previous studies have already shown the positive effects of NMES on the exercise capacity of patients with cardiovascular disorders,^{8,9} as well as its safety regarding the hemodynamic and respiratory responses to its use.^{10,11} However, studies evaluating the use of NMES immediately after cardiac surgery are lacking, wherein patients are more restricted to the bed and often require vasoactive drugs.

The aim of this study was to evaluate the hemodynamic and respiratory responses of patients to NMES session performed in the immediate postoperative period of cardiac surgery.

Material and Methods

Study design and population

This is a pilot, randomized, parallel, two-arm, controlled trial performed at the cardiac ICU from October 2013 to March 2014. This study was carried out in accordance with the Declaration of Helsinki of 1975 (revised in 1983), was approved by the Research Ethics Committee under number 429.256 and all the patients provided their written consent. This study was submitted to the Brazilian Registry of Clinical Trials (*Registro Brasileiro de Ensaio Clínicos-REBeC*) under number RBR-8vkw87. This study was initially performed to verify safety and, subsequently, continued research with the creation of a protocol to be used in this population to verify the benefits of NMES.

Patients admitted to the ICU within the first 48 h after coronary artery bypass grafting and/or valve replacement were eligible for the study. Those excluded were patients under mechanical ventilation, age younger than 18 years old, body mass index > 40 kg/m², previous neuromuscular diseases, dementia or cognitive disorder, patients with intra-aortic balloon and internal pacemaker, hemodynamic instability, mean arterial pressure < 50 mmHg or > 120 mmHg, dyspnea with oxygen saturation by pulse oximetry (SpO₂) < 90%, patients with metallic implants, dermatitis, damaged skin in the area to be stimulated, and sensitivity changes.

Randomization

Once the patients met the inclusion criteria, they were randomly assigned by an independent participant using the electronic randomization system: <http://random.org>, in a simple and confidential manner, to the experimental group, who underwent NMES, or the control group, who used sham NMES.

Blinding

The blinding of the investigators who carried out the study was not performed. However, the patients were blinded to the NMES/sham NMES use.

Intervention

In the intervention group, the use of NMES occurred in only one instance, during the first 48 h of ICU stay. The surface electrodes were attached to the quadriceps and gastrocnemius muscles bilaterally through the FES current, for 60 min, with a 50-Hz frequency, 200-ms pulse duration, time on of 3 s, and time off of 9 s (NEUROMED 4080 CARCI Brazil). The NMES intensity was adjusted to obtain a visible muscular contraction and, in case of doubt, the contraction was confirmed by palpation of the involved muscles. The patients did not voluntarily perform muscle contraction.

Similar to the experimental group, patients in the control group had surface electrodes attached to the same muscle groups for 60 min with the NMES device switched off (sham NMES).

Outcome measures

The hemodynamic variables (heart rate, HR; systolic blood pressure, SBP; diastolic blood pressure, DBP; and mean blood pressure, MBP) and respiratory variables (respiratory rate, RR and SpO₂) were collected before the intervention (baseline), every 15 min during NMES (15, 30, 45, and 60 min) and after 15 min of the recovery period.

Regarding the study hemodynamic variables, the HR was verified by a multiparametric monitor (OMNL, OMNIMED, Belo Horizonte, Brazil) connected to the patient through disposable electrodes on the thorax. MBP, DBP and SBP were measured by invasive invasive direct method through radial artery puncture.

Regarding the respiratory variables, RR was measured by counting the breaths (inspiration and

expiration) for 1 min. SpO₂ was measured with a pulse oximeter placed on the patient's finger, connected to the multiparametric monitor.

Statistical analysis

Data are shown as mean and standard deviation and the categorical variables are shown as absolute numbers and percentages. The statistical analyses were performed with the software SPSS version 15.0 (IBM Corp., Armonk, NY, EUA). Data distribution was evaluated by the Shapiro–Wilk test. The analysis of variance for repeated measurements (ANOVA) was used to compare changes in means over the six timepoints (rest, 15, 30, 45, 60 min and 15 min after of the recovery period), corresponding to the intragroup analysis. Two-way repeated measures ANOVA was used to compare means between two groups over the six timepoints, corresponding to the intergroup analysis. The Chi-Square test was used for categorical variables and the t-test for independent samples was used to compare the numerical variables regarding patients' characteristics between the groups. Values of $p < 0.05$ indicated statistical significance.

Results

The study included 30 patients submitted to cardiac surgery, with 15 patients in the experimental group and 15 in the control group, respectively (Figure 1). In the experimental group, the use of NMES occurred in the first 23.13 ± 5.24 h and, in the control group, 22.20 ± 5.46 h after cardiac surgery.

No complications were observed during our protocol, and none of the patients were excluded. The sample characteristics are shown in Table 1.

No change was found in the hemodynamic and respiratory variables in the patients submitted to neuromuscular electrostimulation, as well as in the control group patients. In addition, all hemodynamic and respiratory parameters remained within normal limits (Table 2).

Discussion

The main finding of this study was that an NMES session did not result in any changes in HR, SBP, DBP, MBP, RR, and SpO₂ in patients in the immediate postoperative period of cardiac surgery.

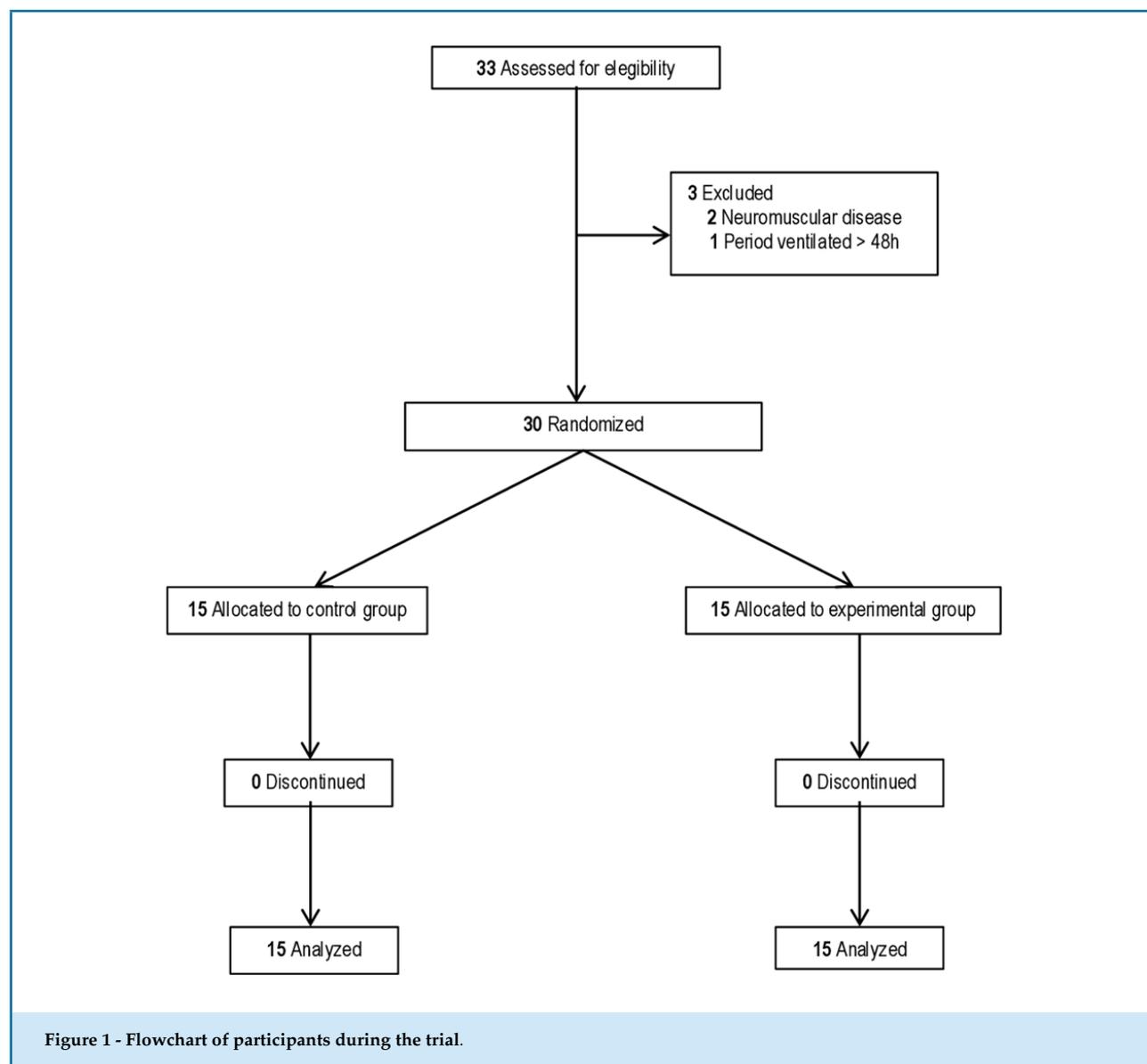
In the past, many professionals working with cardiovascular rehabilitation hesitated to prescribe NMES to patients with heart disease, contraindicating electrotherapy due to the risk of cardiac arrhythmia.³ Additional concerns that could contribute to the non-indication of NMES would be the concern that repeated sustained muscle contractions would elevate total peripheral resistance, resulting in acute elevations in blood pressure and hemodynamic overload, increasing the risk of cardiovascular complications in critically-ill patients.¹²

Despite these facts, NMES has been proposed as a promising adjuvant therapy to increase the physical capacity of patients involved in cardiovascular rehabilitation programs, such as patients hospitalized for heart failure,¹³ and in patients in the postoperative period of cardiac surgery.¹⁴

Some authors have already investigated hemodynamic responses to the use of NMES in healthy subjects,¹⁵ exercise plus NMES in patients with heart failure,¹⁰ and in patients under critical care.¹¹ However, only one study investigated the safety of NMES immediately after cardiac surgery.³ In this study, no patient showed changes in blood pressure and HR that exceeded the safety criteria defined by the study. The mean variation was a maximum of 2.1 mmHg for SBP and 1.7 bpm for HR.³

In the present study, the majority of the patients used inotropic agents, such as dopamine, dobutamine, noradrenaline, and/or needed vasopressor support to maintain their hemodynamic stability, which would lead to extra concerns regarding the cardiovascular system during NMES application. However, no statistical or clinical changes were observed (4.53 bpm for HR; 2.93 mmHg for SBP, 3.27 mmHg for DBP and 1.73 mmHg for MBP). No cardiac arrhythmia was reported either.

A previous study found that a session of NMES in critically-ill patients caused an increase in SBP and HR of 6 mmHg and 5 bpm, respectively, although the authors stated that this result was not clinically significant.¹⁶ Another author also found small changes in HR, of approximately 1 bpm, and in SBP and DBP, of approximately 1 mmHg, with no statistical significance when NMES was applied on the femoral quadriceps of critically-ill patients.¹⁷ These borderline increases in BP and HR after the use of NMES in critically-ill subjects are in agreement with the results presented by this study, wherein one can observe similar variations of these variables, including in the control group, with no statistical and clinical difference between the groups.



Moreover, no reports of muscle pain, discomfort, or fatigue that could lead to interruption of NMES therapy, or even a dyspnea complaint, confirmed by the maintenance of the respiratory variables of RR and SpO₂, were observed. Our findings are in agreement with those of another study that found no significant changes in RR and SpO₂ with the use of NMES in critically-ill patients.¹⁷

Our study had no dropouts. This is in accordance to previous studies that reported low dropout rates of 1.5% in patients in the postoperative period³ and 11% for patients with heart failure.¹⁸ These data support the use of NMES, because it was well tolerated by the patients during the acute phase, when they are submitted to invasive procedures and subject to pain.^{2,19,20}

The parameters used in the NMES studies are divergent, ranging from 250 ms–400 ms for pulse duration, 1.75 Hz–100 Hz for frequency, and 2–12 s to 4–24 s for the clicks.²¹ Some authors report that high frequencies ≥ 50 Hz improved muscle strength,²² whereas others state that the intensity of NMES response varies based on the patient's interaction.¹⁶

Differently from the present study, another study has shown that NMES induced energy expenditure and cardiovascular response similar to other types of exercise in other patient profiles, with higher HR increases, but using low-frequency NMES techniques.²³ This same study even suggested that this technique using low frequency would lead to higher physiological

Table 1 - Patients' characteristics

	NMES group	Control group	p
Type of surgery			
Coronary artery bypass grafting, n. (%)	7 (46.67)	5(33.33)	0.45
Valve Replacement, n. (%)	7 (46.67)	10(66.67)	0.26
Coronary artery bypass grafting + valve replacement, n. (%)	1 (6.67)	0 (0)	0.30
Comorbidities, n. (%)	12 (80.00)	10 (66.67)	0.40
Hypertension, n. (%)	7 (46.7)	8 (53.33)	0.71
Diabetes, n. (%)	2 (16.67)	1 (10.00)	0.54
Rheumatic fever, n. (%)	7 (58.33)	5 (50.00)	0.45
Stroke, n. (%)	-	1 (10.00)	0.30
Time between admission to ICU and application, mean (SD), (hours)	23.13 (5.24)	22.20 (5.46)	0.64
Male sex, n. (%)	9 (60.00)	5 (33.33)	0.14
Age, mean (SD), (years)	49.87 (14.37)	50.93 (14.56)	0.84
Left ventricular ejection fraction, mean (SD)	57.60 (10.49)	61.07 (7.84)	0.31
Cardiopulmonary bypass time, mean (SD) (min)	106.33 (15.52)	104.00 (17.95)	0.70
Intravenous Drugs at sessions, n. (%)	8 (53.33)	9 (60.00)	0.71
Dobutamine, n. (%)	5 (62.50)	4 (44.44)	0.69
Dopamine, n. (%)	4 (50.00)	3 (33.33)	0.66
Norepinephrine, n. (%)	3 (37.50)	2 (22.22)	0.62
Nipride, n. (%)	0 (0)	2 (22.22)	0.14
Tridil, n. (%)	1 (12.50)	0 (0)	0.30

NMES: neuromuscular electrical stimulation, SD: standard deviation, ICU: intensive care unit; Chi-Square Test; Independent Sample Test.

responses than other classically used protocols with high and moderate frequencies, similar to that used in the present study. In this aspect, another factor that must be taken into account is the stimulated muscle mass, because larger muscular masses could lead to higher physiological responses.²³

However, regardless of the variety of parameters used in the studies, a systematic review of NMES efficacy in critically-ill patients indicates that this is a relatively safe method for use in this type of patient,²¹ which is in agreement with our data.

Thus, we proposed that NMES be used as post-surgical therapy considering the possible benefits related to the use of this resource, as a shorter period of exercise restriction, smaller strength decline and faster

recovery of muscle strength, consequently resulting in higher tolerance by patients to recover their ambulation capacity, functional levels and performance of activities of daily life.

Study limitations

This study was limited by the use of a single session of an NMES protocol. Other modalities of NMES should be tested, as well as different times of use in patients at the postoperative period of cardiac surgery.

Conclusion

In the present study, NMES did not promote changes in hemodynamic and respiratory responses in the

Table 2 - Results of hemodynamic and respiratory response reported as mean and standard deviation

Outcome	Groups														Overall effect
	NMES (n = 15)							Control (n = 15)							
	Rest	15 min	30 min	45 min	60 min	15 after	P value*	Rest	15 min	30 min	45 min	60 min	15 after	P value*	
HR	82.13 (10.87)	83.87 (12.70)	86.67 (19.57)	83.13 (11.53)	83.33 (12.50)	82.06 (11.34)	0.945	81.00 (14.81)	79.87 (5.58)	81.53 (13.80)	80.73 (13.68)	82.47 (12.82)	81.73 (13.90)	0.997	0,527
SBP	111.67 (14.43)	114.60 (14.97)	112.93 (13.34)	114.53 (12.78)	113.93 (12.86)	112.40 (12.91)	0.928	108.80 (17.79)	114.40 (18.16)	111.80 (15.94)	112.60 (17.93)	113.40 (16.83)	113.53 (18.07)	0.964	0,784
DBP	65.13 (14.34)	66.93 (12.81)	65.93 (13.39)	67.60 (13.13)	68.4 (13.65)	65.27 (13.05)	0.981	64.47 (10.78)	66.67 (11.08)	66.00 (10.14)	65.80 (10.24)	64.73 (7.91)	65.47 (9.08)	0.991	0,388
MBP	81.40 (12.98)	82.67 (10.87)	81.40 (11.49)	83.30 (10.12)	81.93 (10.46)	81.20 (9.27)	0.995	81.27 (12.76)	82.87 (11.34)	81.40 (11.63)	83.47 (10.62)	82.13 (10.23)	83.07 (10.40)	0.992	0,922
RR	24.33 (3.24)	23.60 (3.22)	22.60 (2.38)	23.00 (3.42)	22.93 (1.83)	23.40 (2.75)	0.634	23.40 (4.47)	23.93 (4.25)	22.67 (3.51)	23.20 (4.77)	24.33 (4.47)	24.13 (4.17)	0.896	0,089
SpO ₂	97.13 (1.77)	96.87 (2.17)	96.87 (1.69)	96.80 (1.78)	96.93 (1.94)	97.07 (1.83)	0.996	96.40 (2.29)	96.47 (1.50)	96.40 (2.20)	97.13 (1.46)	96.87 (2.13)	97.47 (1.30)	0.511	0,322

NMES: Neuromuscular Electrical Stimulation; HR: heart rate (beats/min); SBP: systolic blood pressure; (mmHg); DBP: diastolic blood pressure (mmHg); MBP: mean blood pressure (mmHg); RR: respiratory rate (breaths/min); SpO₂: oxygen saturation by pulse oximetry (%); 15 after: 15 minutes after; *: p values in intra-group comparison; t- p values in intergroup comparison. ANOVA, p > 0.05.

immediate postoperative period of patients submitted to cardiac surgery.

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Author contributions

Conception and design of the research: Cerqueira TCF, Cerqueira Neto ML, Cacao LAP, Carvalho VO, Mendonça JT. Acquisition of data: Cerqueira TCF. Analysis and interpretation of the data: Cerqueira TCF, Cerqueira Neto ML, Cacao LAP, Carvalho VO, Mendonça JT. Statistical analysis: Cerqueira TCF. Obtaining financing: Cerqueira Neto ML. Writing of the manuscript: Cerqueira TCF, Cerqueira Neto ML, Carvalho VO. Critical revision of the manuscript for intellectual content: Cerqueira TCF, Cerqueira Neto ML, Cacao LAP, Carvalho VO, Mendonça JT.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

This article is part of the thesis of Doctoral submitted by Telma Cristina Fontes Cerqueira, from Universidade Federal de Sergipe.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Universidade Tiradentes (UNIT) under the protocol number 429.256. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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