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Research article

Effect of Local High-Frequency Vibration Therapy (LMV) Undergoing Minimally Invasive Cardiac Surgery A Randomized Controlled Trial (RCT)

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Abstract

Background: Several studies have demonstrated the efficacy of rehabilitation in patients undergoing cardiac surgery. In the scientific panorama, in fact, we can observe multiple types of stimulation and treatments, but to date there is no univocal protocol for this type of patient, which is becoming increasingly numerous. This raises the question of which method is more effective in reconditioning such patients, and whether the association of various methods, using also electro-medical equipment can be a real added value to significantly improve their health status.

Purpose: The purpose of this randomized controlled clinical trial is to understand the benefits that can be obtained by associating treatment with LMV-Vibra 3.0 to traditional rehabilitation care. And thus contribute to the creation of a treatment protocol in which traditional rehabilitation techniques are associated with localized high-frequency muscle vibration therapy (LMV).

Method: 40 patients undergoing aortic valve replacement with minimally invasive technique at the U.O.C. of Cardiac Surgery of Policlinico Gemelli (Rome) were enrolled and randomized into two groups: (study group performed usual care rehabilitation treatment and control group performed usual care rehabilitation and vibration stimulation (LMV-Vibra 3. 0), all patients after meeting the inclusion criteria were evaluated pre and postoperatively with different evaluation scales: (VAS, SPPB, Hand-grip, SF-36, 6M-WT), in order to better understand the clinical variations and their physical performance throughout the rehabilitation period, with particular attention to the perception of pain, and their quality of life, all patients were re-evaluated up to sixty days postoperatively**.**

Results: From the data analyzed we can state that no patient had any particular post-operative complications due to the surgery, and no deaths were recorded at 30 days after surgery, moreover there were no statistically significant differences between the two groups in the incidence of major complications. We can affirminstead that the treatment group recorded a significant improvement in the 6M-WT ($p < 0.01$) compared to the control group, and the results show that there are significant differences between the

control group and the treatment group when considering the parameters Physical Functioning ($p < 0.01$), Role Physical ($p < 0.01$) and General Health ($p < 0.01$).

Conclusion: The results of this study have shown that the association of local muscle vibration (LMV), is really useful in patients undergoing this type of intervention, improving the physical and functional capacity, with consequent impact on the general health status. This study, to be considered as a pilot study, offers great opportunities for future studies.

Keywords: Rehabilitation; Cardiovascular; Local Muscle Vibration (LMV); Electrostimulation

Introduction

Cardiovascular diseases represent the first cause of mortality and morbidity in Western countries; very often patients suffering from them need cardiac surgical procedures [1]. Functional recovery during the post-surgery period is closely related to the type of procedure performed, and the way in which surgery is performed (election vs. urgency) and the individual characteristics of the patient (age, comorbidity, nutritional status, etc.), is entrusted to specific rehabilitation programs. Post-operative rehabilitation aims to optimize physical recovery, reduce the incidence of complications and ensure a rapid return to activities of daily living.

Traditional rehabilitation protocols are centered on respiratory re-education exercises, exercises for the recovery of muscle strength, gradual reconditioning of aerobic activity and postural re-education. Recently, in the field of instrumental physical therapy have been introduced devices, which through the delivery of high-frequency muscle vibration therapy (LMV), are able to positively affect the control of pain, the recovery of muscle tone and strength, improving balance, resistance to physical activity and motor coordination. To date, the majority of studies on these devices have focused on the rehabilitation of patients affected by neurological diseases [2,3] or in the context of functional recovery after orthopedic surgery [4,5]. No study has investigated the impact of focal mechanical vibration therapy in the patient undergoing cardiac surgery. Therefore, the aim of our study was to evaluate, through a prospective randomized trial, the results of a protocol with vibration therapy in addition to common postoperative rehabilitation programs.

Material and Method

In this randomized, interventional controlled clinical trial 40 consecutive patients undergoing aortic valve replacement with minimally invasive technique between July 2020 and November 2020 at the U.O.C. of Cardiac Surgery of Policlinico Gemelli (Rome) were enrolled. This is a single center study and should be considered a pilot study.

Eligibility criteria

The inclusion criteria of the study required patients older than 18 years, patients operated at the Cardiac Surgery O.U. of our hospital, in election for aortic valve replacement with minimally invasive technique, and patients should not need associated cardiac procedures (coronary artery bypass, mitral valve repair/replacement, ascending aorta/aortic root replacement, etc.). Patients with cognitive impairment, basic neuro-motor deficits, patients who had previously undergone cardiac surgery, or those unable to provide informed consent were excluded from the study.

Randomisation and blinding

After verifying the inclusion/exclusion criteria and signing the informed consent, through a "block" methodology with an allocation ratio of 1:1, 40 patients were randomized to receive traditional post-cardiac surgery rehabilitation treatment (20 patients, control group) or traditional post-cardiac surgery rehabilitation treatment combined with segmental focal mechanical stimulation using the Vibra 3.0 device (20 patients, treatment group).

Objectives

All 40 patients had as general objective, in the short and medium term, the recovery of maximum autonomy in AVQ, recovery of respiratory function, prevention of complications in the respiratory system, gradual reconditioning of aerobic capacity; in the long term, reintegration into the socio-familial environment, with the control of cardiovascular risk factors. The rehabilitation programs were composed as follows: analytical and global mobilization, gait re-education, respiratory re-education with aids, aerobic exercises (pedal/cyclette and postural re-education.

Access to the gymnasium was carried out with telemetric control, and during therapeutic exercise all patients were monitored for clinical signs and vital parameters. They were also required to wear a sternal protection vest.

Measures

The efficacy of the treatment with Vibra 3.0 was verified through the following scales: visual-analogue pain scale (VAS), 6-minute walk test (6M-WT), hand grip, short physical

performance battery (SPPB), short-form health survey-36 (SF-36). The results of the above assessments, together with demographic, anamnestic, laboratory and instrumental data were collected in a dedicated Database.

Patients underwent four assessments according to the following procedure:

t0 : the day before surgery; history taking, clinical examination, demographic data acquisition; VAS, SPPB, Hand-grip, SF-36, 6M-WT; adverse events;

t1 : on postoperative day five; VAS, SPPB, Hand-grip, SF-36, 6M-WT; adverse events; t2 : on postoperative day 20; VAS, SPPB, Hand-grip, SF-36, 6M-WT; adverse events.

t3 : at follow-up visit on 60th postoperative day; VAS, SPPB, Hand-grip, SF-36, 6M- WT adverse events;

Device, Operation, and Stimulation Protocol

The Vibra 3.0 is a certified medical device capable of generating simultaneous selective mechano-sonic square wave vibrations on multiple outputs. The vibrations are transmitted through special transducers placed on different muscular districts. Through the selection of appropriate frequencies (available frequencies 30-900 Hz with pressure intensity > 600 mbar pp), the mechanoreceptors of Meissner and Merkel (located in the most superficial part of the skin), the corpuscles of Ruffini and Pacini (located deeper), the Golgi organs (present in the myotendinous junctions) and the fibers of neuromuscular spindles are stimulated. The afferent stimulus reaches the spinal cord via the rapidly conducting large-caliber myelinated fibers, where it gives rise to the Spinal Gate (pain control), tonic vibratory reflex (RTV), and reciprocal inhibition. The afferent impulses from the spinal cord reach the suprasegmental centers where they integrate the efferent motor response that amplifies fiber recruitment.

Figure 1: Application of dome transducers.

Interventions

In this study protocol, the use of the Vibra 3.0 involved bilateral application of dome transducers in 4 different regions of the body, (deltoid mid-bundle, quadriceps femoris, tibialis anterior, forearm flexors). Patients performed 6 applications/week for a period of 3 weeks, for a total of 18 applications. The duration of each application was 40 minutes, at a frequency of 100 Hertz (Hz) and an intensity of 2, performed in the morning, before the normal rehabilitation treatment, so as not to create an overload that could create sleep disturbances for the patient. All 40 patients were undergoing the usual rehabilitation process at the rehabilitation department of our hospital.

Minimally invasive aortic valve replacement technique

All procedures were performed under general anesthesia (induced through standard protocols) and with the aid of transesophageal echocardiography.

The surgical technique involved a 4- to 5-cm skin incision starting 1 cm below the Louis angle (Figure 2 A) and a high partial sternotomy with preservation of the distal portion of the sternal body and the xiphoid process. Arterial cannulation occurred systematically in the ascending aorta. In contrast, venous cannulation was performed percutaneously through puncture by Seldinger technique of the right common femoral vein. Left ventricular drainage and retrograde cardioplegia administration were performed either conventionally or percutaneously using the Endovent (Edwards Lifesciences, Irvine, California, USA) and/or the ProPlege (Edwards Lifesciences, Irvine, California, USA), at the surgeon's discretion. All percutaneous approaches were conducted under ultrasound control and, when in the hybrid room, also with the aid of radioscopy (Figure 2 B) [6]. Aortic clamping was performed centrally.

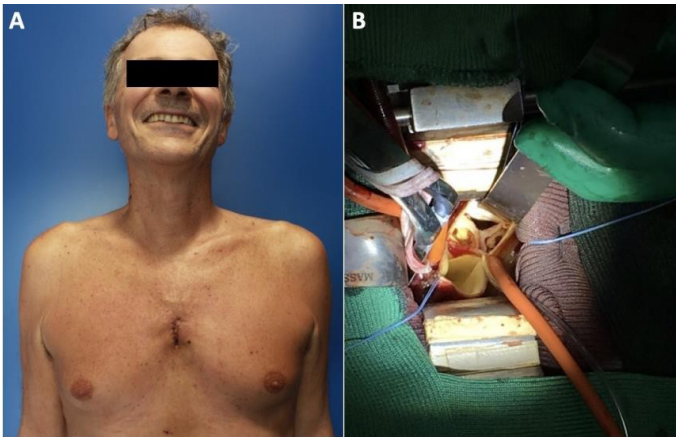

Figure 2 A: (A) Postoperative outcome in patient on postoperative day Va after aortic valve replacement with minimally invasive technique (B) Surgical procedure (surgeon's perspective): the surgical field is extremely reduced. As can be seen, only the aortic clamp and the arterial cannula (hidden behind the clamp) occupy the surgical field. All other lines necessary to the heart-lung machine, are peripheral and placed percutaneously.

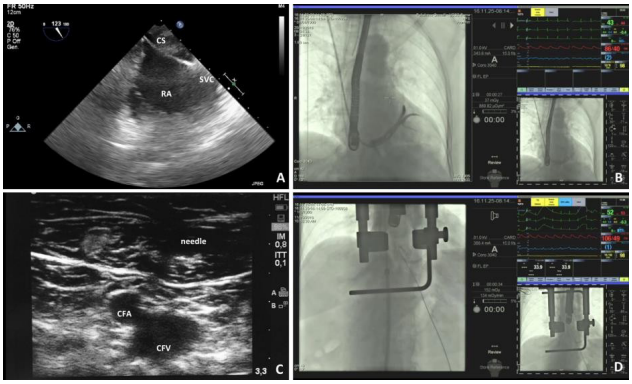

Figure 2 B: (A) Monitoring by transesophageal echocardiography of catheter placement for retrograde cardioplegia administration (ProPlege). (B) In the hybrid room, ProPlege placement is also confirmed radioscopically. (C) Echo-guided puncture of the right common femoral vein (CFV). (D) Advancement of the venous cannula and its precise positioning are also checked radioscopically.

Myocardial protection was accomplished by anterograde and/or retrograde administration of cold crystalloid or cold blood cardioplegia, at the surgeon's discretion. In order to reduce the risk of gas embolism, carbon dioxide was continuously insufflated into the operative field. Excision of the native aortic valve was performed in line with traditional techniques. Valve replacement was achieved with the use of interrupted sutures equipped with pledgets.

Ethics

Approval to conduct this study was obtained from the Ethics Committee of the Fondazione Policlinico Agostino Gemelli in Rome. Correct and detailed information about what the study was and about the machinery used (vibra 3.0) regarding what was expected of the participants was provided to the patients. Participants were asked to sign written informed consent, and they were given sufficient time to decide whether to take part in this study. They were also informed that their participation was voluntary and that they were free to withdraw from the study at any time without negative consequences for their subsequent treatment in the hospital.

Data analysis

Continuous variables were summarized as mean ± standard deviation if normally distributed or as median (interquartile range) if otherwise. Categorical variables were summarized as absolute and relative frequency. The Kolmogorov - Smirnov test was used to test the normality of the distribution of continuous variables before further analysis. Student's t test or Mann-Whitney test, as appropriate, was used to compare continuous variables, depending on the type of distribution of the variable in question. Fisher's exact test was used for comparisons of categorical variables. All tests were two-tailed and the significance level set at 0.05 (type I error). ANOVA for repeated measures of physiatric tests was used for repeated measures analysis. Sphericity of the model assessed by Greenhouse- Geisser epsilon. All analyses were conducted with SPSS software version 19.0.

Results

Preoperative characteristics

Table 1 summarizes the baseline characteristics of the enrolled patients, divided into the control group and the treatment group.

	Entire Cohort (n=40)		
	Control Group (n=20)	Treatment Group (n=20)	P Value
Age, Years	72.4±5.7	72.2±6.3	0.91
Male	14(70)	18(90)	0.24
BMI, Kg/m^2	25.8±2.9	26.2±3.9	0.71
BMI>30 Kg/m^2	3(15)	2(10)	1
Haemoglobin, g/dl	13.8±1.5	13.3±1.7	0.33
NYHA≥III	8(40)	9(45)	1
Syncope	1(5)	0(0)	1
Current Smoker	13(65)	11(55)	0.75
Hypertension	18(90)	20(100)	0.49
Diabetes Mellitus	7(35)	6(30)	1
Dyslipidemia	15(75)	14(70)	1
COPD	4(20)	2(20)	0.66
previous Stroke	1(5)	1(5)	1
PVD	2(10)	3(15)	1
Renal Failure*	2(10)	1(5)	1
Atrial Fibrillation	3(15)	3(15)	1
EF	62.5±10.3	65.3±3.5	0.26
MMSE	29.4±0.6	29.3±0.6	0.6
STS Score	2.4±1.4	2.2±1.3	0.64
STS Score MM	12.8±6.2	13.1±5.2	0.87

BMI -Body Mass Index-; NYHA -New York Heart Association, heart failure rating scale; COPD -Chronic Obstructive Pulmonary Disease; previous heart attacks; PVD -Peripheral Vascular Disease; EF -Ejection Fraction; MMSE -Mini Mental State Examination, cognitive impairment-, STS score -Society Thoracic Surgeon risk of mortality- and STS Score MM - Predicted Risk of Mortality & Morbidity).

*Glomerular filtration rate (calculated by Cockcroft and Gault formula) <50 mL/min without dialysis or with dialysis.

Table 1: Baseline characteristics of enrolled patients.

Baseline characteristics of study patients did not differ statistically significantly between the two groups. The mean age of the control group was 72.4 ± 5.7 years, whereas in the treatment group the mean age was 72.2 ± 6.3 years (p = 0.91).

Of the 20 patients in the control group, 14 were male (70%) while in the treated group there were 18 men (90%) (p = 0.24). Patients with hypertension accounted for 90% of the population in the control group and 100% in the treatment group (p = 0.49). The diagnosis of diabetes mellitus also did not differ between the two groups: the incidence was 35% in the control group and 30% in the "treatment" group (p = 1). Dyslipidemia afflicted 75% of the population in the control group and 70% in the treatment group, respectively (p = 1). The ejection fraction was 62.5 ± 10.3 for the control group and 65.3 ± 3.5 for the treatment group with no statistically significant differences (p = 0.26). The predicted risk of mortality according to the Society of Thoracic Surgeons score (STS score) was 2.4 ± 1.4 for the control group and 2.2 ± 1.3 for the treatment group (p = 0.64). The predicted risk of mortality and morbidity was 12.8 ± 6.2 for the control group and 13.1 ± 5.2 for the treatment group (p = 0.87).

Procedural data and postoperative outcomes

Table 2 summarizes the main procedural data while Table 3.3 reports the postoperative outcomes. The two groups of patients did not differ in terms of duration of surgery (226 ± 37 minutes for the control group, 234 ± 39 for the treatment, p = 0.51), duration of extracorporeal circulation time (100 ± 24 minutes for the control and 103 ± 26 for the treatment, p = 0.71), and duration of aortic clamping (72 ± 18 and 75 ± 22 for control and treatment, respectively, p = 0.64).

	Entire Cohort (n=40)		
	Control (n=20)	Treatment (n=20)	P Value
Operative Time, Min			
Cardiopulmonary by pass	100±24	103±26	0.71
Aortic Cross-Damp	72±18	75±22	0.64
Surgery	226±37	234±39	0.51
percutaneous Venous Cannulation	19(95)	20(100)	1
EndoVent	13(65)	15(75)	0.73
Propledge	3(15)	4(20)	1
Tissue Prosthesisi	19(95)	20(100)	1
Rapid dDeployment Prosthesisi*	1(5)	2(10)	1
Conversion to Full Sternotomy	-	-	-

*Intuity Elite (Edwards Lifesciences, Irvine, CA, USA)

Table 2: Procedural data.

No patients required conversion to full sternotomy. In 65% and 75% of patients in the control and treatment groups, respectively, EndoVent was used (p = 0.73). Similarly, in 15% and 20% of patients in the control and treatment group, respectively, the Proplege was used (p = 1). In all but one patient in the control group (5%), a biological prosthesis was used. More specifically, in 5% and 10% of patients in the control and treatment groups, respectively, facilitated-release prostheses of the Edwards Intuity type (Edwards Lifesciences, Irvine, California, USA) were used (p = 1).

There were no deaths at 30 days after surgery. We did not record statistically significant differences in the incidence of any of the major complications between the two study groups. Specifically, 3 patients in the control group (15%) and 2 patients (10%) in the treatment group required transfusion of concentrated hematins (p = 1). Ventilatory support had a mean duration of 6.9 ± 3.8 hours for the control group and 7.1 ± 3.3 hours for the treatment group (p = 0.86). ICU length of stay was 1.9 ± 1.1 days and 1.7 ± 1.3 days for the control and treatment groups, respectively, with no statistically significant differences (p = 0.60). Similarly, the total hospital stay was 6.9 ± 1.8 days and 7.2 ± 1.4 days for the control and treatment groups, respectively (p = 0.56).

	Entire Cohort (n=40)		
	Control (n=20)	Treatment (n=20)	P Value
30-day Mortality	0(0)	0(0)	
Postoperative drainage during the first 24h, ml	323±296	253±204	0.39
Ventilatory support, Hours	6.9±3.8	7.1±3.3	0.86
ECMO	0(0)	0(0)	
IABP	0(0)	0(0)	
Inotropes	2(10)	3(15)	1
Stroke	0(0)	0(0)	
Peripheral vascular complications	0	0(0)	
Re-exploration for bleeding	1(5)	0(0)	1
New-onset atrial fibrillation	6(30)	4(20)	0.72
New-onset haemodyalisis	0(0)	0(0)	

Nea PMK implantation	0(0)	1(5)	1
Blood transfusion	3(15)	2(10)	1
Deep wound complications	0(0)	0(0)	
ICU stay, days	1.9±1.1	1.7±1.3	0.6
Hospital stay, days	6.9±1.8	7.2±1.4	0.56

ECMO -Extra Body Membrane Oxygenation; IABP -Aortic Counterpulsator; new pace-maker implant; Coronary Intensive Care Unit stay; hospital stay.

Table 3: Postoperative outcomes.

Multidimensional impact of the Vibra 3.0 device.

Table 4 and Figure 3 describe the results of the Visual Analogue Pain Scale (VAS), six minutes-walking test (6MWT), hand grip, and Short Physical Performance Battery (SPPB) tests. All performance indicators (6M-WT, SPPB, and hand grip) showed a similar time course. At t1, in fact, there was a clear reduction in the functional capacity of the patient, which then progressively increased at t2 and t3. The same applies to postoperative pain, which, after an initial significant increase at t1, decreased at t2 and t3. These variations "within groups" were all statistically significant as demonstrated by the repeated measures ANOVA analysis whose results are reported in table 4.

The treatment group showed a significant improvement in the 6M-WT ($p < 0.01$) compared to the control group. With regard to the other tests, although not reaching a statistically significant difference, it should be noted that the trend is positive with a better performance of the hand grip and SPPB and reduced postoperative pain as evidenced by the VAS scale.

		Entire Cohort (n = 40)		
		Control Group (n = 20)	**Treatment Group (n = 20)**	**p value**
VAS				
	t0	0.4±0.6	0.3±0.6	epsilon*: 0.8 between-groups 0.134 within-groups < 0.01
	t1	5.6±1.0	6.3±1.0	
	t2	4.4±1.1	3.8±1.5	
	t3	3.3±0.9	2.2±0.7	
6M-WT				
	t0	282.8±47.0	281.8±51.0	epsilon*: 0.7 between-groups 0.009 within-groups < 0.001
	t1	220.8±75.9	206.3±47.4	
	t2	317.0±64.8	413.0±74.5	
	t3	338.0±61.1	422.5±94.3	
SPPB				
	t0	10.6±1.2	9.8±1.4	epsilon*: 0.8 between-groups 0.87 within-groups < 0.001
	t1	9.5±1.7	8.9±1.0	
	t2	9.4±1.3	10.1±1.0	
	t3	9.9±1.4	10.5±1.0	
H-Grip Dx				

	t0	33.1±5.2	32.5±5.0	epsilon*: 0.5 between-groups 0.81 within-groups < 0.001
	t1	30.6±5.9	30.7±6.0	
	t2	32.1±4.7	33.2±5.1	
	t3	32.4±4.5	33.3±5.0	

Table 4: Results of VAS, 6M-WT, SPPB, H-Grip tests of control and treated group patients.

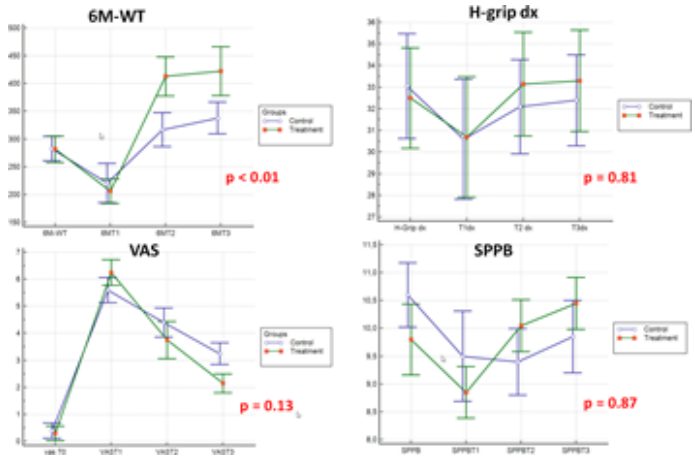

Figure 3: Results of VAS, 6M-WT, SPPB, H-Grip tests of control group patients (blue line) and treated patients (green line) at times t0, t1, t2, and t3.

Table 5 shows the results of the SF-36 test. This test consists of eight domains, four referring to physical health and four referring to mental health.

The eight domains are respectively: physical functioning (PF - physical activity), role-physical (RF - role and physical health), bodily pain (BP - physical pain), general health (GH - general health status), vitality (VT - vitality), social functioning (SF - social activities), role emotional (RE - role and emotional status), mental health (MH - mental health).

		Entire Cohort (n=40)		
		Control (n=20)	Treatment (n=20)	P Value
SF36 Heath Survey				
Physical Functioning				
	t0	61±3	62±5	epsilon*: 0.7 between-groups 0.01 within-groups < 0.01
	t1	58±4	57±3	
	t2	60±3	65±2	
	t3	62±2	67±1	
Role Physical				
	t0	52±4	51±2	epsilon*: 0.8 between-groups < 0.01 within-groups < 0.001
	t1	46±3	46±4	
	t2	47±4	52±2	
	t3	51±5	55±5	

Bodily Pain				
	t0	59±2	57±1	epsilon*: 0.6 between-groups 0.34 within-groups < 0.001
	t1	49±4	48±2	
	t2	51±6	52±5	
	t3	57±2	56±4	
General Health				
	t0	47±4	43±3	epsilon*: 0.7 between-groups 0.01 within-groups < 0.001
	t1	41±3	40±4	
	t2	43±3	48±5	
	t3	46±4	51±4	
Vitality				
	t0	41±4	39±3	epsilon*: 0.8 between-groups 0.02 within-groups < 0.01
	t1	38±4	37±2	
	t2	45±3	53±3	
	t3	50±5	58±4	
Social Functioning				
	t0	53±2	51±4	epsilon*: 0.9 between-groups 0.04 within-groups < 0.01
	t1	46±2	47±4	
	t2	48±3	50±2	
	t3	51±5	55±3	
Role-Emotional				
	t0	53±3	53±3	epsilon*: 0.5 between-groups 0.91 within-groups < 0.01
	t1	48±4	49±4	
	t2	50±5	53±3	
	t3	54±4	54±2	
Mental Health				
	t0	60±4	61±3	epsilon*: 0.6 between-groups 0.11 within-groups < 0.01
	t1	57±4	57±3	
	t2	59±3	59±2	
	t3	62±5	63±5	

Table 5: Results of the SF-36 test for the control group and the treated group.

Regarding the domains referring to physical health, (Figure 4 A), the results show that there are significant differences between the control and treatment groups when considering the parameters PhysicalFunctioning ($p < 0.01$), Role Physical ($p < 0.01$) and General Health ($p < 0.01$).

Similarly to the VAS pain self-assessment scale, we also recorded no statistically significant differences between the two groups when considering the Bodily Pain domain of the SF-36 ($p = 0.34$).

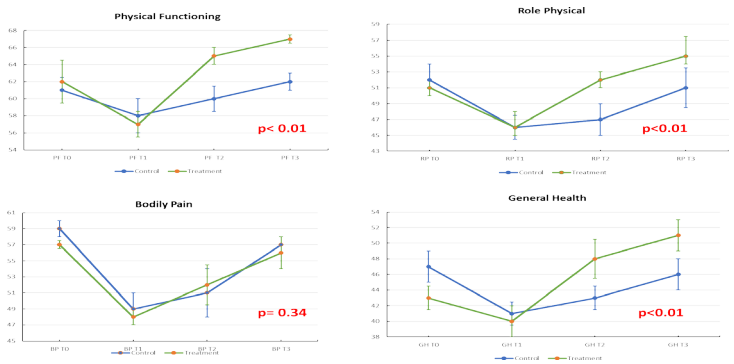

Figure 4: (a). Results of the SF-36 test for the four domains referred to physical health. The blue line represents the control group, the green line the "Usual Care" + Vibra3.0 group.

Considering instead the remaining four domains referred to mental health, (Figure 4 B) showed a statistically significant difference between the two groups for the domains Vitality and Social Functioning (respectively p =

0.02 and p = 0.04) and non-significant for the domains Role Emotional (p = 0.91) and Mental Health (p = 0.11). The study of significance within the group itself ("within groups"), has shown that for each domain the perception of the patient with respect to his own state of health both physical and mental varies significantly during the four moments of assessment.

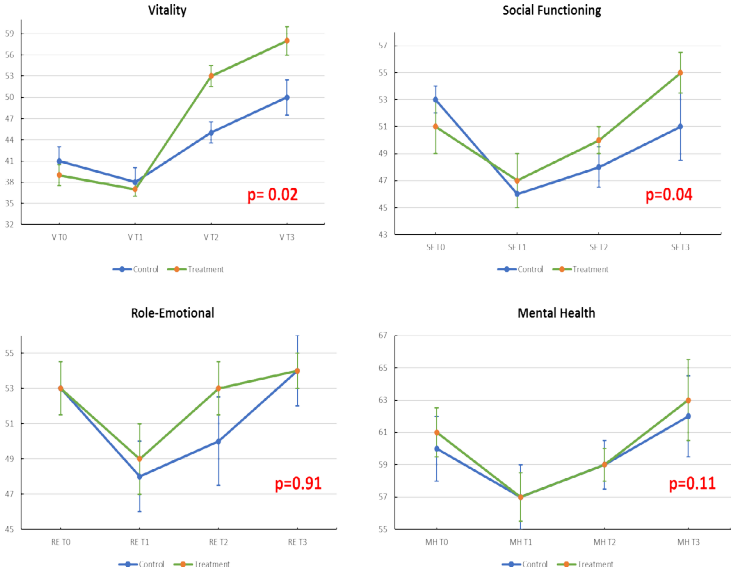

Figure 4 (b). Results of the SF-36 test for the four domains referred to mental health. The blue line represents the control group, the green line the "Usual Care" + Vibra3.0 group.

Discussion

The efficacy of rehabilitation in patients undergoing cardiac surgery has been well studied [7,8], but to date no protocols have been conducted that included, in addition to the normal aerobic and respiratory conditioning, stimulation with focal selective vibrations in association. Therefore, the aim of this work was to compare the results of an associated intervention of focal vibratory stimulation, to a traditional rehabilitation protocol, in a population of patients undergoing cardiac surgery.

In order to reduce possible confounding factors, we decided to limit the study to patients undergoing aortic valve replacement with a minimally invasive approach. Indeed, minimally invasive surgery has previously been associated with better functional recovery and faster return to daily activities than conventional approaches [9]. For this reason, including patients who underwent conventional sternotomy and minimally invasive approach indiscriminately would have introduced a bias in the study methodology. On the other hand, having included only patients who underwent minimally invasive surgery might have led us to evaluate our hypothesis in a population that, by its basic characteristics alone, would have had an optimized postoperative rehabilitation course.

It is necessary to underline that the patients in the two study groups were comparable not only in their preoperative characteristics (this is expected and due to the randomization process itself) but also and above all in their postoperative course. Any differences in the postoperative complications, in fact, could have ended up affecting in a decisive way the results related to the rehabilitation period and functional recovery.

After an initial, expected worsening (t1), in fact, all the indicators showed a progressive curve ofimprovement (t2 and t3), whose "within group" variability was statistically significant in ANOVA analysis for repeated measures. Moreover, we observed that, with regard to each individual indicator, the treatment group achieved a performance at t3 that was systematically better than the baseline value (t0). The same result cannot be said, however, for the control group, at least for the Hand-grip, SPPB and numerous items of the SF-36. This result is of considerable interest as it underlines how a targeted rehabilitation program with focal vibrational stimulation can not only restore a physical status equal to the pre-operative one but, in fact, significantly better.

From the "between groups" comparison, however, it emerges that physical performance recovers significantly better in the group treated with Vibra 3.0. We believe that this result is a direct consequence of increased segmental muscle strength, improved joint stability and balance control, as already reported in previous studies [10]. Specifically, we documented better results of the 6M-WT ($p < 0.01$) and both items of the SF-36 rating scale specific to physical performance (PF: $p < 0.01$; RF: $p < 0.01$). With regard to SPPB and hand grip, although not reaching statistical significance, both indicators have a trend towards faster recovery in the treated group. The explanation for this phenomenon is multifactorial. First, the small number of patients enrolled. Then, with regard to hand grip, it has been shown in previous studies that strength in the upper limbs critically depends on proper muscle tone and trunk stability [11,12].

Because of the limitations imposed in the postoperative period (use of the corset, avoidance of abduction of the arms, avoidance of loading of the scapulohumeral girdle), the cardiac surgical patient tends to significantly reduce, even for antalgic purposes, the use of the upper limbs and this may have affected the results of the hand-grip test. Similarly, the SPPB assesses the ability to maintain balance in different conditions (normal, semi-tandem, and tandem), the ability to get up from a chair without the aid of the upper limbs, and the walking speed over 4 linear meters. Except for this last task, the former could have been influenced by the specific conditions in which the patient undergoing cardiac surgery finds himself (sternal pain, inability to use the upper limbs, etc) or require skills to which the patient had not previously been pre-conditioned (maintaining control in tandem and semi-tandem conditions) or otherwise habitual, such as walking.

In previous studies, mainly conducted in cohorts of patients with stroke outcomes, the use of vibration therapy has been associated with a reduction in postoperative pain due to mechano-acoustic stimulation [13,14]. Although we were unable to demonstrate such an outcome in our experience, both the VAS scale and the specific SF-36 scale item show a definite trend toward this outcome. Again, the small number of patients may have played a role.

A finding of particular interest was that the treatment group showed significantly better Vitality and Social Functioning at t2 and t3 than the control group. This result may be a direct consequence of the better recovery of physical performance in the treatment group. On the other hand, it is fair to imagine that a better physical capacity may correspond to a better tone of mood and, therefore, of social relations. Similarly, a rapid and complete recovery of physical function may have contributed to a better perception of the state of general health (Health General) that we documented in the treatment group. Of no less interest, the fact that the association of a device like the Vibra 3.0 to the usual rehabilitation protocols may have induced in the patient the feeling of greater assistance and care. In fact, unlike conventional rehabilitation pathways, the use of the Vibra 3.0 increases the extent of the patient-therapist relationship. Although not reaching statistical significance, the treated patient revealed a greater "Role-Emotional", especially at the t2 interval. This area needs further evaluation, possibly with the integration of psychological rating scales.

The use of vibration in the postcardiac surgery rehabilitation setting is not entirely new. In a recent randomized trial, Chaves and colleagues [15] proposed a protocol involving the performance of static and dynamic exercises on a vibration/oscillation platform in elective patients undergoing cardiac surgery. In this case, the vibration starts from the feet and propagates through the whole body ("Whole Body Vibration"). Although the authors report promising results, the use of the "Whole Body Vibration" is characterized by the fact that the mechanical wave generated by the vibration undergoes, in its propagation along the tissues of the body, a deformation. This generates, in turn, resonance phenomena with the frequencies of the joints with amplification of the mechanical energy itself and possible damage to joint structures [16-18].

Moreover, this type of therapy could have detrimental consequences in terms of the healing process and risk of sternotomy wound dehiscence in the cardio-operated patient. Localized vibration with Vibra 3.0, on the contrary, does not present such criticalities. It is practically free of side effects and can be used even in patients who are not at all or poorly cooperative (who, precisely because of their poor compliance, benefit less from the usual rehabilitation protocols that require the active collaboration of the patient). Moreover, unlike electro- stimulation, focal vibrational stimulation can also be administered to patients with pacemakers and defibrillators, which are frequent in the post-cardiac surgery rehabilitation period. Finally, although not the subject of our analysis, it is possible to hypothesize that the integration of Vibra 3.0 in the rehabilitation pathway may have an advantage also in terms of cost-effectiveness and optimization of resources. In fact, beyond the positioning and removal of transducers and set-up of the machine, the therapist does not need to be present during the administration of therapy, being able to devote himself to the treatment of other patients.

Ultimately, this pilot study demonstrated that the addition of focal vibration therapy with Vibra 3.0 in the rehabilitation pathway of the cardiac surgical patient significantly improves functional recovery. This result is primarily driven by an optimization of physical performance, but does not end with it. In fact, pain reduction, improved perception of one's overall health status, and an implemented return to social functioning contribute critically. Based on these results, we believe it is possible to proceed to a larger scale study of patients, undergoing different types of cardiac surgery.

Limitations of this Study

This study has limitations that need to be acknowledged.

First, this study enrolled a small number of patients, so it is considered underpowered and its conclusions are not definitive. On the other hand, it was intended to be a pilot study aimed at investigating the feasibility of a larger clinical trial.

Second, the patients enrolled in the study were highly selected, low-risk, undergoing minimally invasive aortic valve surgery alone. For these reasons, it is not possible to generalize the results, which also need to be validated in a population with different characteristics.

Finally, this study lacks a medium-term follow-up that could clarify whether the observed trend goes to further improvement or, rather, returns toward baseline values.

Conclusion

In conclusion, as part of the rehabilitation pathway of cardiac surgery patients, focal controlled mechanical vibration therapy appears to significantly improve functional recovery and physical performance, reduce the perception of postoperative pain, and improve general health and social functioning. However, further studies are needed to confirm the results of this pilot study on a larger scale of patients undergoing different types of cardiac surgery.

References

1. Fortes JV, Silva MG, Baldez TE, et al. (2016) Mortality Risk after Cardiac Surgery: Application of Inscor in a University Hospital in Brazil's Northeast. Braz J Cardiovasc Surg 31: 396-9.
2. Celletti, et al. (2017) Focal Muscle Vibration and Progressive Modular Rebalancing with neurokinetic facilitations in post- stroke recovery of upper limb. Clin Ter 2017 168: e33-36.
3. Murillo N, Valls-Sole J, et al. (2014) Focal vibration in neurorehabilitation. Eur J Phys Rehabil Med 50: 231-42.
4. Bily W, Franz C, et al. (2016) Effects of Leg-Press Training With Moderate Vibration on Muscle Strength, Pain, and Function after Total Knee Arthroplasty: A Randomized Controlled Trial. Arch Phys Med Rehabil 97: 857-65.
5. Pei-Yun Wang et al. (2019) Acute and Long-Term Effects of Mechanotherapy on the Outcome After an Achilles Repair: A Prospective Cohort Study With Historical Controls. Arch Phys Med Rehabil 100: 2046- 2052.
6. Bruno, et al., (2019) Improved Patient Recovery with Minimally Invasive Aortic Valve Surgery: A Propensity- Matched Study. Innovations 14: 419–427.
7. McMahon SR, Ades PA, Thompson PD (2017) The role of cardiac rehabilitation in patients with heart disease. Trends Cardiovasc Med 27: 420□425.
8. Price KJ, Gordon BA, Bird SR, Benson AC (2016) A review of guidelines for cardiac rehabilitation exercise programmes: Is there an international consensus?. Eur J Prev Cardiol 23: 1715□1733.
9. Brown ML, McKellar SH, Sundt TM, et al. (2009) Ministernotomy versus conventional sternotomy for aortic valve replacement: a systematic review and meta-analysis. J Thorac Cardiovasc Surg 137: 670–679.
10. Filippi GM, Brunetti O, Botti FM, et al. (2009) Improvement of stance control and muscle performance induced by focal muscle vibration in young-elderly women: a randomized controlled trial. Arch Phys Med Rehabil 90: 2019□2025.
11. Misayake, et al., (2013) Core exercises elevate trunk stability to facilitate skilled motor behavior of the upper extremities. Journal of Bodywork and Movement Therapies 12: 259-265.

12. Ben Kibler W, et al., (2006) The Role of Core Stability in Athletic Function Sports Medicine 36: 189–198.

13. Constantino C, Galuppo L, Romiti D (2014) Efficacy of mechano-acoustic vibration on strength, pain, and function in poststroke rehabilitation: a pilot study. Top Stroke Rehabil 21: 391□399.

14. No authors (1992) Vibration therapy for pain. Lancet 339: 1513□1514.

15. Jussara R. Chaves, Daniel L. Borges, João Vyctor S. Fortes, et al. (2018) Study of the effect of whole body vibration exercise in cardiac surgery postoperative care: a protocol proposition. Revista HUPE, Rio de Janeiro 17: 7-11.

16. Tihanyi TK, HorvÃ¡th M, Fazekas G, HortobÃ¡gyi T, Tihanyi J. Clin Rehabil. 2007 ; 21:782-9.

17. van Nes IJ, Latour H, Schils F, Meijer R, van Kuijk A, Geurts AC. Stroke. 2006, 37: 2331-5.

18. Filippi G. M., Camerota F. La vibrazione meccanica focale nella terapia del movimento. 2012 FisiOnline.