Original Article

The efficacy of using Tri-Ball breathing exerciser in respiratory function recovery of the patients undergoing cardiac surgery

VOLODYMYR VITOMSKYI[1,2], KHALED AL-HAWAMDEH[1], OLENA LAZARIEVA[1], MARYNA VITOMSKA[1]

[1]*National University of Ukraine on Physical Education and Sport, Ukraine*
[2]*GI «Scientific and Practical Medical Center for Pediatric Cardiology and Cardiac Surgery of the Ministry of Health of Ukraine» (Ukrainian Children's Cardiac Center), Ukraine*

ABSTRACT

Objective: To investigate the effect of using Tri-Ball breathing exerciser on the results of the pulmonary function test in the patients undergoing cardiac surgery. Design: prospective randomized controlled trial. Setting: hospitalized care. Participants: 66 patients of both sexes were randomly divided into control group (CG) and training group (TG). Interventions: Both groups received standardized physical therapy (early mobilization; therapeutic exercises; chest wall vibrations; percussions; coughing; calm deep breathing without simultaneous movements of the limbs or other parts of the body to rest between therapeutic exercises and reduce respiratory and heart rates). TG patients also used Tri-Ball breathing exerciser to train inspiratory muscles. Main Outcome Measures: the results of the pulmonary function test before the surgery and on the 7 postoperative days. Results: pulmonary function had no statistical difference in CG and TG patients both before the surgery and on the 7 postoperative days. Vital capacity reduced from 103.81 ± 13.20% to 76.84 ± 14.65% in CG and from 104.18 ± 13.20% to 76.38 ± 16.18% in TG. The reduction of peak expiratory flow was less pronounced in both groups: from 96.91 ± 14.05% to 79.19 ± 18.08% in CG and from 98.77 ± 19.38% to 82.03 ± 20.75% in TG. Inspiratory indicators (forced inspiratory vital capacity, forced inspiratory volume in one second, peak inspiratory flow) also did not confirm any additional benefit of using Tri-Ball breathing exercises, despite the fact that it is aimed to train deep, strong and quick inhalation. Tiffeneau index had no statistical changes in CG ($p = .257$), though it showed statistical improvement in TG ($p = .031$). Conclusions: The study did not confirm any benefits of using Tri-Ball breathing exercises in the physical therapy program.

Keywords: Physical therapy; Inspiratory muscle training; Cardiac surgery; Pulmonary rehabilitation; Incentive spirometry.

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Corresponding author. *National University of Ukraine on Physical Education and Sport; 1 Phizkultury Street, Kyiv, 03680, Ukraine. https://orcid.org//0000-0002-4582-6004*
E-mail: vitomskiyvova@gmail.com
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INTRODUCTION

Reduced pulmonary function and postoperative pulmonary complications (PPCs) have a significant impact on the recovery of the patients after cardiac surgery (CS) (Vitomskyi, 2020). Reasons for this impairment include general anaesthesia, opening of the thorax, surgical trauma, cardiopulmonary bypass, loss of thoracic mechanics, increased interstitial lung water, pleural effusions and diaphragmatic dysfunction (Westerdahl, 2015).

Physical therapy (PT), including respiratory PT, is routinely offered to the patients following CS (Vitomskyi & Al-Hawamdeh, 2020). Traditionally, prevention and treatment of pulmonary complications have included early mobilization and physical therapy interventions, including a variety of respiratory manoeuvres such as deep breathing exercises, coughing, incentive spirometry (Stein et al., 2009). The surveys of physical therapists show that there are various treatment options and opinions about the best way to restore pulmonary function and reduce PPCs after CS, and there is a need to develop internationally approved guidelines in order to establish optimal content and timing of postoperative breathing exercises (Westerdahl & Olsén, 2011).

The main respiratory PT interventions include deep breathing exercises, diaphragmatic breathing, pursed lip breathing, sustained maximal inspiration, incentive spirometry, positive expiratory pressure device breathing, inspiratory resistance – positive expiratory pressure, inspiratory muscle training (IMT), continuous positive airway pressure. The benefits of using a number of respiratory PT techniques have been refuted or proved controversial. In particular, there is no difference in the use of maximal inspiratory breathing exercises, incentive spirometry or early mobilization alone for improving lung volumes and airflow or in preventing PPCs (Dull & Dull, 1983). Therefore, it is important to approve the optimal strategy for the use of PT in order to restore pulmonary function.

Objective

To investigate the effect of using Tri-Ball breathing exerciser on the results of the pulmonary function test (PFT) in the patients undergoing cardiac surgery.

MATERIAL AND METHODS

Organization of the research

The patients were randomly divided (at 1:1 ratio; envelope method) into control group (CG) and training group (TG). The study protocol was approved by the institutional review board and the local medical ethics committee (Ethics Committee approval protocol №1 of 21.01.2020). All patients were informed about the study protocol and gave written informed consent.

Setting

Hospitalized care.

Participants

The study included 66 patients of both sexes, who were submitted to CS. All procedures were performed by median sternotomy on cardiopulmonary bypass with cardioplegic arrest.

The exclusion criteria were: patients with unstable angina pectoris at the moment of selection or during the program, congestive decompensated heart failure, lack of intellectual capacity, complex ventricular and uncontrolled arrhythmia, uncontrolled high blood pressure, cerebrovascular accident.

Interventions

Both groups received standardized PT (early mobilization; therapeutic exercises; chest wall vibrations; percussions; coughing; calm deep breathing without simultaneous movements of the limbs or other parts of the body to rest between therapeutic exercises and reduce respiratory and heart rates).

Before the surgery, the patients were briefly consulted by a physical therapist on the aims and content of PT and activation algorithm after the surgery. The postoperative protocol of PT called for the following practice of patient's early mobilization: sitting on the bed with the legs dangling on the 1 postoperative day (POD); standing (getting up with the help and under the control of a physical therapist, holding on a medical movable walker; agreed with an anaesthesiologist) and on-the-spot walking if feasible on the 1-2 POD; on-the-spot walking, walking within the ward on the 2 POD; walking in the hospital corridor on the 3 POD; walking up and down the stairs on the 4-5 POD. Besides, all patients performed therapeutic exercises with a physical therapist and therapeutic walking under the control of a physical therapist. Sessions (about 20 minutes each) with a physical therapist were conducted 2 times a day on the 1 and 2 PODs, 1-2 times on the 3 POD, 1 time starting from the 4 POD. In case of a necessity (patient's condition, the need for motivation), the physical therapist could increase the number and the length of the sessions.

The groups differed in respiratory physical therapy: TG patients additionally performed respiratory exercises with a Tri-Ball breathing exerciser to train the inspiratory muscles (at least three repetitions of 10 strong, full and rapid inhalations through the breathing exerciser at the sessions with a physical therapist; recommendations to perform 3 sets with 10 repetitions every hour in order to lift all three balls of the breathing exerciser (600, 900 and 1200 cc / sec) with each inhalation.

If a participant was not able to lift all three balls this was not considered a treatment failure, since selecting participants on this basis would contribute to the concentration of patients with better scores in TG. At the same time, such selection would be impossible in CG.

TG patients were asked to start from a lower lung volume before starting the forceful inhalation. Training with breathing exerciser started from the 1 POD. During the 1 and 2 PODs the exercises performed every hour were supervised by medical staff, afterwards the patient recorded independently performed exercises in the diary.

Outcome measures

Demographic variables, clinical history were recorded on entry to the trial.

Both groups were submitted to PFT before the surgery and on the 7 POD. The patients performed at least 3 PFT attempts using Spirodoc MIR spirograph and Winspiro PRO software. Individual rates were calculated automatically according to Knudson/ERS. The personal performing the spirometry was blinded regarding participants group allocation.

Statistical analysis

The materials of the research were processed in IBM SPSS 21 program of statistical analysis. Mathematical processing of numerical data was fulfilled with the help of variation statistics. The analysis of quantitative indicators distribution's correspondence to the law of normal distribution was checked by Shapiro-Wilk test (W).

Mean value and root-mean-square deviation ($\overline{x} \pm S$) were additionally calculated for the results of indicators that corresponded to the law of normal distribution.

Median value (Me) and upper and lower quartiles (25%; 75%) were calculated for the indicators with a non-normal distribution. Student's t-test (for independent or dependent groups) was used to measure the significance of the difference, provided there was a normal distribution of study results; Mann-Whitney U test (for independent groups) and $\chi 2$ criterion were used provided the indicators had a distribution other than normal.

RESULTS

CG included 25 males and 7 females, and TG included 20 males and 14 females (p = .092). Significant differences in anthropometric data, NYHA functional class, time indicators of the operation were not found (Table 1).

Table 1. The main characteristics of the samples.

Indicators	CG (n = 32)	TG (n = 34)	p
Age, years	63 (53; 69.5)	64 (58; 70)	.361*
Body weight, kg	81.75 ± 12.81	81.28 ± 15.81	.895#
Body length, cm	169.75 ± 9.01	167.12 ± 9.41	.251#
Body mass index, kg/m^2	28.34 ± 3.77	29.12 ± 5.24	.491#
EF, %	53.53 ± 7.57	51.77 ± 11.54	.468#
AH, degree	2 (0; 3)	2 (2; 3)	.277*
NYHA, class	2.5 (2; 3)	3 (2; 3)	.456*
AVL duration, hour	7 (6; 9)	8.5 (6; 11,2)	.186*
Operation duration, min.	360(322.5;398.8)	337.5(295;446.2)	.476*
CPB duration, min.	152(139;202)	190.5 (144.8;233)	.096*

*Note: EF - ejection fraction; AH – arterial hypertension; AVL - artificial lung ventilation; CPB - cardiopulmonary bypass; # - Student's t-test; * - Mann-Whitney U-test.*

Table 2. Results of comparing cardiac surgeries in patient groups according to χ^2, units (%).

Operations		CG (n = 32)	TG (n = 34)	p
CABG		21 (65.6)	18(52.9)	.295
Surgery for	MV	5(15.6)	18(52.9)	.001
	AV	11(34.4)	16(47.1)	.295
	Ao	1(3.1)	3(8.8)	.332
	TV	6(18.8)	7(20.6)	.851

Note: CABG - coronary artery bypass graft; MV – mitral valve; AV – aortic valve; TV – tricuspid valve; Ao – aortic.

When analysing CS, it was found that the groups of the patients had no significant difference in the frequency of most interventions, only the frequency of interventions on the mitral valve was statistically higher in TG patients (Table 2). However, this difference cannot be considered critical, since the duration of operations was statistically identical in the groups. It should be noted that the use of one and two internal mammary arteries in CABG was determined in 21.9% and 34.4% of CG patients, and 26.5% and 17.6% (p = .298) in TG patients.

The patients of the groups had no significant difference in PFT test before the surgery, showing in general good test results. It should be noted that six CG and seven TG patients had $FEV_1/VC < 70\%$.

Table 3. The indicators of the pulmonary function test before the surgery.

Indicators	CG (n = 32)	TG (n = 34)	p
VC, % predicted	103.81 ± 13.20	104.18 ± 13.20	.917
FVC, % predicted	102.13 ± 14.08	100.91 ± 13.96	.726
FEV_1, % predicted	101.53 ± 18.27	100.71 ± 15.41	.843
FEV_1/ VC, %	77.64 ± 9.65	76.40 ± 8.06	.571
FEV_1/ FVC, %	79.73 ± 8.83	80.09 ± 7.88	.863
PEF, % predicted	96.91 ± 14.05	98.77 ± 19.38	.659
FEF_{25-75}, % predicted	87.43 ± 33.34	95.88 ± 35.21	.321
FIVC, % predicted	96.69 ± 15.07	95.56 ± 17.41	.780
FIV_1, % predicted	114.53 ± 22.32	114.87 ± 22.05	.951
PIF, % predicted	69.66 ± 18.73	70.35 ± 21.77	.890

Note: VC - vital capacity; FVC - forced vital capacity; FEV1 - forced expiratory volume in one second; FEV1/ VC - Tiffeneau index; FEV1/ FVC - Tiffeneau-Pinelli index; PEF - peak expiratory flow; FEF25-75 - forced expiratory flow at 25–75% of forced vital capacity; FIVC - forced inspiratory vital capacity; FIV1 - forced inspiratory volume in one second; PIF - peak inspiratory flow.

When assessing the pulmonary function on the 7 POD, CG and TG groups showed no significant differences (Table 4), which confirms the absence of any benefits of including the Tri-Ball breathing exercises in the physical therapy program. Volume and flow indicators were worse than before the surgery (p = .000). Volume decrease was more pronounced than flow decrease. Besides, the number of patients with $FEV_1/ VC < 70\%$ dropped to 3 in CG and to 4 in TG.

Table 4. The indicators of the pulmonary function test on the seventh postoperative day.

Indicators	CG (n = 32)	TG (n = 34)	p
VC, % predicted	76.84 ± 14.65	76.38 ± 16.18	.904
FVC, % predicted	75.63 ± 14.84	74.32 ± 17.51	.746
FEV_1, % predicted	73.79 ± 19.81	76.18 ± 18.55	.615
FEV_1/VC, %	79.36 ± 8.61	78.84 ± 8.56	.808
FEV_1/FVC, %	81.91 ± 8.65	82.49 ± 9.35	.795
PEF, % predicted	79.19 ± 18.08	82.03 ± 20.75	.556
FEF_{25-75}, % predicted	69.63 ± 24.36	75.06 ± 33.25	.454
FIVC, % predicted	71.81 ± 14.92	70.77 ± 18.17	,799
FIV_1, % predicted	88.09 ± 19.39	86.59 ± 22.51	.773
PIF, % predicted	57.38 ± 14.93	58.62 ± 18.08	.763

Note: VC - vital capacity; FVC - forced vital capacity; FEV1 - forced expiratory volume in one second; FEV1/VC - Tiffeneau index; FEV1/FVC - Tiffeneau-Pinelli index; PEF - peak expiratory flow; FEF25-75 - forced expiratory flow at 25–75% of forced vital capacity; FIVC - forced inspiratory vital capacity; FIV1 - forced inspiratory volume in one second; PIF - peak inspiratory flow.

DISCUSSION

It should be noted that all participants in TG were instructed the same way regardless of their age, height, weight and lung function. At the second examination, 64.7% of TG patients were able to lift three balls of a breathing exerciser during forced inhalation, 29.4% - two balls, 5.9% one ball.

The study did not confirm any benefits of including respiratory training with the help of Tri-Ball breathing exercises in the physical therapy. Both CG and TG patients showed statistically worse volume and flow indicators on the 7 POD than during the first test. There were no significant differences between the groups

before and after the surgery. It should be noted that VC and FVC indicators in both groups decreased approximately by 27%. FEV_1 decrease comprised 27.7% predicted in CG, and 24.5% predicted in TG. All indicators, except FEV_1/VC and FEV_1/FVC, were statistically lower than the initial values ($p = .000$). Tiffeneau index ($p = .257$) and Tiffeneau-Pinelli index ($p = .062$) had no statistical changes in CG, which confirms that surgery has no impact on obstructive pulmonary dysfunction. At the same time, Tiffeneau-Pinelli index ($p = .078$) had no statistical changes in TG, whereas Tiffeneau index had a statistical improvement ($p = .031$), though the difference was not large and clinically significant. The number of patients with $FEV_1/VC < 70\%$ decreased in both groups, which is the result of a more significant decrease of VC than FEV_1 in such patients.

The impact of the operation was more pronounced in the volume indicators (24-28% decrease predicted). Flow indicators had a slightly less decrease (11-20% predicted). Despite the fact that the Tri-Ball breathing exerciser is aimed at training deep, strong and quick inhalation, forced inhalation indicators were not better in TG.

Previous studies of inspiratory muscle training have reported on both the presence and absence of its efficacy.

According to Hulzebos et al. (2005), the use of IMT during preoperative period (20 minutes of IMT, 7 times a week, for at least 2 weeks before CABG surgery) confirmed its efficacy among the patients at high risk of developing a pulmonary complication, namely by reducing the incidence of PPCs and duration of postoperative hospitalization (median value of 7 vs. 8 days). It should be noted, that loading in this study gradually increased (according to the patient's results) starting from 30% MIP measured at baseline. However, the study presented only preoperative PFT, MEP (maximum expiratory pressure) and MIP (maximum inspiratory pressure) indicators.

Prophylactic IMT (using a threshold trainer for 30 min/day for 2 weeks, 1 month before CABG surgery) led to the absence of any difference between preoperative and postoperative indicators of respiratory muscle function, PFT, and gas exchange in the training group, and to their significant decrease in the control group (Weiner et al., 1998).

At the same time, the study of Ferreira et al. (2009) showed no clinical benefits of preoperative IMT (at least 2 weeks before cardiac surgery) at 40% MIP measured at baseline: the surgery led only to significant changes in forced vital capacity (FVC), the maximum voluntary ventilation (MVV) and FEV_1/FVC indicators in the main group at the repeated examination immediately before surgery; changes of the arterial blood gases and of the MIP and MEP (maximum expiratory pressure) before and after the cardiac surgery were similar in both groups, with the outcomes also being similar. Besides, the diagrams presented in the study indicate slightly better MIP and MEP indicators in the control group.

In routine care the use of inspiratory threshold loading device in the preoperative period (7 days a week, 20 minutes uninterrupted each day, for at least 2 weeks) among the patients at high risk of PPCs does not influence the frequency of postoperative pneumonia, ventilation time, length of stay in the intensive care unit, or total postoperative length of stay (Cordeiro et al., 2016).

A systematic review and meta-analysis of Mans et al. (2015) evaluates the efficacy of preoperative IMT among the patients undergoing open cardiac, thoracic, or upper abdominal surgery, which confirms the positive impact on MIP in the preoperative and early postoperative periods, as well as on the lung function

recovery. There were no statistically significant differences between the groups for the remaining outcomes, including the length of hospital stay.

Another systematic review and meta-analysis (Katsura et al, 2015) of the studies among the patients undergoing open cardiac and major abdominal surgery confirmed the influence of preoperative IMT on the reduction of postoperative atelectasis, pneumonia, and duration of hospital stay. However, the researchers emphasize that the potential for overestimation of treatment effect due to lack of adequate blinding, small-study effects, and publication bias needs to be considered when interpreting the present findings (Johnson et al., 1996).

According to the recent systematic review (Karanfil & Møller, 2018), preoperative IMT may reduce the risk of developing PPCs following CABG and heart valve surgery. However, the researchers emphasize that more trials are needed to support and strengthen the evidence found in this systematic review before preoperative routine implementation of this kind of training.

Concerning the efficacy of using postoperative IMT (for 4 weeks starting from the 3 POD, twice daily), Cargnin et al. (2019) confirmed the recovery of preoperative MIP level and lung function among the patients undergoing heart valve replacement surgery, whereas the placebo group showed worse recovery results.

A positive impact of using IMT (with variable loading, for 12 months) on the increase of MIP and paralyzed diaphragm mobility after CS has been confirmed (Kodric et al, 2013). It is noteworthy that the initial MIP indicators (68.0 ± 24.9 cmH_2O vs. 58.7 ± 27.3 cmH_2O), as well as MEP indicators (137.5 ± 44.7 cmH_2O vs. 109.6 ± 62.1 cmH_2O) were slightly better in the IMT group. At the same time, the level of the initial MIP was very close to the results of ordinary patients after CS (Cordeiro et al, 2016; Johnson et al, 1996; Savci et al, 2011) or even better (Stein et al, 2009).

The study of Cordeiro et al. (2016) confirmed positive effect of including IMT in the treatment protocol of the patients transferred to the inpatient unit (40% of the postoperative MIP, 3 sets with 10 repetitions, twice daily until hospital discharge). In particular, final MIP indicators were better in the intervention group (69.5 ± 14.9 vs. 83.1 ± 19.1 cmH_2O, $p = .0073$).

Positive effect of including IMT in the standardized protocol of physical therapy starting from the first POD was confirmed (Matheus et al, 2012). VC and tidal volume indicators were higher in the intervention group when assessing respiratory function on the 3 POD, though there was no information concerning the benefits of MIP, MEP, and peak expiratory flow.

In one of the studies (Savci et al, 2011), the use of IMT during five days in the preoperative period and five days in the postoperative period (two times per day, between 15% and 45% MIP) led to MIP increase (up to 95.45 cmH_2O) as compared to the initial values in the intervention group at the time of hospital discharge (5.77 POD on average), whereas the control group showed MIP decrease to 57.24 cmH_2O. Such a distinct result casts doubt on the possibility of its achieving after the surgery during 5 days, since MIP may not be resumed to the initial level even during 8 weeks (Johnson et al, 1996).

At the same time, the study Savci et al. (2011) did not determine any advantages of the intervention group in the duration of postoperative hospital stay and final indicators of FEV_1, FVC, FEV1/FVC, MEP. Noteworthy is the statement of the authors that the length of intensive care unit stay was significantly longer in the control

group than the intervention group, though the numeric data indicate the opposite (32.52 (12.33) hours for the intervention group vs. 30.13 (11.86) hours for the control group).

Concerning the relation between respiratory muscle strength and lung function, it should be noted that the study of Urell C. et al. determined that respiratory muscle strength is restored and does not reduce two months after CS, unlike lung function. Therefore, the researchers emphasize that interventions aimed at restoring optimal postoperative lung function should focus on other interventions rather than respiratory muscle strength training (Urell et al, 2016).

Thus, the results of this study supplemented the data on the specificities of lung function dynamic in the patients following CS. New data were obtained on the changes in lung function on the 7 POD among the patients receiving Tri-ball, as well as on the changes in flow indicators when using Tri-ball. Most of the previous studies have focused on long-term or short-term use of IMT. This study assessed the impact of Tri-ball breathing exercises, probably during the most reasonable time, taking into account the recovery of the patient's general well-being and the length of the inpatient physical therapy program after CS.

CONCLUSIONS

According to the results of the pulmonary function test, patients of the control group and training group did not differ both before the surgery and on the 7 postoperative days. VC indicator decreased from 103.81 ± 13.20% to 76.84 ± 14.65% in the control group, and from 104.18 ± 13.20 to 76.38 ± 16.18 in the training group. PEF decrease was less pronounced in both groups, namely from 96.91 ± 14.05% to 79.19 ± 18.08% in the control group and from 98.77 ± 19.38 to 82.03 ± 20.75 in the training group. Inspiratory indicators of the pulmonary function test also did not confirm any additional effect of implementing Tri-Ball breathing exercises, despite the fact that it is aimed at training deep, strong and quick inhalation.

AUTHOR CONTRIBUTIONS

(%)	Volodymyr Vitomskyi	Khaled Al-Hawamdeh	Olena Lazarieva	Maryna Vitomska
Research concept and design	60	20	10	10
Collection and/or assembly of data	70	15	0	15
Data analysis and interpretation	70	15	0	15
Writing the article	70	15	0	15
Critical revision of the article	70	0	15	15
Final approval of article	70	10	10	10

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