Preoperative respiratory strength training is feasible and safe and improves pulmonary physiologic capacity in individuals undergoing cardiovascular surgery

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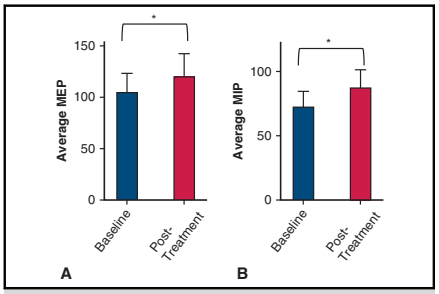
ABSTRACT

Objective: To determine the safety, feasibility, and physiologic impact of a preoperative respiratory strength training (RST) program in individuals undergoing elective cardiac surgery (CS).

Methods: Twenty-five adults undergoing an elective CS at an academic hospital setting enrolled and completed RST 5 days/week (50 repetitions, 50% training load, ≥3 weeks) at home via telehealth in this open-label prospective cohort study. RST adherence, telehealth attendance, and adverse events were tracked. Pre- and post-RST outcomes of maximum expiratory pressure (MEP), maximum inspiratory pressure (MIP), voluntary cough spirometry, and patient-reported dyspnea were collected. Descriptive analyses and Wilcoxon signed rank-tests were performed.

Results: Two participants (9%) did not complete the prescribed RST program. No significant RST-related adverse events occurred. Treatment adherence for all enrolled participants was 90%, and telehealth attendance was 99%. Of the CS patients who completed the prescribed program (n = 23; 91%), treatment adherence and telehealth attendance were excellent (98% and 100%, respectively). Significant increases in primary outcomes were observed: MEP mean change, +15.4 (95% confidence interval [CI], +3.4 to +27.3, $P < .007$); MIP mean change, +14.9 (95% CI, +9.4 to +20.4, $P < .0001$). No statistically significant differences in voluntary cough or perceived dyspnea outcomes were observed ($P > .05$).

Conclusions: These preliminary data demonstrate that a preoperative RST program is safe and feasible and can improve short-term respiratory physiologic capacity (MEP and MIP) in CS patients. Future research is warranted to validate the current findings in a larger cohort of CS patients and to determine whether RST improves postoperative extubation outcomes, airway clearance capacity, and aspiration following cardiac surgery. (JTCVS Open 2023;15:324-31)



Preoperative pulmonary function improved in cardiac surgical patients completing RST.

CENTRAL MESSAGE

Preoperative respiratory muscle strength training is feasible and safe and improves respiratory physiologic capacity.

PERSPECTIVE

This preliminary research study demonstrates the safety, feasibility, and short-term physiologic impact of a "prehabilitation" respiratory strength training program in cardiac surgical patients. Additional research is needed to determine whether proactive exercise-based training regimens in this patient population may improve postoperative swallowing safety and health outcomes.

Swallowing impairment (dysphagia) is a confirmed postoperative complication of cardiac surgery (CS) associated with significant morbidity and mortality.[1-4] Recent data from our center using fiberoptic endoscopic evaluation of swallowing revealed unsafe swallowing in 94% (66% penetration, 29% aspiration) and inefficient swallowing

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Abbreviations and Acronyms

CS = cardiac surgery
EMST = expiratory muscle strength training
IMST = inspiratory muscle strength training
LCADL = London Chest Activity of Daily Living
MEP = maximum expiratory pressure
MIP = maximum inspiratory pressure
OR = odds ratio
PEF = cough peak expiratory flow
RST = respiratory strength training
SLP = speech-language pathologist

(ie, pharyngeal residue) in 52% of CS patients during the acute postoperative recovery phase.[3] Compared to nonaspirating CS patients, aspirating CS patients waited 85 hours longer to resume oral intake, had a 43% longer hospital length of stay (LOS), a $50,000 higher cost of care, and higher rates of pneumonia (odds ratio [OR], 2.6), reintubation (OR, 5.7), and death (OR, 2.8).[3] We also noted that compared to aspirating patients with an ineffective or absent cough response to clear tracheal aspirate, those with an effective cough response to clear tracheal aspirate had reduced rates of pneumonia (0% vs 23%), reintubation (0% vs 29%), mortality (0% vs 9%), and readmission (0% vs 15%); shorter hospital LOS (15 days vs 21 days), and lower cost of care ($93,000 vs $136,000).[3] This latter finding revealed a potential modifiable treatment target, airway clearance physiologic capacity to reduce postoperative aspiration, to target in CS patients undergoing planned procedures in the form of a "prehabilitation"[5] respiratory strength training (RST) program. Although it has not yet been explored in preoperative CS patients, prior research studies in other patient populations with impaired pulmonary function and airway clearance physiologic capacity have demonstrated that an RST program is safe (eg, minimal adverse events) and feasible and improves respiratory muscle strength, cough effectiveness, and swallowing safety.[6-8] Furthermore, preliminary studies in CS patients and other postoperative patient populations have found that inspiratory muscle strength training (IMST) may reduce postoperative adverse health outcomes that may be related to aspiration, including pneumonia and hospital LOS.[9,10]

The current prospective pilot study aimed to test the hypothesis that a preoperative RST program to reduce postoperative aspiration would be safe and feasible and would lead to improvements in expiratory and inspiratory pressure generation and airway clearance physiologic capacity in CS patients.

METHODS

Research Participants

Twenty-five individuals attending the University of Florida Cardiovascular clinic, undergoing an elective CS, and who lived within a 150-mile radius of the study site were recruited to participate in this study (Figure 1). Inclusion criteria for study participation was: 1) adult between 18 to 90 year old, 2) undergoing an elective CS via sternotomy or extended thoracotomy in three or more weeks, 3) willing to undergo evaluation procedures and to participate in the RST program, and 4) have access to a computer, tablet, or other electronic device and the internet for telehealth sessions. This research study was approved by the University of Florida's Institutional Review Board on 6/25/2021(IRB202100993) and all enrolled research participants provided written informed consent for publication of study data.

Study Design

This was an open-label prospective cohort study conducted in 25 CS patients (ClinicalTrials.gov identifier NCT04887415). Enrolled research participants underwent baseline assessments of pulmonary function (MEP and MIP) and cough function (voluntary PEF and cough spirometry) and completed self-reported dyspnea using the validated London Chest Activity of Daily Living (LCADL) scale. Following baseline testing, participants underwent RST in the home via telehealth with one in-person home therapy session conducted at each participant's midpoint to reassess MEP and MIP and to recalibrate the respiratory strength trainers. After the prescribed RST program, participants completed a second post-RST preoperative assessment.

RST Protocol

The RST program consisted of expiratory muscle strength training (EMST) and IMST using the EMST-75 Lite (for 0-75 cmH_20) or the EMST-150 (for 30-150 cmH_20) and the IA-150 devices (Aspire Products), respectively. Trainers were calibrated to a 50% load of individualized MEP and MIP values. The CS patients performed 25 repetitions each (5 sets of 5 repetitions) of the expiratory and inspiratory exercises, 5 days/week leading up to their surgical procedure. The patients were given training logs to track completion of the RST exercises to measure adherence.

Telehealth sessions. Telehealth sessions were conducted by a research speech-language pathologist (SLP) at least once per week via a secure version of Zoom. During telehealth sessions, the research SLP ensured that participants performed the prescribed exercises with correct form, completed a safety and adverse event check, answered participant questions, assisted with adherence issues, monitored adverse events, and aided participants in adjusting the resistance of the expiratory and inspiratory training devices based on participant exertion ratings using the Borg Category Ratio 10 Scale.[11] During the adverse event check, the research SLP asked research participants if they were experiencing any pain, fatigue, discomfort, or other adverse events related to the RST protocol. Attendance for telehealth sessions was tracked.

Home visits. In addition to weekly telehealth sessions, a home visit was conducted by a research SLP midway through the RST program. During the home visit, the research SLP performed check-ins similar to telehealth sessions, retested MEP and MIP, and recalibrated the training devices to meet the 50% training load target.

Evaluation Procedures and Outcome Measures

All pulmonary function measures were performed by a research SLP in accordance with standardized protocols and guidelines from the American Thoracic Society[12-14] with research participants in an upright seated position with nose clips in place.

Primary outcome measures: MEP and MIP. MEP and MIP measurements were obtained using the MicroRPM handheld device (Micro Direct). For MEP testing, research participants were instructed to take a deep breath in, place their mouth around the mouthpiece, and blow out as forcefully as possible. As needed, the research SLP assisted with lip seal by holding the sides of participant's cheeks to prevent air leakage. For MIP testing, research participants were instructed to expel all the air out of their lungs, place their mouth around the mouthpiece, and breathe in as forcefully as possible. Each participant performed 3 MEP and MIP

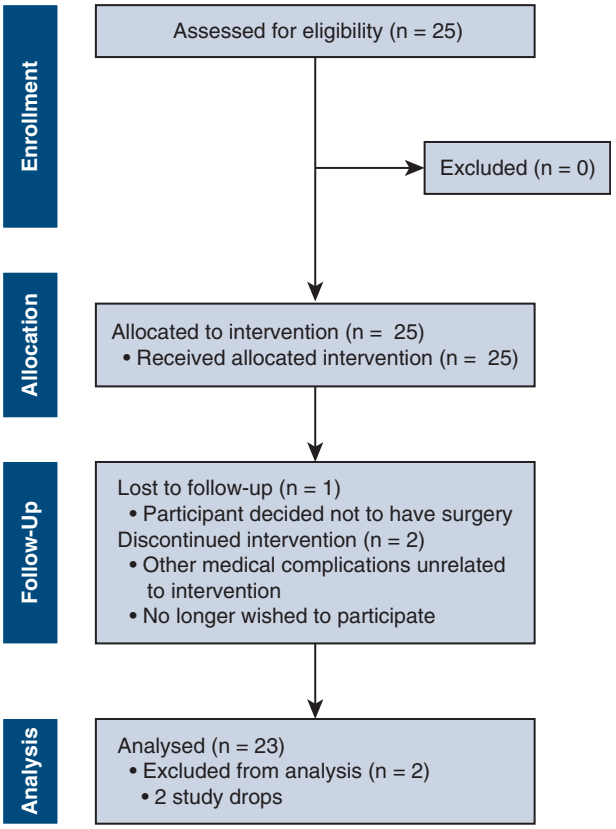

FIGURE 1. CONSORT flowchart of recruitment and enrollment for clinical trial NCT04887415 from September 2021 to September 2022.

trials. Average MEP and MIP values were used to calibrate expiratory and inspiratory devices and for subsequent analyses.

Voluntary cough PEF and cough spirometry. Voluntary PEF was obtained using a handheld analog Mini-Wright peak flow meter (Clement Clarke International) with an disposable face mask (Ambu) attached to minimize the risk of particle aerosolization. For PEF measurements, participants were instructed to cough hard, like something was stuck in their throat. Participants performed 3 PEF trials, and the highest value was used for analyses. Voluntary cough spirometry was performed using an oral pneumotachograph (MLT 1000; ADInstruments) connected to an Ambu disposable face mask. Cough waveforms were recorded using LabChart Version 7 (Microsoft) on a Mac desktop computer for subsequent analyses. For voluntary cough spirometry, participants were instructed to breathe normally for several breaths before taking a deep breath in and coughing hard like there was something stuck in their throat. Three cough trials were obtained, and the peak values were used for analyses.

LCADL questionnaire. Participants completed the LCADL[15] questionnaire via a REDCap survey on an iPad to measure patient-reported dyspnea during activities of daily living. This questionnaire was selected to more effectively capture how dyspnea impacts individuals during functional day-to-day activities.

Data Analysis

Voluntary cough spirometry metrics. Voluntary cough spirometry measurements were performed in a blinded and randomized fashion. One trained rater performed cough spirometry analyses using LabChart Version 7 according previously established rating protocols.[16,17] To assess intra-rater reliability, the primary rater randomly selected 20% of the cough spirometry files to re-rate. Re-ratings were performed at least 1 month after the initial rating. To assess inter-rater reliability, a second trained rater randomly selected 20% of the cough spirometry files to rate. Cough spirometry metrics obtained from analyses included inspiratory phase duration, inspiratory peak flow rate, compression phase duration, expiratory phase duration, peak expiratory flow rate, and cough volume acceleration.[17]

TABLE 1. Patient characteristics (N = 25)

Characteristic	Value
Age, y, mean ± SD	67.9 ± 11.3
Sex, n (%)	
Male	14 (56)
Female	11 (44)
Race, n (%)	
White	22 (88)
Black	1 (4)
Unknown	2 (8)
Ethnicity, n (%)	
Non-Hispanic	22 (92)
Hispanic	1 (4)
Unknown	1 (4)
Surgery type, n (%)	
Mitral valve	8 (32)
Aorta graft	3 (12)
Aortic arch	3 (12)
Maze procedure	3 (12)
Multiple valve replacement	2 (8)
Aortic root	1 (4)
CABG	1 (4)
LVAD	1 (4)
Tricuspid valve	1 (4)
Mini aortic valve	1 (4)
Atrial appendage ligation with an Atriclip	1 (4)

CABG, Coronary artery bypass grafting; *LVAD*, left ventricular assist device.

Statistical Analysis

Demographic information and pulmonary and cough function data were exported directly from our secure online database, REDCap,[18,19] into JMP version 16.1.0[20] and Prism version 9.4.1 (GraphPad Software) for statistical analyses. Descriptive statistics were used to summarize demographic information and pulmonary and cough function data. Intraclass correlation coefficients (ICCs) with 95% confidence intervals (CI) were used to calculate inter-rater and intrarater reliability for voluntary cough spirometry metrics. Mean differences with 95% CIs were calculated, and the Wilcoxon signed-rank test was performed to assess pre-RST to post-RST changes in pulmonary and cough function.

RESULTS

Twenty-five adults undergoing an elective CS who met the inclusion criteria were recruited and enrolled in the study. As shown in Figure 1, 2 individuals (9%) withdrew from the study for reasons unrelated to the RST program (ie, other medical complications unrelated to RST, no longer wished to participate). No individuals who were approached about participating in this study were unable to participate because of technology barriers for telehealth sessions. Participant demographic data are summarized in Table 1.

TABLE 2. Pulmonary, cough, and swallow function data from 23 CS patients before and after RST

Outcome measures	Pre-RST, mean (SD)	Post-RST, mean (SD)	*P* value
Pulmonary function tests			
Maximum expiratory pressure, cmH_20	105.6 (40.9)	120.9 (49.7)	.007*
Maximum inspiratory pressure, cmH_20	73.2 (26.4)	88.1 (30.9)	<.0001*
Voluntary cough peak expiratory flow and cough spirometry metrics			
Voluntary cough peak expiratory flow, L/min	337.7 (128.5)	352.7 (144.3)	.18
Inspiratory phase duration, s	2.02 (1.18)	1.84 (1.04)	.36
Inspiratory peak flow rate, L/s	−2.42 (1.09)	−2.87 (1.75)	.30
Compression phase duration, s	0.33 (0.18)	0.39 (0.28)	.64
Expiratory phase duration, s	0.04 (0.03)	0.04 (0.02)	.68
Peak expiratory flow rate, L/s	8.99 (3.39)	9.21 (3.01)	.79
Cough volume acceleration, L/s/s	302.60 (203.18)	362.13 (275.75)	.57
LCADL dyspnea scale			
LCADL total score	24.95 (11.48)	20.52 (7.99)	.19

RST, Respiratory strength training; *LCADL*, London Chest Activity Daily Living. *Statistically significant, $P < .05$.

Adherence for all CS patients enrolled in the study was 90% (35,900 of 39,900 completed repetitions), and telehealth attendance was 99% (138 of 140 sessions). Among those who completed the study, adherence was 98% (35,750 of 36,650 completed repetitions), and telehealth attendance was 100% (135 of 135 sessions). Study participants completed the RST program 5 to 7 days/week (mean, 5.3 ± 1.5 days) across a range of 3 to 10 weeks (mean, 5.9 ± 1.8 weeks) leading up to surgery at a 50% MEP/MIP training load. No significant study-related adverse events were observed. Minor adverse events reported by research participants included pain (n = 2), dizziness (n = 7), migraine (n = 1), dry throat (n = 1), and bloody nose (n = 1).

Primary Outcome Measures: MEP and MIP

Descriptive outcomes for MEP and MIP are provided in Table 2 and Figures 2 and 3. Significant differences between pre-RST and post-RST were observed for both MEP (+15.4; 95% CI, +3.4 to +27.3; $P = .007$) and MIP (+14.9; 95% CI, +9.4 to +20.4; $P < .0001$). A sex subanalysis revealed a significantly greater pre-RST to post-RST improvement in MEP in males compared to females (+28.8 [95% CI, +15.3 to +42.3] vs −2.1 [95% CI, −17.5 to +13.3]), with an average 30.9 cm H_20 increase in MEP for men versus women (95% CI, +10.5 to +51.3; $P = .005$) (Figure 4).

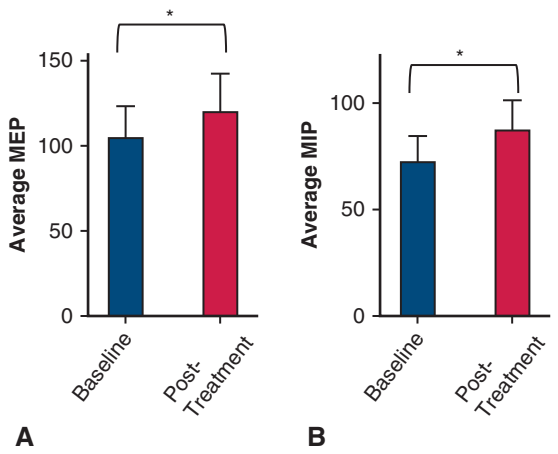

FIGURE 2. Mean baseline and post–respiratory strength training group data for primary outcomes of maximum expiratory pressure (*MEP*, in cmH_20) (A) and maximum inspiratory pressure (*MIP*, in cmH_20) (B).

Secondary Outcomes

Inter-rater and intrarater reliability across cough spirometry metrics ranged from good to excellent (average ICC for inter-rater reliability, 0.95 [95% CI, 0.93- 0.96]; average ICC for intrarater reliability, 0.90 [95% CI, 0.86-0.92]). Descriptive data for voluntary cough PEF and spirometry outcomes are summarized in Table 2. No significant differences in secondary cough outcomes were noted pre-RST to post-RST ($P > .05$). LCADL total scores did not significantly differ pre-RST to post-RST ($P > .05$) (Table 2).

A graphical abstract of the study methods and results is provided in Figure 5.

DISCUSSION

In this prospective preliminary research study, we found that a preoperative moderate- load combined expiratory/inspiratory RST program was safe and feasible and led to statistically significant improvements in primary outcomes (MEP and MIP) but in not voluntary cough or LCADL secondary outcomes. These significant improvements in primary outcome measures are encouraging, and future larger-scale clinical trials with adequate power will examine the potential impact of preoperative RST on secondary outcomes.

Our retention, adverse events, RST adherence, and telehealth session attendance data support that a preoperative

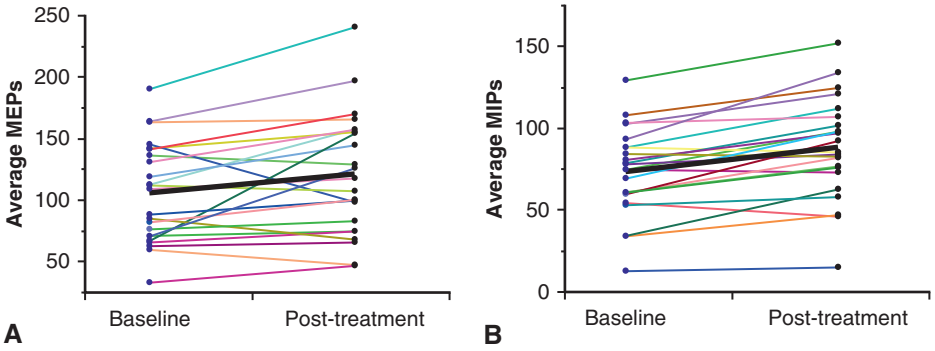

FIGURE 3. Mean baseline and post–respiratory strength training participant-level data for primary outcomes of maximum expiratory pressure (*MEP*, in cmH_20) (A) and maximum inspiratory pressure (*MIP*, in cmH_20) (B).

RST program in CS patients is feasible and safe. Weekly telehealth sessions and an in-person home visit from a research SLP at the midway point of the treatment protocol likely contributed to the good study retention and excellent RST adherence across research participants. The 2 study drops in this cohort highlight that demographic (eg, age) and individual-level patient factors (eg, other significant health conditions, lack of motivation to complete the exercises) may negatively impact RST adherence. Therefore, clinicians working with this patient population may want to carefully select CS patients who may benefit the most from completing this prospective intervention. Additionally, future studies may consider tracking RST adherence in a more sophisticated manner (eg, a phone application) versus using paper training logs to allow for more contemporaneous tracking of treatment completion. Notably, given the promising preliminary data from this study, an at-home "prehabilitation" RST program with remote monitoring may have great potential to gain traction as a preventive exercise program for CS patients awaiting an elective CS.

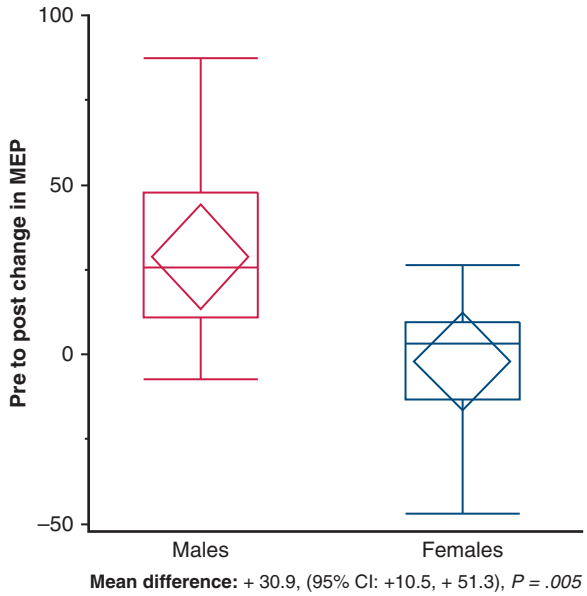

FIGURE 4. Mean (95% confidence interval) change in maximum expiratory pressure (*MEP*) from before to after respiratory strength training. *CI*, Confidence interval.

Across research participants, a combined RST regimen led to improvements in expiratory and inspiratory pressure generation (MEP and MIP). On average, MEP and MIP increased by 17.5% and 22.7%, respectively. Almost 1 in every 2 participants (43%) demonstrated a >15% increase in their expiratory generation pressure, and more than two-thirds (70%) increased their inspiratory pressure generation capacity. These findings are encouraging given that a moderate training load of 50% was used. Furthermore, the observed gains in MIP in this cohort of CS patients were similar to research studies in other patient populations that have reported improvements in pressure generation of 25% to 42% following an RST program, which also led to improvements in cough function and swallowing safety.[6,8,21] However, although gains in MEP for the present study were significant, they were lower compared to those seen in other studies that used higher training loads and longer training durations. This finding reveals important areas for future study, including dose-response across participants and determining the optimal RST treatment duration and exercise load for CS patients. Future larger-scale clinical research trials are warranted in a larger cohort of CS patients to confirm and expand on these findings to determine the optimal treatment dosage, as well as the long-term impact of completing this "prehabilitation" treatment protocol on postoperative recovery, including reducing the incidence of aspiration and adverse health outcomes. Although not examined in the current study, prior research examining IMST in CS patients and other postoperative patient populations have found that IMST leads to reduced rates of pulmonary complications and hospital LOS.[9,10]

Another interesting finding from the current study cohort was that men had significantly higher gains in MEP post-RST than women, illuminating that sex may have an

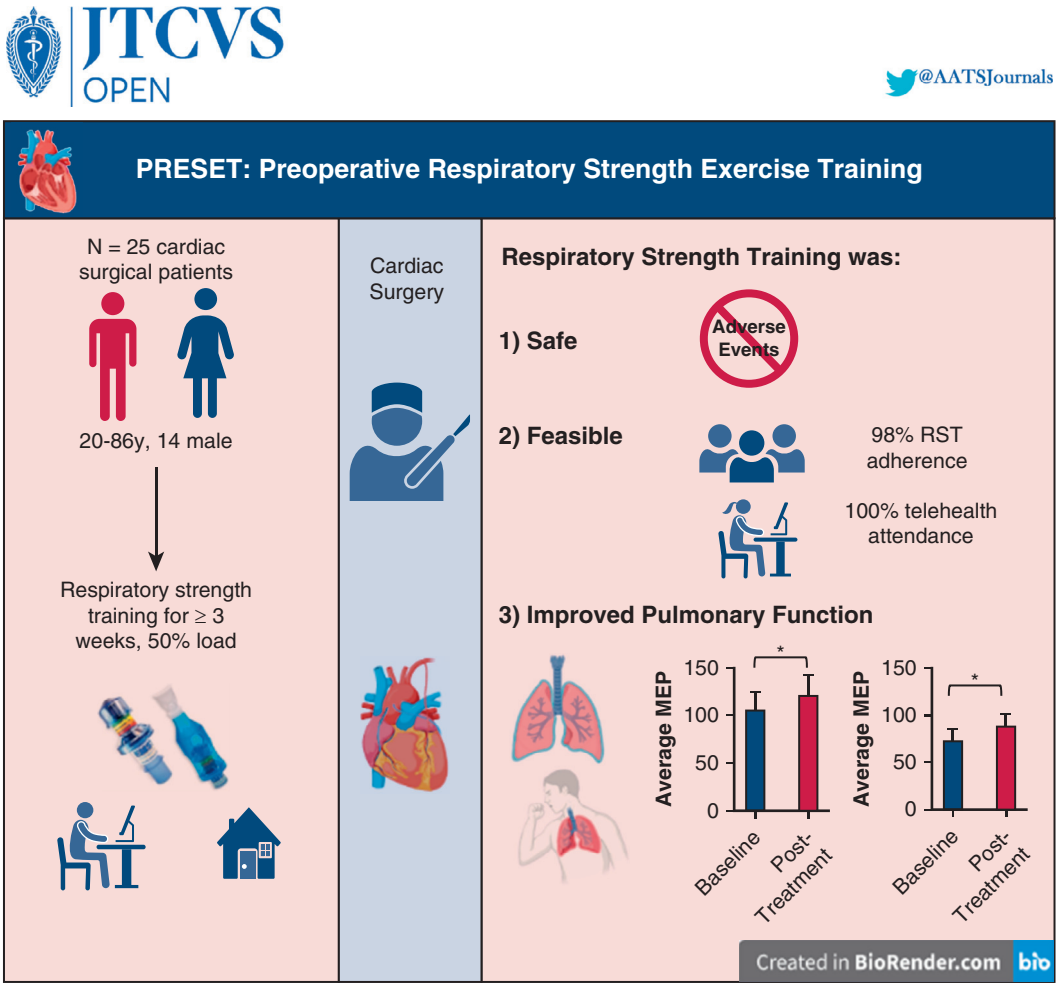

FIGURE 5. Preoperative respiratory strength training was safe and feasible and led to improvements in respiratory physiologic capacity in adults undergoing elective cardiac surgery. *RST*, Respiratory strength training; *MEP*, maximum expiratory pressure; *MIP*, maximum inspiratory pressure.

important role in the response to treatment for RST. This finding is aligned with prior research that has shown anatomic and physiologic sex-based differences in respiratory function during exercise.[22] For example, women are known to have smaller lungs compared to men even after accounting for size differences, to have smaller airways than men, and to have a different overall lung and ribcage shape than men.[22] These anatomic differences likely contribute to physiologic differences during exercise for women, including an increased work of breathing, increased likelihood of exercise-induced arterial hypoxemia, and increased activation of accessory respiratory muscles during inspiration.[22] Given these anatomic and physiologic differences in respiratory function between men and women, women with cardiopulmonary diseases may have an elevated risk of pulmonary-associated medical complications compared to men. Furthermore, emerging research evidence has found that women have unique cardiovascular risk factors and tend to present with more severe cardiovascular disease at a later age and with more comorbidities.[23] These risk factors are known to negatively impact health outcomes, mortality, and recovery for women following CS.[23] As such, it may be particularly important for women undergoing CS to participate in proactive RST regimens preoperatively, yet limited research currently exists regarding the impact of rehabilitation or "prehabilitation" in women.[24-26]

Although post-RST changes in voluntary PEF, cough spirometry metrics, and LCADL scores did not reach statistical significance, promising improvement trends emerged with these secondary outcome measures. On average, voluntary PEF improved from 338 L/min to 353 L/min, and LCADL self-perceived dyspnea score improved from 25 to 20. These findings are encouraging given that it suggests generalization of the RST training regimen to other relevant respiratory and cough measures, which is in line with prior work examining the impact of EMST in other patient populations with reduced airway clearance

physiologic capacity and swallowing safety impairments.[6,8,21] Conducting larger-scale clinical research trials may provide further insight into whether a combined EMST/IMST training regimen results in short-term to long-term improvements in other vital respiratory and cough metrics in CS patients.

Limitations

Although this is the first known research study to prospectively examine the safety, feasibility, and impact of preoperative RST on CS patients, it has several limitations. This was a preliminary pilot research study, and as such, the sample size was relatively small (n = 23 completed the study), and the inclusion criteria for participating in the study were broad, leading to a more heterogenous sample (eg, demographics, surgery type, time to surgery). We also did not specifically examine potential demographic risk factors that might have contributed to patient outcomes (eg, body mass index, other respiratory diagnoses, ejection fraction) owing to the pilot nature of this work. However, it will be important to investigate how these demographic and health-related variables may impact risk profiles of CS patients in future larger-scale clinical trials. Although this preliminary study resulted in no significant study-related adverse events and few minor adverse events, it will be important to further examine safety in future clinical trials because of the small sample size if the current study. In addition to this, it is possible that the RST adherence rates in this study are biased, given that individuals willing to participate in this study are more likely to be adherent than individuals uninterested in participating. Furthermore, there was no control group in this study, which limits the ability to draw firm conclusions regarding the efficacy of RST in CS patients. Given the small sample size, it was challenging to comprehensively examine how demographic and surgical factors impact adherence and response to RST. Additionally, given that this was the first study to examine RST in CS patients, optimal dosage parameters for RST (eg, intensity, repetitions, duration) were unknown, emphasizing a need for future research to determine the most favorable exercise training regimen in this patient population. Given the unknowns regarding optimal treatment dosage parameters and the real-world challenges of surgery scheduling, a standardized treatment schedule and duration was not implemented in the present study; however, future studies may consider using a more standardized approach to further understand RST treatment efficacy and effectiveness.

CONCLUSIONS

Implementing a preoperative RST program in CS patients is safe and feasible and leads to improvements in expiratory/inspiratory pressure generation. Larger-scale trials are needed to statistically power the potential impact of "prehabilitation," exercise-based regimens such as RST on swallowing safety and health outcomes in CS patients.

Conflict of Interest Statement

All authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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