

Resisted breathing exercise versus incentive spirometer training on vital capacity in postoperative radical cystectomy cases: a pilot randomized controlled trial

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Received 6 January 2016

Accepted 2 October 2016

Bulletin of Faculty of Physical Therapy
2016, 21:61–67

Background

Radical cystectomy at times involves respiratory physical therapy aiming to reverse pulmonary dysfunction, thus avoiding postoperative pulmonary complications that increase hospital morbidity.

Objective

The aim of this study was to investigate the effects of resisted breathing exercise versus incentive spirometer (IS) training on vital capacity (VC) outcomes in postoperative radical cystectomy cases.

Patients and methods

Forty male and female patients between 40 and 80 years of age who had undergone radical cystectomy participated in this study. Patients were randomly assigned into two equal groups of 20 each; both groups received traditional physical approaches. In addition, group A (19 men and 1 woman) received IS training for 15 min daily for 6 weeks, and group B (16 men and 4 women) received resisted breathing exercise for 15 min daily, for 6 weeks. The primary outcome was VC, which was measured using an electronic spirometer.

Results

This study showed a significant increase ($P < 0.05$) in VC in both groups on comparing pretreatment and post-treatment values within each group. After 6 weeks of treatment, between-group statistical analysis showed equal improvements in VC ($P = 0.52$). Nevertheless, the percentage of improvement in VC was 43.5% (2.46 ± 0.64), higher than that in the resisted breathing exercise group at 23.9% (2.34 ± 0.53).

Conclusion

IS produced better objective improvement in VC compared with the usage of resistive breathing exercise. However, both are considered as a gold therapeutic tool in the management of pulmonary complication after radical cystectomy.

Keywords:

bladder cancer, breathing exercise, incentive spirometer, radical cystectomy

Bulletin of Faculty of Physical Therapy 21:61–67

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1110-6611

Introduction

Bladder cancer is the fifth most common genitourinary malignancy (after lung, breast, prostate, and colon cancers), fourth in prevalence among men and eighth among women [1]. The current standard treatment for invasive bladder cancer is radical cystectomy with extended pelvic lymphadenectomy, which has shown to be superior to partial cystectomy [2].

Following major abdominal surgery, pulmonary complications are the leading cause of postoperative morbidity and mortality affecting 25–50% of patients [3]. In addition, these complications can lead to increased patient discomfort, increased consumption of resources, and longer length of stay, and thus an overall increase in healthcare costs [4].

Radical cystectomy at times involves respiratory physical therapy aimed to reverse pulmonary dysfunction after radical cystectomy, thus avoiding pulmonary complications [5]. Surgery and general anesthesia have direct effects on the respiratory system depending on the organ/system involved and modality of delivery. As a result, surgical interventions may lead to postoperative pulmonary complications that increase hospital morbidity, prolong hospital stay, and add to healthcare costs. Postoperative pulmonary complications are related to the induction of respiratory muscle dysfunction [6].

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Chest physical therapy is widely applied by surgical units in an attempt to reduce pulmonary complications. However, evidence for its efficacy and studies comparing different physical therapy modalities are relatively limited [7]. Postoperative physical therapy aims to promote maximal inspiration to expand collapsed alveoli and prevent further atelectasis [7].

Incentive spirometer (IS) is a feedback system to encourage patients to take a deep breath and produce a sustained maximal inspiration for the primary purpose of opening and stabilizing atelectasis areas of the lung [8]. It provides low-level resistive training while minimizing the potential of fatigue to the diaphragm muscle. Generally, this treatment is performed frequently up to every hour, and its purpose is to treat and prevent atelectasis, especially in postoperative thoraces and abdominal patients [9]. It is simple to use and provides the patient with visual feedback on flow and volume [10].

Physiotherapists also use breathing exercises to promote secretion removal, increase thorax mobility, enhance relaxation, control breathlessness [11], increase pulmonary ventilation, and improve mobilization of the chest wall [12]. There are many types of breathing exercises such as diaphragmatic breathing, pursed lip breathing, segmental breathing, low-frequency breathing, sustained maximal inspiration breathing, and breathing exercises connected with postural exercises [13]. Resisted breathing exercises programs in the form of inspiratory resistive muscle training and abdominal weights training are very effective for respiratory training and improvement in pulmonary function [14].

This study was carried out to determine the effect of IS training versus resisted breathing exercises on vital capacity (VC) after radical cystectomy of bladder carcinoma.

Patients and methods

A prospective, parallel-group, pilot randomized controlled trial with a 1 : 1 allocation ratio was conducted from Jan. 2013 to Aug. 2013, at a research laboratory of our university. Patients of both sexes (35 male and 5 female) who underwent radical cystectomy and had reduced VC postoperatively were recruited from the National Cancer Institute, Cairo University. The patients participated in the study after signing an informed consent form before data collection. Recruitment began after approval was obtained from the Ethics Committee of the Faculty of Physical Therapy, Cairo University.

The conscious patients were included if they were free from any pathological conditions that might affect the results. Their ages ranged from 40 to 80 years, their weights ranged from 60 to 90 kg, and their heights ranged from 150 to 190 cm. The exclusion criteria included the following: inability to understand written and verbal instructions, having mental or psychological disorders, presence of systemic diseases that may interfere with the objectives of the study, and a history of cardiac abnormalities.

Postoperative physical therapy program was started when the patients were extubated from mechanical pulmonary ventilator and ICU equipment (on the first to second day postoperatively) and then continued every other day for 6 weeks postoperatively. Patients were randomly selected to be enrolled equally into this blinded, randomized, controlled trial. The assignment to groups was carried out by a therapist who was blinded to the research protocol. Patients' random assignments were performed through two stages: first, physical therapists who were working in the National Cancer Institute, Cairo University, reported all patients who fulfilled the inclusion criteria of the study; and second, after medical counseling, patients were assigned randomly to either group A or group B. Group A, the IS group, ($n=20$) included patients who were treated with IS three times per day for 15 min each time with rest interval every 5 min daily for 6 weeks postoperatively. Group B, the resisted breathing exercises group, ($n=20$) included patients who received breathing exercises three times per day for 15 min each time with rest interval every 5 min daily for 6 weeks postoperatively. The participants were assigned randomly to two groups of equal numbers by rolling of a dice by an independent person: group A (when the dice revealed an odd number) and group B (when the dice revealed an even number). The randomization restricted to permuted blocks of size of 4 to ensure that equal numbers are allocated to each group.

All patients underwent complete history taking, including the patient's name, age, address, and telephone number, followed by the height and weight of each participant recorded from the height and weight scale (personal history). In addition, they were asked about any history of previous abdominal surgeries (past history). Detailed analysis of the present surgery was carried out (present history). Medical history included information on drugs used. Physical examination included general examination and local examination of chest expansion. Routine laboratory investigations, mainly a complete blood count, were carried out. All patients were informed about the

nature and the effect of the treatment and measurement devices. The patients were instructed to report any side effects during the management. All patients received the same medical treatment and traditional physical therapy (early mobilization and range of motion exercises).

Treatment procedures

The patients in both groups completed a postoperative 6-week pulmonary rehabilitation program consisting of IS training and resisted breathing exercise. IS is a mechanical respiratory therapy device introduced in an attempt to reduce postoperative respiratory dysfunctions [15]. It provides visual feedback in terms of volumetric success as a patient takes a deep breath. The Voldyne volume ranges from 0 to 4000 ml [16]. The patient was placed in a comfortable position and instructed to exhale to the maximum with the first breath. The patient was instructed to place the IS in his or her mouth, and then inhale to the maximum through the device and hold the inspiration for several seconds. The sequence was repeated 5–10 times for 15 min/day with rest interval every 5 min daily for 6 weeks postoperatively [17]. Resisted breathing exercise was performed using sandbags delivered through two surfaces with a light weight placed on the skin above the diaphragm, with a weight of 0.5, 1, 1.5, and 2 kg for creating some resistance to the diaphragm muscle. The patient was instructed to lie in a supine or slightly head-up position. The patient must know how to breathe in with the primary use of the diaphragm muscle. A small weight (3–5 lbs) is placed over the epigastric region of the abdomen. The patient is instructed to train how to breathe deeply while trying to keep the upper chest quiet. The resistance should not interfere with the full excursion of the diaphragm. Gradually, the therapist should increase the time that the patient breathed against the resistance weight. The weight was increased when the patient could sustain the diaphragmatic breathing patterns for 15 min. The procedure was repeated three times per day with rest interval every 5 min daily for 6 weeks postoperatively.

Outcome measures

The primary outcome measure for determining treatment assessment was the VC using the Morgan Trans Flow test (Electronic Spirometer) (ME 87 ED; Morgan Scientific Inc. Haverhill, USA; Kent, UK). It is a computerized apparatus to measure pulmonary function test for recording VC. VC was measured in all participants upon entry into the study (on the first or second day postoperatively) and after 6 weeks of treatment. Patients were placed in a comfortable

position (correct sitting position) and the therapist made sure that nose clip was in the best place. Patients aimed to achieve a predetermined flow or to achieve a preset and he encouraged to hold the breath for 2–3 s at full inspiration. A short, sharp inspiration can activate the flow-generated IS device with little increase in VC, but with a volume-dependent device an increase in VC must be achieved before the preset level can be reached [15]. Incentive spirometer (IS) activated by an inspired tort, that breathing visualized by an uplifted plate and balls in a transparent cylinder sustained inspiration a calibrated scale on the cylinder [18]. The results of this test were printed and saved automatically on a hard disk. The reliability, construct validity, and responsiveness to change have all been demonstrated in various populations [17,18].

Sample size determination

The sample size was determined a priori to provide 80% power to detect an effect size of 0.5 on VC outcome measure. As a pilot study, the sample size was 18 patients per each group, and, to account for possible participant dropouts, the sample size was increased to 20 patients per group [19].

Statistical procedures

All statistical measures were carried out using the statistical package for social studies, version 19 for Windows (IBM Corp., Armonk, New York, USA). In this study, the mean and SD were calculated for all patients (two groups of the study). Descriptive statistics and a *t*-test were used for comparison of the mean demographic data between the two groups. Comparisons were made using the independent *t*-test to compare the IS training and resisted breathing groups for parametric data (age, weight, and height) and VC values. Paired *t*-test was used to compare pretreatment and post-treatment values in the same group (within group) [20]. A value of *P* less than 0.05 is considered statistically significant.

Results

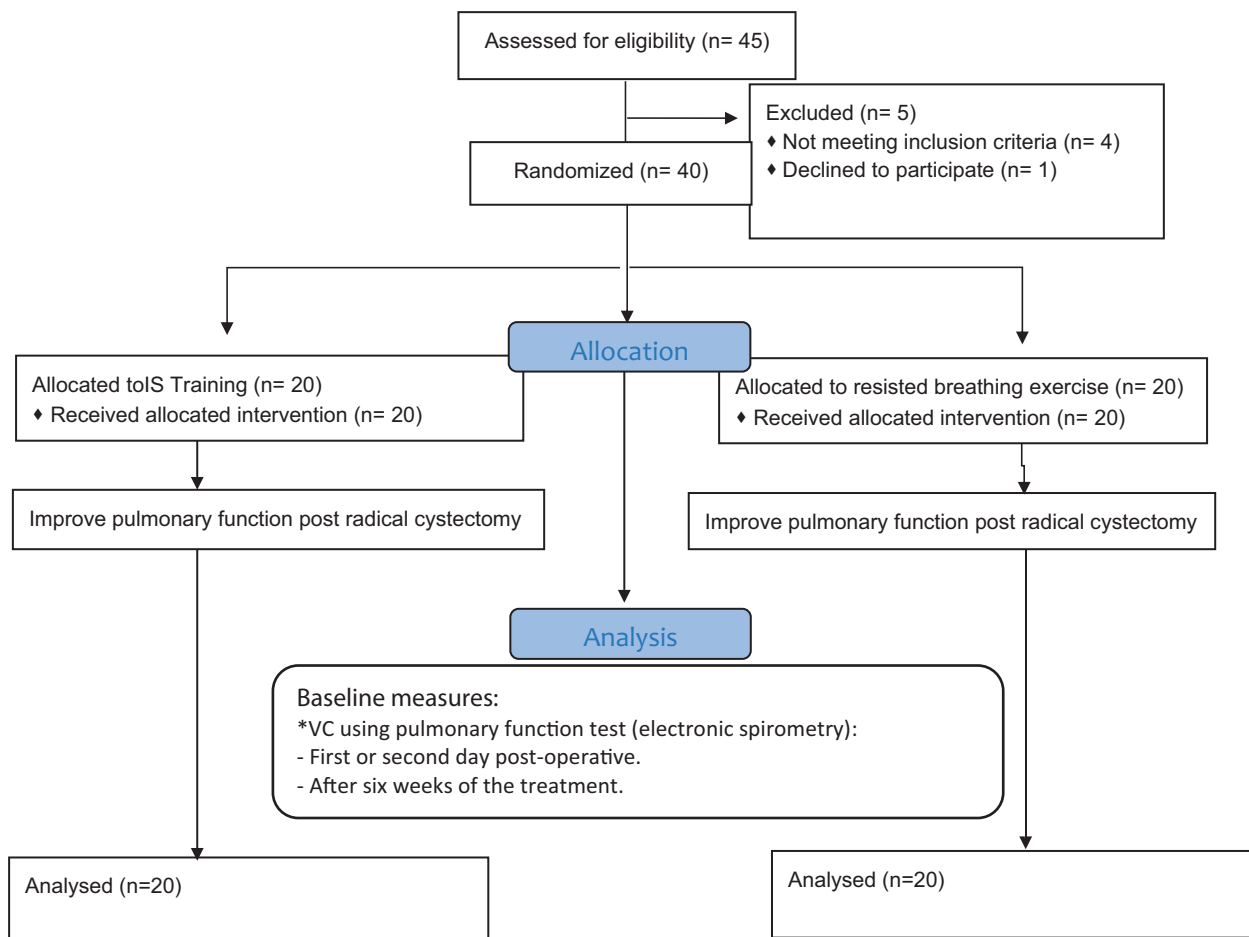
A diagram of patients' retention and randomization throughout the study is shown in Fig. 1. Initially, patients were screened, and, after the screening process, 40 patients were found eligible to participate in the study. In total, 40 (100%) patients completed the first assessment on the first to second day postoperatively (pretreatment), and 40 (100%) patients completed the entire study. The demographic characteristics of the patients are shown in Table 1. In the baseline of treatment there were no significant differences in mean values of age, weight, and height between the two groups of the study.

Vital capacity results

As revealed in Table 2, at pretreatment measurement, no significant differences were found between the two groups in the VC. The mean value of VC in the IS group before treatment application was 1.81 ± 0.53

($0.78-2.7$), whereas the mean value of VC in the resisted breathing group was 1.77 ± 0.56 ($0.44-2.6$). At post-treatment measurement, there was a statistically significant increase ($P=0.0001$) in the VC following 6-week interventions in both groups.

Figure 1



Flow chart of the study.

Table 1 Patient demographic data

Variables	Groups (N=20 for each group)		Mean±SD	T-value	P-value
Age (years)	A		59.6±9.5	-1.078	0.288 ^a
	B		62.65±8.29		
Weight (kg)	A		69.85±12.26	0.576	0.568 ^a
	B		67.8±10.15		
Height (cm)	A		168.35±4.08	1.723	0.093 ^a
	B		165.3±6.78		

A, IS group; B, resisted breathing group; IS, incentive spirometer; P-value, probability level. ^aNonsignificance.

Table 2 Comparison between pretreatment and post-treatment application values of vital capacity for both groups of the study (groups A and B)

	VC for group A (N=20) (I)		VC for group B (N=20) (I)	
	Pretreatment	Post-treatment	Pretreatment	Post-treatment
Means±SD	1.81±0.53	2.46±0.64	1.77±0.56	2.34±0.53
Percentage of improvement		43.5		23.9
T-value		-7.95		-14.73
P-value		0.001*		0.001*

A, IS group; B, resisted breathing group; IS, incentive spirometer; P-value, probability level; VC, vital capacity. *Significant.

The mean value of VC after 6 weeks of treatment application (post-treatment) in the IS group was 2.46 ± 0.64 (1.01–3.6), whereas the mean value of VC in the resisted breathing group after 6 weeks of treatment application was 2.34 ± 0.53 (0.96–3.13). The percentage of improvement in VC was 43.5% in the IS group and 23.9% in the resisted breathing group after 6 weeks of treatment applications.

VC at pretreatment measurement ($P=0.89$) and after 6 weeks of treatment application ($P=0.52$) is presented in Table 3. Independent *t*-test analyses revealed nonsignificant differences between groups A and B as regards VC.

Discussion

Patients undergoing radical cystectomy are at risk of developing pulmonary complication and respiratory system problems (decreased VC) postoperatively. In this study, the therapeutic efficacy of IS and resisted breathing exercise approaches was compared between the two different groups (groups A and B) in improving VC following radical cystectomy. The comparison of VC values between the two groups after 6 weeks of treatment revealed significant differences in favor of the IS training group compared with the resisted breathing exercise group. The results of this study showed that both groups showed an improvement after pulmonary rehabilitation but with different percentages; the resistive breathing exercise group had a percentage of improvement of 23.9% after 6 weeks of treatment application (post-treatment) compared with pretreatment value of the same group. This improvement can be due to the use of sand bag on the diaphragm and may reduce symptoms of anesthesia or fatigue, restore voluntary control of the respiratory musculature to facilitate better breathing, increase chest expansion, and improve VC [21].

On comparing the VC values between the resistive breathing exercise group and the incentive spirometry group before and after the rehabilitation program, the results showed that maximum improvement appeared in the IS group with a percentage of improvement of 43.5% after 6 weeks of treatment application (post-treatment)

when compared with before application of treatment (pretreatment) in the same group. This improvement might be based on mechanical bases. The improvement in VC using IS is mainly due to an increase in thoracic cage diameters: vertical, lateral, and anteroposterior. In addition, IS provides visual stimulation to patients of the inspired volume during an active inspiration, thus improving respiratory capacity. Moreover, it could increase the production of surfactant, which cause decreased surface tension, increased lung compliance, decreased work of breathing, opening of collapsed alveoli to prevent atelectasis, reduced air trapping, and the increase in the respiratory muscle mechanical efficiency to generate power and to inspire more deeply [17]. These results are in agreement with those reported by Celli *et al.* [22] and Overend *et al.* [23].

Celli *et al.* [22] compared a no-treatment control group with groups receiving 15 min of IS, intermittent positive pressure breathing, or deep breathing in patients who had undergone both upper and lower abdominal surgery. The authors suggested that IS following upper abdominal surgery may be better because it appeared to shorten the patient's length of stay.

The difference in improvement of vital capacities between the two groups has several potential advantages: optimized effective inspiratory efforts by patients achieving a visual 'target', which promotes patient compliance; following the simple instructions, the patient can use the device independently and at will; and the device is cheap and disposable. Despite these potential advantages, most pieces of evidence do not support the hypothesis that IS is superior to other postoperative physiotherapy techniques or assisted lung expansion. However, these pieces of evidence are generally of low quality. A systematic review published in 2001 identified 46 studies for analysis. Thirty-five studies were rejected due to flawed methodology, leaving 11 for the evaluation. Of these 11 studies, seven included less than 50 participants and six involved patients undergoing cardiac surgery. Only two studies were conducted on patients following abdominal surgery and included greater numbers of patients ($n=65$ and 172), but both compared IS (patient-generated tidal

Table 3 Comparative analysis of vital capacity (l) between two groups of the study (pretreatment and post-treatment)

Variables	Groups (N=20 for each group)	Mean \pm SD	T-value	P-value
Pretreatment	A	1.81 \pm 0.53	0.142	0.888 ^a
	B	1.77 \pm 0.56		
Post-treatment	A	2.46 \pm 0.64	0.649	0.52 ^a
	B	2.34 \pm 0.53		

A, IS group; B, resisted breathing group; IS, incentive spirometer; P-value, probability level. ^aNonsignificance.

volumes) with methods of administering positive pressure [e.g. continuous positive airway pressure and intermittent positive pressure breathing (machine-generated tidal volumes)] [24]. The scientific thinking that the IS improved VC can be attributed to the fact that it focuses on promoting the maximal inspiratory effort [7]. The IS promotes this enhanced inspiration through visual feedback and encourages enthusiasm among patients who use it. There is clear evidence that maximal inspiratory exercises decrease postoperative atelectasis and improve diaphragmatic activity and decreased work of breathing [10]. From the previous discussion of these results and according to reports of research studies in the field related to the present study, it could be concluded that the results of this study support the expectation that the application IS and resisted breathing exercise intervention are effective and have a great enhancement to improve VC after radical cystectomy of bladder carcinoma. Moreover, the application of IS, which is easily applied to these cases, induced a greater improvement of VC and better control of pulmonary performance compared with the resisted breathing exercise approach.

Study limitations

A lot of effort was taken with each patient to reduce the influence of possible errors inherent in the study. However, our analysis had potential limitations, each of which indicates directions for future study. The primary limitation was the lack of investigator blinding, as we educated the participants as regards the validities of both treatment arms and informed them that both had real potential for benefiting the participants. We informed the participants that there is no existing evidence that suggests that one treatment approach was superior to the other. Every effort was made to standardize the treatment and assessment protocols to minimize potential bias due to the lack of blinding. The use of a blinded, independent outcome assessor is highly recommended for future research. Other limitations were the physiological variation in VC from participant to participant, the effects of environmental variables during treatment time, such as unmentioned fatigue or pains, the level of patient's co-operation with therapist as it was affecting the level of understanding, and the degree of patient's awareness.

Future studies are needed to identify the ideal parameters of pulmonary rehabilitation programs to maximize benefits and minimize patient healthcare costs, to clarify the effect of other therapeutic exercise for better respiratory status of patients, to

confirm the effect of respiratory exercises on VC, with more than 6 weeks, and to evaluate the ability of other clinical tests for assessment of VC after radical cystectomy in bladder carcinoma patients.

Conclusion

This study added to the literature that the usage of IS produces better objective improvement in VC compared with the usage of resistive breathing exercise. However, both are considered as a gold therapeutic tool in the management of pulmonary complication after radical cystectomy. Moreover, both methods safely improve diaphragmatic muscle strength that substantially improves pulmonary VC for postradical cystectomy patients.

Acknowledgements

First of all I would like to kneel thanking to ALLAH who enabled me to conduct this work.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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