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# A randomized clinical trial in improving pulmonary function and functional capacity in pediatric open abdominal surgery☆,☆☆,★

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ABSTRACT

*Purpose:* Pulmonary function and functional capacity gets compromised and reduced after open abdominal surgery. We assessed whether Preoperative physiotherapy education (POPE) along with postoperative physiotherapy (POP) preserve pulmonary function and functional capacity after open abdominal surgery among Pediatric population. Hence, the goal of this study was to determine the effectiveness of POPE combined with POP against the standard treatment care of, Postoperative physiotherapy (POP) only in improving pulmonary function and functional capacity in pediatric open abdominal surgery.
*Methods:* Twenty one children aged, 5–17 years old undergoing the open abdominal surgery were randomized to POPE and POP group (Intervention arm 1) and Postoperative physiotherapy group (POP) only group (Intervention arm 2). Primary outcome measure was pulmonary function measured by computerized spirometry. Six minute walk test (6MWT), Ten meter walk test (10mWT), Timed up and go test (TUGT) and Nine stair climbing test (9SCT) were used as secondary outcome measures to measure functional capacity along with chest expansion. Pulmonary function measured by spirometery, 10mWT, TUG and chest expansion were measured 1 day before undergoing abdominal surgery (Pre-OP), post-operative day 1 (POD1) and post-operative day 5 (POD5) while 6MWT and 9SCT were measured only at POD1 and POD5.
*Results:* Eighteen children who were undergoing open abdominal surgery completed this trial.
No statistical difference were noted in Spirometric parameters from Pre-OP to POD5 in both the groups, they are almost approximate to preoperative values, but from POD1 to POD5, statistical difference were noted in all the Spirometric parameters in Intervention arm 1 as compared to Intervention arm 2. Statistical significant improvement ($p < 0.05$) were noted in TUGT, 10mWT, 9SCT from Pre-OP to POD5 and from POD1 to POD5 also in Intervention arm 1 as compared to Intervention arm 2.
*Conclusion:* There is sufficient evidence to confirm that POPE combined with POP might improve pulmonary function and functional capacity in children undergoing open abdominal surgery.
*Type of study:* Treatment study.
*Level of evidence:* Level I.



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Pulmonary function is doubtlessly affected after open abdominal surgery, because of the pain caused by incisions and the physiological changes caused by the surgery [1]. A patho-physiological reduction in respiratory muscle function and lung volumes due to the effects of anesthesia and surgical duration leads to decrease in pulmonary function, functional capacity and risks of postoperative pulmonary complications (PPC) after open abdominal surgery [2]. Anesthesia and surgical duration inhibits cough reflex and depresses mucocilliary clearance, which further contributes to PPC and decrease in pulmonary function [2].

The role of physiotherapy in this area is very essential. Preoperative physiotherapy education (POPE) given for 30 min prior to the surgery helps in preserving pulmonary function and functional capacity after open abdominal surgery [3]. Preoperative inspiratory muscle training with power breathe device for 15 min, twice a day helps in improving inspiratory muscle power. The other Physiotherapeutic interventions consists of deep breathing exercises and segmental breathing exercises helps in preserving pulmonary function and minimizing the risks of PPC [3]. Aerobic exercises, pelvic and trunk rotation exercises, relaxation exercises and limb active range of motion exercises performed for 50 min prior to the surgery also helps in preserving pulmonary function and promoting exercise adherence post-surgery [4]. Preoperative physiotherapy along with postoperative physiotherapy (POP) also shows improvement in children with cardiac surgery [5].

The Six minute walk test (6MWT) is used to measure cardiovascular endurance and functional capacity following abdominal and cardiac surgery. Spirometry is a gold standard outcome measure, used to assess pulmonary function [6]. Spirometry and 6MWT are excellent tests for assessing pulmonary function and functional capacity before and after open abdominal surgery [7] .To best our knowledge, there is no study available, determining and comparing the effects of POPE following POP, and POP only in children undergoing open abdominal surgery. Therefore, the aim of our study is to determine and compare the effects of POPE following POP, and POP only in children undergoing abdominal surgery. We hypothesize the null hypothesis as no significance difference in the outcomes between POPE with POP and POP only. Similarly, the alternate hypothesis as significant difference in the outcomes between POPE with POP and POP only.

## 1. Patients and methods

### 1.1. Ethical statement

This was a two group pretest posttest, Open label, randomized clinical trial undertaken at Pediatric surgery ward, department of Pediatrics of a recognized tertiary care teaching hospital with children enrolled and followed-up between August, 2018 and March, 2019. Purposive sampling was used to recruit sample from the children admitted in the pediatric surgery ward. Informed assent and consent were taken from children along with parental consent before their recruitment. Ethical clearance was obtained from institutional research ethics committee of Maharishi Markandeshwar (Deemed to be university), Mullana, Ambala, Haryana (IEC/MMU/2018/1189) on 12 June, 2018. The study was registered in Clinical trials.gov with unique reference number NCT03543904, on 1 June, 2018. The study strictly followed the standard ethical principles adopted by World Medical Association which include the medical research involving human subjects, Helsinki declaration, Revised 2013, and the ethical guidelines adopted by the Council for International Organizations of Medical Sciences (CIOMS), the international ethical guidelines for health-related research involving human subjects (Revised, 2016). The study also adopted the ethical guidelines that followed the national ethical guidelines for biomedical and health research involving human participants by Indian council of Medical Research (ICMR), 2017.

### 1.2. Inclusion criteria

Children admitted in the pediatric surgery ward, planned for the open abdominal surgery through the following abdominal incisions- inguinal incision, left subcostal incision, right subcostal incision, Kehr incision, McBurney incision, transverse incision, thoraco-abdominal incision, Median and Paramedian incision were included. Children aged between 5 and 17 years, who follow and obey simple commands, and willing to participate in the trial were included in the study.

### 1.3. Exclusion criteria

Children with mental retardation, physical disability, children with other surgeries, and other medical condition which prevent them in participating in the trial were excluded from the study.

### 1.4. Randomization and blinding

Randomization was performed by using 1:1 simple randomization method [8]. Blinding of the participants was not possible, as it was an open label trial [9].

### 1.5. Study procedure

Total 32 children were screened for the eligibility and assessed for the enrollment. Out of 32, eight children were not found eligible according to the inclusion criteria, and parents of three children were refused for participation of their child in the study. Therefore a total of 21 children who were undergoing open abdominal surgery were recruited in this study. Eleven children were allocated to the intervention arm 1 receiving POPE and POP while 10 children were allocated to the intervention arm 2 receiving POP only. In the intervention arm 1, children received preoperative assessment and POPE approximately 30 min, single session, and 1 day before surgery during their admission for surgery. POPE mainly consisted of deep breathing exercises, trunk and pelvic mobility exercises and leg range of motion exercises. POP consisted of deep breathing exercises, segmental breathing exercises, active cycles of breathing techniques (ACBT), limb range of motion exercise and early ambulation program. The children in the intervention arm 2 received the above POP only. Children in both the group were assessed 1 day before surgery (Pre-OP), on Postoperative day one (POD1) and Postoperative day five (POD5). Follow up on POD1 was taken because to see that how much pulmonary function was decreased immediately after surgery and with the help of physiotherapeutic interventions, to what extent it might got increased on POD5. These exercises were incorporated into the protocol as in Supplementary File 1, titled, “Post abdominal surgery rehabilitation protocol (PARP) adapted from Neha's-Post abdominal surgery rehabilitation protocol (N-PARP)” ©Neha Sharma and copyrighted under the Copyright office, Government of India with unique registration no: L-79385/2018 dated 10th December, 2018 as given in our published pilot study [10]. The research work performed has been reported in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines and CONSORT flowchart highlighting the blueprint of the trial is displayed in Fig. 1.

### 1.6. Outcome measures

#### 1.6.1. Primary outcome

Spirometry was the primary outcome measure used to assess pulmonary function before and after open abdominal surgery. FVC (Forced vital capacity), FEV1 (Forced expiratory volume in 1 second), FEV1/FVC Ratio (Tiffeneau-Pinelli index), and PEFR (Peak expiratory flow rate) were the Spirometric measurements taken. These measurements were taken Pre-OP, POD1 and POD5.

#### 1.6.2. Secondary outcome

Six minute walk test (6MWT) was used to assess the functional capacity after open abdominal surgery. 6MWT measurements were taken on Pre-OP and POD5 along with Borg's Rate of Perceived

Exertion (RPE) scale. Other secondary outcome measures including Ten meter walk test (10mWT), timed up and go test (TUGT) and chest expansion were taken on Pre-OP, POD1 and POD5. But nine stair climbing test (9SCT) were measured on two occasion, Pre-OP and POD5.

### 1.7. Data analysis

Data were recorded using the statistical software, statistical package for the social sciences (SPSS) version 20.0 (Armonk, NY: IBM Corp.) Normality of the collected data were analyzed with Shapiro Wilk test as the sample size was lesser than 50 [11]. As the data were not normally distributed, the variables were summarized as median and inter quartile range (IQR). Both the groups were compared preoperatively with POD1 and POD5 variables. Mann-Whitney U test was used for between the group comparison to establish the statistical significance among Pre-OP, POD1 and POD5. Friedman test and Wilcoxon Signed rank test were used for within the group analysis to establish the statistical significance. A p-value of $<0.05$ was considered as statistically significant. Effect size and post hoc power analysis were performed to determine the level of type-II error. Within the group effect size was calculated by Cohen's d effect size index using the formulae: $(M1\text{-}M2) \div SD_{Pre,}$ where M1 is the mean of preoperative value, M2 is the mean of postoperative values and $SD_{Pre}$ is the standard deviation of baseline values which are specified in Table 3 and Table 4. Between the group effect sizes were calculated using Hedges' g formulae: $[(M1\text{-}M2) \div SD^{*}_{Pooled}]$ X $\{[(N\text{-}3) \div (N\text{-}2.25)]$ X $[\sqrt{(N\text{-}2)} \div N]\}$ [12], as both the groups were dissimilar in size and sample size was less than 20 ($n < 20$). By using Hedges' g inflation of bias could be minimized [12–15]. Effect sizes within the group and between the group were interpreted according to the Cohen's Classification: 0.2 = Small change, 0.5 = Moderate change and 0.8 = Large change [14]. Intention to treat analysis (ITT) for three missed to follow up cases were not performed because for performing ITT, the minimum required sample should be at least 45 participants in each group. Hence, only per-protocol analysis was performed [16].

## 2. Results

Out of 21 children who underwent open abdominal surgery, three children were missed to follow up. Two from the intervention arm 1 and one from the intervention arm 2 were the drop-outs. Hence, in the final trial nine children received POPE and POP whereas nine children in other group received POP only. The final sample population

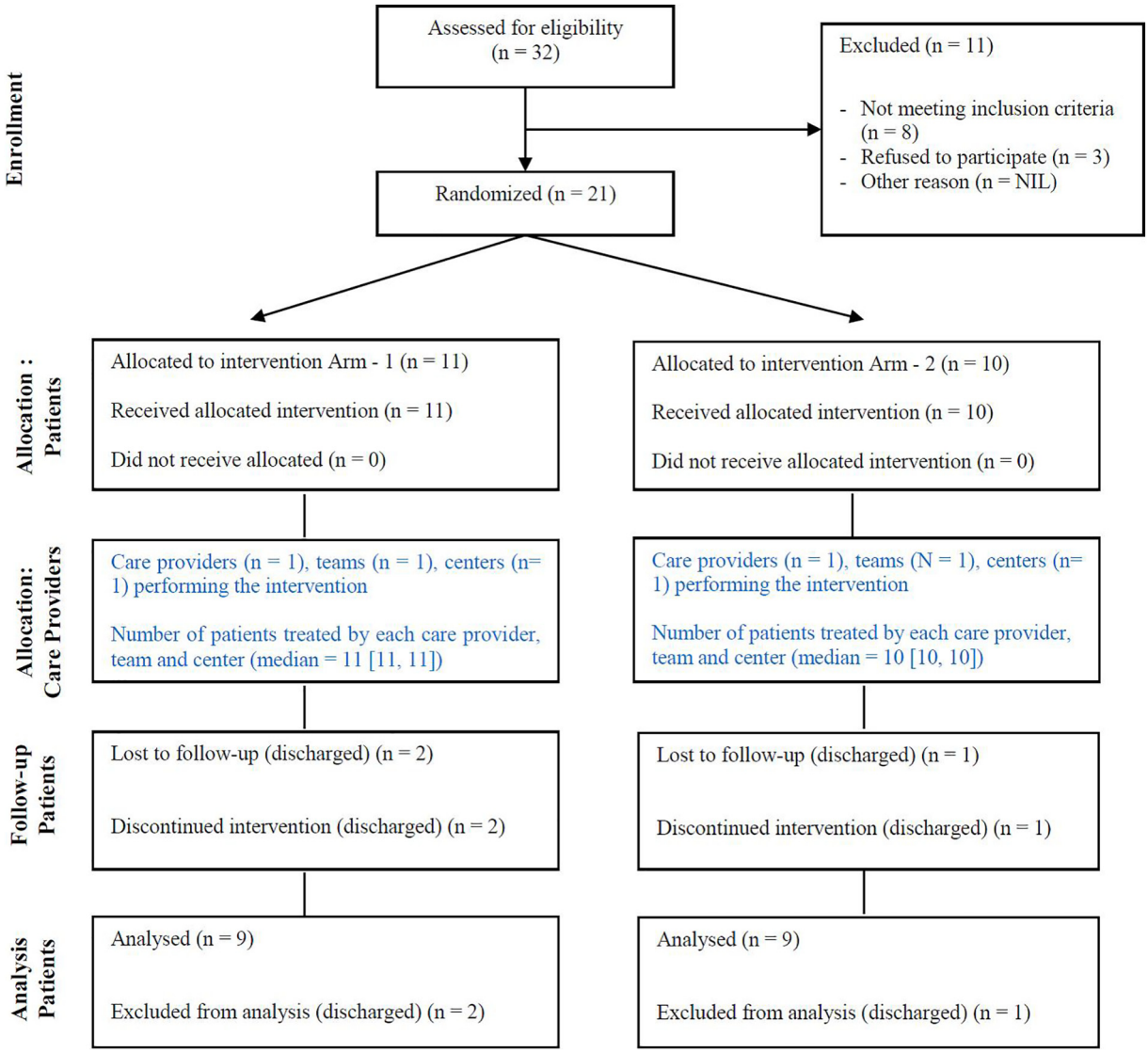


**Fig. 1. Modified Consolidated Standards of Reporting Trials (CONSORT) flow diagram for the randomized clinical trial of nonpharmacologic treatments.** An extra box per intervention group relating to care providers and centers has been added. IQR = interquartile range; max = maximum; min = minimum.

**Table 1**
Demographic characteristics of children undergoing open abdominal surgery.

| Demographic dimensions | Intervention Arm 1 (Median and IQR) | Intervention Arm 2 (Median and IQR) | P Value |
|---|---|---|---|
| Age (years) | 12 (11,15) | 12 (7.5, 13.5) | 0.22 |
| Height (Cm) | 135 (121.5, 152.5) | 129 (120, 161) | 0.65 |
| Weight (Kg) | 29 (26.5, 39.5) | 29 (26.5, 37.5) | 0.80 |
| BMI (Kg/m$^2$) | 16.5 (14.1, 18.7) | 17.6 (15.5, 18.9) | 0.31 |

POPE, preoperative physiotherapy education; POP, postoperative physiotherapy; BMI, body mass index; IQR, interquartile range.

consisted of 18 children aged between 5 and 17 years. Detailed demographic dimension of the children recruited are displayed in Table 1. Within the group comparison of spirometric parameters, 10mWT, TUGT and chest expansion on Pre-OP, POD1 and POD5 using Freidman test and Wilcoxon signed rank test for 6MWT and 9SCT are given in Table 2. Between the groups comparison of outcome measures on Pre-OP and POD5 were compared using Mann-Whitney U test are given in Table 3. Effect size within the group and between the groups was also reported in Table 3. Between the groups comparisons of outcome measures on POD1 and, POD5 values using Mann-Whitney U test are given in Table 4. Effect size within the group and between the groups were also calculated with Hedges' g formulae [12,15,17] and displayed in Table 4. As priori sample size calculation was not performed, G * Power 3.1.9.4 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany; http://www.gpower.hhu.de/) was used to calculate power of the study using post-hoc power analysis [18]. From Table 3, it was evident that the study is sufficiently powered (power of the study >90%) for the outcome measures, TUGT (100% power), 6MWT (94% power), and 9SCT (93% power). From Table 4, it is evident that the study is sufficiently powered for the outcome measures, FVC (99% power), FEV1 (98% power), PEFR (91% power), T4 (99% power), T10 (99% power). Hence, there is sufficient evidence to prove that the pulmonary function and functional capacity is preserved in POPE group among children undergoing open abdominal surgery and the level of type-II error is less than 10%.

## 3. Discussion

Pulmonary function and functional capacity is undoubtedly affected following open abdominal surgery because of the prolonged effects of anesthesia and surgical duration which further leads to PPC [19]. Therefore, POPE might have positive effects on pulmonary function after open abdominal [10]. In contrary to this, our study proved alternate hypothesis found to be true, as significant difference were noted in pulmonary function (primary outcome measure) in POPE and POP group (Intervention Arm 1) as compared with POP only group (Intervention Arm 2), from Table 4. This was further confirmed and justified with effect size (>0.8) and power analysis (>90%) as given in Table 4. Respiratory physiotherapy is widely used to maintain pulmonary function after abdominal surgery [20]. The study was performed on 21 children with three missed to follow up cases. Abdominal surgery might lead to change in pulmonary function after abdominal surgery. According to American Thoracic Society (ATS) guidelines, Spirometry is an "excellent" outcome measure, used for assessing pulmonary function [21]. We included Spirometry in our study for assessing pulmonary function in children undergoing abdominal surgery. Main parameters used in spirometry are FVC, FEV1, PEFR, and FEV1/FVC Ratio. The present study compared POPE combined with POP against the common mode of post-surgery rehabilitation, POP only in preserving pulmonary function and functional capacity in children undergoing open abdominal surgery. Pulmonary function and functional capacity is preserved after open abdominal surgery as compared to the preoperative measurements in POPE group. No adverse effects of the physiotherapeutic interventions were noted in both the groups. The advantage of POPE along with POP helps in preserving pulmonary function, functional capacity, and minimizing the risks of PPC after open abdominal surgery. We conducted this study, to compare the effects of POPE followed by POP, and POP only to confirm the internal validity of this trial, because internal validity can't be verified without the comparison group as in our previous study [10].

Previous studies have shown that POPE helps in preserving pulmonary function in open abdominal surgery in adult age group. In previous literature [19], on adult age group, Spirometry parameters (FVC, FEV1, and PEFR) were taken before and after surgery. Immediately after surgery, on POD1, POD2, and POD3, Spirometric parameters were reduced as compared to the preoperative values, but on POD4 and 5, significant improvement were noted in Spirometric parameters as compared to the Pre-OP values [19]. In our preliminary study [10], Spirometric parameters (FVC, FEV1, FEV1/FVC ratio and PEFR) were decreased on POD1 as compared with Pre-OP values but on POD5, Spirometric parameters were getting improved. In present study, FVC only improved in POPE and POP group (Intervention Arm 1) from Pre-OP to POD5 as compared to the POP group, shown in Table 3. Within the group analysis showed improvement ($p < 0.001$) in all the Spirometric parameters in POPE and POP group (Intervention Arm 1) as shown in Table 2. 6MWT is considered as exceptionally important for testing cardiopulmonary endurance [7]. In previous study [22] among adult population, 6MWT was taken along with Spirometry, for measuring functional capacity and PPC after abdominal surgery. Patients in the experimental group showed increase in the scores, while compared to the control group [22]. In our preliminary study [10], 6MWT values decreased on POD5, when compared with Pre-OP values. But, in the study, statistical significant difference were noted in the 6MWT values in both the groups (Intervention Arm 1 and Intervention Arm 2) ($p < 0.05$) as

**Table 2**
Within-group comparison of outcome measures between Pre-OP, POD1 and POD5.

| | Intervention Arm 1 | | | | Intervention Arm 2 | | | |
|---|---|---|---|---|---|---|---|---|
| Outcome measures | Pre-OP | POD1 | POD5 | P-Value | Pre-OP | POD1 | POD5 | P-Value |
| FVC (%)* | 74 (72.5, 91) | 58 (46.5, 63.5) | 77 (68, 93.5) | <0.001 | 62 (49.5, 106.0) | 39 (27.0, 47.0) | 56 (48, 67) | <0.001 |
| FEV1 (%)* | 87 (63, 103) | 53 (51.5, 71.4) | 83(60.5, 95.5) | <0.001 | 57 (37.0, 65.0) | 36 (26.0, 48.0) | 58 (48.5, 65.5) | <0.001 |
| PEFR (%)* | 75(41, 96) | 34 (30, 64.5) | 70 (44.5, 85.5) | <0.001 | 32 (29.0, 53.0) | 29 (19.0, 32.0) | 46 (38.5, 72.5) | <0.001 |
| FEV1/FVC Ratio (%)* | 106 (89,117) | 83 (64,100) | 98 (82, 116) | <0.001 | 92 (64.0, 106.0) | 84 (75.0, 103) | 89 (66, 102.5) | <0.001 |
| 10mWT (m/s)* | 12.7 (11.5, 14.3) | 19.8 (18.5, 22.0) | 16.9 (14.6, 18.9) | <0.001 | 13.1 (11.8, 14.8) | 18.5 (16.9, 20.8) | 19 (17.1, 20.2) | <0.001 |
| TUGT (s)* | 12.9 (11.4, 14.1) | 21.1 (18.4, 25.6) | 20.8 (17.2, 23.9) | <0.001 | 16.2 (11.7, 19.8) | 23.9 (20.1, 25.0) | 21.8 (18.7, 24.3) | <0.001 |
| T2 (cm)* | 2.3 (2.0, 2.7) | 1.5 (0.6, 1.6) | 2.1 (2.0, 3.0) | <0.001 | 2.0 (1.5, 2.1) | 1.0 (0.5, 1.5) | 1.5 (1.5, 2.0) | <0.001 |
| T4 (cm)* | 3.9 (3.1, 4.6) | 2.1 (1.5, 2.7) | 3.8 (2.2, 4.4) | <0.001 | 2.9 (1.7, 3.3) | 1.5 (1.5, 1.9) | 2.3 (1.8, 2.7) | <0.001 |
| T10 (cm)* | 4.8 (4.2, 5.5) | 2.5 (1.6, 2.9) | 4.0 (3.5, 4.9) | <0.001 | 4.1 (3.1, 4.3) | 2.0 (1.7, 2.5) | 3.0 (2.7, 3.6) | <0.001 |
| 6MWT (m) † | 469 (409, 492) | ---------- | 410 (380, 413) | <0.001 | 423 (365, 513) | ---------- | 381 (341, 468) | <0.001 |
| 9SCT (s) † | 12.9 (10.5, 16.7) | ---------- | 17.4 (16.0, 25.7) | <0.001 | 15.3 (13.9, 16.0) | ---------- | 18.8 (17.0, 21.6) | <0.001 |

**Abbreviations:** FVC, Forced vital capacity; FEV1, Forced expiratory volume in 1 second; PEFR, Peak expiratory flow rate; FEV1/FVC ratio, Tiffeneau-Pinelli index; TUGT, Timed up and go test; 10Mwt, Ten meter walk test; POPE, Preoperative physiotherapy education; POP, Postoperative physiotherapy; Pre-OP, Preoperative; POD1, Postoperative day one; POD5, Postoperative day five; T2, Axillary level; T4, Nipple level; T10, Xiphi-sternum level; 6MWT, Six minute walk test; 9SCT, Nine stair climbing test; *Fried man test; † Wilcoxon signed rest.

**Table 3**
Comparison of outcome measures between Pre-OP and POD5 values.

| Intervention Arm 1 | | | | | Intervention Arm 2 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Outcome measures | Pre-OP–POD5 | P-Value | Effect size within the group‡ | Power | Pre-OP–POD5 | P-Value | Effect size within the group‡ | Power | P-Value between the groups | Effect size between the group§ |
| FVC (%)* | 4 (−1.5, 5) | 0.26 | 0.11 | 6.0% | 6 (2.5, 20) | 0.04 | 0.42 | 19% | 0.13 | 0.68 |
| FEV1 (%)* | 4 (−1.5, 8) | 0.14 | 0.15 | 6.7% | 4 (−18, 7) | 0.55 | 0.25 | 9.8% | 0.38 | 0.02 |
| PEFR (%)* | 4 (−7, 9.5) | 0.68 | 0.02 | 5.0% | -1 (−21, 5) | 0.40 | 0.44 | 20.4% | 0.43 | 0.4 |
| FEV1/FVC Ratio (%)* | 2 (−4, 16.5) | 0.44 | 0.35 | 14.5% | 7 (−13.5, 22) | 0.55 | 0.15 | 6.7% | 0.93 | 0.05 |
| 10mWT (m)* | −3.6 (−4.6, −3.1) | 0.01 | −0.60 | 33.7% | −6.5 (−8.3, −1.5) | 0.01 | 2.04 | 99% | 0.54 | 0.45 |
| TUGT (s)* | −7.4 (−10.9, −3.1) | 0.01 | −3.04 | 100% | −5.6 (−8.9, −1.9) | 0.02 | 1.43 | 95% | 0.54 | 0.39 |
| Chest expansion T2 (cm)* | 0.1 (−0.3, 0.5) | 0.51 | 0.14 | 6.5% | 0.1 (−0.1, 0.50 | 0.13 | 0.60 | 3.3% | 0.73 | 0.26 |
| T4 (cm)* | 0.4 (0.05, 1.41) | 0.06 | 0.54 | 28% | 0.3 (−0.6, 1.4) | 0.37 | 0.30 | 1.2% | 0.60 | 0.18 |
| T10 (cm)* | 0.5 (0.3, 1.2) | 0.01 | 1.00 | 72% | 0.5 (−0.2, 1.5) | 0.06 | 1.16 | 83% | 0.60 | 0.00 |
| 6MWT (m) † | 59 (37, 82) | 0.01 | 1.41 | 94% | 35 (18,48) | 0.00 | 0.65 | 38% | 0.11 | 0.76 |
| 9SCT (s) † | −5.4 (−8.0, −4.0) | 0.00 | 1.00 | 93% | −3.7 (−5.7, −2.9) | 0.01 | 2.6 | 99% | 0.10 | 1.20 |

**Abbreviations:** FVC, Forced vital capacity; FEV1, Forced expiratory volume in one second; PEFR, Peak expiratory flow rate; FEV1/FVC ratio, Tiffeneau-Pinelli index; TUGT, Timed up and go test; 10Mwt, Ten meter walk test; Pre-OP, Preoperative; POD1, Postoperative day one; POD5, Postoperative day five; POPE, Preoperative physiotherapy education; POP, Postoperative physiotherapy; T2, Axillary level; T4, Nipple level; T10, Xiphi-sternum level; 6MWT, Six minute walk test; 9SCT, Nine stair climbing test; *Mann-Whitney U test; †Wilcoxon Signed Rank test; ‡Cohen's d formulae; §Hedges g formulae.

shown in Table 3. Within the group analysis showed improvement in 6MWT values on POD5. The values are approximate equal or near to Pre-OP in both the groups as displayed in Table 2.

For other outcome measures such as 10mWT, TUGT, 9SCT, and chest expansion, no evidence is available in adult and pediatric abdominal and thoracic surgeries. We used 10mWT, to measure the risk of fall [23], TUGT for measuring balance and functional mobility [24], 9SCT for measuring functional capacity [25] and chest expansion [26] for measuring chest wall mobility in children undergoing open abdominal surgery. The cutoff score of 10mWT is more than 10s which predicts risks of fall [27]. In our preliminary study [10], children completed the test in 16.8 s, which is more than 10s and similar findings were observed in the study. Children in POPE group completed the test in 16.9 s, whereas children in POP group completed the test in 19 s on POD5 which is shown in Table 2. Between the group analysis revealed statistical significance difference as ($p < 0.05$) shown in Table 3. We also used TUGT, to assess balance. TUGT is having very good correlation with balance in among the pediatric population ($r = 0.97$) [27], so this test was used in the study. A standard reference norm of healthy children for this test is ranged between 3.2 s and 6.7 s [27]. In our preliminary study [10], children completed the test ranged between 12.2 s and 16.0 s. Similar results were obtained in the study, children in Intervention Arm 1 completed the test in 20.8 s on POD5, whereas in Intervention Arm 2, children completed the test in 21.8 s shown in Table 2. No statistical significant difference ($p > 0.05$) were noted among TUGT scores between the groups as shown in Table 3. Children took more time to complete the test before and after open abdominal surgery might be due to the pain over the incision site. The stair climbing test was used for measuring functional capacity before and after surgery [28]. We used 9SCT, as we anticipated children are more active and having more functional capacity after surgery as compared to the adult population. In our preliminary study [10], statistical significant difference ($p < 0.05$) were noted between Pre-OP and POD5 values. In the present study, children completed the test in 17.4 s, which is approximate to the preoperative values in Intervention Arm 1, whereas in Intervention Arm 1 children completed the test in 18.8 s as shown in Table 2. No statistical significant difference were noted between preoperative and postoperative values between the groups ($p > 0.05$) shown in Table 3. Chest expansion is mainly used to measure chest wall expansion and thoracic mobility in patients with thoraco-abdominal surgery [29]. We assessed chest wall expansion and thoracic wall mobility in all the three levels in our study. In our preliminary study [10], no statistical significant differences were noted in preoperative and POD5 chest expansion values. In our main study, statistical significant difference were only noted in T10 chest expansion level ($p < 0.05$), whereas at the level of T2 and T4, no statistical significant difference were noted between the groups ($p > 0.05$) shown in Table 3. Within the group analysis showed significant difference ($p < 0.05$) in the both groups. Results showed improvement in chest expansion and thoracic mobility, as the POD5 values are approximate to the Pre-OP values in Intervention Arm 1 as shown in Table 2.

Single centered study, small sample size and single preoperative physiotherapy session were the main limitations of the study which might

**Table 4**
Comparison of outcome measures between POD1 and POD5 values.

| Intervention Arm 1 | | | | | Intervention Arm 2 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Outcome measure | POD1-POD5 | P-Value | Effect size within the group‡ | Power | POD1–POD5 | P-Value | Effect size within the group‡ | Power | P-Value between the groups | Effect size between the group§ |
| FVC (%)* | −17.0 (−31.5, −6.7) | 0.00 | 1.8 | 99% | −15.0 (−27.0, −8.5) | 0.00 | 0.7 | 55% | 0.73 | 0.29 |
| FEV1 (%)* | −18.5 (−31.7, −5.2) | 0.00 | 1.4 | 98% | −15.0 (−30.5, −5.0) | 0.01 | 0.7 | 59% | 0.60 | 0.19 |
| PEFR (%)* | −17.5 (−34.5,-8.0) | 0.00 | 1.1 | 91% | −22.0 (−35.5, −9.5) | 0.00 | 1.9 | 99% | 0.86 | 0.04 |
| FEV1/FVC Ratio (%)* | −16.5 (−27.2, −1.75) | 0.00 | 0.7 | 55% | −18.0 (−29.5, 16.0) | 0.37 | 0.2 | 14.1% | 0.93 | 0.13 |
| TUGT (s)* | 1.75 (−.67, 4.6) | 0.37 | 0.2 | 15% | 1.4 (−.20, 3.2) | 0.15 | 0.2 | 15.2% | 0.73 | 0.10 |
| 10mWT | 2.40 (−.01, 4.0) | 0.00 | 0.7 | 55% | 0.10 (−2.1, 2.7) | 1.00 | 0.0 | 0.5% | 0.01 | 0.95 |
| Chest expansion T2 (cm)* | −1.0 (−1.6,-.15) | 0.02 | 1.0 | 88% | −0.7 (−1.0,-.01) | 0.01 | 1.5 | 99% | 0.73 | 0.22 |
| T4 (cm)* | −.70 (−1.7,-.30) | 0.05 | 1.6 | 99% | −0.7 (−1.2, −.30) | 0.04 | 2.0 | 99% | 0.60 | 0.24 |
| T10 (cm)* | −1.0 (−2.3,-.57) | 0.00 | 2.2 | 99% | −0.90 (−1.9,-.20) | 0.02 | 1.8 | 99% | 0.60 | 0.00 |

**Abbreviations:** FVC, Forced vital capacity; FEV1, Forced expiratory volume in one second; PEFR, Peak expiratory flow rate; FEV1/FVC ratio, Tiffeneau-Pinelli index; TUGT, Timed up and go test; 10Mwt, Ten meter walk test; Pre-OP, Preoperative; POD1, Postoperative day one; POD5, Postoperative day five; POPE, Preoperative physiotherapy education; POP, Postoperative physiotherapy; T2, Axillary level; T4, Nipple level; T10, Xiphi-sternum level; POPE, Preoperative physiotherapy education; POP, Postoperative physiotherapy; *Mann-Whitney U test; ‡Cohen's d formulae; §Hedges g formulae.

affect the generalizability of the results. Moreover, the participants in this study represented a convenience sample of children recruited from the pediatric surgery ward posted for open abdominal surgery which might have led to some degree of selection bias. Nevertheless, this was the first study among pediatric population in open abdominal surgery to estimate the effects of preoperative physiotherapy education in pediatric population. Though the study had small sample size, the study was sufficiently powered. As this clinical trial compared the new proposed intervention (POPE and POP) against the standard care, POP in the children undergoing open abdominal surgery, this can be rightly called as phase-III randomized clinical trial [30]. Future studies can target larger sample size extending into phase-IV randomized clinical trial to see beneficial effects of POPE in children undergoing laparoscopic or open abdominal surgery.

## 4. Conclusion

There is sufficient evidence to confirm that POPE might have a positive effect in improving pulmonary function and functional capacity. Thus the feasibility N-PARP protocol regarding POPE and POP is established and verified. Hence, the protocol can be applied safely in the children undergoing open abdominal surgery.

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## References


[1] Boden I, Browning L, Skinner EH, et al. The LIPPSMAck POP ( lung infection prevention post surgery – major abdominal – with pre-operative physiotherapy ) trial: study protocol for a multi-centre randomised controlled trial. Biomed Cent. 2015; 16:1–15. https://doi.org/10.1186/s13063-015-1090-6.

[2] Patman S, Bartley A, Ferraz A, et al. Physiotherapy in upper abdominal surgery – what is current practice in Australia? Arch Physiother. 2017;7:1–11. https://doi.org/10.1186/s40945-017-0039-3.

[3] Boden I, Skinner EH, Browning L, et al. Preoperative physiotherapy for the prevention of respiratory complications after upper abdominal surgery: pragmatic, double blinded, multicentre randomised controlled trial. BMJ. 2018;360:569–73. https://doi.org/10.1136/bmj.j5916.

[4] Stephensen D, Hashem F, Corbett K, et al. Effects of preoperative and postoperative resistance exercise interventions on recovery of physical function in patients undergoing abdominal surgery for cancer: a systematic review of randomised controlled trials. BMJ Open Sport Exerc Med. 2018;4:e000331. https://doi.org/10.1136/bmjsem-2017-000331.

[5] Felcar JM, Guitti JC dos S, Marson AC, Cardoso JR.. Preoperative physiotherapy in prevention of pulmonary complications in pediatric cardiac surgery. Rev Bras Cir Cardiovasc. 2008;23:383–8. https://doi.org/10.1590/S0102-76382008000300016.

[6] Santos BFA, Souza HCD, Miranda APB. Performance in the 6-minute walk test and postoperative pulmonary complications in pulmonary surgery: an observational study. 2016;20:66–72.

[7] Keeratichananont W, Thanadetsuntorn C, Keeratichananont S. Value of preoperative 6-minute walk test for predicting postoperative pulmonary complications 2016: 18–25. https://doi.org/10.1177/1753465815615509.

[8] Shields N, Bennell KL, Radcliffe J, et al. Is strength training feasible for young people with Prader-Willi syndrome? A phase I randomised controlled trial. Physiother (United Kingdom); 2019. https://doi.org/10.1016/j.physio.2019.01.016.

[9] Kahan BC, Cro S, Doré CJ, et al. Reducing bias in open-label trials where blinded outcome assessment is not feasible; strategies from two randomised trials. Trials. 2014; 15:1–6.

[10] Sharma N, Sree BS, Aranha VP, et al. Preserving pulmonary function and functional capacity in children undergoing open abdominal surgery: a one group pretest–posttest, quasi experimental pilot trial. J Pediatr Surg. 2020;55(10): 2191–6.

[11] Yazici B, Yolacan S. A comparison of various tests of normality. J Stat Comput Simul. 2007;77:175–83. https://doi.org/10.1080/10629360600678310.

[12] Hedges' g: Definition, Formula - Statistics How To. [Internet]. [Accessed 9 April 2020]. Available from: https://www.statisticshowto.com/hedges-g/.

[13] Lakens D. Calculating and reporting effect sizes to facilitate cumulative science: a practical primer for t-tests and ANOVAs. Front Psychol. 2013;4:863. https://doi.org/10.3389/fpsyg.2013.00863.

[14] Sullivan GM, Feinn R. Using effect size – or why the P value is not enough. J Grad Med Educ. 2012;4:279–82.

[15] Ellis PD. Introduction to effect sizes. The Essential Guide to Effect Sizes: Statistical Power, Meta-Analysis, and the Interpretation of Research Results. United Kingdom: Cambridge University Press; 2010. p. 10.

[16] Shah PB, Boutis K, Willan A. Intention-to-treat and per-protocol analysis. Can Med Assoc J. 2011;183:2011. https://doi.org/10.1503/cmaj.111-2032.

[17] Marfo P, Okyere GA. The accuracy of effect-size estimates under normals and contaminated normals in meta-analysis. Heliyon. 2019;5:e01838. https://doi.org/10.1016/J.HELIYON.2019.E01838.

[18] Faul F, Erdfelder E, Lang A-G, et al. G*power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods. 2007;39:175–91.

[19] Kumar AS. Comparison of flow and volume incentive spirometry on pulmonary function and exercise tolerance in open abdominal surgery: a randomized clinical trial. J Clin Diagnostic Res. 2016;10:2–7. https://doi.org/10.7860/JCDR/2016/16164.7064.

[20] Chumillas S, Ponce JL, Delgado F, et al. Prevention of postoperative pulmonary complications through respiratory rehabilitation; a controlled clinical study. Prev Postoper Pulm Complicat through Respir Rehabil A Control Clin Study. 1998;79:5–9.

[21] Miller MR, Hankinson J, Brusasco V, et al. Standardisation of spirometry. Eur Respir J. 2005;26:319–38. https://doi.org/10.1183/09031936.05.00034805.

[22] Soares SM. Pulmonary function and physical performance outcomes with preoperative physical therapy in upper abdominal surgery: a randomized controlled trial. Clin Rehabil. 2013;27:616–27.

[23] Bahrami F, Noorizadeh Dehkordi S, Dadgoo M. Inter and intra rater reliability of the 10 meter walk test in the community dweller adults with spastic cerebral palsy. Iran J Child Neurol. 2017;11:57–64.

[24] Nicolini-Panisson RD, Donadio MVF. Timed "Up & Go" test in children and adolescents. Rev Paul Pediatr. 2013;31:377–83. https://doi.org/10.1590/S0103-05822013000300016.

[25] Dong J, Mao Y, Li J, et al. Stair-climbing test predicts postoperative cardiopulmonary complications and hospital stay in patients with non-small cell lung cancer. Med Sci Monit. 2017;23:1436–41. https://doi.org/10.12659/MSM.900631.

[26] Olsén MF, Lindstrand H, Broberg JL, et al. Measuring chest expansion; a study comparing two different instructions. Adv Physiother. 2011;13:128–32. https://doi.org/10.3109/14038196.2011.604349.

[27] Srisim K, Saengsuwan J. Amatachaya S. Functional assessments for predicting a risk of multiple falls in independent ambulatory patients with spinal cord injury. 2015; 38:439–45.

[28] Bradford M, Waldrop MG, Mims AH, et al. Timed stair climbing is the single strongest predictor of perioperative complications in patients undergoing abdominal surgery. J Am Coll Surg. 2017;222:559–66. https://doi.org/10.1016/j.jamcollsurg.2016.01.010.Timed.

[29] Adedoyin RA, Adeleke OE. Reference values for chest expansion among adult residents in Ile-Ife. J Yoga Phys Ther. 2012;2:2–5. https://doi.org/10.4172/2157-7595.1000113.

[30] Portney LG. Principles of clinical trials. Foundaitons Clin. Res. Appl. to evidence-based Pract. 4th ed., Philadelphia: USA: FA Davis Company; 2020; 201–4.