How to Identify Suitable Candidates With Pectus Excavatum for Vacuum Bell Therapy?

Eunjue Yi  
Korea University Anam Hospital

Kwanghyoung Lee  
Korea University Anam Hospital

Younggi Jung  
Korea University Anam Hospital

Jae Ho Chung  
Korea University Anam Hospital

Han Sung Kim  
Yonsei University

Sungho Lee (sholeemd@korea.ac.kr)  
Korea University Anam Hospital

Hyonggin Ahn  
Korea University College of Medicine

Research Article

Keywords: pectus excavatum, vacuum bell, outcomes.

DOI: https://doi.org/10.21203/rs.3.rs-557373/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Abstract

Vacuum bell therapy has been an acceptable substitute for pectus excavatum patients who want to improve their appearance but avoid surgical correction. The aim of this study was to assess the pre-treatment characteristics of patients with pectus excavatum and to establish characteristics that can potentially help identify ideal candidates for vacuum bell therapy. Expected improvements in thoracic indices were evaluated using pre-treatment chest computed tomography, which was performed before and after applying a vacuum bell device. Treatment results after 1-year of application were evaluated using changes in the Haller index before and after treatment. The patients were categorized into two groups: those with Haller index less than 0.5 (Group 1) and those with Haller index greater than or equal to 0.5 (Group 2). Pre-treatment Haller index was significantly lower in Group 1 than in Group 2 (3.1±0.46 vs. 4.2±1.14, respectively, p<0.001). The expected improvement in Haller index in Group 2 was significantly higher than that in Group 1 (3.3±0.60 vs. 2.8±0.54, respectively, p=0.001). The cut-off value of the expected improvement in Haller index was 0.46 with a sensitivity of 75.8% and a specificity of 83.3%. Patients who demonstrated pliability with a vacuum bell were identified as suitable candidates.

Introduction

Although minimally invasive surgical repair (MIRPE) is the gold standard treatment for pectus excavatum (PE), there is a need for less invasive therapeutic methods that can effectively manage pain and are not associated with severe complications. The vacuum bell device has been used for several decades as a feasible and safe treatment for patients with PE. It has demonstrated effectiveness in carefully selected patients with PE who wish to avoid surgical corrections. However, it is contraindicated in conditions, such as musculoskeletal disorder, vasculopathy, coagulopathy, and cardiac disorders.

We have adopted this method since 2016 at our institute and have encountered over 100 cases. However, we are still unsure of which patients stand to potentially benefit from this non-invasive treatment and what type of clinical presentation could be a good predictor of therapeutic efficacy. Therefore, we assessed our short-term clinical experiences with vacuum bell therapy, evaluated the pre-treatment characteristics and treatment outcomes using various indices, and tried to identify the appropriate clinical indications for this non-surgical treatment.

Materials And Methods

Study approval

This study protocol and a waiver of informed consent were approved by the Institutional Review Board of Korea University Anam Hospital (IRB number: 2018AN0080). All methods including retrospective data collection and analysis were performed in accordance with relevant Korean guidelines and regulations.

Patients

Between January 2016 and December 2019, we encountered 119 patients with PE who received vacuum bell therapy for more than 1 year. Of them, 26 patients decided to stop the treatment and underwent surgical correction during the follow-up period. They were excluded from the study. Patients who did not undergo chest computed tomography (CT) before undergoing vacuum bell therapy (30 patients) were also excluded.
Our inclusion criteria were as follows: (1) received vacuum bell therapy for more than 1 year; (2) visited the outpatient department at least four times to evaluate treatment effects; and (3) underwent chest CT before starting treatment.

The medical records of the patients were reviewed retrospectively. Pre-treatment characteristics, including Haller index (HI), and post-treatment results were evaluated. The changes in HI after vacuum bell application were calculated using chest radiographs. The patients were classified into two groups according to the post-treatment changes in HI of ≥ 0.5 (Group 1) or < 0.5 (Group 2). This study was approved by the Institutional Review Board of the Korea University Anam Hospital (IRB number: 2018AN0080).

**Definition of thoracic indices**

The thoracic indices used for pre-treatment characteristics and post-treatment changes were defined as follows. Haller index was calculated according to the definition by Haller in 1987; it is an index derived from dividing the greater transverse diameter of the chest by the shortest anteroposterior diameter. Usually, chest CT is used for estimations; however, chest roentgenography (chest radiographs) can also be used. On chest radiographs, HI was calculated by dividing the greater transverse diameter on posteroanterior view by the shortest distance between the vertebrae and sternum (shortest anteroposterior diameter) on lateral view (Fig. 1).

The asymmetry index (AI) was designed to quantify chest deformities that could not be recognized using HI. It includes the largest sagittal distance of the right and left chest within the same slice of chest CT as that used for HI measurement. The ratio is calculated as AI = R/L, where R means right and L means left. An AI > 1.0 implies right asymmetry, while an AI < 1.0 indicates left-skewed PE.

The correction index (CI) is a novel index proposed by S.D. St. Peter; it is calculated using chest CT and expressed as a percentage ratio. The minimum distance between the anterior spine and posterior aspect of the sternum (narrowest point) is described as “AP min.” The maximum distance between the anterior portion of the chest and a horizontal line across the anterior spine (widest point) is called “AP max.” It was calculated according to the following formula: ([AP max]−[AP min])/[AP max]; Fig. 2). It has been reported to be related to the possible percentage of correction in chest deformities using MIRPE. In this study,

Thoracic indices on chest CT and radiographs obtained after 1 year of treatment with a vacuum bell were measured on similar slices and were used for post-treatment comparison with the pre-treatment images.

**Pre-treatment examination**

A specially designed non-enhanced chest CT for patients with PE was performed before deciding the treatment method. Chest CT was performed to obtain two sets of non-enhanced transverse images. One was an ordinary condition, and the other was taken after a vacuum bell device was applied to the chest wall defect. Chest radiography and electrocardiography were routinely performed before starting the treatment.

After careful physical examination and review of imaging studies, patients were informed about the conservative treatment and possibility of surgery. For patients who wanted to try the non-invasive treatment, the first application of a vacuum bell device was performed in an outpatient department based on precise instructions and under careful supervision of attending clinicians. Four types of vacuum bell devices (16, 19, and 26 cm, and a specialized dumbbell-shaped device for women) with different sizes and shapes were available. The appropriate size and shape of the devices were carefully chosen after several trials. Presence of a caregiver was compulsory if the
patients were under 18, and they were encouraged to learn how to use the device if the patients were under 15 years of age. Application of the device for a minimum of 30 minutes twice a day was recommended initially. Patients were then encouraged to extend the duration to 2 hours or four times if they were tolerable.

**Measurement of pre-treatment thoracic indices**

Thoracic indices including HI, AI, and CI were measured in two ways using chest CT before and after vacuum bell application. The largest transverse and anteroposterior diameters at the deepest points of the sternum were measured with and without the application of the vacuum bell device on chest CT. The improvements in thoracic indices were measured and compared between the two phases. The pre-treatment HI was also measured using chest roentgenography to compare with the post-treatment outcomes.

The range of sternal depression (depth of PE), which is the anteroposterior distance of the deepest point of the sternum, was measured with the patient in a horizontal supine position on a flat table during deep inhalation using a designed scale rod. This clinical index was evaluated twice during the first visit. It was measured without any manipulation. Then the vacuum bell was applied on the patient’s chest for 30 minutes. Second measure was performed after waiting 5 minutes from the time of the device had been removed. The expected sternal elevation was calculated using these two parameters.

**Follow-up**

Regular outpatient follow-ups were recommended every 3 months. The depth of PE was measured at each visit, and chest radiography was performed after 1 year of treatment. Photographic documentation was obtained at the first and 1-year follow-up visits (Fig. 3). Follow-up chest CT was not performed to avoid unnecessary exposure to radiation.

**Estimation of treatment efficacy**

For estimation of the treatment response, changes in HI were calculated using the initial and 1-year follow-up chest radiographs. The initial HI on chest CT and chest radiography were positively correlated (Pearson coefficient = 0.905, p < 0.001). A reduction of ≥ 0.5 in HI (since the mean overall HI before the treatment was 3.7 and 3.25 was considered the surgical threshold) was considered a successful treatment outcome in our study. The daily duration and the frequency of the vacuum bell device was recorded as reported by the patients and caregivers. Subsequently, the compliance and complications were assessed.

**Evaluation of pre-treatment variables for identifying suitable candidates**

The patients were categorized into two groups: Group 1 included patients with changes in HI < 0.5, and Group 2 included those with changes in HI ≥ 0.5. Pre-treatment characteristics, including expected improvements in thoracic indices and sternum depth, were compared. The cut-off value for the expected improvement in HI in Group 2 was measured.

**Results**

*Patient demographics and initial examinations*
A total of 63 patients were enrolled in this study. Group 1 comprised 33 patients (31 men and two women), and Group 2 consisted of 30 patients (all men). The body mass index (BMI) in Group 2 was significantly lower than that in Group 1 (p=0.001), while other demographic factors demonstrated no significant differences. The pre-treatment patient characteristics and clinical information are summarized in Table 1.

**Comparison of pre-treatment thoracic indices with post-treatment values**

Both pre-treatment HI and depth of PE in Group 2 were significantly higher than those in Group 1 (p<0.001 and p=0.021, respectively). The expected improvement in HI was significantly higher in Group 2 than that in Group 1 (p=0.001), which appeared to be correlated with post-treatment changes in HI after 1 year (0.93±0.400 vs. 0.18±0.197, respectively, p<0.001); however, the response with the depth of PE was not. The expected depth of PE (Changes in AP diameter with and without VBT application) was significantly better in Group 2 than in Group 1 (9.3±5.48 vs. 15.0±6.80, respectively, p=0.001) but post-treatment response demonstrated no statistically significant differences (0.66±0.838 vs. 0.67±1.002, respectively, p=0.957).

Pre-treatment and expected changes in AI were not significantly different between the groups, whereas CI demonstrated significant differences pre-treatment condition, but the expected changes following vacuum bell application were not significantly different. We could not measure the post-treatment changes in AI and CI because post-treatment chest CT was not performed.

Poor compliance and complication rates were not statistically different between the groups (p=1.000 and p=0.457, respectively). The duration and frequency of vacuum bell application also demonstrated no statistical differences between the groups (p=0.669 and 0.671, respectively). The pre-treatment and post-treatment outcomes are summarized in Table 2.

**Cut-off values based on pre-treatment estimation**

The estimated cut-off value in Group 2 in expected improvement in HI a receiver-operating characteristic (ROC) curve of 0.46, sensitivity of 75.7%, and specificity of 83.3% (area under the curve=0.846, p<0.001). The ROC curve is shown in Figure 4.

**Discussion**

Conservative management of PE using a suction device suffered long periods of neglect before the efforts of E. Klobe in 1992 because of inadequate materials and relevant side effects. The newly designed vacuum bell consisted of a silicon ring with a transparent polycarbonate window instead of glasses which old style suction cups were made of.

Vacuum bell therapy has been successfully established as a conservative management for PE; however, there is a lack of information on precise clinical indications as well as assessment tools in estimating the treatment achievement, which limits its use by clinicians. Difficulties in clinical evaluations may be attributed to the application of vacuum bell therapy being largely dependent on a patient’s preference.

A prerequisite for vacuum bell therapy is a patient’s desire for non-surgical corrections, despite all clinical evidence relating to beneficial patient characteristics including a mild degree of PE, symmetric deformities, sternal depth greater than 1.5 cm, or younger age than preadolescence. Clinicians cannot ignore the patients’ desire to avoid
pain and possible complications caused by surgery even when their clinical experience suggests surgical solutions.

Similar to other studies that have attempted to identify indications or objective assessment tools, we aimed to evaluate suitable pre-treatment patient characteristics associated with successful treatment outcomes. We estimated changes in HI 1 year after treatment and traced the variables that were associated with changes in HI ≥ 0.5. We found that the expected improvement in HI was profoundly correlated with the availability of vacuum bell therapy (Figure 4).

This observation appears to be associated with chest wall flexibility, which has been reported to be related to successful treatment of PE, either surgically or non-surgically 12. Patients with more flexible chest wall can be expected to achieve better treatment outcomes. Based on this factor, clinicians would be able to tell their patients how their chest deformities will change after 1 year of vacuum bell therapy. The expected CI or HI calculated using chest CT taken after applying a vacuum bell device and the expected improvement in sternal depth could be supplementary tools in predicting outcomes.

Unlike the other two thoracic indices associated with good treatment outcomes, AI was not correlated with the treatment response. Symmetry has been demonstrated to be related to improved therapeutic efficacy 11. Although we did not examine the effects of symmetry on vacuum bell therapy, we believed that the discordance between improvement in chest deformity (improvement in HI ≥ 0.5) and expected AI would be reflected in the results.

A low BMI was associated with better outcomes after vacuum bell therapy (p=0.001), while other pre-treatment factors including sex, age, and AI with or without vacuum bell therapy demonstrated no statistically significant differences between the two groups (p=0.366 and p= 0.228, respectively). A low BMI is believed to be related to the effectiveness of sternal lifting 13.

Young age at the initiation of treatment was associated with good outcomes. Initiating the therapy before adolescence and age<12 years demonstrated significantly positive treatment results 11. Another study reported that age<18 years was associated with better effects than those after starting treatment at age>18 years 12. In our study, age was not significantly associated with improvements in HI (p=0.233, univariate analysis). This was probably due to the age distribution of our patients (mean age, 15.3±6.23 years; 95% confidential interval, 13.78–16.92). Age was not significantly different between the groups. Most of the patients were adolescents; therefore, we could not identify the actual effects of age on efficacy of vacuum bell therapy.

The initial depth of PE in Group 2 was significantly larger than that in Group 1, which was opposite to findings of other studies 3,11,12,14 that reported that less severe depth in PE was related to excellent outcomes. This might be related to chest wall flexibility; patients with a large depth of PE achieve excellent results if they have good flexibility. The depth of PE measured 1 year after vacuum bell therapy demonstrated no significant differences between the groups (Table 2).

Improvement in the depth of PE demonstrated a flattening tendency as the treatment periods passed more than 1-year in our study (Figure 5). We believe that this finding could support our study design of comparing pre-treatment variables based on the improvements at 1 year. We evaluated treatment efficacy using chest radiographs and physical examination and would recommend patients to undergo surgery if they had less improvements in HI (usually less than 0.5, according to our findings).
Our study had several limitations. First, we enrolled patients regularly followed according to our treatment strategy. Therefore, we believe that all patients received a relatively homogenous treatment course, which could partly explain the lack of statistical significance. The choice for vacuum bell therapy depended on the patients and not clinical data; patients who were expected to not benefit from non-surgical treatment could be included in our study. Pre-treatment characteristics, such as HI, demonstrated significant differences between the groups. This inclusion bias implies inevitable limitations.

Successful long-term treatment results have been seen with MIRPE for PE. It is important to assure patients that vacuum bell therapy is not a substitute for surgery. MIRPE has resulted in excellent clinical results without fatal complications in a majority of patients. Vacuum bell therapy could offer satisfactory treatment results with few minor complications and less discomfort, and clinicians should not disregard that enormous effort has to be made by the patients and their caregivers to maintain treatment effects of vacuum bell therapy since the hassle of constant devotion often trumps small period of suffering induced by surgery.

In conclusion, expected improvements in HI as well as CI based on pre-treatment chest CT after applying a vacuum bell device could be used in predicting treatment efficacy. Patients who demonstrated pliability with a vacuum bell were identified as suitable candidates.

**Abbreviations**

MIRPF; minimally invasive surgical repair

PE; pectus excavatum

CT; computed tomography

HI; Haller index;

AI; Asymmetry index

CI; Correction index

BMI; body mass index

ROC, receiver-operating characteristic

**Declarations**

**Acknowledgments**

We would like to thank Editage (www.editage.co.kr) for English language editing.

**Funding**

None.

**Author contributions**
YE analyzed the data and drafted the manuscript. LSH and AH conceptualized the study and reviewed the manuscript. LKW and CJH collected the data. JY and KHS analyzed the data. All authors have read and approved the final manuscript.

**Competing interests**

The authors declare no competing interests

**References**

1. Haecker, F. M. The vacuum bell for conservative treatment of pectus excavatum: the Basle experience. *Pediatr Surg Int.* **27**, 623–627 https://doi.org/10.1007/s00383-010-2843-7 (2011).

2. Haecker, F. M. & Mayr, J. The vacuum bell for treatment of pectus excavatum: an alternative to surgical correction? *Eur J Cardiothorac Surg.* **29**, 557–561 https://doi.org/10.1016/j.ejcts.2006.01.025 (2006).

3. Haecker, F. M. & Sesia, S. Vacuum bell therapy. *Ann Cardiothorac Surg.* **5**, 440–449 https://doi.org/10.21037/acs.2016.06.06 (2016).

4. Haecker, F. M. & Sesia, S. Non-surgical treatment of pectus excavatum. *J Vis Surg.* **2**, 63 https://doi.org/10.21037/jovs.2016.03.14 (2016).

5. Haller, J. A., Kramer, S. S. & Lietman, S. A. Use of CT scans in selection of patients for pectusexcavatum surgery: a preliminary report. *Journal of pediatric surgery.* **22**, 904–906 (1987).

6. Lawson, M. L. *et al.* Reliability of a standardized protocol to calculate cross-sectional chest area and severity indices to evaluate pectus excavatum. *Journal of pediatric surgery.* **41**, 1219–1225 (2006).

7. Peter, S. D. S. *et al.* A novel measure for pectus excavatum: the correction index. *Journal of pediatric surgery.* **46**, 2270–2273 (2011).

8. Poston, P. M. *et al.* Defining the role of chest radiography in determining candidacy for pectus excavatum repair. *Innovations.* **9**, 117–121 (2014).

9. Haecker, F. M. & Martinez-Ferro, M. in Chest Wall Deformities and Corrective Procedures 137–160(Springer, 2016).

10. Patel, A. J. & Hunt, I. Is vacuum bell therapy effective in the correction of pectus excavatum? *Interactive Cardiovasc Thorac Surg.* https://doi.org/10.1093/icvts/ivz082 (2019).

11. Obermeyer, R. J. *et al.* Nonoperative management of pectus excavatum with vacuum bell therapy: A single center study. *J Pediatr Surg.* **53**, 1221–1225 https://doi.org/10.1016/j.jpedsurg.2018.02.088 (2018).

12. Lopez, M. *et al.* Preliminary study of efficacy of cup suction in the correction of typical pectus excavatum. *J Pediatr Surg.* **51**, 183–187 https://doi.org/10.1016/j.jpedsurg.2015.10.003 (2016).

13. Togoro, S. Y. *et al.* The vacuum bell device as a sternal lifter: an immediate effect even with a short time use. *Journal of pediatric surgery.* **53**, 406–410 (2018).

14. Schier, F., Bahr, M. & Klobe, E. The vacuum chest wall lifter: an innovative, nonsurgical addition to the management of pectus excavatum. *J Pediatr Surg.* **40**, 496–500 https://doi.org/10.1016/j.jpedsurg.2004.11.033 (2005).

15. Nuss, D., Obermeyer, R. J. & Kelly, R. E. Nuss bar procedure: past, present and future. *Annals of cardiothoracic surgery.* **5**, 422 (2016).
Tables

Table 1. Patient characteristics
| Variables                | Group 1 (N=33) | Group 2 (N=30) | Total          | p-value |
|--------------------------|----------------|----------------|----------------|---------|
|                          | mean±sd        | mean±sd        | mean±sd (95% CI) |         |
| Age                      | 16±7.54 (845)  | 14.2±4.18 (934) | 15.4±6.23 (845) | 0.254   |
| Sex                      |                |                |                | 0.493   |
| Female                   | 2 (6.1%)       | 0 (0.0%)       | 2 (3.2%)       |         |
| Male                     | 31 (93.9%)     | 30 (100.0%)    | 61 (96.8%)     |         |
| BMI (kg/m²)              | 19±2.39 (1625) | 16.4±3.84 (921) | (17.8±3.45) (925) | 0.001   |
| Family history           |                |                |                | 0.094   |
| No                       | 32 (56.1%)     | 25 (83.3%)     | 57 (90.5%)     |         |
| Yes                      | 1 (3.0%)       | 5 (16.7%)      | 6 (9.5%)       |         |
| Smoking history          |                |                |                | 0.334   |
| None                     | 29 (87.9%)     | 29 (96.7%)     | 58 (92.1%)     |         |
| Ex                       | 2 (6.1%)       | 0 (0.0%)       | 2 (3.2%)       |         |
| Current                  | 2 (6.1%)       | 1 (3.3%)       | 3 (4.8%)       |         |
| Comorbidity              |                |                |                | 0.535   |
| Mitral regurgitation     | 0 (0.0%)       | 1 (3.0%)       | 1 (1.6%)       |         |
| Scoliosis                | 1 (3.0%)       | 1 (3.0%)       | 2 (3.2%)       |         |
| Arrhythmia               | 1 (3.0%)       | 0 (0.0%)       | 1 (1.6%)       |         |
| Atopy                    | 0 (0.0%)       | 1 (3.0%)       | 1 (1.6%)       |         |
| Onset periods            |                |                |                | 0.922   |
| Infant (0~1-year)        | 0 (0.0%)       | 1 (3.3%)       | 1 (1.6%)       |         |
| Toddler (1~3-year)       | 1 (3.0%)       | 1 (3.3%)       | 2 (3.2%)       |         |
| Child (3 ~ 10-year)      | 9 (27.3%)      | 8 (26.7%)      | 17 (27.0%)     |         |
| Preadolescent (10 ~ 13-year) | 13 (39.4%) | 11 (36.7%)     | 24 (38.1%)     |         |
| Adolescent (13 ~ 19-year) | 8 (24.2%)     | 8 (26.7%)      | 16 (25.4%)     |         |
| Adult (>19-year)         | 2 (6.1%)       | 1 (3.3%)       | 3 (4.8%)       |         |
| EKG findings             |                |                |                | 0.473   |
| NSR                      | 31 (93.9%)     | 26 (86.7%)     | 57 (90.5%)     |         |
| Sinus bradycardia        | 2 (6.1%)       | 3 (10.0%)      | 5 (7.9%)       |         |
| Incomplete RBBB   | 0 (0.0%) | 1 (3.3%) | 1 (1.6%) |
|-------------------|----------|----------|----------|
| Nuss operation history | 0.321    |          |          |
| Yes               | 0 (0.0%) | 1 (3.3%) | 1 (1.6%) |
| No                | 33 (100.0%) | 29 (96.6%) | 62 (98.4%) |
| Symptoms          | 0.359    |          |          |
| Chest discomfort  | 0 (0.0%) | 1 (3.3%) | 1 (1.6%) |
| Palpitation       | 0 (0.0%) | 1 (3.3%) | 1 (1.6%) |
| Dyspnea           | 1 (3.0%) | 0 (0.0%) | 1 (1.6%) |
| Cough             | 0 (0.0%) | 1 (3.3%) | 1 (1.6%) |
| Low body weight   | 0 (0.0%) | 1 (3.3%) | 1 (1.6%) |
| None              | 32 (97.0%) | 26 (86.7%) | 58 (92.1%) |

BMI, body mass index; EKG, electrocardiography; RBBB, right bundle branch block; NSR, Normal sinus rhythm; sd, standard deviation.

Table 2. Thoracic indices before and after vacuum bell therapy.
| Variables                                      | Group 1 (N=33) | Group 2 (N=30) | Total (N=63) | p-value |
|-----------------------------------------------|----------------|----------------|-------------|---------|
|                                               | mean±sd (95% CI) | mean±sd (95% CI) | mean±sd (95% CI) |         |
| **HI**                                        |                |                |             |         |
| Pre-treatment                                 |                |                |             |         |
| Chest CT                                      | 3.2±0.79 (2.2–6.7) | 4.2±1.16 (2.9–8.5) | 3.7±1.10 (2.2–8.9) | <0.000  |
| CXR                                           | 3.1±0.46 (2.2–8.3) | 4.2±1.14 (3.0–8.3) | 3.6±1.00 (2.2–8.3) | <0.000  |
| Vacuum bell application                        |                |                |             |         |
| Chest CT (Expected HI)                        | 2.8±0.54 (2.1–5.2) | 3.3±0.60 (2.2–4.5) | 3.0±0.61 (2.1–5.2) | 0.001   |
| Changes in AP diameter (mm)                   | 9.3±5.48 (1.2–21.7) | 15.0±6.80 (2.4–28.2) | 12.0±6.72 (1.2–28.2) | 0.001   |
| Post-treatment (CXR)                          |                |                |             |         |
| 1-year FU                                     | 2.9±0.46 (2.0–3.9) | 3.2±0.93 (2.4–6.8) | 3.1±0.73 (2.0–6.8) | 0.292   |
| **Asymmetry Index**                           |                |                |             |         |
| Pre-treatment                                 | 1.00±0.780 (0.84–1.21) | 0.97±0.638 (0.85–1.12) | 0.98±0.719 (0.84–1.21) | 0.366   |
| Vacuum bell application (Expected)            | 1.00±0.061 (0.89–1.11) | 0.97±0.079 (0.82–1.15) | 0.98±0.071 (0.82–1.15) | 0.228   |
| **Correction Index**                          |                |                |             |         |
| Pre-treatment                                 | 0.14±0.826 (0.00–0.38) | 0.23±0.125 (0.03–0.49) | 0.18±0.114 (0.00–0.49) | 0.003   |
| Vacuum bell application (Expected)            | 0.06±0.061 (0.00–0.23) | 0.15±0.125 (0.00–0.59) | 0.10±0.106 (0.00–0.59) | 0.001   |
| **Changes in HI**                             |                |                |             |         |
| Pre-post vacuum bell application               | 0.39±0.308 (0.02–1.53) | 0.97±0.782 (0.28–4.37) | 0.67±0.648 (0.02–4.37) | <0.000  |
| **After treatment**                           | 0.18±0.197 (0.25–0.46) | 0.93±0.400 (0.50–2.08) | 0.54±0.487 (0.25–2.08) | <0.000  |
| **Depth of PE (cm)**                          |                |                |             |         |
| Initial                                       | 2.3±1.14 (0.0–6.2) | 2.7±0.92 (0.0–4.3) | 2.4±1.06 (0.0–6.2) | 0.021   |
| After vacuum bell                             | 1.9±0.80 (0.0–2.2) | 2.2±0.89 (0.0–2.0) | 2.0±0.85 (0.0–2.0) | 0.088   |
|                        | 3.7) | 3.7) | 3.7) | 3.7) |
|------------------------|------|------|------|------|
| **3-month FU**         | 2.0±0.76 (0.0–3.5) | 2.3±0.84 (0.0–4.0) | 2.2±0.81 (0.0–4.0) | 0.030 |
| **6-month FU**         | 1.9±0.82 (0.0–3.4) | 2.2±0.80 (0.0–3.5) | 2.0±0.83 (0.0–3.5) | 0.053 |
| **1-year FU**          | 1.6±0.92 (0.0–3.2) | 2.0±0.81 (0.0–3.2) | 1.8±0.88 (0.0–3.2) | 0.061 |
| **Changes after treatment** | 0.67±1.002 (-1.50–3.10) | 0.66±0.838 (-2.40–2.50) | 0.67±0.921 (-2.40–3.10) | 0.957 |
| **Poor compliance**    | 6 (18.2%) | 5 (16.7%) | 11 (17.5%) | 1.000 |
| **Vacuum bell application duration (Hour)** | 0.669 |
| 0.5                    | 3 (9.1%) | 4 (13.3%) | 7 (11.1%) |
| 1                      | 25 (75.8%) | 20 (66.7%) | 45 (71.4%) |
| 2                      | 5 (15.2%) | 5 (16.7%) | 10 (15.9%) |
| 3                      | 0 (0.0%) | 1 (3.3%) | 1 (1.6%) |
| **Vacuum bell application frequency (per day)** | 0.671 |
| 1                      | 11 (33.3%) | 12 (40.0%) | 23 (36.5%) |
| 2                      | 17 (51.5%) | 13 (43.3%) | 30 (47.6%) |
| 3                      | 4 (12.1%) | 5 (16.7%) | 9 (14.3%) |
| 4                      | 1 (3.0%) | 0 (0.0%) | 1 (1.6%) |
| **Vacuum bell size**   | 0.487 |
| 1                      | 5 (15.2%) | 7 (23.3%) | 12 (19.0%) |
| 2                      | 22 (52.4%) | 20 (66.7%) | 42 (66.7%) |
| 3                      | 4 (57.1%) | 3 (10.0%) | 7 (11.1%) |
| 4                      | 6 (6.1%) | 0 (0.0%) | 2 (3.2%) |
| **Complications**      | 0.457 |
| Chest tightness        | 1 (3.0%) | 1 (3.3%) | 2 (3.2%) |
| Skin erosion           | 1 (3.0%) | 2 (6.7%) | 3 (4.8%) |
| Skin erythema          | 0 (0.0%) | 1 (3.3%) | 1 (1.6%) |

CT, computed tomography; CXR, chest radiography; FU, follow-up; HI, Haller index; PE, pectus excavatum; sd, standard deviation.
Evaluation of pre-treatment and expected improvements in thoracic indices. (a) Chest computed tomography (CT) taken before vacuum bell application is shown. Haller index was derived by dividing the largest horizontal diameter inside the ribcage (red arrow) by the anteroposterior diameter (shortest distance between the vertebrae and sternum, yellow arrow). (b) Chest CT taken after vacuum bell application is shown. Expected improvement in Haller index was measured as described above. (c) Posterior-anterior (PA) view on chest radiograph is illustrated. The greatest transverse diameter (largest horizontal diameter within the ribcage) was measured (red arrow) (d) Lateral view on chest radiograph is shown. The anteroposterior diameter (shortest distance between vertebrae and sternum) was measured (yellow arrow). Haller Index was calculated by dividing the transverse diameter by anteroposterior diameter.
Measurement of asymmetry index (AI) and correction index (CI) using chest computed tomography (CT). (a) Measuring AI before applying vacuum bell (VB) device: The largest sagittal distance of the right (R) and left (L) chest at the same slice on chest CT as that used for HI was used in the formula was AI=R/Lx100, where T is the greater transverse diameter and A is the shortest distance between the vertebrae and sternum. (b) Measurement of AI during application of a VB device: Assessments were performed using the chest CT slice as that used before. (C) Measuring CI before applying a VB device: The minimum distance between the posterior mediastinum and anterior spine (AP min) and maximum distance between the anterior spine and anterior portion of chest wall (AP max) were measured. CI was calculated as follows: CI = ([AP max]-[Ap min])/[AP max]×100). Estimated percentage ratio is the percentage of possible correction in chest depth after treatment.
Figure 3

Evaluation of treatment outcomes after 1 year of vacuum bell (VB) application. Pictures and chest radiographs were taken from a 17-year-old male patient just before starting treatment (a, b, e, f) and at 1 year after VB therapy (c, d, g, and h). (a) Anterior view before VB application; (b) lateral view before VB application; (c) anterior view at 1 year after treatment; (d) lateral view at 1 year after treatment; (e) anteroposterior view on chest radiographs taken before starting therapy; (f) lateral view before starting therapy; (g) anterolateral view after 1 year of treatment; and (h) Lateral view after 1 year of treatment.
ROC curves of pretreatment variables. (a) Expected Asymmetric index. The cut-off value was 0.92 with 87.8% sensitivity and 36.7% specificity, which showed no statistical significance (p=0.236). (b) Expected Correction index. The cut-off value was 0.07, with 78.8% sensitivity and 73.3% specificity (p<0.001). (c) Expected Haller index. The cut-off value was 3.1, with 87.9% sensitivity and 53.3% specificity (p<0.001). (d) Expected improvement in Haller index. The cut-off value was 0.46, with 75.8% sensitivity and 83.3% specificity (p=0.001). (e) Expected improvement in depth of PE. The cut-off value was 0.4cm, with 48.5% sensitivity and 76.7% specificity which showed no statistical significance (p=0.411). (f) Expected improvement in sternal depth (calculated from chest CT). The cut-off value was 0.8cm, with 48.5% sensitivity and 86.7% (p<0.001). (g) BMI. The cut-off value was 18.5, with 58.0% sensitivity and 82.8% (p<0.001). (h) Age. The cut-off value was 16, with 33.0% sensitivity and 93.3%, which
showed no statistical significance (p=0.251). (i) comparison with ROC curves of variables which showed higher classification performance. The Expected improvement in HI revealed better capability than other variables.

**Figure 5**

Age distribution and depth of pectus excavatum (PE) according to the treatment periods. The initial mean depth was 2.4±1.06cm (range, 0.0–6.2), and the depth at 5 minutes after vacuum bell application was 2.0±1.06cm (range, 0.0–3.7). The actual changes in depth of PE after 1 year of treatment was 0.67±1.06cm (range, -2.4–3.10), which was not significantly different between Group 1 and Group 2. The changes in the depth of PE appeared to not be predictive factors of treatment outcomes; the graph could suggest the possible trends in sternal depth after applying a vacuum bell device.