



Surgical versus Vacuum Bell Therapy for the Correction of Pectus Excavatum: A Comparison of 1-Year Treatment Outcomes

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Background: The purpose of this study was to compare 1-year clinical outcomes between patients who underwent a Nuss operation or vacuum bell therapy and to present vacuum bell therapy as a possible alternative treatment modality for patients who prefer non-surgical correction of pectus excavatum.

Methods: We conducted a retrospective review of pectus excavatum patients who had undergone vacuum bell therapy for more than 1 year and examined patients who had undergone Nuss bar removal more than 1 year previously. The treatment outcomes were evaluated by comparing changes in the Haller index before and after treatment in both patient groups.

Results: We included 57 patients in this study and divided them into 2 groups according to the type of treatment received. Both groups showed no significant difference in the post-treatment Haller index after 1 year of follow-up, although the Nuss operation group showed a greater change in the Haller index than the vacuum bell group.

Conclusion: Although the Nuss operation is a well-established and effective treatment of choice to correct pectus excavatum, vacuum bell therapy showed comparable outcomes and could become an alternative treatment modality for select patients who prefer non-invasive treatment.

Keywords: Pectus excavatum, Vacuum bell, Outcomes

Introduction

For many years, minimally invasive surgical repair of pectus excavatum (MIRPE) has been widely accepted as the treatment of choice for pectus excavatum (PE) patients. However, there remains a need for a non-invasive treatment modality to reduce patient anxiety and postoperative pain. As an alternative to surgical correction, vacuum bell therapy (VBT) has been performed in these patients for many decades and has proven its feasibility and effectiveness. VBT should be recommended to a carefully selected population of PE patients, as well as those who do not desire invasive treatment.

Our institution has administered VBT to over 100 patients diagnosed with PE. However, the optimal clinical indications and the best assessment method for the application of this non-invasive treatment continue to be topics of

investigation. Therefore, the treatment of choice is mainly determined by patients' preferences. With limited data on the vacuum bell procedure and its effectiveness, we set out to compare 1-year clinical data between the VBT and MIRPE treatment modalities and to discuss whether VBT should be recommended to patients seeking non-surgical correction for PE.

Methods

Patients

All patients who had undergone Nuss bar removal after PE correction and were followed for more than 1 year, as well as those who had used VBT for more than 1 year between January 2016 and December 2020, were included in our medical record review. In total, 113 patients had been



diagnosed with PE and were either continuing treatment with a vacuum bell device or had undergone MIRPE. The inclusion criteria were as follows: (1) patients with at least 4 records of routine outpatient visits after treatment initiation; (2) patients who applied the vacuum bell device for at least 1 hour each day for more than 1 year; (3) patients with available pre-treatment chest computed tomography (CT) scans and routine follow-up chest roentgenography (chest X-ray) films to enable the proper evaluation of any treatment effect. Patients who began treatment before the age of 6 and who still had not undergone Nuss bar removal during the study period were excluded from the study.

In total, we enrolled 57 patients and divided them into 2 groups according to the treatment method. Group 1 consisted of patients treated with VBT and group 2 consisted of patients who underwent MIRPE. The change between the pre-treatment Haller index (HI) as calculated from chest CT and the 1-year post-treatment HI was compared to validate the efficacy of both treatment modalities. This study was approved by the Institutional Review Board (IRB) of Korea University Anam Hospital (IRB approval no., 2018AN0080). The requirement for informed consent from individual patients was omitted because of the retrospective design of this study.

Examination protocol

Candidates for VBT were assigned to receive specially designed, non-enhanced chest CT that comprised 2 sets of transverse images. The first set was obtained following the standard protocol, while the second set was collected immediately after applying the vacuum bell device. These pre- and post-application CT images were used to calculate the pre-treatment HI and the immediate post-treatment HI in VBT group and to evaluate the pliability of the chest wall, which is one of the most important factors to evaluate when choosing the suitable treatment modality. Pre-treatment CT images were also obtained for the MIRPE group, while post-treatment CT images were obtained during routine follow-ups within 3 months of receiving the Nuss operation. In both patient groups, physical examinations, chest X-rays, and electrocardiograms were performed as routine pre-treatment examinations.

After reviewing the above-described data from initial studies, either surgical correction or a non-invasive treatment modality was proposed to patients. Those who preferred non-invasive treatment received a properly sized and shaped vacuum bell device and training in our outpatient clinic under careful supervision of clinicians. The size of

the vacuum bell device was adjusted as the patient grew during routine follow-up visits.

The patients' caregivers were encouraged to obtain detailed instructions on how to properly apply the VBT at home. Depending on the severity of the deformity, daily treatment length and frequency were recommended. Usually, a minimum of 30 minutes per application and a schedule of 2 applications daily were recommended for the initial treatment. This was increased to 2 hours per application and 4 applications per day depending on the patients' compliance with the treatment routine (Fig. 1).

Measurement and calculation of thoracic deformities

The HI was obtained by calculating the ratio between the largest transverse diameter of the thoracic cage and the anteroposterior diameter at the deepest sternal deformity using both the pre-treatment chest CT scans and plain chest X-rays taken during visits at the outpatient clinic. Any discrepancy between the 2 sets of chest CT scans represented the pliability of the chest wall (Fig. 2). The expected improvement of the bony thorax was carefully reviewed, and appropriate candidates for VBT were selected. For the vacuum bell group, the post-treatment HI calculated 1 year after application of VBT was compared with the pre-treatment HI to verify the treatment effect. In the surgical group, the HI obtained at 1 year after Nuss bar removal was calculated to validate and compare the effectiveness of invasive treatment versus non-invasive corrective methods.

All patients were recommended to receive regular follow-up in our outpatient department every 3 months. Chest X-ray imaging was performed at 1 year following the commencement of VBT in the non-invasive group and 1 year after Nuss bar removal in the surgical group.

Results

Patient baseline characteristics

We enrolled 57 patients in this study; 33 were treated with a vacuum bell device, while 24 received treatment via MIRPE. Most patients were male ($n=52$, 91.23%). The average body mass index of the 2 patient groups had no statistically significant difference (group 1, 18.61 ± 2.57 kg/m²; group 2, 18.58 ± 2.16 kg/m²; $p=0.961$), and no patients had other comorbidities. Most patients in both groups had begun developing a sternal deformity during their preadolescent period (group 1, 39.4%; group 2, 45.83%). The most com-

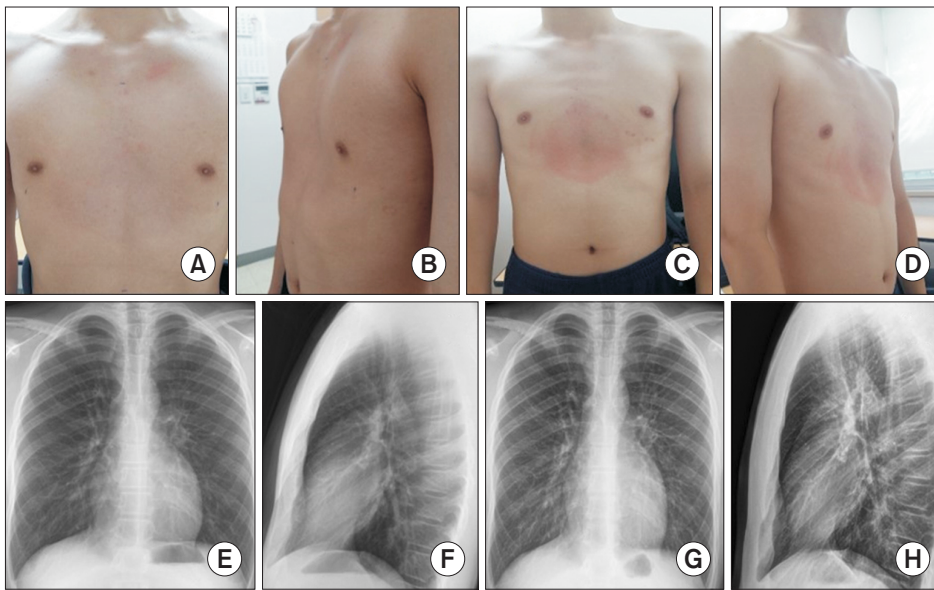


Fig. 1. One-year post-treatment outcomes after vacuum bell application. Pictures and chest X-rays from a 17-year-old male patient just (A, B, E, F) before starting treatment and (C, D, G, H) after 1 year of using vacuum bell therapy with the caregiver's permission and supervision. (A) Anterior view before the vacuum bell was applied. (B) Lateral view before the vacuum bell was applied. (C) Anterior view at 1 year after treatment. (D) Lateral view after 1 year of treatment. (E) Anteroposterior chest X-ray view obtained before starting therapy. (F) Lateral view before starting therapy. (G) Anteroposterior view after 1 year of treatment. (H) Lateral view after 1 year of treatment.

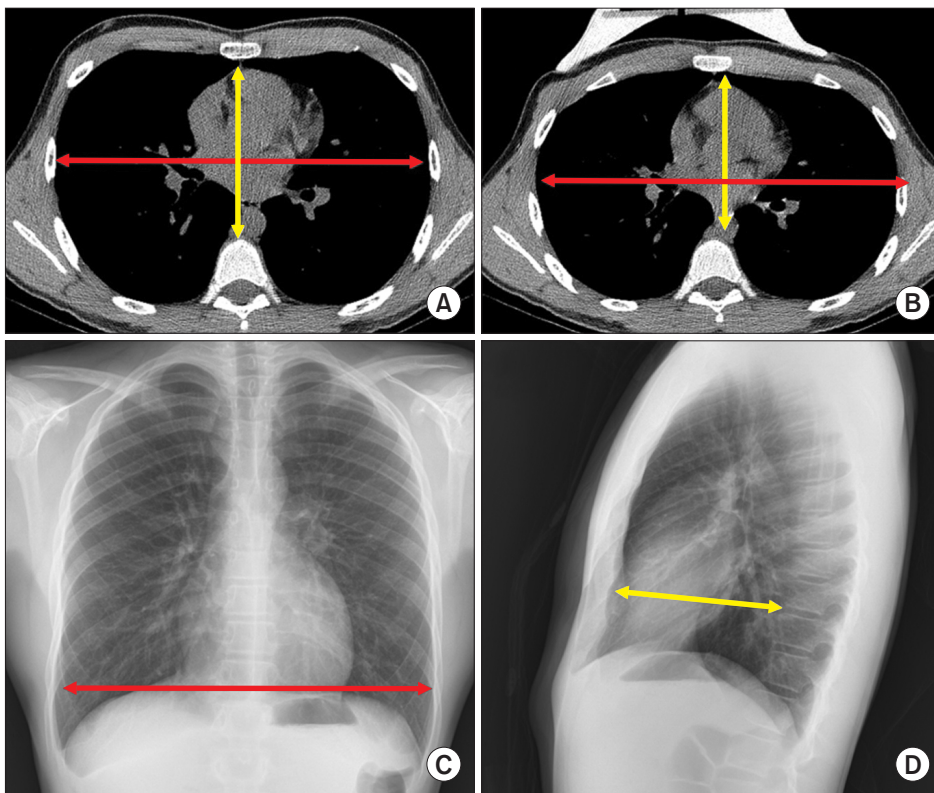


Fig. 2. Evaluation and validation of chest wall pliability by calculating the Haller index (HI) from chest computed tomography (CT) scans. (A, B) The HI was calculated by dividing the greatest transverse diameter of the internal rib cage (red arrow) by the anteroposterior diameter from the sternum to the anterior facet of the vertebra at the deepest point of the deformity (yellow arrow). (A) Axial chest CT without application of a vacuum bell. (B) The HI obtained from a chest CT scan while the vacuum bell device was applied. A decrease in the HI indicates improvement of pectus excavatum. The greater the difference, the greater the pliability of the bony thorax and better treatment result can be expected with vacuum bell therapy. (C, D) Calculation of the HI using plain chest X-rays. The HI can be calculated by dividing (C) the greatest transverse diameter (red arrow) from the posteroanterior view and by (D) the narrowest anteroposterior diameter (yellow arrow) from the lateral view.

mon symptoms were palpitations in group 1 (n=3, 9.1%) and dizziness in group 2 (n=2, 8.3%) (Table 1).

Comparison of treatment responses

The pre-treatment HIs calculated from chest CT and

chest X-rays were significantly higher in group 2 than they were in group 1 (p=0.043 and p=0.036, respectively). The HIs obtained from chest CTs performed immediately after treatment did not show significant differences between the 2 groups (group 1, HI=3.06±0.67; group 2, HI=3.07±0.46; p=0.954). The HI determined at 1-year post-treatment was

Table 1. Patient characteristics

Characteristic	Group 1 (n=33)	Group 2 (n=24)	Total (n=57)	p-value
Age (yr)	16.48±8.21	16.13±3.95	16.3±6.7	0.843
Sex				0.405
Male	31 (93.9)	21 (87.5)	52 (91.23)	
Female	2 (6.1)	3 (12.5)	5 (8.77)	
Body mass index (kg/m ²)	18.61±2.57	18.58±2.16	18.6±2.39	0.961
Family history				0.746
No	31 (53.9)	22 (91.7)	53 (92.98)	
Yes	2 (6.1)	2 (8.3)	4 (7.02)	
Smoking history				0.685
None	28 (84.8)	18 (75.0)	46 (80.70)	
Ex-smokers	2 (6.1)	0	2 (3.51)	
Current	3 (9.1)	6 (25.0)	9 (15.79)	
Comorbidity				NA
Yes	0	0	0	
No	33 (100.0)	24 (100.0)	57 (100.0)	
Onset period				0.718
Childhood	10 (30.3)	9 (37.47)	17 (33.33)	
Preadolescent	21 (39.4)	11 (45.83)	24 (42.11)	
Adolescent	10 (30.3)	4 (16.67)	14 (24.56)	
Electrocardiography findings				0.822
Normal sinus rhythm	30 (90.9)	20 (83.33)	50 (87.72)	
Sinus bradycardia	3 (9.1)	3 (12.5)	6 (10.53)	
Incomplete right bundle branch block	0	1 (4.17)	1 (1.75)	
Symptoms				NA
Chest discomfort	1 (3.0)	1 (4.1)	2 (3.51)	
Palpitations	3 (9.1)	1 (4.1)	4 (7.02)	
Dyspnea	0	0	0	
Dizziness	0	2 (8.3)	2 (3.51)	
None	30 (87.9)	16 (83.50)	45 (85.96)	

Values are presented as mean±standard deviation or number (%). Group 1, vacuum bell therapy; group 2, minimally invasive surgical repair of pectus excavatum (Nuss operation).

NA, not available.

obtained from plain chest X-rays for both groups and did not show statistical significance (group 1, HI=3.01±0.62; group 2, HI=2.88±0.78; p=0.473).

Although the post-treatment HI between the 2 groups did not show statistical significance (p=0.954 and p=0.473 for immediate post-treatment and 1-year post-treatment, respectively), the degree of HI improvement in group 2 was significantly greater than that observed in group 1. The average amount of improvement in the HI immediately after commencement of treatment for both groups was 0.55±0.47 in group 1 and 1.18±0.85 in group 2 (p=0.03); at 1-year post-treatment, the HI values were 0.58±0.49 and 1.31±0.56, respectively (p<0.01). The average lift in the sternum depression in group 1 was 9.62±4.89 mm immediately after treatment and 13.02±8.53 mm 1 year later. This lift was much greater in group 2, which showed respective average sternal lift values of 16.02±9.46 mm and 28.75±14.9 mm.

Post-treatment complications were reported in 11 pa-

tients. Patients who received VBT showed skin erosion (n=2, 6.06%), while pleural effusion in the surgical group was the most common complication (n=3, 5.26%) (Table 2). However, all complications resolved spontaneously.

Discussion

PE is the most common chest wall deformity, with a prevalence of approximately 0.1 and 0.8 per 100 persons [1]. PE does not always have detrimental effects on internal organ function, but some patients experience complications including dyspnea, palpitations, and angina. Aside from functional issues, psychological stress due to the abnormal external physiology is the main complaint that leads patients to seek PE correction as the deformity develops and becomes more prominent during the earlier period of life [2]. Until recently, surgical correction was the only treatment option available for PE. The Ravitch procedure is an

Table 2. Comparison of treatment effects and complications

Variable	Group 1 (n=33)	Group 2 (n=24)	Total (n=57)	p-value
Haller index				
Pre-treatment				
Chest CT	3.6±1.10 (2.1–6.7)	4.24±1.2 (2.9–8.5)	3.88±1.17 (2.1–8.5)	0.043
CXR	3.6±0.98 (2.2–8.3)	4.19±1.1 (3.0–8.3)	3.84±1.07 (2.2–8.3)	0.036
Post-treatment				
Immediate (CT)	3.06±0.67 (2.4–5.2)	3.07±0.46 (2.6–6.8)	3.06±0.59 (2.4–6.8)	0.954
After 1 yr (CXR)	3.01±0.62 (2.2–8.3)	2.88±0.78 (2.1–5.2)	2.96±0.69 (2.1–8.3)	0.473
Changes in Haller index				
Immediate (CT)	0.55±0.47 (0.02–1.53)	1.18±0.85 (0.92–1.11)	0.82±0.72 (0.02–1.53)	0.03
After 1 yr (CXR)	0.58±0.49 (0.25–2.08)	1.31±0.56 (0.95–1.82)	0.88±0.76 (0.25–2.08)	<0.01
Changes in AP diameter (mm)				
Chest CT	9.62±4.89 (1.2–21.7)	16.02±9.46 (1.3–30.2)	12.31±7.78 (1.2–30.2)	0.05
CXR	13.02±8.53 (2.4–28.2)	28.75±14.9 (5.4–36.2)	19.65±13.94 (2.4–36.2)	<0.01
Complications				
				NA
Chest tightness	1 (3.0)	NA	1 (3.0)	
Skin erosion	2 (6.06)	NA	2 (3.51)	
Skin erythema	1 (3.0)	NA	1 (1.75)	
Pleural effusion	NA	3 (12.5)	3 (5.26)	
Pneumothorax	NA	2 (8.33)	2 (3.51)	
Wound infection	NA	1 (4.17)	1 (1.75)	
Bar dislocation	NA	1 (4.17)	1 (1.75)	

Values are presented as mean±standard deviation (range) or number (%). Group 1, vacuum bell therapy; group 2, minimally invasive surgical repair of pectus excavatum (Nuss operation).

CT, computed tomography; CXR, chest X-ray; AP, anteroposterior; NA, not available.

open sternal correction technique performed using wedge osteotomy and was once the standard of care. However, since the introduction of MIRPE by Nuss et al. [3] in 1998, this minimally invasive surgical procedure has gained wide popularity and has been adopted in many centers around the world; it is now considered the gold standard for PE correction [1,3,4]. MIRPE is a very successful surgical technique, but can have complications such as pneumothorax, pleural effusion, bar dislocation, and damage to internal organs such as the heart [5,6]. Cardiac perforation is the most critical complication while performing MIRPE since the surgeon must tunnel underneath the sternum by blunt dissection; in some patients, the underbed of the sternum can lie only a few millimeters apart from the anterior aspect of the heart. To minimize the risk of critical complications, the application of a vacuum device during the Nuss procedure to elevate the sternum while performing substernal tunneling was proposed by Schier et al. [7]. Shortly thereafter, the application of VBT as an alternative, non-invasive method for correcting PE was proposed and has been extensively performed by Haecker et al. [8-10]. However, the precise indications for VBT and the most appropriate assessment method for choosing proper candidates for this procedure continue to be debated. A previous

study proposed variables that predict a better outcome of VBT, which include younger age (age <11 years), symmetric deformities, and chest wall depth <1.5 cm [11].

Our institution was the first center in South Korea to incorporate VBT for PE and has done so for many years. We offer both MIRPE and VBT to PE patients; candidates for each treatment are chosen after a thorough pre-treatment evaluation. However, patients' desire for non-invasive correction of PE cannot be disregarded. Therefore, despite the evidence regarding which procedure offers better treatment outcomes, one of the most important factors in the consideration of VBT is patient choice.

Our study included 2 groups of PE patients. Group 1 comprised patients who had been undergoing VBT for more than 1 year with good treatment compliance, while group 2 included patients who had previously undergone MIRPE and were at least 1-year post-Nuss bar removal.

The baseline characteristics of the patients in the 2 groups showed no statistically significant differences. However, the average pre-treatment HI was significantly different between the 2 groups. The average HI of the MIRPE patients was greater, which indicates severe initial sternal deformities. This discrepancy arises from the fact that our institution recommended surgical correction as

the primary treatment of choice to those with severe PE. Although the average HI after commencing treatment showed no significant differences, the amount of HI improvement after 1 year was much greater in group 2, signifying that surgical correction produced a better treatment effect, as shown by the degree of sternal elevation (group 1, 13.02 ± 8.52 mm; group 2, 28.75 ± 14.9 mm; $p < 0.01$). These results affirm that MIRPE has a larger treatment effect than VBT, and clinicians should consider surgical correction for those with more severe sternal depressions while carefully selecting candidates for VBT and considering switching to MIRPE if the treatment effect is insufficient.

Only 4 patients (12.06%) in the VBT group reported minor skin complications, while 7 patients (29.17%) in the MIRPE group experienced various surgical complications. Although none of these complications required invasive treatment, a single case of Nuss bar dislocation was discovered during routine follow-up. However, the sternal lift remained stationary, and the patient would soon have the bar removed. Therefore, no immediate intervention was performed, and the patient underwent a successful bar removal operation.

MIRPE is a successful and relatively safe surgical intervention for PE. After accounting for all study parameters, we determined that surgical correction using a Nuss bar is a superior and relatively safe treatment of choice for PE correction from the standpoint of the degree of sternal correction. However, there is always the possibility of severe complications, such as cardiac perforation. These rare but critical complications could raise uncertainty among patients about whether to choose surgical correction or non-invasive therapy for PE. Our study showed that over 85% of patients did not experience any cardiac or respiratory symptoms before PE treatment. Most patients visited our department for cosmetic issues associated with sternal depression; therefore, the recommendation for surgical intervention is not typically accepted by these patients at the initial counseling session. Many patients request an alternative, non-invasive method to correct PE, and VBT is the only modality currently available. As mentioned earlier, PE correction is mainly performed for cosmetic issues. While the degree of HI improvement was greater in the MIRPE group, the post-treatment HI in both groups did not differ significantly. This might mean that from a cosmetic standpoint, VBT could deliver comparably satisfactory results to those of MIRPE in certain PE patients. Nevertheless, the results for all our study parameters once again proved that MIRPE remains an excellent treatment of choice with outstanding treatment outcomes.

Our study had some limitations. First and most importantly, the choice to undergo VBT was strongly influenced by patients' preferences. Therefore, an appropriate selection process for VBT candidates was not achievable. As a result, a number of patients demonstrated an inadequate treatment effect after undergoing VBT for 1 year and had to switch their treatment modality to MIRPE. Second, although VBT proved to be an applicable treatment method, its effect is strongly dependent on patient and caregiver compliance. Most patients are underage, so their caregivers' dedication and attention to VBT application is critical for achieving a satisfactory result. Lastly, VBT cannot be applied to patients with severe chest wall asymmetry. The vacuum bell must be well placed on the patient's chest wall and must be airtight. Any asymmetry of the bony thorax hinders the sealing of the vacuum bell and compromises its treatment effects. Therefore, a physical examination and careful candidate selection must be performed before initiating VBT.

In conclusion, MIRPE is an effective treatment of choice for patients with a severe chest wall deformity. However, VBT showed comparable outcomes and could serve as an alternative treatment modality for select patients who prefer non-invasive PE treatment.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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