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The Vacuum Bell device as a sternal lifter: An immediate effect even with a short time use

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ABSTRACT

Background: To minimize cardiac perforation during the minimally invasive repair of pectus excavatum (MIRPE), several surgeons have suggested using a suction device to intraoperatively lift the sternum. Whether or not this technique is effective for all PE patients is not yet known. As such, our aim was to quantify the extent to which a suction device is capable of lifting the sternum with a short duration of use.
Methods: 30 PE patients received a low-dose CT scan as part of standard PE evaluation. A Vacuum Bell suction was then applied for only two minutes, and a repeat CT scan was obtained only at the deepest point of the chest wall deformity. We compared chest dimensions before and after Vacuum Bell suction.
Results: The Vacuum Bell lifted the sternum in all 29 patients included in the analysis. The absolute change in depth ranged from 0.29 to 23.67 mm (M = 11.02, SD = 6.05). The average improvement in Haller index was 0.76. The suction was most effective for individuals with low BMI and smaller chest depths. Efficacy was not associated with gender, age, or chest morphology.
Conclusions: The Vacuum Bell device effectively lifted the sternum in PE patients with different demographics and chest morphologies. Future research is needed to address whether or not the device reduces risk of cardiac perforation during MIRPE.
Levels of evidence: Prognosis Study Level IV.

Pectus excavatum (PE) is the most common chest wall deformity, occurring in approximately 1 in 300 live births. Although many patients remain asymptomatic, others experience cardiopulmonary (e.g., dyspnea, palpitations, chest pain) or psychosocial symptoms (e.g., body image concerns). For a variety of reasons, patients with PE may seek treatment [1,2].

Until recently, surgery was the only available treatment. Standard surgical techniques include the open Ravitch procedure or the Nuss procedure, which is also referred to as the minimally invasive repair of PE (MIRPE) [3,4]. While considered minimally invasive, MIRPE is certainly not free from complications, and in a few patients, cardiac perforation has been described [5,6].

Despite the fact that the idea of using a vacuum for PE treatment was first contemplated more than a century ago, only recently has a negative pressure device become available for use. The Vacuum Bell (Eckart Klobe, Mannheim, Germany) is a suction cup that creates a vacuum on the anterior chest wall and is activated by a patient-controlled hand pump. Four different sizes and a model fitted for women are available, allowing selection according to an individual patient's age and size (Fig. 1). Complications and side effects can include subcutaneous hematoma, petechial bleeding, dorsalgia, and transient paresthesia of the upper extremities [7].

The vacuum device has at least four proposed applications. First, it may allow some patients with PE to avoid surgery [7]. Second, the suction device may be useful in preparation for surgery. Third, the device may be helpful if a surgical implantable bar has to be removed earlier than scheduled. Finally, it has been used intraoperatively as the vacuum device is externally applied for a short duration to lift the sternum away from the heart during MIRPE to provide more working space for safely guiding the bar(s) across the mediastinum under thoracoscopic visualization [8,9].

Although assumed to be effective when used as the only treatment in patients with PE [10], there is no measurement of its efficacy in lifting the sternum during surgery [8,9,11]. As such, we wanted to assess the efficacy of a vacuum device as a tool for temporarily lifting the sternum in a research setting that includes patients of different ages and types of PE. The primary aim of this study is to characterize changes in sternum position before and after a brief application of the vacuum device.

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Fig. 1. The four Vacuum Bell's oval sizes for men and the model fitted for woman.

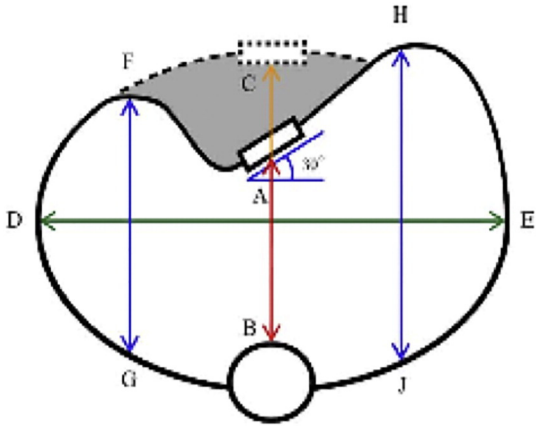

Fig. 2. Thorax scheme with indications of the measures taken from thoracic CT scan made before and after the use of the negative pressure: a) sagittal distance between the posterior aspect of the sternum (A) and the anterior spine (B); b) laterolateral distance (D–E); c) sagittal distance of right (F–G) and left (H–J) hemithorax; d) sternum angle rotation; e) sagittal distance between posterior sternum (C) in its hypothetical corrected position and the anterior spine (B) minus the distance between the posterior sternum in real position (a) and anterior spine (B).

1. Material and methods

Between February and May 2013, 30 patients who had PE were evaluated to determine whether they could be included in a funded trial designed to evaluate the degree to which the Vacuum Bell lifts the sternum. The inclusion criteria for the study were patients with PE ages 8 to 35 years old. Exclusion criteria were complex mixed carinatum/excavatum cases, comorbidities including skeletal diseases, coagulation dysfunction, cutaneous diseases in the thoracic wall, angiopathies, pregnancy, and obesity with Body Mass Index (BMI) > 30. The study was conducted in the Thoracic Surgery Departments of the Heart Institute (InCor) from the Clinics Hospital at the University of São Paulo Medical School, Brazil, where all patients were treated. Patients gave written informed consent, and the study was approved by the Research Ethics Committee of the institution (CAPPesq no. 0171/11, ClinicalTrials NCT01816373).

Criteria for patient selection in the study were the same as we use for evaluation of PE candidates for operative correction. The evaluation includes history, physical examination, and chest wall deformity morphology classification into saucer or cup subtypes [12]. Laboratory tests as part of the PE operative evaluation protocol include pulmonary function tests, chest radiographs, cardiac evaluation with electrocardiogram and echocardiography, and a baseline low-dose thoracic CT scan with measurement of the Haller Index (HI), as originally described [13].

During the first consultation, the appropriate sized cup suction is chosen and it is determined if the patient can tolerate a negative pressure to a maximum of 300 mbar. As part of the protocol, the HI is then measured with a low-dose CT scan to evaluate the patient's HI. During this CT examination, we tested the capacity of the Vacuum Bell to apply traction on the anterior chest wall. Before the baseline CT scan was performed, on each patient, the deepest point of the PE was marked with a radiopaque mark and the Vacuum Bell was positioned over the chest wall defect at that site. The patients were instructed not to take a deep inspiration and the CT scan was done with the patient in respiratory pause.

After the initial scan, the negative pressure in the Vacuum Bell was activated to minus 160 mmHg, corresponding to around 21% below atmospheric pressure, for about two to three minutes, and CT images were then obtained only at the level of the deepest point of the chest wall, again with the patients in respiratory pause when in quiet inspiration. Several different measurements were made (Fig. 2).

With the various measurements both before and after use of the vacuum device, it was possible to calculate the HI, correction index, degree of sternal torsion, and asymmetry index in which asymmetry to the right or left side was evaluated. Data were captured using Research Electronic Data Capture (REDCap) [14]. We examined the changes between baseline and post-Vacuum Bell measurements along with standard deviations (M ± SD). Correlations were used to describe relationships between two continuous variables. When comparing distributions across binary variables such as gender and symmetry, a t-test was used. Alpha level was set to 0.05. All analyses were done using the statistical software R 3.2 for Mac (www.r-project.org).

2. Results

All patients reported some degree of discomfort in the chest owing to the negative pressure that was applied, but none reported pain that prevented completion of the exam. Most of the patients developed local hyperemia and eight patients developed petechia in the region where the vacuum was applied, but this disappeared within a few hours. There was no permanent skin discoloration or discomfort. There were no reports of transient paresthesia of the upper extremities during the application. Also, the sternum recoiled to its original position once the suction was discontinued.

2.1. Basic patient information

There were 26 males and 3 females. Also, subject #10 was excluded from analysis because his measured distance between the sternum and the vertebral column was larger during baseline than in the CT scan made with the vacuum applied, resulting in a worsened Haller index after chest suction. As such, analysis was completed on 29 patients with ages ranging between 11 and 35 (M = 17.62, SD = 6.11).

2.2. Sternal elevation

The characteristics of the patients who were evaluated for trial inclusion and individual values for chest depth, width, and HI are shown in Table 1. Initial HI values ranged from 2.38 to 10.96 (M = 4.38, SD = 1.75) and HI values after Vacuum Bell use ranged from 1.48 to 10.22 (M = 3.63, SD = 1.51). Improvements in Haller index are shown in Table 2. The individual absolute difference in HI ranged from 0.07 to 2.67 (M = 0.76, SD = 0.52) and percent difference in HI ranged from 2.10% to 40.80% (M = 17.06%, SD = 9.19%). For all patients included in the analysis, HI improved (decreased) with short-term Vacuum Bell use. This is further demonstrated by a paired-samples t-test, $t(28) = 7.86$, $p < 0.001$.

To better understand how these HI values correlate to other chest wall measurements, pre- and post-Vacuum Bell chest widths and depths were examined. Prior to the vacuum, the initial minimum distances between the sternum and vertebral column ranged from

Table 1
Patient demographics, chest morphology, and chest measurements.

Patient	Gender	Age	BMI	Chest wall symmetry	Chest wall subtype	Initial Depth	Initial Width	Initial HI	Final Depth	Final Width	Final HI
1	Male	12	18.26	Symmetric	Cup	97.52	232.12	2.38	102.68	226.67	2.21
2	Male	33	26.60	Symmetric	Cup	50.25	280.34	5.58	58.36	278.75	4.78
3	Male	16	18.95	Asymmetric	Cup	70.38	214.12	3.04	78.87	215.62	2.73
4	Male	15	21.21	Symmetric	Cup	39.29	254.88	6.49	50.69	259.23	5.11
5	Female	11	17.36	Symmetric	Cup	57.22	213.71	3.73	75.72	206.89	2.73
6	Female	12	19.83	Symmetric	Saucer	41.53	204.90	4.93	59.42	210.23	3.54
7	Male	16	16.96	Symmetric	Cup	70.98	252.25	3.55	87.91	241.17	2.74
8	Male	15	19.17	Asymmetric	Saucer	52.77	246.36	4.67	62.27	250.01	4.01
9	Male	11	16.80	Symmetric	Cup	61.24	219.11	3.58	81.08	221.50	2.73
10	Male	21	19.37	Symmetric	Saucer	57.54	269.50	4.68	55.70	270.59	4.86
11	Male	22	25.38	Symmetric	Cup	96.42	241.35	2.50	96.71	143.36	1.48
12	Male	15	23.83	Asymmetric	Cup	51.73	229.52	4.44	59.46	230.01	3.87
13	Male	24	19.28	Symmetric	Saucer	70.07	236.14	3.37	78.51	238.87	3.04
14	Male	35	23.20	Symmetric	Cup	72.49	279.42	3.85	79.72	280.09	3.51
15	Male	26	23.63	Symmetric	Saucer	79.96	267.02	3.34	81.71	267.03	3.27
16	Male	16	20.52	Symmetric	Saucer	51.70	242.10	4.68	66.68	247.45	3.71
17	Male	16	18.81	Symmetric	Saucer	49.78	246.80	4.96	57.51	247.56	4.30
18	Male	21	19.25	Symmetric	Cup	63.35	250.17	3.95	76.53	251.99	3.29
19	Female	18	17.24	Symmetric	Saucer	20.91	229.22	10.96	22.61	230.97	10.22
20	Male	15	18.38	Symmetric	Cup	54.82	256.75	4.68	78.49	259.39	3.30
21	Male	12	18.44	Asymmetric	Saucer	83.70	245.83	2.94	95.58	240.64	2.52
22	Male	20	22.66	Symmetric	Saucer	66.08	269.79	4.08	74.78	269.75	3.61
23	Male	20	17.88	Asymmetric	cup	33.77	254.54	7.54	54.36	264.57	4.87
24	Male	23	23.51	Symmetric	Cup	73.23	274.00	3.74	81.80	273.93	3.35
25	Male	14	16.23	Asymmetric	Cup	75.11	241.07	3.21	80.34	237.95	2.96
26	Male	11	20.32	Symmetric	Cup	71.61	239.01	3.34	76.90	235.85	3.07
27	Male	14	16.36	Symmetric	Saucer	53.51	225.55	4.22	72.52	226.82	3.13
28	Male	12	17.13	Asymmetric	Cup	59.38	244.84	4.12	72.99	248.79	3.41
29	Male	17	14.96	Symmetric	Saucer	44.52	257.71	5.79	55.43	258.48	4.66
30	Male	19	21.60	Symmetric	Saucer	68.24	245.91	3.60	81.68	250.62	3.07

Depth and width values are represented in millimeters; Haller index does not have units.

20.91 mm to 97.52 mm (M = 61.43, SD = 17.39). After Vacuum Bell use, this depth ranged from 22.61 mm to 102.68 mm (M = 72.46, SD = 16.22). The absolute change in depth ranged from 0.29 mm to 23.67 mm (M = 11.02, SD = 6.05). Percent change in depth ranged from 0.30% to 60.97% (M = 20.18, SD = 13.8).

The differences in the efficacy of short-term Vacuum Bell use across variables such as age, gender, BMI, initial depth, initial HI, pectus symmetry, and pectus subtype were also examined. Table 2 includes the most relevant statistical measures. Vacuum Bell efficacy was assessed by examining absolute change in depth, percent change in depth, absolute change in HI, and percent change in HI. There was no effect of age on the device efficacy. It was found that higher BMIs were associated with decreased efficacy in terms of increased chest depth by absolute difference, $r(27) = -0.45$, $p < 0.05$, and by percent change, $r(27) = -0.39$, $p < 0.05$. However, BMI had no relationship with efficacy from an HI standpoint. By correlation, percent change in depth, but not absolute change in depth, was higher for individuals starting with lower depth measurements, $r(27) = -0.59$, $p < 0.001$, compared to $r(27) = -2.0$, $p = 0.054$. Interestingly, by correlation, absolute change in HI, but not percent change in HI, was also higher for individuals starting with lower depth measurements, $r(27) = 0.51$, $p < 0.05$, compared to $r(27) = 0.07$, $p = 0.70$. Based on absolute change in depth, percent change in depth, absolute change in HI, and percent change in HI, there was no effect of gender ($p = 0.77$, $p = 0.50$, $p = 0.23$, $p = 0.63$, respectively), symmetry ($p = 0.99$, $p = 0.83$, $p = 0.88$, $p = 0.73$, respectively), or pectus subtype ($p = 0.69$, $p = 0.84$, $p = 0.61$, $p = 0.31$, respectively) on Vacuum Bell efficacy.

3. Discussion

It is important to search for maneuvers that help decrease the risk of cardiac damage during the retrosternal tunnel creation in MIRPE. In this

Table 2
Improvements in depth and HI associated with patient age, BMI, initial depth, initial HI, gender, symmetry and chest morphology subtype.

	Absolute Change in Depth	Percent Change in Depth	Absolute Change in HI	Percent Change in HI
Age	$r(27) = -0.36$, $p = 0.06$	$r(27) = -0.29$, $p = 0.13$	$r(27) = -0.13$, $p = 0.51$	$r(27) = -0.21$, $p = 0.27$
BMI	$r(27) = -0.45$, $p < 0.05$ *	$r(27) = -0.39$, $p < 0.05$ *	$r(27) = -0.21$, $p = 0.27$	$r(27) = -0.12$, $p = 0.54$
Initial Depth	$r(27) = -0.36$, $p = 0.054$	$r(27) = -0.59$, $p < 0.001$ **	$r(27) = -0.61$, $p < 0.001$ ***	$r(27) = -0.20$, $p = 0.29$
Initial HI	$r(27) = 0.05$, $p = 0.80$	$r(27) = 0.33$, $p = 0.08$	$r(27) = 0.51$, $p < 0.05$ *	$r(27) = 0.07$, $p = 0.70$
Gender	$t(2.2) = -0.33$, $p = 0.77$	$t(2.3) = -0.80$, $p = 0.50$	$t(3.4) = -1.5$, $p = 0.23$	$t(2.3) = -0.55$, $p = 0.63$
Symmetry	$t(12.9) = 0.12$, $p = 0.99$	$t(7.9) = -0.22$, $p = 0.83$	$t(6.9) = -0.15$, $p = 0.88$	$t(10.4) = 0.36$, $p = 0.73$
Subtype	$t(26.2) = 0.40$, $p = 0.69$	$t(26.8) = 0.20$, $p = 0.84$	$t(26.7) = 0.51$, $p = 0.61$	$t(26.9) = 1.0$, $p = 0.31$

Statistics for improvement in depth and HI associated with age, BMI, initial depth, and initial HI are expressed as correlations. Statistics for improvement in depth and HI associated with gender, symmetry, and subtype are expressed as unpaired t-tests. Significance values: * indicates $p < 0.05$, ** indicates $p < 0.01$, *** indicates $p < 0.001$.

study, we have attempted to quantify the effectiveness of utilizing temporary chest suction to lift the depressed sternum. We have demonstrated that the Vacuum Bell device improved HI across different chest morphologies and patient characteristics, even with a short application of 2–3 min. Our results suggest that temporary intraoperative use of the Vacuum Bell may be effective in lifting the sternum, although corroboration of our findings will be necessary in the intraoperative setting.

To date, MIRPE has resulted in at least 16 cases of cardiac injuries leading to death in two patients and severe brain injury in one patient [15]. It would not be unreasonable to assume that the real number of cardiac injuries is larger, given that this complication may be underreported [16].

There are two reasons – one technical and the other epidemiological – that, when combined, may explain why creating the substernal tunnel is potentially dangerous. From a technical standpoint, the pectus introducer used in the original technique was a 56.8 cm long metallic instrument that in less skilled hands acted as a dangerous lever. Epidemiologically, PE is not very prevalent and general thoracic surgeons usually do not perform the surgery. As a result, becoming skilled with the pectus introducer tool is difficult.

Aside from the use of intraoperative suction, several different techniques have been described to help avoid this complication. These strategies include more dorsal incisions for tunnel creation, more cranial dissection of the retrosternal tunnel, pectus tunneloscopy, and the use of regular or dedicated sternal lifters. However, most of these techniques are based on individualized devices that are usually available only to the developer of the device [17–23]. One technique that does not require special instruments and can be widely utilized is a small subxyphoid incision, allowing insertion of the surgeon's finger into the substernal space to help guide the bar across the mediastinum. This technique can be used by all surgeons and does not rely on a special instrument. A recent report described its use in 554 patients [24].

Of the 30 patients that were part of this study, we excluded one patient from analysis because the distance between the sternum and the vertebral column was larger during baseline than when the vacuum was applied. Although asked to not follow the automatic voice command from the CT scanner, this patient inadvertently inspired during the CT scan. In this case, his deep inspiration moved the sternum more than the negative pressure applied by the vacuum. Interestingly, even in the original paper in which Haller reported his pectus index, a specific protocol has not been described in terms of depth of respiration during the CT scan [12].

It is important to note that the HI, which is the most common parameter used for defining the severity of chest wall defects, is likely being measured without systematization in most places. Nonetheless, in this study, we standardized the protocol to obtain the measurements from the CT scans. Since we could not find specific guidelines, we instructed our patients to remain in respiratory pause while in quiet inspiration during CT acquisition.

Our results have confirmed that, with just 2–3 min of negative pressure applied to the anterior thoracic chest wall, the sternum was pulled forward in all our study patients independent of age, gender, chest symmetry, and pectus subtype. By examining changes during suction, we found that individuals with lower BMI and with a smaller chest depth tend to have more sternal lift with the vacuum. By examining changes in HI before and after vacuum use, it was found that a smaller initial excavation depth or higher initial HI is associated with better short-term Vacuum Bell efficacy.

In other words, if short-term Vacuum Bell efficacy is defined by an improvement in the distance between the sternum and vertebral column, then greater efficacy is associated with lower BMI. If short-term Vacuum Bell efficacy is defined by decrease in HI, then improved efficacy is associated with a greater distance between the sternum and vertebral column.

Our study has some important limitations. First, it is a pilot study and had a limited number of patients. Second, since PE is not a consistent entity, the different chest wall morphologies have different responses to short-term suction. Third, our criteria included patients from 8 to 35 years old, but this does not encompass all potential PE patients undergoing operative correction. Fourth, although we have shown an increase in the distance between the sternum and vertebral column with the vacuum device, we cannot say with certainty that an increased distance between the heart and sternum also occurs.

Even with these limitations, conclusions may be drawn. The sternum lifted even with only 2–3 min of traction. Importantly, the results were not dependent on age. Results overall confirm that the device may be a valuable intraoperative tool to enhance the safety of MIRPE. Also, if it was used for a few months preoperatively, we hypothesize that sternal elevation might be even more pronounced. However, it must be kept in mind that cardiac injury is still a possibility despite adequate elevation of the sternum. It will be important to continue to evaluate the Vacuum Bell and its use in PE patients.

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Conflict of interest statement

None to declare.

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