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Review

Vacuum Bell: Is It a Useful Innovative Device for Pectus Excavatum Correction?

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Abstract

Pectus Excavatum (PE) or "funnel chest," the most common deformity of the anterior chest wall characterized by sternal depression, can be repaired via either operative or non-invasive techniques. Vacuum Bell (VB) device is the most widespread of the latter one which can be applied either intraoperatively or as monotherapy. The present narrative review examines the efficacy of that innovative method. A thorough search of the literature resulted in 13 English-written articles concerning VB therapy from its first description to February 2019. The studies included patients with mild to moderate PE, mainly evaluated via Haller-Index and/or sternum depth prior to and following treatment. Concerning depth-improvement, 37-90% showed amelioration while 10-40% of them an excellent correction to normal. In 42%, Haller-Index also improved with a median decrease of 0.3 after VB application. A correlation was attempted to be found between the efficacy of VB and factors such as the frequency and duration of VB application, patient age, gender, PE severity and type, and differential pressure of the suction cup. Complications may be frequent yet mild and temporary. Intraoperatively, VB widows Minimally Invasive Repair of Pectus Excavatum (MIRPE) operation a safer procedure with greater results. VB as conservative treatment is an effective and well-tolerated alternative therapeutic option for selected patients with PE who meet specific criteria. It also constitutes a device of significant efficacy, appropriate for intraoperative use during MIRPE procedure.

KEYWORDS: Thoracic wall, chest deformities, pectus excavatum, funnel chest, vacuum bell

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INTRODUCTION

Pectus Excavatum (PE) or "funnel chest" is a deformity of the anterior chest wall characterized by sternal depression, which typically begins at the mid-portion of the manubrium and progresses toward the xiphoid process. It is the most common anterior chest wall disorder (90%), while its incidence ranges between 1 in 400 and 1 in 1000 live births.[1] The ratio between male and female is almost 5 to 1[1,2] and it is more common (95%) in Caucasian people.[3,4] It can be either sporadic, which is the most usual presentation, or it may be associated with connective tissue disorders, neuromuscular disease, and other genetic disorders. Most patients are asymptomatic, although some may appear with cardiopulmonary (dyspnea, palpitations, chest pain)[5] or psychological symptoms.[6] It is noteworthy that PE, as a progressive deformity, may change during growth, especially in puberty. Indeed, PE of mild severity may become severe in less than 6-12 months.[7] Pectus excavatum is classified as symmetric or asymmetric, where the depression may be unilateral, mostly on the right side, and it can present with 3 different types: "cup-shaped" (deep, narrow and with a small diameter), "saucer-type" (broad and shallow), or "Grand-Canyon-type" (deep as a channel).[8-10] Regarding its severity, PE is classified as mild, moderate, or severe. To evaluate the severity of PE, Haller Index (HI) or Pectus Severity Index (PSI) (normal ≤ 2.5), depth of sternum (normal ≤ 0.5 cm), Pectus Correction Index (PCI), and Asymmetry Index (AI) (normal range between -0.05 and $+0.05$),[11] measured with chest radiography or computed tomography, have been widely used. Since the 1950s, patients with Pectus Excavatum have been submitted to surgical correction of the deformity by a technique first described by Ravitch[12] and subsequently by the modified Ravitch procedure. In 1998, in an attempt to avoid the operative disadvantages of this procedure, D. Nuss[13] proposed a minimally invasive repair of PE (MIRPE). This procedure remains an appealing choice for both patients and surgeons because it combines shorter operating time and improved cosmetic results due to smaller incisions. However, advancement and placement of the retrosternal bar during the MIRPE procedure have been associated with serious complications, including haemothorax, pneumothorax, rupture of the diaphragm, injury to internal mammary vessels, and perforation of the heart.[14] The risks of surgical procedures led to the development of less invasive methods for correction of PE, such as Vacuum Bell (VB), a device that can be used either intraoperatively or as monotherapy. In 1992, an engineer named E. Klobe, who had PE, manufactured and applied to himself VB as monotherapy for the elevation of the sternum. It was firstly proposed by Schier et al.,[15] but it is considered to be "off-label," as the device is not manufactured sterile. They described the use of this technique to create negative pressure up to 15% below the atmospheric pressure by application on the anterior chest wall (Figure 1). It is operated via a hand pump by the patient, who learns to place the middle of the device's window above the deepest point of the deformity. There are 3 different sizes of VB approved by the FDA (16, 19, and

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22 cm in diameter, respectively), accordingly to patient's age, ventral surface, and self-perception of the deformity, while a particular model is available for adolescents and adult female patients (Figure 2).[16] There are specific indications and contraindications that render a patient suitable or unfit for Vacuum Bell. According to Haecker,[17] it is indicated in patients with mildly severe PE and/or who do not want to undergo surgical correction. Obermeyer et al.[18] added as candidates for VB application, patients with moderate to severe PE who are too young for surgery. Moreover, VB can be used intraoperatively to facilitate retrosternal space dissection and bar placement during MIRPE procedure.[15] In addition, it can be useful in the removal of the bar and in preparation for surgery of rigid chest walls.[19] Contrarywise, VB is contraindicated in patients suffering from skeletal disorders (e.g., osteogenesis imperfecta, osteoporosis, Glisson's disease), vasculopathies (e.g., Marfan's syndrome, aortic aneurysm or dilated aortic root), coagulopathies (e.g., hemophilia, thrombocytopenia), and cardiac disorders.[14,16-18,20-21] These pathologies can be excluded with the use of a standardized evaluation protocol prior to VB application, according to Haecker et al.[14,16,17,20,21]

MATERIAL AND METHODS

This study presents a narrative review of Vacuum Bell use since its first description until February 2019, when an online search of the literature was performed in PubMed. The search item used is: "((((pectus excavatum) OR pectus excavatum [MeSH Terms])) AND ((nonsurgical treatment) OR vacuum bell)." This search resulted in 23 articles. The inclusion criteria were studies of any design, related only to humans and without any restriction concerning the time of publication. The exclusion criteria were articles written in languages other than English, the full text was not available or belonged to grey literature. Finally, additional articles, which were cited as references in the articles of the initial literature search, were also researched manually (Figure 3). The details and relevant outcomes of these papers are shown in Table 1.

RESULTS

The success of Vacuum Bell procedure as a conservative treatment of Pectus Excavatum has been mainly evaluated via the Haller-Index and/or depth of sternum measurement prior to and following its application. All the studies referred to patients suffering from mild to moderate severity of PE (depth range: 0.9-6.3 cm). Based on depth change, 37-90% of patients showed improvement,[14,17,20,22-24] while in 10-40% of them, an excellent correction, defined as the elevation of the sternum to normal, was accomplished.[14-18,20,24] However, depth-improvement definitions vary between researchers, including elevation of more than 1-1.5 cm in 3 months[14,17,20] and reduction in depth over 67% of the initial.[18] Measuring the HI, St Louis et al.[22] observed improvement in 42% of the patients, with a median decrease of 0.3 (7.7% of the initial) after Vacuum Bell application, while it ranged between 2.9 and 6.1 before the procedure. Within the last 15 years, many questions have arisen regarding the factors that can potentially influence the long-term outcomes of VB therapy. An important factor is the frequency and duration of its application. Most studies propose a minimum use of 30 minutes twice a day, but there is no consensus on the maximum duration of use. The initial approach proposed by Schier et al.[15] suggested a minimum use of 30 minutes up to 5 hours twice per day on a daily basis. Haecker et al. proposed the use of the cup as many hours as the patient could tolerate without observing better results in elevation of the sternum to normal levels (20%[15] versus 10-14.7%[14,17,20]). The last author also noted that the duration and frequency of daily application depend on the patient's individual decision and motivation. In accordance with this, a case series by St. Louis et al.[22] showed significant improvement in deformity-depth in patients who used the device for more than 2 hours per day compared to those who demonstrated less compliance (<2 hours per day, 4-6 days per week). This may serve as an indicator of the patient's motivation.[22] Recommendations for the appropriate time of usage have also been suggested by Lopez et al., who noted that better results could be obtained with optimal use of 4 or more hours per day. However, Obermeyer et al., in their retrospective study, gradually increased the application time from 30 to 120 minutes twice per day and found that reported daily use over 60 minutes per day was not associated with improved outcomes (OR = 5.0, $P = .129$).[18] As far as the duration of treatment is concerned, the first few months are the most decisive regarding deformity correction, but the exact time of discontinuation is yet to be defined. In particular, the depth of the deformity improved by at least 1 cm in the first month[15] and by 1.5 cm in 69–79%[14,20] of patients during the first 3 months. The time needed for satisfactory improvement (residual median sternum depth: 0.9 cm) varies between different studies. According to Lopez et al.,[24] it can be obtained in 6 months, while excellent correction needs just a 5-month therapy for 1/5 of the patients[15] or a 10-month treatment for 1/3 [24] to a whole 18-month time for 10-14.7% of patients,[14,20] which is quite controversial. A recent study[18] found the use of over 12 months as a predictive factor of an excellent outcome (OR = 3.1, $P = .03$). According to Haecker and Sesia[16] experience of 434 patients, in children to pre-adolescents with a mild, symmetric PE (depth < 3 cm) with a flexible chest wall, the duration of treatment is expected to be 12-15 months, whereas in adolescents to adults with a moderate PE (depth > 3 cm) and less flexible chest wall, the duration of treatment is expected to be 24-36 months, with careful and close monitoring. All the authors support that exercise and physiotherapy are significant factors for a successful outcome. The results may also depend on the age of the first application. In two studies, authors observed better results in pediatric patients than adults concerning depth elevation; 37,5% versus 11,7% excellent correction [24] and more successful outcome during the first 6-9 months,

Main Points

- Pectus Excavatum (PE) is the most common deformity of the anterior chest wall
- Vacuum Bell (VB) as conservative treatment is an effective and well-tolerated alternative therapeutic option for selected patients with PE who meet specific criteria
- Vacuum Bell (VB) can be considered as a device of significant efficacy, appropriate for intraoperative use during MIRPE procedure.

Table 1. Characteristics of Included Studies

	Type of Study	No of Patients in Analysis	Age	Gender	Initial Haller Index	Initial Depth
Haecker et al.[14]		133 patients	3-61yo* (16.21)	110 males, 23 females		2-5 cm
Haecker et al.[17]		93 patients	3-61yo (17.8)	77 males, 16 females		2-5 cm
Schier et al. 2005[15]		VB**: 60 patients MIRPE*** and VB: 14 children	6.1-34.9 yo (14.8)	56 males, 4 females in patients with VB only		
Haecker et al. 2016[16]		STUDY 2014: 140 patients	3-61yo (16.05)	112 males, 28 females		1-6.3 cm (2.7 cm)
Obermeyer et al. 2018[18]	Retrospective chart review	115/180 patients	mean: 12.7 ± 3.2 yo	104 males, 11 females		0.6-5 cm (1,77 ± 0,68 cm)
Togoro et al. 2018[19]	Prognosis Study	29 patients	11-35yo.(17.62)	26 males, 3 females	2.38-10.96 (4.38)	2.091 cm 9.752 cm (6.143 cm)
Haecker et al. 2006[20]		34 patients	6-52 yo (17.8)	31 males, 3 females		2.5-5 cm
St Louis et al. 2019[22]	Treatment study; case series with no comparison group	31/40 patients	6-21 yo (14)		2,9-6,1 (3.9)	1,3-3,5 cm (2.3 cm)
Van-Schuppen et al. 2018[23]	Single-case trial	1 patient	13	1 male	3.1	
Lopez et al. 2016[24]	Preliminary qualitative, retrospective treatment study	73/84 patients	18-40 years old (22.8) and 3-17 years old (11.5)	52 males, 21 females	4.5 (3.2-10)	2.3 cm (0.9-4.4 cm)
Sesia et al. 2018[25]	Retrospecctive Diagnostic Study	53/62 patients	6-20 years old (14)	39 males, 14 females		
Haecker et al. 2012[26]		12/50 patients	9-28 years old (14.95)	11 males, 1 female	3.25-7.4 (5.05)	
Elsayed et al. 2015[27]	Case series	9 patients	9-31 years old (16)	7 males, 2 females		

*Years old; **Vacuum Bell; ***Minimally Invasive Repair of Pectus Excavatum.

respectively.[20] Another 2 studies noticed the difference between children and adolescents. More specifically, St. Louis et al.[22] reported significantly greater Haller Index improvement ($P = .01$) in children under 10 years old, while Obermeyer et al.[18] showed that age under 11 years is a predictive factor for an excellent outcome and over 18 for poor results (4/4 patients had correction < 67%). This implies that puberty spurt may constitute a chronicle landmark, after which the efficacy of VB device could be decreased. However, in 2 studies,[22,25] age played no role in depth of sternum elevation. Sesia et al. showed no statistically significant difference between patients of 6-10, 11-15, and 16-20 years old.[25] A year later, St. Louis et al. also suggested that age of treatment onset had no significant association with depth change. Gender has also been investigated as a potential predictor of clinical outcome. Between the 2 genders, all but one of the included studies reported almost the same percentage of sternum depth correction. St. Louis et al.[22] demonstrated that although there was no statistically significant difference between 2 genders in deformity depth elevation, males used to have better results concerning HI correction in univariate analysis ($P = .02$). However, this difference was not evident in a multivariate analysis. Two other factors that may affect the success rate of the application of VB are the initial sternum depth and the type of Pectus Excavatum. Sesia et al.,[25] comparing sternum depth in relation to patients' age, verified a difference between different age groups; patients aged 16-20 years old had deeper sternum depression compared to children aged 6-10 years old ($P = .02$) and to adolescents aged 11-15 years old ($P = .04$). However, no difference was found between patients with either symmetric or asymmetric type of PE.[20,24] Specifically, Obermeyer et al. noticed that symmetric type (OR = 3.3, $P = .075$) and cup-shaped PE (OR=1.8, $P = .339$) are not associated with improved outcomes. Contrariwise, the initial depth of sternum under 1.5 cm (OR = 4.6, $P = .003$) and a flexible chest wall (OR = 14.8, $P = .001$) are predictive of excellent correction. The first report of VB use[15] suggested the application of a

differential pressure inside the suction cup up to 15% of the atmospheric pressure (i.e., 150 mbar). In an attempt to determine whether higher differential pressure is a variable predictive of better results, Obermeyer et al.[18] followed a protocol of gradually increasing differential pressure (applied pressure; stage I: 20- 50 mbar, II: 51-70, III:71-130, IV>131). He showed that higher suction cup pressure (stage III or IV) is not associated with improved outcomes (OR = 0.77, $P = .449$), suggesting that the elevation of the sternum may be enough even with lower levels of pressure. Advocating the above observation, Sesia et al.[25] noticed a positive correlation between age and pressure, supporting that the younger the patient is, the lower the differential negative pressure required to obtain a complete correction. However, when comparing ETPR (the ratio between the sternum elevation and the differential negative pressure) to the patient's age, they found no difference between the 3 different groups (6-10, 11-15, and 16-20 years old). Similarly, Haecker and Sesia,[16] in a pilot study, claimed that proper monitoring of differential pressure, as measured by an electronic device, according to the depth of PE throughout treatment may optimize the results. The important conclusions from this ongoing trial about the correlation between patient's age and the negative pressure required to elevate the sternum is yet to be extracted. Complications of VB treatment may be frequent yet mild and temporary. The most common include discomfort or moderate chest pain in almost every patient[14-17,19,20] petechiae 23.5-29%,[14,17-20,22,24] skin discolouration 9.7%,[15,22] seroma 6.5%[22] and dorsalgia 6.5%-50%.[14-17,20,22] None of these was permanent and all subsided shortly after cup removal, lowering of pressure, or a short pause in treatment. The pain experienced was transient and too mild to be treated with analgesics. Adolescents and older patients are more likely to develop subcutaneous hematomas that disappear within a few hours and rarely transient paresthesia of the upper extremities that disappears when lower pressure is applied, contrary to children under 10 years old, who did not report such complications. Rarely, skin thickening or blistering (1 patient),[18] costal flaring (1 patient),[22] asymmetric PE with carinatum deformity on the left side (1 patient) [22] and rib fractures[14,16,20] have been reported. Very few patients abandoned treatment due to complications; 7 patients because of skin problems, such as discoloration, irritation, and acne,[22,24] and 2 patients due to orthostatic disturbances during the first application.[15]

Intraoperative Use of Vacuum Bell

Schier and Bahr in cooperation with Klobe, were pioneers in the intra-operative use of Vacuum Bell during Nuss procedure (MIRPE), in 2005.[15] They described an innovative technique that achieved an elevation of sternum and ribs within 2 minutes of use, confirmed via intra-operative thoracoscopy, proving to be a safer way of retrosternal space dissection and bar placement.[15] The same technique was applied by Haecker and Sesia[26] from 2005 to 2010 in 50 patients, demonstrating a clear elevation of the sternum, a safer introduction and advancement of the bar, no cardiac or mammary vessels injuries or pericardial damage, and no need for a non–cosmetically accepted midline incision to elevate the sternum. In a case series of 9 patients, Elsayed et al. applied VB for 5 minutes with 60-minute intervals before reapplying negative pressure in order to avoid subcutaneous hematoma, with similar results.[27] The latest study by Togoro et al.[19] has most extensively examined this procedure, measuring Haller–Index and the minimum distance between the sternum and vertebral columns. A difference ($t = 7.86$, $P < .001$) was found in HI absolute value decrease before (median HI = 4.38, SD = 1.75) and after (median = 3.63, SD = 1.51) suction cup application, with a difference, ranged between 2% and 40% (median = 17.06%, SD = 9.19%). The absolute change in depth ranged from 2.9 cm to 2.3 cm (median = 1.1 cm, SD = 6.05 cm), while percent change in depth ranged from 0.3% to 60.97% (median = 20.18%, SD = 13.8%). Despite the increase of minimum distance between sternum and vertebrae, it is not declared whether the distance between heart and sternum had also increased. The efficacy of this method was decreased in patients with higher BMI in terms of increased chest depth by both absolute difference ($r = -0.45$, $P < .05$) and percentage ($r = -0.39$, $P < .05$). By correlation, percent change in depth, but not absolute change, was higher in patients with lower initial depth ($r = -0.59$, $P < .01$). Based on the absolute change in depth, percent change in depth, absolute change in HI, and percent change in HI, there was no effect of gender, symmetry, or pectus subtype on VB efficacy.

DISCUSSION

A patient with PE can be treated either operatively or conservatively. The thoracic or pediatric surgeon should carefully select and propose the most appropriate method, taking into consideration at the same time the patients' needs and worries. Although MIRPE is a well-established and effective treatment, many patients are not willing to undergo surgery due to possible complications, postoperative pain, and risks of imperfect aesthetic results. Vacuum Bell is an effective alternative for selected patients, who meet specific criteria. Appropriate candidates are patients with mild to moderate PE. Small deformity depth and flexible chest wall seem to be factors that improve the outcome; depth under 1.5 cm is a predictive of an excellent outcome. There is no difference in the correction of the chest wall deformity depth in patients with symmetric or asymmetric PE, although asymmetry may still be visible after the end of this procedure. Most researchers agree that younger patients are more likely to benefit from VB treatment. Specifically, the onset of treatment at an age under 11 years old is a predictive of an excellent outcome, while puberty spurt seems to be a landmark after which the efficacy of VB could be decreased. However, there are 2 studies that found no difference between patient's age and sternum elevation, which implies that further research needs to be done. Regarding patients' gender, the evidence available shows that both male and female have similar possibilities to have excellent results. Besides the thorough screening of the patients suitable for conservative treatment, the proper usage of VB is of utmost importance. The suction cup should be applied daily twice per day for at least 30 minutes each time, but there is no consensus on the maximum duration of use. One study suggests the application of the cup for over 2 hours, another one recommends more than 4 hours use for optimal results, while there is one that showed no difference in results with over 1 hour of daily use. Similarly, researchers'

recommendations appear differences in the total duration needed for excellent outcomes, varying from 5 to 18 months, but the first few months seem to be the most decisive in deformity correction. According to Haecker et al.,[14,16,17] who included a satisfactory number of patients in their studies, the duration of treatment is expected to be 12-15 months in children to pre-adolescents with mild to moderate, symmetric PE with a flexible chest wall, whereas in adolescents to adults with moderate PE and a less flexible chest wall is expected to last 24-36 months. A differential pressure inside the suction cup lower than 70 mbar could be as effective as the one which was initially suggested (up to 15% of the atmospheric or 150 mbar), but close monitoring of the pressure according to depth throughout treatment may be needed to achieve optimal results, as shown in an ongoing clinical trial. All in all, VB is an effective and relatively safe treatment method with little and mild complications comparing to surgery that rarely leads to discontinuation of treatment. The general satisfaction of both patients and their parents is good; 31.5% rated the results as excellent, and 58.5% were very satisfied,[24] while 43.6% stated that they were satisfied in another study.[16] However, a non-negligible percentage of patients ranging from 1.37% to 17.86%[14-17,22,24] abandoned the therapy completely or requested surgical treatment after a period of time due to unsatisfactory results or decreased motivation. This illustrates the importance of the careful selection of treatment method according to patients' characteristics and their motivation. Finally, VB can also be used intraoperatively during the Nuss procedure to elevate the sternum leading to safer retrosternal space dissection and bar advancement and placement. As a result, no complications, such as cardiac or mammary vessel injuries or pericardial lesions, occurred, and the cosmetic result is better. This procedure was found to be suboptimal in patients with higher BMI and higher initial depth. Many more steps should be taken to be sterilized, and be approved by FDA in order to be labeled to be used intraoperatively.

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