

15 years clinical application of the vacuum bell for conservative treatment of pectus excavatum

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15 years clinical application of the vacuum bell for conservative treatment of pectus excavatum – lesions we have learned

Author

Frank-Martin Haecker^{1,2,3}

Affiliations

¹Paediatric Surgery, Surgical Clinic, American Hospital Dubai, Dubai, United Arab Emirates

²Department of Paediatric Surgery, Children's Hospital of Eastern Switzerland, St. Gallen, Switzerland

³Faculty of Medicine, University of Basel, Basel, Switzerland

Correspondence

Frank-Martin Haecker, MD

Professor of Paediatric Surgery, Consultant Paediatric Surgery, American Hospital Dubai

P.O. Box 5566

Dubai, United Arab Emirates

Email: fmh@muttenznet.ch

Abstract

Objective: For decades, open surgical repair was the only available method to treat congenital and acquired Pectus excavatum (PE). Donald Nuss described in 1998 a minimally invasive technique for surgical repair of PE (MIRPE), and today MIRPE is performed with increasing frequency worldwide. However, despite its minimally invasive approach, with the widespread use of the MIRPE procedure the character and number of complications have increased. 15-20 years ago, non-surgical measures such as vacuum bell therapy were established as a useful complement to treat PE patients.

Methods: A selective review of the English spoken current literature with focus on vacuum bell therapy was performed, including an analysis of our own studies.

Results: Within the last 5-10 years, an increasing number of studies were identified reporting on conservative treatment of PE using the vacuum bell. There were no randomized and/or prospective studies comparing conservative treatment vs. surgical repair or conservative treatment vs. no specific therapy. Variables predictive of an excellent outcome could be identified. Especially in younger PE patients, conservative treatment is reported with increasing frequency.

Conclusion: Non-operative treatment of PE with the vacuum bell proved to be safe and a potential alternative to surgical repair in carefully selected patients. Patient's age at diagnosis and severity of the PE represent relevant variables to decide which kind of therapy might be successful to correct PE. Especially in PE patients under the age of 10 years, non-surgical treatment seems to represent the first step of specific therapy.

Key words: Pectus excavatum - conservative treatment - vacuum bell

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1. Introduction

Pectus Excavatum (PE) represents the most common congenital chest wall deformity, occurring in approximately 1 in every 300-400 births, and shows a male predominance (approx. 4:1 ratio). General terms share the opinion that PE deformity is “only a cosmetic problem”, PE patients do not suffer from relevant clinical symptoms, and open surgical repair is the only available method to correct the defect. An essential paradigm shift occurred with the introduction of the technique of minimally invasive repair of Pectus excavatum (MIRPE) by D. Nuss in 1998 [1]. The non-surgical technique of applying suction to the ventral chest wall to elevate the sternum was first described in a textbook of Paediatrics in the early 19th century [2], and taken up in the early 20th century by an engineer, using a vacuum bell (VB) made from silicon [3, 4]. The introduction of MIRPE as well as the VB therapy, and an increasing interest and patient’s introspection have changed the view on the treatment of PE within the last 15-20 years. An increasing number of Paediatric PE patients (< 10 years of age) with a mild degree of PE are referred to the outpatient clinic. In many cases of these Paediatric patients, the degree of pectus deformity does not immediately warrant surgery, yet patients may benefit from some type of non-surgical treatment. Adolescent and adult patients who refused operative treatment by previously available procedures due to several reasons, now appear at the outpatient clinic and request to be considered for conservative treatment methods. Furthermore, reports on character and number of possible complications

associated with the MIRPE [5, 6] have made conservative VB therapy a focus of interest of patients, their parents as well as surgeons.

This review summarizes the current English spoken literature focusing on non-surgical repair of PE. A special focus was set on identification of variables predictive of an excellent outcome.

2. Methods

The review of the literature included specific terms such as: “vacuum bell”, “chest wall lifter”, “pectus excavatum” and “funnel chest”. The data bases used were: PubMed, Embase, Scopus and MEDLINE, and the first 10 pages of Google Scholar. The search was restricted to English-language publications and human studies.

3. Results

A total of 25 studies reporting on conservative treatment of PE using the VB could be identified. 8 of these 25 studies described the effectiveness of the VB to elevate the sternum as a method of treatment, but did not analyze a specified patient population. 5 studies with an abstract in English had to be excluded, since the manuscript was in French (2), German (2) and Chinese (1), respectively. Furthermore, two articles summarized relevant, but partial aspects of previous published retrospective studies [7, 8]. The remaining 10 studies are listed in the table [4, 9-17]. There were no randomized and/or prospective studies comparing conservative treatment vs. surgical repair and/or conservative treatment vs. no specific therapy. Two studies

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included a prospective kept data base, but the analysis was retrospective [14, 17].

Summarizing the results of the studies listed in the table, VB therapy as a non-operative treatment of PE proved to be safe and efficient in carefully selected PE patients. Variables predicting a good to excellent outcome include a mild symmetric PE, chest wall depth < 1.5cm, age < 11 years, remaining chest wall flexibility, daily application of the VB more than 2 hours, and VB use over 12 consecutive months.

Figures 1 and 2 show two of these patients before and after treatment.

Complications and side effects include petechiae, local pain and back pain, thickening and/or darkening of the skin, blistering and paresthesia of the upper extremity during application. None of these complications were permanent and severe. With modification of the daily application, or a short pause if needed, cessation of all side effects could be achieved.

Figure 1: 5 year old girl before vacuum bell therapy (figure 1a, depth of PE: 1.7cm) and after 9 months (figure 1b, depth of PE: 0.4cm)

Figure 1a



Figure 1b



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Figure 2: 10 year old boy before vacuum bell therapy with concomitant costal flaring (figure 2a, depth of PE: 1.8cm) and 3 months after cessation of vacuum bell therapy, duration of therapy: 9 months (figure 2b, depth of PE: 0.5cm)

Figure 2a



Figure 2b



4. Discussion

Albeit the deformity is noticeable at birth in the majority of PE patients, most paediatric PE patients present with a mild degree of PE, which is usually stable during childhood. However, what we observe and have to realize is the fact that there is an increase of PE severity in nearby all patients during pubertal growth spurt. Therefore observation until after puberty is mandatory, especially in infants, paediatric and adolescent patients, even if specific

treatment is not necessary in every PE patient. The incidence and the relevance of concomitant cardiopulmonary symptoms in PE patients are still discussed controversially in the literature, and are not topic of this review.

In its first description more than 100 years ago [2], a glass bell was used applying a vacuum to elevate the sternum in a PE patient. Although described a long time ago, the routine use of the VB technique could not be established due to different reasons.

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The technique was taken up in the early 20th century by an engineer, using a VB made from silicon [3, 4]. Pilot studies describing the use of VB therapy in PE patients published more than 10 years ago described promising initial results in a small number of patients [4, 9]. CT-scans showed that the device lifted the sternum and ribs immediately [4]. The effect of the VB was also confirmed using the device for sternal elevation during the MIRPE procedure [18, 19]. The use of the VB led to a clear elevation of the sternum and this was confirmed by thoracoscopy.

Within the last 10 years, an increasing number of studies reported on an increasing number of patients [table], and the first systematic retrospective study summarizing the results of 133 patients was published in 2011 [10]. Albeit the number of included patients increased and many authors followed their own detailed treatment algorithm, no randomized and/or prospective studies comparing conservative treatment vs. surgical repair and/or conservative treatment vs. no specific therapy were performed until today. Furthermore, general accepted guidelines concerning the indication for VB therapy are still missing. However, according to others and our own experience, approximately 80% of PE patients applied for conservative treatment using the VB whereas only 20% underwent surgical repair [7, 14]. Complications and side effects reported in the literature were only moderate and temporary. Therefore it would be useful to have guidelines available. A consensus conference may enable us to determine such guidelines.

The studies listed in the table show heterogeneity in different aspects like patients age, selection criteria, treatment protocol, etc.. However, the results of the most recent studies identified variables predicting a successful outcome. PE patients who presented with symmetric and mild PE, seemed to show a more successful outcome than those with asymmetric and deep PE. Obermeyer et al. reported on an excellent outcome for patients ≤ 11 years, chest wall depth ≤ 1.5 cm, chest wall flexibility, and VB use over 12 consecutive months [16]. Furthermore, St. Louis et al. identified remaining chest wall flexibility and daily application of the VB more than 2 hours as additional relevant factors [17]. Chest wall depth ≤ 2.0 cm, patients' age ≤ 11 cm and patients' motivation as variables predicting successful outcome could be identified in our own cumulative studies [10, 14, 20].

Of course, measurement of the applied negative pressure as mentioned by Obermeyer et al. [16] is helpful. However, at present the measurement device is only available for the outpatient clinic visit, and not for the PE patient during daily VB application at home. Furthermore, long-term outcome including follow-up more than 10 years is still missing.

Concerning the relevance of chest wall flexibility, we could confirm that the applied differential negative pressure required to lift the sternum is lower or higher dependent on patient's age [21, 22]. Furthermore, there was a statistically significant correlation between depth of PE and patient's age. That confirms patients age as a relevant variable for a successful outcome and corroborate the

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recommendation the see PE patients at younger age, early before puberty.

Of course, the VB therapy for conservative treatment of PE has limitations. As already mentioned above, there are no standardized guidelines available concerning the indication when to start with the application. After delivering the device to the patient and instruction of daily application, there is no possibility to monitor the application at home. We have to rely on self-reported use of the VB at home with regard to daily application time and applied pressure. Positioning of the device and intensity of the negative pressure may vary from day to day. Objective assessment of success of VB therapy is still difficult, and also the definition of success may vary according to individuals. Complications and side effects as reported above have to be noticed.

Furthermore, concomitant malformations like asymmetry and/or costal flaring may affect the efficacy of the treatment method. The importance of patients' age, severity of the defect and flexibility of the chest wall were already mentioned.

5. Conclusion

In conclusion, VB therapy seems to be safe and has been established as an additional useful tool in specific treatment of PE patients. Identified variables let us recommend starting the application in children under the age of 10 years, if needed. VB therapy is a complement in the specific treatment of PE patients, applicable to a significant majority of PE patients, and may allow some patients with PE to avoid surgery.

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Table

Author	Year	Number of patients	Age of patients (median; range)	Follow-up
Schier F et al. [4]	2005	60 patients	14.8 years; 6.1-34.9	10 months (2 to 18 months)
Haecker F-M et al. [9]	2006	34 patients	17.8 years; 6-52	10.4 months duration of treatment
Haecker F-M [10]	2011	93 patients*	17.8 years; 3-61	16 months (3 to 60 months)
Haecker F-M [11]	2011	133 patients*	16.21 years; 3-61	16 months (3 to 60 months)
Lopez M et al. [12]	2016	73 patients	Adults/children	13 months (6 to 24 months)
Haecker F-M et al. [13]	2016	300 patients*	16.28 years; 2-61	27.6 months (1 to 73 months)
Haecker F-M et al. [14]	2016	434 patients*	16.2 years; 2-61	27.9 months (1 to 76 months)
Togoro SY et al. [15]	2017	30 patients	8-35 years	n. a.
Obermeyer R et al. [16]	2018	115 patients	12.7 years; 4-23	12 months (4 to 48 months)
St. Louis E et al. [17]	2019	31 patients	14 years; 6-21	18 months (12 to 24 months)

*cumulative study building on previous patients group; n. a: not applicable

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