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Is vacuum bell therapy effective in the correction of pectus excavatum?

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Summary

A best evidence topic in thoracic surgery was written in accordance to a structured protocol. The question addressed was: 'In patients with a pectus excavatum deformity, is vacuum bell therapy (VBT) an effective treatment?' Altogether, 19 papers were found using the reported search of which 7 represented the best evidence to answer the clinical questions. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes and results of these papers are tabulated. Numerous groups have demonstrated the utility of VBT in pectus excavatum; the largest series has followed up patients over 13 years with sternal elevation of >1 cm being demonstrated in 105 patients. Initial age <11, initial chest wall depth <1.5 cm and chest wall flexibility have all been associated with better outcomes. The effects of VBT have been confirmed on computed tomography scanning and intraoperatively to lift the sternum to facilitate retrosternal soft tissue dissection during the Nuss procedure. There was significant heterogeneity in the studies reviewed, in terms of patient age, selection criteria, the VBT protocol, length of follow-up time following completion of VBT and the metrics used to assess success of therapy. VBT is a safe therapy for treating pectus excavatum in a non-surgical conservative manner with few complications reported. However, the success of VBT is largely dependent on patient compliance and motivation. Permanence of correction after completion of VBT needs to be properly assessed through rigorous follow-up, and currently the success of correction, i.e. permanence, remains in the hands of the patient.

Keywords: Pectus excavatum • Vacuum bell therapy • Cup suction therapy • Haller index

INTRODUCTION

A best evidence topic was constructed according to a structured protocol. This is fully described in the ICVTS [1].

THREE-PART QUESTION

In [patients with a pectus excavatum deformity], is [vacuum bell therapy] an [effective] treatment?

CLINICAL SCENARIO

You are a thoracic consultant reviewing a 14-year-old boy with pectus excavatum (PE) in clinic. He is reluctant to take his shirt off in public and has started to withdraw from his normal activities. He is keen to seek treatment, but his parents have reservations about surgical correction. They would like to discuss the possibility of vacuum bell therapy (VBT). You decide to review the literature for non-operative treatment options and to determine whether VBT is an effective treatment option for this young patient.

SEARCH STRATEGY

Medline March 2005 to March 2018. Search strategy employed as follows using PubMed interface: (funnel chest OR pectus excavatum) AND (vacuum bell OR lifter).

SEARCH OUTCOME

A total of 19 papers were identified. Relevant papers were identified, and their references screened. Of these, 7 papers were deemed to provide the best evidence to answer our clinical question. These are presented in Table 1.

Table 1: Best evidence papers

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Haecker and Mayr (2006), Eur J Cardiothorac Surg, Switzerland [2] Retrospective case series analyses (level IV evidence)	34 Patients (31 males, 3 females) Aged 6–52 years (median 17.8 years) Paediatric subgroup (n = 23, age <18 years) Adult (>18 years), n = 11 Mean duration of treatment; 10.4 months (range 1–18) VBT protocol 30 min use twice daily for 4–6 weeks, then several hours/day for 12–15 months	Elevation of sternum Sustained elevation Complications	Sternal lift experienced in 34 patients; elevation lasted longer in adult group (30–60 min) More successful in paediatric subgroup in first 6–9 months Improvement of at least 1.5 cm after 3 months treatment, n = 27 (79%) Sternum lifted to a normal level at 12 months, n = 5 (14.7%) Sternal pain (n = 34), subcutaneous haematoma, recurrent transient paraesthesia in upper limbs (n = 2)	3 Patients with asymmetric PE; sternal depth decreased after 9 months, but asymmetry persisted Preoperative assessment included CT scanning of the thorax, PFT, echocardiography, photo documentation and depth of PE recorded (range of 2.5–5 cm) Follow-up was on a 3–6 monthly basis with photography and clinical examination
Haecker (2011), Pediatr Surg Int, Switzerland [3] Retrospective case series analyses (level IV evidence)	133 Patients (110 males, 23 females) Aged 3–61 years (median 16.21 years) Treated for 1–36 months maximum VBT protocol as above	Elevation of sternum Discontinuation of VBT	>1 cm elevation, n = 105 (79%) after 3 months use Normal level, n = 18 at 18 months 13 Patients stopped after 19.9 months; decreasing motivation (n = 9), poor results (n = 4)	Cumulative study building on patient group from 2006
Haecker and Sesia (2016), Ann Cardiothorac Surg, Switzerland [4] Retrospective case series analyses (level IV evidence)	434 Patients (82 female, 352 male) Aged 2–61 years (median 16.2 years) Subset of 140 patients analysed (112 male, 28 female) Treated for 6–69 months maximum (average 20.5 months)	Sternal elevation Complications	Normal level, n = 61 at 21.8 months Follow-up: 27.6 months Skin irritation (13.6%) Pain during application (12.1%) Haematoma (7.1%)	Cumulative study building on patient group from 2006 to 2011 Daily application time was 107.9 min/day (10–480 min) Subset analysed were consecutive patients who had the most complete documentation thus allowing for a more comprehensive analysis
Lopez *et al.* (2016), J Pediatr Surg, France [5] Retrospective case series analyses (level IV evidence)	84 Patients with typical PE. 11 patients excluded (mixed carinatum/excavatum defect) 73 Patients divided into 2 groups; I: aged >18 (n = 17, mean age 22.8 years), II: aged <18 (n = 56, mean age 11.5 years) Mean HI [performed using CT in 29 cases (more severe PE)]: 4.5 (3.2–10) VBT protocol – progressively increased from 45 to 60 min use 3 times per day	Depth of PE Drop-out rate	9 mm (0–30 mm) at 6 months I: 22–17 mm at 6 months II: 22–11 mm at 6 months Sternal flattening, n = 23 at 10 months Abandoned treatment (n = 1) and follow-up (n = 3) due to unsatisfactory outcome	This group defined PE based on symmetry, type and the presence of costal flaring There was no specific mention of follow-up in patients with satisfactory outcome after completion of VBT

Continued

Table 1: Continued

Author, date, journal and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Obermeyer *et al.* (2018), J Pediatr Surg, USA [6] Retrospective case series analyses (level IV evidence)	180 PE patients, 115 patients analysed (remaining 65 were either lost to follow-up, discontinued use or had insufficient data to be included in the analysis) VBT protocol advanced in stages, titrated upwards according to suction pressure	PE correction Complications	Outcome excellent (depth <0.51 cm) ($n = 23$) Petechiae ($n = 27$)	An excellent correction was defined as a chest wall depth equal to the mean depth of a reference group of 30 male children without PE (0.51 cm) There was no specific mention of follow-up in patients with satisfactory outcome after completion of VBT
Schier *et al.* (2005), J Pediatr Surg, Germany [7] Retrospective case series analyses (level IV evidence)	60 Patients with PE Aged 6.1–34.9 years (median 14.8 years) Symmetrical PE ($n = 57$), asymmetrical PE ($n = 3$) VBT protocol: 30 min twice/day increasing to 5 h/day	Sternal elevation	1 cm elevation: 85% of patients after 1 month Normal level: 20% of patients after 5 months	Follow-up of 2–18 months (median 10 months) There was no specific mention of follow-up in patients with satisfactory outcome after completion of VBT
Togoro *et al.* (2017), J Pediatr Surg, Brazil [8] Retrospective case series analyses (level IV evidence)	30 Patients with PE Aged 8–35 years old PE symmetry: 7 asymmetric, 23 symmetric VBT applied for 2 min to 160 mmHg, followed by repeat CT scan at the deepest point in the chest	Sternal elevation	Significant HI improvement ($P < 0.001$): $n = 30$	Analysis completed on 29 patients
Haecker and Sesia (2012), J Laparoendosc Adv Surg Tech A, Switzerland [9] Retrospective case series analyses (level IV evidence)	50 Patients aged 9–28 years (mean 14.95 years) 39 Males, 11 females Average preoperative HI: 5.05	Sternal elevation during the Nuss procedure Intraoperative complications	VBT use led to a clear elevation of the sternum as confirmed on thoracoscopy $n = 0$	Retrospective evaluation of a prospectively collected database

CT: computed tomography; HI: Haller index; PE: pectus excavatum; PFT: pulmonary function tests; VBT: vacuum bell therapy.

RESULTS

Dr Haecker's group from Basel, Switzerland, have by far the largest experience in the use of VBT for managing PE conservatively and have reported on a series of patients in several different studies over a period of 13 years. Their initial experience is described in a study from 2006 [2]; in 27 patients (79%), after 3 months of treatment, there was a sustained improvement of at least 1.5 cm; in 5 patients (14.7%), the sternum was lifted to a normal level at 12 months. It is important to bear in mind here that the issue of permanence of correction can only be truly assessed when VBT is completed and the vacuum bell is no longer being worn. The author does state that after 12 months, the patients had the motivation to continue with the application which seems to suggest that VBT was ongoing.

Dr Haecker's group further reported in 2011 [3] on a larger group of patients which builds on the study from 2006 [2]. Based on their pilot study [2], indications for VBT included mild PE in patients wanting to avoid surgery. In 105 patients (79%) after 3 months of treatment, an elevation of more than 1 cm was noted. In 1 patient, aged 9, the longest follow-up after VBT discontinuation was 5 years with 'permanent success that is still visible today'.

The most recent reported series from the same group [4] retrospectively analysed a subset of 140 patients who were treated with VBT; pretreatment PE depth range was 1–6.3 cm (average 2.7 cm). In 61 patients, the sternum was lifted to a normal level after 21.8 months; after completing VBT, patients were followed up for 27.6 months, and there was no regression to PE during that time. Fifty-four patients were still undergoing treatment at the time of reporting.

Haecker's studies over the past 13 years essentially report on the same, but growing cohort of patients, the methodology, selection protocols and follow-up are homogeneous across the

studies. In the total cohort of 434 patients, however, there has been no definitive mention of the overall average length of VBT or indeed the compliance with VBT. Follow-up overall remains an issue particularly given that permanent correction should be defined as evidence of fixed resolution of the defect after completion of VBT and the subsequent patient follow-up length stated. The issue with the initial reported series from 2006 was that we did not have any idea about 'permanence of correction' which is crucial to this technique, but this is addressed by the larger series reported in 2011 and 2016 which show that correction lasts some 27.6 months post-completion of treatment. It would, however, have been more useful if provided over a 13-year period from when patient recruitment initially began, although this could reflect an absence of evidence of such permanence.

Lopez *et al.* [5] performed a preliminary study to evaluate, by means of a qualitative score, the efficacy of cup suction in the correction of PE. Correction was based on when the deepest point was <5 mm and when the patient, parents and the doctor deemed the result to be aesthetically pleasing. At 6 months, all patients were showing improvement under active treatment; the mean depth of PE was 9 mm (0–30). The mean depth reduced from 22 to 17 mm after 6 months of treatment in group I; similarly in group II, this decreased from 22 to 11 mm.

Obermeyer's group [6] retrospectively analysed 180 PE patients who were treated with VBT over 4 years. Depth of PE, flexibility, symmetry and shape of the chest wall were all accounted for during follow-up visits. Chest wall flexibility was evaluated by having the patient perform a Valsalva manoeuvre at maximal inspiration and assessing whether there was flattening of the anterior chest wall. If the patient's anterior chest wall flattened during this manoeuvre, then the patient was classified as having a flexible pectus deformity. An excellent correction (depth < 0.51 cm) was achieved in 23 patients. The variables that were statistically predictive of an excellent outcome were initial age <11 ($P = 0.013$), initial chest wall depth <1.5 cm ($P = 0.003$) and chest wall flexibility ($P < 0.001$). Patients that used VBT for over 12 months consecutively were more likely to achieve an excellent correction ($P = 0.03$).

Schier *et al.* [7] reported on the treatment of PE with VBT in 60 patients, aged 6.1–34.9 years (median 14.8 years). After 1 month of use, elevation of 1 cm was noted in 85% of patients; after 5 months, the sternum was lifted to a normal level in 20% of patients.

The effect of VBT lifting the sternum and anterior chest wall has been confirmed on computed tomography scanning [7, 8] and more commonly thoracoscopically where VBT has been used to lift the sternum intraoperatively during the Nuss procedure [9]. 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 (mean = 11.02, standard deviation = 6.05). The average improvement in Haller index was 0.76. The suction was most effective for individuals with low body mass index and smaller chest depths. Efficacy was not associated with gender, age or chest morphology [8].

Haecker *et al.* [9] evaluated the use of VBT intraoperatively to elevate the sternum during the Nuss procedure. The use of the VBT was deemed safe and effective in lifting the sternum, as it facilitated retrosternal dissection of the soft tissues and insertion of the Nuss bar with reduced risk of cardiac, visceral or mammary artery injury.

The studies reviewed have shown heterogeneity in terms of age of the treatment cohort, selection criteria (type of PE, symmetry, presence of costal flaring), the VBT protocol, the length of follow-up time during and most importantly following completion of VBT, and the metrics used to assess success of therapy. As such, interpreting results across groups is difficult. All groups [4–7] considered age and type of PE prior to commencing VBT and they identified factors such as younger age, symmetry and less severe PE (depth < 3 cm) and adequate chest wall flexibility as favourable and reasoned that severe, asymmetric PE and stiff chest walls presented a high risk for failure of 'non-surgical' treatment. Obermeyer *et al.* [6], however, found that symmetric PE ($P = 0.075$) and more discrete PE ($P = 0.339$) were not associated with improved outcomes.

A combination of subjective and objective measures was used to assess the success of therapy [2, 5]. Perhaps the strictest definition of an 'excellent' result was by using a reference group of children with normal chest walls [6].

CLINICAL BOTTOM LINE

In conclusion, VBT is a safe therapy for treating PE in a non-surgical conservative manner. VBT has been shown to have higher success rates in those who present earlier, have milder forms of PE, symmetric PE, a more compliant chest wall and lack of costal flaring. Objectively assessing success of treatment is difficult and the definition of success may vary according to individuals; radiographic and non-invasive methods to assess PE should be considered. The more pertinent issue is addressing the permanence of correction with sustained follow-up after completion of VBT in order to fully evaluate the effectiveness of this treatment modality.

Conflict of interest: none declared.

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