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Monitoring the effectiveness of the vacuum bell during pectus excavatum treatment: Technical innovation

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ABSTRACT

Background: The vacuum bell (VB) is a valid and the only non-invasive treatment for pectus excavatum (PE). To elevate the sternum the patient himself creates a differential negative pressure inside the VB using a hand pump. A distance and differential pressure measuring device (DPMD) enables us for the first time to assess objectively those parameters.

Methods: After approval by the institutional review board, 53 patients recruited from our outpatient clinic were included in this retrospective study and distributed into three groups (group 1 aged 6 to 10 years; group 2 aged 11 to 15 years; group 3 aged 16 to 20 years). Sternum elevation and differential negative pressure inside the VB compared to atmospheric pressure were assessed with the DPMD, a device developed by engineers at the University of Applied Sciences, Northwestern Switzerland. Pressure-elevation curves were recorded during VB therapy. For statistical comparison of the groups, analysis of variance was used. Post-hoc analysis was performed using the Tukey–Kramer test. A *p*-value of less than 0.05 was considered to be statistically significant.

Results: The VB therapy was monitored in 53 children (39 males, 14 females) aged from 6 to 20 years (average, 14 years). Relationships were established between the differential negative pressure inside the vacuum bell, the elevation of the sternum, and the patient's age. The younger the patient, the lower is the differential negative pressure difference required to obtain a complete elevation of the sternum. Patient's age, weight, the pectus depth, the differential negative pressure inside the VB, and the elevation of the sternum were correlated. When comparing the depth 25 of the pectus excavatum to the patient's age, a statistically significant difference was verified between the groups 3 and 1 ($p = 0.0291$) and 3 and 2 ($p = 0.0489$). The older the patient, the deeper is the pectus excavatum. However, no statistically significant difference between the groups was found when comparing the sternum elevation to the patient's age ($p = 0.4574$) and the elevation to pressure ratio to the patient's age ($p = 0.8048$). The sternum elevation and the elevation to pressure ratio are independent of the patient's age.

Conclusions: DPMD supplies objective data of the elevation of the sternum and the related pressure inside the VB during its application. Correlation between the patient's age, the elevation of the sternum and the pressure inside the VB were demonstrated, but additional data are needed to better understand their relationship and their impact in the treatment of PE by VB.

Study type: Diagnostic Study.

Level of evidence: IV.

The vacuum bell (VB) represents the only available non-operative treatment for patients with pectus excavatum (PE). Previous studies have shown how the VB elevates the sternum [1,2], and demonstrated short-term efficacy of the VB [2–5]. As previously described, the patient creates a differential negative pressure inside the VB using a hand pump and thereby elevates the sternum [3–5]. So far, no tool has been available to measure the effect of the VB during its application in the patient, i.e. the degree of elevation of the sternum and the related pressure inside the VB. Engineers at the University of Applied Sciences, Northwestern Switzerland, developed a distance and differential pressure measuring device (DPMD) that enabled us to measure objectively such parameters [6].

The aim of the present study was

- To present initial data supplied by the DPMD and the possible relationship between those data

Abbreviations: ANOVA, Analysis of variance; CPr, Cardiopulmonary resuscitation; cm, Centimeter; ETPR, Elevation to pressure ratio; DPMD, Distance and differential pressure measuring device; mbar, Millibar; n.s., not significant; PE, Pectus excavatum; VB, Vacuum bell.

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- To evaluate our hypothesis that the younger the patient is, the lower is the differential negative pressure required to obtain a complete elevation of the sternum

1. Methods

1.1. Ethical approval and patient characteristics

After approval by the institutional review board (2017–00005) we retrospectively analyzed demographic and measurement data of children with PE recruited from our specialized out-patient clinic for chest wall deformities at the University Children's Hospital of Basel between 01.06.2015 and 31.05.2016. In total 62 patients with PE were recruited. Because of inhomogeneous patient groups and small sample size, four patients younger than 6 years and five older than 20 years were excluded. 53 children (39 males, 14 females) aged from 6 to 20 years (average, 14 years) were enrolled in the study and underwent monitoring during VB application. The study cohort was 100% Caucasian. None of the patients had additional relevant concomitant disease.

Since our patient population consists of peers mainly between 6 and 20 years, and according to our clinical experience based on a study group of more than 500 patients we recommend starting VB therapy before the age of 10 years [3,5]. This is in contrast to the generally recommended age to perform surgical repair of PE at the age of 13 to 16 years. Since the chest wall is very flexible at this young age, the correction of the PE usually takes less than 6 months. This early strategy ensures sustained compliance and therapeutic success during puberty, when in case of recurrence of the PE the treatment by the VB needs to be pursued. Moreover, in accordance with our experience the total length of treatment seems to be shorter if the recurrent PE was treated previously and at a younger age by the VB.

Thus, the patients were divided into three groups: group 1 aged 6–10 years; group 2 aged 11 to 15 years; group 3 aged 16 to 20 years.

1.2. Application of the VB

Details concerning the application of the VB by the patient himself are described previously [3–5].

1.3. Monitoring of the VB application at the out-patient clinic

Assessment and monitoring of the patients who apply the VB at the out-patient clinic include the measurement of the following parameters: height and weight of the patient, the depth of PE, the elevation of the sternum in cm, the related differential negative pressure inside the VB in mbar, and photographic documentation. The depth of PE is measured in the supine position, at rest, and at end-expiration using a designed scaled rod (Fig. 1). The elevation of the sternum and the differential negative pressure are measured with our DPMD (Fig. 2).

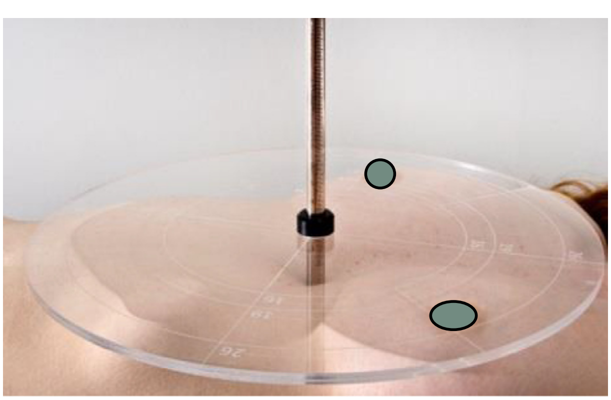

Fig. 1. Scaled rod for measuring the depth of the pectus excavatum.

1.4. Distance and differential pressure measuring device (DPMD)

In collaboration with the Institute for Medical and Analytical Technologies of the University of Applied Sciences and Arts, Northwestern Switzerland, we developed a distance and pressure measuring device (DPMD). The DPMD allows the measurement of the differential negative pressure inside the VB and the related elevation of the sternum during the application of the VB. The DPMD is placed on the top of the VB, and does not alter the usage of the VB and does no harm to the patient or the physician. Moreover, if it fails to operate correctly it does not influence the efficacy of the VB.

The DPMD is available for different VB models, and is intended to determine the elevation of the chest (h_c), taking into account the change of height of the VB during its application (h_s), and the tilted change of height because of an asymmetrical chest wall [6]. Therefore, a measurement method was chosen that includes detection of the height change outside the VB (h_1,h_2), within the VB (h_0) and calculation of the chest elevation (h_C). To detect a tilt precisely and distinguish deformation of the VB at least three additional height measuring points outside the VB are required. For practicality of application currently only two of these points are used, assembled on one axis with the third detector for measuring the height within the VB (h_0). It is essential to use three identical measurement points during VB application for precise chest wall elevation measurement. If the tilt of VB in relation to the human body remains constant or is kept at small angles, there is no impact on the elevation height.

The pressure dependent chest elevation ($h_C(p)$) can be derived according to

$$h_C(p) = h_0(p_0) - h_0(p) - \sum_{i=1}^{n} \frac{h_i(p_0) - h_i(p)}{n}$$

where p_0 denotes the pressure at the atmospheric level (reference), and h_i the distance values of the three sensors (equation adopted from [6]). A positive value of the chest elevation ($h_C(p)$) represents an elevated chest, thus a reduction of deformation.

During the VB application, because of the differential negative pressure inside the VB (blue), indicated in Fig. 3 with dotted lines, the chest wall (red) will elevate (h_C) toward the observation window, while the VB because of its flexible silicon ring will move toward the chest (h_S). An elevation of the sternum occurs, depending on the applied pressure. Pressure and distance sensors are integrated only in the DPMD.

1.5. Accuracy of the DPMD

Three optical triangulation sensors are used (Sharp GP2Y0A41SK0F) within the DPMD [6,7], providing suitable accuracy and reproducibility ($\sigma \approx 1\ mm$) of the distance measurement (d) within a specified range of $d = 0 - 15\ cm$. For measurement of the pressure differential a pressure sensor (Honeywell 26PCBFA6D 5PSI) based on the piezo resistive bridge, was applied to detect the pressure difference within and outside the VB. The pressure sensor is placed within the tubing leading from the hand pump toward the VB.

The sensors are interfaced to a standard personal computer, using a micro controller interface (Arduino Mega 2560), with correction of nonlinearity of the sensors, performing calculation of the chest elevation (h_C) according to the equation above. The height and pressure data are transmitted to the computer using a cable. Different sizes of DPMD were designed to fit on the four different sizes of VB. Calculation of the chest wall elevation according to the above equation, revealed an