Healthcare Improvement Scotland | SHTG Advice on health technologies

SHTG Recommendations
June 2025

In response to an enquiry from the Scottish National Chest Wall Service

The Vacuum Bell device for people with Pectus Excavatum

Recommendations for NHSScotland

The vacuum bell device should be available as a non-surgical treatment option for selected people who have a pectus excavatum that is negatively affecting their physical and/or psychological wellbeing.

Multidisciplinary team decision making on the use of the vacuum bell device should take into account factors that may be associated with successful treatment outcomes: a younger age at treatment onset, a flexible chest wall, a smaller pre-treatment chest wall depth, patient motivation and acceptance of the treatment, and support from patients' caregivers.

There should be ongoing data collection on the effectiveness and safety of the vacuum bell device for people with pectus excavatum, to help inform optimal treatment protocols.

NHSScotland is required to consider the Scottish Health Technologies Group (SHTG) recommendations.

What were we asked to look at?

We were asked to assess the vacuum bell (VB) device for people with a pectus excavatum (PE). We were asked to consider clinical effectiveness, cost effectiveness, safety and patient issues, and we were also asked to look at other factors such as optimal wear time, whether effectiveness varies depending on the severity of the PE, and the optimal age for treatment.

Why is this important?

PE can be apparent from birth, or it can appear in young people following a growth spurt, typically between ages 11 and 14 years. It is caused by an abnormal growth of the cartilage ribs that attach to the breastbone, resulting in the front of the chest having a sunken appearance. In people who are only mildly affected, there are no negative effects on physical health. In more severe cases, PE may influence heart and lung function. For some people, the appearance of a chest wall difference can impact on their quality of life and psychological wellbeing. PE is the most common congenital chest wall difference, and the incidence is reported to be up to 8 per 1,000 live births.

The VB device may be used by people with mild PEs to help improve quality of life, especially when no other treatment options are available. Use of the VB device may help reduce the need for surgery for people with a more pronounced PE, or may help to prevent a mild PE from becoming more severe during puberty.

What was our approach?

To produce our SHTG Recommendations we reviewed the published literature on the clinical and cost effectiveness, patient experience and safety of the VB device for the treatment of people with PE. A submission from the Pectus Matters patient group informed our recommendations. More information about SHTG Recommendations is available on our website.

What next?

Our recommendations will be shared with colleagues at the Scottish National Chest Wall Service to inform discussions on future service delivery. The Scottish National Chest Wall Service, which offers treatment to children and young people (aged 0 to 16 years) across Scotland, is an NHS National Services Scotland national specialist service.

Key points from the evidence

1. We identified 15 studies on the use of the VB device for people with PE. Thirteen were retrospective reviews of medical records,[1-13] one was a prospective case series[14] and one was a small randomised controlled trial (RCT).[15] The studies were heterogeneous and prone to bias. The retrospective studies were mostly small, patients self-reported their daily wear time, and only people who completed the treatment were included in the final analyses. It is not clear from most of the studies if the treatment benefits that are reported are maintained in the longer term.

2. The largest (n=259) and most recent study (2024), from The Netherlands, reported that 86 out of 165 people who completed treatment with the VB device considered it a success (52.1%). Treatment was considered successful if patients, parents and a surgeon regarded the result as aesthetically pleasing.[12]

3. Eleven of the 15 studies reported on the effectiveness of the VB device. The outcomes and how they were measured varied across the studies. In the four oldest studies the sternum was raised to a normal level in 13.5% to 31.5% of participants following treatment for up to 18 months.[2, 3, 9, 14] The remaining seven studies, published since 2018, reported a positive treatment outcome in approximately 20% to 50% of patients selected for treatment with the VB device.[1, 4-7, 10, 11]

4. Evidence suggests that a younger age at treatment onset (approximately ≤11 years) and a flexible chest wall are factors associated with successful treatment outcomes with the VB device.[1, 3, 5, 7, 10, 11, 13] A smaller pre-treatment chest wall depth may also be associated with improved outcomes.[6, 7, 11, 12] One small, preliminary RCT (n=26) reported that treatment with the VB device may be further optimised if patients are also offered a standardised physiotherapy programme.[15]

5. Three of the studies reported improved patient outcomes in people who wore the VB device for longer periods of time.[8, 10, 12]

6. Optimal daily wear time cannot be determined from the available literature, and it is likely to differ depending on the age of the patient and the nature of their PE. Younger patients (aged ≤11 years) with a pliable chest wall may only require, and tolerate, shorter daily wear times. Two studies did not find evidence of improved outcomes with longer wear times (>60 minutes and >150 minutes), with one reporting that successful treatment outcomes were observed in several people who chose to wear the VB device for less than 60 minutes per day.[5, 7]

7. Five of the studies reported that total duration of treatment was associated with improved patient outcomes.[5-7, 11, 12] Two studies suggested that use of the VB device should last at least 12 months,[7, 11] and another two studies reported that treatment should last 24 months.[5, 12] The optimal total duration of treatment is likely to vary according to the age of the patient and the nature of the PE.

8. The VB device may not be suitable for some people with asymmetrical PEs if this means the device cannot be attached to the chest wall (that is, a vacuum cannot be created). Breast development may also impede use of the VB device.
9. No safety concerns with the VB device were identified. Most people are able to tolerate treatment with the VB device, and the side effects and complications reported in the literature do not appear to be permanent or severe. Side effects noted in the literature include chest wall pain, back pain, skin irritation, haematoma, upper extremity paraesthesia, petechiae, thickening/darkening of the skin and blistering. As the VB device is typically used to treat PE in children and young people, support and supervision by a parent or carer is required.
10. A patient organisation told us how people can be negatively affected by a difference in their chest wall appearance, with some people experiencing significant psychological and/or physiological consequences. Some people with PE become self-conscious and withdraw from activities that they would otherwise enjoy. For people with more pronounced PEs, the compression in the chest can impede normal functions such as walking, exercising and swallowing. No literature was identified on the patient experience of using the VB device.
11. We estimated and compared the total costs of first line conservative management for PE (an initial in-clinic appointment followed by virtual appointments with a physiotherapist, quarterly for up to 18 months), surgical management and treatment with the VB device. The cost of treatment with the VB device (estimated between £468 and £503 per patient) was higher than the cost of conservative management alone (£192), but far lower than the costs of surgical management (£15,003 modified Ravitch procedure; £13,513 Nuss procedure).
12. We were unable to conduct a cost-effectiveness analysis comparing use of the VB device with usual care options because of a paucity of evidence for key parameters. Gaps in the evidence included efficacy of VB compared with usual care, and evidence relating to health-related quality of life following VB device or usual care.

SHTG Council considerations

1. The Council acknowledged that the evidence base is limited, consisting mainly of retrospective studies which are more prone to bias. The Council agreed that, on balance, the body of evidence was sufficient to demonstrate that the VB device was likely to provide positive treatment outcomes in a selected group of patients, with few safety concerns.

2. The Council noted that the VB device is mainly offered to people with a mild PE as a conservative treatment option, when they would not normally be eligible for surgery and have no other treatment options. The VB device also has the potential to

treat people with more moderate and severe PEs to reduce the need for surgery. The Council recognised the patient and service benefits from fewer surgeries.

3. A topic expert from the Scottish National Chest Wall Service described the patient pathway for people with a chest wall difference in NHSScotland. The first VB device was prescribed in NHSScotland in 2018, and since then nearly 400 have been fitted. The expert noted that most patients are aged between 5 and 16 years (median age 13). The service in Scotland includes physiotherapists, surgeons and psychologists. Consultations are provided remotely when feasible.

4. Following discussion with the topic expert, the Council noted that treatment with the VB device requires considerable commitment from patients and their parents or carers, and progress can be slow. The topic expert suggested that approximately 30% of people who start treatment with the VB device do not complete treatment. It was suggested that one way to improve adherence to treatment may be to use new technology, for example three dimensional (3D) photographs, so that the patient can better visualise the ongoing improvement in their chest wall difference and hopefully continue using the VB device. The topic expert advised that a key factor in a patient's decision to continue treatment is their own desire to correct the PE, which outweighs the influence of their parents or carers.

5. The Council heard from a patient organisation, Pectus Matters, who described the impact that a chest wall difference can have on individuals. The physical effects for some people are significant, particularly for those whose cardiorespiratory functions are impacted. Pectus Matters also stressed the substantial psychological consequences of PE for some people. Young people and adolescents are especially susceptible to negative feelings and self-consciousness about their bodies. The resulting impact on their desire to participate in regular activities should not be underestimated.

6. The Council considered the costs of the VB device, including the first line treatment costs of VB device use, conservative management and surgery. Economic modelling comparing costs and effectiveness was not possible because of a lack of relative outcomes data. The Council highlighted the low cost of the VB device and the potential for the device to be good value for money, even if only a small portion of patients benefit from using the device.

7. The Council noted the reusable nature of the VB device, and the potential environmental and cost benefits for the service. The topic expert advised that a VB device is currently likely to only be used by two patients sequentially, because regular use and cleaning causes deterioration in the silicone VB device material.

8. The Council noted the importance of ongoing data collection by the Scottish National Chest Wall Service, and subsequent review of these data. The Scottish service has an established patient pathway for people with chest wall differences, and considerable experience of prescribing the VB device. Ongoing data collection will help further our

understanding of, for example, the patients most likely to benefit from treatment and optimal treatment protocols.

Contents

Introduction

PE is a chest wall difference caused by the ribs and breastbone (sternum) growing inwards, giving the chest wall a sunken appearance. In some people, the PE is apparent from birth. In most people it appears, or becomes more pronounced, following the growth spurt that typically happens during adolescence.[16]

For many people, their chest difference does not affect activity and does not cause psychological harm. Some people are affected psychologically, physiologically or both. PE can cause issues with self-esteem and depression, causing people to withdraw from activities that they would otherwise enjoy. In a small number of people with more pronounced PEs, there can be a compressive effect on the heart and lungs, causing disturbances in cardiac and respiratory functions and a reduced ability to perform forceful cardiovascular activities.[15, 17]

PE can be classified as mild, moderate or severe, based on the Haller Index (HI) or chest wall depth. Assessment of PE severity may also take into account whether the depression is symmetric or asymmetric (where the depression is unilateral).[18] In order to be accurately categorised, people may be offered investigative procedures, such as chest radiography or CT. Experts in Scotland advise that PE severity classifications are often assigned subjectively, based on the consensus of the treating multidisciplinary team.

Surgery is not indicated for most people with PE. When required, there are two surgical procedures for PE, both of which may be offered in NHSScotland[19]:

- the modified Ravitch procedure (open surgery), where the affected part of the chest is exposed to allow the surgeon to remove the abnormally shaped cartilage ribs
- the Nuss procedure (minimally invasive surgery) in which a metal bar is implanted and remains in the chest for 2-3 years.

The majority of patients who undergo PE surgery are offered the Nuss procedure. The modified Ravitch procedure tends to be offered to patients with the most complex chest wall differences. The Scottish National Chest Wall Service advised that in 2023/2024, 20 Nuss procedures were performed in Scotland in people with PE. Five modified Ravitch procedures were carried out, but not in people with PE.

People with a PE that may benefit from surgery may prefer to explore nonsurgical options such as physiotherapy or treatment with the VB device.

The Scottish National Chest Wall Service has advised that in recent years, substantially more people have been seeking use of the VB device, with 104 prescribed in 2023/24.

Research question:

The primary research question is:

- What is the clinical effectiveness, cost effectiveness, safety and patient experience of the VB device for the treatment of people with PE?

The following supplementary questions were also considered.

- Does the evidence for the effectiveness of the VB device differ depending on the severity of the PE?
- What is the evidence on optimal daily wear time, and the optimal length of overall treatment duration?
- What is the evidence around patient adherence to recommended wear time and treatment duration?
- What is the impact on the quality of life for children and young people with PE?
- What is the optimal age to be treated with a VB device?

Literature search

A systematic search of the secondary literature was carried out between 9 and 10 October 2024 to identify systematic reviews, health technology assessments and other evidence-based reports. Medline, Embase and Web of Science databases were also searched for systematic reviews and meta-analyses.

The primary literature was systematically searched between 9 and 10 October 2024 using the following databases: Medline, Embase and Web of Science. Results were limited to English language publications.

Key websites were searched for guidelines, policy documents, clinical summaries, economic studies and ongoing trials.

Concepts used in all searches included: pectus excavatum, vacuum bell therapy, minimally invasive surgery (Nuss procedure). A full list of resources searched, and terms used are available on request.

Health technology description

The VB device is a non-surgical treatment option for people with PE. It is a flexible silicone suction cup that adheres to the chest and connects to a portable vacuum pump. A gentle vacuum is created, and the suction brings the sternum forward. As the chest wall is still flexible in adolescence, it can remodel into a new position if the sternum is held forward for a long period of time.[17] Patients are advised to wear the VB device for 2 hours per day, and are told that it may be necessary to use it for at least 12 months.[20]

According to a survey of clinical experts from 47 institutions around the world, indications to apply the VB device include: a mild degree of PE, as an alternative to surgical repair, patients under the age of 10 years, and for pre-treatment before surgical repair.[21] In NHSScotland, the VB device is most often used for people with a mild PE, who would not be eligible for surgery. There is no exact definition of a 'mild' PE, and the Chest Wall Service in Scotland advises that diagnosis is subjective and based on the expert consensus of the multidisciplinary team (MDT). The VB device may also be used in people with a more moderate and severe PE, some of whom would traditionally be offered surgery. There is the potential for VB treatment to reduce the need for surgery in some people.

Treatment with the VB device is contraindicated in people with skeletal disorders (for example, osteogenesis imperfecta, osteoporosis, Glisson's disease), vasculopathies (for example, Marfan's syndrome, aortic aneurysm or dilated aortic root), coagulopathies (for example, haemophilia, thrombocytopenia) and cardiac disorders.[18]

Epidemiology

PE is the most common congenital chest wall difference with a reported incidence of up to 8 per 1,000 live births. PE is approximately five times more common in males than females.[22] 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.[18] The severity of the PE may change over time, especially during puberty.

The Chest Wall Service in Scotland have advised that nearly 400 individuals with PE have now been provided with a VB device in NHSScotland. There are approximately 70 to 100 prescriptions annually. Around 15 PE surgeries are performed each year in Scotland, predominantly the Nuss procedure, with modified Ravitch procedures used selectively. Referrals to the Scottish service have increased in recent years, and while the use of the VB device has risen, the number of surgeries has remained constant (Personal communication, Ashely Johnstone, Clinical Lead, Scottish National Chest Wall Service, 4 April 2025).

Clinical effectiveness

Summary of identified studies

We identified 15 studies on the use of the VB device for people with PE (*Table 1*).[1-13, 15] Thirteen were retrospective reviews of medical records from single centres,[1-13] one was a prospective case series[14] and one was an RCT.[15] All were relatively small with only five including more than 100 participants,[2, 6, 7, 11, 12] and the largest including 259 participants.[12] The majority of the participants included in the studies were aged under 18, but nine studies included adults.[2-5, 7, 9, 10, 12, 14]

The evidence on the use of VB devices is limited in quality. The studies identified are at a high risk of bias and are heterogeneous regarding participant age, selection criteria for VB treatment, follow-up duration and assessed outcomes. The VB treatment protocols varied considerably within and

between studies, with daily use time and total duration of treatment being largely dependent on patient motivation and tolerability of the VB device.

In this section, the clinical effectiveness evidence has been summarised under two headings:

- What is the evidence that the VB device is effective in treating people with PE?
- What factors influence the success of treatment with VB devices?

What is the evidence that the VB device is effective in treating people with PE?

The evidence for the clinical effectiveness of the VB device for treating people with PE comes from 12 studies.[1-7, 9-12, 14] The four oldest studies reported promising results, with the sternum being raised to a normal level in 13.5% to 31.5% of participants who were treated for up to 18 months. All studies suggested that further research was required on the long-term effectiveness of the VB device, and on optimal treatment duration.[2, 3, 9, 14]

Of the more recent studies, only one study compared outcomes for people treated with the VB device with people who underwent the Nuss procedure.[4] Jung *et al* performed a retrospective study of 57 participants from the Republic of Korea, 33 were treated with the VB device and 24 underwent the Nuss procedure.[4] For the participants who used the VB device, a minimum of 30 minutes wear time twice per day was recommended for the initial treatment. This was increased to 2 hours per application, and up to four times per day depending on the patients' preferences. Patient outcomes were evaluated by comparing the HI before and after treatment in both groups. The pre-treatment HIs calculated from chest CT and chest X-rays were significantly higher in the group that underwent the Nuss procedure, compared with people who used the VB device. The HIs (mean ± standard deviation [SD]) obtained from chest CTs performed immediately after treatment were not significantly different between the two groups (VB group, HI=3.06±0.67; Nuss group, HI=3.07±0.46; p=0.954). The HI determined at 1-year post-treatment was obtained from plain chest X-rays for both groups, and there was no statistically significant difference between them (VB group, HI=3.01±0.62; Nuss group, HI=2.88±0.78; p=0.473). The degree of HI improvement was significantly better in the group that underwent the Nuss procedure. The authors concluded that while the Nuss procedure is an effective treatment of choice for patients with more pronounced chest wall differences, treatment with the VB device showed comparable outcomes and could serve as an alternative treatment modality for select patients who prefer non-invasive PE treatment.

The remaining seven studies are heterogeneous in terms of included participants, treatment protocols, length of follow-up and outcomes assessed, which makes grouping them difficult. A summary of each is provided, starting with the most recent.

- Lei *et al* (2024, n=72, China) followed-up patients for a mean of 3.3 years (range 1.1 to 4.4 years). The initial mean (± SD) HI in the treatment group was 3.73±1.01, and the final average HI was 3.49±1.02. The authors categorised participants based on the percentage correction of the HI. A total of 18 (25.0%) patients demonstrated an 'excellent' correction (final HI ≤3.25), 13 (18.1%) patients achieved a 'good' correction

and four patients (5.6%) exhibited a 'fair' correction. The remaining (n=37) patients experienced a 'poor' outcome.[5]

- van Braak *et al* (2024, n=259, The Netherlands). Participants were advised to wear the VB device two to three times per day initially for 30 to 60 minutes, gradually increasing the duration and the applied suction as tolerated. After 2 to 3 months, they were advised to wear the device overnight and during routine activities. Follow-up was a median of 64 months (interquartile range 48.0 to 87.0). At the time of analysis 165 people (63.7%) had completed treatment, and the treatment was considered a success for 86 (52.1%). Of 15 patients who were using the VB device while awaiting a Nuss procedure (n=15), four no longer required surgery (26.7%).
- Luo *et al* (2022, n=139, China). This study was limited to children aged less than 7 years (mean 4.6 years). Participants were recommended to use the VB device for at least 30 minutes twice a day and were followed-up at a median of 9 months. Forty-three participants (30.9%) had their PE corrected (that is, to a depth of less than 3 mm) and stopped treatment.[6]
- Toselli *et al* (2022, n=186, Argentina) followed-up patients for a maximum of 24 months, and complete correction was achieved by 31 (17%), while 83 (45%) remained under surveillance (still receiving treatment). Treatment was considered a failure in nine of the patients. Withdrawal rates were high (n=63, 34%). Using a standardised classification system (Obermeyer's classification of degrees of PE correction), the authors reported that 35% of participants had excellent/good results, 25% fair results and 40% poor/worse results.[11]
- Furuta *et al* (2020, n=15, Japan). Participants in the study were initially advised to use the VB device for 30 minutes per day. This was increased by 30 minutes every week, until after a month of treatment when participants were advised to use the device for 2 hours, once or twice a day. The authors reported that the depth of depression reduced in 14 of the participants (mean 8.7 mm) but that minimal change occurred in the HI. They suggested that the difference was the result of a significant thickening of subcutaneous fat, rather than lifting of the sternum.[1]
- St Louis *et al* (2019, n=31, Canada). Participants' median frequency of use was 7 days per week (range 4 to 7 days), and median daily wear time was 1.9 hours (range 0.4 to 5.5 hours). At a median follow-up of 18 months (range 12 to 24 months), 25 patients showed improvement based on depth and HI. The median HI before treatment was 3.9 (range 2.9 to 6.1) and decreased by an average of 0.3.[10]
- Obermeyer et al (2018, n=115, USA) asked participants to gradually increase the application time from 30 minutes to 120 minutes, twice per day and treatment duration ranged from 4 months to 4 years. An 'excellent' correction (chest wall depth ≤0.51 cm) was achieved in 23 patients (20%).[7]

What factors influence the success of treatment with VB devices?

Age

In five of the retrospective studies the authors concluded that commencing treatment with the VB device at a younger age was associated with better patient outcomes.[1, 3, 5, 7, 10] Three studies reported that patient outcomes did not differ by age.[11-13]

Of the retrospective studies which concluded that a younger age of treatment onset was associated with better outcomes, the largest was by Obermeyer *et al* (n=115).[7] The authors reported that an excellent outcome (defined as a chest wall depth equal to the mean depth of a reference group of 30 male children without PE) was more likely for patients ≤11 years (OR=3.3, p=0.013).[7] Similar findings were reported by Lei *et al* (n=72)[5] who divided participants into four categories based on the percentage correction of the PE at follow-up. Lei *et al* reported that an initial age ≤11 years was predictive of a non-poor outcome (that is, an excellent, good or fair outcome) (OR=3.94, p=0.013).

Age was also reported as a predictor of treatment success in three smaller retrospective series.[1, 3, 10] In one of the early studies, Haecker *et al* (2006, n=34) noted that the elevation of the sternum was more successful within the first 6 to 9 months of application in paediatric patients (aged 18 years and under). Adult participants demonstrated a slower but continuous decrease of PE.[3] St Louis *et al* reported that a younger age of treatment onset (≤10 years) was associated with greater improvement in HI but not depth of the PE.[10] Furuta *et al* concluded that the improvement rate on elevation of the chest wall was better in preteenagers than teenagers, although the difference they reported was not statistically significant (possibly because the study was underpowered).[1]

Toselli *et al* (n=186) reached opposite conclusions to the above studies. The authors categorised patients according to a standardised classification system (Obermeyer's classification of degree of PE correction). When comparing patients with good or excellent results with those with unsatisfactory results (<good), no statistically significant difference was found for age (10 years versus 12 years, p=0.055).[11] Similarly Yi *et al* (n=63) reported that age was not significantly associated with improvements in HI (p=0.233).[13] van Braak *et al* (n=259) reported that clinical outcomes did not vary in comparing patients under the age of ten (n=12), eleven (n=20), and twelve (n=31) with those over the ages of ten, eleven and twelve (p=0.72, p=0.65, p=0.23 respectively).[12] It should be noted that the cohorts in the studies by Yi *et al* and van Braak *et al* were, on average, older than those in other studies (participants mean age was approximately 15 years in both studies).

Flexibility of chest wall

Two of the retrospective studies reported that the flexibility of the chest wall at the start of treatment could be used to predict which patients may have better outcomes with the VB device.[7, 13]

Yi *et al* split their study participants into two groups based on the post-treatment changes in HI: those with changes less than 0.5 (group 1) and those with changes greater than or equal to 0.5 (group 2).[13] They then assessed the pre-treatment characteristics of patients, to establish which characteristics were associated with the better outcome. They concluded that the patients with a more pliable chest wall at treatment onset were the most likely to have a successful treatment

outcome. The pliability of the chest wall was determined by using the pre-treatment chest CT scans, which were performed with and without the VB device. This enabled the authors to calculate what the expected improvements in HI could be with treatment. Pre-treatment HI without VB application was significantly lower in group 1 than in group 2 (3.1 versus 4.2, p<0.001). The expected improvement in HI (that is, the HI when the VB was initially applied) in group 2 was significantly higher than that in group 1 (3.3 versus 2.8, p=0.001). This appeared to be correlated with mean post-treatment changes in HI after 1 year in group 1 and group 2 (0.18 versus 0.93, p<0.001).

Obermeyer *et al* reported that an excellent outcome (defined as a chest wall depth equal to the mean depth of a reference group of 30 male children without PE) was more likely in participants with chest wall flexibility (OR=14.8, p<0.001).[7] Chest wall flexibility was evaluated by having the patient perform a Valsalva maneuver at maximal inspiration and assessing whether there was flattening of the anterior chest wall.

van Braak *et* al reported that a flexible chest wall led to worse patient outcomes.[12] They assessed chest wall flexibility by attaching the VB to the patient's chest, applying suction, and subsequently assessing sternal elevation. Flexibility was deemed present when sternal elevation occurred effectively within minutes. In their discussion the authors suggest that this discrepancy with other studies is because of their 'subjective method for assessing thorax flexibility' and conclude that this finding should be treated with caution.

Initial chest wall depth, HI and symmetry of PE

Two of the retrospective studies compared the characteristics of patients with good treatment outcomes with those who had less successful treatment outcomes and reported that smaller chest wall depth at treatment initiation was one factor associated with positive clinical outcomes. Obermeyer *et al* reported that an 'excellent' outcome was more likely in participants with a chest wall depth ≤1.5 cm (OR=4.6, p=0.003).[7] Toselli *et al* stated that when comparing patients with good/excellent results with those with unsatisfactory results, patients with good/excellent results had a lower initial pectus depth (mean=1.6 cm versus 2.0 cm, p=0.001).[11] These findings were supported by two further retrospective studies. In the first (Luo *et al*), which included younger children (mean age 4.6 years; n=139), multifactor logistic regression analysis showed that initial depth (OR=0.69, 95% Confidence Interval [CI] 0.58 to 0.84, p<0.001) was an independent predictor of complete correction.[6] van Braak *et al* reported that both objectively- and subjectively-measured deeper PEs were associated with a lower rate of success.[12]

Two of the smaller retrospective studies found no evidence of an association between initial chest wall depth or HI and clinical outcome. Lei *et al* reported that people who had an initial HI ≤3.5 did not necessarily experience improved outcomes (OR=1.32, p=0.619).[5] Yi *et al* also stated that depth of PE was not related to positive outcomes, and reported that positive outcomes were more likely in the patients who showed chest wall pliability with VB device application before treatment commenced.[13]

With regard to the symmetry of the PE, one of the retrospective case series (Haecker *et al*) included three patients with an asymmetric PE, and noted that while treatment with the VB device decreased

the depth of the PE after 9 months, the asymmetry was still visible.[2] Two of the other retrospective studies (Lei *et al*; Obermeyer *et al*) reported no clear evidence of an association between a symmetric PE and improved outcomes.[5, 7]

Daily wear time

All the studies we identified described the treatment protocol that was recommended to the included participants (*Table 1*). Most protocols set a minimum use of 30 minutes twice a day, and several recommended that participants gradually increase their wear time and number of applications every day. No protocols set an upper limit. Daily wear time was influenced by patient characteristics (for example, age) and also their acceptance and tolerability of the treatment. As a result, the reported wear times varied widely between participants.

Three of the retrospective studies reported that daily wear time (as recorded by the participants) was associated with improved outcomes. van Braak *et al* reported that increased daily wear time and overnight use were both factors that led to a higher success rate. In comparing those who had successful versus unsuccessful treatment they reported:

- a higher percentage of successfully treated patients wore the VB overnight compared with those unsuccessfully treated (58.1% versus 30.4%, p<0.001)
- the average daily wear time was greater in the successfully treated patients compared with the unsuccessfully treated patients (3 hours versus 2 hours, p=0.002).[12]

Prada Arias *et al* evaluated the efficacy of the VB device during puberty in 50 participants from Spain with a mean age of 12.5 years (range 10 to 14 years). Participants were categorised into groups according to the daily hours of use (≤ 3 hours; 4 to 5 hours; ≥ 6 hours) and treatment duration (6 to 12 months; 13 to 24 months; 25 to 36 months; > 36 months). The authors reported that the reduction in PE depth was associated with daily hours of use (p=0.01):

- ≤ 3 hours: mean reduction 14.99% (±31.12 SD)
- 4 to 5 hours: mean reduction 17.48% (±30.48 SD)
- ≥ 6 hours: mean reduction 45.51% (±17.7 SD).

The authors suggested that for maximum benefit, the VB device should be used for at least 6 hours/day during puberty.[8] St Louis *et al* reported that improvements in chest wall depth were superior with device usage of at least 2 hours per day (p<0.01).[10]

In contrast, two studies did not find an association with increased daily wear time and improved outcomes. Obermeyer *et al* concluded that reported daily use of over 60 minutes per day was not associated with improved outcomes (OR=5.0, p=0.129). The authors noted that they had 'several' patients (exact number not given) who used the VB device for less than 60 minutes per day and still achieved an excellent correction.[7] Lei *et al* reported no clear evidence of associations between daily use time ≥150 min (OR=0.96, p=0.940) and improved outcomes in 74 participants.[5]

Total duration of treatment

Five of the retrospective studies reported that total duration of treatment was associated with improved patient outcomes. Both Obermeyer *et al* and Toselli *et al* concluded that treatment for at least 12 months was associated with improved patient outcomes:

- Obermeyer *et al* reported that an excellent outcome was more likely for patients who used the VB device over 12 consecutive months (OR=3.1, p=0.030)[7]
- Toselli *et al* reported that patients with good/excellent results had a longer treatment duration (mean 19 months versus 13 months, p<0.0001), and that a length of treatment >12 months was one of the best determinants of success.[11]

Two of the other studies concluded that longer treatment durations (>24 months) were beneficial:

- van Braak *et al* found the median treatment duration was longer in successfully treated patients compared with unsuccessfully treated patients (24.0 months versus 13.5, p<0.001)[12]
- Lei *et al* found that use of the VB device for over 24 consecutive months was one of the factors that was predictive of an excellent, good or fair outcome (OR=6.70, p=0.014).[5]

In the study by Luo *et al* that included a younger patient cohort (mean age 4.6 years), who underwent shorter total treatment durations (median follow-up time of 9 months), multifactor logistic regression analysis showed that treatment period (OR=1.58, 95% CI 1.23 to 2.04, p<0.001) was an independent predictor of complete correction of the PE ().[6]

Physiotherapy

A small preliminary RCT, by Alaca *et al*, analysed the effect of a standardised physiotherapy programme applied in addition to treatment with a VB device.[15] The study included 26 male participants aged between 11 and 18 years. Group 1 (n=13) were advised to use the VB device for 30 to 60 minutes, twice a day, for 12 weeks. Group 2 (n=13) received the same treatment but also attended a physiotherapy programme for 12 weeks.

After 12 weeks of treatment, sternal depression showed a statistically significant decrease from baseline in both groups (mean improvement 6.66 mm in group 1 [p=0.04] versus 12.86 mm in group 2 [p<0.001]), although the improvement in sternal depression was greater in group 2 (p=0.009). Similarly, anthropometric index values showed improvement in both groups, but better results were observed in group 2 than in group 1 (p<0.05).

Several other outcomes were included in the study. Severity of PE, the patient's perception of their PE and parental physiological quality-of-life scores improved in both groups (p<0.05). Posture, satisfaction with treatment and the patients' physiological quality-of-life scores were significantly better in group 2 (p<0.05).

Based on these findings, the authors concluded that patients undergoing treatment with a VB device should also be offered a rehabilitation programme to maximise potential benefits of the therapy.

Table 1: Summary of studies included in evidence review

	Reference	Patients	Treatment protocol	Follow-up	Results
1	Schier *et al* (2005)[9] Retrospective review of medical records Germany	N=60 (56 males, 4 females) Age 6.1 to 34.9 years (median, 14.8 years)	Recommended wear time was a minimum of 30 minutes, twice a day, up to 5 hours per day (median=90 minutes)	2 to 18 months (median=10 months)	After 1 month, all patients had an elevation of the sternum depression by 1 cm. After 5 months, the sternum had been elevated to the normal level in 12 patients (evaluated immediately after application of the suction cup). One patient has finished therapy after 9 months with good results. At follow-up, all patients were highly satisfied and continued to use the cup. One child requested surgery after a short trial because of discomfort with the cup. Patient progress was documented using photography, radiography and plaster casts of the defect.
2	Haecker *et al* (2006)[3] Retrospective review of medical records Switzerland	N=34 (31 males, three females) Age 6 to 52 years (median 17.8 years) Before starting treatment, depth of the PE ranged from 2.5 cm to 5 cm	Recommended wear time was a minimum of 30 minutes, twice a day (although the daily wear time varied significantly between patients)	Follow-up at 3 to 6 monthly intervals Treatment duration between 1 and a maximum of 18 months (median=10.4 months)	In all patients, the sternum and the ribs were lifted immediately after first application of the device, although the elevation subsided after 30 to 60 minutes. The elevation of the sternum was more successful within the first 6 to 9 months of application in paediatric patients (aged 18 years and under). Adult patients demonstrated a slower but continuous decrease of PE. In 27 patients (79%), after 3 months of treatment, a permanent elevation of more than 1.5 cm was documented. In five patients (14.7%), the sternum was permanently lifted to a normal level after 12 months. In three patients with asymmetric PE, the depth of PE decreased after 9 months, but the asymmetry was still visible. All patients except one were satisfied with the use of the VB device. Standardised evaluation before starting the procedure included 3D CT scan, pulmonary function tests, cardiac evaluation with electrocardiogram and echocardiography and photo documentation. In addition, the depth of PE was measured. Patient progress was documented using photography and clinical examination.
3	Haecker *et al* (2011)[2]	N=133 (110 males, 23 females) Age from 3 to 61 years	Recommended wear time was a minimum of 30 minutes, twice a day (although the daily wear time	Follow-up at 3 to 6 monthly intervals	CT scans showed that the device lifted the sternum and ribs immediately. 105 showed a permanent lift of the sternum of more than 1 cm after 3 months of daily application. In 18 patients the sternum was lifted to a normal level after 18 months. In three patients with asymmetric PE, the depth of PE had decreased after 9 months,

	Reference	Patients	Treatment protocol	Follow-up	Results
	Retrospective review of medical records Switzerland	(median 16.21 years) Before starting treatment, depth of the PE ranged from 2 cm to 5 cm	varied significantly between patients)	Treatment duration between 1 month to a maximum of 36 month	but the asymmetry was still visible. Thirteen patients stopped the application and underwent minimally invasive repair of the PE. Standardised evaluation before starting the procedure included history of the patient and his family, clinical examination, cardiac evaluation with electrocardiogram and echocardiography and photo documentation. The depth of PE was measured in a standardised supine position. Patient progress was documented using clinical examination and by measuring the depth of PE.
4	Lopez *et al* (2016)[14] Evaluation/ prospective case series France	N=73 (52 males and 21 females) Group 1 patients ≥18 year (n=17) Mean age 22.8 years Group 2 patients <18 years (n=56) Mean age 11.5 years	During the first week, the system was to be used three times a day for 45 to 60 minutes per application. After this, patients were instructed to increase the duration of use The mean time of use of the device was 4 hours daily	Mean follow-up was 28 months (range 9 to 41 months)	At 6 months, the mean depth of PE was 9 mm (range 0 to 30 mm) across all patients. Group 1, before treatment, the mean depth PE was 25 mm (9 to 45 mm). At 6 months of treatment, the mean depth PE was 17 mm (0 to 30 mm). The mean utilisation time was 3 hours daily (1 to 12 hours). Group 2, before treatment, the mean depth PE was 22 mm (10 to 38 mm). At 6 months of treatment, the mean depth was 11 mm (5 to 25 mm). The mean utilisation time was 4 hours daily (1 to 12 hours). 23 patients completed the treatment and exhibited flattening of the sternum. The mean treatment duration to normal reshape was achieved at 10 months (range 4 to 21 months). The remaining patients were reported as improving under continuing active treatment. The mean depth of PE in this group was 12 mm (range 4 to 30 mm), after a mean treatment duration of 9 months (range 2 to 22 months). No patients experienced a relapse after finishing the treatment.
5	Obermeyer *et al* (2018)[7] Retrospective review of medical records	N=115 (104 males, 11 females) Age from 4 to 23 years (mean=12.7)	Gradually increased the application time from 30 to 120 minutes twice per day	Median 12 months (range 4 months to 4 years)	An 'excellent' correction (depth ≤0.51 cm) was achieved in 23 (20%) patients. A good correction was achieved in 19 (17%), with the remaining having a fair or poor outcome. Patient characteristics predictive of an excellent outcome included: - initial age ≤11 years (OR=3.3, p=0.013) - initial chest wall depth ≤1.5 cm (OR=4.6, p=0.003)

	Reference	Patients	Treatment protocol	Follow-up	Results
	USA	Initial depth of PE ranged from 0.6 cm to 5 cm			- chest wall flexibility (OR=14.8, p<0.001) - patients that used the VB over 12 consecutive months (OR=3.1, p=0.030) Patient characteristics not associated with improved outcomes included: - a symmetric PE (OR=3.3, p=0.075) - cup shape deformity (OR=1.8, p=0.339) - reported daily use over 60 minutes (OR=5.0, p=0.129) - higher suction pressure stage III or IV (OR=0.7, p=0.449).
6	St Louis *et al* (2019)[10] Retrospective review of medical records Canada	N=31 Age from 6 to 21 years (median=14 years) Median depth and HI at treatment onset were 2.3 cm and 3.9 cm	Median frequency of use was 7 days per week (range 4 to 7 days), and median daily wear time was 1.9 hours per day (range 0.4 to 5.5 hours)	Median 18 months (range 12 to 24 months)	25 patients showed improvement based on depth or HI measurement. The median depth prior to receiving therapy was measured to be 2.3 cm (range 1.3 to 3.5 cm), which decreased on aggregate by 0.5 cm (21.7%) with treatment. - linear regression models revealed a significant decrease in depth when patients used the VB for more than 2 hours per day (p<0.01) and 7 days per week (p<0.01) - univariate and multivariate analyses suggested that age of treatment onset had no significant association with depth change The median HI before treatment was 3.9 (range 2.9 to 6.1) and decreased by 0.3 on average at the latest follow-up. Univariate analysis demonstrated that the patients who started VB therapy after the age of 11 years had significantly less change in HI when compared with those who started under 10 (p<0.01).
7	Furuta *et al* (2020)[1] Retrospective review of medical records	N=15 (13 males and two females) Age range between 6	Initially used for 30 minutes a day, and this was increased by 30 minutes every week, until after a month of treatment	Not given in paper	Four patients were able to discontinue vacuum treatment within a year, with permanent improvement. Nine patients decided that the effect was insufficient and either continued treatment intermittently or discontinued treatment at their own discretion - two had moderately effective vacuum treatment, but they or their family were not satisfied and they underwent Nuss surgery

	Reference	Patients	Treatment protocol	Follow-up	Results
	Japan	and 17 years (mean=11.1 years) Split into two groups for analysis (G1 = preteenagers [<13 years], G2 = teenagers [≥13 years])	when patients used the device for 2 hours, once or twice a day		The depth of depression reduced in 93.3% of 15 patients (mean=8.7 mm). Minimal change occurred in the HI but the subcutaneous fat thickened significantly (11/15 patients). The improvement rate on elevation of the chest wall was better in G1 than G2 (54.0% versus 51.3%).
8	Alaca *et al* (2020) RCT China	N=26 (all male) Age 11 to 18 years	Group 1: patients used the VB 30 to 60 minutes twice a day for 12 weeks (n=13). Group 2: patients used the VB 30 to 60 minutes twice a day and attended a physiotherapy programme for 12 weeks (the details of this programme are included in the study) (n=13)	12 weeks of treatment	Sternal depression showed a statistically significant decrease from baseline in both groups (mean improvement was 6.66 mm in group 1 [p=0.04] and 12.86 mm in group 2 [p<0.001]), although the improvement in sternal depression was greater in group 2 (p=0.009). Anthropometric index values showed improvement in both groups, but better results were observed in group 2 than in group 1 (p<0.05). A number of other outcomes were included in the study. In short, modified percent depth and scores from the T3 region (distance between the most prominent point of the sternum and the spinous process of the vertebra at the same level) showed improvement only in group 2 (p<0.01), whereas severity of PE, the patient's perception of their PE and parental physiological quality-of-life scores improved in both groups (p<0.05). Posture, satisfaction with treatment and the patients' physiological quality-of-life scores were significantly better in group 2 (p<0.05).
9	Yi *et al* (2021)[13] Retrospective review of medical records	N=63 (61 males and two females) Age: mean 15.4 years	Basic VB protocols included 30-minute application twice a day. Patients were encouraged to extent duration or increase	12 months	Patients split into two groups according to the post-treatment changes in HI calculated using chest radiographs: those with changes in HI less than 0.5 (group 1) and those with greater than or equal to 0.5 (group 2). Expected improvements in thoracic indices and sternum depth were calculated from pre-treatment chest CT with and without VB devices.

	Reference	Patients	Treatment protocol	Follow-up	Results
	Republic of Korea	(95% Confidence Interval 8 to 45)	the number of times of application per day.		Both pre-treatment HI and depth of PE in group 2 were significantly higher than those in group 1 (p<0.001 and p=0.021, respectively): - HI 4.2 versus 3.1 (p<0.001) - depth 2.7 versus 2.3 (p=0.021) The expected improvement in HI in group 2 was significantly higher than that in group 1 (3.3 versus 2.8, p=0.001), which appeared to be correlated with post-treatment changes in HI after 1 year (0.93±0.400 versus 0.18±0.19). The expected depth of PE was significantly better in group 2 than in group 1 (9.3 versus 15.0, p=0.001) but post-treatment response demonstrated no statistically significant differences (0.66 versus 0.67, p=0.957). Age was not significantly associated with improvements in HI (p=0.233).
10	Jung *et al* (2021)[4] Retrospective review of medical records Republic of Korea	N=57 (52 males, five females) Mean age: 16.3±6.7 Group 1 (n=33): patients treated with VBT Group 2 (n=24): patients who underwent	A minimum of 30 minutes per application and a schedule of two applications daily were recommended for the initial treatment. This was increased to 2 hours per application and four applications per day depending on the patients' preferences.	1 year post treatment	The change between the pre-treatment HI as calculated from chest CT and the 1-year post-treatment HI was compared to validate the efficacy of both treatment modalities. The pre-treatment HI was significantly greater in group 2. Both groups showed no significant difference in the post-treatment HI immediately after treatment, and after 1 year of follow-up. - immediately after treatment: Group 1 HI=3.06±0.67; Group 2 HI=3.07±0.46; p=0.954 - 1-year post-treatment: Group 1 HI=3.01±0.62; Group 2 HI=2.88±0.78; p=0.473 The Nuss operation group showed a greater change in the HI than the VB group. - the average change in the HI immediately after commencement of treatment for both groups was 0.55±0.47 in group 1 and 1.18±0.85 in group 2 (p=0.03) - at 1-year post-treatment, the change in HI values were 0.58±0.49 and 1.31±0.56, respectively (p<0.01)

	Reference	Patients	Treatment protocol	Follow-up	Results
		the Nuss procedure			
11	Toselli *et al* (2022)[11] Retrospective review of medical records Argentina	N=186 (149 males, 37 females) Mean age 11.9 years (±6.5 years). Patients' correction was categorised as excellent, good, fair, poor or worse	The first 6 months are comprised of a gradual increase in the time and amount of negative pressure to be applied by the VB until the skin of the area of interest comes in contact with the glass of the cup (maximum suction). Following that, maximum vacuum is applied as much as possible.	24 months	In all patients treated with VBT: - complete correction was achieved by 31 (17%), while 83 (45%) remained under surveillance - failure rates were low (n=9; 5%) - withdrawal rates were 63 (34%) - 35% had excellent/good, 25% fair, and 40% poor/worse results When comparing patients with good/excellent results with those with unsatisfactory results, patients with good/excellent results had a longer treatment duration (mean 19.0 months versus 13.0 months, p<0.0001), and lower initial pectus depth (mean 1.6 cm versus 2.0 cm, p=0.001). No statistically significant difference was found for age (10 years versus 12 years, p=0.055). The best determinants of success were an initial pectus depth ≤1.8 cm and a length of treatment >12 months.
12	Luo *et al* (2022)[6] Retrospective review of medical records China	N=139 (87 males, 52 females) All patients aged less than 7 years Mean age of 4.6 (± 1.7) years	All patients were recommended to use the VB for a minimum of 30 minutes, twice daily or more, according to patients' preferences	Median 9 months	43 (30.9%) with a depth of less than 3 mm met the criteria to stop treatment and showed cosmetic results. The changes in depths (p<0.001) and depth ratio (p<0.001) were statistically significant in 55 patients with three or four follow-ups (only p-values provided). Multifactor logistic regression analysis showed that initial depth (OR=0.69, 95% CI 0.58 to 0.84, p<0.001) and treatment period (OR=1.58, 95% CI 1.23 to 2.04, p<0.001) were independent predictors of complete correction.
13	Prada Arias *et al* (2023)[8]	N=50 (41 males, nine females)	Patients were categorised into groups according to	Follow-up checks were	No significant differences among groups were observed in terms of baseline PE depth, thoracic index and final PE depth.

	Reference	Patients	Treatment protocol	Follow-up	Results
	Retrospective review of medical records Spain	Mean age of 12.5 years (range 10 to 14 years)	the daily hours of use (≤ 3 hours; 4 to 5 hours; ≥ 6 hours) and treatment duration (6 to 12 months; 13 to 24 months; 25 to 36 months; > 36 months), and they were statistically analysed.	made every 3 to 6 months	The reduction in PE depth (%, SD) was associated with the daily hours of use, with significant differences, p=0.01: - ≤ 3 hours: mean 14.99 (±31.12) - 4-5 hours: mean 17.49 (±30.48) - ≥ 6 hours: mean 45.51 (±17.7) The reduction in PE depth was not associated with treatment duration. Complications were mild. Three patients withdrew from follow-up, and five out of the 25 patients who completed treatment achieved a good repair.
14	Lei *et al* (2024)[5] Retrospective review of medical records China	N=72 (57 males and 15 females) Mean age of 11.0 years old, ranging from 3 to 24	For the first week, recommended use was 30 minutes twice a day, with the pressure controlled. By the fifth week, daily wear of 2.5 hour was recommended, with increases in the negative pressure. They also advised increased wear time/pressures for adults.	Follow-up period ranged from 1.1 to 4.4 years (mean 3.3 years)	For HI: - 18 patients (25.0%) showed excellent correction - 13 patients (18.1%) achieved good correction - four patients (5.6%) had fair correction. The remaining patients had a poor outcome. Characteristics predicting a non-poor prognosis included initial age ≤11 years (OR=3.94, p=0.013) and patients with use over 24 consecutive months (OR=3.95, p=0.013). No clear evidence of associations between a symmetric PE (OR=1.27, p=0.675), initial HI ≤3.5 (OR=1.32, p=0.619), and daily use time ≥150 min (OR=0.96, p=0.940) with improved outcomes. A total of nine patients (12.5%) achieved a correction index reduction below 10. Patients who started VB therapy at age >11 had significantly less change compared with those who started at age ≤11 (p<0.05). Complications included chest pain (5.6%), swollen skin (6.9%), chest tightness (1.4%) and erythema (15.3%).
15	van Braak *et al* (2024)[12] Retrospective review of medical records	N=259 (231 males, 28 females) Median age was 15 years	Patients were instructed to begin using the VB two to three times per day for 30 to 60 minutes, gradually	Median follow-up was 64.0 months (interquartile range 48.0 to 87.0)	At the time of analysis: - 18.9% (n=49) of patients were still being treated - 17.4% (n=45) were lost to follow-up - 63.7% (n=165) completed treatment, with a 52.1% (n=86/165) success rate.

	Reference	Patients	Treatment protocol	Follow-up	Results
	The Netherlands	(interquartile range was 13 to 16)	increasing the duration and the applied suction as tolerated. After 2 to 3 months, this centre also recommends overnight wear and during routine activities.		More time spent daily on VB therapy, total treatment duration, and overnight use led to a higher success rate (p=0.002, p<0.001, p<0.001 respectively). Complications (22.8%, n=59) were minor, recurrence occurred in 2.3% (n=2/86) of patients. Of the patients treated while awaiting a Nuss procedure, 26.7% (n=4/15) no longer required the Nuss procedure. Breast growth made 39.3% (n=11/28) of female patients quit treatment. Deeper PEs (p=0.02, p=0.009), flexible chest wall (p=0.007) and symptomatic PE (p=0.02) resulted in lower success rates. Clinical outcomes did not vary in comparing patients under the age of 10 (n=12), 11 (n=20), and 12 years (n=31) to those over the ages of 10, 11 and 12 years (p=0.72, p=0.65, p=0.23 respectively).

Safety

Treatment with the VB device is typically well-tolerated, and the side effects and complications reported in the literature do not appear to be permanent or severe. Side effects noted in the literature include chest wall pain, back pain, skin irritation, haematoma, upper extremity paraesthesia, petechiae, thickening/darkening of the skin and blistering.[1-13]

As the VB device is typically used to treat PE in children and young people, support and supervision by a parent or carer is required.

In NHSScotland, patients are required to attend a face-to-face appointment before being provided with the VB device to practice the application to ensure that the correct pressure is applied. The patients are then followed-up every 3 months to ensure that they are tolerating the device and that it is being used correctly. Parents or carers are advised that they should supervise the patient at home. The risks of skin break down are highlighted at the clinic and in the patient information sheet provided. Patients are also given contact details for the physiotherapy service should they have any concerns.

Patient and social aspects

What the literature tells us

We did not identify any literature that focused on patients' experiences of using the VB device.

To help address this evidence gap, any future studies should record how many people stop using the device before the treatment is complete, why they stop treatment and also document patients' positive experiences. Better understanding of the impact of patients' tolerance and motivation to continue using the devices would be beneficial.

What clinical experts told us

Clinical experts informed us that some people with a PE have no psychological or physiological consequences and so choose not to receive treatment. Some people with PE are affected psychologically, physiologically or both. Patients have different preferences, perceptions and experiences. For example, some people may be diagnosed with a 'mild' PE, but the impact on their psychological wellbeing is significant and so they are keen to explore treatment options. Other people may have more pronounced chest wall differences, but it does not impact on their life. Some people may want to treat their PE but want to explore non-surgical options.

A clinical expert suggested that there is a need for greater awareness of chest wall services among people with PE and primary care clinicians, including the availability of non-surgical treatment options.

What a patient organisation told us

In preparing this evidence review, we received a submission from a patient organisation, Pectus Matters, who provide information and support to people with chest wall differences and their families and carers throughout the UK. They explained how chest wall differences affect people's daily lives, emphasising that each individual's experience is unique. Some people are not affected, but for others, their chest wall difference causes them to become self-conscious and withdraw from activities that they would otherwise enjoy. For people with more pronounced PEs, the compression in the chest can impede normal functions such as walking, exercising and swallowing. The patient submission also described the impact on parents and carers, who may struggle to access timely care and support for their child.

In our patient submission questionnaire, we asked what patients and their carers wanted from the VB device. Pectus Matters told us that they want:

- the VB device to be readily available to children and young people for whom it is suitable, at an age where it is most likely to be effective
- a national database to be established which continually gathers data on the safety and effectiveness of the VB devices, and also on the optimal treatment protocol
- the VB device to be prescribed by an MDT, with regular follow-up and monitoring.

Their submission included a statement from two parents and a clinical expert. Both the parents had children with severe PEs, and expressed frustration that their child had not commenced treatment with the VB device when they were younger:

> *'The vacuum bell for us was life changing, we had been fighting since 2019 to prove that our son had a clinical need for pectus surgery and the vacuum bell helped us do this. On the day the vacuum bell was fitted, our son said for the first time he could breathe properly…We would have definitely been keen to use this device at a younger age in attempts to prevent his malformation from worsening.'*

> *'My 17 year old son was … finally offered a VB in October 2022 and started to use it with a great level of compliance. Unfortunately, in spite of having worn the VB for several hours each day over a period of 18 months, it has not helped to correct his chest. I do believe the VB may have helped him had he been diagnosed much sooner and received non-surgical treatment at the age of 10 or 11.'*

Their submission also noted concerns about PE being diagnosed too late in some people, at an age when the VB device may be less effective or when the PE has become too severe for conservative treatment to be an option.

The full submission from Pectus Matters is available on the SHTG website.

Cost effectiveness

Value proposition

The VB device may offer benefit for people with PE in two different ways.

1. Using a VB device could mean that a proportion of people with PE avoid surgical intervention. Surgical procedures are resource intensive and costly for the health service compared with use of a VB device.
2. Not all people with PE are eligible for, or choose, surgical intervention and instead are managed conservatively. Conservative management for PE patients does not alter the shape of the chest wall. For these people, the VB device may improve PE outcomes including their health-related quality of life (HRQoL) associated with body image and perceived ability to engage in activities.

Published economic evidence

Our literature search found no published economic evidence for the use of the VB device in PE.

SHTG cost analysis

Method

We estimated the costs associated with different PE management strategies in Scottish clinical practice using pathway and resource use information from the Scottish Chest Wall Service. Unit costs for these resources were sourced from the Public Health Scotland (PHS) Cost Book 2022/23,[23] the National Schedule of NHS Costs 2022/23[24] and the Personal Social Services Research Unit (PSSRU) Unit Costs of Health and Social Care 2023 Manual[25] (*Table 2*). The Scottish Chest Wall Service provided acquisition costs for the VB device.

Table 2: Unit costs for resources associated with PE management strategies

Item	Cost	Source
In-clinic physiotherapist led appointments (MDT, discharge following treatment with VB device and post-surgery follow-up)	£75	Specialist Allied Health Professional outpatient clinic–physiotherapist (PHS Cost Book 2022/23)
Surgeon time, per hour	£141	Hospital-based doctors–Consultant: surgical (PSSRU)
Band 5 physiotherapist, per hour	£39	Hospital-based scientific and professional staff (PSSRU)
Vacuum bell, per device	£480	Chest Wall Service

The clinical pathway for people with PE varied according to whether surgical intervention was under consideration or not. A patient's pathway is initiated by an in-clinic MDT appointment run by a physiotherapist at band 7. If a person is considered a potential candidate for surgery, a surgeon will also attend the MDT.

The chest wall service provided the cost of a VB device (£480). A device is likely to be used by two people before it becomes unusable because of degradation or damage. The average duration of treatment with the VB was estimated to be 12 months. During this time people are followed-up every 3 months by a physiotherapist at band 5 to review progress and provide support via video call. A final face-to-face discharge appointment follows VB treatment, where the device is returned and clinical photography and chest measurements are obtained. No further chest wall service input is required following successful VB treatment. For people who have successful VB treatment that was initiated with a surgical MDT, the estimated cost per patient in the pathway was £503; if the initial MDT was considering conservative management, then the estimated cost per patient in the pathway was £468 (*Table 3)*. Costs were not included for any subsequent PE management following treatment with the VB device, which could include a surgical procedure or further conservative management, due to insufficient data.

Following an initial MDT appointment, conservative management of PE consists of virtual appointments with a physiotherapist at band 5, quarterly for up to 18 months. The total estimated cost of conservative management was £192 per person (*Table 4*).

People who are eligible for surgical intervention can receive either the modified Ravitch procedure or the Nuss procedure. The Nuss procedure requires a follow-up surgical procedure to remove a bar inserted during the first procedure. Clinical experts validated the selection of proxy costs for each of these procedures from the Schedule of NHS Costs 2022/23. Costs included an inpatient stay following the procedure. Costs were also included for follow-up appointments. This meant that the estimated total costs for people receiving the modified Ravitch and Nuss procedures were £15,033 and £13,513 per person, respectively (*Table 5*). Costs are not included for surgical complications and so the estimated costs may be an underestimate of the true costs of the PE procedures.

Results

The estimated per person costs for treatment with a VB device (£468-£503) are higher than for conservative management (£192) but much lower than for surgical management with the modified Ravitch (£15,033) or the Nuss procedure (£13,513). These costs are estimates comparing first line treatment options.

Table 3: Vacuum bell costs

Item	Cost	Source
MDT conservative management, in-clinic, physiotherapist led	£75	Chest Wall Service, PHS Cost Book 2022/23

MDT surgical management, in-clinic, physiotherapist led plus 15 minutes surgeon time	£110	Chest Wall Service, PHS Cost Book 2022/23, PSSRU
Vacuum bell 2 uses per device	£240	Chest Wall Service
Follow-up appointments, virtual (30 minutes Band 5 physiotherapist time quarterly for 12 months)	£78	Chest Wall Service, PSSRU
Discharge appointment, in-clinic, physiotherapist led	£75	Chest Wall Service, PHS Cost Book 2022/23
Total, VB device for people considered for conservative management	**£468**	
Total, VB device for people considered for surgical management	**£503**	

Table 4: Standard of care costs, conservative management

Item	Cost	Source
MDT conservative management, in-clinic, physiotherapist led	£75	Chest Wall Service, PHS Cost Book 2022/23
Ongoing physiotherapy appointments, virtual (30 minutes of Band 5 physiotherapist time, quarterly for 18 months)	£117	Chest Wall Service, PSSRU
Total	**£192**	

Table 5: Standard of care costs, surgical management

Item		**Cost**	**Source**
MDT surgical management, in-clinic, physiotherapist led plus 15 minutes surgeon time		£110	Chest Wall Service, PHS Cost Book 2022/23, PSSRU
Modified Ravitch procedure			
Proxy for surgical procedure	DZ63D–Major Thoracic Procedures between 2 and 19 years	£14,486	Chest Wall Service, National Schedule of NHS Costs 2022/23

Follow-up appointments at 3 weeks, 3-months and 6-months in-clinic, physiotherapist led plus 30 minutes surgeon time		£437	Chest Wall Service, PHS Cost Book 2022/23, PSSRU
Total costs modified Ravitch procedure		**£15,033**	
Nuss procedure			
Proxy for first surgical procedure	DZ02L–Complex Thoracic Procedures, between 2 and 18 years	£11,685	Chest Wall Service, National Schedule of NHS Costs 2022/23
Proxy for bar removal procedure	DZ71Z–Minor Thoracic Procedures	£1,281	
Follow-up appointments at 3 weeks, 3-months and 6-months, in-clinic, physiotherapist led plus 30 minutes surgeon time		£437	Chest Wall Service, PHS Cost Book 2022/23, PSSRU
Total costs Nuss procedure		**£13,513**	

Limitations

It was not possible to conduct an economic evaluation of treatment with a VB device compared with PE management without the VB device because of a lack of evidence for key parameters.

Evidence of comparative clinical efficacy of the VB device compared with surgical or conservative management was absent. For an economic evaluation, these comparative data with VB are required for both populations separately (that is, those considered for surgery and those considered for conservative management) as the costs and consequences of routine clinical practice without the VB device are different in each group.

For example, in the surgical intervention group, people who have successful treatment with the VB device could avoid the health care resource costs and the negative HRQoL consequences (surgical complications) associated with a surgical intervention. People who have unsuccessful treatment with the VB device could incur costs associated with the VB device plus surgical costs. The proportion of people who could have treatment with a VB and then no longer require surgery in Scottish clinical practice is unknown. It is also uncertain whether successful treatment with the VB device, in terms of not requiring a subsequent surgical procedure, delivers similar outcomes for people with PE as a surgical procedure.

In the population considered for conservative management, patients who have unsuccessful treatment with a VB device may incur some additional costs of conservative management in addition to the costs of treatment with VB device. As treatment with the VB device is likely to be more costly than conservative management, the value of the device to patients and the service depends on the

extent of the health and HRQoL benefits for people treated with the VB device compared with conservative management.

Discussion

The current evidence base consists mainly of retrospective reviews of medical records. We did not identify any prospective studies that compared treatment with the VB device to surgery or to no specific therapy. The studies we found were heterogeneous and prone to bias. As well as the studies being small and retrospective, patients self-reported their daily wear time, and in most only people who completed the treatment were included in the final analyses. It is also not clear from most of the studies if the treatment benefits that are reported are maintained in the longer term. Despite the lack of higher-quality studies, the collective evidence indicates that there are some people with a PE who can benefit from treatment with a VB device.

There was a lack of economic evidence for the VB device. As a result of a lack of clinical effectiveness evidence and health-related quality-of-life data we were only able to estimate first line treatment costs for the VB device and the alternatives, conservative management and surgery. The cost of treatment with a VB device was higher than for conservative management but it may be cost effective if the comparative health benefits are sufficient. Treatment with the VB device is far lower than the cost of both surgical options available to people with PE. If some people avoid surgery for their PE, then the VB device may offer significant resource savings for the management of this group of patients in NHSScotland.

With regard to patient selection criteria, the evidence suggests that a younger age at treatment onset (approximately ≤11 years) and a flexible chest wall may be associated with successful treatment outcomes. Given that the chest wall is known to become less pliable with age, this may be the reason younger people have better treatment outcomes. We also found some studies that reported that a smaller pre-treatment chest wall depth was associated with improved outcomes, although the evidence we identified was not fully consistent.

Asymmetry is often quoted as being related to less successful treatment outcomes with the VB device, although we did not find evidence to support this. One study included three patients with an asymmetric PE, and treatment with the VB device reduced the chest wall depth but the asymmetry was still visible at the end of the treatment. It is possible that for some people with an asymmetrical PE, the VB device would be unable to adhere properly to the chest wall, which would render the treatment ineffective.

For wear time, most studies suggested a minimum use of 30 minutes twice a day, but several recommended that participants gradually increase their wear time and number of applications every day, with none detailing an upper limit. In the studies, the reported wear times varied widely between participants. We found some evidence that greater improvements are seen in people who wear the VB device for longer periods of time. However, the optimal daily wear time cannot be determined from the current literature, and it is likely to differ depending on the age of the patient and the nature of their PE. Younger patients (aged ≤11 years) may only require, and tolerate, shorter

daily wear times. It is also noteworthy that two studies did not find evidence of improved outcomes with longer wear times (>60 minutes and >150 minutes), with one reporting that successful treatment outcomes were observed in several people who chose to wear the VB device for less than 60 minutes per day.

For duration of treatment, the first few months seem to be the most decisive regarding PE correction, but the exact time of discontinuation is yet to be defined.[18] We found two studies which suggested that use of the VB device should last at least 12 months, and another two studies reporting 24 months. However, as with wear time, the optimal total duration of treatment is likely to vary according to the age of the patient and the nature of the PE. Older patients may need to use the device for longer periods of time, and improvements may be observed in younger patients who use the VB device for shorter treatment durations. Based on their expert opinion and experience of prescribing the VB device, Haecker *et al* (2016) suggest that 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 to 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 to 36 months, with careful and close monitoring.[26]

The success of treatment with the VB device is dependent on patient acceptance of the treatment, and continued motivation to use it as prescribed. We identified studies which reported that over 30% of people withdrew from treatment with the VB device, or were lost to follow-up. Further exploration of the factors that determine patient acceptance and continued use of the VB device could help inform patient selection criteria. One of our peer reviewers noted, that in their experience, parental and family support was an important factor in patients' continued motivation to use the VB device.

One study reported that the reduction in chest wall depth was the result of the thickening of the subcutaneous adipose tissue where the VB device was applied, and not of changes to the bones or cartilage.[1] This finding was not reported in the other studies, and it has been challenged because of limitations with the study (including a very small sample size and unclear description of the treatment protocol).[27] However, it warrants investigation in future research. A proper understanding of how the VB device works is important, as it may imply that the device should only be offered to patients for whom the appearance of the chest wall is impacting their psychological wellbeing, rather than for patients who have reduced cardiac and lung capacity.

Finally, most of the participants in the included studies were male. As it stands, the evidence does not suggest any difference in improvement in chest wall depth with the use of the VB device between the genders. One study noted that breast growth made 39.3% (n=11/28) of female participants quit treatment. The authors proposed that breast growth makes it harder to use the VB device, but also that for some people the development of breasts masks the PE.

Conclusion

The current body of evidence indicates that the VB device may be effective and safe for selected patients with PE. The evidence base is limited, but as it stands, it suggests that treatment is most

likely to be successful in people who have a mild PE, who have a chest wall depth (<1.5 cm), who are younger (age <11 years), who have a flexible chest wall, who wear the VB for longer periods during the day, and who use the device for at least 12 to 24 consecutive months.

Further research is required so that standardised treatment protocols and patient selection criteria can be developed. Further evidence is required before the cost effectiveness of the VB device in people with PE can be established. The cost of first line treatment with the VB device was higher than for conservative management but lower than the options for surgical management.

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Appendix: Definitions

Haller Index (HI): A ratio of thoracic width and height, measured from an axial computed tomography (CT) image and used to describe the internal dimensions of the thoracic cage. A normal HI would be 2 or less, and a significant PE would be greater than 3.25.[28]