Pectus Excavatum and Poland's Syndrome Surgical Correction AHM

Clinical Indications for Procedure

- Surgical treatment for severe pectus excavatum deformities that cause functional deficit are considered medically necessary when **ALL** of the following criteria are met

    - Documentation of complications arising from the sternal deformity. Complications include but may not be limited to **1 or more** of the following
        - Asthma
        - Atypical chest pain
        - Cardiopulmonary impairment documented by respiratory and/or cardiac function tests
        - Exercise limitation
        - Frequent lower respiratory tract infections
    - An electrocardiogram or echocardiogram has been done if a heart murmur or known heart disease is present to define the relationship of the cardiac problem to the sternal deformity
    - CT scan of the chest demonstrates a pectus index, derived from dividing the transverse diameter of the chest by the anterior-posterior diameter, greater than 3.25.
    - Surgical reconstruction of musculoskeletal chest wall deformities associated with Poland's syndrome that cause functional deficit medically necessary - See Breast Reconstruction AHM Guideline
    - Bracing and surgical procedures to correct pectus carinatum cosmetic because this deformity does not cause physiologic disturbances from compression of the heart or lungs
- Current role remains uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology. See Inappropriate Uses for more detailed analysis of the evidence base. The following interventions for the treatment of pectus excavatum are considered experimental and investigational because their effectiveness has not been established.
    - The magnetic mini-mover procedure
    - The vacuum bell

- Dynamic Compression System

Evidence Summary

Background

- Pectus excavatum is often a cosmetic defect, but it may have varied anatomic and symptomatic presentations. There is no conclusive evidence supporting the existence of a functional component whose physiological basis can be consistently defined. Until recently, the indications for surgery in patients with pectus excavatum were based solely on clinical judgment because the extensive literature on pectus excavatum demonstrates that there is a discordance between patients' subjective assessment of shortness of breath and objective measures of cardiorespiratory function. In more recent years, the judgment of when to proceed with surgery has been made more objective by following the pectus index criteria advocated by Haller for surgical intervention. CT scans used in patients being evaluated for surgery document more clearly the severity of the foreshortening of the anteroposterior diameter of the chest, the degree of cardiac compression and displacement, the degree of lung compression and other unexpected problems. It clarifies the need for operation by showing the dramatic internal morbidity of what is often portrayed as a "cosmetic" deformity.
- As originally described by Sir Alfred Poland, Poland's Syndrome consists of absence or hypoplasia of the pectoralis major and minor muscles, hypoplasia or absence of nipple and breast, hypoplasia of subcutaneous fat, absence of axillary hair, and partial absence of the upper costal cartilages and portions of ribs, usually the second, third, and fourth. The absence of the sternal head of the pectoralis major muscle is considered the minimal expression of this syndrome (Wilhelmi & Cornette, 2002). Brachysyndactyly, ectrodactyly, and ectromelia are frequently described associations.
- In children with very severe deformity, staged procedures involving split rib grafts from the contralateral side combined with Teflon felt or Marlex mesh have been advocated. This results in a stable chest wall, abolition of paradoxical movement, and protection of the subjacent viscera. In the absence of the pectoralis major and with deficient breast and subcutaneous tissue, the chest is still visibly asymmetric. As soon as the asymmetry becomes a problem for the adolescent female patient, a round tissue expander can be placed beneath the pectoralis muscle and hypoplastic breast through a transaxillary incision, to avoid scars on the breast itself. The prosthesis is then inflated at appropriate intervals to maintain symmetry until development of the opposite breast stabilizes, at

which time the expander can be replaced with a prosthetic mammary implant or an autologous soft-tissue transfer using pedicled myocutaneous flap

- Schier et al (2005) described their experience in using a vacuum to pull the abnormal chest wall outward in patients with PE. A suction cup was used to create a vacuum at the chest wall. A patient-activated hand pump was used to reduce pressure up to 15 % below atmospheric pressure (atm). The device was used by 60 patients (56 males and 4 females), aged 6.1 to 34.9 years (median of 14.8 years), for a minimum of 30 mins, twice-daily, up to 5 hours per day (median of 90 mins). Patient progress was documented using photography, radiography, and plaster casts of the defect. In 14 children this method was used during the Nuss procedure to enlarge the retrosternal space for safer passage of the introducer. Follow-up occurred between 2 and 18 months (median of 10 months). Computed tomographic scans showed that the device lifted the sternum and ribs within 1 to 2 mins; this was confirmed thoracoscopically during the Nuss procedure.
- The suction cup enlarged the retrosternal space for safer passage of the introducer. Initially, the sternum sank back after few minutes. After 1 month, an elevation of 1 cm was noted in 85 % of the patients. After 5 months, the sternum was lifted to a normal level in 12 patients (20 %) when evaluated immediately after using the suction cup. All patients exhibited moderate subcutaneous hematoma, although the skin was not injured. One patient suffered from transient paresthesis in the right arm and leg; 2 patients experienced orthostatic disturbances during the first application of the suction cup. There were no other complications. In patients with PE, application of a vacuum effectively pulled the depressed anterior chest wall forward.
- The initial results proved dramatic, although it is not yet known how much time is required for long-term correction. The authors concluded that this vacuum method holds promise as a valuable adjunct treatment in both surgical and non-surgical correction of PE.
- Haecker and Mayr (2006) examined the benefits of conservative treatment of patients with PE by means of the vacuum bell. A suction cup is used to create a vacuum at the anterior chest wall. A patient-activated hand pump is used to reduce the pressure up to 15 % below atm. Three different sizes of vacuum bell exist that were selected according to the individual patient's age. When creating the vacuum, the lift of the sternum was obvious and remained for a different time period. The device should be used for a minimum of 30 mins (twice-daily), and may be used up to a maximum of several hours daily. Presently, a 12- to 15-month course of treatment is recommended. In addition, the device was used intra-operatively during the minimally invasive repair (MIRPE) procedure to enlarge the retrosternal space to ensure safer passage of the introducer in a few patients.
- A total of 34 patients (31 males and 3 females), aged 6 to 52 years (median of 17.8 years) used the vacuum bell for 1 to maximum 18 months (median of 10.4 months). Follow-up

included photography and clinical examination every 3 months. Computed tomographic scans showed that the device lifted the sternum and ribs immediately. In addition, this was confirmed thoracoscopically during the MIRPE procedure. After 3 months, an elevation of more than 1.5 cm was documented in 27 patients (79 %). After 12 months, the sternum was lifted to a normal level in 5 patients (14.7 %). Relevant side effects were not noted. The authors concluded that the vacuum bell has proved to be an alternative therapeutic option in selected patients with PE. Moreover, they stated that while the initial results proved to be dramatic, long-term results are so far lacking, and further evaluation and follow-up studies are necessary.

- Haecker (2011) provided additional data on the 2006 trial by Haecker and Mayr; but the conclusion remained unchanged. A total of 133 patients (110 males and 23 females) aged from 3 to 61 years (median of 16.21 years) used the vacuum bell for 1 to a maximum of 36 months. Computed tomographic scans showed that the device lifted the sternum and ribs immediately. In addition, this was confirmed thoracoscopically during the MIRPE procedure. A total of 105 patients showed a permanent lift of the sternum for more than 1 cm after 3 months of daily application; 13 patients stopped the application and underwent MIRPE. Relevant side effects were not noted. The authors concluded that the vacuum bell has proved to be an alternative therapeutic option in selected patients suffering from PE. The initial results proved to be dramatic, but long-term results are so far lacking, and further evaluation and follow-up studies are necessary.
- Harrison et al (2007) noted that correction of PE results in measurable improvement in lung capacity and cardiac performance as well as improved appearance and self-image. The Nuss and modified Ravitch approaches attempt to correct the chest wall deformity by forcing the sternum forward in 1-step and holding it in place using a metal strut. The initial operation requires extensive manipulation under general anesthesia and results in post-operative pain, requiring hospitalization and regional anesthesia. Pain and disability may last for weeks. Both procedures are expensive. A better principle would be a gradual bit-by-bit repair via small increments of pressure applied over many months. These researchers developed the magnetic mini-mover procedure (3MP) and applied this strategy to correct PE. The procedure uses magnetic force to pull the sternum forward.
- An internal magnet implanted on the sternum and an external magnet in a non-obtrusive custom-fitted anterior chest wall orthosis produce an adjustable outward force on the sternum. Outward force is maintained until the abnormal costal cartilages are remodeled and the pectus deformity is corrected. These investigators implanted a magnet in human skeletons and measured the force applied to the sternum when the distance between the internal and external magnets was varied in increments. With the 2 magnets 1 cm apart, the outward force was adequate to move the sternum at least 1 cm. They also mapped the magnetic field in the 2-magnet configuration and found that maximum field strengths at the surface of the heart and at the outer surface of the orthosis were at safe levels.

- The authors concluded that the 3MP allows correction of PE by applying magnetic force over a period of months. Crucial questions raised during the design, re-design, and simulation testing have been satisfactorily answered, and the authors have received a Food and Drug Administration (FDA) Investigation Device Exemption (G050196/A002) to proceed with a phase I to II clinical trial.
- Harrison et al (2012) performed a pilot study of safety, probable efficacy, and cost-effectiveness of 3MP. A total of 10 otherwise healthy patients, aged 8 to 14 years, with severe pectus excavatum (pectus severity index [PSI] greater than 3.5) underwent 3MP treatment (mean of 18.8 +/- 2.5 months). Safety was assessed by post-implant and post-explant electrocardiograms and monthly chest x-rays. Efficacy was assessed by change in pectus severity index as measured using pre-treatment and post-treatment computed tomographic scan. Cost of 3MP was compared with that of standard procedures. The 3MP device had no detectable ill effect. Device weld failure or mal-positioning required revision in 5 patients. Average wear time was 16 hrs/day.
- Pectus severity index improved in patients in the early or mid-puberty but not in patients with non-compliant chest walls. Average cost for 3MP was $46,859, compared with $81,206 and $81,022 for Nuss and Ravitch, respectively. The authors concluded that the 3MP is a safe, cost-effective, outpatient alternative treatment for pectus excavatum that achieves good results for patients in early and mid-puberty stages.
- Ji and Luan (2012) reviewed the current development in therapy of congenital funnel chest. The main therapies for congenital funnel chest are thoracoplasty (Ravitch sternum elevation procedure and minimal invasive Nuss procedure) and prosthesis implantation. The magnetic mini-mover procedure and the vacuum bell are still in the research phase.
- An UpToDate review on "Pectus excavatum: Treatment" (Mayer, 2013) states that "Currently, surgical correction for PE is done with either the modified Ravitch procedure (open resection of the subperichondrial cartilage and sternal osteotomy, with placement of an internal stabilizing device), or the Nuss procedure (minimally invasive technique in which a curved bar is inserted to lift the sternum; the bar is removed about two years later)".
- An UpToDate review on "Pectus carinatum" (Nuchtern and Mayer, 2014) states that "In more than 90 percent of patients, pectus carinatum deformity is first noted during early adolescence, and it often worsens dramatically during the adolescent growth spurt. The defect does not resolve spontaneously. The vast majority of patients have no physiologic symptoms, and cosmetic appearance is the primary concern ....The decision of whether to treat depends on the severity of the defect, and the patient and family's level of concern".

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Footnotes

[A] See Clinical Indications for Procedure in this guideline. [A in Context Link 1]

[B] In patients without air leak, chest tubes may be managed with water seal instead of suction. [B in Context Link 1]

[C] See Intensive, Intermediate, and Telemetry Care Guidelines [C in Context Link 1]

[D] Chest tubes may be discontinued if there is no air leak and drainage is 450 mL per day or less. [D in Context Link 1]

[E] Stable chest x-ray shows expected postoperative changes without pneumothorax, evidence of new infection, or other complications. [E in Context Link 1]

[F] Use oral or parenteral pain medication as needed. [F in Context Link 1]

[G] Patient is either afebrile or at the expected temperature related to the process being diagnosed. [G in Context Link 1]

[H] Chest tubes may be discontinued if there is no air leak and drainage is 450 mL per day or less. [H in Context Link 1]

[I] Discharge planning may be done as part of Outpatient Care Planning, initial Hospital Care Planning, or in preparation for hospital discharge. [I in Context Link 1]

[J] Treating providers may include thoracic surgeon, pulmonologist, oncologist, and radiation oncologist. [J in Context Link 1]

Codes

CPT® or HCPCS: 11960, 11970, 11971, 19340, 19342, 19357, 19361, 19364, 19366, 19367, 19368, 19369, 20900, 20902, 21740, 21742, 21743