



Clinical Commissioning Policy Proposition: Surgical correction for pectus deformity (all ages)

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**Clinical Commissioning Policy Proposition:
Surgical correction for pectus deformity (all ages)**

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Plain Language Summary

This policy proposition aims to confirm NHS England's commissioning approach to surgical correction for pectus deformity.

Pectus deformities are a relatively common developmental problem affecting approximately 1 in every 400 people in the UK, predominantly teenagers and young adults, but also smaller children. It affects boys more than girls with a ratio of 3:1 with the deformity often becoming apparent during puberty. There are two basic types of pectus deformity - pectus excavatum (PE), or "funnel chest", and pectus carinatum (PC), or "pigeon chest". PE is more common. Whilst for the majority of people the deformity will be minimal, in moderate and severe cases it can be associated with psychological distress leading to withdrawal, social isolation and concerns about appearance.

Pectus surgery is the surgical correction of the deformity. Two surgical procedures have been assessed as part of the evidence review to inform this policy, these are: Nuss (minimally invasive repair of pectus excavatum – MIRPE) and Ravitch (open surgery).

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of surgical correction for pectus deformity.

1. Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission surgical correction for pectus deformity.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether surgical correction for pectus deformity will be routinely commissioned is planned to be made by NHS England by June 2016 following a recommendation from the Clinical Priorities Advisory Group.

2. The proposed intervention and clinical indication

Pectus abnormalities cover a range of deformities affecting the anterior thorax, specifically the sternum and adjacent rib cartilages. The incidence is less than 10 per 1,000 population, with the vast majority of patients being affected to only a very minor degree.

Pectus abnormalities arise due to an unevenness of the growth of the chest wall and are therefore commonest in teenagers and young adults, but can also affect children. It is more common in males. There are two main types of deformity – pectus excavatum and pectus carinatum, the former being the commoner of the two. Typically they are isolated deformities but they are sometimes associated with other musculoskeletal or connective tissue abnormalities such as scoliosis, Poland's syndrome and Marfan's syndrome. They can be familial.

Most pectus deformities become apparent in the first decade of life but are often not noticed until the adolescent growth spurt. If not corrected, the deformity is permanent.

There are currently a number of surgical and non surgical techniques available and individuals with a pectus deformity may be referred to a thoracic surgical clinic for advice. Based on NHS Secondary Users Services data, it is estimated that approximately 380 pectus surgery operations are performed by the NHS in England each year.

This policy considers the evidence for two surgical procedures used to correct pectus deformity - Nuss (minimally invasive repair of pectus excavatum – MIRPE) and Ravitch. The Nuss procedure is generally only applicable in pectus excavatum whilst the Ravitch procedure can be used for both pectus excavatum and pectus carinatum.

3. Definitions

Pectus deformities are a relatively common developmental problem principally affecting teenagers and young adults, but also smaller children.

Pectus excavatum (PE) is a congenital abnormality in the growth of the costal cartilages and results in a depressed sternum and a hollowed out or sunken appearance of the chest wall. There are many types of PE described but typically it can be mild, moderate or severe depending on the depth of depression of the sternum. PE may be simple or complex (mixed), symmetrical or asymmetrical.

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Pectus carinatum (PC) is a congenital abnormality of the growth of the costal cartilages resulting in a protruding sternum. There are many types of PC described, but again it is typically mild, moderate or severe in relation to the degree of protrusion of the sternum. PC may be simple or complex (mixed), symmetrical or asymmetrical.

Pectus surgery is the surgical correction of the deformity.

Nuss procedure (minimally invasive repair of pectus excavatum – MIRPE): This “keyhole surgery” procedure involves placing one or two curved steel bars inside the patient’s chest behind the sternum, forcing it back into a more normal shape. The bars are left in place for several years and are then removed with a second operation. The Nuss procedure is generally only applicable in pectus excavatum. It involves small incisions at the side of the patient’s chest and avoid the necessity for a scar at the front.

Ravitch procedure: This is an open operation suitable for both PE and PC. It is carried out through an incision at the front of the patient’s chest. Cuts are made in the rib cartilages on each side and on the sternum to allow correction of the deformity. For PE, some form of support is usually required to support the sternum once it has been brought forward. This used to involve insertion of a metal bar (which would necessitate a second operation for removal) but nowadays a mesh is more likely to be used. Ravitch procedures can be used for any pectus abnormality including pectus carinatum and the more complex deformities.

4. Aim and objectives

This policy aims to define NHS England's commissioning position on surgical correction for pectus deformity.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for adults and children with pectus chest deformities.

5. Epidemiology and needs assessment

In the UK approximately 1 in every 400 people will have a pectus deformity. It affects boys more than girls with a ratio of 3:1. The deformity often becomes apparent during pubertal growth spurts.

Based on NHS Secondary Users Services data, it is estimated that approximately 380 pectus surgery operations are performed by the NHS in England each year.

6. Evidence base

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of surgical correction for pectus deformity .

The evidence review of surgical correction of pectus excavatum using the Nuss procedure (minimally invasive repair of pectus excavatum) or the Ravitch/modified Ravitch procedure (open thoracic surgery) was undertaken with a view to answer the following research questions:

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- Is there evidence that surgical correction improves cardiorespiratory reserve and functionality for the patient?
- Is there evidence that surgeon volume impacts on the outcomes of surgery (infection and revision rates)?
- What is the evidence in terms of quality, safety and adverse events associated with surgical correction?
- Is there evidence relating to eligibility and thresholds for surgery?

In summary, the current body of clinical evidence is largely limited to case series and reports. As such, the systematic reviews and meta-analysis of these observational studies are at risk of significant bias and confounding. Most studies do not attempt to address statistical heterogeneity between studies or take into account surgical skill variations amongst individual surgeons, between centres and over time. The absence of a standardised measure/scale to weigh clinical benefits (physical, psychological and quality of life) against the significant morbidity caused by the procedures presents a challenge to any conclusion regarding benefits of the intervention.

Cardiorespiratory reserve, functional and physical outcomes:

Johnson et al, 2014 found no linkage between ages of operative treatment with outcomes. There was no clear difference in outcomes between the Nuss and Ravitch populations across all age groups, but slightly better outcomes in the Nuss paediatric group as compared to all other groups. Nasr et al, 2010 found no difference in patient satisfaction between both techniques among studies looking at this outcome. A meta-analysis of 2476 cases (1555 Nuss, 921 open surgery) from 23 international studies (Chen et al, 2012) reported more improvement in physiological measures of lung function with the Nuss procedure compared to open surgery, with best results 3 years after surgery. Authors also reported that cardiovascular function after surgery improved by greater than one-half standard deviation. However, no supporting analysis was included in the publication. This meta-analysis was powered to compare physiological pulmonary function change by type of pectus procedure performed and time after surgery. None of the studies had a healthy (non-pectus) or no-intervention comparator arm or linked the physiological lung function with clinical presentation (dyspnoea, chest pain, exercise intolerance) pre- and post-surgery. Hence, it cannot be used to draw an inference on the clinical effectiveness of pectus procedure on lung function. Authors also reported that cardiovascular function after surgery improved by greater than one-half standard deviation. However, no supporting analysis was included in the publication. Other large case series (Kelly et al, 2013. Žganjer et al, 2011) report positive improvement of chest wall in varying degrees as well as improvement in pulmonary function. Most studies report 80-90% good to excellent anatomic surgical outcomes. Given the limitations in the study design, the overall evidence in this category needs to be viewed with caution.

Outcomes of surgery (infection and revision rates):

There were no studies that directly compared the impact of surgeon volume and outcomes of surgery. In a retrospective review of all primary Nuss procedure repairs of pectus excavatum performed in a one large US centre over 21 years, complications decreased markedly over 21 years since surgery was first offered in the centre. Bar displacement rate requiring surgical repositioning decreased from 12% in the first decade to 1% in the second

decade (Kelly et al, 2010). This provides a limited view of the impact of surgical experience and patient volume on outcomes.

Quality, safety and adverse events associated with surgical correction:

NICE guidance in 2009 (IPG310; 2009) concluded that current evidence on the safety and efficacy of placement of pectus bar for pectus excavatum (also known as MIRPE or the Nuss procedure) is adequate to support its use provided that normal arrangements are in place for clinical governance, consent and audit. It confirmed that placement of pectus bars for pectus excavatum should be carried out only by surgeons with cardiac and thoracic training and experience, who are capable of managing cardiac or liver injury, and where there are facilities for this. The procedure should be carried out only by surgeons with specific training in inserting the device, and they should perform their initial procedures with an experienced mentor. The efficacy and safety of the procedure was based on data from a UK register for 260 patients and multiple case series, small surveys and expert opinion.

The systematic literature review did not find any randomised control trials or high quality meta analysis that could further update the comparative efficacy of different types of surgeries or provide a comparison with a no-intervention group. The best available evidence comes from a systematic review of 39 studies involving 807 adult and 2716 paediatric cases (Johnson et al, 2014) which focused on comparison of the Ravitch, Nuss, and other surgical treatments for pectus excavatum across age groups. The analysis showed that complication rates varied across studies however Nuss and Ravitch procedures were generally safe for paediatric and adult patients with no perioperative mortality reported. Re-operation rates in adults were highest for implant procedures at 18.8% followed by Nuss 5.3% and Ravitch 3.3% but there was no significant difference in re-operation rates in children. Nasr et al, 2010 found that there was no significant difference in overall complication rates between both techniques in the nine studies included in the meta-analysis. Looking at specific complications, postoperative pneumothorax and hemothorax, the rate of reoperation because of bar migration or persistent deformity was significantly higher in the Nuss group. Most case series identified major and minor complications related with the surgery ranging from allergy to nickel (Nuss bars), pneumothorax, hemothorax and pericardial tears in perioperative period to bar displacement and asymmetrical corrections that required re-operations.

Eligibility and thresholds for surgery:

Leading US centres report inclusion criteria for surgery as severe pectus excavatum that fulfils two or more of the following: CT index greater than 3.25, evidence of cardiac or pulmonary compression on CT or echocardiogram, mitral valve prolapse, arrhythmia, or restrictive lung disease (Kelly et al, 2007. Kelly et al, 2010).

Self-perception has been identified as an important element in decision making in pectus surgery. There is significant body image dysmorphia and poor co-relation between objective physiological and perceived impact (mental quality of life and self-esteem) in patients with pectus deformities (Steinman et al, 2011). This highlights the role of psychological evaluation in patient selection and possible need for counselling and management of expectations for patients with exaggerated dysmorphic tendencies.

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Evidence indicates that median age for pectus surgery is increasing, with many surgeries in patients above the age of 18 years without any significant difference in outcomes amongst the younger and older patients. (Johnson et al, 2014. Kelly et al, 2010)

7. Documents which have informed this policy

NICE interventional procedure guidance [IPG310], August 2009

8. Date of review

This document will lapse upon publication by NHS England of a commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by June 2016).