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Change in cardiorespiratory parameters following surgical correction of pectus excavatum: protocol for the historical-prospective HeartSoar cohort

Carey Meredith Suehs ,1 Nicolas Molinari,2 A Bourdin ,3 Laurence Solovei4

1 Respiratory Diseases, Medical Information, Univ Montpellier, Centre Hospitalier Régional Universitaire de Montpellier, Montpellier, France

2 Medical Information, IMAG; CNRS, Univ Montpellier, Centre Hospitalier Régional Universitaire de Montpellier, Montpellier, France

3 Respiratory Diseases, PhyMedExp, CNRS, INSERM, Univ Montpellier, Centre Hospitalier Régional Universitaire de Montpellier, Montpellier, France

4 Thoracic Surgery, Univ Montpellier, Centre Hospitalier Régional Universitaire de Montpellier, Montpellier, France

Correspondence to

Dr Carey Meredith Suehs; careysuehs@protonmail.com

ABSTRACT

Introduction

How cardiorespiratory function changes following the surgical correction of pectus excavatum (PE) often gives mixed results, with meta-analyses demonstrating no benefit in terms of pulmonary function but improvement in cardiac function. Functional responses may depend on type of surgery, follow-up time and/or the patient's presurgical functional status, and debate persists on the purely aesthetic nature of such surgery. The aim of this protocol is to analyse data describing lung function and incremental exercise testing before vs after the surgical correction of PE.

Methods and analysis

A historical-prospective before–after surgical correction of PE cohort will be constituted. Historical inclusions are recruited during follow-up visits at approximately 12, 24, 36 or 48 months following a prior surgery (with presurgical data mined from patient records). Prospective inclusions are recruited during presurgical work-ups and followed for 1 year following surgery. The data collected include spirometry, incremental exercise testing, body mass index, body composition, questionnaires targeting general health status, self-esteem and body image. Any complications due to surgery are also described.

The primary outcome is oxygen pulse during incremental exercise testing, and 44 data points are required to demonstrate a moderate postsurgical change (ie, a Cohen's effect of $d=0.5$). Wilcoxon signed-rank tests or t-tests for paired data will be used for before–after comparisons (with false discovery rate corrections for secondary analyses).

Ethics and dissemination

This study will be conducted according to the principles of the Declaration of Helsinki (as revised in 2013) and was approved by a randomly assigned, independent, ethics committee (Comité de Protection des Personnes Sud-Méditerranée II, reference number: 218 B21) as per French law on 6 July 2018. Informed, written consent for study participation is required of all study candidates prior to enrolment. Results will be published in an international peer-reviewed journal.

Trial registration number NCT03770390; Clinicaltrials. gov.

INTRODUCTION

One of the aetiologies retained to explain congenital malformations of the chondrosternal plastron is the abnormal development of the costal cartilages,¹ resulting in a projection of the sternal body backwards, as in pectus excavatum (PE), or forwards, as in pectus carinatum. PE is by far the most common congenital chest defect, found in 1/250 adults.² The repercussions of these malformations have been traditionally considered as aesthetic in nature with a significant psychosocial impact.^{3–5} In fact, avoidance behaviours are observed in 80% of cases, which can lead to not only a disabling social withdrawal but also a reduction in physical activity and subsequent sedentary lifestyle.³

Following surgical correction of PE, meta-analyses initially suggested no change in resting pulmonary function⁶ but significant improvement in cardiovascular parameters.⁷ Subsequently, pulmonary function results were found to differ in meta-analyses according to the type of procedure performed, with forced expiratory volume in one second improvements found after bar removal in association with minimally invasive surgical techniques as compared with open Ravitch procedures.⁸ However, the latter was associated with improved stroke volume during incremental exercise testing, while minimally invasive techniques were not.⁸ Finally, meta-regression indicates that improvements in lung function following minimally invasive procedures are time dependent,⁹ thus requiring multiyear follow-up to correctly document changes.

During a first observational study carried out on patients with PE operated on at the Arnaud de Villeneuve University Hospital in Montpellier between December 2009 and July 2016 (NCT03086499), we were able to identify three distinct functional groups among PE patients consulting for surgery: (1) mostly normal function, (2) primarily lung dysfunction and (3) reduced exercise capacity. The aim of the present study is to supplement the previous results by measuring the effects of surgical intervention on the cardiorespiratory function of operated patients, along with parameters associated with quality of life.

Study objectives

The primary objective of the HeartSoar study is to evaluate the gain in cardiorespiratory function before versus after the surgical correction of PE. Secondly, we will also address surgical complications, changes in BMI, self-esteem and quality of life after surgery. Interactions between outcomes and (1) type of surgery, (2) length of follow-up and/or (3) functional group will be evaluated. Finally, in a subset of patients, the feasibility of per-operative, continuous, finger-cuff monitoring of a battery of haemodynamic variables will be assessed.

METHODS AND ANALYSIS

Study design

HeartSoar is a historical-prospective, single-centre, surgical cohort study evaluating the effect of routine surgical correction of PE with retrosternal bar implantation on cardiorespiratory function, body mass index (BMI) and composition, quality of life and self-image. A within-patient before–after design (figure 1A) will be used to detect correction-induced changes in parameters derived from exercise testing, spirometry, body composition and three validated self-questionnaires. Due to the relative rarity of PE operations in general, inclusions will occur either during routine postoperative yearly check-ups for previously operated, ‘historical-prospective’ PE patients or during routine preoperative consults for prospective patients (figure 1B). For the latter subset of patients, an ancillary study describing and exploring the evolution of haemodynamic parameters during surgery is also foreseen.

Public and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Study setting and population

This study takes place at the Arnaud de Villeneuve Hospital within the University Hospitals of Montpellier system, Montpellier, France. PE patients at least 14 years of age who previously underwent or who now require corrective surgery and meeting the eligibility criteria stipulated in table 1 will be included. The single-payer national health insurance programme in France ensures that patients are likely to represent a large range of socioeconomic and urban versus rural backgrounds. Included patients will be followed for approximately 12, 24, 36 or 48 months depending on the historical or prospective nature of the inclusion (see figure 1).

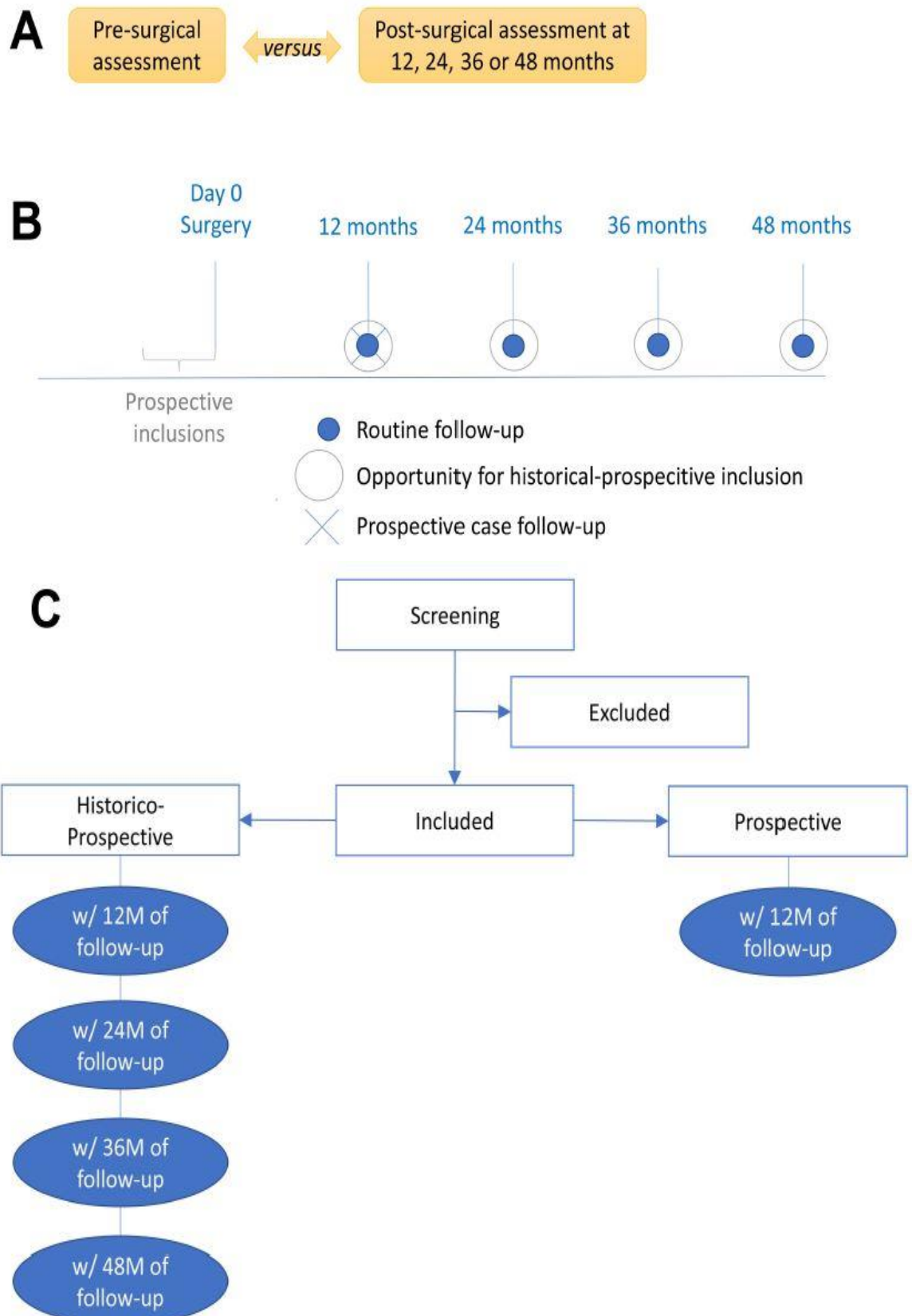


Figure 1 Graphic presentation of the HeartSoar study design. (A) Before-after design will be deployed, comparing pre-surgical to post-surgical assessments. (B) Due to the relatively limited patient pool, inclusions can be prospective or historical-prospective in nature. Prospective inclusions have a routine follow-up visit at 12 months. Routine visits occurring within 48 months of surgery also present opportunities for historical-prospective inclusions. (C) The expected study flowchart.

Characterising the population

The following preoperative data are collected in order to describe the study population: age, sex, follow-up time (months), four measures of deformation severity or type (the Haller and correction indices, as well as the percentage auto-correction, and the CHIN classification) and the presence/absence of the following: (1) family antecedents of pectus (none, excavatum, carinatum, arcuatum), (2) scoliosis, (3) Marfanoid syndrome, (4) patient-reported dyspnoea on effort, (5) patient-reported palpitations, (6) patient-reported pain, (7) patient-reported psychosocial impact. We additionally characterised the position of the patient's heart as (a) compressed between the sternum and spine, (b) displaced to the left or (c) normal. Finally, baseline functional status (ie, mostly normal function, primarily lung dysfunction or reduced (exercise capacity) will be given. The latter is determined according to a classification algorithm as determined in NCT03086499.

Characterising surgery

Surgical corrections are performed as a mini-invasive or open technique, depending on the needs of each patient.

Mini-invasive surgical techniques

Mini-invasive techniques for PE corrections were first described by Donald Nuss in 1988.¹⁰ This technique consists in correcting the deformation using one or two (rarely three) intrathoracic, surgical steel bars placed in a retrosternal position during video-thoracoscopy. The stress applied by the bar(s) to the sternum makes it possible to correct the deformation by projecting the sternum forward and thwarting its position downwards. The bars are later removed, usually 3 years after surgery. The optimal age for bar placement is towards the end of puberty, so that bar removal corresponds to the end of growth, which is thought to minimise recurrence of the malformation. The term 'mini-invasive' is used in opposition to 'open' surgical techniques.

Open surgical techniques

Open surgery for PE correction dates back to the 1940s, and today are referred to as modified Ravitch sterno-chondropasty. The surgical approach is a bi-submammary incision. The technique consists in partially and electively resecting the pathological cartilages, generally the third to seventh. Transverse osteotomies are performed at the level of the sternum in order to correctly reposition the latter, which is further supported by the placement of a retrosternal steel bar. This time, the bar is removed at 6 months during a short hospitalisation.

Recorded data

The following surgical data will be recorded: the type of intervention (mini-invasive vs open), the operative time in minutes, the number of bars required, the estimated blood loss (mL), the length of hospital stay (days).

Table 1 Eligibility criteria for the HeartSoar study

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> ▶ Patient with pectus excavatum (PE) ▶ Minimum age of 14 years ▶ The patient underwent corrective surgery within 4 years of enrolment and is scheduled for a follow-up visit—OR—the patient is scheduled for corrective surgery during the inclusion period ▶ Collection of informed written consent* ▶ Patient covered by the French single-payer health insurance programme 	<ul style="list-style-type: none"> ▶ Impossibility for the patient to participate in his/her next annual follow-up visit ▶ Absence of exercise test data and respiratory function test data performed during the preoperative check-up ▶ Subject in exclusion period required by another protocol ▶ Pregnant or lactating woman, patient unable to give consent, protected adult, vulnerable persons† ▶ Subject deprived of liberty by judicial or administrative decision ▶ Participation of the subject in another interventional protocol ▶ Failure to properly inform the patient (eg, a language barrier)
<p>*Patient and legal guardian, if applicable. †According to French Health Code articles L.1121-6, L.1121-7, L.1211-8, L.1211-9.</p>	

Assessments and outcomes

An overview of outcomes is provided in [table 2](#). The primary outcome is the maximum oxygen pulse (O₂-pulse; ml O₂/heartbeat) during incremental exercise testing. How the outcome-generating assessments were conducted are described in the following paragraphs. Data were prospectively recorded or recovered from patient files according to the type of inclusion.

Incremental exercise testing

Incremental exercise testing is performed on a stationary bicycle (Ergometrics 900, Ergo-line, Germany) according to the American Thoracic Society/American College of Chest Physicians statement.¹¹ The patient's theoretical maximum power is first calculated according to age, sex and BMI. The test then starts with a 3 min warm-up period at 20% of maximum power. Subsequently, power is incremented, according to the physician's discretion, every minute until volitional fatigue. Derived variables, as listed in [table 2](#), were either prospectively recorded or recovered from the patient's file.

Lung volumes and function

Plethysmography (Body Box; Medisoft, Dinant, Belgium) and spirometry are carried out according to current recommendations^{12–14} and used to provide lung volume and function parameters in both litres and % predicted values, as listed in [table 2](#).

Haemodynamic variation during surgery

A limited number (convenience sampling) of prospectively included patients will be monitored during surgery via the ClearSight system for non-invasive monitoring (Edwards Lifesciences). The latter uses a finger cuff to record several haemodynamic variables (as listed in [table 2](#)) in a continuous fashion: mean arterial pressure, cardiac output, cardiac index, stroke volume, stroke volume indexed to body surface area and stroke volume variation.

Table 2 The HeartSoar outcomes with units and planned time frame and analysis type

Patient-specific measure	Units	Planned time frames and analysis type
Incremental exercise testing		
Maximum oxygen consumption (VO ₂ max)	ml/kg/min and %predicted	BVA—CCTPD
Maximum heart rate (MHR)	beats per minute (bpm)	BVA—CCTPD
*O ₂ pulse = VO ₂ max/MHR	ml O ₂ /beat	BVA—CCTPD
Anomaly in O2 pulse according to physician	yes/no	BVA—CDPD
Ventilatory threshold (VT: the point at which ventilation rate increases faster than VO ₂)	% VO ₂ max	BVA—CCTPD
Breathing reserve (% of maximal voluntary ventilation)	% of maximal voluntary ventilation	BVA—CCTPD
Lung volumes and function		
Functional residual capacity (FRC)	litres (L) and % predicted	BVA—CCTPD
Residual volume (RV)	litres (L) and % predicted	BVA—CCTPD
Total lung capacity (TLC)	litres (L) and % predicted	BVA—CCTPD
RV/TLC	% L/L	BVA—CCTPD
Forced expiratory volume in 1 s (FEV1)	litres (L) and % predicted	BVA—CCTPD
Forced vital capacity (FVC)	litres (L) and % predicted	BVA—CCTPD
FEV1/FVC	% L/L	BVA—CCTPD
Haemodynamic variation during surgery		
Mean arterial pressure	mmHg	BAR—CCTPD
Cardiac output	L/min	BAR—CCTPD
Cardiac index	L/min/m ²	BAR—CCTPD
Stroke volume	ml/b	BAR—CCTPD
Stroke volume indexed to body surface area	ml/b/m ²	BAR—CCTPD
Stroke volume variation	%	BAR—CCTPD
Symptoms		
Patient-reported dyspnoea on effort	Presence/absence	BVA—CDPD
Patient-reported palpitations	Presence/absence	BVA—CDPD
Patient-reported pain	Presence/absence	BVA—CDPD
Patient-reported psychosocial impact	Presence/absence	BVA—CDPD
BMI, body composition and weight intentions		
Body mass index (BMI)	kg/m ²	BVA—CCTPD
Percentage lean mass (PLM)	%	BVA—CCTPD
Percentage fat mass (PFM)	%	BVA—CCTPD
Patient ranking of the following statements: ▶ 'I would like to lose weight' ▶ 'I would like to gain weight' ▶ 'I would like to gain muscle mass' ▶ 'I am dieting in order to lose weight' ▶ "I eat a lot in the hope of gaining weight" ▶ 'I eat a lot in the hope of gaining muscle mass' ▶ 'I can't eat enough to gain weight/muscle mass'	Likert score ranging from 1 to 5	BVA - CCTPD
Questionnaires		
Short Form 36 (SF-36)	Score	BVA—CCTPD
Rosenberg Self Esteem Scale (RSES)	Score	BVA—CCTPD
Body Esteem Scale (BES)	Score	BVA—CCTPD
Harms		
Per- and post-operative complications	Presence/absence	Descriptive

*The primary endpoint.

BAR, per-operative changes in haemodynamics before vs after bar placement; BVA, before vs after pectus excavatum correction; baseline vs 1, 2 3 or 4 years (± 3 months) after surgery; CCTPD, comparison of central tendency for paired data; CDPD, comparison of distributions for paired data.

BMI, body composition and weight intentions

Height and weight measurements were recovered from patient files or recorded for BMI calculations. Additionally, body composition was measured using an OMRON BF-511 weight scale. The patients were also asked to use a 5-point likert scale (completely true, somewhat true, I don't know, somewhat untrue and completely untrue) to rank the following seven statements: (1) I would like to lose weight, (2) I would like to gain weight, (3) I would like to gain muscle mass, (4) I am dieting in order to lose weight, (5) I eat a lot in the hope of gaining weight, (6) I eat a lot in the hope of gaining muscle mass and (7) I can't eat enough to gain weight/muscle mass.

Questionnaires

Three validated questionnaires will be administered to patients: (1) general health status and quality of life will be assessed using the Short Form 36^{15 16}, (2) the Rosenberg Self Esteem Scale will be used to assess general aspects of self-esteem¹⁷ and (3) attitudes and feelings regarding the body and appearance will be captured using the Body Esteem Scale.^{18 19}

Complications

The presence/absence of the following complications were recorded at the preoperative and postoperative time frames: bar shift, rotation or reaction; displacement or breakage of stabilisers/wires, pneumothorax, pneumothorax >20%, pneumothorax with chest tube, haemothorax, stitch abscess, skin rash, pneumonia, atelectasis, pleural effusion, pleural effusion and thoracenteses, recurrence of PE, infection, ileus/severe constipation, readmission, pulmonary embolism, urinary tract infection, urinary retention (and catheterisation), bleeding requiring transfusion, reoperation for bleeding, respiratory insufficiency requiring oxygen support for >48 hour, persistent pain after day 30 requiring step 3 pain control, other complications with precisions. The postoperative date at which complications appeared was also recorded.

Sample size

According to data collected in a previous study (NCT03086499), we are expecting a presurgical O₂-pulse at around 13.2±3.4 mL O₂/min. In order to detect a moderate effect size associated with surgical PE correction (ie, a Cohen's effect size of d=0.5, corresponding to a postoperative change in O₂ pulse of 1.5±3 mL O₂/min) with a type 1 error rate set at $\alpha=0.05$ and power at 90% (type 2 error: $\beta=0.10$), 44 data points would be required. In order to allow for a large loss to follow-up (this rather young population can be hard to follow), we propose including 70 patients.

Logistics

The practical deployment of this study is based on the routine pathways of patients coming in for postsurgical check-ups (historical prospective cases) or for presurgical assessments (prospective cases). To this end, upcoming consultation lists within the department were systematically screened for potential candidates. All consecutive patients were targeted to avoid recruitment bias. Candidates were proposed study participation and appropriate consent

procedures during their next consult. An overview of the study visits and associated assessments is presented in [table 3](#).

Table 3 The visits and assessments occurring during the HeartSoar study			
Visit:	Preoperative consult	Surgery	Postoperative follow-up
Timeframe	-4 to -1 months	Day 0	A single visit at 12, 24, 36 or 48 months (± 3 months)
Historical-prospective inclusions			
Verification of eligibility criteria			●
Consent procedures			●
Prospective inclusion with a single visit at 12 months			
Verification of eligibility criteria	●		
Consent procedures	●		
Intervention evaluated via the before-after design			
Surgical correction of pectus excavatum		●*	
Assessments/data recording			
Baseline data recording	●*		
Incremental exercise testing	●*		●
Lung volumes and function	●*		●
BMI, body composition and weight intentions	●*		●
Questionnaires (SF-36, RSES, BES)	●†		●
Surgical data recording		●*	
Haemodynamic variation during surgery		●†	
Complications		●*	●
*For historical-prospective inclusions, these data are recovered in as much as possible from patient files.			
†Prospective inclusions only.			
BES, Body Esteem Scale; BMI, body mass index; RSES, Rosenberg Self Esteem Scale; SF-36, Short Form 36.			

Historical-prospective inclusions

Only one visit, a routine postoperative consult, is required for historical-prospective inclusions ([table 3](#)). These routine visits are performed annually at the participating hospital and may occur at approximately 12, 24, 36 or 48 months after surgery, with generous leeway (± 3 months). During this visit, the study will be proposed to the patient, and consent procedures are implemented if he/she is interested in participating. In addition to the recovery of baseline data, assessments are performed in line with [table 3](#), namely, incremental exercise testing, pulmonary volumes and function, BMI, body fat percentage and quality-of-life/ self-esteem questionnaires.

Prospective inclusions

Patients in this group have not yet had corrective surgery and are invited to participate in the study during their presurgical work-up, which will include the assessments listed in [table 3](#). Patients will then follow a routine pathway, with a postsurgical follow-up visit at 1 year following surgery. The data recovered enable a before– after evaluation of the effect of surgical correction of PE on variables issuing from key HeartSoar assessments, namely, incremental exercise testing, pulmonary volumes and function, BMI, body composition and quality-of-life/self-esteem questionnaires.

Potentially missing data

Given differences between medical staff in how they chart, the historical-prospective nature of this study and potential loss-to-follow-up, we are expecting missing data. This missingness will be clearly described for all variables in the final paper. Our general goal in the before-versus-after design is to not replace or impute missing data but simply work with those data available.

Statistical analysis plan

The study flowchart, documenting the numbers of patients screened, included, and followed-up will be presented according to [figure 1C](#). Loss to follow-up will also be indicated. Descriptive statistics will be presented as numbers and percentages for qualitative variables, means±SD for normally distributed (according to Shapiro-Wilkes tests) quantitative variables or as medians with their IQRs for other quantitative variables.

Comparisons of central tendency for paired quantitative data

Tests appropriate for paired quantitative data (paired t-tests or paired Wilcoxon's signed rank tests according to variable distributions) will be used to evaluate the effects of surgery on the various outcomes, as indicated in [table 2](#). A false discovery rate correction will be applied to secondary variables.

Comparison of distributions for paired qualitative data

The McNemar test for paired qualitative data will be used to compare distributions before versus after surgery as indicated in [table 2](#). The false discovery rate correction again applies to these secondary variables.

Important cofactors

Baseline functional status (mostly normal function, primarily lung dysfunction or reduced exercise capacity), type of surgery, whether or not bars were in place during post-surgical assessments, and the duration of follow-up are likely to impact results. Interactions between outcomes and these variables will be tested.

Ancillary study

Finally, the ancillary data will be analysed in a similar fashion as a separate feasibility study.

Study time frames and status

The first inclusion in the HeartSoar study took place on 10 December 2018. Inclusions halted during the COVID-19 pandemic, which also caused delays in follow-up visits. At the time of submission of this manuscript, inclusions are still ongoing, and the study is expected to end in June 2023. Data analysis is expected to start in July 2023.

ETHICS AND DISSEMINATION

Ethics oversight

This study will be conducted according to the principles of the Declaration of Helsinki (as revised in 2013) and was approved by a randomly assigned, independent, ethics committee (Comité de Protection des Personnes Sud-Méditerranée II, reference number: 218 B21) as per French law on 6 July 2018. Informed, written consent for study participation is required of all study candidates prior to enrolment.

De-identifying data

The only identifying data allowed in the study-specific data collection tools are patient first and last initials and year of birth. Otherwise, patients are differentiated by an assigned anonymous study number only.

Data entry and quality verifications

Data are entered into a Microsoft Access database created specifically for this study. Data quality verifications are performed on database extractions by sponsor clinical research associates at key times throughout the study (beginning, annually, and at the end of the study).

Monitoring study conduct

Study monitors deployed by the sponsor will audit the study at regular intervals (at study kick-off, once per year during the study and the end of the study). The aim is to verify that consent procedures and protocol content are respected according to internal quality procedures. Monitoring visits result in a detailed traceability report.

Dissemination

The study results will be published in an international peer-reviewed journal.

Twitter

Carey Meredith Suehs @SuehsCarey

Contributors

CMS and LS wrote the first draft of the manuscript. NM gave important statistical input and corrections. CMS, LS, NM and AB give important intellectual input and corrections. All authors approved the final version of the manuscript.

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Competing interests

AB reports grants, personal fees, non-financial support and other from Astra Zeneca, grants, personal fees and other from GSK, grants, personal fees, non-financial support and other from Boeringher Ingelheim, personal fees, non-financial support and other from Novartis, personal fees and other from Teva, personal fees and other from Regeneron, personal fees, non-financial support and other from Chiesi Farmaceutics, personal fees, non-financial support and other from Actelion, other from Gilead, personal fees and non-financial support from Roche, outside the submitted work. CMS reports a previous unrelated grant and personal fees from Astra Zeneca. NM reports personal fees from Astra Zeneca and an unrelated grant from GSK. LS has no conflicts of interest to declare.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication

Not applicable.

Provenance and peer review

Not commissioned; externally peer reviewed.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ HeartSoar will prospectively confirm changes in incremental exercise test parameters and lung function before versus after surgical correction of pectus excavatum.
- ⇒ Interactions between change in function and type of surgery, length of follow-up and baseline functional status will be evaluated.
- ⇒ Per-operative monitoring of cardiac output using a non-invasive finger-cuff device will provide novel data at the time of bar placement.
- ⇒ The limitations of this study include its single-centre, observational nature.
- ⇒ Exhaustive patient list screening is used to minimise potential recruitment bias.

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