Minimally Invasive Repair of Pectus Excavatum

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Chapter 4

Correlation baseline State anxiety and pain after pectus excavatum correction

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Under review

Abstract

Introduction

A major concern in the early post-operative phase after correction of pectus excavatum is pain. Most studies only focus on pain management in the first days after surgery and describe methods to alleviate the pain immediately post-operatively. The severity of post-operative pain may be influenced by anxiety. So far, few studies have looked into the relation between anxiety and post-operative pain after pectus excavatum correction.

The aim of this study was to investigate the correlation between pre-operative anxiety and late post-operative pain scores.

Materials and Methods

Prospective cohort study. Anxiety was assessed with the State and Trait Anxiety Inventory questionnaire. Visual analogue pain score assessed pain at rest and on activity. Anxiety was measured before surgery and pain scores 6 weeks post-surgery. A hierarchical linear regressions analysis was performed to investigate the correlation between baseline anxiety and pain measurements 6 weeks after surgery.

Results

136 patients were included. State anxiety was not associated with post-operative pain (mean of pain on activity and in rest), only with pain on activity after 6 weeks. Age and sex were no effect modifiers in any of the models. Relevant confounding factors, although not significant, were encountered as trait, sex, minor complications, epidural duration, major complications and number of stabilizer plates. The explained variance of state anxiety on visual analogue pain scores after 6 weeks was minimal.

Conclusion

Pre-operative anxiety does not appear to influence post-operative pain after thoracic wall deformity correction.

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Introduction

The most important anterior chest wall deformity is the pectus excavatum (PE). It predominantly affects males. The prevalence of PE is about 1 in 400 [1]. The most important complaints are cosmetic and shortness of breath during exercise. The NUSS surgical procedure is reported to give good cosmetic results [2]. In addition studies reporting physical improvement after correction are increasing in number [3].

Pain is an important problem after any kind of surgery, but especially thoracic surgery may be very painful [4]. In surgical correction of PE with a NUSS-bar the indentation of the sternum is corrected with implanting a steel bar underneath the sternum and the required new position of the sternum is immediately achieved. When explaining the procedure to patients the surgeon often refers to braces for crooked teeth, however the remodeling of the teeth often takes years whereas in PE correction the remodeling is done in seconds. And the pain is accordingly.

In the literature, most studies only focus on pain management in the first days after surgery [5]. In these studies pain was a significant problem for many patients possibly impacting on satisfaction with the results [6]. It may thus be worthwhile to influence pain and pain sensation in these patients in order to improve the satisfaction with the results of surgery.

It is known that the level of experienced pain is influenced by a number of factors such as depression, stress, anxiety, pain catastrophizing, and insomnia [7,8]. Patients are informed about the severe post-operative pain that may occur, and this may induce anxiety. However, so far few studies have looked into the relation between baseline anxiety and post-operative pain in pectus excavatum patients. This study assesses the relationship between anxiety and pain in patients with a planned surgical correction of a pectus excavatum.

Methods

Study design

Participants were recruited from three academic hospitals and one large general hospital in the Netherlands. Patients 12 years of age and older with a pectus excavatum scheduled for surgical correction of a PE were eligible for inclusion in this study. The exclusion criteria were poor proficiency in the Dutch language and prior chest wall surgery. For the current study participants were asked to complete questionnaires before surgery (T1) and 6 weeks (T2) after surgery. The pre-operative questionnaire was completed during the last outpatient clinic visit prior to surgery. Post-operative questionnaires were sent to the patients on the predefined follow up moment. If no direct response was received a reminder by either mail or telephone was used.

Questionnaires used were a demographic questionnaire, the STAI questionnaire to assess anxiety and the VAS score to measure experienced pain.

The demographic questionnaire asked about age, sex, social habits, school and/or work, family history, and sports activities.

The Dutch validated short version of the State and Trait Anxiety Inventory (STAI) was used. Items were scored on a four point Likert scale and subsequently these scores were added up. Scores of STAI state can vary between 6 and 24 with a higher score indicating more anxiety. The resulting score can either be used as total score or dichotomized in high or not-high, with cut-off scores derived from the manual. The short versions have good reliability and validity [9].

Pain in rest and during activity post-operatively was measured with a 100 mm Visual Analogue Scale (VAS), with anchors at 100 mm (worst pain imaginable) and 0 mm (no pain at all) [10].

In addition to the questionnaires the medical records of the participants were checked for duration of surgery, type of procedure, type of pain medication used and duration of pain medication taken both in hospital and after discharge. Furthermore, postoperative morbidity was registered. This was defined as surgical complications occurring within 6 weeks after the operation. These complications were divided into major and minor complications. Major complications comprised early recurrence of the pectus within 6 weeks, wound

infection, hematoma for which re-do surgery was required, pneumonia and bar dislocation. Minor complications comprised urinary catheter infections, pneumothorax and seroma. These data were obtained from the database in which the surgical complications are consistently registered. Since all these perioperative factors may influence the relation between the level of preoperative anxiety and pain at the 6 weeks measurement, they were considered possible confounders. Age and sex were also deemed possible effect modifiers.

Statistical procedure

The focus of this study was on the relationship between preoperative anxiety (STAI-state (T1)) and postoperative pain (VAS pain (T2)) after 6 weeks, both continuous variables. A hierarchical linear regressions analysis was performed. The mean VAS score was calculated from the VAS score in rest and the VAS score during activity for any individual patient.

Categorical variables are presented as numbers (percentage). Continuous variables with a normal distribution are described with mean ± standard deviation. Two tailed p-value below 0.05 was considered statistically significant in all analyses.

Analysis Plan

IBM SPSS Statistics 23 was used for all statistical analyses. First of all, the data were checked for erroneous values and missing data. Respondents with relevant missing data were not encountered in this study group. To answer the hypotheses hierarchical regression analyses were used.

In model 1 the 'crude' effect of State anxiety (X) on the primary outcome variable mean VAS pain score after 6 weeks was viewed. In model 2 A the possible influence of the effect modifiers sex and age were assessed with interaction terms. The peri-operative confounders (type of pain medication, duration of pain medication) and of confounders such as STAI Trait and number of stabilizer plates used, number of bars used, major or minor complications on the relationship between X and mean VAS pain score after 6 weeks (Y) was assessed in model 2B. Model 3 repeated analyses in a patient group without postoperative complications. Model 4 consisted of two submodels 4A and 4B. It was a repeat analysis with VAS pain score at rest respectively VAS pain score on activity after 6 weeks as the dependent variables instead of the mean VAS pain score. Relevant confounding was defined as a 10% change in regression coefficient (B). Effect modification was defined as a significant value ($p<0.05$) of the regression coefficient of the interaction term.

Sample size calculation
The size of the study population was based on a conservative estimate for the effect of state anxiety on postoperative pain scores after 6 weeks. Previous studies have shown a very high percentage of patients with high levels of direct operative pain. In the literature a difference in mean VAS score of 14 mm is considered as the minimal clinically importance difference (MCID)[11].

Based on the above sample size calculation was performed using G*Power 3.1 [12]. The effect size of 0.15 with a Power of 0.8, significance level of 0.05 and number of predictions 10, requires a total sample size of 118. With an expected 5% drop-out rate, at least 127 participants needed to be included.

Results

One hundred thirty six patients participated in the multicenter cohort study. There were 121 male and 15 female participants. The median age was 16 years (range 12-22 years). Fifteen patients received more than one Nuss bar during operation. The number of placed Nuss bars depends on the per-operative correction of the pectus excavatum. If residual pectus excavatum exists after the first bar placement a second bar is placed behind the sternum and fixed onto the chest wall (ribs). Stabilizer plates are used to prevent rotation of the bar by blocking rotation through support on the ribs. One hundred and seven patients had one stabilizer plate implanted, 29 had two stabilizer plates. The number of patients who suffered one or more complication was 26 (19%). Major complications were seen in 9 persons (7%). Baseline characteristics and results are shown in Table 1.

Relationship state anxiety and VAS score after 6 weeks (the models)
In model 1 the crude analysis between state anxiety and mean VAS pain scores 6 weeks postoperative shows a non-significant relation (B 0.08, 95% BI -0.02-0.17, p-value 0.11). The direct analysis reports an R-square(R^2) of 0.02. This shows that a very small part (2 percent) of the variance in the mean VAS pain score is contributed to state anxiety.

In model 2 we explored the possible effect modification caused by sex and age by adding them to the regression model. The interaction term of state anxiety-sex and the interaction term state anxiety-age showed respectively a p-value of 0.65 and 0.44. Which means that neither sex nor age as an interaction term had

a significant influence on the relation between state anxiety and mean VAS pain score at 6 weeks. The model 2A adjusted for both (demographic factors) sex and age showed a p-value of 0.28). The adjusted model 2B with confounders (see table 2) did not lead to significance, even more the regression coefficient turned negative showing an inverted effect of state anxiety on mean VAS pain score after 6 weeks. (B -0.02, 95%BI -0.14 – 0.10, p-value 0.76). The R-square was 0.10 meaning that a little more than 10% of variance in mean VAS pain score after 6 weeks was explained by the combined factors in the adjusted model 2.

Table 1. Patients clinical characteristics and peri-operative results

Variables	
Age (years)	16 (12-22)
Males	121 (89%)
Pre-operative Questionnaires	
STAI state	11.2 ± 3.3
STAI trait	16.3 ± 4.9
Per-operative	
Nuss bars one versus two implants	121(89%)
Stabilizer plate one versus two implants	107(79%)
Postoperative	
Major complications	9 (6.6%)
Minor complications	17(12.5%)
Total complications	26(19,1%)
Epidural use/duration (in days)	3.5 ± 1.3
Oral pain medication (in hospital in days)	5.9 ± 1.7
Pain scores postoperative 6 weeks	
Mean VAS pain score	24 ± 19
VAS pain score in rest	18 ± 19
VAS pain score in activity	29 ± 21

Categorical variables are presented as numbers, continuous variables as mean ± standard deviation. Age is presented as mean with range.

In model 3 we explored the group of patients who did not suffer a complication. This group of patients should in theory have a smaller physical impact on their bodies and therefore less inflammation and less pain. The same hierarchical regression analyses as in model 2 was performed. The relationship between state

anxiety and VAS pain score after 6 weeks in patients without complications was not significant. The R square was 0.03 showing that there was little explained variance in this crude analysis. Interaction terms for sex or age were both not significant. The definitive model 3 was adjusted for proven confounders sex and epidural and did neither reach significants (p-value 0.17).

For analysis of the components of the mean VAS pain score after 6 weeks, a separate regression analysis was performed for dependent variable VAS pain score 6 weeks in rest (model 4A) and VAS pain score 6 weeks in activity (model 4B).

The relationship between state anxiety and VAS pain score after 6 weeks in rest was just as the relationship with the mean VAS pain score not significant (p-value 0.51). Testing of the interaction terms showed no significance. Adjusted model 4 A for confounders neither showed significance (p-value 0.22).

In model 4B the relationship between pre-operative state anxiety and dependent variable VAS pain score in activity after 6 weeks gave a p-value of 0.024, making it significant (B 0.13, 95% BI 0.02 – 0.23). This (crude) model did not show a more than explained variance of the VAS pain score in activity of 3.8%. The interaction terms and the adjusted model with confounders were not significant.

The results of the analyses of the 'crude' and adjusted models are summarized in Table 2.

Table 2. Results model analyses

	B	95% BI	p-value
Model 1 crude	0.08	-0.02 – 0.17	0.11
Model 2A adjusted for demographic factors (sex and age)	0.05	-0.04 – 0.15	0.28
Model 2B adjusted for trait anxiety, sex, minor complications, epidural duration, major complications, number stabilizer plates	-0.02	-0.146 – 0.10	0.76
Model 3 crude	0.09	-0.01 – 0.197	0.07
Model 3 adjusted for sex, epidural duration	0.07	-0.03 – 0.17	0.17
Model 4A crude	0.03	-0.06 – 0.13	0.51
Model 4A adjusted for sex, trait anxiety, minor complications, epidural duration	0.07	-0.19 – 0.04	0.22
Model 4B crude	0.13	0.02 – 0.23	0.02
Model 4B adjusted for trait anxiety, sex, minor complications	0.04	-0.10 – 0.17	0.56

B represents the regression coefficient. BI represents the confidence intervals. A p-value below 0.05 was considered statistically significant.

Discussion

In the current study the relationship between state anxiety measured pre-operatively and VAS pain scores 6 weeks post-operatively was assessed. In this study this relationship was not significant for the mean VAS pain score and the VAS pain score in rest and the 'crude' analysis influence of state anxiety on the variance in mean VAS pain scores after 6 weeks was 2.9% maximum. Evaluation of potential confounders showed there was a non-significant confounding effect from total score trait anxiety, sex, minor complications, duration epidural, major complications and number of stabilizer plates in model 2. Despite the significant finding of the crude analysis of the dependent variable VAS pain score in activity, the reported average VAS pain score after 6 weeks was below 3 in all three groups (activity, rest, mean). Furthermore the explained variance was just 3.8%.

In other diagnoses the relationship between anxiety and pain has been studied as well [13-20]. These studies report different results. Explained variance in pain scores postoperatively varied between 10 and 22 % [15]. However, other studies showed a definite relationship in a univariate analysis, but adding measurements such as the STAI did not change the relationship [16]. Furthermore, anxiety was a strong predictor of pain medication used both in-hospital as after discharge [14,17].

One important difference between the current study and the aforementioned studies is the age of the patients. With regard to age there seemed to be a different impact on anxiety depending on age and pain [18]. In this study the patients were predominantly adolescents whereas in the other studies only adults are included. It may be that other factors than anxiety influence pain experience in adolescents. There is literature to suggest that female patients are less capable of coping with pain and also a gender difference exists towards anxiety [19]. However, literature on this subject is scarce. What is known is that adolescents may be more inclined to pain catastrophizing [20] and thus experience more pain without this being reflected in scores on state anxiety. Patients do receive extended information about the procedure and the resulting post-operative pain. This may either lead to catastrophizing with resulting higher pain experience [8] or may lead to better handling of the pain due to better preparation [7]. Although this last phenomenon is especially studied in cancer patients and patients with chronic pain, pain education may very well have the same effect in other patient groups. Another important factor is that the pain is scored 6 weeks after the surgical procedure. After discharge from the hospital patients receive a booklet with daily restrictions for the first 6 weeks. These restrictions include no sports activities, no lifting of heavy objects, and sleeping in supine position. It may be that once patients are allowed to mobilize fully the relationship between state anxiety and pain changes. It is known that anxiety may lead to more self-imposed restrictions in daily activities [21].

Limitations

Limitations of the study could be the study population who was derived from different hospitals. Although the surgical procedure and peri-operative policies are similar for the whole group, the amount of inflicted damage to tissue during surgery and dynamic pain management may have had effect on pain outcome scores.

Conclusion

There is no significant relation between anxiety measured with STAI state pre-operative and mean VAS pain scores or VAS pain scores in rest after 6 weeks. However, there is a significant relationship between state anxiety pre-operative and VAS pain score in activity 6 weeks post-operatively in a surgical corrected pectus excavatum patient group.

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