Psychological interventions for acute pain after open heart surgery (Protocol)

Tefikow S, Barth J, Trelle S, Strauss BM, Rosendahl J

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Psychological interventions for acute pain after open heart surgery

Susan Tefikow[1], Jürgen Barth[2], Sven Trelle[3], Bernhard M Strauss[1], Jenny Rosendahl[1]

[1]Institute of Psychosocial Medicine and Psychotherapy, University Hospital of Jena, Jena, Germany. [2]Department of Social and Preventive Medicine, University of Bern, Institute of Social and Preventive Medicine, Bern, Switzerland. [3]CTU Bern & Institute of Social and Preventive Medicine (ISPM), University of Bern, Bern, Switzerland

Contact address: Susan Tefikow, Institute of Psychosocial Medicine and Psychotherapy, University Hospital of Jena, Stoystrasse 3, Jena, Thuringia, 07743, Germany. susan.tefikow@med.uni-jena.de.

A B S T R A C T

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the efficacy of psychological interventions as an adjunct to standard surgical care compared to standard surgical care or attention control in adults undergoing open heart surgery.

BACKGROUND

Description of the condition

Open heart surgery is one of the most frequently conducted major surgical procedures in general hospitals. About 400,000 coronary artery bypass graft surgeries (CABG) and 100,000 valve surgeries were performed in the United States in 2007 (Roger 2011). In Germany, about 40,000 CABG procedures and about 25,000 valve surgeries were registered in 2010 (Gummert 2011).

One of the most disturbing issues in open heart surgery is the fact that acute pain is a severe and undertreated problem (Cogan 2010), despite enormous advances in postoperative pain management. Acute pain is the most common patient complaint after open heart surgery and pain relief is often perceived as inadequate during the hospital recovery period (Aslan 2009; Valdix 1995).

The worst pain is experienced during the first 48 hours which are spent in the intensive care unit (ICU). Following intensive care, the presence of chest tubes and their removal, endotracheal tube suctioning, vomiting, turning, breathing and change of dressing are also severely painful experiences for patients (Aslan 2009; Gelinas 2007). Pain symptoms after open heart surgery can be multiple, are described as burning or throbbing, located mainly in the thorax at the site of sternal incision, and may be of visceral, musculoskeletal or neurogenetic origin (Cogan 2010; Gelinas 2007).

Acute postoperative pain has negative consequences. It has been shown that cardiac surgical patients with severe levels of acute postoperative pain have a 3.5 times higher risk of suffering from chronic pain after cardiac surgery (Cogan 2010). Evidence also demonstrates that postoperative pain is a significant predictor of postoperative wound healing (McGuire 2006), a key variable of postoperative recovery in open heart surgery. Moreover, poor pain management may lead to depression (Cogan 2010) in addition to negative pulmonary, cardiac, gastrointestinal and musculoskeletal effects. There is clear evidence that post-CABG depression predicts decreased health-related quality of life, reduced activity levels, chronic chest pain, poorer cardiac symptom relief, as well as increased rates of rehospitalisation and mortality independent of cardiac status, somatic comorbidity or the extent of surgery (Barth 2004; Blumenthal 2003; Burg 2003; Connerney 2001; Doering 2005; Goyal 2005; Mallik 2005; Oxlad 2006; Pignay-Demaria 2003). However, to our knowledge there are no empirical studies which test the pathways between acute postoperative pain after CABG, post-CABG depression and worse surgical long-term outcomes in one model. Thus, the underlying mechanisms as yet remain unclear.

It is not surprising that acute postoperative pain after open heart surgery is mainly determined by surgery-related factors (e.g. duration and the location of surgery; Sommer 2008). However, given the association between anxiety, depression and several aspects of postoperative outcome, such as mortality, wound healing and complications (Ai 2006; Connerney 2001; Ho 2005; Mavros 2011; Perski 1998; Saur 2001; Stengrevics 1996; Szekely 2007; Tully 2008), research has also addressed the question as to whether the psychological condition of patients influences postoperative pain levels after open heart surgery.

Consequently, attempts have been made to determine if psychological interventions can successfully reduce acute postoperative pain and improve the course of physical and psychological recovery of open heart surgery patients.

Description of the intervention

The present review focuses on psychological interventions which are defined as interventions based on established psychological theories of behaviour and behaviour change, with identifiable components of treatment, specifically designed to alter surgery-related mental distress, negative beliefs and non-compliance in order to improve the postoperative recovery after open heart surgery. Psychological interventions in the context of cardiac surgery are conducted as an adjunct to standard surgical care within the time of hospitalisation by physicians, psychologists, nurses or other trained treatment providers (e.g. former patient models), containing either personal communication, printed information (leaflets), or audio or video recordings (Tigges-Limmer 2011). The following classes of psychological intervention are common in the context of cardiac surgery:

Psychoeducational interventions which are defined as the provision of information about pre-, intra- and postoperative medical procedures with a special focus on associated psychological responses, sensations and emotions. These interventions also involve behavioural instructions about appropriate ways patients can adhere to medical advice to support their recovery.

Cognitive-behavioural methods comprising methods of cognitive restructuring, reframing and reappraisal based on the evaluation of patients' specific needs according to their individual situation.

Relaxation techniques are described as teaching or instructing patients systematically in, for example, progressive muscle relaxation, relaxing breathing techniques, (self) hypnosis, guided imagery or autogenic training (Green 2005; Michie 2008).

These interventions can partially overlap with other kinds of interventions, such as those that focus on psychological preparation of adults undergoing surgery under general anaesthesia, which will be covered by another Cochrane review that is currently being developed (Powell 2010). Moreover, the analgesic effects of clinical hypnosis will be the focus of another Cochrane review also considering the context of medical procedures (Hallquist 2007).

How the intervention might work

There is no evidence-based model for how psychological interventions in the context of cardiac surgery might reduce postoperative pain. However, it is reasonable to assume that psychological in-

terventions might reduce pain by the alteration of surgery-related mental distress, negative beliefs and non-compliance, as well as their interactions with each other.

Psychological interventions focus on the reduction of anxiety, depression and mental distress, which in consequence might affect pain. There is evidence that negative emotions decrease the pain perception threshold (Rainville 2005). In studies on non-cardiac surgical patients levels of anxiety and depression predicted post-operative pain (Arpino 2004; Granot 2005; Johnston 1988; Linn 1988; Mathews 1981; Munafo 2001). In addition, in studies on patients undergoing cardiac surgery it was demonstrated that psychosocial variables such as anxiety, depression and perceived social support are also associated with postoperative pain (Con 1999; Jette 1996; Karlsson 1999; Morone 2010).

Psychological interventions also deal with non-compliance to alter patients' behaviour. Open heart surgery patients are less likely to remain passive in their course of recovery if they are informed about the importance of compliance with early postoperative mobilisation and thereby might have a decreased rate of postoperative complications and lower levels of postoperative pain.

Cognitive interventions focus primarily on changing negative or dysfunctional beliefs and attitudes towards surgery into more positive and helpful ones. For example, a positive, confident, self efficient attitude towards surgery and the recovery period is associated with reduced anxiety, facilitates postoperative behavioural activation and thereby might decrease pain levels (Heye 2002).

Why it is important to do this review

Clinical trials have investigated whether psychological interventions are successful in reducing acute postoperative pain levels and in enhancing physical and psychological postoperative recovery after open heart surgery. However, no comprehensive systematic review or meta-analysis has been carried out so far.

OBJECTIVES

To assess the efficacy of psychological interventions as an adjunct to standard surgical care compared to standard surgical care or attention control in adults undergoing open heart surgery.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) irrespective of blinding, language, publication date or publication status. We will limit inclusion to studies with a sample size of at least 20 participants in each trial arm at first postoperative assessment.

Types of participants

We will include all adult patients (male and female patients aged over 18) undergoing open heart surgery (valve procedures with or without cardiopulmonary bypass (CPB), coronary surgery with or without CPB, congenital lesion, surgery of thoracic aorta, other cardiac surgery, e.g. resection of heart neoplasm and assist devices). We will exclude studies on emergency procedures and heart transplantation because patients differ - among other factors - in disease severity and time to be psychologically prepared for surgery. We will include participants independent of their pre- and postoperative mental health status.

Types of interventions

As described above (see 'Description of the intervention' section) we will focus on the following classes of psychological interventions provided within the time of hospitalisation:

- Psychoeducational interventions.
- Cognitive-behavioural methods.
- Relaxation techniques.

We will include studies not explicitly labelling their intervention as described above if the techniques used can be assigned to one of the classes mentioned.

If the intervention group receives a combination of a psychological intervention and a non-psychological intervention we will exclude the study. If a combination of different psychological intervention classes is provided in a study we will include the study and the process of binary coding will allow for a detailed description of treatment components.

Studies which focus on life-style changes, pharmacological or psychotherapeutic long-term treatment after discharge of high-risk cardiac surgery patients with an *a priori* or a posterior diagnosis of major depression or anxiety disorder will not be in the scope of our review. Long-term psychological interventions included in cardiac rehabilitation programmes have been covered by another Cochrane review (Whalley 2011).

We will exclude music interventions as pain, distress and anxiety-reducing effects of music in various cardiac patient populations have been already addressed in a recent Cochrane review (Bradt 2009).

The control group will be:
- 'treatment as usual', defined as the standard surgical care of the hospital with no psychological intervention provided to the control group;
- 'attention control', defined as providing the same amount of time and attention, but with no specific psychological intervention offered to the control group.

Types of outcome measures

We expect multiple time points of postoperative outcome measures. We will pool these multiple measures according to the following time intervals:

- 1st interval - short-term effects: outcome measures within the first 48 hours postoperatively.
- 2nd interval - middle-term effects: outcome measures within the last 48 hours before discharge.
- 3rd interval - long-term effects: outcome measures after discharge.

Primary outcomes

1. Number of patients with self reported pain intensity reduction of at least 50% from baseline.
2. Number of patients below 30/100 mm on the visual analogue scale (VAS) in self reported postoperative pain intensity.
3. Self reported postoperative pain intensity measured on continuous or categorical scales, or other self reported pain intensity scales or questionnaires with satisfactory reliability and validity.

Secondary outcomes

1. Observer-reported postoperative median time to remedication.
2. Observer-reported postoperative number of patients remedicated.
3. Observer-reported postoperative analgesic use measured via patient-controlled analgesia (PCA), which will be converted into morphine equivalents.
4. Self reported postoperative mental distress (defined as negative affect, anxiety, depression, mood, well-being, relaxation) measured via:
    i) visual analogue scales (VAS), numerical rating scales (NRS), verbal rating scales (VRS);
    ii) Profile of Mood Scale (POMS, McNair 1971);
    iii) Brief Symptom Inventory (BSI, Derogatis 1983);
    iv) State Anxiety form of State-Trait-Anxiety-Inventory (STAI-S, Spielberger 1983);
    v) Hospital Anxiety and Depression Scale (HADS, Zigmond 1983);
    vi) other self reported psychological distress rating scales with satisfactory reliability and validity.
5. Self and observer-reported postoperative levels of mobility measured via, for example, the six-minute walk test (Guyatt 1985).
6. Observer-reported time to extubation.

If a study reports both continuous and dichotomous outcomes on pain intensity or analgesic use, dichotomous outcomes will be preferred.

We will report the incidence of postoperative complications; however, we will not run meta-analytic procedures for this outcome as pooling of various postoperative complications with different severity levels might lead to pooled heterogeneous estimates with no clear interpretation. Postoperative complications are defined as common consequences or events that are associated with the surgical procedure adversely affecting the patient's prognosis (Jacobs 2007; Rosendahl 2009): myocardial infarction, reoperation, cardiac arrest, prolonged ventilation (> 24 hours), rethoracotomy, wound infection, renal failure, pneumothorax, pericardial effusion, pleural effusion, arrhythmia and transient delirium.

Search methods for identification of studies

Electronic searches

A MEDLINE search strategy, based on both indexed and free-text terms and incorporating the Cochrane Highly Sensitive Search Strategy for identifying randomised controlled trials, is shown in Appendix 1. We will adapt the strategy for the Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, Web of Science and PsycINFO. Where possible we will use the 'related articles' and 'cited by' options of eligible studies to identify additional relevant studies.

Searching other resources

We will check lists of references of relevant articles, previous reviews and books in order to identify more eligible studies. Additionally, we will screen conference proceedings, search the ProQuest Dissertations and Theses Full Text Database, contact the authors of relevant studies and reviews, and use the mailing list services of expert societies to identify any unpublished material.

Data collection and analysis

Selection of studies

Two review authors will screen titles and abstracts of retrieved articles for eligibility independently (ST and JR). Disagreement among review authors will be resolved through discussion and consultation with a third review author (JB).

Data extraction and management

Two review authors (ST and JR) will extract data independently using a pilot-tested electronic data extraction form. Disagreement will be resolved through discussion and consultation with a third review author (JB). In order to obtain missing information, we will contact study authors for clarification.
We will extract the following information from primary studies:

- Information on publication (title, authors, year, publication status, language, country).
- Population (clinical patient characteristics, sample size, age, gender).
- Intervention class.
- Control group type.
- Outcomes (time interval of measurement, effect size-related parameters (including frequencies, change scores, means, standard deviations, t or F values, and probability levels).

Assessment of risk of bias in included studies

Two review authors (ST and JR) will independently assess the risk of bias of each included study using the common markers of internal validity recommended by the new Cochrane 'Risk of bias' tool (Higgins 2011). We will use a consensus method to resolve disagreements and a third review author (JB) will be consulted if disagreements should persist. We will explore the influence of each methodological component on effect size estimation separately in sensitivity analyses (Juni 2001).

Measures of treatment effect

We will use the risk ratio (RR) as a measure of treatment effect for all dichotomous outcomes. Additionally, we will calculate number needed to treat to benefit (NNTB) for dichotomous outcomes. We will use the hazard ratio for time-to-event outcomes. We will use Hedges' adjusted g for all continuous outcomes. Hedges' g is similar to Cohen's well-known effect size but includes an adjustment to correct for small sample size. It is calculated by dividing the differences in mean values with the pooled standard deviation (Cohen's effect size) multiplied by a bias adjustment.

With regard to the continuous primary outcome (self reported postoperative pain intensity), we pre-specify a minimal clinically important group mean difference of g = 0.4, corresponding to 10 mm on a 100 mm visual analogue scale (VAS). This difference has been found to be clinically significant in a randomised controlled study examining effects of relaxation on postoperative pain (Good 1999), since it has been associated with significantly reduced distress and also with reduced heart and respiratory rates moderating sympathetic nervous system activity.

Unit of analysis issues

We will measure all outcomes at the participant level.

Dealing with missing data

Whenever possible we will use results from an intention-to-treat (ITT) analysis. If outcome data for dichotomous outcomes are incompletely reported (e.g. the analysis set is smaller than the number of participants randomised) we will use the reported analysis population. If outcome data for time-to-event are incompletely reported we will use methods as previously reported to derive appropriate measures (Parmar 1998). If standard deviations (SDs) are not provided for continuous outcomes, we will calculate them from standard errors or confidence intervals (CI) as described elsewhere (Reichenbach 2007).

Assessment of heterogeneity

We will quantify heterogeneity using the I^2 statistic and Tau^2 (Higgins 2002). We will estimate Tau^2 using the DerSimonian-Laird method (DerSimonian 1986). We will perform no formal statistical tests for heterogeneity. We will assess any heterogeneity in meta-regression models and sensitivity analyses as described below.

Assessment of reporting biases

We will assess reporting biases and small study effects visually in funnel plots and formally as described previously (Sterne 2011).

Data synthesis

We will meta-analyse outcome data using a random-effects approach. We will use the generic inverse variance method with heterogeneity estimated using the DerSimonian-Laird method (DerSimonian 1986). Depending on the number of reported time points for pain intensity we will consider using repeated-measures meta-analysis to pool pain intensity across time points (Peters 2008).

Subgroup analysis and investigation of heterogeneity

To identify sources of heterogeneity, we will conduct random-effects meta-regression according to different intervention classes and control group types (Harbord 2008; Thompson 2002).

Sensitivity analysis

We will carry out sensitivity analyses to explore the effects of 'Risk of bias' components (as explained in the 'Assessment of risk of bias in included studies' section). Furthermore, we will stratify analyses to studies which allowed effect size estimation under uncertainty (e.g. by providing results only with P value and sample sizes) versus studies which allowed effect size estimation with a proper amount of certainty (e.g. by providing results with means, standard deviations and sample size of compared groups).

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1 exp Pain/
2 Pain, Postoperative/
3 pain*.mp.
4 1 or 2 or 3
5 exp Cardiac Surgical Procedures/
6 Sternotomy/ or sternotomy.mp.
7 Thoracotomy/ or thoracotomy.mp.
8 Cardiopulmonary Bypass/
9 (CABS or CABG).mp.
10 ((heart* or coronary or cardio* or cardiac or valve* or congenital lesion* or thoracic aorta) adj5 (surg* or intervention* or procedure* or bypass*)).mp.
11 5 or 6 or 7 or 8 or 9 or 10
12 Patient Education as Topic/
13 (inform* or educat* or psychoeducat* or knowledge* or instruct* or communicat*).mp.
14 exp Psychotherapy/
15 exp Mind-Body Therapies/
16 (psychotherap* or psychologic* or behaviour* or behavior* or cognit*).mp.
17 (problem adj5 solv*).mp.
18 (relax* or breath*).mp.
19 (hypno* or self-hypno* or auto-hypno* or suggest* or (autogenic adj5 train*)).mp.
20 (imag* or attention* or distract* or visuali* or refram* or reapprais*).mp.
21 Emotions/ or emotion*.mp.
22 (cope or coping or counsel*).mp.
23 ((stress* or anxiety or anxious*) adj5 (manag* or therap* or treat*)).mp.
24 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
25 4 and 11 and 24
26 randomized controlled trial.pt.
27 controlled clinical trial.pt.
28 randomized.ab.
29 placebo.ab.
30 clinical trials as topic.sh.
31 randomly.ab.
32 trial.ti.
33 26 or 27 or 28 or 29 or 30 or 31 or 32
34 25 and 33
key:
mp = protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier
pt = publication type
ab = abstract
sh = subject heading
ti = title

HISTORY

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CONTRIBUTIONS OF AUTHORS

ST: Draft protocol, develop a search strategy, search for studies, obtain copies of studies, select which studies to include, extract data from studies, enter data into RevMan 5 (RevMan 2011), carry out the analysis, interpret the analysis, draft the final write-up of the review, update the review, methodologist.

JB: Carry out the analysis, interpret the analysis, methodologist.

STr: Carry out the analysis, interpret the analysis, methodologist and statistician.

BS: Draft protocol, draft the final write-up of the review.

JR: Draft protocol, develop a search strategy, search for studies, select which studies to include, extract data from studies, draft the final write-up of the review.

DECLARATIONS OF INTEREST

None known

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