STUDY PROTOCOL

Effectiveness of Communication Strategies in the Management of Chronic Postsurgical Pain: Protocol for a Systematic Review and Meta-Analysis

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Purpose: To describe the details of a systematic review to assess the current evidence about the efficacy of communication strategies on the prevention of chronic postsurgical pain (CPSP).

Methods: The protocol for this systematic review was based on the Cochrane Handbook methodology and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) recommendations. A systematic search of the literature on electronic databases Medline, Embase, Cochrane Library, CINAHL, PsycINFO, and Web of Science (from the inception to 19 June 2022) was carried out using predefined search terms to identify relevant studies. This review will include randomized clinical trials or observational studies. The search strategy consisted of keywords and index terms related to "clinician", "communication" or "post-surgical pain". Inclusion criteria are as follows: randomized clinical trials or observational studies using a parallel group design that assess the efficacy of communication interventions in patients undergoing surgery and that assess pain and pain-related disability. We considered interventions that included any type of written, verbal, and non-verbal communication in combination with other interventions or without. Control groups may include no communication intervention or another intervention distinctly different. We excluded studies with follow-up duration of less than 3 months, patients aged <18 years, and studies for which no reviewer had language proficiency (eg, Chinese, Korean). Descriptive statistics will be used to summarize quantitative findings. Meta-analysis will only be considered if at least three studies used the same outcome with comparable interventions, as we expect a wide heterogeneity of study population and settings.

Conclusion: This systematic review and meta-analysis will be an important source for clinicians and researchers to understand the influence of communication to prevent CPSP.

Study Registration: This protocol is registered with the International Prospective Register of Systematic Reviews (PROSPERO). Registration number: CRD42021241596.

Keywords: chronic post-surgical pain, communication, education, pain prevention, systematic review

Introduction

Due to high direct and indirect costs, pain-related disability, psychological consequences, and impact on quality of life, chronic pain is a major individual and public health problem. Chronic pain conditions represent an increasing burden of disease and are among the top 10 causes of disability globally.^{1,2} Approximately 20% of adults suffer from chronic pain.^{3,4} Chronic postsurgical pain (CPSP) is defined as pain that develops or increases in intensity after a surgery or a tissue injury, and persists beyond the healing process (ie, for at least 3 months) after the initiating event.⁵ Surgery is an important and iatrogenic cause for pain and it accounts for a substantial proportion of individuals suffering from chronic

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pain.^{6–8} On average, the overall prevalence of CPSP after surgery is 40%⁶ and varies greatly depending on the type of surgery from 10 to $85\%^7$ (eg, up to 65% in thoracotomy⁹ and up to 85% in limb amputation¹⁰).

Pain perception per se is a life-saving sensory reflex aimed to prevent harm. Acute postsurgical pain is a combination of nociceptive (acute tissue injury, eg, cutting the skin), inflammatory (wound healing with inflammatory pathways), and neuropathic pain (in cases of injury to neuronal structures).¹¹ However, pain is a subjective and self-reported experience.¹² In comparable tissue damage, acute pain perceptions may vary from very little to extreme pain.^{7,11} Pain perception is influenced by individual predisposing factors (eg, peripheral or central sensitization),¹³ priming effects (eg, verbal suggestion, cognitive and affective factors),¹² surgical and anesthetic techniques,¹⁴ the use of nonopioid analgesic drugs, and avoidance of short-acting opioids during surgery.¹⁵ Central and peripheral sensitization have been suggested as risk factors for the development of CPSP.^{16,17} Sensitization refers to an increased responsiveness of nociceptive neurons to their normal input in the central nervous system and in the periphery.¹⁸ As a result, patients may feel disproportionate and prolonged pain (hyperalgesia), feel pain elicited by normally innocuous stimuli (allodynia), and pain may spread beyond the surgical site (secondary hyperalgesia). Further, psychological and behavioral factors (eg, depression, anxiety, kinesiophobia, or self-efficacy),^{19,20} activation of pain concepts in memory,²¹ and verbal suggestion¹² may play an important role in the individual pain experience.

Many risk factors for CPSP, such as demographic, clinical (eg, preoperative comorbidities or disability), and surgeryrelated factors, are not modifiable.²² Potentially modifiable factors such as psychological and behavioral factors (eg, depression, anxiety, kinesiophobia, or self-efficacy) may be mitigated by education and communication.^{19,20} Further, priming effects such as verbal suggestion¹² may be used to influence pain perception after surgery. Although guidelines recommend to screen for risk factors for CPSP before and after surgery and provide preoperative education including a pain management plan^{23,24} to reduce the risk for CPSP,²⁵ recommendations are less specific on how to effectively communicate with patients.^{23,24} In particular, ambiguous or frightful illness information and verbal suggestion have been found to activate pain memory and increase pain.^{12,26,27} Therefore, it has been suggested that clinicians should avoid negative verbal suggestions and ambiguous messages. At the same time, patients require adequate information and education about their condition, and insufficient communication may decrease the patient's satisfaction with pain management and result in distrust.²⁸ Clinicians need to find a balance between providing accurate illness information (eg, during preoperative discussion of the procedure and potential complications) together with reassurance by reducing worries, showing empathy, and building a solid working relationship.^{29,30} Language is the main tool for communication between clinicians and patients. To date, the key determinants for communication that influences pain perception and reduce the risk for CPSP remain unclear.

The aim of this study is to systematically review the current evidence about the influence of communication strategies on the risk for CPSP. Further, we aim to identify promising or successful elements in patient-centered communication that may be recommended for clinical use.

Methods

The protocol for this systematic review was developed and reported according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement.³¹ It was registered to the International Prospective Register of Systematic Reviews (PROSPERO) database on 14. May 2021 (Registration number CRD42021241596).

Data Sources and Searches

We developed the search strategy by consulting the relevant literature, through discussion within the research team, and with the help of an experienced librarian (SK). The search strategy consisted of keywords and index terms related to "clinician", "communication" or "post-surgical pain". We searched Medline (EBSCO), Embase (Elsevier), the Cochrane Library (Wiley), Cinahl (EBSCO), PsycINFO (EBSCO), and Web of Science from the inception to June 19, 2022. For the full search strategy for all databases see <u>Supplementary File</u>. Bibliographies of primary studies meeting the inclusion criteria, review articles, and guidelines on the topic will be searched manually to identify further eligible studies. Further, we will screen trial registries, conference proceedings, and search the grey literature for potentially relevant studies. In case insufficient information is provided, we will contact the authors of potentially eligible studies.

Eligibility Criteria

Inclusion and Exclusion Criteria

The systematic review will include randomized clinical trials (RCTs) and prospective observational studies using a parallel group design that assessed the efficacy of communication interventions in patients undergoing surgery on their postsurgical pain and/or function with a postsurgical follow-up of at least 3 months. We will also consider studies using a pre- and post-intervention design to improve clinical outcomes.

We will include all types of communication approaches (verbal, written, visual, and non-verbal communication) with a therapeutic intention. Communication may have an educational, psychological or informative intent. We will categorize interventions into elements that may be compared across different studies. Interventions should be compared to a control group that may include standard care, waiting lists, and other types of communication (eg, information sheet and pamphlet). We included languages that the research team had sufficient language proficiency (ie, English, French, German, Italian, Spanish, Swedish, and Dutch).

Excluded are studies on patients not undergoing surgery, with an age <18 years, and of other non-eligible populations (eg, general population and health survey). Further, we will exclude observational studies without a comparison group, studies with other designs (eg, case series, cross-sectional studies, and retrospective chart reviews), studies that did not assess pain and/or function as an outcome, and studies published in a language that the research team had insufficient language proficiency (eg, Chinese and Korean).

Outcomes

Outcome measures considered for this systematic review are based on the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations.³² The primary outcome measure is pain intensity and pain-related disability. CPSP was defined as pain persisting for three or more months after surgery.⁵ Chronic postsurgical disability was defined as persisting disability for three and more months after surgery. Secondary outcomes include global improvement, quality of life, emotional functioning, satisfaction with treatment, adverse events, adherence to the treatment, and pain medication use. All outcome measures for pain and pain-related function will be extracted as reported in their primary studies and operationalized.

Study Selection

EndNote (V.20) will be used for reference management during the review. All titles and abstracts will be screened for eligibility independently by two reviewers (AF and BK). All potentially relevant references will then be read in full text by the two reviewers (AF and BK). The study selection process will be reported using the PRISMA flow diagram.³¹ Any disagreements between the reviewers will be resolved through discussion or by third-party arbitration (MW).

Data Extraction and Quality Assessment

Extracted data will include all details specific to the research question and will be extracted using a predefined spreadsheet. We will extract information on the following domains: population and study setting, study design, follow-up duration, type of surgery, type of intervention, and control group. Outcome measures will be operationalized. One reviewer will extract the information from all studies, and a second reviewer will verify the information. We will also contact corresponding authors for additional information if data is ambiguous or missing from the published study.

The quality of individual studies included in the systematic review will be independently rated by two reviewers with the Scottish Intercollegiate Guidelines Networks (SIGN) checklists for RCTs and cohort studies.³³ Disagreements between the reviewers will be discussed and resolved by consensus within the research team. We will summarize the quality of the best available evidence by using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.^{34–36}

Data Synthesis Descriptive Analysis

A narrative synthesis of the outcomes of the selected studies will be presented in the final review. This will include the types of intervention and control groups, the patient population, and procedure-specific information such as type of surgery, anesthesia technique, the study setting, and characteristics of the population such as age, sex, and disease. Interventional outcomes will be summarized and wherever available, information will be provided on the clinical importance of the presented findings. We will analyze the elements of communication interventions that were included in a specific intervention and compare studies with communication strategies that decreased the risk for CPSP to studies without influence on CPSP.

Statistical Analysis

We expect a wide heterogeneity of study populations and settings. Therefore, we anticipate limited grounds for a metaanalysis. If at least three studies used the same outcome and comparable interventions, we will report pain levels and the prevalence of CPSP before and after the intervention, and the overall mean change. The overall mean difference will be calculated by subtracting the mean change in the control group from that in the treatment group. Meta-analysis will be conducted to assess the treatment effect of the communication intervention on postsurgical pain and will be reported as standardized mean difference (SMD) for each individual study and its 95% confidence interval (CI) or odds ratio (OR) and the corresponding 95% CI. The effect sizes will be presented with a forest plot for each study. The overall effect sizes will be estimated using both fixed-effects models and random-effects models. Next, I2 statistics will be used to assess heterogeneity and identify the potential sources of heterogeneity.

Potential publication- and small sample size bias will be assessed by visual inspections of funnel plots and also Egger's test. All of the statistical analysis will be performed with the R statistical software.³⁷ A p value <0.05 will be considered statistically significant for all analyses.

Discussion

The prevalence of chronic pain is likely to increase due to the demographic shift and increased life-expectancy. Surgery is one of the main contributing factor for pain and a potential risk factor for CPSP. The negative implications of chronic pain include not only pain-related disability but also depression, anxiety, and reduced quality of life.^{38,39} Therefore, prevention of chronic pain should be a main focus in clinical practice. Communicating with patients is a key component during a medical consultation.⁴⁰

Patients awareness and knowledge about pain and non-pharmacological options to influence pain is a grey area of literature. Inadequate information and conflicting illness information are a key challenge for clinicians when communicating with patients.⁴¹ For example, clinicians are legally required to inform patients before surgery about the procedure, all relevant potential complications, and alternative treatment options. During this process, frightful illness information is provided not only to patients but also to family members. As a result, pain concepts in memory may be activated²¹ and negative verbal suggestion¹² potentially increase pain perception and result in unhealthy coping concept in patients and their family. As a result, providing positive reassurance during the peri- and postoperative period may be perceived as ambiguous and may not result in the intended effects.

How to address these challenges and how to best use the power of words, education and positive suggestion is not fully understood. For example, a telehealth intervention during and after spine surgery improved pain at three months compared to usual care⁴² but showed no influence on CPSP after cardiac bypass surgery^{43,44} or oral cancer surgery.⁴⁵ Communication may not only influence pain perception but also behaviour and adherence to non-pharmacological care after surgery. In low back pain, pain education, graded exposure and multimodal interventions have been found to be the most effective for behavior modification and compliance with exercise with long-term improvement.⁴⁶ Compared to multimodal interventions, self-management and coaching provided only short-term or no benefits.⁴⁶ Poor patient adherence may decrease the effectiveness of advice and home-based rehabilitation exercises. According to self-determination theory, support from

health care practitioners can promote patients' autonomous motivation and greater long-term behavioral persistence (eg, adherence to physiotherapists' recommendations⁴⁷).

Limitations

The main limitation of this systematic review will be that many interventions are multifaceted and it will be difficult to determine the influence of communication per se. Further, individual interactions between a clinician and patient are also influenced by trust and sympathy. We will not be able to distinguish between these factors and the communication method as such. However, we expect to compile a comprehensive overview about the current literature on communication interventions in surgery and thus provide important recommendations for clinicians and researchers.

Conclusion

This systematic review and meta-analysis will be an important source for clinicians and researchers to understand how communication may be used to prevent CPSP. We aim to identify promising or successful elements in patient-centered communication that may be recommended for clinical use in patients undergoing surgery.

Abbreviations

CPSP, chronic postsurgical pain; SIGN, Scottish Intercollegiate Guidelines Networks; RCT, randomized controlled trial; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; IMMPACT, Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials; SMD, Standardized mean difference; CI, confidence interval; OR, odds ratio.

Ethics Approval

Ethics approval is not applicable for this study since no original data will be collected. The results will be disseminated through peer-reviewed publication.

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Author Contributions

Asha-Naima Ferrante and Barbara K. Keller shared first authorship. Martin Grosse Holtforth and Maria M. Wertli shared last authorship. All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests.

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