



## Original article

# Is chronic postsurgical pain surgery-induced? A study of persistent postoperative pain following breast reconstruction



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## ABSTRACT

**Background:** Chronic postsurgical pain (CPSP) is a reported risk for women undergoing breast reconstruction, but it remains unclear that such persistent pain is induced by reconstructive surgery. To address this concern, this prospective cohort study examined the prevalence of and risk factors associated with CPSP among women undergoing breast reconstruction.

**Materials and methods:** Women (n = 1996) recruited for the Mastectomy Reconstruction Outcomes Consortium (MROC) Study were assessed preoperatively and at two-years postoperatively for relevant medical/surgical variables, pain experience, body physical well-being, anxiety, depression, and reconstruction procedure type and characteristics.

**Results:** Nearly half of the entire sample reported some level of preoperative pain. At two years there were statistically significant but not clinically meaningful increases in both pain intensity and chest/upper body discomfort but a decrease in affective pain rating. Average clinical pain severity was strikingly similar for preoperative and postoperative assessments. Preoperative levels of pain, acute postoperative pain, and (marginally) level of depression held consistent relationship at two-year follow-up with all outcome measures. Autologous flap reconstruction was associated with more severe CPSP compared to TE/I reconstruction. Older age, higher BMI, bilateral reconstruction, and adjuvant radiation and chemotherapy were associated with CPSP and chest/upper body discomfort for at least one outcome measure at two years.

**Conclusions:** The substantial rate of preoperative pain and comparable prevalence of preoperative and postoperative pain ratings suggest that persistent pain after breast reconstruction may not necessarily reflect surgery-induced pain. Future research will need to determine those factors that contribute to long-term pain following breast reconstruction.

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## 1. Introduction

Understanding the development of chronic postsurgical pain (CPSP) following major surgery, including breast cancer surgery,

has become a major concern [1–4], but there has been relatively little attention to the risk of CPSP following breast reconstruction [5]. From one-fourth to one-half of women who undergo post-mastectomy breast reconstruction report persistent pain months and years after surgery [5–15]. However, determining the incidence of CPSP due specifically to breast reconstruction may be confounded by methodological problems inherent in the examination of CPSP [16–19] and is particularly difficult when immediate reconstructive surgery is chosen given the substantial risk of CPSP associated with mastectomy [20,21]. Preliminary evidence suggests that women who receive breast reconstruction, compared with those who undergo mastectomy-alone, do not report higher rates

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of CPSP [7,9,22].

CPSP is defined as ongoing pain that persists for at least 3 months beyond surgery, and should reflect a new onset of persistent pain that is directly attributable to the surgical procedure under study [16,17]. In addition, it should be of sufficient severity to cause clinically meaningful impairment in functional ability and quality of life [17,23]. Identified methodological problems with prior studies of CPSP following major surgery leave unclear whether the presence of postoperative pain reported by a particular surgical cohort is merely an estimate of the prevalence of pain in the postoperative period or actually reflects a new incidence of surgically-related pain, [16]. The majority of investigations of CPSP following major surgery, including breast reconstruction, are retrospective and cross-sectional in study design and fail to control for the contribution of preoperative pain when interpreting the etiology of CPSP being reported [18,19,24], and, moreover, rely on potentially inaccurate patient recall of prior pain experience [25,26]. In addition, the majority of these studies fail to quantify the clinical significance of postoperative pain and thus are unable to establish whether CPSP is of sufficient clinical concern to compromise a woman's functional ability [2,17,23]. As a result, there is concern that prior investigations of CPSP may overestimate the incidence of surgery-induced and clinically relevant persistent postoperative pain [27].

This study will examine the prevalence of and risk factors associated with CPSP for women seeking breast reconstruction following mastectomy. To address identified methodological limitations in previous investigations, this prospective study will examine the report of the presence and severity of persistent pain prior to surgery and at two years postoperatively. Persistent pain following surgery and site-specific (e.g., upper body and chest) physical discomfort will be compared for patients grouped by type and timing of reconstructive surgery. Additional medical factors, surgical procedure characteristics, demographic variables, and standardized measures of both anxiety and depression will also be obtained to assess their contribution to post-reconstruction reports of CPSP.

## 2. Materials and methods

### 2.1. Study setting and participants

Patients were recruited as part of the Mastectomy Reconstruction Outcomes Consortium (MROC) Study, a five-year prospective, multicenter cohort study of mastectomy reconstruction patients funded by the National Cancer Institute (NCI 1R01CA152192). Appropriate Institutional Review Board (IRB) approval was obtained from all participating sites. Women 18 years or older undergoing first-time unilateral or bilateral mastectomy, and immediate or delayed breast reconstruction, were eligible for MROC participation. Fig. 1 depicts the consortium enrollment process for MROC including exclusion criteria. Reasons for exclusion included early withdrawal subjects who did not complete preoperative baseline questionnaires ( $n = 1316$ ), low volume procedure type ( $n = 213$ ), mixed reconstruction timing ( $n = 37$ ), reconstructive failure ( $n = 117$ ), and less than 2-year follow-up ( $n = 738$ ). Of a total of 4417 women enrolled by July 2016, a remaining sample of 1996 served as the study cohort.

### 2.2. Study design and data collection

Relevant clinical data such as medical and surgical factors were collected via medical record reviews by trained research assistants at each site. Self-administered Patient Reported-Outcome questionnaires (PROs) assessing various patient and demographic

characteristics, psychological status (depression and anxiety symptom severity), pain experience, and chest and upper body discomfort were collected preoperatively and postoperatively at one week, one-year and two-years after the initiation of reconstruction. Most patients completed questionnaires electronically via the Internet in a password protected patient-portal of the study's database system (the Velos eResearch System).

### 2.3. Description of surgical procedures and sample composition

Based on patient preference, reconstructive surgery for this study included one of seven available techniques. Most commonly, patients underwent implant-based reconstructions, either one-staged, direct-to-implant techniques (DTI;  $n = 93$ , 4.7%) or two-staged procedures (TE/I;  $n = 1263$ , 63.3%) in which implant placement was preceded by a temporary tissue expander. The study cohort also included women receiving latissimus dorsi procedures (LD;  $n = 64$ , 3.2%), or four types of abdominally-based tissue flap procedures: pedicle transverse rectus abdominis musculocutaneous flaps (PTRAM;  $n = 77$ , 3.9%), free TRAM (FTRAM;  $n = 87$ , 4.4%), deep inferior epigastric artery perforator (DIEP;  $n = 350$ , 17.5%), and superficial inferior epigastric artery perforator (SIEA;  $n = 62$ , 3.1%) flaps.

To determine if CPSP is related to selected medical and surgical factors associated with reconstructive surgery, patients were assessed for their body mass index (BMI), and lymph node management (none, sentinel lymph node biopsy [SLNB] or axillary lymph node dissection [ALND]) at the time of reconstruction. In addition to surgical procedure type (TE/I, DTI, LD, PTRAM, FTRAM, DIEP, SIEA), patients were further categorized by laterality (unilateral vs. bilateral), and timing of reconstruction (immediate vs. delayed). To assess the influence of adjuvant cancer therapies, patients were also stratified for a history and timing of both radiation and chemotherapy (none, before reconstruction, during or after reconstruction).

### 2.4. Measures

#### 2.4.1. Pain assessment

For the three pain metrics, participants were asked to provide a single global rating of their current level of pain experience per each metric's standard instructions. The same questionnaire format was repeated for all preoperative and postoperative pain assessments. Overall pain intensity was assessed by the Numerical Pain Rating Scale (NPRS) [28], which provides a single measure of overall pain intensity drawn from an ordinal numerical scale reflecting increasing pain severity, ranging from 0 to 10. A broader measure of pain experience was obtained by the McGill Pain Questionnaire-Short Form (MPQ-SF) [29]. The MPQ-SF contains 15 descriptors of pain experience (11 sensory, 4 affective) and provides separate measures of the sensory and affective components of pain experience. The sensory pain rating (MPQ-Sensory Rating) quantifies the sensory dimensions of pain experience including mechanical, spatial and temporal characteristics (range 0–33) while the affective pain rating (MPQ-Affective Rating) provides a measure of the subjective unpleasantness or suffering associated with pain (range 0–12). For both the NPRS and MPQ-Sensory Rating and MPQ-Affective Rating, higher scores indicate more severe pain experience.

#### 2.4.2. Chest and upper body discomfort

Symptoms of chest and upper body discomfort associated with reconstructive surgery were assessed by The BREAST-Q [30]. The BREAST-Q includes a Physical Well-being: Chest and Upper Body Scale utilized in this study, which solicits problems over the prior

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