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Review Article

The Impact of Massage Therapy on Function in Pain Populations—A Systematic Review and Meta-Analysis of Randomized Controlled Trials: Part III, Surgical Pain Populations

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Disclosure: The Evidence for Massage Therapy (EMT) Working Group (diverse stakeholders making up the steering committee and subject matter experts) contributed to the protocol development and provided input throughout the entire project; all analyses were conducted independently by Samueli Institute. All recommendations set forth in this report were made collectively with the EMT Working Group and Samueli Institute during an expert round table and are based on the evidence revealed through the systematic review and gaps that emerged through the process.

Abstract

Objective. Pain is multi-dimensional and may be better addressed through a holistic, biopsychosocial approach. Massage therapy is commonly practiced among patients seeking pain management; however, its efficacy is unclear. This systematic review and meta-analysis is the first to rigorously assess the quality of the evidence for massage therapy's efficacy in treating pain, function-related, and health-related quality of life outcomes in surgical pain populations.

Methods. Key databases were searched from inception through February 2014. Eligible randomized controlled trials were assessed for methodological quality using SIGN 50 Checklist. Meta-analysis was applied at the outcome level. A professionally diverse steering committee interpreted the results to develop recommendations.

Results. Twelve high quality and four low quality studies were included in the review. Results indicate massage therapy is effective for treating pain [standardized mean difference (SMD) = −0.79] and anxiety (SMD = −0.57) compared to active comparators.

Conclusion. Based on the available evidence, weak recommendations are suggested for massage therapy, compared to active comparators for reducing pain intensity/severity and anxiety in patients undergoing surgical procedures. This review also discusses massage therapy safety, challenges within this research field, how to address identified research gaps, and next steps for future research.

Key Words. Systematic Review; Meta-Analysis; Massage Therapy; Pain; Function; Health-Related Quality of Life

Introduction

Public Health Significance of Surgery-Related Pain

Pain management is a critical and challenging issue for patients who are either about to undergo or recovering

from surgical or operative procedures. If acute postoperative pain is effectively managed at the acute stage or during immediate postsurgical periods, patients are often able to recover uneventfully and return to their normal daily activities [1]. However, a significant number of patients transition into chronic post-surgery pain (CPSP) [1,2] or persistent postsurgical pain (PPP) [3], defined as pain lasting longer than 2 to 3 months after surgery [2,4]. For example, one study assessing the cause of chronic pain reported that 22.5% of chronic pain was attributed to surgery [5]. Such pain, in turn, places significant psychosocial and economic burdens on patients and represents a major public health problem [3,6].

Surgery-related pain, whether acute or chronic, is closely associated with various functional outcomes, including sleep, mood, quality of life, and sleep disturbances [7]. Moreover, patients who are about to undergo surgery commonly experience fear and anxiety, which complicate pre- and post-surgical pain management [4,8] and increases the likelihood of developing subsequent CPSP [4]. In fact, as pain becomes chronic, anxiety and fear intensify and avoidance behaviors become more frequent, interfering with daily activities and negatively affecting the patients' emotional wellbeing and quality of life. Thus, understanding the relationship between pain and functional outcomes is important in effectively addressing postsurgical pain and minimizing the progression of acute postsurgical pain to chronic pain.

Current Treatment Approaches and Challenges

Conventionally, the primary treatment regimen for addressing surgical pain and discomfort is opioid-based analgesia and other pharmacologic interventions [8,9]. Despite the usefulness of such interventions, there are significant safety concerns related to the high risk of adverse effects. Opioid-based analgesia, for instance, is associated with various side effects ranging from nausea and vomiting to respiratory depression and possible dependence, addiction, and/or abuse [4]. An increasing body of evidence suggests that pharmacologic interventions do not sufficiently address all factors involved in the experience of pain [10,11]. Studies show that psychosocial aspects of the patients' pain experience must also be recognized and treated in order to stop or minimize the progression of postsurgical acute pain to chronic pain [9]. A more effective surgical pain treatment regimen would improve physical pain and also address emotional pain, such as fear and anxiety, as well as other pain-related functional outcomes.

Massage Therapy for Surgery-Related Pain

With the growing recognition of the close association between pain and functional outcomes, there has been an increasing emphasis on treating the whole person—the body, mind, and spirit—of patients who are either about to undergo or are recovering from surgery [12]. A growing body of literature supports the integration of massage therapy, a commonly prescribed holistic pain management therapy, in caring for patients undergoing surgery [13–17]. For example, the cardiovascular surgery unit at Mayo Clinic Rochester has integrated massage therapy into its multidisciplinary program to provide a more holistic approach to treating surgery-related pain [12,18]. Likewise, massage therapy has been successfully implemented at various hospitals to decrease patient anxiety, improve postsurgical outcomes, and speed the recovery process [19].

Despite its growing clinical use, there continues to be an ongoing debate about the efficacy of massage therapy for surgery-related pain. Interpretation of research findings is complicated by the diversity of massage therapies as well as the heterogeneity of patient populations or different types of surgeries [20]. An independent assessment and synthesis of various primary research studies is, therefore, needed to better understand the efficacy of massage therapy for surgery-related pain and its related functional outcomes. No meta-analysis has been conducted on this specific topic to date, making it challenging to justify the integration of massage therapy into the treatment and management of pain experienced by surgical patients.

Purpose

The purpose of this systematic review and meta-analysis is to provide an objective, independent, and transparent analysis of the research published to date on massage therapy for treating pain and improving function in those patients suffering from pain resulting from surgical procedures. More specifically, this review aims to: 1) begin to more clearly define both concepts of massage and function for the surgical field; 2) determine the efficacy of massage for treating individuals either recovering from or about to undergo a surgical/operative procedure and experiencing some sort of pain (e.g., across the spectrum from acute to chronic) that is affecting function-related (e.g., pain, activity, sleep, mood, stress) and other (e.g., health-related quality of life, physiological) outcomes that may affect daily life; 3) describe the characteristics and safety issues of massage as reported in the literature to date and whether they adhere to the proposed Standards for Reporting Interventions in Clinical Trials of Massage (STRICT-M) criteria offered in this analysis [21]; 4) synthesize the evidence to draw initial conclusions based on the current state of the science from which recommendations can be made for its application; and 5) identify gaps to guide a future research agenda.

Methodology

A systematic review and meta-analysis was conducted using Samueli Institute's systematic review process known as the Rapid Evidence Assessment of Literature (REAL©) [22], which has been used by a variety of organizations to date [23–27]. The Evidence for Massage

Therapy (EMT) Working Group, comprised of a diverse group of stakeholders including a full steering committee and subject matter experts, contributed to the review's protocol development. The systematic review team followed the developed protocol to independently evaluate the quantity and quality of the available English, peer-reviewed literature in order to present the results to the EMT Working Group, who then interpreted the evidence to suggest recommendations for the field. The protocol for this systematic review is registered with PROSPERO under registration number CRD42014008867.

Concepts and Definitions

The authors agreed to use a broad scope when conducting the review and consequently examined the state of the science regarding the impact of massage therapy on function for all individuals experiencing pain. Rather than restricting the population up front, the authors decided to allow the literature base to identify subgroup populations and dictate decisions surrounding which subgroups should be included and examined in the review. This systematic review focuses on the subgroup of surgical pain populations. Other populations, including those experiencing pain and seeking consultation from their general practitioner as well as cancer patients [21,28], are assessed in other articles within this series.

Pain

The authors agreed to rely on the definition set forth by the Pain Management Task Force.

An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Pain is always subjective. Pain can be acute or chronic [29].

Massage Therapy

After careful review of various definitions of massage therapy [21,30,31], authors decided to utilize the following broad definition of massage therapy in order to encompass the majority of interventions typically recognized as massage.

The systematic manipulation of soft tissue with the hands that positively affects and promotes healing, reduces stress, enhances muscle relaxation, improves local circulation, and creates a sense of well-being.

Function

Given the multi-dimensionality of pain and its subsequent effect on various function-related outcomes, it is important to address pain through a biopsychosocial approach in order to best address the whole patient. Consequently, the authors examine function-related outcomes of pain, activity, sleep, mood, and stress, as well as health-related quality of life (HrQoL), and physiological (i.e., relating to one's physiology including the physical and chemical phenomena and processes involved) outcomes.

Study Eligibility Criteria

Articles were included if they met all of the following criteria: (a) human population who are either about to undergo or are recovering from a surgical procedure and experiencing pain as defined above; (b) massage therapy, as defined above, administered (i) alone as a therapy, (ii) as part of a multi-modal intervention where massage effects can be separately evaluated, or (iii) with the addition of techniques commonly used with massage, as pre-defined by the EMT Working Group (i.e., external application of water, heat, cold, lubricants, background music, aromas, essential oils, and with the addition of tools that may mimic the actions that can be performed by the hands); (c) sham, no treatment or active comparator (i.e., those in which participants are actively receiving any type of intervention); (d) assessment of at least one relevant functional outcome (as defined above), and; (e) the study being a peer-reviewed randomized controlled trial (RCT) study design published in the English language.

Additionally, interventions were included if they were not necessarily labeled as massage or massage therapy but included the use of manual forces and soft-tissue deformation as well as gliding, torsion, shearing, elongation, oscillating, percussive, and joint movement methods (i.e., touch, compression, gliding, percussion, friction, vibration, kneading, movement, positioning, stretching, holding) [21]. Note that interventions solely performed by tools (e.g., chair massage) were excluded.

Search Strategy

PubMed, CINAHL, Embase, and PsycInfo, were searched from database inception through February 2014. Authors explored MeSH within MEDLINE and consulted with subject matter experts to determine the best keywords to yield the most powerful search (Figure 1). Variations of the search strategy for the remaining databases are available upon request from the primary author. The EMT Working Group reviewed the yielded list of citations to confirm the retrieved search included the literature they were familiar with. Thereafter, Mobius Analytics Systematic Review System (Mobius Analytics Inc, Ottawa, Ontario) was utilized for all data entry and execution of the systematic review.

Study Selection

Three reviewers (LX, AP, CP) used the pre-defined study eligibility criteria to independently screen titles and abstracts of the citations yielded from the search. A Cohen's kappa for inter-rated agreement of >0.90 was

(pain) AND ("massage" OR massotherap* OR "musculoskeletal manipulation" OR "myofascial release" OR neuromuscular therap* OR "strain counterstrain" OR "trager" OR "proprioceptive neuromuscular facilitation" OR "bodywork" OR "rolfing" OR "structural integration" OR trigger point therap* OR "manual lymph drainage" OR manual therap* OR "lomi" OR hydrotherap* OR "passive motion" OR heat therap* OR "gliding" OR knead* OR "friction" OR "holding" OR "percussion" OR "vibration" OR "direct pressure" OR "skin rolling" OR "manual stretch" OR "manual stretches" OR "manual stretching" OR "contract-relax" OR "passive stretch" OR "passive stretches" OR "passive stretching" OR "rocking" OR "traction")

Figure 1 PubMed search string.

maintained throughout the entire screening phase. Disagreements about inclusion were resolved through discussion and consensus, by one of the review managers (CB, CC) or, ultimately, by the EMT Working Group.

Methodological Quality Assessment and Data Extraction

Methodological quality (i.e., risk of bias/internal validity) was independently assessed by three reviewers (LX, AP, CP) using the Scottish Intercollegiate Guidelines Network (SIGN) 50 Checklist [32] for RCTs, a validated and reliable assessment tool widely used in the literature. The External Validity Assessment Tool (EVAT ©) [33] was used to measure the generalizability of research to other individuals (i.e., external validity) and other settings (i.e., model validity) outside the confines of a study.

Descriptive data was also extracted regarding the surgical/operative procedure the patient is about to undergo or is recovering from; whether massage was offered as an intervention pre-, during-, or post-surgical intervention; sample entered/completed, intervention and control/comparison description and dosage; relevant function measures and corresponding results and statistics; effect sizes; and author's main conclusions. The authors also noted whether power calculations to achieve sufficient effect sizes and adverse events were reported.

Proposed STRICT-M Checklist and Analysis

There have been recent developments in enhancing the reporting of interventions [34]. For example, the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) [35] is a formal extension of the Consolidated Standards of Reporting Trials (CONSORT) [36] statement that expands the general content surrounding the acupuncture intervention description to improve the completeness of reporting interventions in controlled acupuncture trials. Because complete and accurate trial reports can facilitate translation and replicability, the authors adapted this guideline to relate to massage therapy interventions. Specifically, the criteria addresses design elements deemed important for quality control of massage therapy studies such as the intervention's rationale, technique, treatment regimen and dosing; other treatment components; practitioner background; and control/comparator interventions. Subsequently, the authors refer to this review's STRICTA-based checklist as the proposed Standards for Reporting Interventions in Clinical Trials of Massage (STRICT-M) [21].

Data Synthesis and Analysis

Meta-Analysis

When reported, the sample size, mean or pre-post difference, and standard deviation for each treatment group were extracted. Effect sizes were calculated for each comparison (i.e., massage vs. active comparator, massage vs. sham, and massage vs. no treatment) for the functional outcomes related to pain: pain intensity/severity, activity, stress, mood (i.e., anxiety), sleep (i.e., fatigue), and HrQoL, where available. If a study had more than one active comparator (e.g., physical therapy or acupuncture), the biostatistician randomly chose one active comparator for analysis by flipping a coin. A minimum of three studies was required to perform a meta-analysis for each subset of data. An unbiased estimate was calculated using Cohen's d effect size for subgroup analyses that pooled across several scales [37,38]. A pooled random-effects estimate of the overall effect size

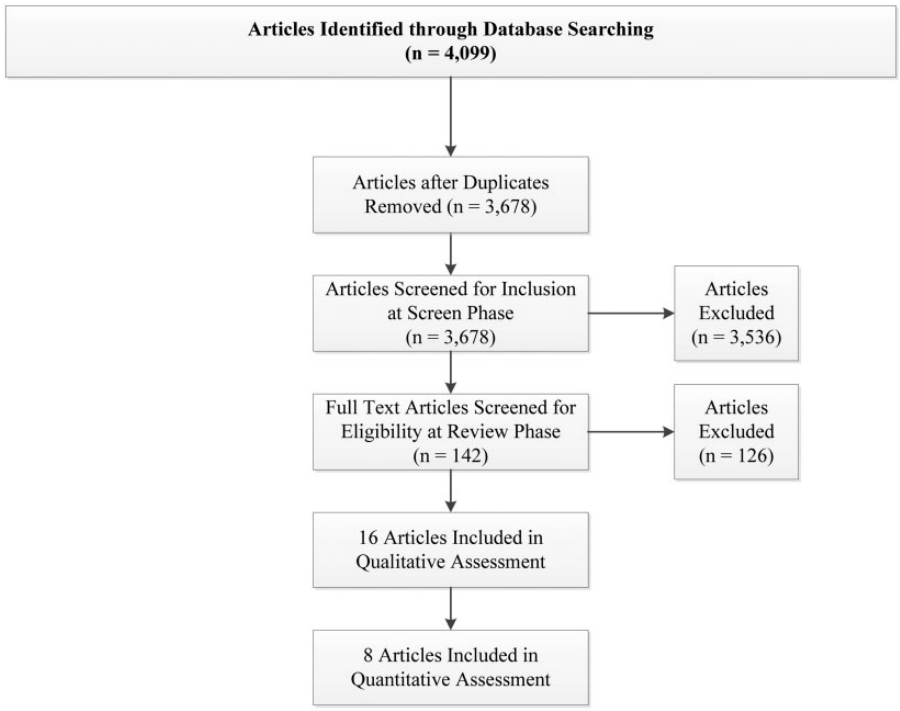


Figure 2 Flow chart.

was estimated for all studies judged clinically similar enough to warrant a meta-analysis. The individual trial outcomes were weighted by both within- and between-study variation in this synthesis. For a reduction in pain intensity/severity, fatigue and anxiety, a negative effect size indicates that the massage therapy treatment group is favored. For improved activity (i.e., increase in range of motion) and HrQoL, a positive effect size indicates that the massage therapy treatment is favored. Publication bias was also assessed using the Egger regression asymmetry test [38,39]. Heterogeneity was assessed using I^2 and tested via Q statistics. For pain intensity/severity, a clinical translation into the Visual Analogue Scale (VAS), 0–100, was conducted for clinical interpretation using a standard deviation of 25 points; a 20-mm difference on the VAS as clinically relevant [40]. All meta-analyses were conducted with Comprehensive Meta-Analysis version 2.2 (Meta-Analysis.com, Englewood, NJ).

Evidence Synthesis

The EMT working group and systematic review team convened to: 1) review the evidence revealed through the systematic review and meta-analysis; 2) further synthesize the evidence in order to determine the overall confidence in the estimate of the effect and magnitude of the effect, and evaluate safety as being reported in the results; and 3) provide an overall recommendation concerning the benefit/risk for massage therapy. The conclusions reached and recommendations made are in no way to be construed as clinical guidelines, but are rather recommendations about the benefit/risk of massage therapy for surgical pain management, based solely on the evidence gathered from this systematic review.

Results

Characteristics of Included Studies

The database searches yielded a total of 3,678 articles that examined three subgroups of populations including individuals with pain conditions for which they would generally seek treatment from their general practitioner, individuals with cancer pain, and those experiencing pain related to a surgical procedure. Results regarding the first two subgroups are reported elsewhere [21,28]. See Figure 2 for flow chart of included studies.

Sixteen studies, published between 1999 and 2013, examined the use of massage pre-[15,41], during[42], and post-surgery/operative [9,13,14,41,43–52] procedure. Massage techniques, including those named as massage therapy [13–15,43,44,50], massage [9,41,45,47–49,53], M technique massage [46], Swedish massage [52], and effleurage [42], were compared to a variety of named controls, including relaxation [14,15,48], attention [9,41,51], standard care [43,45,46], routine care [9,51], usual care [13,52], amniocentesis [42], rest [44], normal activity [48], standard analgesia [49], no treatment [50], vibration

Table 1 SIGN 50 checklist quality assessment [32]

	Percentage (N)		
	Poor	Adequate	Well
Appropriate and clearly focused question	6.2% (1)	43.8% (7)	50.0% (8)
Randomization	50.0% (8)	31.2% (5)	18.8% (3)
Allocation concealment	75.0% (12)	18.8% (3)	6.2% (1)
Percentage of dropouts	31.2% (5)	25.0% (4)	43.8% (7)
Baseline similarities	–	12.5% (2)	87.5% (14)
Group differences	12.5% (2)	75.0% (12)	12.5% (2)
Outcome reliability/validity	12.5% (2)	12.5% (2)	75.0% (12)
Intention-to-treat analyses	43.8% (7)	31.2% (5)	25.0% (4)
Multi-site similarities	100.0% (5)	–	–

SIGN = Scottish Intercollegiate Guidelines Network.
SIGN criteria was modified to exclude *blinding* and was weighed accordingly because of this.

therapy [52], as well as an undescribed control [47]. Most studies focused on the effect of massage on pain, sleep, stress, mood, and HrQoL outcomes in patients dealing either with post-operative pain [9,50–52] or undergoing or recovering from procedures such as amniocentesis [42], cardiac surgery [13,14,43,44,48], hip or knee arthroplasty [45], craniofacial surgery [46], cesarean delivery [47], laparoscopic sterilization [49], and port placement [41]. Treatment dosages varied from a single 10-minute session to 12 daily 10-minute sessions for 6 days. Among the studies, 66.8% of participants were male and 33.2% were female with a mean age of 49.8 (range: 10 months–66.7 years across studies). Note only one study was conducted in an infant population; all others were adult populations. See Supplementary Data Table S1 for full descriptions of all included studies.

Methodological Quality of Included Studies

Based on the SIGN 50 criteria used to assess the methodological quality of the studies, the majority (N = 12) of studies were of either acceptable (+) [9,14,15,41,43–45,50–52,54] or high (++) quality [46]; four [13,47–49] studies were deemed low (0) quality. Most studies addressed an appropriate and clearly focused question, drop out percentages, baseline similarities, group differences, and outcome reliability and validity either well or adequately. Studies were equally divided regarding reporting transparent randomization procedures, with half addressing these processes either well or adequately and the remaining studies doing so poorly. Conversely, criteria surrounding allocation concealment and intention-to-treat analyses were poorly addressed indicating these procedures were either unsuccessful or not described. All five multi-site studies poorly addressed similarities between sites (Table 1) [9,47,48,52,54].

According to the EVAT, over half of the studies described the recruitment (62.5%) and participation (60.0%) aspects of external validity adequately, indicating that the populations being studied and the source from which they came are understood well enough that results can be generalized to other patients in real-life settings. Conversely, a little over half of the studies described model validity poorly, with only a small percentage doing so either adequately (38.5%) or well (7.7%). As such, the staff, places, and facilities being used in these studies are not clearly understood, making replication and eventual translation and implementation difficult (Table 2).

STRICT-M Analysis

The EMT Working Group and review team convened to draft the proposed STRICT-M requirements, adapted from STRICTA [35], and analyzed the systematic review's literature pool according to these criteria (Table 3) [21]. Half of the studies included a rationale for selecting the massage intervention and all studies described the massage technique, however, no studies used specific terms to do so. Only some details of the massage technique were described; location of massage (93.8%) and description of pressure (68.8%) were detailed by most, but treatment variation (37.5%), amount of time spent massaging each location (31.3%) and the response sought (0.0%) were not thoroughly described by many, which challenges the replicability for future studies or clinical practice. In general, dosing, particularly information on the frequency (75.0%), duration (87.5%), and number of treatment sessions (75.0%) over a specified time frame (50.0%), was well-reported throughout the studies. Of the studies that used additional massage-related interventions meeting the review's eligibility criteria (i.e., lubricant, relaxation techniques), 50% described these interventions well. All studies provided massage in a hospital setting.

Eight studies included one provider, while one did not specify the number of providers. Seven studies included multiple providers, but only two described the interaction between providers. Although most studies (81.3%) described the type of massage practitioner,

Table 2 EVAT quality assessment [33]

	Percentage (N)			
	Poor	Adequate	Well	NA
Recruitment	6.3% (1)	87.4% (14)	6.3% (1)	0
Participation	30.8% (4)	53.8% (7)	15.4% (2)	3
Model validity	40.0% (6)	53.3% (8)	6.7% (1)	1

EVAT = External Validity Assessment Tool.

only one study described the practitioner's qualifications. Massage was administered by a massage therapist or nurse in most studies, though massage was also provided by a researcher (N = 2) and physiotherapist. See Table 3 for full detail of the STRICT-M analysis.

The comparator interventions were described by almost all studies (87.5%), however, the rationale for employing the intervention was only described by one study (6.3%). Dosing information including number (56.3%), frequency (62.5%), and duration (62.5%) of each control treatment over a specified time frame (56.3%) was addressed by most studies.

Adverse Events

Three studies [13,44,46] reported no adverse events occurred. One study [9] reported serious adverse events; however, the events were determined as unrelated to the administered massage intervention. The remaining studies did not mention or describe adverse events.

Results According to Functional Outcome

Pain

One high (++) [46], 11 acceptable (+) [9,14,15,41–45,50–52], and four low (0) [13,47–49] quality studies investigated the efficacy of massage therapy on pain outcomes in cardiac, total hip or knee arthroplasty, craniofacial, cesarean, genetic amniocentesis, laparoscopic, cardiopulmonary artery bypass graft, cancer, medical cardiovascular, and non-specified surgical pain populations. The majority of studies administered massage post-procedure; however, one study [15] provided massage pre-operation. Massage techniques primarily consisted of massage therapy, back massage, M technique massage, foot and hand massage, foot massage, light pressure effleurage massage, and therapeutic Swedish massage; 11 [9,13–15,41,44,45,47,50–52] of the 16 massage therapy studies were reportedly efficacious for treating pain, while the remaining studies displayed non-significant results.

Activity

No studies included in this analysis assessed activity; however, because most studies were conducted over a short time frame and in populations preparing for, undergoing, or recovering from a surgical procedure, activity outcomes may not be relevant to this clinical population.

Sleep

Two acceptable (+) quality studies [14,50] examined the efficacy of massage therapy on sleep-related outcomes following cardiac surgery and cardiopulmonary artery bypass graft surgery. Massage therapy was reported to be efficacious for improving sleep quality after cardiopulmonary artery bypass graft surgery [50]. The second study reported a post-cardiac surgery benefit of improved fatigue but no such improvement was found for sleep apnea and other sleep parameters [14].

Stress, Mood, Health-Related Quality of Life

There were one high (++) [46], nine acceptable (+) [9,14,15,41–43,45,51,52] and two low (0) [13,48] quality studies investigating the efficacy of massage on stress, mood, and/or HrQoL in surgery populations. Massage techniques, primarily consisting of massage and massage therapy, were administered post-surgery in all studies except one in which massage was offered pre-surgery [15]. Eight studies [9,13–15,41,44,45,48] displayed significant results for mood outcomes and two [15,44] for HrQoL. No significant results emerged from the stress outcome studies.

Physiological

There was one high (++) [46], four acceptable (+) [14,43,45,52], and two low (0) [47,48] quality studies examining physiological outcomes. Massage therapy improved physiological outcomes in individuals following total hip and knee arthroplasty [45], and cesarean delivery [47], but not for improving such outcomes after craniofacial surgery and an abdominal laparotomy [52].

Table 3 STRICT-M analysis

	Percentage (N)
1. Massage Rationale	
a. Reasoning for treatment provided	50.0% (8)
b. Extent to which treatment varied	37.5% (6)
2. Details of Massage Technique	
a. Name and description of massage technique	100.0% (16)
b. Details of intervention using terms	–
c. Location of massage	93.8% (15)
d. Amount of time spent massage each location	31.3% (5)
e. Description of pressure	68.8% (11)
f. Response sought	–
3. Treatment Regimen Related to Dosing	
a. Number of treatment sessions over what time	75.0% (12)
b. Time frame (total duration)	50.0% (8)
c. Frequency	75.0% (12)
d. Duration of each treatment	87.5% (14)
4. Other Components of Treatment	
a. Details of massage-related interventions	50.0% (1 out of 2)
b. Massage equipment	–
c. Setting	100.0% (16)
5. Practitioner Background	
a. Type of practitioner	81.3% (13)
b. Qualifications	6.3% (1)
6. Control or Comparator Interventions	
a. Rationale for control	6.3% (1)
b. Name and description of control	87.5% (14)
c. Number of control sessions	56.3% (9)
d. Time frame (total duration)	56.3% (9)
e. Frequency	62.5% (10)
f. Duration of each treatment	62.5% (10)

Results regarding post-cardiac surgery physiological outcomes were mixed with some studies reporting improvement [43,45] and others reporting no such effect [14,48].

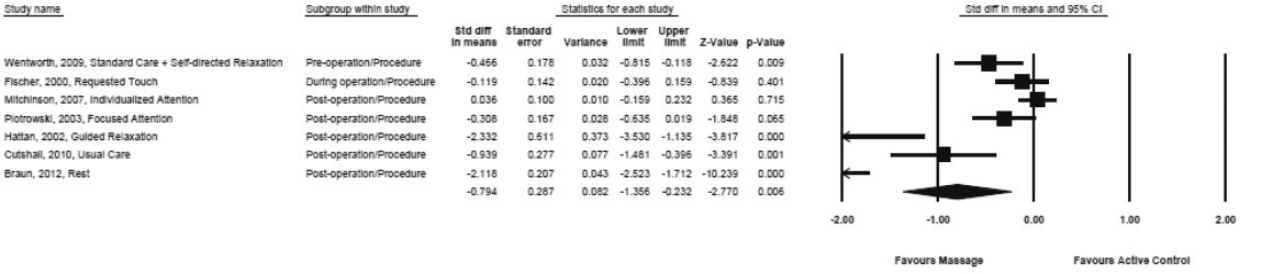
Evidence Synthesis

Of the 16 studies included in the systematic review, eight studies provided sufficient data to be included and pooled in the meta-analysis assessing the efficacy of massage therapy, compared to other active comparators on pain intensity/severity and anxiety at baseline and immediate post-treatment. There was insufficient literature available that assessed other timepoints or other function-related outcomes, or compared massage therapy to no/sham treatment. Treatment comparators are denoted beside the author names in the forest plots (see Figures 3A–B for plotted meta-analysis results). Publication bias was assessed across all subgroup analyses; although there was no indication of publication bias in any analysis (see Figure 3A–B for Egger's test *P* values), publication bias cannot be completely ruled out due to the small number of trials pooled. All studies, regardless of whether their data was pooled for meta-analysis, were considered for the overall evidence synthesis if there were at least three or more studies within a subgroup (Table 4).

Massage vs. No Treatment or Sham

Because there was an insufficient amount of studies (N = 2) comparing massage to no treatment, no evidence synthesis was performed for this subgroup on pain intensity/severity outcomes. Massage administered post-surgical procedure, however, was found to improve pain/intensity in both studies [47,50]. No studies comparing massage to sham treatment were included in this review. Similarly, there were no studies comparing massage therapy to either a sham or no treatment control that reported on stress, mood or HrQoL outcomes. As such, evidence syntheses were not performed for these subgroups either.

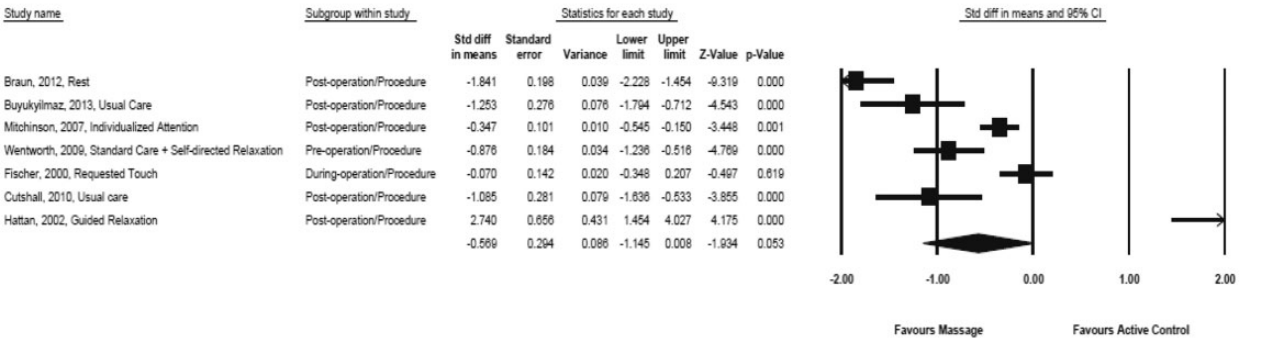
A



NOTES: Weights are from random effects analysis

Heterogeneity: Q-value = 106.11, I^2 = 94.35%; Publication bias: Egger's test P-value = 0.07

B



NOTES: Weights are from random effects analysis

Heterogeneity: Q-value = 96.40, I^2 = 93.78%; Publication bias: Egger's test P-value = 0.82

Figure 3 (A) Results of massage vs. active comparator(s) meta-analysis for pain populations undergoing surgical procedures: pain intensity/severity at post-treatment (sample size analyzed, N = 1101). (B) Results of massage vs. active comparator(s) meta-analysis for pain populations undergoing surgical procedures: Anxiety at post-treatment (sample size analyzed, N = 1015).

Massage vs. Active Comparator(s)

Pain Intensity/Severity

Fourteen studies, involving 2,270 participants undergoing a surgical procedure, compared the efficacy of massage therapy to an active comparator on pain intensity/severity. Originally, the authors pooled eight of these studies resulting in an overall standardized mean difference (SMD) of −1.59 (95% CI, −2.36 to −0.82; I^2 = 96.81%). One study, however, had a calculated effect size of −13.37 favoring massage. Labeling this study as an outlier, the authors excluded this study from the analysis in order to produce a more conservative estimate. Subsequently, only seven studies (1,101 participants) were analyzed yielding a SMD of −0.79 (95% CI, −1.36 to −0.23; I^2 = 94.35%). Translated into the VAS, the reduction in pain intensity is −19.85 (95% CI, −33.90 to 5.80) (Figure 3A).

There is a large degree of heterogeneity among the types of active comparators grouped together in this analysis (Figure 3A). When administered post-surgery, massage therapy was found to be more efficacious in reducing pain than rest, usual care, and guided relaxation, but not an individualized attention group. Massage therapy was also found to be more efficacious than standard care plus self-directed relaxation pre-surgery, but not when compared to requested touch during amniocentesis. Realizing there is heterogeneity among these studies both within the type of comparator intervention used and time of administration (e.g., pre-, during, or post-surgical procedure), pooled results indicate massage therapy seems to reduce pain intensity/severity for surgical patients. All but three of these studies were either high or acceptable quality. Only four of the 14 studies reported on safety, reporting no adverse events. Given the relatively high quality of this subset of studies but lack of safety information, further research is *likely* to have an important impact on the confidence in the estimate of the effect. A weak recommendation was suggested by the EMT Working Group for massage therapy compared to

active comparators in reducing pain intensity/severity for surgical populations experiencing pain (Table 4).

Anxiety

Seven of these studies (1,015 participants) had sufficient data on anxiety using the Visual Analogue Scale (VAS-anxiety) resulting in a SMD of -0.57 (95% CI, -1.15 to 0.01; $I^2 = 93.78\%$) in favor of massage therapy (Figure 3B). Note that the studies pooled for this analysis, with the exception of two studies, were the same ones pooled for the pain analysis; while Piotrowski et al. 2003 [51] was excluded from this analysis because they did not assess anxiety outcomes, Büyükyılmaz and Aştı 2013 [45], which was excluded from the pain analysis due to outlying data, was included. All but two studies were rated as either high or acceptable quality.

Similar to the other massage vs. active comparator meta-analysis, there is wide variation in the types of comparators used and time of massage intervention. Even though the overall positive effect is prevalent across the studies pooled, further research is *likely* to have an important impact on the confidence in the estimate of the effect. It is essential to not only determine the appropriate types of comparators to be used in future studies, but also understand the preferences for introducing such an intervention pre-, post-, or during a surgical procedure. Until appropriate controls are identified in order to best understand the effect of massage and a set of reporting guidelines (e.g., STRICT-M Checklist) are developed to help guide the translation of future efforts, a weak recommendation in favor of massage therapy for treating anxiety in surgical populations was suggested by the EMT Working Group (Table 4).

Discussion

Based on this systematic review and meta-analysis, massage therapy was found to not only be relatively safe, with infrequent adverse events, but also more efficacious than other active treatments for treating pain and anxiety in surgical populations. Because there were only a few studies that reported on HrQoL, sleep disturbance or fatigue, and emotional stress, the evidence synthesis could not be carried out for these outcomes. Future research should focus on conducting studies on these outcomes to better understand the total impact massage has on the whole person. In addition, there was insufficient data available to compare massage to sham/no treatment. Consistency of results is questioned due to the large degree of heterogeneity across the pooled studies. Pain and pain-related functional deficits are inevitable companions to most types of surgical procedures. Patients need to be aware of these challenges that can occur before, during, and after such procedures and should be offered tools to help mitigate or minimize pain-related consequences of surgery to allow for the optimization of whole-person healing during this critical time.

Further, it is still unclear how massage therapy could relieve surgery-related pain. It is possible that massage mediates its beneficial effect by providing educated, welcomed touch that reduces the transmission of noxious stimuli and alters pain perception. Although a growing body of evidence based research emphasizes the importance of human touch in facilitating healing and recovery from pain [4], the underlying mechanisms by which massage affects the body are still under investigation [55–57].

This is the first systematic review that examines the evidence base for massage therapy as a possible intervention for treating pain and function-related outcomes in individuals either recovering from or undergoing surgical procedures. Although there appears to be value for providing massage therapy as a beneficial component in the healing process for surgical patients, this systematic review identified several gaps that need to be addressed by future research before firm conclusions regarding massage as a standard and effective tool for such populations can be made.

Methodology

Overall, the majority of studies were high or acceptable quality. While most aspects of internal validity were adequately addressed, many studies failed to either successfully carry out or describe allocation concealment and intention-to-treat procedures. Similarly, only half [13,43,45,47,49–52] of the studies did not mention blinding at all. Conversely, five [9,14,15,46,54] studies were single blinded (e.g., patients were blinded) and three [41,44,48] did not employ blinding procedures but discussed their rationale for excluding such procedures. While blinding of patients may not be appropriate or possible in massage trials, blinding of data collectors and outcome assessors is often achievable. Although this review excluded blinding from its risk of bias assessment due to these challenges, the authors tracked whether blinding procedures were mentioned, as they should, at the very least, be discussed regardless of whether blinding is possible. Authors should always clearly state who was blinded or, if blinding was not carried out, discuss attempts made towards blinding or why blinding was not possible. Moreover, although most studies described aspects of external validity, several failed to fully address model validity (i.e., staff, places, and facilities used), making it difficult to completely understand how these studies may be replicated and massage therapy implemented into practice. While this review was limited to evaluating peer-reviewed RCT studies, the inclusion of more qualitative research into future systematic reviews could add value to these more real-world practice challenges.

In order for research to be trusted and allow for translation to occur, research must be conducted according to the highest possible standard and reporting must be transparent and clearly reproducible. The aforementioned methodological flaws hinder the minimization of

Table 4 Evidence synthesis

Outcome/ Comparison	Number of Participants Completed (N)	Confidence in the Estimate of the Effect*	Effect Size†	Reported Studies Safety Grade (N)‡	Strength of the Recommendation§
PAIN¶					
vs. Active Comparator(s)	2270 (14)	B	−0.79 (95% CI, −1.36, −0.23), 7 studies	+2 (4)	Weak, in favor
STRESS, MOOD, HEALTH-RELATED QUALITY OF LIFE¶					
vs. Active Comparator(s)	2150 (12)	B	Anxiety: −0.57 (95% CI, −1.15, 0.01), 7 studies	+2 (4)	Weak, in favor

Definitions for scoring are based on Samueli Institute's Overall Synthesis Evaluation Criteria (adapted from other standard synthesis methods).

*(A) Further research is very unlikely to change our confidence in the estimate of effect; *(B)* Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate; *(C)* Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate; *(D)* Any estimate of effect is very uncertain.

†Calculated as the standardized mean difference using Cohen's d effect size estimation where 0.2 is considered a *small*, 0.5 a *medium* and 0.8 a *large* overall effect.

‡Safety ranges from (+2) appears safe with infrequent adverse events and interactions to (− 2) appears to have serious safety concerns that include frequent and serious adverse events and/or interactions.

§Ranges from *Strong Recommendation in Favor* indicating that the EMT Working Group is very certain that benefits do outweigh risks and burdens to *Strong Recommendation Against* indicating that the EMT Working Group is very certain that benefits do not outweigh the risks and burdens.

¶Negative effect indicates improvement in massage intervention compared to control intervention.

bias, thereby impacting the validity of results. To avoid such flaws, the authors encourage the adherence of future research to CONSORT guidelines. Doing so would help ensure critical study elements are carried out and reported, increasing the confidence in the results shown, thereby allowing for translation and eventual implementation.

Challenges to Implementation

The use of massage in hospital settings is becoming seemingly more popular. For instance, the Mayo Clinic incorporated massage therapy into routine postoperative management of cardiac surgery patients after feasibility and confirmatory trials demonstrated the successful use of massage post-cardiac surgery. In order to successfully implement massage into clinical practice and for policy change to occur in hospital settings, the what, who and how of massage therapy, as it relates to surgical patients, needs to be clearly understood. The authors encourage future research to focus on identifying the specifics of massage including style of therapy needed for different conditions or operative procedures, location of massage and amount of time spent there, appropriate pressure to apply, adequate dosing and time of administration, practitioner type, qualifications, and credentialing and licensing requirements. These factors must be carefully considered before clinical guidelines regarding the use of massage in surgical units across hospitals can be created.

Although knowing this information is essential for replication in a real-world setting, many studies included in this systematic review failed to report on these items. For example, variations in massage treatment, amount of time massaging each location, and response sought were lacking in the majority of these studies. Further, most studies described the type of the massage practitioner; however, only one described the practitioner's qualifications. Although practitioners' qualifications are likely associated with trial efficacy, specifically an improvement in outcomes [58], this concept is difficult to fully understand as this information is typically underreported [59,60]. As such, the authors encourage researchers to utilize standard reporting guidelines, such as the proposed STRICT-M Checklist described in this report, when developing protocols and reporting clinical trials so this vital information is not missed. Once this information is better understood, a panel of experts can convene to determine the optimal intervention technique, treatment regimen, and dose needed to ensure successful treatment of surgical patients experiencing pain.

Determining the most optimal time to deliver massage in a surgical population is another important factor to examine. The studies captured in this review examined massage offered pre-, post- or during surgical procedures. While this heterogeneity complicates interpretation, and since this is the first systematic review to examine surgical populations, the authors agreed to take a broader stance and include all studies regardless of time of massage administration. Massage offered before surgery has been anecdotally reported to relieve much of the anxiety and tension associated with the anticipation of having surgery, helping the patient feel less stressed, and lowering the patient's expectations for pain. It is believed that this could in turn enhance the patient's ability to heal quicker and with fewer complications. Despite these potential benefits, very few studies examining the effect of pre-surgery massage were captured in this review, as most focused on post-surgical massage.

To determine if the time of massage administration would account for some of the heterogeneity among the pooled studies, the authors conducted sub-analyses on post-surgical populations. Regarding pain intensity/severity, five post-surgical intervention studies were pooled, producing an overall SMD of −1.05 (95% CI, −1.94 to −0.18; $I^2 = 96.08\%$). Five studies with anxiety outcomes were pooled yielding an overall SMD of −0.54 (95% CI, −1.42 to 0.35; $I^2 = 94.93\%$). Although both analyses showed significant effects favoring massage, results did not seem to account for the inconsistency among studies, suggesting that there are heterogeneities beyond those relating to time of massage and administration.

Research Challenges

Future research should focus on selecting appropriate controls in order to best determine the effectiveness of massage. The majority of studies compared massage to another active therapy (i.e., rest, usual care, relaxation, attention) and reported massage was superior to most of these comparators. Comparative effectiveness research should be conducted to better understand these comparisons. While no studies included information on cost, the authors encourage future research to conduct cost analyses and include additional outcomes, such as feasibility, length of hospital stay, and medication use, when deciding which intervention is most practical and appropriate for implementation.

No studies compared massage to sham therapy and only two compared massage to no treatment. Most massage trials typically have used no treatment control groups, which does not control for nonspecific effects of attention and touch. Consequently, massage interventions tend to be more successful than such a control. Similarly, wait list controls do not control for placebo effects, and treatment as usual controls often assign individuals to care that they may have already tried in the past and have found unsuccessful. To ensure positive effects are truly attributable to massage and that massage is not being given an "unfair advantage" by comparing it to inappropriate controls, massage must be assessed against controls that are equally credible, acceptable and seemingly identical to massage. Perhaps the most promising comparison group, then, would be a sham group (e.g., sham massage, light touch). However, the field is currently divided about what constitutes an appropriate sham control: While some believe a touch control elicits nonspecific physiological effects and is therefore not a true placebo, proponents argue that it is an appropriate

sham treatment as people frequently touch each other. Given the issues surrounding relevant control groups, future research should focus on identifying control groups to truly determine the efficacy of massage. Further, patient expectation was not measured by any study included in this review; however, because it can contribute to a placebo effect, the authors encourage future trials to include questions about patient and practitioner expectation during the trial period.

It is important to utilize not only appropriate control/comparators but also standardized patient-reported outcomes that are perceived as valid, sensitive and reliable for ensuring impactful results in healthcare. Doing so helps inform trustworthy policy decisions for cost-effective treatments that are meaningful to the patient and focus on whole person healing. The Patient Reported Outcomes Measurement Information System (PROMIS) was initiated by the National Institutes of Health (NIH) to develop reliable and valid patient-reported items to evaluate medical interventions for persons with a wide range of chronic diseases and demographic characteristics. It can be offered as a national resource for precise and efficient measurement of patient reported symptoms and other health outcomes meaningful to patient function [61]. The Pain Assessment Screening Tools and Outcomes Registry (PASTOR) [62] is an example of a clinical pain assessment tool that utilizes PROMIS domains in order to standardize approaches to pain management. Such assessment tools are not only less time-consuming than using multiple individual assessment tools, but also patient-centered as they are based on patients' perspectives from an individualized patient centered care model. This current review examined PROMIS and PASTOR domains to pre-define the function related outcomes of interest. Researchers should be encouraged to take advantage of PROMIS domains in future clinical trial work on massage therapy to ensure patient-centered care is at the forefront of research and to create both effective and easy translation and combinability of future results for the massage field. Specifically for surgical populations, the timescale inherent in many of these tools, however, requires careful attention to ensure they are precise enough to measure changes in the typical abbreviated hospital stay. In addition, while the authors used a clinically important cut-off point of 20 mm for the VAS for the reduction in pain, this should be interpreted with caution. What constitutes a clinically important change will vary for each individual and likely goes beyond just a reduction in pain, and is also impacted by psychological, physical, social, and spiritual functioning.

Suggested Next Steps for Future Research

1. Encourage researchers to standardly follow the CONSORT Checklist to prepare reports of trial findings to facilitate a complete and transparent report, aiding in their critical appraisal and interpretation.
2. Consider the proposed STRICT-M Checklist offered throughout this systematic review and adapt it for use in future trials.
3. Consider the use of PROMIS and PASTOR in future clinical trials in the field of massage therapy.
4. Sort through the issue of heterogeneity in the current literature base, considering items 1–3, and make recommendations regarding standard criteria for future protocol development.
5. Conduct comparative effectiveness research, incorporating cost benefit analyses on the use of massage therapy in pre and post-surgery populations in hospital settings.

Conclusion

Massage therapy appears to be efficacious for reducing pain and anxiety in patients who are either about to undergo or are recovering from surgical procedures. This is the first reported attempt to pool the current literature base surrounding massage therapy for patient-reported functional outcomes in surgical patients experiencing pain. There is a wide degree of heterogeneity among these studies that needs to be addressed in order to adequately influence policy change and make definitive recommendations regarding massage therapy. This review identified several research gaps. Reporting requirements need to be more stringent and standardly enforced to ensure bias free results that can be translatable for future work and implementation. Guidelines (e.g., proposed STRICT-M Checklist) specific to massage therapy research should also be adapted to ensure intervention components around dosing, timing, massage pressure, practitioner qualifications, and credentialing are appropriate for surgical populations in hospital settings. Uniform, valid, and reliable measures should be consistently utilized in studies to not only address the whole patient perspective, but also guide future work in this area. Once these gaps are addressed, comparative effectiveness research can be proposed, taking into account cost benefit analyses, in order to determine whether massage therapy is an appropriate intervention to offer patients who are either about to undergo or are recovering from surgical procedures in hospital settings. The promising results yielded from this systematic review and meta-analysis warrant the investment of both time and resources into addressing recommendations offered in this report to guide future research and ultimately offer massage therapy as a beneficial tool for surgical patients experiencing pain.

Supplementary Data

Supplementary Data may be found online at http://painmedicine.oxfordjournals.org.

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