Acute Postoperative Pain Management Using Massage as an Adjuvant Therapy

A Randomized Trial

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Hypothesis: Adjuvant massage therapy improves pain management and postoperative anxiety among many patients who experience unrelieved postoperative pain. Pharmacologic interventions alone may not address all of the factors involved in the experience of pain.

Design: Randomized controlled trial.

Setting: Department of Veterans Affairs hospitals in Ann Arbor, Michigan, and Indianapolis, Indiana.

Patients: Six hundred five veterans (mean age, 64 years) undergoing major surgery from February 1, 2003, through January 31, 2005.

Interventions: Patients were assigned to the following 3 groups: (1) control (routine care), (2) individualized attention from a massage therapist (20 minutes), or (3) back massage by a massage therapist each evening for up to 5 postoperative days.

Main Outcome Measure: Short- and long-term (>4 days) pain intensity, pain unpleasantness, and anxiety measured by visual analog scales.

Results: Compared with the control group, patients in the massage group experienced short-term (preintervention vs postintervention) decreases in pain intensity (P=.001), pain unpleasantness (P<.001), and anxiety (P=.007). In addition, patients in the massage group experienced a faster rate of decrease in pain intensity (P=.02) and unpleasantness (P=.01) during the first 4 postoperative days compared with the control group. There were no differences in the rates of decrease in long-term anxiety, length of stay, opiate use, or complications across the 3 groups.

Conclusion: Massage is an effective and safe adjuvant therapy for the relief of acute postoperative pain in patients undergoing major operations.

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ESPITE THE AVAILABILITY of opioid analgesics, studies have demonstrated that many patients have a substantial degree of unrelieved discomfort after an operation.¹⁻⁸ Pain is often undertreated owing to patient and clinician barriers. Patients

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frequently fear dependency, are concerned about adverse effects of analgesics, believe that suffering should be accepted without complaint, or worry about bothering nurses. Physicians and nurses may possess personal biases, cultural attitudes, or knowledge deficits that lead to prescribing or administering ineffective doses of analgesics.^{2,4,7,9-17}

The undertreatment of pain persists despite awareness of ineffective practices. Education, although essential, has proved insufficient alone to overcome ingrained clinician behavioral patterns.¹⁸ Recent attempts to address the issue include making pain a fifth vital sign and the implementation of new pain standards by the Joint Commission for Accreditation of Healthcare Organizations.¹⁹⁻²⁵ Clearly, alternative approaches to managing postoperative pain that supplement current practice may prove more effective than efforts at achieving better adherence to a regimen of opiate administration alone.

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The problem of pain is more than just patient discomfort. Pain can affect physical functioning, including the ability to cough and breathe deeply, move, sleep, and perform self-care activities. This may contribute to unintended and serious postoperative complications.^{1,26-30} Furthermore, ineffective pain relief may result in significant

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psychological distress, potentially leading to sensory overload, anxiety, confusion, and even delirium.³¹⁻³³ Surgical patients report that pain is one of the highest environmental stressors they encounter.^{34,35}

Pain has sensory and affective components. Sensory qualities are described in relation to time, intensity, pressure, and location of pain. The affective component of pain is related to the emotional context and often described as "unpleasantness."³⁶⁻⁴⁰ Pharmacologic interventions alone may not effectively address all of the factors involved in the conscious experience of pain.

Massage is any systematic form of touch or manipulation performed on the soft tissues of the body that provides comfort and promotes health.⁴¹⁻⁴³ Touch and massage have been used for centuries to treat pain.⁴⁴ When integrated with pharmacologic treatment, massage may be useful in the management of acute postoperative pain.

Although several case reports and experimental studies have addressed the potential benefits of massage on pain,⁴⁵⁻⁵² only 2 clinical trials have examined the effect of massage on acute postoperative pain.^{53,54} In the first study, Nixon et al53 found that patients who received massages experienced reduced pain levels when compared with control participants. However, the study had several limitations: it was limited to 39 participants; massage method and length, times of day, and anatomical sites varied between subjects; details on opiate use were lacking; and pain unpleasantness was not measured. Piotrowski et al⁵⁴ conducted the second study as a pilot study before the present one. Pain intensity and unpleasantness in response to massage or individualized attention were assessed. There was a significant difference in the rate of decrease of pain unpleasantness between the control and massage groups. The same trend was found for pain intensity but was not statistically significant. The present study was designed to have adequate statistical power to detect the effect seen previously and to examine the short-term effect of massage on pain, anxiety, and functional recovery.

METHODS

DESIGN

We designed this randomized controlled trial to evaluate the effects of a back massage on patients' self reported perceptions of postoperative pain, anxiety, and functional recovery. Patients undergoing major thoracic or abdominal operations were randomized into 3 groups and received (1) routine care (control group), (2) individualized attention from a massage therapist (MT) for 20 minutes but no massage (individualattention group), or (3) a 20-minute back massage each evening by an MT (massage group). The study aim was to compare the perceived relief of pain and anxiety, opiate use, pulmonary function, postoperative complications, and length of stay (LOS) between the 3 groups. The primary hypotheses were that perceived postoperative pain and anxiety decrease over time more rapidly in the massage group compared with the individualattention and control groups and that perceived postoperative pain and anxiety are immediately reduced as a short-term effect in the massage group compared with the other groups. We also hypothesized that massage, through its effects on pain relief, would enhance the recovery of pulmonary function. Randomization was stratified by surgical type and study site and, within each stratum, blocked randomization was performed to further enhance group balancing. The biostatistician in our group (H.M.K.) performed the randomization. Sequentially numbered envelopes with group assignments were prepared ahead of time and given to coordinators at each site.

PATIENTS

Patients were recruited from February 1, 2003, through January 31, 2005, at Department of Veterans Affairs medical centers in Ann Arbor, Michigan, and Indianapolis, Indiana. All veterans requiring operations with a sternotomy or an abdominal incision that entered the peritoneal cavity and was at least 8 cm were considered eligible. Patients were excluded if they were blind, deaf, or delirious; could not understand English; or had severe mental illness. Patients were identified from surgery schedules or surgery clinic schedules. Most patients were recruited before surgery. Institutional review board approval was obtained at both medical centers.

OUTCOMES AND MEASUREMENTS

The primary outcomes of pain intensity, pain unpleasantness, and anxiety were measured using visual analog scales (VAS). Each VAS was anchored by phrases at opposite ends of a 10-cm line. The anchoring phrases were "no pain" and "severe pain" for intensity and "not at all unpleasant" and "as unpleasant as can be" for unpleasantness. For anxiety, the phrases were "no anxiety" and "as anxious as I can be." Delirium was assessed using the Bedside Confusion Scale.⁵⁵ This test consisted of a visual assessment of the patient's alertness and then a rating of how well the patient recited the months of the year backward. State and trait anxiety levels were assessed using selected questions from the State-Trait Anxiety Inventory, a well-validated instrument designed to help differentiate anxiety as a personality trait vs anxiety in response to stress.⁵⁶

PROCEDURE

After consenting to participate, the patients completed a baseline questionnaire containing selected questions from the State-Trait Anxiety Inventory and demographics. Patients also rated their current levels of pain intensity and unpleasantness. The study coordinator performed spirometry on patients who did not undergo preoperative pulmonary function tests to obtain baseline forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV₁) using commercially available software (Breeze Suite; MedGraphics, St Paul, Minnesota) on a laptop computer.

Patients were asked to complete each VAS each morning between 9 and 11 AM, beginning on postoperative day 1 and continuing through day 5 or until discharge if earlier. After ensuring that the patient was extubated and well enough to be visited, the site coordinator or research assistant asked the patient to rate the levels of pain and anxiety. Each day, delirium was assessed using the Bedside Confusion Scale. Spirometry was performed on postoperative days 1, 3, and 5.

INTERVENTIONS

Nationally certified MTs provided interventions to the 2 experimental groups each evening between 6 and 8 PM. Patients randomized to the control group received routine care from nursing staff. Patients in the individual-attention group received, in addition to routine care, dedicated time (≤ 20 minutes) with the MT each evening on postoperative days 1 through 5 or until discharge. The purpose of this group was to assess the effect of emotional support independent of massage. Patient-MT

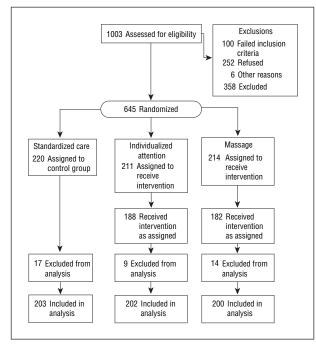


Figure 1. The progress of patients throughout the trial. The number of patients included in the analysis is derived from the number assigned to receive the intervention minus the number excluded from the analysis.

discussions were informal and spontaneous and typically included such topics as family, hobbies, and personal interests.

In addition to routine care, patients in the massage group received up to a 20-minute effleurage back massage. Most of the patients who underwent sternotomy received their massages while leaning forward in a chair and resting their head and arms on their tray table. If the patient received the massage while lying in the bed, he or she lay in a lateral recumbent position supported by pillows. The MTs were instructed to use medium pressure but to be responsive to a patient's tolerance. Patients were instructed to relax and encouraged to inform the MT if they became uncomfortable, wanted to change position, wished to stop, or required modification of the technique.

Each evening, research assistants collected the pain and anxiety VAS findings within 30 minutes before and after the intervention. Every effort was made to keep the research assistants blinded to the patient's group assignment. The MT and research assistant coordinated their efforts by using a centrally located log, where they recorded times of patient interaction.

OTHER DATA

Daily opioid use, including the drug name, dose, and route and the time of administration, were collected. The total amount of daily analgesic use was normalized by converting the daily opioid dose to the intravenous morphine equivalent. On the sixth postoperative day, patients completed a questionnaire that asked about satisfaction with pain management. Those in the massage group also completed questions about their experience with massage. Data on postoperative complications occurring within 30 days after surgery were collected from patient records.

STATISTICAL ANALYSIS

The sample size was determined to have 80% power to detect a difference in the rate of decline in the pain intensity score of 0.22 (scale range, 0-10) per day during the first 4 postoperative days with an α of .05, assuming 4 measurements (including baseline) per patient, within-subject correlation of 0.05, and σ of 2.3 (estimated from the pilot data). No interim analysis was planned.

All analyses were performed with the intention-to-treat method. Baseline comparisons of demographic variables across the 3 groups were analyzed using χ^2 tests or analysis of variance where appropriate.

Initially, the individual daily scores and daily mean scores of pain intensity, pain unpleasantness, and anxiety were explored graphically for each postoperative day by group. Missing data were assessed to determine whether missing outcome variables were ignorable.⁵⁷

Each of the outcome variables were collected 3 times daily (ie, morning, preintervention, and postintervention). To estimate the time-averaged effect while accounting for the potential correlation within multiple measurements of the same patient and to model the trend over time, a random-effect growth curve model was used.⁵⁸ The model included a random intercept for each patient to adjust for the within-subject correlation and for time as the number of days since randomization to model the trends over time. Dummy variables for the massage and attention groups were used to model group effects, and an interaction term of time × group was used to model the potential differential rate of change in outcome over time across the groups. A coefficient of the time × massage group interaction term of less than zero would suggest a faster decrease in outcome for the massage group relative to the control group. The model also included daily opiate consumption normalized by body mass index.

Although it would be impossible to determine whether missing data mechanisms are ignorable, under the assumption of ignorable missingness, a likelihood-based analysis such as a longitudinal model with random effects is valid given that the model is correctly specified.⁵⁹ However, we also used the chained stochastic imputation method to impute missing outcomes and covariates using observed data.⁶⁰ We then repeated the analyses for the 3 primary outcome variables using the multiple imputation method. Estimates from the imputed data sets were combined to obtain variable estimates and appropriate standard errors after accounting for both between- and withinimputation variation.⁶¹

For logistical reasons, spirometry data (FEV₁ and FVC) were collected at fewer than 20% of the planned measurement times at one study site; therefore, these analyses were restricted to one site. We evaluated the effect of the interventions on the day 5 FEV₁ and FVC percentages predicted using multiple regression with independent variables of group indicators, incision type indicators, and other potential covariates. For complications, a logistic regression model was used to assess the effect of the intervention on the occurrence of any complication. The LOS was skewed to the right, so we analyzed it as is and after truncating at 30 days (99th percentile). We performed statistical analyses using Stata, version 9.1 (StataCorp, College Station, Texas), and SAS, version 9.1 (SAS Institute Inc, Cary, North Carolina) statistical software, and set statistical significance at .05.

RESULTS

PATIENT CHARACTERISTICS

We approached 1003 patients and, of 903 who were eligible, 645 consented, 252 refused, and 6 were initially screened but unable to be located thereafter for various reasons. Reasons for refusal included lack of interest, discomfort with being touched, anxiety about surgery, and

Table 1. Demographic Variables by Treatment Group

		Treatment Group ^a			
Characteristics	Control (n=203)	Individual Attention (n=202)	Massage (n=200)	Total (N=605)	P Value ^b
Male ^c	200 (98.5)	200 (99.0)	196 (98.0)	596 (98.5)	.70
Race ^c					
White	173 (85.6)	174 (86.6)	177 (88.9)	524 (87.0)	
Black	27 (13.4)	24 (11.9)	17 (8.5)	68 (11.3)	.72
Other	2 (9.9)	3 (1.5)	5 (2.5)	10 (1.7)	
Age, mean±SD, y	63.8 ± 10.1	64.2±10.3	63.5 ± 10.3	63.8±10.2	.79
Preoperative pain intensity score, mean±SD Annual income, \$ ^c	1.63 ± 2.4	1.42±2.4	1.22±2.2	1.42±2.3	.30
≤20 000	133 (71.9)	108 (61.7)	114 (64.4)	355 (66.1)	
20 001-30 000	27 (14.6)	34 (19.4)	30 (16.9)	91 (16.9)	
30 001-40 000	9 (4.9)	20 (11.4)	23 (13.0)	52 (9.7)	.41
>40 000	16 (8.6)	13 (7.4)	10 (5.6)	39 (7.3)	
Marital status ^c	- ()		- ()	(-)	
Married	96 (50.0)	86 (46.7)	80 (44.7)	262 (47.2)	
Divorced, separated, or widowed	81 (42.2)	82 (44.6)	77 (43.0)	240 (43.2)	50
Never married	9 (4.7)	12 (6.5)	18 (10.1)	39 (7.0)	.53
Living with someone	6 (3.1)	4 (2.2)	4 (2.2)	14 (2.5)	
Posttraumatic stress disorder ^c	18 (8.9)	19 (9.4)	16 (8.0)	53 (8.8)	.88
Education ^c	. ,	. ,	. ,	. ,	
<12 y	28 (14.9)	39 (21.2)	38 (21.2)	105 (19.1)	
Completed high school or GED	76 (40.4)	67 (36.4)	71 (40.0)	214 (38.8)	.37
Some college	58 (30.9)	62 (33.7)	52 (29.1)	172 (31.2)	.57
\geq 4 y of college	26 (13.8)	16 (8.7)	18 (10.1)	60 (10.9)	
Combat history ^c	94/192 (49.0)	82/183 (44.8)	89/181 (49.2)	265/556 (47.7)	.64

Abbreviation: GED, general equivalency diploma.

^aUnless otherwise specified, data are expressed as number (percentage) of patients.

^b Calculated to compare distributions of patient characteristics across the 3 intervention groups using the χ^2 test for categorical variables and analysis of

variance for continuous variables.

^cPercentages are calculated of those with data for the variable.

not wanting to be bothered. Of the 645 patients who were randomized, postoperative pain and anxiety scores were not collected for 40 (17 from the control group, 9 from the individual-attention group, and 14 from the massage group) for the following reasons: receiving mechanical ventilation or reintubated (17 patients), withdrawal from the study (11), return to the operating room (5), delirium or a neurological problem (2), and other miscellaneous logistical reasons (5). These patients were not included in the analysis. Of the remaining 605 participants, 203 were assigned to the control group, 202 to the individual-attention group, and 200 to the massage group (Figure 1). There were no significant differences across the 3 groups in age, sex, education, marital status, preoperative pain intensity, history of military combat, or posttraumatic stress disorder (Table 1). The median age was 64 (mean±SD, 63.8±10.2) years, and the participants were overwhelmingly male (98.5%). The sternum was the most common incision site (64.0%).

Of the 605 participants, 221 (36.5%) had all 5 usual pain intensity measurements, and the corresponding numbers were similar for the other outcomes. The pattern of missing data was random for the 5 postoperative days. Missingness in the postoperative day 1 pain intensity measurement was not associated with the preoperative pain intensity measurement or the treatment group. Older patients (P=.02) and those undergoing sternotomy (P=.004) were more likely to have missing day 1 pain

intensity measurements. Increasing age, the presence of a sternotomy, and the site were similarly associated with missingness in the postoperative day 1 pain unpleasantness and anxiety measurements. No statistical differences were seen across the 3 groups in preoperative pain intensity, unpleasantness, state and trait anxiety, or postoperative day 1 pain intensity or unpleasantness (**Table 2**). Morning anxiety on postoperative day 1 was higher in the individual-attention group (P=.02), but there was no difference across the 3 groups in postoperative day 1 preintervention anxiety (P=.89).

SHORT-TERM EFFECT

The daily mean short-term changes for the pain intensity, pain unpleasantness, and anxiety scores all showed significant improvement from preintervention to postintervention measurements (**Table 3**). Although shortterm improvement was significant for all 3 groups for each of the 3 outcome variables, the massage group had a significantly greater improvement in short-term outcomes than did the individual-attention or the control group. In particular, for pain intensity, the individualattention group did not differ from the control group (P=.54), but the massage group had an additional 0.34 reduction in pain score (P=.001), averaged across the 5 postoperative days (**Table 4**) after controlling for daily preintervention pain intensity level. Similarly, the

Table 2. Daily Mean Pain Intensity, Pain Unpleasantness, and Anxiety Scores in the 3 Treatment Groups^a

Scale			Mean±SD Score						
			Postoperative Day Since Randomization						
	Treatment Group	Preoperative	1	2	3	4	5		
Pain intensity ^b	Individual attention	1.4±2.4	6.0±2.8	5.1±2.8	4.4±2.7	3.9±2.6	4.0±2.7		
	Control	1.6±2.4	6.1±2.7	5.5 ± 2.5	4.8±2.6	4.2±2.6	3.7 ± 2.5		
	Massage	1.2±2.2	5.9 ± 3.0	5.2±2.7	4.4±2.5	3.6 ± 2.5	3.7 ± 2.6		
Pain	Individual attention	1.7±2.8	6.2±2.8	5.1±2.9	4.4±2.8	4.1±2.7	4.1±2.8		
unpleasantness ^c	Control	1.7±2.6	6.1±2.8	5.6±2.7	4.8±2.7	4.1±2.7	3.7 ± 2.5		
	Massage	1.4±2.5	6.0 ± 3.2	5.2±2.9	4.5±2.6	3.7 ± 2.7	3.7 ± 2.6		
Anxiety	Individual attention	2.9±1.7 ^d	3.3 ± 3.2	2.7±3.1	2.5±2.8	2.1±2.5	2.4 ± 2.8		
	Control	3.2±1.7 ^d	2.6±2.8	2.7±2.9	2.4±2.6	2.5±2.6	2.1±2.5		
	Massage	3.0±1.7 ^d	2.5 ± 3.0	2.4±2.8	2.2±2.6	2.0±2.5	2.2±2.7		

^aAll pain and anxiety scores are daily averages of scores measured in centimeters on a 10-cm visual analog scale, except the preoperative anxiety scores. ^bMeasured as usual pain in the past 24 hours.

^cMeasured as usual pain unpleasantness in the past 24 hours.

^d Preoperative anxiety scores are trait anxiety scores and range from 0 to 10, with 10 indicating most anxious.

Scale	Treatment Group	Postoperative Day Since Randomization, Mean \pm SD Score						
		1	2	3	4	5		
Pain intensity ^b	Individual attention	0.4±1.9	0.3±1.9	0.6±1.8	-0.0±1.7	0.1±1.4		
	Control	0.3±1.9	0.5±1.8	0.2±1.6	0.1±1.3	0.2±1.3		
	Massage	1.1±2.0	0.4±1.9	0.5 ± 2.0	0.6±1.9	0.3±1.2		
Pain	Individual attention	0.5±2.1	0.5 ± 2.2	0.5 ± 2.0	0.1±1.7	0.2±1.6		
unpleasantness ^c	Control	0.6±2.2	0.4±1.7	0.5±1.7	0.1±1.5	0.1±1.4		
	Massage	1.1±2.5	0.7 ± 2.4	0.7±1.9	0.7±1.8	0.4±1.3		
Anxiety	Individual attention	0.4±1.7	0.4 ± 1.9	0.6±1.8	0.1±1.5	0.4±1.8		
	Control	0.4±2.1	0.1 ± 2.0	0.4 ± 2.0	0.2±1.9	0.1±1.5		
	Massage	1.1±2.6	0.6 ± 2.2	0.6±1.7	0.6±1.9	0.5±1.7		

^aShort-term reductions (measured in centimeters) were calculated as the reduction from before intervention to after intervention. Larger values correspond to greater improvement.

^bMeasured as usual pain in the past 24 hours.

^cMeasured as usual pain unpleasantness in the past 24 hours.

Table 4. Model for Daily Short-term Change in Pain Intensity					
	Coefficient	SE	P Value	95% CI	
Preintervention pain ^a	0.24	0.01	<.001	0.21 to 0.27	
Massage group ^b	0.34	0.10	.001	0.14 to 0.54	
Individual-attention group ^c	0.06	0.10	.54	-0.14 to 0.27	
Time, d ^d	0.02	0.03	.57	-0.04 to 0.07	
Intercept	0.25	0.09	.005	0.08 to 0.42	

Abbreviation: CI, confidence interval.

^aThe scores are centered by subtracting the mean value of 4.0 for a sensible interpretation of the intercept.

^b Indicator for the massage group, with the control group as the reference group.

^cIndicator for the individual-attention group, with the control group as the reference group.

 $^{\rm d}$ Takes values of 0, 1, 2, 3, and 4 for postoperative days 1, 2, 3, 4, and 5, respectively.

time-averaged short-term reduction in the pain unpleasantness score was significant in all 3 groups (P=.001), but an additional reduction of 0.41 in the pain unpleasantness score (P<.001) was observed in the massage group compared with the control group, whereas there was no difference between the individual-attention and control groups (P=.45). The anxiety score also showed a short-term daily reduction in each of the 3 groups (P=.007), with the massage group showing an additional reduction of 0.48 (P<.001) compared with the control group.

For all 3 outcome variables, the daily short-term improvement was significantly associated with the daily preintervention values of the outcome. Greater improvement was associated with a worse preintervention outcome (a higher score) and, although the amount of unadjusted daily outcome improvement decreased during the 5 postoperative days (Table 3), after controlling for the daily preintervention scores of the outcome and group, no time effect was found.

LONG-TERM EFFECT

The pain intensity score declined over time at different rates across the 3 groups (**Figure 2**), but by postoperative day 5, the mean scores were at a similar level (P=.56 by analysis of variance). We therefore used pain data from postoperative days 1 to 4 to model the differing rates of

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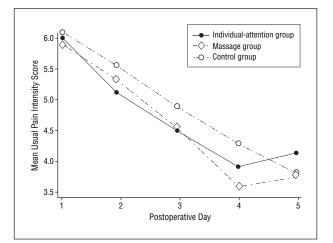


Figure 2. The mean daily usual pain intensity scores in the control and 2 intervention groups.

Table 5. Model for Long-term Change in Pain Intensity ^a							
	Coefficient	SE	P Value	95% CI			
Day 1 pain ^b	0.52	0.03	<.001	0.46 to 0.57			
Time, d ^c	-0.60	0.08	<.001	-0.75 to -0.45			
Time × massage	-0.22	0.09	.02	-0.40 to -0.03			
Time × attention	0.09	0.10	.35	-0.10 to 0.28			
Total opiate dosage ^d	0.15	0.08	.046	0.00 to 0.30			
Preoperative pain ^b	0.14	0.03	<.001	0.08 to 0.21			
Trait anxiety ^b	-0.003	0.05	.95	-0.09 to 0.09			
Sternotomy	0.29	0.17	.10	-0.05 to 0.63			
Lobectomy	0.41	0.38	.28	-0.33 to 1.15			

Abbreviation: CI, confidence interval.

^a Although not shown here and not statistically significant, the model was also adjusted for age using dummy variables for 4 age categories.

^bScores can range from 0 to 10, with 10 indicating greatest pain or anxiety, depending on the scale.

^cTakes values of 0, 1, 2, 3, and 4 for postoperative days 1, 2, 3, 4, and 5, respectively.

^d Total opiate dosage consumed is expressed as the intravenous morphine equivalent for 24 hours and divided by body mass index.

decline across the 3 groups. After controlling for preoperative pain level, anxiety trait, age, type of incision, daily opiate consumption, and postoperative day 1 pain level, the pain intensity score was shown to decline significantly at a rate of 0.60 per day (P < .001; **Table 5**). This can be translated as a reduction in the pain score of 1.80 $(0.60 \times 3 \text{ days})$ from postoperative days 1 to 4 for the control group. Pain scores in the individual-attention group did not decline faster than they did in the control group (P=.35), but in the massage group they declined by an additional 0.22 per day (P=.02), giving an estimated decline in the pain score of 2.46 from days 1 to 4. When daily anxiety and confusion were added to the model, they were significantly associated with daily pain intensity, but the decline in the pain score in the massage group was still evident (P=.049), which did not support the hypothesis that the faster reduction in pain was primarily mediated through reduction in confusion or anxiety.

The pain unpleasantness score also declined significantly faster in the massage group than in the control group (**Figure 3**), after controlling for opiate use and

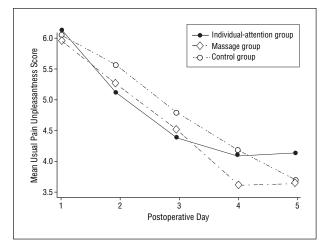


Figure 3. The mean daily usual pain unpleasantness scores in the control and 2 intervention groups.

Table 6. Model for Long-term Change in Pain Unpleasantness^a

	Coefficient	SE	P Value	95% CI
Day 1 unpleasantness ^b	0.54	0.03	<.001	0.48 to 0.59
Time, d ^c	-0.60	0.08	<.001	-0.75 to -0.44
Time × massage	-0.25	0.10	.01	-0.44 to 0.06
Time × attention	0.01	0.10	.93	-0.18 to 0.20
Total opiate dosage ^d	0.17	0.08	.03	0.02 to 0.33
Preoperative unpleasantness ^b	0.08	0.03	.007	0.02 to 0.14
Trait anxiety ^b	0.03	0.05	.58	-0.07 to 0.12
Sternotomy	0.37	0.18	.04	0.02 to 0.73
Lobectomy	0.34	0.40	.40	-0.45 to 1.13

Abbreviation: CI, confidence interval.

^a Although not shown here and not statistically significant, the model was also adjusted for age using dummy variables for 4 age categories.

^bScores can range from 0 to 10, with 10 being greatest pain or anxiety, depending on the scale.

^c Takes values of 0, 1, 2, 3, and 4 for postoperative days 1, 2, 3, 4, and 5, respectively.

^dTotal opiate dosage consumed is expressed as the intravenous morphine equivalent for 24 hours and divided by the body mass index.

preoperative unpleasantness. The pain unpleasantness score declined 0.60 per day in the control group, which is a reduction of 1.80 (0.60×3 days) from postoperative days 1 to 4 (**Table 6**). The pain unpleasantness score declined faster in the massage group by an additional 0.25 cm per day (*P*=.01), but the rate in the individual-attention group was not different from that of the control group (*P*=.93). Unlike the pain intensity score, when daily anxiety was added to the model, the rate of decline in the massage group was still different from that of the individual-attention and control groups, but the rate of decline was reduced to 0.18 (*P*=.07), suggesting that the reduction in pain unpleasantness in the massage group might be mediated through reduction in anxiety.

Although the daily morning (long-term) anxiety score also decreased over time (**Figure 4**), no long-term effect of massage on anxiety was found. The decrease in anxiety over time was significant (P=.03), but the anxiety score declined at a faster rate in the individual-attention group than it did in the other 2 groups (P=.04), likely owing

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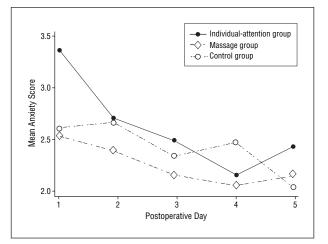


Figure 4. The mean daily anxiety scores in the control and 2 intervention groups.

to a significantly greater anxiety level in the individualattention group on the first day, although the results were adjusted for the postoperative day 1 anxiety level.

MULTIPLE IMPUTATION

We created 5 imputation data sets. To impute missing outcome values and time-dependent covariates, we used incision type (which did not have any missing values) as a predictor, along with all observed outcome values and covariates. Results from the multiple imputations were generally similar to the results without imputation. The massage group showed a faster decline than the control group in pain intensity and unpleasantness. However, unlike the analysis without imputation and although not statistically significant, the individual-attention group also showed a faster rate of decline in pain intensity (0.13 per day faster; P = .09) and pain unpleasantness (0.15 per day faster; P = .07) compared with the control group. No difference was found between the individual-attention and massage groups for either pain measure.

OPIATE CONSUMPTION

Mean opiate consumption declined daily for patients in all groups, reaching a similar level by day 5 (**Figure 5**). The mean opiate dosage on day 1 was not significantly different across the groups (P=.82), and the daily opiate consumption declined at an estimated rate of 6.9 mg/d (P<.001), with no differential rate of decrease across the groups.

SATISFACTION

The satisfaction score can range from 0 to 10, with 10 indicating most satisfied. The mean \pm SD scores were not different across the 3 groups (*P* = .50) and were 8.2 \pm 2.7, 8.4 \pm 2.5, and 8.5 \pm 2.4 for the individual-attention, control, and massage groups, respectively. When patients in the massage group were asked whether the massages affected their pain, the mean response was 7.4 (0 indicates a great deal worse; 10, a great deal better). When asked whether the massages were helpful, the mean re-

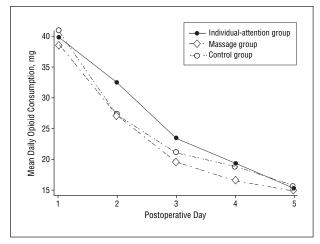


Figure 5. The mean total opiate consumption (calculated as milligrams of intravenous morphine equivalent in 24 hours) in the control and 2 intervention groups.

sponse was 8.3 (0 indicates not at all helpful, 10, very helpful).

FUNCTIONAL OUTCOME

The mean \pm SD FEV₁ percentage predicted was 74% \pm 19% preoperatively (281 patients), 32% \pm 16% on postoperative day 1 (68 patients), and 43% \pm 17% on postoperative day 5 (179 patients), and the FVC percentage predicted was 82% \pm 17% preoperatively, 36% \pm 18% on postoperative day 1, and 49% \pm 18% on day 5. After controlling for age and the preoperative and postoperative day 1 values of the outcome, the individual-attention group had greater function on postoperative day 5 than did the other groups for FEV₁ (*P*=.04) and for FVC (*P*=.07) percentages predicted.

COMPLICATIONS AND LOS

There was no difference in complication rate or LOS between any of the groups. At least 1 complication was experienced by 122 of 605 patients (20.2%) during the 30 days after the operation, and the complication rate was higher in patients with abdominal incisions (P < .001), patients with renal insufficiency (P = .003), and patients with diabetes (P = .001). The LOS was a mean±SD of 8.8±8.1 days, with a median of 7 days. The LOS was longer in patients who underwent sternotomy but was not affected by group or incision after controlling for the following 3 variables predictive of LOS: older age (P = .001), chronic obstructive pulmonary disease (P = .003), and renal insufficiency (P < .001).

ADVERSE EVENTS

None of the patients reported any adverse events related to the massage intervention. However, several serious adverse events occurred related to the operations. Nine patients died during the study, and 7 of them were in the individual-attention group. After careful review of patient medical records, we determined that the deaths were unrelated to the interventions.

COMMENT

This study is, to our knowledge, the largest randomized controlled trial of massage as adjuvant therapy for acute postoperative pain. It has confirmed and extended observations from our preliminary study showing a more rapid rate of decline in pain unpleasantness in patients receiving massage.⁵⁴ In this study, significant decreases in the rates of both pain intensity and unpleasantness were seen during the first 4 postoperative days in subjects receiving massage. Although there were methodological differences between the preliminary study and this study, the long-term effects of massage on pain perception were preserved. In addition, we have demonstrated the feasibility of incorporating massage into routine postoperative care.

Perhaps the most important observation from this study is the immediate (short-term) effects of massage on pain intensity, unpleasantness, and anxiety. These significant reductions were most pronounced on the first postoperative day. A 1-point (1-cm) reduction in the pain score (of a possible 10) on a VAS in the acute postoperative setting may sometimes require the administration of several small (eg, 1-mg) boluses of parenteral morphine, depending on the individual. This suggests that massage may be quite a potent pain reliever in some patients. Although the morning anxiety level was higher on postoperative day 1 in the individual-attention group, the reasons for the greater initial level of anxiety in this group are unclear. The analysis of the long-term effect of the interventions on anxiety was adjusted for the day 1 anxiety level.

In a recent case-control study, Taylor et al⁶² examined the development of postoperative respiratory events. Respiratory events were defined as respiratory depression (<10 breaths/min) and/or a decrease in oxygen saturation (<90%) during narcotic administration that was reversed by naloxone hydrochloride. The authors concluded that the first 24 hours of postoperative care are a high-risk period for respiratory events. The most robust effect of massage in the short-term relief of pain was seen on postoperative day 1. Massage may potentially be a safer alternative as-needed form of pain relief. With proper training, health care providers at the bedside (especially nurses) may now have a powerful nonpharmacologic tool to directly address their patients' pain and anxiety.

As was reported in our preliminary study, no significant differences in opiate consumption were seen between groups in this study. Because patients had limited to no control over administration of their opioid medications, opiate consumption might be spared if massage were available on a more frequent as-needed basis (eg, once or twice a shift).

Although individualized attention was not associated with any significant effects on pain perception, it did have a significant effect on FEV_1 percentage predicted, whereas massage did not. Massages were not given in proximity to the pulmonary function testing, which may account for the lack of an effect. The ability of massage to help relieve pain did not translate into any reduction in the complication rate or LOS. This observation is consistent with the lack of an effect on pulmonary function. However, further research is warranted to better define the relation between the timing of massage interventions and patient functional recovery.

There are some limitations of this study. Virtually all the patients in this study were elderly men (Table 1). Results should thus be interpreted with some caution when extrapolating to other populations. There was also a potential self-selection bias among participants in the study because patients who were not interested in being touched refused to participate. This bias may have enhanced the response seen in the group receiving massage. Because of the intimate nature of massage and the variation in cultural attitudes regarding touch, it is unlikely that all patients would choose to have massage. However, twothirds of subjects in this study were willing to participate (Table 1), which suggests that massage would be acceptable to a large proportion of patients. In addition, patients who received massages reported a high level of satisfaction with the therapy. It has been suggested in the context of opiate trials for cancer pain relief that a 2-point reduction on a VAS may be a more clinically meaningful outcome.63 However, such a standard may not be entirely applicable to acute procedural pain that rapidly decreases in intensity during the early postoperative period. In addition, because of a limited ability to alter the basic pattern of postoperative care, it was not possible in this study to perform dose-response interventions (eg, increased time of massage or increased number of massages per day) that could potentially demonstrate even greater reductions in pain intensity, unpleasantness, and anxiety.

The effectiveness of massage in reducing both the intensity and unpleasantness of pain suggests that it may act through more than one mechanism. Our modeling suggests that massage-mediated reduction of anxiety may be an important mechanism in reducing pain unpleasantness, the affective component of the pain experience that is related to suffering. Suffering has been defined as "the state of severe distress associated with events that threaten the intactness of the person."64(p 640) Major operations can be such a perceived threat. Fears of death or prolonged disability coupled with the physiologic experience of postoperative pain create the substrate for depersonalization and suffering. Massage may ameliorate suffering by helping to relieve the anxiety that so effectively synergizes with pain to create distress. Our modeling also demonstrated that the faster rate of reduction of pain intensity was largely independent of any effect of massage on anxiety. This implies that massage is also acting through another pathway distinct from its influence on affect. Possible mechanisms could include the creation of competing sensory input consistent with the gating theory of pain⁵¹ or perhaps through the generation of humoral mediators (eg, endorphins).65

Historically, massage was a common experience for postsurgical patients. As health care systems have become more complex and administrative demands on nursing time have increased, the tradition of nurse-administered massage has been largely lost. With the recent emphasis on assessing pain as the fifth vital sign²⁴ tempered by renewed concerns for patient safety,⁶² it is time to reintegrate the use of effective and less dangerous approaches to relieve patient distress.

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INVITED CRITIQUE

M assage has been used as a medical therapy since the time of Hippocrates, around 400 BC, until the focus of medical care shifted to biological science. Therapeutic benefits of massage therapy include vasodilatation, increased skin temperature, and relaxation of mind and body. Massage is also thought to reduce lactic acid levels in the muscles, stimulate healing of the connective tissues, and increase lymphatic and venous circulation.¹

Increased awareness for better pain control has led treating physicians to use nontraditional modalities such as massage therapy, music, and relaxation techniques. In recent attempts to reinforce adequate pain control, the Joint Commission for Accreditation of Healthcare Organizations recommended making pain the fifth vital sign.²

The conscious experience of pain has 2 components: a sensory neurohumoral component arising locally from the surgical incision and an affective component strictly related to the patient's perception of pain, which is often described as "unpleasantness." Massage may be a useful adjuvant therapy for the management of pain, with its greatest effect related to modulating the perception of the unpleasantness of pain.³

In this issue of the *Archives*, Mitchinson et al conducted a large randomized controlled trial of massage as adjuvant therapy for the control of acute postoperative pain in veterans undergoing major abdominal operations or sternotomies. In this study of 605 patients, significant decreases in the rates of the pain intensity and unpleasantness were seen during the first 4 postoperative days in 200 patients receiving massage. The limitations of the study include an inherent bias in the patient population, a nonstandardized pain control method, and the subjective nature of the measured outcomes.

Nevertheless, the authors have demonstrated the feasibility of incorporating massage therapy to improve immediate postoperative pain intensity and unpleasantness and patient anxiety. Further trials to address objective measured outcomes, such as narcotic requirements, length of hospital stay, and functional recovery, would be beneficial.

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