

Integrative Care Therapies and Pain in Hospitalized Children and Adolescents: A Retrospective Database Review

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Abstract

Background: Complementary or integrative care therapies are promising adjunctive approaches to pain management for pediatric inpatients that are currently underused and understudied. The purpose of this study was to examine the potential benefits of integrative care therapies delivered to hospitalized children and adolescents at a large Midwestern academic pediatric medical center over a 1-year period.

Methods: A retrospective chart review of an inpatient clinical database maintained by integrative care therapists over a 1-year period was used for the current study. Pre/post pain and relaxation scores associated with the delivery of inpatient integrative care therapies (primarily massage therapy and healing touch) were examined.

Results: Five-hundred nineteen hospitalized children and adolescents were treated by integrative care therapists for primarily pain or anxiety needs. Patients had a mean age of 10.2 years (standard deviation, 7.0), 224 were female (43%), 383 were white (74%), and most (393 [77%]) received massage therapy. Mean pain and relaxation scores decreased significantly from pre- to post-therapy across all demographic and clinical subgroups ($p \leq .001$).

Conclusions: Although integrative care therapies are increasingly requested and offered in children's hospitals, provision of these approaches is driven primarily by consumer demand rather than evidence-informed practice. Future controlled studies should examine the incremental effects of integrative care therapies as an adjunct to conventional treatment, assess how these therapies work mechanistically, and determine whether they improve outcomes, such as pain and cost, for hospitalized children and adolescents.

APPROXIMATELY 3.1 MILLION CHILDREN AND ADOLESCENTS are hospitalized in the United States each year.¹ Recent findings suggest that pain is a common and prevalent problem for pediatric inpatients. For example, Stevens and colleagues (2012) found that among 3822 children and adolescents hospitalized across eight Canadian hospitals, 33% reported moderate to severe pain.² In the United States, Kozlowski and colleagues (2012) found that 86% of pediatric inpatients experienced pain and discomfort related to their hospital visit.³ In addition, painful procedures are common during inpatient pediatric visits, and children do not always receive adequate pain management interventions to accompany these procedures.⁴ The most common approach to inpatient pediatric pain management involves pharmacologic treatment;⁵ however, these medications are costly and often carry adverse effects.^{6,7}

Complementary or integrative care therapies are promising adjunctive approaches to pain management for pediatric inpatients that are currently underused and understudied in this population. Pain conditions are the most commonly reported medical reason for which people turn to complementary or integrative care therapies.^{8,9} When used in combination with conventional pharmacotherapy, integrative care therapies may enhance pain control, and with fewer adverse effects, thereby enhancing quality of life for these children and, potentially, reducing total hospital charges for hospitalized children with pain. As defined by the National Center for Complementary and Alternative Medicine, there are four broad categories of integrative care therapies to consider: (1) natural products (e.g., herbs, supplements), (2) mind-body medicine (e.g., yoga, acupuncture), (3) manipulative and

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body-based practices (e.g., massage, chiropractic), and (4) "other" complementary and alternative medicine practices (e.g., energy therapies, such as healing touch, and whole medical systems, such as Traditional Chinese Medicine).¹⁰ Certain therapies are increasingly being offered in children's hospitals as part of multidisciplinary approaches to pain management,¹¹ in particular massage therapy, acupuncture, yoga, music therapy, craniosacral therapy, and energy therapies, although evidence on their efficacy or effectiveness remains limited.

Extant research supports the effectiveness of several integrative care therapies for managing pain conditions in general.¹² In hospitalized adults, preliminary evidence supports the efficacy of massage therapy, acupuncture, and relaxation strategies for inpatient pain management.¹³⁻¹⁶ In a recent retrospective, observational study of 1837 hospitalized adult patients, integrative care therapies had immediate and beneficial effects on pain scores, with an average pain reduction of approximately 55%.¹³

A small number of preliminary studies suggest that several integrative care techniques may be promising approaches to managing pediatric pain. Results of a nonrandomized study of a 3-week integrated multimodal approach that included psychotherapy, attention-defocusing techniques, physiotherapy, and music and art therapy among 167 inpatient adolescents with pain indicated significant reductions in pain intensity and pain disability, as well as anxiety and depression ($p \leq .001$).¹⁷ Results from a randomized controlled trial found that healing touch was associated with decreased pain, stress, and fatigue for inpatient pediatric oncology patients,¹⁸ and music therapy was associated with reduced pain and anxiety during and after lumbar puncture in children.¹⁹ In a qualitative study of children undergoing hematopoietic cell transplantation, 15 parents reported that their child experienced significant relief from pain and nausea and greater relaxation and ease falling asleep after a massage and acupressure therapy.²⁰ These preliminary findings suggest that further research on integrative care for pain and relaxation in hospitalized children/adolescents is warranted. No studies have been reported using observational retrospective data of ongoing pediatric inpatient integrative care clinical services as a first step to assessing preliminary effectiveness to help guide the design of future clinical trials.

Therefore, the overall purpose of this study was to examine the potential benefits of integrative care therapies delivered to hospitalized children and adolescents at a large Midwestern academic pediatric medical center over a 1-year period. Specifically, this study used a retrospective clinical database review to examine pain and relaxation ratings immediately before and after receipt of integrative care therapies. The central hypothesis was that integrative care therapies (specifically massage therapy and healing touch) would be associated with decreased pain and enhanced relaxation/comfort in hospitalized children and adolescents. A secondary aim included determining the number of patients who achieved a 30% and a 50% reduction in pain after receipt of these therapies.

Methods

Patients

The total number of patients included 519 children and adolescents hospitalized at Cincinnati Children's Hospital

Medical Center in the calendar year 2009 who were seen for an integrative care therapy during their hospital stay, primarily because of anxiety or pain. Patients had a mean age of 10.2 years (standard deviation [SD], 7.0), 224 were female (43%), 383 were white (74%), and most (393 [76%]) received massage therapy while an inpatient. The mean (SD) length of stay for patients was 12 days (24.0). Patients had a range of chronic health conditions, such as cystic fibrosis, cancer, or headaches, and various acute conditions requiring hospitalization, mirroring the clinical demographics of the hospital.

Procedure

In 2009, integrative care therapists provided 4749 visits to a total of 2404 children and adolescents. Because this time-frame preceded the use of electronic medical records at the hospital, therapists in the Integrative Care Department systematically captured key data before and after each integrative visit by entering data into a Microsoft Access (Microsoft Corp., Redmond, Washington) clinical database. An institutional review board-approved retrospective chart review was completed on this database. The clinical database contained standard demographic patient information; reason for integrative care referral; integrative care therapy received; and pre-/post-treatment outcomes, including pain and relaxation/overall presentation (e.g., asleep, agitated). All pre/post outcomes were collected within 5 minutes before and after delivery of the integrative care therapy.

Initial data cleaning was conducted on the clinical database, including 4749 integrative care visits to 2404 children, to make data suitable for analytic purposes. To clean the database, the research team excluded outpatients in general and inpatients who did not have complete pre/post data on at least one outcome variable (e.g., pain or relaxation). In addition, because most patients in the database have chronic conditions that necessitate multiple hospitalizations, only the patient's first hospitalization and first integrative care visit (during the study period) was selected in order to minimize the effect of previous integrative care exposure on outcomes. This process led to a sample of 1233 patients. Finally, because of the differences in primary outcome measures, babies in the neonatal intensive care unit were excluded from the current analysis. Therefore, of the 2404 original pediatric patients who had received integrative care services, 519 met all these requirements and were thus included in these analyses. As this was a retrospective database review, no informed consent was provided. The institutional review board at Cincinnati Children's Hospital Medical Center approved the study.

Outcome measures

Patients (integrative care therapists as a proxy if the child was nonverbal) provided pain ratings on a numeric scale consistent with standard clinical practice. Pain ratings were provided immediately before and immediately after receipt of the integrative care therapy for patients who were referred for pain or reported pain at the time of treatment. The pain scale used by integrative care was selected by the admitting nurse on the basis of hospital guidelines and was used consistently by all disciplines for a given child according to his or her developmental and clinical status (e.g., age, developmental, arousal level).

Numerical Rating Scale (NRS-11). The NRS-11 is a verbal measure of pain administered by asking patients to self-report how much pain she or he is currently experiencing on an 11-point scale (0=defined as no pain; 10=defined as the most or worst pain). The NRS-11 is one of the most commonly used self-report measures of pain in pediatric clinical settings and is ideally used with children age 8 years and older.²¹ Although minimal published research has been completed on NRS-11, preliminary evidence suggests it has good convergent validity with the visual analogue and faces pain rating scales.²²

Face, Legs, Activity, Cry, Consolability (FLACC). The FLACC²³ is a behaviorally-based pain scale generally used for children ranging from newborn to age 8 years and nonverbal children older than age 8 years. The FLACC measures five domains of pain behavior: facial expression, leg movement, activity level, crying, and consolability. Each subscale is rated on a three-point scale, where 0 indicates no pain, 1 indicates occasional pain, and 2 indicates frequent to constant pain. The five subscales are then combined for an overall pain rating ranging from 0, indicating relaxed/comfortable, to 10, indicating severe pain, discomfort, or both. The FLACC correlates highly with both the COMFORT scale and the Checklist of Nonverbal Pain Indicators.²⁴ It has also demonstrated high interrater reliability and internal consistency.²⁴

Relaxation. Treating therapists observed and recorded patients' level of relaxation/comfort on a six-point scale pre/post-therapy. The data were recoded for purposes of analyses as the following: 0=asleep, 1=very relaxed/drowsy, 2=calm/comfortable, 3=slight tension/restless, 4=tense/agitated, or 5=extreme tension/agitated/inconsolable.

Data analysis

Descriptive statistics were calculated for demographic and clinical variables of interest (e.g., source of referral) across this full sample, as well as across three subsets of patients to be described below. Next, two separate subgroups of patients were created: those who were administered the NRS-11 and those who received the FLACC pain measure to eliminate potential confounds due to clinical and demographic differences between these patients (e.g., age, verbal ability). Paired-sample *t*-tests were used to compare mean pain scores pre/post-therapy for both subgroups. The number of patients who achieved 30% and 50% reductions in pain (standard cutoffs in pain research)²⁵ were examined by using a standard percentage-change formula and frequency counts. Patients with a 0 level of pretherapy pain were not included in the percentage-reduction analyses because there is no possible reduction from a starting score of 0. Finally, paired-samples *t*-tests were used to examine pre/post-treatment relaxation scores in a subset of patients (subgroup 3) who had pre/post-therapy relaxation scores and who were not asleep before the therapy. IBM SPSS Statistics 19 program was used for data analyses.

Results

Demographic and clinical characteristics

Characteristics of the full sample ($n=519$) and each of the three subsets of patients are presented in Table 1. Patients in

TABLE 1. DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF SAMPLE

Variable	Sample			
	Full sample	NRS-11	FLACC	Relaxation
Patients (n) ^a	519	230	113	286
Mean age (SD) (y)	10.2 (7.0)	14.0 (4.8)	3.4 (4.3)	10.1 (6.4)
Sex, n (%)				
Male	295 (57)	98 (43)	58 (51)	131 (46)
Female	224 (43)	132 (57)	55 (49)	155 (54)
Ethnicity, n (%) ^b				
White	382 (74)	178 (77)	77 (68)	210 (73)
African-American/black	91 (18)	31 (14)	23 (20)	52 (18)
Other	27 (5)	8 (4)	5 (4)	10 (4)
Unknown	19 (4)	11 (5)	8 (7)	13 (5)
Therapy type, n (%)				
Manipulative therapy	393 (76)	179 (78)	80 (71)	222 (78)
Energy therapy	107 (20)	45 (20)	28 (25)	60 (21)
Combination therapy ^c	171 (33)	117 (51)	44 (39)	100 (35)
Other	14 (3)	3 (1)	4 (3)	4 (1)
Missing	5 (1)	3 (1)	1 (1)	0 (0)

^aSubsamples do not sum to the full sample because of overlap between pain and relaxation participants.

^bTotal percentages do not always sum to 100% because of rounding.

^cManipulative therapies combined with energy therapies administered consecutively during the same integrative care visit.

FLACC, Face, Legs, Activity, Cry, Consolability; NRS-11, Numerical Rating Scale; SD, standard deviation.

the NRS-11 subgroup ($n=230$) had a mean (SD) age of 14.0 (4.8) years, 132 (58%) were female, and 178 (77%) were white. In the FLACC subgroup ($n=113$), patients had a mean (SD) age of 3.4 (4.3) years, 55 (49%) were female, and 77 (68%) were white. Patients in the relaxation dataset ($n=286$) had a mean (SD) age of 10.1 (6.4) years, 155 (54%) were female, and 210 (70%) were white.

Across all 519 patients, referrals to integrative care came most often from nurses (41%); secondarily from holistic health specialists (28%); and, to a smaller extent, from physicians, the patient or family, or child life specialists (23% total). The most common integrative care therapy delivered was manipulative or body-based therapy (e.g., massage therapy; 77%), followed by energy therapies (e.g., healing touch; 21%). Other therapies delivered, although to a much lesser extent, included music therapy (<1%) and mind-body and breathing techniques (<1%). Approximately 45% of patients received two therapies (e.g., massage therapy and energy therapy) within a single integrative care visit. A total of 230 children and adolescents were present in both the pain and the relaxation analyses because they had pre/post scores available for both outcome variables.

Pain and relaxation scores pre/post-therapy

Mean pain scores significantly decreased from pre- to post-therapy across both the NRS-11 and FLACC subgroups, with an average reduction in pain score from 4.4 to 2.9 on the NRS-11 ($t=12.0$; $p\leq 0.001$) and from 2.6 to 0.8 on the FLACC

($t=8.1$; $p\leq 0.001$). Analyses indicated that over half of the children (97 of 183) in the NRS-11 subgroup achieved a more than a 30% reduction in pain, whereas more than three quarters (61 of 73) of the children in the FLACC subgroup met the 30% pain reduction threshold. Pain reduction was greater than 50% for 72 children (39%) in the NRS-11 subgroup and 56 children (77%) in the FLACC subgroup. Relaxation scores significantly decreased (lower scores = more relaxed) from pre- to post-therapy, with average scores declining from 2.8 to 1.7 ($t=16.4$; $p\leq 0.001$).

Discussion

Although integrative care therapies are increasingly requested and offered in children's hospitals, they are still driven primarily by consumer and provider demand rather than evidence-informed practice. Practice-based research that evaluates ongoing clinical services as they relate to health outcomes are currently underused in integrative care and have great potential to both inform future targeted clinical trials and drive clinical practice improvement efforts. In 2005, 86% of the pediatric anesthesia fellowship programs in the United States provided one or more integrative medicine therapies for pediatric pain management, including biofeedback (65%), guided imagery (49%), hypnosis (44%), massage (35%), and acupuncture (33%).²⁶ As these therapies are increasingly incorporated into conventional medical settings and training of health professionals, it is critical to better understand their scientific basis for efficacy or effectiveness. While research on integrative care therapies in pediatrics is increasing,^{27,28} this appears to be the first pediatric inpatient observational study assessing the preliminary efficacy of integrative care therapies for pain and relaxation in hospitalized children and adolescents.

This study found that both pain and relaxation significantly improved for these patients after primarily massage therapy and healing touch interventions. In addition, pain scores improved by more than 50% in half of the patients who had both pre/post pain data; this has major clinical implications for potentially improving pain management in these patients. Pain is a major clinical issue for hospitalized children and incurs major costs for hospitals as unresolved pain can be related to longer hospital stays, increased number of adverse events, higher incidence of pain medications and procedures, and ultimately can negatively affect the child's and families' quality of life.^{29,30} Future studies should evaluate pain medications in combination with delivering adjuvant integrative care therapies to assess their combined effect on outcomes.

Relaxation is another primary reason that integrative care therapists are requested in the inpatient pediatric setting. A child who is agitated or anxious before a medical procedure ultimately takes more time and resources from the medical team to manage. These preliminary findings suggest that these therapies are related to both reduced pain and increased relaxation in these hospitalized children and adolescents. A study on massage therapy in children has shown that increased parasympathetic effect and inducing the relaxation response are an active part of the effectiveness of the treatment.³¹ Nonpharmacologic approaches to decrease stress, reduce pain, and enhance relaxation may offer complementary and added benefit to the current pharmacologic

standards most often used. In an era of the Affordable Care Act,³² with hospitals under increased pressure to get patients better quicker and more effectively, integrative care therapies may be a critical piece to the puzzle that is currently under-recognized and undervalued.

As with any study, this study is not without limitations. Because this was a retrospective database review, clinical scales were used rather than measures with stronger psychometric properties. In addition, one of the pain measures (i.e., the FLACC) and the relaxation measure were determined via therapist report, rather than patient self-report or an objective rater, which has the potential to introduce bias. It was also not possible to report on use of pain medications in combination with these therapies, although future studies would be strengthened by including pain medications in the analyses. Finally, without a control group, it is not clear whether these children reported better pain and increased relaxation simply because of time and attention from the therapist, or whether the therapy itself was actually responsible for the improved outcomes. Nonetheless, important conclusions can still be drawn.

These findings suggest that the delivery of integrative care services, particularly massage and healing touch, are associated with improvements in patient- and therapist-assessed pain scores and relaxation among a large, inpatient pediatric population. Given the prevalence of pain and limitations of conventional treatment options alone, these results highlight the importance and potential value of conducting rigorous studies of integrative care therapies for pediatric inpatient pain. Future controlled studies should examine the incremental effects of integrative care therapies as an adjunct to conventional treatment; assess how these therapies work mechanistically; and determine whether they improve outcomes, such as pain and cost, to inform models incorporating integrative therapies into treatment planning for hospitalized children and adolescents.

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Author Disclosure Statement

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