JAOA ORIGINAL CONTRIBUTION

Intramuscular Ketorolac Versus Osteopathic Manipulative Treatment in the Management of Acute Neck Pain in the Emergency Department: A Randomized Clinical Trial

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Ketorolac tromethamine injected intramuscularly (IM) has been shown to be an effective analgesic in treating patients with acute musculoskeletal pain in the emergency department (ED). The authors compare the efficacy of a single dose of IM ketorolac to osteopathic manipulative treatment (OMT) as delivered in the ED for the management of acute neck pain. A randomized clinical trial was conducted in three EDs. A convenience sample of 58 patients with acute neck pain of less than three weeks' duration were enrolled. Subjective measures of pain intensity on an 11-point numerical rating scale were gathered from patients immediately before treatment and one hour afterward. Subjects received either OMT or 30 mg, IM ketorolac. Subjects' perceived pain relief was also recorded at one hour after treatment on a subjective 5-point pain relief scale. Twenty-nine patients received IM ketorolac, and 29 patients received OMT. Although both groups showed a significant reduction in pain intensity, 1.7±1.6 (P <.001 [95% CI, 1.1–2.3]) and 2.8±1.7 (P <.001 [95% CI, 2.1–3.4]), respectively, patients receiving OMT reported a significantly greater decrease in pain intensity (P=.02 [95% CI, 0.2–1.9]). When comparing pain relief at one hour posttreatment, there was no significant difference between the OMT and ketorolac study groups (P=.10). The authors found that, at one hour posttreatment, OMT is as efficacious as IM ketorolac in providing pain relief and significantly better in reducing pain intensity. The authors conclude that OMT is a reasonable alternative to parenteral nonsteroidal anti-inflammatory medication for patients with acute neck pain in the ED setting.

Acute musculoskeletal neck pain is a common complaint among the general population in the United States and is a frequent problem for patients presenting to the emergency department (ED). Up to 71% percent of Americans can recall experiencing an episode of neck pain or stiffness in their lifetimes.[1]

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In the ED, providing pain relief for patients with neck pain is the primary goal—after any significant pathology or injury has been excluded from diagnostic evaluation. Patients are commonly treated with nonsteroidal anti-inflammatory drugs (NSAIDs). Osteopathic manipulative treatment (OMT) is another treatment modality that may be considered, however. Manipulation of the cervical spine for neck pain (and headache) is the second most common use of spinal manipulative therapy.[2]

Osteopathic manipulative treatment is based on osteopathic principles and practice. Fundamental to the science and art of osteopathic medicine is the recognition of the body's inherent ability to restore homeostasis and heal itself. Various osteopathic manipulative (OM) techniques are applied in regions of somatic dysfunction (ie, areas of impaired or altered function of the body framework) to promote blood flow through the tissues, thus enhancing the body's own healing ability.

Terminology used to describe manual therapies varies. Osteopathic physicians use the term *manipulation* to describe over 100 different OM techniques.[3] In the literature, many researchers use the term *manipulation* to describe high velocity, low amplitude (HVLA) thrust techniques. A thrust is a force applied to the joint that moves it beyond the passive range of motion and often produces an audible click at the joint.[4] Mobilization is a nonthrust form of manipulation[5-7] that applies a manual force to the spinal joints within the passive range of motion.[6]

The term *manipulation* in our study describes manipulative therapies as used by chiropractors, physiotherapists, other "manual therapists," *and* osteopathic physicians—as when we inquired of study subjects prior to study enrollment if they had ever received "prior manipulation." The term *osteopathic manipulative treatment* (ie, OMT), however, is used in our study only when osteopathic physicians in the treatment of patients use OM techniques. In this study, the OM techniques used by osteopathic physicians include HVLA thrust, soft tissue, and muscle energy techniques.

Although expert panels, studies, and reviews have found manipulation to be effective in the reduction of acute,[8,9] subacute,[10] and chronic low back pain,[11] there is a lack of data from randomized controlled trials on the benefits of manipulation for acute neck pain.[7,12] Manipulation[7,8] and

Figure. *Acute neck pain in the emergency department: ketorolac tromethamine injected intramuscularly versus osteopathic manipulative treatment. Study inclusion and exclusion criteria.*

Checklist

Inclusion Criteria
- Acute musculoskeletal neck pain of less than three weeks' duration[7]
- Patient aged between 18 years and 50 years

Exclusion Criteria*
- Bleeding ulcer (or peptic ulcer disease)
- Bony abnormalities
- Carotid bruits
- Cerebrovascular accident
- Coagulopathy or bleeding disorder
- Drug abuse
- Engaged in litigation or receiving compensation
- Hypersensitivity to nonsteroidal anti-inflammatory drugs or aspirin
- Infection of the spinal cord
- Inflammatory joint disease†
- Lactating (ie, breast feeding)
- Ligamentous instability
- Neck surgery
- Neurologic deficit‡
- Osteomalacia
- Osteoporosis
- Peptic ulcer disease
- Pregnancy
- Psychiatric disturbance
- Radiculopathy§
- Radiographic contraindications to osteopathic manipulative medicine//
- Received treatment with any of the following treatment modalities:
  - corticosteroids (prolonged use)
  - intramuscular ketorolac¶
  - lithium
  - manipulation¶
- Renal failure
- Renal insufficiency
- Skeletal metastasis
- Spondylolisthesis
- Temperature higher than 37.8°C (>100°F)
- Trauma classified as substantial with distracting injuries, alcohol involvement, or other factors precluding a reliable exam#
- Vertebrobasilar insufficiency

* Exclusion criteria was evaluated based on current findings upon physical examination or in subsequent laboratory testing, by direct evidence or a high index of suspicion for a given condition or disease, or in a prior diagnosis as revealed in history taking.
† In addition to inflammatory joint disease, rheumatoid arthritis and ankylosing spondylitis were also exclusion criteria for this study.
‡ Patients were excluded from this study if they had evidence of neurologic deficit such as signs of cervical myelopathy, progressive unilateral muscle weakness, motor loss, or sensory loss.[2]
§ Patients were excluded from this study if they had suspected or known (ie, diagnosed in prior testing) cervical radiculopathy or sensory changes that include paresthesia or hyperesthesia (or both) of a dermatomal distribution, or pain radiation into the upper extremity that follows a dermatomal pattern.[2]
// See Methods, on pages 59-60 of this article, for more information on radiographic contraindications for osteopathic manipulative treatment as used in the current study.
¶ Patients were excluded from this study if they had received treatment with intramuscular ketorolac or manipulation for the current episode of neck pain.
\# Trauma caused in an average "fender-bender" automobile accident is not considered substantial trauma.[2]

mobilization[7,8,13] are probably more effective treatment modalities than is standard care provided by a general practitioner for subacute or chronic neck pain.

Ketorolac tromethamine injected intramuscularly (IM) has been shown to be an effective analgesic in treating acute musculoskeletal pain in the ED.[14-17] There have been no studies evaluating the efficacy of OMT in the treatment of patients with acute neck pain in the emergency department. Therefore, the purpose of this study is to compare the clinical efficacy of a single dose of IM ketorolac with a single intervention with OMT in the treatment of acute neck pain in patients presenting to the ED. We hypothesized that OMT was as efficacious as IM ketorolac in providing pain relief for acute neck pain in the ED setting.

Methods

We conducted a randomized clinical trial that compared the use of OMT to IM ketorolac for the relief of acute neck pain. The Brooke Army Medical Center Institutional Review Board in the Department of Clinical Investigation at Fort Sam Houston in San Antonio, Texas, approved this study. All study subjects provided written informed consent.

This study was conducted at three ED teaching hospitals: two Level I urban trauma centers, and one Level III community hospital. All three facilities have an annual census of approximately 55,000.

Fifty-eight patients were enrolled by convenience sampling over 3 and one half years, from January 1999 through June 2002. Eligible patients included those presenting to the ED during shifts in which at least one of the three enrolling physicians were present. The two authors (T.M.M. and B.J.S) and one additional osteopathic physician were enrolling physicians. All three enrolling physicians were osteopathic physicians that specialize in emergency medicine and routinely use OMT for patient treatment in the ED. Schedules were variable and did not correspond to any particular time of day or day of the week.

Patients were given the option to refuse study enrollment at the time informed consent was requested. Potential subjects were enrolled in the study if inclusion criteria were met and none of the exclusion criteria applied (*Figure*).

Enrolling physicians randomly assigned patients to receive either OMT or IM ketorolac using a predetermined random number table.[18] The treatment arm was not disclosed to patients until after informed consent was obtained. Attempts were not

Table 1
Acute Neck Pain in the Emergency Department: Characteristics of Study Subjects (N=58)

Characteristic	Ketorolac Group (n=29)	Osteopathic Manipulative Treatment Group (n=29)	*P*
	No. (%)		
■ **Age, y**	**30 ± 9**	**29 ± 8**	**.61**
■ **Sex**			**.29**
□ Female	14 (48)	18 (62)	
□ Male	15 (52)	11 (38)	
■ **Race**			**.73**
□ Asian	. . .	. . .	
□ Black	7 (24)	6 (21)	
□ Hispanic	2 (7)	3 (10)	
□ White	19 (66)	20 (69)	
□ Other	1 (3)	. . .	
■ **Symptom Duration (Median), d***	**1.0**	**1.0**	**.56**
■ **Treatment Modalities Previously Used**			
□ *Nonsteroidal anti-inflammatory drugs*†			*.26*
– Yes	7 (24)	11 (38)	
– No	22 (76)	18 (62)	
□ *Prior manipulation*‡			*.45*
– Yes	5 (17)	3 (10)	
– No	24 (83)	26 (90)	
■ **Etiology of Pain**			**.96**
□ On awakening	5 (17)	4 (14)	
□ Motor vehicle accident	16 (55)	18 (62)	
□ Torticollis	2 (7)	2 (7)	
□ Other	6 (21)	5 (17)	

* The range for symptom duration was 1 to 7 days for the ketorolac group and 1 to 15 days for the osteopathic manipulative treatment group.
† Patients were asked if they had used nonsteroidal anti-inflammatory drugs in the past 24 hours.
‡ As noted in *Figure*, two of the exclusion criteria for this study were the use of manipulation or intramuscular ketorolac for the current incident of pain. The eight patients who reported having received manipulation in the past did not receive it for the current incident of pain prior to enrollment in this study.

made to blind patients or physicians as to which treatment was being given at the time of treatment.

Radiographs of the cervical spine were obtained if there was a history of trauma and if patients were unable to be cleared clinically. Radiographic contraindications to manipulation[2] used in this study included, but were not limited to, the following:

□ active inflammatory arthritis (ankylosing spondylitis, rheumatoid arthritis),
□ anomalies that were congenital (eg, unstable os odontoideum,
□ anteroposterior spinal canal stenosis of greater than 11 mm,
□ bone diseases including infections (eg, discitis, osteomyelitis, tuberculosis),
□ fractures that were acute or unhealed,
□ misalignment that was obvious (of >3 mm of translocation, or >11% of kyphotic angulation),
□ neoplastic disease in the cervical region,

Table 2
Acute Neck Pain in the Emergency Department:
Pain Intensity Scores on 11-point Numerical Rating Scale (Pre- and Posttreatment) (N=58)

Score	Ketorolac Group* (n=29)	Osteopathic Manipulative Treatment Group† (n=29)	*P*
Pretreatment	5.6 ± 2.4	6.1 ± 1.7	.40
Posttreatment‡	3.9 ± 2.7	3.3 ± 1.9	.36
Total Change	1.7 ± 1.6	2.8 ± 1.7	.02

* Within the ketorolac group, $P<.001$ (95% CI, 1.1–2.3).
† Within the osteopathic manipulative treatment group, $P<.001$ (95% CI, 2.1–3.4).
‡ Posttreatment score was requested from patients at one hour after treatment.

Table 3
Acute Neck Pain in the Emergency Department:
Pain Relief Scores on a 5-point Pain Relief Scale* (N=58)

Score	Ketorolac Group (n=29)	Osteopathic Manipulative Treatment Group (n=29)
	No. (%)	
A – No Relief	5 (17)	1 (3)
B – Some Relief	9 (31)	10 (34)
C – Moderate Amount of Relief	9 (31)	7 (24)
D – A Lot of Relief	6 (21)	10 (34)
E – Complete Relief	. . .	1 (3)

* Within both study groups, for subjects receiving pain relief at one hour after treatment, $P=.10$.

- ossification of the posterior longitudinal ligament,
- osteoporosis classified as severe;
- Paget's disease, or
- septic arthritis.

Patients with a history of nontraumatic neck pain and no clinical indications did not receive radiographs prior to study enrollment. Because pain scores are subjective, no minimum score was required for study inclusion.

All patients received an initial structural exam. Enrolling physicians palpated the cervical region to assess patients for tissue texture changes, joint restrictions, and areas of tenderness. In addition, enrolling physicians examined patients' heads and necks through range of motion tests (ie, for flexion, extension, side bending, and rotation) to determine any additional areas of somatic dysfunction.

Osteopathic manipulative techniques performed included a combination of HVLA thrust, muscle energy, and soft tissue techniques.[19] One or more OM techniques were used to optimize the treatment's therapeutic benefits. The specific combination of the three OM techniques used was left to the discretion of the enrolling physician and was based on patients' needs, as assessed by the physician.

Intervention with OMT lasted less than 5 minutes and was completed by the enrolling physician.

Table 4
Acute Neck Pain in the Emergency Department:
Patients With Prior Use of Nonsteroidal Anti-inflammatory Drugs
Pain Intensity Scores on 11-point Numerical Rating Scale (Pre- and Posttreatment) (N=18)

Score	Ketorolac Group* (n=7)	Osteopathic Manipulative Treatment Group† (n=11)	*P*
Pretreatment	4.6 ± 1.9	6.0 ± 2.1	.16
Posttreatment‡	2.4 ± 1.4	3.7 ± 2.2	.16
Total Change	2.2 ± 2.0	2.3 ± 1.9	.95

* Within the ketorolac group, *P*=.03 (95% CI, 0.3–4.1).
† Within the osteopathic manipulative treatment group, *P*<.01 (95% CI, 1.0–3.6).
‡ Posttreatment score was requested from patients at one hour after treatment.

Table 5
Acute Neck Pain in the Emergency Department:
Patients With Prior Use of Nonsteroidal Anti-inflammatory Drugs
Pain Relief Scores on a 5-point Pain Relief Scale* (N=18)

Score	Ketorolac Group (n=7)	Osteopathic Manipulative Treatment Group (n=11)
	No. (%)	
A – No Relief	2 (29)	1 (9)
B – Some Relief	. . .	4 (36)
C – Moderate Amount of Relief	2 (29)	5 (45)
D – A Lot of Relief	3 (43)	. . .
E – Complete Relief	. . .	1 (9)

* Within both study groups, for subjects receiving pain relief at one hour after treatment, *P*=.69.

For patients receiving pain management with IM ketorolac, an order for 30 mg was given by the enrolling physician and administered by the nursing staff.

Patients were asked to use the 11-point Numerical Rating Scale (NRS-11)[20,21] to evaluate their perceived pain intensity immediately prior to treatment and again at one hour post-treatment. Patients were given the following instructions, first verbally and then in print, for rating the intensity of their pain:

> On a pain scale from zero (0) to ten (10), with zero (0) being no pain, and ten (10) being the worst pain you've ever had, how much pain do you feel right now? Please write your pain level on the line provided.

We decided to have patients reassess pain intensity at one hour to allow the ketorolac sufficient time to reach peak plasma concentration and to observe patients for side effects.[21,22]

When asking patients to reassess their pain intensity levels at one hour after treatment, we hoped to avoid carry-over bias and, therefore, did not allow patients to view the previous pain intensity scores they provided immediately prior to treatment. Additionally, enrolling physicians were not allowed to look at the results of self-evaluated patient pain intensity scores (a cover sheet was provided) or to ask patients verbally how they had rated their level of pain intensity.

Patients were also asked to use a descriptive 5-point Pain

Table 6
Acute Neck Pain in the Emergency Department:
Patients With No Prior Use of Nonsteroidal Anti-inflammatory Drugs
Pain Intensity Scores on 11-point Numerical Rating Scale (Pre- and Posttreatment) (N=40)

Score	Ketorolac Group* (n=22)	Osteopathic Manipulative Treatment Group† (n=18)	*P*
Pretreatment	6.0 ± 2.5	6.2 ± 1.5	.78
Posttreatment‡	4.4 ± 2.8	3.1 ± 1.7	.10
Total Change	1.6 ± 1.4	3.1 ± 1.5	< .01

* Within the ketorolac group, $P<.001$ (95% CI, 1.0–2.2).
† Within the osteopathic manipulative treatment group, $P<.001$ (95% CI, 2.3–3.8).
‡ Posttreatment score was requested from patients at one hour after treatment.

Table 7
Acute Neck Pain in the Emergency Department:
Patients With No Prior Use of Nonsteroidal Anti-inflammatory Drugs
Pain Relief Scores on a 5-point Pain Relief Scale* (N=40)

Score	Ketorolac Group (n=22)	Osteopathic Manipulative Treatment Group (n=18)
	No. (%)	
A – No Relief	3 (14)	. . .
B – Some Relief	9 (41)	6 (33)
C – Moderate Amount of Relief	7 (33)	2 (11)
D – A Lot of Relief	3 (14)	10 (56)
E – Complete Relief	. . .	. . .

* Within both study groups, for subjects receiving pain relief at one hour after treatment, $P=.01$.

Relief Scale (PRS-5) to evaluate their perceived pain relief at one hour posttreatment. They were instructed to circle the letter next to the best description of the amount of relief they had since receiving treatment: A, No Relief; B, Some Relief; C, Moderate Amount of Relief; D, A Lot of Relief; E, Complete Relief.

We estimated a decrease in pain scores of 1.4 (20%) or greater to be clinically significant. A sample size of 58 total patients provided an 80% chance (power) of detecting an improvement in pain of 20% when tested at the .05 α level. Pearson's χ^2 test was used to test for differences between the OMT group and the ketorolac group with respect to categorical demographic and comorbid variables. Two-tailed *t* tests were used to compare the two study groups for differences in age and in the pre-to-post pain intensity changes reported by patients' subjective measures. Comparisons on the PRS-5 scale were tested using the Mantel-Haenszel χ^2 test for trend. The correlations were tested using the Spearman rank-order correlation. Testing was performed using the .05 α level. The statistical package used for data analysis was Statistical Analysis System software (Version 8.2, SAS Institute Inc, Cary, NC).

Results

A total of 58 patients were enrolled as subjects in this study. Twenty-nine patients were placed in each of the two study

Table 8
Acute Neck Pain in the Emergency Department:
Patients With Prior Use of Manipulation
Pain Intensity Scores on 11-point Numerical Rating Scale (Pre- and Posttreatment) (N=8)

Score	Ketorolac Group* (n=5)	Oseopathic Manipulative Treatment Group† (n=3)	*P*
Pretreatment	6.6 ± 3.0	5.0 ± 1.0	.42
Posttreatment‡	5.0 ± 3.5	1.3 ± 0.6	.13
Total Change	1.6 ± 0.6	3.7 ± 1.2	.01

* Within the ketorolac group, $P<.01$ (95% CI, 0.9–2.3).
† Within the osteopathic manipulative treatment group, $P=.03$ (95% CI, 0.8–6.5).
‡ Posttreatment score was requested from patients at one hour after treatment.

Table 9
Acute Neck Pain in the Emergency Department:
Patients With Prior Use of Manipulation
Pain Relief Scores on a 5-point Pain Relief Scale* (N=8)

	Ketorolac Group (n=5)	Osteopathic Manipulative Treatment Group (n=3)
Score	**No. (%)**	
A – No Relief	1 (20)	. . .
B – Some Relief	2 (40)	. . .
C – Moderate Amount of Relief	2 (40)	. . .
D – A Lot of Relief	. . .	3 (100)
E – Complete Relief	. . .	. . .

* Within both study groups, for subjects receiving pain relief at one hour after treatment, $P=.03$.

groups. Baseline subject characteristics were similar among the subjects enrolled in each study group; most patients had less than one day of acute neck pain before presenting to the ED. The majority of patients (58%) had cervical strain resulting from a motor vehicle collision (*Table 1*).

Patients' pain intensity scores recorded before treatment and one hour after treatment and their perceived pain relief at one hour posttreatment (PRS-5) are summarized in *Tables 2* and *3*. Both groups had similar baseline pain intensity scores and showed clinically significant improvement in subjective pain intensity measures (NRS-11) one hour after treatment. However, patients in the OMT group showed a statistically significant decrease in self-reported pain intensity ($P=.02$ [95% CI, 0.2–1.9]). When comparing perceived pain relief at one hour, there was no significant difference between the OMT and ketorolac groups ($P=.10$).

Eighteen patients reported taking NSAIDs in the 24 hours before seeking treatment in the ED. Among these 18 subjects, there was no statistically significant difference between subjects in the ketorolac and OMT groups in decrease of pain intensity at one hour after treatment ($P=.95$ [95% CI, −2.1 to 1.9]) (*Table 4*). Similarly, among these 18 patients there was no statistically significant difference when they were asked to report pain relief at one hour after treatment ($P=.69$) (*Table 5*). How-

Table 10
Acute Neck Pain in the Emergency Department:
Patients With No Prior Use of Manipulation
Pain Intensity Scores on 11-point Numerical Rating Scale (Pre- and Posttreatment) (N=50)

Score	Ketorolac Group* (n=24)	Oseopathic Manipulative Treatment Group† (n=26)	*P*
Pretreatment	5.4 ± 2.2	6.2 ± 1.8	.17
Posttreatment‡	3.7 ± 2.5	3.6 ± 1.9	.86
Total Change	1.8 ± 1.7	2.7 ± 1.7	.07

* Within the ketorolac group, $P<.001$ (95% CI, 1.0–2.5).
† Within the osteopathic manipulative treatment group, $P<.001$ (95% CI, 2.0–3.3).
‡ Posttreatment score was requested from patients at one hour after treatment.

Table 11
Acute Neck Pain in the Emergency Department:
Patients With No Prior Use of Manipulation
Pain Relief Scores on a 5-point Pain Relief Scale* (N=50)

Score	Ketorolac Group (n=24)	Osteopathic Manipulative Treatment Group (n=26)
	No. (%)	
A – No Relief	4 (17)	1 (4)
B – Some Relief	7 (29)	10 (38)
C – Moderate Amount of Relief	7 (29)	7 (27)
D – A Lot of Relief	6 (25)	7 (27)
E – Complete Relief	. . .	1 (4)

* Within both study groups, for subjects receiving pain relief at one hour after treatment, $P=.37$.

ever, as noted, these 18 subjects demonstrated a statistically significant decrease in pain intensity scores (*Table 4*).

Osteopathic manipulative treatment was more effective than ketorolac for decreasing pain levels reported among the remaining 40 patients who had not taken NSAIDs within the past 24 hours—as demonstrated in both subjective pain measures (NRS-11: $P<.01$ [95% CI, 0.6–2.4]; PRS-5: $P=.01$) (*Tables 6* and *7*).

Few patients in either study group had previously received manipulation. Five patients in the ketorolac group and three patients in the OMT group reported having received manipulation before this study. (As noted in the exclusion criteria, potential subjects were excluded from this study if they received manipulation to treat the current incident of pain.) Those who had previously received manipulation demonstrated statistically significant decreases in pain intensity scores, with OMT outperforming ketorolac ($P=.01$ [95% CI, 0.6–3.5]) (*Table 8*). The difference in reported pain relief at one hour was also in favor of the OMT group with all three in that group having reported receiving "A Lot of Relief" as a result of intervention with OMT ($P=.03$) (*Table 9*).

Patients in both study groups who had not previously been treated with manipulation reported decreased pain with both ketorolac and OMT. Neither the difference reported in

Table 12
Acute Neck Pain in the Emergency Department: Correlation of Pain Relief Scores and Posttreatment Pain Intensity Scores for Both Study Groups at One Hour After Treatment (N=58)

Score	No.	Posttreatment	Total Change
A – No Relief	6	5.7±2.2	0±0.6
B – Some Relief	19	5.2±2.1	1.4±1.4
C – Moderate Amount of Relief	16	3.1±1.7	2.4±0.6
D – A Lot of Relief	16	1.8±1.2	3.6±1.4
E – Complete Relief	1	. . .	6

pain intensity scores nor in pain relief scores was statistically significant between study groups ($P=.07$ [95% CI, −1.9 to 0.1] and $P=.37$, respectively) (*Tables 10* and *11*).

Self-reported pain scores after treatment on both subjective scales have a statistically significant correlation ($\rho=0.7$; $P<.001$). The difference between the pre- and posttreatment pain intensity scores (NRS-11) was also found to be significantly correlated with the pain relief scores (PRS-5) at one hour after treatment ($\rho=0.7$; $P<.001$) (*Table 12*).

After group assignment, attempts were not made within the study design to prevent the patient or physician from knowing which type of treatment was being given. Since patients completed the outcome measures, the value of a blinded evaluation is limited. Although a placebo arm was not used, most patients were unfamiliar with manipulation; as noted, eight patients had previously received manipulation, but no patient had received manipulation for the current episode of pain.

Adverse effects for these two treatment modalities were minimal for both groups. Within the ketorolac group, eight patients cited one or more of the following adverse effects: arm soreness, bad taste in mouth, dizziness, drowsiness, dyspepsia, heart racing, lightheadedness, nausea, or vomiting. In the OMT group, one patient stated that her arm felt "funny" after manipulation but that she had normal muscle strength, sensation, and deep tendon reflexes. No further adverse effects were observed for this patient while she was in the ED.

Comment

The results of this study suggest that OMT is significantly better than IM ketorolac in decreasing pain intensity and that it is as efficacious as IM ketorolac in providing pain relief for patients with acute neck pain in the ED. Both study groups showed significant decreases in pain intensity, but there was no significant difference between the groups' self-reported pain relief levels at one hour after treatment. The two subjective scales were correlated, although not perfectly, and it is not surprising that one is significant while the other is not. Since the pain relief scale has only ordinal scale variables, one would expect it to be less sensitive.

Neither age, gender, nor etiology of pain appeared to significantly confound the results. Study subjects who received manipulation in the past showed a greater decrease in pain intensity and improved pain relief with OMT than with ketorolac. We can speculate that patients may have learned to expect more from manipulation if they had a positive experience in the past. This may explain why this subgroup had a more favorable outcome with OMT than with IM ketorolac. It is difficult to draw any definite conclusions, however, since patient numbers were small for these subgroups.

In an attempt to represent the true population, patients were not excluded from this study if they had taken NSAIDs in the 24 hours before they presented to the ED. Bartfield et al[16] found that subjective pain score reduction was not significantly affected by recent use of NSAIDs, nor with concurrent use of muscle relaxants. Our study did not show significant differences between pain intensity scores for those who had taken NSAIDs within the past 24 hours. Interestingly, patients who had not taken NSAIDs before presenting to the ED showed more improvement in pain levels when treated with OMT rather than with IM ketorolac. A larger group of patients and an additional test arm combining medication and OMT would be required to clarify any increased efficacy of the combination of these modalities, however. Previous studies have suggested that patients do better with this combination.[23,24]

Multiple studies have evaluated manual therapy for neck pain[13,23-39] but only four studies have investigated acute neck pain and only mobilization techniques were used in those studies.[40-43] Mobilization for acute neck pain may be beneficial for some patients when used in combination with other treatments.[7,8] A single intervention with manipulation has been shown to decrease neck pain.[23,24,29,44] Our results are consistent with prior studies in the observation that patients may receive immediate improvement

in pain with a single intervention with manipulation.

The true incidence of complications from OMT is unknown since reporting is only in the form of case reports, a case control study, and surveys. Complications have been attributed to cervical manipulation with rotational technique, misdiagnosis, failure to recognize the onset or progression of neurological signs or symptoms, and the presence of coagualopathies.[2,45,46] Mild to moderate transient adverse reactions may occur in about 50% of patients after chiropractic spinal manipulation.[47] Vick et al[46] found that 20% of injuries reported to have occurred when "manipulation" was the treatment modality used, and the therapy was provided by someone other than an osteopathic physician, chiropractor, or "qualified physician." Cerebrovascular accidents account for 66% of reported injuries after manipulation and 90% of deaths.[46] The incidence of stroke after neck manipulation has been estimated to be from 0.5 to 2 incidents per million manipulations.[48]

A nested case control study by Rothwell et al[49] revealed that for every 100,000 persons younger than 45 years receiving chiropractic care, approximately 1.3 cases of vertebral basilar accidents (VBA) attributable to chiropractic care would be observed within 1 week of treatment. Although attempts have been made to relate VBA to manipulation, the literature does not clearly identify patients at risk nor define the type of mechanical trauma—neck movement or manipulative technique—which may precipitate vertebrobasilar artery dissection.[50]

Nonsteroidal anti-inflammatory drugs are generally considered safe, but mild adverse effects may include: gastrointestinal pain, diarrhea, dyspepsia, or nausea (7%–13%); constipation, flatulence, gastrointestinal "fullness," vomiting, or stomatitis (1%–3%); anorexia, gastritis, increased appetite, or rectal bleeding (<1%).[51] Serious complications such as gastrointestinal bleeding, gastrointestinal perforation, or renal failure are rare. Dabbs and Lauretti[48] evaluated the risk of serious injury or death resulting from cervical manipulation compared with NSAIDs and concluded that cervical manipulation for neck pain is much safer than the use of NSAIDs. Of the 1500 patients reported in clinical trials of manipulation, no complications were reported.[2]

In the current study, we found a relatively high incidence (27%) of adverse effects associated with IM ketorolac. Only one patient in the OMT group reported an adverse effect, and it was minor with no serious complications. Although our study and previous trials are encouraging in that they did not present severe complications, it would be incorrect to deem cervical manipulation as completely benign and risk free; large controlled studies are needed to determine risks and true incidence of associated complications.

This study was limited by the lack of blinding of the patient or physician to treatment, no use of placebo, the use of subjective measures to evaluate pain intensity levels and relief, no tracking of refusal rates, convenience sampling, and no long-term follow up.

It was not possible to blind the patients or physicians to study treatment protocols. After study enrollment, participating patients were informed they were receiving either manipulation or an intramuscular injection of ketorolac. As noted, enrolling physicians enrolled and treated all study subjects. Although patients may be partially blinded by including naïve patients (ie, those with no previous experience with the treatment under study),[52] we did not exclude patients with prior manipulation to gain a better representation of the population. Physicians may have been partially blinded if they had not enrolled and treated each patient. However, this study protocol was not feasible at our institutions and, therefore, introduced an increased likelihood of examiner bias.

Neither a placebo nor sham treatment was employed. Authors of some studies have argued that "sham manipulation" is impractical.[53,54] Any therapeutic effect observed, they assert, may be attributed to the powerful psychological placebo effect of the "laying-on-of-hands."[5,55-57] We believe that no sham treatment could be demonstrably "invalid" while at the same time appearing valid to patients. A structural exam was included in both arms of the study protocol and may have resulted in a placebo or an active response. This active response may have reduced the possibility of attributing a difference where none exists (type I error) to treatment with OMT.

The current dosing recommendations for IM ketorolac in the United States are 30 mg to 60 mg, with the lowest dose recommended for patients aged to 65 years, patients who are renally impaired, and patients weighing less than 50 kg.[51] Efficacy ratings between 30 mg and 90 mg of ketorolac have been comparable.[58-61] There is no published data that suggests that ketorolac, 60 mg, is superior to 30 mg.[62] We chose 30 mg, ketorolac injected intramuscularly since we felt it was felt prudent to prescribe ketorolac at the lowest dosage necessary to control pain and minimize adverse effects.[63,64] It is possible that our patients did not get an optimal response with 30 mg, however, and may have reported more positive subjective outcomes with 60 mg dosing.

Our outcome measure of pain relief was subjective. It can be argued that some objective means (eg, range of motion testing) should have also been used in evaluating treatment efficacy. However, physiologic measures do not always reflect how patients feel,[65] and disassociations among treatment outcomes have been documented in several studies.[66]

Additionally, we did not record refusal rates. Our results may be skewed toward more positive results since those enrolled may have desired manipulation or intramuscular injection. Patients who did not want either manipulation or an IM injection were free to exclude themselves as potential study subjects.

Using a convenience sample of patients also introduces selection bias. If alternate sampling methods had been used (eg, random sampling), study results may have been strengthened. In addition, less time may have been required to com-

plete the study. The use of random sampling methods was not a feasible option for the current study, however.

Our investigation observed only the immediate, subjective effects of OMT and IM ketorolac in decreasing patients' reported levels of pain. Although this outcome is clearly desirable, the therapeutic goal is long-term pain relief. Just as multiple doses of analgesics may be required for pain relief, more than one intervention with OMT may be necessary to achieve long-term pain relief.

In summary, OMT appears to be an efficacious treatment option for patients with acute neck pain in the ED setting. For patients who have contraindications to NSAIDS, OMT is a reasonable treatment alternative. Osteopathic manipulative treatment is as effective as IM ketorolac in providing patients with pain relief, and it is significantly better than IM ketorolac in decreasing pain intensity.

Future studies are recommended. Additionally, it may be appropriate to examine the effects of combination therapy—OMT and medical analgesia compared with OMT or medication alone—as well as cost-benefit analysis and the long-term benefits of OMT when it is performed in the ED.

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