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Original Contributions

The Relative Efficacy of Seven Skeletal Muscle Relaxants. An Analysis of Data From Randomized Studies

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□ **Abstract—Background: Low back pain (LBP) causes 2.6 million visits to U.S. emergency departments (EDs) annually. These patients are often treated with skeletal muscle relaxants (SMRs). Objectives: The goal of this study was to determine whether efficacy of SMRs is associated with age, sex, or baseline LBP severity. Methods: This was a planned analysis of data from 4 randomized studies of patients with acute nonradicular LBP. Patients were enrolled during an ED visit and followed-up 1 week later. The primary outcome was improvement in the Roland-Morris Disability Questionnaire (RMDQ) between ED discharge and the 1-week follow-up. We compared the change in RMDQ among 8 groups: placebo, baclofen, metaxalone, tizanidine, diazepam, orphenadrine, methocarbamol, and cyclobenzaprine. All patients also received a nonsteroidal anti-inflammatory drug. We performed analysis of variance to determine statistically significant differences between medications and linear regression to determine the association of age, sex, and baseline severity with the primary outcome. Results: The mean improvement in RMDQ per group was placebo 10.5 (95% confidence interval [CI] 9.5–11.5), baclofen 10.6 (95% CI 8.6–12.7), metaxalone 10.3 (95% CI 8.1–12.4), tizanidine 11.5 (95% CI 9.5–13.4), diazepam 11.1 (95% CI 9–13.2), orphenadrine 9.5 (95% CI 7.4–11.5), methocarbamol 8.1 (95% CI 6.1–10.1), and cyclobenzaprine 10.1 (95% CI 8.3–12). The between-group differences were not statistically significantly different. Results were similar regardless of age, sex, and baseline severity. Higher baseline RMDQ was associated with greater clinical improvement (B coefficient 5.7, $p < 0.01$). Adverse medication effects were more common with cyclobenzaprine than with placebo ($p < 0.01$). Conclusions: Among patients in the ED with acute LBP treated with a nonsteroidal anti-inflammatory drug, SMRs do not improve outcomes more than placebo. Neither age, sex, nor baseline impairment impacts these results.**

□ **Keywords—baclofen; cyclobenzaprine; diazepam; ibuprofen; low back pain; metaxalone; methocarbamol; naproxen; orphenadrine; tizanidine**

Introduction

Low back pain (LBP) is one of the most commonly encountered ailments in clinical practice and is responsible for 2.6 million visits to U.S. emergency departments (EDs) annually (1). Many patients with acute LBP experience substantial improvement in the first month, but up to one third report persistent back pain, and 1 in 5 report some limitations in activity. These persistent symptoms are associated with high costs, including those related to health care, and indirect costs from missed work or reduced productivity (2).

Skeletal muscle relaxants (SMRs) are a group of medications commonly used to treat LBP. They include a variety of drugs with different mechanisms of action. In 2000,

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the U.S. Medical Expectations Panel Survey found that of the 44 million prescriptions written for the 24.5 million patients with both acute and chronic LBP, 18.5% were for SMRs, making this drug class the most commonly prescribed for musculoskeletal disorders (3). However, there is mostly limited, heterogeneous, and lower-quality evidence of their clinical efficacy (4).

In this planned analysis of data collected during 4 randomized, placebo-controlled studies conducted sequentially in the same clinical setting, we compared the efficacy and side effect profiles of 7 different SMRs with placebo and determined whether efficacy was associated with age, sex, baseline LBP-related functional impairment, or history of LBP.

Methods

Study Design and Setting

This was a planned analysis of data gathered from 4 randomized, double-blind, placebo-controlled studies of patients with new-onset, nontraumatic, nonradicular musculoskeletal LBP. In each of these studies, patients who presented to an ED with acute musculoskeletal LBP were enrolled in the study at the time of discharge from the ED, and followed up with a structured interview by telephone 7 days later. In the first study, patients were randomized to treatment with 10 days of naproxen plus cyclobenzaprine, naproxen plus oxycodone/acetaminophen, or naproxen plus placebo (April 2012–December 2014) (5). In the second study, patients were randomized to treatment with 7 days of naproxen plus diazepam or naproxen plus placebo (June 2015–February 2016) (6). In the third study, patients were randomized to treatment with 7 days of naproxen plus placebo, naproxen plus orphenadrine, or naproxen plus methocarbamol (March 2016–February 2017) (7). In the fourth study, patients were randomized to treatment with 7 days of ibuprofen plus metaxalone, ibuprofen plus tizanidine, ibuprofen plus baclofen, or ibuprofen plus placebo (May 2017–July 2018) (8). For the purpose of this current study, the subgroup of patients treated with oxycodone/acetaminophen were excluded from analysis because they did not receive an SMR.

The study protocols for all 4 studies were similar, with the exception of slightly different exclusion criteria, which were necessary because of different contraindications to the SMRs (Table 1). In each one of the 4 studies, research personnel provided each patient with a LBP educational intervention before discharge. All patients provided written informed consent. These studies were each reviewed and approved by the Albert Einstein College of Medicine Institutional Review Board.

Subject Selection

Patients were considered for inclusion if they were 18–69 years of age and presented to the ED primarily for management of acute LBP, defined as pain of 2 weeks' duration or less originating between the lower border of the scapulae and the upper gluteal folds, and received a diagnosis consistent with nontraumatic, nonradicular, musculoskeletal LBP, as determined by the attending emergency physician. Patients were required to have functionally impairing back pain, which we defined as a score >5 on the Roland-Morris Disability Questionnaire (RMDQ) (9). Patients were excluded for radicular pain, pain duration for >2 weeks, direct trauma to the back within the previous month, or a history of experiencing LBP on average more than several times per year. The inclusion and exclusion criteria for each of the 4 studies are listed in Table 1.

Measures

We used the RMDQ to measure functional impairment. To measure pain, we used an ordinal pain scale on which participants described their worst LBP pain over the previous 24 hours as severe, moderate, mild, or none.

At baseline, we recorded participants' age, sex, RMDQ score, and the frequency of previous episodes.

Outcomes

The primary outcome was improvement in the RMDQ between ED discharge and the 1-week follow-up. A 5-point improvement on this scale is generally considered a clinically significant improvement (9). Important secondary outcomes included moderate or severe LBP 1 week after the ED visit and medication adverse effects, assessed by asking patients to report any symptoms from the medications and dichotomizing their responses (yes/no).

Analysis

Baseline characteristics of the cohort, including age, sex, index RMDQ score, and type of SMR received, are reported as mean with standard deviation (SD), median with interquartile range, or frequency with percent, as appropriate.

We compared the change in RMDQ between baseline and 1-week follow-up among 8 groups: 1) placebo, 2) baclofen, 3) metaxalone, 4) tizanidine, 5) diazepam, 6) orphenadrine, 7) methocarbamol, and 8) cyclobenzaprine. Results are reported as mean improvement with 95% confidence intervals (CIs). We performed analysis of variance to determine whether the between group differences were statistically significant. We report pain intensity and ad-

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Table 1. Inclusion and Exclusion Criteria

Study, Dates of Enrollment, Total Sample Size	Inclusion Criteria	Exclusion Criteria
All participants received ibuprofen and were randomized to metaxalone, tizanidine, baclofen, or placebo; May 2017–July 2018, N = 320	Adults 18–64 years of age	Pregnancy or breastfeeding; allergy to, intolerance of, or contraindication to any of the investigational medications
All participants received naproxen and were randomized to diazepam or placebo; June 2015– February 2016, N = 114	Adults 21–69 years of age	Pregnancy or breastfeeding; allergy to, intolerance of, or contraindication to any of the investigational medications
All participants received naproxen and were randomized to orphenadrine, methocarbamol, or placebo; March 2016–January 2017, N = 240	Adults 18–69 years of age	Pregnancy or breastfeeding; allergy, intolerance, or contraindication to the investigational medications
All participants received naproxen and were randomized to cyclobenzaprine, oxycodone/acetaminophen, or placebo; April 2012–September 2014, N = 323	Adults 21–64 years of age	Pregnancy or breastfeeding; allergy, intolerance, or contraindication to the investigational medications; chronic opioid use currently or in the past

verse medication effects as frequency with percent and compare the results using chi-square tests.

To determine the association of age, sex, baseline RMDQ severity, and history of back pain with the primary outcome, we built a linear regression model, in which the improvement in RMDQ (baseline RMDQ – RMDQ 1 week) was the dependent variable and medication or placebo, age, sex, previous episodes of LBP, and baseline RMDQ were the independent variables. We dichotomized baseline RMDQ at the median and previous episodes of LBP as yes or no. We included a measure of medication adherence in the model. Specifically, we asked each participant during the 1-week follow-up how frequently they had used the SMR. Their answers were trichotomized into the following categories: at least once daily, sometimes, or never/ rarely.

To determine the association of the predictor variables with moderate or severe LBP at 1 week, we built a logistic regression model in which the presence of moderate or severe pain at 1 week was the dependent variable and medication, age, sex, SMR adherence, previous episodes, and baseline RMDQ were the independent variables. Finally, to evaluate the association between medication adverse effects and the different SMRs, we built a logistic regression model in which medication adverse effects (yes/no) was the dependent variable and the 7 SMRs plus placebo were the independent variables. Age and sex were included in this latter model as covariates.

Results

A total of 887 patients were enrolled. Of these, 856 (96.5%) provided 1-week outcome data. Characteristics of the cohort at baseline are shown in Table 2. Marked functional impairment during the index visit, as measured by the RMDQ, was common.

Table 2. Baseline Variables

Variable	N = 887
Age (years), mean (SD)	39 (11)
Sex, n (%)	
Male	497 (56)
Female	390 (44)
RMDQ baseline, median (IQR)	18 (16-22)
Previous episode of LBP	
Yes	592 (67)
No	293 (33)
Missing	2
SMR received, n (%)	
Placebo	323 (36)
Baclofen	80 (9)
Metaxalone	79 (9)
Tizanidine	79 (9)
Diazepam	57 (6)
Orphenadrine	80 (9)
Methocarbamol	81 (9)
Cyclobenzaprine	108 (12)

IQR = interquartile range; LBP = low back pain; RMDQ = Roland-Morris Disability Questionnaire; SD = standard deviation; SMR = skeletal muscle relaxant.

The mean improvement in RMDQ for each group is shown in Table 3. There were no statistically significant

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Table 3. One Week Outcomes

Skeletal Muscle Relaxant	Mean Improvement in RMDQ (95% CI)	Pain Intensity Reported as None or Mild, n/N (%)	Any Adverse Event Reported, n/N (%)
Placebo	10.5 (9.5–11.5)	200/308 (65)	48/296 (16)
Baclofen	10.6 (8.6–12.7)	53/79 (67)	7/73 (10)
Metaxalone	10.3 (8.1–12.4)	47/75 (63)	6/69 (9)
Tizanidine	11.5 (9.5–13.4)	51/75 (68)	6/72 (8)
Diazepam	11.1 (9.0–13.2)	39/57 (68)	12/57 (21)
Orphenadrine	9.5 (7.4–11.5)	52 /78(67)	7/74 (9)
Methocarbamol	8.1 (6.1–10.1)	49/80 (61)	14/75 (19)
Cyclobenzaprine	10.1 (8.3–12.0)	62/103 (60)	35/99 (35)

CI = confidence interval; RMDQ = Roland-Morris Disability Questionnaire.
Discrepancies in the N values reflect patients who were lost to follow-up and missing data.

Table 4. Frequency of Use of SMRs

SMR	Frequency of Use, n (%)		
	Never/Rarely	Sometimes	Daily or More Frequently
Placebo	50 (16)	40 (13)	218 (71)
Baclofen	4(5)	8 (11)	63 (84)
Metaxalone	8 (11)	10 (14)	54 (75)
Tizanidine	12 (16)	13 (18)	49 (66)
Diazepam	8 (14)	9 (16)	39 (70)
Orphenadrine	12 (15)	9 (12)	57 (73)
Methocarbamol	14 (18)	7 (9)	57 (73)
Cyclobenzaprine	18 (18)	13 (13)	71 (70)

SMR = skeletal muscle relaxant.
Missing data are related to participants lost to follow-up and to participants who did not provide an answer to this question.

differences among the groups ($p = 0.37$). With regard to pain intensity at 1 week, there were also no statistically significant differences among the groups ($p = 0.93$; Table 3). Frequency of use of the SMRs is shown in Table 4. Most patients reported using these medications at least once daily.

As shown in Table 5, sex, age, baseline RMDQ score, and history of previous episodes of LBP did not meaningfully impact the association between the SMRs, placebo, and the 1-week outcomes. Patients who used SMRs at least once per day were less likely to improve than patients who used the SMRs never or only once. Baseline RMDQ was directly associated with clinical improvement, indicating that more severely impaired patients were more likely to improve.

Adverse medication effects were reported by 135 (16.6%) of 815 participants (Table 3). These were more common with cyclobenzaprine than with placebo, occurring in 35% vs 16% ($p < 0.001$) of patients (Table 3). Women were more likely to report medication adverse effects than men (Table 5).

Discussion

In this analysis of data from 4 ED-based randomized trials, SMRs, when combined with a nonsteroidal anti-inflammatory drug (NSAID), failed to outperform an NSAID plus placebo with regard to improvement in functional impairment and pain among patients with acute, nonradicular LBP. While the SMRs were generally and surprisingly well tolerated, there was a notable exception—patients who received cyclobenzaprine reported nearly 3 times as many adverse medication effects as patients who received placebo. Age, sex, LBP history, and baseline severity of the LBP did not impact the efficacy outcomes, though women were more likely to report medication-related adverse events.

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Table 5. Multivariable Regression Models Describing the Association Between the SMRs and 1-Week Outcomes

Independent Variables	Improvement in RMDQ Between ED Visit and 7 Days Later, B Coefficient (95% CI), *p* Value	Presence of Moderate or Severe Pain at 7 Days, OR (95% CI), *p* Value	Any Adverse Event Reported, OR (95% CI), *p* Value
SMR (vs placebo)			
Baclofen	−0.09 (−2.25 to 2.06), 0.93	1.0 (0.6–1.7), 0.96	0.6 (0.3–1.4), 0.23
Metaxalone	0.05 (−2.12 to 2.23), 0.96	1.1 (0.7–1.9), 0.64	0.5 (0.2–1.2), 0.10
Tizanidine	0.93 (−1.23 to 3.09), 0.40	0.9 (0.5–1.6), 0.74	0.4 (0.2–1.0), 0.05
Diazepam	0.83 (−1.62 to 3.28), 0.51	0.8 (0.4–1.5), 0.50	1.3 (0.6–2.6), 0.50
Orphenadrine	−1.12 (−3.24 to 0.99), 0.30	0.9 (0.6–1.6), 0.78	0.5 (0.2–1.3), 0.15
Methocarbamol	−2.51 (−4.62 to −0.41), 0.02	1.2 (0.7–2.0), 0.44	1.2 (0.6–2.3), 0.67
Cyclobenzaprine	−0.67 (−2.57 to 1.23), 0.49	1.2 (0.8–1.9), 0.40	2.9 (1.7–4.9), <0.01
Use of SMR during the week following ED discharge (vs never/rarely)			
Sometimes	−1.40 (−3.58 to 0.78), 0.21	1.0 (0.6–1.8), 0.89	2.5 (1.1–5.5), 0.03
Daily	−2.04 (−3.69 to −0.40), 0.02	1.1 (0.7–1.7), 0.65	1.9 (1.0–3.6), 0.06
Age in years	−0.02 (−0.07 to 0.04), 0.53	1.0 (1.0–1.0), 0.74	1.0 (0.9–1.0), 0.11
Women (vs men)	−0.90 (−2.07 to 0.26), 0.13	1.2 (0.9–1.6), 0.17	1.5 (1.0–2.3), 0.03
High RMDQ score at baseline (vs low)	5.74 (4.58–6.90) <0.01	1.1 (0.8–1.4), 0.68	Not included in adverse event model
LBP previously (vs never previously)	−0.38 (−1.62 to 0.86), 0.55	0.8 (0.6–1.0), 0.09	Not included in adverse event model

CI = confidence interval; ED = emergency department; LBP = low back pain; OR = odds ratio; RMDQ = Roland-Morris Disability Questionnaire; SMR = skeletal muscle relaxant.

The results of this study add a layer of complexity to the current understanding of the role of SMRs for acute LBP. While the SMRs have been shown to be efficacious as monotherapy for acute LBP, combining a SMR with a NSAID confers no additional benefit (2,4). Thus, when physicians prescribe a SMR for patients with acute LBP, the physician should consider whether it is worthwhile to continue the NSAID.

Our a priori hypothesis was that combining NSAIDs with SMRs would benefit those patients who were more severely impaired at baseline or patients with a history of episodes of LBP. Neither of these hypotheses proved true. There was an association between severe functional impairment at baseline and improvement in functionality during the subsequent week. This may be a manifestation of regression to the mean, a reflection of the generally good prognosis of acute LBP, or an artifact of measuring a biological phenomenon with a 24-item scale. Daily use of the SMRs was associated with less improvement in RMDQ score. Most likely, this is because patients with early good outcomes were less likely to continue to use the investigational medication.

In this analysis, cyclobenzaprine was associated with adverse events with an OR of 2.9 (95% CI 1.7–4.9). Similarly, in a meta-analysis of 14 RCTs from 13 publications comparing cyclobenzaprine with placebo for treatment of back pain, adverse effects, typically drowsiness, dry mouth, dizziness, and nausea, occurred in 53% of participants who received cyclobenzaprine compared with 28% who received placebo (10). Patients who receive this medication should be counseled about the frequency of adverse medication side effects.

It is interesting that neither adverse events nor efficacy were associated with age, although the same is not true of sex: women were more likely to experience adverse events. It is also surprising that in this analysis, SMRs, with the exception of cyclobenzaprine, did not cause more adverse effects than placebo, a finding not reflective of the bulk of published studies of SMRs (4). This may be a result of the infrequent use of the SMRs by many patients in our study. In fact, frequency of use itself was associated with adverse events. Perhaps patients who did not tolerate the SMRs simply stopped using them and therefore had no adverse effects to report.

Limitations

A number of limitations in this analysis must be mentioned. First, these studies were conducted in 2 urban EDs in the Bronx, New York. It is not clear whether

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these results can be generalized to a broader population. Second, this study was an analysis of data gathered from 4 previous ED studies, rather than one specifically designed to answer the current study question primarily. Third, we did not examine a comprehensive set of biopsychosocial predictions (e.g., depression or psychosomatization), because they have previously been shown not to be predictive of poor LBP outcomes in an ED population (11,12). Fourth, we excluded older adults, even though this is an important subgroup of patients that is at high risk for persistent pain and that is also at risk for medical complications. We did so because of increased risk from the investigational medications. Finally, a possible confounder of our work is NSAIDs received because patients who received baclofen, tizanidine, or methocarbamol were coadministered ibuprofen while all the other patients received naproxen. However, published data do not indicate any substantial difference in efficacy between these two types of NSAID (13).

Conclusions

In conclusion, the combination of an NSAID and a SMR did not improve acute LBP outcomes more than an NSAID plus placebo, regardless of age, sex, baseline functional impairment, or history of LBP.

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ARTICLE SUMMARY

1. Why is this topic important?

Low back pain (LBP) is a common chief complaint among patients in the emergency department. The role of skeletal muscle relaxants (SMRs) in the management of this ailment is ill-defined.

2. What does this study attempt to show?

Previous research has demonstrated that adding a SMR does not improve LBP outcomes among patients who are taking a nonsteroidal anti-inflammatory drug (NSAID). This study attempts to define whether this is also true among patients with LBP who are more severely impaired, and also whether sex or age should matter when considering a SMR.

3. What are the key findings?

The most important finding is that we could not identify a subgroup of patients who benefit from adjunctive therapy with a SMR. Women were more likely to experience side effects.

4. How is patient care impacted?

SMRs should not be used routinely in LBP patients who are taking nonsteroidal anti-inflammatory drugs

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