

Supplementary Online Content

Friedman BW, Dym AA, Davitt M; et al. Naproxen with cyclobenzaprine, oxycodone/acetaminophen, or placebo for treating acute low back pain: a randomized clinical trial. *JAMA*. doi:10.1001/jama.2015.13043

eTable 1. Outcomes Among Patients Who Used the Investigational Medication More Than Once

eTable 2. Additional Outcomes

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. Outcomes Among Patients Who Used the Investigational Medication More Than Once

Outcome	Naproxen + placebo (n=80)	Naproxen + cyclobenzaprine (n=84)	Naproxen + oxycodone/acetaminophen (n=71)	Difference between cyclobenzaprine and placebo	Difference between oxycodone/APAP and placebo	Difference between cyclobenzaprine and oxycodone/APAP
Mean improvement in RMDQ between ED visit and one week later	9.0 (98.3%CI: 6.9, 11.2)	10.1 (98.3%CI: 7.6, 12.5)	10.8 (98.3%CI: 8.3, 13.2)	1.1 (98.3%CI: -2.2, 4.3) ¹	1.7 (98.3%CI: -1.5, 5.0) ¹	0.7 (98.3%CI: -2.8, 4.2) ¹
Worst LBP during previous 24 hours						
Mild/ none	42 (53%)	50 (60%)	50 (70%)	7% (95%CI: -8, 22%)	18% (95%CI: 3, 33%)	11% (95%CI: -4, 26%)
Moderate/ Severe	38 (48%)	34 (40%)	21 (30%)			
Frequency of LBP during previous 24 hours						

...continued eTable 1.

Outcome	Naproxen + placebo (n=80)	Naproxen + cyclobenzaprine (n=84)	Naproxen + oxycodone/acetaminophen (n=71)	Difference between cyclobenzaprine and placebo	Difference between oxycodone/APAP and placebo	Difference between cyclobenzaprine and oxycodone/APAP
Never/ rarely	32 (40%)	38 (45%)	34 (48%)	6% (95%CI: -8, 21%)*	8% (95%CI: -6, 23%)*	2% (95%CI: -12, 16%)*
Sometimes	20 (25%)	22 (26%)	18 (25%)			
Frequently/ always	28 (35%)	24 (29%)	19 (27%)			
Use of medication for LBP during previous 24 hours						
No meds	28 (35%)	33 (39%)	26 (37%)	4% (95%CI: -10, 19%)	2% (95%CI: -14, 17%)	3% (95%CI: -13, 18%)
Took meds	52 (65%)	51 (61%)	45 (63%)			

...continued eTable 1.

Outcome	Naproxen + placebo (n=80)	Naproxen + cyclobenzaprine (n=84)	Naproxen + oxycodone/acetaminophen (n=71)	Difference between cyclobenzaprine and placebo	Difference between oxycodone/APAP and placebo	Difference between cyclobenzaprine and oxycodone/APAP
Desires same medication subsequent episode of LBP (2)						
Yes	53 (66%)	63 (75%)	55 (79%)	9% (95%CI: -5, 23%)**	12% (95%CI: -2, 26%)**	4% (95%CI: -10, 17%)**
No	23 (29%)	17 (20%)	13 (19%)			
Not sure	4 (5%)	4 (5%)	2 (3%)			
Median number of days until able to return to usual activities (3)	5 (IQR: 2, >7)	4 (IQR: 3, >7)	4 (IQR: 3, >7)	0 (95%CI: -1, 1)	0 (95%CI: -1, 1)	0 (95%CI: -1, 1)

...continued eTable 1.

Outcome	Naproxen + placebo (n=80)	Naproxen + cyclobenzaprine (n=84)	Naproxen + oxycodone/acetaminophen (n=71)	Difference between cyclobenzaprine and placebo	Difference between oxycodone/APAP and placebo	Difference between cyclobenzaprine and oxycodone/APAP
Median number of days until able to return to work (4)	(n=63), 3 (2, 4)	(n=71), 3 (2, 5)	(n=56), 2 (1, 5)	0 (95%CI: -1, 1)	0 (95%CI: 0, 1)	0 (95%CI: -1, 1)

RMDQ: Roland Morris Disability Questionnaire. This is a 24 item instrument measuring low back pain related functional impairment. On this instrument, 0 represents no low back pain related functional impairment and 24 represents maximum functional impairment.

1. Between group difference, improvement in RMDQ

2. Participants were asked: "The next time you have back pain, do you want to take the same medications you've been taking this past week?"

3. Patients who had not yet recovered at the time of the one week phone call were categorized as >7 days.

4. Only employed patients are included.

*Never/rarely/sometimes versus frequently/ always

** Yes versus no/ not sure

eTable2. Additional Outcomes

Outcome variable	Naproxen + placebo	Naproxen + cyclobenzaprine	Naproxen + oxycodone/acetaminophen	Difference between cyclobenzaprine and placebo	Difference between oxycodone/APAP and placebo	Difference between cyclobenzaprine and oxycodone/APAP
One week outcome						
0-10 pain score, mean (1)	3.9 (95%CI: 3.3, 4.5) (n=104)	3.6 (95%CI: 2.9, 4.3) (n=103)	3.4 (95%CI: 2.8, 4.0) (n=104)	0.3 (95%CI: -0.6, 1.2)	0.5 (95%CI: -0.4, 1.4)	0.2 (-0.8, 1.1)
Three month outcomes						
Resumption of usual activities (2)	(n=96)	(n=99)	(n=99)			
Resumed all activities	80 (83%)	80 (81%)	74 (75%)	3% (95%CI: -8, 13%)	9% (95%CI: -3, 20%)	6% (95%CI: -5, 18%)*
Not yet resumed all activities	16 (17%)	19 (19%)	25 (25%)			
Working hours (3)	(n=96)	(n=99)	(n=100)			
Not working at all	16 (17%)	20 (20%)	20 (20%)	6% (95%CI: -6, 19%)*	10% (95%CI: -2, 22%)*	3% (95%CI: -9, 16%)*
Working fewer hours	5 (5%)	8 (8%)	12 (12%)			
Working the same number of hours	70 (73%)	60 (61%)	58 (58%)			
Working more hours	5 (5%)	11 (11%)	10 (10%)			

1. At the time of the 7 day follow-up, participants were asked to describe their worst LBP in the previous 24 hours using a 0 to 10 scale, on which 0 represented no pain and 10 the worst pain imaginable

2. At the time of the 3 month follow-up, participants were asked if they were able to resume all activities as compared with the time period prior to the ED visit

3. At the time of the 3 month follow-up, participants were asked to compare the number of hours they were currently working with the time period immediately prior to their ED visit

* not working at all/ working fewer hours versus same number/ more hours