ORIGINAL RESEARCH

Structured Management of Chronic Nonmalignant Pain with Opioids in a Rural Primary Care Office

Kevin S. McCann, MD, Shawndra Barker, MD, Raymond Cousins, Adam Franks, MD, Clinton McDaniel, MD, Stephen Petrany, MD, and Eric Riley, MD

Introduction: **The use of opioid medication for nonmalignant chronic pain (NMCP) increased dramatically during the last 20 years. There have been regulatory changes implemented to reduce the risk of harm to both patients and society. Much of the burden of monitoring these patients is falling on primary care physicians (PCPs), who do not have the time or resources to handle what is entailed in a best-practice approach to NMCP.**

Methods: **A retrospective study was conducted with all patients on opioid medication for NMCP who were enrolled onto an individual PCP's practice. All were required to engage with a new care system. Patients had the option to remain on opioids, to wean opioids, or to transfer care. Patients who remained in the practice on opioids were required to have an office visit on a day dedicated solely to NMCP every 3 months. Each visit involved verifying the controlled substance contract, a urine drug screen, board of pharmacy monitoring, pain-targeted history and physical, calculation of the average morphine equivalents used, and evaluations of pain, functional status, and mood. Characteristics more likely to lead to weaning from opioids were monitored, as was the program effect on the patients remaining on opioids.**

Results: **With this practice model, 32 patients treated with opioids for NMCP were enrolled. Of these, 38% (n = 12) elected to wean opioids, 53% (n = 17) continued opioid medication, and 9% (n = 3) transferred care. Mean morphine equivalent mg/day was the prime determinant for ability to wean (17.01 mg/day) compared with maintaining (30.61 mg/day) ($P = .0397$; CI, 0.68 to 26.51). Patients maintaining opioid treatment showed no statistically significant change in any measured data point from beginning until end of the evaluation period.**

Conclusion: **Given the choice of following a specific structured care system of opioid medication management or leaving the practice, most patients agreed to the structured system. This approach provided a high degree of compliance with controlled substance regulations and is associated with a reduced number of opioid prescriptions. Patients who were on lower doses of opioid medication are more likely to wean their use with this model. (J Am Board Fam Med 2018;31:57–63.)**

Keywords: **Chronic Pain, Controlled Substances, Opioid Analgesics, Patient Compliance, Pharmacy, Primary Care Physicians, Retrospective Studies**

Nonmalignant chronic pain (NMCP) in general is widespread, affecting approximately 100 million adults in the United States. It costs $560 to $635 billion dollars annually, outdistancing the cost of heart disease, cancer, or diabetes[1] and is the predominant reason for disability in most Americans.[2] The treatment of NMCP has the potential to have rippling effects that permeate our society. Approximately 5 to 8 million Americans use opioid medications for the treatment of chronic pain.[2] However, the opioid class of medication is associated with significant increases in morbidity and mortality. Compared with nonopioid medications the hazard ratio for total mortality is 1.64 during the first 6 months and for the first 30 days is 4.16.[3]

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From the Department of Family and Community Health, Joan C. Edwards School of Medicine, Marshall University, Huntington, WV.
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Corresponding author: Kevin S. McCann, MD, 4600 Route 152, Lavalette, WV 25535 (E-mail: mccann2@marshall.edu).

Despite this, the use of opioid medications for NMCP is escalating although reports on the magnitude of this have varied. Studies note that visits requiring the use of opioid medications for the treatment of pain increased from 11.3% to 19.6% between 2000 and 2010.[4] Furthermore, from 1996 to 2011 there was an overall increase in opioid medication use of 1448% and misuse of 4680%.[5] Making the situation even more complicated is that 40% to 70% of people treated for chronic pain may not be receiving ideal treatment.[2]

Although opioid medication use in NMCP is fraught with risk, there is some limited evidence to support their use. The executive summary of the National Institutes of Health (NIH) Pathways to Prevention Workshop on The Role of Opioids in the Treatment of Chronic Pain states that, "Patients, providers and advocates all agree that there is a subset of patients for whom opioids are an effective treatment for their chronic pain, and that limiting or denying access to opioids for these patients can be harmful."[2] However, this summary goes on to caution that there have been certain groups identified, such as those with psychiatric illness and previous substance abuse history, as being at higher risk to misuse opioids. Unfortunately, these same groups who were more likely to misuse opioid medications were also more likely to be prescribed opioid medications and less likely to be involved in a structured monitoring program.[2] A prudent approach to using opioid medications for NMCP would thus involve careful individualized risk/benefit assessment conducted within structured visits.

Chronic pain is being increasingly managed by primary care providers who have limited amounts of time to address a problem that requires a multidimensional approach in patients who frequently have significant medical comorbidity and polypharmacy.[2] Careful monitoring and documentation of such complex patients is difficult to accomplish within a typical primary care office workflow. To adhere to evidence-based guidelines for managing patients with NMCP[6–10], we developed a systematic approach within our rural practice that adhered to best-practice guidelines. This was accomplished by compartmentalizing a day of managing chronic pain into the schedule once each month. We retrospectively studied the impact of this change in approach to the management of NMCP patients in the rural primary care practice over 18 months.

Methods

In starting this structured monitoring plan, a list of patients with NMCP on opioid medications was generated from a targeted search of the electronic health record of a single rural practitioner's practice to assure that all qualifying patients in this group were notified of the specifics 3 months before the change in practice. The notification letter explained that this change was to improve care and to become compliant with both legal and professional obligations. Protocol options for the patients were to continue opioid medication management of their chronic pain, manage their pain without opioids, or be referred to another provider for pain management. One day each month was dedicated solely to the management of chronic pain patients on opioid medication in 1-hour blocks.

Before each visit, the patients completed a packet of information pertinent to chronic pain including a review of systems checklist, family history checklist, social history pertinent to chronic pain, Brief Pain Inventory Short Form (a standardized, patient-scored tool evaluating pain's intensity and effect on quality of life)[11], Zung Depression scale (a standardized, patient-scored depression scale)[12], SOAPP-R diversion risk assessment tool (a standardized diversion risk score)[13], and a Roland disability rating scale for low back pain (a standardized back pain scale).[14] The data for the above history and tools were completed by the patient and available to the clinician before the visit. The physician aided in the completion of the forms, if incomplete, in the context of the visit. In addition to the data gathering tools, the packet also included information regarding the safe disposal of medication, chronic pain and the different options for treatment, opioid medication side effects, and abuse/dependency (all written at less than an average ninth grade reading level as scored by the Flesch-Kincaid[15] system). A structured clinical note was created detailing the dates of last drug screen, the date of signing of chronic pain agreement, the date of the last review of the controlled substance database, the data from the patient completed packet noted above as well as structured history, examination, assessment, and plan (Appendix).

After an 18-month period, a retrospective chart review of the electronic health record was con-

Table 1. A Comparison of Baseline Characteristics between Those Who Remained on Opioids (A) Versus Those Who Weaned Off (B)

	Overall (N = 29)	Group A (N = 17)	Group B (N = 12)	*P* Value	95% CI
Total patients	29	17 (59%)	12 (41%)		
Mean age (years)*	66.86	65.88	68.25	.485	−9.23 to 4.50
Age range (years)	48 to 81	48 to 81	55 to 80		
Male†	20 (69%)	12 (71%)	8 (67%)		
Female†	9 (31%)	5 (29%)	4 (33%)		
Mean of total number of medications*	11.24	11.65	10.66	.614	−2.97 to 4.93
Range of total number of medications	2 to 21	2 to 21	3 to 19		
Mean morphine equivalents mg/day*	24.98	30.61	17.01	.040	0.68 to 26.51
Standard deviation of morphine equivalents		19.03	12.52		
Neck	4 (14%)	2 (12%)	2 (17%)		
Upper back	2 (7%)	2 (12%)	0		
Lower back	17 (59%)	12 (71%)	5 (42%)		
Shoulder	1 (3%)	1 (6%)	0		
Knee	1 (3%)	0	1 (8%)		
Polyarthralgia	3 (10%)	0	3 (25%)		
Peripheral neuropathy	1 (3%)	0	1 (8%)		
Comorbid conditions					
Psychiatric diagnosis† present	16 (55%)	10 (59%)	6 (50%)	.221	
Current smoker†	5 (17%)	2 (12%)	3 (25%)	.864	

Group A are those who remained on opioid medication. Group B are those who weaned off opioid medication.
*Analysis with independent T-Table test.
†Analysis with Chi Square Test.
CI, confidential interval.

ducted by the primary care physician of the 32 patients within the program. The primary goal was to determine whether the program affected the number of NMCP patients who continued to use opioid medications. The secondary goal was to compare those who continued opioid medications to those who chose to wean off them. Inclusion criteria included being seen by the provider during the study period between March 2014 and September 2015, treatment for NMCP with opioid medication and the capacity to make medical decisions. Exclusion Criteria were less than 18 years old, pregnancy, and lacking capacity to give consent. The data collected by the primary care physician from each visit was deidentified by assigning each patient a randomized number designation and stored on a password-secured computer. The independent samples *t*-test and the χ^2 test were applied to compare the opioid medication users with those who chose to discontinue (weaned group) at the beginning of the study (Table 1). In addition, we compared several measures for the chronic opioid medication users at the start and end of the study period using the paired samples *t*-test for continuous variables (Table 2). All analyses were performed using IBM SPSS Statistics 22. The project was approved by the Internal Review Board of Marshall University (No. 720850-2).

Results

Of the 32 NMCP patients on opioid medication, 3 were referred to other providers, leaving 29 subjects for our study analysis. Table 1 provides a comparison of the 17 NMCP patients who continued on opioid medication (Group A) with the 12 patients who discontinued opioid medication (Group B). The 2 groups were similar on all measurements except for the morphine-equivalent daily dose (MEDD), with patients electing to wean off of opioid medication having a statistically lower initial MEDD.

Table 2 provides a comparison of several measures for the NMCP patients who remained on opioid medication (Group A) within the opioid management program, from initial visit to final visit of the 18-month study period. Depression, pain, and quality-of-life scores demonstrated stability

Table 2. A Comparison of Beginning to End Measures for Those Who Remained on Opioid Medication During the First 18 Months of the Structured Program

Group A	Beginning	End	T	Df	*P* Value	95% CI
MEDD*	30.61	28.84	0.763	16	.457	(−3.14 to 6.67)
MEDD (range)	3.3 to 60	3.3 to 60				
MEDD (SD)	19.03	18.60				
BPI Pain Scale (0 to 10)* (mean)	5.75	6.20	0.95	16	.356	(−1.44 to 0.55)
BPI pain (range)	3 to 8	3.8 to 9.3				
Pain (SD)	1.22	1.77				
BPI Quality of Life Scale (0 to 10)* (mean)	5.84	6.11	0.460	16	.651	(−1.50 to 0.96)
BPI quality of life (range)	1.7 to 9.1	1.7 to 9.7				
BPI quality of life (SD)	2.08	2.21				
Zung Depression Scale (20 to 80)* (mean)	40.35	42.37	0.772	16	.451	(−7.93 to 3.6)
Zung (range)	29 to 57	25 to 53				
Zung (SD)	8.2	7.53				

Group A is those patients who continued opioid use and engaged the program. Morphine equivalents represents the mean MEDD in mg/day. BPI Pain Scale is the mean of pain scores for the BPI with range of 0 (no pain) to 10 (maximal pain). BPI Quality of Life is the mean score for how much pain has interfered with quality of life with range of 0 (no impairment from pain) to 10 (maximal impairment from pain). Zung Depression Scale is in raw score with a range of 20 to 80 possible, with less than 40 considered normal mood and above this with progressively worse mood.
*Analysis is with paired *t*-Table test.
BPI, Brief Pain Inventory Short Form; CI, confidential interval; MEDD, morphine-equivalent daily dose; SD, standard deviation.

through the time studied even if 1 patient, who had an accident at the end of the monitored period, was not factored out as an outlier.

Discussion

This project began with a desire to create a structured approach to manage NMCP by following evidence-based guidelines for best practice with the intent of delivering consistent care quality and mitigating angst related to compliance. This approach required a change in practice to a more intentional process for managing chronic pain. The result of this was that of the original 32 patients, 17 (52%) remained on opioid medications, 12 (38%) stopped opioid medications, and 3 (9%) were transferred or referred to other physicians. This rate of opioid medication discontinuation is much higher than has been reported in previous studies. In Connecticut, a Veterans Administration study that used education and encouragement for primary care physicians to adhere to the Stepped Care Model of Pain Management, failed to demonstrate any change in the percentage of primary care patients receiving opioid medications ($P = .20$) but the percentage receiving greater than 120 MEDD declined by 11%.[16,17] Another studied approach allowed physicians to compare their compliance with their institutions' various opioid medication compliance policies for NMCP treatment against peers through an electronic health record's clinical dashboard. It found only a small reduction in patients receiving opioids from 3.4% to 3.1% (9% relative change, $P = .057$).[18] Both studies looked at ways to motivate providers to comply with best-practice guidelines, one used an organizational intervention and the other depended on peer comparison. However, both differed from our approach in 2 ways. They did not require compliance and they did not designate a specific time for providers to address only NMCP. It is reasonable to conclude that these 2 factors may have contributed to the higher rate of opioid medication discontinuation observed in our study.

The most striking finding was that the patient population that stopped opioid medications were on a significantly lower MEDD. Intuitively, this makes sense in that patients who require less opioid medication might be more likely to forego that analgesic instead of complying with the extra protocol. This would allow more focused targeting of those on lower dosage opioid medications, who may be more capable of discontinuation with a structured intervention. Opioid medication discontinuation has been previously shown to positively correlate with lower MEDD although not with a specific intervention.[19]

To ensure that the protocol was not creating unintended harm to the group that chose to maintain opioid medication treatment for their NMCP (Group A), scores for pain (as measured by the Brief Pain Inventory Short Form [BPI]Pain scale), quality of life (as measured by the BPI pain interference scores) and depression (as measured by the Zung depression scale) were monitored throughout the 18-month period. No statistically significant change was noted in any of these 3 categories, despite having 1 participant who had an accident with onset of severe musculoskeletal pain near the end of the study period. Furthermore, MEDD did not significantly change during the study period, although a downward trend was noted. Clearly, the protocol was not associated with a significant reduction in pain control or functionality.

Study Limitations

Primarily, the small size, single geographic region, and solo rural practice do not demonstrate applicability to other practice scenarios. In addition, the financial impact on our practice of isolating visits for the treatment of NMCP patients with opioid medication was not determined. Furthermore, our retrospective study does not provide the reliability of a prospective trial. Future research should focus on determining the application of this model to other practice types and populations to determine feasibility, clinical outcomes, and financial impact. In addition, longitudinal monitoring of the weaned patients (Group B) would give insight into the effect of alternative management methods on chronic pain symptoms, quality of life, and depression, while observing for any tendency to relapse back to opioid medication over time.

The misuse of opioids in America has become widespread with devastating medical and social consequences. The efficient and judicious structured management of patients with NMCP is an important element of defense against this growing problem. This practice model demonstrated that a single rural primary care practice can feasibly implement a structured approach to opioid medication management in NMCP and that such an approach may elicit a prominent decrease in usage. The knowledge that a lower opioid medication dosage is associated with a higher discontinuation rate could help providers concentrate efforts to wean opioid medication on those who are most likely to respond.

Conclusion

This study describes the process of a change in a single rural primary care practice to strict adherence of nationally determined standards for the management of opioid medications for NMCP through a once-monthly focused day of evaluation of such patients. The model was associated with a reduction in patients continuing opioid medications, and indicated an initially lower opioid medication burden increased the likelihood of successful opioid medication weaning.

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To see this article online, please go to: http://jabfm.org/content/31/1/57.full.

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Appendix. Template for Chronic Pain Management Structured Subjective Objective Assessment Plan (SOAP) Note

Chief complaint: chronic pain management visit	
Controlled substance database last reviewed	
Urine drug screen last obtained	
Pain contract signed	
History of present illness (one or more chronic pain disorders)	
Location	
Intensity	
Quality	
Duration	
Frequency	
Associated symptoms	
Modifying factors	
Previous treatments that helped	
Previous treatments that did not help	
Review of systems	
Mental health problems	YES/NO
Recent thoughts of suicide	YES/NO
Adequate sleep	YES/NO
Paralysis or loss of function	YES/NO
Incontinence	YES/NO
Fever	YES/NO
Change in weight	YES/NO
Previous history of cancer	YES/NO
Impairment to vision	YES/NO
Dry mouth	YES/NO
Syncope	YES/NO
Witnessed apnea	YES/NO
Constipation	YES/NO
Itching	YES/NO
Changes in sexual function	YES/NO
Past medical history: see below	
Past surgical history: see below	
Family history	
Suicide	YES/NO
Alcohol or drug abuse	YES/NO
Social history	
Smoking currently	YES/NO
Alcohol use ever	YES/NO
Illegal drug use	YES/NO
Marijuana use	YES/NO
Currently abused	YES/NO
Currently working	YES/NO
Living situation changes	YES/NO
Brief Pain Inventory Short Form scores	
Roland Disability score	
SOAPP-R score	
Zung Depression raw score	
Physical examination	
Patient is alert and in no apparent distress	
Gait is	
Strength is /5 with flexion and extension at	
Deformity not present	
Assessment	
Is patient meeting previous goal markers for pain control?	
What are patient's new goals markers for pain control?	
Is there evidence for improvement in function?	
What will be planned goal for improvement in function next visit?	
Are there signs of diversion?	
Are there adverse effects of medication?	
Does the risk versus benefit ratio favor continuing narcotic pain medication?	
Has patient tried safer options for pain control (NSAID, ACET, Tramadol, Lidocaine, topical NSAID, or PT)?	
Plan	
Patient given handout on prescription drug abuse	
Patient given handout on safe medication disposal	
Does patient require more extensive monitoring? Pill counts, urine drug screens.	

NSAID, Nonsteroidal Anti-Inflammatory Drugs; ACET, Acetaminophen; PT, Physical Therapy.