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Geographic Variation of Chronic Opioid Use in Fibromyalgia

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Abstract

Background—Opioid use for the treatment of chronic nonmalignant pain has increased drastically over the past decade. Although no evidence of efficacy exists supporting the treatment of fibromyalgia (FM) with chronic opioid therapy, a large number of patients are receiving this therapy. Geographic variation in the use of opioids has been demonstrated in the past, but there are no studies examining variation of chronic opioid use.

Objective—This study examines both the extent of geographic variation and the factors associated with variation across states of chronic opioid use among patients with FM.

Methods—Using a large, nationally representative dataset of commercially insured individuals, the following characteristics were examined: sex, disease prevalence, physician prevalence, illicit drug use, and the prescence of a prescription monitoring program. Other contextual and structural characteristics were also assessed.

Results—The analysis included 245,758 patients with FM; 11.3% received chronic opioid therapy during the study period. There was a 5-fold difference between the states with the lowest rate of use (∼4%) and those with the highest (∼20%). The weighted %CV was 36.2%. Percent female and previous illicit opioid use rates were associated with higher rates of chronic opioid use, and FM prevalence and physician prevalence were associated with lower rates. The presence of a prescription monitoring program was not significantly correlated.

Conclusions—Geographic variation in chronic opioid use among patients with FM exists at rates similar to those seen in other studies examining opioid use. This large level of geographic variation suggests that the prescribing decision is not based solely on physician-patient interaction but also on contextual and structural factors at the state level. The level of physician and condition

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prevalence suggest that information dissemination and peer-to-peer interaction may play a key role in adopting evidence-based medicine for the treatment of patients suffering from FM and related conditions. Level of diagnosis prevalence as a predictor of evidence-based practice has not been reported in the literature and is an important contribution to research on geographic variation.

Keywords

chronic nonmalignant pain; fibromyalgia; FM; geographic variation; opioid

Introduction

Fibromyalgia (FM) is an idiopathic, functional disorder characterized by chronic widespread myalgias and diffuse tenderness.[1] Although the etiology of FM remains unclear, it is increasingly evident that disordered central pain processing is the primary source of the syndrome. FM is diagnosed in ∼5% of women[2] and 1.6% of men[3] (∼6 million patients) in the United States. Patients suffering from FM experience significantly increased health care utilization and costs compared with the general population.[4,5]

Treatment of FM typically focuses on management of pain and lack of restorative sleep. Treatment is generally multimodal, consisting of pharmacologic agents, 3 of which are approved by the US Food and Drug Administration specifically for FM, and nonpharmacologic therapies found to be effective in randomized controlled trials such as aerobic exercise, tai chi, and yoga. One of the increasingly common therapy choices for FM pain is opioid analgesics, despite there being little evidence of efficacy supporting their use in FM patients and despite guidelines from professional societies specifically discouraging the use of these agents.[6] Chronic opioid therapy for the control of chronic non-malignant pain of many types has increased tremendously over the past decade.[7] Even with the lack of evidence regarding efficacy and the unique pathophysiology of FM patients that make chronic opioid therapy especially troubling,[8] the pattern of use in FM has mirrored that of use in other chronic nonmalignant pain conditions.[9]

The elevated rate of opioid use in FM is troublesome due to the lack of efficacy of these agents and to the myriad societal and individual adverse effects associated with their use.[10] These effects include those commonly seen with acute use (constipation, pruritus, respiratory depression, nausea, vomiting, delayed gastric emptying, sexual dysfunction, muscle rigidity and myoclonus, sleep disturbance, pyrexia, diminished psychomotor performance, cognitive impairment, dizziness, and sedation) as well as chronic use (hormonal and immune effects, abuse and addiction, tolerance, and hyperalgesia) of this class of drugs. Opioid-induced hyperalgesia is of particular concern in FM patients because treatment with these medications may not only be inefficacious but also may result in the manifestation of a separate pain condition. Although opioid-induced hyperalgesia can occur in any patient treated with opioids, the dysregulated opioidergic pathways seen in FM patients is cause for increased concern.[7]

Geographic variation in care patterns is well documented for some disease states and medication classes. Significant differences in utilization rates between geographic regions has been shown in colorectal cancer,[11] cardiac care procedures,[12] antihypertensive

medications,[13] and stimulant agents.[14] Review of the geographic literature regarding general opioid use finds considerable variation, with state-level factors explaining the majority of the different patterns.[15–19]

To the best of our knowledge, no studies have been published to date examining geographic variation in chronic opioid prescribing for patients with FM. The overall goal of the current study was to understand prescribing patterns that may explain the widespread utilization of a treatment choice that is not based on evidence of efficacy and that has the potential for significant harms. This study sought to answer 2 research questions. First, to what extent does geographic variation exist between states for chronic opioid utilization in patients with FM? Based on the literature examining acute opioid use, we expected that geographic variation would exist across states for chronic opioid prescribing for FM patients.[15,16,20,21] Second, what association is seen between contextual and structural factors and the rate of chronic opioid use at the state level? We predicted the current study results would generally mirror those of previous work in this area,[15,16,20,21] with the proportion of female patients and rate of previous illicit opioid use within a state being positively associated with chronic opioid use, and the presence of a state-level prescription monitoring program (PMP) and the prevalence rate of physicians in a state being negatively associated. In addition, we examined a new factor not previously studied in this literature: the prevalence of FM diagnosis within states.

Materials and Methods

Study Cohort Definitions

Our research team licensed deidentified patient health claims information for a large commercially insured population for the period January 1, 2007, to December 31, 2009. The dataset is a nationally representative sample of commercially insured patients across the United States and includes 15 million covered individuals. Data are collected at the patient level and linked across administrative and health data, including: administrative data (plan type, sex, age, and eligibility date spans), pharmacy claims (national drug code, strength, quantity and date dispensed, days' supplied, and pricing) physician and facility claims (physician or facility code, procedure codes, diagnosis codes, revenue codes, diagnosis-related group, service dates, and pricing) and laboratory test results (laboratory test name and result). The dataset was searched for patients with FM as identified by using *International Classification of Disease, Ninth Revision, Clinical Modification* (ICD-9-CM) code 729.1 (myalgia and myositis, unspecified). Patients aged 18 to 64 years with at least 1 FM claim between January 1, 2007, and December 31, 2009, were included in the sample. Patients with malignancies were excluded from analysis. Using this method, we identified 245,758 individuals from the 48 contiguous states and Washington, DC; Alaska and Hawaii were excluded due to small sample sizes in those states. The University of Kentucky institutional review board provided approval for this study.

Outcome Variables

Chronic opioid therapy, defined as receiving a day supply in excess of one-half the total eligibility span (months the patient was consecutively enrolled in a plan included in the

dataset) for an individual patient, was the outcome of interest. Similar outcome measures have been used previously to describe chronic opioid use.[22] This individual-level outcome was aggregated to the state level to provide the prevalence of chronic opioid use over the 3-year cross-section for each state. Receipt of opioids was based on paid prescription claims for opioid medications. Each claim was associated with a day supply calculated at the pharmacy based on directions for use from the prescriber. Using American Hospital Formulary Service codes[23] and verifying with Pharmaprojects Therapeutics Class Codes,[24] drugs were divided into 2 classes: opioids and nonopioids. Tramadol was classified as nonopioid despite its activity as a ligand of μ-opioid receptors because this agent has been studied in patients with FM and found to be efficacious.[25] It should be noted, however, that this drug is not approved by the US Food and Drug Administration for FM.

Covariates

Sample characteristics collected at the individual level included age, sex, and eligibility span. Means of individual-level variables were calculated for each state for the entire study period and used as state-level characteristics. The level of FM prevalence in a state was calculated by dividing the number of patients with an FM diagnosis in the dataset for a given state by the total state sample in the health claims database. State-level variables were adapted from 2 previous studies measuring geographic variation in opioid use. Curtis et al[15] included proportion of female subjects, rate of illicit drug use, state prevalence of surgeons, presence of a statewide PMP, and age. We adapted these variables for our data and outcomes, resulting in the following variables: proportion of females within our patient sample, rate of previous illicit drug use and rate of previous illicit opioid use taken from the 2008 Substance Abuse and Mental Health Services Administration National Survey on Drug Use and Health,[26] state prevalence of physicians and surgeons (defined as number of physicians of any kind or of surgeons per 100,000 persons in a state from the Kaiser Permanente Family Foundation),[27] and the presence of a statewide PMP at the beginning of the study period.

Beyond these variables, economic and health care quality variables were added based on the work of Webster et al.[16] State unemployment rate and median income were included from the US Department of Labor for July 2008, the midpoint of the study period. Physician discipline sanction rates were taken from Public Citizen.[28] Health care quality state rankings were taken from The Commonwealth Fund as an average of the 2007 and 2009 biannual rankings.[29] Level of evidence-based medicine was calculated based on The Dartmouth Atlas report for quality care.[30]

Data Analysis

Individual-level factors were aggregated and descriptive analysis was performed. Geographic variation between states was measured by using the weighted %CV, the ratio of the SD of the prevalence rates to the mean rate among states, weighted according to the study population in each state, as the precision of the states with larger sample sizes should be greater. The weighted %CV is commonly used to measure variation across disparate studies and has been the primary measure used in gauging geographic variation of opioid use. To analyze potential contributing factors to chronic opioid use among FM patients, we

performed a robust multivariate linear regression by using 2 models. The first model used only variables predicted to have an effect on chronic opioid use rates (sex, previous illicit opioid use, physician prevalence, FM prevalence, and presence of a PMP); this limited model mitigated the concern regarding the number of degrees of freedom in the regression. The second model included all covariates from the limited model as well as several contextual and structural characteristics identified in Curtis et al[15] and Webster et al.[16] These covariates were described earlier, and the full list can be found in Table I. All calculations and analyses, including geographic variation analysis, were performed by using Stata version 11.2 (Stata Corp, College Station, Texas). Map generation was performed by using spmap and uscoord within Stata. For all analyses, the entire 3-year period was treated as a single cross-section.

Results

The analysis included 245,758 patients with a diagnosis of FM from the 48 contiguous states and Washington, DC. Of these patients, 11.3% received chronic opioid therapy during the study period (Table II). Most patients were female (70%), and the mean age was 44.7 years. Overall, patients received nearly 70 prescriptions per year, and ∼10% of these were for opioid medications. The average eligibility span for patients in the sample was ∼2 of the total 3-year study period. The national prevalence of FM for this sample was 1.56%. For individual states, the minimum was 0.72% (Vermont) and the maximum was 2.98% (North Dakota). Geographic variation in the prevalence of FM can be seen in Table I and Figure A. Figure B shows the geographic variation in the primary outcome of interest (ie, patients receiving chronic opioid therapy). The weighted %CV for chronic opioid therapy in this population of patients was 36.2%, a level similar to that seen in previous opioid studies using this measure.[15,16,20] The states with the lowest proportion of chronic opioid use were South Dakota, North Dakota, and New York, each <5%. The states with the highest proportion of chronic opioid use in FM patients were Utah, Nevada, and West Virginia, each ∼20%.

The results of the limited and extensive multivariate regressions are shown in Table I. The limited model examined factors hypothesized to be associated with chronic opioid use in patients suffering from FM; these factors behaved generally as predicted. Percent female and illicit opioid use each was associated with increased chronic opioid use whereas prevalence of physicians and FM were each negatively associated. However, the prediction that the presence of a statewide PMP would be negatively associated with chronic opioid use in this condition was rejected; this variable was not statistically significant. The extended model largely supports these findings, indicating little sensitivity to the additional covariates. Each of these variables maintains their significance independent of other included factors. The only additional variable with a significant association with chronic opioid use was state population.

Discussion

This study accomplished 2 research objectives. The first was to assess the level of geographic variation of chronic opioid use for patients with FM. We examined data within a

large commercially insured population, extracting a sample with a diagnosis of FM. Using these data, we found that nearly 1 in 8 patients with FM were receiving chronic opioid therapy. This rate is similar to that seen in other studies of FM.[31] Comparisons across states found a 5-fold difference between the most conservative (South Dakota, 3.95%) and liberal (Utah, 20.18%) opioid prescribers. The weighted %CV for chronic opioid therapy in this population was 36.2%.

The rate of geographic variation in the current study is similar to that seen in previous literature examining the variation of opioid use across states. Curtis et al[15] examined use of opioids for any condition across states by using a similar dataset and found a weighted %CV of 45%. Zerzan et al[20] examined opioid prescribing in a Medicaid population and reported a weighted %CV of 50%. Webster et al[16] examined variation in opioid prescribing for acute, work-related low back pain and found a weighted %CV of 53%. Compared with our results, the weighted %CV was slightly higher in each of these studies, which may be a result of the outcome measures used. Each of these studies examined acute use of opioids in addition to chronic use; variation among opioid use in these scenarios intuitively would be greater.

The second aim of the current study was to examine the association of various population and structural variables with chronic opioid use in FM patients. The robust multivariate linear regressions report several factors that were significantly associated with chronic opioid use in this population. These variables, both those aggregated from individuals within the sample and those taken from values for states, explained three-quarters of the variability in the dataset. As seen in Webster et al,[16] much of the between-state variation is explained by state-level factors; this finding stresses the importance of characteristics not associated with an individual patient or provider and highlights those factors outside the physician-patient relationship that can affect the adoption of a certain therapy choice.

As previously reported in the literature,[15,21] the proportion of patients that are female was positively associated with increased rates of chronic opioid use. This correlation was seen in both the limited and the extensive model and is attributed to the greater exposure of female subjects to medications in general and to opioids in particular that has been reported in the literature.[21] The rate of previous illicit opioid use in a state population has been shown to be positively associated with general opioid use[15] and was associated similarly in the current study. An intuitive argument for this finding is that increased illicit use is associated with increased supply, which in turn is associated with increased prescribing. Consistent with the findings of Webster et al,[16] we found that the number of physicians per capita was significantly and negatively associated with use of opioids in patients with FM. This finding could be explained by greater peer-to-peer interaction, resulting in more information diffusion, or by reduced work burden, resulting in better knowledge of or adherence to evidence-based medicine. This finding is discordant with Curtis et al[15] and with a recent study by McDonald et al,[19] likely due to the inclusion of opioids for acute care in their models. Each of these studies focuses on the total amount of opioids prescribed rather than on a repeated treatment choice for an individual such as the use of chronic opioid therapy. It is worth noting that each of these studies also saw a significant association in the prevalence of surgeons with opioid prescribing due to the high level of opioid use for postsurgical care;

neither the current study nor the study by Webster et al reported this association because neither outcome would be sensitive to the prevalence of surgeons.

Furthermore, an unexpected significantly negative associated variable was the prevalence of ICD-9-CM code 729.1 use in a given geographic area. The explanation for this observation remains speculative. Increased physician numbers may be associated with increased opportunity for peer-to-peer interaction and educational opportunities. It could also be that the physicians most likely to use this diagnostic code for patients with chronic musculoskeletal pain may be more likely to accept FM as an entity, and they therefore more closely adhere to evidence-based treatment for the disorder.

The presence of a statewide PMP was not significantly associated with chronic opioid use in patients with FM. This factor was significant in Curtis et al[15] but not in Webster et al[16] or McDonald et al.[19] The article by Curtis et al focuses exclusively on Schedule II controlled medications, which would be more sensitive to the effects of a PMP because every state that employs a PMP controls for Schedule II medications, although not necessarily for other controlled medications. Much variation exists in characteristics of PMPs, which can be proactive or reactive, mandatory or optional, and have varying regulations governing use of program data. In addition, the effectiveness of PMPs across states is currently debated in the literature, with assessments of PMP effectiveness frequently reporting weak or inconclusive results.[32–34]

The only other significantly associated variable was state population. States with large populations were less likely to prescribe opioids chronically for this population of patients. This may be an indicator of the development of the health care system within more populous states; for instance, increased penetration of health maintenance organizations, which is associated with state population, leads to decreased use of opioid medications.[19,35] However, quality variables such as evidence-based medicine use in states and health care quality rankings were not found to be significantly associated with chronic opioid use. In addition, state economic indicators such as median income and unemployment rate were not significantly related to use within FM patients.

The findings of this study confirm and extend those in previous studies looking at geographic variation of opioid use. Westert and Groenewegen[36] reported that social context and structural factors affect prescribing behavior. This study extends that theoretical framework by confirming a relationship with factors such as physician prevalence, disease prevalence, and state population.

There are limitations to this study. The diagnosis code used to identify patients with FM is not specific to this condition. However, we would argue that no condition identified by using this ICD-9-CM code should be treated with chronic opioids according to current guidelines.[7] It should be noted that there is no specific ICD-9-CM code for FM. ICD-9-CM code 729.1 is widely used as a surrogate for this diagnosis in the FM literature, although the authors recognize that other conditions characterized by nonspecific myalgias will be included in the dataset. It is assumed that the vast majority of the patients will have FM or a related nonspecific cause of muscle pain. Although some data were aggregated from

individual patient-level data, the analysis was conducted according to state. Levels of comorbid conditions were not considered as a confounding variable. The calculation of the chronic opioid use variable may also be a concern; because it only considers day supply and span of eligibility, there is a possibility that patients received several opioid medications, thus concurrently bolstering their observed day supply. However, for the majority of patients, this calculation still results in having a day supply of > 183 days during a single year or 537 days over the entire period. This measure has been previously used in similar research,[20] and its clinical significance seems evident.

Conclusions

Chronic opioid therapy for the treatment of FM and other types of chronic nonmalignant musculoskeletal pain is a practice based not on evidence but on other factors that have been heretofore unreported in the literature. The current study reports 1 set of characteristics that results in wide geographic variation in opioid use similar to that previously reported in other pain conditions. This large level of geographic variation suggests that the prescribing decision is based not solely on physician-patient interaction but also on contextual and structural factors. The association of the level of physician and condition prevalence suggests that information dissemination and peer-to-peer interaction may play a key role in adopting evidence-based medicine for the treatment of patients suffering from FM and related conditions. Level of diagnosis prevalence as a predictor of evidence-based practice has not been reported in the literature and is an important contribution to research on geographic variation.

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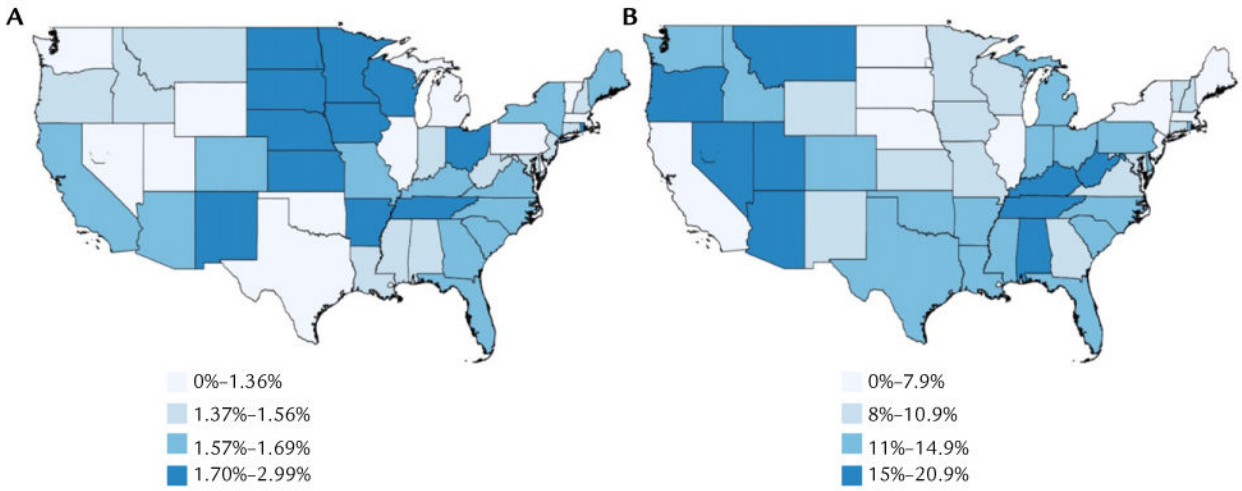

Figure.

(A) Prevalence of fibromyalgia. (B) Patients with fibromyalgia receiving chronic opioid therapy. Patients were classified by using International Classification of Diseases, Ninth Revision, Clinical Modification code 729.1.

Table I

Multivariate linear regression: chronic opioid analgesic use among patients with fibromyalgia (FM).

	Coefficient (SE)	
Variable	**Limited**	**Extensive**
Sample female (%)	0.429 (0.111)*	0.349 (0.151)†
Previous illicit opioid use (%)	0.015 (0.040)*	0.012 (0.004)*
Physician prevalence (per 100,000)	−0.133 (0.027)*	−0.170 (0.040)*
Sample FM prevalence (%)	−4.257 (1.053)*	−5.269 (1.026)*
Prescription monitoring program	0.0145 (0.007)	0.009 (0.011)
Sample age (y)	–	−0.652 (0.431)
State population (1,000,000)	–	−0.194 (0.056)*
Evidence-based medicine (%)	–	0.123 (0.118)
Illicit drug use (%)	–	−0.003 (0.004)
Surgeon prevalence (per 100,000)	–	0.406 (0.320)
Health care quality rank	–	0.005 (0.003)
Unemployment rate (%)	–	0.008 (0.005)
Median income ($1000)	–	−0.029 (0.090)
Physician sanctions (per 100,000)	–	0.001 (0.029)
Constant	−0.163 (0.072)†	0.120 (0.206)
R^2	0.624	0.731

*$P < 0.01$.

†$P < 0.05$.

Table II

Sample characteristics for patients with fibromyalgia according to state.

State	No. of Patients	Female (%)	Age (y)	FMS Prevalence (%)	Chronic Opioid Therapy (%)
National	245,758	69.9	44.7	1.56	11.65
Alabama	1759	72.1	44.7	1.48	16.71
Arkansas	2565	74.7	45.2	1.81	13.06
Arizona	8376	73.1	45.4	1.62	16.95
California	12,053	64.9	43.7	1.58	7.35
Colorado	7478	68.7	44.6	1.62	12.58
Connecticut	1667	69.2	44.4	1.57	8.76
Washington, DC	269	70.6	42.5	0.76	5.58
Delaware	175	66.3	45.5	0.90	14.86
Florida	27,658	70.3	45.7	1.57	14.88
Georgia	16,962	72.8	46.4	1.70	9.81
Iowa	2048	69.9	46.9	1.82	8.74
Idaho	575	73.4	43.9	1.42	14.26
Illinois	6480	67.6	44.3	1.25	7.81
Indiana	4057	71.7	45.5	1.53	14.52
Kansas	2443	68.0	44.3	1.84	9.01
Kentucky	2242	71.5	44.1	1.66	17.08
Louisiana	4099	69.0	44.7	1.52	11.34
Massachusetts	2377	67.3	45.2	1.36	7.07
Maryland	4971	68.4	44.1	1.47	10.28
Maine	238	73.1	46.3	1.62	7.56
Michigan	1770	67.7	43.3	1.21	11.69
Minnesota	18,219	72.7	43.6	2.29	9.49
Missouri	8469	71.6	45.1	1.65	8.93
Mississippi	1969	71.6	44.8	1.57	14.07
Montana	165	78.2	46.8	1.38	15.76
North Carolina	8857	70.3	45.6	1.61	14.11
North Dakota	607	62.8	42.3	2.98	4.94

State	No. of Patients	Female (%)	Age (y)	FMS Prevalence (%)	Chronic Opioid Therapy (%)
Nebraska	2325	69.8	45.0	1.92	7.35
New Hampshire	411	74.9	46.2	1.38	8.03
New jersey	4287	63.2	42.9	1.40	6.04
New Mexico	2257	73.6	46.4	2.03	9.26
Nevada	1152	67.1	43.5	1.18	19.79
New York	8154	62.8	42.0	1.69	4.99
Ohio	15,101	72.8	45.5	1.75	12.85
Oklahoma	1975	68.7	43.4	1.34	13.82
Oregon	1553	72.9	45.5	1.51	17.84
Pennsylvania	3355	69.8	44.2	1.23	11.60
Rhode Island	3911	71.9	45.8	2.18	13.63
South Carolina	2716	70.8	45.2	1.60	13.66
South Dakota	506	68.6	45.2	2.29	3.95
Tennessee	5021	70.9	44.3	1.71	7.31
Texas	24,775	70.2	44.3	1.28	11.60
Utah	1670	71.2	41.9	1.17	20.18
Virginia	5836	67.4	43.6	1.69	8.69
Vermont	32	59.4	47.5	0.72	9.38
Washington	2262	71.0	45.4	1.20	13.84
Wisconsin	9215	68.8	45.6	1.79	9.38
West Virginia	545	73.6	45.5	1.38	19.63
Wyoming	151	68.2	43.8	1.01	10.60