Effects of Opioids on Clinical Outcomes

M. Gostine [1], F. Davis[2], R. Risko[2], J. Peterson[3]

[1]Michigan Pain Consultants, PC, [2]ProCare Pain Solutions; [3]Grand Valley State University

Background and Objective

The Centers for Disease Control has declared an epidemic of prescription drug overdoses[1]. The Institute of Medicine issued a blueprint for transforming pain care in the United States[2]. To address these mandates we examined our practice outcomes to determine the impact opioids have on chronic pain relief.

Study Methods

Clinical Setting

The study was conducted at MPC, an interdisciplinary community-based pain medicine practice, based in Grand Rapids, MI established in 1984. The practice has 7 clinical locations covering a service area of 6 counties in West Michigan. The data were collected using the Pain Health Assessment (PHA) within the PRISM™ Care Management System. The PRISM™ System provides real-time clinical data to analyze and inform patient care, estimate narcotic risk, and track outcomes. This is an integral component of current healthcare movements toward patient centeredness, quality management and best practice in pain medicine as recommended by the Institute of Medicine[1].

The PHA data is routinely gathered from chronic pain patients in the practice using IRB approved language in the consent forms.

Pain Health Assessment

The Pain Health Assessment (PHA) is a patient self-assessment instrument that provides demographic, medical and social history. It was inspired by the SF-36 and contains core outcomes domains that evaluate the efficacy and effectiveness of treatments, consistent with the recommendations of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT). Responses were coded on an 11 point numeric and descriptive pain intensity scale with 0 “most positive” and 10 “most negative”.

PAM Advisor

The PAM Advisor is part of the PRISM ™ Care Management System. It advises a patient risk score based on psychosocial impairment gathered from the PHA (Figure 1). The PAM Advisor is necessary for establishing comparison groups for research and population analyses purposes.

Figure 1: shows PAM descriptions and the population distribution.

PAM	Description	% of Population
1	Low anatomical pathology, Good psychosocial health	9.0%
2	High anatomical pathology, Good psychosocial health	31.7%
3	Low anatomical pathology, Poor psychosocial health	5.2%
4	High anatomical pathology, Poor psychosocial health	54.1%

Population Selection

Patients were selected based on having had an initial PHA taken between August 1, 2010 and March 31, 2013. In addition, patients who also had a cumulative PHA taken between June 1, 2013 and July 15, 2013 were identified. There were a total of 1,032 patients who met criteria (Figure 2); 61.4% were female, 38.6% male. The 532 opioid users were placed into dosage groups (Low, Moderate, High, Very High) (Figure 3). This sample is representative of the practice as a whole.

Study Methods *(Continued)*

Figure 2 shows descriptive statistics between the three patient groups.

Variable	Mean	SD	Mean	SD	Mean	SD
Age	56.3	15.8	53.0	13.4	52.6	13.7
Initial Avg. Pain	5.9	1.8	6.4	1.7	6.2	1.6
Follow-up Avg. Pain	4.9	2.1	5.7	1.7	5.6	1.7
Percent Relief	63.2	24.5	56.7	19.8	58.3	22.9
Treatment Months	14.0	9.6	13.9	9.7	14.7	9.9

Figure 3 shows how the dosage groups were defined and the percent of opioid users within each dosage group.

Opioid Users within each Dosage Group

Low dose:	*1 – 20 meq*	*30% of patients*
Moderate dose:	*21 – 49 meq*	*39% of patients*
High dose:	*50 – 100 meq*	*18% of patients*
Very High dose:	*≥101 meq*	*13% of patients*

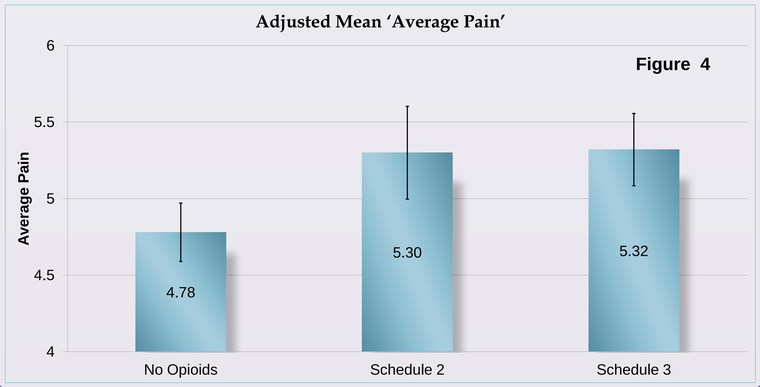
Statistical Analyses

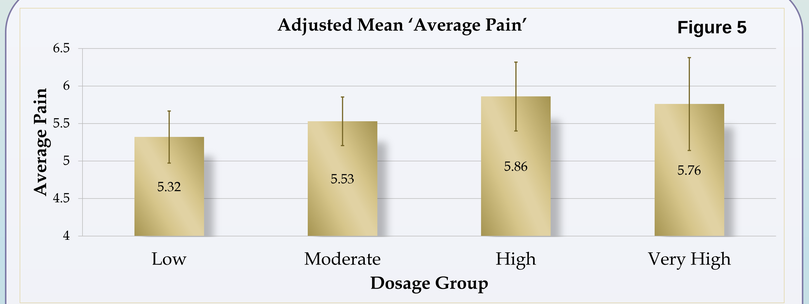
Dependent variables included: Self-report average pain level and percent pain relief due to treatment received. Comparisons were made between three patient groups: schedule 3 opioid users, schedule 2 opioid users and non-opioid users. An analysis of covariance with a Tukey HSD adjustment was conducted to compare across groups while controlling for: age, gender, PAM advisor, length of treatment, and average pain at intake.

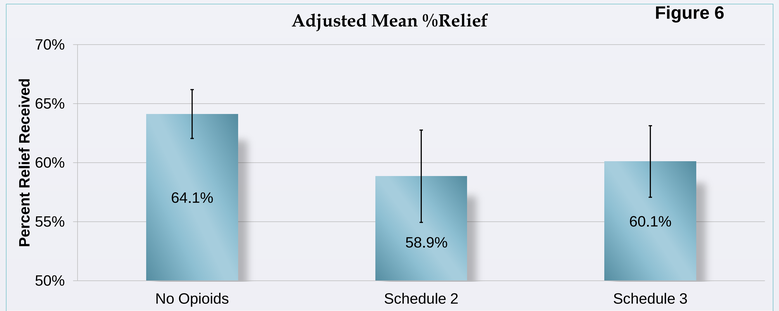
Results

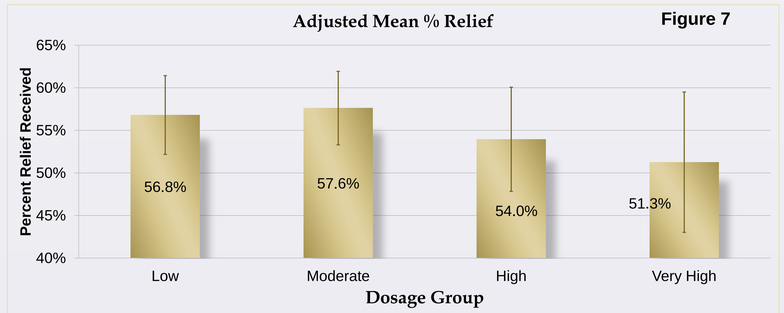
- Patients not prescribed opioids had significantly lower average pain than those taking schedule 2 opioids (p-value = .0038) and schedule 3 opioids (p-value <.0001) (Figure 4).
- Patients not prescribed opioids had significantly higher percent relief than those taking schedule 2 opioids (p-value = .029) and schedule 3 opioids (p-value = .039), on average (Figure 6).
- There was no statistical evidence that suggested a difference in the mean outcomes between dosage groups, for both average pain and percent relief (Figures 5 & 7).

❖ *Note: Error bars in the graphs indicate 95% confidence intervals.*









Conclusions & Recommendations

Opioid use did not contribute to patient outcomes as much as we anticipated. We did not see a dose response curve in any outcome measure. Dose response curves, whereby increasing dose results in improved therapeutic response, are typically interpreted as a hallmark of drug efficacy. Our findings suggest that opioids may not be efficacious for all patients in the population studied for improving outcomes. Additional studies are needed to determine the effects of opiate use in the context of multimodal treatments. Further research is also needed to better understand individual responses and to identify which patients are feasible for opiate therapy.

References

1) Policy Impact: Prescription Painkiller Overdoses. Centers for Disease Control and Prevention. 2013. Retrieved from http://www.cdc.gov/homeandrecreationalsafety/rxbrief/ CDC .

2) Relieving Pain in America: A Blue Print for Transforming Prevention, Care, Education, and Research. *Institute of Medicine of the National Academies*. 2011 June