Prospective Study

An Observational Study on the Use of a Patient Navigator to Help Improve Outcomes in Patients on Chronic Opioids

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Background: In the United States, the prevalence of opioid use disorders has increased in recent years along with an attendant rise in the incidence of chronic pain disorders and prescription opioid use. Patient navigation services have been used to improve health outcomes in cancer and other chronic disease states, but it is unclear whether the implementation of patient navigation services can facilitate improved outcomes among patients receiving chronic opioid therapy.

Objectives: The objective of this study was to compare the outcomes of patients receiving chronic opioid therapy plus patient navigation services and those receiving chronic opioid therapy as a part of usual care.

Study Design: This was a prospective, observational study. Consecutive patients receiving chronic opioid therapy were enrolled, with alternating assignments to patient navigation (n = 30) or usual care (n = 30). Participants in the patient navigation group received support from a non-physician, non-advanced practice provider staff member who initiated frequent contact via telephone, telemedicine, or in-clinic visits to discuss the patient's health goals. The minimum follow-up period was 90 days. Outcomes qualitatively compared across groups included final pain score, final morphine milligram equivalent (MME) per day, and discharge rates. Risk factors for discharge within the navigation group were assessed. Patient feedback was also solicited.

Setting: This study was conducted at a single independent pain clinic in the United States.

Results: Demographic features were similar between the navigator group and the control group. The control group had a higher average initial pain score (7.0/10) than the intervention group (5.9/10) and were receiving a higher initial dose of opioids (23.1 vs 19.0 MME/d). After an average follow-up of 108.7 days, patients in the navigator group had a 16% decrease in final opioid dose compared with a 23% increase in the control group. Furthermore, patients in the control group were discharged from the practice at a higher rate (23.3% vs 6.6%), suggesting increased opioid misuse in the control group compared with the navigator group. In the navigator group, higher levels of anxiety and depression were the primary predictors of discharge.

Limitations: This was a single-center study with a small sample size. The generalizability of these results to other clinic settings is unknown.

Conclusions: Patient navigation decreased opioid use and practice discharge compared with usual care in an independent pain clinic, suggesting a role for patient navigation in reducing opioid misuse and potentially reducing adverse events.

Key words: Opioid prescribing, patient navigation, Opioid Risk Tool, opioid nonadherence, anxiety, depression

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The US is in the midst of an opioid crisis that has resulted in about 19,000 opioid-related deaths per year, culminating in more than 450,000 deaths involving opioids between 1999 and 2018 (1,2). COVID-19 has accelerated this crisis, with over 81,000 drug overdose deaths reported between May 2019 and May 2020—the highest number of overdose deaths ever reported in a 1-year period. The use of synthetic opioids (primarily illicit fentanyl) was the main driver of the increase in overdose deaths, rising by 38.4% during this 12-month period (3).

Since 1990, the number of opioid prescriptions in the United States (US) has quadrupled, suggesting a correlation between clinician opioid prescribing patterns and the rising rate of opioid misuse and subsequent opioid use disorder (3,4). In the National Survey on Drug Use and Health, the incidence of heroin use was 19-fold higher among those who had previously used prescription opioid analgesics in the last year (6). Furthermore, a majority of people who used opioids for nonmedical purposes obtained them from friends or relatives, indicating that opioid overprescribing and patient nonadherence to proper disposal of unused medications may contribute to the high rate of opioid misuse in the US (7).

The increasing prevalence of chronic opioid therapy in the US has been linked with the rising incidence and recognition of chronic pain in the population along with clinicians' desire to reduce suffering (8). As such, pain medicine specialists play a vital role in the safe use of opioids as well as the prevention and recognition of opioid misuse (8). Strategies for preventing opioid misuse are multimodal and include comprehensive initial patient assessment, screening for opioid misuse through routine urine drug testing and pill counts, utilization of prescription drug monitoring programs, and evaluation of the effectiveness of opioid analgesia, among others (8). However, earlier studies have failed to identify demographic or physiologic predictors of opioid misuse, and noncompliance with clinic opioid policies remains a common reason for patient discharge from pain management practices (9).

Pain management with chronic opioid therapy may benefit from patient engagement strategies similar to those used in other chronic disease states. One such intervention is the use of patient navigators. Patient navigators are trained, non-physician, and non-advanced practice provider (APP) personnel who can help patients to identify their health goals and overcome barriers to achieving those goals. Patient navigators are often nurses, social workers, or lay staff, including patient peers (13). Although patient navigation services were initially developed to reduce gaps in care among patients with cancer, they are increasingly used with success in other chronic disease states, including diabetes, nicotine addiction, and heart failure (13-15). Patient navigator tasks can be tailored according to the needs of the disease state and may include disease or health system education, health goal setting, identification, and development of strategies to overcome systemic or financial barriers, facilitation of care coordination, referral to community resources, and serving as patient and caregiver support systems (13).

To evaluate whether patient navigation services can improve clinical outcomes in patients with pain receiving chronic opioid therapy, we developed an observational study at an independent pain practice. In this study, we compared the outcomes of patients who received patient navigation services with those of patients who received usual care.

Methods

To assess the differences in outcomes for patients provided with patient navigator services, an observational study was conducted at an independent pain management clinic, Suncoast Pain Management, PA (Mississippi, USA). A total of 60 consecutive patients prescribed chronic opioid therapy were enrolled. Baseline data collected included patient demographics, type of pain, pain score, initial opioid dosing, and scores on standard practice intake questionnaires, including the Opioid Risk Tool for estimation of risk for aberrant opioid-related behaviors, Patient Health Questionnaire [PHQ]-9 for evaluation of major depressive disorder (MDD) symptoms, and Generalized Anxiety Disorder (GAD)-7 for evaluation of anxiety symptoms.

Patients were assigned to either receive patient navigation services (navigator group) or usual care (control group). Patients in the navigator group had access to a non-physician, non-APP staff member who acted as a health coach. The patient navigator initiated frequent contact with patients via phone, telemedicine, or in-clinic visits to discuss the patient's health goals. All patients in the navigator group were contacted at least once per week by their nurse navigator; although, more frequent contact was permitted if the navigator identified additional need. In both groups, patients were scheduled for monthly physician office visits as part of their follow-up.

Patients were followed up for at least 90 days. At

the end of the study period, outcomes were qualitatively compared across groups. Key outcomes included final pain score, final MME per day, and discharge rates. Baseline risk factors for discharge within the navigation group were assessed. Patient feedback was also solicited and used to develop themes related to patient perceptions of the benefits of patient navigation services.

RESULTS

A total of 60 patients were enrolled in this prospective observational study. The groups were similar in terms of average age, gender distribution, proportion with spinal pain, and average Opioid Risk Tool score (Table 1). Compared with the control group, the navigator group had a lower average initial pain score (5.9 vs 7.0 out of 10) and were prescribed lower initial morphine milligram equivalents (MMEs) per day (19.0 vs 23.1).

On average, participants were followed up for 4.0 clinic visits over 108.7 days (mean of 111.5 days in the navigator group and 105.8 days in the control group). At the end of the study period, outcomes were compared across groups (Table 2). Despite the final pain scores remaining similar to baseline in both groups, we noted differences in final mean MME per day. In the navigator group, final mean opioid usage decreased by 16%, from 19.0 MME per day at baseline to 16.0 MME per day at final follow-up. In contrast, final mean opioid usage increased by 23% in the control group, from 23.1 to 28.4 MME per day.

Discharge rates were also lower in the navigator group compared with the control group (6.6% vs 23.3%; Table 2). Although the reasons for discharge were not documented for the purpose of this study, it is clinic policy to discharge patients in cases of opioid nonadherence. The most common reason for nonadherence is a positive urine drug screen, followed by failing a nonscheduled pill count, which are randomly performed approximately every 3 months. Therefore, it can be reasonably assumed that the higher rates of discharge in the control group are indicative of opioid misuse or nonadherence.

Predictors for misuse and discharge in the navigator group were assessed. The factor with the strongest association with patient discharge was a score of 12 or higher on both the PHQ-9 and the GAD-7, indicative of moderate or severe MDD and moderate or severe generalized anxiety disorder. Patients in the navigator group who met these criteria had a 40% chance of noncompliance and subsequent discharge. A score of

12 or higher on the PHQ-9 and the GAD-7 was a stronger risk factor for noncompliance than other validated measures, including the Opioid Risk Tool score.

Patient feedback was used to develop qualitative themes related to the benefits of patient navigation services (Table 3). Participants in the navigator group reported that they felt the patient navigator was able to assist with facilitating prompt medical care, improve communication and promote patient health and comfort, and function as a knowledgeable resource to ensure medication and clinical visit adherence.

Table 1. *Demographics among participants who received patient navigator services and those treated as usual (controls).*

Characteristics	Navigator group (n = 30)	Control group (n = 30)
Age, mean	59.4 years	60.6 years
Gender, female	63%	56%
Spinal pain	93%	87%
Opioid Risk Tool score, mean	0.97	1.08
Initial pain score (out of 10), mean	5.9	7.0
Initial MME, mean	19.0 per day	23.1 per day

MME, morphine milligram equivalent.

Table 2. *Participant outcomes among participants who received patient navigator services and those treated as usual (controls).*

Characteristics	Navigator group (n = 30)	Control group (n = 30)
Follow-up, mean	111.5 days	105.8 days
Number of clinic visits, mean	4.0	4.0
Final pain score (out of 10)	5.9	7.1
Final MME per day, mean	16.0	28.4
Discharge rate	6.6%	23.3%

MME, morphine milligram equivalent.

Table 3. *Themes and samples of participant feedback.*

Theme	Example patient feedback
Facilitating timely patient health care	"[The patient navigator] was excellent at getting me seen sooner whenever I had a problem."
Improving communication and promoting patient health and comfort	"It was great talking with [the patient navigator] because when you get old, no one ever thinks about their grandmother anymore."
Knowledgeable resource	"It made it easier for me to have [the patient navigator] take care of my scheduling. It is hard for me to keep track of everything."

Discussion

We have shown for the first time that patient navigation services reduced chronic opioid therapy dosing and discharge rate from an independent interventional pain clinic. After a follow-up of more than 3 months, patients who received navigation services were using less MME per day and had lower nonadherence based on the discharge rates. In the control group, nearly one-quarter of patients (23.3%) were discharged compared with 6.6% of patients in the navigation services group. Of note, the rate of patient discharge at the pain clinic where this study was conducted was 22% in 2002, suggesting that the discharge rate has remained unchanged over the last 2 decades (11).

The benefits of patient navigation reported here are in line with past studies in other chronic disease states. Navigation has been most extensively studied for cancer-related health care. For patients undergoing cancer treatment, navigation services were shown to improve access to community resources, timeliness of patient education, access to financial assistance, and overall patient satisfaction (17-19). For cancer screening, patient navigation was shown to increase the proportion of patients with timely follow-up after abnormal mammography results (19,20). For other disease states, such as diabetes, patient navigation has also been shown to improve clinical outcome measures, including better glycemic control, more frequent clinic visits, and higher rates of arrivals to scheduled appointments (21). However, robust investigations into the quantitative benefits of patient navigation are largely lacking (22), and well-designed randomized controlled trials will be essential to validating the findings reported here and in other studies.

In our study, the overall dose of opioids was decreased in the intervention group without an increase in pain score. And yet, the extant literature indicates that patients are frequently resistant to opioid dose reduction, or tapering, due to a low perceived risk of opioid overdose and a high perceived risk of increased pain. Additionally, many patients believe nonopioid therapies are poorly effective, increasing fears about opioid tapering. In past studies, patients who successfully tapered chronic opioid therapies reported that social support and contact with a trusted health care provider were key components to their success (23). In the present study, access to patient navigation services may have helped to facilitate opioid tapering by addressing misconceptions related to opioid safety, effectiveness of nonopioid pain interventions, and the risk for increased pain with opioid dose reductions.

In addition to patient-level benefits for navigation services, wider practice-level benefits are also important for consideration, including income generation and enhanced patient satisfaction. Patient navigation services require investment from practices, with one study estimating the costs at $275 per patient. In our study, patient navigators were paid between $15 and $22 per hour. At this time, there is no way that physicians can bill for their time for patient navigation services, and thus this intervention incurs a cost for the clinic. However, we expect that patient navigation services can generate a return on investment. While most cost-effectiveness analyses have evaluated patient navigation services in the context of payer- and systems-level interventions, it can reasonably be assumed that reduced rates of patient discharge and increased clinic visit scheduling and attendance will result in net cost savings for clinics (21,24). Furthermore, our study and others have shown that patients have favorable views of navigation services (25-27), which can increase patient satisfaction and retention at clinics while ultimately improving the quality of care.

The Opioid Risk Tool is commonly used in pain practices to identify patients at risk for opioid misuse, but our study showed that scores on the Opioid Risk Tool did not correlate with discharge in the navigation group. Instead, we found that higher scores on commonly used depression and anxiety scales were the best indicators of discharge risk. This outcome correlates well with past studies that have shown that mental health disorders may be important risk factors for opioid misuse (9,16). In addition to MDD and anxiety, other mental health disorders such as bipolar disorder, non-opioid substance use disorders, and panic disorder have also been shown to increase the risk for prescription opioid misuse (16). Improving the understanding of the risk factors for opioid misuse is a key component of tailoring interventions to prevent opioid use disorder among patients prescribed chronic opioid therapy for pain conditions. If our findings are confirmed, pain clinics could consider using the presence of moderate or severe mental health disorders, along with any other opioid misuse risk factors, to stratify selected at-risk patients to navigation services.

The patient navigation model used in this study is scalable and can be modified to best serve the needs of pain centers and their patients. Key tenets of any successful navigation program are outlined in Fig. 1 and include continuous and proactive engagement between the patient and navigator. Patient naviga-

tors can be nurses or laypeople, as past studies have shown no differences in outcomes with navigators from different backgrounds (19). Regardless of clinical background, navigators should receive training to ensure consistency among staff and to maximize patient engagement. Additionally, physicians and APPs should receive training to optimize collaboration with patient navigators and identify clinical and support roles to prevent duplication of efforts and ensure seamless patient care. Practices can consider further engaging patients in the navigation process by developing a written or verbal contract. The American Cancer Society's Take Action Program serves as an excellent model for most practices. In the Take Action process, patients meet with patient navigators to identify activation level and barriers and to set goals. Patients are then encouraged to work on those goals, and navigators check in with patients via phone or telehealth platforms (29).

Our results should be viewed within the context of the limitations of the observational nature of the study. This was a single-center study with a small sample size and relatively short duration of follow-up, and the generalizability of these results to other clinic settings is currently unknown. Because of the median follow-up of 111 days, it is possible that compliance issues extending beyond the random compliance check at about 3 months were not captured in the study. Furthermore, we did not evaluate patient adherence to navigator visits, which would be a valuable metric for future studies to determine the cost-benefit of this intervention. Due to the observational nature of the study and the small sample size, statistical significance testing was not undertaken. This study should be considered hypothesis-generating only, as conclusions about causality cannot be definitively made. Additional, appropriately powered studies

are needed to confirm these results and determine whether they are broadly applicable across pain practices. Furthermore, the durability of the positive results is unknown.

CONCLUSIONS

In this observational, single-center study, implementation of a patient navigation service decreased opioid use and practice discharge rates compared with usual care in patients receiving chronic opioid therapy. Patient navigation is a scalable intervention that can be used to decrease the rate of patient noncompliance and improve patient satisfaction. Additional studies into the benefits of patient navigation services for those receiving opioid therapy are urgently needed.
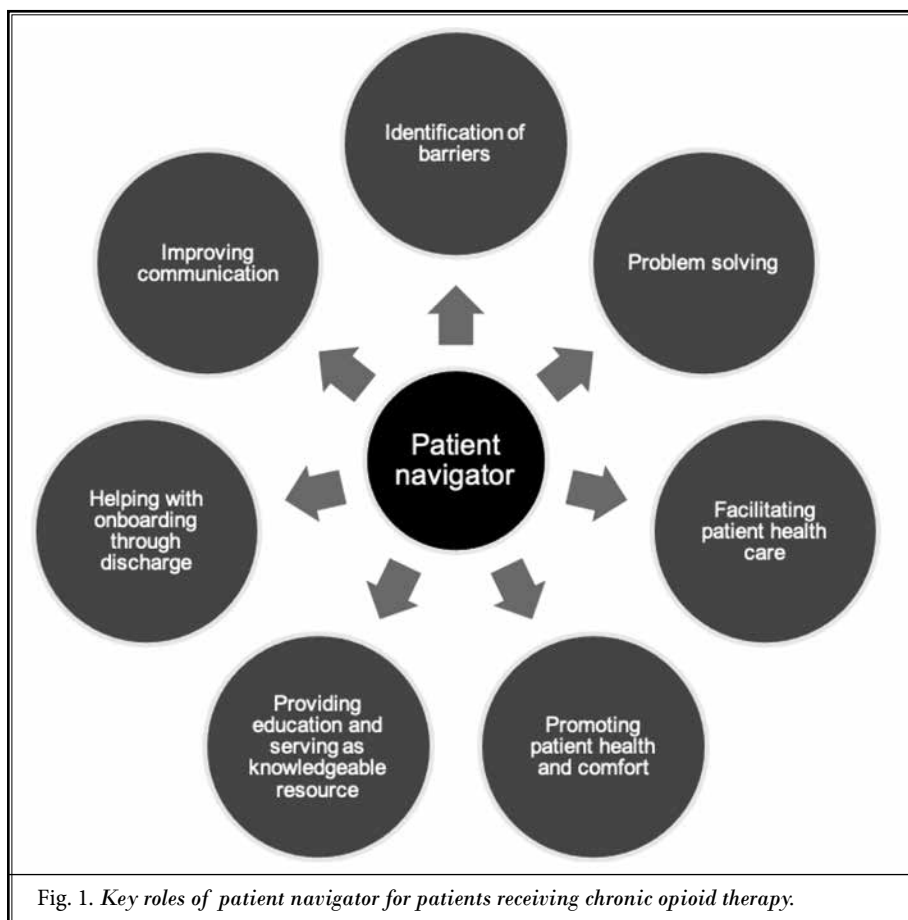
Acknowledgments

Fig. 1. *Key roles of patient navigator for patients receiving chronic opioid therapy.*

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