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Publication Date

2025-01-09

DOI

10.1080/10903127.2024.2449512

TITLE PAGE

Prehospital buprenorphine in treating symptoms of opioid withdrawal – a descriptive review of the first 131 cases in San Francisco, CA

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ABSTRACT

Prehospital buprenorphine in treating symptoms of opioid withdrawal - a descriptive review of the first 131 cases in San Francisco, CA

OBJECTIVES: Opioid use disorder (OUD) remains a common cause of overdose and mortality in the United States. Emergency medical services (EMS) clinicians often interact with patients with OUD, including during or shortly after an overdose. The aim of this study was to describe the characteristics and outcomes of patients receiving prehospital buprenorphine for the treatment of opioid withdrawal in an urban EMS system.

METHODS: We performed a retrospective chart review of all initial cases of administration of buprenorphine-naloxone from April 2023 - July 2024 during the first 16 months of a program involving prehospital EMS administration of buprenorphine-naloxone by EMS clinicians to patients with OUD experiencing acute opioid withdrawal in San Francisco. The primary outcome involved reduction in Clinical Opioid Withdrawal Score (COWS) and other adverse events including worsened withdrawal (or increased COWS), nausea, patient destination, and loss to follow up were also assessed.

RESULTS: Buprenorphine was administered to 131 patients. In 82 (62.6%) cases, patients presented in withdrawal after receiving naloxone from bystanders or EMS as a treatment for overdose. The average COWS prior to administration was 16.1 ± 6.5 and the median COWS prior to administration was 15 (IQR: 11-19). Of the 78 cases where a COWS was available, 74 (94.9%) experienced symptom improvement, with the median COWS dropping from 15 (IQR: 11-19) to 7 (IQR: 4-13) between first and last recorded values. No adverse effects were reported in prehospital records. There was one reported in-hospital incident of withdrawal in the Emergency Department presumably precipitated by buprenorphine. Data on outcomes after

EMS transport were limited. Only six patients were successfully contacted at 30 day follow up, but five of these patients were in long-term OUD treatment programs, and three reported sustained abstinence from opioid use. During case review, we found two cases where physicians assisted EMS personnel in recognizing recent methadone use, but no other missed exclusion criteria requiring physician input.

CONCLUSIONS: In San Francisco, prehospital administration of buprenorphine for acute opioid withdrawal by EMS clinicians resulted in symptomatic improvement, and case review suggests administration can be safe without direct EMS physician oversight.

Keywords: Buprenorphine, Emergency Medical Services, Opioid Overdose

MAIN DOCUMENT

Prehospital buprenorphine in the treatment of symptoms of opioid withdrawal - a descriptive review of the first 131 cases in San Francisco, CA

INTRODUCTION

Opioid use disorder (OUD) remains a common cause of overdose and death in the United States. From April 2023 - March 2024, 99,684 deaths in the United States and 11,538 deaths in California were associated with drug overdose, a majority of which were identified as opioid-related (1). There is also evidence that patients who suffer from one drug overdose are at significantly increased risk of mortality, most notably mortality due to repeat overdose. Patients discharged from the emergency department (ED) after non-fatal opioid overdoses have been found to have a one-year mortality rate of 5.5 percent (2). Buprenorphine and buprenorphine-naloxone have been widely utilized as treatments for OUD and many studies have shown these medications to be effective in reducing rates of overdose (2, 3, 4, 5).

Buprenorphine has traditionally been administered in clinics or EDs. Significant barriers to care in these settings include lack of provider awareness and training, inadequate resources or time, and/or stigma surrounding treatment of patients with OUD (6). One 2022 study across 5,800 hospitals demonstrated that buprenorphine was only prescribed to one in 12 patients leaving the ED after a suspected opioid overdose (7). Many of the people at highest risk of overdose may also not be willing or able to engage with medical personnel in traditional clinic or hospital settings. One study found that 42% (674/1600) of patients who were given naloxone outside of the hospital for opioid overdose subsequently refused transport to a hospital, and that those who declined emergency medical services (EMS) transport were at increased risk of repeat overdose (8).

Prehospital personnel have a unique opportunity to engage with patients at the highest risk, especially as 30% of patients who die from overdose were found to have used EMS services in the year before their deaths (9). Emergency Medical Services (EMS) clinicians often interact with patients during or shortly after overdose, and many patients with OUD choose not to present to the hospital after interacting with EMS (10). Although the benefits of buprenorphine in the treatment of OUD are well described, there is a risk of buprenorphine-precipitated withdrawal. When administering this medication to patients who are in acute opioid withdrawal, such as after receiving naloxone to treat an overdose, this risk is mitigated (11, 12).

Initiation of buprenorphine in the prehospital setting is emerging as a treatment option for both acute withdrawal and opioid use disorder with withdrawal symptoms, and has been found effective in limited studies (5, 13, 14). However, use of buprenorphine by EMS has not been widely examined. This paper discusses program implementation and reviews the characteristics and outcomes of the initial 131 cases of buprenorphine-naloxone administration by EMS clinicians to patients with acute opioid withdrawal in San Francisco from April 2023 - July 2024.

METHODS

Setting

San Francisco is a densely populated city in Northern California with over 800,000 residents. This city has a long history of harm reduction initiatives including community-based naloxone distribution. The San Francisco EMS Agency, the regulatory agency that oversees all EMS provider organizations operating within the city, has a tiered system, with over 600 paramedics from three 9-1-1 response agencies, the largest of which is a fire-based EMS agency that also houses a community paramedicine division. Since 2016, with the growing presence of fentanyl,

San Francisco saw a steep rise in opioid overdoses, with over 5,000 EMS calls per year related to overdose and 647 opioid overdose deaths recorded in 2022 (16). Beginning in 2018, the EMS system sought to augment the robust community-based harm reduction and treatment initiatives with interventions that could reach people who use drugs (PWUD) who might not otherwise be served in more traditional clinical settings. First, in 2019 the EMS system launched a (first in California) Leave Behind Naloxone program for first responders, allowing EMS providers to distribute nasal naloxone to patients and bystanders at risk for experiencing or witnessing an overdose (17). In 2021, the San Francisco Fire Department (SFFD) expanded its Community Paramedicine (CP) Division to include a dedicated unit called the Street Overdose Response Team, to respond to increasing numbers of unhoused individuals experiencing overdose and to provide navigation to resources, including medically assisted therapy (18). This study was approved by the institutional review board of the Public Health institute covering all sites involved in the EMS Bridge expansion in California (IRB#I19-009).

Intervention

In 2023, the San Francisco EMS Agency developed protocols and educational materials in conjunction and collaboration with a statewide program to connect EMS with OUD treatment and overdose prevention resources (EMS Bridge, www.emsbridge.org) for administration of buprenorphine-naloxone (hereafter referred to as buprenorphine) by EMS clinicians. All San Francisco transport units and community paramedics were included. The initial protocol development has been previously described and includes administration of 16-24 mg SL buprenorphine every 30-60 mins for patients with a Clinical Opioid Withdrawal Score (COWS) of eight or greater (14, 15). Indications for buprenorphine included clinical evidence of acute opioid withdrawal, and in each case a COWS was documented . The protocol also suggested recalculating a COWS score at ten minutes and 20 minutes to monitor for changes. Exclusion

criteria included age under 18 years, pregnancy, use of methadone within ten days, altered mental status, evidence of severe acute decompensated medical illness such as use of CPAP or signs of stroke, recent suspected intoxicant co-ingestion (e.g. use of benzodiazepines or alcohol such that capacity was impaired), and/or inability to understand the risks and benefits of buprenorphine administration. In every case, a base hospital physician was contacted prior to buprenorphine initiation as part of the protocol. The data from these calls was reviewed during monthly continuous quality improvement (CQI) meetings by prehospital clinicians, hospital-based clinicians, addiction medicine specialists, and substance use navigators. For the purpose of analysis, all data were de-identified.

Measures and analysis

Simple descriptive characteristics were reported of the data, including patient age, gender identity, status as housed or unhoused, race and ethnicity, COWS before and after buprenorphine administration, dose and timing of buprenorphine given in the prehospital environment, ultimate patient destination, affiliation of EMS clinicians involved, presence or absence of any adverse events. Descriptive statistics, e.g. interquartile ranges and means, were performed using these variables. A narrative account of each patient interaction was reviewed, and would occasionally include additional information such as recent naloxone administration, recent overdose, and/or additional medications. Where available, information about patients' care in the ED and follow up was reviewed. All data was obtained with the aid of EMS Bridge from anonymized electronic Patient Care Reporting records.

RESULTS

A total of 139 calls by EMS clinicians to base hospital physicians regarding patients who were deemed eligible for buprenorphine administration were reviewed from April 2023 to July 2024. In eight cases, buprenorphine was withheld based on the advice of the base hospital physician. In one case, the diagnosis of acute opioid withdrawal was unclear. In two cases, the patients had a history of recent methadone use (a contraindication per protocol). Of the five remaining cases in which buprenorphine was withheld after base hospital consultation, three instances were attributed to physician misunderstanding of the protocol and safety profile, and two were due to confusion or disagreement on the part of EMS personnel and physicians over the COWS threshold for treatment, which was subsequently clarified in the protocol after CQI review.

A total of 131 patients received buprenorphine administered in the field by EMS clinicians. Patient ages ranged from 22 to 59 years, with an average age of 43.6, and a median age of 38 (IQR: 23-48). A total of 102 patients (77.9%) identified as male and 29 (29.8%) identified as female. 78 patients (59.5%) were identified as unhoused, 43 (32.8%) as housed, and in 10 cases (7.6%) the patient's housing status was unknown. Patient race and ethnicity were documented by EMS for 127 patients, with most identified as White (76 or 59%). 76 (53.4%) of patients received naloxone prior to EMS arrival and one patient was given naloxone by EMS for a total of 77 (58.8%) patients presenting in naloxone-precipitated withdrawal. Doses of naloxone given by both EMS clinicians and bystanders ranged from 0.4 to 32 mg, with an average dose of 9.4 mg and median dose of 8 mg. Data on use of specific opioids was limited, but 102 (77.9%) patients endorsed fentanyl use specifically within the last 72 hours. The average COWS prior to buprenorphine administration was 16.1 ± 6.5 and the median COWS prior to administration was 15 (IQR: 11-19). Two patients did not have COWS recorded prior to buprenorphine administration.

A total of 22 patients (16.8%) received a second dose of buprenorphine. The total dose of buprenorphine administered by EMS ranged from 4 to 24 mg, with a median total dose of 16 mg, given to 96 patients. Two patients received a total dose of 4 mg, 11 patients received 8 mg, and 22 patients received 24 mg.

A ten-minute reassessment to determine the need for a second dose was recorded for 12 patients (9.2%). For these 12 patients, the median COWS was 4.5 (IQR: 2.8 – 6) and the average COWS was 4.8 ± 2.7 (Table 3). In five cases, on ten-minute reassessment the COWS was only recorded as “improved”, without a numeric value. Seventy-four patients (56.5%) had COWS recorded at 20 minutes after administration, at which time the median COWS was 8 (IQR: 5-13) and the average COWS was 9.5 ± 6.4.

Overall, 74 (94.9%) patients reported symptom improvement, with the median COWS dropping from 15 (IQR: 11-19) to 7 (IQR: 4-13) between first and last recorded values. In four cases, the COWS stayed the same.

No adverse effects were reported during the prehospital care, although at least one patient was treated for suspected buprenorphine-precipitated withdrawal during their ED stay. An interdisciplinary root cause analysis, involving a team of EMS, emergency physicians, toxicologists, and addiction medicine physicians, determined that prehospital buprenorphine administration may have contributed to this patient’s symptoms. It was controversial whether these symptoms were due to buprenorphine-precipitated withdrawal versus undertreatment. Six patients declined transport to the hospital against medical advice or eloped from care, and three were transported to non-hospital destinations (sobering centers or shelters). 122 patients were subsequently transported to the hospital, with 80 transported to community hospitals, 20 to a public hospital, and 22 to a university hospital. One patient eloped upon arrival at the ED.

Data on outcomes after treatment or transport were limited. Although a public health-based post-overdose outreach team was referred to each overdose patient, those records are yet to be linked to the prehospital record and were not fully available during the CQI process. However, limited information was available for 57 of the patients' (43.5%) ED care. Of these 57 patients, 12 received additional buprenorphine before discharge from the ED, five received a prescription for outpatient buprenorphine, and nine received prescriptions for naloxone. Sixteen patients received resources and/or referrals to long term substance use counseling. One was admitted for further treatment. Attempts were made to contact 48 of these patients after discharge from the ED. Most could not be reached, but six were successfully contacted at 7, 14, and 30 day follow up. Five of these patients were in long-term OUD treatment programs, and three of these five patients reported sustained abstinence from opioid use.

DISCUSSION

These results contribute to the growing evidence supporting the feasibility and safety of EMS-administered buprenorphine for people with OUD. Notably, in 59 (approximately 44% of) cases patients received buprenorphine administered by non-specialty trained paramedics, who had not received specialized training beyond basic education regarding the buprenorphine protocol and opioid use disorder. These cases show that paramedics are able to assess for opioid withdrawal and to administer buprenorphine, with limited additional training.

Our pilot study did not reveal any clinical events during prehospital care that would raise safety concerns. Although several patients did receive other medications such as ondansetron as well as buprenorphine, review of the cases showed this was used as an adjunct therapy for relief of

existing withdrawal symptoms, rather than to treat nausea or other side effects caused by buprenorphine administration.

Limited information was available for 57 of the patients' (43.5%) ED care. Without direct access to hospital records, EMS agencies relied on asking for follow up information from hospitals via email, which yielded inconsistent results. A more robust, streamlined approach to data collection is currently in development. Although this follow up data is limited, when community paramedics were involved, they often attempted to follow up to provide additional coordination of care. Most overdose survivors do not receive interventions promoting medication treatment—an approach demonstrated to reduce mortality–much less connection to resources. Although few patients could be contacted at follow up, sustained abstinence from opioid use at 30 day follow up by even 2.2% of patients who were given buprenorphine (three out of 131) suggests combined interventions of both buprenorphine induction by non-specialty paramedics and wraparound care by community paramedics can lead to sustained change, in addition to symptom relief from withdrawal.

One of the greatest challenges involved in treating patients suffering from OUD involves the reluctance of these patients to engage with medical services. Only six patients (4.6%) of those given buprenorphine by paramedics during this case review declined transport and remained in the community, significantly fewer than other quoted numbers of non-transports among patients following overdose (8). While it is difficult to determine without further study, and these numbers cannot be directly compared as not all of those patients receiving buprenorphine presented after overdose, it is possible that offering symptom relief from withdrawal in the field may make patients with OUD more amenable to transport, thereby allowing them to connect further with medical care.

Community paramedics from the Street Outreach Response Team (SORT) were also involved in approximately 56% of cases. The use of community paramedicine teams to support initiation and administration of the protocol may have contributed to higher rates of engagement. In addition to having specialized training, these paramedics also have dedicated extra time to spend with patients, unlike transport paramedics, which may affect both rates of transport to the hospital and patients' willingness to undergo hospital transport.

One factor that may limit implementation of this project elsewhere is utilization of real-time base physician oversight. In San Francisco, a single EMS base hospital provides online medical direction for all EMS clinicians. Since buprenorphine was a relatively new medication, it was felt that base physician consultation would support EMS decision-making and lower the barrier to prehospital buprenorphine administration. However, in several cases, physician input led to deviation from the protocol resulting in buprenorphine being withheld from potentially eligible patients. Base Physician follow-up education was provided in these cases. While base physician consultation helped identify two cases of recent methadone use, no other near misses were discovered during case review. Emergency Medicine clinicians have varying levels of comfort prescribing buprenorphine, even without an X-waiver requirement, and the ease of access to outpatient treatment clinics for ongoing care may further hinder the long-term success of these programs. A thorough review of cases did not show clearly whether patients benefited from real-time oversight, implying that online supervision of paramedics may not be necessary for successful implementation of buprenorphine in the field.

Opioid withdrawal symptoms can result from either abstinence or naloxone administration following an overdose. In our study, over 40% of patients experienced withdrawal due to abstinence rather than naloxone-induced symptoms. This finding is consistent with another

implementation study and indicates a significant need for low barrier opioid withdrawal treatment programs (13).

LIMITATIONS

This study has several limitations. First, this was conducted in a single urban EMS syste m, which limits its generalizability to other jurisdictions and settings. Additionally, the majority of buprenorphine administrations were made by specialized community paramedic (post-overdose) teams, which may not be feasible in all EMS systems. However, while San Francisco has the largest implementation with the highest number of administrations in California, ten other California Local EMS Agencies are also participating in the pilot program, demonstrating scalability. An additional limitation relates to missing data elements in the protocol. A significant portion of encounters did not include a repeat COWS assessment. This was thought to be due to a variety of factors including high rates of transport to the hospital, short transport times in a small geographic area, and EMS clinician error. Furthermore, the peak effect of buprenorphine is approximately one hour after administration, which means adverse events and/or sustained symptom improvement may have happened after patients left the care of EMS personnel (19). Finally, this protocol did not include an integrated follow-up plan and follow-up was further complicated by a high proportion of patients with unstable housing or experiencing homelessness. Although a robust referral system exists for both hospital-based and community-based outreach to patients following treatment for OUD, there has been significant difficulty in matching outcomes between those programs due to data-systems issues. Therefore, reporting on 7- and 30-day follow-up outcomes was not feasible for most cases included in this program. The California BRIDGE program is working on a centralized database to better track follow-up outcome measures in the future.

CONCLUSIONS

Prehospital administration of buprenorphine for acute opioid withdrawal by EMS clinicians in San Francisco has been feasible to implement and shows evidence of reduction of symptoms of opioid withdrawal. Further study of long-term outcomes, safety, and effectiveness is warranted.

ACKNOWLEDGEMENTS: The authors would like to acknowledge the EMS Bridge Program, the San Francisco EMS Agency and Department of Emergency Management, the San Francisco Fire Department, the San Francisco Department of Public Health, American Medical Response, and King American Ambulance.

FUNDING SOURCES: The EMS Bridge Program (which developed the protocol used in this study) has received support from the California Department of Public Health and the CareStar Foundation.

DECLARATION OF INTEREST STATEMENT: The authors report there are no competing interests to declare.

DECLARATION OF GENERATIVE AI IN SCIENTIFIC WRITING: The authors did not use a generative artificial intelligence (AI) tool or service to assist with preparation or editing of this work. The author(s) take full responsibility for the content of this publication.

DATA SHARING STATEMENT: The data analyzed in this manuscript is not part of a publicly available data set. However, the raw data may be made available on request.

AUTHORSHIP STATEMENT: H Hern, M Mercer, J Lacocque and A Herring conceived of this project. J Lacocque, M Mercer, M Mason, J Wiebers, J Graterol, E Silverman, and E Gunn

undertook the data collection. A Gurley undertook the analysis. All authors participated in interpretation of the data. A Gurley and H Hern wrote the first draft of the manuscript. All authors commented on drafts of the manuscript.

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TABLE CAPTIONS & FIGURE CAPTIONS

Figure 1: Change in Median Clinical Opioid Withdrawal Scale (COWS) over time

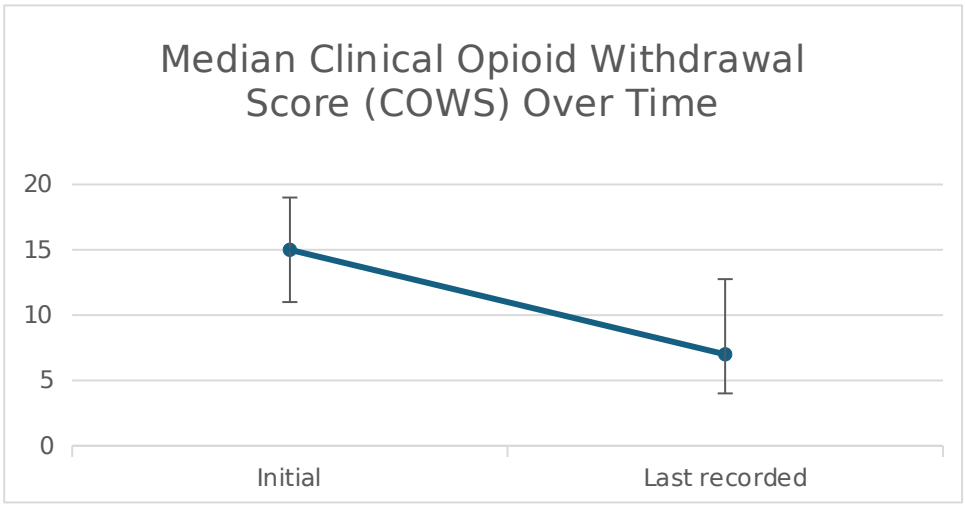

Table 1: Patient Characteristics including demographics and clinical outcomes

Table 1: Patient Characteristics and Outcomes

Patient Characteristic or Outcome Variable	**Number or percent**
Total patients treated with buprenorphine	131
Mean patient age in years (range)	43.6 (22-59)
Gender	
Male (%)	102 (77.9%)
Female (%)	29 (29.8%)
Race/Ethnicity**	
Asian	6

Black/African American	34
Latino/a/x	17
Native American/American Indian	2
Pacific Islander/Native Hawaiian	2
White	80
Other	0
Housing Status (%)	
Unhoused	78 (59.5%)
Housed	43 (32.8%)
Unknown Housing Status	10 (7.6%)
Patient Treatment and Outcomes	
Total patients with initial COWS reported	129 (98.5%)
Total patients with secondary COWS reported	78 (59.5%)
Need for Repeat Dosing	
Single dose of buprenorphine given	109 (83.2%)
Second dose of buprenorphine given	22 (16.8%)
Total Cumulative Dose of Buprenorphine Administered	

4 mg	2 (1.5%)
8 mg	11 (8.4%)
16 mg	96 (73.3%)
24 mg	22 (16.8%)
Average Clinical Opioid Withdrawal Scale	
Average Initial COWS (and standard deviation)	16.2 (6.5)
Average COWS at 20 minutes (and standard deviation)	9.4 (6.3)
Patient Destination	
Community Hospital	80 (61.1%)
University Hospital	20 (15.3%)
Public Hospital	22 (16.8%)
Remained in community (i.e. AMA)	6 (4.6%)
Non-hospital destination (e.g. sobering center)	3 (2.3%)

Table 1 footnotes: EMS clinicians often documented patients as belonging to more than one category when documenting race. Percentages for these categories are therefore not reported.