The Journal of Emergency Medicine, Vol. 52, No. 1, pp. 52–58, 2017
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0736-4679/$ - see front matter

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Evidence Based Medicine

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IS A PREHOSPITAL TREAT AND RELEASE PROTOCOL FOR OPIOID OVERDOSE SAFE?

Daniel Kolinsky, MD,* Samuel M. Keim, MD, MS,† Brian G. Cohn, MD,* Evan S. Schwarz, MD,* and Donald M. Yealy, MD‡

*Division of Emergency Medicine, Washington University School of Medicine, St. Louis, Missouri, †Department of Emergency Medicine, The University of Arizona College of Medicine, Tucson, Arizona, and ‡Department of Emergency Medicine, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania

Corresponding Address: Samuel M. Keim, MD, MS, Department of Emergency Medicine, The University of Arizona College of Medicine, PO Box 245057, Tucson, AZ 85724

☐ **Abstract—Background: The current standards for domestic emergency medical services suggest that all patients suspected of opioid overdose be transported to the emergency department for evaluation and treatment. This includes patients who improve after naloxone administration in the field because of concerns for rebound toxicity. However, various emergency medical services systems release such patients at the scene after a 15- to 20-min observation period as long as they return to their baseline. Objectives: We sought to determine if a "treat and release" clinical pathway is safe in prehospital patients with suspected opioid overdose. Results: Five studies were identified and critically appraised. From a pooled total of 3875 patients who refused transport to the emergency department after an opioid overdose, three patient deaths were attributed to rebound toxicity. These results imply that a "treat and release" policy might be safe with rare complications. A close review of these studies reveals several confounding factors that make extrapolation to our population limited. Conclusion: The existing literature suggests a "treat and release" policy for suspected prehospital opioid overdose might be safe, but additional research should be conducted in a prospective design.** © **2016 Elsevier Inc. All rights reserved.**

☐ **Keywords—emergency medical services; naloxone; opioid overdose; prehospital**

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CASE PRESENTATION

Paramedics have administered 0.4 mg of naloxone intravenously (IV) to a somnolent patient with a known history of IV heroin addiction. The patient rapidly is aroused to an alert state. He admits to using heroin from a new source and verbalizes that it was clearly more potent than he initially suspected. After 20 min on the scene, he requests to sign an Against Medical Advice (AMA) refusal form. According to protocol, the paramedics have contacted medical control to report a potential refusal of transport. The patient's housemate has agreed to observe him, but you wonder if this "treat and release" practice is safe.

CONTEXT

Opioid abuse remains an increasing problem in the United States because of the high prevalence of heroin abuse and the increasing abuse of prescription opioid medications. The sale of opioid pain relievers (OPRs) has steadily increased since 1999, and the rates of both deaths from overdose and hospital admission for treatment have increased (1). This includes an increase in the abuse of longer-acting agents, such as methadone. In the United States, death rates from prescription OPR overdose quadrupled between 1999 and

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2010, while deaths from heroin increased at a slower rate (2). With the advent of prescription drug monitoring databases, there has been resurgence in the abuse of heroin. However, OPRs are still frequently abused. In 2010, there were 135,971 United States (US) emergency department (ED) visits and 16,651 deaths in the US caused by OPR overdose (3,4). The estimated total ED cost for those discharged from the ED was $234,542,324 (3).

The mainstay of treatment for opioid overdose is the mu opioid receptor antagonist naloxone. Naloxone is safe to administer, and severe adverse events are rarely reported (5). Most emergency medical services (EMS) systems mandate that all patients suspected of opioid overdose be transported to the emergency department (ED). This includes patients who improve after naloxone administration because of concerns that they are at risk for rebound toxicity related to the short half-life of naloxone compared to the longer duration of action of other opioids. Some have advocated for up to 6 h of observation after reversal of toxicity (6). However, the increase in ED overcrowding and lengthy wait times has led to efforts to develop methods to disposition these patients more rapidly. One group created a prediction rule for safe, early discharge of patients with presumed opioid overdose within 1 h of arrival to the ED (7).

The next step might be to question policies to transfer all opioid overdoses to the ED for evaluation and observation. In various European EMS systems, releasing such patients at the scene after a 15- to 20-min observation period, as long as they return to their baseline, is standard practice (8). One study determined risk factors (i.e., age >50 years and overdose during the weekend) that identify high-risk patients who are poor candidates for this strategy (9). The goal of this review is to determine if a "treat and release" policy is supported by the current available evidence.

EVIDENCE SEARCH

A PubMed MEDLINE search was performed with the keywords "prehospital AND naloxone" and "emergency medical services AND naloxone AND opioid overdose" with no limits, yielding 118 articles. EMBASE was searched with the terms "emergency medical services AND naloxone AND opioid overdose," resulting in 42 citations. All citations were reviewed to identify original research evaluating the safety of administering naloxone to patients with suspected opioid toxicity in the prehospital setting and not transporting them to the hospital. Five relevant articles were identified. One article was excluded because its dataset was used in a larger trial that was included (10). The bibliographies of these articles were reviewed for additional references, but none were identified.

EVIDENCE REVIEW

Prehospital Treatment of Opioid Overdose in Copenhagen—Is it Safe to Discharge on Scene?

Population. This study included all patients with suspected opioid overdoses evaluated by the Medical Emergency Care Unit (MECU) in Copenhagen, Denmark, from 1994 to 2003 (11).

Study design. This was a retrospective chart review of all patients diagnosed with an opioid overdose in the MECU database. All overdose cases with a Danish social security number were checked for survival data with the Central Personal Registry, and autopsy reports on all subjects who died within 48 h of MECU contact were collected. Mandatory toxicologic screening was a part of these autopsy reports and included the substance most likely to be the cause of death. Patients who died within 48 h of MECU contact were further classified as "rebound toxicity unlikely" or "rebound toxicity likely" based on police investigations; patients seen alive >6 h after MECU contact were classified as "rebound toxicity unlikely."

Primary outcome. The primary outcome was the risk of dying from rebound toxicity within 48 h of being released by the MECU.

Exclusion criteria. All patients diagnosed on scene by the MECU doctor were included. However, patients without a Danish social security or patients who refused to provide their social security number could not be followed in the Central Personal Registry.

Main results. There were 2241 cases of opioid overdose with a positive patient identification that were released at the scene. Among these, 18 deaths within 48 h were identified for an all-cause mortality rate of 0.80% within 48 h. Four of these cases were excluded: 2 patients were not given naloxone, 1 case was admitted to the hospital after MECU contact for an unrelated reason, and 1 subject committed suicide by hanging. Therefore, 14 deaths (0.62%) possibly caused by rebound opioid toxicity were identified. Opioid rebound toxicity was found to be the likely cause of death in 3 cases (0.13% [95% confidence interval {CI} 0.04–0.39%). Another 1427 patients where positive identification was not obtained were treated for a presumed opioid overdose and released at the scene. Follow-up could not be obtained for any of these patients.

Assessment for Deaths in Out-of-Hospital Heroin Overdose Patients Treated with Naloxone Who Refuse Transport

Population. This study included all patients with suspected opioid overdoses evaluated by San Diego EMS or a mobile intensive care nurse (MICN) from 1996 to 2000 (12).

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Study design. This was a retrospective chart review conducted using the San Diego County Quality Assurance Network database and the San Diego County Medical Examiner's (ME) Office database. A list was compiled of all paramedic responses in San Diego County in which a patient received naloxone and signed out AMA before transport. A second list was compiled of all cases in the ME database in which a metabolite of morphine was noted as contributing to the cause of death. The 2 lists were cross-referenced to identify any patients treated with naloxone by paramedics within 12 h preceding the time of death documented by the ME's office.

Primary outcome. The primary outcome was the death from rebound opioid toxicity within 12 h of being released by San Diego EMS or MICN.

Exclusion criteria. Patients who received naloxone and were subsequently released by EMS without transport that were later confirmed dead within 12 h having morphine listed as a contributory cause of death on the ME's report were included in the study. Patients not meeting these criteria were excluded.

Main results. There were 998 patients identified who received naloxone and were released AMA by the paramedics. The mean age was 37.7 years, and 83.8% were male. There were 601 deaths reported by the ME database in which morphine was listed as contributing to the cause of death. The mean age of these patients was 40.1 years, and 83.6% were male. After cross-referencing these lists, no deaths attributable to an opioid overdose, identified by the presence of a morphine metabolite on toxicology screening, could be identified within 12 h of naloxone administration by EMS (0%; 95% CI 0–0.37%).

No Deaths Associated with Patient Refusal of Transport After Naloxone-Reversed Opioid Overdose

Population. All patients successfully treated with naloxone by the San Antonio Fire Department (SAFD) EMS for suspected opioid overdose that were not transported to the hospital were included (13).

Study design. SAFD EMS retrospectively reviewed electronic medical records of all patients presenting with opioid toxicity that were not transported after receiving naloxone. Patients with a normal mental status and normal vital signs after receiving naloxone were allowed to refuse hospital transport and were released at the scene. The authors compiled a report of all patients who received naloxone and were not transported during a 20-month period from November 2007 to June 2009. The ME cross-referenced that list for any fatalities in their system and then made a separate list of all deaths that occurred within either 48 h or 30 days of the patient being released by SAFD EMS. The ME also manually searched their database for any patients matching the description of a patient that was treated and released by SAFD.

Primary outcome. The primary outcome was 48-h mortality in patients who were successfully treated with naloxone and not transported to the hospital.

Exclusion criteria. Patients who could not be resuscitated and died in the field or who were transported to the hospital were excluded.

Main results. SAFD treated 1700 patients with naloxone, of which 552 patients refused transport. The cohort consisted of mostly male patients (72%), with an average age of 38 years (range 13–91 years). No attempt was made to identify the opioid that the patient used or the route of ingestion. Nine deaths were identified by the ME's office, with only 2 occurring within 30 days of treatment by SAFD. The first patient died from a combined ingestion of heroin and cocaine 4 days after being released. The second patient died from a gunshot wound 7 days after being released.

Recurrent Opioid Toxicity After Prehospital Care of Presumed Heroin Overdose Patients

Population. All patients with presumed heroin overdoses who were evaluated by Helsinki EMS from 1995 to 2000 were included (14).

Study design. EMS records from Helsinki were retrospectively reviewed for patients presenting after a presumed opioid overdose. In addition to symptoms, patients must have been witnessed using heroin or had circumstantial evidence of drug use. Patients with a suspected opioid overdose with a Glasgow Coma Score (GCS) $\leq$8 were considered as overdoses, even in the absence of respiratory depression, and were treated with naloxone. Patients were considered to be naloxone responders if their GCS improved to >8, their respiratory rate was >12 breaths/min, and their peripheral oxygen saturations were >90%. In addition to their name and date of birth, EMS records included the type of opioid used and the route of administration. Data from all patients who were treated and released were compared to both the ME records and cardiac arrest database to determine if any patients died within 12 h of being released. Of note, Helsinki EMS differs in that it is organized into a 3-tier system, with the first 2 tiers consisting of firemen or paramedics. The third tier is a mobile intensive care unit staffed by emergency medical technician/firemen and an emergency physician.

Primary outcome. The primary outcome was death within 12 h after evaluation and treatment by Helsinki EMS.

Exclusion criteria. Patients who suffered from signs and symptoms of heroin overdose that were witnessed

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EBM – Therapy Studies

Searching for, appraising and applying the best available evidence to assist clinical decision regarding therapeutic interventions. The Randomized Clinical Trial (RCT) produces the gold standard evidence regarding Therapy. Prospective Cohort studies are useful for evaluating therapies, primarily for comparative effectiveness and for establishing prognosis. The Cohort is weaker in design than the RCT because of the potential for bias. Retrospective Cohort studies are even weaker still for many reasons one of which is the lack of standardized data entry.

Randomized Controlled Trial (RCT)

Also known as the "Clinical Trial," the RCT is a study design that compares intervention to control groups. Fundamental to this design is the assignment of participants to a group by the formal process of randomization. All participants should be equally likely to be assigned to either the intervention or control group. The three general advantages of this design over other methods are 1) removal of bias associated with the allocation of participants to groups, 2) the production of comparable and evenly balanced groups and 3) the assurance of the validity of the statistical tests used.

Cohort Study

The Cohort Study is typically a prospective investigation of a key outcome in a group of individuals who do not have the outcome in which some have a known risk factor compared to others that do not have the exposure. Both groups are then followed to compare the incidence of the outcome of interest. A retrospective cohort would start with a group of individuals with the disease in question and investigators would study the group for the presence of specific risk factors, e.g., treat and release versus ED observation, and their relative outcomes. These studies are known to be susceptible to bias as the physician or patient preferences determined which therapy they received.

Selection Bias

When patients are selected in a manner that systematically introduces error into a study, section bias typically is present. Cases should be carefully selected to be representative of the disease in question, e.g., intravenous heroin user. Spectrum bias, a form of selection bias, occurs when patients are selected by a non-blinded physician investigator because they are more likely to fit the expected outcome desired, e.g., heroin-only versus possible mixed opioid overdose.

Figure 1. Evidence-based medicine teaching points.

using heroin or showed evidence of drug use evaluated and treated by Helsinki EMS that were later confirmed dead within 12 h. Patients who were not meeting these criteria were excluded. Patients with polysubstance ingestion, alcohol use, or the use of any opioid other than heroin were excluded.

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Main results. Helsinki EMS treated 269 patients for a presumed opioid overdose from January 1995 to December 2000. Of these, 124 patients were excluded, leaving 145 total patients. Four patients were excluded because of insufficient data; the rest were excluded because of coingestion of alcohol, other drugs, or opioids other than heroin. Patients were mostly male (82.8%), with a median age of 26 years (25th and 75th quartile range 21–32 years). Most patients did not report the route of abuse (97 patients; 66.9%). A mobile intensive care unit with an emergency physician present at 124 (86.7%) encounters. Most patients (70.7%) received ≤0.4 mg of naloxone with a nearly equal amount receiving naloxone either IV (37.4%), IM or SC (28.5%), or IV and IM or SC (26.8%). There were 84 patients (57.9%) who were treated and released on the scene. Of these, 71 (85%) were administered naloxone, 8 (9.5%) recovered after ventilator assistance, and 5 (6.0%) recovered without receiving any medical care. Review of records did not find any patients who died within 12 h of receiving naloxone and being released in the field.

CONCLUSION

Current literature seems to support that a "treat and release" EMS protocol might be safe in patients who return to baseline and are hemodynamically stable after receiving naloxone. Caution should be used when interpreting these studies given questions regarding the external validity of their results in areas with different patterns of opioid abuse (Figure 1).

Commentary

Dr. Donald M. Yealy: The authors tackle an important and evolving issue in medicine and society: caring for those with the most direct sequelae of opioid abuse, something increasing over the past 20 years from both illicit and prescriptive sources. The current study addresses the short-term risk of naloxone reversal by EMS providers after opioid overdose absent any further care associated with that event.

As naloxone became more available—first delivered only by physicians and nurses in the hospital, then onto EMS providers, and now by other first responders and people without a formal medical role (i.e., family, friends, and acquaintances)—the question of safety vs. reward rises (15-18). Twenty years ago, the dominant question was "How long after ED reversal must I keep all?" Now, the question broadens to "What should we do with EMS-reversed patients? What can we do about those reversed outside the floodlights of organized medical care?"

Similar to data decades ago on safety after ED opioid reversal, the current study shows that EMS patients who have no obvious ill-toward effects in the immediate post-reversal interval have a very low short-term morbid or mortal event rate (19). Earlier research defined the safety of empiric naloxone use by paramedics, quelling concerns about aspiration, lung injury, and circulatory perturbations (10,11,20,21). The challenge is reconciling how to ensure good overall care beyond immediate effects of reversal; naloxone—given intravenously or via nasal spray—has a quick onset and short duration, usually under an hour. If the offending opioid has an effect above the safety level (impairing consciousness and breathing) longer than this hour, perhaps the same exposure means imminent and avoidable harm absent longer observation. In the field, this means transfer to an ED or an alternative site equipped and willing to give care (few of these latter exist).

Trying to estimate the adequacy of the initial reversal depends on knowing or estimating both pharmacokinetics (i.e., how a drug got deployed and gets eliminated —the first the biggest issue as long-acting or oral preparations creating more variation and duration than intravenous use) and pharmacodynamics (i.e., how a drug works at the receptor—a fear with newer designer agents and some known opioids, like fentanyl and carfentanil). By definition, ED opioid reversal and release means longer observation intervals and time distance from exposure than EMS treat and release—so a direct transfer of our knowledge gained from ED observations is unwarranted. However, the current data show a similar pattern for the EMS "treat and release" group if no untoward effects persisted—thousands of uses, very rare bad outcomes. While all the existing data are flawed by nature, depending on unstructured surveillance that may miss important features, it is unlikely a comparative trial will ever occur—so aside from better surveillance, these will be the kind of data that drive practice. Finally, it is hard to know if the rare short-term bad outcomes, notably death, are from the sentinel exposure or a choice for re-exposure after reversal; the potential interventions vary for these different causes.

Complicating the equation are two other concerns: patient rights and the longer term sequelae of "treat and release." Where are the real limits in forcing or coercing an ED trip for the seemingly well patient after reversal with a short-acting opioid? If we assess capacity and find it intact, can we do anything other than advise and recommend, highlighting risks? In addition, capacity assessment and risk counselling is likely more variable and overall less used in lay reversal, another growth area in advoiding opioid overdose deaths—but we still value the reversal programs that save lives. The current research cannot guide us on this issue, but it is hard to imagine a way patients lose their rights to autonomy even after an overdose once capacity exists.

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Will EMS opioid reversal without a mandatory evaluation lead to more distant unintended consequences, such as eventual death or other harm? Again, the current data do not offer us insight; we do not know if more risky actions and other harms occur because of the ease of reversal of "one mistake" (22). Breaking the cycle of addiction is hard, and the influx of newer or alternative opioids makes self-titration riskier yet seemingly safer because reversal is often nearby.

We are in the middle of (another) opioid addiction cycle and spate of deaths, and we have tools that can be delivered by many to resolve the most immediate threat: suffocation from the agent. How to best resolve the bigger picture will likely require more extensive work; until then, we know for any health care provider delivering naloxone that rapid and complete response has a small later recidivism risk, especially if the offending opioid isn't in an oral, repository, or long-acting form. For others, we must balance our safety worries—small but real—with patient rights once capacity exists.

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ARTICLE SUMMARY

Why is this topic important?

The current standard for US emergency medical services suggests that all patients suspected of opioid overdose be transported to the emergency department for evaluation and treatment.

What does this review attempt to show?

This review suggests that a "treat and release policy" by emergency medical services in the field is a reasonable and safe alternative to a mandatory emergency department visit.

What are the key findings?

The total number of patients who refused transport to the emergency department after an opioid overdose was 3875. The total number of deaths attributed to rebound toxicity was 3. Two of the 4 included studies were conducted more than a decade ago. The pattern of opioid abuse may be different today. In addition, 2 of 4 studies were conducted by emergency medical service systems in European countries, where a physician is a member of the crew and can evaluate and treat patients in the field.

How is patient care impacted?

Implementing a "treat and release" policy would reduce the number of unnecessary emergency department visits. While this strategy appears safe and effective, it should be used with caution because these studies were conducted on different patient populations.

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