

# Project for the introduction of prehospital analgesia with fentanyl and morphine administered by specially trained paramedics in a rural service area in Germany

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**Background:** In patients with serious illness or trauma, reduction of severe pain is a key therapeutic goal of emergency medical service (EMS) teams. In Germany, only physicians are allowed to use opioid analgesics. In the rural EMS area studied, the mean arrival time for paramedics is 8 minutes, 23 seconds, and for the rescue physician between 10 minutes, 30 seconds and 16 minutes, 59 seconds, depending on EMS site. In cases of parallel callouts, rescue-physician arrival times may be considerably longer.

**Objective:** During this project, we assessed the administration of the opioid analgesics morphine and fentanyl by specially trained paramedics with regard to analgesia quality and patient safety.

**Materials and methods:** During the 18-month study period, specially trained paramedics administered morphine or fentanyl to patients with severe pain if indicated and if a rescue physician was not available in time. Besides basic documentation, pain intensity (using a numeric rating scale) and oxygen saturation were measured initially and at hospital handover.

**Results:** During the 18 months, 4,285 emergency callouts were attended to by the 13 specially trained paramedics of the district (total callouts during this period 21,423). In 77 patients (1.8%), fentanyl (n=53/68.8%) or morphine (n=24/31.2%) was administered. Based on the measurements obtained with the numeric rating scale at the start of treatment (7.9) and upon hospital handover (3.3), pain reduction was 4.52 overall (41.5%,  $P<0.001$ ): 4.64 with fentanyl (42.9%,  $P<0.001$ ) and 4.25 with morphine (43.2%,  $P<0.001$ ). None of the patients had an oxygen saturation  $<95\%$  at the time of handover, and no patient developed opioid-induced respiratory depression requiring treatment.

**Conclusion:** The results of this study indicate that the administration of opioid analgesics by specially trained and qualified paramedics is safe and effective.

**Keywords:** prehospital analgesia, paramedics, fentanyl, morphine

## Introduction

One of the basic tasks of emergency medical service (EMS) staff is to treat pain. According to McLean et al,<sup>1</sup> 20% of prehospital patients experience acute moderate–severe pain. Part of prehospital pain management is the administration of effective analgesics. In Germany, only certified physicians are allowed to administer opioid analgesia. The need for adequate analgesia is undisputed.<sup>2</sup> In Germany, patients are entitled to receive emergency care by paramedics within a defined aid period, usually 10 minutes (according to regional protocols) and to be treated by a physician (rescue physician) already at the emergency site within the shortest possible time period.

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Given the low density of emergency physician bases in rural areas, the availability of a rescue physicians is not reliably ensured for all emergency callouts at any time. In addition to greater distances between rescue-physician base and site of emergency, distances between emergency site and nearest suitable hospital are also larger, resulting in increased travel times of rescue physicians. Furthermore, the number of physician-accompanied patient transfers from district hospitals to tertiary-care centers for which no emergency transport vehicles (intensive care vehicle, rescue helicopter) is available is higher in rural areas compared with metropolitan areas.<sup>3</sup>

Consequently, situations in which patients experience severe and very severe pain with no rescue physician readily available to administer adequate analgesia are not uncommon.<sup>3</sup> As such situations occur at statistically predictable frequency, there is a case for introducing defined procedures for the provision of effective analgesia by paramedics. Potent analgesics commonly used in prehospital emergency medicine include the  $\mu$ -opioid-receptor agonists fentanyl and morphine, as well as ketamine, an *N*-methyl-D-aspartate-receptor antagonist.<sup>3–5</sup>

A comparatively low percentage of patients attended to by EMS staff<sup>6</sup> require treatment with opioids ( $\mu$ -agonists) or ketamine for severe and very severe pain (numeric rating scale [NRS] 7–10). In a study by Friesgaard et al, specially trained paramedics administered fentanyl during approximately 80,000 emergency callouts to 2,348 patients (approximately 3%).<sup>3</sup> Apart from treatment of the primary condition, early (and secure) administration of potent analgesics is crucial in the management of patients experiencing severe and most severe pain (NRS 7–10). The aim of our study was to evaluate whether the administration of narcotic analgesics (morphine or fentanyl) by paramedics according to a defined (and trained) algorithm is safe and beneficial for patients.

## Materials and methods

Prior to the start of the project, qualified paramedics with 2 years (Rettungsassistenten) and 3 years of professional training (Notfallsanitäter) were trained in the administration of morphine and fentanyl. Paramedics participating in the project received a self-learning script to be completed within 4 weeks. Subsequently, they attended a 1-day training session (8 hours) with a written and oral final exam. Besides basic pharmacological (pharmacology, indications, administration, dosage) and organizational information (eg, documentation, positioning), the training program included information about the detection and management of complications, with a special emphasis on respiratory depression.

Initially, the project was conducted over a period of 18 months. After data analysis, it was continued for another 18 months. During the total project period of 3 years, no complications related to the administration of fentanyl or morphine by specially trained paramedics occurred, and benefits for patients were demonstrated. Based on these findings, administration of these substances by specially trained paramedics was included in the regional prehospital emergency-management algorithms along with the requirement that defined criteria (eg, no rescue physician available, NRS >6) were met.

For acute coronary syndrome, these treatment algorithms recommend analgesia with intravenous morphine (if NRS >6) at doses of 2 mg every 3–5 minutes (until NRS <3, maximum total dose 10 mg). For injury-related pain, titrated intravenous administration of fentanyl in doses of 0.05–0.1 mg every 3–5 minutes (until NRS <3, maximum total dose 0.3 mg) is specified in the algorithms.

This retrospective analysis of anonymized EMS-callout data was approved by the ethics committee of the Medical Association of Lower Saxony (opinion statement of the ethics subcommittee of the Medical Association of Lower Saxony dated January 12, 2017). Callouts were documented in prehospital patient care reports (Dividok version EPro-01030801). Besides biometric anonymized patient data, NRS scores, and oxygen-saturation levels (time points EMS arrival/hospital handover), oxygen insufflation, choice of opioid analgesic, use of medications (opioids, antiemetics, antagonists), and complications were recorded. For statistical analysis, the software SPSS 24 was used.

## Results

Over a period of 18 months, 4,285 emergency callouts were attended to by the 13 specially trained paramedics of the district (total callouts during this period 21,423). In 77 cases (1.8%), opioid analgesics were administered by paramedics. Patient data and indications are shown in Table 1. For prehospital analgesia, paramedics administered fentanyl in 53 (68.8%) cases (mean dose 0.15 mg, SD 0.07 mg) and morphine in 24 (31.2%) cases (mean dose 4.38 mg, SD 2.58 mg) (Table 2). With a mean NRS score of 7.9 (range 3–10; SD 1.55) before start of treatment and 3.3 (range 1–7; SD 1.25) at handover in hospital, the pain reduction achieved was highly significant ( $P < 0.001$ ) (Table 2, Figure 1). However, no significant difference with regard to pain reduction was found between the morphine group and the fentanyl group (Figure 1). Treatment with opioids had no effect on oxygen saturation measured by pulse oximetry, and no saturation

**Table 1** Patient data and indications

Data/indications	n/Age (years)	Percentage	Initial NRS	NRS on handover
Male	39/51.8	50.6		
Female	38/66.5	49.4		
<b>Total</b>	77	100		
Abdomen	16	20.8	8	3.8
ACS	9	11.7	6.8	2.7
Trauma	52	68.5	8	1.6
<b>Trauma regions</b>				
Pelvis	3	3.9		
Thoracic/lumbar spine	14	18.2		
Upper extremity	14	18.2		
Polytrauma	3	3.9		
Traumatic brain injury	1	1.3		
Chest	1	1.3		
Lower extremity	16	20.8		

**Abbreviations:** NRS, numeric rating scale; ACS, acute coronary syndrome.

below 95% was measured in any patient, with 54 patients (70%) receiving oxygen insufflation.

A total of 54 patients (70.1%) received oxygen insufflation at a mean flow rate of 4.6 L/min (range 2–15 L/min, SD 3.1 L/min). In the remaining cases, oxygen-saturation levels before and during transport and at the time of handover in hospital were higher than 95%. Severe respiratory depression requiring administration of opioid antagonists or measures to secure airway patency was not observed in any of the cases.

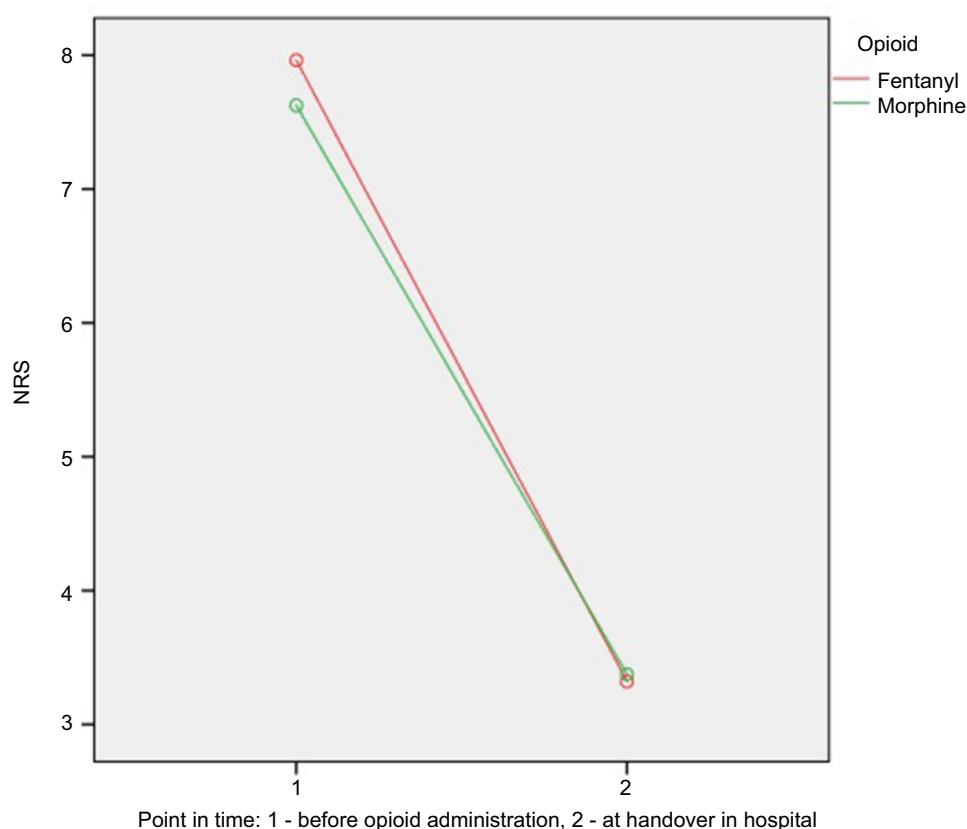
## Discussion

In this study, EMS-callout data collected during a project evaluating the prehospital administration of morphine and fentanyl by paramedics were analyzed retrospectively. Emergency patients experiencing severe and most severe pain

**Table 2** Opioid administration and pain reduction

Opioid	Frequency	Percentage	Mean dose	Initial NRS	NRS on handover
<b>Fentanyl</b>	53	68.8	0.15 mg	8	3.3
<b>Morphine</b>	24	31.2	4.4 mg	7.6	3.4
<b>Total</b>	77	100		7.9	3.3

**Abbreviation:** NRS, numeric rating scale.

**Figure 1** Pain reduction with morphine/fentanyl.

**Abbreviation:** NRS, numeric rating scale.

require immediate and adequate analgesia. Whether effective medication is administered by a certified physician or by a specially trained paramedic under the same safety requirements in situations where no rescue physician is available is of minor importance to patients.

Before the start of the project, no studies and publications regarding the administration of opioids by paramedics in Germany were available. Therefore, we were not able to adopt an existing best-practice implementation strategy. The combination of the strong analgesic potency of  $\mu$ -opioid-receptor agonists with the ability to reverse their effects easily by administering an opioid antagonist is an advantage of these drugs over other analgesic agents. Therefore, the primary question is whether the administration of opioid analgesics by specially trained paramedics in situations where no rescue physician is available results in increased risk for patients.

The paramedics were trained to detect and treat opioid-induced respiratory depression (eg, oxygen insufflation, mask ventilation, antagonist administration). However, the most dreaded complication requiring reversal with naloxone was actually not observed in any patient, neither in our project nor in the significantly larger study by Friesgaard et al analyzing 2,348 cases treated with fentanyl.<sup>3</sup> In our study, the administration of fentanyl and morphine resulted in significant pain reduction (NRS 7.9→3.3, pain reduction 4.52;  $P<0.001$ ). In the study by Friesgaard et al,<sup>3</sup> pain reduction was considerably less (NRS 3) and 60% of patients experienced moderate–severe pain at the time of handover in hospital. Friesgaard et al used fentanyl exclusively and at a lower dose compared with our study (0.09 mg vs 0.15 mg).

Another working group,<sup>7</sup> also administering fentanyl exclusively, demonstrated a reduction in pain intensity by NRS 4.7. These authors also administered fentanyl at a lower dose (0.118 mg vs 0.16 mg in our study), but reported a slightly larger pain reduction compared with our study (NRS 4.7 vs NRS 4.5). However, their study included patients undergoing interhospital transport, which may explain the wider spread (SD 2.7 vs 1.55 in our study).

Morphine was administered by paramedics in the prehospital situation at a mean dose of 8.6 mg in Kill et al<sup>5</sup> and at a mean dose of 8.5 mg (pain reduction by NRS 5.4) in Greb et al.<sup>4</sup> The mean morphine dose in our study was 4.38 mg, resulting in a pain reduction of NRS 4.25. From the studies discussed, it can be concluded that adequate doses of these analgesics result in higher pain reduction, while no serious increase in side effects is to be expected.

Considerations regarding the choice of substances to be used in the prehospital management of severe and most severe pain always include ketamine (in combination with midazolam), because the risk of respiratory depression associated with this drug is lower. In Schempf et al, emergency paramedics administered in 170 cases a combination of 1 mg midazolam and 0.25 mg/kg body weight ketamine for pain (NRS  $\geq 5$ ),<sup>8</sup> with the option of repetition after 10 minutes with 0.25 mg/kg body weight ketamine. Serious side effects (eg, respiratory depression requiring mechanical ventilation) were not observed with this approach. Paramedic-delivered analgesia resulted in a mean pain reduction of NRS  $6\pm 2$  ( $P<0.001$ ) in this study.

In another study evaluating the administration of midazolam and ketamine by paramedics, cumulative doses of midazolam and ketamine were  $1\pm 0.4$  mg and  $27\pm 12$  mg, respectively, resulting in a pain reduction of NRS 5 (from 8 to 3). Likewise, in this study no potentially life-threatening complications related to ketamine/midazolam were observed.<sup>9</sup> From the studies available, it can be concluded that the administration of both ketamine/midazolam and opioid analgesics by paramedics in the prehospital management of severe pain represents a feasible approach with regard to safety and efficacy. In keeping with the Apfel score used to predict postoperative nausea and vomiting, antiemetic agents were administered according to the algorithm for opioid analgesia followed in our EMS area. Against this background, initial analyses found that including the parameter “nausea/vomiting” in this study would not have provided any meaningful information.

We considered it a prerequisite for this project that a physician experienced in emergency medicine was available for advice under a defined telephone number at all times. During the 1.5 years the project was carried out and the subsequent 1.5 years of observation of its practical application, this option was never made use of, even though all emergency paramedics were aware of the availability of this backup. The EMS team debriefing at the end of our study revealed that all paramedics involved felt sufficiently competent in the application of the concept of administering the opioid analgesics morphine and fentanyl.

## Limitations

The data included in this study were collected during a quality-assurance project and analyzed retrospectively. Limitations of this study include the lack of a control group and the limited number of cases, as only patients treated by paramedics eligible for participating in this project were included.

## Conclusion

The treatment of severe and most severe pain with fentanyl or morphine administered intravenously by paramedics according to a defined treatment algorithm is effective and safe.

## Disclosure

The authors report no conflicts of interest in this work.

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