Abstract—Background: Agitated patients are the primary source of injury to patients and providers during ambulance transport. Objective: Our primary hypothesis was that the addition of a chemical restraint agent (midazolam) to a restraint protocol would reduce agitation to a greater extent than a restraint protocol with physical restraint alone. Methods: The local emergency medical services restraint protocol (RP) was implemented on October 1, 2006. It included a form for data collection about each restrained patient. On April 1, 2007, chemical restraint (CR) using midazolam in addition to physical restraints was made available through the RP, and paramedics were educated in its use. Transported patients were divided into pre-CR and post-CR. The post-CR group was split into those who received and those who did not receive midazolam. Agitation was measured on a validated agitation behavior scale with a parametric (Rasch) adjustment. Results: There were 96 patients in the pre-CR group and 522 patients in the post-CR group. Forty-three percent of the pre-CR group and 49% of the post-CR group had a decrease in agitation during transport (NS). Of the 522 in the post-CR group, 110 were physically restrained and given midazolam (21%) and 412 were physically restrained without midazolam (79%). There was a significantly greater decrease in agitation scores (−17 ± 21 vs. −7 ± 17) in the subjects receiving midazolam compared to those who did not. Conclusion: If available, CR is used in about 20% of restrained patients. When CR is used, there is a decrease in the subject’s agitation.

Keywords—injury prevention; prehospital care; patient restraints

INTRODUCTION

The threat and frequency of violence in the prehospital setting makes restraining violent or agitated patients an important issue to emergency medical service (EMS) providers (1–6). Restraining agitated patients in the EMS environment is critical to the safety of both the patient and the EMS provider.

Options for management of the agitated patient are limited and include verbal conversation or physical or chemical restraint. The most common form of physical restraint used is a four-point soft restraint. Physical restraints in the prehospital setting have been studied and have shown potential adverse outcomes such as sudden death presumably due to positional asphyxia, severe acidosis, a state of excited delirium, or a combination of these factors (7–18).

Use of chemical restraint may improve management of severely agitated patients. There is little literature evaluating the safety and efficacy of chemical restraints in the prehospital setting. Most of the literature on chemical restraints involves emergency departments (EDs) as
well as psychiatric emergency services. Two studies looking at chemical restraints in the EMS setting looked at the safety and efficacy of adding chemical restraints to physical restraints but were focused on the pediatric population (19–21).

Our hypotheses were the following: 1) the addition of a chemical restraint agent (midazolam) to a restraint protocol would reduce agitation to a greater extent than a restraint protocol with physical restraint alone; and 2) certain variables can predict the use of chemical restraint by paramedics, when it is available.

**METHODS**

**Study Design and Timeline**

This is a before-and-after quasi-experimental study of the effect of the addition of chemical restraint to a restraint protocol (RP). The study was conducted in collaboration with a large urban private ambulance service EMS provider that responds to over 80,000 calls per year. The single provider transports > 30,000 patients per year to area hospitals in the city limits. The city has a population of approximately 500,000 people.

The Agitated Behavior Scale (ABS) is illustrated in Table 1. Subjects were included if they were restrained by EMS personnel and they had a pre- and post-restraint agitated behavior score recorded on the data form. The protocol and data collection form were developed administratively by an expert panel of three emergency physicians and three to four paramedics. It was then rolled out for the paramedic service, and the introduction included a very standardized slide set and educational goals on its use.

The pre-chemical restraint (pre-CR) phase of the study was conducted from October 1, 2006 to April 1, 2007, when the local EMS RP without chemical restraints was implemented, with education of prehospital personnel on the proper use of physical restraints as well as the restraint protocol. Along with routine information, a data collection form was introduced that included questions about the following: reason for restraints, circumstances of the incident, causes of patient behavior, and patient and provider injuries. An ABS score was completed at initial contact and at final patient turnover at the ED. No medications were available for patient sedation during the turnover phase.

The post-chemical restraint (post-CR) phase of the study was conducted from April 1, 2007 when chemical restraint (CR) using midazolam was added to the restraint protocol (Appendix), until October 1, 2008 when the study was terminated. Midazolam 5 mg intramuscularly (i.m.) or 1–2 mg intravenously (i.v.), with an optional repeat dose to a maximum of 2.5 mg i.v., was used. All doses were reduced by half if comorbid conditions were present, including age > 65 years, congestive heart failure, or chronic obstructive pulmonary disease (COPD). All patients receiving CR were also placed in physical restraints. The paramedics were directed to use CR whenever they felt they needed it and asked to document the reason for use on the data collection form.

The primary comparison was between the pre-CR group and the entire post-CR group. It was meant to simulate the comparison of an EMS service with CR vs. an EMS service without the availability of CR. The purpose was to determine whether the addition of CR to the protocols made any difference in the overall observed agitation ratings.

The second comparison was on a-priori-determined subgroups within the post-CR group. The post-CR group was split into two subgroups: one of patients who received physical restraints without the use of CRs (post-NOMID), and one of patients who received both physical and CRs (post-MID). These two groups were compared for differences in results obtained with and without the use of CR. Questions about CRs were added to the data collection form and paramedics were again educated on the use of the RP and CR. Data sheet questions were used in the prediction model to determine the reasons for making the decision to use CR. A flow chart of the subjects entered and the phases of the study is shown in Figure 1.

**Measurement**

The ABS developed by Corrigan’s team was used to determine the efficacy of the intervention (22–24). Corrigan has been able to demonstrate that the scale has excellent content as well as concurrent and construct validity. They showed that inter-rater correlations ranged from 0.7 to 0.92 for the total score. The scale consists of a 13-question validated scale for agitation. Each question could be rated 1–4, for a total possible score ranging...
from 13 to 52. Our main outcome measure was the change in ABS scores at final release compared to initial contact (Table 1). Based on previous work, we categorized the degree of agitation clinically using the grouping values of 21 or less as no agitation, 22–28 as mild agitation, 29–35 as moderate agitation, and >35 as severe agitation (25).

Statistics

Bogner et al. constructed an interval scale based on the ABS using rating scale analysis, or Rasch analysis, which converts raw ABS scores into a scale with interval properties, allowing for parametric statistical testing. This Rasch adjustment was used to ensure appropriate test statistics for ABS scores (23). Data were analyzed using analysis of variance, t-test, and Wilcoxon signed rank sum for paired comparison of ABS scores. The power of the study was 80%, to show a difference of 20% between groups with 95 patients per group.

For the logistic model, only subjects entered after the availability of CR were included (post-CR). The outcome variable for the model was whether or not CR was given. Predictor variables used in the model included age, gender, reason for restraint, cause of behavior requiring restraint, initial ABS score, and injury or assault to the patient or provider before restraint use. These were first compared with CR using univariate contingency tables. Variables significant by univariate analysis were then entered into a multivariable model and goodness of fit was determined. Predictor variables were used to construct a model that predicted the use of CR during the post-CR phase only. Variables were entered into a multivariable model if they were significant ($p < 0.05$) on univariate analysis. Adjusted odds ratios and 95% confidence intervals were calculated for variables with $p < 0.05$. A Hosmer-Lemeshow statistic was used for goodness of fit (SPSS 15.0, SSPS Inc., Chicago, IL).

Human Research Review Committee

The study was an evaluation of the data collected only and was approved under an expedited protocol by our human research review committee.

RESULTS

There were 618 subjects entered into the study; 65% of the study subjects were men. The average age was 35 ± 15 years. Figure 1 shows the breakdown of study groups. During the study period, none of the subjects had major adverse events while under the care of EMS.

Overall Assault or Injury Analysis

Provider injuries occurred in 189 cases (31%). These occurred while restraining the patient in 22 cases (11%). The injuries required medical intervention in 41 (22%) and led to lost days of work in 36 cases (19%).
were no significant differences in injuries between the pre-CR and post-CR groups, as shown in Table 2.

Post CR Analysis

CRs were used in 110 of the cases in the post-CR group. The rationale for use of CR was the following: mechanical restraint was ineffective in 95 (86%), the patients were struggling against physical restraints in 100 (91%), the paramedic was unable to adequately assess the patient in 99 (90%), and the CR was needed to facilitate application of physical restraints in 29 (26%). Although midazolam doses ranged from 2.5 mg to 10 mg, routes of administration were either i.m. or i.v., and there were no significant relationships between either dose or route and decrease in agitation.

There were significant differences in provider injury, initial ABS score, change in ABS scores, and the percentage of subjects with a decrease in agitation between the post-NOMID and the post-MID groups. These results are shown in Table 3.

DISCUSSION

Since the formation of EMS through the National Highway Safety Act of 1966, there always has been a concern for patient safety and for EMS personnel safety, especially with the agitated patient. The threat and frequency of violence in the prehospital setting makes the restraining of violent patients an important issue to EMS providers (1). When surveyed, anywhere from 61% to 92% of EMS providers have reported being assaulted on the job (5,6). In one prospective study, violent encounters occurred 4.5% of the time. In the same study, factors were identified that might predict violent episodes, such as sex of the patient, age of the patient, and time of day (4).

Educating the providers in alternative methods of restraint before using CR was an important part of the study. Due to this high rate of on-duty assaults, an emphasis has been placed on educating prehospital providers on how to manage the violent patient. Options for management of the agitated patient are limited and include verbal de-escalation, or physical or chemical restraint. It is recommended that EMS providers approach the patient in a non-threatening manner and attempt to communicate...
with him in a calm voice while avoiding eye contact. If this initial approach, followed by attempted verbal de-escalation, is unsuccessful, then physical restraints have typically been applied when the patient presents a risk of harm to themselves or to others. EMS providers must consider a broad differential diagnosis and have a variety of restraint options available to them to avoid harming either the patient or themselves. One study found multiple factors that correlated with assaults on EMS personnel, such as: contact between midnight and 6:00 a.m., female gender, violent behavior, patient injured under supervision, patient arrested, and a perceived need for CR by EMS personnel (27). Given the limited options for EMS providers to use with agitated patients, it is hypothesized that targeting patients exhibiting any of these factors may prevent injury.

The most common form of restraint used is a four-point soft restraint. Physical restraints in the prehospital setting have been studied(28,29). Studies on physical restraints show adverse outcomes such as sudden death, presumably due to positional asphyxia, severe acidosis, a state of excited delirium, and a combination of these factors (8–14,17,18,30). EMS providers were carefully educated in these concepts before being given access to CR.

We found that, when available, CR was used in about 21% of transported patients who were restrained. We were unable to find any other studies evaluating this parameter. We also could not find any other studies looking at why the providers chose CR in the cases in which they did, or why they avoided it in other cases.

In our study, the simple addition of CR to our restraint protocol did not change patients’ agitation levels at hospital presentation. However, CR was used in subjects with significantly higher ABS scores. We did not expect the initial ABS scores to change but did expect to see a decrease in final ABS scores with the addition of CR. The lack of a significant difference may have been due to the small percentage of patients who received CR. Therefore, the second phase of the study, in which we compared specifically those who received and those who did not receive CR, became important in understanding the effect.

Subjects who received CR were those with significantly higher starting ABS scores than those restrained patients not receiving CR (39 ± 8 vs. 34 ± 9; difference = 5, 95% confidence interval 3.1–6.9), therefore leading to an overall significant difference in the change

<table>
<thead>
<tr>
<th>Table 4. Degree of Agitation Based on ABS Score Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-CR (n = 96)</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td><strong>Initial Agitation Level</strong></td>
</tr>
<tr>
<td>No agitation</td>
</tr>
<tr>
<td>Mild agitation</td>
</tr>
<tr>
<td>Moderate agitation</td>
</tr>
<tr>
<td>Severe agitation</td>
</tr>
</tbody>
</table>

ABS scores defined as follows: 22 or less = no agitation, 23–28 = mild agitation, 29–35 = moderate agitation, and > 35 = severe agitation. Differences between initial and final agitation levels were significant at p < 0.01 for all three groups.

ABS = Agitated Behavior Scale; CR = chemical restraint.

<table>
<thead>
<tr>
<th>Table 5. Univariate Analysis of Variables Considered in Predicting Use of CR Medication (Midazolam)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variables Considered</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>Age (split at &lt; or &gt; mean of 35.0)</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Reason for restraint</td>
</tr>
<tr>
<td>Prevent injury to patient</td>
</tr>
<tr>
<td>Prevent injury to EMS provider</td>
</tr>
<tr>
<td>Potential life or limb threat</td>
</tr>
<tr>
<td>To facilitate assessment</td>
</tr>
<tr>
<td>Verbal and hands-on methods were ineffective</td>
</tr>
<tr>
<td>Apparent cause of behavior</td>
</tr>
<tr>
<td>Drugs</td>
</tr>
<tr>
<td>Medical</td>
</tr>
<tr>
<td>Trauma</td>
</tr>
<tr>
<td>Psychiatric</td>
</tr>
<tr>
<td>High pre-restraint agitation score</td>
</tr>
<tr>
<td>Responder injury or assault during the restraint process</td>
</tr>
</tbody>
</table>

CR = chemical restraint; EMS = emergency medical services. |  |  |  |  |  |

<table>
<thead>
<tr>
<th>Table 6. Logistic Model Results Showing Variables that Predict Use of CR by EMS and the Increase in Odds of Using CR Based on the Variable Being Positive*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variables Entered</td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td>Reason for restraint</td>
</tr>
<tr>
<td>Potential life or limb threat</td>
</tr>
<tr>
<td>To facilitate assessment</td>
</tr>
<tr>
<td>Verbal and hands-on methods were ineffective</td>
</tr>
<tr>
<td>Responder injury or assault during the restraint process</td>
</tr>
</tbody>
</table>

CR = chemical restraint; EMS = emergency medical services; OR = odds ratio; CI = confidence interval.

* The model was developed with significant variables from the univariate analysis.
in ABS score between those who did and those who did not receive CR, even though overall, the final ABS scores were the same. Paramedics were more likely to use chemical sedation agents for life and limb threats, to facilitate assessment, after an assault on the responder, and for patients who started with higher ABS scores.

We did not observe any adverse outcomes due to midazolam over the 18-month study period. Due to midazolam’s rapid onset (minutes), even with i.m. injection, and short half-life (1.5–2.5 h), it is a good option for chemical sedation in the prehospital setting. One study comparing i.m. midazolam, haloperidol, and lorazepam in restraining violent and severely agitated ED patients found that midazolam achieved more rapid control of patients than lorazepam or haloperidol (31). There has been a reluctance to add protocols for CRs with benzodiazepines due to the potential side affects, especially given that alcohol ingestion is not always known before CR on scene. Our results support the use of midazolam for CR by EMS.

This study was unique in that the measure of agitation was a validated scale that paramedics completed on restraining a patient and then again on presentation to the ED. The validated ABS scale was used to reduce provider variability on scoring. We also noted that there were no age or gender differences between subjects who received CR and those who did not.

This study is also unique in that it looked at safety of CR use, which is not well described in the EMS literature. Most of the literature on CRs comes from EDs and psychiatric emergency services. There is little literature evaluating the safety and efficacy of CRs in the prehospital setting. Only two studies looking at CRs in the EMS setting looked at the safety and efficacy of adding CRs to physical restraints, but they were focused on the pediatric population (20,21).

Limitations

Although the ABS score is validated in other environments, it has never been implemented in the EMS setting. It is possible that it does not clearly measure agitation in the out-of-hospital environment. Some of the questions, such as pulling at tubes, are more clearly aimed at an inpatient environment. Also, although EMS personnel found the ABS scale applicable and easy to use, it would be valuable in the future to validate a shortened ABS scale to increase the ease of use. Although the score reflects clinical agitation in a number of environments, this is the first test of it in the prehospital setting.

Another limitation may be the subjectivity between EMS providers on when CRs should be employed. We could not control the use of CR because this was our outcome variable. Provider variability would be difficult to assess without a much larger study sample size. CR may be used with lower initial ABS scores as EMS providers become more comfortable with the use of CR. We also did not capture reasons why the paramedics did not use CR in the cases where it was available but not used, or vital sign changes that may be related to CR use, or decisions against CR use.

In addition, the paramedics were unblinded to the medication and were also the ones doing the scoring on the agitation scale. This could have introduced a bias into their results. Due to the nature of the study, paramedics may have been more reluctant to use sedation drugs because they knew they were being observed on completion of the form, as a type of Hawthorne effect. It is also possible that in some of the cases with injury, the paramedics did not complete a restraint form.

Adverse events and safety of CR for the patients was difficult to assess in this study. The few adverse events that were recorded were minor abrasions, contusions, and small lacerations in < 2% of the cases. One case of a lost i.v. line with blood splatter was recorded in a subject receiving CR. Because the patients receiving CR were the most agitated, it is difficult to assess the causality of these injuries, and their numbers were too small for statistical analysis. There were no paramedic comments on changes in patient condition due to the use of sedation.

Our numbers were too small to determine differences in paramedic injuries or assault due to the restraining process. Most of the paramedic injuries were being spit on, punched, kicked, or scratched. We were not able to determine which of these specifically occurred during the restraining process and whether they were decreased after the use of CR. They might actually be higher in the post-MID group because they could be the reason that the paramedic chose to use CR on some patients.

In addition, there is no information on excluded patients. We do not believe there were any restrained subjects missed because it is required that our personnel complete the form for all cases of restraint use, and the service did not report any missed cases during the study period. We could have missed some cases in which the subject was severely agitated but EMS was too busy with the patient to complete the form.

We did not perform an outcome analysis to evaluate the effects of CR, such as effect on length of hospital stay, and adverse outcomes related to CR after final contact with EMS providers. Too many other variables play into the outcome of these patients during their stay in the ED and hospital that made it impossible to tie the outcomes seen to the use of CR by EMS providers.

CONCLUSION

If available, CR is used by EMS personnel in about 20% of restrained patients. The availability of CR in an EMS
protocol does not diminish overall agitation among patients transported. However, when CR is used, there is a decrease in patient agitation. Paramedics were most likely to use chemical sedation agents for life or limb threats, to facilitate assessment, after an assault on the responder, and for the most agitated patients.

REFERENCES


APPENDIX: PROTOCOL USED IN THE STUDY

Chemical Restraint protocol

Chemical Sedation for the Agitated and Delirious Patient.

Designation of Condition: Chemical sedation should be reserved for those patients who remain violently agitated, despite verbal de-escalation attempts and physical restraint, and in the judgment of the paramedic, pose a continued risk to themselves or to the EMS provider.

Chemical restraint is a measure to be employed as a last resort and should be used only after all other less invasive means of control have been exhausted. Midazolam should never be administered as a “convenience” measure. Although many patients remain uncooperative and verbally abusive after physical restraint, most of these patients usually DO NOT necessarily require mandatory chemical sedation. If you are in doubt as to whether chemical restraint is indicated, contact MCEP.

Field Treatment:

☐ Assess patient and determine that he/she remains uncooperative and violently agitated, despite verbal de-escalation attempts and physical restraint maneuvers. (Remember to record these observations later, including the ABS scale)
☐ If possible, obtain set of vital signs
☐ Administer Midazolam: 5 mg IM (administration into the deltoid muscle is preferred). Elderly patients (age > 65), patients with known COPD, and patients on medications that enhance midazolam’s effects (see below) should receive half of the normal adult dose (2.5 mg IM). Consideration for lower dosage (< 5 mg IM) should be given for patients with a recent known co-ingestion of opiates or large amounts of alcohol, and small patients (< 50 kg).
Repeat IM dosing will require MCEP approval.

In order to prevent injury or inadvertent needle stick to the patient or the provider, DO NOT attempt to administer the medication prior to obtaining secure physical control of the patient.

If an IV is in place, Midazolam may be administered via IV route. If given intravenously (IV), it should be given in 1–2-mg increments every 2 minutes up to a total dosage of 2.5 mg. Administration of more than 2.5 mg (IV) will require on-line MCEP approval.

**CAUTION:**

A. Inappropriate use of either physical or chemical restraint (use that does not conform to the designation of condition) may be considered an infringement on the patient’s civil rights. EMS providers must be aware of risk/benefit of restraint and the need for appropriate documentation.

B. Midazolam is a potent respiratory depressant, especially when given intravenously. Most episodes of respiratory depression or arrest can be managed with bag-valve-mask.

C. Drug interactions that prolong the respiratory depressant effects of midazolam include: Antifungals (e.g., ketoconazole and fluconazole), HIV Antiviral drugs (protease inhibitors and reverse transcriptase inhibitors), macrolides antibiotics (e.g., erythromycin) and certain anti-depressants (SSRI inhibitors).

D. Midazolam is also a cardiovascular depressant and may cause hypotension. It has been noted to cause mild to moderate drops in blood pressure, especially in patients who are volume depleted

**Contraindications:**

1. Administration to patient prior to attempts at less invasive means of behavioral control.
2. Allergy to benzodiazepine
3. SBP < 90 mm Hg.
4. Unable to maintain airway, or anticipation that airway control would be very difficult. (e.g., significant facial or airway trauma)
5. Pre-pubescent minors

**Mandatory Post Medication Procedures:**

A. Obtain and record vital signs every 5 minutes
B. Continuous monitoring of heart rate (HR) and oxygen saturation
C. Completely fill out restraint form and agitation scale
D. Be prepared to manage the airway
E. Be prepared to manage drops in blood pressure.
ARTICLE SUMMARY

1. Why is this topic important?
   Injuries to patients and providers during Emergency Medical Services (EMS) transport is a major concern of prehospital delivery services.

2. What does this study attempt to show?
   This study evaluates a protocol that adds a chemical restraint agent to the routine management of violent and agitated patients and evaluates the effect using a validated agitation scale.

3. What are the key findings?
   We found that chemical agents are used often with restrained patients when available to the prehospital providers, and that the addition of chemical restraints leads to a decrease in agitation among patients receiving the agent.

4. How is patient care impacted?
   This could impact the ability of EMS personnel to use chemical agents in field care to decrease the risk of injury to the providers and their patients.