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## Clinical Communications

### EVIDENCE-BASED TREATMENT OF PSYCHIATRIC PATIENT

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**Abstract**—There is controversy concerning the proper treatment of psychiatric patients in the emergency department. Emergency physicians commonly use physical or chemical restraints or both in the course of treating psychiatric patients. This review applies the rigors of an evidence-based evaluation of the literature concerning the choices of treatment for these patients. © 2005 Elsevier Inc.

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#### INTRODUCTION

Treatment of psychiatric patients in the emergency department (ED) is primarily conducted with physical and chemical therapy. The approach to treatment modalities is fraught with problems, with little concurrence in the literature. The purpose of this collective review is to examine the evidence for the treatment of psychiatric patients in the ED to assist in treatment decisions made by emergency physicians (EPs).

All literature presented in this review contains the level of evidence according to the U.S. Preventive Services Task Force (1). The evidence is graded from levels I through III. Level I indicates randomized controlled trials; level II includes controlled trials without randomization, cohort or case controlled trials and multiple time series with or without intervention; and level III is expert

opinions. Case reports and one physician's opinion are considered without evidence.

Medline was queried for all the English language articles related to medical clearance of the psychiatric patient for the last 30 years using the key terms "treatment," "psychiatric patients," and "emergency department". All studies that were performed in the ED were referred. Articles were screened for their relevance to Emergency Medicine, research technique, and setting of the study. Review articles and those providing personal opinions were screened out from further review.

There are three reasons to treat psychiatric patients in the ED: to improve patient cooperation, to reduce patient agitation, and to begin the therapeutic process. Some patients are unwilling or unable to communicate their history and cooperate with the emergency personnel. Although historical information may be obtained from the patient's family or friends, bystanders, police and ambulance personnel, understanding the patient's perspective concerning his presentation to the ED is essential. Sometimes it is only after the administration of anti-psychotic medications or anti-anxiety agents that the patient will provide a useful history. Studies concerning the ability of medications to render patients' behavior more cooperative are lacking.

Psychiatric patients are frequently agitated in the ED and may constitute a threat of injury to themselves or others. The number of psychiatric patients who present with assaultive behavior at psychiatric facilities has been

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found in observational studies to be 4–60% (level II) (2–8). The number of actual violent episodes in EDs has been studied in Britain but has not been well studied in the United States. British studies have reported violent episodes at a rate of 2% on a daily basis and 12% on a weekly basis in accident and emergency departments (level II) (2,3). A survey study of ED medical directors found that a number of EDs have violence problems (level II) (4). Forty-one of the 127 surveyed institutions reported one verbal threat a day, and 23 report a weapon threat each month. Although there are estimates of the number of true violent episodes in EDs, breakdown into the numbers of untreated psychiatric patients causing these problems is not known.

The third reason to treat patients in the ED is to begin the treatment process early in a patient's presentation. The differentiation in the ED between the uses of medications for restraint vs. treatment is somewhat obscure. The use of psychotropic medications as an intervention after an assessment of the patient and a plan of care intended to improve a patient's underlying condition is considered treatment. In contrast, the use of these medications without such an assessment and plan would be considered a restraint (9). Unfortunately, no level I or II studies have been found that examine the indications for treatment of the psychiatric patient in the ED.

Few studies have been done to determine whether restraint (either chemical or physical) or seclusion is preferable. A survey of 20 psychiatric medical directors, conducted by the Association for Emergency Psychiatry, found that 14 of 20 respondents said their protocol was to physically restrain patients and medicate them before a medical work-up (level III) (10). This association is, unfortunately, devoid of emergency physician representation.

## PHYSICAL RESTRAINTS

Physical restraints are commonly used in the ED. Studies have examined the purposes and indications for physical restraints in the ED. The reason to restrain patients on the medical floors may be different than those found in the ED. Studies on medical units provide contradictory results (level II) (11–16). Robbins and others used an average of two restraints on 17% of patients in an acute medical unit to prevent patients from getting out of bed (level II) (11). Neufeld et al. found a decrease of serious injuries with a reduction of restraint usage (level II) (13). Although the numbers of restrained patients in the ED has varied from 7–25%, the indications for physically restraining a patient are not well studied (4,17–23). Indications for restraints have been studied in one observational ED study. According to this study, patients were

restrained for violent and disruptive behavior (29.2%), agitation (25.2%), being suicidal (16.8%), being homicidal (7.4%), alcohol or drug intoxication (7.4%), confusion (6.4%), catatonia (1.7%), or dementia (1.7%) (level II) (26).

Both the Health Care Financing Authority (HCFA) (now termed the Center for Medicare and Medicaid Services) and the Joint Commission for Accreditation of Health Care Organizations (JCAHO) have requirements for the use of restraints (25–29). HCFA has standards for ordering, assessing, monitoring, reevaluating, and terminating restraints (25–27). JCAHO standards TX 7.1 through TX7.1.16 regulate the use of seclusion and restraint for all behavioral health settings (28,29). JCAHO based their requirements on a report in the Hartford Courant that found 142 deaths from restraints in psychiatric hospitals from 1988–1999 (no evidence) (30–32). Alternatives to restraints, promoted by JCAHO and others, have not been evaluated in the ED setting.

There are many anecdotal studies in non-acute care environments describing the complications concerning the use of physical restraints (level II and no evidence) (33–63). Many of these studies were performed in nursing homes, psychiatric or medical facilities, but none was conducted in the ED. Complications of restraints included problems of elimination, aspiration pneumonia, circulatory obstruction, cardiac stress, skin breakdown, poor appetite, dehydration, and accidental death. Cocaine use has been found to be associated with restraint deaths (no evidence) (61–63). Stratton et al. reported two cases of death secondary to hogtie (hobble) restraints (no evidence) (62). Hicks and colleagues described five cases of patients who had cardiovascular collapse while being restrained using this technique (no evidence) (63).

Few data about restraint complications exist in the Emergency Medicine setting. In a survey study of medical directors of Emergency Medicine residency programs, 13% of the 127 respondents reported significant injuries during the restraint process over the last 5 years, including fractures and head injuries (level III) (4). Only one prospective trial of complications can be found in the literature (level II) (28). This study found that the rate of complications was 5.4%, without major injuries or mortality. Twelve complications were reported: getting out of restraints (6), injuring others (2), vomiting (1), injuring self (1), injuring another (1), and hostile or increased agitation (1). However, this was a one-hospital study performed after the initiation of the new standards by HCFA and the JCAHO.

Although the rate of complications may be related to the number and type of restraints, the age of the patient, the application process, and the underlying medical condition, studies analyzing such correlations are limited. Emergency physicians rarely consider the psychologi-

cally adverse effects of demoralization and loss of self-esteem found by Rosen and DiGiacomo (no evidence) (49). Although most would agree that restraint use should be limited, some believe the risk of not restraining potentially dangerous or actively suicidal patients outweighs the preference to restrict its use. A study comparing numbers, types and positions of restraints would be valuable.

## CHEMICAL RESTRAINTS

In the ED, there is an ill-defined difference between the use of psychotropic medications as an intervention after patient assessment and plan of care, and the use of these medications to control behavior without an assessment and treatment plan. The literature demonstrates a paucity of good ED studies concerning the use of chemical restraints. Most studies on this topic found in the medical literature were done by psychiatric emergency services, with few comparative trials of different medications or combinations of medications.

The choice of anti-psychotic or anti-anxiety agents depends upon the patient's medical or psychiatric diagnosis. Seventeen of 20 psychiatric medical directors stated that it is very difficult to determine the etiology of violent behavior, making the assessment even more uncertain (level III) (10). The current opinion is based on a consensus of documents by emergency psychiatrists, without input from emergency physicians (9). Allen et al., in their consensus document, recommend that patients with a general medical etiology be given high-potency conventional anti-psychotics, benzodiazepine, or a combination of both. Patients with substance intoxication should be given benzodiazepine. Patients with primary psychiatric disturbance should be given high-potency conventional anti-psychotics, benzodiazepine, or a combination (level III) (9). Many times in the ED there is difficulty in determining the diagnosis to determine the proper medication to be used.

The choice of administration of these medications, i.e., whether orally, intramuscularly or intravenously, also has not been well studied in the ED setting. Hoge and others performed a prospective study of the refusal of oral treatment with anti-psychotic agents on a sample of 1434 psychiatric patients at four acute inpatient units. They found that 103 of the 1434 (9.3%) refused oral medications. Most of these patients were older and from a higher social class and fewer were on anti-parkinson medications (level II) (64).

The choice of medication also may be influenced by the time of onset of the medication. Few studies are found that have assessed the time of onset for different medications given by varying routes of administration.

Haloperidol given intravenously was reported as "fast," and given intramuscularly (i.m.) was noted to need 30–60 minutes (9). Benzodiazepine intramuscularly was found to require 15–30 minutes; orally it was "rapid." The consensus document concluded that the therapeutic difference between i.m. and oral delivery is relatively minor, and that there was little difference in effectiveness accounted for by dose or kinetics (level III) (9). A survey of 20 psychiatric medical directors found that 15 of 20 respondents stated that i.m. was the most common route, and 11 of 20 used haloperidol plus lorazepam, with or without benzotropine i.m. (level III) (10). In one ED study in which 110 patients were given haloperidol, 19 patients received it i.v. and 7 received it orally. In this trial, disruptive behavior in 83% of patients was eliminated in 30 minutes. In 15% the effects were sub-optimal, and no effect was found. No correlation between route and time of onset was found in the study (level II) (65).

The optimal dosing of haloperidol has not been well studied. In three studies of multiple dosing of haloperidol, 7.4–41 mg of haloperidol produced 36–45% improvement. A lesser dose produced an intermediate response (level II) (66–68). The use of benzotropine in these trials has not been well documented. Baldessarini and others determined a dose response curve based on these studies. They found that the single dose of 7.5–10 mg of haloperidol would produce the most immediate effect with the least amount of complications (69). In another analysis of studies using haloperidol, Donlon and others examined the literature, finding 650 patients who received from 1–30 mg i.m. The patients required from one to four injections every 30 to 60 minutes, a dosage that was reported as rapidly effective for agitated and belligerent patients (level II) (5).

The determination of which agent or agents to use in the ED has likewise not been well studied. In an analysis of 22 studies, only three were performed in an ED (70–72). In a review of all three studies, the use of all medications, including haloperidol, lorazepam, loxapine, chlorpromazine, molindone, phenobarbital, amobarbital, droperidol, flunitrazepam, and combination was reviewed (9). The authors stated, "It would appear that lorazepam alone is superior to haloperidol for agitation." They found that "Combinations studies did not use comparable doses but did demonstrate that the combination is better in the first few hours."

Most of the ED studies have used droperidol, haloperidol, lorazepam, or some combination of these agents (70–72). These studies evaluated both the effectiveness of these agents and their side effects. The major noted complications were sedation, dystonic reactions, and hypotension. Haloperidol was administered to 136 patients to control behavior; 18 during resuscitation, 40 for mental health, 90 for intoxication, and 23 with head trauma.

**Table 1. Treatment Process**

Process	Description	Evidence (Reference)	Comments
Reason to treat: Improve patient cooperation	May increase ability to assess the patient	None	Uncooperative or agitated patients may benefit from early treatment
Reason to treat: Reduce patient agitation	May reduce the risk of assaultive behavior	Observational trial (5–8)	First obligation is to keep patient and staff safe
Reason to treat: Begin the therapeutic process	Use of therapeutic assessment and plan	Expert opinion. No trials (9)	Chemical treatment may not be restraint if part of a therapeutic plan
Process of physical restraint application	Number and type of restraints and application process	None	Need for studies to determine the best means to prevent and apply physical restraints
Physical restraints Complication rate	JCAHO and CMS found 142 deaths from restraints (27–30)	5.4% found in only one ED study (24)	Unlikely major complications with its use
Choice of chemical agents in medical, psychiatric and substance abuse populations	Medical and psych: anti-psychotics, benzodiazepines or combination Substance abuse: benzodiazepines	Expert opinion (9)	Consider atypical anti-psychotic agents to reduce complication rate
Choice of chemical agents in special populations	Pregnancy: conventional anti-psychotics Children: benzodiazepines or antihistamines Elderly: atypical anti-psychotics	Consensus studies (9,78,79)	Studies are not performed in these populations
Route	Most patients accept oral	Prospective trial on psych floor (64)	No trials in the ED comparing oral, sublingual or i.m.
Typical anti-psychotics	Haloperidol frequently used in the ED	Multiple trials of the use in the ED (68–72)	Optimal dosing not well studied
Atypical anti-psychotics	Both Ziprasidone and Olanzapine have indication for acute agitation	Studies rarely done in the ED (76–79)	Fewer side effects and less sedation than typical anti-psychotics
Anxiolytics	Lorazepam can be used i.m. or oral	A few studies infer that lorazepam is superior to haloperidol (9,70–72)	Obvious problems with sedation and respiratory depression in high dose
Combination	Combination of haloperidol and lorazepam may be superior to haloperidol alone	Some reasonable studies (9,10,71)	Problems with sedation side effects may increase with combinations
Physical and chemical	Most would add chemical restraint to patient already physically restrained	One study did not find increased complication rate with combination (24)	Probably safe
Seclusion	Used as alternative to imminently violent patients.	One study found the seclusion use in 61% of the EDs (4)	Reasonable alternative to chemical or physical restraint.

Four patients had complications, including hypotension (level II) (65). In a study comparing haldoperidol and droperidol, 30 patients were given haloperidol, and 35 droperidol (70). Intramuscular droperidol decreased combativeness significantly more than i.m. haloperidol at 10 and 30 minutes. Intravenous administration showed no significant difference between the two drugs. Sedation was not examined in this study. Hypotension was found with equal doses of both drugs in eight patients (level II)

(70). A review of the process of the rapid tranquilization method enrolled 98 agitated, aggressive, undifferentiated patients over 18 months, who were given intramuscular lorazepam (2 mg), haloperidol (5 mg), or combination. Haloperidol produced more Extra Pyramidal Symptoms (EPS) symptoms than the other medications. There was no difference in sedation among the groups; however, the study did not evaluate blood pressure between groups (level II) (73). In a large retrospective study of 2468

patients in 1998, 82% were treated for agitation, and smaller numbers were treated for pain, vomiting, headache and anxiety. There were 96 with transient hypotension, 40 with dystonia, three with seizures, two with respiratory arrests, and one with a cardiac arrest (level II) (72). It is interesting to note that one small study demonstrated a marked increase in violent behavior with high potency (haloperidol) vs. low potency neuroleptics (chlorpromazine) (level II) (74).

Although many side effects of the anti-psychotics are problematic, problems with droperidol have resulted in FDA "black box" labeling. Cases of QT prolongation torsades de pointes have been reported in patients receiving INAPSINE at doses at or below recommended doses. Some cases have occurred in patients with no known risk factors for QT prolongation, and some cases have been fatal (75).

The use of the atypical anti-psychotics in the ED is very limited. Olanzapine has recently received FDA approval for the treatment of acute agitation associated with both schizophrenia and bipolar mania (level I) (76,77). Another drug manufacturer has received an indication from the FDA for the use of intramuscular ziprasidone for the treatment of acute agitation in the schizophrenic patient. Use in other types of agitated patients has not been FDA approved. Ziprasidone can be used orally or i.m., and is unrelated to phenothiazine or butyrophenone. It reportedly has a low incidence of dystonia and hypotension, but there is a concern about QT prolongation (77,78). One drug company-sponsored trial found that ziprasidone was more effective than haldoperidol for the acute treatment of agitation, but this was a study of patients admitted to a psychiatric unit (level I) (79). Hypotension was found with equal doses of both drugs in eight patients. Risperidone, another atypical anti-psychotic, given orally, is indicated for treatment of schizophrenia. It has an infrequent incidence of dystonia and hypotension. Risperidone does not have an indication for acute treatment of agitation (78).

The use of medications in special populations such as pregnant women, children, the mentally challenged, and the elderly has not been studied. Consensus documents have noted that the use of high-potency conventional anti-psychotics lacks known teratogenicity in pregnant women (level III) (80). In children, low dose benzodiazepine or antihistamine or the anti-psychotics (risperidone or olanzapine) are recommended (level III) (9). Mentally challenged patients, as well as the elderly, should be given atypical anti-psychotics (level III) (9).

In an interesting study making a case for "rapid neuroleptization," Anderson and others gave 24 patients with acute functional psychoses treatment with i.m. haloperidol over 3 hours (level II) (67). Almost

complete remission of thought disorder was found in 11 patients. Patients were given 15–45 mg; EPS was found in eight patients, and blurred vision in four. The study raised the feasibility of outpatient management in the ED for the treatment of acute psychotic episodes.

## SECLUSION

Seclusion had various definitions but most would agree that seclusion places a patient in a room with a locked door (level III) (81). Allen et al.'s consensus document found that seclusion is used as an alternative to restraint for imminently violent patients (level III) (9). A search of the literature concerning the use of seclusion in the ED elicited one limited study. Lavoie et al., in their study of ED directors, documented the use of seclusion by 61% of the 127 respondents to their violence survey (level II) (4). Outside of the ED, seclusion had been used commonly on the psychiatric and adolescent units. The use of seclusion has varied from 4–58% of patients admitted to an adult psychiatric unit (level II) (82–86). Oldham et al. found a correlation with age, marital status, and type of admission, and Soloff and Turner found legal status and race to be correlated with its use (level II) (84,87). One study in the psychiatric literature addressed complications of seclusion; Mattson and Sack found that assaultiveness (32 of 63), no note by primary therapist (26 of 63), self-injury (10 of 63), destruction of the seclusion room (5 of 63), deterioration of mental status (7 of 63), and deterioration of physical status (5 of 63) were the most common (level II) (83). Up to 60% of the adolescent patients admitted to a psychiatric faculty were placed in seclusion (level II) (81,88–92). Most of these patients are placed in seclusion for aggressive or agitated behavior. Erickson and Realmuto found that borderline patients are more frequently placed in seclusion than the patients with schizophrenia, hypomania or depression (level II) (92).

## COMBINATION THERAPY

Little information can be found in the medical literature concerning the combination of therapies. A consensus document noted that 14 of 20 medical directors reported that their protocol was to physically restrain patients and medicate them before a medical work-up (level III) (9). Although chemical and physical restraints are commonly used in combination in the ED, there are no known studies concerning the effects and complications of combination therapy.

## CONCLUSIONS

Although there are studies that have evaluated selected chemical therapy in the ED, studies into the reasons to treat psychiatric patients in the ED and the use of physical and chemical restraints, seclusion, and combination therapy are sorely lacking. There is general concurrence that patients should be physically restrained, followed by chemical restraint. Multiple doses of haloperidol, with or without benzodiazepines, are commonly given orally or intramuscularly in the ED to treat psychiatric patients.

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