Reducing seclusion through involuntary medication: A randomized clinical trial

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Article info

A B S T R A C T

Purpose: To evaluate whether seclusion and coercive incidents would be reduced in extent and number if involuntary medication was the first choice of intervention.

Methods: Patients admitted to an acute psychiatric ward were randomly allocated to two groups. In Group 1, involuntary medication was the intervention of first choice for dealing with agitation and risk of violence. In Group 2, seclusion was the intervention of first choice. Patients’ characteristics between the groups were compared by Pearson χ² and two-sample t-tests; the incidence rates and risk ratios (RRs) were calculated to examine differences in number and duration of coercive incidents.

Results: In Group 1, the relative risk of being secluded was lower than in Group 2, whereas the risk of receiving involuntary medication was higher. However, the mean duration of the seclusion incidents did not differ significantly between the two groups; neither did the total number of coercive incidents.

Conclusions: Although the use of involuntary medication could successfully replace and reduce the number of seclusions, alternative interventions are needed to reduce the overall number and duration of coercive incidents. A new policy for managing acute aggression — such as involuntary medication — can be implemented effectively only if certain conditions are met.

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1. Introduction

Coercive measures are controversial: while they are intended to protect patients and those around them, they restrict freedom and are usually applied against a patient’s will. The use of coercive measures can be highly traumatic for patients and staff (Bonner et al., 2002; Moran et al., 2009), and can also cause serious ethical dilemmas for clinicians and policymakers. The lack of consensus within and between countries on the best method of dealing with acute emergencies (Janssen et al., 2008; Kaltiala-Heino et al., 2003; Korkeila et al., 2002; Martin et al., 2007a; Raboch et al., 2010; Steinert and Lepping, 2009) may lie in a dearth of evidence from controlled trials on the effectiveness, benefit or harm of involuntary medication, seclusion and restraint (Nelstrop et al., 2006; Sailas and Fenton, 2000; Walsh and Randell, 1995). While involuntary medication is the preferred method of dealing with emergencies in most European countries (2010), Dutch psychiatric clinicians use it in only 22% of the situations that require coercion. Instead, they prefer seclusion as the method of containment (59%) (Dutch Mental Health Inspectorate, 2008).

The Dutch preference for seclusion in emergencies is not supported by scientific evidence or legal regulations: under the Netherlands’ Mental Health Act, seclusion and involuntary medication are ranked equally as techniques for managing acute violence. However, involuntary medication is used less often, due to a non-evidence-based cultural norm that intramuscular administration of medication is a more serious violation of the integrity of an individual’s body than being locked up in a seclusion room. This norm is probably derived from other Dutch mental health regulations that greatly restrict involuntary medication-based treatment in non-violent patients who refuse medication, even when they have been hospitalized involuntarily and suffer from severe acute psychosis (Ministerie van Volksgezondheid Welzijn en Sport, 2002).

Although it has been shown that seclusion and involuntary medication are preferred by equal numbers of Dutch patients (Georgieva et al., 2012; Veltkamp et al., 2008), clinicians’ preference for seclusion is not necessarily shared by those who suffer its consequences. Greater use of medication than of seclusion would fit better with what patients want, and might also reduce the use of seclusion. This is especially important for countries...
aiming in reducing seclusion, for example the Netherlands, where the misapplication and overuse of seclusion (e.g. the mean duration of seclusion is 103.2 h; Janssen et al., 2009) has become the focus of a national programme for reducing its use (Herrmann et al., 2008; Tilburg et al., 2008). A comparable initiative in replacing seclusion and mechanical restraint with physical restraint and medication has been reported recently in Germany (Steinert, 2011). However the evaluation of the efficacy of this initiative is still in progress.

While the therapeutic effect of seclusion is both unproven and seriously questioned (Legris et al., 1999), the administration of rapid antipsychotic tranquilizers reduces the positive symptoms of psychosis and reduces arousal, particularly to stress and stimulation (Baker et al., 2009). Besides that, it has been preferred by patients as a better treatment option (Sheline and Nelson, 1993), while patients have perceived mechanical restraint and seclusion more as “punishment” (Berrios and Jacobowitz, 1998; Cano et al., 2011). Among patients who refused to take their medication, two studies found higher rates and longer periods of restraint or seclusion (Bloom et al., 1984; Kasper et al., 1997).

Similarly, we recently demonstrated not only that involuntary medication was as effective as seclusion in improving psychosocial functioning (GAF scores) and reducing aggression, but also that medicated patients experienced less coercion and stress, and felt less humiliated than secluded patients (Georgieva et al., 2012).

We therefore performed a randomized clinical trial to establish whether the number and duration of seclusion and coercive measures would be reduced if involuntary medication was the first choice intervention for dealing with acute agitation on an acute psychiatric ward.

2. Methods

2.1. Hospital characteristics, study design and data collection

This study took place in the south–west of The Netherlands, in acute wards in a psychiatric hospital (Mental Health Centre West North Brabant) that provides care to a catchment area of around 276,000 people. Between November 2007 and August 2010, all patients being admitted were randomly allocated to two groups. In Group 1, involuntary medication was the intervention of first choice for dealing with agitation and risk of violence. In Group 2, seclusion was the intervention of first choice. In this respect, Group 2 involved “treatment as usual.” Patients in both groups were treated by the same clinicians (psychiatrists and nurses) in identical wards with equal numbers of beds and staffing. Restrictive measures were applied only when de-escalation techniques alone did not prove sufficient. The use and duration of restrictive measures in the two groups was then compared.

This study design was approved by the local Medical Ethical Committee on the grounds that involuntary medication and seclusion are ranked equally under the Dutch Mental Health Act, and that there is no scientific evidence to show that seclusion is a better treatment option than involuntary medication. The Medical Ethical Committee waived the requirements for informed consent, because the research involved no extra risks to the patients, and data were collected as part of a policy-control procedure.

Data on socio-demographic and clinical variables were collected prospectively from patients’ records; they consisted of gender, age, ethnicity, voluntary or involuntary admission status, and duration of the hospitalization. Psychiatric diagnoses were made by the psychiatrist on the ward. After nurses had been trained in the respective instruments, they rated patients’ mental functioning, uncooperativeness with treatment, and insight into the illness immediately after a patient had been admitted. Data on the use of restrictive measures were extracted from the hospital database.

2.2. Instruments

At admission, the patient’s general wellbeing and level of functioning were assessed by nurses using the short version of Kennedy Axis V (Kennedy, 2003). This consists of four domains: (1) psychological impairment, (2) social skills, (3) violence, and (4) activities of daily living (ADL) and occupational skills, all of which are rated from 10 to 100. A higher score reflects better functioning. The mean score of these domains is used to derive the Global Assessment of Functioning (GAF) score. Research has shown that GAF scores based on clinical judgment and scores based on the Kennedy Axis V have sufficient validity and reliability, but only the Axis V method was used here due to its greater ability to estimate a patient’s differential functioning (Higgins and Purvis, 2000).

The level of uncooperativeness and lack of judgment and insight at admission were assessed on the basis of items G8 and G12 of the Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987). Each item was rated on a scale from one (absent) to seven (extreme).

2.3. Definition of involuntary medication

As rapid tranquilization was not a routine practice for dealing with emergencies in this ward, we drafted a treatment pathway describing the route of administration and the type of a rapid tranquilizer. Its purpose was to ensure that the staff was fully aware of the rapid tranquilization policy and procedure, and that they would apply it safely and effectively. Rapid tranquilization involved the oral or intramuscular administration of a combination of haloperidol and promethazine to achieve rapid, short-term behavioural control of any extreme agitation, aggression or potentially violent behaviour that placed the individual and those around them at risk.

The combination of haloperidol and promethazine was recommended as the medication of first choice since several recent studies have shown it to have the best and most rapid tranquilizing effect (Alexander et al., 2004; Huf et al., 2007, 2009a, 2009b; Raveendran et al., 2007). This recommendation did not override the individual responsibility of clinicians to choose appropriate medications on the basis of the individual patient’s medical history and symptom severity. Initially, 10 mg haloperidol and 100 mg promethazine, or lorazepam 2.5–5 mg was offered as oral medication to the agitation patients with psychotic or non-psychotic symptoms, respectively, because research showed oral medication to be as effective as intramuscular formulations (Currier and Medori, 2006), and also to be perceived as less coercive than intramuscular (IM) medication (Patel et al., 2010). Furthermore, it reduces the risks associated with injections, avoids physical restraint, is preferred by clinicians (Allen and Currier, 2004). Nevertheless, in some situations patients refused to take the medication orally, so IM medication (5 mg haloperidol and 50 mg promethazine or 2.5–5 mg lorazepam) was used.

When “as required” medication was administrated during seclusion, it was counted as involuntary medication in both conditions due to the coercive character of the setting.

2.4. Definitions of seclusion and restraint

Seclusion involves the placement of a patient in a locked room from which free exit is denied to provide protection for the patient or others. This room is thought to provide isolation and reduction of sensory stimuli (Mayers et al., 2010). Physical or mechanical restraint was defined as any physical means or mechanical device that protects the patient (or others) from injury by limiting his or her movement, physical activity, or normal access to his or her body.

The term coercive measure covers a sequence of coercive episodes (seclusion, mechanical restraint or involuntary medication) for less than 24 h. If an interruption lasts for more than 24 h, any further incident of seclusion, restraint or involuntary medication is counted as a new incident (Janssen et al., 2011).

2.5. Statistical analyses

We calculated summary statistics of the subjects’ demographic characteristics in both conditions. Where appropriate, we used the Pearson $\chi^2$ test to test differences between categorical variables, and independent two-sample t-tests to test differences between continuous variables. Between conditions, we used chi-square to compare and test the number and the duration of the seclusion incidents, and the number of times involuntary medication was administered. In these comparisons, the incidence rates (the number of measures/1000 admission days) and prevalence rates (the number of seclusion hours/1000 h) were calculated, following the same procedure applied earlier (2008). On the basis of these raw incidence rates, we calculated the risk ratios (RRs) for an event for each of the groups (procedure of Smithson, 2003). The significance level for all statistical tests was set at 0.05, two-tailed.

3. Results

3.1. Study population

During the research period, a total of 659 admissions were included in the study, accounting for 8544 hospitalization days. These 659 admissions involved 520 individual patients, 109 of
whom (21%) were readmitted at least once. Coercive measures were used on 85 of the admitted patients (13%).

Table 1 compares patient characteristics on admission between Group 1 (in which involuntary medication was the first choice for dealing with acute agitation) and Group 2 (in which seclusion was the first choice). As there were no statistically significant differences in demographic and clinical variables between the groups apart from the percentages of secluded and involuntary medicated patients, the randomization procedure had been successful. Mostly patients underwent one coercive incident per admission either single or in combination. Analyses of the data at the level of individual patients instead of admissions led to the same results as readmissions occurred infrequently.

3.2. Coercive measures

In total, 128 coercive measures were reported. As 35% of them consisted of a combination of two or more coercive interventions in which involuntary medication had been combined with seclusion and/or mechanical restraint, a total of 177 individual measures were registered. Table 2 shows the overall incidence rate of the coercive measures.

The incidence rates of seclusion per 1000 admission days were 7.8 in Group 1 and 15 in Group 2. The incidence rates of involuntary medication per 1000 admission days were 11.8 in Group 1 and 4.6 in Group 2. These differences between the groups were statistically significant, confirmed again by the relative risks. The relative risk of being secluded was lower in Group 1 than in Group 2 (RR = 0.54, p < 0.001), while the relative risk for involuntary medication was higher in Group 1 than in Group 2 (RR = 2.58, p < 0.001). However, the total number of coercive measures (individual or combined) did not differ significantly between the two groups. Furthermore, the total duration of the seclusion incidents per group showed that Group 1 had a lower relative risk of staying in seclusion than Group 2 did (RR = 0.54, p < 0.001). However, when the relative risk was calculated on the basis of the mean duration of the seclusion incidents, no significant differences were found between the groups.

4. Discussion

4.1. Involuntary medication versus seclusion

The aim of this study was to evaluate whether seclusion and other coercive measures could be reduced in extent and number if involuntary medication was the first choice of intervention in case of agitated and violent behaviour on an acute ward, using a randomized clinical trial design. It was found that the use of seclusion could successfully be reduced when involuntary medication was the intervention of first choice. However, the mean time spent in seclusion as well as the total number of coercive measures did not differ between the two groups.

These findings are particularly important in countries that aim to reduce seclusion. Recent research has shown not only that medication is as effective as seclusion, but also that patients experience it as less coercive (Georgieva et al., 2012). Especially if it is administered orally, medication may be a justified substitute for seclusion if a coercive intervention is judged to be appropriate and if the patient’s preferences are not known.

However, due to the higher risk of serious side effects (Marco and Vaughan, 2005) and cardiac complications (Marder, 2006), and also to the risk that sedatives are administered excessively (regularly, “as required” or involuntary), it should be used with caution. Several studies showed that the dosages of regular or “as required” psychotropic medication were increased or changed more frequently in aggressive patients than in non-aggressive patients (Craig and Bracken, 1995; Goedhard et al., submitted for publication-a; Goedhard et al., 2007; Goedhard et al., submitted for publication-c), although aggressive patients treated with psychotropic medication were at higher risk for negative treatment outcomes including transfer to a more restrictive ward or...
being hospitalized for a period longer than 6 months (Goedhard et al., submitted for publication-b).

These findings indicate that even when patients do not constitute a serious threat to themselves or others, sedatives are often used to calm disruptive patients (Thapa et al., 2003). One disadvantage of this is that long-term sedation can make it less easy for individuals to develop the daily living and coping skills they need to function outside the inpatient setting (Donat, 2005). The overuse of sedative medication may also compensate for staff shortages or inadequacies or for the lack of daily therapeutic activities in the ward, although there have been only studies demonstrating a significant relationship between staffing levels and use of seclusion and mechanical restraint (Donat, 2002; Morrison and Lehane, 1995). As such prescribing practices could easily be underreported; they might easily become a form of hidden coercion, especially in countries where the administration of involuntary medication is not tightly restricted by the law and where no systematic registration of oral and intramuscular sedative medication is required.

At first, therefore, less restrictive alternatives should be considered, especially because the introduction of involuntary medication in our study reduced neither the total number of coercive measures nor the mean duration of seclusion. Various interventions have already been proven to be effective in reducing the number and duration of seclusion and restraint. They include Psychiatric Intensive Care Units (PICU) for seriously disturbed patients (Georgieva et al., 2009), structured risk assessment (Aberthalden et al., 2008), increased staffing (Donat, 2002), improvement of behavioural staff competences (Donat, 2005), improved case-review procedures (Donat, 2003), legal regulations such as the “1 h rule” (Currier and Farley-Toombs, 2002; LeBel et al., 2010), crisis management and de-escalation interventions (Jonikas et al., 2004; Lewis et al., 2009), and others (Stewart et al., 2010).

4.2. Implementing a new policy for managing acute aggression

Although the psychiatrists and nurses working at the wards in our study were instructed to use involuntary medication only in agitated patients assigned to Group 1, nearly three-quarters of the patients in Group 1 (74%) were also secluded. With regard to their level of uncooperativeness or to their global assessment of functioning (GAF) upon admission, these patients did not differ significantly from those who were involuntary medicated only (71% of them underwent coercive measures during the first 24 h after admission). Besides that 10 seclusions took place in the experimental condition without involuntary medication, as reported in Table 2.

We may therefore conclude that patients’ conditions were not the main factor determining whether an agitated patient was given involuntary medication or put into a seclusion room. Obviously, staff members found it difficult to manage agitation and violence using only involuntary medication and not seclusion. In previous research, the use of seclusion was associated with the availability of a seclusion room (Bowers et al., 2010). However, seclusion facilities should not be eliminated completely if no other effective alternatives exist, as more staff injuries might result (Hafner et al., 1989), or the most extremely violent patients might need to be transferred to special psychiatric settings with secure facilities (Kingdon and Bakewell, 1988).

We had hypothesized that because rapid tranquilization would be used significantly more often in Group 1 than in Group 2, the mean duration of the seclusion incidents in Group 1 would be significantly shorter, as the seclusion would be terminated once the rapid tranquilization had taken effect. The fact that we found no support for this hypothesis may suggest that staff had difficulty in changing their old habits, and kept patients in seclusion even when they had become calm. We should note that, at 30–32 h, the mean duration of a seclusion episode in this study was much longer than that provided under the standards of the American Joint Commission (4 h for adults), and also than that in most other European countries (Martin et al., 2007b; Steinert et al., 2009). It was nonetheless much shorter than the 16-day mean duration reported earlier in other Dutch psychiatric facilities (Janssen et al., 2008). In the Dutch psychiatric context, where the overuse of seclusion has become a focus of a national reduction programme, involuntary medication thus could help reduce the number of seclusion incidents. However, in our study the average duration of seclusion incidents was not reduced, meaning that involuntary medication by itself is probably not enough to decrease duration of seclusion.

It thus seems that we were unable to achieve the structural change in staff attitudes and ward culture that would be required...
to completely replace seclusion with involuntary medication and to reduce the duration of seclusion. For the benefit of psychiatric services that are interested in replicating our efforts, we therefore list the main factors that may have hampered the successful implementation of this new policy: (1) in emergencies, and especially during night shifts and weekends, psychiatric nurses could not always rely on receiving prompt assistance from extra staff or the physicians on call; (2) nurses were not used to physically restraining aggressive patients for long periods while rapid tranquilization took effect; and (3) they also found such restraint difficult and confronting, being afraid that they would afterwards be unable to repair the damaged therapeutic relationship with the patients they had restrained. Previous research has shown not only that therapeutic holding enabled patients to regain behavioural control after a shorter period (a mean of 21.2 min) than after seclusion (a mean of 4–16 h) (Miller et al., 1989), but also that therapeutic holding was perceived as less punitive in paediatric psychiatric facilities than mechanical restraints were (Berrios and Jacobowitz, 1998). Despite that, the nursing staff was less concerned about the risk of harming the therapeutic relationship when secluding or restraining patients. Probably because seclusion and mechanical restraint were common practices and their execution require usually shorter personal contact with the patient than physical restraint. The considerations of the staff in our study may therefore indicate the presence of irrational beliefs due to undeveloped skills and inadequate training (Dickinson and Wright, 2008).

Overall, our study showed that the implementation of a new policy — using involuntary medication as a first choice for managing acute aggression — was only partly achieved. In general, the success of the implementation of such a new policy depends on number of conditions, as described earlier (2004). First and foremost, the new policy has to be clearly prioritized as an objective of the facility. This priority is then clearly and consistently disseminated, with regular reminders by clinical and administrative leaders. Secondly, measures need to be registered and also evaluated in an objective way. Third, the procedure is described thoroughly in a policy guideline that was in conformity with ethical and medical requirements and standards for best practices (such as those written by the National Institute of Clinical Excellence (NICE, 2005) and has become part of daily routine. Fourth, staff needs to be open for reflection on their actions in the context of working under pressure. Fifth, all stakeholders, including representatives of patients, need to be informed and actively involved in the implementation of the new policy. Sixth, the implementation process should be evaluated regularly in a performance-monitoring and feedback procedure discussing each incident. Apart from this, sufficient psychiatric staffing must be motivated, well-trained, and sufficient in number. To prevent the overuse of sedative medication, all use of involuntary medication should be registered and monitored systematically. Additional interventions are needed to reduce the total number and duration of coercive measures. Finally, we recommend a replication of this randomized clinical trial in other hospitals where seclusion is the coercive measure of first choice, as well as studying the relative use and (side)effects of involuntary medication, seclusion and other coercive measures.

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