The prevention of deep venous thrombosis in physically restrained patients with schizophrenia

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SUMMARY

Background: Physical restraint and seclusion are associated with several risks.  Antipsychotic drug use increases this risk.  Objective: To evaluate whether the risk of thromboembolism in physical restraint and seclusion of patients with psychosis, treated with antipsychotic medication, was considered by taking preventive measures.  Method: Anonymous data on all consecutively admitted patients with schizophrenia, treated with antipsychotic medication, between 2002 and 2009, were analysed.  Diagnostic information and data about seclusion procedures and medication were collected.  Preventive measures of thromboembolism in patients in physical restraint were assessed by reviewing case notes and the medication prescribed at the time of seclusion.  Results: Seclusion of patients with psychosis is common.  Out of 679 identified patients, 170 had been secluded (472 events).  Physical restraint use was not a rare event (N seclusions with restraint use 296, 62.7%).  Pharmacological preventive measures (use of heparine drugs) were taken frequently to prevent deep vein thrombosis (DVT) by physical restraint or isolation.  Sixty-five (38.2%) out of 170 secluded patients, including a majority of patients who had been under physical restraint, had been administered anticoagulants at the time of seclusion.  Conclusions: Preventive measures were routinely administered in clinical practice and were effective in the prevention of DVT.  For a clinical setting, it is important to establish a clear and detailed management plan on seclusion and fixation taken into account in all possible risks of physical restraint.

Introduction

Physical restraint is implemented when patients are assaultive, threatening or at risk for harming themselves or others (1).  Definitions of restraint range widely.  Broadly, ‘restraint’ refers to physically restricting movement.  Most commonly, it refers to confining the limbs on a specially designed bed (that is ‘four-point’ or ‘five-point’ restraint), but it can also mean restraining patients to a chair, limiting arm or leg movement (‘ambulatory restraint’), or restraining the whole body with a camisole or a straight jacket (2).

The practice of restraint puts patients at risk, as it is associated with physical injury or even death (2,3).  The types of physical injury include dehydration, choking, circulatory and skin problems, loss of strength and mobility, and incontinence (2,4).  Restraint may be perceived as punitive and aversive, with the potential for traumatic sequels (2).  Physical restraints are also a risk factor for deep venous thrombosis (DVT) (2,5–9).

Deep vein thrombosis is partial or complete obstruction of leg veins by a thrombus causing oedema, distention and pain in one leg.  About 30% of patients develop a chronic disease with episodic recurrence of thromboembolism (10).  The most critical complication of DVT is pulmonary thromboembolism.  Prolonged immobility, trauma, surgery that can trigger blood clots, pregnancy and coagulopathy are known risk factors for DVT.  A strong relationship between antipsychotic drugs and the occurrence of DVT has been reported (11–14).  Other independent risk factors for venous thromboembolism include increasing patient age, obesity, active cancer, central vein catheterisation, prior superficial vein thrombosis, varicose veins and neurological disease with leg paresis (10,15,16).

A lot of research has been carried out on the prevention of DVT in surgical patients, patients with...
prevention of DVT in patients with schizophrenia

The study was carried out at the psychiatric hospital of the University Psychiatric Center KU Leuven Campus Kortenberg. This monocentric study used a retrospective and descriptive design. Electronic patient records with information about diagnosis, episodes of seclusion, case notes and medication prescriptions were linked.

Consecutive admissions were identified from the hospital databases. Anonymous data were collected from the study period between 2002 and 2009 and used for analysis. In this analysis, we investigated episodes of seclusion and restraint in patients suffering from schizophrenia treated with antipsychotic medications. Systematic electronic recording of all episodes of seclusion by nurses on the wards was implemented in 2002. Prophylaxis of thromboembolism in isolated patients and patients under physical restraint were investigated by reviewing the medication that had been prescribed during and after the time of seclusion.

The sample was described by descriptive statistics. For further statistical analysis of data, Statistical Analysis Software (SAS; Statistical Analysis System, Cary, NC) program was used.

At each admission, patients were informed about electronic patient records and the possibility of these being anonymously included in scientific research. Data of the patients who had refused this possibility on admission were excluded from the study. The study was approved by the Scientific and Ethical board of the UPC KU Leuven.

Results

Admission data

Admissions were identified from the hospital databases. Data were collected from adult inpatients with schizophrenia and treated with antipsychotic medications in the study period between 1st June 2002 and 31st March 2009. Data were collected on 11 different wards, supervised by senior clinicians who work on the same ward for a long time (for most > 10 years). Somatic care is offered by three general practitioners who are dedicated to specific wards and who are employed by the hospital. Moreover, all of them have > 10 years experience in the ward to which they are appointed.

All patients had a clinical diagnosis of schizophrenia. The study population consisted of 467 (68.8%) male patients and 212 (31.2%) female patients with an average age of 41.8 (SD 14.4) years. The majority of the sample was Caucasian (97.7%).

The total number of admissions during this time was 1310. The average number of admissions per patient was 1.9 (SD 1.6) with an average duration of 393 days (SD 836, including both full and partial admissions).

Deep venous thrombosis as a complication following restraint is still not well recognised, and only few studies describe this association and the possible preventive strategies (5,7,9). The aim of this study is to establish whether the risk of thromboembolism in secluded and physically restrained patients with schizophrenia, treated with antipsychotic medication, was considered by taking preventive measures.

Method

The study was carried out at the psychiatric hospital of the University Psychiatric Center KU Leuven
Data on seclusion and physical restraint

There were 472 episodes of seclusion (in 170 of the admitted patients, 25.0%) during the study period. Episodes per patient ranged from 1 to 32. The mean number of seclusion episodes per patient was 2.8 (SD 3.9). The mean duration of an episode was 3.7 days (SD 7.8, min. 0.03 and max. 67.3). A total of 82 (17.4%) episodes of seclusion had a total duration from 2 days to 1 week, whereas 70 (14.8%) episodes lasted longer than 1 week and the majority of seclusions (320, 67.8%) lasted < 2 days. One individual had been secluded on different occasion for a mean duration of 88.8 h (SD 187.2, min. 0.7 and max. 1615).

We registered 176 (37.3%) episodes of seclusion without the use of physical restraints (Table 2). In 296 (62.7%) episodes, physical restraint was used. In 223 (75.3% or 47.2% of all seclusions) of these last cases, five-point fixation was administered. Out of the 170 secluded patients, 138 (81.2%) underwent at least one episode with physical restraints.

Patients that were secluded were on average younger [mean age 37.6 (SD 12.1) years; df = 1, F = 20.3 p < 0.0001], and there was a trend that men were more likely to be secluded (df = 1, χ² = 3.0 p = 0.0827).

Characteristics of and reasons for seclusion

The majority of seclusions were carried out during an acute admission (280% or 59.3% at a closed ward...
and 146% or 30.9% on other admission wards) and rarely in rehabilitation settings (46% events or 9.7%).

In 321 (68.0%) out of 472 seclusions, preventive measures had been taken to avoid isolation (Table 3). In 332 (70.3%) seclusion events, the patient was assessed by a psychiatrist prior to seclusion. One hundred and ninety (40.2%) isolations were carried out with consent of the patient. A total of 247 (52.3%) seclusions had been performed in acute crisis situations. Extra help from outside the ward was needed during the episode of seclusion in 230 (48.7%) patients.

The electronic seclusion register indicates four main reasons, alone or in combination, for which seclusion was needed: disorganised behaviour (69.2%), risk behaviour (51.6%), destructive behaviour (43.2%) and behaviour that is disruptive to the environment (32.0%) (Table 4).

Aggression to staff was the most frequent destructive behaviour recorded (109 events, 23.1% of seclusions or 77.9% of destructive behaviours towards others). Destructive behaviour resulted in injuries in 38 events (19 members of staff, 15 patients and 5 family members) and damaged property on 18 occasions.

Table 5 shows the medication at the time of the first seclusion. At the moment of seclusion, the 170 patients had 232 prescriptions of different antipsychotic agents. In 54.3%, these were second-generation antipsychotics, in 18.1% first-generation antipsychotics and 27.6% were sedative first-generation agents.

Preventive measures for thromboembolism during seclusion and the use of physical restraints

Sixty-five (38.2%) out of 170 secluded patients were administered anticoagulants as a preventive measure for DVT during the timeframe of a seclusion period. In 83 (17.6%), all seclusions anticoagulants were given. DVT prophylaxis was more frequent in seclusions lasting > 1 day and in patients which were physically restrained (276 seclusions < 1 day, 11 treatments, all but 1 in fixedated patients; 196 seclusions > 1 day, 72 treatments of which only 3 in not physically restrained patients).

We registered 100 prescriptions of anticoagulants, all low-molecular weight heparins. Five different anticoagulants were prescribed. The most frequently prescribed anticoagulants were dalteparin and nadroparin (Table 6). The mean duration of treatment with anticoagulants was 8.5 days (SD 8.8, min. 1 and max. 41). No other preventive measures were documented in the case notes.

A retrospective investigation of electronic data from our medical centre (only available from 4 July 2007) showed that the treatment with anticoagulants was effective and safe in prevention of thromboembolism during seclusion. No cases of thromboembolism or coagulation disorders were observed. In the pharmacy database, no prescriptions of coumarin drugs were registered in patients who underwent a seclusion episode during the entire study period.

Discussion

This is the first study carried out to assess whether specific preventive measures were taken to prevent DVT following physical restraint. Seclusion of patients suffering from a psychotic disorder is common. A total of 679 patients with psychosis were admitted, of which 170% or 25% had been secluded (472 seclusion events). The most common reasons for isolation were disorganised behaviour, including agitation and confusion, and risk behaviour, including suicide threats and threats with violence.

An analysis of all episodes of seclusion from our sample shows that physical restraint was used frequently. In 170 patients, there were 472 episodes of seclusion with 296 episodes (62.7%) under physical restraint (81.2% of secluded patients).

| Table 3 Preventive measures to prior to seclusion |
|--------------------------------------------------|
| Preventive measure (N seclusions = 472*) | Frequency | Percentage (%) |
| Consultation with psychiatrist prior to seclusion: | 332 | 70.3 |
| Seclusion in acute crisis situation | 247 | 52.3 |
| Seclusion with consent of patient | 190 | 40.2 |
| **Preventive measures prior to seclusion** |
| Individual discussion of crisis with patient | 228 |
| Notification/value | 118 |
| Specific intermediary steps proposed | 241 |
| Negotiation | 82 |
| Individual consultation | 96 |
| Extra medication | 139 |
| Referral to room | 144 |
| Alternative to seclusion | 36 |
| Change in treatment programme | 3 |
| Extra supervision | 88 |
| Appointment team member | 15 |
| Total preventive measures prior to seclusion (N) | 557 |
| Total intermediary steps proposed (N) | 603 |
| Extra medication given | 252 | 53.0 |
| Extra medication voluntarily accepted | 71 | 15.0 |
| Formal debriefing after seclusion | 214 | 45.3 |

*Multiple labels possible in the same patient/seclusion episode.
Our data show that preventive measures for DVT were used in 38.2% of patients who had been isolated. They were administered anticoagulants as a preventive measure for DVT mainly in episodes with physical restraint use. Use of anticoagulants was more frequent in seclusions lasting more than 1 day in physically restrained patients. During the study period, there were neither clinical cases of DVT detected nor side-effects of short-term anticoagulant treatment.

Heparin drugs with a low-molecular weight can be effectively used as a preventive measure for DVT in restrained patients. However, data are still missing on other preventive measures such as hydration, wearing anti-embolism stockings and regular physical exercise of lower extremities (5,7,9). DVT as a complication following restraint is still not well-recognised and only few studies describe this association and the possible preventive strategies (5–7).

The lack of trial-derived evidence regarding the effects of seclusion and restraint is surprising given the invasiveness of the intervention and its continued use over time (20). A prospective patient case-note analysis conducted in seven English psychiatric intensive care units shows that disturbed behaviour is managed differently in each unit, either dependent upon facilities or local policies. Use of seclusion and restraint was significantly associated with patient violence, property damage and level of psychiatric symptoms (21). Further restraint reduction initiatives and alternatives to restraints are clearly necessary (6,22,23), especially if violence is not the reason for seclusion (20,24). Staff education, use of specially trained personnel and the patient’s family as treatment partners and a variety of de-escalation techniques, including one-on-one discussions, extra sedative medication, use of peer-advisers, walking the grounds, voluntary return to the patient’s living quarters, have proven effective (6). Those with serious mental illness and their relatives could well prespecify which technique they would find preferable should their mental state or behaviour seriously deteriorate (20). There is strong evidence that supports the use of interventions to reduce the use of seclusion in psychiatric facilities. Common features of the programmes for change that were reviewed by Gaskin et al. (22) were leadership, the monitoring of seclusion episodes, staff education and changing the therapeutic environment.

A combined literature review on initiatives to reduce seclusion and restraint in 12 different countries suggests that there are huge differences in the percentage of patients subject to and the duration of coercive interventions between countries (25).

| Table 4 Reasons for seclusion |
|------------------------------|
| Reasons for seclusion (N seclusions = 472*) | Frequency | Percentage (%) |
| Destructive behaviour | 204 | 43.2 |
| Aggression towards objects | 76 | |
| Aggression towards others | 140 | |
| Staff | 109 | |
| Other patients | 39 | |
| Others (visitor, …) | 14 | |
| Aggression to self | 38 | |
| Self harm | 27 | |
| Suicide attempt | 12 | |
| Other | 2 | |
| Total recorded destructive behaviours (N) | 457 | |
| Disorganised behaviour | 327 | 69.2 |
| Loss contact reality | 223 | |
| Confusion | 128 | |
| Agitation/mania | 97 | |
| Intoxication | 23 | |
| Extreme experience of anxiety | 111 | |
| Other | 32 | |
| Total recorded disorganised behaviours (N) | 624 | |
| Risk behaviour | 244 | 51.6 |
| Fugue | 80 | |
| Threats with violence | 136 | |
| Suicide threats | 46 | |
| Danger of arson | 12 | |
| Other | 37 | |
| Total recorded risk behaviours (N) | 311 | |
| Behaviour disruptive to the environment | 151 | 32.0 |
| Disturbance of during the night | 49 | |
| Breaking ward rules | 119 | |
| Other | 6 | |
| Total recorded disruptive behaviours (N) | 171 | |
| Patients request | 43 | 9.1 |
| Other main reason | 29 | 6.1 | |

*Multiple labels possible in the same patient/seclusion episode.

| Table 5 Medication at first seclusion (N patients = 170, 232 different prescriptions) |
|--------------------------------|
| Antipsychotic agent | Frequency | Percentage (%) |
| Amisulpride | 11 | 4.7 |
| Aripiprazole | 6 | 2.6 |
| Clozapine | 11 | 4.7 |
| Olanzapine | 40 | 17.2 |
| Quetiapine | 20 | 8.6 |
| Risperidone | 38 | 16.4 |
| Total second-generation antipsychotic | 126 | 54.3 |
| First-generation antipsychotic | 42 | 18.1 |
| Sedative first-generation antipsychotic | 64 | 27.6 |
Prevention of DVT in patients with schizophrenia

The strengths of this study are the large number of patients and seclusions over a long study period together with detailed electronic data capture during seclusion. Nevertheless, the results of this study should be interpreted with caution. A retrospective design with limited power was used. The sample of inpatients was collected at one location and can therefore not be generalised. Another limitation is the lack of data on other risk factors for DVT in the patients from our sample and the absence of a control group who did not get prophylactic treatment.

Further research is needed. Prospective studies on the incidence of DVT in restrained patients are needed (7). At present, only a small number of case studies are available on this subject (5,6,9,26). Large-scale multi-centre studies are required to evaluate which other preventive measures can be effective. Randomised trials are urgently needed to assess the effects of seclusion and restraint in patients with psychosis (20), and further research is needed into specific practices used to manage seriously disturbed behaviour (21). Physical restraint should be compared with other interventions such as pharmacological treatment, communication skills, adaptations to the environment and well-trained staff (27). Comparisons between countries and different practices can help to overcome prejudice and improve clinical practice (25).

Table 6 Overview of prescribed anticoagulant medication

| Medication         | Frequency | Percentage (%) |
|--------------------|-----------|----------------|
| Enoxaparin s.c. (Clexane) | 5         | 5.0            |
| Dalteparin s.c. (Fragmin)  | 20        | 20.0           |
| Nadroparin s.c. (Fraxiparine) | 74       | 74.0           |
| Heparin s.c. (Heparine Leo) | 1         | 1.0            |

S.c., subcutaneous.

Conclusions

This is the first study carried out to assess whether preventive measures were taken to prevent DVT following physical restraint in adult patients with psychosis, treated with antipsychotic medication. Seclusion of patients with psychosis and the use of physical restraint are common. In the hospital where the study was carried out, pharmacological preventive measures were taken frequently to prevent DVT during physical restraint or seclusion. Other preventive strategies were either absent or not documented.

Despite the fact that only few studies describe the association between restraint and DVT, the risk should not be ignored. Future research is needed on the risks associated with restraint, the association between DVT and physical restraint, the risk associated with antipsychotic agents and the impact of other risk factors for DVT and possible preventive measures that could be taken.

Physical restraint and seclusion should be avoided as much as possible and alternative strategies should be tried first. For a clinical setting, it is important to establish a clear and detailed management plan on seclusion incorporating the possible risks for the physical health of the patient.

Author contributions

M. De Hert designed the study. M. De Hert and G. Einfinger wrote the first draft of the study. E. Scherpenberg, M. Wampers and J. Peuskens commented and contributed to the subsequent revisions. E. Scherpenberg collected the data and M. Wampers helped with the data management and performed the statistical analysis.

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