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

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Disclosures

- M. De Hert has been a consultant for, received grant/research support and honoraria from, and been on the speakers/advisory boards of Astra Zeneca, Bristol-Myers Squibb, Eli Lilly, Janssen-Cilag, Lundbeck, Pfizer and Sanofi-Aventis.
- G. Einfinger, E. Scherpenberg and M. Wampers have no conflict of interest relevant to this paper.
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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, was analyzed. 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 not uncommon. 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 dugs) were taken frequently in order to prevent 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. No cases of DVT occurred. 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 all possible risks of physical restraint.

What is known?

Physical restraint during seclusion and the use of antipsychotic agents can be a risk factor for DVT. The risk of deep vein thrombosis (DVT) and its increased risk of mortality is underestimated in the literature. Little is known about the frequency and effectiveness of preventive measures. Clinical guidelines on the prevention of thromboembolism in patients with physical restraints are not available

What is new?

This is the first study carried out to assess whether preventive measures were taken in order to prevent DVT following physical restraint. The use of heparin drugs with a low molecular weight was both safe and effective. Future research is needed on the risks associated with restraint, the association between DVT and physical restraint, the risk factors for DVT and possible preventive measures that can be taken.

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 "4-point" or "5-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).

DVT is partial or complete obstruction of leg veins by a thrombus causing edema, 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 (11-13). Other independent risk factors for venous thromboembolism include increasing patient age, obesity, active cancer, central vein catheterization, prior superficial vein thrombosis, varicose veins and neurological disease with leg paresis (10.15-16).

A lot of research has been done on the prevention of DVT in surgical patients, patients with prolonged hospital stay and prolonged air travel (17-18). In addition to exercise and hydration for all travelers, compression stockings are helpful for long-haul travelers (18). In medical patients, unfractionated heparin has a higher rate of bleeding complications than low molecular weight heparin. There is no evidence for the use of aspirin, warfarin, or mechanical methods. Low molecular weight heparin or fondaparinux as safe and effective agents are recommended in the thromboprophylaxis of medical patients (18).

In order to explore the association between DVT and physical restraints, and establish possible measures to prevent thromboembolism we recently published a systematic literature review (Medline, Cochrane Library, Psycinfo and Invert) using the following terms in different combinations: 'prevention', 'thrombosis', 'psychiatry', 'psychiatric inpatient prophylaxis', 'restraints', 'seclusion', 'physical fixation', immobilization', 'venous thrombosis', 'thromboembolism' and 'pulmonary embolism' (19).

Only six articles were identified which met the following inclusion criteria: papers published from 1998, the authors reported specifically on the association between physical restraint and DVT in psychiatric patients or preventive measures regarding the latter, papers

published in Dutch or English. Papers were excluded if they met one of the following exclusion criteria: articles concerning restraint of children, papers concerning the perception by nurses and patients of restraint and articles which only reported on preventive measures for DVT in medical patients. All six articles (Table 1.) reported an association between physical restraint and DVT. There were no management guidelines available for prevention of DVT specific to psychiatric settings. A first management algorithm was proposed by Maly et al. in 2008 (7). Results showed that hydration, wearing anti-embolism stockings, regular physical exercise of lower extremities and repeated use of heparin drugs with a low molecular weight were the most recommended preventive measures (5,7,9).

DVT as a complication following restraint is still not well recognized 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 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 thrombembolism 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 SAS (Statistical Analysis Software) 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 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 June 1st 2002 and March 31st 2009. Data was 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 3 GP's who are dedicated to specific wards and who are employed by the hospital. Also all of them have >10 years experience on 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 1,310. 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).

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). 82 (17.4%) episodes of seclusion had a total duration from 2 days to one week, while 70 (14.8 %) episodes lasted longer than one week and the majority of seclusions (320, 67,8%) lasted less than two days. One individual had been secluded on different occasion for a mean duration of 88.8 hours (SD 187.2, min 0.7 and max 1.615).

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 males were more likely to be secluded (df=1, $Chi^2=3.0$ p=0.0827).

Characteristics of and reasons for seclusion

The majority of seclusions were done 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 in order 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 the patient. 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%) of cases .

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

Aggression to staff was the most frequent destructive behavior recorded (109 events, 23.1% of seclusions or 77.9% of destructive behaviors towards others). Destructive behavior 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 thromboemebolism 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%) of 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 fixated 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 04/07/2007) showed that 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 in order to prevent DVT following physical restraint.

Seclusion of patients suffering from a psychotic disorder is not uncommon. 679 patients with psychosis were admitted, of which 170 or 25%, had been secluded (472 seclusion events). The most common reasons for isolation were disorganized behavior, including agitation and confusion, and risk behavior, 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).

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 no 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 recognized and only few studies describe this association and the possible preventive strategies (5-6,7).

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 behavior 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 deescalation 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 behavior 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 programs 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).

The strengths of this study are the large N 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 generalized. Another limitation are 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 is needed (7). At present only a small number of case studies are available on this subject (5-6,9,26). Large-scale multi-center studies are required to evaluate which other preventive measures can be effective. Randomized trials are urgently needed in order 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 behavior (21). Physical restraint should be compared to 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).

Conclusions

This is the first study carried out to assess whether preventive measures were taken in order 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 is common. In the hospital where the study was carried out, pharmacological preventive measures were taken frequently in order 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.

Authors contribution

M. De Hert designed the study. M. De Hert and G. Einfinger wrote the first draft of the paper, 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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Table 1. Literature review on deep venous thrombosis (DVT) and physical restraints.

Study	Aim	Design	Results	Discussion/recommendation
Hem et al. 2006 (26)	Explore association between DVT and physical restraints	Case report, 2 patients	DVT occurred in 2 patients who were in restraints too long.	Physical restraints are frequently used in psychiatric hospitals but the associated risks are not well studied.
Laursen et al. 2005 (5)	Explore association between DVT and physical restraints	Case Report, 1 patient	The risk of DVT and pulmonary embolism is associated with prolonged immobilization during seclusion with restraints, even without the presence of other risk factors of DVT.	Need for early detection and treatment in people who are restrained. Preventive measures for DVT are recommended for all patients.
Lazarus 2001 (6)	Explore association between DVT and physical restraints	Case report, 2 patients	Immobilization is a known risk factor for DVT but the risk of mortality is not recognized. This may be due to a time delay between restraint and death, or that obstruction due to cloths occurs when the patient starts to move.	Recommendation to reduce the use of physical restraints. This could be achieved by highly skilled staff, improved communication skills, alternative aggression management techniques.
Malý et al. 2008 (7)	Develop an algorithm to prevent DVT in patients with mental illness	Review	Management algorithm, with risk scoring system, based on the literature on chirurgical patients Individual assessment of risk factors and personalized preventive measure from movement of the lower limbs, hydration and use of heparin.	First attempt of develop management guidelines for DVT specific to psychiatric settings. There is a lack of empirical evidence to support the proposed guideline and there is a need for additional research.
Mohr et al. 2003 (2)	Explore causes of death linked to physical restraints	Review	There is little attention for and research on the possible mortality associated with the use of restraints. Close monitoring and observation of patients, by highly trained staff, is crucial in all restrained patients.	Recommendation for future research both on the risks associated with the use of restraints and safe and effective alternatives.
Ramirez et al. 2001 (9)	Explore association between DVT and physical restraints	Case report, 1 patient	DVT was associated with prolonged immobilization in a patient with multiple other risk factors. The use of heparin drugs with a low molecular weight could have prevented DVT.	Preventive measures for DVT from clinical guideline in general medicine or surgery should be used in psychiatric patients.

Table 2. Type of physical restraint.

Restraint	Number of seclusions	Percentage (%)
none	176	37.3
1-point	20	4.2
2-point	7	1.5
3-point	39	8.3
4-point	7	1.5
5-point	223	47.2

Seclusions lasting > 1 days (N=196)			
Restraint	Number of seclusions	Percentage (%)	
none	63	32.1	
1-point	2	1.0	
2-point	2	1.0	
3-point	15	7.7	
4-point	4	2.0	
5-point	110	56.1	

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:	321	68.0
Individual discussion of crisis with patient	228	
Notification/warning	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 program	3	
Extra supervision	88	
Appointment team member	15	
Total N preventive measures prior to seclusion	557	
Total N intermediary steps proposed	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)

Table 4. Reasons for seclusion.

Reasons for seclusion N seclusions = 472*	Frequency	Percentage (%)
Destructive behavior:	204	43.2
Aggression towards objects	204 76	43.2
Aggression towards objects Aggression towards others	76 140	
Aggression towards others Staff	109	
	39	
Other patients		
Others (visitor,)	14	
Aggression to self	38	
Self harm	27	
Suicide attempt	12	
Other	2	
Total N recorded destructive behaviors	457	
Disorganized behavior:	327	69.2
Loss contact reality	223	
Confusion	128	
Agitation/mania	97	
Intoxication	23	
Extreme experience of anxiety	111	
Other	32	
Total N recorded disorganized behaviors	624	
Total IN recorded disorganized benaviors	024	
Risk behavior:	244	51.6
	80	51.0
Fugue Threats with violence	136	
Suicide threats	46	
Danger of arson	12	
Other	37	
Total N recorded risk behaviors	311	
Behavior disruptive to the environment:	151	32.0
Disturbance of during the night	49	
Breaking ward rules	119	
Other	6	
Total N recorded disruptive behaviors	171	
Detients request	40	0.4
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



Table 6. Overview of prescribed anticoagulant medication.

enoxaparin s.c (Clexane) 20-60 mg Dalteparin s.c (Fragmin) 2500 IU- 10000 IU Dadroparin s.c (Fraxiparine) 7500 ^E - 25000 ^E Deparin s.c. (Heparine Leo) 100 U/ml S.c. subcutaneous)	5 20 74 1	5.0 20.0 74.0 1.0
Palteparin s.c (Fragmin) 2500 IU- 10000 IU adroparin s.c (Fraxiparine) 7500 ^E - 25000 ^E eparin s.c. (Heparine Leo) 100 U/mI	74	74.0
	1	1.0
s.c. subcutaneous)		