Pisa Syndrome (Pleurothotonus): Report of a Multicenter Drug Safety Surveillance Project

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Background: Pisa syndrome is usually regarded as a rare adverse event of neuroleptic medication. However, its frequency and predisposing factors have yet to be defined. Here, we investigated risk factors of Pisa syndrome occurring in a large population of psychiatric patients surveyed during a multicenter drug safety project.

Method: Twenty episodes of Pisa syndrome were documented in 17 patients within a population of 45,000 psychiatric patients monitored by a multicenter drug safety surveillance project (Projekt zur Überwachung der Arzneimittelsicherheit in der Psychiatrie) between 1990 and 1997. All results were related to the epidemiologic data provided for this population and systematically analyzed regarding history of medication, current medication, comedication, and clinical course.

Results: A constellation of putative risk factors was found in the majority of patients: previous treatment with classical neuroleptics, combined pharmacologic treatment, female gender, old age, and the presence of an organic brain disorder. Given these risk factors, Pisa syndrome was also documented with atypical neuroleptic drugs such as clozapine, olanzapine, and sertindole.

Conclusion: We conclude that Pisa syndrome is a very rare adverse event occurring with neuroleptic treatment. In patients exhibiting the reported constellation of risk factors, neuroleptic drugs should be administered with particular caution.

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In 1972, Ekbom and colleagues[1] described 3 elderly women with an unusual abnormality of posture showing a tonic sideward flexion and slight rotation of the trunk in a sagittal plane. The patients kept this body posture while lying, sitting, or standing and showed a tendency to turn in the opposite direction to the path of walking. As this peculiar syndrome occurred while the patients were being treated with butyrophenones, it was interpreted as a drug side effect and named "Pisa syndrome" after the well-known Italian Renaissance building. Later, the term was discussed controversially and criticized as being dehumanizing.[2] Other terms such as *pleurothotonus* or *tetanus lateralis* have been suggested and applied, together with "neuroleptic induced" or "drug induced."[3–6] The term *Pisa syndrome,* however, has been accepted by the majority of authors.

Thirteen years after the first description of Pisa syndrome, Yassa[7] published 2 other cases. That publication was followed by numerous case reports,[8–21] 3 small cumulative case reports,[2,22,23] and 2 larger case studies[24,25] with 20 and 27 patients, respectively. No epidemiologic data have been considered so far. The only prospective study, performed by Yassa and colleagues,[26] found Pisa syndrome in 11 of 133 patients in a single psychogeriatric institution. Although Pisa syndrome has occurred with classical, atypical, and antidepressant drugs, case reports and previous studies have not been conclusive regarding risk factors, time course, history of medication, current medication, and comedication.

We monitored 45,000 psychiatric patients included in a multicenter drug safety surveillance project between 1990 and 1997 and observed 20 episodes of Pisa syndrome. We relate our findings to the epidemiologic data for the surveyed population. Moreover, we systematically analyze and discuss further risk factors such as comedication and comorbidity.

METHOD

The Project for Surveillance of Drug Safety in Psychiatry (Projekt zur Überwachung der Arzneimittelsicherheit in der Psychiatrie [AMSP]) was established at the Department of Psychiatry, Ludwig-Maximilian University,

Munich, Germany, in 1990. It currently includes 32 psychiatric institutions,[27] where 45,000 psychiatric patients were monitored between 1990 and 1997. The AMSP succeeded a similar, previous drug surveillance program, the Surveillance of Drugs in Psychiatry (Arzneimittelüberwachung in der Psychiatrie).[28] Clinically severe adverse drug reactions (ADRs) were documented according to the criteria of the project and comprised psychiatric, neurologic, or other medical conditions occurring as adverse drug effects. An ADR was defined as any adverse event occurring at doses adequate for therapeutic or prophylactic treatment. Adverse events due to intoxication or lack of efficacy were excluded.

The evaluation included ADRs to all marketed psychotropic drugs. Only ADRs rated as "clinically severe" were assessed. The study protocol as reported in a review article by Grohmann and colleagues[28] gives a detailed definition of inclusion criteria that rely on the severity of the event itself and its potential danger to the patient's health. Several neurologic ADRs were explicitly listed, including Pisa syndrome, beside severe or hitherto unknown extrapyramidal motor symptoms, e.g., parkinsonism only if disabling in everyday functioning, tardive dyskinesia, malignant and catatonic neuroleptic syndrome.

Pisa syndrome was defined as a tonic flexion of the trunk that was maintained while sitting, lying, standing, or walking, as originally described by Ekbom and colleagues.[1] Episodes secondary to orthopedic or neurologic conditions were not included.

In the ongoing AMSP study, ADR data are collected and analyzed as previously described.[28] In brief, ADRs are documented by trained psychiatrists. Physicians, who act as drug monitors, contact all colleagues at regular intervals, at least every 2 weeks.

When an ADR occurs, the treating psychiatrist is interviewed by the drug monitor, and the case is documented with a standardized questionnaire. Age, gender, and psychiatric and somatic diagnoses are recorded along with a detailed description of the adverse event, potential risk factors, clinical measures taken because of the ADR, and its subsequent outcome. Comorbidity with central nervous system (CNS) disorders or pathology is assessed on the basis of the patient's charts containing results of structural neuroimaging (computed tomography, magnetic resonance imaging), lumbar puncture, and electroencephalography. Drug treatment prior to the ADR is documented along with the duration of treatment and changes in dosage. Previous exposure to the imputed drugs, drug treatment after the adverse event, and outcome in case of rechallenge are also documented.

The case is then forwarded to the AMSP center at the psychiatric department of the University of Munich, reviewed by a senior member of the team, and then discussed at a central case conference in which drug monitors from all centers participate, as well as representatives of the Federal Health Agency (Bundesinstitut für Arzneimittel und Medizinprodukte) and the Pharmaceutical Commission of the German Medical Profession (Arzneimittelkommission der deutschen Ärzteschaft). This conference is held to achieve a valid and final judgment on the imputation of a drug in ADRs. In addition to ADRs, the general drug use in the participating centers is regularly documented by the AMSP to estimate the frequency of an ADR occurring with a certain drug.

Data on drug use in the participating centers are based on 2 reference days per year. All drugs given on a reference day are recorded along with age, gender, and dosages, as well as diagnoses for all patients under AMSP surveillance. In addition, the participating centers provide the number of inpatients monitored per year as well as the mean duration of inpatient treatment for all monitored patients; both are broken down according to diagnostic groups.

Between 1990 and 1997, medication was documented for 13,580 of the 45,000 inpatients surveyed. Table 1 summarizes the medications taken by the surveyed population compared with those received by Pisa syndrome patients.

RESULTS

Epidemiology

Between 1990 and 1997, 45,000 patients were surveyed by the AMSP. During the period of surveillance, 20 episodes of Pisa syndrome occurred in 17 patients as drug-related adverse events (frequency of Pisa syndrome was 17/45,000 ≈ 0.04% related to the surveyed population). A total of 65.7% of all patients were being treated with neuroleptics; thus, the risk of developing Pisa syndrome after neuroleptic treatment was 0.06%.

The Pisa syndrome episodes were documented in 13 women and 4 men. A similar preponderance of women was not observed in the investigated population (46.6% male, 53.4% female). The mean age of patients with Pisa syndrome was 61.9 years (range, 33–86 years) and was significantly higher than in the overall surveyed population (Table 2).

Comorbidity

The relevant clinical information for all reported episodes is shown in Table 3. There was evidence for a CNS pathology in all patients: a clinical diagnosis of an organic brain disorder was established for 9 patients (i.e., encephalomyelitis disseminata, Lewy body dementia, Alzheimer's disease, congenital brain damage, and arteriosclerotic encephalopathy); electroencephalogram, nuclear magnetic resonance, or cranial computed tomography showed pathologic findings in 5 patients; and psychopharmacologic drugs were combined in extreme dosages likely to be relevant in CNS toxicity for 3 patients.

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Table 1. Comparison Between Frequencies for Single Substances and Drug Groups in All Patients Monitored in the AMSP Between 1990 and 1997 and in Patients With Pisa Syndrome[a]

Substance	Frequency in AMSP, %	No. of Episodes of Pisa Syndrome[b]
Neuroleptics		
Butyrophenones		
Haloperidol[c]	18.4	5 [3]
Haloperidol decanoate[c]	2.3	[1]
Pipamperone[d]	3.6	2
Melperone[e]	3.9	2 [1]
Phenothiazines		
Perphenazine[c]	1.0	1
Trifluoperazine[c]	0.4	1
Promethazine[e]	4.8	2
Levomepromazine[e]	6.5	1
Thioxanthenes		
Zuclopenthixol[c]	0.9	1
Flupenthixol[c]	3.7	1
Atypical neuroleptics		
Zotepine[c]	1.5	1
Sertindole[c,f]	0.2	1
Olanzapine[c,f]	1.8	1
Clozapine[d]	11.7	4
Sulpiride[e]	0.2	1
Prothipendyl[e]	3.3	2
Lithium	8.6	6
Carbamazepine	10.2	2
Tricyclic antidepressant	21.2	2
Other antidepressant	12.6	2
Benzodiazepine	24.0	13
Antiparkinsonian medication	15.1	1

[a]Abbreviation: AMSP = Projekt zur Überwachung der Arzneimittelsicherheit in der Psychiatrie.
[b]The sum of the numbers of episodes reported for the individual drugs is higher than the total number of episodes since patients could be taking more than one drug. Values in brackets denote number of Pisa syndrome episodes that occurred subsequent to discontinuation of the drug.
[c]High neuroleptic potency.
[d]Medium neuroleptic potency.
[e]Low neuroleptic potency.
[f]These drugs have only been available since 1997.

Table 2. Comparison Between Age and Gender Distribution of All Patients Under Surveillance During the AMSP and Patients With Pisa Syndrome[a]

Characteristic	% of All Patients	% of Patients With Pisa Syndrome
Age, y		
< 40	38.3	5.88
40–59	34.5	35.29
≥ 60	27.2	58.82
Gender		
Male	46.6	23.53
Female	53.4	76.47

[a]Abbreviation: AMSP = Projekt zur Überwachung der Arzneimittelsicherheit in der Psychiatrie.

Causative Medication

In all patients, Pisa syndrome occurred with neuroleptic treatment, but not with neuroleptic monotherapy. Haloperidol was involved in 8 episodes, either during initiation and continuation of treatment or after discontinuation of the drug (3 patients). Ten of the 17 patients developed Pisa syndrome during treatment with classical neuroleptics. Six patients had been treated with atypical neuroleptics—4 with clozapine, 1 with olanzapine, and 1 with sertindole—but all patients had previously received a classical neuroleptic at least once. In 8 patients, an extended neuroleptic treatment for several months or years was documented. In 6 cases, Pisa syndrome occurred subsequent to discontinuation of a neuroleptic medication.

In 2 patients who had previously experienced Pisa syndrome, this adverse drug effect also occurred upon reexposure to the same or different neuroleptic. One patient experienced 2 episodes of Pisa syndrome, and 1 experienced 3. Drug combinations with lithium (6 episodes) and benzodiazepines (13 episodes) were frequent. When the frequencies were compared with those of the surveyed psychiatric population (see Table 3), lithium, atypical neuroleptics, and benzodiazepines appeared to be overrepresented. A comedication with tiapride or biperiden was associated with the onset of Pisa syndrome in 2 episodes. In the majority of episodes, Pisa syndrome occurred within 2 weeks after a new psychopharmacologic treatment was started.

Clinical Course and Outcome

In all cases but one, Pisa syndrome resolved completely upon treatment. Symptoms persisted in a 33-year-old patient with encephalomyelitis disseminata because neither appropriate treatment nor neuroleptic dose reduction was feasible. Remarkably, all patients showed an indifference to their gross abnormality of posture. No disturbance of balance or orientation in space was observed apart from the actual Pisa syndrome. Neuroleptic medication was discontinued in 12 episodes, and dosage was reduced in 5 episodes. In 1 episode, dosage of 1 neuroleptic was reduced while a second neuroleptic was discontinued. In 1 episode, lithium was reduced. In addition, biperiden was applied in 7 episodes prior to recovery from Pisa syndrome. One patient was treated with tiapride.

DISCUSSION

In the present study, we compared the occurrence of Pisa syndrome with data from a large epidemiologic database and found Pisa syndrome to be a rare adverse event related to treatment with neuroleptics. We newly describe further components of a characteristic constellation of predisposing factors: the presence of an organic brain disorder, old age, female gender, current or previous treatment with classical neuroleptics, and combined pharmacologic treatment.

To date, 89 cases of Pisa syndrome have been reported in numerous case reports,[7–21] 4 small cumulative case reports,[1,2,22,23] and 3 case series.[24–26] Since only minimal epidemiologic data are available, any conclusions regarding

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Table 3. Relevant Clinical Information for All Reported Episodes[a]

Patient[b]	Organic CNS Disorder	Prior/Current Treatment With Classical Neuroleptics	Drugs in Combination[c]	Changes in Psychopharmacologic Drug Treatment Within 14 Days Preceding Onset of PS: Treatment Changed	Drug Added	Dosage Increased	Drug Discontinuation	Treatment With: Atypical Neuroleptics[d]	Benzodiazepines[d]	Lithium[d]	Age > 50 y	Female
1	✓	✓	✓	✓	✓				✓			
2[e]	✓	✓	✓	✓	✓			✓		✓		✓
3	✓	✓	✓	✓	✓	✓		✓	✓			✓
4	✓	✓	✓	✓	✓	✓			✓	✓		✓
5	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	
6	✓	✓	✓	✓	✓	✓		✓			✓	✓
7	✓	✓	✓	✓	✓	✓			✓		✓	✓
8	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓
9	✓	✓	✓	✓	✓						✓	
10	✓	✓	✓	✓	✓						✓	
11	✓	✓	✓	✓	✓		✓		✓		✓	✓
12	✓	✓	✓	✓	✓		✓	✓			✓	✓
13	✓	✓	✓	✓			✓		✓	✓	✓	✓
14	✓	✓	✓	✓	✓		✓		✓		✓	✓
14	✓	✓	✓	✓	✓				✓		✓	✓
14	✓	✓	✓	✓	✓				✓		✓	✓
15	✓	✓	✓	✓	✓				✓	✓	✓	✓
15	✓	✓	✓	✓	✓				✓	✓	✓	✓
16[f]	✓	✓	✓	✓	✓	✓		✓			✓	✓
17	✓	✓	✓	✓	✓		✓				✓	✓

[a]Abbreviations: CNS = central nervous system, PS = Pisa syndrome. Symbol: ✓ = yes.
[b]Patient 14 had 3 episodes of PS; patient 15 had 2 episodes of PS.
[c]Includes every kind of pharmacologic treatment.
[d]Drugs that appeared to be overrepresented in patients who developed PS.
[e]Same case as case 4 described by Kurtz and colleagues.[23]
[f]Case described by Padberg and colleagues.[21]

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frequency and risk factors of Pisa syndrome are difficult to deduct at the present time.

In the present study, Pisa syndrome appears to be a rare adverse event, occurring in 0.04% of our surveyed population. The frequency of Pisa syndrome has been discussed with controversy. Pilette[2] commented on a case report[8] and concluded that Pisa syndrome occurs fairly commonly. In contrast, Guy and colleagues[3] proposed that Pisa syndrome may be an extremely rare side effect. However, 2 large series with 20 and 27 patients were reported, but these did not relate cases to an epidemiologic database.[24,25] In our study, the frequency of Pisa syndrome may be underestimated owing to the nature of the AMSP project, which only registers reported adverse events. However, the documented rarity of Pisa syndrome is consistent with the clinical impression of Pisa syndrome being an extremely rare adverse event in a general psychiatric population. In an elderly population, Pisa syndrome is presumably more frequent. In 133 psychogeriatric patients, 11 cases (8.3%) of Pisa syndrome were observed.[26] Pisa syndrome has rarely been found in young patients, although Turk and Lask[15] described the unusual case of a 15-year-old girl suffering from an organic brain disorder. Similarly, we found age to be a risk factor since 76% of our patients were older than 50 years of age and the average age of patients with Pisa syndrome was higher than in the surveyed population.

Regarding gender differences for Pisa syndrome, we found a female/male ratio of about 3:1 (see Table 2). This finding is consistent with previous reports[2] of 89 Pisa syndrome cases, comprising 59 women and 24 men (gender was not reported in 6 patients).

Evidence of an organic brain disorder was present in all patients in our study. This confirms the earlier hypothesis that comorbidity with CNS disorders may increase the risk of experiencing Pisa syndrome.[1,24] This notion is further supported by the observation of spontaneously occurring and daily fluctuating Pisa syndrome in a 60-year-old patient with Alzheimer's dementia and bradykinesia.[14]

To address the question of whether Pisa syndrome is an acute or tardive dyskinesia, we thoroughly assessed the time course of drug treatment in relation to the onset of Pisa syndrome. In our patient sample, we observed both no coincidence of previous neuroleptic medication with Pisa syndrome in some patients and an acute onset of Pisa syndrome after neuroleptic treatment in others. The notion of Pisa syndrome as an acute syndrome was further supported by the following findings: (1) Pisa syndrome always occurred within 2 weeks after a drug change involving neuroleptics, lithium, and benzodiazepines and (2) an improvement could be observed after drug discontinuation or dose reduction. However, the issue of whether Pisa syndrome is an acute or tardive condition has been controversial. Ekbom and colleagues[1] interpreted the clinical features as an unusual presentation of an acute dyskinesia. Pisa syndrome was later regarded as tardive dyskinesia.[8,9] Suzuki and colleagues[24] concluded that Pisa syndrome might occur as acute or tardive dysto-

nia, based on a complex pathogenesis. Inada and Yagi[29] mentioned Pisa syndrome as a form of dystonia among different neuroleptic-induced syndromes. Therefore, at present, Pisa syndrome appears to be neither a purely acute nor tardive syndrome, but perhaps both.

In previous reports, Pisa syndrome has usually been interpreted as dystonia or dyskinesia. However, this interpretation was mainly based on the general clinical impression and was not empirically verified. Therefore, the question of whether Pisa syndrome is an extrapyramidal syndrome is currently unanswered, and the pathophysiology still needs to be elucidated.

In our study, all patients received neuroleptic treatment. In 6 cases, clozapine or other atypical neuroleptics were involved. However, all patients had received prior treatment with at least 1 classical neuroleptic. A case series of Pisa syndrome occurring with atypical neuroleptics (clozapine) was reported previously by Kurtz and colleagues.[23] Similar to our findings, all patients in that series had received classical neuroleptic treatment prior to clozapine. Thus, no evidence exists to date that an atypical neuroleptic may cause Pisa syndrome without prior treatment with classical neuroleptics. However, it is not clear whether this association just reflects the long-standing general psychogeriatric practice to use classical neuroleptics as first-line drugs for psychotic features, agitation, and aggression in the elderly or whether prior treatment with classical neuroleptics is a necessary condition. Therefore, atypical neuroleptics should be administered with caution in patients at risk for Pisa syndrome who have already received a classical neuroleptic treatment during the prior course.

Several cases have been described in which reexposure or change of medication to a different neuroleptic class resulted in a relapse of Pisa syndrome.[1,13,22,24,26] Similarly, we observed relapsing Pisa syndrome in patients who were treated successively with different neuroleptics.

In all cases of Pisa syndrome reported here there was a change of psychotropic medication within the last 14 days prior to the onset of Pisa syndrome in that a drug was discontinued, a further drug was added, or the dosage changed. In accordance with the literature, Pisa syndrome appears to be dose related. One of our patients developed symptoms only after a dose increase, and remission could often be achieved by dose reduction. However, 2 cases were reported showing a spontaneous remission after an increase of the clozapine dose[23] or simultaneous treatment with a second neuroleptic and biperiden.[22] Remarkably, Pisa syndrome also occurred in 4 cases when neuroleptics were discontinued, suggesting a withdrawal effect.

Interestingly, polypharmacologic treatment seems to predispose to Pisa syndrome. In our observations, all patients received a combination of several substances. We found a comedication with lithium in 6, and with benzodiazepines in 13 of 20 episodes. Both drugs were more frequently taken by Pisa syndrome patients (30% and 65%) compared with the general AMSP population (8.6% and 24%).

In a single case,[20] Pisa syndrome was previously described as occurring during treatment with tricyclic antidepressants but not with neuroleptics. In regard to our findings, it appears to be relevant that this patient received high dosages of 3 different antidepressants (amitriptyline, 150 mg/day; imipramine, 150 mg/day; and nortriptyline, 150 mg/day). We did not observe tricyclic antidepressants as causative medication and even found antidepressants to be underrepresented in Pisa syndrome patients compared with the overall surveyed population.

Various treatment strategies have been recommended for Pisa syndrome. Ekbom and colleagues[1] described the syndrome as reversible and treatable with antiparkinsonian drugs, but had simultaneously interrupted any neuroleptic treatment. Successful treatment with amantadine[11] or trihexyphenidyl[24] or by replacing haloperidol with the dopamine D_2-selective antidopaminergic drug pimozide[17] has been reported. Furthermore, Guy and colleagues[8] suggested replacing classical with atypical neuroleptics.

Our data do not support the latter suggestion, because Pisa syndrome may also occur with atypical neuroleptics, e.g., clozapine, sertindole, olanzapine. According to our experience and other investigations,[1,22,24] dose reduction or discontinuation of neuroleptics leads to an amelioration of symptoms or even complete remission in the majority of patients and can be regarded as a first-line treatment of Pisa syndrome. With appropriate treatment, Pisa syndrome appears to be a reversible adverse event, but one that may last from several days to months and has nevertheless to be considered as serious.

We conclude that Pisa syndrome is a very rare adverse event during neuroleptic treatment. Pisa syndrome can occur during therapy with various classical and atypical neuroleptic drugs. A characteristic constellation of conditions appears to predispose to Pisa syndrome: the presence of an organic brain disorder, old age, female gender, previous treatment with at least one classical neuroleptic medication, and combined pharmacologic treatment.

Drug names: amantadine (Symmetrel and others), amitriptyline (Elavil and others), biperiden (Akineton), carbamazepine (Tegretol and others), clozapine (Clozaril and others), haloperidol (Haldol and others), nortriptyline (Pamelor and others), olanzapine (Zyprexa), perphenazine (Trilafon and others), pimozide (Orap), promethazine (Phenergan and others), trifluoperazine (Stelazine), trihexyphenidyl (Artane and others).

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