Increased morbidity and mortality related to asthma among asthmatic patients who use major tranquillisers

K S Joseph, Lucie Blais, Pierre Ernst, Samy Suissa

Abstract

***Objective*—To assess the potentially increased risk of death or near death from asthma in asthmatic patients with psychosis.**

***Design*—Case-control study.**

***Setting*—The computerised health databases of the Canadian province of Saskatchewan.**

***Subjects*—131 cases of death or near death from asthma identified within a cohort of asthmatic patients; 3930 matched non-cases.**

***Exposure and outcome measures*—The exposure of interest was the use of major tranquillisers in the period before an outcome event. Outcomes included death or near death from asthma.**

***Results*—Crude analyses showed that asthmatic patients who had used major tranquillisers in the previous 12 months were at a 3·2 (95% confidence interval 1·4 to 7·5) times greater risk of death or near death from asthma than asthmatic patients who did not use major tranquillisers. Past users of major tranquillisers who had recently discontinued use were at a particularly high risk (relative risk 6·6; 2·5 to 17·6). Adjustment for use of antiasthma drugs and other confounders abolished this excess risk.**

***Conclusions*—Asthmatic patients who use major tranquillisers seem to be at an increased risk of death or near death from asthma. Physicians treating asthmatic patients with a history of use of major tranquillisers should exercise greater caution with regard to management of such patients.**

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Introduction

The problems associated with the management of patients with coexisting bronchial asthma and psychosis have been documented in the medical literature.[1-3] Various reasons have been proposed to explain the suboptimal clinical outlook in these patients. Firstly, such patients tend to aggravate their clinical condition through non-compliance and "abuse" of medical facilities.[1] Also, physicians may be reluctant to use systemic corticosteroids out of concern about aggravating the psychosis.[2,4] Furthermore, major tranquillisers used for the treatment of schizophrenia and other psychoses cause sedation and are thus contraindicated during acute asthma attacks.[5,6] Respiratory dysfunction has also been reported as a consequence of the extrapyramidal side effects of major tranquillisers.[7] Finally, the suboptimal outlook may be the consequence of a theoretical antagonism between the classes of drugs used for the two illnesses.[8,9] Whereas major tranquillisers have complex effects on the autonomic nervous system, long term use of β agonists may interfere with the mental state of patients with psychosis.

The above mentioned clinical concerns are based almost solely on case reports. Only one epidemiological study[10] has shown an increased risk of death from asthma or of hospital readmission associated with the use of psychotropic drugs and with past use of tranquillisers, neuroleptics, antidepressants, or anticonvulsants considered as a single exposure. We therefore conducted a population based study to quantify the increased risk of death or near death from asthma among asthmatic patients who use major tranquillisers.

Patients and methods

We tested our hypothesis with data from the Saskatchewan Asthma Epidemiology Project. The methods and study population have been described in detail previously.[11,12] Briefly, we identified a cohort of 12 301 subjects aged between 5 and 54 years who had been dispensed 10 or more prescriptions for common antiasthma drugs between 1978 and 1987 from the computerised files of the Saskatchewan prescription drug plan.[13,14] All fatal and near fatal asthma attacks were identified within this cohort. This information was used to obtain death certificates, coroners' reports, necropsy reports, and hospital discharge summaries. Forty six deaths were classified as probably due to asthma. Near fatal attacks of asthma (defined as non-elective intubation during an acute asthma attack or hypercarbia, or both—that is, arterial $PCO_2 > 45$ mm Hg) were identified with the additional use of emergency procedure and billing codes as well as selected screening of hospital records. Eighty five patients were identified with a near fatal episode probably due to asthma.

Thirty non-cases were selected from the cohort for each case identified after we matched for the index date (that is, time of the case event) and the year of entry into the cohort. Users of major tranquillisers were identified from the prescription database as those subjects who had received at least one prescription for a major tranquilliser in the 12 months preceding the index date. Major tranquillisers listed in the Saskatchewan formulary during the study period included chlorpromazine, chlorprothixene, fluphenazine, flupenthixol, haloperidol, mesoridazine, pericyazine, perphenazine, pimozide, piperacetazine, pipothiazine, thioridazine, thiothixene, and trifluoperazine. Users of antidepressants, sedatives, antihypertensives, and hypoglycaemic agents were similarly identified for the purpose of confirming the specificity of any potential effect. Information on exposure status was used to estimate relative risks (incidence density ratios, technically[15]).

The crude association between use of major tranquillisers and death or near death from asthma was deemed to be of interest per se, in accordance with general epidemiological principles.[16-18] This was because use of antiasthma drugs and health services was considered to be (at least partly) in the causal pathway between psychosis and death or near death

from asthma. Specifically, if psychotic patients are non-compliant with concurrent antiasthma drug treatment as a consequence of their psychosis, adjustment for use of antiasthma drugs would not be warranted.

To investigate the potential mechanism by which use of major tranquillisers increased the risk of death or near death from asthma we studied the time relation of drug use to outcome by anchoring the scale of aetiological time to the moment of outcome classification.[19] Two mutually exclusive time windows of major tranquilliser use were created a priori within the one year period preceding the index date. The first time window for major tranquilliser use spanned the two months immediately before the index date; the second time window extended from two months to 12 months before the index date. Any drug use in the former time window was termed recent use, while use within the latter time window was referred to as past use. The two determinants so constructed were conceptualised as mutually confounding.

Although the crude relation between major tranquilliser use and death or near death from asthma was deemed to be of direct interest, we also studied the effect of adjustment for use of health services and antiasthma drugs and other confounders. This was done to ascertain whether these confounding variables would partially or completely explain the potential differences in risk between users and non-users of major tranquillisers. The number of admissions to hospital for asthma in the 12 months before the index date was used to quantify use of health services, while use of antiasthma drugs in the two months before the index date was quantified by using the number of canisters or prescriptions filled for each of the following drugs: inhaled fenoterol, inhaled salbutamol, inhaled corticosteroids, inhaled sodium cromoglycate, other inhaled sympathomimetics, nebulised salbutamol, oral fenoterol, oral salbutamol, oral corticosteroids, ipratropium bromide, theophylline compounds, and other oral sympathomimetics. Age, sex, area of residence, and receipt of social assistance were other potential confounders included in the initial model.

Step down regression analyses were carried out with conditional logistic regression for matched sets.[17] As the final model contained numerous terms we used a confounder score[20] to express the background risk associated with major tranquilliser use. This was accomplished by calculating a confounder score (CS) for each subject based on the β coefficients ($\hat{\beta}_i$) of all confounding variables (X_i) obtained from the final model ($CS = E\hat{\beta}_i X_i$). The confounder score was then introduced as a single term in the regression model along with the indicators for exposure.

Table 1—*Crude relative risks for death or near death from asthma associated with use of specific drugs in 12 months preceding index date*

Determinants	Cases		Non-cases		Estimated relative risk (95% confidence interval)
	Yes	No	Yes	No	
Major tranquillisers	6	125	58	3872	3·2 (1·4 to 7·5)
Antidepressants	8	123	164	3766	1·5 (0·7 to 3·1)
Antihypertensives	11	120	222	3708	1·5 (0·8 to 2·9)
Sedatives	20	111	347	3583	1·9 (1·2 to 3·1)
Hypoglycaemics	1	130	37	3893	0·8 (0·1 to 6·0)

Table 2—*Crude relative risks for use of major tranquillisers or sedatives within two mutually exclusive time windows: within two months of index date (recent use) and between two months and 12 months before index date (past use). No use refers to absence of use in either time window*

Determinant	Cases	Non-cases	Estimated relative risk (95% confidence interval)
Major tranquillisers:			
No use (reference)	125	3872	1·0
Recent use only	0	10	0·0 (0·0 to 15·6*)
Past use only	5	23	6·6 (2·5 to 17·6)
Recent and past use	1	25	1·3 (0·2 to 9·6)
Sedatives:			
No use (reference)	111	3583	1·0
Recent use only	0	16	0·0 (0·0 to 7·4*)
Past use only	11	189	1·9 (1·0 to 3·7)
Recent and past use	9	142	2·0 (1·0 to 4·1)

*Upper confidence limit computed by using exact methods.[21]

Table 3—*Proportion of non-case subjects (n=3930) who received at least one canister of or prescription for listed antiasthma drug in two months before index date or who were admitted to hospital at least once for asthma during previous 12 months*

Confounder	Major tranquillisers		Sedatives	
	Non-users (n=3872)	Users (n=58)	Non-users (n=3583)	Users (n=347)
β Agonists (inhaled or nebulised)	1898 (49·0)	21 (36·2)	1746 (48·7)	173 (49·9)
Oral salbutamol	282 (7·3)	9 (15·5)	254 (7·1)	37 (10·7)
Inhaled steroids	451 (11·7)	10 (17·2)	397 (11·1)	64 (18·4)
Oral steroids	203 (5·2)	2 (3·5)	170 (4·7)	35 (10·1)
Theophylline	775 (20·0)	23 (39·7)	691 (19·3)	107 (30·8)
Admission to hospital	322 (8·3)	6 (10·3)	288 (8·0)	40 (11·5)

Results

Users of major tranquillisers received an average of five prescriptions during the 12 months before the index date (mean for cases and non-cases, three and five, respectively). Crude analyses showed that asthmatic patients who had used major tranquillisers in the previous 12 months were at a 3·2 (95% confidence interval 1·4 to 7·5) times greater risk of death or near death from asthma than asthmatic patients who did not use the same drugs (table 1). The risk among users of antidepressants, antihypertensives, and hypoglycaemic agents was not significantly higher, although users of sedatives were at a 1·9 (1·2 to 3·1) times greater risk of death or near death from asthma.

Table 2 presents the crude effects of use of major tranquilliser or sedatives within the prespecified time windows. Continuous use of major tranquillisers across the 12 months before the index date (that is, past and recent use) was not associated with increased risk, although past use with recent discontinuation significantly increased the risk of death or near death from asthma (relative risk 6·6; 2·5 to 17·6). Both past and continuous use of sedatives was associated with a nominally significant risk of death or near death from asthma. Step down regression yielded a final model that contained terms for area of residence; number of admissions to hospital in the previous year; numbers of canisters of inhaled fenoterol, inhaled salbutamol, inhaled corticosteroids, and other inhaled antiasthma drugs; and numbers of prescriptions for nebulised salbutamol, oral salbutamol, oral corticosteroids, and theophylline.

The distribution of the above mentioned variables differed between users and non-users of major tranquillisers and to a lesser extent between users and non-users of sedatives (table 3). The mean confounder score (expressing background risk) among non-case users of major tranquillisers or sedatives was higher than that among non-users of the same drugs. Adjustment for confounders abolished the

Table 4—*Relative risks for use of major tranquillisers or sedatives before and after adjustment for number of admissions to hospital (in previous 12 months), antiasthma drugs (in previous two months), and other confounders. Background risk due to these confounders was summarised as confounder score and introduced into regression model*

Variable	Crude		Adjusted	
	Relative risk (95% confidence interval)	P value	Relative risk (95% confidence interval)	P value
Major tranquillisers (previous 12 months)	3·2 (1·4 to 7·5)	<0·01	1·3 (0·3 to 4·7)	0·73
Sedatives (previous 12 months)	1·9 (1·2 to 3·1)	0·01	1·4 (0·8 to 2·5)	0·29
Confounder score	2·7 (2·4 to 3·1)	<0·01	2·7 (2·4 to 3·1)	<0·01

Table 5—*Relative risks for use of major tranquillisers or sedatives within two mutually exclusive time windows: within two months of index date (recent use) and between two months and 12 months before index date (past use). "Crude" model contained four listed determinants only, while adjusted model also included all confounders, with antiasthma drug use quantified in previous two months*

Determinant	"Crude"		Adjusted	
	Relative risk (95% confidence interval)	P value	Relative risk (95% confidence interval)	P value
Major tranquillisers:				
Recent use	0·2 (0·0 to 1·5)	0·11	0·1 (0·0 to 2·8)	0·16
Past use	5·4 (2·0 to 14·5)	<0·01	2·4 (0·6 to 9·7)	0·23
Sedatives:				
Recent use	1·0 (0·4 to 2·3)	0·92	1·1 (0·4 to 3·1)	0·89
Past use	1·8 (0·97 to 3·4)	0·06	1·4 (0·7 to 3·0)	0·35

crude associations between use of major tranquillisers or sedatives in the previous 12 months and death or near death from asthma (table 4). Table 5 shows the results of regression with exposure to major tranquillisers and sedatives specified in terms of its time relation to the index event. "Crude" regression analysis (not adjusted for confounding variables but adjusted for mutual confounding between the determinants) showed that only past users of major tranquillisers were at a significantly increased risk for the outcome. Adjustment for confounders resulted in non-significant associations for all determinants.

Discussion

We have shown that asthmatic patients who use major tranquillisers are at increased risk for the serious complications of asthma. Furthermore, analyses carried out according to the timing of use of major tranquillisers showed that subjects who discontinue their antipsychotic drugs are at higher risk of death or near death from asthma. Given the chronic nature of most psychoses such drug discontinuation most likely represents a worsening of the psychosis rather than a remission of the mental illness.

Key messages

- Asthmatic users of major tranquillisers are at an increased risk of death or near death from asthma
- Past users of major tranquillisers who have recently discontinued use are at particularly high risk
- Physicians treating asthmatic patients should consider a history of use of major tranquillisers as a marker for identifying patients at higher risk for the serious complications of asthma

Differential rates of mortality from various causes have been observed among schizophrenic patients as compared with the general population.[22,23] Interestingly, these mortality consequences (for instance, mortality due to lung cancer) have been explained on the basis of a differential distribution of psychological and behavioural risk factors (for example, smoking patterns).[24,25] Given the psychological and behavioural component associated with asthma and its management,[3,26] the findings of our study are not entirely unexpected, at least with regard to use of major tranquillisers. Unlike previous reports linking asthma mortality with depression, especially in children,[27-29] our study did not show an increased risk among users of antidepressants, possibly on account of age differences in study populations.

The fact that adjustment for use of antiasthma drugs diluted the crude associations at issue could imply increased risk secondary to differential prescribing of antiasthma drugs between users and non-users of major tranquillisers. Such differential prescribing, however, could be a consequence of patients' attitudes and compliance and other factors associated with the mental illness. Given that the number of prescriptions for antiasthma drugs was conceptualised as an index of asthma severity and that drug prescription does not necessarily represent sustained use, the higher mean confounder score among non-case users of major tranquillisers suggests that psychotic patients with asthma receive medical care at more severe stages of asthma, perhaps without adequate follow up.

Even though patients suffering from coexisting asthma and psychosis constitute a small segment of the population, their problems present a challenge to the medical profession. Physicians treating asthmatic patients should use a history of major tranquilliser use as a marker for identifying patients at high risk for the serious complications of asthma.

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Commentaries:

Physical illness in psychiatric patients may be managed poorly

Teifion Davies

Psychiatric disorders are known to be associated with an excess mortality from all causes.[1] A recent study that used a community based case register of psychiatric patients found their all cause standardised mortality ratio to be 1·63.[2] Mortality was greatest among younger patients (8·82 for ages 14 to 24 years) and men (2·24); the rate in schizophrenic patients was 1·76. In another case register study[3] the cause specific mortality ratio from respiratory diseases was raised significantly among schizophrenic subjects (men 3·01, women 2·17), as was that from cardiac causes (men 1·69, women 1·37). These findings were thought to reflect the high rate of cigarette smoking (over 50% of subjects smoked more than 15 cigarettes a day). Antipsychotic drugs (major tranquillisers) have been implicated in sudden, unexpected death largely on theoretical grounds. To date, the clearest evidence of a causal relation comes from a series of case reports of death after acute treatment with high doses of antipsychotics.[4] Several antipsychotic drugs in routine use (for example, the phenothiazines) have stabilising effects on the cardiac membrane similar to those of antiarrhythmic agents and, similarly, may provoke arrhythmias under certain conditions. How long these adverse cardiac effects persist after cessation of antipsychotic drugs is not clear. β Adrenergic agonists (such as salbutamol) used in the treatment of asthma, however, may produce hypokalaemia, and this is known to potentiate the arrhythmogenic effects of antipsychotic drugs.

How, then, should we view the findings of Joseph *et al*? Firstly, we should treat them with caution: six deaths and "near fatal" episodes occurred in those patients considered to be asthmatic and receiving antipsychotic drugs. The study was retrospective, and there is uncertainty that all cases and causes of death were ascertained accurately; the true risk may have been underestimated. The demographic details and psychiatric diagnoses of the six index and 125 reference cases (asthmatic patients not receiving antipsychotics) are not stated. This is important in view of the age, sex, and ethnic differences in the prevalence and outcome of both asthma and psychosis and because although many asthma deaths occur in children, it is relatively rare for children to receive antipsychotic drugs.

Secondly, however, this study is a timely reminder of the importance of careful management of comorbid physical illness in this group of often difficult patients.[5] In some surveys as many as 40% of psychiatric patients living in the community have untreated physical disorders. Many, and especially those with severe mental illnesses such as schizophrenia or the other psychoses, are poorly compliant with treatment or fail to maintain contact with health services.[5] Asthma is a common disorder which is associated with considerable morbidity, and its prevalence may be increasing in Western societies. It is likely then that general practitioners and hospital specialists will be confronted increasingly with psychiatric patients who require treatment for asthma or other physical illness. They should ensure that these patients receive a full physical and psychiatric assessment and a comprehensive follow up.

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Asthmatic patients with psychosis need special care

Mark L Levy

The results of this important retrospective population based case-control study indicate that asthmatic patients who are prescribed major tranquillisers or sedatives during the previous 12 months are at increased risk of death from asthma or near fatal attacks. This effect increased if the patient's use of tranquillisers was reduced during the previous two months. The apparent differential prescribing of antiasthma drugs between users and non-users of major tranquillisers and the implication that psychotic patients receive predominantly acute rather than chronic care is worrying. These findings are of importance to all health professionals who care for patients with asthma; they provide a useful marker for identifying some people at high risk of death from asthma; and they provoke a number of practical as well as theoretical discussion points. It seems from this study that patients on major tranquillisers receive most of their asthma care during attacks. While there may be various explanations for this phenomenon, clinicians should ensure adequate follow up after attacks and make maximum use of the opportunity to examine and deal with the reasons for the lack of control of asthma. Asthmatic patients are at increased risk of death after attacks,[1] and it seems sensible to provide more rigorous follow up for those who are prescribed antipsychotic drugs. Clear communication is needed between different sectors of health provision when a patient's asthma goes out of control, thus avoiding the inadequate follow up elucidated in this study. Perhaps some community psychiatric nurses could be trained to manage asthma and take responsibility for psychotic patients. This training may be provided by joint efforts between primary and secondary care in combination with approved, validated courses for nurses, such

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