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## PREVALENCE OF CATATONIC SIGNS AND SYMPTOMS IN DRUG NAÏVE/ DRUG FREE PERSONS SUFFERING FROM SCHIZOPHRENIA IN ADULT PSYCHIATRIC CLINIC

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**ABSTRACT** **Objective:** To investigate the prevalence of catatonic signs and symptoms in drug naïve/drug free persons suffering from schizophrenia and its association with clinical and socio-demographic variables.

**Method:** A total of 5043 patients were screened during 8 months period, out of which 61 adults suffering from schizophrenia who gave informed consent were taken up for the study. They were assessed for presence of catatonic symptoms from a key relative using Bush Francis Catatonia Screening Instrument (BFCSI) and then were examined for catatonic signs with Bush Francis Catatonia Rating Scale (BFCRS). Subjects who had at least two catatonic signs were considered as displaying catatonic features. Severity of psychopathology was assessed using the Positive and Negative Syndrome Scale (PANSS).

**Results:** 23 out of 61 subjects had catatonic features (37.3% of total sample). Catatonic signs were found to be more frequently present in persons having Undifferentiated and Catatonic subtypes. Catatonic signs were significantly more frequent in males and in subjects with higher mean PANSS negative, general psychopathology and total scores.

**Conclusion:** The prevalence of catatonic signs and symptoms in drug naïve/drug free persons suffering from schizophrenia in adult psychiatric is 37.3% and in turn reflects that catatonic phenomenon are still prevalent among them. It also shows correlation of catatonic phenomenon with severity of psychopathology. Further studies with larger sample size needs to be done to give greater credence to results.

**KEYWORDS :** Catatonia, Schizophrenia, Prevalence.

### INTRODUCTION

Catatonia, a term coined by Kahlbaum in 1874 has undergone changing definitions and implications over the years. It is now regarded as a neuropsychiatric syndrome resulting from dysfunction of the brain's motor regulation centers and consists of specific motor and behavioral signs accompanying a mental or medical disorder. It is reported to occur in 10% - 37.7% of adult patients with major psychiatric disorders.<sup>12</sup> The current view considering catatonia an uncommon feature of Schizophrenia is misleading. More accurate view would be that while the acute presentation dominated by catatonic phenomenon appear to have declined in frequency, the individual catatonic phenomenon are still prevalent among persons suffering from Schizophrenia. The present study was carried out in the light of paucity of systematic Indian studies investigating catatonia in adult persons suffering from Schizophrenia.

### METHODS

#### Study design and samples

This study was a cross-sectional hospital based study conducted at the Central Institute of Psychiatry (CIP), Kanke, Ranchi. A total of 5043 Patients who presented for first time at CIP between a period of ten months, out of which 61 adults suffering from Schizophrenia from both inpatient and outpatient department fulfilling the inclusion/exclusion criteria were taken up for the study by purposive sampling technique. The study sample consisted adults suffering from Schizophrenia aged between 18-60 years as per ICD-10 DCR who were Drug Naïve/Drug free of antipsychotics for last 4 weeks, 8 weeks if on depot antipsychotics. Patients having comorbid organic or neurological disorders, other psychiatric disorders and substance dependence were excluded from the study. Detailed socio-demographic and other variables were recorded in the proforma designed for the study. Screening of cases fulfilling the inclusion/exclusion criteria for catatonic symptoms was done by Bush Francis Catatonia Screening Instrument (BFCSI)<sup>3</sup> from a key relative; a key relative was defined as someone who remained with the patient for most of the time, preferably one of the first degree relative or spouse. Bush Francis catatonia rating scale was then applied on each patient to rate catatonic signs among them. Each patient was assessed for severity of psychopathology using the PANSS scale.

#### Statistical Analysis

Data analysis was done using Statistical Package for Social Science (SPSS) 10.0. Descriptive statistics were used to illustrate sample characteristics. <sup>2</sup> test was used to compare between groups on discrete variables. Independent sample t test was applied to derive group differences on continuous variables. The level of significance of <0.05 (two tailed) was adapted.

### RESULTS

#### Sample characteristics

The mean age was 31.75 ( $\pm$  7.11) years. Male participants were almost five times, 50 (82%), as compared to females 11 (18%). Concerning socio-occupational status, 26 (42.7%) were from lower, 24 (39.3%) from middle and 11 (18%) were from higher socio-economic status. With regard to education, 8 (13.1%) were illiterate, 8 (13.1%) had got primary education (i.e. upto sixth standard), 33 (54.1%) had received secondary education (i.e. upto XIIth standard) whereas 12 (19.7%) were graduates or having higher education. With regard to residence, more participants were from rural background 42 (68.9%), as compared with Urban 13 (21.3%) and suburban background, 6 (9.8%). Clinical variables of the patient population show that the mean age of onset of illness was 27.36 ( $\pm$  7.09) years and the mean duration of illness following which they were included in the study was 4.22 ( $\pm$  3.63) years. It also shows the mean drug free duration after which assessment for catatonic signs and symptoms was done, which was found to be 15.32 ( $\pm$  14.94) months.

Out of 61 patients, 22 (36.1%) were drug naïve whereas 39 (63.9%) were drug free (i.e. no antipsychotics for last 4 weeks, 8 weeks if on depot antipsychotics). Regarding different subtypes of schizophrenia included in the study, 23 (37.8%) had paranoid schizophrenia, 34 (55.7%) had undifferentiated schizophrenia, 1 (1.6%) had catatonic schizophrenia whereas 3 (4.9%) had other subtypes of schizophrenia (including schizophrenia unspecified).

#### Prevalence and distribution of catatonic signs

Out of 61 subjects included in the study, 23 (37.3% of the entire sample) subjects had at least 2 catatonic signs. The incidence of catatonic features among paranoid schizophrenia patients (N=23) was found to be 4.3% (N = 1), among undifferentiated schizophrenia patients (N = 34) was 61.8% (N = 21) whereas among catatonic schizophrenia patients was 100% (N = 1), which was found to be statistically significant.

Catatonic signs were significantly more frequent in males and in patients with higher mean PANSS negative, general psychopathology and total score. The mean score of total PANSS negative score among patients with and without catatonic features was 27.08 ( $\pm$  6.02) and 19.76 ( $\pm$  5.28) respectively. With respect of PANSS total score, the mean among patients with and without catatonic features was found to be 86.69 ( $\pm$  15.51) and 76.26 ( $\pm$  13.41) respectively. Among the different catatonic signs Negativism, Stupor, Mutism, Staring, Rigidity, Posturing, Mitgehen, were found to be more frequently present, whereas Echopraxia / Echolalia, Mannerism, Gagenhalten, Grasp reflex, Perseveration and Combativeness were found to be absent in the sample population.

**Table 1: Socio-demographic characteristics of the patient population (N=61)**

Variables		N = 61 N (%)
Sex	Male	50 (82.0)
	Female	11 (18.0)
Education	Illiterate	8 (13.1)
	Primary	8 (13.1)
	Secondary	33 (54.1)
	Graduate & above	12 (19.7)
Residence	Rural	42 (68.9)
	Urban	13 (21.3)
	Suburban	6 (9.8)

**Table 2(a): Clinical characteristics of the patient population (N=61)**

Variables	Mean ± SD
Age of onset (years)	27.36 ± 7.09
Duration of illness (years)	4.22 ± 3.63
Drug free duration (months)	15.32 ± 14.94

**Table 2(b): Clinical characteristics of the patient population (N=61)**

Variables	N (%)	
History of drugs	Absent	22 (36.1)
	Present	39 (63.9)
Diagnosis	Paranoid	23 (37.8)
	Undifferentiated	34 (55.7)
	Catatonic	1 (1.6)
	Others	3 (4.9)

**Table 3(a): Prevalence of catatonic signs and symptoms in schizophrenic patients (in entire sample)**

		N = 61	Catatonic signs and symptoms (Prevalence) n (%)
Diagnosis	Paranoid	23	1 (1.6)
	Undifferentiated	34	21 (34.1)
	Catatonic	1	1 (1.6)
	Others	3	0 (0)
	Total	61	23 (37.3)

**Table 3(b): Prevalence of catatonic signs and symptoms in individual subtypes of schizophrenia patients (as per diagnosis)**

Diagnosis	N = 61	Catatonic signs present	%
Paranoid	23	1	4.3
Undifferentiated	34	21	61.8
Catatonic	1	1	100.0
Others	3	0	0

**Table 4: Comparison of socio-demographic and clinical variables (categorical) between patients with and without catatonic signs and symptoms**

Variables	Catatonic signs & symptoms		χ <sup>2</sup> (df=1)	P	
	Absent (N=38) N (%)	Present (N=23) N (%)			
Sex	Male	34 (89.5)	16 (69.6)	3.84	<0.05
	Female	4 (10.5)	7 (30.4)		
Diagnosis	Paranoid	22 (57.9)	1 (4.3)	22.74	<0.001
	Undifferentiated	13 (34.2)	21 (91.3)		
	Catatonic	0 (0)	1 (4.3)		
	Others	3 (7.9)	0 (0)		

**Table 5: Group difference of socio-demographic and clinical variables (continuous) between patients with and without catatonic signs and symptoms**

Variables	Catatonic signs and symptoms		t	P
	Absent N = 38 (M ± SD)	Present N = 23 (M ± SD)		
PANSS positive scale total	21.26 ± 3.78	19.21 ± 6.28	1.413	NS

PANSS negative scale total	19.76 ± 5.28	27.08 ± 6.02	-4.977	< 0.001
PANSS general psychopathology total	35.23 ± 7.43	40.39 ± 7.97	-2.554	<0.01
PANSS total score	76.26 ± 13.41	86.69 ± 15.51	-2.774	<0.01

NS = Non significant

PANSS = Positive and negative Syndrome Scale (Key et al. 1987)

**Table 6: Distribution of each catatonic sign in schizophrenia**

Catatonic signs	n (%)
1. Negativism	16 (26.2)
2. Immobility/Stupor	14 (22.9)
3. Mutism	13 (21.3)
4. Staring	13 (21.3)
5. Rigidity	12 (19.7)
6. Posturing/catalepsy	11 (18.0)
7. Mitgehen	7 (11.5)
8. Ambitendency	5 (8.2)
9. Stereotype	5 (8.2)
10. Excitement	4 (6.6)

**DISCUSSION:**

Rates of catatonia among schizophrenic patients have varied widely in different studies. It is reported to occur in 10% - 37.7% of adult patients with major psychiatric disorders.<sup>1,2</sup> A challenging question concerns changes in the rate of catatonia over time but differences in methodology limit definitive answers. In our study, the prevalence of catatonic signs in drug naive/drug free persons suffering from schizophrenia was found to be 37.3%, which is in accordance with the finding of Cernovsky.<sup>4</sup> In the study by Cernovsky et al. the sample was almost double than the current study, was a prospective study and 40.2% of schizophrenic patients were found to have catatonic features. Although studies reviewed by Stompe<sup>6</sup> and colleagues showed a significant decline in catatonic schizophrenia, consistent evidence of decline across investigations could not be demonstrated. However, studies of changes in the rate of catatonic schizophrenia have demonstrated an average decrease of 57% during the twentieth century. Moreover, different studies have used different diagnostic criteria for diagnosing catatonia. In accordance with the standardized instrument used for the index study, the presence of two or more signs was considered diagnostic of catatonia. This is less stringent than that of another criteria asking for at least four signs.<sup>6</sup> The methodological differences among studies of catatonia remain significant and underscore the lack of consensus on the definition of catatonia. Investigators have used the DSM, ICD, or Leonhard systems for diagnosing catatonia and underlying disorders, resulting in different rates. Differences in assessment techniques, definitions of symptoms, and thresholds for diagnosis have also been a limiting factor. Moreover, cross-sectional surveys of the incidence or prevalence of catatonia may provide an incomplete picture leading to underestimates of its occurrence in association with other disorder.

This study was conducted in a tertiary level psychiatric setup in a developing country. It has been found that significant differences in results also stem from the choice of population studied. For example, there is consistent evidence that catatonia is diagnosed more often in developing nations<sup>7,8,9</sup> and in chronic institutional settings<sup>10</sup> as replicated in the present study where mean duration of illness was 4.22 (±3.63) years.

In the current study significant difference was observed among patients with and without catatonic signs in terms of total PANSS Negative Scale (p < 0.001). It reflects that from a dimensional perspective, motor features play a central role in the relationship among syndromes of psychoses. Positive and negative motor syndromes are interrelated among themselves, and in turn they are closely but differentially related to negative mood and disorganization syndromes.<sup>11</sup> Significant difference was also noted in terms of total PANSS general psychopathology scale (P = 0.01) and PANSS Total Score (P = 0.007), which was in contradiction to the finding of Peralta et al. (2001) where the psychotic syndromes were not correlated with either positive motor syndrome (comprised Parakinesia, mannerism and agitation) or negative motor syndrome (comprised of stupor, mutism and negativism).

This study has also tried to reflect the frequency of various catatonic

signs and symptoms among different subtypes of schizophrenia other than catatonic subtypes also and it was found that catatonic signs were more frequently present in undifferentiated subtype in addition is catatonic subtype. Several other studies have also shown that catatonia is not consistently diagnosed during episodes in the same patient and that patients with other subtypes of schizophrenia may develop catatonic signs on occasion.

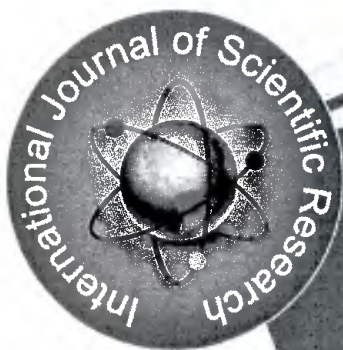
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## DISEASE MONGERING AND PSYCHIATRY: A REVIEW

## Psychiatry

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## ABSTRACT

**Summary:** The problem of disease mongering is attracting increasing attention, though an adequate working definition remains elusive. Disease mongering is the selling of sickness that widens the boundaries of illness and grows the markets for those who sell and deliver treatments. It is exemplified most explicitly by many pharmaceutical industry funded disease-awareness campaigns, more often designed to sell drugs than to illuminate or to inform or educate about the prevention of illness or the maintenance of health. Different forms of disease mongering practices have been identified like aspects of ordinary life, such as menopause, being medicalised; mild problems portrayed as serious illnesses and risk factors such as high blood cholesterol and low bone density being framed as diseases. Drug companies are by no means the only players in this drama. Informal alliances of pharmaceutical corporations, public relations companies, doctors' groups, and patient advocates promote these ideas to public and policymakers, often using mass media to push a certain view of a particular health problem. While these different stakeholders come to these alliances with different motives, there is a confluence of interests resulting in health problems routinely being framed as widespread, severe, and treatable with pills. Currently, these alliances are working with the media to popularize little-known conditions thus lending credence to inflated prevalence estimates. This is happening at a time when pharmaceutical companies perceive a need to build and maintain markets for big-selling products and when pipelines for new and genuinely innovative medicines are perceived as being weak. Like the marketing strategies that drive it, disease mongering poses a global challenge to those interested in public health, demanding in turn a global response. A much more vigorous effort is needed from within civil society to understand and to challenge this corporate process.

## KEYWORDS

## INTRODUCTION

Convincing healthy people that they are sick and in need of medicines creates an enormous market for drugs and medicines. The concept of what is and what is not a disease at times can be extremely slippery. Many of life's normal processes like birth, ageing, sexuality, unhappiness and death can be medicalised. Medicalisation is the process of turning ordinary life events and its customary ups and downs into medical conditions<sup>1</sup>.

Disease mongering is the selling of sickness that widens the boundaries of illness and grows the markets for those who sell and deliver treatments. It can also be argued that disease mongering is the opportunistic exploitation of both a widespread anxiety about frailty and a faith in scientific advance and "innovation"- a powerful economic, scientific, and social norm<sup>2</sup>. Disease mongering can also turn ordinary ailments into medical problems, see mild symptoms as serious, treat personal problems as medical ones, see risks as diseases, and frame prevalence estimates to increase potential markets. The problem of disease mongering is attracting increasing attention<sup>3,4</sup>, though an adequate working definition remains elusive. The term was first described by Lynn Payer<sup>5</sup> in the 1990s. It is exemplified most explicitly by many pharmaceutical industry funded disease awareness campaigns, more often designed to sell drugs than to illuminate, inform or educate about the prevention of illness or the maintenance of health. This is happening at a time when pharmaceutical companies perceive a need to build and maintain markets for their big-selling products and when pipelines for new and genuinely innovative medicines are perceived as being weak.

There is a very thin dividing line between promoting knowledge and understanding of a disease, and disease mongering, in many instances. Infact large "grey zones" exist between disease and normality and this might help to explain the increased use of "lifestyle drugs" and self prescription of psychiatric medication<sup>5</sup>. It may be absurd to decide on the concept of a disease and define who should be treated. There will always be "normal" people who will want treatment and "sick" people who will refuse it<sup>6</sup>.

## VARIOUS STRATEGIES OF DISEASE MONGERING

Different authors have described various forms of disease mongering activities companies can use to stimulate drug sale.

- Ordinary life processes or ailments can be converted into medical problems. Baldness has been suggested as the classic example. Baldness has been publicized to lead to panic and emotional difficulties which can have impact on job prospects and personal

well-being<sup>6</sup>. Recently, medicines are increasingly available for conditions which have so far been regarded as the natural result of ageing or as part of the normal range of human emotions.

- The second common strategy is to consider mild symptoms as portending a serious disease. This is exemplified by the case of irritable bowel syndrome (IBS). A mild functional disorder has been converted into a serious disease requiring drug treatment. Mild personal and social problems are also being converted into medical ones.
- Risk factors can be conceptualized and publicized as diseases. High blood pressure, raised cholesterol levels and osteoporosis have been suggested as examples<sup>4</sup>. In the case of osteoporosis, drug companies have sponsored meetings to define the condition and have funded studies of treatments. Conceiving osteoporosis as a disease is ethically complex as it is a component of normal ageing process. It has been publicized that slowing bone loss can decrease the risk of future fractures. However, the risk of serious fractures in absolute terms is low, and long-term preventive treatment can offer only small reductions in risk<sup>2</sup>.
- Disease prevalence estimates can be framed to maximize the size of a problem<sup>4</sup>. Erectile Dysfunction (ED) is the classic example. The pharmaceutical company marketing drug to treat erectile dysfunction publicized that ED was of significant concern to many, perhaps even most, men or at least those over 40 years of age. The criterion of success for treating ED had to be redefined. And finally, the drug had to be seen as an important treatment option for men with any degree of ED, including rare or transient failures to achieve or maintain erections.
- Promotion of anxiety about future ill health in healthy individuals and to use various life style modification drugs<sup>2</sup>.
- Introduction of questionable new diagnoses such as social anxiety disorder that are hard to distinguish from normal life<sup>6</sup>.
- Promotion of drugs as a first-line solution for problems previously not considered medical, such as disruptive classroom behaviour and problematic sexual relationships<sup>4</sup>.
- Selective use of statistics to exaggerate the benefits of treatment<sup>4</sup>.

## DISEASE MONGERING IN RELATION TO PSYCHIATRY

The psychiatric community has also not been left untouched by disease mongering and has now become the major disease invention branch of big pharmaceuticals. Over the last few decades some of the new psychiatric diagnoses have come up and some of the previous diagnoses have received much attention by pharmaceutical companies. Drug companies market the "treatment" that happens to

have been recently FDA approved. It can also be noticed how new diseases or disorders only get publicized and advertised after the FDA approves a big pharma drug to treat them. These diseases apparently spontaneously afflict huge numbers of people in the days following the FDA approval of any drug that might treat such diseases. It has been claimed that big pharma hires psychiatrists to invent and then to publicize new "diseases." They actually sit around in rooms, brainstorming new disease ideas and figuring out how to convince the public that those diseases exist<sup>6</sup>.

**Bipolar Disorder:** From the 1950s on, the depressions of manic-depressive illness have been treated with antidepressants and the manias with antipsychotics or lithium. Lithium was the only agent thought to be prophylactic against further episodes of manic-depressive illness<sup>7</sup>. But lithium was not originally referred to as a mood stabilizer. The term "mood stabilizer" had barely been heard of before 1995 when a pharmaceutical company got license for using the anticonvulsant sodium valproate for treating acute mania. After 1995, there was a dramatic growth in the frequency with which the term "mood stabilizer" appeared in the title of scientific articles. By 2001, more than a hundred article titles a year featured this term. Repeated reviews make it clear that the academic psychiatric community still has not come to a consensus on what the term "mood stabilizer" means<sup>8,9,10</sup>. But this lack of consensus did not get in the way of the message that patients with bipolar disorders needed to be detected and once detected needed mood stabilizers, and perhaps should only be given these drugs and not any other psychotropic drugs<sup>11</sup>. The first group of drugs to colonize this new mood stabilizer niche was anticonvulsants. Robert Post in the 1980s suggested that anticonvulsants might stabilize moods by a comparable quenching of the kindling effect of an episode of mood disorders on the risk of further episodes<sup>12</sup>. It was this idea that provided a pharmacological rationale for treatment of bipolar disorders that was so attractive to pharmaceutical companies, and, in their hands, the growth of awareness of mood stabilization and of bipolar disorders was sensational.

Bipolar disorders entered the DSM (*Diagnostic and Statistical Manual of Mental Disorders*) in 1980. At the time, the criteria for bipolar I disorder (classic manic-depressive illness) involved an episode of hospitalization for mania. Since then, the community based disorders bipolar II disorder, bipolar disorders NOS (not otherwise specified), and cyclothymia have emerged. With their emergence, estimates for the prevalence of bipolar disorders have risen from 0.1% of the population having bipolar I disorder (involving an episode of hospitalization for mania) to 5% or more when the definition of bipolar disorders includes the aforementioned community disorders<sup>13</sup>. There has always been a rationale to using antipsychotics in bipolar disorders, as they are effective in acute manic states. However, no companies making antipsychotics had previously sought a license for prophylaxis against bipolar disorders. Against a background of epidemiological studies indicating that the prevalence of bipolar disorders might be greater than previously thought, and growing academic interest in the condition, various pharmaceutical companies (i.e. Lilly, Janssen, and Astra-Zeneca) who are the makers of the antipsychotics (olanzapine, risperidone, and quetiapine) marched in to market these drugs for prophylaxis of bipolar disorder. This, in turn, greatly expanded the number of companies with an interest in making the "bipolar market." Recently a psychiatrist stated that he is a disease monger. While the possibility of over-diagnosis of the disorder exists, the diagnosis is not invalid and the actual evidence shows that bipolar disorder has been largely undiagnosed or under-diagnosed<sup>14</sup>. This necessarily raises the prospect that increased efforts to detect and to treat people risks crossing the line where the benefits of treatment outweigh its risks. Along with this expansion in prevalence estimates came new journals on bipolar disorder, a slew of bipolar societies, and annual conferences, many heavily funded by pharmaceutical companies.

**Attention Deficit Hyperactivity Disorder (ADHD):** Over the last twenty years, attention deficit hyperactivity disorder (ADHD) has emerged as a disorder of importance in childhood. Prescription of psychostimulants for ADHD escalated in many countries through the 1990s. Between 1990 and 1995, prescriptions of methylphenidate for young people increased 2.5-fold in the US<sup>14</sup> and 5-fold in Canada<sup>15</sup>. In some countries rates of treatment for children in 2000 were nine times those in 1990<sup>16</sup>. ADHD joins dyslexia and glue ear as disorders that are considered significant primarily because of their effects on educational performance. Medicalising educational performance can help children

receive specialized medical and educational services, at the same time it can lead to them receiving medications or surgical therapies which may have short-term and long-term ill effects.

In the case of ADHD, there has been a complex, often heated debate in the public domain about the verity of the illness and the personal cost-benefit ratio of treatment with psychostimulant medication. ADHD is, however, a disorder of educational performance, and so teachers have a critical role in advocating for the illness, and its medical treatment.

Conrad argued that when disorders previously viewed as non-medical are redefined as sicknesses, non-medical people often perform the "everyday routine work" of disseminating understanding of the new sickness<sup>17</sup>. With ADHD, the teacher's work extends beyond simply ensuring the disorder is understood by parents. Instead, the teacher participates in establishing the diagnosis. The role of the teacher as the sickness and treatment broker for ADHD has been elaborated more clearly for ADHD than for any other childhood disorder. The DSM-IV diagnostic criteria accord teachers a formal role in diagnosis through specialised assessment instruments such as the Connors Teacher's Rating Scale<sup>18</sup>. An informal role also exists for teachers as "disease-spotters." There appears to be considerable difference internationally in the alacrity with which teachers engage in disease-spotting.

**Sisi syndrome:** It is an alleged form of depression that came to light for the first time in 1998 by a pharmaceutical company<sup>19</sup>. According to the company, people suffering with this syndrome characteristically hide their illness by pretending to be active and positive about life, while in reality they are depressed and might need treatment with antidepressants. The syndrome is named after the 19th century Austrian Empress Elisabeth, nicknamed Sisi, who was said to have suffered from it. In 2003 an analysis of the literature by independent sources revealed no proof of the existence of Sisi Syndrome and discussed the incident as an example of the new kinds of marketing strategies by drug companies, referring to it as "disease mongering"<sup>19</sup>.

**Mild Cognitive Impairment:** Whether mild cognitive impairment (MCI) can be considered a clinical entity is still a matter of debate. Gauthier and Touchon have argued, based on epidemiological evidence, that many subjects labeled as having MCI do not worsen over time and may revert to normal cognitive abilities<sup>20</sup>. Nevertheless, specific drug treatment for MCI has been proposed. Two RCTs have been conducted to investigate whether donepezil delays the onset of dementia in people with MCI. These studies failed to demonstrate any efficacy, while showing a worse safety profile among patients receiving active drug compared with the placebo group. In the first published trial<sup>21</sup>, significant treatment effects were not seen in the primary efficacy measures, while more patients treated with donepezil experienced adverse events compared with patients treated with placebo (88% versus 73%). Despite this negative result, a new trial was conducted by Petersen et al., comparing donepezil, vitamin E, and placebo<sup>22</sup>. This study did not show a significant difference among the three groups in the rate of progression from MCI to Alzheimer disease over a three-year period.

Nevertheless, the authors stress some limited effects on secondary measures: a reduced likelihood of progression to Alzheimer disease only during the first 12 months of treatment, and a benefit of donepezil among carriers of one or more apolipoprotein E  $\epsilon 4$  throughout the three-year follow-up. This latter claim, in particular, was not supported by the data as the study was not statistically powered to evaluate the effect of the treatment in separate groups of apolipoprotein E  $\epsilon 4$  carriers. Although Petersen et al. conceded that the results "do not provide support for a clear recommendation for the use of donepezil in persons with mild cognitive impairment," they did suggest that their findings "could prompt a discussion between the clinician and the patient about this possibility"<sup>22</sup>.

**Erectile dysfunction:** Sexual life has become vulnerable to disease mongering for two main reasons. First, a long history of social and political control of sexual expression created reservoirs of shame and ignorance that make it difficult for many people to understand sexual satisfaction or cope with sexual problems in rational ways. Second, popular culture has greatly inflated public expectations about sexual function and the importance of sex to personal and relationship satisfaction. Thus the public is led to expect high rewards from sexual life without having tools to achieve these rewards. This sets the stage for disease mongering, a process that encourages the conversion of

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