

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: N/A

ACTIVE INGREDIENT: N/A

Study No: NIS-NES-XXX-2011/3

Multicentre, retrospective, observational study to assess clinical management patterns of depressive patients in Andalusia.

Developmental Phase: Non-Interventional Study

Study Completion Date: December/2013

Date of Report: July/2014

OBJECTIVES:

Cross-sectional epidemiological study with the following objectives:

- 1) To determine the prevalence of mental illness among the Andalusian population and,
- 2) To identify possible risk factors for these types of disorders that can be targeted by preventive interventions.

At the end of 2011, the pilot phase was completed, which consisted in carrying out the entire study in the population of the Granada province. The study has currently been extended to the other Andalusian provinces. This is the first study of its kind which uses standard diagnostic procedures (ICD-10 and DSM-IV) with the intention of diagnosing the prevalence of mental illness in general. An additional characteristic is that it can specifically identify psychotic symptomatology, cognitive impairment and personality disorders, which are not usually assessed in this kind of study, making it one of the most innovative studies in Europe at present.

METHODS:

The prevalence of mental illness was established from diagnoses based on the validated Spanish version of the MINI Neuropsychiatric structured diagnostic interview, which

establishes diagnoses for the main mental illnesses following the diagnostic criteria of the WHO (ICD-10).

The following risk factors are examined: sociodemographic variables (gender, age, level of education, marital status and employment status), variables of social adversity (abuse or stressful life events), psychological variables (cognitive functioning, level of global performance and previous personality) and biological variables (risk genotypes), following a broad paradigm of mental health as understood from a bio-psycho-social perspective.

RESULTS:

Prevalence

Of the 1176 inhabitants of the Granada province invited to participate in the study, 367 (31%) refused to participate and 809 (69%) finally completed the interviews, 43.6% were men and 56.4% were women.

The mean age of individuals who completed the interview was 47.06 years (SD=16.53); and when arranged according to age group, the most frequent corresponded to individuals from 35-49 years. Most participants had completed secondary education, most were unemployed (60.6%) and the majority were in some kind of stable relationship at the time of the study (73.1%).

When the point prevalence was examined, in other words, the proportion of people who have a mental illness at a particular time, this was found to be 22.9% for any mental illness, and when the same analysis was carried out for lifetime prevalence, the most frequent disorders corresponded to anxiety disorders (12.6%), followed by affective (16.1%) and then psychotic disorders (2.5%). The point prevalences were also determined for the different disorders and the results are recorded in Table 1.

On the other hand, on examination of the lifetime prevalences for mental illnesses, in other words, the proportion of individuals who at some time in their lives met diagnostic criteria for a mental illness, it was found that almost 27% of the population had suffered at least one of the mental illnesses included in the study. When this prevalence was broken down into the major groups of mental illnesses it was found that the most frequent corresponded to affective disorders (16.9%), followed by anxiety disorders (15.4%), while the least frequent corresponded to psychotic disorders (3.6%). Nonetheless, the diagnostic instrument used is more effective at establishing the current diagnosis or point prevalence than lifetime prevalence, so it is recommendable to record the point prevalences, which are shown in Table 1.

Table 1. Point prevalence of the principal mental illnesses after the PISMA-ep study (Pilot phase, Granada province)

Prevalences of the main disorders assessed in PISMA-es

DISORDER	% (n)	DISORDER	% (n)
Current major depression	12.7 (103)	Agoraphobia without panic attacks	3.4 (27)
Recurring major depression	7 (57)	Social phobia	3.4 (28)
Dysthymia	3.6 (29)	OCD	1.5 (12)
Current hypomania	0.4 (3)	PTSD	1.2 (10)
Current mania	0.6 (5)	Current psychosis	2.4 (19)
Life-long anxiety disorder	6 (48)	Life-long psychosis	3.5 (28)
Current anxiety with limited symptoms	7.4 (70)	Depression with psychotic symptoms	1.4 (12)
Current anxiety	2.3 (18)	Bulimia	0.2 (2)
Anxiety without agoraphobia	0.8 (7)	GAD	4 (33)
Anxiety with agoraphobia	0.9 (7)	Antisocial personality disorder	0.4 (4)

Possible Risk Factors

Another objective of the study was to examine possible risk factors that increase the risk of having one of the mental illnesses considered here. The risk factors that most increased the risk of having a mental illness were child abuse and a family history of mental illness. In other words, sexual abuse (OR=4.667; CI=1.596-13.641, p=0.005) and psychological abuse (OR=2.404; CI=1.420-4.070, p=0.002) in early childhood increased the risk of individuals having a mental illness. A family history of mental illness also increased the risk of mental illness (OR=2.404; CI=1.420-4.070, p=0.002). Other factors that were positively associated with having a mental illness corresponded to: being a woman, having experienced stressful life events in the preceding year, having only a basic level of education, being unmarried or without a stable partner and being unemployed.

PISMA-ep Study – Univariate analysis Potential risk factors for any mental illness (current)

Risk factor	OR (95% CI), p
Being a woman	2.139 (1.484-3.083), p<0.000
Basic educational level	1.904 (1.267-2.861), p=0.001
Unmarried or without partner	1.581 (1.095-2.282), p=0.019
Unemployed	1.150 (1.041-1.271), p=0.001
Family history	2.363 (1.656-3.372), p<0.000
Psychological abuse in childhood	2.404 (1.420-4.070), p=0.002
Sexual abuse in childhood	4.667 (1.596-13.641), p=0.005
Stressful life events	1.965 (1.282-3.013), p=0.001

Other Associations of Mental Illness with Potential Risk Factors

	Current MI	Mean	SD	Significance (p)
<i>Age</i>	No	47.76	16.758	.710
	Yes	48.29	15.229	
AVEs	No	1.34	1.304	.0001
	Yes	2.16	1.691	
SF 12 Physical	No	48.69	10.47	.001
	Yes	42.11	13.75	
SF 12 Emotional	No	52.57	7.64	.001
	Yes	38.92	11.61	
GAF Functionality	No	93.95	9.261	.0001
	Yes	76.28	14.43	
SAPAS scale	No	2.81	1.357	.0001
	Yes	3.97	1.461	
<i>Impulsivity trait</i>	No	.209	.272	.70
	Yes	.246	.296	
Neuroticism trait	No	.34	.244392	.0001
	Yes	.60420	.24	
<i>CAGE test for alcohol</i>	No	.34	.793	.080
	Yes	.19	.556	
<i>Fägerstrom test for nicotine</i>	No	5.15	3.260	.090
	Yes	4.55	3.387	