During the past fifteen years, several new atypical antipsychotic medications suitable for the treatment of symptoms in schizophrenia entered the marketplace. In the process of drug development, the sponsoring pharmaceutical manufacturers designed and implemented multiple major clinical studies demonstrating efficacy for each of the new agents. The design and implementation of these sponsored preapproval clinical studies were intimately linked with the prerequsite to comply with regulatory requirements for approval of a new atypical agent. The conditions for approval motivate the pharmaceutical industry to perform efficacy studies using the same trial design elements, and uniform data analytic approaches for the evaluations. This presentation, using the FDA's Summary Basis of Approval database, will overview established practice of providing evidence to regulatory authorities about the claimed properties of new pharmaceutical products with regard to antipsychotic efficacy. The overall designs including the timing of evaluations, psychometric rating scales used for evaluations, and the use of both measured and derived outcome variables as well as other principal characteristics of the trials, such as the choice of population for efficacy analyses, and methods of handling missing data will be reviewed. The established conventions and procedures will be contrasted with scientific concepts and principles and practical utility.

Symposium: Pharmacological prevention of suicide

S34.01

Lowering suicide rates: Realistic or Quixotic

D. Healy. *North Wales Department of Psychological Medicine, Cardiff University, Bangor, UK*

Background and Aims: There have been concerns about the risk benefit ratio of treatment with antidepressants and antipsychotics in the light of recent evidence pointing to a risk of suicide induction during the course of treatment with antidepressants. These concerns have led to a series of recent studies exploring national rates of suicide and correlating these with data on antidepressant consumption, which apparently showed reductions in suicides since the advent of the SSRIs.

The data from controlled trials on antidepressants and antipsychotics however point to increased suicide and suicide attempt rates. Against this background we have looked at suicide rates in schizophrenia in North Wales from the pre- and post-antipsychotic eras and have compared suicide rates in the Nordic countries with autopsy and ill-defined death rates, and antidepressant sales, during the period 1961 through to 2003.

Results: There has been a 10-fold rise in suicide rates in schizophrenia since the introduction of the antipsychotics. In the Nordic countries, there is no relationship between antidepressant consumption and suicide rates but a close correlation between suicide rates and both autopsy and ill-defined death rates, which appear to need further clarification.

Conclusions: Combined these datasets suggest efforts to reduce suicide rates, in particular efforts that rely on psychotropic drug use may be quixotic.

S34.02

Prediction and prevention of suicide in mood disorders

Z. Rihmer. *Deparmtent of Clinical and Theorethical Mental Health, Semmelweis Medical University, Budapest, Hungary*

Background and Aims: Major mood disorders are quite prevalent, but frequently underreferred, underdiagnosed and undertreated illnesses. The early recognition and appropriate treatment of unipolar and bipolar mood disorders is particularly important, since untreated mood disorders carry extremely high risk of both attempted and committed suicide. Recent studies clearly show that suicidal behaviour in patients with major mood disorders is state and severity dependent and this means that suicidality markedly decreases or vanishes after clinical recovery from major depressive episode or from dysphoric mania. However, since the majority of mood disorder patients never committ and more than half of them never attempt suicide, special clinical characteristics of the illness as well as some familial and psycho-social factors should also play a contributory role in this self-destructive behavuour.

Results: Considering the clinically explorable suicide risk factors in patients with mood disorders (family and/or personal history of suicidal behaviour, early onset of the disorder, severe depressive episode/hopelessness, agitated/mixed depression, bipolar II diagnosis, comorbid Axis I and Axis II disorders, adverse life situations, lack of social and medical support), in the majority of the cases, suicidal behaviour is predictable with a good chance. There are also several evidences that (succesfull) long-term treatment of unipolar depressives (with antidepressants and/or lithium) and bipolar patients (with mood stabilizers and with antidepressants/antipsychotics) substantially reduces the risk of attempted and completed suicide, even in this high-risk population. Most recent studies also show that supplementary psycho-social interventions (psychoeducation, and targeted psychotherapies) further improve the results.

S34.03

Suicide prevention: Updated findings

L. Tondo [1,2,3]. [1] *McLean Hospital, Harvard Medical School, Belmont, MA, USA* [2] *Department of Psychology, University of Cagliari, Cagliari, Italy* [3] *Mood Disorder Center Lucio Bini, Cagliari, Italy*

Background and Aims: International suicide rate in developed countries averages 13.3 x 100.000 population, a rate increased from 1955 to 2001 by 3.3% which has decreased from 1990 to 2001 by 11.7%. This decline may be associated with an improved health care, including medical interventions, with the most relevant role is attributed to treatments with antidepressants. Most of the studies showing an inverse correlation between increased usage of antidepressants and decreased suicide rates are based on ecological designs which do not provide information on the individual level.

Results: In order to prevent suicidal behavior it is fundamental to know that: [a] 90% of all suicides are associated with a psychiatric disorder, especially mood disorders that account for more than a half of all completed suicides; [b] the ratio of attempts to suicide in the general population is about 20:1, whereas the same ratio is about 5:1 in Bipolar Disorder (BPD) patients, showing higher lethality of suicide attempts. Indeed, the Standardized Mortality Ratio reaches the highest value (20; normal value = 1) in mood disorder patients among all psychiatric disorders, with little differences between BPD I and II, and Major Depressive Disorder.

Conclusions: Early interventions are important since suicide occurs in patients with BPD in the first years after illness onset. From

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