INTRODUCTION

Long-term and even life-long drug treatment is a characteristic feature of modern psychiatric therapy. This is due to the fact that many psychiatric patients suffer from recurrent diseases for which the risk of relapses can be calculated with certain probabilities. The drugs used for treatment and prevention of these diseases are investigated insufficiently, particularly as regards their chronic effects. There exist hundreds of controlled, mainly phase III trials lasting several weeks. However, controlled long-term phase IV trials, such as in the area of lithium or neuroleptic maintenance treatment are rare and have never been performed for longer than 3 years (3, 4, 9, 10).

"Controlled" means mostly control against placebo. Only in a few studies similar or different drugs are compared with each other over periods of several years. Statements about long-term effects and side-effects of psychotropic drugs are based on anecdotal reports or on retrospective compilations of mostly not well-documented therapy.

For scientific purposes and for rational therapeutic decisions we need more knowledge among other about: (1) drug effects in long-term treatment, (2) the side-effects under long-term treatment, particularly the dependence of side-effects on other factors: social, psychological, pharmacological, or others, (3) patients' compliance (7) under the condition of long-term treatment.

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Of course, it would be preferable to have long-term controlled studies over periods of 10 and more years. If "controlled" means studies controlled against placebo, it is quite clear that this cannot be done by ethical reasons.

It appears obvious that the findings of open phase IV long-term studies can only refer to patients in whom normal tolerance and at least some efficacy of a drug was already demonstrated during acute treatment or during the first years of long-term treatment. Thus, probably highly selected patient groups would have been studied finally. This, however, offers an advantage in so far as quite realistic conditions similar to those in therapeutic practice would be prevailing; yet in addition use could be made of all technical approaches for treatment control and treatment documentation as they are available in a scientific institution. This kind of organized long-term follow-up studies allows prospective as well as retrospective conclusions. Clinical outcome, frequency of already known side-effects under these special conditions can be studied in a prospective way. If new questions are formulated, such a well documented patient sample could lead to more valid retrospective conclusions as if, for the solution of a certain problem, cases from different institutions, often badly documented and treated under very different settings, have to be compiled and evaluated.

The presented paper describes the aim and structure of two specialized outpatient clinics which serve to answer some of the questions mentioned before.

METHODS

One of the outpatient clinics takes care of schizophrenic patients under long-term neuroleptic treatment, the other clinic is specialized on depressed patients treated with lithium salts. The following parameters are regularly assessed and documented: (a) Somatic, e.g. neurological and laboratory parameters according to standard programs. (b) Differential psychopathology including social data. For this purpose, different kinds of rating scales, particularly a rather detailed documentation system, the AMDP-system (2), are used. (c) Patient compliance by means of assessment of drug plasma levels. (d) Differential assessment of side-effects on documentation systems which allow statistical evaluation (2). (e) Accurate documentation of medication and co-medication.

The schizophrenic outpatient clinic takes care of 170 patients who are actually active participants, whereas around 450 patients are recorded in the files. In the lithium-clinic there are 200 patients in the files and around 100 are active participants. The average number of consultations is 11.8 per patient and year for the schizophrenic patients (2000 consultations per year), and 8 consultations per patient per year in the lithium-clinic (8).