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VALID GROUNDS FOR THE SWITCH OF ORIGINAL ANTIPSYCHOTICS WITH GENERICS

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SUMMARY

Patients' non-compliance in treatments, such as irregular taking of medication, represents an enormous problem with psychiatric patients in general. This difficulty occurs especially in patients suffering from chronic mental illnesses such as schizophrenia.

There are not any significant differences in the efficacy of reducing the positive symptoms in schizophrenia between the conventional and the atypical antipsychotics. However, the effects which are manifested in negative schizophrenia symptoms or in the patients' cognitive functioning, favour the atypical antipsychotics. When it comes to adding the subjective well-being of the patients and their improvement of the quality of life, then, the advantages of atypical antipsychotics are unquestionable.

New trends in medicine are increasingly impinge on the pharmacoeconomy, which aims at reducing treatment cost. This trend is getting progressively stronger in the world and as such, it certainly will not bypass Croatia.

Pharmacists and General Practice doctors (GP) are permitted, by the law, to replace the original medicament prescribed by a specialist doctor, with a cheaper one from the same generic group of medicaments, with a purpose of cutting down the treatment costs.

Is there always a valid justification for such practice, and should it become a rule for all the patients out there?

This is a case report of a patient who suffers from paranoid schizophrenia. He has been on a treatment with atypical antipsychotics and has kept in a good and stable remission for the past seven years. His therapy consisted of olanzapine in a dose of 15 mg in the evening, throughout the whole period of his 7-year remission. A month ago, his GP doctor self- initially prescribed a generic olanzapine. The impact of this decision on to the mental state of the patient as well as his trust in the treatment itself is described in this report.

Key words: *schizophrenia – antipsychotic - compliance*

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INTRODUCTION

Patient's non-compliance is one of the major difficulties in the pharmacotherapy of schizophrenia, particularly with regard to long-term treatments, which as a result, leads to an increase in the risk for a relapse of non-compliant patients (Fenton et al. 1997).

Compliance can be defined by many definitions but commonly it is defined as the degree to which the patient's behaviour is consistent with medical advice (San et al. 2008).

Research reports that treatment non-compliance is a cause to nearly 55% of relapse incidences in schizophrenic patients (San et al. 2008).

Weiden et al. (2004) argue there is a significant correlation between hospitalization risk among schizophrenic patients and compliance, with lower compliance leading to a higher hospitalization risk, indeed this is the highest possible risk factor for hospitalization.

Medication adherence is defined as the degree of the patient's consistency with the previously defined mode of treatment, whereas non-adherence refers to an incorrect mode of taking a certain number of medication doses or, in some cases, a certain number of medication doses not taken at all, which jeopardizes the therapeutic outcome. There are consequences of non-adherence, such as non-remitting symptoms, relapse, or recurring or fluctuating adverse effects (San et al. 2008).

The formulation and the administration of the medication and the number of tablets distributed into daily doses, with the purpose of an easier application, are of great importance for every psychiatric patient, especially for the psychotic ones. Practice has shown the fact that patients prefer the administration of their therapy in tablets rather than the intramuscular formulation of the medication (San et al. 2008).

The selection of antipsychotics and formulations of the medications should be conducted individually for each patient. Reduction of psychotic symptoms and avoidance of the antipsychotic side-effects are of great importance. To achieve such antipsychotic effectiveness in terms of reduction or elimination of the symptoms, especially the relapse risk and prevention of the illness and hospitalization – compliance is of great importance. It is essential to take into consideration

the fact that chronic mental patients, due to their lifelong conditions, will have to adhere to their therapies for the rest of their lives.

There are numerous advantages of atypical antipsychotics in comparison to the typical ones, with some of them being essential from the patient's point of view.

Some atypical antipsychotics (risperidone, olanzapine, clozapine) are known to improve the patients' subjective quality of life (Naber et al. 2005).

The quality of life and the subjective well-being on atypical antipsychotic treatment is based on the patient's subjective evaluation (patient's self-report). A satisfying quality of life and a subjective well-being of the patient are reflected in his/her closer environment, including all the structures (medical and non-medical) with which the patient comes into contact.

CASE REPORT

A 41 year old man, unmarried, unemployed, living alone, suffers from paranoid schizophrenia. He was the youngest of five children, raised in a family with all the members sharing their living environment. Now he is living alone in his own property. He is entitled to a low pension which he receives regularly. His brothers and sisters live abroad, care for him and support him financially, and keep up regular phone contacts and visits. He is able to take care of everything independently.

His upbringing took place in a village. He accomplished his secondary school education. His first mental disturbances emerged during his regular military service at the age of 19 (1987). At that time, he was hospitalized due to an acute psychosis. We do not hold any medical records for the period of 1987 - 1997. as the patient lived abroad, but according to the information we gathered from the patient, he was hospitalized a few times. He used to be on an antipsychotic therapy– clozapine.

He commenced ambulatory treatment in our institution in the 1998. Diagnostics performed at the time, revealed and confirmed paranoid schizophrenia – F20.0 (ICD 10, DSM IV). Since then, the patient was hospitalized four times. He received regular ambulatory treatments during the intervals between the episodes. The treatment consisted of conventional antipsychotics (promazine, haloperidol, fluphenazine) and atypical ones (clozapine, risperidone). The pharmacotherapy mentioned was not well accepted by the patient. The medications were distributed into several daily doses, however, a few of the antipsychotics caused some mild side-effects.

The last hospitalization of the patient occurred seven years ago. At the time of his last admission, olanzapine was introduced which was gradually titrated to a therapy dose of 15 mg daily, in combination with an anxiolytic (diazepam, a 10 mg dose at bed time) and an antidepressant (paroxetine, a 20 mg dose).

The patient remained in a stable remission for the past seven years, and has been on daily 15 mg olanzapine monotherapy for the last four years (in the meantime, the tablets were switched to velotab form). He adhered to the therapy which he took regularly and by himself, without any supervision. He never missed his therapy dose which is always taken at the same time – 08:30 p.m. According to his current mental state, an ambulatory check-up every three months was be sufficient; they could be even less frequent, but the patient insists that his check-ups should be on a regular monthly basis. He is very cooperative in his treatment, he tolerates his therapy well. No side-effects occurred on the olanzapine therapy. Considering that he is living on his own, his functioning can be evaluated as enviably well.

A month ago, the patient made an unscheduled visit to the clinic, due to a certain problem. He immediately stated that he had visited his General Practictitioner only two days before, and that the doctor prescribed him generic olanzapine tablets instead of the usual olanzapine in the velotab form, which he was used to and which he had been regularly taking for years. Allegedly, the doctor's justification for such a changeof medication was cost reduction, but he assured the patient that the medication is equally effective, just coming a different manufacturer and considerably cheaper from the original. The patient was in doubt, concerned and quite distressed because of the newly prescribed medication. He had become used to the same therapy of several years, and it had enabled him to remain healthy and now he was refusing to take the medication, even if there was the slightest risk of his being ill again. He was begging for help.

DISCUSSION

The case presented opens up a few questions and dilemmas which could be discussed however, our intention is to point out the positive side of the issue.

Treatment non-compliance by psychotic patients poses a great difficulty which is frequently experienced in our everyday practice.

This case manifested the benefits and successful treatment results of olanzapine as a monotherapy in treating paranoid schizophrenic patients. The best indicator is a psychosis remission for a period of seven years, using an atypical antipsychotic, in a stable 15 mg dose in the evening.

In terms of the efficiency of the medicament towards the symptoms of the illness, the patient built trust, and security, in the antipsychotic given. Easy administration and its formulation are additional advantages.

Due to the reasons mentioned, the patient's subjective experience with the atypical antipsychotic, is positive. This is the ground for good medication adherence and a patient's compliance. The quality of life and the well-being level are, according to the patient's report, on a fulfilling level. The patient himself used to say: "I'm feeling as if I'm healthy".

The fear from relapsing again is understandable in the case of a chronic patient, but it is also an evidence of an unreserved criticism and awareness. Being capable to care for your own health is also an indication of thorough health. Asking support and help from a psychiatrist as well as the trust the patient showed towards him, reveals a good therapeutic relationship between the patient and his psychiatrist. This trust is undoubtedly higher than towards a GP doctor, as exposed in this case.

CONCLUSION

The price of the medication should not be the only or the leading criterion for the selection of an adequate pharmacotherapy. Due to the evident efficiency in achieving and obtaining a long-term remission and the patient's trust towards his therapeutic medication and its' formulation, we believe a medication switch in our patient's case, in order to cut down costs, would induce more damage than good.

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