

# Safety profile and adverse effects of use of olanzapine in pregnancy: A report of two cases

Manoj K. Sahoo<sup>1</sup>, Harshita Biswas<sup>1</sup>, Vinita Singh<sup>2</sup>

Departments of <sup>1</sup>Psychiatry, <sup>2</sup>Obstetrics and Gynaecology, Tata Main Hospital, Jamshedpur, Jharkhand, India

### ABSTRACT

Women with schizophrenia have a high risk for symptom exacerbation or relapse during pregnancy and thereafter. Relapses are more frequent when antipsychotics are discontinued. Continuation of antipsychotic during pregnancy has become common and olanzapine is commonly prescribed antipsychotic. It is very important to know the safety profile of olanzapine in Indian settings. Aim of our paper is to report two cases of olanzapine use pregnancy, discuss its safety profile, and adverse effects on mother and foetus. In both of our cases, olanzapine was continued throughout pregnancy and the patients remain clinically stable as per psychiatric symptoms. In case 1 whole antinatal and perinatal period was normal except patient has oligohydramnios and low birthweight baby and in case 2 she had oligohydramnios and large baby. Our cases add to the safely data of use of olanzapine in pregnancy, particularly in Indian settings. While conclusive elucidation still awaits more such reports from India and well-controlled studies.

**Keywords:** Olanzapine, pregnancy, safety

### Introduction

Pregnancy can be a very challenging time for women with long-term mental illnesses. Women with schizophrenia have a high risk for symptom exacerbation or relapse during pregnancy and thereafter. Relapses are more frequent when antipsychotics are discontinued.<sup>[1]</sup> Most of the two generation antipsychotics have been in use since the 1990s. Olanzapine, one of the two 2 generation antipsychotics, is a category C drug and there is no unequivocal evidence of harm to the foetus.<sup>[2]</sup>

Various sources have reported adverse effects due to exposure of olanzapine during pregnancy like, Goldstein *et al.*<sup>[3]</sup> reported outcomes of 37 olanzapine-exposed pregnancies ascertained

prospectively. Of the 37 pregnancies, 14 were terminated by therapeutic abortions with no abnormalities reported in the foetus. In the rest of the pregnancies ( $n = 23$ ), normal birth without complications occurred in 16 cases; spontaneous abortion occurred in 3; stillbirth in 1; prematurity in 1; postmaturity in 2 cases, with one of new born developing perinatal complications in the form of meconium aspiration after cesarean section; and no major malformation in any case. The rates of complications were less than or comparable to the range of base rates for general population.

The reported data of safety of use of olanzapine throughout pregnancy in Indian population is very sparse.<sup>[2,4]</sup> As per UNICEF (2016), with the birth of 25 million children each year India accounts for nearly one fifth of the world's annual child births and olanzapine being most commonly prescribed antipsychotics by psychiatrists in India.<sup>[5]</sup> Nowadays, olanzapine is also widely used by primary care physicians for various indications.<sup>[6]</sup> So, it is important to discuss the safety profile of olanzapine in pregnancy with reference to primary care physicians.

**Address for correspondence:** Dr. Manoj K. Sahoo,

Senior Consultant, Department of Psychiatry, Tata Main Hospital and Assistant Professor, Department of Psychiatry, Manipal Tata Medical College, Jamshedpur - 831 001, Jharkhand, India.

E-mail: drmanojshahoo@gmail.com

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It is very pertinent to report and discuss two such cases, which will add to the safety profile of olanzapine use throughout pregnancy without much complication to mother and fetus in Indian populations.

## Case Series

### Case 1

Mrs SM, 32 year, is a known case of schizophrenia referred from obstetrics and gynecology OPD for psychiatric evaluation in view of her psychiatric diagnosis and review of medication. She is a known case of schizophrenia since last 7 years. She was treated with Olanzapine 10 mg/d and tab trifluoperazine 20 mg/d. She improved over a period of 6 months and was maintaining well on tab olanzapine 10 mg/d and tab trifluoperazine 5 mg and trihexyphenidyl 2 mg 1 tab daily. While on above combination of medicine she conceived again. She came to psychiatric OPD in her 8<sup>th</sup> week of pregnancy. Both patient and family members were explained about the risk and benefit of continuation of drugs. She was continued on tab olanzapine 5 mg/day. She followed up regularly in psychiatric and gyne OPD throughout pregnancy. Her routine USG 12 weeks, anomaly scan at 18 weeks, and triple markers tests for chromosomal abnormalities were normal. Her routine blood tests including blood sugar and blood pressure remained normal throughout her pregnancy. She was admitted at 34 weeks of gestation for less liquor which was managed conservatively and discharged. Finally, she was admitted at 37 weeks for with less liquor and lower section cesarean section (LSCS) was done in view of previous cesarean section. Delivered a baby boy weighing 2.25 kg. Baby was normal and APGAR score was 8. She was discharged on 4<sup>th</sup> day. Baby was healthy with and had normal developmental milestones. Now, he is 7-year-old going to school and not having any academic or behavioral problem.

### Case 2

Mrs MS, 29 year, had history of 1<sup>st</sup> episode of schizophrenia 3 years back, which was treated with tab olanzapine 10 mg/d, patient recovered in 3 months, and stopped medication on her own. She got married 2 years back and after 2 months of marriage she relapsed with manic and mood incongruent psychotic symptoms. She responded well to combination of Tab sodium valproate 800 mg/d and tab olanzapine 10 mg/d. She came for follow-up at 10 weeks of pregnancy Patient was exposed to both the drugs till 10 weeks of pregnancy. The risk of exposure of both the drugs were explained to the patient and family members. They choose to continue the pregnancy. Tab sodium valproate was stopped but tab olanzapine 5 mg was continued to prevent relapse of psychotic symptoms. She continued tab olanzapine 5 mg throughout pregnancy without exacerbation of psychiatric symptoms.

She followed up regularly in psychiatric and gyne OPD throughout pregnancy. Her routine USG 12 weeks, anomaly scan at 18 weeks and triple markers tests for chromosomal abnormalities were

normal. She developed pregnancy induced hypertension and hypothyroidism during pregnancy and continued tab thyroxine 50 mcg 1 tab daily. Persistent less AFI (oligohydramnios) and large for gestational age baby observed during routine ultrasound for anti-natal check-up. However, there was no maternal or foetal distress during the follow up. Her blood sugar was normal during follow up. She was admitted at 38 weeks of gestation, on admission her USG suggested AFI of 7.9 cm and expected foetal weight 3.8 kg. She had an emergency cesarean section, intraoperative liquor was clear, birth cry was present with birth weight of 4.2 kg. Postoperative period was uneventful. Baby is healthy with normal developmental milestones. Now he is 2-year-old with no developmental issues.

## Discussion

In both of our cases it was decided to continue olanzapine throughout pregnancy after explaining the relative risk and benefit. In case 1 whole anti natal and perinatal period was normal except patient has oligohydramnios and low birthweight baby and in case 2 she had oligohydramnios and large baby with body weight 4.2 kg. In case 1 oligohydramnios and low birthweight of the baby could not be attributed to other causes thus can be attributed to olanzapine but in case 2 oligohydramnios can be due to both the factors like pregnancy induced hypertension and exposure drugs like olanzapine. In a case reported by Choi *et al.*<sup>[7]</sup> similar finding of baby with oligohydramnios was observed. In the literature, of both low birth weight and large baby has been reported due to exposure to olanzapine.<sup>[8]</sup>

With respect to the postnatal long-term effects, like in our case, Gati *et al.*<sup>[9]</sup> stated there were no postnatal behavioral sequelae in children was seen up to the age of 6–10 years, which is also seen in our cases.

There are very few reported cases of data on safety profile of use of olanzapine in pregnancy in India. Our article adds to the safety data in the Indian context.

## Summary and Conclusion

Based on review of literature and outcome in both of our cases, it is justified to use olanzapine as it adds to the safely data of use of olanzapine in pregnancy, particularly in Indian settings. The case reports also highlight, there is no postnatal behavioral sequelae observed in the follow-up of the children of those patients. As there are ethical limitations of clinical trials of drugs during pregnancy. More such reports and well-controlled studies from India and other subcontinents with conclusive explanation is still required. Hence, such reports hold a great clinical significance.

## Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients

understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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### Conflicts of interest

There are no conflicts of interest.

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