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# Aripiprazole in pregnancy – A case report

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## Abstract

Aripiprazole falls under FDA Pregnancy Category C, previously the safety of aripiprazole treatment during pregnancy mainly consisted of case reports. Two large prospective studies[1,2] described the outcome of pregnancy in females exposed to aripiprazole and neither of the studies indicated a higher risk for using aripiprazole in pregnancy compared to other SGA. Aripiprazole is used frequently in treatment of women with bipolar disorder or schizophrenia during childbearing years. Three such women who conceived on aripiprazole and continued on the same treatment till third trimester were followed up. Patients were started on haloperidol after 37 weeks of gestation and restarted on aripirazole after stopping lactation (six to eight months after delivery). Children were followed up till one year of age and are developmentally healthy.

**Keywords:** Antipsychotics; Aripiprazole; Pregnancy.

## Introduction

Aripiprazole is a second generation antipsychotic medicine that has been used in the treatment of schizophrenia and bipolar disorder. It has a low metabolic risk profile. Aripiprazole functions as a partial agonist at the dopamine D2 and the serotonin 5-HT1A receptors, and as an antagonist at serotonin 5-HT2A receptor. Aripiprazole is used frequently in treatment of women with bipolar disorder or schizophrenia during childbearing years, due to its efficacy and relatively low metabolic risk profile. Women with mental illnesses are likely to have more unplanned pregnancies than women without a mental illness[1]. The management of severe mental illness in pregnancy such as schizophrenia and bipolar disorder is challenging because there is a need to consider both maternal and fetal wellbeing in selection of treatment. The natural course of these disorders, during pregnancy, mark the antenatal and post natal period a time with high risk of relapse. Hence, ceasing treatment is not a viable option if health and wellbeing are to be maintained[2]. Indeed, it has been suggested that most patients cannot safely stop their treatment during pregnancy and the discontinuation of effective treatment carries a risk that is usually greater than the risk of malformations or peripartum adverse events[3]. Though pregnancy is a time of high risk of metabolic complications such as gestational diabetes and the postpartum period is often a time when sedation can compromise infant care [4] but due to ethical reasons (as is the case with other psychotropics )there are no prospective randomized placebo controlled trial to

assess safety of aripiprazole during pregnancy. However, animal data are available and the amount of exposure and outcome data for human fetuses and infants has recently increased, providing published prospective safety data in relatively large numbers of pregnant women treated with aripiprazole.[5] Available data do not suggest an elevated foetal malformation risk in pregnancy, there is less information available on pregnancy and neonatal complications.[4]

**Methods**

This case report presents three females on aripiprazole at dosage of 5mg to 10 mg, aged 25, 29 & 36 years with no known medical co morbidity. Two diagnosed (ICD 10/DSM IV) to be suffering from schizophrenia and one with bipolar disorder. Two patients were referred from Obstetrics &Gynecology department of the hospital and were on treatment from private hospitals and one patient was on treatment from the psychiatry OPD of the hospital. Patients did not exhibit any psychopathology at the time of presentation. Patients presented at 12 weeks, 16 weeks and 20 weeks of gestation. Baseline investigations and ultrasound examination were normal except for anemia in one case which improved with Iron supplementation. Since all three patients had no active psychopathology the dose of medicine was reduced to 5mg in one patient and other two were continued at 5 mg. Patients and caregivers were informed about the present evidence of safety profile of psychotropic in pregnancy and risk of switching to other antipsychotic or stopping antipsychotic was explained. Patient continued on aripirazole and followed up regularly in psychiatry opd. Children were followed up till one year of age and are developmentally healthy.

**Results**

Aripiprazole was not associated with an increased risk of gestational diabetes or pregnancy induced hypertension. All three patients had uneventful antenatal period. Patients were gradually switched to haloperidol in last two weeks of gestation starting at 2.5 mg HS. Patients had normal vaginal delivery with no foetal complications. Birth weight of babies was 2.25 kg, 2.45kg and 2.75kg respectively. Patient with bipolar disorder developed symptoms of mania at 3 weeks post partum. Dose of haloperidol was increased to 10 mg. Patient stabilized after 1 month. All three patients breast fed their babies for 6-8months. Thereafter, patients were gradually switched to aripiprazole.

**Limitations**

The findings need to be replicated in a larger, well-designed study. The dose at which aripiprazole was used in all three patients could have resulted in no effect on pregnancy or congenital malformation in children.

**Conclusions**

Findings demonstrate that aripiprazole is not likely to cause a metabolic risk in pregnancy or congenital malformation in children of mothers treated with aripirazole.

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