D.1.2 Women of childbearing age

Study details	Participants	Methods	Results	Comments
Full citation Golbe,L.I., 19870731, Parkinson's disease and pregnancy, Neurology, 37, 1245-1249, 1987 Ref Id 306405 Country/ies where the study was carried out USA Study type Qualitative semi-structured interview Aim of the study To study the interactions between PD and pregnancy Study dates	Sample size N=18 women Inclusion criteria females diagnosed with PD before the age of 40 who had become pregnant after onset of PD symptoms ; no other criteria listed Exclusion criteria Not listed	Details Suitable cases ascertained through 1) announcements in newsletters of United PD foundation and American PD association; 2) follow-up inquiries of people who responded to an unrelated questionnaire in the UPDF newsletter; 3) referrals from colleagues patients questioned by telephone regarding accuracy of diagnosis of PD; medications take at time of conception and during pregnancy labour and delivery complications of pregnancy, labour, and delivery subsequent health of the child nature and degree of PD symptoms before, during, and after pregnancy side-effects of anti PD drugs before, during, and after pregnancy symptomatic course of PD since the pregnancy Interventions NA	Results 18 women met diagnostic criteria, of whom 24 pregnancies were reported after onset of PD symptoms mean age at time of conception 34.6 +- 6.1 years pregnancy occurred a mean of 4.1 (4.2) years after diagnosis of PD 4 elective abortions in 3 women one, age 41, performed because trisomy 21 revealed Other 3 performed because patient feared consequences of the PD/pregnancy combination for herself and child no obstetric or neurologic complications reported prior to the abortions obstetric complications 3 women each had 1 spontaneous miscarriage medications taken during these pregnancies were amantadine and benztropine, amantadine and levodopa (w/o carbidopa), and benztropine and diphenhydramine. the 2 miscarriages reported at 4thmonth were not associated with gross foetal abnormalities women had had previous uneventful pregnancies (2 and 3, respectively) maternal ages at time of miscarriage 31, 38, 42; mean 37 (5.6)	Overall Risk of Bias 1. Is a qualitative approach appropriate? Yes - interview appropriate for this study 2. Is the study clear in what it seeks to do? Yes - clearly seeks to understand pregnancy experience in women with a diagnosis of PD 3. How defensible /rigorous is the design and methodology- methodology reasonably rigorous. Serious of question about pregnancy experience and complications as well as PD symptoms and medication asked of each women 4. How well was the data collection carried out? Methodology of data collection unclear. Not clear how many women were approached and excluded, and if so, why/ 5. Is the role of the researcher clearly described? Role of researcher not described 6. Is the context clearly described? Context not described; some women describing pregnancy of up to 35 years ago, other only 1 month ago. Context of PD and treatment experience potentially very different over this span of time

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received August 4 1986, accepted Oct 13 1986, , published 1987 Source of funding Not listed			mean maternal age for successful pregnancies was 33.1 (6.0) disease duration at time of conception similar in successful pregnancy 4.2 (4.5) years and miscarriage group 3.0 (2.6) years all 4 pregnancies (in 4 diff women) during which amantadine was received were associated with complications: 2 miscarriages first trimester vaginal bleeding proteinuria and hypertension, diagnosed with preeclampsia in 3rd pregnancy. In same patient first pregnancy in which only on levodopa/carbidopa taken was uneventful 4/16 pregnancies in which amantadine not taken were associated with complications no reports of premature labour or delivery one C-section because of inadequate progression of labour All children, mean age 7 years (range 1 month to 32 years) apparently healthy neurological complications minor exacerbation of PD symptoms or appearance of new symptom during pregnancy was reported in 11/ pregnancies in all 11, reported rate of progression during pregnancy was greater than during the months before or after pregnancy in only one of these did symptoms improve after delivery one women reported increase of duration of action of levodopa/carbidopa	7. Were methods reliable? Methods not clearly written, difficult to assess reliability 8. Is data analysis sufficiently rigorous? Data analysis is not sufficiently rigorous. Statistical analyses not reported. 9. Is the data 'rich' i.e. how well are contexts described, has diversity of perspective been explored, how well was detail and depth demonstrated, are responses compared and contrasted across groups/sites? Depth of detail and 'richness' of data lacking. Many areas which are not well explained. 10. Is the analysis reliable? Analysis not described in detail; therefore, not reliable. Some women were retrospectively recalling experience up to 35 years prior, high potential for bias. 11. Are the findings convincing? Findings are in keeping with case studies and general consensus opinion 12. Are findings relevant to aims of the study? Yes 13. Conclusions? May be some association between amantadine and obstetric outcomes. Levodopa/carbidopa does not appear to induce any obstetric complications. Symptoms of PD

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			no subject reported a significant functional change in disability the one women who had dopa-induced chorea noted transient worsening of that symptom during pregnancy depression reported de novo during pregnancy in one case and resolved after delivery another 4 pregnancies (in 3 women) were followed by postpartum depression not requiring drug treatment only one women (who also reported depression during pregnancy) reported nausea and vomiting after the first trimester	may worsen as a complication of pregnancy. Does not appear to be any association between birth defects and PD 14. How clear and coherent is reporting of ethics? Ethics not reported Overall assessment: Serious risk of bias Other information Authors state no obvious pathophysiologic common denominator among the amantadine-associated pregnancy complications. No definite statement can be made as to any causal relationship between amantadine and obstetric complications, however these anecdotal evidences may provide some informative value - further research in this area warranted overall incidence of miscarriage, 3 of 20 (15%) lies within the normal range of between 10- 20% for the general population study revealed no major ill effect of the major anti-PD drug levodopa/carbidopa on the 6 pregnancies during which it was taken - but numbers too small to support claim levodopa safe during pregnancy