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PREGNANCIES IN PATIENTS WITH RHEUMATOID ARTHRITIS: TREATMENT DECISIONS, COURSE OF THE DISEASE, AND PREGNANCY OUTCOMES

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Background: Observational data so far suggest that biologic disease modifying antirheumatic drugs (bDMARDs) can be safely used in patients with rheumatoid arthritis (RA) until conception/awareness of pregnancy. However, little is known about the course of the disease during pregnancy in women who stopped bDMARDs in the first trimester, how to treat high disease activity (e.g. glucocorticoid use) and the influence of treatments on the birth outcome.

Objectives: To study the outcomes of pregnancies and the courses of disease activity in RA patients under different treatment regimens.

Methods: We analysed pregnancies and their outcomes that were reported to the German biologics register RABBIT until end of 2014, stratified by treatment at the time of conception. In a subgroup of patients with pregnancies reported between 2001 and 2011, data of the regular RABBIT study visits were complemented by telephone interviews with particular focus on the course of pregnancy as well as disease activity and treatment during pregnancy. Descriptive statistics were applied to study associations between pregnancy outcomes and exposure to bDMARDs, glucocorticoid use as well as the course of self-reported disease activity.

Results: In 1,715 female RA patients ≤ 45 years, 95 pregnancies in 78 patients were reported. At time of conception 51 pregnancies were exposed to bDMARDs (26x etanercept, 10x adalimumab, 4x tocilizumab, 4x certolizumab pegol, 3x rituximab, 2x abatacept, 1x infliximab, and 1x golimumab). Out of 44 women unexposed to bDMARDs at time of conception, 9 were biologic naive and 35 had received their last infusion or injection at least 4 weeks (rituximab 6 months) before conception (10x etanercept, 9x adalimumab, 2x tocilizumab, 1x infliximab, 13x rituximab).

The rates of spontaneous abortions were similar across treatment regimens and in the range of the rates of the general population (~ 15-20%). Induced abortions were reported in 4 out of 95 pregnancies (one due to trisomia 21 with cardiac defect).

More than one third of patients (37%) exposed to bDMARDs at conception also required bDMARDs and/or ≥10 mg/d glucocorticoids later in pregnancy. All preterm births occurred in patients with ≥10 mg/d glucocorticoids.

Table: Pregnancy outcomes in the cohort and the interviewed subgroup (the latter with course of disease and treatment during pregnancy). LI = last infusion/injection before conception, ADA = adalimumab, RTX = rituximab

Image/graph:

All (n=78 patients)	bDMARD naive	bDMARD stopped before conception	bDMARD at conception	
No. of pregnancies	9	35	51	
Induced abortions (%)	0	3 (9)	1 (2)	
Spontaneous abortions (%)	0	4 (11)	10 (20)	
Live births (%)	9 (100)	28 (80)	40 (78)	
Malformations		1x anal atresia with urogenital malformation (ADA, LI 4 weeks); 1x congenital nystagmus (ADA, LI 6 months); 1x trisomia 21 with cardiac defect (RTX, LI 8 months, induced abortion)	1x talipes (ADA, talipes also present in the mother)	
Subgroup of patients with telephone interviews (n=55)			**bDMARD stopped after conception**	**bDMARD continued during pregnancy**
Pregnancies	7	21	26	9
Disease activity during pregnancy [0-10, 0 = best]				
1st trimester mean (sd)	3.6 (2.6)	4.1 (2.3)	3.4 (2.7)	5.3 (3.3)
2nd trimester mean (sd)	3.1 (2.4)	3.9 (2.3)	3.7 (2.7)	5.0 (3.1)
3rd trimester mean (sd)	3.0 (2.4)	4.0 (2.7)	4.0 (3.0)	5.4 (3.2)
Increase of disease activity during pregnancy, n (%)	0	3 (14.3)	5 (19.2)	1 (11.1)
Flares yes n (%)	3 (42.9)	5 (23.8)	9 (34.6)	1 (11.1)
Treatment with glucocorticoids during pregnancy				
Glucocorticoids > 10mg/d (%)	0	9 (42.9)	10 (38.5)	5 (55.6)
Birth outcome				
No. of preterm births	0	4	4	0
No. of mature births	7	17	22	9
Birth weight mean (sd)	2956 (337)	3172 (660)	3064 (445)	3088 (268)

Conclusions: Within this limited sample of pregnancies we confirmed previous reports and found no increased risk of malformations or other harmful consequences in patients exposed to biologic treatment around the time of conception.

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