

non-renal SLE, pointing to an increased need of surveillance in LN patients during pregnancy.

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CONCENTRATIONS OF SUBCUTANEOUSLY ADMINISTERED BELIMUMAB IN HUMAN BREAST MILK IN A WOMAN WITH SYSTEMIC LUPUS ERYTHEMATOSUS: A CASE REPORT

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Objective Belimumab is a human IgG1-lambda monoclonal antibody that inhibits the B-cell survival factor BLyS. It is used in patients with active systemic lupus erythematosus (SLE). Since data on the safety of belimumab during breastfeeding is scarce, we investigated belimumab concentrations measured in breast milk of a woman with SLE initiating treatment with subcutaneous belimumab due to a lupus flare three months after delivery.

Methods Our patient stopped giving breastfeeding when she started on subcutaneously administered belimumab. During the phasing out of breastfeeding she pumped breast milk to prevent engorgement. Milk samples were collected two and four weeks after the initiation of belimumab. Belimumab concentrations were measured by using an in-house developed enzyme-linked immunoabsorbent assay (ELISA).

Results Belimumab concentrations measured in two breastmilk samples were 0.264 ug/mL at day 14 and 0.885 ug/mL at day 28 (table 1).

Conclusion This case report shows that subcutaneously administered belimumab was transferred to breastmilk. The higher concentration at day 28 is probably caused by the low volume and long stasis of the breastmilk during phasing out. The concentrations measured in breast milk were much lower than those measured in serum of adult patients (around 70 ug/mL).¹ The actual serum level of belimumab in the infant is supposed to be low, because of proteolysis in the infant's stomach and low intestinal absorption. However data on infant serum levels are not available and urgently needed in order to be able to weight the possible risk of transfer of belimumab to the

infant against the positive effects of breastfeeding for mother and infant.

REFERENCE

1. Struempfer H, M Thapar, D Roth. Population pharmacokinetic and pharmacodynamic analysis of belimumab administered subcutaneously in healthy volunteers and patients with systemic lupus erythematosus. *Clin Pharmacokinet*, 2018;**57** (6):717–728.

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PREGNANCY OUTCOMES IN SLE PATIENTS TREATED WITH BELIMUMAB: THE ITALIAN EXPERIENCE

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Objective To describe pregnancy outcomes in patients with SLE treated with belimumab before and/or during pregnancy.

Methods Data of prospectively-followed pregnancies (2014–2022) in 7 Italian centers were retrospectively collected.

Results Twenty-four SLE pregnancies were included (median age at conception: 33 [21–37] years; 15 primigravidae).

Belimumab was stopped in 4 cases preconceptionally, in 10 at positive pregnancy test and in 10 during pregnancy (4 during the 1st trimester, 3 during the 2nd trimester and 3 during the 3rd trimester). The timing of discontinuation was planned with the patient during preconception counselling.

Other medications included prednisone (92%); antimalarials (83%); azathioprine (46%); calcineurin-inhibitors (25%); low-dose aspirin (88%); heparin (58%).

At preconception, median SLEDAI was 4(2–4).

One patient who discontinued belimumab at the 11th week had active nephritis from preconception.

Three flares (cutaneous; pericarditis; hematologic) occurred during the 3rd trimester in the group of patients who discontinued belimumab at positive pregnancy test, while 1 flare (cutaneous + articular) occurred in the 1st trimester in the group of patients who continued belimumab.

Live-birth rate was 87.5%. Two miscarriages and 1 intrauterine fetal death (37th week; fetus with 21-trisomy and atrioventricular defect) occurred. One perinatal death occurred (patient with thrombotic+obstetric APS and lupus nephritis who underwent heterologous assisted reproductive technology -embryodonation- and developed eclampsia with cerebral haemorrhage at 25th week; an urgent cesarean section was performed; the newborn died after 3 days).

Two cases of pre-eclampsia in patients with multiple risk factors were observed.

Five newborns were hospitalized in Intensive Care Unit for: milk protein intolerance; desaturation; respiratory distress; prematurity (2 cases). One sepsis starting from urinary tract

Abstract P137 Table 1 Belimumab concentrations measured in breast milk

Time	Day 1	Day 8	Day 14	Day 15	Day 22	Day 28
Subcutaneously administration of belimumab (dosage)	200 mg	200 mg		200 mg	200 mg	
Concentration of belimumab in breast milk			0.264 ug/mL			0.885 ug/mL