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

P137 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.

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

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P138 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 haemorrage 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

infection occurred in a 2-months-old infant with calico-pyelic and ureteral dilatation at birth. One newborn presented with interatrial defect and situs inversus (paternal 10 chromosome inversion).

Conclusions Despite our data do not allow definitive conclusions, the live birth rate and the exclusion of drug-related congenital defects are encouraging. SLE flares occurred more frequently after Belimumab discontinuation at positive pregnancy test. We suggest that women on good disease control while on belimumab could be offered to continue it and to discuss discontinuation timing according to their specific risk/benefit ratio.

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P139 THE FAMALE STUDY: INVESTIGATING FAILING MATERNAL-FETAL TOLERANCE IN PREGNANT WOMEN WITH SLE

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Objective Pregnant women with systemic lupus erythematosus (SLE) have an increased risk of maternal complications and adverse fetal outcomes, like preeclampsia, preterm birth and fetal growth restriction. Interestingly, this increased risk persists in subsequent pregnancies, whereas it decreases in healthy women due to the development of maternal-fetal tolerance. Since maternal-fetal tolerance is crucial for a healthy pregnancy, we hypothesize that its failure contributes to the increased risk of pregnancy complications in women with SLE. Therefore, we initiated the FaMaLE study to investigate failing maternal-fetal tolerance in pregnant women with SLE.

Methods In the FaMaLE study, healthy women and women with SLE are included in their first trimester of pregnancy (<14 weeks gestational age (GA)) at Amsterdam UMC. Peripheral blood is collected once every trimester, within 48 hours before delivery and 5–12 weeks after delivery. Furthermore, the placenta is collected after delivery. Whole blood, peripheral blood mononuclear cells (PBMC) and placenta are freshly analyzed by flow cytometry.

Results First we set up a protocol for obtaining single-cell suspensions containing both immune cells and stromal cells from the placental basal plate and chorioamniotic membranes. Furthermore, we designed 5 flow cytometry panels to freshly analyze composition of placental cells, PBMC and whole blood. Currently 19 SLE patients are included in the study, of whom 15 have delivered (6 with complications) and 11 completed the study. Preliminary analysis of these 11 patients revealed a decreased CD4/CD8 ratio in the blood throughout and after pregnancy in women who experienced pregnancy complications. Furthermore, we found a decreased trophoblast/stromal cell ratio in the placenta of these patients.

Conclusions In conclusion, we designed a workflow to study blood and placenta in SLE patients with and without pregnancy complications. In preliminary analysis we found significant differences in blood and placenta, which require validation in the rest of the cohort (total 18 healthy controls and 60 SLE patients). These data will provide novel insights into the development and failure of maternal-fetal tolerance, and thereby into pregnancy complications in women with SLE.

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P140 PREGNANCY AND SYSTEMIC LUPUS ERYTHEMATOSUS: EXPERIENCE IN A PREGNANCY CLINIC

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Objective Adverse events during pregnancy are common in systemic lupus erythematosus (SLE). For this reason, EULAR

Abstract P140 Table 1 Demographic and clinical characteristics

Cases, n (%)	56 (100)
Age at 1st visit, mean (SD), years	35.6 (4.5)
BMI, mean (SD)	23.1 (4.1)
Smoke, n (%)	
never	39 (69.7)
active	6 (10.7)
previous smoker	11 (19.6)
Hypertension, n (%)	3 (5.4)
Diabetes, n (%)	0 (0)
Dyslipidemia, n (%)	1 (1.8)
Previous nephritis, n (%)	9 (16.1)
Disease duration, days, median (IQR)	2845 (998.0–5325.0)
ART, n (%)	13 (23.2)
anti-Ro positive, n (%)	12 (21.4)
APL positive, n (%)	25 (46.3)
APS associated, n (%)	6 (10.7)
Never pregnant, n (%)	23 (41.1)
Previous newborn, n (%)	33 (59)
Previous abortion, n (%)	23 (41.1)
High pregnancy risk, n (%)	54 (96.4)
Preconceptional counselling	
Pregnant at 1st visit, n (%)	24 (29.3)
Treatment adjustment, n (%)	15 (26.8)
Contraindicated pregnancy, n (%)	2 (3.6)
Not adjustment needed, n (%)	15 (40.3)
Corticosteroid use at 1st visit, n (%)	15 (26.8)
Corticosteroid daily at 1st visit, mg/day, median (IQR)	5 (2.5–15.0)
cDMARDS at 1st visit, n (%)	11 (19.6)
bDMARDs at 1st visit, n (%)	2 (3.6)
Hydroxychloroquine at 1st visit, n (%)	29 (51.8)
Aspirin at 1st visit, n (%)	16 (28.6)
Anticoagulation at 1st visit, n(%)	4 (7.1)
Pregnancy, n (%)	45 (80.4)

ART (additional reproductive therapies), APL (antiphospholipid antibodies), APS (antiphospholipid syndrome), bDMARDS (biological disease-modifying antirheumatic drugs), BMI (Body Mass Index), RA (rheumatoid arthritis), cDMARDS (conventional disease-modifying antirheumatic drugs).