

#### **4. Risk of Ocular Anomalies in Children Exposed in Utero to Antimalarials: Data from the Offspring of SLE mothers Registry**

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Antimalarials are usually continued during SLE pregnancies, with recent observational studies showing no excess risk of retinopathy or visual impairment in exposed children. However, most studies limited their follow-up to the first year of life, and none were population-based. Thus, within a large population-based cohort, we aimed to determine if SLE offspring exposed in utero to antimalarials have an increased risk of developing ocular anomalies during childhood compared to unexposed SLE offspring.

We used data from the "Offspring of SLE mothers' Registry (OSLER)," which includes all women with  $\geq 1$  hospitalization for delivery after SLE diagnosis, identified through Quebec's healthcare databases (1989-2009). Within OSLER, data on in utero drug exposures are available for children born to a mother on the public drug plan throughout pregnancy. In this subgroup, we identified an exposed group including children born to SLE mothers filling  $\geq 1$  prescription for antimalarials during pregnancy, and an unexposed group including children born to SLE mothers without a prescription for antimalarials during pregnancy. We ascertained the occurrence of ocular anomalies, including retinopathies, ocular congenital anomalies, tumors, and refractive or other visual disturbances, based on  $\geq 1$  hospitalization or  $\geq 2$  physician visits with a relevant diagnostic code (i.e.  $\geq 2$  months but  $\leq 24$  months) from birth to the end of follow-up (i.e. age 18, death, or end of study).

We identified 155 children born to a SLE mother with drug coverage throughout pregnancy. Of these, 25 children were exposed to antimalarials and 130 unexposed. Mean follow-up was 8.0 (SD 5.4) years. We identified one case of ocular anomaly in the exposed group and 3 cases in the unexposed group (4% versus 2%; difference 2%, 95%CI -4, 20). In the exposed group, the ocular diagnosis was an unspecified retinal disorder recorded during the hospitalization for delivery, while the child was 3 days old and which was not associated with prematurity. In the control group, all cases were based on physician visits related to refractive and other visual disturbances, between 2.9-8.1 years.

In 25 children exposed to antimalarials in this sample, one had a retinopathy. Due to the low number of events and limited precision of our estimates, we were unable to definitively demonstrate an increased risk of ocular anomalies during childhood in SLE offspring exposed to antimalarials compared to unexposed SLE offspring. However, the potential benefits for pregnant SLE women to continue taking antimalarials should be weighed against the possible risk.