Risk of Adverse Neonatal Outcomes after Pandemic Vaccination in Italy

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Background:
A systematic review of 120 studies related to the 2009 pandemic influenza infection in pregnancy confirmed the worsening of birth outcomes including low birth weight and preterm delivery (Mosby et al., 2011). Moreover, all severe respiratory infections in pregnant women, such as pneumonia, are linked with an increased risk of prematurity and low birth weight as well as with pregnancy complications (Graves, 2010). Thus vaccination against influenza is considered an essential element of prenatal care. During 2009 pandemic in Italy only one vaccine containing MF59 adjuvant was available and data on its use in pregnant women were limited.

Objectives:
To evaluate the risk of adverse neonatal outcomes after pandemic MF59 adjuvanted vaccination during pregnancy.

Methods:
We carried out a registry based retrospective cohort study covering the population of the Lombardy Region in Northern Italy (> 9.8 millions inhabitants in 2010). All pregnancies of resident women whose delivery occurred between 1 October 2009 and 30 September 2010 were identified through the Regional birth registry. The vaccination status, pregnancy and birth outcomes, and background information of the pregnant women were retrieved by linking Lombardy Regional registries for prescriptions and vaccination, hospital discharge database and medical birth registry. The neonatal outcomes concerned preterm and very preterm births (if the delivery occurred within 33-36 gestational weeks or <= 32 gestational weeks respectively) and birth weight. Low birth weight was defined as a newborn of less than 2500 grams; very low birth weight identified newborns of less than 1500 grams. A multivariate regression models adjusted by propensity score was adopted to estimate the odds ratios of events in association with the vaccination during pregnancy.

Results:
There were 86 171 eligible pregnancies in Lombardy, with 6 246 women exposed to pandemic vaccine (57.9% were vaccinated in the third trimester and 40.9% in the second one). The adjusted odds ratios for vaccinated women were 0.99 (95% CI 0.87 – 1.13) for preterm birth and 0.64 (95% CI 0.45 – 0.91) for very preterm birth. The vaccination was not associated to an increased risk of low birth weight (adjusted OR 0.91, 95% CI 0.79 – 1.05) while the risk of very low birth weight appears to be decreased amongst vaccinated women (adjusted OR 0.60, 95% CI 0.40 – 0.90).
Conclusion:
Pandemic influenza vaccination during the pregnancy using an MF-59 adjuvanted formulation does not appear to increase the risk of adverse neonatal outcomes. The potential confounding role of the healthy vaccinee effect may partly explain the protective estimates.

References:

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