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The fetal safety of enoxaparin use during pregnancy

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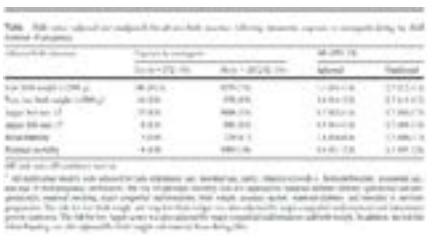
Introduction: Enoxaparin is widely used during pregnancy as pregnancy is a hypercoagulable state. Many studies investigated enoxaparin effectiveness during gestation however, its fetal safety has scarcely been investigated.

Objective: To evaluate fetal safety following exposure to Enoxaparin during pregnancy.

Methods: A population-based, retrospective cohort study was performed by linking computerized databases, including the drug dispensing registries of Clalit Health Services in Israel and maternal and infant hospital records, between 1998 and 2009. Multivariate logistic regression models were used to examine associations between first and third-trimester exposure to enoxaparin, major malformations and other adverse birth outcomes, adjusted for confounders.

Results: From a total of 109,473 singleton pregnancies, 418 and 572 were exposed to enoxaparin during the first and third trimesters, respectively. Exposure to enoxaparin during the first trimester of pregnancy was not associated with an increased risk of major congenital malformations [adjusted odds ratio (aOR) 1.1, 95% confidence interval (CI) 0.8–1.6], while exposure during the third trimester was not associated with an increased risk of low birth weight (aOR 1.1, 95% CI 0.8–1.4), low Apgar score (aOR 0.9, 95% CI 0.4–1.8), or risk of perinatal mortality (aOR 0.6, 95% CI 0.1–2.9).

Conclusion: Exposure to enoxaparin during pregnancy was not associated with an increased risk of major malformations in general or according to organ systems.



Recent Publications

1. Daniel S, Koren G, Lunenfeld E, Levy A. Immortal time bias in drug safety cohort studies: spontaneous abortion following nonsteroidal antiinflammatory drug exposure. Am J Obstet Gynecol. 2015 Mar;212(3):307.
2. Daniel S, Koren G, Lunenfeld E, Levy A. NSAIDs and spontaneous abortions - true effect or an indication bias? Br J Clin Pharmacol. 2015 Oct;80(4):750-4.
3. The fetal safety of clomiphene citrate: a population-based retrospective cohort study. Weller A, Daniel S, Koren G, Lunenfeld E, Levy A. BJOG. 2017 Mar 23.
4. Vaginal antimycotics and the risk for spontaneous abortions. Daniel S, Rotem R, Koren G, Lunenfeld E, Levy A. Am J Obstet Gynecol. 2018.02.013.

5. Risk of major congenital malformations following first trimester exposure to vaginal azoles used for treating vulvovaginal candidiasis: a population based retrospective cohort study. Rotem R, Fishman B, Daniel S, Koren G, Lunenfeld E, Levy A. BJOG. 2018 Nov;125(12):1550-1556.

Biography

Amalia Levy is the chair of the Department of Public Health in the Faculty of Health Sciences in Ben-Gurion University of the Negev. She has a BSc in biology, master's degree in public health, and PhD in epidemiology. Her main research field is Pharmacoepidemiology, predominantly research on detection of drug-induced congenital malformations and spontaneous abortions. With collaboration of the Soroka Medical Center, Clalit Health Services, and Motherisk Programs, Levy's researches study a large cohort of pregnancies in southern Israel, using advanced methodological and statistical methods. These researches evaluated the safety of drugs during pregnancy, including metoclopramide, antihypertensive drugs, folic acid antagonists, NSAID's, enoxaparin, and vaginal azoles. These studies were published in several prestigious medical journals such as The New England Journal of Medicine, American Journal of Obstetrics and Gynecology, The British Journal of Clinical Pharmacology, The British Journal of Obstetrics and Gynecology and Drug Safety.

Notes: