

SMOKING DURING PREGNANCY VERSUS NO SMOKING AND USING NICOTINE REPLACEMENT THERAPIES (NRT)

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A Critical Review of “Smoking Habits, Nicotine Use, and Congenital Malformations.”

Morales-Suarez-Varela MM, Bille C, Christensen K, Olsen J Obstet Gynecol. 2006 Jan; 107(1):51-57.

It is critical to discuss smoking in pregnancy when talking about alcohol use, as many women who drink alcohol concurrently smoke cigarettes.¹ Most women are aware that smoking is detrimental to her unborn baby, however because it is so addictive, it is extremely difficult to quit. Nicotine Replacement Therapies (NRT) have become popular in recent years to assist individuals in withdrawing from cigarette smoking. Despite the fact there have not been any studies on the safety of these therapies during pregnancy, most notably in the first trimester, nicotine substitutes are often recommended as “the lesser of two evils”. Despite the lack of safety data, NRT is recommended during pregnancy in France, as it was felt that cigarettes, in addition to containing nicotine are composed of many other harmful chemicals, and being exposed to a single agent would be less harmful to the fetus.²

This study was published recently, where researchers attempted to examine whether maternal smoking and use of nicotine substitutes during the first 12 weeks of pregnancy increased the prevalence of congenital malformations. They used the Danish National Birth Cohort (1997-2003) where they identified 76,768 pregnancies. Of these women, 20,603 were exposed to cigarette smoking and 250 were exposed to nicotine substitutes and the remaining 56,165 women denied smoking during pregnancy. This information was recorded on each woman’s record from an interview that was completed between 11-25 weeks gestation. The smokers were asked details of their smoking habits which included, when they smoked, how many cigarettes a day, as well as if they had used a nicotine substitute in the first trimester of pregnancy. They

also controlled for age, parity, BMI, alcohol intake, maternal education. These variables were included in logistic regression models and were dropped one by one unless they changed the effect size by more than 5%. Prior to analyzing the data they classified all the congenital malformations as major or minor, following the EUROCRAT criteria.

RESULTS

Children born to nonsmokers, but who used nicotine substitutes, had a slightly increased risk of congenital malformations, relative rate ratio was 1.61(95% confidence interval 1.01-2.58) and when the analysis was restricted to musculoskeletal malformations, the relative prevalence rate ratio was 2.63(95% confidence interval 1.53-4.52) Their conclusion was that their results showed no increase risk for malformations in women who smoked during pregnancy, however they identified an increased risk in nonsmokers using nicotine substitutes. They hypothesized that the reasons for this result could be that the nicotine used to substitute tobacco smoking may reach a higher peak doses than in smoking and nicotine in substitutes is not heated as in smoking.

Our main concern with the publication of this paper, is the negative effect it may have on women who responsibly made the decision to give up smoking while pregnant, with the aid of nicotine substitutes. Smoking cigarettes is extremely addictive, however these women were able to quit with the help of nicotine substitutes and probably felt justifiably proud, feeling that they were protecting their unborn fetus by not smoking. Imagine how they felt after seeing the results of this study! Despite the authors stating in the results section that nicotine had only a slightly increased risk for malformations, with 250 women in their study exposed to nicotine substitutes, compared to 20,603 smokers, their conclusion stated that they identified an increased risk for

malformations in infants of non-smokers using nicotine substitutes, which comes across as rather a definitive statement.

However, pharmacologically, nicotine substitutes result in nicotine levels substantially below those achieved with active cigarette smoking³ and therefore, this spurious result does not have any biological plausibility.

Already, the media has translated the information in ways that we are sure that the authors did not anticipate, with headlines such as, "Use of nicotine patches, gum in first 12 weeks of pregnancy can increase risk of birth defects,"² and "Pregnant women quitting smoking beware: nicotine substitutes may harm the fetus".³

In fact, even an online well respected medical publication, which has more than 100,000 physician subscribers reported on the paper with the headline: "Nicotine substitute use while pregnant linked to more congenital malformations".⁴ All of these headlines differed considerably from the authors title, which did not mention an increased risk, and our concern, based on our experience at Motherisk,⁵ is that it could have prompted women to take up smoking again as it may have appeared from this study to be a safer alternative.

This is the first study to examine the safety of NRT compared to smoking and nonsmoking pregnant women, with the unexpected result of a lower rate of malformations in infants whose mothers who smoked cigarettes compared to women who used NRT. However, the results of

this study should not change any recommendations regarding smoking during pregnancy, women should be encouraged to quit and if they cannot, they should be encouraged to cut down the number of cigarettes they smoke per day and finally, it would still appear that NRT is the safer alternative.

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