



## Editorial

## Safety and Efficacy of Nicotine Replacement Treatment During Pregnancy

## Seguridad y efectividad del tratamiento sustitutivo con nicotina durante el embarazo

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The scientific community agrees that tobacco smoke is the main avoidable cause of morbidity and mortality. Prevention of active consumption and exposure to environmental tobacco smoke are priority aims in public health policies. The main strategies for the control of smoking include reducing exposure to environmental tobacco smoke, delaying the start of smoking and increase in quitting. In this last section, treatment of the nicotine addiction with the use of replacement therapy is one of the main interventions.<sup>1</sup>

Active tobacco consumption during pregnancy and maternal exposure to environmental smoke involve risks to the foetus due to the possible harmful effects of nicotine on the perinatal results, the health of the new born and throughout childhood.<sup>2,3</sup> In particular, maternal tobacco consumption increases the risk of miscarriage, placenta previa, placental abruption, low birth weight, pre-term birth, perinatal death, cleft palate, sudden infant death syndrome and neonatal abstinence syndrome. Furthermore, it has been associated with cognitive deficiencies and childhood behavioural disorders.<sup>4</sup>

Tobacco smoke contains numerous toxins that can explain these negative results to exposure, including carbon monoxide, nicotine, cyanide, cadmium and a variety of carcinogens. Carbon monoxide is considered the major biologically present toxin in tobacco smoke for the foetus. It reduces the supply of oxygen to the foetus and its exposure during pregnancy is a well-established cause of abnormal foetal brain development and foetal growth delay. Nicotine can reduce the oxygen and nutrients available to the foetus by reducing placental blood flow which can also directly affect the development of neurons and other cells.<sup>3-8</sup>

The main recommendation to prevent foetal exposure to the toxic substances found in tobacco smoke is to avoid active smoking and protect the pregnant woman from passive exposure to environmental tobacco smoke. In this respect, the most effective strategies that aid in smoking cessation during pregnancy are based on structured interventions of medical advice supplemented, in cases of major dependence meeting specific criteria, with nicotine replacement

therapy; all within the context of preventive programs carried out by sexual, reproductive and maternity health professionals that include a gender perspective.<sup>9-11</sup>

The recommendation of prescribing nicotine replacement treatment during pregnancy is not uniformly reported in all the clinical practice guides available to professionals, which could lead to confusion. In summary, 2 practical questions are presented: the effectiveness and safety of the intervention during gestation. In this respect, there are recent revisions of the scientific evidence with respect to the effectiveness and safety of interventions for the reduction of smoking during pregnancy that help in clarifying the subject.<sup>12-16</sup>

These publications summarise the evidence from systematic revisions of the effectiveness and safety of smoking cessation during pregnancy and are specified in two reports by the National Institute for Health and Clinical Excellence (NICE).<sup>12,13</sup>

As far as effectiveness, the main conclusions of the revision are, firstly, that as a whole the cessation interventions are effective in the late stage of pregnancy and significantly reduce incidences of low birth weight and pre-term births. Secondly, interventions based on cognitive behaviour therapy for cessation and nicotine replacement therapy during pregnancy have also proven to be effective.

As far as safety is concerned, there is no evidence that nicotine replacement therapy increases incidences of low birth weight and there is insufficient data on the impact on neonatal mortality or other negative perinatal results.

Nicotine replacement treatment can have two potential benefits during pregnancy. It can reduce or eliminate foetal exposure to others toxins present in tobacco smoke (specially carbon monoxide) and facilitates the overall reduction of the dose and duration of nicotine exposure (if used following controlled treatment guidelines and the end result is smoking cessation).

Furthermore, there is solid theoretical reasoning that recommends the use of pharmacological intervention given that nicotine replacement therapy is probably much safer than continued tobacco consumption during pregnancy.<sup>17</sup>

According to the currently available evidence, the use of nicotine replacement therapy is an intervention that can be recommended during pregnancy for women who are heavy smokers and want to

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quit, who have tried and failed, after quantifying it along with the level of nicotine dependence.<sup>9,11-13,18-21</sup> Prescription should be based on the context of treatment based on active smoking cessation and avoiding passive exposure, as a supplement to medical advice and with the woman's consent.

## References

1. Stead LF, Perera R, Bullen C, Mant C, Lancaster T. Nicotina replacement therapy for smoking cessation. *Cochrane Database Syst Rev*. 2008. (1): CD000146
2. Pichini S, Puig C, García O, Pacifici R, Figueroa C, Vall O, et-al. Determinantes sociodemográficos del hábito tabáquico durante el embarazo y efectos neonatales en Barcelona. *Med Clin (Barc)*. 2002; 118:53-6.
3. García-Algar O. Síndrome de abstinencia neonatal de la nicotina. *Arch Bronconeumol*. 2008; 44:509-11.
4. [accessed 2010 Mar 7]. Available from: <http://www.treatobacco.net>.
5. Leonardi-Bee J, Smyth A, Britton J, Coleman T. Environmental tobacco smoke and fetal health: systematic review and meta-analysis. *Arch Dis Child*. 2008; 93:F351-61.
6. Kanellopoulos TA, Varvarigou AA, Karatza AA, Beratis NG. Course of growth during the first 6 years in children exposed in utero to tobacco smoke. *Eur J Pediatr*. 2007; 166:685-92.
7. Cordoba R, García N, Suarez RG, Galvan C. Exposición al humo ambiental de tabaco en la infancia. *An Pediatr (Barc)*. 2007; 67:101-3.
8. Julvez J, Ribas-Fito N, Torrent M, Forn M, García-Esteban R, Sunyer J. Maternal smoking habits and cognitive development of children at age 4 years in a population-based birth cohort. *Int J Epidemiol*. 2007; 36:825-32.
9. García-Algar O, Pichini S, Pacifici R, Castellanos E. Consejo para promover el abandono del consumo de tabaco en el embarazo: guía clínica para profesionales sanitarios. *Aten Primaria*. 2003; 32:481-91.
10. Jané M, Martínez C. Guia clínica per promoure l'abandonament del consum de tabac durant l'embaràs. Departament de Salut. Generalitat de Catalunya. Barcelona. 2006.
11. Jané M, Martínez C, Vela E. Protocol del Programa "Embaràs sense fum". Direcció General de Salut Pública. Barcelona. 2007. [accessed 2010 Mar 7]. Available from: <http://www.gencat.cat/salut/depsalut/html/ca/dir2071/index.html>.
12. [accessed 2010 Mar 7]. Available from: <http://www.nice.org.uk/nicemedia/pdf/QuittingSmokingInPregnancyDraftGuidanceForConsultation.pdf>.
13. [Accessed 2010 Mar 7]. Available from: <http://www.nice.org.uk/nicemedia/pdf/QuittingSmokingInPregnancyBriefingPaper.pdf>
14. Coleman T, Thornton J, Britton J, Lewis S, Watts K, Coughtrie MW, et-al. Protocol for the smoking, nicotine and pregnancy (SNAP) trial: double-blind, placebo-randomised, controlled trial of nicotine replacement therapy in pregnancy. *BMC Health Serv Res*. 2007; 7:2.
15. Lumley J, Chamberlain C, Dowswell T, Oliver S, Oakley L, Watson L. Interventions for promoting smoking cessation during pregnancy.[update of Cochrane Database Syst Rev, 4]:CD001055; PMID: 15495004]. *Cochrane Database Syst Rev*. 2009. (3):CD001055
16. Oncken C, Dornelas E, Greene J, Sankey H, Glasmann A, Feinn R, et-al. Nicotine gum for pregnant smokers: a randomized controlled trial. *Obstet Gynecol*. 2008; 112:859-67.
17. Coleman T. Reducing harm from tobacco smoke exposure during pregnancy. *Birth Defects Res C Embryo Today*. 2008; 84:73-9.
18. Osadchy A, Kazmin A, Koren G. Nicotine replacement therapy during pregnancy: recommended or not recommended?. *J Obstet Gynaecol Can*. 2009; 31:744-7.
19. Einarson A, Riordan S. Smoking in pregnancy and lactation: a review of risks and cessation strategies. *Eur J Clin Pharmacol*. 2009; 65:325-30.
20. Rore C, Brace V, Danielian P, Williams D. Smoking cessation in pregnancy. *Expert Opin Drug Saf*. 2008; 7:727-37.
21. Coleman T. Recommendations for the use of pharmacological smoking cessation strategies in pregnant women. *CNS Drugs*. 2007; 21:983-93.