Varenicline and Pregnancy

1. Systematic Review and Meta-Analysis to Assess the Safety of Bupropion and Varenicline in Pregnancy.

Author(s): Turner, Emily; Jones, Matthew; Vaz, Luis R; Coleman, Tim

Source: Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco; Mar 2018

Publication Date: Mar 2018

Publication Type(s): Journal Article

PubMedID: 29579233

Abstract: Smoking in pregnancy is a substantial public health issue, but, apart from nicotine replacement therapy (NRT), pharmacological therapies are not generally used to promote cessation. Bupropion and varenicline are effective cessation methods in non-pregnant smokers and this systematic review investigates their safety in pregnancy. Methods: We searched MEDLINE, EMBASE, CINAHL and PsychINFO databases for studies of any design reporting pregnancy outcomes after bupropion or varenicline exposure. We included studies of bupropion used for smoking cessation, depression, or where the indication was unspecified. Depending on study design, quality was assessed using the Newcastle-Ottawa Scale or Cochrane Risk of Bias Tool. Most findings are reported narratively but meta-analyses were used to produce pooled estimates for the proportion of live births with congenital malformations and of the mean birthweight and gestational age at delivery following bupropion exposure. Results: 18 studies were included: two randomised controlled trials, eleven cohorts, two case-control studies and three case reports. Study quality was variable. Gestational safety outcomes were reported in 14 bupropion and four varenicline studies. Meaningful meta-analysis was only possible for bupropion exposure, for which the pooled estimated proportion of congenital malformations amongst live-born infants was 1.0% (95% CI= 0.0-3.0%, I²= 80.9%, 4 studies) and the mean birthweight and mean gestational age at delivery was 3305.9g (95% CI= 3173.2-3438.7g, I²= 77.6%, 5 studies) and 39.2 weeks (95% CI= 38.8-39.6, I²= 69.9%, 5 studies) respectively. Conclusions: There was no strong evidence that either major positive or negative outcomes were associated with gestational use of bupropion or varenicline. PROSPERO registration number CRD42017067064. Implications: We believe this to be the first systematic review investigating the safety of bupropion and varenicline in pregnancy. Meta-analysis of outcomes following bupropion exposure in pregnancy suggests that there are no major positive or negative impacts on the rate of congenital abnormalities, birthweight or premature birth. Overall, we found no evidence that either of these treatments might be harmful in pregnancy, and no strong evidence to suggest safety, but available evidence is of poor quality.
2. Smoking cessation strategies in pregnancy: Current concepts and controversies.

Author(s): Ioakeimidis, Nikolaos; Vlachopoulos, Charalambos; Katsi, Vasiliki; Tousoulis, Dimitrios

Source: Hellenic journal of cardiology : HJC = Hellenike kardiologike epitheorese; Oct 2018

Publication Date: Oct 2018

Publication Type(s): Journal Article Review

PubMedID: 30296484

Abstract: Smoking during pregnancy is a risk factor associated with adverse pregnancy outcomes. Despite the fact that these outcomes are well known, a considerable proportion of pregnant women continue to smoke during this critical period. This paper evaluates critically smoking cessation interventions targeting pregnant women. We describe the findings of key published studies, review papers and expert statements to report the efficacy and safety of strategies for smoking cessation in pregnancy, including counselling and pharmacotherapy. Counselling appears to improve quit rates but mainly when used in combination with pharmacological therapy. Pharmacotherapy is recommended for women who are heavy smokers and are unable to quit smoking on their own. Nicotine replacement therapy is a reasonable first-line drug option. It is recommended that women who are pregnant, or planning to become pregnant, should be informed of potential risks for the foetus before considering smoking cessation therapy with bupropion or varenicline. Pregnant women view electronic nicotine delivery systems as being safer than combustible cigarettes, and this indeed may be the case; however, further evidence is required to assess their effectiveness as a smoking cessation aid and their safety for the mother and the child. Postpartum relapse is a significant problem, with approximately one out of two quitters relapsing in the first 2 months after delivery. These women should be considered 'at risk' and provided with ongoing support.

Database: Medline

**Author(s):** Barboza, Jose

**Source:** Expert opinion on pharmacotherapy; Oct 2018; p. 1-10

**Publication Date:** Oct 2018

**Publication Type(s):** Journal Article

**PubMedID:** 30332554

**Abstract:**
INTRODUCTION Tobacco use is the most preventable cause of death worldwide, with over 7 million deaths per year. Smoking during pregnancy causes harm to the mother, fetus, and can result in problems for the infant from childhood into adulthood. Practitioners should ask all expectant mothers about tobacco use. For expectant mothers who smoke or recently quit, practitioners should advice to quit and provide psychosocial interventions. Rates of smoking during pregnancy differ between geographical locations, with estimates of 10.8% in the UK and 7.2% in the US. Practitioners should provide expectant mothers unable to quit smoking with information about the risks and benefits of pharmacotherapy and use a patient-centered approach to determine the use. Although there is no definitive evidence on birth outcomes, nicotine replacement therapy and bupropion are adequate pharmacotherapies to help those unable to quit. AREAS COVERED Herein, this author looks at the various pharmaceutical strategies to help patients cease smoking and provides expert perspectives on the subject. EXPERT OPINION Additional research on pharmacotherapy is warranted, especially with varenicline. Practitioners working with pregnant patients should be familiar with the evidence for pharmacotherapy in smoking cessation during pregnancy. This evidence can be difficult to navigate due to conflicting results and limitations with the trials.

**Database:** Medline

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4. Varenicline is more effective than nicotine replacement therapy during pregnancy: Findings from the smoking mums (maternal use of medications and safety) study

**Author(s):** Choi S.K.Y.; Tran D.T.; Jorm L.R.; Havard A.; Preen D.B.; Kemp-Casey A.; Randall D.; Einarsdottir K.

**Source:** Pharmacoepidemiology and Drug Safety; Aug 2018; vol. 27; p. 100-101

**Publication Date:** Aug 2018

**Publication Type(s):** Conference Abstract

Available at Pharmacoepidemiology and Drug Safety - from Wiley Online Library Science, Technology and Medicine Collection 2017

**Abstract:**
Background: Studies in the general population suggest that varenicline is more effective than nicotine replacement therapy (NRT) for smoking cessation. However, clinical guidelines recommend against the use of varenicline during pregnancy and suggest NRT be used when the expected benefits outweigh the potential risks. Objective(s): To evaluate whether varenicline was more effective than NRT for smoking cessation when used during pregnancy as evidence on this question is lacking. Method(s): Routinely-collected records of all births (1 January 2011 to 31 December 2012) in New South Wales and Western Australia were used to identify a cohort of women who smoked during the first 20 weeks of pregnancy (self-reported). Pharmaceutical dispensing data were linked to birth records to identify varenicline or NRT dispensing in the first 20 weeks of pregnancy. Smoking cessation was defined as women reported not smoking (ie, quitting) after the first 20 weeks of pregnancy. Inverse probability of treatment weighting with propensity scores were used to account for differences in socio-demographic, obstetric characteristics, and pre-existing co-morbidities between the two treatment groups. Crude and adjusted rate differences (RD) with 95% confidence intervals (CI) were calculated. Result(s): Overall, 117 women used varenicline
and 135 NRT in the first 20 weeks of pregnancy. In the unweighted sample, more women who used varenicline quit smoking after the first 20 weeks than women using NRT (28.2 vs 11.1%, crude RD: 17.1%, 95% CI: 7.4-26.8%). In the weighted sample, quitting rate was 12.7% (95% CI: 0.8-24.6%) higher in pregnant smokers who used varenicline (27.4% vs 14.7%) when compared with those who used NRT. Conclusion(s): Pregnant smokers using varenicline were more likely to quit smoking than those using NRT. This information will assist health care providers to make informed recommendations, but data regarding safety of varenicline in pregnancy are also urgently needed. Future studies with greater statistical power are required to confirm our results.

Database: EMBASE

5. First trimester exposure to varenicline was not associated with increased risk of major birth defects: Findings from the smoking MUMS (Maternal Use of Medications and Safety) study

Author(s): Tran D.T.; Choi S.; Jorm L.R.; Havard A.; Preen D.B.; Kemp-Casey A.; Einarsdottir K.; Randall D.

Source: Pharmacoepidemiology and Drug Safety; Aug 2018; vol. 27 ; p. 352

Publication Date: Aug 2018

Publication Type(s): Conference Abstract

Abstract: Background: Varenicline is an effective smoking cessation pharmacotherapy in the general population but guidelines recommend against its use during pregnancy, because data about maternal and fetal safety are insufficient. Objective(s): To assess the effects of exposure to varenicline in the first trimester on major birth defects in liveborn children. Method(s): Routinely-collected records of births (conceived between Jan 2008 and Apr 2012) in New South Wales, Australia were linked to administrative pharmaceutical dispensing data for mothers and hospital records for both mothers and children. First trimester exposure was defined as days covered by dispensing of varenicline (anatomical therapeutic chemical code N07BA03) overlapping with the first 12 weeks of gestation. The outcome was any major birth defects, identified from children’s hospital admissions in the first 18 months of life, excluding chromosome disorders and anomalies due to viral infections and exogenous agents. Children exposed to teratogenic medications in the first trimester were excluded. Logistic regression models were used to compare the outcome in varenicline-exposed children with that in children born to (a) mothers who smoked and did not use any smoking cessation pharmacotherapy during pregnancy and (b) mothers who did not smoke during pregnancy, adjusting for maternal socio-demographic characteristics, obstetric factors and medical conditions. Result(s): Among 884 varenicline-exposed children, 25 (2.83%) had a major birth defect. Among 44368 unexposed children of smoking mothers and 336090 unexposed children of non-smoking mothers, 3.00% and 3.03% respectively had a major birth defect. After adjusting for potential confounders, varenicline exposure was associated with 2% and 6% reduction in the likelihood of birth defects, compared with untreated smoking (odds ratio [OR]: 0.98, 95% confidence interval [CI]: 0.66-1.47) and non-smoking (OR: 0.94, 95% CI: 0.63-1.40), respectively. Conclusion(s): First trimester use of varenicline was not associated with increased risk of major birth defects compared with no therapy. Although this is the largest study investigating the possible teratogenic effects of varenicline to date, the number of exposed cases was still limited. Precaution in interpreting these findings is recommended, as is further research with larger sample sizes, to increase precision and examine specific birth defects.

Database: EMBASE
6. Nicotine replacement therapy for smoking cessation during pregnancy

Author(s): Bar-Zeev Y.; Lim L.L.; Bonevski B.; Gruppetta M.; Gould G.S.

Source: Medical Journal of Australia; Jan 2018; vol. 208 (no. 1); p. 46-51

Publication Date: Jan 2018

Publication Type(s): Review

PubMedID: 29320660

Abstract: Nicotine replacement therapy (NRT) is recommended in current Australian clinical guidelines for pregnant women who are unable to quit smoking unassisted. * Clinicians report low levels of prescribing NRT during pregnancy, due to safety concerns and low levels of confidence in their ability to prescribe NRT. * Animal models show that nicotine is harmful to the fetus, especially for brain and lung development, but human studies have not found any harmful effects on fetal and pregnancy outcomes. * Studies of efficacy and effectiveness in the real world suggest that NRT use during pregnancy increases smoking cessation rates. These rates may be hampered by the fact that studies so far have used an NRT dose that does not adequately account for the higher nicotine metabolism during pregnancy and, therefore, does not adequately treat withdrawal symptoms. * Further research is needed to assess the safety and efficacy of higher dosages of NRT in pregnancy, specifically of combination treatment using dual forms of NRT. * As NRT is safer than smoking, clinicians need to offer this option to all pregnant women who smoke. A practical guide for initiating and tailoring the dose of NRT in pregnancy is suggested. Copyright © 2018 AMPCo Pty Ltd. Produced with Elsevier B.V. All rights reserved.

Database: EMBASE

7. Smoking cessation during pregnancy

Author(s): anonymous

Source: Obstetrics and Gynecology; Oct 2017; vol. 130 (no. 4)

Publication Date: Oct 2017

Publication Type(s): Review

PubMedID: 28937573

Available at Obstetrics and Gynecology - from Free Medical Journals . com
Available at Obstetrics and Gynecology - from Ovid (LWW Total Access Collection 2015 - Q1 with Neurology)

Abstract: Smoking is one of the most important modifiable causes of poor pregnancy outcomes in the United States, and is associated with maternal, fetal, and infant morbidity and mortality. The physical and psychologic addiction to cigarettes is powerful; however, the compassionate intervention of the obstetrician-gynecologist can be the critical element in prenatal smoking cessation. An office-based protocol that systematically identifies pregnant women who smoke and offers treatment or referral has been proved to increase quit rates. A short counseling session with pregnancy-specific educational materials and a referral to the smokers’ quit line is an effective smoking cessation strategy. The 5A’s is an office-based intervention developed to be used under the guidance of trained practitioners to help pregnant women quit smoking. Knowledge of the use of the 5A’s, health care support systems, and pharmacotherapy add to the techniques providers can use to support perinatal smoking cessation. The use of alternative forms of nicotine, such as e-cigarettes and vaping, have increased substantially in recent years, but there are little data regarding the health effects of these agents, either in the general population or in pregnant women specifically.

Database: EMBASE
8. Is the use of smoking cessation pharmacotherapies during pregnancy consistent with clinical guidelines? findings from the smoking MUMS (Maternal Use of Medications and Safety) study

Author(s): Havard A.; Tran D.T.; Jorm L.R.; Preen D.B.; Einarsdottir K.

Source: Pharmacoepidemiology and Drug Safety; Aug 2017; vol. 26 ; p. 506-507

Publication Date: Aug 2017

Publication Type(s): Conference Abstract

Available at Pharmacoepidemiology and Drug Safety - from Wiley Online Library Science, Technology and Medicine Collection 2017

Available at Pharmacoepidemiology and Drug Safety - from Unpaywall

Abstract: Background: As there is no conclusive evidence regarding the efficacy or safety of smoking cessation pharmacotherapies (SCP) during pregnancy, clinical practice guidelines advise against during-pregnancy use of varenicline and bupropion, and recommend nicotine replacement therapy (NRT) only when the expected benefits outweigh the risks. Objectives: This study examined the extent to which during-pregnancy use of SCP in Australia is consistent with these guidelines.

Methods: Routinely collected midwifery data for all deliveries in the two Australian States of New South Wales and Western Australia between May 2011 and April 2012 were linked to hospital separations and pharmaceutical dispensing data. Instances where the date and quantity of SCP dispensed suggested use between the dates of conception and delivery were identified and reported as the proportion of women who smoked during pregnancy. Multivariable logistic regression models examined the relationship between SCP use and demographic characteristics, parity, history of depression, history of respiratory disorders, and quantity smoked. Separate models were constructed for NRT and varenicline (not bupropion, due to insufficient users), with smokers who did not use any SCP as the comparison group. Results: Utilisation ranged from 1.2-1.6% for NRT patches, 0.04-0.05% for bupropion and 0.9-1.7% for varenicline (ranges are reported because two methods were used to identify women who smoked). NRT use was more likely in women aged 30 to 34 years (OR = 2.25, 95% CI 1.20-4.23), and those with a history of depression (OR = 2.17, 95% CI 1.36-3.47). A history of depression was also associated with use of varenicline (OR = 1.87, 95% CI 1.14-3.06).

Conclusions: The limited use of bupropion during pregnancy is consistent with clinical guidelines, while the more common use of varenicline is concerning given its unknown safety during pregnancy. Use of varenicline among women with a history of depression is also a concern, given the boxed warning, mandated by US Food and Drug Administration, about the possible increased risk of psychiatric events associated with Varenicline use. Conversely, it is encouraging that utilisation of NRT patches was greater among women with a history of depression, given withdrawal from nicotine can exacerbate depression.

Database: EMBASE
9. Birth outcomes associated with the use of smoking cessation pharmacotherapies in pregnancy: Findings from the smoking mums (maternal use of medications and safety) study

**Author(s):** Tran D.T.; Havard A.; Jorm L.R.; Preen D.B.; Kemp-Casey A.; Einarsdottir K.; Randall D.

**Source:** Pharmacoepidemiology and Drug Safety; Aug 2017; vol. 26 ; p. 435-436

**Publication Date:** Aug 2017

**Publication Type(s):** Conference Abstract

Available at [Pharmacoepidemiology and Drug Safety](https://onlinelibrary.wiley.com/doi/abs/10.1002/ps.4610) - from Wiley Online Library Science, Technology and Medicine Collection 2017

Available at [Pharmacoepidemiology and Drug Safety](https://onlinelibrary.wiley.com/doi/10.1002/ps.4610) - from Unpaywall

**Abstract:** Background: Evidence regarding maternal and fetal safety of smoking cessation pharmacotherapies (SCP) is insufficient, yet data indicate these medicines are used during pregnancy. Objectives: To estimate the risk of adverse birth outcomes associated with the use of bupropion (not licensed for depression in Australia), varenicline and nicotine replacement therapy (NRT) transdermal patches among women who smoked cigarettes during pregnancy. Methods: Birth data routinely collected for all deliveries in the States of New South Wales and Western Australia (n = 976,285 conceived Jan 2004-April 2012) were linked to pharmaceutical dispensing, hospital separation and mortality data. Birth outcomes included preterm birth (gestation < 37 weeks), small for gestational age (SGA), admission to newborn special care units (NSCU), neonatal resuscitation, pre-labour rupture of membranes (PROM), 5-minute Apgar score <7 and perinatal mortality. Logistic regression models estimated effects of bupropion, varenicline and NRT separately with women who smoked and did not use any SCP as the comparison group. Maternal sociodemographic, pregnancy and labour characteristics, quantity smoked, diabetes and hypertension were adjusted for. Results: Compared to non-SCP group, women who used bupropion (n = 251) had similar risk of preterm birth (odds ratio: 0.63: 95%CI: 0.36-1.08), SGA (1.00: 0.71-1.41), resuscitation (1.06: 0.65-1.74), NSCU admission (1.00: 0.68-1.48), and PROM (0.59: 0.26-1.33). Varenicline users (n = 1118) had significantly lower risk of preterm birth (0.65: 0.51-0.83), SGA (0.72: 0.60-0.87) and similar risk for NSCU admission (1.02: 0.85-1.23), resuscitation (0.94: 0.74-1.19), PROM (1.07: 0.80-1.43), Apgar < 7 (0.82: 0.49-1.37) and perinatal mortality (1.55: 0.85-2.80). The use of NRT patches (n = 346) was not associated with preterm birth (1.01: 0.71-1.43), SGA (0.96: 0.71-1.29), NSCU admission (1.18: 0.87-1.58), resuscitation (1.35: 0.95-1.92), PROM (1.18: 0.72-1.94) and Apgar < 7 (0.96: 0.45-2.07). Conclusions: This study did not find elevated risk of adverse birth outcomes relating to the use of medicines for quitting among pregnant women, while there was a reduction in the risk of preterm and small infants among women who used varenicline.

**Database:** EMBASE
Firsthand and secondhand tobacco use is linked to a multitude of harmful illnesses, adverse perinatal outcomes, and death. Cessation attempts among women may be hampered by their unique biologic response to nicotine. Current research has revealed epigenetic changes from intrauterine nicotine exposure that have intergenerational consequences. Multiple studies have demonstrated the efficacy of various pharmacologic tobacco cessation interventions in conjunction with behavioral counseling. Based on this evidence, the US Preventative Services Task Force (USPSTF) 2015 guideline recommends pharmacologic therapy for all nonpregnant persons who smoke in addition to behavioral counseling. The effectiveness of pharmacologic treatments among pregnant women is less clear, with far fewer studies evaluating potential benefits and harms. While exposure to pharmacologic therapies raises concerns for fetal safety, these potential risks must be weighed against those of continued tobacco use, which guarantees fetal exposure to nicotine. First-line tobacco cessation medications include nicotine replacement therapy (NRT), bupropion, and varenicline. Second-line medications include nortriptyline and clonidine. Pharmacokinetics, effectiveness, regimens, and safety profiles for nonpregnant, pregnant, and lactating women are reviewed. Alternative tobacco cessation options and potential new pharmacologic tobacco cessation agents are discussed. Initiating brief interventions, using the 5A's and 5R's model is described.
11. Pregnancy outcomes after maternal varenicline use; analysis of surveillance data collected by the European Network of Teratology Information Services.

Author(s): Richardson, J L; Stephens, S; Yates, L M; Diav-Citrin, O; Arnon, J; Beghin, D; Kayser, A; Kennedy, D; Cupitt, D; Te Winkel, B; Peltonen, M; Kaplan, Y C; Thomas, S H L

Source: Reproductive toxicology (Elmsford, N.Y.); Jan 2017; vol. 67 ; p. 26-34

Publication Date: Jan 2017

Publication Type(s): Multicenter Study Journal Article Observational Study

PubMedID: 27851994

Abstract: Varenicline is a smoking cessation aid for which limited data exist concerning safety during human pregnancy. This multicentre prospective observational comparative cohort study was undertaken using surveillance data collected by the European Network of Teratology Information Services. The study sample consisted of 89 varenicline exposed pregnancies and two matched comparator groups; 267 non-teratogen exposed (NTE) controls and 78 exposed to nicotine replacement therapy or bupropion (NRT/B) for smoking cessation. For all exposed pregnancies, varenicline use only occurred in the first trimester, with a considerable proportion discontinuing use in the very early stages of pregnancy. The major congenital malformation rate (n=2/89, 2.25%) was in keeping with the expected background rate (2-4%), and was not significantly increased for first trimester varenicline-exposed infants in comparison with non-exposed controls (vs. NTE: OR 2.02, 95%CI 0.166 to 17.9, vs.NRT/BOR 0.874, 95%CI 0.0620 to 12.3). However, the small sample size produced very imprecise risk estimates.

Database: Medline

12. A critical review of smoking, cessation, relapse and emerging research in pregnancy and postpartum

Author(s): Meernik C.; Goldstein A.O.

Source: British Medical Bulletin; 2015; vol. 114 (no. 1); p. 135-146

Publication Date: 2015

Publication Type(s): Article

PubMedID: 25926615

Available at British Medical Bulletin - from Oxford Journals - Medicine

Available at British Medical Bulletin - from Unpaywall

Abstract: Introduction: Smoking during pregnancy causes adverse health outcomes. Though the prevalence of smoking among pregnant women has declined, postpartum relapse rates remain high and smoking-related maternal, fetal and infant morbidity and mortality remains a public health burden. Sources of data: A comprehensive literature search on smoking in pregnancy was conducted to provide a practical review for health professionals. Areas of agreement: Psychosocial support is an effective evidence-based treatment for pregnant women. Bio-psycho-socio factors that influence likelihood of quitting and remaining quit should be addressed. Areas of controversy: Electronic cigarettes are marketed as a harm reduction tool, but research on safety and effectiveness are lacking for pregnant women. Growing points: The safety and efficacy of pharmacotherapy for use among pregnant women remains unclear. Clinicians should increase discussions regarding all resources for tobacco use treatment and secondhand smoke (SHS) exposure during pregnancy and postpartum and offer psychosocial support to all pregnant women. Areas timely for developing research: Research on developing stronger tobacco control policies in low-and middle-income countries, increasing cessation and relapse prevention among pregnant smokers with mental health conditions and increasing the impact of evidence-based supports, such as the quitline, among
pregnant women can decrease consumption of tobacco in pregnancy. Copyright © The Author 2015. Published by Oxford University Press.

**Database:** EMBASE

### 13. Pharmacological interventions for promoting smoking cessation during pregnancy.

**Author(s):** Coleman, Tim; Chamberlain, Catherine; Davey, Mary-Ann; Cooper, Sue E; Leonardi-Bee, Jo

**Source:** The Cochrane database of systematic reviews; Dec 2015 (no. 12); p. CD010078

**Publication Date:** Dec 2015

**Publication Type(s):** Research Support, Non-u.s. Gov't Meta-analysis Journal Article Review Systematic Review

**PubMedID:** 26690977

Available at The Cochrane database of systematic reviews - from Cochrane Collaboration (Wiley)

Available at The Cochrane database of systematic reviews - from Unpaywall

**Abstract:**

**BACKGROUND:** Smoking in pregnancy is a public health problem. When used by non-pregnant smokers, pharmacotherapies (nicotine replacement therapy (NRT), bupropion and varenicline) are effective for smoking cessation, however, their efficacy and safety in pregnancy remains unknown. Electronic Nicotine Delivery Systems (ENDS), or e-cigarettes, are becoming widely used but their efficacy and safety when used for smoking cessation in pregnancy are also unknown.

**OBJECTIVE:** To determine the efficacy and safety of smoking cessation pharmacotherapies (including NRT, varenicline and bupropion), other medications, or ENDS when used for smoking cessation in pregnancy.

**SEARCH METHODS:** We searched the Pregnancy and Childbirth Group's Trials Register (11 July 2015), checked references of retrieved studies, and contacted authors.

**SELECTION CRITERIA:** Randomised controlled trials (RCTs) conducted in pregnant women with designs that permit the independent effects of any type of pharmacotherapy or ENDS on smoking cessation to be ascertained were eligible for inclusion. The following RCT designs are included. Placebo-RCTs: any form of NRT, other pharmacotherapy, or ENDS, with or without behavioural support/cognitive behaviour therapy (CBT), or brief advice, compared with an identical placebo and behavioural support of similar intensity. RCTs providing a comparison between i) any form of NRT, other pharmacotherapy, or ENDS added to behavioural support/CBT, or brief advice and ii) behavioural support of similar (ideally identical) intensity. Parallel- or cluster-randomised trials were eligible for inclusion. Quasi-randomised, cross-over and within-participant designs were not, due to the potential biases associated with these designs.

**DATA COLLECTION AND ANALYSIS:** Two review authors independently assessed trials for inclusion and risk of bias and also independently extracted data and cross checked individual outcomes of this process to ensure accuracy. The primary efficacy outcome was smoking cessation in later pregnancy (in all but one trial, at or around delivery); safety was assessed by 11 outcomes (principally birth outcomes) that indicated neonatal and infant well-being; and we also collated data on adherence with trial treatments.

**MAIN RESULTS:** This review includes a total of nine trials which enrolled 2210 pregnant smokers: eight trials of NRT and one trial of bupropion as adjuncts to behavioural support/CBT. The risk of bias was generally low across trials with virtually all domains of the 'Risk of bias' assessment tool being satisfied for the majority of studies. We found no trials investigating varenicline or ENDS. Compared to placebo and non-placebo controls, there was a difference in smoking rates observed in later pregnancy favouring use of NRT (risk ratio (RR) 1.41, 95% confidence interval (CI) 1.03 to 1.93, eight studies, 2199 women). However, subgroup analysis of placebo-RCTs provided a lower RR in favour of NRT (RR 1.28, 95% CI 0.99 to 1.66, five studies, 1926 women), whereas within the two non-placebo RCTs there was a strong positive effect of NRT, (RR 8.51, 95% CI 2.05 to 35.28, three studies, 273 women; P value for random-effects subgroup interaction test = 0.01). There were no differences between NRT and control groups in rates of miscarriage, stillbirth, premature birth, birthweight, low
birthweight, admissions to neonatal intensive care, caesarean section, congenital abnormalities or neonatal death. Compared to placebo group infants, at two years of age, infants born to women who had been randomised to NRT had higher rates of 'survival without developmental impairment' (one trial). Generally, adherence with trial NRT regimens was low. Non-serious side effects observed with NRT included headache, nausea and local reactions (e.g. skin irritation from patches or foul taste from gum), but these data could not be pooled.AUTHORS' CONCLUSIONS
NRT used in pregnancy for smoking cessation increases smoking cessation rates measured in late pregnancy by approximately 40%. There is evidence, suggesting that when potentially-biased, non-placebo RCTs are excluded from analyses, NRT is no more effective than placebo. There is no evidence that NRT used for smoking cessation in pregnancy has either positive or negative impacts on birth outcomes. However, evidence from the only trial to have followed up infants after birth, suggests use of NRT promotes healthy developmental outcomes in infants. Further research evidence on NRT efficacy and safety is needed, ideally from placebo-controlled RCTs which achieve higher adherence rates and which monitor infants' outcomes into childhood. Accruing data suggests that it would be ethical for future RCTs to investigate higher doses of NRT than those tested in the included studies.

Database: Medline


Author(s): Patnode, Carrie D; Henderson, Jillian T; Thompson, Jamie H; Senger, Caitlyn A; Fortmann, Stephen P; Whitlock, Evelyn P

Source: Annals of internal medicine; Oct 2015; vol. 163 (no. 8); p. 608-621

Publication Date: Oct 2015

Publication Type(s): Journal Article Review Research Support, U.s. Gov't, P.h.s.

PubMedID: 26389650

Available at Annals of internal medicine - from Unpaywall

Abstract: BACKGROUND Tobacco use is the leading cause of preventable death in the United States. PURPOSE To review the effectiveness and safety of pharmacotherapy and behavioral interventions for tobacco cessation. DATA SOURCES Databases and 8 organizational Web sites were searched through 1 August 2014 for systematic reviews, and PubMed was searched through 1 March 2015 for trials on electronic nicotine delivery systems. STUDY SELECTION Two reviewers examined 114 articles to identify English-language reviews that reported health, cessation, or adverse outcomes. DATA EXTRACTION One reviewer abstracted data from good- and fair-quality reviews, and a second checked for accuracy. DATA SYNTHESIS 54 reviews were included. Behavioral interventions increased smoking cessation at 6 months or more (physician advice had a pooled risk ratio [RR] of 1.76 [95% CI, 1.58 to 1.96]). Nicotine replacement therapy (RR, 1.60 [CI, 1.53 to 1.68]), bupropion (RR, 1.62 [CI, 1.49 to 1.76]), and varenicline (RR, 2.27 [CI, 2.02 to 2.55]) were also effective for smoking cessation. Combined behavioral and pharmacotherapy interventions increased cessation by 82% compared with minimal intervention or usual care (RR, 1.82 [CI, 1.66 to 2.00]). None of the drugs were associated with major cardiovascular adverse events. Only 2 trials addressed efficacy of electronic cigarettes for smoking cessation and found no benefit. Among pregnant women, behavioral interventions benefited cessation and perinatal health; effects of nicotine replacement therapy were not significant. LIMITATION Evidence published after each review's last search date was not included. CONCLUSION Behavioral and pharmacotherapy interventions improve rates of smoking cessation among the general adult population, alone or in combination. Data on the effectiveness and safety of electronic nicotine delivery systems are limited. PRIMARY FUNDING SOURCE Agency for Healthcare Research and Quality.

Database: Medline

Author(s): Siu, Albert L; U.S. Preventive Services Task Force

Source: Annals of internal medicine; Oct 2015; vol. 163 (no. 8); p. 622-634

Publication Date: Oct 2015

Publication Type(s): Practice Guideline Journal Article Research Support, U.s. Gov't, P.h.s.

PubMedID: 26389730

Available at Annals of internal medicine - from Patricia Bowen Library & Knowledge Service West Middlesex University Hospital NHS Trust (lib302631) Local Print Collection [location] : Patricia Bowen Library and Knowledge Service West Middlesex university Hospital.

Available at Annals of internal medicine - from Unpaywall

Abstract: DESCRIPTION Update of the 2009 U.S. Preventive Services Task Force (USPSTF) recommendation on counseling and interventions to prevent tobacco use and tobacco-related disease in adults, including pregnant women.

METHODS The USPSTF reviewed the evidence on interventions for tobacco smoking cessation that are relevant to primary care (behavioral interventions, pharmacotherapy, and complementary or alternative therapy) in adults, including pregnant women.

POPULATION This recommendation applies to adults aged 18 years or older, including pregnant women.

RECOMMENDATION The USPSTF recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration-approved pharmacotherapy for cessation to adults who use tobacco. (A recommendation). The USPSTF recommends that clinicians ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant women who use tobacco. (A recommendation). The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of pharmacotherapy interventions for tobacco cessation in pregnant women. (I statement). The USPSTF concludes that the current evidence is insufficient to recommend electronic nicotine delivery systems for tobacco cessation in adults, including pregnant women. The USPSTF recommends that clinicians direct patients who smoke tobacco to other cessation interventions with established effectiveness and safety (previously stated). (I statement).

Database: Medline

**Author(s):** Leung, Lesley W S; Davies, Gregory A

**Source:** Journal of obstetrics and gynaecology Canada : JOGC = Journal d'obstetrique et gynecologie du Canada : JOGC; Sep 2015; vol. 37 (no. 9); p. 791-797

**Publication Date:** Sep 2015

**Publication Type(s):** Journal Article Review

**PubMedID:** 26605448

**Abstract:** Although pregnancy often motivates women to quit smoking, 20% to 25% will continue to smoke. Smoking is associated with adverse obstetric and neonatal outcomes such as placental abruption, stillbirth, preterm birth and sudden infant death syndrome, and it is therefore important to motivate women to quit during pregnancy. In this review, we explore the efficacy and evidence for safety of strategies for smoking cessation in pregnancy, including behavioural and pharmacologic therapies. The PubMed, Medline, EMBASE, and Cochrane databases (1990 to 2014) were accessed to identify relevant studies, using the search terms "smoking cessation," "pregnancy," "medicine, behavioural," "nicotine replacement products," "bupropion," and "varenicline." Studies were selected based on the levels of evidence presented by the Canadian Task Force on Preventative Health Care. Based on our review of the evidence, incentives combined with behavioural therapy appear to show the greatest promise for abstaining from smoking in the pregnant population. Nicotine replacement therapy administered in the form of gum may be better than using transdermal forms to avoid high levels of nicotine in the fetal circulation. One small trial demonstrated that bupropion is an effective aid for smoking cessation and that it does not appear to be associated with an increased risk of major congenital malformations. The currently available studies of varenicline in pregnancy are insufficient to provide evidence for the safety or efficacy of its use.

**Database:** Medline

17. Maternal use of varenicline and risk of congenital malformations

**Author(s):** Olsen M.; Froslev T.; Pedersen L.; Ehrenstein V.; Sorensen H.T.; Petronis K.R.; Mo J.; Granath F.; Kieler H.

**Source:** Pharmacoepidemiology and Drug Safety; Sep 2015; vol. 24 ; p. 244

**Publication Date:** Sep 2015

**Publication Type(s):** Conference Abstract

Available at [Pharmacoepidemiology and Drug Safety](https://onlinelibrary.wiley.com/doi/issue/10.1002/pd.4965) - from Wiley Online Library Science, Technology and Medicine Collection 2017

Available at [Pharmacoepidemiology and Drug Safety](https://onlinelibrary.wiley.com/doi/issue/10.1002/pd.4965) - from Unpaywall

**Abstract:** Background: Smoking during pregnancy is associated with a variety of adverse birth outcomes. Varenicline is indicated for smoking cessation in adults. As with most prescription drugs, the human teratogenic potential of varenicline is unknown. Objectives: The aim of this study was to estimate the prevalence of congenital malformations among infants exposed and not exposed to varenicline in utero. Methods: The Danish and Swedish medical birth registries were used to identify all live-born infants born after 1 May 2007 and conceived after 1 December 2006, the date when varenicline first became available in the two countries. This interim look included infants born between 1 May 2007 and 31 December 2011. All infants were followed up for congenital malformations until their first birthday. Data on maternal varenicline use and congenital malformations in offspring were collected from nationwide registries of dispensed prescriptions and hospital admissions. We defined as varenicline-exposed those infants born to mothers with at least...
one prescription for varenicline redeemed immediately before pregnancy to date of birth. Infants not exposed to varenicline at any time during pregnancy were divided into two comparison groups, smoking-exposed and smoking-unexposed, based on maternal smoking status selfreported at the first antenatal care visit. Chromosomal abnormalities were not included in the analysis. Results: Eleven (4.3%) of the 254 varenicline-exposed infants had malformations: five affected the circulatory system (2.0%), two affected the digestive system (0.8%), two affected the urinary system (0.8%), and two affected the limbs (0.8%). Among varenicline-unexposed infants, 2753 (4.2%) of the 65 296 smoking-exposed and 27 270 (4.2%) of the 65 139 smoking-unexposed had malformations; the distribution of organ specific malformations was similar in the varenicline-exposed infants, the smoking-exposed comparison group, and the smoking-unexposed comparison group. Conclusions: Based on this interim look at the study data, the prevalence of malformations among varenicline-exposed infants did not appear to be higher than among varenicline-unexposed infants.

Database: EMBASE


Author(s): Kaplan, Yusuf Cem; Olgac Dündar, Nihal; Kasap, Burcu; Karadas, Baris

Source: Case reports in obstetrics and gynecology; 2014; vol. 2014 ; p. 263981

Publication Date: 2014

Publication Type(s): Journal Article

PubMedID: 24639907

Available at Case reports in obstetrics and gynecology - from Europe PubMed Central - Open Access

Abstract: To the best of our knowledge this is the first case report describing exposure to varenicline, an α 4 β 2 nicotinic acetylcholine partial receptor agonist used for smoking cessation therapy in pregnancy. A 29-year-old multiparous woman with an unplanned pregnancy has used varenicline 2 mg/day unintentionally yet regularly 4 weeks from her last menstrual period. Fetal ultrasound performed at each trimester, detailed anomaly scan, and fetal echocardiography which were performed at the 22nd gestational week showed normal fetal growth with no malformations. The patient delivered a healthy baby at the 38th week of gestation with normal Apgar score and physical examination findings. Age-appropriate physical and neurological development of the child has been observed for 6 months. Although it is not possible to draw definitive conclusions, this case report may contribute to the current available limited data regarding the safety of varenicline use in pregnancy.

Database: Medline
19. Is it safe to use smoking cessation therapeutics during pregnancy?

**Author(s):** De Long, Nicole E; Barra, Nicole G; Hardy, Daniel B; Holloway, Alison C  
**Source:** Expert opinion on drug safety; Dec 2014; vol. 13 (no. 12); p. 1721-1731  
**Publication Date:** Dec 2014  
**Publication Type(s):** Research Support, Non-u.s. Gov't Journal Article Review  
**PubMedID:** 25330815  
**Abstract:** INTRODUCTION Worldwide, 10 to 35% of pregnant women smoke. It is clear that smoking cessation has positive impacts for both the mother and child, yet many women are still unable to quit due to the addictive properties of nicotine. There are limited data surrounding their safety and efficacy in pregnancy. AREAS COVERED This review highlights evidence from clinical studies and animal experiments regarding the effects of smoking cessation therapeutics on pregnancy, neonatal and long-term postnatal outcomes. EXPERT OPINION There are insufficient data at this time to recommend the use of varenicline and/or bupropion for smoking cessation during pregnancy. In addition, the efficacy and safety of nicotine replacement therapy use for smoking cessation in pregnant women has not been clearly demonstrated. Until further studies are completed, there will continue to be considerable uncertainty regarding the use of these drugs in pregnancy despite the well-documented benefits of smoking cessation.  
**Database:** Medline

20. Smoking cessation in pregnancy

**Author(s):** Phelan S.  
**Source:** Obstetrics and Gynecology Clinics of North America; Jun 2014; vol. 41 (no. 2); p. 255-266  
**Publication Date:** Jun 2014  
**Publication Type(s):** Review  
**PubMedID:** 24845489  
**Abstract:** More than 400,000 deaths occur per year in the United States that are attributable to cigarette smoking; the risks to the general public are widely known. The risk to women, especially those who are pregnant, is less commonly known. During pregnancy, smoking increases the risk of low birth weight infants, placental problems (previa and/or abruption), chronic hypertensive disorders, and fetal death. It is proposed that much of this happens because of vasoconstriction with decreased uterine blood flow from nicotine, carbon monoxide toxicity, and increased cyanide production. Infants of smoking mothers have increased risks, such as sudden infant death syndrome. © 2014 Elsevier Inc.  
**Database:** EMBASE
Exposure to the smoking cessation medicine varenicline during pregnancy: a prospective nationwide cohort study.

Author(s): Harrison-Woolrych, Mira; Paterson, Helen; Tan, Ming

Source: Pharmacoepidemiology and drug safety; Oct 2013; vol. 22 (no. 10); p. 1086-1092

Publication Date: Oct 2013

Publication Type(s): Research Support, Non-u.s. Gov't Journal Article

PubMedID: 23926076

Available at Pharmacoepidemiology and drug safety - from Wiley Online Library Science, Technology and Medicine Collection 2017

Abstract: PURPOSE The purpose of this study was to investigate the extent of exposure to varenicline during pregnancy in 'real-life' post-marketing use and follow-up all pregnancy exposures to identify maternal and fetal outcomes. METHODSThis was a prospective observational cohort study conducted in New Zealand using intensive prescription event monitoring methods. A nationwide cohort of patients dispensed varenicline during a 4-year period was established from pharmacy dispensing data. Women of reproductive age were followed up with specific questionnaires to identify exposure to varenicline during pregnancy and maternal and fetal outcomes. RESULTSBetween 1 April 2007 and 31 March 2011, 23,721 patients were dispensed varenicline. Pregnancy questionnaires were sent for 6882 women of reproductive age, representing 29% all patients (54% female/unknown sex patients) in the varenicline cohort. The frequency of pregnancy exposure in women for whom a valid pregnancy questionnaire was returned was 23/2739 = 0.84%. For the 23 reports of pregnancy identified, exposure to varenicline was from the time of conception for 19 cases. Duration of exposure during pregnancy ranged from 1 day to 16 weeks. Adverse outcomes were identified in five of 17 live births: one baby had birth asphyxia and recurrent chest infections, one had gastrooesophageal reflux, one was diagnosed with ankyloglossia and two had feeding difficulties. CONCLUSIONSThis study suggests that approximately 1% of women of reproductive age prescribed varenicline may be exposed to this medicine during pregnancy. This could result in significant fetal exposure worldwide and indicates the need for a global pregnancy register for varenicline.

Database: Medline
22. **Efficacy and safety of pharmacotherapy for smoking cessation among pregnant smokers: a meta-analysis.**

**Author(s):** Myung, S-K; Ju, W; Jung, H-S; Park, C-H; Oh, S-W; Seo, Hg; Kim, Hs; Korean Meta-Analysis (KORMA) Study Group

**Source:** BJOG: an international journal of obstetrics and gynaecology; Aug 2012; vol. 119 (no. 9); p. 1029-1039

**Publication Date:** Aug 2012

**Publication Type(s):** Meta-analysis Journal Article Review

**PubMedID:** 22780818

Available at BJOG: an international journal of obstetrics and gynaecology - from Wiley Online Library Science, Technology and Medicine Collection 2017

Available at BJOG: an international journal of obstetrics and gynaecology - from Unpaywall

**Abstract:**

**BACKGROUND:** The efficacy and safety of pharmacotherapy for smoking cessation among pregnant smokers has not yet been established.

**OBJECTIVE:** To investigate the efficacy and safety of pharmacotherapy for smoking cessation among pregnant smokers.

**SEARCH STRATEGY:** A search was made of PubMed, Embase and CENTRAL in June 2011.

**SELECTION CRITERIA:** Randomised controlled trials (RCTs), quasi-RCTs and retrospective or prospective controlled studies were included.

**DATA COLLECTION AND ANALYSIS:**

The main analyses were designed to examine the efficacy of pharmacotherapy for smoking cessation among pregnant smokers based on the longest follow-up data available and from data obtained at the latest available time-point in pregnancy in each study. MAIN RESULTS: Of 74 articles identified from the databases, seven studies (five RCTs, one quasi-RCT and one prospective study) involving a total of 1386 pregnant smokers, 732 in the intervention groups and 654 in the control groups, were included in the final analyses. In a fixed-effects meta-analysis of all seven studies based on the longest follow-up data available, pharmacotherapy had a significant effect on smoking cessation (relative risk [RR] 1.80; 95% confidence interval [CI] 1.32-2.44). Subgroup meta-analysis by type of study design also showed similar findings for RCTs (RR 1.48; 95% CI 1.04-2.09) and other types of studies (RR 3.25; 95% CI 1.65-6.39). The abstinence rate at late pregnancy in the intervention ranged from 7 to 22.6% (mean abstinence rate 13.0%; 95% CI 10.9-15.2%). A few minor adverse effects and serious adverse effects were reported in several studies.

**AUTHOR'S CONCLUSION:** This study indicates that there may be clinical evidence to support the use of pharmacotherapy for smoking cessation among pregnant smokers. Further RCTs are needed.

**Database:** Medline
23. Pharmacotherapeutic Management of Nicotine Dependence in Pregnancy

**Author(s):** Clark S.M.; Nakad R.

**Source:** Obstetrics and Gynecology Clinics of North America; Jun 2011; vol. 38 (no. 2); p. 297-311

**Publication Date:** Jun 2011

**Publication Type(s):** Review

**PubMedID:** 21575802

**Abstract:** Smoking in pregnancy can cause serious adverse antenatal and postnatal morbidities, and a significant number of women continue to smoke in pregnancy despite these consequences. Early intervention in the form counseling from their physicians, pregnancy-specific self-help materials, counseling sessions with a health educator, and/or continued follow-up can result in better pregnancy outcomes and possibly long-term cessation. If a woman cannot quit despite these measures, pharmacotherapy can be considered. Currently, nicotine replacement therapy (NRT), transdermal patches, and bupropion are used in pregnancy, but data on the safety and efficacy are largely lacking. © 2011 Elsevier Inc.

**Database:** EMBASE
24. What do we know about the role of pharmacotherapy for smoking cessation before or during pregnancy?

**Author(s):** Oncken, Cheryl A; Kranzler, H R

**Source:** Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco; Nov 2009; vol. 11 (no. 11); p. 1265-1273

**Publication Date:** Nov 2009

**Publication Type(s):** Research Support, Non-u.s. Gov't Research Support, N.i.h., Extramural Journal Article Review

**PubMedID:** 19717542

Available at Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco - from Oxford Journals - Medicine

Available at Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco - from Unpaywall

**Abstract:** SIGNIFICANCEGiven the substantial health risks of smoking during pregnancy, and the potential of pharmacotherapy to enhance quit rates, a need exists to examine the utility of pharmacotherapy for smoking cessation during pregnancy. LITERATURE REVIEWWe briefly review the first-line medications that are recommended for smoking cessation in nonpregnant adults. Additionally, we review the toxicity of tobacco smoke and the potential risks of pharmacotherapy as evidenced by animal studies. We review in more detail studies conducted in pregnant women, including (a) observational studies, (b) short-term safety and longer term uncontrolled studies, and (c) randomized controlled clinical trials (both effectiveness and efficacy studies). DISCUSSIONBecause the safety and efficacy of pharmacotherapy for smoking cessation during pregnancy have not been established, no definitive recommendations can be made on the topic. Effectiveness trials have shown that nicotine replacement therapy (NRT) enhances smoking cessation during pregnancy, but efficacy trials have not shown an advantage for NRT compared with placebo treatment. Small sample size or poor medication compliance (with either the dose or the duration of treatment) may contribute to lack of efficacy in placebo-controlled NRT trials. However, these trials showed that NRT did not adversely affect birth outcomes and increased birth weight. Based on these findings and the fact that all medications have some risk, psychosocial interventions should be the first treatment option for pregnant smokers. Additional research is needed to determine fully the risks and benefits of the various pharmacotherapies for smoking cessation during pregnancy.

**Database:** Medline
25. Are nicotine replacement therapy, varenicline or bupropion options for pregnant mothers to quit smoking? Effects on the respiratory system of the offspring.

Author(s): Maritz, Gert S

Source: Therapeutic advances in respiratory disease; Aug 2009; vol. 3 (no. 4); p. 193-210

Publication Date: Aug 2009

Publication Type(s): Journal Article Review

PubMedID: 19706643

Available at Therapeutic advances in respiratory disease - from Unpaywall

Abstract: Nicotine occurs in tobacco smoke. It is a habit-forming substance and is prescribed by health professionals to assist smokers to quit smoking. It is rapidly absorbed from the lungs of smokers. It crosses the placenta and accumulates in the developing fetus. Nicotine induces formation of oxygen radicals and at the same time also reduces the antioxidant capacity of the lungs. Nicotine and the oxidants cause point mutations in the DNA molecule thereby changing the program that controls lung growth and maintenance of lung structure. The data available indicate that maternal nicotine exposure induces a persistent inhibition of glycolysis and a drastically increased AMP level. These metabolic changes are thought to contribute to the faster aging of the lungs of the offspring of mothers that are exposed to nicotine via the placenta and mother’s milk. The lungs of these animals are more susceptible to damage as shown by the gradual deterioration of the lung parenchyma. The rapid metabolic and structural aging of the lungs of the animals exposed to nicotine via the placenta and mother’s milk, and thus during phases of lung development characterized by rapid cell division, is likely due to ‘programming’ induced by nicotine. Since varenicline, a partial nicotine agonist, has basically the same structure as nicotine, and also binds to acetylcholine receptors in competition with nicotine (but with largely the same effect), it is not advisable to use nicotine or varenicline during gestation and lactation. Furthermore, the use of individual vitamin supplements is also not advisable because of the negative impact on the program that controls maintenance of lung structural and functional integrity and aging. A more appropriate smoking cessation program will also include a mixture of antioxidant nutrients such as in tomato juice.

Database: Medline
26. Smoking cessation in pregnancy.

Author(s): Rore, Craig; Brace, Vicki; Danielian, Peter; Williams, David

Source: Expert opinion on drug safety; Nov 2008; vol. 7 (no. 6); p. 727-737

Publication Date: Nov 2008

Publication Type(s): Journal Article Review

PubMedID: 18983219

Abstract: BACKGROUND Pregnant women who continue to smoke expose their developing fetus to a wide range of risks. Assisting these patients to stop smoking can be an important intervention for the health of the baby and the mother. The management of pregnant smokers can be challenging, due to the potential risks of pharmacotherapy. There are a number of options available to the clinician to aid smoking cessation in non pregnant women. These include nicotine replacement therapy (NRT), bupropion, varenicline, and a range of non-drug therapies. OBJECTIVE To provide guidance to prescribers on the best way to manage smoking cessation in the pregnant patient, reviewing the risks and efficacy of the different approaches. METHODS An extensive literature search was carried out to find original studies which examined issues surrounding the safety and efficacy of methods of smoking cessation in pregnancy. RESULTS/CONCLUSION NRT is the agent of choice for smoking cessation in pregnancy as the safety of other therapies in pregnancy have not yet been proved.

Database: Medline

27. Recommendations for the use of pharmacological smoking cessation strategies in pregnant women.

Author(s): Coleman, Tim

Source: CNS drugs; 2007; vol. 21 (no. 12); p. 983-993

Publication Date: 2007

Publication Type(s): Journal Article Review

PubMedID: 18020479

Abstract: Maternal smoking during pregnancy causes significant fetal morbidity and is a public health problem, as 36% of women in the UK and 11% of those in the US smoke during pregnancy. Behavioural support for smoking cessation, provided outside of routine antenatal care, is effective for promoting smoking cessation by pregnant women, but relatively few pregnant women access such support. Effective pharmacological aids to smoking cessation, which have been trialled in nonpregnant populations, include nicotine replacement therapy (NRT), bupropion and varenicline; however, there is very little evidence to justify the use of these drugs in pregnancy. Also, for safety reasons, it is doubtful that definitive trials investigating the effectiveness of either bupropion or varenicline for smoking cessation will be conducted in pregnant women in the foreseeable future. In the short to medium term, research information relating to the use of these drugs in pregnancy is, therefore, likely to be derived from observational studies that are more difficult to interpret than clinical trials. This article assesses the evidence for the effectiveness and safety of using NRT, bupropion and varenicline for smoking cessation during pregnancy. The principle recommendations made are that NRT may be safer than smoking in pregnancy, and pregnant women who have unsuccessfully tried to stop smoking without pharmacotherapy may consider using NRT in subsequent quit attempts after informed discussion with their doctor. There is no evidence, however, that NRT is actually effective for smoking cessation in pregnancy. With currently available evidence, bupropion and varenicline cannot be recommended in pregnancy for smoking cessation.

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