

NRT in pregnancy: the evidence

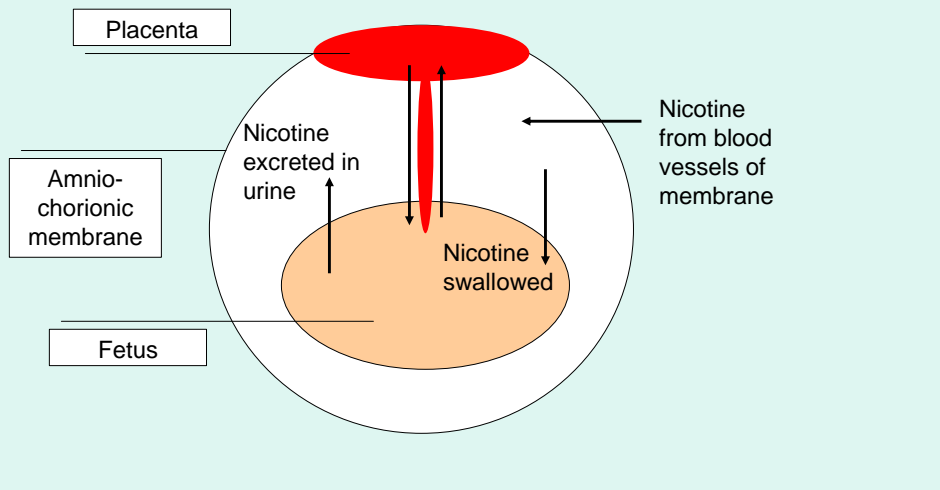
Hayden McRobbie

Tobacco Dependence Research & Treatment Centre, Barts
and The London School of Medicine, University of London

Words of wisdom

- Many pregnant smokers are highly dependent and so find it hard to quit
- NRT is not a magic cure
- Intensive behavioural support is crucial to helping pregnant smokers to stop

Nicotine and the fetus



Nicotine on trial

Accused of

- Utero-placental insufficiency

Verdict

- Evidence suggests that nicotine does not have significant effects on placental blood flow

Nicotine is bad for you brain

- Neurotransmitters act as growth factors for neural development
 - Nicotine acts on nACh receptors
 - Stimulation of these receptors at the wrong time halts nerve cell proliferation
- = REDUCED NUMBER OF NEURONS
in parts of the brain

What does this mean?

- Behavioural and learning difficulties
- May increase the risk of cot death
- Seems to be a dose-response relationship

Adverse effects of nicotine in pregnancy are probably influenced by:
DOSE, RATE, & ROUTE of delivery

What about NRT?

- Cannot be said to be without risk because it contains nicotine
- But experts agree that there is less risk than continued smoking
 - Smaller dose of nicotine
 - Slower deliver
 - Not absorbed into the arterial system

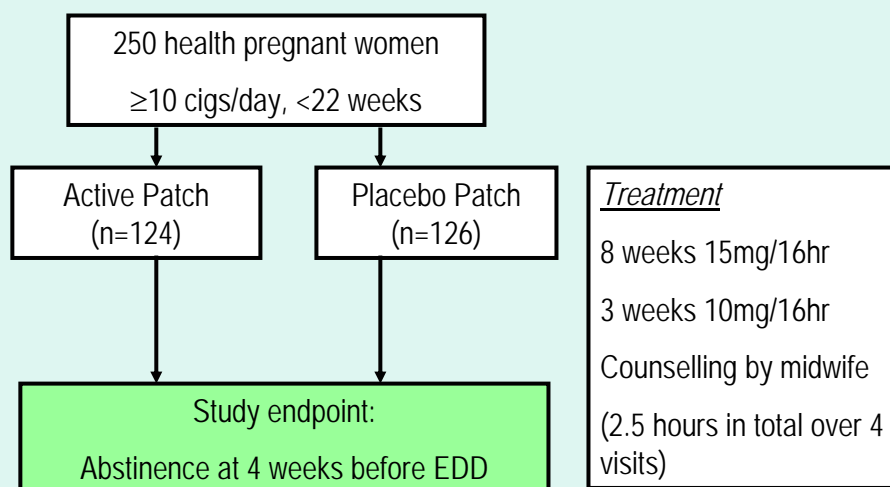
Safety Data

Study	N	NRT	AE's
Oncken (1996)	19	Gum 6 days	No
Wright (1997)	6	Patch 6 hours	No
Oncken (1997)	17	Patch 8 hours	↓Foetal HR Not clinically significant
Ogburn (1999)	21	Patch 4 days	No

Efficacy data

- Only two randomised controlled trials published so far
- More are in the 'pipeline'

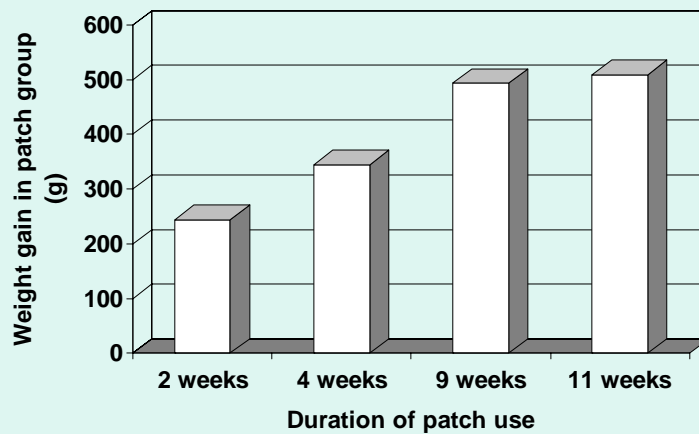
Wisborg *et al* 2000...



Wisborg et al 2000

Active Patch	Compliance	Placebo Patch
Median use: 14 (0-77) 17% used all 15mg 11% used all 10mg		Median use: 7 (0-77) 8% used all 15mg 7% used all 10mg
21%	Abstinence	19%
3457g	Birth weight	3271g
8%	% Premature	10%
120 ng/ml	Maternal cotinine	153 ng/ml

Birth weight



Why didn't it work?

Possible reasons

- Pregnant women metabolise nicotine faster
- 15mg patches were not enough
- These were probably highly dependent smokers

The dilemma



Pros & Cons

Pros

- NRT doubles the chances of success in the general population of smokers
- It is safer than smoking

Cons

- No good evidence on efficacy in pregnant smokers
- NRT is not risk free
- Product licensing is a barrier for some (fearful of litigation)

Risk vs. Benefits

- NICE Guidelines also raise this issue of risks and benefits
- 'Advised to use NRT only after careful consideration of risks and benefits and after a discussion with a healthcare professional.'

Weighing up the risks

- *'..risk of cigarette smoking during pregnancy is far greater than the risk of exposure to pure nicotine.'*
- *'...use of NRT is probably not without risk...'*
- *'On balance, the use of NRT to aid smoking cessation during pregnancy seems reasonable.'*

Benowitz & Dempsey, 2004

Recommendations

1. NRT be used in combination with support
2. Use the lowest dose of nicotine effective for achieving cessation (oral products better)
3. If cannot tolerate oral products (e.g. due to nausea) use a patch
4. If using a patch, use 16-hr only
5. Initiate treatment as early as possible
6. Creation of a national registry for NRT use

Benowitz & Dempsey. Pharmacotherapy for smoking cessation during pregnancy *Nicotine & Tobacco Research*, Volume 6, Supplement 2, April 2004

Breastfeeding

- Serum concentrations of nicotine in infants breastfeeding are low
- This is even lower in mothers using NRT compared to smoking
- ETS is more risky to the infant

Benowitz & Dempsey. Pharmacotherapy for smoking cessation during pregnancy *Nicotine & Tobacco Research*, Volume 6, Supplement 2, April 2004

Suggestions for the future

- Changes in product licensing?
- Registry of NRT use?

- Education of smokers and healthcare professionals
- Continued professional development