Abstracts

Nicotine patches don't help pregnant smokers

Nicotine patches do not work for pregnant women, and guidelines that recommend this form of treatment for pregnant women who smoke should be revisited, say researchers. In the largest trial so far, women given nicotine patches on top of the usual behavioural counselling were no more likely to quit for good (until delivery) than women given placebo patches (9.4% (49/521) v. 7.6% (40/529); odds ratio (OR) 1.26, 95% confidence interval (CI) 0.82 - 1.96).

The active patches worked better for the first month of the trial (abstinence: 21.3% (111/521) v. 11.7% (62/529); OR 2.05, 95% CI 1.46 - 2.88), but over 90% of the women in both groups stopped using their patches after that. Perhaps the active patches contained too little nicotine to make a noticeable difference to cravings. Pregnant women may need more than the usual 15 mg per 16 hours because nicotine is cleared so fast during pregnancy.

Future trials could test higher doses of nicotine replacement, but this would have to be done carefully, says a linked editorial. Nicotine is a known teratogen in animals. Very poor adherence seems to be the biggest problem, in this and other trials. Now we need to find out why pregnant women who smoke are so much more likely to give up on their treatment than their cigarettes.

Coleman T, et al. N Engl J Med 2012;366:808-818.

Meta-analysis of individual patient data in randomised trials of self-monitoring of blood glucose in people with non-insulin treated type 2 diabetes

This study assessed the effectiveness of self-monitoring blood glucose levels in people with non-insulin treated type 2 diabetes compared with clinical management without self-monitoring, and to explore the effects in specific patient groups. The meta-analysis was based on individual participant data.

The data sources were Medline, Embase, and a recent systematic review of trials on self-monitoring of blood glucose. Chief investigators of trials published since 2000 were approached for additional information and individual patient data.

Randomised controlled trials in patients with non-insulin treated type 2 diabetes comparing an intervention using self-monitoring of blood glucose with clinical management not using self-monitoring were included.

A total of 2 552 patients were randomised in the six included trials. A mean reduction in HbA_{1c} level of -2.7 mmol/mol (95% confidence interval (CI) -3.9 to -1.6; 0.25%) was observed for those using self-monitoring of blood glucose levels compared with no self-monitoring at 6 months. The mean reduction in HbA_{1c} level between groups was 2.0 mmol/mol (3.2 - 0.8; 0.25%) at three months (5 trials) and 2.5 mmol/mol (4.1 - 0.9; 0.35%) at 12 months (3 trials). These estimates were unchanged after imputing missing data, and estimates of effect in trials with higher loss to follow-up or a possibility of co-intervention compared with those with lower loss to follow-up and no co-intervention did not differ significantly (p=0.21). The difference in HbA_{1c} levels between groups was consistent across age, baseline HbA_{1c} level, sex, and duration of diabetes, although the numbers of older and younger people and those with HbA_{1c} levels >86 mmol/mol (10%) were insufficient for interpretation. No changes occurred in systolic blood pressure (-0.2 mmHg, 95% CI -1.4 - 1.0), diastolic blood pressure (-0.1 mmHg, -0.9 - 0.6), or total cholesterol level (-0.1 mol/l, 95% CI -0.2 - 0.1).

Evidence from this meta-analysis of individual patient data was not convincing for a clinically meaningful effect of clinical management of non-insulin treated type 2 diabetes by self-monitoring of blood glucose levels compared with management without self-monitoring, although the difference in HbA_{1c} level between groups was statistically significant. The difference in levels was consistent across subgroups defined by personal and clinical characteristics.

Farmer AJ, et al. BMJ 2012:344 [doi: 10.1136/bmj.e486] (published 27 February 2012).

Offer medical treatment first for adults with stable coronary artery disease

Each year, around 400 000 USA adults with stable angina have a percutaneous coronary intervention (PCI), despite increasing evidence that this procedure does not prolong survival, prevent heart attacks, or improve symptoms more than medical treatment alone. A new meta-analysis confined to trials that compared modern PCIs with modern drug protocols confirms that PCI, including stenting, does not benefit adults with stable coronary artery disease.

The authors and a linked editorial agree that the USA has a problem. While the government and funding agencies push hard for large comparative effectiveness trials, providers are busy ignoring the results, wilfully or otherwise. They must be persuaded to change direction, says the editorial. Guidelines already recommend best medical treatment first. Averting or deferring even a third of elective PCIs in stable patients would save the health economy between $6bn and $8bn a year.

The new meta-analysis pooled results from eight trials published in the past 10 years. Most adults assigned to PCI were given a bare metal stent plus recommended medical treatment. Adults assigned to drugs alone were prescribed similar treatments, which included aspirin, a statin, a β-blocker, and an angiotensin-converting enzyme inhibitor. Four-fifths of the participants were men.

Mortality during 4.3 years of follow-up was 8.9% in adults treated with PCI and 9.1% in those given recommended medical treatments alone (odds ratio (OR) 0.98, 95% confidence interval (CI) 0.84 - 1.16). Around a third of both groups had enduring angina (29% v. 33%; OR 0.80, 95% CI 0.60 - 1.05). Between 8% and 9% had a non-fatal myocardial infarction (8.9% v. 8.1%; OR 1.12, 95% CI 0.93 - 1.34). Results for unplanned revascularisations were less clear cut (21.4% v. 30.7%; OR 0.78, 95% CI 0.57 - 1.06) but do not undermine the clear message from analyses of deaths and heart attacks, say the authors. Adults with stable angina or ischaemia that appears on stress