
Design: Randomized clinical trial

Population/sample size/setting:
- 102 patients (48 women, 54 men, median age 56) scheduled for hernia repair, laparoscopic cholecystectomy, or hip/knee prosthesis in 4 university hospitals in Stockholm
- Eligibility based on smoking of >2 cigarettes daily for at least 1 year before inclusion, and age 18 to 79
- Exclusion based on alcohol or drug abuse, pregnancy, mental illness or dementia, and poor Swedish language proficiency

Main outcome measures:
- Randomized to an intervention group (n=48) or control (n=54)
- Intervention started 4 weeks before surgery, and included weekly meetings of telephone counseling with a nurse trained in smoking cessation therapy, the telephone number to a hot line providing smoking cessation advice, and free nicotine resin gum from 4 weeks preop to 4 weeks postoperatively
- No bupropion or varenicline was offered
- Control group received standard care, with little or no information about smoking cessation
- Smoking status was evaluated by both self-report and by measurements of CO in expired air
- Complications were evaluated at 2 to 3 week clinic visits by a study nurse blinded to treatment group, and by telephone interview 4 weeks postop
- Three groups of smoking cessation success were defined: smoking cessation at least 3 weeks preop, with CO<=10 parts per million (ppm), smoking cessation 1 to 2 weeks preop, with CO<=10 ppm, or those who continued to smoke or only reduced smoking
- Complications were classified as wound complications (such as superficial infection, skin necrosis, deep infection, hematoma), gastrointestinal, pulmonary or cardiovascular complications, sepsis, prosthesis problems, death, or having to redo surgery
- There were 38 hernia operations, 25 hip prostheses, 12 knee prostheses, and 27 laparoscopic cholecystectomies
- The total number of complications in the intervention group was 10 of 48 patients (21%); most were wound complications, UTI, or GI related
- The total number of complications in the control group was 22 of 54 (41%), with distribution similar to that of the intervention group
- Only 20 patients were nonsmokers for the entire study period; 9 ceased smoking for 1-2 weeks preop, and 73 continued or only reduced smoking
- In the 20 successful quitters, there were 3 complications (15%); in the 73 who only reduced or continued smoking, there were 27 complications (37%)
Authors’ conclusions

- Perioperative smoking intervention initiated as late as 4 weeks before elective surgery reduces the risk of postoperative complications
- A large proportion of patients who were assessed for eligibility (76 of 238) refused to participate; this may reduce the external validity of the study

Comments:

- Most of the complications could be identified only on a clinic visit, not by telephone; therefore, most of the complications in Table 4 must have been assessed at the 2 to 3 week visit in the postop period
- Statistical significance is seen only when all complications are combined, since the number of separate complications is small
- The per protocol analysis in table 5 complements the intention to treat analysis in table 4
- Although the p value for any complication in table 5 is reported as 0.14, this is for a categorical chi square; since these are ordered categories, the better test to use is the chi square for trend, where the p value is 0.05
- The baseline risk for postoperative complications in major surgery (under general anesthesia, for example) is higher than the risk for soft tissue surgery in the upper extremity
- Therefore, even though there is no reason to expect that the relative risks would be different for operations done for cumulative trauma, the absolute risk differences would be small, and the number needed to treat to prevent a single delay in wound healing would be very large

Assessment: Adequate for an evidence statement that smoking cessation intervention with nicotine resin gum and counseling prior to major surgery can reduce postoperative complications