Smoking cessation among diabetes patients: results of a pilot randomized controlled trial in Kerala, India

BACKGROUND

- Diabetes and tobacco use are widely prevalent in India.
- Smokers with diabetes have a higher risk of cardiovascular disease, stroke, diabetic retinopathy, and peripheral arterial disease.
- 52% of diabetes patients who smoke in Kerala, India were not advised by their physician to quit.
- Data on smoking cessation in patients with diabetes in low to middle income countries are limited.

OBJECTIVE

- To assess the effectiveness of diabetes-specific smoking cessation counseling delivered by a non-doctor health care professional, in addition to a cessation message to quit delivered by a doctor

METHODS

- **Design:** parallel-group, randomized controlled trial
- **Duration:** 6 months
- **Inclusion Criteria:** male, literate, diabetes patients 18 years and older who have smoked in the past month; native to the clinic catchment area, with a high probability that they would be treated at the clinic for the next 6 months; willingness to participate in the study
- **Exclusion Criteria:** females
- **# patients enrolled:** 224 (112 in each group)
- **Interventions used:**
    - Intervention group-1: 3-minute long diabetes-specific smoking cessation message delivered by a doctor at each clinic visit
    - Intervention group-2: 3-minute long diabetes-specific smoking cessation message delivered by a doctor at each clinic visit + 30-minute long diabetic-specific tobacco cessation counseling sessions at each clinic visit delivered by a non-doctor diabetes educator
- **Primary Outcome Measure:** seven day smoking abstinence (quit rate) measured by the question "During the past 7 days, did you smoke even a puff?"
- **Secondary Outcome Measure:** harm reduction, defined as a decrease in the average number of cigarettes/bidis smoked per day of more than 50% of baseline use
- **Power:** not reported
- **Data handling method used:** intention to treat and complete case (per protocol)

RESULTS

- 196/224 patients followed up at month 6
- **Primary Outcome Measure:** Based on the complete case analysis, the quit rate was 14.3% in Intervention group-1 and 59.2% in Intervention group-2 at 6 months. The adjusted odds ratio for quitting was 10.7 ($p < 0.001$, 95% CI: 5.1-22.7). Based on the intention to treat analysis, the quit rate was 12.5% in Intervention group-1 and 51.8% in Intervention group-2 at 6 months. The adjusted odds ratio was 8.4 ($p < 0.001$, 95% CI: 4.1-17.1).
- **Secondary Outcome Measure:** Based on the complete case analysis, the harm reduction rate was 29.8% in Intervention group-1 and 50% in Intervention group-2. The adjusted odds ratio for harm reduction was 2.6 ($p = 0.025$, 95% CI: 1.1-5.8). Based on the intention to treat analysis, the harm reduction rate was

25.5% in Intervention group-1 and 37% in Intervention group-2. The adjusted odds ratio for harm reduction was 1.9 (p = 0.101, 95% CI: 0.8 – 4.1).

- **Authors' conclusions:** Utilizing non-doctor diabetes educators to deliver diabetes-specific tobacco cessation counseling sessions is an effective method to reduce smoking and prevent life threatening diabetes complications.

STRENGTHS

- Doctors and diabetes educators were trained and examined on tobacco cessation in diabetes patients.
- Statisticians were blinded.

LIMITATIONS

- Infrequent follow-up visits and did not address whether or not patients smoked in between follow-up appointments prior to last seven days
- Self-reported outcomes, not confirmed by biochemical verification
- Counselors were not blinded when collecting follow-up data
- Females, patients < 18 years old, and illiterate smokers were excluded.
- Limited baseline information about smoking history (e.g. duration of smoking, attempts to quit, etc)
- Did not report power
- Short duration

CONCLUSIONS

- Considering the weaknesses of the study, further research is necessary.
    - The quit rate should be redefined as abstinence from smoking in the last 7 days prior to the follow-up appointment, with the addition of no relapses in between follow-up appointments.
    - Researchers should utilize biochemical verification to confirm the patient-reported results.
    - Counselors should be blinded when collecting follow-up data
    - A third group who have not received any intervention is necessary to evaluate efficacy of a doctor-delivered message to quit.
    - Follow-up with patients for longer than 6 months should be used to determine long-term efficacy
- Smokers with diabetes should be encouraged to quit to prevent diabetes-related complications. Although the results from this study are promising, they cannot prove the efficacy of the study interventions.

References:

Thankappan *et al.*: Smoking cessation among diabetes patients: results of a pilot randomized controlled trial in Kerala, India. BMC Public Health 2013, 13:47.

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