Lung Age Bio-feedback Using a Portable Lung Age Meter with Brief Advice During Routine Consultations Promote Smoking Cessation – Know2quit Multicenter Randomized Control Trial

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Abstract

Background presenting lung age data to smokers who were invited for a formal spirometry has been shown to increase quit rate at 12 months. Main Objective Here, we evaluate the effect of informing active smokers of their lung age using a portable Vitalograph during routine GP consultations on smoking cessation intentions and quit behavior. Methods Four hundred and two active smokers from 5 General Practices had their smoking behaviors and stages on Prochaska’s wheel of change (WOC) evaluated before consultation. Patients randomized to the control arm received standardized smoking cessation advice during routine consultations. Patients in the intervention arm received, in addition, lung age information derived from a portable Vitalograph. Self-reported quit rates and progression on the WOC were assessed at 4 weeks post-intervention. Results Quit rates at 4 weeks in the control and intervention arms respectively were 12.0% and 22.1% (difference 10.1%, p=0.01, 95% CI 1.5% to 18.7%; number needed to treat 10). Net positive progression on the WOC in the control and intervention arms respectively were 7.3% and 29.1% (difference 21.8%, p=0.02, 95% CI 13.2% to 30.4%; number needed to treat 4.6). Smokers with poorer lung age values were just as likely to quit as those with normal lung ages. Smokers in the intervention group were more likely to request pharmacotherapy to support quitting (p<0.0001). Conclusion When promoting smoking cessation during clinical consultations, providing ‘lung age’ biofeedback to patients using a Vitalograph is a clinically effective intervention to foster quitting and positive intentions towards quitting.

Keywords: Addiction and abuse (cigarette); General practice/family medicine; Prevention; Health education; Communication; Case control design

Introduction

Tobacco consumption is unquestionably linked with mortality; it kills up to half of those who smoke regularly [1-3]. As it is difficult to motivate people to quit smoking, new methods to foster quitting are being explored. These include small monetary payments for healthy behavior and providing bio-feedback of spirometrically-determined “lung age”, which is the age of an average healthy person with similar spirometric test results [4]. Lung age is commonly estimated from regression equations for the forced expiratory volume in one second (FEV1) in healthy non-smokers, and constitutes the age at which the FEV1 measured in an individual equals the predicted value of FEV1, taking into account age, height, sex and ethnicity [5,6]. Quit rate increased in situations where patients were invited for formal spirometry and informed of their lung age as opposed to being given the raw FEV1 value [4,7]. The prime hypothesis of this study was that providing smokers with lung age information during routine consultations using a hand-held lung age meter will foster intentions to quit and actual quit attempts at one month, over and above usual care.

Methods

Study design

This is a multicentre randomized controlled trial with an experimental intervention that consists of providing smokers with their lung age information during routine consultations, in addition to usual care. The primary outcome of interest was the proportion of patients abstinent from smoking at one month as a result of the intervention. We considered an incremental quit rate of 10% as a result of the intervention to be a clinically meaningful effect size in comparison with routine care. On the basis of a one tailed hypothesis that the intervention would not increase smoking behavior, we calculated that a sample size of 250 patients in each study arm would allow us to observe this effect size or one greater with 80% power at a significance level of 5%. The data were analyzed using SPSS version 18. The effects of the intervention on nominal and ordinal outcomes were examined using the Chi Square test. The distribution of lung-age across categories of changed smoking behavior was examined using the Kruskal-Wallis test and the Independent Samples Median Test. Intention and readiness to quit smoking was assessed using Prochaska’s and DiClemente’s transtheoretical Wheel of Change (WOC) model [8]. The relative effects of lung age, Wheel of change and Cessation Support on quit behavior were examined by Ordinal and Logistic Regression. Lung age difference refers to the difference between lung age as determined on the Vitalograph and chronological age.

Questionnaire

The study questionnaire consisted of sections examining basic demographic data, smoking behaviour including pack years (average...
number of cigarettes smoked per day multiplied by the number of years smoked divided by 20), the stage on the wheel of change for intention to quit, known co-morbidities and documentation of the type of cessation support provided during the initial consultation. Information on previous quitting (number of attempts and types of cessation support required), smoking status of partners and current employment status were used to confirm baseline comparability of groups. At one month after the initial consultation, a second questionnaire was sent to all participants. They were examined for changed smoking behavioral patterns and intentions to quit on the wheel of change (Table 1). Telephone calls were made to patients after a further 2 weeks if questionnaires were not returned to maximize response rate.

### Outcome measures

**Primary:**
- Rates of change of smoking behavior at one month, with possible categories of (i) quit for one month, (ii) quit for the previous week, (iii) stopped smoking, but relapsed, (iv) smoking the same number of cigarettes, (v) smoking more. Abstinence for one month was considered the most salient outcome; the effect size and the number needed to treat are based on this criterion.
- Stage on the wheel of change as regards intention to stop smoking, with possible categories of (i) pre-contemplation, (ii) contemplation, (iii) preparation (iv) action (Table 1).

**Secondary:**
- Effects of lung age difference and stage on the wheel of change on quit outcomes.

### Study protocols

Protocols were standardized across all investigating General Practices and included:
- Guidelines on the delivery of smoking cessation advice in a personalized fashion based on the A, B, and C guidelines of the ICGP and New Zealand guidelines [9].
- Vitalograph – Detailed instructions on the use of the COPD-6 Vitalograph.
- Pharmacotherapy – prescription guidelines for Varenicline, Bupropion and Nicotine Replacement Therapy based on the British National Formulary (BNF 63).
- Patient information leaflet – all participants received the same type of advice leaflet – just be smoke free – from the Irish Cancer Society [10].

### Randomization procedure

Allocation groups, as determined by computer-generated random numbers (even=control), were concealed in sequentially numbered opaque sealed envelopes by an independent clerk unrelated to the Practices.

### Recruitment, allocation and intervention

All patients presenting to an investigating GP on a given day regardless of the reasons for routine consultations were presented with a research pack at the desk. Non-smokers indicated their status on the front page of the pack and were excluded. From the pack, all smokers received study information and were invited to consent to participation if they did not meet the exclusion criteria (Figure 1). These included unavailability for follow-up, enrolment in another smoking cessation research study, current use of smoking cessation pharmacotherapy, use of domiciliary Oxygen, history of major lung disease (lung cancer, Tuberculosis, Sarcoidosis) and cognitive dysfunction. Typically, questionnaires were completed in the waiting rooms.

At an appropriate stage during the consultation, the doctor opened the next of serially numbered opaque sealed envelopes to reveal the allocation group for each patient. All patients received standardized personalized brief smoking cessation advice including an offer of cessation support in the form of pharmacotherapy or a follow-up review as appropriate and also the standard patient information leaflet. Participants in the intervention arm additionally had their lung age assessed using the desktop Vitalograph lung age meter. Lung age results were explained, recorded on an advice slip and given to these patients.

### The Vitalograph

The Vitalograph lung age meter is a portable desktop device, which has been validated to evaluate the actual and % predicted FEV1 to an accuracy better than ± 3% (performance standard: American Thoracic Society and European Respiratory Standards 2005) [11]. It estimates the lung age to help illustrate the impact of smoking on the subject’s lungs based on the age, height, gender and FEV1.
Settings

Two rural and 3 urban General Practises located in the South-East of Ireland. Patients were recruited to the study over a period of 6 months.

Results

Baseline characteristics

The mean age of all patients was 39.7 years with a standard deviation (SD) of 14.8 years. The intervention arm did not differ from the controls (p>0.05) with respect to all measured baseline characteristics (Table 2). Lung ages were skewed towards higher values; mean, median and standard deviation values were 17.5, 14.0 and 18.7 years respectively.

Follow-up – quit rates

Self-reported quit rates at 4 weeks in the intervention and control arms respectively were 22.1% and 12% (difference 10.1%, Chi square=14.9; df=5; p=0.01; 95% CI 1.5% to 18.7%; number needed to treat 10). By contrast, 12.1% of smokers in the intervention arm had relapsed within one month (Figure 2). Fewer smokers in the intervention group, 39.9% versus 46.7% in controls, were smoking the same number of cigarettes after 4 weeks. Within the intervention group, lung age did not differ significantly across all possible categories of quit outcomes (p=0.88), indicating that smokers with poorer lung age values were just as likely to quit as those with normal lung ages.

Progression on the wheel of change

The net positive progressions on the wheel of change in the control and intervention arms respectively were 7.3% and 29.1% (difference 21.8%; Chi=14.9; df=6; p=0.02, 95% CI 13.2% to 30.4%; number needed to treat 4.6) (Figure 3).

In the bivariate analysis, stage on the wheel of change was a strong predictor of smoking cessation, with smokers in the action stage being much more likely to quit than those in pre-contemplation, (Chi 22.1; df 10; p<0.05). However in the multivariate analysis, there was no residual effect on quitting of stage on the wheel of change, after accounting for the independent effect of providing smokers with information on their lung age (action, p=76; contemplation, p=0.08; pre-contemplation p=0.11; lung age feedback p<0.05).

Effect of lung age versus cessation support on quitting

Smokers in the intervention group were more likely than controls to request pharmacotherapy (Chi 25.0; df 6; p<0.0001). A multivariate analysis showed that lung age information and cessation support interventions had independent but significant (p<0.05 and p<0.001 respectively) effects on promoting cessation.

Discussion

Only one patient decline consent to participate in this study indicating that, this was a well-motivated study population who did not view participating in research as a burden. The relatively young mean age (39.7 years) of all participants is consistent with data from the Irish SLÁN report and indicates that smokers in this study are representative of the age cohort of the Irish population in which smoking is most prevalent [12]. The median difference between lung age and chronological age in this group of smokers was 14 years, confirming the harm to lung function caused by continued smoking. Hence, we advocate that practitioners take the opportunity at all consultations to promote smoking cessation interventions.

Our principal finding is that, in addition to brief cessation support during routine consultations, providing lung age bio-feedback to smokers along with pharmacotherapy significantly increases the proportion who quit within a month. One in 10 smokers will quit with this method. Although previous studies did show a clinically significant effect of lung age on quitting using formal spirometry, this is the first study that assessed a similar effect using the portable Vitalograph lung bio-feedback meter.

### Table 2: Baseline characteristics of groups. Figures are absolute numerical values unless stated otherwise.

| Variable                          | Control (n = 209) Mean; Median; SD | Intervention (n = 193) Mean; Median; SD | Intervention (n = 193) Mean; Median; SD |
|-----------------------------------|-----------------------------------|----------------------------------------|----------------------------------------|
| Age – mean; median; SD            | 40.8; 40.0; 14.9                  | 38.5; 37.0; 14.6                       | 0.113                                  |
| Pack years – mean; median; SD     | 19.0; 15.0; 17.0                  | 16.6; 12.0; 16.1                       | 0.139                                  |
| Males (%)                         | 80 (38.3)                         | 76 (40.4)                              | 0.661                                  |
| Actively employed                 | 95 (45.5)                         | 71 (36.8)                              | 0.78                                   |
| Socio-economic groups:            |                                   |                                        | 0.33                                   |
| • Professional                    | 8 (3.8)                           | 4 (2.1)                                |                                        |
| • Self-employed                   | 15 (7.2)                          | 13 (6.7)                               |                                        |
| • Clerical                        | 27 (13)                           | 18 (9.3)                               |                                        |
| • Skilled manual                  | 35 (17.6)                         | 24 (12.4)                              |                                        |
| • Semi-skilled                    | 9 (4.3)                           | 5 (2.6)                                |                                        |
| • Unskilled                       | 112 (53.8)                        | 127 (65.8)                             |                                        |
| Level of education                |                                   |                                        | 0.59                                   |
| • Primary                         | 39 (18.7)                         | 31 (16.1)                              |                                        |
| • Secondary                       | 124 (59.3)                        | 122 (63.2)                             |                                        |
| • Tertiary                        | 46 (22)                           | 39 (20.2)                              |                                        |
| Co-morbidities                    |                                   |                                        | 0.07                                   |
| Partner smokes                    | 97 (46.1)                         | 87 (45.1)                              | 0.79                                   |
| Preceding attempts at quitting    |                                   |                                        | 0.75                                   |
| • Never attempted                 | 35 (16.7)                         | 34 (17.6)                              |                                        |
| • Attempted once                  | 63 (30.1)                         | 59 (30.6)                              |                                        |
| • More than one attempt           | 111 (53.1)                        | 99 (51.3)                              |                                        |
| Stage on the WOC                  |                                   |                                        | 0.89                                   |
| • Pre-contemplative               | 44 (21.1)                         | 38 (19.7)                              |                                        |
| • Contemplative                   | 84 (40.2)                         | 82 (42.5)                              |                                        |
| • Preparation                     | 81 (38.8)                         | 73 (38.8)                              |                                        |

SD: Standard Deviation; WOC: Wheel of Change
The methodology of this study reduces the potential for invitation bias or the motivated-volunteer effect as our cohort represents smokers who were ‘caught in the very act’ in that they had sought the consultation for other reasons and not specifically with a view to seeking smoking cessation support. With respect to age, gender, co-morbidities, smoking history, socio-economic status and preparedness to change smoking behavior, our study cohort are representative of typical smokers a GP might encounter on a regular basis regardless of practice type and style. Consequently our study has good generalizability. Although assessing lung age does add an extra 1 to 2 minutes to the consultation time, this can translate into a cost-effective and clinically effective intervention, which can be easily incorporated into routine consultations.

Conflict of Interest

Authors disclose no conflicts of interests or affiliation with any organization, or company that might bias this work.

Funding

Funding was provided through a research grant from the Research and education Foundation of the Irish College of General Practitioners.
Acknowledgement

• GP investigators and Support Staff:
  o Dr Mark Walsh – Northgate Medical Centre, New Ross, County Wexford.
  o Dr Karl Roulston – Northgate Medical Centre, New Ross, County Wexford.
  o Dr Niamh Carew – Northgate Medical Centre, New Ross, County Wexford.
  o Dr Shane Kavanagh – Whiterock Family Practice, County Wexford.
  o Dr Jane Ojedokun – Parnell Clinic, Waterford City, Waterford.
  • Dr Martin Rouse – Research coordinator/Programme Director, South East GP Training Programme.

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