Clinical trial comparing nicotine replacement therapy (NRT) plus brief counselling, brief counselling alone, and minimal intervention on smoking cessation in hospital inpatients


SMOKING

Background: Guidelines recommend that smoking cessation interventions are offered to all smokers willing to make a quit attempt. Since the effectiveness of routine provision of behavioural counselling and nicotine replacement therapy (NRT) to smokers admitted to hospital has not been established, a randomised controlled trial of these interventions given together compared with counselling alone or minimal intervention was performed in hospital inpatients.

Methods: Medical and surgical inpatients who were current smokers at the time of admission were randomised to receive either usual care (no additional advice at admission), counselling alone (20 minute intervention with written materials), or NRT plus counselling (counselling intervention with a 6 week course of NRT). Continuous and point prevalence abstinence from smoking (validated by exhaled carbon monoxide <10 ppm) was measured at discharge and at 3 and 12 months, and self-reported reduction in cigarette consumption in smokers was assessed at 3 and 12 months.

Results: 274 inpatient smokers were enrolled. Abstinence was higher in the NRT plus counselling group (n=91) than in the counselling alone (n=91) or usual care (n=92) groups. The difference between the groups was significant for validated point prevalence abstinence at discharge (55%, 43%, 37% respectively, p=0.045) and at 12 months (17%, 6%, 8%, p=0.03). The respective differences in continuous validated abstinence at 12 months were 11%, 4%, 8% [p=0.25]. There was no significant difference between counselling alone and usual care, or in reduction in cigarette consumption between the treatment groups.

Conclusions: NRT given with brief counselling to hospital inpatients is an effective routine smoking cessation intervention.
Box 1 Eligibility criteria for patients

Inclusion criteria
• Male and female medical and surgical inpatients who were smokers whose last cigarette was within 28 days before admission.
• Able to provide written informed consent and understand English.
• 18 years of age or older.
• Expected to comply with the protocol.
• An acceptable level of consciousness.
• Expected duration of hospitalisation of at least 24 hours.
• Planning to remain at their current address for the next 12 months.
• Access to the telephone.
• Resident within a reasonable travelling distance from the hospital.

Exclusion criteria
• Pregnant (including suspected pregnancy), planned pregnancy, or breast feeding.
• Admission for psychiatric care.
• History of alcohol and/or illicit drug abuse in the last 12 months.
• Terminal illness (prognosis less than 12 months).
• Concurrent use of another investigational medication and/or treatment.
• Previous enrolment into this study.
• History of alcohol and/or illicit drug abuse in the last 12 months.
• Concurrent use of another investigational medication and/or treatment.
• Admission for psychiatric care.
• Hypersensitivity towards nicotine or menthol.
• Previous enrolment into this study.
• Acute cerebrovascular accident.

Follow up
All patients were asked whether they had smoked since enrolment, details of any adverse events were elicited, and exhaled carbon monoxide was measured immediately before discharge or at 7 days after enrolment, whichever was sooner. All patients were also invited to attend for review or interview by telephone 3 and 12 months after enrolment to ascertain whether they had smoked since their last visit, any adverse events, whether they had purchased any additional NRT, and to complete the SF-36 quality of life questionnaire. Exhaled carbon monoxide was measured in all patients who reported not smoking by home visit in those who were reviewed by telephone. Patients who did not attend their follow up appointments and/or could not be contacted after a minimum of two telephone calls were considered lost to follow up and assumed to be smoking.

Sample size and power
Our original power calculation assumed that each hospital would admit an average of four eligible smokers per day, yielding 540 patients per centre in 6 months and 1620 patients (540 patients in each treatment group) in total. Assuming that 5% of patients in usual care would not be smoking at 12 months, this sample size would have provided approximately 90% power at 5% significance to detect a doubling of the cessation rate to 10.2% at 12 months in the NRT plus counselling group. In the event the final sample size was lower than planned, mainly because the study was abandoned at two centres before completion of follow up.

Analysis of data
The primary outcome measure was continuous abstinence (defined as abstinence from any smoking from enrolment) validated by an exhaled carbon monoxide measurement of <10 parts per million (ppm) at discharge, 3 months and 12 months. Secondary outcome measures were point prevalence validated abstinence (defined as abstinence from any smoking since the previous visit) at discharge, 3 months and 12 months, reduction in cigarette consumption in those still smoking (measured as change from baseline in cigarettes per day) at 3 and 12 months, and quality of life at 3 and 12 months computed in terms of the eight dimensions of SF-36. Analysis was performed on an intention-to-treat basis using \( \chi^2 \) tests and risk ratios with 95% confidence intervals (CI) to compare abstinence at each follow up and, where significant, post hoc pairwise comparisons were performed. Absolute cigarette consumption in those who continued to smoke, measured as self-reported cigarettes per day, was compared between groups by the Kruskal-Wallis non-parametric test with post hoc pairwise comparisons using the Mann-Whitney U test.

RESULTS

Baseline characteristics and rates of follow up
A total of 1068 patients were screened at Nottingham City Hospital, of whom 274 (26%) were eligible and consented to be enrolled, 92 to usual care, 91 to counselling alone, and 91 to NRT plus counselling (fig 1). Baseline characteristics (table 1) and admission diagnoses (table 2) did not differ significantly between the treatment groups. Of those randomised to receive counselling and NRT, 57 (63%) chose a transdermal patch, 12 (13%) chose an inhalator, 10 (11%) chose gum, seven (8%) chose sublingual tablets, and one (1%) chose the nasal spray; four patients (4%) declined to use any NRT. Reviews were carried out in the total patient population at discharge in 251 (92%), at 3 months in 171 (62%), and at 12 months in 112 (41%, fig 1). Most of those lost to follow up did not attend their appointment and could not be contacted by telephone, although a small number were excluded after enrolment because they were discharged within 24 hours of admission.

Abstinence from smoking and reduction in consumption
Validated abstinence at discharge was significantly higher in the NRT plus counselling group than in the counselling alone or usual care groups (55%, 43% and 37% respectively, \( p=0.045 \), table 3) with a risk ratio (RR) for validated abstinence in those receiving NRT relative to those who were not of 1.38 (95% CI 1.06 to 1.80, \( p=0.018 \)). The difference between counselling alone and usual care was not significant. At 3 months abstinence remained highest in the NRT plus counselling group but the difference was not significant (table 3).

Inclusion of the data available at discharge and at 3 months from the 123 participants recruited at the two London centres made no appreciable difference to these findings.

At 12 months abstinence rates were highest for the NRT plus counselling group and similar or lower in the counselling alone relative to the usual care group (table 3). The continuous validated abstinence rates for NRT plus counselling relative to counselling alone or usual care were 11%, 4%, and 8%, respectively (\( p=0.25 \)), and for validated point abstinence 17%, 6% and 8% (\( p=0.03 \)). The RR for continuous validated abstinence for NRT plus counselling versus the other two groups combined was 1.83 (95% CI 0.76 to 4.12, \( p=0.15 \)), and for validated point abstinence the RR was 2.51 (95% CI 1.25 to 5.03, \( p=0.009 \)). The effect of counselling alone was not significantly different from usual care (RR for validated point abstinence 0.58, 95% CI 0.18 to 1.88, \( p=0.4 \)).
Figure 1  Flow of patients through study. NRT=nicotine replacement therapy.

<table>
<thead>
<tr>
<th>Baseline demographic characteristics and smoking history of all patients and by treatment groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1</td>
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<td>--------------------------------------------------------------------------------------------------</td>
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<tr>
<td><strong>Baseline characteristics</strong></td>
</tr>
<tr>
<td>All patients (n=274)</td>
</tr>
<tr>
<td>Usual care (n=92)</td>
</tr>
<tr>
<td>Counselling alone (n=91)</td>
</tr>
<tr>
<td>NRT + counselling (n=91)</td>
</tr>
<tr>
<td>Sex (% male)                                      163 (59.5)                                      54 (58.7)                                      51 (56.0)                                      58 (63.7)</td>
</tr>
<tr>
<td>Mean (SD) age                                    49.4 (15.7)                                    51.0 (15.8)                                    47.8 (15.3)                                    49.3 (15.9)</td>
</tr>
<tr>
<td>Ethnicity                                         White                                            260 (95.9)                                     90 (98.9)                                      85 (95.5)                                     85 (93.4)</td>
</tr>
<tr>
<td>Black                                            10 (3.7)                                       1 (1.1)                                        4 (4.5)                                        5 (5.5)</td>
</tr>
<tr>
<td>Other                                             1 (0.4)                                        0                                              0                                              1 (1.1)</td>
</tr>
<tr>
<td>Smoking history                                  Median (range) cigarettes/day                     17 (1–80)                                      15 (1–60)                                      20 (3–40)                                      20 (3–80)</td>
</tr>
<tr>
<td>Mean (SD) years smoked                           33.5 (16.2)                                    35.4 (16.0)                                    32.1 (15.8)                                    33.1 (16.6)</td>
</tr>
<tr>
<td>Median (IQR) FTND                                5 (3–6)                                        5 (3–6)                                        4 (2–6)                                        5 (3–6)</td>
</tr>
<tr>
<td>Mean (SD) Glover-Nilsson                         40.3 (10.3)                                    41.6 (10.5)                                    39.3 (9.5)                                     40.0 (10.7)</td>
</tr>
<tr>
<td>Any previous serious attempt to stop smoking, n (%) 222 (81.0)                              73 (79.4)                                      73 (80.2)                                      76 (83.5)</td>
</tr>
<tr>
<td>NRT=nicotine replacement therapy; FTND=Fagerström test of nicotine dependence.</td>
</tr>
</tbody>
</table>

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Reduction in cigarette consumption at 3 months was greater in the NRT plus counselling group than in the counselling alone or usual care groups but not significantly so (mean (SD) reduction 8.3 (9.0), 6.3 (9.3) and 3.3 (9.9) cigarettes per day, respectively). There was no significant difference between the three treatment groups at 12 months (p=0.56).

Quality of life
Both dimensions of quality of life were similar across the three treatment groups at baseline and at 3 months. The dimension measuring role limitation due to physical problems alone differed between treatment groups at 12 months (p=0.05) with values on this score being better for those in the NRT plus counselling group than in the other two treatment groups.

Adverse events
There were 89 adverse events in a total of 65 patients, 33 of which were serious (three deaths and 30 other events, primarily due to complications of the admitting illness); there was no significant difference between the three treatment groups at 12 months (p=0.05).

Table 2 Main admission diagnosis classified by system in the treatment groups

<table>
<thead>
<tr>
<th>Main admission diagnosis</th>
<th>Usual care</th>
<th>Counselling</th>
<th>NRT + counselling</th>
<th>Total, N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td>21</td>
<td>20</td>
<td>20</td>
<td>61 (22.3)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>23</td>
<td>19</td>
<td>16</td>
<td>58 (21.2)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>16</td>
<td>17</td>
<td>16</td>
<td>49 (17.9)</td>
</tr>
<tr>
<td>Renal and urinary</td>
<td>7</td>
<td>9</td>
<td>9</td>
<td>25 (9.1)</td>
</tr>
<tr>
<td>Musculoskeletal, connective tissue and bone</td>
<td>2</td>
<td>7</td>
<td>6</td>
<td>15 (5.5)</td>
</tr>
<tr>
<td>General</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>14 (5.1)</td>
</tr>
<tr>
<td>Reproductive and breast</td>
<td>3</td>
<td>1</td>
<td>6</td>
<td>10 (3.6)</td>
</tr>
<tr>
<td>Vascular</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>8 (2.9)</td>
</tr>
<tr>
<td>Neurological</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>7 (2.6)</td>
</tr>
<tr>
<td>Injury</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>4 (1.5)</td>
</tr>
<tr>
<td>Other systems</td>
<td>7</td>
<td>9</td>
<td>6</td>
<td>22 (8.0)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Total</td>
<td>92</td>
<td>91</td>
<td>91</td>
<td>274 (100)</td>
</tr>
</tbody>
</table>

NRT=nicotine replacement therapy.

Table 3 Number (%) abstinent before discharge and at 3 and 12 months follow up

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Self-reported point prevalence abstinence</th>
<th>Validated point prevalence abstinence</th>
<th>Validated continuous abstinence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Usual care</td>
<td>Counselling</td>
<td>NRT + counselling</td>
</tr>
<tr>
<td>Discharge</td>
<td>39 (42.4)</td>
<td>43 (47.3)</td>
<td>55 (60.4)**</td>
</tr>
<tr>
<td>3 months</td>
<td>12 (13.0)</td>
<td>15 (16.5)</td>
<td>18 (19.8)</td>
</tr>
<tr>
<td>12 months</td>
<td>9 (9.8)</td>
<td>8 (8.8)</td>
<td>17 (18.7)</td>
</tr>
</tbody>
</table>

NRT=nicotine replacement therapy.
*p=0.04 ($\chi^2$ test); †p=0.03 ($\chi^2$ test).

DISCUSSION
This study shows that a smoking cessation package providing NRT with brief counselling significantly increases point prevalence abstinence at 1 year in hospital inpatients. The study also shows an increase of approximately twofold in continuous abstinence at 1 year that is consistent with the magnitude of the reported effect of NRT in outpatient and primary care populations, but was not statistically significant in the present study. The effect of counselling alone was not significantly different from usual care.

Although 26% of patients screened were subsequently randomised, there was a wider range of admission diagnoses than in previous studies of NRT in hospital inpatients, and patients’ cigarette consumption was typical of the national UK population, suggesting that our findings may be more generalisable to the UK population of inpatient smokers than previous work.

As part of a pragmatic approach, those patients randomised to the NRT plus counselling group were given a free choice of a range of nicotine products. While there is no evidence to suggest that any product is significantly better than another, patients overwhelmingly chose to use the transdermal patch which is the most widely purchased form of NRT in the UK (F Nilsson, personal communication, 2002). A previous study of smokers’ preferences for NRT products has shown a similar pattern. A small proportion (4%) of those randomised to counselling and NRT chose to refuse it, which may have distorted the true effect of NRT. Only a minority of patients obtained additional NRT after discharge, and the numbers did not vary significantly between treatment groups (data not shown). This study was placebo controlled because we aimed to conduct a pragmatic study of the effectiveness of the routine delivery of a package of NRT and brief counselling, rather than to test the efficacy of NRT.

Our finding that counselling alone had no effect on smoking cessation in these patients conflicts with current evidence on the efficacy of similar interventions in clinical contexts outside hospital. This finding may be due to low study power, but it is possible that the lack of effect was due to the relatively brief nature of the counselling given, or to the fact that no follow up support was offered since counselling involving greater contact is associated with greater cessation rates. However, an alternative inference, which is supported by evidence from a systematic review of other hospital based trials that smoking cessation counselling without subsequent follow up is ineffective, is that brief counselling simply does not work in hospital inpatients. Further studies are necessary to determine whether more sustained behavioural support is more effective in this context.

This is the first randomised controlled trial to show the effectiveness of NRT measured as point prevalence abstinence at 12 months in smokers admitted to hospital. In contrast with
other studies of inpatient therapy in restricted disease subgroups, \cite{10,11,12,13,14,15} this study has addressed the effectiveness of routine service provision to patients admitted to hospital regardless of diagnosis, and suggests that NRT given in association with brief counselling is effective, although further larger studies are needed to confirm whether there was a real effect on continuous abstinence. Subgroup analysis of our results revealed a similar effect of NRT with brief counselling in patients with and without smoking related diseases (data not shown). Our findings are in contrast to a recent paper in which Hand and colleagues showed that a 3 week course of NRT given in conjunction with intensive counselling (four sessions lasting up to 2.5 hours in total) did not significantly increase cessation rates over counselling alone in hospital patients with smoking related disease who were willing to see a counsellor. \cite{16} Possible reasons for the failure of NRT in this study include the restriction to patients with smoking related diseases, a group which may be less successful at stopping smoking than other hospital patients. \cite{17,18} that NRT may not be effective in hospital patients, and that the course of NRT given may have been too short, although the 1 year cessation rate in the counselling group was 14% compared with 7% in our study, suggesting that greater counselling input was more effective. Our findings, taken in conjunction with those of Hand et al, suggest that either NRT or intensive counselling are similarly effective in hospital patients, but that NRT plus brief counselling is a more practically applicable approach. We conclude that, in the absence of contraindications, NRT should be given with brief counselling as a routine therapy to all smokers admitted to hospital who indicate that they are prepared to try to stop smoking.

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