A randomised controlled trial of the effects of screening for ulcer-type dyspepsia

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SUMMARY One hundred and ninety-nine male London office workers with dyspeptic symptoms elicited by a self-administered questionnaire were randomly allocated to intervention and control groups to assess the potential benefits of screening. The members of the intervention group were interviewed and examined, and those men who were considered to have a possible or probable peptic ulcer received a barium meal examination (53%). At the clinical interview the intervention group were advised against both smoking and drinking alcohol. Eighteen months later both groups were recalled for interview and examination and their sickness absence in the intervening period was assessed. The intervention group did not alter their cigarette consumption but did reduce their alcohol intake by an average of 10%. The control group increased their alcohol intake by 20%. Both groups tended to improve symptomatically, and there were no differences in symptoms between the groups at the end of the study. Sickness absence was not affected by the intervention. It is concluded that screening for ulcer-type dyspepsia is not justifiable in male London office workers.

The symptoms arising from a peptic ulcer may be relieved by pharmacological treatment, operative treatment, or simply changes in life style such as stopping smoking, drinking less alcohol, and taking regular meals. It is therefore possible that screening for patients with a peptic ulcer will detect subjects who will benefit from the diagnosis and treatment of their condition.

London civil servants were sent a health questionnaire to detect those with cardiorespiratory and other diseases, and the questionnaire detected 199 men with ulcer-type dyspepsia. The men were randomly divided into two groups: the intervention group was recalled and given medical advice and the control group was not contacted. After 18 months both groups were recalled and their general well-being, sickness absence, and symptoms compared.

Subjects and methods

The 199 men in the intervention trial were civil servants, aged 35–54, working in London for the Ministry of Defence, to whom a questionnaire had been sent by post. They were identified if they said “yes” to the question, “Do you suffer from stomach pain or discomfort?” and either “yes” to the question, “Is this pain relieved by antacid medicines?” or if they marked a diagram showing that the pain occurred in the epigastrium. These questions, of 11 eliciting dyspeptic symptoms, had been found in previous surveys to give optimum false-positive and false-negative rates. The characteristics of the intervention and control groups are given in table 1. There were no significant differences between the groups at entry to the trial.

Ninety of the 95 men (95%) in the intervention group were interviewed by a doctor at the medical centre of the Civil Service Medical Advisory Service, and 82 (86%) were seen again after 18 months. Of the 104 men randomly allocated to the control group, 91 responded after 18 months (88%).

Intervention consisted of:

1 Medical screening

The subjects had blood pressure, height, and weight measured. A resting electrocardiogram was recorded, forced expiratory volume in one second measured, and full blood count and biochemical screening performed.
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Table 1 Characteristics of intervention and control group at randomisation and average changes in smoking habits and beverage intake 18 months after entry to the study

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n = 95)</th>
<th>Control group (n = 104)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age (years)</td>
<td>46.9</td>
<td>47.6</td>
</tr>
<tr>
<td>% Smoking cigarettes initially</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>% Cigarette smokers stopping</td>
<td>9</td>
<td>16</td>
</tr>
<tr>
<td>% Starting</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Initial tea consumption (cups/day)</td>
<td>4.8</td>
<td>4.9</td>
</tr>
<tr>
<td>Change in consumption</td>
<td>-0.3</td>
<td>+0.1</td>
</tr>
<tr>
<td>Initial coffee consumption (cups/day)</td>
<td>2.1</td>
<td>2.0</td>
</tr>
<tr>
<td>Change in consumption</td>
<td>-0.1</td>
<td>+0.1</td>
</tr>
<tr>
<td>Initial spirits (glasses/week)</td>
<td>1.6</td>
<td>1.3</td>
</tr>
<tr>
<td>Change in consumption</td>
<td>+0.8</td>
<td>+1.5</td>
</tr>
<tr>
<td>Initial wine, sherry etc (glasses/week)</td>
<td>2.0</td>
<td>1.9</td>
</tr>
<tr>
<td>Change in consumption</td>
<td>-0.2</td>
<td>+0.3</td>
</tr>
<tr>
<td>Initial beer (half pints/week)</td>
<td>6.2</td>
<td>5.5</td>
</tr>
<tr>
<td>Change in consumption</td>
<td>-1.6</td>
<td>-0.1</td>
</tr>
</tbody>
</table>

2 INTERVIEW BY THE PHYSICIAN

Individuals were interviewed, examined, and given the following advice:

2.1 To stop smoking where appropriate.
2.2 To abstain from alcohol.
2.3 To take meals often and regularly.

The patients were also classified on clinical grounds into “no peptic ulcer,” “possible peptic ulcer,” and “probable peptic ulcer” groups. Individuals with a possible or probable ulcer were advised:

2.4 To attend the radiology department of Hammersmith Hospital (head of department, Professor R Steiner) for a barium meal examination.
2.5 That their general practitioners would receive a report of the radiological examination and that the subject should visit them in four weeks time.

3 CONTACT WITH THE GENERAL PRACTITIONERS

When a barium meal was requested

3.1 Letters were sent before the radiological examination informing them of the proposed appointment and asking them if they had any objections.
3.2 Copies of the final radiological report were forwarded.

When a barium meal was not requested

A report was sent concerning the results of screening.

4 AFTER 18 MONTHS

Intervention steps 1, and 2.1 to 2.3 were repeated. With the control subjects, no action was taken for 18 months when intervention steps, 1 and 2.1 to 2.3 were arranged.

Results

Table 1 gives the characteristics of the intervention and control groups at randomisation and the changes in cigarette and beverage consumption observed over the 18-month trial period. Intervention did not affect the consumption of cigarettes, tea, or coffee. The consumption of spirits, however, increased by an average of 0.8 glasses a week in the intervention group and wine consumption decreased by 0.2 glasses and beer consumption by 1.6 glasses (0.8 pints a week). The corresponding changes in the control group were an increase of 1.5 glasses (spirits) and 0.3 glasses (wine) and a decrease of 0.1 glasses (beer). The change in total alcohol consumption averaged a decrease of one glass a week in the intervention group, and this was significantly different from the average increase of 1.7 glasses in the control group (p<0.05).

At randomisation 48 (53%) of the intervention group were considered to have a possible or probable peptic ulcer on examination and were advised to have a barium meal. Twenty-five had radiological evidence of either peptic ulcer or related condition. Ten were judged to have a hiatus hernia, two oesophageal reflux, eight duodenal scarring, three an active duodenal ulcer, one an active gastric ulcer, and one a gastric ulcer scar.

Table 2 Diagnostic state at the end of 18 months, treatment received, and sickness absence of the intervention and control groups during the 18 months’ follow-up

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum number with available information</td>
<td>82</td>
<td>91</td>
</tr>
<tr>
<td>Clinical impression after 18 months</td>
<td>79.5</td>
<td>77.4</td>
</tr>
<tr>
<td>No peptic ulcer (%)</td>
<td>16.7</td>
<td>17.9</td>
</tr>
<tr>
<td>Possible peptic ulcer (%)</td>
<td>3.8</td>
<td>4.8</td>
</tr>
<tr>
<td>Probable peptic ulcer (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment given over 18 months</td>
<td>38.8</td>
<td>37.5</td>
</tr>
<tr>
<td>Antacids (%)</td>
<td>7.5</td>
<td>2.3</td>
</tr>
<tr>
<td>Cimetidine (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other medical treatment (%)</td>
<td>5.0</td>
<td>2.3</td>
</tr>
<tr>
<td>Surgery (%)</td>
<td>3.8</td>
<td>2.3</td>
</tr>
<tr>
<td>Off sick in 18 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>With gastric complaint (%)</td>
<td>5.9</td>
<td>4.4</td>
</tr>
<tr>
<td>With other complaint (%)</td>
<td>72.9</td>
<td>73.3</td>
</tr>
<tr>
<td>No of days off sick</td>
<td></td>
<td></td>
</tr>
<tr>
<td>With gastric complaint (%)</td>
<td>94.1</td>
<td>95.6</td>
</tr>
<tr>
<td>1–10 days (%)</td>
<td>5.9</td>
<td>2.2</td>
</tr>
<tr>
<td>&gt;10 days (%)</td>
<td>0.0</td>
<td>2.2</td>
</tr>
<tr>
<td>With other complaint (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 (%)</td>
<td>27.4</td>
<td>26.7</td>
</tr>
<tr>
<td>1–10 days (%)</td>
<td>44.1</td>
<td>51.1</td>
</tr>
<tr>
<td>&gt;10 days (%)</td>
<td>28.6</td>
<td>22.2</td>
</tr>
</tbody>
</table>
have a possible or probable peptic ulcer and 23% in
the control group. The treatment given to the two
groups did not differ greatly. Over a third in both
groups had received antacids; six of the intervention
group took cimetidine and three surgical treatment,
against two in the control group who took cimetidine
and two who received surgical treatment.

Table 2 also gives the proportions “off sick” in the
two groups over the 18-month period together with
the percentage having no days, 1–10 days, and more
than 10 days off sick. Again there were no significant
differences between the two groups.

All patients reported stomach pain at the time of
randomisation either relieved by antacids or
occurring in the epigastrium. After 18 months 34% of
the intervention and 27% of the control group no
longer complained of stomach pain (table 3). Twelve
patients in the intervention group reported vomiting
at randomisation; four no longer complained at
reassessment 18 months later. Eight patients in the
control group reported this symptom initially and one
further patient developed it during the 18 months.
(No significant differences between the groups.)

Discussion

A self-administered questionnaire was used to detect
patients with ulcer-type dyspepsia, and an estimated
minimum of 28% had radiological abnormalities of
the oesophagus, stomach, or duodenum. By means of
a randomised controlled trial we investigated the
possible benefits of such a screening exercise. We
tried to determine whether individuals detected by a
screening programme will act on therapeutic advice
and if they do so whether they will be symptomatically improved. The therapeutic advice
was directed against smoking and alcohol and was
combined with a physical examination and a routine
medical assessment including blood tests and
electrocardiogram. In addition, if the subjects were
considered to have a possible or probable peptic ulcer
at clinical interview and examination they were
advised to have a barium meal. It must be emphasised
that only 48 of 95 had a radiological investigation as it
was not considered justifiable to conduct a
radiological examination when an abnormality was
considered unlikely at clinical interview. Some of the
remaining 47 subjects may also have had an
abnormality on radiological examination.

Nearly half of those who had a barium meal had no
radiological abnormality. Nevertheless, “x-ray
negative” dyspepsia has been shown to be a common
precursor of demonstrable peptic ulceration, and a
screening programme should also detect these
subjects. Again, no widely accepted method of
classification of subjects as “ulcer” or “no ulcer,”
exists, and many would prefer a diagnosis of
“Moynihan's disease” on the basis of the
characteristic pain pattern. Proof that
dyspepsia-positive subjects have a normal stomach
requires both endoscopy and a barium meal, and
some abnormalities—for example, a duodenal scar
on the barium meal—may no longer have been
associated with the subjects’ symptoms.

The trial was concerned with the effect of a
package of procedures on symptoms, a pragmatic
approach in the sense that we are concerned with the
effect of giving therapeutic advice and not whether a
particular behaviour change could be beneficial. We
cannot conclude that stopping smoking would not be
beneficial, only that advice to stop smoking had no
impact either on the habit or the symptoms.

One consequence of the pragmatic approach is that
if the patients do not act on advice then the trial may
have to be repeated to test alternative intervention
strategies. The intervention group, however, reduced
their consumption of alcohol by an average of 10%
whereas the control group increased theirs by 20%.
The effect of intervention on alcohol consumption
was statistically significant, but the numbers no
longer reporting stomach pain after 18 months were
similar in the two groups. Intervention was therefore
capable of altering behaviour to some extent but did
not dramatically influence outcome. Possibly more
effective strategies to alter behaviour would have
succeeded in reducing symptoms and it is true that
the trial was not sensitive enough to show only a small
improvement.

Screening and intervention can have adverse
effects, and the discovery of hypertension may be
followed by an increase in sickness absence (an effect
of “labelling”). Sickness absence did not increase
significantly in the intervention group despite their
tendency to receive more medical treatment (table
2). Screening did not appear to be harmful and may
be expected to benefit a small proportion of patients.
In view of the costs, however, (self-administered
questionnaires, physician interviews, and
radiological examination) we cannot recommend

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Table 3 Percentage net loss of gastrointestinal symptoms after 18 months. Percentage net loss = % losing symptom
- % gaining symptom (100% = total number in group)

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stomach pain</td>
<td>33-7</td>
<td>27-0</td>
</tr>
<tr>
<td>Stomach pain relieved by antacids</td>
<td>32-6</td>
<td>31-7</td>
</tr>
<tr>
<td>Stomach pain occurring in epigastrium</td>
<td>18-9</td>
<td>21-2</td>
</tr>
<tr>
<td>Stomach pain relieved by food</td>
<td>15-8</td>
<td>13-5</td>
</tr>
<tr>
<td>Stomach pain made worse by aspirin</td>
<td>10-5</td>
<td>7-7</td>
</tr>
<tr>
<td>Vomiting</td>
<td>4-9</td>
<td>- 1-1</td>
</tr>
<tr>
<td></td>
<td>(gain)</td>
<td></td>
</tr>
</tbody>
</table>
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screening for ulcer-type dyspepsia in the type of population studied. We do not claim that screening and intervention will not prevent a rare event such as perforation or haematemeses. Proof of such a rare benefit must come from a very large study and the costs of such intervention would be very high.

We are indebted to the clerical and nursing staff of the Civil Service Department Medical Advisory Service; to Miss P Clifton and Mrs L Daly for data handling, and to Professor R Steiner and the Department of Radiology, Hammersmith Hospital, for the barium meal examinations.

References

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