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DOI: 10.1136/bmj.327.7417.712

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Association between falls in elderly women and chronic diseases and drug use: cross sectional study
Debbie A Lawlor, Rita Patel, Shah Ebrahim

Abstract

**Objective** To assess the associations between having had a fall and chronic diseases and drug use in elderly women.

**Design** Cross sectional survey, using data from the British women's heart and health study.

**Setting** General practices in 23 towns in Great Britain.

**Participants** 4050 women aged 60-79 years.

**Main outcome measure** Whether women had had falls in the previous 12 months.

**Results** The prevalence of falling increased with increasing numbers of simultaneously occurring chronic diseases. However, no such relation with falling was found in the fully adjusted data for the number of drugs used. Circulatory disease, chronic obstructive pulmonary disease, depression, and arthritis were all associated with an increased odds of falling. The fully adjusted, population attributable risk of falling associated with having at least one chronic disease was 32.2% (95% confidence interval 19.6% to 42.8%). Only two classes of drugs (hypnotics and anxiolytics, and antidepressants) were independently associated with an increased odds of falling. Each class was associated with an increase of about 50% in the odds of falling, and each had a population attributable risk of < 5%.

**Conclusion** Chronic diseases and multiple pathology are more important predictors of falling than polypharmacy.

Methods

**Participants** The women were participants in the British women's heart and health study. Full details of the selection of participants and measurements taken have been reported in previous studies.

**Assessment of falls** In the self completed questionnaire participants were asked whether they had had a fall in the previous 12 months, how many times they had fallen, and whether they had received medical attention for any falls. No specific definition of a fall was given in these questions. As in other studies, we defined frequent falling as at least two falls in the previous 12 months.1

**Assessment of chronic diseases** We collated details of clinical diagnoses of each of the women's chronic diseases, together with the dates of first diagnosis, from a combination of review of primary care medical records, interviews by a research nurse, and the participants' responses to the questionnaire. Coronary heart disease was defined as any previous diagnosis of myocardial infarction or angina. Circulatory disease was defined as any diagnosis of myocardial infarction, angina, stroke, transient ischaemic attack, aortic artery disease, or peripheral artery disease. Chronic obstructive pulmonary disease included asthma and chronic bronchitis, and eye disease included cataracts and glaucoma.
Assessment of current drug use

Participants were asked to bring all their current medicines to the clinic visit, and at the research nurse’s interview a full drug history was taken. Drugs were coded according to the British National Formulary: hypnotics and anxiolytics (drugs in section 4.1); antidepressants (4.3); any central nervous system drugs (4.1 to 4.11); analgesics (4.7 and 10.1.1); cardiovascular system drugs (2.1 to 2.12); endocrine system drugs (6.1 to 6.7); and respiratory system drugs (3.1 to 3.3). In analysing the data on analgesic drugs we did a sensitivity analysis in which non-steroidal anti-inflammatory drugs were not included in the definition (only drugs in section 4.7 were included). The results of this sensitivity analysis did not differ significantly from the results presented here.

Other measurements

We measured blood pressure with a Dinamap 1846SX vital signs monitor (GE Clinical Services, Northampton). We took two measurements in succession, with a 1 minute interval, on the right arm, with the participant seated and the arm supported on a cushion at chest level. Participants were then asked to stand, with their arms relaxed and at their sides, and two standing measurements were taken. The mean of the two measurements was used in all analyses. Postural hypotension (or consumption on most days) of any alcohol; and heavy drinking, defined as ≥14 units of alcohol a week. Social class was derived, in the case of married women, from the longest held occupation of the husband or, in single women, from her own longest held occupation. Social class was defined according to the registrar general’s classification.

Statistical analysis

We used multiple logistic regression to assess associations with falls. Of the 4286 women who participated 425 could not be assigned an adult social class. These women were likely to have been married to unemployed men, and as their risk factor profiles were similar to those of women in social class V they were allocated to this group, as in previous analyses. Sensitivity analyses in which these women were excluded showed no significant difference in the findings. There were a few missing data for each of the other variables, and the multivariable analyses were conducted on the 3742 women (92%) with complete data on all the variables that were included in the final fully adjusted models.

<table>
<thead>
<tr>
<th>Table 1 Characteristics of women who had had no fall or at least one fall in the previous 12 months. Values are percentage of women (95% confidence interval), adjusted for age, except where otherwise indicated</th>
</tr>
</thead>
<tbody>
<tr>
<td>No falls (n=3864) At least one fall (n=686) P value</td>
</tr>
<tr>
<td>Mean age (years) 68.6 (66.4 to 68.9) 70.1 (69.7 to 70.5) &lt;0.001</td>
</tr>
<tr>
<td>Chronic diseases</td>
</tr>
<tr>
<td>Coronary heart disease 14.0 (12.9 to 15.2) 23.3 (20.3 to 26.6) &lt;0.001</td>
</tr>
<tr>
<td>Any circulatory disease 16.8 (15.5 to 18.1) 26.7 (23.5 to 30.1) &lt;0.001</td>
</tr>
<tr>
<td>Diabetes 4.9 (4.3 to 5.7) 6.9 (5.2 to 9.0) 0.04</td>
</tr>
<tr>
<td>Thyroid disease 11.4 (10.3 to 12.5) 14.2 (11.8 to 17.3) 0.04</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease 22.6 (21.2 to 24.0) 30.8 (27.4 to 34.3) &lt;0.001</td>
</tr>
<tr>
<td>Depression 15.8 (14.5 to 17.1) 27.0 (23.6 to 30.6) &lt;0.001</td>
</tr>
<tr>
<td>Eye disease 13.9 (12.8 to 15.1) 19.9 (17.0 to 23.0) &lt;0.001</td>
</tr>
<tr>
<td>Arthritis 41.7 (40.0 to 43.3) 56.2 (54.5 to 58.9) &lt;0.001</td>
</tr>
<tr>
<td>Pastoral hypotension† 17.1 (15.8 to 18.5) 17.6 (14.8 to 20.9) 0.75</td>
</tr>
<tr>
<td>Low standing blood pressure† 7.6 (6.7 to 8.6) 7.3 (5.5 to 9.7) 0.81</td>
</tr>
<tr>
<td>Drugs taken</td>
</tr>
<tr>
<td>Hypnotics and anxiolytics 4.3 (3.7 to 5.1) 8.6 (6.7 to 10.9) &lt;0.001</td>
</tr>
<tr>
<td>Antidepressants 9.0 (8.1 to 10.0) 17.1 (14.4 to 20.1) &lt;0.001</td>
</tr>
<tr>
<td>Any central nervous system drug 23.5 (22.1 to 25.0) 36.9 (33.3 to 40.6) &lt;0.001</td>
</tr>
<tr>
<td>Any analgesic 12.6 (11.6 to 13.8) 18.1 (15.4 to 21.1) &lt;0.001</td>
</tr>
<tr>
<td>Any cardiovascular disease drug 40.9 (39.3 to 42.6) 50.4 (46.7 to 54.2) &lt;0.001</td>
</tr>
<tr>
<td>Any endocrine system drug 19.9 (18.5 to 21.2) 21.4 (18.5 to 24.7) 0.25</td>
</tr>
<tr>
<td>Any respiratory system drug 10.2 (9.2 to 11.2) 13.1 (10.8 to 15.9) 0.03</td>
</tr>
<tr>
<td>Socioeconomic position</td>
</tr>
<tr>
<td>Manual social class (III manual, IV, or V) 52.0 (50.2 to 53.7) 55.3 (51.4 to 59.1) 0.12</td>
</tr>
<tr>
<td>From derived area 19.3 (18.9 to 20.6) 20.7 (17.3 to 23.3) 0.61</td>
</tr>
<tr>
<td>Physiological and behavioural characteristics</td>
</tr>
<tr>
<td>Alcohol consumption (g/day) 17.5 (16.1 to 18.8) 17.5 (14.8 to 20.5) 0.80</td>
</tr>
<tr>
<td>Physical activity (≥14 units alcohol a week) 5.5 (4.8 to 6.3) 6.0 (4.4 to 8.0) 0.39</td>
</tr>
<tr>
<td>Mean body mass index (kg/m²) 27.4 (27.2 to 27.6) 28.4 (28.0 to 28.8) &lt;0.001</td>
</tr>
<tr>
<td>Mean HDL cholesterol concentration (mmol/l) 1.66 (1.65 to 1.68) 1.64 (1.60 to 1.67) 0.22</td>
</tr>
<tr>
<td>Triglyceride concentration (mmol/l) 1.66 (1.65 to 1.68) 1.68 (1.62 to 1.74) 0.41</td>
</tr>
<tr>
<td>Hypertension 50.6 (48.7 to 52.4) 51.6 (47.5 to 55.4) 0.39</td>
</tr>
<tr>
<td>Mean forced expiratory volume in 1 second (l) 1.59 (1.57 to 1.61) 1.94 (1.90 to 1.99) 0.02</td>
</tr>
<tr>
<td>Mean haemoglobin concentration (g/l) 135.4 (135.0 to 135.8) 133.9 (133.1 to 134.8) 0.002</td>
</tr>
<tr>
<td>Hip or wrist fracture in previous 12 months 0.2 (0.1 to 0.4) 6.8 (5.1 to 8.9) &lt;0.001</td>
</tr>
</tbody>
</table>

*Reduction in blood pressure between standing and sitting of ≥20 mm Hg systolic blood pressure or ≥10 mm Hg diastolic pressure.
†Systolic blood pressure ≤100 mm Hg or diastolic blood pressure ≤60 mm Hg.
‡Blood pressure >160/95 mm Hg or patient taking treatment for blood pressure.

BMJ VOLUME 327 27 SEPTEMBER 2003 bmj.com
model. These 3742 women did not differ from the women without complete data in age or in the prevalence of any falls, frequent falls, or falls where the women received medical attention (P > 0.4 for all variables). We estimated population attributable risks of falling for risk factors from the fully adjusted logistic regression models, using maximum likelihood estimates as proposed by Greenland and Drescher. In all analyses we used robust standard errors, which take into account the clustering effects in each town, to calculate 95% confidence intervals. We used Stata version 8.0 (StataCorp, College Station, TX, 2002) for all statistical analyses.

Results

Of the 4286 participants 4050 (94%) provided data on falls. There were no differences between the women who provided these data and the other women in age, prevalence of any chronic diseases, drug use, or socioeconomic position (P > 0.15 for all variables). Of the 4050 women 686 had fallen at least once in the previous 12 months, giving a prevalence of 16.9% (95% confidence interval 15.8% to 18.1%). The prevalence of frequent falling was 7.0% (6.2% to 7.8%) and of falls where medical attention was given was 6.8% (6.0% to 7.6%).

Women who had fallen at least once in the previous 12 months were older than women who had not fallen and were more likely to have chronic diseases, more likely to be taking drugs, and had a higher body mass index (table 1). Postural hypotension and low standing blood pressure were not associated with falling. The women who had fallen had a lower mean haemoglobin concentration, and this inverse association remained even when data were adjusted for social class, body mass index, chronic diseases, and each class of drug used. The fully adjusted odds ratio of any falls for an increase in haemoglobin concentration of one standard deviation was 0.90 (0.81 to 0.99). Very few of the women had anaemia: no women had a haemoglobin concentration below 80 g/l, 15 had a concentration below 100 g/l, and 222 (5.5%) had a concentration below 120 g/l. Alcohol consumption was not related to falling. In the 12 months before the women's baseline examination 55 women (1.28%) had had a fractured hip (15 women) or wrist (44 women). Women who had had a fall in the previous 12 months were much more likely to have had a fracture than the women who hadn't had a fall (table 1).

Drug use and falls

Just over 70% (2887) of the women were taking at least one drug, and 622 (15.4%) were taking five or more drugs. There was a strong linear association between the number of drugs that women took and whether they had had a fall (figure). However, the association was not significant when the data were adjusted for chronic diseases and other potential confounding factors. The crude odds ratio for a fall in the previous 12 months for each additional drug taken was 1.14 (1.10 to 1.19), but the fully adjusted odds ratio was 1.01 (0.96 to 1.06). Linear associations between frequent falls and falls receiving medical attention and the number of drugs taken were similar, with the fully adjusted models showing no significant associations. Use of hypnotics or anxiolytics and use of antidepressants were associated with an increased odds of falling, even with adjustment for chronic disease status (including ever having had a diagnosis of depression) and other potential confounding factors (table 2). In the fully adjusted analyses analgesics, cardiovascular system drugs, endocrine system drugs, and respiratory disease drugs were not independently associated with having had a fall (table 2).

Chronic disease and falls

Nearly three quarters (2961) of the women had at least one chronic disease. There was a marked linear trend of increasing odds of falling with increasing number of chronic diseases (figure). This association remained even after adjustment for drug use and other potential confounding factors. The crude odds ratio for any fall in the previous 12 months for each additional simultaneously occurring disease was 1.46 (1.36 to 1.56), and the fully adjusted odds ratio was 1.37 (1.25 to 1.49). We found similar linear trends for the association between increasing numbers of simultaneously occurring chronic diseases and frequent falls and treated falls, and these associations remained significant in the fully adjusted models.

Circulatory disease, chronic obstructive pulmonary disease, depression, and arthritis were each associated with an increased odds of falling, even with adjustment for drug use and other potential confounding factors (table 3). The population attributable risk of having had at least one fall in the previous 12 months,

Table 2 Relation between drug use and falls in previous 12 months in 3742 UK women aged 60-79 years. Values are crude or fully adjusted* odds ratios (95% confidence interval)

<table>
<thead>
<tr>
<th>Type of drug</th>
<th>Any falls (n=464) vs no falls (n=3102)</th>
<th>Two or more falls (n=265) vs no falls (n=3102)</th>
<th>Falls where medical attention was given (n=246) vs no falls (n=3102)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Crude</td>
<td>Fully adjusted</td>
<td>Crude</td>
</tr>
<tr>
<td>Hypnotics and anxiolytics</td>
<td>1.94 (1.41 to 2.68)</td>
<td>1.41 (1.00 to 1.98)</td>
<td>2.65 (1.76 to 3.88)</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>2.02 (1.58 to 2.59)</td>
<td>1.53 (1.13 to 2.02)</td>
<td>2.63 (2.03 to 3.49)</td>
</tr>
<tr>
<td>Any central nervous system drug</td>
<td>1.49 (1.34 to 1.66)</td>
<td>1.25 (1.11 to 1.41)</td>
<td>1.81 (1.57 to 2.08)</td>
</tr>
<tr>
<td>Analgesics</td>
<td>1.25 (1.01 to 1.55)</td>
<td>1.00 (0.79 to 1.25)</td>
<td>1.51 (1.14 to 2.00)</td>
</tr>
<tr>
<td>Any cardiovascular drug</td>
<td>1.11 (1.04 to 1.18)</td>
<td>0.96 (0.89 to 1.05)</td>
<td>1.24 (1.14 to 1.34)</td>
</tr>
<tr>
<td>Any endocrine system drug</td>
<td>1.13 (0.96 to 1.33)</td>
<td>0.95 (0.79 to 1.18)</td>
<td>1.22 (1.09 to 1.34)</td>
</tr>
<tr>
<td>Any respiratory system drug</td>
<td>1.09 (0.98 to 1.23)</td>
<td>0.91 (0.78 to 1.06)</td>
<td>1.21 (1.03 to 1.42)</td>
</tr>
</tbody>
</table>

*Adjusted for age, body mass index, haemoglobin concentration (continuous variables), circulatory disease, diabetes, thyroid disease, asthma or bronchitis, depression, cataract or glaucoma, arthritis, heavy alcohol consumption (binary variables), and adult social class (I, II, III non-manual, III manual, IV, V) (indicator variable).
estimated from the fully adjusted models, was 6.2% (2.0% to 10.0%) for coronary heart disease, 6.2% (1.6% to 10.5%) for circulatory disease, 8.0% (3.3% to 12.4%) for chronic obstructive pulmonary disease, 9.4% (5.4% to 13.3%) for depression, and 17.4% (10.4% to 23.9%) for arthritis. The fully adjusted odds ratio of having had a fall in the previous 12 months associated with having at least one of the chronic diseases in table 3 was 1.81 (1.42 to 2.31), and the population attributable risk was 32.2% (19.6% to 42.8%). When we stratified the analyses by the year in which the participant's disease was first diagnosed, we found positive associations between falls and diseases diagnosed before (including up to 10 years before) the year in which the women had a fall.

Table 3: Relation between diagnoses of chronic diseases and falls in previous 12 months in 3742 UK women aged 60-79 years.

<table>
<thead>
<tr>
<th>Type of disease</th>
<th>Any falls (n=640)</th>
<th>v no falls (n=3102)</th>
<th>Two or more falls (n=265)</th>
<th>v no falls (n=3102)</th>
<th>Falls where medical attention was given (n=248)</th>
<th>v no falls (n=3102)</th>
<th>Crude</th>
<th>Fully adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary heart disease</td>
<td>1.82 (1.42 to 2.35)</td>
<td>1.50 (1.16 to 1.90)</td>
<td>2.83 (2.14 to 3.75)</td>
<td>2.12 (1.49 to 3.03)</td>
<td>1.82 (1.30 to 2.50)</td>
<td>1.64 (1.11 to 2.42)</td>
<td>1.05</td>
<td>1.05</td>
</tr>
<tr>
<td>Any circulatory disease</td>
<td>1.73 (1.42 to 2.12)</td>
<td>1.42 (1.10 to 1.83)</td>
<td>2.63 (2.00 to 3.44)</td>
<td>1.96 (1.39 to 2.77)</td>
<td>1.76 (1.30 to 2.38)</td>
<td>1.56 (1.02 to 2.36)</td>
<td>1.05</td>
<td>1.05</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1.33 (0.90 to 1.90)</td>
<td>1.23 (0.85 to 1.78)</td>
<td>1.49 (0.91 to 2.56)</td>
<td>1.92 (0.69 to 2.15)</td>
<td>1.26 (0.73 to 2.18)</td>
<td>1.07 (0.58 to 1.98)</td>
<td>1.05</td>
<td>1.05</td>
</tr>
<tr>
<td>Thyroid disease</td>
<td>1.30 (1.00 to 1.68)</td>
<td>1.20 (0.90 to 1.61)</td>
<td>1.77 (1.25 to 2.50)</td>
<td>1.79 (1.13 to 2.76)</td>
<td>1.38 (0.92 to 2.00)</td>
<td>1.23 (0.80 to 1.90)</td>
<td>1.05</td>
<td>1.05</td>
</tr>
<tr>
<td>COPD</td>
<td>1.49 (1.24 to 1.80)</td>
<td>1.48 (1.19 to 1.84)</td>
<td>1.51 (1.14 to 1.98)</td>
<td>1.38 (1.00 to 1.90)</td>
<td>1.53 (1.15 to 2.04)</td>
<td>1.51 (1.09 to 2.10)</td>
<td>1.05</td>
<td>1.05</td>
</tr>
<tr>
<td>Depression</td>
<td>2.07 (1.63 to 2.64)</td>
<td>1.76 (1.41 to 2.21)</td>
<td>2.67 (2.01 to 3.56)</td>
<td>2.11 (1.54 to 2.99)</td>
<td>2.45 (1.82 to 3.31)</td>
<td>2.19 (1.58 to 3.02)</td>
<td>1.05</td>
<td>1.05</td>
</tr>
<tr>
<td>Eye disease</td>
<td>1.48 (1.18 to 1.84)</td>
<td>1.22 (0.87 to 1.54)</td>
<td>1.96 (1.14 to 3.36)</td>
<td>1.21 (0.86 to 1.69)</td>
<td>1.41 (1.00 to 1.97)</td>
<td>1.16 (0.81 to 1.67)</td>
<td>1.05</td>
<td>1.05</td>
</tr>
<tr>
<td>Arthritis</td>
<td>1.92 (1.46 to 2.52)</td>
<td>1.60 (1.33 to 1.93)</td>
<td>2.09 (1.62 to 2.70)</td>
<td>1.88 (1.33 to 2.70)</td>
<td>1.76 (1.36 to 2.33)</td>
<td>1.44 (1.05 to 1.97)</td>
<td>1.05</td>
<td>1.05</td>
</tr>
</tbody>
</table>

*Adjusted for age, body mass index, haemoglobin concentration (continuous variables), circulatory disease, diabetes, thyroid disease, asthma or bronchitis, depression, cataract or glaucoma, arthritis, and heavy alcohol consumption (binary variables), and adult social class (I, II, III non-manual, III manual, IV, V) (indicator variable).

OSOP=chronic obstructive pulmonary disease.

Effects of combined multiple pathology and polypharmacy
When number of drugs taken and number of chronic diseases were included in the same regression model they combined multiplicatively. The odds ratio for a fall for each additional chronic disease, adjusted for number of drugs taken, was 1.39 (1.29 to 1.51), and that for each additional drug taken, adjusted for number of chronic diseases, was 1.05 (1.01 to 1.09). There was no strong evidence of a statistical interaction between number of drugs and number of chronic diseases (P = 0.16) and no evidence of statistical interactions between any of the individual chronic diseases and their relevant treatment (P > 0.15 for all diseases).

Discussion
The risk of falling rose with the number of drugs taken and the number of chronic diseases each woman had, but the association was stronger for multiple pathology than for polypharmacy and remained in the fully adjusted analyses. The population attributable risk of falling associated with having any chronic disease was much higher (32%) than that associated with use of psychotropic drugs (between 2% and 5%). Thus in public health terms targeting prevention and control of chronic diseases rather than polypharmacy may be a more useful strategy for preventing falls in elderly people. Factors commonly supposed to be associated with falls, such as postural hypotension, alcohol consumption, and reduced physiological reserve (as shown by low forced expiratory volume in 1 second) were not associated with falls in this study.11 12 Contrary to evidence in previous reviews that risk factors differ for single falls, frequent falling, and treated falls, we found similar risk factor profiles for the different types of fall.13 14

Limitations of the study
Our response rate (60%) is moderate but consistent with other large contemporary epidemiological surveys.15 As reported previously our respondents were slightly younger than non-respondents and were less likely to have a primary care medical record of stroke or diabetes, although the prevalence of coronary heart disease and cancer did not vary between respondents and non-respondents. Because chronic diseases are associated with falling we may have underestimated the prevalence of falls. The associations of chronic diseases

Prevalence of falls in the previous 12 months and number of drugs taken (crude data and fully adjusted for age, each chronic disease, body mass index, alcohol consumption, haemoglobin concentration, and social class)
and drug use with falling would only be exaggerated if the associations among non-respondents were in the opposite direction to the associations among respondents or if they were non-existent, both of which are unlikely.

Our study is cross-sectional and may therefore be susceptible to reverse causality. With respect to the effects of antidepressants and hypnotics or anxiolytics, it is possible that having had a fall may lead to anxiety or depression and therefore treatment for these conditions. However, assessing the association between drug use and the prevalence of falling is relevant, because the plausible mechanism by which central nervous system drugs result in falls is related to their contemporary use.\(^5\) That there was an association between falls and number of chronic diseases among women whose diagnosis had been made before the year of the fall indicates that these associations are not due to reverse causality.

We could not assess the effect of all the major chronic diseases that affect this age group. In particular, we did not collect information on cognitive function. However, that the participants were able to complete a detailed health questionnaire suggested that few if any women had severe dementia. Elderly people may under-report falls.\(^5\) Any such misclassification is likely to be non-systematic and would therefore dilute the associations. We used a crude indicator of the severity of falls: whether the participant had had medical attention. Although having received medical attention may indicate a greater severity of fall, it also reflects sociodemographic and personal factors that influence the likelihood of getting medical care after a fall.

**Implications**

As in other studies, our results show an association between the number of psychotropic drugs taken and the risk of falling.\(^5\) Although the population attributable risk of falling associated with these drugs was small, they may be an important cause of morbidity in people using them. Trials have shown that gradual withdrawal of psychotropic drugs is feasible among elderly people and is associated with a decreased risk of falling.\(^5\)

Chronic diseases may increase the risk of falls through direct effects of the disease and indirect effects, such as reduced physical activity, muscle weakness, and poor balance. Perhaps because observational research has focused more on drug use than chronic diseases, the effect of specific chronic diseases on the risk of falling has not been the main focus of controlled trials of interventions to prevent falls, although the inclusion of exercises specifically aimed at reducing falls as well as at improving cardiovascular fitness in cardiac rehabilitation programmes has been recommended.\(^9\) Chronic diseases and multiple pathology, rather than polypharmacy, may be the most important predictors of falling.

Acknowledgments: The British women’s heart and health study is co-directed by SE, Peter Whincup, Goya Wannamethee, and DAL. We thank Carol Bedford, Alison Emerton, Nicola Frecknall, Karen Jones, Mark Taylor, and Katherine Wornell for collecting and entering data, all the general practitioners and their staff who supported data collection, and the women who participated in the study.

Contributors: All authors developed the study’s aim and design and managed its data. DAL undertook the initial analysis and coordinated the writing of the paper. All authors contributed to the final version. DAL will act as guarantor for the paper.

Funding: The British women’s heart and health study is funded by the Department of Health. DAL is funded by a Medical Research Council and Department of Health training fellowship.

Competing interests: None declared.

Ethical approval: Local ethics committees approved the study, and 99.4% of participants gave written informed consent for their medical records to be available.