

Alarm symptoms in early diagnosis of cancer in primary care: cohort study using General Practice Research Database

Roger Jones,¹ Radoslav Latinovic,² Judith Charlton,² Martin C Gulliford²

EDITORIAL by Fox and Fletcher

¹Department of General Practice and Primary Care, Division of Health and Social Care Research, King's College London School of Medicine at Guy's, King's College and St Thomas' Hospitals, London SE1 6SP

²Department of Public Health Sciences, Division of Health and Social Care Research, King's College London School of Medicine at Guy's, King's College and St Thomas' Hospitals, London SE1 3QD

Correspondence to: R Jones
roger.jones@kcl.ac.uk

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ABSTRACT

Objective To evaluate the association between alarm symptoms and the subsequent diagnosis of cancer in a large population based study in primary care.

Design Cohort study.

Setting UK General Practice Research Database.

Patients 762 325 patients aged 15 years and older, registered with 128 general practices between 1994 and 2000. First occurrences of haematuria, haemoptysis, dysphagia, and rectal bleeding were identified in patients with no previous cancer diagnosis.

Main outcome measure Positive predictive value of first occurrence of haematuria, haemoptysis, dysphagia, or rectal bleeding for diagnoses of neoplasms of the urinary tract, respiratory tract, oesophagus, or colon and rectum during three years after symptom onset. Likelihood ratio and sensitivity were also estimated.

Results 11 108 first occurrences of haematuria were associated with 472 new diagnoses of urinary tract cancers in men and 162 in women, giving overall three year positive predictive values of 7.4% (95% confidence interval 6.8% to 8.1%) in men and 3.4% (2.9% to 4.0%) in women. After 4812 new episodes of haemoptysis, 220 diagnoses of respiratory tract cancer were made in men (positive predictive value 7.5%, 6.6% to 8.5%) and 81 in women (4.3%, 3.4% to 5.3%). After 5999 new diagnoses of dysphagia, 150 diagnoses of oesophageal cancer were made in men (positive predictive value 5.7%, 4.9% to 6.7%) and 81 in women (2.4%, 1.9% to 3.0%). After 15 289 episodes of rectal bleeding, 184 diagnoses of colorectal cancer were made in men (positive predictive value 2.4%, 2.1% to 2.8%) and 154 in women (2.0%, 1.7% to 2.3%). Predictive values increased with age and were strikingly high, for example, in men with haemoptysis aged 75-84 (17.1%, 13.5% to 21.1%) and in men with dysphagia aged 65-74 (9.0%, 6.8% to 11.7%).

Conclusion New onset of alarm symptoms is associated with an increased likelihood of a diagnosis of cancer, especially in men and in people aged over 65. These data provide support for the early evaluation of alarm symptoms in an attempt to identify underlying cancers at an earlier and more amenable stage.

INTRODUCTION

Referral from primary to secondary care is often triggered by a general practitioner's awareness of so called "alarm symptoms," features in the clinical

presentation that are considered to predict serious disease.¹⁻³ The evidence base for the alarming nature of many alarm symptoms is, however, weak.

Haematuria is thought to account for approximately four consultations per thousand patients per year in primary care in the United Kingdom. The presence of painless, macroscopic haematuria is widely regarded as an alarm symptom suggesting the presence of a urinary tract neoplasm, but little information collected in the primary care setting is available to support this assertion.⁴

Dysphagia is a relatively common problem and is often regarded as an alarm symptom mandating urgent referral. However, as in many conditions of interest, the information available to guide decision making is derived largely from secondary care settings.⁵⁻⁷ A recent systematic review described wide variation in the sensitivity and specificity of alarm symptoms for upper gastrointestinal malignancies.⁸

Haemoptysis occurs in up to 40% of patients with bronchitis, and is also seen in other less serious upper respiratory conditions, but it is an important alarm symptom for the presence of bronchial carcinoma, pulmonary tuberculosis, and pulmonary embolism. Little information is available on the outcome of hospital referrals for haemoptysis.⁹⁻¹¹ The most recent publication, a population based case-control study, found generally low positive predictive values for symptoms associated with lung cancer except for haemoptysis, with a positive predictive value of haemoptysis alone of 2.4%, but with much higher positive predictive values when haemoptysis was accompanied by other symptoms.¹²

Rectal bleeding is a common symptom.¹² Patients who present with this condition are likely to be referred for lower bowel endoscopy or a specialist opinion after evaluation by the primary care physician. Given the relative infrequency of a diagnosis of malignant or serious inflammatory disease, guidance is needed to help primary care physicians to select patients with rectal bleeding for whom urgent investigation or referral is most appropriate.¹³⁻¹⁷ Few epidemiological data are available to provide an evidence base for these decisions.

The General Practice Research Database is the world's largest primary care database, representing around 13 million patient years, contributed to by

several hundred representative general practices in the UK. We set out to determine the incidence of alarm symptoms, and the association between these symptoms and subsequent diagnosis of neoplasms, by using a retrospective cohort design.

METHODS

Practice and patient selection

We selected all 128 general practices contributing a sufficient standard of data between 1 January 1994 and 31 December 2000. We selected all 923 605 patients who were registered with these practices between 1 January and 31 December 1994 and were aged 100 years or less in 1994. We identified patients whose first recorded occurrence of each alarm symptom (haematuria, haemoptysis, dysphagia, or rectal bleeding) was after 31 December 1994 and who had not previously been diagnosed as having any cancer.

We evaluated each patient's record for new occurrences of associated cancers. For haematuria, we evaluated urinary tract neoplasms, excluding neoplasms of reproductive organs; for dysphagia, we evaluated oesophageal neoplasms; for haemoptysis, we evaluated respiratory tract neoplasms; and for rectal bleeding, we evaluated colorectal neoplasms.

Analysis

To obtain information on the underlying incidence of cancer and the value of symptoms for detecting cancer, we estimated: for each alarm symptom-outcome pair, the incidence of new alarm symptoms in patients not previously diagnosed as having cancer; in patients with new occurrences of alarm symptoms, the proportions with related cancer outcomes diagnosed over time (positive predictive value); and the proportions of cancer patients who had previous alarm symptoms in defined preceding time intervals (sensitivity).

In patients who presented with alarm symptoms, we determined whether a first diagnosis of the associated

neoplasm occurred in successive quarters up to five years. We evaluated the proportion of patients with symptoms who were diagnosed as having cancer in the next three years as the positive predictive value for the symptom. We compared the observed number of new diagnoses of associated cancers in patients with alarm symptoms with the number expected if the age and sex specific cancer incidence rates for the study population applied to the sample of patients who had the symptom of interest. We compared the observed and expected numbers of cancer occurrences by using a standardised incidence ratio as an estimate of the likelihood ratio of a positive test. For each patient with a cancer diagnosis, we determined whether a record of the relevant alarm symptom existed during the preceding three years.

RESULTS

Our population consisted of 923 605 eligible patients registered with 128 practices in 1994. We found 11 138 first occurrences of haematuria, 4822 of haemoptysis, 6003 of dysphagia, and 15 314 of rectal bleeding in patients aged 15 years or older between 1 January 1995 and 31 December 2000. Table 1 shows the age and sex standardised incidence rates for alarm symptoms and their associated cancers in the population aged 15 years and over, using the European standard population for reference. Each group of neoplasms was more frequent in men than in women; respiratory tract neoplasms were the most frequent, and oesophageal neoplasms were the rarest. First episodes of alarm symptoms were generally between 10 and 20 times more frequent than associated neoplasms, but this was not so for haemoptysis, which was only three times more frequent than the incidence of respiratory neoplasms. The mean age at first symptom was 58.5 (SD 18.9) years for haematuria, 61.6 (18.0) years for dysphagia, 54.5 (19.4) years for haemoptysis, and 52.5 (18.8) years for rectal bleeding.

Table 1 | Incidence of neoplasms and alarm symptoms in population aged 15 years and older from 1995 to 2000

| Site | Symptom | | Neoplasm | |
|-------------------|---------|---|----------|---|
| | Cases | Incidence per 100 000 person years (95% CI) | Cases | Incidence per 100 000 person years (95% CI) |
| Urinary tract | | Haematuria | | Urinary tract neoplasms |
| Men | 6411 | 285.1 (278.1 to 292.2) | 883 | 35.6 (33.2 to 38.0) |
| Women | 4727 | 206.0 (199.8 to 212.2) | 330 | 10.5 (9.3 to 11.7) |
| Respiratory tract | | Haemoptysis | | Respiratory tract neoplasms |
| Men | 2938 | 138.5 (133.4 to 143.6) | 1135 | 45.0 (42.3 to 47.6) |
| Women | 1884 | 83.6 (79.7 to 87.6) | 636 | 21.1 (19.3 to 22.8) |
| Oesophagus | | Dysphagia | | Oesophageal neoplasms |
| Men | 2631 | 117.1 (112.6 to 121.7) | 282 | 11.6 (10.2 to 13.0) |
| Women | 3372 | 130.8 (126.1 to 135.6) | 158 | 4.4 (3.6 to 5.1) |
| Rectum and colon | | Rectal bleeding | | Colorectal neoplasms |
| Men | 7533 | 361.2 (353.0 to 369.5) | 739 | 30.2 (27.9 to 32.4) |
| Women | 7781 | 354.9 (346.6 to 363.2) | 644 | 19.4 (17.8 to 21.0) |

European standard population used as reference.

Table 2 | Observed related diagnoses of cancer in first six months and three years after first alarm symptom, positive predictive value, and likelihood ratio for cancer after symptom

| | No with symptom | Cumulative No of cancer diagnoses | Positive predictive value (%) (95% CI) | Expected No of cancer diagnoses | Likelihood ratio (95% CI) |
|---------------------------------|-----------------|-----------------------------------|--|---------------------------------|---------------------------|
| Six months after first symptom | | | | | |
| Haematuria: | | | | | |
| Men | 6385 | 349 | 5.5 (4.9 to 6.1) | 3.1 | 110.9 (99.2 to 122.5) |
| Women | 4723 | 117 | 2.5 (2.1 to 3.0) | 0.5 | 215.3 (176.3 to 254.3) |
| Haemoptysis: | | | | | |
| Men | 2930 | 169 | 5.8 (5.0 to 6.7) | 1.4 | 116.7 (99.1 to 134.3) |
| Women | 1882 | 63 | 3.3 (2.6 to 4.3) | 0.4 | 153.1 (115.3 to 190.8) |
| Dysphagia: | | | | | |
| Men | 2628 | 138 | 5.3 (4.4 to 6.2) | 0.4 | 347.9 (289.9 to 405.9) |
| Women | 3371 | 70 | 2.1 (1.6 to 2.6) | 0.3 | 266.2 (203.8 to 328.5) |
| Rectal bleeding: | | | | | |
| Men | 7523 | 138 | 1.8 (1.5 to 2.2) | 1.8 | 75.3 (62.7 to 87.8) |
| Women | 7766 | 119 | 1.5 (1.3 to 1.8) | 1.5 | 78.1 (64.1 to 92.1) |
| Three years after first symptom | | | | | |
| Haematuria: | | | | | |
| Men | 6385 | 472 | 7.4 (6.8 to 8.1) | 18.9 | 25.0 (22.7 to 27.2) |
| Women | 4723 | 162 | 3.4 (2.9 to 4.0) | 3.3 | 49.7 (42.0 to 57.3) |
| Haemoptysis: | | | | | |
| Men | 2930 | 220 | 7.5 (6.6 to 8.5) | 8.7 | 25.3 (22.0 to 28.7) |
| Women | 1882 | 81 | 4.3 (3.4 to 5.3) | 2.5 | 32.8 (25.6 to 40.0) |
| Dysphagia: | | | | | |
| Men | 2628 | 150 | 5.7 (4.9 to 6.7) | 2.4 | 63.0 (52.9 to 73.1) |
| Women | 3371 | 81 | 2.4 (1.9 to 3.0) | 1.6 | 51.3 (40.1 to 62.5) |
| Rectal bleeding: | | | | | |
| Men | 7523 | 184 | 2.4 (2.1 to 2.8) | 11.0 | 16.7 (14.3 to 19.1) |
| Women | 7766 | 154 | 2.0 (1.7 to 2.3) | 9.2 | 16.8 (14.2 to 19.5) |

In the next stage of the analysis, we omitted data for patients with incomplete dates for first symptoms: 30 with haematuria, 10 with haemoptysis, 4 with dysphagia, and 25 with rectal bleeding. Diagnoses of cancer were most often made in the first three months after the onset of alarm symptoms; very few diagnoses of cancer were made later than three years after symptom onset. Table 2 gives the observed numbers of new occurrences of related cancers in the first six months and three years after symptom onset, with positive predictive values and likelihood ratios for each symptom. Haematuria and haemoptysis had the highest predictive values for cancer, followed by dysphagia and rectal bleeding.

In secondary analyses, we searched for diagnoses of cancer other than those that we had pre-specified. After haematuria, inclusion of cancers of the reproductive organs yielded 21 additional cancers in women and 158 cancers in men, mostly cancers of the prostate. Inclusion of these cancers in the analysis would give a positive predictive value of 3.9% in women and 9.9% in men. After dysphagia, inclusion of gastric cancers yielded 17 additional cancer diagnoses in women and 30 in men. Inclusion of these cancers gave positive predictive values of 5.2% in women and 6.9% in men. Estimates based on the pre-specified cancers may thus be conservative for these symptoms. The predictive value of each alarm symptom for cancer over the

next three years showed substantial effects of both age and sex (see bmj.com).

To test the sensitivity of the symptoms for detecting cancer, we examined the proportion of patients who received a diagnosis of cancer in either 1999 or 2000 who had been recorded as having an alarm symptom in the preceding three years. The sensitivity of haematuria for a diagnosis of urinary tract cancer was 58.7% in men and 51.2% in women. The sensitivity of haemoptysis for a diagnosis of respiratory tract cancer was 22.2% in men and 13.6% in women. The sensitivity of dysphagia for a diagnosis of oesophageal cancer was 58.3% in men and 53.8% in women, and the sensitivity of rectal bleeding for a diagnosis of rectal cancer was 33.3% in women and 25.1% in women.

DISCUSSION

This study provides estimates for the increased likelihood of diagnosis of a related cancer after the first episode of four common alarm symptoms often encountered in primary care. In the first three months after the first presentation with haematuria, haemoptysis, dysphagia, or rectal bleeding, the likelihood of a diagnosis of cancer was greatly increased. Over three years, the relative increase was highest for oesophageal cancer after dysphagia and lowest for a diagnosis of colorectal cancer after rectal bleeding. The increased likelihood of a diagnosis of

WHAT IS ALREADY KNOWN ON THIS TOPIC

Alarm symptoms or “red flags” are often used to identify patients whose symptoms need investigation

The evidence for the “alarming” nature of some of these symptoms is weak

WHAT THIS STUDY ADDS

Likelihood ratios for a diagnosis of cancer after haematuria, haemoptysis, dysphagia, and rectal bleeding are high in the first six months and fall towards unity at around three years

Predictive values for a diagnosis of cancer vary according to age, sex, and alarm symptom, and rise with age

The data provide support for the selection of patients presenting with these symptoms in general practice and needing urgent investigation

cancer remained high during the first year after an alarm symptom but gradually declined over time.

Strengths and limitations

This study has the strength of a large registered and accurately characterised population, drawn from a large number of general practices. Previous studies have evaluated the quality of data in the General Practice Research Database with satisfactory results,^{18,19} and the population of patients we have studied is likely to be similar to the general population of the UK and of other Western societies. The incidences we report are broadly similar to those reported from cancer registries. Our analyses included only well defined groups of associated neoplasms. We acknowledge that alarm symptoms may be caused by other serious conditions, both neoplastic and non-neoplastic, as our secondary analyses showed.

We also acknowledge that greater imprecision is likely in the recording of symptoms than of medical diagnoses, and we do not know how long the symptoms were present before they were first recorded at a general practice consultation. In addition, we are not able to accurately characterise the nature of some of these alarm symptoms. Different presentations are likely to carry different pathological implications. Studies by Bruyninckx et al and Summerton et al both emphasised the importance of associated symptoms in patients with haematuria and their propensity to “amplify” the predictive value of a single symptom.^{20,21}

Implications

We have shown a significantly increased risk of cancer being diagnosed in the three to six month period after presentation with an alarm symptom. Different risks are attached to different alarm symptoms, different sexes, and different age ranges.

For haematuria, the risk of a cancer being diagnosed is greatly increased in the first three to six months after presentation, particularly in younger patients and, in the later years, in middle aged men and older women. Our results suggest that investigations should be done with a minimum of delay in patients in the

highest risk groups identified in this study. Haemoptysis has an unsurprisingly low sensitivity for a respiratory tract malignancy, most likely because of its frequent association with respiratory tract infection. However, unexplained haemoptysis is associated with a very high risk of a diagnosis of cancer, particularly in the three month period after haemoptysis.

Dysphagia is also associated with a high rate of diagnosis of oesophageal cancer, particularly in men, in the three to six month period immediately after presentation, suggesting that dysphagia unexplained by non-neoplastic diseases such as reflux oesophagitis should be investigated promptly. Finally, rectal bleeding is associated with high rates of cancer diagnosis in the 90 day period immediately after presentation. A recent study from general practice in the UK suggested that one in 10 patients presenting with rectal bleeding have colonic neoplasia, and the authors recommended full investigation of all patients with rectal bleeding on the basis of these figures.²²

Conclusions

Taken overall, our results provide additional support for the concept of alarm symptoms in primary care. The association between alarm symptoms and high rates of cancer diagnosis vary somewhat between men and women and across different age ranges, and individual alarm symptoms have different sensitivities and specificities for a final diagnosis of cancer.

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Use of administrative data or clinical databases as predictors of risk of death in hospital: comparison of models

Paul Aylin,¹ Alex Bottle,¹ Azeem Majeed²

EDITORIAL by Mohammed

¹Dr Foster Unit, Imperial College London, London EC1A 9LA

²Department of Primary Care and Social Medicine, Imperial College London

Correspondence to: P Aylin
p.aylin@imperial.ac.uk

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ABSTRACT

Objective To compare risk prediction models for death in hospital based on an administrative database with published results based on data derived from three national clinical databases: the national cardiac surgical database, the national vascular database and the colorectal cancer study.

Design Analysis of inpatient hospital episode statistics. Predictive model developed using multiple logistic regression.

Setting NHS hospital trusts in England.

Patients All patients admitted to an NHS hospital within England for isolated coronary artery bypass graft (CABG), repair of abdominal aortic aneurysm, and colorectal excision for cancer from 1996-7 to 2003-4.

Main outcome measures Deaths in hospital. Performance of models assessed with receiver operating characteristic (ROC) curve scores measuring discrimination (<0.7=poor, 0.7-0.8=reasonable, >0.8=good) and both Hosmer-Lemeshow statistics and standardised residuals measuring goodness of fit.

Results During the study period 152 523 cases of isolated CABG with 3247 deaths in hospital (2.1%), 12 781 repairs of ruptured abdominal aortic aneurysm (5987 deaths, 46.8%), 31 705 repairs of unruptured abdominal aortic aneurysm (3246 deaths, 10.2%), and 144 370 colorectal resections for cancer (10 424 deaths, 7.2%) were recorded. The power of the complex predictive model was comparable with that of models based on clinical datasets with ROC curve scores of 0.77 (v 0.78 from clinical database) for isolated CABG, 0.66 (v 0.65) and 0.74 (v 0.70) for repairs of ruptured and unruptured AAA, respectively, and 0.80 (v 0.78) for colorectal excision for cancer. Calibration plots generally showed good agreement between observed and predicted mortality.

Conclusions Routinely collected administrative data can be used to predict risk with similar discrimination to clinical databases. The creative use of such data to adjust for case mix would be useful for monitoring healthcare

performance and could usefully complement clinical databases. Further work on other procedures and diagnoses could result in a suite of models for performance adjusted for case mix for a range of specialties and procedures.

INTRODUCTION

Routine administrative databases are increasingly being used for performance monitoring in healthcare (such as www.healthcarecommission.org.uk, www.drfooster.co.uk, www.ihl.org/IHI/Programs/Campaign/).¹ In comparisons of performance between clinicians or organisations it is essential to adjust for several parameters including comorbidity and severity of disease (case mix). Routine data, however, might contain insufficient information for adequate adjustment. Clinical databases, run by various bodies including professional societies, could potentially record more detailed clinical information and might permit better adjustment for case mix.

We examined mortality for three index procedures (coronary artery bypass graft, abdominal aortic aneurysm repair, and colectomy for bowel cancer) used in three large clinical datasets (the national adult cardiac surgical database, the national vascular database, and a colorectal cancer database collected by the Association of Coloproctology of Great Britain and Ireland). We compared risk adjustment models for mortality, based on hospital episode statistics (HES) administrative data, with published models based on data from the clinical databases and assessed the ability of each model to predict death. Details of the clinical datasets and HES data are on bmj.com.

METHODS

We extracted data on all admissions in England for isolated coronary artery bypass graft (CABG, OPCS4 codes K40-K46), repair of abdominal aortic aneurysm (OPCS4 codes L18-L21), and colorectal excision

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