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Underreporting of suspected adverse drug reactions to newly marketed ("black triangle") drugs in general practice: observational study

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Data on side effects of newly launched drugs are limited,[1] highlighting the need for effective postmarketing surveillance. An inverted black triangle (▼) on product literature identifies new products. Suspected adverse reactions to these drugs, however minor, should be reported to the Committee on Safety of Medicines through the yellow card scheme.[2] Adverse reactions are underreported,[3] and few doctors in the United Kingdom know the meaning of the "black triangle" symbol.[4] We assessed the degree of underreporting of suspected adverse reactions to new drugs in general practice and determined if reporting varied when reactions were severe or previously unrecognised.

Patients, methods, and results

The Drug Safety Research Unit performs observational cohort studies (prescription event monitoring) on selected newly marketed drugs in general practice. All patients in England who have been dispensed selected new drugs are identified for these studies by the Prescription Pricing Authority. Questionnaires ("green forms") are subsequently sent to prescribers asking about clinical events, suspected adverse drug reactions, and events reported to the Committee on Safety of Medicines as suspected adverse reactions. For the 10 drugs we examined (acarbose, risperidone, fluvastatin, tramadol, gabapentin, famciclovir, lansoprazole, zolpidem, venlafaxine, and losartan) median exposure was 46 435 (interquartile range 24 524 to 55 735) patient months. Events recorded by general practitioners as suspected adverse reactions, and those stated as having been reported to the Committee on Safety of Medicines, were classified as serious or non-serious, using the definition published in the British National Formulary.[2] We determined whether the event was listed ("labelled") in the summary of product characteristics at the time of the study; events not listed were classified as unlabelled. Reports stating "non-specific side effects" or intolerance were not classified. By calculating a risk ratio, using non-serious labelled events as the reference group, we determined the likelihood of each category of adverse reaction being reported to the Committee on Safety of Medicines.

There were 3045 events (in 2034 patients) reported as suspected adverse reactions on the green forms during the 10 studies. General practitioners indicated that they had reported 275 (9.0%; 95% confidence interval 8.0% to10.0%) of these reactions to the Committee on Safety of Medicines: reporting was highest for serious unlabelled reactions (26/81; 32.1%) and lowest for non-serious labelled reactions (94/1443; 6.5%) (table). Serious unlabelled and non-serious unlabelled reactions were significantly more likely to be reported than were non-serious labelled reactions. According to general practitioners' responses, the proportion of serious labelled reactions also reported on yellow cards (7/64; 10.9%) was only slightly greater than that of non-serious labelled reactions.

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Suspected adverse drug reactions reported by general practitioners on green forms for 10 newly marketed "black triangle" drugs during prescription event monitoring studies 1994-7

Type of adverse reaction	Adverse drug reactions: No stated on green form	Adverse drug reactions: No (%) also reported to Committee on Safety of Medicines	Risk ratio (95% CI)
Non-serious:	2400	235 (9.8)	—
Labelled	1443	94 (6.5)	Reference
Unlabelled	957	141 (14.7)	2.3 (1.8 to 2.9)*
Serious:	145	33 (22.8)	3.5 (2.4 to 5.0)*
Labelled	64	7 (10.9)	1.7 (0.8 to 3.5)
Unlabelled	81	26 (32.1)	4.9 (3.4 to 7.2)*
Not categorised†	500	7 (1.4)	—
Total	3045	275 (9.0)	—

*P<0.0001.
†Insufficient information available for an assessment of severity or of status as labelled or unlabelled.

Comment

These findings show a selective reporting bias to the Committee on Safety of Medicines, with general practitioners notifying a greater proportion of adverse reactions that are of greatest clinical concern. Our estimates are subject to potential reporting and recall biases. Some doctors who had submitted a yellow card may not have completed the green form. We would have underestimated the proportion of yellow cards submitted if green form responders were less likely to complete yellow cards than green form non-responders. It seems more plausible that green form responders would be at least as likely to report yellow cards as green form non-responders. Doctors may not have indicated that a yellow card was submitted. As the number of yellow cards reported per doctor is low,[5] the impact of recall bias on our estimates is probably limited. Our overall estimate of underreporting corresponds to previous estimates.[5] The message that doctors should submit yellow cards for all suspected adverse drug reactions to "black triangle" drugs should be reinforced.

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Neglect of growth and development in the clinical monitoring of children and teenagers with inflammatory bowel disease: review of case records

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Failure of growth and retarded sexual development are serious and common problems in children and teenagers with inflammatory bowel disease, particularly Crohn's disease. Thus height, weight, sexual staging, and bone age should be closely monitored in such patients. In 1989 we reported serious underrecording of these variables of growth in a cohort of Scottish children with inflammatory bowel disease.[1] We assessed the situation a decade later.

Subjects, methods, and results

We studied 28 boys and 13 girls aged ≤16 years at first admission to hospital with ulcerative colitis (n=14) or Crohn's disease (n=27). These patients, identified from the Scottish hospitals database of inpatients statistics for 1984-88, were resident in four of the Scottish regions.

We reviewed the patients' case records and noted whether height, weight, bone age, and sexual development were recorded. The frequencies of recording of these variables of growth were analysed by specialty of consultant. Since 14 (34%) of the patients were attending one consultant's (A) clinic, the frequencies of recording by this consultant were considered separately.

The table summarises the results. With the exception of consultant A, gastroenterologists, physicians, and surgeons made few recordings of height, and very few recordings of bone age or sexual development were made by any specialty, including paediatricians.

Comment

The causes of Crohn's disease and ulcerative colitis are unknown, but abundant evidence supports the clinical illness as being a composite effect of several variables both symptomatic and indolent. These include inflammatory disease activity, side effects of drugs, psychological distress, destructive ulceration, bone demineralisation, and growth failure. Growth failure is not confined to patients of paediatricians as growth and sexual maturation of young people with Crohn's disease often continue until age 20 or later. Despite this, few consultants in adult medicine or surgery record the physical development of teenage patients; perhaps the doctor assumes nothing specific can be done about growth failure, or this neglect may simply be an oversight.

We do not know if such neglect is unique to gastroenterologists, or whether similar findings would have emerged from studying the case records of teenagers with cancer, renal failure, asthma, rheumatic diseases,