sexual intercourse before their operations and had had none since. Of the remainder, many more of the patients with ileostomies reported an increase. None the less, half the patients with ileostomies and three quarters of the patients with colostomies reported impaired urinary or sexual function. Women's main problems were dryness of the vagina; discomfort during intercourse; dyspareunia; orgasmic dysfunction; and problems with contraception. Around a quarter had urinary difficulties (mainly patients with colostomies), over half of whom had severe problems. Of the men the main complaints were of perineal pain on intercourse; some loss of sexual drive; problems with erection (particularly with a colostomy); difficulties with penetration (again mostly patients with colostomies); ejaculation not being the same as before the operation; and orgasmic impairment. Urinary difficulties were experienced by a quarter of the men a quarter of whom reported severe problems. Unlike in women there was no difference in the incidence of urinary problems between patients with colostomies and patients with ileostomies. Fifty eight patients had reported their sexual or urinary problem, but only eight had been referred to a specialist. Most received no help, and many were not even given sympathy.

Most patients with a stoma will continue to be inter- mittently reviewed in hospital. When they are well and the stoma is long established the review may be yearly: doctors will establish that there has been no recurrence of disease and that there are no structural problems with the stoma—such as prolapse, retraction, stenosis, or a parastomal hernia. Junior doctors may be unfamiliar with managing stomas and may leave problems with the appliance—soreness, odour, leakage, and so on—to the local stomatherapist. Patients usually accept this pattern of follow up: hospital doctors for the disease and the topography of the stoma and stomatherapists for the problems of skin care, diet, and collecting the effluent. It is often from stomatherapists and other patients that patients really learn to live with their stoma, but clearly their lives could be much improved. General practitioners have much to offer, as long as they are well informed, because they are sensitive, highly trained in interviewing skills, and willing to listen. Not only may they support emotionally and professionally (when there are genitourinary problems) but they may also mobilise help in the community to redecorate, iron, and shop.

KAY NEALE
Research Assistant
ROBIN PHILLIPS
Consultant Surgeon
St Mark's Hospital,
London EC1V 2PS

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Heart disease in Asians in Britain

Commoner than in Europeans, but why?

About one million immigrants from the Indian subcontinent live in Britain. The clinical impression is that they present young with diffuse coronary artery disease, and this is supported by scientific investigation. In a survey of 3657 deaths of immigrants from the Indian subcontinent about a 20% excess was due to circulatory disease when compared with deaths in Europeans.1-7 The highest proportional mortality ratio for ischaemic heart disease was seen in Bengalis, who had an excess of 70%. Admissions to hospital of Indian Asians for myocardial infarction was similar or greater than those seen in Europeans of all ages.1-5 An excess of deaths from ischaemic heart disease has also been described in Indians compared with other ethnic groups and reported from other areas such as the West Indies, East Africa, and Singapore.5-9 These findings suggest that this problem is related not to the country of immigration but to shared environmental or genetic factors.

Analysis of coronary arteriographic findings show quantitatively more severe arterial disease in Asians than in Europeans.1 Although it is generally considered that there is more disease affecting the distal coronary arterial vessels, this was not the case in a study of 34 Asians undergoing coronary arteriography.3 This impression of diffuse distal coronary arterial disease may be related to the high prevalence of diabetes in Asians and not to a specific ethnic pattern.

Analysis of conventional risk factors in Asians suggests that hypertension, diet, and stress may be important as smoking is probably less common among Asian men and is rare among Asian women.9 But current risk factors cannot explain the excess rate of ischaemic heart disease found among Asians. Hypertension is more common in Indian Asians than in Europeans, but this is unlikely to account for the differences in deaths from coronary artery disease.10 Death from stroke is not more common among these immigrants, and African and West Indian immigrants have a much higher incidence of hypertension but a lower mortality from coronary artery disease. Diabetes is at least twice as common in Indian Asians as in Europeans,11 and this will enhance the premature development of atherosclerosis and mortality from coronary heart disease.

The total cholesterol and high density lipoprotein concentrations seen in Asian men are similar to those in British men, and the concentrations in Asian women are lower than in British women.11,12 The diet of Indians from the subcontinent is low in saturated fats, and they have a favourable ratio of polyunsaturated to saturated fat intake in the diet compared with that in the British population (0.85 v 0.28, respectively).12,13 One hypothesis forwarded for this discrepancy is that ghee, a clarified butter product prized in Indian cooking, contains cholesterol oxide (12-3% of sterols), which is not found in fresh butter; and in both animal and in vitro studies cholesterol oxides had angiototoxic and atherogenic properties.13 Also important in explaining the excess of heart disease in Asians may be low concentrations of n 3 polyunsaturated fats in the diet and the hypothryoidism that is widespread in Indian women.

Finally, it is uncertain how important stress is in causing coronary artery disease in any community, but the process of migration and the psychosocial difficulties immigrants have in adapting to cultural change have been implicated in the
A European CSM?

The European Community aims at creating a fully integrated internal market by 1992, and this will naturally apply to pharmaceutical products. The community is likely to extend and drastically revise the legislation for licensing medicines within Europe, and ultimately decisions on whether a medicine is to be marketed in Britain may be taken in Europe rather than in Britain.

When Britain joined the European Community in 1973 it already had a machinery for regulating medicines, and the community had a directive with three aims: to set rules on producing and distributing proprietary medicines that would safeguard public health; to attain the first aim without hindering the development of the pharmaceutical industry; and to eliminate disparities affecting the internal market. European directives do not have to be translated exactly into national laws, but when national legislation and a European Community directive are at variance the directive takes precedence.

European Community directives issued in 1976 set up a procedure whereby after a product had been approved for marketing in one member state other countries could recognise the first country’s assessment and issue their own national marketing authorisation. Mutual recognition should have led to a collection of national marketing authorisations for each medicine. In the same year the community also set up the Committee on Proprietary Medicinal Products to consider cases in which national regulatory authorities had taken divergent opinions on whether to approve a medicine for licensing.

The Committee on Proprietary Medicinal Products soon recognised that the system had been set up before the standards set by national authorities had been adequately harmonised. Therefore it set up working parties to produce detailed guidelines on three issues: evaluating safety (covering acute toxicity, repeated dose toxicity, carcinogenicity, mutagenicity, and pharmacokinetics); testing efficacy; and harmonising the dossier that pharmaceutical companies have to present for marketing approval in each of the member states. This multistate procedure has now been modified to allow companies to appeal to the Committee on Proprietary Medicinal Products if it reaches an adverse opinion on their products.

Mutual recognition has not worked well. In 12 years no licence granted in one country has been unequivocally recognised in another. The European Commission has recently produced a report on the current procedures and has to produce recommendations for future improvements by the end of 1988. Fundamental changes are clearly inevitable. Furthermore, new proposals will need to be radical because so many national regulatory authorities are failing to cope with their existing workload. In Britain and West Germany approvals for new products are taking two to six times longer than the limits laid down by the community—that is, 120 days with an additional 90 days in exceptional circumstances (such as when referral to an advisory committee is necessary).

The commission might propose a central authority for registering all innovative products and products of biotechnology. Such a procedure of making decisions centrally was foreshadowed in 1987, when a directive known as the High Technology Directive set up a mechanism whereby the Committee on Proprietary Medicinal Products would consider applications for new biotechnology products and give an opinion before they were considered in individual countries. The committee’s opinion is not binding on member states, so changes could be introduced to make these “opinions” into “binding decisions.” This procedure should allow greater harmonisation, but any centralised European regulatory body set up should probably be independent of the existing machinery of the Committee on Proprietary Medicinal Products. The question of whom such a body would be accountable to has yet to be resolved. Adequate input from expert advisory bodies would be essential if such a system were to have the confidence of the public and professions. It seems, however, that the future of regulating medicines lies in the European Community rather than in the individual member states.

JOHN P GRIFFIN
Director,
Association of the British Pharmaceutical Industry,
London SW1A 2DY