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(Accepted 19 February 1992)

Predicting psychiatric admission rates

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Abstract

Objective—To determine the numbers of actual and expected psychiatric admissions for the residents of the district health authorities of England and to develop a model to indicate which social, health status, and service provision factors best explain the variation of the actual from the expected psychiatric admissions; to use this model to predict psychiatric admissions for district health authorities as an aid to resource allocation.

Design—The actual psychiatric admissions for district health authority residents were extracted from data of the 1986 Mental Health Enquiry. Expected admissions were calculated using the age, sex, and marital status structure of each district health authority and the national psychiatric admission rates related to age, sex, and marital status. Standardised psychiatric admission ratios were calculated as the ratios of the numbers of actual to expected psychiatric admissions. A wide range of social, health status, and service provision data were used as the explanatory variables in regression analyses to determine which combination of factors best explained the variation between districts of standardised psychiatric admission ratios.

Setting—The 168 652 psychiatric admissions recorded for the 1986 Mental Health Enquiry, after exclusion of mental handicap and psychogeriatric admissions.

Results—The actual number of psychiatric admissions varied from 79% above to 54% below the expected number of admissions from age, sex, and marital status for the districts of England. The most powerful variables to explain this variation were the rate of notification of drug misusers, standardised mortality ratios, and levels of illegitimacy in each district. A complex model was developed which could be used to predict district psychiatric admissions as an aid to resource allocation. A simpler model was also developed (which was less powerful than the more complex model) based on the underprivileged area score. One advantage of this model was that it could be used at the level of electoral wards as well as district health authorities.

Introduction

In their report on bed norms and resources the Working Party of the Royal College of Psychiatry found a high correlation of social and demographic factors based on national census data to psychiatric admission rates for the populations within electoral wards of the former health district of South Ham-

smith and within the districts of the North West Thames Regional Health Authority.¹ In reviewing previous work the working party found many reports suggesting that the prevalence of psychiatric disorders correlates with various social and demographic variables.²⁻⁷ Most of this work found that the prevalence of specific disorders such as schizophrenia⁸⁻¹⁰ and alcoholism,⁹ suicide,^{11,12} and parasuicide^{13,14} was strongly related to various social and demographic factors. The working party also identified five studies, then unpublished, that showed a relation between admission rates and rural or urban status of the population served, poverty, isolation, ethnicity, unemployment, and owner occupied housing.

Initially the aim of the royal college's working party was to explain the large variation in provision of psychiatric beds among health districts by studying 20 psychiatric units in district general hospitals with high, medium, and low bed turnovers. A significant factor that affected bed use was length of stay, but variations in length of stay could not be explained by differences in the amount or type of service available. Their finding of a correlation of 0.67 between underprivileged area scores^{15,16} and psychiatric admission rates across the electoral wards of South Hammersmith and a similar correlation of 0.76 between underprivileged area scores and admission rates for the health districts of the North West Thames Regional Health Authority suggested that social factors could be powerful predictors of psychiatric hospital use; this would be of importance if confirmed for larger and more extensive population groups.

If a strong relation between social and demographic factors and admission rates holds for other population groups, theoretical issues arise regarding the direction of causality. Equally important are the implications for health care planning. The relation between actual service use and the need for services is difficult to determine because of the problems in defining need and the paucity of accurate and reliable data regarding the prevalence of psychiatric illness in each district health authority. A study in district health authorities of standardised mortality ratios for suicide plus other unspecified injury, averaged from 1982 to 1986, showed a correlation coefficient of 0.51 with the crude psychiatric admission rate of district residents.

The royal college's report suggests that admission rates may be taken as a proxy for service need. Their relation to the underlying social characteristics of the population may be used to estimate the expected service requirements, which can be compared with service provision.

We report here a total population study of psychiatric

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BMJ 1992;304:1146-51

admission rates in all health districts in England to determine how these rates are related to more than 150 social, demographic, and health care variables, including various established social deprivation indices, indicators of poverty and isolation, and indicators of health care supply and availability. We have developed a model that can be used by planners to predict a level of psychiatric service provision for a district population. In so doing we have gone considerably further than the royal college's report by explaining the variation in use of psychiatric inpatient care on the basis of the characteristics of the population served.

Method

Our purpose was to study acute general psychiatry. It is possible to calculate the rate of admission to psychiatric hospitals from data collected annually up to 1986 for the Mental Health Enquiry.¹⁷ The district of residence and district of treatment of patients admitted to hospital for treatment by a psychiatrist are recorded as part of the inquiry's data. From this it is possible to calculate the total admissions for the residents of the district health authorities of England. A wide range of data is available from other sources regarding the demographic, social, and health status of the residents of these districts and the extent and availability of services from hospitals, general practitioners, and community psychiatric and non-psychiatric services and nursing homes. These data can be used to study the associations of these variables with psychiatric admission rates, which in turn can be used as a proxy for service need.

Of all psychiatric admissions recorded by the inquiry, those for mental handicap (18%) and psychogeriatrics (11%) were excluded from further study, as were any other admissions with a diagnosis of senile dementia (ICD code 290). For the years before 1986 the district of residence was not well recorded on the inquiry's returns and the data were inadequate for studying the admission rates of the residents of each district. For 1986, however, the data were relatively complete: only 779 (0.49%) of the 168 652 admissions remaining after mental handicap and psychogeriatric admissions had been removed were coded only to a region of residence and not to a district of residence. A total of 7784 (4.62%) admissions were not coded to either a region or district of residence. The admissions for which the district of residence was not recorded were allocated to each district in proportion to the total number of district admissions.

As a check on accuracy and completeness, data extracted from the original tapes of the Mental Health Enquiry were compared with data from two other sources for 1986. The SH3 returns, which record the numbers of patients treated in each district for all specialty groups, were obtained and from these the returns for psychiatry (excluding mental handicap and psychogeriatrics) were calculated. In addition, the NHS performance indicator MI3 for the age-sex standardised psychiatric admission rate of district residents for 1985-6 was obtained. In six of the 191 districts (Paddington and North Kensington, Camberwell, Wandsworth, North Birmingham, Preston, and West Lambeth) there were substantial differences in standardised admission ratios between the Mental Health Enquiry data for 1986 and either or both the performance indicator data or the SH3 data. Therefore the data from these six districts were excluded from the analyses, leaving 185 districts.

National admission rates by age and sex and by age, sex, and marital status were calculated from the Mental Health Enquiry data for the whole of England. They were then applied to the age, sex, and marital status structures of each district to calculate the numbers of

admissions in each district that would have been expected if the national rates had been applied. An overall crude national admission rate (without allowance for age, sex, or marital status) was also used to give an expected number of admissions based on the total population rate alone. The actual utilisation rates can be compared with these expected utilisation rates to produce an estimate of under (or over) utilisation of services by district residents. The actual number of admissions for the residents of each district (based on the Office of Population Censuses and Surveys' population estimates) divided by the expected number of admissions, calculated as described ($\times 100$), gave the standardised psychiatric admission ratio (SPAR) based on population alone (SPAR_{popn}), age and sex standardisation (SPAR_{as}), and age, sex, and marital status standardisation (SPAR_{asms}).

The Pearson correlation coefficients of more than 150 independent variables with the standardised psychiatric admission ratios, SPAR_{popn}, SPAR_{as}, and SPAR_{asms} for 1986 for the 185 districts were calculated. These variables included a wide range of social, health status, and health service provision factors including those reflecting hospital and general practice provision, community based psychiatric and non-psychiatric health service and nursing home provision, and the supply of community based and hospital medical and nursing staff, as well as psychiatric beds. They are summarised in appendix 1.

Finally, after the admission rates for age, sex, and marital status were standardised as described above to control for the effects of these variables, a stepwise regression analysis was used to determine which combination of these independent or explanatory variables most economically explained the variation of the standardised psychiatric admission ratios.

Results

The national psychiatric admission rates of men and women varied by age but were fairly similar, the rates for women being a third greater than for men in the 45-70 age group (fig 1). Unmarried people of both sexes had much higher psychiatric admission rates than did married people up to about age 75 (the maximum difference being a sixfold increase for unmarried men compared with married men in the 40-44 age group) (fig 2). As a result, expected psychiatric admissions calculated using the age, sex, and marital status structure of a district were found to differ by up to 30% from the values based on the age and sex structure alone. Differences in marital status structures therefore account for an important source of variation in the admission rates between health districts.

CORRELATIONS BETWEEN ACTUAL AND EXPECTED NUMBER OF ADMISSIONS

We first calculated the association between the

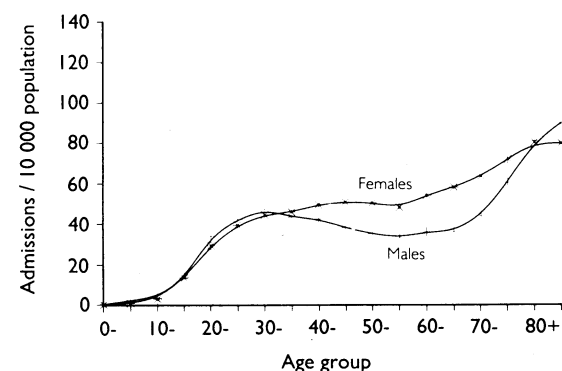


FIG 1—Psychiatric admission rates by age and sex. Source: Mental Health Enquiry, 1986

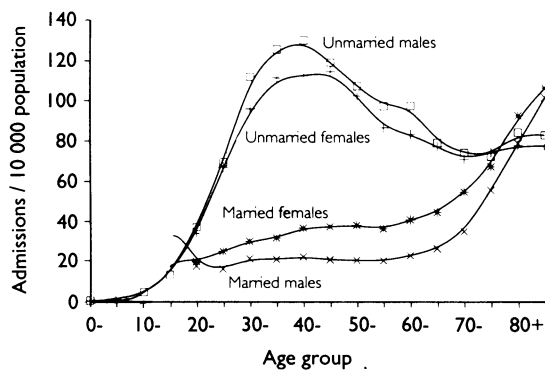


FIG 2—Psychiatric admission rates by age, sex, and marital status. Source: *Mental Health Enquiry, 1986*

actual (observed) and the expected numbers of admissions for the 185 districts of England. These are indicated by the Pearson product moment correlation coefficients between them: 0.78 for admissions based on population size alone (explaining 61% of variance); 0.79 for admissions based on age and sex (explaining 62%); and 0.83 for admissions based on age, sex, and marital status (explaining 69%). By comparison, a correlation coefficient of 0.89 was found between the actual number of admissions and the number predicted with the best fit regression analyses (described below). With a model using the more easily available underprivileged area score and crude admission rates the correlation between the actual and predicted admissions is 0.84.

CORRELATION BETWEEN STANDARDISED ADMISSION RATIOS AND OTHER VARIABLES

The values for each district of 169 variables (summarised in appendix 1) which might have been associated with psychiatric admission rates were correlated with $SPAR_{popn}$ (the standardised psychiatric admission ratio based on population alone and national overall admission rates). The strongest correlation coefficients (given in brackets) between different types of factors were: (a) indicators of isolation: percentage of single person households, old people living alone, and unmarried people (0.57 to 0.55); (b) illegitimacy (0.53); (c) composite measures of social deprivation: the Department of the Environment index,¹⁸ underprivileged area score, and the Townsend index¹⁹ (0.53 to 0.48); (d) indicators of poverty: households lacking a car, personal service workers—socioeconomic group 7, and unskilled workers—socioeconomic group 11 (0.54 to 0.45), unemployment (0.37); (e) first and total notifications of drug misusers in 1988 (0.53 and 0.51); (f) the availability of non-psychiatric hospital services: availability of non-psychiatric beds, total consultants (and consultants plus junior doctors) per head of population (0.52 to 0.42); (g) levels of mortality and morbidity: standardised mortality ratios to age 65 and for all ages, proportion of the population temporarily sick (0.50 to 0.47); (h) high population density: population density (0.40), overcrowding of households (0.36).

One of the highest correlations of $SPAR_{popn}$ was with the percentage of unmarried people (0.55). This illustrates the importance of controlling for marital status by calculating the age, sex, and marital status standardised psychiatric admission ratios ($SPAR_{asms}$).

To examine the association between psychiatric admission rates after taking account of age, sex, and marital status, the values of $SPAR_{asms}$ were correlated with the wide range of variables. The highest correlations were with standardised mortality ratio to age 65 (0.50), percentage of the elderly who live alone (0.48), illegitimacy (0.47), and standardised mortality ratio for bronchitis and emphysema, ischaemic heart disease,

and circulatory system disease (0.47 to 0.39) (see appendix 2 for highest correlation coefficients).

All the correlation coefficients cited above were highly significant ($p < 0.0001$).

REGRESSION ANALYSES

As shown above, the proportion of the variation of the actual number of admissions of district residents which was explained by the numbers expected based on population size alone, population age and sex structure, and population age, sex, and marital status structure (and national admission rates) was 61%, 62%, and 69% respectively. Further regression analyses of the ratio of the actual to the expected admissions were carried out to determine how much additional variation could be explained by social, health status, and service factors. When interpreting the results of regression analyses of the relation between psychiatric admission rates and social factors the problems of multicollinearity and linearity of the model must be borne in mind.²⁰

The regression analyses using, in turn, $SPAR_{popn}$ and $SPAR_{asms}$ as dependent variables gave models in which the following independent, or explanatory, variables were found to contribute most strongly to the explanation of the variance at the $p < 0.0001$ level of significance (the results for $SPAR_{as}$ were similar to those for $SPAR_{popn}$): (a) for $SPAR_{popn}$: percentage unmarried, 1986, plus percentage born in the United Kingdom, 1981, plus percentage in socioeconomic group 7, personal service workers, 1981 ($r^2 = 0.44$); (b) for $SPAR_{asms}$: the rate of notifications of drug misusers, 1988, plus percentage illegitimacy, 1986, plus standardised mortality ratio, 1986 ($r^2 = 0.33$) (or plus standardised mortality ratio, 1986, for ischaemic heart disease: $r^2 = 0.35$).

The model using standardised ratios for age, sex, and marital status as dependent variables together with notification rate of drug misusers and the standardised mortality ratio or the standardised mortality ratio for ischaemic heart disease as independent variables was used to calculate the values of $SPAR_{asms}$ that would be predicted from the regression equation for the 185 districts. Using the overall standardised mortality ratio, the ratio to age 75, or the ratio for ischaemic heart disease made little difference. Using the ratio for ischaemic heart disease with the rate of first notifications of drug misuse explained almost as much ($r^2 = 0.34$) of the variance of $SPAR_{asms}$ as did the full model ($r^2 = 0.35$), and these variables were used in the final model shown in appendix 3.

The final model was used to predict the numbers of psychiatric admissions for each district. Figure 3 shows the relation between these and the actual number of admissions for each of the 185 districts. The predicted admissions correlated with a correlation coefficient of 0.89 with the actual admissions. There was no significant difference in the model if the

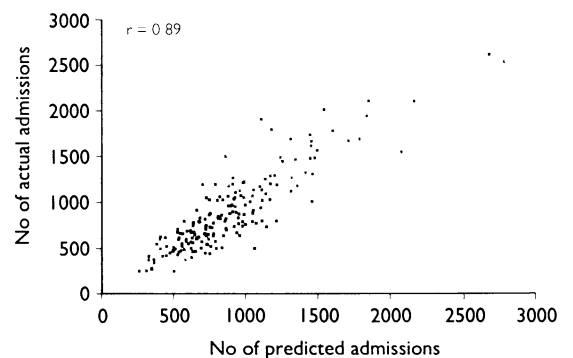


FIG 3—Actual versus predicted psychiatry admissions, district health authorities, 1986, determined with $SPAR_{asms}$ and recommended model

districts of inner London were removed from the analyses (to investigate whether the high admission rates in inner London have an unduly large influence).

The table shows the ratios ($\times 100$) of the actual admissions for the regions of England to the predicted psychiatric admissions using this model. Also shown are the ratios of the actual admissions for the regions of England to the expected number of admissions based on the age, sex, and marital status structures of the district's population and national admission rates (SPAR_{asms}).

Ratios ($\times 100$) of actual psychiatric admissions to predicted admissions

Region	Actual admissions + admissions expected from age, sex, marital status structures, and national rates	Actual admissions + predicted admissions using full model
Northern	113	100
Yorkshire	120	107
Trent	89	91
East Anglia	89	101
North West Thames	92	98
North East Thames	94	93
South East Thames	104	116
South West Thames	106	121
Wessex	100	111
Oxford	75	90
South Western	87	96
West Midland	93	94
Mersey	125	99
North Western	116	95

With many of the models the proportion of psychiatric nurses working in the community was also significant at the $p < 0.05$ or $p < 0.01$ levels: the higher the proportion of psychiatric nurses working in the community the lower the admission rates, after allowance for the other factors included in the model. Similarly, the proportion of psychiatric nurses in training was associated with higher admission rates.

Regression analyses were also carried out using the crude psychiatric admission rates per 1000 resident population as the dependent variable and the underprivileged area score as the independent variable. Appendix 3 shows the relation between these variables for the district health authorities of England. The correlation coefficient of the number of admissions predicted by this method and the actual number per district is 0.84. The districts' underprivileged area score explains 23% of the variation of districts' crude psychiatric admission rates. A similar analysis was carried out for crude psychiatric admission rates by electoral ward, using Körner data for 1988-91, in one regional health authority (about 800 wards). The annual rate per 1000 population was found to be $3.80 + 0.075$ (SD 0.0076) \times ward underprivileged area score (excluding mental handicap and psychogeriatric admissions).

Discussion

National psychiatric admission data for one year (1986) were analysed to determine the relation between admission rates and social, demographic, health, and service provision indices. The analysis shows interesting relations with all these influences and provides a useful tool for identifying resource needs.

The importance of the influence of marital status on psychiatric admission rates has been shown. The Resource Allocation Working Party (RAWP) recommended that marital status be used for calculating the allocation of psychiatric resources²¹ and these recommendations were followed. This paper supports the wisdom of this judgment and, in addition, suggests that the number of psychiatric admissions for a district can be predicted by using a regression model that standardises for the effects of age, sex, and marital

status and allows for the drug misuser notification rate and standardised mortality ratios.

From April 1991, partly as a result of the review of the NHS,²² the revenue resources allocated to regional health authorities for providing all hospital and community health services for their resident populations have been calculated as the sum of a number of costs per age group (age groups 0-4 to 85 and over) multiplied by the number of residents in each age group in the region, all multiplied by the square root of the standardised mortality ratio to age 75 (averaged from 1985 to 1989) for the region. These allocations include the resources for psychiatric hospital inpatient services, which represent about 10% of the total costs.²³ No allowance is made in this allocation, at the regional level, for the important factors, such as marital status, influencing the use of psychiatric inpatient services. However, regions are able to take these factors into account in their subregional allocations to district purchasing authorities. Doing so in a region with low levels of social deprivation would make a difference of up to about 3% to district hospital and community health service revenue allocations within the region (with an average of about 1% difference). The change would be greater in a region with high levels of social deprivation.

In the regression analyses, the only psychiatric service variables that added significantly to the explanation of variance in district admission rates were the proportions of psychiatric nurses in a district working in the community (having more nurses was significantly associated with lower admission rates) and the proportion of psychiatric nurses in training (higher values were associated with higher admission rates). This finding may be worth following up with field studies, although in the models it added only a small amount to the proportion of the variance explained.

When the actual numbers of psychiatric admissions (excluding those for mental handicap and psychogeriatrics) in each region were compared with the numbers expected based on national admission rates and the age, sex, and marital status structures of the districts in each region, without taking account of any other factors, Mersey and Yorkshire regions had higher admissions than expected and Oxford region lower than expected. When, in addition, allowance was made for the levels of drug misuser notification rates and standardised mortality ratios in the regions by regression analysis, then the predicted admissions for Mersey region approximated more closely to the actual numbers of admissions (that is, the ratio of actual to predicted admissions approached 1). The table indicates that age, sex, and marital status standardised psychiatric admission ratios of the two South Thames regions were more than 10% greater than the values for the North Thames regions. This difference persisted when the factors in the model were allowed for. This was partly as a result of the very high psychiatric admission rates for West Lambeth district.

The comparison between the results from these models gives an indication of the effect of allowing for factors other than the age, sex, and marital status structure of districts when studying psychiatric admissions.

The model using underprivileged area scores and crude admission rates, though it explained less of the variation of psychiatric admission rates than did the more complex model described above, is nevertheless more powerful than using only population size and age-sex structure. This simpler model could be useful for predicting crude psychiatric admission rates at census electoral ward level because the age, sex, and marital status structure of the ward populations and the drug notification rates needed for the more detailed model are usually not known at ward level, whereas tables of underprivileged area scores are available. This could

be helpful when calculating service requirements within local authority or health authority boundaries.

We have shown the relation between a wide variety of social, demographic, health care, and service variables and the number of psychiatric admissions for 185 of the 191 health districts in England in 1986. A regression model explains 79% of the variation of the number of admissions per district. The fivefold difference in crude admission rates observed among health districts was explained largely by differences in the health and social characteristics of the district populations. Differences in health care delivery policy may account for some of the remaining unexplained variation.

The approach that we have adopted highlights certain factors such as drug misuse, illegitimacy, measures of general illness, and a variety of social conditions that are associated with higher rates of admission in certain populations. Many of our findings are consistent with those found by Thornicroft when he studied data for the South East Thames region.²⁰ The formulas derived from the regression analyses that can be used to calculate the predicted numbers of admissions for a district are given in appendix 3. The more complex model could be used where data on the expected numbers of admissions according to age, sex, and marital status, drug misuser rates, and standardised mortality ratio are available. The less powerful model using crude admission rates and underprivileged area scores can be used in the United Kingdom, on the basis of underprivileged area score data which are available for electoral wards from Brian Jarman and have been published for districts.²⁴ We recommend that the simple or full model be substituted for the model proposed in the Royal College of Psychiatrists' report.¹

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(Accepted 19 February 1992)

Appendices

1. SUMMARY OF INDEPENDENT VARIABLES USED FOR CORRELATION AND REGRESSION ANALYSES

(A full list of the variables used is available on request.)

For each DHA for various years:

Health status

Infant mortality rates
Perinatal mortality rates
Neonatal mortality rates
Postneonatal mortality rates
Proportions of births under 2500 g
Standardised mortality ratios, full age range and to 65, 75, and 85
Standardised mortality ratios for each ICD group and for common causes of death
Childhood death rates

Social factors

Composite social indices:
Underprivileged area score
Vera Carstairs deprivation index
Townsend deprivation index
NE and NW Thames socioeconomic group bed use weighting (excluding geriatrics)
NE and NW Thames socioeconomic group bed use weighting (including geriatrics)
Department of the Environment social index

Individual variables:

% Population single, widowed, or divorced, 1981
% 1981 total population aged 65 and over
% 1981 total population elderly alone
% 1981 total population aged under 5
% 1981 total population in lone parent family
% 1981 total population unskilled (social class V, socio-economic group 11)
% 1981 economically active population unemployed
% 1981 total population lacking basic amenities
% 1981 total population overcrowded (>1/room)
% 1981 total population moved house in year
% 1981 total population New Commonwealth/Pakistan origin
% 1981 total population born outside UK
% 1981 total population born Pakistan
% 1981 total population born New Commonwealth
% 1981 total population European origin
% 1981 total population Caribbean origin
% 1981 total population Ireland origin
% 17 year olds not in education 1981
Population density 1983 and 1985 (per hectare)
% Economically active and resident population permanently or temporarily sick, 1981
% Households with no car, 1981
% Households not owner occupier, 1981
% Households single occupier, 1981
% Social classes I-V, 1981
% Socioeconomic groups 1-17, 1981
Illegitimacy index, 1986
Drug misusers first notification/100 000, 1988
Drug misusers renotification/100 000, 1988

Supply variables

Hospital services-non-psychiatry and psychiatry:
Wide range of supply data relating to consultants, junior doctors, bed availability mental illness nurses in hospital
Community services:
Mental illness nurses in day hospitals and community
General practice average list size, group practices, general practitioners' ages
Community health services expenditures
Nursing homes: private bed supply, beds for elderly

2. SIX HIGHEST PEARSON CORRELATION COEFFICIENTS AMONG 169 INDEPENDENT VARIABLES

Correlation coefficients with SPAR_{popn} and SPAR_{asms}. N=185, all correlation coefficients significant at p<0.0001.

SPAR_{popn}—Standardised admission ratio based on district population size and national overall rate

% Households single occupier households 1981	0.573
% Over 65s living alone 1981	0.559

% Population single, widowed, or divorced 1981	0.546
Households with no car 1981	0.545
Average illegitimacy index 1982-1987	0.536
% Private households with no care 1981	0.533

DRUG1STN = drug misusers, 1st notifications/100 00 resident population, 1988
 SMR (IHD) = standardised mortality ratio averaged 1981-5 for ischaemic heart disease

SPAR_{asm}—Standardised admission ratio based on district age, sex, and marital status composition

Standardised mortality ratio for ages under 65, 1986	0.503
Standardised mortality ratio for ages under 75, 1986	0.487
% Over 65s living alone, 1981	0.481
Standardised mortality ratio 1981-5 bronchitis, emphysema and asthma	0.474
Average standardised mortality ratio 1981-7	0.471
Illegitimacy index 1986	0.467

Predicted admissions for each district are calculated as the predicted value of SPAR_{asms} times the expected admissions based on the district's age, sex, and marital status structure and national psychiatric admission rates by age, sex, and marital status.

The model used explains 34% of the variation of SPAR_{asms} values between districts. The predicted values of SPAR_{asms} are calculated and multiplied by expected values to give predicted numbers of admissions.

The predicted admissions explain 79% of the variation between districts of actual admissions.

Simple model

$$\text{Crude rate} = 3.65 + 0.034 \times \text{UPA SCORE} \quad (\pm 0.0046)$$

where:

Crude rate = psychiatric admissions/1000 resident population
 UPA SCORE = district underprivileged area score

3. REGRESSION EQUATIONS USED FOR DISTRICT MODELS (standard error of coefficient shown in brackets)

Full model

$$\text{SPAR}_{\text{asms}} = 12 + 0.66 \times \text{DRUG1STN} + 0.82 \times \text{SMR (IHD)} \quad (\pm 0.10) \quad (\pm 0.11)$$

SPAR_{asms} = standardised psychiatry admission ratio
 = actual admissions/age, sex, marital status expected admissions of residents, 1986 × 100

Note that: (a) psychiatric admissions do not include mental handicap or psychogeriatrics; (b) figures apply to districts for 1986.

Short term treatment of dermatophyte onychomycosis with terbinafine

M J D Goodfield, L Andrew, E G V Evans

Abstract

Objective—To evaluate the effect of short term treatment with terbinafine on dermatophytosis.

Design—Multicentre, randomised, double blind placebo controlled trial of 250 mg/day terbinafine for 12 weeks in dermatophyte onychomycosis.

Setting—Eight dermatology centres in the United Kingdom.

Patients—112 patients (mean age 44, range 19-78), 99 with mycologically proved toenail infections and 13 with fingernail infections, of whom eight were subsequently excluded and 19 failed to complete the study.

Intervention—Terbinafine 250 mg daily or placebo for 12 weeks. Follow up for 36 weeks after stopping treatment.

Main outcome measures—Mycological cure (negative results on microscopy and culture) and clinical cure at the end of follow up, adverse events, and biochemical and haematological variables at monthly intervals during treatment.

Results—After follow up 82% (37/45) (95% confidence interval 68% to 92%) mycological cure and 69% clinical cure were recorded for evaluable patients treated with terbinafine for toenail infection and 71% (5/7) (30% to 96%) mycological cure and clinical cure for those treated for fingernail infection. The corresponding values for those treated with placebo were 12% (3% to 31%) mycological cure and no clinical cure for toenail infections and 33% (1% to 91%) mycological cure and no clinical cure for fingernail infections. On an intention to treat basis for toenail infections the figures were 73% (38/52) (58% to 85%) mycological cure for terbinafine compared with 6% (0% to 30%) for placebo ($p < 0.007$). Two withdrawals were related to adverse events with terbinafine, and there were no significant abnormal laboratory test results.

Conclusion—12 weeks' terbinafine is effective and safe treatment for nail dermatophytosis.

Introduction

Fungal infections of the nail (onychomycosis) are common and may occur in 2% to 5% of the population.¹ Most involve dermatophytes (dermatophytosis), most commonly *Trichophyton rubrum* or *Candida* spp. Griseofulvin is the standard treatment for dermatophytosis of nails, being given orally for up to 18 months for toenail infections and for 12 months for fingernail infections.^{2,3} Results, however, are poor, and a cure is achieved in less than 40% of toenail and 70% of fingernail infections,⁴ with relapse of at least 20% at one year after apparently successful treatment.⁴ Thus an overall cure rate of less than 30% is achieved with this drug. Among newer antifungal agents, liver toxicity has limited the usefulness of oral ketoconazole to short term treatment,⁵ itraconazole may be effective,⁶ but is licensed for only four weeks' use, and topical application of tioconazole is probably of value only as adjunctive treatment⁷; amorolfine remains unassessed in Britain.

Terbinafine is currently the most interesting of a new class of synthetic antimycotic agents, the allylamines.⁸ It may be taken orally and is fungicidal, inhibiting the fungal enzyme squalene epoxidase, which is important in the biosynthesis of ergosterol, an essential constituent of the fungal cell membrane. Inhibition of squalene epoxidase leads to a decrease in membrane ergosterol and accumulation of intracellular squalene, both of which are thought to contribute to the fungicidal action of terbinafine.⁹ This action is different from that of azole antifungals, which also inhibit ergosterol production in fungi, but by inhibiting lanosterol demethylase, an enzyme dependent on cytochrome P-450.¹⁰ Other cytochrome P-450 linked enzymes are also inhibited by azole derivatives, though less with triazoles such as itraconazole. Possibly, these differences may explain the different side effects of these three groups of drugs.¹¹

Terbinafine is effective in the treatment of dermatophyte infections of skin and nails,¹²⁻¹⁴ and its use

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BMJ 1992;304:1151-4