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Review

The Australian Register of Antiepileptic Drugs in Pregnancy: Changes over time in the epileptic population

F.J.E. Vajda^{a,*}, T.J. O'Brien^a, J. Graham^a, C.M. Lander^b, M.J. Eadie^b^a Department of Medicine and Neurosciences, Royal Melbourne Hospital and University of Melbourne, Grattan Street, Parkville, VIC 3050, Australia^b Royal Brisbane and Women's Hospital and University of Queensland, Brisbane, QLD, Australia

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ABSTRACT

The demographic characteristics, details of pregnancies, epilepsies, and treatment of 855 pregnant women with epilepsy enrolled in the Australian Antiepileptic Drugs in Pregnancy Register during 1999–2005 were compared with the corresponding data for the 801 women enrolled from 2006–2012. We estimate that the Register captures approximately 1 in 12 of all pregnancies in Australian women with epilepsy. A number of statistically significant changes were found, with nearly all explained by factors such as re-enrolment of women who had enrolled earlier pregnancies, changes in general population behaviour, altered attitudes to prescribing valproate and using it in lower doses, and the advent of newer antiepileptic drugs which have displaced the use of older agents. It appears that the Register has continued to capture a reasonably representative sample of pregnant Australian women with epilepsy as time has passed.

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1. Introduction

The Australian Register of Antiepileptic Drugs in Pregnancy was set up in 1999 with the intention of collecting information on the risks of foetal malformations associated with human intrauterine exposure to antiepileptic drugs (AED). Additionally, information was collected concerning various details of the characteristics of the female population whose pregnancies were being followed. This information to the end of the year 2005 was analysed to measure the inclusion of pregnant women with epilepsy (WWE) compared to the Australian population as a whole [1].

The current communication reassesses changes in the proportion and nature of participating women, and it is restricted to reporting only on WWE, comprising the vast majority of participants and a homogeneous group.

2. Materials and methods

Information about the existence of the Register and its contact details is provided to pregnant WWE by their treating medical practitioners, and by various lay organisations. After that, contact with the Register is left to the discretion of the women so informed. If they decide to participate, data concerning the present

pregnancy are recorded in a computer database. With permission from the women involved, certain medical details are obtained from their treating medical practitioners.

All contact with the Register is made by telephone. Details of the progress of the current pregnancy are included in the Register on four occasions: at recruitment, at approximately 7 months of pregnancy, within 1 month after giving birth and, finally, 1 year after giving birth.

At the initial interview, information is also sought concerning all of the woman's previous pregnancies. The women's contact details are kept in a separate database, the only linkage mechanism between the two databases being an identification number. Ethical oversight of the project has been the province of the institutional Ethics Committees of St Vincent's Hospital, Monash University and the University of Melbourne at different times.

Register data have been analysed by confidence interval methods, mainly employing odds ratios.

3. Results

3.1. Proportion of pregnant Australian WWE captured by the Register

Annual publications provide information on the number of WWE in Australia who have given birth each year, and on the total numbers of women in the country who have given birth. Data on WWE from the state of New South Wales were not available in

* Corresponding author. Tel.: +61 3 9819 3056; fax: +61 3 9342 2577.

E-mail address: vajda@netspace.net.au (F.J.E. Vajda).

the publications, and data from the state of Victoria are absent for some years. If the data for pregnant WWE from these two states (which were unavailable) and the available data for all women from Victoria who gave birth in the same period are omitted from the calculation, over the 4 year period there were 3761 pregnancies in WWE out of a total of 705,597 pregnancies. Hence WWE comprised 0.53% of all pregnant women in Australian states other than New South Wales and Victoria. Over the same 4 year period there was a total of 1,153,628 Australian women who gave birth (the available Victorian data now being included). Of these, 0.53% would be expected to have been WWE, that is, 6149 women, and 533 (8.67%) of them had found their way into the Register. It therefore seems likely that around 1 in 12 pregnancies of Australian WWE have been recorded in the Register [2].

3.2. Comparisons of data from 1999–2005 and 2006–2012

There were 855 pregnancies to WWE in the Register from 1999 to the end of 2005, and 801 subsequently from January 2006 to the end of 2012. Their various characteristics are compared below.

3.3. Demography

Table 1 contains various demographic details of the two cohorts of pregnant WWE. In relation to demographics, there have been statistically significant increases in the mean age of the women becoming pregnant; in the proportion of women of Asian race

being recruited; in the proportion of women being in part-time employment, with fewer being engaged in home duties; and in the proportion of referrals from medical practitioners apart from neurologists and obstetricians. The percentage of re-enrolling women increased. Statistically significant decreases occurred in the proportion of women of European descent; in those engaged in office work; in those with incomes below \$AUD50,000 per annum (unfortunately, there was no indexing for the effects of inflation); in those from rural environments; in those from South Australia; and in referrals from obstetricians.

3.4. The pregnancies

Details relevant to the pregnancies of the two cohorts are shown in Table 2.

There was a statistically significant increase in recruitments prior to 20 weeks of pregnancy, and statistically significant decreases in the rates of deliberate abortions, folate intake during pregnancy (though not prior to pregnancy), numbers of tobacco smokers and users of alcohol in pregnancy, and also proportionately fewer women who had previously had offspring with malformations.

3.5. Pregnancy outcomes

Pregnancy outcomes in the two cohorts are shown in Table 3. There were no statistically significant differences.

Table 1
Demographic characteristics of pregnant women with epilepsy in the Register before and after the end of 2005

Criterion	1999–2005	2006–2012	Difference/OR	95% CI
Number of pregnancies	855	801	Difference	
Mean age, years (SD)	30.52 (4.55)	30.98 (4.73)	0.46 years	0.013, 0.91
<i>Ethnicity (%)</i>			OR	
European	98.8	95.6	3.86	1.90, 7.05
Indigenous	0.59	0.87	0.668	0.21, 2.11
Asian	0.59	3.00	0.190	0.07, 0.50
Other	0	0.50		
<i>Employment (%)</i>				
Full-time	48.5	52.4	0.856	0.71, 1.04
Part-time	24.4	30.7	0.730	0.59, 0.91
<i>Employment nature (%)</i>				
Home duties	29.4	25.0	1.249	1.00, 1.55
Office work	28.7	15.7	2.160	1.70, 2.75
Various professions	15.4	17.1	0.884	0.68, 1.15
Unemployed	2.2	2.00	1.116	0.57, 2.19
Others	24.3	40.2	0.478	0.39, 0.59
<i>Income < \$AUD50,000 (%)</i>	35.3	12.1	3.964	3.07, 5.11
<i>Residence</i>				
Urban	72.5	75.9	0.837	0.67, 1.04
Regional	15.0	17.5	0.831	0.64, 1.08
Rural	12.5	6.4	2.104	1.48, 2.98
<i>State of residence (%)</i>				
NSW	23.2	22.7	1.027	0.82, 1.29
VIC	35.4	37.3	0.922	0.75, 1.13
QLD	22.0	20.6	1.086	0.86, 1.38
WA	9.2	11.1	0.814	0.59, 1.12
SA	5.7	3.4	1.721	1.07, 2.78
TAS	1.9	2.5	0.745	0.38, 1.45
ACT	1.8	1.7	1.004	0.48, 2.09
NT	0.8	0.2	3.298	0.68, 15.9
<i>Referral source (%)</i>				
Neurologist	49.2	48.7	1.022	0.84, 1.24
Obstetrician	9.2	3.2	3.035	1.93, 4.74
Other medical practitioners	3.3	7.5	0.418	0.26, 0.66
Nurse	4.2	2.0	2.303	1.25, 4.24
Epilepsy society	8.0	5.9	1.386	0.94, 2.04
Internet	2.3	3.7	0.616	0.35, 1.09
Re-enrolment	16.4	25.4	0.573	0.45, 0.72

Statistically significant differences ($p < 0.05$) are shown in bold.
CI = confidence interval, OR = odds ratio, SD = standard deviation.

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