

# Incidence of Alzheimer's disease in a rural community in India

## The Indo-US Study

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**Article abstract**—*Objective:* To determine overall and age-specific incidence rates of AD in a rural, population-based cohort in Ballabgarh, India, and to compare them with those of a reference US population in the Monongahela Valley of Pennsylvania. *Methods:* A 2-year, prospective, epidemiologic study of subjects aged  $\geq 55$  years utilizing repeated cognitive and functional ability screening, followed by standardized clinical evaluation using the Diagnostic and Statistical Manual of Mental Disorders, 4th edition, and the National Institute of Neurological and Communicative Disorders and Stroke–Alzheimer's Disease and Related Disorders Association criteria for the diagnosis, and the Clinical Dementia Rating scale for the staging, of dementia and AD. *Results:* Incidence rates per 1000 person-years for AD with CDR  $\geq 0.5$  were 3.24 (95% CI: 1.48–6.14) for those aged  $\geq 65$  years and 1.74 (95% CI: 0.84–3.20) for those aged  $\geq 55$  years. Standardized against the age distribution of the 1990 US Census, the overall incidence rate in those aged  $\geq 65$  years was 4.7 per 1000 person-years, substantially lower than the corresponding rate of 17.5 per 1000 person-years in the Monongahela Valley. *Conclusion:* These are the first AD incidence rates to be reported from the Indian subcontinent, and they appear to be among the lowest ever reported. However, the relatively short duration of follow-up, cultural factors, and other potential confounders suggest caution in interpreting this finding.

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Alzheimer's disease and other dementias are already a major public health problem among the elderly in industrialized countries. These dementias could also have a devastating impact on developing countries, whose populations are aging the most rapidly; by the year 2020, approximately 70% of the world's population aged  $\geq 60$  will be located in developing countries, with 14.2% in India.<sup>1</sup> The existing disease burden of communities can be estimated by cross-sectional prevalence studies, but the rate at which new disease develops can be measured only in prospective incidence studies. Incidence rates for dementia (including AD) appear to be lower in East Asia than in the United States or Europe.<sup>2</sup> There are several previous reports of dementia prevalence in developing countries in Asia and Africa,<sup>3–8</sup> but few reports of incidence.<sup>9–12</sup> We previously reported the prevalence of AD in Ballabgarh, a rural community in Northern India, as the lowest in the world (0.62% for age  $\geq 55$  and 1.07% for age  $\geq 65$ ).<sup>8</sup> We now report incidence rates from Ballabgarh after 2 years of follow-up, this being the first such report from the Indian subcontinent.

**Methods.** *Background.* The Indo-US Cross-National Dementia Epidemiology Study (1991–1999) represents a

collaboration between the University of Pittsburgh and the Center for Ageing Research in India. Informed consent was obtained from all study participants according to procedures approved by the University of Pittsburgh Institutional Review Board (IRB) and by the Human Volunteers Protection Committee of the Center for Ageing Research. We first developed screening and clinical evaluation instruments for the largely illiterate, Hindi-speaking, rural elderly Ballabgarh population, ensuring comparability to those being used in the reference US cohort in the rural mid-Monongahela Valley.<sup>13–15</sup> Subsequently, we undertook a prevalence survey<sup>8</sup> and a follow-up incidence survey (reported here) in Ballabgarh.

*Study population.* The prevalence cohort, described previously,<sup>8</sup> consisted of all 5126 consenting individuals aged  $\geq 55$  from the rural community of 28 villages from Ballabgarh in the northern Indian state of Haryana. Subjects were selected according to their ages listed in the local census; subsequently, their ages were confirmed in person by reference to personal and historical sentinel events, as is standard research practice in developing countries.<sup>16</sup> At study entry, 43 subjects had prevalent dementia, including 32 with AD. The follow-up study could only be conducted, with available funds, in the first 16 of the original 28 villages. The incidence cohort consisted of 2698 previously nondemented subjects, 71.4% illiterate, in these 16 villages.

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Background, methods, and 10-year incidence rates for dementia in the reference US population in the Monongahela Valley, aged  $\geq 65$  years at study entry, have been reported previously.<sup>17</sup>

*Instrument development for Ballabgarh study.* The first stage of the study was devoted to developing instrumentation appropriate to the study population. The cognitive screening instruments had to be reliable and valid, sensitive and specific for dementia, culturally and linguistically appropriate to the population, usable with illiterate Hindi-speaking subjects, and also as comparable as possible in content, format, and relative level of difficulty to the cognitive test battery used in the reference US population in the Monongahela Valley. The Hindi instruments were developed by means of a systematic, iterative process. Teams of clinicians (neurologists, neuropsychologists, psychiatrists) and a psychometrician, some bilingual, from the two centers in India and the US first selected potential items from the English-language battery and translated them from English to Hindi, with a different group back-translating them into English. Selected items were first tested in urban, educated, bilingual elderly volunteers in New Delhi, India; then pretested in successive groups of 30 illiterate rural elderly persons in Ballabgarh; then pilot-tested on a random sample of 100 rural older adults; then field-tested in an age-stratified sample of approximately 350 rural elderly individuals, each of whom also underwent independent clinical examination by the neurologist. After each iteration, distributions of test scores were examined and compared with those observed in the Monongahela Valley, with appropriate modifications being made at each step.<sup>13,14</sup> Using the same iterative process, a functional ability scale, in questionnaire form for administration to the subject's family member, was developed de novo for this population. It included items related to older adults' routine activities in this rural Indian setting.<sup>15</sup> Test items were examined and modified to maximize ease of administration and comprehension, acceptability to study participants, and reliability of test administration and scoring.

*Screening.* All subjects were screened, and a subset identified for detailed clinical evaluation. Screening was first performed at baseline during the prevalence survey<sup>8</sup> and repeated, after approximately 2 years, in the incidence cohort. Trained interviewers administered a standardized Hindi cognitive screening battery, based on the Consortium to Establish a Registry for AD (CERAD) neuropsychological panel,<sup>18</sup> to the subjects. The cognitive tests included a general mental status test, the Hindi Mental State Examination (HMSE),<sup>13</sup> analogous to the Mini-Mental State Examination (MMSE);<sup>19</sup> learning and delayed recall of a 10-item word list; fluency for categories of fruits and animals; a confrontation naming test; and a test of constructional praxis.<sup>14</sup> Interviewers also administered the functional ability questionnaire (Everyday Abilities Scale for India, EASI) to a family member.<sup>15</sup> Thus, even when subjects were cognitively untestable because of, for example, sensory impairment, illness, or severe dementia, it was possible to obtain functional ability data from a reliable informant. As in the prevalence study,<sup>8</sup> based on their screening scores subjects were classified as "cognitively impaired" using the following operational criteria: 1) scores at or below the 10th percentile of the sample on the

general mental status test; or 2) scores at or below the 10th percentile of the sample on at least one memory test and one other test. Subjects were classified as "functionally impaired" based on inability to perform three or more items on the functional ability scale. In addition, for the incidence survey, subjects were classified as "cognitively declined" based on the following operational criteria: declines in scores since the previous screening, 1) by amounts  $>95\%$  of the cohort on the general mental status test, 2) by amounts  $>95\%$  of the cohort on at least two other tests of more specific cognitive domains, or 3) to scores at levels below the "impairment" criteria established at baseline. All "cognitively impaired," "functionally impaired," and "cognitively declined" subjects, and all subjects unable to complete the cognitive tests, were referred for clinical (diagnostic) evaluation.

In both our US and Indian community studies, we used percentile-based screening criteria for impairment (cross-sectional) and decline (longitudinal), based on the study population itself. This approach was considered less potentially biased than using an arbitrary or conventional cutoff derived from experience with clinical samples or different communities. Further, there are no standard cutoffs on even the English-language tests other than the MMSE, no standard cutoffs on any of the Hindi instruments we developed, and no well-established standard cutoffs for decline on any tests. The screening tests and cutoffs themselves were used not to diagnose dementia but only to select a group of individuals for more detailed diagnostic examination. We reasoned that the individuals with dementia in the community are those with the lowest cognitive and functional performance, and those who have declined the most in these spheres over time. The 10th percentile cutoff for impairment, and the 95th percentile cutoff for decline, are compatible with our goals of detecting most or all prevalent and incident cases in the population at large, given the average reported prevalence of dementia of approximately 5% and the average reported incidence of dementia of approximately 1% per year, in Western populations aged  $\geq 65$  years.<sup>20</sup>

*Clinical evaluation and diagnosis.* The clinical evaluation established the presence or absence of a dementia syndrome, its stage of severity, likely cause, and estimated date of onset. Clinical evaluation was conducted on all consenting selected subjects, using a standardized diagnostic protocol,<sup>8</sup> by the project medical officer (R.P.) and neurologist (V.C.) in the subjects' homes or other accessible location within the village. The evaluators were blind to the screening data. The evaluation followed the assessment protocols of CERAD<sup>18</sup> and the University of Pittsburgh AD Research Center (ADRC), modified for field use, as also followed in the reference US study<sup>17</sup> and identical to that previously used in the prevalence survey.<sup>8</sup> It included a focused history and general physical, neurologic, and mental status examinations of the subject, and an interview with a reliable informant. For subjects who died between screening and clinical evaluation, family members were interviewed by the neurologist and the medical officer to determine whether the subject met criteria for dementia before death. In patients diagnosed with dementia, head MRI scan, complete blood count, chemistry screen, thyroid function tests, and syphilis serology were performed to assist in the etiologic diagnosis of dementia.

**Identification of incident cases.** Using the aforementioned information, dementia was diagnosed according to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV), criteria<sup>21</sup> and staged according to the Clinical Dementia Rating scale (CDR).<sup>22</sup> On the CDR, a score (stage) of 0 indicates no dementia whereas scores of 0.5, 1, 2, and 3 represent possible/incipient, mild, moderate, and severe dementia. A case of incident dementia was defined as an individual who fulfilled criteria for a DSM-IV diagnosis of dementia and a CDR rating of at least 0.5, with estimated disease onset occurring subsequent to study entry (baseline assessment). In subjects determined to have dementia with CDR stage  $\geq 0.5$ , the presence of clinically diagnosable AD was determined according to National Institute of Neurological and Communicative Disorders and Stroke–Alzheimer’s Disease and Related Disorders Association criteria,<sup>23</sup> further classifying the subjects as having probable AD, possible AD, or other (non-AD) dementia.

**Statistical methods.** Incidence rates were calculated by dividing the number of cases with onset of dementia in each age group by the number of person–years of observation in that group. Person–years were calculated from the time of study entry for each individual until the time of dementia onset, or until the last date the subject was known to be nondemented (death, dropout, or most recent contact). Incidence rates were also calculated within both sex categories and four age categories (55 to 64, 65 to 74, 75 to 84, 85 and older); 95% confidence intervals around these rates were obtained based on Poisson distributions (appropriate for rare events).

To compare overall incidence rates among those aged  $\geq 65$  years in Ballabgarh and the Monongahela Valley (where the study population was aged  $\geq 65$  years), we standardized both rates using the age distribution of the 1990 US population.<sup>24</sup> We also compared age-specific incidence rates for age groups 65 to 74, 75 to 84, and  $\geq 85$  between the two samples. Statistical significance was determined by calculating rate ratios (and associated standard errors) of the two age-specific incidence rates.

**Results.** At entry into the study at baseline, 2745 subjects aged  $\geq 55$  in the 16 villages underwent cognitive and functional screening. Among them, 15 subjects found to be demented at study entry (prevalent cases) were excluded from the incidence calculations. Among the 2730 remaining subjects, 32 dropped out without completing any of the incidence phase screening or evaluation procedures and were excluded from the incidence cohort. At follow-up, both cognitive and functional data were obtained from 2384 subjects and their informants. Only functional information were obtained from informants of an additional 224 subjects, 187 of whom had died before cognitive screening and 37 of whom were cognitively untestable. Ninety subjects died before follow-up screening, but information regarding their mental and functional status before death was obtained from their family members; they were therefore included in the incidence study sample. Thus the final incidence cohort totaled 2698 subjects.

The mean (SD) age of the incidence cohort was 66.2 (7.2) years at study entry. Men comprised 53.3% of the cohort, had a mean (SD) age of 67.2 (7.5) years, and were older than the women, who had a mean (SD) age of 65.2 (6.8) years ( $p < 0.001$  by Wilcoxon Rank Sum test). The

**Table 1** Age and sex distribution of Ballabgarh incidence cohort

Age group	Men	Women	Total
55–64 y	656 (48.4)	700 (51.6)	1356 (50.3)
65–74 y	587 (56.2)	457 (43.8)	1044 (38.7)
75–84 y	159 (63.9)	90 (36.1)	249 (9.2)
$\geq 85$ y	35 (71.4)	14 (28.6)	49 (1.8)
Total	1437 (53.3)	1261 (46.8)	2698 (100)

Data expressed as n (%).

longer life expectancy of men over women is common in certain rural parts of India.<sup>25</sup> Age and sex distributions are shown in table 1. The mean (SD) HMSE score for the 2384 subjects who completed cognitive testing was 26.4 (3.4) at baseline and 26.1 (3.8) at follow-up.

Of the 2698 members of the incidence cohort, 490 (18.2%) were selected for clinical evaluation by the “impairment” and “decline” screening criteria described earlier. Among them, 401 subjects (81.8%) were clinically evaluated in person. The presence or absence of dementia was determined solely on the basis of the neurologist’s and the medical officer’s interview with the families of 18 subjects (3.7%) who died between screening and clinical evaluation, and 71 subjects (14.5%) who were alive but refused or were unavailable for examination.

There were 10 incident cases (2 with CDR = 0.5 and 8 with CDR  $\geq 1$ ) of probable or possible AD; a single additional incident case of probable vascular dementia is excluded from this report. Seven of these 10 subjects were cognitively testable at follow-up; their HMSE scores ranged from 11/30 to 24/30, with a mean (SD) score of 15.7 (4.8). The crude (i.e., unadjusted) overall incidence rate, with 95% confidence intervals, per 1000 person–years was 1.74 (0.84 to 3.20) for AD with CDR  $\geq 0.5$  in those aged  $\geq 55$  and 3.24 (1.48 to 6.14) in those aged  $\geq 65$ . Age-specific incidence rates, by sex, of AD with CDR  $\geq 0.5$  in the Ballabgarh and Monongahela Valley cohorts are shown in table 2. Age-specific incidence rates in Ballabgarh were lower than in the Monongahela Valley for age groups 65 to 74 ( $p = 0.003$ ) and 75 to 84 ( $p = 0.002$ ), but not different among the  $\geq 85$  age groups ( $p = 0.150$ ) in which the samples and the number of cases were the smallest. Standardized against the age distribution of the US population (according to the 1990 US Census<sup>24</sup>), the overall AD incidence rate among those aged  $\geq 65$  years was 4.70 per 1000 person–years in Ballabgarh; the corresponding rate in the Monongahela Valley was 17.5 per 1000 person–years.

**Discussion.** We previously reported the development of standardized study methods and instruments and the prevalence rates for dementia (including AD) in the rural, largely illiterate, Hindi-speaking population in Ballabgarh, India. We now report the results of a 2-year incidence survey of AD in the same community. Because incidence reflects the true rate of disease occurrence, comparing incidence among populations allows hypotheses to be generated regarding differential distributions of risk and protective factors. Suggestions that the incidence of AD is lower in Asia than in Europe and

**Table 2** Incidence rates (per 1000 person-years) of AD with Clinical Dementia Rating  $\geq 0.5$  in Ballabgarh (India) and the Monongahela Valley (USA)

Age group	Ballabgarh cohort, India						Monongahela Valley cohort, USA*					
	Men			Women			Total			Total		
	Cases	Person-years	Rate (95% CI)	Cases	Person-years	Rate (95% CI)	Cases	Person-years	Rate (95% CI)	Cases	Person-years	Rate (95% CI)
55–64	0	1219.57	0 (0.00–3.03)	1	1321.17	0.76 (0.02–4.22)	1	2540.74	0.39 (0.01–2.19)	N/A	N/A	N/A
65–74	2	1334.71	1.50 (0.18–5.41)	1	1120.28	0.89 (0.02–4.97)	3	2454.99	1.22 (0.25–3.57)	24	3522.63	6.8 (4.34–10.14)
75–84	2	408.63	4.89 (0.59–17.67)	1	213.08	4.69 (0.11–26.14)	3	621.71	4.82 (1.00–14.11)	99	3830.70	25.8 (21.00–31.46)
$\geq 85$	2	86.71	23.06 (2.79–83.27)	1	34.18	29.25 (0.74–162.95)	3	120.89	24.81 (5.12–72.54)	30	564.86	53.1 (35.83–75.82)
Total $\geq 55$	6	3049.98	1.97 (0.72–4.28)	4	2688.71	1.49 (0.40–3.81)	10	5738.33	1.74 (0.84–3.20)	N/A	N/A	N/A
Total $\geq 65$	6	1620.26	3.70 (1.36–8.01)	3	1159.84	2.59 (0.53–7.56)	9	2780.10	3.24 (1.48–6.14)	153	7918.19	19.32 (16.49–22.6)

\* Monongahela Valley cohort was aged  $\geq 65$ .

North America<sup>2</sup> have in fact been based on very few Asian incidence studies of AD: one from Japan,<sup>10</sup> one from China,<sup>9</sup> and one from Taiwan,<sup>11</sup> reporting rates ranging from 5.1 to 8.9 per 1000 person-years among those aged  $\geq 65$ . Further, not all Asian countries are “developing,” and natives of South Asia (e.g., India), although non-white, are genetically Caucasoid.<sup>26</sup> The overall AD incidence rate among those aged  $\geq 65$  years in Ballabgarh, standardized against the age distribution of the 1990 US population, was 4.7 per 1000 person-years, considerably lower than the 17.5 found by using similar methods and criteria<sup>22</sup> in our largely white reference US population in the Monongahela Valley of Pennsylvania.<sup>17</sup> Before generalizing the Ballabgarh data to the entire Indian subcontinent, it should be noted that rates in this cohort are based on a small number of cases and limited follow-up. Most likely, there are substantial regional differences in AD incidence within the heterogeneous population of India.

As previously discussed in our report of low prevalence of AD in Ballabgarh,<sup>8</sup> a major challenge to studying AD in this community was the lack of dementia screening instruments that were in the local dialect, culturally appropriate, suitable for testing illiterate individuals, and also comparable to the tests being used in the reference US population of the Monongahela Valley.<sup>27</sup> The first 3 years of our study were in fact devoted to developing such instruments.<sup>13–15</sup> The illiteracy of three-quarters of our cohort, raising concern about the possibility of false positive cognitive screens, was part of our motivation for concomitantly collecting functional ability information from subjects’ families. The fact that all older adults in this community lived with their families allowed us always to question a relative, which was particularly useful when subjects were cognitively untestable for any reason or even recently deceased. Dementia was diagnosed, using standard DSM and CDR criteria, when there was a history or evidence of both cognitive and functional decline sufficient to interfere with daily functioning. It is possible that very mild dementias were underestimated because

the daily functional demands on older adults in rural India are limited by their living with, and being cared for, by their families. Further, they live in a “low-tech” environment that does not include, for example, the daily use of telephones, bank accounts, or supermarkets. Finally, even when they recognized certain functional limitations in the subjects, family members may have under-reported them out of traditional respect or low expectations of the elderly, or dismissed them as reflective of normal aging.

There are other, possibly inter-related, reasons for the low incidence of AD in the Ballabgarh cohort. Low average life expectancy in India, with fewer persons living into age of risk, might reduce incidence, especially if there is selectively earlier mortality of those at increased risk. Low incidence rates may also suggest the presence of underlying protective factors, or the absence of underlying risk factors. The frequency of the *APOE\*4* allele, a known risk factor for AD, is low (0.073) in the elderly Ballabgarh cohort as compared with the Monongahela Valley cohort (0.11)<sup>26</sup> and other western populations, perhaps because of selective survival of noncarriers of the *E\*4* allele. Notably, the very low educational level of this population, often considered a risk factor for AD,<sup>20</sup> did not appear to be reflected in high incidence rates. However, given the relatively short duration of follow-up in our study, the small number of incident cases, the wide confidence intervals, and our stated concerns about potential under-reporting of mild disability, we urge caution in the interpretation and generalization of our results. Future research might include large samples, longer follow-up, and multiple study sites within the Indian subcontinent. The potential presence of unique protective factors, such as those related to diet and environmental exposures, provide testable hypotheses for future investigation.

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