Prevalence and Risk Factors of Diabetic Nephropathy in an Urban South Indian Population

The Chennai Urban Rural Epidemiology Study (CURES 45)

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OBJECTIVE — The aim of this study was to determine the prevalence of diabetic nephropathy among urban Asian-Indian type 2 diabetic subjects.

RESEARCH DESIGN AND METHODS — Type 2 diabetic subjects (n = 1,716), inclusive of known diabetic subjects (KD subjects) (1,363 of 1,529; response rate 89.1%) and randomly selected newly diagnosed diabetic subjects (NDD subjects) (n = 353) were selected from the Chennai Urban Rural Epidemiology Study (CURES). Microalbuminuria was estimated by immunoturbidometric assay and diagnosed if albumin excretion was between 30 and 299 μg/mg of creatinine, and overt nephropathy was diagnosed if albumin excretion was ≥300 μg/mg of creatinine in the presence of diabetic retinopathy, which was assessed by stereoscopic retinal color photography.

RESULTS — The prevalence of overt nephropathy was 2.2% (95% CI 1.51–2.91). Microalbuminuria was present in 26.9% (24.8–28.9). Compared with the NDD subjects, KD subjects had greater prevalence rates of both microalbuminuria with retinopathy and overt nephropathy (8.4 vs. 1.4%, $P < 0.001$; and 2.6 vs. 0.8%, $P = 0.043$, respectively). Logistic regression analysis showed that A1C (odds ratio 1.325 [95% CI 1.256–1.399], $P < 0.001$), smoking (odds ratio 1.464, $P = 0.011$), duration of diabetes (1.023, $P = 0.046$), systolic blood pressure (1.020, $P < 0.001$), and diastolic blood pressure (1.016, $P = 0.022$) were associated with microalbuminuria. A1C (1.483, $P < 0.0001$), duration of diabetes (1.073, $P = 0.003$), and systolic blood pressure (1.031, $P = 0.004$) were associated with overt nephropathy.

CONCLUSIONS — The results of the study suggest that in urban Asian Indians, the prevalence of overt nephropathy and microalbuminuria was 2.2 and 26.9%, respectively. Duration of diabetes, A1C, and systolic blood pressure were the common risk factors for overt nephropathy and microalbuminuria.

Diabetes Care 30:2019–2024, 2007

Diabetic nephropathy is the leading cause of end-stage renal disease (ESRD) worldwide, and it is estimated that ~20% of type 2 diabetic patients reach ESRD during their lifetime (1). Kidney disease in diabetic patients is clinically characterized by increasing rates of urinary albumin excretion, starting from normoalbuminuria, which progresses to microalbuminuria, macroalbuminuria, and eventually to ESRD. Microalbuminuria is the earliest clinically detectable stage of diabetic kidney disease at which appropriate interventions can retard, or reverse, the progress of the disease.

According to the most recent estimates published in the *Diabetes Atlas 2006* (2), India has the largest number of diabetic patients in the world, estimated to be ~40.9 million in the year 2007 and expected to increase to ~69.9 million by the year 2025. Type 2 diabetes in Asian Indians differs from that in Europeans in several aspects: the onset is at a younger age, obesity is less common, and genetic factors appear to be more common (3). Some studies (4–6) conducted in migrant Asian Indians in the U.K. and Europe have reported increased prevalence of diabetic nephropathy compared with white Caucasians. The few studies published on the prevalence of diabetic nephropathy in India have all been clinic based (7,8). Indeed, the *Diabetes Atlas 2006* (2) does not list a single population-based study on diabetic nephropathy from South Asia. This article reports on the first population-based data on the prevalence of diabetic nephropathy in India.

RESEARCH DESIGN AND METHODS

— Study subjects were recruited from the Chennai Urban Rural Epidemiology Study (CURES), conducted on a representative population of Chennai (formerly Madras) in southern India, the fourth largest city in India with a population of ~5 million. The city of Chennai is divided into 155 corporation wards representing a socioeconomically diverse group. The methodology of the study has been published elsewhere (9). Briefly, in phase 1 of CURES (urban component), 26,001 individuals aged ≥20 years were screened for diabetes using a systematic sampling technique from 46 corporation wards representative of the various social tiers in Chennai. The selection criterion was taken as 20 years of age due to younger age at onset of type 2 diabetes in Indians (9). Self-reported diabetic subjects identified in phase 1 (n =

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Received for publication 18 December 2006 and accepted in revised form 2 May 2007.

Published ahead of print at http://care.diabetesjournals.org on 8 May 2007. DOI: 10.2337/dc06-2554.

Abbreviations: ACEI, ACE inhibitor; ARB, angiotensin receptor blocker; CURES, Chennai Urban Rural Epidemiology Study; ESRD, end-stage renal disease.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—*Prevalence of microalbuminuria and macroalbuminuria in the study population*

Groups	Overall diabetes	NDD	KD	*P* value for KD vs. NDD
n	1,716	353	1,363	
Microalbuminuria				
Overall	462 (26.9)	84 (23.8)	378 (27.7)	NS
With retinopathy	119 (6.9)	5 (1.4)	114 (8.4)	<0.001
Without retinopathy	343 (20.0)	79 (22.4)	264 (19.4)	NS
Overt nephropathy (macroalbuminuria with retinopathy)	38 (2.2)	3 (0.8)	35 (2.6)	0.043
Macroalbuminuria without retinopathy	53 (3.1)	10 (2.8)	43 (3.2)	NS

Data are *n* (%). NS, not significant.

1,529) were classified as known diabetic subjects (KD subjects). Fasting capillary blood glucose was determined using a One Touch Basic glucose meter (LifeScan, Johnson & Johnson, Milpitas, CA) in all subjects. Diabetes was diagnosed using American Diabetes Association criteria (10).

In phase 2 of CURES, all the KD subjects ($n = 1,529$) were invited to our center for detailed studies on vascular complications, and 1,363 consented for both retinal examination and estimation of microalbuminuria (response rate: 89.1%). In addition, 15% percent of subjects with impaired fasting glucose and 10% of subjects with normal fasting glucose in phase 1 were requested to take an oral glucose tolerance test. Thirty-seven of the former group and 14 of the latter group who were detected to have diabetes according to World Health Organization Consulting Group criteria (2-h plasma glucose ≥11.1 mmol/l) (11) were added to the 320 randomly chosen newly detected diabetic subjects (NDD subjects) from phase 1 of the study. Of the total 371 NDD subjects, 353 consented for this study (response rate: 95.1%). Thus, the final study numbers were 1,716 diabetic subjects (KD: 1,363 + NDD: 353). The institutional ethics committee approval was obtained, and informed consent was obtained from all study subjects.

Clinical and biochemical studies

Measurements of weight, height, and waist circumference were obtained using standardized techniques. The BMI was calculated using the following formula: weight (kg)/height (m^2). Blood pressure was recorded in the sitting position in the right arm with a mercury sphygmomanometer (Diamond Deluxe Industrial Electronics and Products, Pune, India) and rounded off to the nearest 2 mmHg. Two readings were taken 5 min apart, and the mean of the two was taken as the final blood pressure reading.

A fasting blood sample was taken for estimation of plasma glucose and serum lipids using a Hitachi 912 autoanalyser (Roche Diagnostics, Mannheim, Germany). A1C was measured by the high-performance liquid chromatography method using the Variant machine (Bio-Rad, Hercules, California).

Estimation of microalbuminuria

Microalbumin concentration was measured in a fasting urine sample using a immunoturbidometric assay (Hitachi 902 autoanalyser; Roche Diagnostics). The mean inter- and intra-assay coefficients of variation were 3.5 and 4.2%, respectively.

Retinopathy

The ocular fundi were photographed using four-field stereo color retinal photography (Zeiss FF 450 plus camera). Photographs were graded by an ophthalmologist (R.M.). The minimum criterion for diagnosis of diabetic retinopathy was the presence of at least one definite microaneurysm in any field photographed. Photographs were assessed and assigned a retinopathy level, and the final diagnosis for each patient was determined from the grading of the worse eye according to the Early Treatment Diabetic Retinopathy Study criteria for severity of an individual eye (12).

Definitions

Hypertension. Subjects with self-reported hypertension and those who had a systolic blood pressure of ≥140 mmHg and/or diastolic blood pressure of ≥90 mmHg (13) were considered to have hypertension.

Smoking. Individuals were classified as nonsmokers and current smokers.

Microalbuminuria. Microalbuminuria was diagnosed if the albumin excretion was between 30 and 299 μg/mg of creatinine (8). Overt nephropathy was diagnosed if albumin excretion was ≥300 μg/mg of creatinine in the presence of diabetic retinopathy.

Statistical analysis

Data were expressed as means ± SD. Students *t* test or one-way ANOVA (Tukey's honestly significant difference comparison) was used to compare continuous variables, and the χ^2 test was used to compare proportions among groups. Logistic regression analysis was done using either microalbuminuria or overt nephropathy as the dependent variable to identify the risk factors. Subjects were also categorized based on the presence of retinopathy to study the risk factors for albuminuria with and without retinopathy. $P < 0.05$ was considered significant. All analysis was done using Windows-based SPSS statistical package (version 10.0; SPSS, Chicago, IL).

RESULTS — There were no significant differences in the baseline values between the 1,363 responders and the 166 nonresponders among the KD subjects (responders versus nonresponders: aged 52 ± 11 vs. 51 ± 12 years, $P = 0.27$; 46.3 vs. 51.7% male, $P = 0.20$; fasting plasma glucose 9.3 ± 4.3 vs. 9.5 ± 4.4 mmol/l, $P = 0.43$; systolic blood pressure 131 ± 22 vs. 130 ± 22 mmHg, $P = 0.581$; diastolic blood pressure 78 ± 12 vs. 77 ± 11 mmHg, $P = 0.31$).

The mean age of the total study population ($n = 1,716$) was 51 ± 11 years, and 44.7% ($n = 744$) were male subjects. Of the total 1,716 diabetic subjects studied, 462 (26.9% [95% CI 24.8–28.9]) had microalbuminuria, 38 (2.2% [1.51–2.91]) had overt nephropathy (i.e., macroalbuminuria with retinopathy), and 53 (3.1% [3.27–3.91]) had macroalbuminuria without retinopathy (Table 1). Compared with the NDD subjects, KD subjects had greater prevalence rates of both microalbuminuria with retinopathy and overt nephropathy (8.4 vs. 1.4%, $P < 0.001$; and 2.6 vs. 0.8%, $P = 0.043$, respectively).

Table 2 presents the clinical and biochemical characteristics of the study subjects. Subjects with overt nephropathy

Table 2—*Clinical and biochemical characteristics of the study population*

Parameters	Normoalbuminuria	Microalbuminuria	Overt nephropathy (macroalbuminuria with retinopathy)	*P* value for trend
n	1,163	462	38	
Age (years)	50 ± 11	52 ± 11*	57 ± 9†‡	<0.0001
Sex (male)	503 (43.3)	225 (48.7)	16 (42.1)	0.181
Duration of diabetes (years)	4 ± 5	5 ± 6§	10 ± 6§‖	<0.0001
Smoking	183 (15.7)	100 (21.6)	7 (18.4)	0.044
BMI (kg/m^2)	25.41 ± 4.24	25.00 ± 4.35	23.61 ± 5.04*	0.004
Waist circumference (cm)	90 ± 10	91 ± 10	89 ± 14	0.864
Systolic blood pressure (mmHg)	126 ± 18	135 ± 24§	142 ± 24§	<0.0001
Diastolic blood pressure (mmHg)	76 ± 11	80 ± 12	79 ± 14	<0.0001
Fasting plasma glucose (mmol/l)	8.2 ± 3.6	10.2 ± 3.9§	12.6 ± 4.3§‖	<0.0001
A1C (%)	8.2 ± 2.1	9.5 ± 2.3§	11.0 ± 2.3§‖	<0.0001
Hypertension (%)	40.8	59.7	86.8	<0.001

Data are means ± SD or *n* (%), unless otherwise indicated. *$P < 0.05$ vs. normal; †$P < 0.01$ vs. normal; ‡$P < 0.05$ vs. microalbuminuria; §$P < 0.001$ vs. normal; ‖$P < 0.001$ vs. microalbuminuria.

were older and had a longer duration of diabetes (*P* for trend <0.0001). Systolic and diastolic blood pressure, fasting plasma glucose, and A1C values were highest among the overt nephropathy group, followed by microalbuminuric and normoalbuminuric subjects (*P* for trend <0.0001). Prevalence of hypertension was higher among subjects with microalbuminuria and overt nephropathy compared with the normoalbuminuric group ($P < 0.001$). Subjects with microalbuminuria who had retinopathy had lower BMI (23.54 ± 3.71 vs. 25.51 ± 4.45 kg/m^2) and waist circumference (88 ± 9 vs. 92 ± 11 cm) but higher fasting plasma glucose (12.1 ± 4.3 vs. 9.6 ± 3.6 mmol/l) and A1C values (10.6 ± 2.0 vs. 9.2 ± 2.2%) and longer duration of diabetes (8 ± 6 vs. 5 ± 5 years) compared with those without retinopathy. Other parameters like age and blood pressure did not vary significantly between the study groups.

Prevalence of microalbuminuria and overt nephropathy was computed in relation to duration of diabetes and A1C. There was an increase in the prevalence of microalbuminuria with the increase in duration of diabetes (duration of diabetes <1.0 year: 22.3%, 1–5 years: 25.7%, 6–10 years: 33.5%, and >10 years: 30.2%; *P* for trend <0.001). There was a significant increase in the prevalence of overt nephropathy with the increase in duration of diabetes (duration of diabetes <1.0 year: 0.7%, 1–5 years: 1.1%, 6–10 years: 3.5%, and >10 years: 7.7%; *P* for trend <0.001). Prevalence of both microalbuminuria (A1C <7.0%: 14.5%, 7.0–8.9%: 22.6%, 9–10.9%: 35.1%, and >10.9%: 43.4%, and overt nephropathy (A1C <7.0%: 0.2%, 7.0–8.9%: 1.1%, 9–10.9%: 3.5%, and >10.9%: 5.5%) increased with the increase in A1C levels (*P* for trend <0.001).

Prevalence of microalbuminuria and overt nephropathy was computed in relation to use of antihypertensive drugs. Of 1,716 subjects, 425 were on antihypertensive medications. Prevalence of microalbuminuria and overt nephropathy (antihypertensive drug users versus others: microlbuminuria: 33.9 vs. 24.6%, $P < 0.001$; overt nephropathy: 6.6 vs. 0.8%, $P < 0.001$) were higher in antihypertensive medication users. Subjects on antihypertensive medications were further categorized as ACE inhibitors (ACEIs)/angiotensin receptor blocker (ARB) users ($n = 121$) and others. There was no significant difference between these two groups with respect to microalbuminuria, whereas overt nephropathy was higher in those on ACEIs/ARBs (ACEI/ARB users vs. others: microalbuminuria: 35.5 vs. 33.2%, $P = 0.26$; overt nephropathy: 11.6 vs. 4.6%, $P = 0.004$).

There were 23 subjects, 21 with KD and 2 NDD, who had renal insufficiency defined as serum creatinine levels ≥1.5 mg/dl. Retinopathy was present in 7 of 21 (33.3%) of KD subjects, which included nonproliferative diabetic retinopathy in 4 and proliferative diabetic retinopathy in 3 subjects. Neither of the NDD subjects with renal insufficiency had retinopathy.

Regression analysis revealed that A1C ($P < 0.001$), smoking ($P = 0.011$), duration of diabetes ($P = 0.046$), systolic blood pressure ($P < 0.0001$), and diastolic blood pressure ($P = 0.022$) were associated with microalbuminuria. Regression analysis was carried out after categorizing microalbuminuric patients with and without retinopathy. A1C and systolic blood pressure were common risk factors for microalbuminuria with retinopathy (A1C odds ratio 1.528 [95% CI 1.393–1.676], $P < 0.001$; systolic blood pressure 1.020 [1.006–1.035], $P = 0.007$) as well as without retinopathy (A1C 1.238 [1.165–1.315], $P < 0.001$; systolic blood pressure 1.021 [1.012–1.031], $P < 0.001$). Smoking (1.613 [1.152–2.259], $P = 0.005$) and diastolic blood pressure (1.018 [1.002–1.034], $P = 0.028$) showed association only with microalbuminuria without retinopathy, while duration of diabetes (1.085 [1.047–1.124], $P < 0.001$) showed an association only with microalbuminuria with retinopathy.

Overt nephropathy showed significant association with A1C ($P < 0.0001$), duration of diabetes ($P = 0.003$), and systolic blood pressure ($P = 0.004$) (Table 3). None of the risk factors except diastolic blood pressure showed an association with macroalbuminuria without retinopathy (odds ratio 1.034 [95% CI 1.002–1.068], $P = 0.048$).

Table 4 compares the prevalence of microalbuminuria and nephropathy in different populations (14–19). The prevalence of overt nephropathy in Indians appears to be lower, while that of microalbuminuria is comparable to that reported earlier studies in other populations.

Table 3—*Multiple logistic regression analysis*

Dependent variable and parameters	Odds ratio (95% CI)	*P* value
Overt nephropathy		
Age	1.023 (0.983–1.065)	0.263
Smoking (yes = 1, no = 0)	1.221 (0.512–2.914)	0.652
A1C	1.483 (1.297–1.695)	<0.0001
Duration of diabetes	1.073 (1.024–1.125)	0.003
Systolic blood pressure	1.031 (1.010–1.053)	0.004
Diastolic blood pressure	0.973 (0.936–1.011)	0.165
Microalbuminuria		
Age	1.002 (0.990–1.015)	0.731
Smoking (yes = 1, no = 0)	1.464 (1.091–2.914)	0.011
A1C	1.325 (1.256–1.399)	<0.0001
Duration of diabetes	1.023 (1.001–1.047)	0.046
Systolic blood pressure	1.020 (1.012–1.028)	<0.0001
Diastolic blood pressure	1.016 (1.002–1.031)	0.022

CONCLUSIONS — This, to our knowledge, is the first population-based study from India on the prevalence of, and risk factors for, diabetic nephropathy. The main findings of this study are that in urban Asian Indians *1*) prevalence of overt diabetic nephropathy was 2.2% and that of microalbuminuria 26.9% and *2*) risk factors for diabetic nephropathy include A1C, duration of diabetes, and systolic blood pressure, while for microalbuminuria smoking and diastolic blood pressure were also risk factors.

We compared our prevalence rates with other population-based studies on diabetic nephropathy. Prevalence of nephropathy was extremely high among Nauruans (75% in self-reported KD subjects and 63% in NDD subjects) (20) and Pima Indians (47%) (21). A population-based study in Egypt recorded a prevalence of albuminuria of 21% among KD subjects (22). It had been earlier reported that migrant Indians have a higher prevalence of diabetic nephropathy compared with the host populations (4–6,23). Compared with these studies and others presented in Table 4, our study shows a lower prevalence of diabetic nephropathy.

The large differences observed in the prevalence of nephropathy among different studies could be attributed to the differences in study design and methodologies adopted for defining the disease. Many of the studies were clinic based, and this could have introduced a referral bias. In addition, most of these studies have not included retinopathy in the definition for diagnosis of diabetic nephropathy. The strength of our study is that it is population based and has included diabetic retinopathy in the definition with the latter diagnosed using retinal color photography. These differences in methodologies used could probably explain the lower prevalence of overt nephropathy observed in our study. However, one cannot rule out the possibility of true ethnic differences in the prevalence of nephropathy due to decreased susceptibility to microvascular disease in native Asian Indians. In support of this, in an earlier study (24) we had reported that the prevalence of diabetic retinopathy is lower in Indians compared with other ethnic groups. These findings, if confirmed by future studies, would be of great interest, as Asian Indians are known to have much higher rates of premature coronary artery disease compared with other ethnic groups (25). There could be several explanations for the lower prevalence of microvascular complications noted in our studies. It is possible that due to wide publicity of the Diabetes Control and Complications Trial and the U.K. Prospective Diabetes Study results control of diabetes is improving globally, including in India, which could have resulted in lower rates of microvascular complications. Second, the prevalence of hypertension is known to be lower in native south Asians, and this may afford a relative protection against diabetic kidney disease (26). Finally, consequent to the greater awareness of the nephroprotective action of ACEIs and ARBs, usage of these drugs for preventing nephropathy has increased. This could also affect the prevalence rates of nephropathy compared with older studies. These are, however, purely speculative and need to be addressed by future, preferably longitudinal, studies.

The criteria used for the diagnosis of

Table 4—*Prevalence of nephropathy and microalbuminuria in type 2 diabetes in different population-based studies*

Author (reference)	Place, year	Sample size, type of study	Prevalence of microalbuminuria (criteria)	Prevalence of macroalbuminuria (criteria)
Bruno et al. (14)	Italy, 1996	1,574, population based	32.1% (20–200 μg/min)	17.6% (>200 μg/min)
Gatling et al. (15)	Poole, U.K., 1988	450, population based	—	7.0% (>300 mg/g creatinine)
Neil et al. (16)	Oxford, U.K., 1993	246, population based	15% (>40 mg/l)	4% (>200 mg/l)
Wirta et al. (17)	Finland, 1995	188, population based	NDD subjects: 29%; KD subjects: 27% (30–300 mg/24 h)	NDD subjects: 4%; KD subjects: 7% (>300 mg/24 h)
Collins et al. (18)	Western Samoa, 1995	162, population based	NDD subjects: 22.0%; KD subjects: 17.2% (30–299 μg/ml)	NDD subjects 3.9%; KD subjects: 6.3% (≥300 μg/ml)
Klein et al. (19)	Wisconsin, 1993	798, population based	25.9% (30–299 mg/l)	16.0% (>300 mg/l)
Unnikrishnan et al. (present study)	Chennai, India, 2004	1,716, population based	26.9% (albumin excretion: 30–299 μg/mg of creatinine)	2.2% (albumin excretion ≥300 μg/mg of creatinine in the presence of diabetic retinopathy)

overt nephropathy in this study included retinopathy, as it makes the diagnosis of diabetic nephropathy more specific. However, we compared the risk factors for albuminuria with and without retinopathy to highlight the possible differences in risk factors. Poor glycemic control, long duration of diabetes, and systolic blood pressure were the risk factors for overt nephropathy. This is similar to results reported in several other studies (1,27).

In the subset of individuals who had macroalbuminuria without retinopathy (possibly suggestive of nondiabetic renal disease), diastolic blood pressure was the only associated risk factor. Moreover, the fact that the prevalence of this entity was higher among the newly detected diabetic subjects suggests that a significant proportion of these individuals could have nonspecific proteinuria/macroalbuminuria associated with uncontrolled hyperglycemia. However, some may indeed have diabetic nephropathy, as studies have shown that some patients in this category have histological changes of diabetic nephropathy (28,29). The prevalence of microalbuminuria in this study was not remarkably different from that reported in other studies. For microalbuminuria, the risk factors were similar to those for overt nephropathy, but smoking and diastolic blood pressures were additional risk factors.

The major limitation of the study is that being an epidemiological study, due to logistic reasons, only one measure of albuminuria was done in spot urine. However, this may not alter the inferences drawn, as most epidemiological studies have only used a single measure. The prevalence of microalbuminuria could, however, have been lower if repeated measurements of albumin were done, as has been shown in clinic-based studies (30). Another limitation is that renal biopsies were not performed, as it is difficult to carry out these procedures in population-based studies due to logistic and ethical reasons.

This study is of importance given the growing epidemic of diabetes in India. It is estimated that as of the year 2007, there are 40.9 million diabetic individuals in India (2). The prevalence of overt nephropathy in this study (i.e., 2.2%), when translated into numbers, would imply that >850,000 individuals in India have overt nephropathy. Most patients with macroproteinuria eventually reach ESRD (1,31). The cost of a renal transplant in India is ~$4,760 U.S. (Rs. 2,00,000), which is unaffordable to the majority of people in India (32). The absolute number of subjects with diabetic nephropathy thus presents an economic burden to both the individual and the society. The large pool of microalbuminuria also suggests that there could be large increases in overt nephropathy with time, unless aggressive control of diabetes and hypertension is initiated.

In conclusion, the results of this study suggest that the prevalence of overt diabetic nephropathy in Asian Indians is lower, while that of microalbuminuria is comparable to that reported in other ethnic groups. Risk factors for overt nephropathy are found to be poor glycemic control, long duration of diabetes, and systolic blood pressure, while for microalbuminuria smoking and diastolic blood pressure were additional risk factors. There is an urgent need to launch a national diabetes control program to tackle the potential economic burden due to diabetic nephropathy in India.

Acknowledgments— The authors thank the Chennai Willingdon Corporate Foundation for their support for the CURES field studies.

This is the 45th report from CURES.

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