RESEARCH

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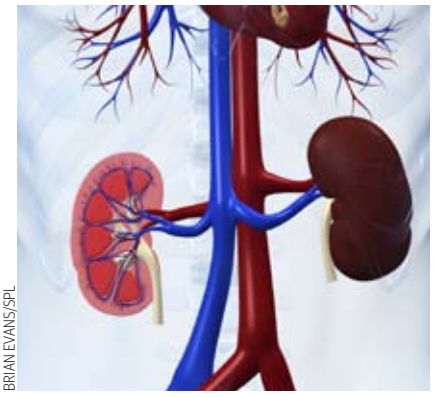


BRIAN EVANS/SPL

THIS WEEK'S RESEARCH QUESTIONS

767 Does a low estimated glomerular filtration rate predict risk of future stroke and, if so, to what extent?

768 How is chronic kidney disease stage associated with risk of major cardiovascular disease and non-vascular mortality among apparently healthy adults?

769 Does preventive treatment with β blockers, brief behavioural therapy, or their combination improve outcomes of an optimised acute migraine drug regimen?

770 Are common pathogenic bacteria associated with acute wheezy episodes in young children and, if so, is the association independent of viral infection?

771 What sociodemographic patterns of risk factors for non-communicable diseases are seen in rural Indian people?

Kidney disease and vascular disorders

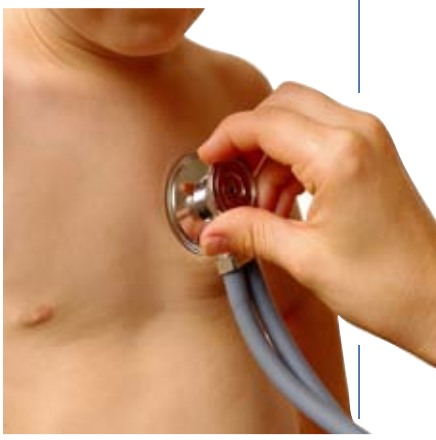
Two pieces of research published in the *BMJ* this week look at the importance of chronic kidney disease in determining a patient's risk of coronary heart disease and stroke.

The first study, by Meng Lee and colleagues, discovered that the risk of incident stroke among people with an estimated glomerular filtration rate of less than 60 ml/min/1.73 m^2 (normal range 100-130 ml/min/1.73m^2) was 43% higher than in those with an estimated glomerular filtration rate of 60-90 ml/min/1.73 m^2 (p 767). The second study, by Emanuele Di Angelantonio and colleagues, found that even the earliest stages of chronic kidney disease are linked to a higher risk of coronary heart disease (p 768).

These two studies were quite different in design and scope: the first was a retrospective meta-analysis, but of prospective studies, including 284 672 participants from a variety of countries like the United States and Japan, whereas the second was a prospective cohort study in 16 958 individuals from Reykjavik, Iceland. Both, however, add important information on risk stratification of patients with chronic kidney disease.

Is it just a viral wheeze?

Received wisdom is that there's no need to prescribe antibiotics for wheeze in young children because any underlying infection is probably viral. But Hans Bisgaard and colleagues' analysis from the Copenhagen Prospective Study on Asthma in Childhood provides evidence to the contrary (p 770). They examined around 900 throat aspirate samples from about 300 wheezing babies and toddlers and found that wheezy episodes defined—at medical examination—as audible wheeze, prolonged expiration, or ronchi on auscultation were significantly and independently associated with both viral infection and bacterial infection (mostly from *H influenzae*, *M catarrhalis*, and *S pneumonia)*. The authors now recommend randomised clinical trials to evaluate the effectiveness of antibiotics in wheezy children.



Preventing migraine

As the United States gets to grips at last with the concept and practice of comparative effectiveness research (*BMJ* 2010;341:c3615) the *BMJ* continues to prioritise randomised controlled trials that compare different treatments head to head, rather than simply against placebo. Kenneth A Holroyd and colleagues from Ohio did such a trial in patients with at least three disabling migraines a month despite taking "optimal" treatment with a 5-$HT_{1B/D}$ agonist or triptan, plus an NSAID or antiemetic drug as required (p 769). Participants were randomised to one of four added treatments: preventive (β blocker) treatment, placebo, behavioural migraine management (comprising group education, relaxation, and cognitive behaviour therapy) plus placebo, or behavioural migraine management plus preventive treatment. For the group that received a β blocker plus behavioural management, compared with each of the three remaining treatments, the number needed to treat to at least halve the number of migraines a month ranged between 2.6 and 3.1.

LATEST RESEARCH: For these and other new research articles see http://www.bmj.com/channels/research.dtl

England-wide variation in rates of caesarean section Adjusted rates of caesarean section in England vary from 14.9% to 32.1% of singleton births, according to Fiona Bragg and colleagues (doi:10.1136/bmj.c5065). Their evaluation of hospital episode statistics from 146 English NHS trusts pinned the cause of this variation on differences in the rates of emergency caesarean section between trusts.

Cerebral palsy and Apgar score Kari Kveim Lie and colleagues' study of 543 064 singleton births in Norway has shown that low Apgar score (<4) 5 minutes after birth is strongly associated with cerebral palsy diagnosed before the age of 5 years (doi:10.1136/bmj.c4990). Interestingly, the association was stronger in children with normal birth weight (≥2500 g) than in children with low birth weight (<1500 g).

Low glomerular filtration rate and risk of stroke: meta-analysis

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EDITORIAL
by Perkovic and Cass
RESEARCH, p 768

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STUDY QUESTION

Does a low estimated glomerular filtration rate (eGFR) predict risk of future stroke and if so to what extent?

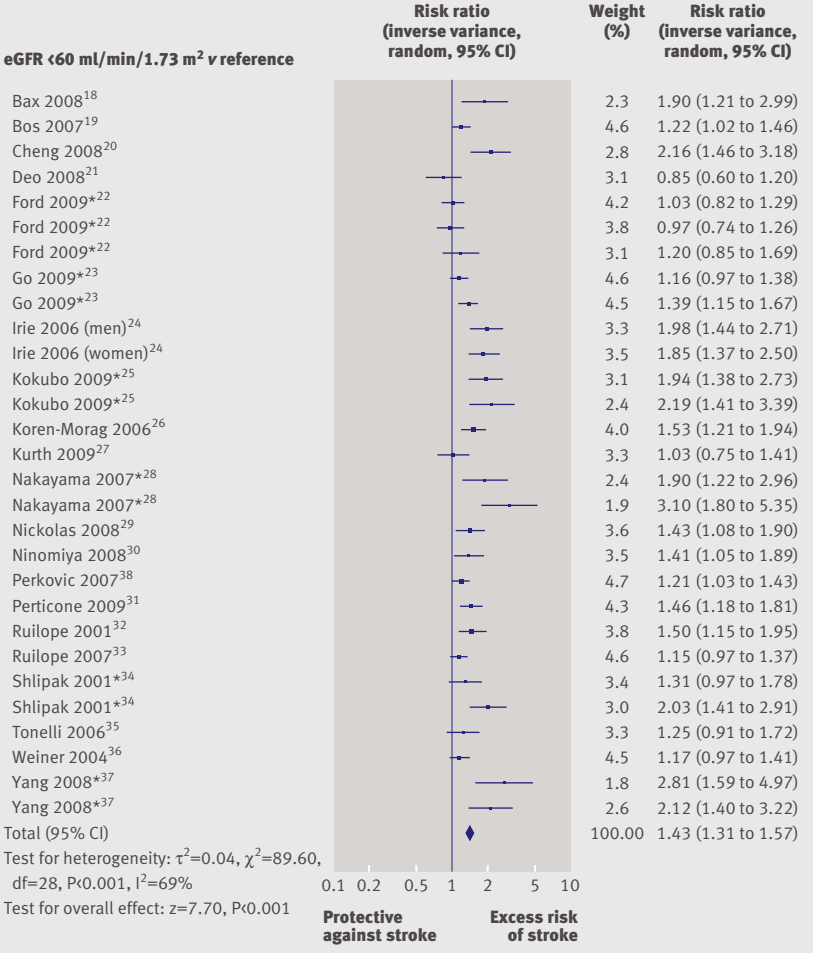
SUMMARY ANSWER

An eGFR ‹60 ml/min/1.73 m^2 independently conferred a 43% higher risk of future stroke when compared with a normal baseline eGFR.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

A meta-analysis showed that an eGFR ‹60 ml/min/1.73 m^2 was associated with all cause and cardiovascular mortality in the general population.
Our meta-analysis showed that people with a baseline eGFR ‹60 ml/min/1.73 m^2 had an independent risk of stroke that was 43% greater than people with a normal baseline eGFR.

RISK RATIO FOR ASSOCIATION OF ESTIMATED GLOMERULAR FILTRATION RATE ‹60 ML/MIN/1.73 M^2 AND RISK OF STROKE IN PROSPECTIVE COHORT STUDIES



Selection criteria for studies

We systematically searched PubMed (1966 to October 2009) and Embase (1947 to October 2009). Our inclusion criteria were studies that prospectively collected data within cohort studies or clinical trials, estimated glomerular filtration rate at baseline using the modification of diet in renal disease or Cockcroft-Gault equations, assessed incident stroke, had a follow-up of at least one year, reported quantitative estimates of the multivariate adjusted relative risk and 95% confidence interval for stroke associated with an eGFR of 60-90 ml/min/1.73 m^2 or ‹60 ml/min/1.73 m^2, or both.

Primary outcome(s)

Relative risk of incident stroke.

Main results and role of chance

Overall, 21 articles derived from 33 prospective studies: 14 articles assessed eGFR ‹60 ml/min/1.73 m^2 and seven assessed both ‹60 ml/min/1.73 m^2 and 60-90 ml/min/1.73 m^2 for a total of 284 672 participants (follow-up 3.2-15 years) with 7863 stroke events. Overall, incident stroke risk increased among participants with an eGFR ‹60 ml/min/1.73 m^2 (relative risk 1.43, 95% confidence interval 1.31 to 1.57; P‹0.001) but not among those with an eGRF of 60-90 ml/min/1.73 m^2 (1.07, 0.98 to 1.17; P=0.15).

Bias, confounding, and other reasons for caution

Significant heterogeneity existed between estimates among patients with an eGFR ‹60 ml/min/1.73 m^2 (P‹0.001). The funnel plots showed no major asymmetry except a relatively small degree of publication bias, with slight under-representation of small studies showing neutral or unexpected protective effects.

Study funding/potential competing interests

ML was supported by a grant from Chang Gung Memorial Hospital, Taiwan (CMRPG 660311, Taiwan). JLS was supported by the specialised programme on translational research in acute stroke (SPOTRIAS) award (P50 NS044378) from the National Institutes of Health, and BO was supported by University of California, Los Angeles-Resource Centers for Minority Aging Research under National Institutes of Health/National Institutes on Aging grant No P30-AG021684. The sponsors played no role in the study design, data collection and analysis, or decision to submit the article for publication.

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Chronic kidney disease and risk of major cardiovascular disease and non-vascular mortality: prospective population based cohort study

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EDITORIAL
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STUDY QUESTION What are the associations of chronic kidney disease stages with risk of major cardiovascular disease and non-vascular mortality among apparently healthy adults?

SUMMARY ANSWER Even the earliest stages of chronic kidney disease are associated with excess risk of subsequent coronary heart disease, and advanced stages of chronic kidney disease are also associated with non-vascular mortality, particularly deaths not attributed to cancer.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Among people with cardiovascular disease and in the general population, impaired kidney function has been associated with increased risk of cardiovascular disease and all cause mortality. Assessment of chronic kidney disease in addition to conventional risk factors only modestly improves prediction of risk for coronary heart disease.

Participants and setting

Men and women who were resident in Reykjavik, Iceland, and adjacent communities were recruited into the Reykjavik Prospective Study between 1967 and 1991.

Design, size, and duration

This was a prospective cohort study of 16 958 people without manifest vascular disease at baseline and with available information on stage of chronic kidney disease (defined by both estimated glomerular filtration rate (eGFR) and urinary protein) at study entry. During a median follow-up of 24 years, 4010 coronary heart disease outcomes and 3875 deaths from non-vascular causes were recorded.

Main results and the role of chance

Compared with the reference group (eGFR 75-89 ml/min/1.73 m^2 and no proteinuria), people with lower renal function within the normal range of eGFR did not have a significantly higher risk of coronary heart disease. By contrast, in 1210 (7%) participants with chronic kidney disease at entry, hazard ratios for coronary heart disease, adjusted for several conventional cardiovascular risk factors, were 1.55 (95% confidence interval 1.02 to 2.35) for stage 1, 1.72 (1.30 to 2.24) for stage 2, 1.39 (1.22 to 1.58) for stage 3a, 1.90 (1.22 to 2.96) for stage 3b, and 4.29 (1.78 to 10.32) for stage 4. Information on chronic kidney disease increased discrimination and reclassification indices for coronary heart disease when added to conventional risk factors (P<0.01), but the incremental gain provided by chronic kidney disease was lower than that provided by diabetes or smoking. Hazard ratios with chronic kidney disease were 0.97 (0.82 to 1.15) for cancer mortality and 1.26 (1.07 to 1.50) for other non-vascular mortality.

Bias, confounding, and other reasons for caution

The standard prediction equations used to estimate glomerular filtration rate were originally developed in patients with kidney disease. We used qualitative urinary dipstick methods routinely used in clinical practice, but quantitative methods should be more sensitive. Lack of correction for within person variability could have resulted in bias. We controlled for major cardiovascular risk factors on our models; however, as our study is observational, residual confounding remains possible.

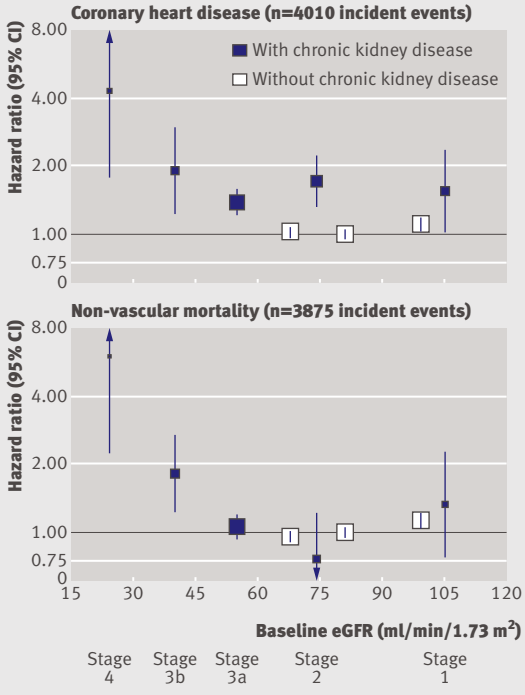
Generalisability to other populations

Our participants were of northern European descent, which may limit generalisability to other ethnicities.

Study funding/potential competing interests

This work is underpinned by a programme grant from the British Heart Foundation.

RENAL FUNCTION AND RISK OF CORONARY HEART DISEASE AND NON-VASCULAR MORTALITY



Hazard ratios adjusted for age, sex, smoking status, history of diabetes, total cholesterol, log triglycerides, systolic blood pressure, and body mass index; compared with people without chronic kidney disease with estimated glomerular filtration rate (eGFR) of 75-89 ml/min/1.73 m^2; and plotted against mean eGFR within each group. Size of data markers is proportional to inverse of variance of hazard ratios

Effect of preventive (β blocker) treatment, behavioural migraine management, or their combination on outcomes of optimised acute treatment in frequent migraine: randomised controlled trial

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STUDY QUESTION Does preventive treatment (β blocker), brief behavioural therapy (behavioural migraine management), or their combination improve the outcomes of an optimised acute migraine drug regimen in frequent migraine?

SUMMARY ANSWER The combined treatment, but not individual treatments alone, improved the outcomes of the optimised acute treatment regimen.

WHAT IS KNOWN AND WHAT THIS STUDY ADDS Preventive drug treatment and behavioural management each seem to yield moderate improvements in migraines, but their benefits remain unclear when they are administered with contemporary acute migraine treatment. Only the combination of preventive drug treatment and brief behavioural management improved outcomes compared with optimised acute treatment.

Design
We did a randomised controlled trial over 16 months to compare the benefits of adding four different preventive treatments to an optimised acute treatment regimen: preventive drug treatment, matched preventive drug placebo, behavioural migraine management plus placebo, or behavioural migraine management plus preventive drug.

Participants and setting
We included 232 adults (mean age 38 years; 79% female) who recorded at least three migraines with disability per 30 days (mean 5.5 migraines/30 days) during optimised acute treatment at two outpatient sites in Ohio, USA.

Primary outcome(s)
The primary outcome was change in the number of migraines per 30 days at month 10.

Main results and the role of chance
The change in the number of migraines per 30 days was larger (−3.3, 95% confidence interval −3.2 to −3.5) with the addition of combined preventive drug and behavioural management to optimised acute treatment than with the addition of any of the remaining three treatments, which did not differ among themselves in effectiveness.

Harms
After dose adjustment, 18/90 (20%) participants on preventive drug treatment and 9/86 (11%) participants on placebo (P=0.08) reported side effects.

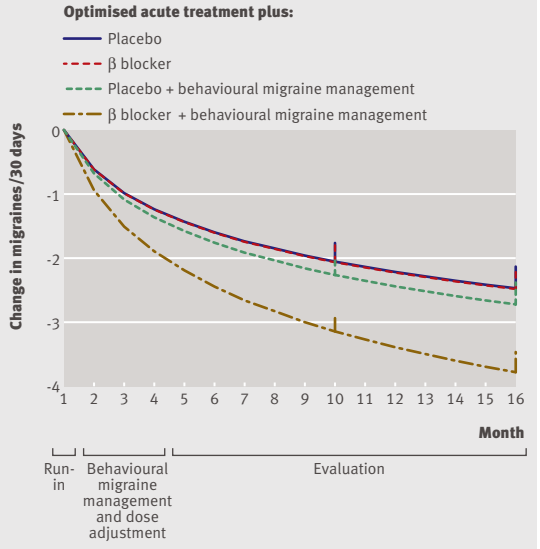
Bias, confounding, and other reasons for caution
In the absence of a comparison group that did not receive either optimised acute treatment or preventive treatment, the effectiveness of optimised acute treatment cannot be accurately assessed.

Generalisability to other populations
Results cannot be readily generalised to people with a primary diagnosis of medication overuse headaches or with a pain disorder other than migraine as their primary presenting problem. Limitations of insurance coverage or other financial considerations may constrain clinicians' ability to optimise acute drug treatment for migraine as was done in this trial.

Study funding/potential competing interests
Grant R01-NS-32374 from the National Institutes of Health provided primary support for this trial. Merck Pharmaceuticals and GlaxoSmithKline Pharmaceuticals (GSK) donated triptans for the trial, which was their only involvement. KAH has consulted for ENDO Pharmaceuticals and for Takeda Pharmaceuticals North America and has received an investigator initiated grant from ENDO Pharmaceuticals and support from the National Institutes of Health. CKC and FJO'D have received funding and honorariums from or consulted for Allergan, GSK, Merck, and UCB Pharma. GEC owns stock in Johnson and Johnson, Novartis, and Wyeth Pharmaceuticals.

Trial registration number
Clinical trials NCT00910689.

MEAN CHANGE IN NUMBER OF MIGRAINES PER 30 DAYS FROM RUN-IN OF OPTIMISED ACUTE TREATMENT ESTIMATED FOR EACH OF FOUR TREATMENTS



Vertical lines at months 10 and 16 indicate primary end point and longer term assessment point

Association of bacteria and viruses with wheezy episodes in young children: prospective birth cohort study

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STUDY QUESTION

Are common pathogenic bacteria associated with acute wheezy episodes in young children and, if so, is the association independent of viral infection?

SUMMARY ANSWER

Bacterial infection of the airways was significantly associated with acute wheezy episodes in young children. This association was independent of viral infection suggesting that bacterial infection may contribute separately to the burden of wheezy symptoms.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Acute wheezy episodes in young children are strongly associated with viral infections but there is no published evidence for an important role for bacterial infection. Despite this, antibiotics are widely used. This paper reports bacteria to be as strongly associated as viruses with acute wheezy episodes.

Participants and setting

Children of asthmatic mothers, aged from 4 weeks to 3 years, participating in the Copenhagen Prospective Study on Asthma in Childhood, Denmark.

Design, size, and duration

The Copenhagen Prospective Study on Asthma in Childhood recruited newborn infants between August 1998 and December 2001 and followed the children prospectively with daily records on symptoms up to age 3 years. The children were seen at the research clinic every six months and for evaluation of acute respiratory symptoms. We analysed airway aspirates collected at these visits for common pathogenic bacteria and viruses. We compared the frequency of bacterial and virus detection in the aspirates during wheezy episodes with that at planned visits without symptoms of lower respiratory tract infection.

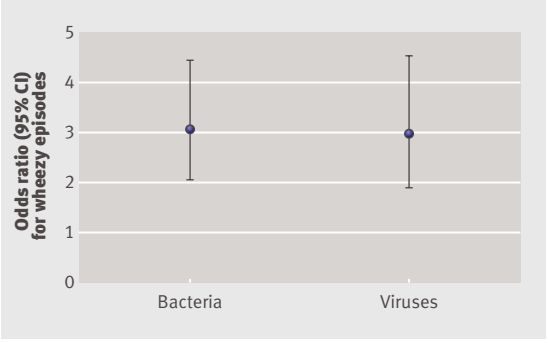
Main results and the role of chance

Overall, 984 samples (361 children) were analysed for bacteria, 844 (299 children) for viruses, and 696 (n=277) for both viruses and bacteria. Wheezy episodes were significantly associated with both viral infection and bacterial infection, with *H influenzae*, *M catarrhalis*, and *S pneumoniae* overall (odds ratio 2.9, 95% confidence interval 1.9 to 4.3; P<0.001). The associations of bacteria and viruses were independent of each other.

Bias, confounding, and other reasons for caution

Clinical diagnosis and sampling were done at the research clinic assuring a standardised approach thereby reducing the risk of misclassification of illness and variation in sampling quality. The children were brought to the clinic for diagnosis of acute respiratory episodes, including wheezy episodes and clinical pneumonia. Although the differentiation between clinical presentations of clinical pneumonia and wheezy episodes may be contested, the strengths of this study were that the diagnosis was made by the same doctors and in accordance with standard procedures, the sampling for pathogens was independent of diagnosis, and the diagnosis was independent of microbiological outcomes. Wheezy symptoms were monitored in daily diaries. This assured that wheezy episodes of a predefined duration led to clinic visits. Results were validated by restricted analysis of episodes with objective wheezing verified by auscultation. The longitudinal study design allowed wheezy participants to act as their own controls when without wheeze.

ASSOCIATION OF VIRUSES AND BACTERIA WITH WHEEZY EPISODES IN CHILDREN AGED UP TO 3 YEARS



Generalisability to other populations

The selection of asthmatic mothers and exclusion of premature babies limits the generalisability of the findings, which need to be replicated in population based studies. Also, our study design only allowed demonstration of a significant association between bacteria and wheezing symptoms but could not definitively prove the causative role of bacteria. This can only be done in a controlled randomised trial of antibacterial treatment.

Study funding/potential competing interests

The Copenhagen Prospective Study on Asthma in Childhood is funded by private and public research funds (see www.copsac.com). The study is supported by the Lundbeck Foundation, the Pharmacy Foundation of 1991, Augustinus Foundation, the Danish Medical Research Council, and the Danish Pediatric Asthma Centre. We have no competing interests.

Sociodemographic patterning of non-communicable disease risk factors in rural India: a cross sectional study

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STUDY QUESTION

What is the sociodemographic patterning of risk factors for non-communicable diseases in rural Indians?

SUMMARY ANSWER

The prevalence of risk factors for non-communicable diseases is high in rural India, particularly in the middle aged, the affluent, and residents of south India.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

The burden of risk factors for non-communicable diseases is high in urban India, and recent reports suggest that this trend may be spreading to rural areas. This study found high levels of risk factors (particularly tobacco use in men and obesity in women) in the presence of prevalent undernutrition, suggesting that the nutrition transition may have spread to parts of rural India. Given the study limitations, the results are not conclusive but strongly warrant careful monitoring and introduction of control measures in rural India.

Participants and setting

During 2005-7, 1983 (31% women) adults aged 20-69 years (49% response rate) were recruited from about 1600 villages in 18 states in India. Most of the participants were from four large states because of a convenience sampling strategy.

Design

This is a cross sectional study.

AGE STANDARDISED PREVALENCE OF RISK FACTORS FOR NON-COMMUNICABLE DISEASES IN RURAL PARTICIPANTS

	Prevalence (% (95% CI))	
	Men (n=1375)	Women (n=608)
Smoke tobacco	20.8 (18.7 to 23.0)	0.7 (0.1 to 1.3)
Chew tobacco	23.9 (21.7 to 26.2)	3.8 (2.4 to 5.2)
Alcohol use	23.5 (21.2 to 25.7)	5.4 (3.7 to 7.2)
Low physical activity	72.1 (69.8 to 74.5)	74.6 (71.0 to 78.1)
Low fruit and vegetable intake	68.6 (66.2 to 71.1)	74.8 (71.3 to 78.3)
Obesity (body mass index ≥25)	18.8 (16.8 to 20.9)	27.7 (24.2 to 31.2)
Abdominal obesity	21.4 (19.3 to 23.6)	18.4 (15.4 to 21.4)
Dyslipidaemia (total:HDL cholesterol ≥4.5)	33.0 (30.5 to 35.5)	34.6 (30.8 to 38.3)
Triglycerides ≥1.69 mmol/l	26.9 (24.6 to 29.3)	27.4 (23.8 to 31.0)
Hypertension	19.5 (17.5 to 21.5)	21.9 (18.9 to 24.9)
Diabetes	6.0 (4.7 to 7.3)	5.1 (3.5 to 6.8)
Underweight	21.2 (19.1 to 23.4)	17.9 (14.8 to 21.0)
Short stature	18.9 (16.8 to 21.0)	24.1 (20.7 to 27.5)

HDL=high density lipoprotein

Primary outcomes

Prevalence of tobacco use, alcohol use, low fruit and vegetable intake, low physical activity, obesity, central adiposity, hypertension, dyslipidaemia, diabetes, and underweight.

Main results and the role of chance

The prevalence of most risk factors was generally high across the whole group (table) and increased with age. Tobacco and alcohol use, low intake of fruit and vegetables, and underweight were more common in lower socioeconomic positions, whereas obesity, dyslipidaemia, and diabetes (men only) and hypertension (women only) were more prevalent in higher socioeconomic positions. For example, 37% (95% CI 30% to 44%) of men smoked tobacco in the lowest socioeconomic group compared with 15% (12% to 17%) in the highest, while 35% (30% to 40%) of women in the highest socioeconomic group were obese (body mass index ≥25) compared with 13% (7% to 19%) in the lowest. Risk factors were also generally more prevalent in south Indians than in north Indians. For example, the prevalence of dyslipidaemia was 21% (17% to 33%) in north Indian men compared with 33% (29% to 38%) in south Indian men, and the prevalence of obesity was 13% (9% to 17%) in north Indian women compared with 24% (19% to 30%) in south Indian women.

Bias, confounding, and other reasons for caution

The participants were rural dwelling siblings of urban factory workers in four large cities of India. Only half of those eligible participated, increasing the possibility of selection bias. It is possible that the rural participants willing to travel to the urban study centre were healthier, or, conversely, the chance of a free health check-up may have attracted the less healthy. The rural participants with an urban sibling (and the rural families that generated migrants) may be different from those without. Available data on selected characteristics of factory participants with and without a participating rural sibling did not suggest that they were substantially different.

Generalisability of the findings

The study participants were relatively more affluent than representative Indian samples. This could be due to the convenience sampling strategy or differences in age and geographical location of the participants. Given the limitations of the study design (convenience sampling and low response rate), the results from this study cannot be regarded as conclusive. However, they highlight the need for careful monitoring and control of risk factors for non-communicable diseases in rural parts of India.

Study funding/potential competing interests

This work is funded by the Wellcome Trust. All researchers are independent of the funding body and have no competing interests.