Proportion of South Asian participants in six multicentre clinical trials

Trial type	Trial population: Sex	Trial population: Age (years)	Trial population: Recruitment	Recruitment figures	No (%) South Asian participants
Hysterectomy	Female	>18 (mean 41.2 (SD 8))	National	1380 randomised	8 (0.6%)
Cancer:					
Colorectal	Male and female	>18 (mean 69; range 25-94)	National	584 on whom ethnicity data are available	1 (0.2%)
Breast	Female (post-menopausal)	Mean 64	Regional	780 randomised	2 (0.3%)
Breast	Female (post-menopausal)	Most >55	Regional	133 randomised	0 (0%)
Ovarian	Female	>18*	Regional	480 registered (242 randomised)	3 (0.6%)
			National	559 registered (300 randomised)	4 (0.7%)
Helicobacter pylori eradication	Male and female	40-49	Regional	8407 participants	145 (1.7%)

Office for National Statistics' latest estimates of proportion of population that is of South Asian origin are 3.8% for the Yorkshire-Humber region and 3.4% for Great Britain as a whole.[3]
*Range and mean unknown.

Asian population. We would have liked to compare more precisely the trials' inclusion criteria of age range and sex with those of the expected South Asian population, but this information is not currently available. Trials that recruited older patients would not be expected to comprise a percentage of South Asian people equal to the overall figures of the Office for National Statistics because the number of elderly South Asian people in the UK population is small.

Increased awareness and monitoring of recruitment and retention of ethnic minority groups in clinical trials are needed, and analysis of data by ethnicity of subjects should be done consistently. More rigorous review by the research ethics committee of clinical trial protocols, payment for translation of information supplied to participants, community participation, and education of ethnic minority groups may contribute to attaining proportional representation of ethnic minorities in trials.

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RESEARCH POINTERS

Average energy intake among pregnant women carrying a boy compared with a girl

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The birth weight of boys is about 100 g heavier than the birth weight of girls, and this seems to be consistent across populations. No study, has examined whether the difference is because the pregnant woman has a higher energy intake or more efficient energy utilisation if she is carrying a male embryo than if she is carrying a female embryo. We report data to support the first hypothesis—that the pregnant woman carrying a boy has a higher energy intake.

Participants, methods, and results

We analysed data from an international prospective study on dietary and non-dietary predictors of pregnancy hormones and outcomes among women in Boston, United States, and Shanghai, China.[1] Because the database of nutrients for the Chinese diet is incomplete, we present data on dietary intakes for the US women only.

Between March 1994 and October 1995, we identified 402 eligible pregnant women during their first routine prenatal visit at the Beth Israel Hospital in Boston and invited them to participate in the study. We followed throughout their pregnancies the 304 women who consented and did not have an early pregnancy termination or twin birth. The study population, study design, and methods have been described.[1]

Pregnant women carrying boys have a 10% higher energy intake than those carrying girls

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Multiple regression derived mutually adjusted* differences in the daily energy intake of 244 women in Boston, 1994-5, during the second trimester of pregnancy

	Mean (95% CI) change in energy intake (kJ/day)	P value
Sex of fetus:		
Female	1.0	
Male	796.2 (8.9 to 1583.4)	0.05
Maternal age (years):		
<30	1.0	
30-34	157.2 (–743.6 to 1057.9)	0.73
35-38	1104.2 (–489.0 to 2697.3)	0.18
Maternal education per level of education† increase	417.4 (–158.6 to 993.3)	0.16
Parity:		
1	1.0	
2	–138.8 (–987.2 to 709.5)	0.75
Maternal height per 5 cm increase	323.8 (–10.7 to 658.2)	0.06
Pre-pregnancy weight per 5 kg increase	122.0 (–133.0 to 376.5)	0.35
Maternal weight gain per kg increase	156.4 (68.7 to 244.1)	<0.001
Gestational age at birth per week increase	–34.5 (–240.4 to 171.4)	0.74

*Adjusted for maternal age (categorically), maternal education (ordinally), parity (categorically), maternal height (continuously), weight before pregnancy (continuously), maternal weight gain up to gestational week 27 (continuously), and exact gestational age at delivery (continuously), estimated from the difference between the date of last menstruation and date of delivery.
†Level 1=high school education; level 2=college education; level 3=graduate education.

We assessed dietary intake during the second trimester by using an extensive questionnaire on the frequency of eating, which is identical to the one used and validated in the nurses' health study.[2] Trained interviewers checked the questionnaire for accuracy and completeness before we mailed it to the women one week before their second prenatal visit (around 27 weeks' gestation). We calculated intake of energy and energy generating nutrients from the data on dietary intake, using standard software.[3] The analysis included 244 pregnant women with adequate covariate and dietary data.

We followed simple cross tabulations and modelled the data through multiple linear regression. The sex of the embryo was our main interest and dependent variables, one at a time, were intakes of energy, animal lipids, vegetable lipids, carbohydrates, and proteins.

Women who were carrying a male embryo had a higher daily energy intake than women who were carrying a female embryo (mean 9025.6 (SE=369.6) kJ *v* 8258.6 (227.2) kJ). After adjustment for potentially confounding covariates indicated in the table, the difference was 796.2 kJ (P=0.049), or 9.6%. We did not observe any effect of sex of the fetus on maternal weight gain, even though weight gain is positively associated with birth weight. Pre-eclampsia, emesis gravidarum, tobacco smoking, and alcohol drinking during pregnancy were not confounders of this relation.

Women carrying male rather than female fetuses had an 8.0% higher intake of protein, a 9.2% higher intake of carbohydrates, a 10.9% higher intake of lipids of animal origin, and a 14.9% higher intake of lipids of vegetable origin. There is no significant heterogeneity among these higher intakes, even though higher intakes tend to be concentrated in the energy dense lipids.

Comment

The energy intake of pregnant women is about 10% higher when they are carrying a boy rather than a girl. Our findings support the hypothesis that women carrying male rather than female embryos may have higher energy requirements and that male embryos may be more susceptible to energy restriction.[4] Although marginally significant, the difference in energy intake between pregnant women carrying boys rather than girls is not trivial—modelling the data through logistic regression indicates that the odds of having a boy rather than a girl is higher by about 35% when maternal energy intake is higher by about one standard deviation. The signal from the fetus responsible for the higher energy intake of women carrying a boy could be related to the strongly anabolic testosterone secreted by the fetal testicles,[5] but other alternatives deserve scientific investigation.

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