

Prophylactic administration of parenteral steroids for preventing airway complications after extubation in adults: meta-analysis of randomised placebo controlled trials

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Cite this as: *BMJ* 2008;337:a1841
doi:10.1136/bmj.a1841

This article is an abridged version of a paper that was published on bmj.com. Cite this article as: *BMJ* 2008;337:a1841

ABSTRACT

Objective To determine whether steroids are effective in preventing laryngeal oedema after extubation and reducing the need for subsequent reintubation in critically ill adults.

Design Meta-analysis.

Data sources PubMed, Cochrane Controlled Trials Register, Web of Science, and Embase with no limitation on language, study year, or publication status.

Selection criteria Randomised placebo controlled trials in which parenteral steroids were compared with placebo for preventing complications after extubation in adults.

Review methods Search, application of inclusion and exclusion criteria, data extraction, and assessment of methodological quality, independently performed in duplicate. Odds ratios with 95% confidence intervals, risk difference, and number needed to treat were calculated and pooled.

Main outcome measures Primary outcome: laryngeal oedema after extubation. Secondary outcome: subsequent reintubation because of laryngeal oedema.

Results Six trials (n=1923) were identified. Compared with placebo, steroids given before planned extubation decreased the odds ratio for laryngeal oedema (0.38, 95% confidence interval 0.17 to 0.85) and subsequent reintubation (0.29, 0.15 to 0.58), corresponding with a risk difference of -0.10 (-0.12 to -0.07; number needed to treat 10) and -0.02 (-0.04 to -0.01; 50), respectively. Subgroup analyses indicated that a multidose regimen of steroids had marked positive effects on the occurrence of laryngeal oedema (0.14; 0.08 to 0.23) and on the rate of subsequent reintubation (0.19; 0.07 to 0.50), with a risk difference of -0.19 (-0.24 to -0.15; 5) and -0.04 (-0.07 to -0.02; 25). In single doses there was only a trend towards benefit, with the confidence interval including 1. Side effects related to steroids were not found.

Conclusion Prophylactic administration of steroids in multidose regimens before planned extubation reduces the incidence of laryngeal oedema after extubation and the consequent reintubation rate in adults, with few adverse events.

INTRODUCTION

Critically ill patients and those undergoing surgery routinely undergo endotracheal intubation to facilitate

mechanical ventilation. As these patients recover, respiratory support is gradually reduced until the patient can breathe unaided and the endotracheal tube can be removed. To avoid airway complications, patients are often given steroids before extubation. Prophylactic steroids substantially reduce the incidence of stridor after extubation in children and tend to decrease the rate of reintubation and stridor in neonates.¹⁻⁴ The evidence to support this approach in adults is limited or controversial^{1,2,5} because of the limited number of randomised trials. Previous meta-analyses based on trials in adults up to 2007 yielded inconclusive or negative results and lack reliability because of small sample sizes.¹⁻³

We carried out an updated meta-analysis to determine whether steroids are effective in preventing laryngeal oedema after extubation in adults and whether they reduce the need for subsequent reintubation and to examine any reported side effects.

METHODS

Search strategy and selection criteria—We searched electronic databases including PubMed, CENTRAL, Web of Science, and Embase. We searched reference lists of review articles and included studies to identify other potentially eligible studies. There was no limitation on language, year of publication, or publication status. Trials were included if they were randomised placebo controlled trials comparing the prophylactic administration of steroids versus placebo before planned extubation in adults, with adequately reported data on either the occurrence of laryngeal oedema after extubation or the rate of consequent reintubation. Two reviewers independently assessed the trials and their methodological quality. Any disagreement between reviewers was resolved by consensus. See bmj.com for details of databases, search terms and data extraction.

Primary and second outcomes—Minor laryngeal oedema, defined as stridor and dyspnoea after extubation, was our primary outcome. Major laryngeal oedema, defined as severe respiratory distress resulting in tracheal reintubation secondary to upper airway obstruction, was our secondary outcome.

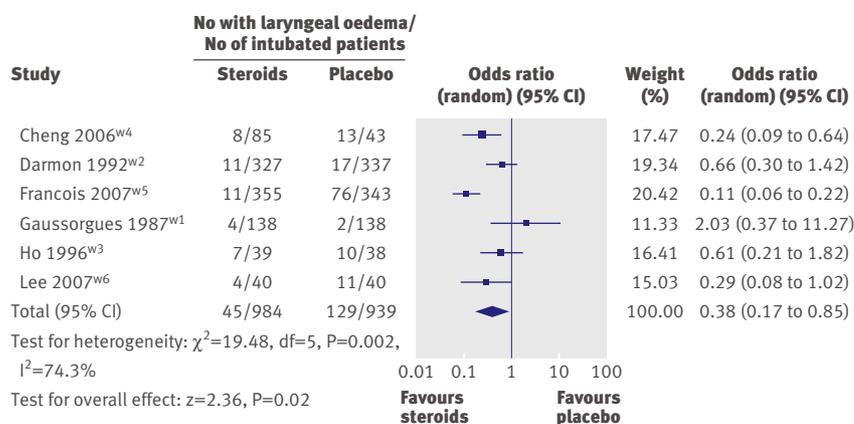


Fig 1 | Effect of steroids on laryngeal oedema after extubation

Statistical analysis—We treated our two outcomes as dichotomous variables and reported odds ratios. We examined heterogeneity with the Q statistic ($P<0.1$, considered significant). We used a random effects model if the Q statistic was significant, otherwise we used a fixed effects model. We carried out subgroup analysis to assess the source of heterogeneity and assessed the presence of publication bias visually with a funnel plot. Differences in risk and number needed to treat were calculated to assess clinical significance. We calculated the power to confirm the reliability of the analyses.

RESULTS

Trials included

Our search strategy initially yielded 1500 citations. Of these, we included six unique studies with 1923 participants in this meta-analysis.^{w1-w6} All trials were undertaken in Europe^{w1 w2 w5} and Asia^{w3 w4 w6} in the past 30 years, and three^{w4-w6} were published after 2000. Two trials were multicentre studies.^{w2 w5} Three of them reported negative results,^{w1-w3} and the others reported positive results.^{w4-w6} Most of the included studies were of high quality (Jadad score ≥ 3) and clearly reported allocation concealment, except that of Gaussorgues et al (Jadad score 1).^{w1} Intention to treat analysis was rarely reported. See bmj.com.

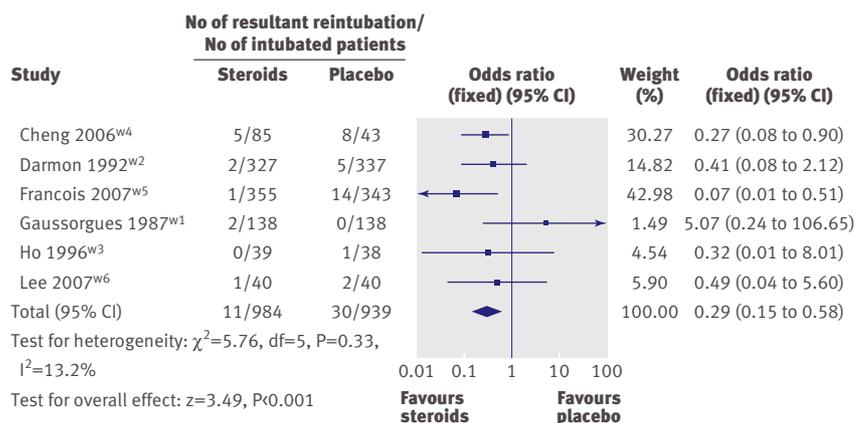


Fig 2 | Effect of steroids on reintubation after extubation

All participants in the six trials were adults who were tracheally intubated for at least 24 hours and were monitored for at least 24 hours after extubation. Two trials mentioned supportive treatments for laryngeal oedema after extubation, such as non-invasive positive pressure ventilation and the inhalation of racemic adrenaline (epinephrine).^{w4 w6} In these studies patients were usually given intravenous steroids sometime before selected extubation but the steroids used and doses varied.

Outcomes for meta-analysis

Meta-analysis indicated that prophylactic steroids before planned extubation decreased the likelihood of laryngeal oedema after extubation (odds ratio 0.38; 95% confidence interval 0.17 to 0.85) and subsequent reintubation (0.29, 0.15 to 0.58) (figs 1 and 2), corresponding with a risk difference of -0.10 (-0.12 to -0.07 ; number needed to treat 10) and -0.02 (-0.04 to -0.01 ; 50), respectively. The Q test, however, showed statistical heterogeneity in the occurrence of laryngeal oedema ($\chi^2=19.48$, $P=0.002$, $I^2=74.3\%$) but not in the rate of reintubation ($\chi^2=5.76$, $P=0.33$, $I^2=13.2\%$). Reanalyses with a random effects model still suggested that the regimen reduced the occurrence of laryngeal oedema (0.38, 0.17 to 0.85), corresponding with a risk difference of -0.10 (-0.20 to 0.00 ; 10). The funnel plot showed apparent asymmetry in laryngeal oedema and reintubation.

Subgroup and sensitivity analysis

The total incidence of laryngeal oedema after extubation and subsequent reintubation was 9.0% and 2.1%, whereas in the subgroup with a multidose regimen the figures were 13.7% and 3.4%. In subgroup analyses of different regimens, multiple intravenous steroids had a marked positive effect on the occurrence of laryngeal oedema (odds ratio 0.14, 0.08 to 0.23) and the rate of subsequent reintubation (0.19, 0.07 to 0.50), corresponding with a risk difference of -0.19 (-0.24 to -0.15 ; number needed to treat 5) and -0.04 (-0.07 to -0.02 ; 25), but there was only a trend towards benefit with single doses.

We also carried out subgroup analyses on the relation between dose of steroid and its effect on laryngeal oedema after extubation and reintubation. We converted all doses of steroids to the equivalent dose of methylprednisolone. There was no significance difference between doses equivalent to 20 mg (odds ratio 0.61 for laryngeal oedema, 0.32 for reintubation) and 40 mg (0.61, 0.47) methylprednisolone, with all confidence intervals including 1 in the single dose regimen. In the multiple dose regimen, however, the effect of steroids equivalent to 160 mg methylprednisolone (0.18, 0.34), however, was much better than that of 100 mg (0.29, 0.49). In addition, the effect of steroids equivalent to 80 mg methylprednisolone (0.11, 0.07) was the best compared with the steroid doses of 100 mg and 160 mg, but this could have been because that study did not include high risk patients and had a large sample size.^{w5} Exclusion of the low quality study^{w1} (Jadad score <3)

WHAT IS ALREADY KNOWN ON THIS TOPIC

Endotracheal intubation can result in laryngeal oedema; after the tube is removed this might lead to subsequent reintubation

Controversy exists regarding the prophylactic administration of steroids to prevent laryngeal oedema and reintubation in adults

WHAT THIS STUDY ADDS

Prophylactic administration of steroids before planned extubation reduces the incidence of laryngeal oedema after extubation and the consequent reintubation rate in adults

Multiple dose regimens are more promising than single doses

and the heaviest weight trial^{w5} did not change the positive direction of our results.

We did subgroup analysis of high risk patients including two trials.^{w4 w6} (See bmj.com for definitions of risk factors.) There were positive effects on the occurrence of laryngeal oedema (0.26, 0.12 to 0.56) and on the rate of subsequent reintubation (0.31, 0.11 to 0.90). We could not carry out a subgroup analysis according to sex as we did not have the required data.

Adverse events analysis

Three studies (n=969) described adverse events,^{w4-w6} but these could not be pooled. In the steroid group, one patient developed septic shock and died 26 hours after extubation, and one developed atelectasis 24 hours after extubation; neither event was considered to be related to the use of steroids. In the placebo group, one patient developed respiratory failure and died 23 hours and 15 minutes after extubation.

DISCUSSION**Principal findings**

The present meta-analysis confirms that, despite various confounding factors, intravenous steroids do decrease the global occurrence of laryngeal oedema after extubation by 62% and subsequent reintubation by 71%. Multiple dose steroids have more marked positive effect, leading to a reduction of laryngeal oedema after extubation by 86% and subsequent reintubation by 81%, but we found no significant differences with single dose regimens. In such strategies, one event of laryngeal oedema after extubation or subsequent reintubation could be avoided by pretreatment with steroids for 10 or 50 patients, whereas with multidose steroids the same benefits can be achieved in five or 25 patients. We also found a possible dose-effect relation between steroid dose and its effect on preventing laryngeal oedema after extubation and reintubation in the multiple dose regimen. Although steroids have several potential adverse events, particularly in patients already at risk of hyperglycaemia and complications of infection, side effects with steroid treatments over 24 hours are minimal.⁶ The included studies found no side effects related to steroids, but adverse events were not often reported.

Single v multiple dose regimens

Our results confirm the benefit of multidose steroids before planned extubation of adults. It is difficult to predict the risk of laryngeal oedema that will require reintubation. Onset of laryngeal oedema usually occurs within eight hours after extubation.^{w1 w2 7} We found possible dose dependent effects in multiple dose regimens but not in single dose regimens. In multiple dose regimens steroids are usually administered at least 12 hours before extubation and repeated almost every plasma half life. This might maintain a high level of anti-inflammatory activity during the period of vulnerability to oedema after extubation.

Strengths and limitations

As we included high quality randomised controlled trials with strong power and obtained relative narrow confidence intervals, our results are more precise than those from previous studies.⁸

A recent meta-analysis⁵ found no clear effect of steroids on preventing laryngeal oedema after extubation and reintubation in adults. That study, however, did not include a recent trial with positive results.^{w6} The addition of this trial, which was not significant in its own right, was sufficient to make the results of our updated meta-analysis significant. The authors of the previous meta-analysis also did not define reintubation as major laryngeal oedema needing tracheal reintubation secondary to upper airway obstruction. This meant that patients^{w2} who needed reintubation during the follow-up period because of clinical deterioration rather than major laryngeal oedema were added to the number of reintubations, especially in the steroid group. The meta-analysis also lacked subgroup analyses of single versus multidose regimens.

Our study also has some limitations. Few of the original studies reported intention to treat analyses, and that reduces the reliability of the data included in this meta-analysis. The use of supportive treatments for laryngeal oedema after extubation in some of the included studies might have reduced the apparent benefit of steroids compared with placebo treatment. The funnel plot shows asymmetry, so we cannot eliminate the possibility of publication bias. We could not do a subgroup analysis by sex because so few trials reported results separately by sex. Finally, because of heterogeneity we had to use a random effects model, which results in wider confidence intervals and thus a more conservative estimate of treatment effect.

We thank Gu Jun at Technology Consulting Group of the National Library of China for help with literature searching and Guanjian Liu at the Chinese Cochrane Centre for his statistical assistance.

Contributors: See bmj.com.

Funding: This work was supported by West China Hospital, Sichuan University, grant No 141070062.

Competing interests: None declared.

Ethical approval: Not required.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Accepted: 7 August 2008

The joint impact on being overweight of self reported behaviours of eating quickly and eating until full: cross sectional survey

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Cite this as: *BMJ* 2008;337:a2002
doi:10.1136/bmj.a2002

This article is an abridged version of a paper that was published on *bmj.com*. Cite this article as: *BMJ* 2008;337:a2002

ABSTRACT

Objective To examine whether eating until full or eating quickly or combinations of these eating behaviours are associated with being overweight.

Design and participants Cross sectional survey.

Setting Two communities in Japan.

Participants 3287 adults (1122 men, 2165 women) aged 30-69 who participated in surveys on cardiovascular risk from 2003 to 2006.

Main outcome measures Body mass index (overweight ≥ 25.0) and the dietary habits of eating until full (lifestyle questionnaire) and speed of eating (validated brief self administered questionnaire).

Results 571 (50.9%) men and 1265 (58.4%) women self reported eating until full, and 523 (45.6%) men and 785 (36.3%) women self reported eating quickly. For both sexes the highest age adjusted mean values for height, weight, body mass index, and total energy intake were in the eating until full and eating quickly group compared with the not eating until full and not eating quickly group. The multivariable adjusted odds ratio of being overweight for eating until full was 2.00 (95% confidence interval 1.53 to 2.62) for men and 1.92 (1.53 to 2.40) for women and for eating quickly was 1.84 (1.42 to 2.38) for men and 2.09 (1.69 to 2.59) for women. The multivariable odds ratio of being overweight with both eating behaviours compared with neither was 3.13 (2.20 to 4.45) for men and 3.21 (2.41 to 4.29) for women.

Conclusion Eating until full and eating quickly are associated with being overweight in Japanese men and women, and these eating behaviours combined may have a substantial impact on being overweight.

INTRODUCTION

Eating quickly, gorging, and binge eating have been associated with total energy intake,¹⁻³ and eating quickly and binge eating have been associated with satiety^{4,5} and insulin resistance.^{6,7} All these eating behaviours may lead to being overweight or

obese.⁸⁻¹⁰ In addition, the positive association of eating quickly with body mass index was observed independent of total energy intake.^{11,12}

We examined whether eating until full (eating a large quantity of food in one meal) and eating quickly are associated with being overweight in a population based sample of adults in Japan. We also examined the combined effect of eating until full and speed of eating on being overweight.

METHODS

We carried out a cross sectional study of 4140 adults (1496 men, 2644 women) aged 30 to 69 in two Japanese communities who participated in surveys on cardiovascular risk from 2003 to 2006. Overall, 3650 (88.2%) participants responded to self administered questionnaires on diet history and 489 (12%) refused. Overweight and body mass index were similar between the two groups. After exclusions, data on 3287 participants (1122 men, 2165 women) were used for the analyses.

To avoid measurement bias we used standardised methods to carry out the surveys.^{13,14} We measured the participants' height and weight and calculated their body mass index. For the purposes of the analysis we considered a body mass index of 25.0 or more as indicating overweight. We also interviewed participants to ascertain data on smoking status, cigarettes smoked daily, occupation, and use of regular physical exercise (≥ 15 minutes or more weekly).

We used a validated, self administered, questionnaire on diet history to assess the participants' dietary habits during the previous month.¹⁵⁻¹⁷ The participants were asked whether they usually eat until full (yes or no) and speed of eating was self reported according to one of five categories: very slow, slow, medium, fast, and very fast. Owing to small numbers of participants in the very fast category we combined the very fast and fast categories into the category for eating quickly. We validated the self reported speed of eating as used

previously.¹¹ We tested the repeatability for self reporting eating until full and eating quickly by repeating the questionnaire survey after one year in a subsample of the participants (1062 men, 1816 women). The κ statistics for eating until full were 0.60 in men and 0.63 in women, and for eating quickly were 0.63 in men and 0.67 in women.

Statistical analysis

We calculated age adjusted mean values for participants' characteristics using analysis of covariance and age adjusted proportions by using logistic regression according to the combination of eating until full and eating quickly.

We calculated odds ratios and 95% confidence intervals by using the logistic regression model for age adjusted odds ratios and multivariable adjusted odds ratios. The multivariable adjustment included age (years), total energy intake (kcal/day), total fibre and alcohol intake (g/day), smoking status (non-smoker; former smoker; and 1-20, 21-40, and ≥ 41 cigarettes consumed daily), occupation (desk worker, service business, manual labour, unemployed), regular physical activity (yes or no), and survey area.

We also tried to determine whether there was a supra-additive association (additive interaction) between eating until full and eating quickly. The relative excess risk due to interaction is the excess risk as a result of joint exposure (see *bmj.com*). The percentage relative excess risk due to interaction is defined as the proportion of disease burden caused by two factors that can be attributed to their interaction. We also calculated the attributable proportion due to interaction (see *bmj.com*)—that is, the proportion of overweight among those both eating until full and eating quickly that is attributable to interaction.

Probability values for statistical tests were two tailed and we regarded $P < 0.05$ as statistically significant.

RESULTS

The mean (standard deviation) age of participants was 55.3 (10.7) for men and 52.4 (11.1) for women, with 379 (33.8%) men and 472 (21.8%) women being overweight (see *bmj.com*). Overall, 571 (50.9%) men and 1265 (58.4%) women reported eating until full and 523

(45.6%) men and 785 (36.3%) women reported eating quickly (very fast and fast categories combined). For both sexes the eating until full and eating quickly group had the highest age adjusted mean values for height, weight, body mass index, and total energy intake than did the group with neither of these eating behaviours.

The eating until full group had higher age adjusted odds ratios for overweight than the not eating until full group for both men and women. The odds ratios were not changed substantially by further adjustment for intake of total energy, total fibre, and alcohol; smoking status; physical activity; and survey area: 2.00 (95% confidence interval 1.53 to 2.62) for men and 1.92 (1.53 to 2.40) for women. The eating quickly group had higher age adjusted odds ratios for overweight than did the not eating quickly group for both sexes. The multivariable adjusted odds ratios for overweight for the eating quickly group was 1.84 (1.42 to 2.38) for men and 2.09 (1.69 to 2.59) for women (table).

The multivariable adjusted odds ratio for overweight for the eating until full and eating quickly group compared with the group with neither of these eating behaviours was 3.13 (2.20 to 4.45) for men and 3.21 (2.41 to 4.29) for women (see *bmj.com*). On the basis of the multivariable adjusted model, the relative excess risk due to interaction for men was 1.10, indicating an excess burden of being overweight of 51.6% (percentage relative excess risk due to interaction, $P < 0.05$) for eating until full and eating quickly, and for women was 1.27, indicating an excess burden of being overweight of 57.4% (percentage relative excess risk due to interaction, $P < 0.01$; see *bmj.com*). The attributable proportion due to interaction was 35.1% for men and 39.6% for women.

DISCUSSION

Eating until full and eating quickly were significantly associated with overweight in Japanese men and women after adjustment for total energy intake and other potential confounders. The combination of the two eating behaviours had a supra-additive effect (additive interaction) on being overweight.

Eating quickly is positively associated with body mass index and increased body weight among Japanese^{11 12} and Western populations.⁸ The

Age adjusted and multivariable adjusted odds ratios and 95% confidence intervals for overweight according to eating until full and eating quickly

Variable	Eating until full	Eating quickly
Men (n=1122):	n=571	n=512
No (%) overweight	234 (41.0)	210 (41.0)
Age adjusted odds ratio	2.04 (1.57 to 2.64)	1.85 (1.44 to 2.38)
Multivariable odds ratio*	2.00 (1.53 to 2.62)	1.84 (1.42 to 2.38)
Women (n=2165):	n=1265	n=785
No (%) overweight	324 (25.6)	233 (29.7)
Age adjusted odds ratio	1.93 (1.54 to 2.40)	2.11 (1.71 to 2.60)
Multivariable odds ratio*	1.92 (1.53 to 2.40)	2.09 (1.69 to 2.59)

*Adjusted for age; smoking status; regular physical activity; occupation; intake of total energy, total dietary fibre, and alcohol; and survey area.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Eating quickly, independent of total energy intake and other confounders, is associated with overweight

WHAT THIS STUDY ADDS

Both eating quickly and eating until full were associated with being overweight, independent of total energy intake and other confounders

These eating behaviours combined may have a substantial impact on being overweight

questionnaire for evaluation of speed of eating used in the present study was the same as the one used in previous studies,^{11 12} and the findings showed essentially the same trends. One study examined associations between the speed of eating and body mass index in Japanese women aged 18; the speed of eating (very slow, slow, medium, fast, and very fast) was found to be significantly and positively associated with body mass index.¹¹ Another study also examined associations between the speed of eating and body mass index but in Japanese men and women aged 35-69 years.¹² Furthermore, the speed of eating was positively associated with the homeostasis model assessment of insulin resistance for middle aged Japanese men and women without diabetes, especially for those who were not obese.⁶ Speed of eating was significantly and positively correlated with total energy intake, but the odds ratio for overweight did not change substantially after adjustment for total energy intake and other confounding variables. Therefore the effect of speed of eating may be unrelated to that of total energy intake.

One study investigated whether gorging was associated with overweight or obesity, but the epidemiological evidence was at best weak.⁹ Moreover, the present study observed that the combination of eating until full and eating quickly was strongly associated with being overweight.

The strength of our study is that we analysed the association of eating behaviour patterns with overweight using population based data for a large number of participants. The study does, however, have several potential limitations. Firstly, eating patterns were self reported and we did not determine the validity for self reporting of eating until full. The participants who reported eating until full, however, had higher total energy intake than the other participants, including those who reported gorging¹ and binge eating, which supports the validity of the questionnaire.³ Secondly, we assessed eating behaviours as simplistic dichotomous outcomes. The validity and reproducibility of eating quickly and the reproducibility of eating until full were, however, reasonably good, and these eating behaviours as simplistic dichotomous outcomes were significantly associated with being overweight. Thirdly, we cannot deny the possibility that other potential confounding factors, such as educational history, may have had an effect on the observed

associations. Fourthly, the cross sectional nature of the study indicates that the observed association between these eating behaviours and overweight does not necessarily indicate causality. It is unlikely, however, that people who are obese then change their eating habits.

In conclusion, eating until full and eating quickly were associated with being overweight in Japanese men and women, and the combination of the two eating behaviours may have a substantial impact on being overweight.

We thank for their cooperation with this study the municipal authorities, officers, and physicians of Ikawa town, Yao city, and Osaka prefecture, and their colleagues in Osaka Medical Center for Health Science and Promotion.

Contributors: See bmj.com.

Funding: This study was supported in part by a contract from the Japanese Ministry of Education (grant in aid for exploratory research No 19659168).

Competing interests: None declared.

Ethical approval: Osaka Medical Center for Health Science and Promotion research ethics committee.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Accepted: 25 August 2008

Prevention of type 2 diabetes in British Bangladeshis: qualitative study of community, religious, and professional perspectives

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Cite this as: *BMJ* 2008;337:a1931
doi:10.1136/bmj.a1931

ABSTRACT

Objective To understand lay beliefs and attitudes, religious teachings, and professional perceptions in relation to diabetes prevention in the Bangladeshi community.

Design Qualitative study (focus groups and semistructured interviews).

Setting Tower Hamlets, a socioeconomically deprived London borough, United Kingdom.

Participants Bangladeshi people without diabetes (phase 1), religious leaders and Islamic scholars (phase 2), and health professionals (phase 3).

Methods 17 focus groups were run using purposive sampling in three sequential phases. Thematic analysis was used iteratively to achieve progressive focusing and to develop theory. To explore tensions in preliminary data fictional vignettes were created, which were discussed by participants in subsequent phases. The PEN-3 multilevel theoretical framework was used to inform data analysis and synthesis.

Results Most lay participants accepted the concept of diabetes prevention and were more knowledgeable than expected. Practical and structural barriers to a healthy lifestyle were commonly reported. There was a strong desire to comply with cultural norms, particularly those relating to modesty. Religious leaders provided considerable support from Islamic teachings for messages about diabetes prevention. Some clinicians incorrectly perceived Bangladeshis to be poorly informed and fatalistic, although they also expressed concerns about their own limited cultural understanding.

Conclusion Contrary to the views of health professionals and earlier research, poor knowledge was not the main barrier to healthy lifestyle choices. The norms and expectations of Islam offer many opportunities for supporting diabetes prevention. Interventions designed for the white population, however, need adaptation before they will be meaningful to many Bangladeshis. Religion may have an important part to play in supporting health promotion in this community. The potential for collaborative working between health educators and religious leaders should be explored further and the low cultural understanding of health professionals addressed.

INTRODUCTION

Previous qualitative studies of lay understandings of diabetes in Bangladeshis have been limited to participants with established diabetes.^{1,2} We explored the attitudes of British Bangladeshis without diabetes to the

risk of developing the disease, and the opportunities for its prevention.

METHODS

This study took place in the London borough of Tower Hamlets, one of the most multiethnic and socioeconomically deprived areas in the UK, with an age adjusted prevalence for diabetes of 5.9%.^{3,4} The study comprised 17 focus groups in three phases: lay people (n=80, 10 groups), Islamic scholars and religious leaders (n=29, four groups), and health professionals (n=20, three groups, and eight individual interviews).

Phase 1: Lay people

We explored the attitudes, values, and beliefs of first and second generation Bangladeshis without diabetes towards the prevention of diabetes. We purposively selected participants to achieve maximum variation by sex, age, body mass index, and family history of diabetes.

Participants completed a questionnaire on age, family history of diabetes, and generation immigrant. We invited 10 participants to each group on the basis of the purposive selection criteria. Groups were heterogeneous for most selection criteria but broadly homogeneous for socioeconomic status, education level, and immigrant generation. We selected equal numbers with and without a family history of diabetes. We summarised the findings from phase 1 into vignettes for use in the phase 2 focus groups.

Phase 2: Islamic scholars and religious leaders

Male volunteers were recruited through mosques, Islamic forums, and Islamic schools. Participants completed a questionnaire similar to that in phase 1, together with information on faith related training and position.

We invited eight to 10 participants to each group. Vignettes were presented to the faith leaders and their perspectives explored, focusing mainly on their interpretation of Islam.

Phase 3: Health professionals

We explored the attitudes and experiences of health professionals working with the Bangladeshi community on managing weight, lifestyle, and diabetes. A focus group was run for nurses (n=6), dietitians (n=6), and health advocates (n=7). We invited 7-10 participants to each group. Participants completed a questionnaire similar to those previously plus information

on training in lifestyle modification. Recruiting busy general practitioners proved impossible, so we changed the study design to individual interviews. We used statements and vignette style clinical scenarios to explore views.

Data processing and analysis

Focus group discussions were transcribed verbatim and analysed by thematic content using the constant comparative method to cover themes.⁵

Data analysis was guided by the PEN-3 health promotion model (see bmj.com),⁶ which seeks to broaden the traditional westernised medical approach to disease prevention.

RESULTS

Lay understanding of diabetes

Knowledge of diabetes was generally high and gleaned primarily through experience of diabetes in a relative or friend. Most participants recognised the central role of personal lifestyle choices including diet, body weight, and physical inactivity in the development of diabetes.

Some believed that traditional vegetables and other bitter foods could prevent diabetes. Other perceived causes included heredity and stress, which were seen as linked to social isolation.¹² A minority of lay participants thought a family history meant diabetes was inevitable, but most thought that risk could be modified through lifestyle change.

Living a "healthy life"

Lay participants and religious leaders emphasised the resonance between Islamic teachings and healthy lifestyle messages. Rice was consistently seen as an important component of the Bangladeshi diet.

Lay participants thought medium sized body images were aesthetically pleasing and associated with "good health." Both underweight and obese body sizes were termed "weak." Health professionals believed (incorrectly) that Bangladeshis associate obesity with health and fertility.

Lay participants saw physical activity as important for mental wellbeing and caring for the body, a central feature of the Muslim way of life. Physical fitness was viewed as enhancing a person's ability to contribute to family duties, and a good way to control weight. Walking was seen as a valuable exercise, and was viewed by lay people and religious leaders as supported by Islamic teachings. Although lay participants saw namaz (prayers five times daily) as adequate exercise for maintaining health, religious leaders were in favour of conventional forms of exercise (especially walking).

Responsibility for diabetes prevention

Some lay participants believed that fear of the impact of diabetes would motivate preventive action across the Bangladeshi community. Others, including Islamic scholars, framed prevention in a more positive but less dramatic way as part of a healthy lifestyle that all Bangladeshis should follow.

"Control" was a strong theme in diabetes prevention in all lay groups. People with diabetes were labelled as "out of control." Control was generally viewed as internal (taking individual responsibility for action), with the family providing behavioural, emotional, and intellectual support. A few lay participants saw control as something to be imposed and policed by the family:

"The family should cook the food which is advisable for him [person with or at risk of diabetes] and not to offer him any food meant for all other members of the family. They should not allow him to eat any food even though he asks for" (P1/FG5: male, first generation, age unknown)

Both lay participants and religious scholars believed that education about faith was one mechanism through which preventive messages could be conveyed. Faith was seen as linked to individuals' confidence and motivation to change behaviour. Religious leaders were seen as trusted sources of information and support.

Fatalism

Many health professionals were reluctant to discuss lifestyle change in consultations, partly because of their own poor cultural and religious understanding and because they perceived Bangladeshis as fatalistic: "They have to believe it to change it" (P3/FG2/R2: health advocate: female, age 35).

Few lay participants expressed religious fatalism, but many suggested that "other people," particularly the older generation, held such beliefs. Religious leaders saw religious fatalism as misinterpretation of Islamic teachings and were keen to address this in their role as educators.

Social roles and expectations

Several traditional social norms were described, especially that women remain in the home, dress modestly, and prioritise family over independence and social freedom. Such norms potentially conflicted with efforts to achieve health related lifestyle change. In some focus groups, women felt strong pressure to conform to traditional norms.

The important social role of food was a prominent theme. Certain foods were considered "everyday" items and were often distinct from "special menu" foods served to guests. Serving curries with reduced oil and spice content ("white" or "pale" curries) was considered inhospitable and shameful to the host:

"We cook special foods in compliance of Bangladeshi society's expectation. Otherwise people will say the new guests are not properly entertained. These foods are cooked for the fear of public scandal" (P1/FG5: female, first generation, age unknown)

Exercise in the Western sense (sports attire, gymnasiums) was seen as alien to the culture and identity of many first (and some second) generation Bangladeshis.

Sporting exercise for women and older people was seen as inappropriate: “That’s the whole reason I don’t go to the gym because I have to wear trackies and all that” (P1/FG2/R4: female, second generation, age 18).

Mixed sex exercise classes were considered inappropriate for both sexes. Some saw classes for women only as acceptable. Running in public did not, in itself, meet with religious disapproval but posed challenges to modesty, particularly for women. Most health professionals were uncertain about attitudes to activity in the Bangladeshi community and found this challenging to explore.

Structural and practical constraints to healthy lifestyle choices

Many Bangladeshis cited structural constraints to increasing their physical activity, including lack of time or money or inability to find childcare. Reluctance to travel owing to fears about safety or difficulties with language created problems for some first generation participants.

Both male and female second generation participants reported heavy reliance on fast foods. Traditional Bangladeshi fruits and vegetables were perceived as expensive, but first generation participants were often unfamiliar with cheaper, more readily available Western alternatives.

Health literacy and English fluency

Lay participants identified poor fluency in English as a major barrier to accessing and understanding basic health information. Poor English also limited people’s willingness to travel, resulting in reliance on local food and exercise provision.

Education was viewed by participants in all three samples as a powerful force of change by lay participants and a route to independence for women. There was also recognition that education could lead to a more liberal interpretation of religious teachings and the ability to resist traditional norms:

“If the woman with hijab is intellectual and she knows the benefits of exercise, she will not care to any comment and will continue taking exercise. She will take care of her body, care for her life and not the public criticism. Then she will remember Allah’s (God’s) instructions. She will carry on doing this irrespective of what the society says” (P1/FG5/R9: female, first generation, age 40)

Many health professionals reported substantial challenges in communicating basic lifestyle information to Bangladeshis with limited health literacy, attributing this to time pressures, the difficulties of the interpreted consultation, or their own limited understanding of cultural aspects of lifestyle.

DISCUSSION

We explored beliefs and values on diabetes prevention in Bangladeshis without diabetes, highlighting several

positive findings. Even in a sample purposively drawn from socioeconomically deprived parts of London, lay participants knew about the link between lifestyle and diabetes, believed that lifestyle change could prevent diabetes, acknowledged individuals’ responsibility in making those changes, and viewed them as aligned with the teachings of Islam. Only a minority held strongly fatalistic beliefs.

Bangladeshi religious leaders agreed that to reject the importance of self care and rely solely on Allah to protect health was a misinterpretation of Islamic teaching and must be addressed through religious education. They saw the most fruitful approach for diabetes prevention as a collaboration between health educators and faith based organisations.

Our findings suggest that the main barrier to positive lifestyle change in this community is not lack of knowledge but a complex value hierarchy in which what is accepted to be healthy (for example, regular activity) is seen as less important than the social norms of hospitality, the religious requirement for modesty, and the rejection of a “sporting” identity or dress.

The powerful effect of social norms on an individual’s behaviour suggests that education and raising awareness alone may be insufficient to effect change in behaviour for some individuals. Our data highlighted important moral conflicts between individualist and collectivist goals, such as the goal of healthy eating compared with the shame to the family of not providing guests with “special menu” foods; even second generation participants struggled with these conflicts.

Practical and structural barriers to a healthy lifestyle were clearly evident. These constraints, along with modesty and identity issues, may explain the much lower levels of participation in formal exercise programmes in Muslim communities compared with European populations, particularly for women.⁷⁻¹¹

Lay participants in our study placed high importance on family support in the prevention of diabetes. They

WHAT IS ALREADY KNOWN ON THIS TOPIC

Diabetes is common in people of Bangladeshi origin living in the United Kingdom

Prevention of diabetes is possible through lifestyle change

WHAT THIS STUDY ADDS

Most Bangladeshis in this study had fair knowledge about the causes of diabetes and how to prevent it, and were keen to take personal responsibility for healthy lifestyle change

The principles of dietary and physical activity changes to prevent diabetes were seen by Bangladeshi lay people and religious leaders as aligned with the teachings of Islam, but advice on the nature of these changes must be adapted to cultural and religious norms

Health professionals admitted withholding preventive advice from Bangladeshis because of an incorrect perception of “fatalism” and lack of confidence in discussing “cultural” issues

also talked about the critical role of poor fluency in English in constraining healthy lifestyle choices. “Educated” Muslim women were seen as better able to resist social pressure and make up their own minds about taking exercise.

Health professionals held several incorrect views (for example, that obesity is valued in Bangladeshis¹²); they expressed a lack of confidence in their ability to provide culturally relevant advice on lifestyle. Professional education on culturally competent lifestyle interventions and approaches to delivering these must be addressed.

CG was funded to undertake this research through a project grant from Diabetes UK. We thank the participants who gave generously of their time; Farah Suraiya, Mohammed Lais, and Tasnuba Subhani for their translation services; and members of the project advisory group.

Contributors: See bmj.com.

Funding: This work was supported by Diabetes UK grant number BDA: RD04/0002780.

Competing interests: None declared.

Ethical approval: East London and City research ethics committee.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Accepted: 22 August 2008

Prescribing “placebo treatments”: results of national survey of US internists and rheumatologists

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ABSTRACT

Objective To describe the attitudes and behaviours regarding placebo treatments, defined as a treatment whose benefits derive from positive patient expectations and not from the physiological mechanism of the treatment itself.

Design Cross sectional mailed survey.

Setting Physicians' clinical practices.

Participants 1200 practising internists and rheumatologists in the United States.

Main outcome measures Investigators measured physicians' self reported behaviours and attitudes concerning the use of placebo treatments, including measures of whether they would use or had recommended a “placebo treatment,” their ethical judgments about the practice, what they recommended as placebo treatments, and how they typically communicate with patients about the practice.

Results 679 physicians (57%) responded to the survey. About half of the surveyed internists and rheumatologists reported prescribing placebo treatments on a regular basis (46-58%, depending on how the question was phrased). Most physicians (399, 62%) believed the practice to be ethically permissible. Few reported using saline (18, 3%) or sugar pills (12, 2%) as placebo treatments, while large proportions reported using over

the counter analgesics (267, 41%) and vitamins (243, 38%) as placebo treatments within the past year. A small but notable proportion of physicians reported using antibiotics (86, 13%) and sedatives (86, 13%) as placebo treatments during the same period. Furthermore, physicians who use placebo treatments most commonly describe them to patients as a potentially beneficial medicine or treatment not typically used for their condition (241, 68%); only rarely do they explicitly describe them as placebos (18, 5%).

Conclusions Prescribing placebo treatments seems to be common and is viewed as ethically permissible among the surveyed US internists and rheumatologists. Vitamins and over the counter analgesics are the most commonly used treatments. Physicians might not be fully transparent with their patients about the use of placebos and might have mixed motivations for recommending such treatments.

INTRODUCTION

Before 1960, administration of inert substances to promote placebo effects or to satisfy patients' expectations of receiving a prescribed treatment was commonplace in medical practice.¹⁻³ With the development of effective pharmaceutical interventions and the increased emphasis on informed consent, the use of placebo treatments in clinical care has been widely criticised.^{4,5}

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Cite this as: *BMJ* 2008;337:a1938 [doi:10.1136/bmj.a1938](https://doi.org/10.1136/bmj.a1938)

This article is an abridged version of a paper that was published on bmj.com. Cite this article as: *BMJ* 2008;337:a1938

Despite the persistent controversy surrounding the use of placebo treatments, there are few systematic data concerning physicians' attitudes towards and use of placebo treatments in the United States.⁶⁻⁸ The few contemporary surveys from other countries suggest that more than half of physicians prescribe placebo treatment.⁹⁻¹¹

To further inform ethical discussions about the appropriateness of recommending placebo treatments, we examined the attitudes and behaviours regarding placebo treatments among a national sample of clinically active internists and rheumatologists in the US.

METHODS

Study population

Using the 2006 American Medical Association masterfile, we randomly selected 1200 physicians listed with the primary specialties of internal medicine (600) or rheumatology (600): a group of physicians who commonly treat patients with debilitating chronic clinical conditions that are notoriously difficult to manage. In June 2007, an independent survey research firm posted a confidential, self administered survey, a \$20 (£11, €15) incentive, and a letter outlining the voluntary nature of participation. Participants were assured that their identities would not be disclosed to investigators. Those who did not respond to the first survey were sent a second six weeks later. Of the 1200 physicians who were sent questionnaires, 679 responded (overall response rate 57%), of whom 334 specialised in internal medicine (56% response rate) and 345 in rheumatology (58% response rate).

Survey instrument

The questions on use of placebo treatment were incorporated into a survey that covered other topics related to complementary and alternative medicine

(details available on request). The survey was developed through a formal process and included a review of existing surveys on the use of placebo treatments.^{9,12} Because the term "placebo" and behaviours surrounding its use can be contentious, we devised a series of non-judgmental questions beginning with broad questions that avoided the term "placebo" and then gradually gained more specificity, culminating in items whose responses used a clear definition of a "placebo treatment." By constructing a series of items in this manner we allowed respondents to describe their attitudes and experiences as accurately as possible.

The first set of three items began with a hypothetical scenario in which a dextrose tablet was shown in clinical trials to be superior to a no treatment control group. Respondents were then asked to rate the likelihood of their personally recommending this treatment to non-diabetic patients with fibromyalgia; how often they recommend a therapy "primarily because you believe it will enhance the patient's expectation of getting better"; and whether recommending treatments in this manner was "obligatory," "permissible," "permissible in rare circumstances," or "never permissible." Respondents were then asked to indicate which of several treatments they had used within the past year primarily as a placebo treatment, defined as a treatment whose benefits derive from positive patient expectations and not from the physiological mechanism of the treatment itself; and how they typically described placebo treatments to patients.

Data management and analysis

We used descriptive statistics to examine physicians' characteristics as well as frequencies of reported behaviours and attitudes. We used multivariate logistic regression to determine if any characteristics of participants were independently associated with regularly prescribing placebo treatments. For this analysis our dependent variable was recommending treatments "primarily to promote patient expectations" at least two to three times a month based on self reporting.

RESULTS

The mean age of the 679 respondents was 51 years (range 28-88), 73% (477/652) were men, and 81% (526/648) were white. Overall, respondents most commonly reported a group practice setting (49%, 334/679), followed by solo practice (27%, 186/679), academic (14%, 96/679), and institutional (4%, 28/679). Respondents and non-respondents did not differ significantly according to age, sex, race, practice setting, or specialty.

When asked if they would recommend a dextrose tablet for a patient with fibromyalgia if trials had shown such treatment to be superior to no treatment, most respondents (58%, 381/654) said they would be very likely or moderately likely to recommend it. Similarly, 46% (298/646) reported actually recommending a treatment primarily to promote patient expectations at

Table 1 Attitudes and behaviours related to prescribing placebos among 679 US general internists and rheumatologists

Question and categories of response	No (%)*
How likely are you to recommend sugar pill proved to be better than no treatment for fibromyalgia?:	
Very likely	160/654 (24)
Moderately likely	221/654 (34)
Unlikely	205/654 (31)
Definitely not	68/654 (10)
How often do you recommend treatment primarily to enhance patient expectation?:	
Never	129/646 (20)
≤1/month	219/646 (34)
2-3/month	182/646 (28)
≥1/week	116/646 (18)
Is it appropriate to recommend treatment primarily to promote patients' expectations?:	
Obligatory	19/642 (3)
Permissible	380/642 (59)
Permissible only in rare circumstance	197/642 (31)
Never permissible	46/642 (7)

*Based on actual numbers.

Table 2 | Treatments used as placebo in past year and how they are described to patients among 679 US general internists and rheumatologists

Question and response items	No (%*)
Recommended as "placebo treatment" in past year:	
At least one of any type	370/679 (55)
Overcounter analgesics	267/648 (41)
Vitamins	243/648 (38)
Sedatives	86/652 (13)
Antibiotics	85/644 (13)
Saline	18/623 (3)
Sugar pills	12/642 (2)
How placebo treatments are typically described to patients:	
Not used	285/637 (45)
Medicine	62/352 (18)
Placebo	18/352 (5)
Medicine with no known effects for your condition	31/352 (9)
Medicine not typically used for your condition but might benefit you	241/352 (68)

*Based on actual numbers of respondents. All 679 respondents answered most questions. Percentages reflect 352 responses of 637 respondents who deemed the question relevant. The 285 respondents who marked "irrelevant—I do not prescribe placebo treatments" were not included in these percentages.

least two to three times a month. The physicians' ethical judgments were also favourable toward the use of placebo treatments, and 62% (399/642) said recommending treatments in this manner was ethically obligatory or permissible (table 1).

Within the previous year, 55% (370/679) of physicians reported having recommended at least one placebo treatment (including "active" and "inactive"). Active placebo treatments were more commonly reported, such as over the counter analgesics (41%), vitamins (38%), antibiotics (13%), and sedatives (13%). Only 2% recommended "sugar pills" and 3% saline (table 2).

When asked to describe how they typically introduce placebo treatments to their patients, 45% (285/637) reported never recommending placebo treatments, implying that 55% (352/637) agreed that they had recommended a placebo treatment as defined. Among these 352, about 68% (241) said they usually describe placebo treatments as "a medicine not typically used for your condition but might benefit you," (table 2).

After we controlled for all other characteristics, neither age, sex, race, specialty, practice setting, nor region was independently and significantly associated with having recommended a placebo treatment.

DISCUSSION

Summary of major findings

Between 46% and 58% of US internists and rheumatologists engage in recommending placebo treatments as defined. To accurately assess attitudes and behaviours relating to placebo treatments, we asked the physicians about recommending placebo treatments in four distinct ways: response to a hypothetical case, self reported behaviour without the term "placebo treatment," self reported behaviour with the term "placebo treatment," and inclusion of "I never use placebo

treatments" as a response option in our item related to communication with patients. The first two of these were asked without introducing the term "placebo" to allow the most candid and unbiased responses. The third and fourth were asked after a careful definition of a "placebo treatment." The similar rates across these four different measures indicate that our findings are unlikely to be the result of question framing, wording, or the specific definition of placebo treatment used.

Relation to other studies

Our results are consistent with the findings of other studies. Recently, Sherman and Hickner surveyed a convenience sample of 231 academic physicians in the Chicago area and found that 45% had used placebo treatments in clinical practice.⁸ Indeed, 8% indicated using placebo treatment more than 10 times in the past year. A Danish survey reported that 86% of 545 general practitioners used a placebo treatment at least once within the past year, and 48% reported using placebo treatments more than 10 times in the past year.¹² Smaller surveys from Israel, the UK, Sweden, and New Zealand report similar results.⁹⁻¹¹

Unresolved questions

Few of the physicians we surveyed recommend inert placebo treatments. The reasons for this are unclear. It might no longer be possible for physicians to write a prescription for a sugar or bread pill. Without the existence of pharmacies to create such pills, and a lack of actual pills being marketed for such use, physicians could not prescribe them routinely even if they wanted to do so. Or they might have understandable reservations about recommending so called "inactive" or "inert" placebo treatments, fearing these treatments are inherently deceptive and are not amenable to contemporary standards of informed consent.

Yet these data also suggest the desire to promote positive therapeutic expectations among patients is prevalent among the surveyed physicians. The

WHAT IS ALREADY KNOWN ON THIS TOPIC

Recommending treatments to promote patients' expectations (placebo treatments) seems to be common in several developed countries

The routine use of placebo treatments raises ethical questions about deception in clinical practice

WHAT THIS STUDY ADDS

Half of the US internal medicine and rheumatology physicians studied reported often recommending placebo treatments, most commonly vitamins, over the counter analgesics, and antibiotics

Most viewed this practice as ethically permissible

Physicians might not be fully transparent with their patients about their motivations but largely avoid prescribing sugar pills and saline

responses suggest a preference for active placebo treatments. Recommending relatively innocuous treatments such as vitamins or over the counter analgesics to promote positive expectations might not raise serious concerns about detrimental effects to patients' welfare. Prescribing antibiotics and sedatives when they are not medically indicated, however, could have potentially important adverse consequences for both patients and public health. In the absence of knowing the physicians' indication or motivation for recommending placebo treatments, the interpretation of our findings remains speculative. These issues deserve further investigation (see bmj.com).

Limitations

The cross sectional, self reported design might not have accurately estimated the actual frequency of recommending placebo treatments. The moderate response rate (57%) also limits our ability to make exact estimates of the behaviour in the entire population of these groups of physicians; and our findings might not be generalisable to attitudes and behaviours in other medical specialties. Furthermore, because these items were included in a survey on complementary and alternative medicine, it is possible that the physicians who chose to respond were more favourably disposed to prescribe placebo treatments than most physicians. However, our findings are consistent with the results of other published studies concerning physicians' use of placebo treatments.

Conclusions

US internists and rheumatologists commonly recommend "placebo treatments." Vitamins and over the counter analgesics are the most commonly prescribed. Physicians who use placebo treatments may not be fully transparent with their patients about their use.

Whether, or under what circumstances, recommending or prescribing placebo treatments is appropriate remains a topic for ethical and policy debates.

Development and implementation of the survey was performed by the Center for Survey Research, University of Massachusetts, Boston, MA. Statistical support was provided by Summit Consulting, LLC, Washington, DC.

Contributors: See bmj.com.

Funding: National Center for Complementary and Alternative Medicine (NCCAM) and the Department of Bioethics, National Institutes of Health, Bethesda, MD. NCCAM was not involved in data collection, analysis, or writing of the manuscript.

Competing interests: None declared.

Ethical approval: University of Massachusetts Boston Institutional Review Board and the Offices of Human Subjects Research at the National Institutes of Health.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Accepted: 19 August 2008

Old age swimming

A retired colleague sent me an email remarking that he had just mown his giant lawn. He added that, according to *Who's Who*, Professor Jeremy (Jerry) Noah Morris, pioneer of social medicine who emphasised the link between exercise and health, is now 98 years old.

A swim before work at the local pool on a Thursday is part of my regular routine. This week, there was an 85 year old vigorously swimming while complaining that others half her age were swimming too slowly and getting in her way. Another woman over 80 years old wasn't particularly energetic but was the only swimmer who had clearly put on lipstick before her swim, and she was wearing the trendiest swim suit. The Asian elderly-ladies-only keep fit group was doing just that, but the 80 year old who usually crosses herself before she dives in was not there. Alan (in his 70s), who repeatedly whizzes along with front crawl in one direction and then dawdles back with backstroke, was swimming as usual and greeted me with, "It must be Thursday." A couple of very elderly gentlemen were discussing their sporting injuries; another mature, white haired, goggle wearing swimmer shouted over from the fast lane a heartfelt criticism of a television programme she

had watched the previous evening. One man of some great age who swam front crawl in ovals and regularly cut across other people who were trying to swim lengths was banned not so long ago for his antisocial swimming behaviour.

So what is this all about? We need to change the perception of junior doctors working with elderly people that they are passive, slow moving, and inactive individuals. Those swimming were ordinary energetic, spirited, older people living life to the full and taking every step to promote their own health. An early morning swim at the local pool should be mandatory for all junior doctors working with older people.

In his *Who's Who* entry, Professor Morris includes walking and swimming among his interests, and the UK government has—long overdue but perhaps heeding his advice—announced a scheme for free swimming, initially for people aged over 60, as part of the 2012 Olympic legacy.

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Cite this as: *BMJ* 2008;337:a1189