Berkala Ilmu Kedokteran
Vol. 29, No. 4, Desember 1997

Iron fortification milk supplementation in reducing the incidence of low birth weight

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ABSTRACT

Tonny Sadjimin - *Iron fortification milk supplementation in reducing the incidence of low birth weight*

The objective of the study was to examine the effectiveness of iron-fortification milk as a supplementation feeding for pregnant women in preventing the incidence of low birth weight. The design of the study was randomized controlled double-masked community trial. The setting were Maternity clinics at the health centers, private clinics, and hospital located in Yogyakarta Municipality, Indonesia. The patients were 138 pregnant women aged 20-30 years, parity of 2 or less, 24-26 gestation weeks, no adverse obstetric history or systemic diseases, signed informed consent. A well-trained field worker at least 24 hours after delivery measured the average weight and length of newborn. The low birth weight was considered to babies who have a birth weight of 2500 g. or less. A logistic regression was used to measure the effect of the intervention to the incidence of low birth weight controlled for several potential confounding variables. The demographic characteristics and laboratory indexes of mothers at the entry were equally distributed between both comparison groups. All 138 mothers were identified during the delivery, but some mothers were refused to have blood drawn at the time of delivery. The incidence of LBW in the study group was 1.4 % and in the control group it was 11.6%, the relative risk of 0.12 (95% CI 0.01 - 0.97). After controlling for potential confounding variable the relative risk become 0.32 (95% CI 0.11 - 0.98).
Lactamil, the iron-fortification milks as the supplementation. protein-energy-micronutrient and vitamins to pregnant women are significantly prevent the incidence of low birth weight.

Key words: **iron - low birth weight - pregnant mother - fortification milk - birth length**

ABSTRAK

Tonny Sadjimin - ***Susu fortifikasi zat besi sebagai minuman suplementasi bagi ibu hamil dalam upaya menekan kejadian bayi berat lahir rendah***

Penelitian ini bertujuan untuk menguji pengaruh susu fortifikasi zat besi sebagai minuman suplementasi bagi ibu hamil dalam upaya menekan kejadian bayi berat lahir rendah. Penelitian dilaksanakan dengan pendekatan rancangan acak terkendali buta ganda. Dilaksanakan di klinik bersalin Puskemas, klinik bersalin swasta, dan rumahsakit di Kotamadya Yogyakarta. Pasien adalah 138 ibu hamil, umur 20-30 tahun, paritas 2 atau kurang, umur kehamilan 24-26 minggu, tanpa riwayat obstetrik buruk dan penyakit sistemik, dan menandatangani surat pernyataan persetujuan (*informed consent*). Berat bayi saat lahir diukur oleh petugas terlatih dengan timbangan yang sama, paling tidak 24 jam setelah lahir. Bayi berat lahir rendah (BBLR) adalah mereka yang lahir dengan berat badan 2500 gram atau kurang. Regresi logistik digunakan untuk mengukur efek intervensi pada kejadian bayi berat lahir rendah dengan pengendalian beberapa variabel berpotensi menggangu. Karakteristik demografik dan indeks laboratorium ibu pada saat masuk penelitian terdistribusi seimbang antara kedua kelompok yang dibandingkan. Semua ibu yang masuk penelitian terdeteksi pada saat melahirkan, namun beberapa ibu menolak untuk diperiksa darahnya pada saat melahirkan. Kejadian BBLR di kelompok penelitian adalah 1,4%, sedangkan di kelompok kontrol mencapai 11,6%, dengan risiko relatif mencapai 0,12 (Batas Kepercayaan 95%, 0,01 - 0,97). Setelah dikendali terhadap variabel berpotensi mengganggu, nilai 'adjusted odd ratio' mencapai 0.32 (Batas Kepercayaan 95%, 0,11 - 0,95). Lactamil, susu fortifikasi zat besi, yang juga mengandung tinggi protein, energi, multivitamin, dan mikro-nutrien sebagai suplementasi minuman pada ibu hamil secara bermakna mencegah kejadian bayi berat lahir rendah.

(B.I.Ked. Vol. 29, No. 4:193-200, Desember 1997)

INTRODUCTION

Infant mortality rate (IMR), which highly influence a by perinatal conditions in Indonesia, is expected as low as 35 per 1000 live births at the year of 2000. The health and welfare of infants are very much affected by the health status of the mothers, including the physical conditions, since the conception and will continue to the weaning period. The nutritional status of the mothers during pregnancy and breast-feeding, therefore, is a crucial component to the outcome of the pregnancy and thereafter. Iron deficiency anemia among pregnant women has been shown to have a strong relationship with the high incidence of low birth weight, prematurity and neonatal death, beside the survival of the mothers. The average hemoglobin level among pregnant mothers in Yogyakarta had been reported at the level of 9.3 g/dl in compare to 8.7 g/dl in other 7 provinces[1]. Iron pill distribution is part of the existing maternal health program provided to pregnant women in Indonesia. However the effectiveness to the health of the pregnant women and their offspring still need to properly study. Schultink *et al.*, in the study about the compliance to iron-supplementation program in Indonesia, showed that only 12 out of 33 pregnant women (36.4 %) really complied to consume the iron tablet[2]. It is anticipated that the low compliance to take iron doses is due to the unacceptable taste from the stomach after the dose.

There are two approaches to prevent the occurrence of iron deficiency, i.e. to reduce iron losses (e.g. reducing menstrual iron losses by using a contraceptive pill or combatting hookworm infestation) or to increase iron absorption. The iron absorption can be increased by 1) modifying the composition of meals – increasing the content of dietary factors enhancing iron absorption or reducing the content of factors inhibiting iron absorption, 2) increasing the iron content of the diet by fortification with iron, or by 3) supplementation with iron tablet. Lactamil (a product of Sarihusada, Yogyakarta, Indonesia), is a milk fortificated with iron aimed as the supplement for pregnant and nursing mothers. The content of Lactamil is presented in TABLE 1. For every 30 mg of Lactamil, as one dose for pregnant women, the energy would be 140.4 kcal, protein 4.5 g, and carbohydrate 17.1 g. The high vitamin C content of the milk is to enhance the optimal absorption of iron. The milk also contents several important micronutrients and vitamins.

The aim of this study was to measure the effectiveness of Lactamil (iron supplementation milk) in reducing the occurrence of low birth weight babies.

TABLE 1. – The composition of Lactamil

	Unit	per 100 gram of Lactamil
Protein	g	15
Fat	g	20
Carbohydrate	g	57
Ash	g	5
Water	g	3
Energy	kcal	468
Vitamin A	IU	3.000
Vitamin D3	IU	600
Vitamin E	IU	10
Vitamin B1	mcg.	1,100
Vitamin B2	mcg	1,400
Vitamin B6	mcg.	1,600
Vitamin B12	mcg	2.7
Vitamin C	mg.	250
Niacinamid	mg	12
Folic Acid	mg.	833
Calcium	mcg.	670
Phosphor	mg.	360
Natrium	mg.	288
Kalium	mg.	650
Chloride	mg.	573
Iron	mg.	24
Zinc	mg.	37
Iodium	mg.	117

MATERIAL AND METHODS

The study has been conducted in 10 health centers in the Municipality of Yogyakarta, The Department of Obstetrics and Gynecology, Dr. Sardjito General Hospital, and one Private Maternity Clinic after signing agreement to participate in the study. This study has been approved by the Ethic Committee on Biomedical Research of the Faculty of Medicine, Gadjah Mada University. Those locations mostly occupied by middle social-economic class population in Yogyakarta. To participate in the study the pregnant women should be in the age of 20 - 30 years, parity of 2 or less, 24 - 28 weeks of gestation age, should not have any adverse history of pregnancy or delivery, and does not have any medical and health problem. All participants had signed an informed

consent before enter the study after received a detailed explanation about the procedure of the study.

The sample size needed for both comparison groups was 138 pregnant women who attended the normal pregnancy care program at the participated clinics. The selection of the clinics was to ensure the high percentage of follow up of individual participant and for the practicality of logistic issues. Participants received a unique random numbered envelope that assigning them to either group, the active milk or the placebo group. The placebo is a cassava powder with the appearance and taste similar to the active milk and consisted of 10 g carbohydrate/100 g powder. All the milk and placebo were prepared in sachets by the Milk Company that did not have access to any of the participants. None of parties who involved in the study accessed to the code number of the study before the termination of investigation. Every pregnant mother received 2 sachets weekly distributed by well-trained field study workers in the collaboration with the clinics. When the subject was not seen at the time of appointment the field worker conducted a home visit to encourage subject to go to the clinic for examination. At the time of recruitment blood samples were drawn, repeated at the time of delivery or at least 24 hours after delivery and sent immediately to the independent clinical laboratory. Participants should consumed 30 grams of the milk or placebo, which was diluted to 180 ml of water, twice a day. Every participant was requested to visit the clinic fortnightly to take the next sachets of milk beside regular clinical examination, during which the clinic reviewed the compliance of the mothers to take the milk. There was no attempt to control the clinics policy on the regular examination and medication, including on providing iron supplementation and vitamins.

At the time of entry each participant was interviewed by a well trained study worker concerning personal social-economic identifications, past-history of pregnancy and delivery, anthropometric measurement (height and weight), and information on individual expectation on pregnancy and site of delivery. The weight of the participants was measured at every visit to the clinic and the last weight before delivery was used to measure the increment of maternal weight during pregnancy. Every participant was visited fortnightly by field worker to measure the compliance to the research procedures and the occurrence of adverse effect of the milk. In the site visit each participant received message to inform the study center about delivery or at least 24 hours after delivery. The study worker using standard weight and height scales measured the weight and length of the babies at least 24 hours after birth.

The main outcome of interest in this study was the incidence of low birth weight (<2500 g). Bivariate statistical analysis was performed using the Chi square test and Student's t test where appropriate. Multiple logistic regression was administered in the analysis to control for potential confounder. Adjusted odds ratios (AORs) and their 95% confidence intervals (CIs) were computed from the logistic-regression coefficients and the corresponding covariate matrix. The potential confounding factors associated with poor perinatal outcome, such as: maternal height and weight at entry, the increment of maternal weight from entry to the latest weighted before delivery, the hematocrit decrease less than 5 at delivery were included in the equation.

RESULTS

There were 138 pregnant women who enter the study and all newborn babies were covered at the termination of the study. The study and control groups were comparable on every socio-demographic characteristics at the start of the study (TABLE 2). There were 34.3% of the study group who completed the primary school education, and 28.6% in the control group which are much better than the total female education at the country level, in 1990 women (10 years and older) who did not complete primary school was 46.7%[1]. Most of the participants were housewives (55.2% in the study group and 57.1% in the control group), and most of them were labor, private business, and few as the civil servant. The level of education of the husband was mostly better than those of the participant of the study. Only 24.2% of the husbands in the study group and 16.1% in the control group have the education of primary school and the rest have higher education (p=0.62). Seventeen percent of the husbands in the study group and 17.7% in control group

TABLE 2. – The comparison between study groups on socio-demographic characteristic of subjects

No. Variables	Study Group		Control Group		χ^2	p
	n	%	n	%		
1. Maternal Education						
No Formal Education	-	-	1	1.6	4.35	0.49
Finished Primary	23	34.3	18	28.6		
Secondary	12	17.9	16	25.4		
High	23	34.3	24	38.1		
Academic/Univesrity	9	13.4	4	6.4		
2. Maternal Occupational						
Civil Servant	3	4.5	6	9.5	5.29	0.38
Peasant			2	3.2		
Labor	9	13.4	9	13.4		
Business	6	9	4	6.3		
Housewife	37	55.2	36	57.1		
Others	12	17.9	6	9.5		
3. Paternal Educational						
Primary	16	24.2	10	16.1	2.63	0.62
Secondary	11	16.7	14	22.6		
High	28	42.4	29	46.8		
Academic/University	11	16.6	9	14.5		
4. Paternal Occupational						
Civil Servant	11	16.7	11	17.7	2.59	0.63
Peasant	2	3	5	8.1		
Labor	16	24.2	13	21		
Business	21	31.8	15	24.1		
Others	16	24.2	18	29		

TABLE 3. – The comparison between study and control groups on several potential confounding variables (at entry)

No. Variables	Study Group X (S.D)	Control Group X (S.D)	t-value	p
1. Maternal Age (yrs)	24.7 (0.3)	23.8 (0.3)	1.61	0.11
2. Maternal Weight (Kg)	52.1 (5.9)	51.6 (5.8)	0.45	0.65
3. Maternal Height (Cm)	153.7 (4.9)	152.0 (5.1)	1.81	0.073
4. Left Mid-Upper-Arm-Circ (Cm)	23.5 (2.4)	23.3 (2.6)	0.47	0.64
5. Hemoglobin (g/dl)	11.2 (1.1)	12.4 (1.4)	0.95	0.34
6. Hematocrit (%)	34.5 (3.3)	34.3 (3.0)	0.3	0.76
7. Total Protein (g %)	6.4 (0.4)	6.4 (0.5)	0.79	0.43

TABLE 4. – The comparison between study groups for several potential confounding variables (at delivery)

No. Variables	Study Group	Control Group	t-value	p
1. Maternal Weight	54.6 (6.0)	53.3 (6.6)	1.12	0.264
2. Increment Maternal Weight	1.83 (0.38)	1.81 (0.39)	0.22	0.827
3. Hemoglobin	12.3 (1.4)	12.3 (1.4)	0.15	0.88
4. Hematocrit	37 (3.9)	37.1 (4.4)	0.06	0.96
5. Total Protein	7 (0.6)	6.8 (0.6)	1.3	0.18

worked as civil servant and most of the husbands' main occupation was business (p=0.63).

The anthropometric measurement and some laboratory indexes of the subjects were similar between both groups (TABLE 3). The average age of women were 24.7 years in the study group and 23.8 years in the control group (p=0.11). The average weight of subject at entry was 52.1 kg in the study group and 51.6 kg in the control group (p=0.65), and the height of the subjects was slightly higher in the study group (153.7 cm) compared to those of the control group (152.0 cm) (p=0.073). Together with the left mid arm circumference it can be seen that the participants

TABLE 5. – Correlation between low birth weight and some potential confounding factors

No. Variables	NBW X (± SD)	LBW X (± SD)	t-value	*p*
1. Maternal Age (yrs)	24.3 (3.0)	23.7 (3.2)	0.57	0.58
2. Maternal Weight (kg)	54.2 (6.3)	51.3 (6.2)	1.33	0.21
3. Increment Maternal Weight	1.84 (0.37)	1.56 (0.53)	1.58	0.15
4. Maternal Height (cm)	153.1 (5.1)	150.0 (4.9)	1.8	0.1
5. Hemoglobin (g/dl)	12.2 (1.4)	12.7 (0.83)	1.26	0.23
6. Hematocrit (%)	36.9 (4.2)	37.9 (2.2)	0.95	0.36
7. Total Protein (g %)	6.9 (0.6)	7.2 (0.3)	2.22	0.047

TABLE 6. – The relative risk of intervention to the incidence of low birth weight short birth length

	Study Group n (%)	Control Group n (%)	R.R.	95% C.I.
Birth weight:				
< 2500 gr	1 (1.4)	8 (11.6)	0.125	0.02 - 0.97
≥ 2500 gr	68 (98.6)	61 (88.4)		
Birth length:				
< 47 cm	5 (7.2)	13 (18.8)	0.384	0.14 - 1.02
≥ 47 cm	64 (92.8)	56 (81.2)		

of the present study were having a better nutritional status than those of the general population. These conditions were anticipated as the result of the design of the study, which recruited the subject from the middle class socio-economic pregnant mothers. The anemia status of the pregnant women at the time of entry was not significantly different between both groups. The average of hemoglobin level in the study group was slightly lower (11.2 g/dL) than the control group (p=0.34) and there was no significant different on hematocrit and total protein average level (p=0.76 and p=0.43, respectively) between the two groups.

At delivery several potential confounding variables were shown no relationship with the comparison groups (TABLE 4). The incremental maternal weight at entry and at delivery was similar between both groups, i.e 1.83 ± 0.38 and 1.81 ± 0.39 for the study group and control group respectively. The laboratory indexes, hemoglobin, hematocrit and total protein, showed no difference between the comparison groups.

The relationship between the occurrence of low birth weight with several potential confounding variables are presented on TABLE 5. None of the maternal anthropometric parameters was shown to have any relationship with the occurrence of low birth weight, eventhough all the indexes were lower among the low birth weight compared to those of normal birth weight. The age and height of the mothers were measured at entry whereas the other measurements were taken at delivery.

The average of birth weight in the study group and control group were 3152 ± 384 and 3008 ± 457 g. respectively (p=0.58) (FIGURE 1). The proportion of newborn babies with birth weight of less than 2500 gram, however, in the study group was 1.4% and in the control group it was 11.6 %, with the Relative Risk of 0.12 (CI 95% 0.01-0.97) (TABLE 6). The proportion of babies with length less than 47 cm. (length of babies at 25 percentiles) was 7.2% in the study group and 18.8% in the control group (p=0.077), the odds risk of 0.384 (95% CI: 0.14 - 1.02) with 11.6 percentage points of difference.

The adjusted odds risk of comparison groups for low birth weight controlling for several potential confounding factors was 3.06 (95% CI= 1.02 - 9.17) with significance level of 0.048 (TABLE 7). Whereas the adjusted odds ratio of comparison groups for the incidence of short birth length of the newborn babies was 6.09 (95% C.I. 1.46 - 25.4) with significance level of 0.013 (TABLE 8). It was also shown that the increment of maternal weight has significant impact to the birth length of the babies, with the odds ratio of 0.21 (95% C.I. 0.05 - 0.89; p=0.034)

TABLE 7. – Adjusted odds ratio for low birth weight after controlling for selected potential confounding factors

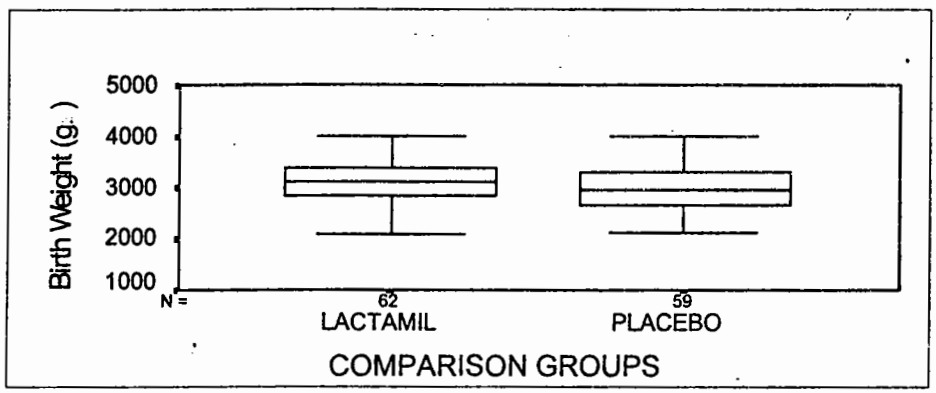
	Odds ratio	95% confidence interval for odds ratio	*p* value
Comparison groups	3.06	1.02 - 9.17	0.046
Maternal height*	0.5	0.85 - 4.71	0.114
Hematocrit*	0.24	0.27 - 1.59	0.235
Increment maternal weight	0.35	0.16 - 1.58	0.352
Maternal weight*	0.8	0.32 - 1.95	0.625

* at entry

TABLE 8. – Adjusted odds ratio for short birth length after controlling for selected potential confounding factors

	Adjusted Odds ratio	95% confidence interval for odds ratio	*p* value
Comparison groups	6.09	1.46 - 25.4	0.013
Increment maternal weight	0.21	0.05 - 0.89	0.034
Maternal height*	0.24	0.05 - 1.03	0.243
Maternal weight*	2.82	0.51 - 15.5	0.235
Hematocrit*	0.84	0.20 - 3.52	0.814

* at entry



Lactamil X = 3152 (± 384) g
Placebo X = 3008 (± 457) g p = 0.058

FIGURE 1. – The mean birth weight by comparison groups

DISCUSSION

The belief of the community to give birth for a big newborn baby is the risk to the live of the mother should be actively intervened in order to improve the quality of human live by giving birth to a better survival rate of the baby. Low birth weight newborns contribute significantly to the high infant mortality rate. Growth before birth is determined by a combination of genetic potential, the mother, and the intra uterine environment, which in turn will affect the birth weight of the newborn[3]. The same authors reported 18 controlled clinical trials have been conducted to prevent and treatment premature labor by three different types of labor inhibitors (hormones, ethanol, and β-symphathomimetics)[4]. In the present study most of the condition under investigation was the maternal health status. Several issues anticipated at the planning were the iron, vitamin, and protein and energy intervention to the normal pregnancy. Many authors suggested to include the birth weight, birth length, placenta weight, ratio placenta weight/birth weight and infant morbidity and mortality in various perspectives as the result

of iron, vitamin, protein and energy maternal intervention[5,6]. The maternal conditions such as the general anthropometric measurement, the anemia, and biochemistry nutrition status were measured during the execution of the study and the results are reported somewhere else.

During pregnancy the need for iron is increased, mostly for the increasing maternal hemoglobin mass (demand: 500-600 mg iron) and for the growing fetus and placenta (demand: 350-450 mg iron)[7]. The hemoglobin level of the mothers during pregnancy and at term was similar to those reported by Lops *et al.*[8] At the beginning of the present investigation, 24-26 weeks gestational age, the average hemoglobin level was 11.2 (± 1.1) g/dL, which is similar to those in their study (11.6 g/dl). The hemoglobin level average at delivery was 12.2 ± 1.2 g/dL in the present study and 12.9 g/dL in their study. The maternal anemia status in the present study at entry was considered as mild anemia which gave no effect of the intervention on the anemia status of the mothers at term.

The incidence of LBW in the control group was lower to those reported by Alisyahbana *et al.*[9] In a community study in West Java she reported that the incidence of LBW was at the level of 13%, which is referred as the national figure of the risk of newborn in Indonesia to born with low birth weight. Scholl *et al.* reported that the incidence of LBW was slightly affected by the maternal anemic status at the odd ratio of 3.10 (95% CI 1.16-4.39) which is much lower than those found in this study (i.e 8.3)[10]. A study conducted by Sagen *et al.* showed a converse result, the average birth weights were reduced by the increased hemoglobin level of the normal pregnant women[6]. In the present study the average of birth weight in the study group was 3135 g (SD ± 381g) and in the control group was 3005 g (SD ± 461g) with level of significance of p=0.058.

The supplementation milk in the present study was not only to provide more iron, but also the vitamins and other micronutrients, protein and energy. Hemminki and Starfield reviewing 17[5] controlled clinical trials, found the apparent lack of the benefit from iron, and the supplementation of several minerals and vitamins produced fewer deliveries before the 40th week and less preeclampsia. The problems found were most probably related to the methodological issues, such as sample sizes and controlling for the cofounders. Thomsen *et al.* showed that the 100 mg/daily iron supplementation started at 16 weeks of gestation significantly increased the anemia status of mothers at the delivery compared to 18 mg/daily.[7] Achadi *et al.* showed in a community study that the iron tablet consumption, maternal height, pregnancy weight gain, and gender of the neonates related to the birth weight[11] and maternal height, the iron tablet consumption, and gender of infant related to the length at birth. Whereas, Viegas *et al.* failed to show a significant higher birth weight in an protein-energy-vitamins and iron supplementation intervention for pregnant mothers[12]. The most likely issues considered in that study, beside methodological problems, was that the health status of the subjects would not appropriate for the intervention. In the second of their study the intervention then showed a significant effect on the favor of heavier birth weight after some issues have been overcome[13]. In a randomized controlled trial among the undernourished pregnant mothers the supplementation of protein-energy-vitamins was significantly increased the average of birth weight compared to those who just received vitamins. Pregnant mothers who received protein-energy-vitamin delivered newborn with the average of 3350 ± 470 g and it was 3020 ± 260 in the group that received vitamin only. In the present study the composition of supplementation milk also provided protein and energy that were higher than those received by the control group who just received ignored addition carbohydrate from the placebo liquid. Eventhough the effect of the intervention did not significantly show any difference for the protein level of the mothers at time of delivery, it was clear that there was a relationship between the incidence of LBW with the protein level. Bhagava *et al.* reported[14] that severe anemia during pregnancy (equal or less than 6.0 g/dL) significantly affected the average of birth weight, with the difference of 496 g[14].

In conclusion, the Lactamil, the iron fortification milk as the supplementation protein-energy-micronutrient and vitamins to pregnant women showed a significant impact to reduce the incidence of low birth weight and short birth length.

ACKNOWLEDGMENT

I wish to acknowledge PT Sarihusada, Yogyakarta and INCLEN Inc., Philadelphia for the support of the study. The Maternity Clinics, the Health Centers, Dr. Sardjito General Hospital, and all participant mothers of this study for their attention and participation. Special thanks also extend to the Department of Social Medicine, School of Medicine, Harvard University for the chance to write the manuscript.

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