ORIGINAL ARTICLE

Effect of personalized home-based support for pregnant women on pregnancy outcomes: a cluster randomized trial

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Abstract

Background. Anemia during pregnancy has been linked to higher maternal and perinatal morbidity and mortality.

The purpose of this study is to examine the impact of individualized home-based care for pregnant women on pregnancy outcomes.

Methods: This was a cluster-randomized experiment done in Burkina Faso's Sindou health area between 2015 and 2016. The intervention included a monthly home-based visit focused on nutritional counseling and pregnancy monitoring for pregnant women, and a training on nutrition for pregnant women, prevention of anemia in pregnancy, and management of anemia in pregnancy for health facility teams. In the control group, prenatal care was administered in accordance with national program guidelines. The primary outcome was the reported prevalence of anemia in pregnancy. The secondary outcomes of still-birth, preterm birth, low birth weight, and abortion were evaluated using a difference in differences analysis and mixed models across the two groups. The sample consisted of 617 pregnant women, with 440 women assigned to the intervention group and 177 assigned to the control group. No maternal fatalities occurred in either group. The intervention decreased stillbirths by -1.6% (95% confidence interval: -3.1% to -0.1%). It had no impact on the rates of low birth weight, premature birth, and abortion.

Conclusion: In rural Burkina Faso, personalized support of pregnant women at home, in conjunction with appropriate prenatal care, reduced stillbirths, but not the rates of low birth weight, preterm birth, or abortion.

Keywords: anemia, pregnancy outcome

INTRODUCTION

Anemia during pregnancy is a public health concern, especially in nations with low incomes. Its prevalence exceeds 50% in most sub-Saharan African countries, including Burkina Faso.[1] Malaria in endemic regions and nutritional deficiencies (mostly iron and folic acid) are the leading causes of anemia during pregnancy. Additional causes of anemia during pregnancy include bleeding, hemoglobinopathies, helminthic infections, and infections (in particular HIV and *Helicobacter pylori*). There is a correlation between anemia and increased maternal and perinatal morbidity and mortality.[2] Anemia during pregnancy contributes to over 10% of perinatal death, preterm, and low birth weight. In situations of severe anemia, maternal mortality and the risk of postpartum hemorrhage increase by a factor of 3.[3,5] To prevent these effects, an adaptive approach to anemia must be implemented in accordance with World Health Organization (WHO) recommendations.[6]

In health facilities in Burkina Faso in 2016, there were 18.9 stillbirths for every 1,000 live births. These clinics reported 35,100 abortions, which accounted for 3.3% of anticipated pregnancies. In 9.4% and 1.95% of live births, low birth weight and preterm birth, respectively, were documented.[7] Burkina Faso's health stakeholders have developed a number of strategies to reduce these unfavorable outcomes, the most important of which are pregnancy monitoring, free care for pregnant women, and family planning. Within this context, the primary strategies for preventing anemia in pregnancy are iron and folate supplementation, intermittent preventive treatment (IPT) of malaria with sulfadoxine-pyrimethamine, and distribution of insecticide-treated nets (ITNs) to pregnant women residing in health facilities. Despite these efforts, the prevalence of anemia in pregnancy in Burkina Faso has remained stable for decades.[8−10] Burkina Faso's Sindou health district undertook a cluster-randomized study concentrating on individualized home-based support from 2015 to 2016 in an effort to solve the issue. Compared to individual-level randomized trials, this study had the advantage of considering the cluster-related mass effect. The major objective was to lower the prevalence of anemia in pregnancy. This study's findings were reported in a prior paper.[11] This article is predicated on the notion that decreasing the prevalence of anemia reduces the incidence of stillbirth, preterm birth, low birth weight, and abortion. It describes how the intervention affected these secondary outcomes.

MATERIALS AND METHODS

This chapter, more detailed in a previous publication,[11] here abridged, presents specific aspects related to secondary outcomes.

Ethical Consideration. The study was conducted in accordance with the terms of the Declaration of Helsinki and all procedures involving the participants were approved by the Ethics Committee of the Centre Muraz (Ref. 022-2014/CE-CM, 22-10-2014) in Bobo-Dioulasso,[12] Burkina Faso. The study has also been approved by the health authorities. Informed and written consent was obtained from all participants. Pregnant women suffering from anemia (hemoglobin level < 11 g/dL) were referred and/or accompanied to their referring health facility. The study did not involve any major risks to the integrity and rights of the participants. The data forms were kept under key; they were de-identified for data entry and processing.

Study design. It was a cluster randomized trial conducted from 2015 to 2016 in Sindou health district in western Burkina Faso.

Participants. The study included pregnant women in the health facilities of Sindou district from August 1 to November 30, 2015. These women were followed up from September 2015 to August 2016. The health facilities were considered as clusters.

Supplementary information The online version of this article (Figures/Tables) contains supplementary material, which is available to authorized users.

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Inclusion criteria of health facilities. All peripheral health facilities in the district were eligible.

Inclusion criteria of pregnant women. All consenting women in their first or second trimester of pregnancy and attending antenatal care in the selected health facilities were included in the study. The gestational age at inclusion was reported from the woman's antenatal visit booklet.

Sample size. Ten clusters of 40 pregnant women each, corresponding to 10 health areas, divided into two groups (6 clusters for the intervention group and 4 clusters for the control group) were selected from a total of 28 health areas in the district. This sample allowed to detect with a threshold of 5% and a power of 80% (two-tailed test), a difference between the mean hemoglobin levels of the two groups of 0.81 g/dL. This estimate accounted for the standard deviation of hemoglobin of 1.5 g/dL observed in a study conducted in Sindou in 2012.[13] A total of 617 women were enrolled in the trial and included in the analysis, including 440 in the intervention group and 177 in the control group; the average number of women per cluster was 62.

Variables

The dependent variables (as secondary outcomes) were:

● % abortion defined as the expulsion of a dead fetus before 22 weeks of gestation;[14]

● % stillbirth defined as the expulsion of a dead fetus after 22 weeks of gestation;[14]

● % low birth weight defined as a birth weight < 2500 g;[15]

● % preterm birth defined as any live birth after 22 weeks and before 37 weeks of gestation;[16]

The birth weight was recorded from the health facility's delivery records. It was measured using electronic baby scales with an accuracy of about 20 g.[17]

The explanatory variables were: (i) group (intervention or control); (ii) characteristics of pregnant women at inclusion (woman age, gestational age at inclusion, gravidity, parity). Maternal age (in years) was categorized as less than 18 years for adolescents and 18 years and older for adults. Gravidity was categorized as primigravida and multigravida, parity as nulliparous and other including primiparous and multiparous Gestational age at inclusion was categorized as first and second trimester.

Implementation

The intervention was based on personalized support for pregnant women at home, combined with capacity building for health teams in the selected health facilities. In the control group, women received the usual package of activities of the national program, without home visits. The detailed description of the intervention is published elsewhere.[11]

Statistical analyses

The aim of the analysis was to measure the effect of the intervention on the frequencies of low birth weight, abortion, preterm birth and stillbirth (as defined in the "variables" section). Baseline characteristics were described in numbers and percentages. Baseline data from the intervention and control arms were analyzed and compared using the generalized estimating equation (GEE) method with adjustment for clusters. GEE with identity link function and exchangeable correlation matrix was also used to estimate the crude difference between the effects in the two groups and the corresponding 95% confidence intervals; also, using the same method, the adjusted effect differences were calculated after controlling for confounding variables. The potential confounding variables considered for each effect were those that were significantly associated with the outcome and that differed significantly between the two groups. It was considered a confounding effect if the relative difference between the differences in crude and adjusted proportions was $\geq$ 15%. The analysis was stratified by gestational age at inclusion (1st or 2nd trimester) to assess the effect of follow-up length. All tests were considered statistically significant if the p-value < 5%. Data were analyzed with SPSS Statistics® 24 and STATA-SE® 16.

RESULTS

Participants

Ten health areas (clusters) were selected in the study, including six and four areas in the intervention and control zones, respectively. The sample include 440

women in the intervention group and 177 in the control group. The flow chart of the study participants is published elsewhere.[11]

Baseline characteristics of pregnant women

As shown in Table 1, all women's characteristics differed significantly between the two groups at inclusion: the proportion of women under 18 years of age was higher in the intervention group, as was the proportion of nulliparous and primigravida. The proportion of women included in the first trimester was higher in the intervention group.

Effect of intervention on pregnancy outcomes

Table 2 shows the differences of frequencies of pregnancy outcomes between the two groups. No maternal deaths were recorded in either group. The proportion of stillbirths was higher in the control group. The frequency of abortion was higher in the control group but this difference was no longer significant after adjustment for clusters (p = 0.08). The frequency of low birth weight was higher in the intervention group, but the cluster-adjusted difference was not significant. The intervention had no significant ef-fect on the frequency of preterm births. There were no confounding factors in individual characteristics for differences of pregnancy outcomes. Intra-cluster correlation coefficients were low for all effects except low birth weight (0 for stillbirth, 0 for preterm birth, 0.02-0.07 for low birth weight, and 0-0.014 for abortion).

DISCUSSION

Initial research demonstrated that individualized home-based support for pregnant women, with an emphasis on nutritional counseling, iron supplementation, malaria and intestinal parasitosis prevention, in conjunction with proper antenatal care, reduced the prevalence of anemia in pregnancy.[11]

Compared to the control group, the intervention group had greater proportions of preterm or low birth weight births and decreased abortion rates; nevertheless, the adjusted frequency differences between the two groups were not statistically significant. Alternatively, there was a modest decline in stillbirths. In neither group was the length of follow-up of pregnant women significantly associated with pregnancy outcomes.

The cluster-adjusted difference in the frequency of stillbirths between the two groups was statistically significant. Since no confounding variable was detected, this supported a potential effect of the intervention. About one-third fewer stillbirths occurred in the intervention group than in the control group. This drop in the frequency of stillbirths may have been attributable to home visits to pregnant women in conjunction with an incentive to seek care early in the event of labor signs. Indeed, it is recognized that delayed access to obstetric care contributes to perinatal death.[18] The stillbirth rate in the control group was comparable to the national average and the worldwide stillbirth rate estimated by Blencowe et al.[7,19] in 2015 to be 1.84%. This increases the probability that this strategy will reduce stillbirths.

The cluster-adjusted difference in the frequency of low birth weight between the two groups was not statistically significant, but the frequency in the control group appeared lower and near to that of the Sindou district and the national average in 2016, which were 12.7% and 9.4%, respectively.[7] The frequency of low birth weight in Sub-Saharan African countries was expected to be 14% in 2015, down from 16.4% in 2000, with a global goal of 2.74% by 2025.[15] This estimate is likewise comparable to the frequency of low birth weight in our study's control group. The relative increase in the frequency of low birth weight in the intervention group may be attributable to the rise in this group's hemoglobin levels.[11] In fact, according to some writers, iron supplementation of non-anemic pregnant women is related with low birth weight, although this association remains controversial.[20] Other writers have claimed, contrary to ours, that measures to reduce low birth weight should be undertaken before or very early in pregnancy.[21]

According to some studies, prenatal nutrition education without micronutrient supplementation is insufficient to lower the prevalence of low birth weight.[22,23] In a cluster-randomized experiment conducted in Burkina Faso, Nikièma *et al.* found that individualized counseling had no influence on preg-

nancy outcomes. At contrast to our study, theirs was conducted exclusively in health care facilities.[24]

Due to the small number of preterm births in our study and the absence of any cases in the control group, we were unable to conduct an effect analysis. The preterm birth rate found in the intervention group was lower than the 3.6% incidence reported for Sindou district in 2016. Nonetheless, this figure was closer to the national preterm birth rate recorded for the same year.[7] Brabin *et al.* (2019) identified a negative effect of iron supplementation as a potential explanation for the greater number of preterm deliveries in the intervention group.[25]

Although the difference in frequency was not statistically significant, the intervention group tended to have fewer abortions. While higher than the 2.5% estimated by Sedgh *et al.* in 2011 in Burkina Faso, the abortion rate in this group was lower than the 5.1% reported in Sindou district in 2016.[7,26] The intervention lacked a dedicated abortion prevention strategy. According to some academics, inadequate family planning and restrictions on the right to abortion are the most frequently cited causes of abortions.[27] The reasons and variables associated with spontaneous (and frequently recurrent) abortions are still poorly understood and not universally accepted.[28] Therefore, the topic of abortion should be investigated in order to develop more effective techniques.

From our findings, the key messages were as follows: i) the intervention, as designed, did not influence the frequencies of low birth weight and abortion; ii) it appeared to be more effective in reducing stillbirth; iii) accounting for inter-cluster variation was required to correct effect inflation due to individual variation; and iv) a larger sample size would be required to assess the intervention's effect on the frequency of preterm birth.

The primary drawback of the study was the random selection of pregnant women from health care institutions. As a result, only geographic areas and health institutions were randomized, but not pregnant women. Despite this, the sample was appropriately representative of the region's pregnant women population considering the high attendance at the health institutions.

CONCLUSION

The study found that personalized home-based support for pregnant women, focusing on nutritional counseling, iron and folic acid supplementation, prevention of malaria and intestinal parasitosis, combined with appropriate prenatal care, can reduce stillbirths but not the frequencies of low birth weight and abortions.

INFORMATION

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TABLE 1: Baseline characteristics of women in both groups.

Characteristics	Intervention, n (%)	Control, n (%)	p [1]
Number of pregnant women	440	177	-
Cluster (health facility)	6	4	
Age (years)			
< 18	70 (16,8)	12 (7,6)	0.005
18+	347 (83,2)	145 (92,4)	
Gestational age at inclusion			0.004
1st trimester	272 (61,8)	74 (41,8)	
2nd trimester	168 (38,2)	103 (58,2)	
Gravidity			
1	46 (12,6)	8 (5,2)	0.036
2+	320 (87,4)	147 (94,8)	
Parity			
0	46 (12,7)	7 (4,6)	0.004
1+	316 (87,3)	147 (95,5)	

[1] *p-values adjusted for clusters.*

TABLE 2: Differences in frequency of pregnancy outcomes between the intervention and control groups.

Pregnancy outcome	n (%)	Difference (IC95%) [1]	p [1]
Maternal death			
Intervention	440 (0)		
Control	177 (0)		
Stillbirth			
Intervention	421 (0,2)	-1,6 (-3,1 à -0,1)	0,03
Control	160 (1,9)		
Preterm birth			
Intervention	421 (1,2)	+1,2 (-1,3 à +2,8)	0,33
Control	160 (0)		
Low birth weight			
Intervention	398 (18,1)	+8,7 (-1,6 à +14,8)	0,12
Control	149 (9,4)		
Abortion			
Intervention	438 (3,9)	-3,6 (-8,5 à +0,5)	0,08
Control	173 (7,5)		

[1] *Confidence intervals and p-values adjusted for clusters.*

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