

The Effect of a Novel Multi-Ingredient Supplement in Pregnant Women

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Abstract

Objective: to investigate the effects of a novel multi-ingredient supplement comprised of high dose whey protein, to improve maternal and perinatal outcomes in pregnant women

Methods: This was an observational retrospective study. Women who received oral supplementation with a novel multi-ingredient supplement (PSIPROTO[®]), comprised of high dose whey protein, were compared with women who did not. Inclusion criteria were singleton pregnancy with body mass index (BMI) higher than 25. The primary outcome of the study was the incidence of adverse pregnancy outcome

Results: 400 women, 200 for each group, were included in the study. The two groups were similar in terms of maternal demographics, and both of them had similar BMI. Maternal age and smoking rate were also similar. Women who received the intervention had a significantly lower maternal weight gain, and lower risk of low birth weight. Notably, 4 women in the intervention group reported intrauterine growth restriction before the intervention, and solved after 2 months of supplementation.

Conclusion: Our retrospective cohort of singleton gestations with BMI >25 showed that PSIPROTO is a safe and efficacy supplement in pregnancy.

Keywords: Supplementation; Iron; Anemia; Pregnancy; Diet; Protein

Introduction

In pregnant women, a healthy lifestyle includes appropriate weight gain, a balanced diet, regular aerobic exercise, and appropriate vitamin and mineral supplementation [1-3]. Every day approximately 300 extra calories are needed, with a balanced diet of protein, fruits, vegetables and whole grains [4]. Animal-based foods (meat, poultry, fish, eggs, and dairy foods) tend to be good sources of complete protein, while plant-based foods (fruits, vegetables, grains, nuts, and seeds) often lack one or more essential amino acid [5]. Proteins are of paramount importance during pregnancy. A pregnant patient should get a minimum of 60 grams of protein a day, which account for approximately 20-25% of the total calorie intake [6]. Whey protein comprises soluble whey proteins and its benefits are well described in the literature [7]. During pregnancy, whey protein intake and high protein supplementation are associated with reduced risk of excessive maternal weight gain [8].

Materials and Methods

This was an observational retrospective study. Data were collected in a dedicated encrypted database and anonymized. Women who received oral supplementation with a novel multi-ingredient supplement (PSIPROTO[®]), comprised of high dose whey protein, were compared with women who did not. PSIPROTO[®] contains Volactive[®] as source of UltraWhey high-performance proteins (6,8 grams for 10 gr of PSIPROTO) included for 10 gr of PSIPROTO and the following: psyllium fiber (0.3 g); myoinositol (0.4g); L-Tryptophan (0.15 g); Magnesium bisglycinate (0.1 g); and vitamin D (1.000 UI) and complexzyme-5 vegan[®] ComplexZyme-5 Vegan[®] -(Amilasi >=240SKB-U Proteasi >=60HUT-U Lattasi >=40ALU-U Lipasi >=10FIPu/>=100LUu Cellulasi >=2CU). The intervention was taken

at the dose of 20 gr per day starting from 14 weeks for 3 months (until 26 weeks). Inclusion criteria were singleton pregnancy with body mass index (BMI) higher than 25. Exclusion criteria were twin pregnancies and multiple gestations. The primary outcome of the study was the incidence of adverse pregnancy outcome, including maternal and perinatal outcomes. The secondary outcomes were maternal weight gain, and birth weight. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) v. 19.0 (IBM Inc., Armonk, NY, USA). Data were shown as means± standard deviation or as number (percentage). Dichotomous data were compared using the chi-square. Comparisons between groups were performed with the use of the T-test to test group means by assuming equal within-group variances. A sample size of 200 women for each group was planned.

Results

400 women, 200 for each group were included in the study. Therefore, 388 participants were available for the final analysis. The two groups were similar in terms of maternal demographics, and both of them had similar BMI. Maternal age and smoking rate were also

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Table 1: Primary and secondary outcomes.

	Intervention group	Control group	P-value
	N = 190	N = 198	
Maternal weight gain (kg)	8.3±3.5	13.8±7.4	<0.01
>15kg during pregnancy	20 (10.5%)	37 (18.7%)	0.03
Intrauterine growth restriction	13 (6.8%)	18 (9.1%)	NS
Miscarriage	7 (3.7%)	5 (2.5%)	NS
Cesarean delivery	51 (26.8%)	63 (31.8%)	NS
Low birth weight	18 (9.5%)	35 (17.7%)	0.02
Fetal macrosomia	12	16	NS

Boldface data, statistically significant

similar. Women who received the intervention had a significantly lower maternal weight gain, with a mean difference of -5.50 kg, and lower risk of low birth weight. Notably, 4 women in the intervention group reported intrauterine growth restriction before the intervention, and solved after 2 months of supplementation. However, the sample size was too small to run statistics [Table 1].

Conclusion

Our retrospective cohort of singleton gestations showed that that PSIPROTO[®] is a safe and efficacy supplement in pregnancy that improves maternal and perinatal outcome. Future, large well-designed placebo-controlled randomized trials are needed to confirm our findings.

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