Aspirin as a modifier on the Effect of Mediterranean diet or Mindfulness-Based Stress Reduction in pregnant women at high risk for SGA: Secondary analysis from the IMPACT-BCN trial

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Objective: The IMPACT BCN trial has recently demonstrated that interventions based on Mediterranean diet (MedDiet) or stress reduction during pregnancy reduce the incidence of small for gestational age (SGA) or late preeclampsia. Whether these beneficial effects could be modified by aspirin during pregnancy is unclear. We aimed to evaluate whether aspirin acted as a modifier on the effect of MedDiet or stress Reduction on the incidence of SGA or late preeclampsia in the IMPACT BCN trial.

Methods: A secondary analysis of a randomized clinical trial with parallel groups conducted at University Hospital in Barcelona, Spain between 2017 and 2020 (IMPACT BCN trial), including 1221 pregnant women at high-risk for SGA randomly allocated at 19-23 weeks' gestation into three groups: usual care (no intervention), MedDiet or stress reduction. Participants in the MedDiet group received monthly individual, group educational sessions and free provision of extra-virgin olive oil and walnuts. Women in the stress reduction group underwent an 8-week mindfulness-based program adapted for pregnancy. End points were established as SGA (defined by birthweight below the 10th centile) and late preeclampsia (occurring after 34 weeks of gestation). A secondary analysis was carried out to assess the effect of MedDiet or stress reduction on SGA and late preeclampsia in the subgroups of women who were exposed or not to aspirin during pregnancy.

Results: Among the 1182 participants who were considered in the intention-to-treat analysis, 376 (31.8%) pregnant women were treated with aspirin during pregnancy (28.9% in usual care, 34.9% in MedDiet and 31.5% in stress reduction group). While the overall incidence of SGA was significantly reduced in both MedDiet and stress reduction groups (Usual care 22% vs MedDiet 14% vs stress reduction 15.6%, p-values 0.004 and 0.02 respectively), a more pronounced effect was observed by MedDiet in those pregnancies treated with aspirin (Usual care 31% vs MedDiet 14% vs stress reduction 22.8%, p-values 0.15 and 0.002 respectively). On the contrary, the stress reduction intervention seems to work better in pregnancies without aspirin (Usual care 18% vs MedDiet 13.7% vs stress reduction 12.3%, p-values 0.15 and 0.05 respectively).
A similar trend was observed for late preeclampsia, with an overall reduction by both interventions (Usual care 9% vs MedDiet 5.1% vs stress reduction 5.4%, p-values 0.04 and 0.05 respectively), a more pronounced effect of MedDiet on women treated with aspirin (Usual care 12.9% vs MedDiet 7.3% vs stress reduction 12.3%, p-values 0.14 and 0.88 respectively) and a more pronounced effect of stress reduction on those pregnancies not on aspirin (Usual care 7.4% vs MedDiet 3.9% vs stress reduction 2.2%, p-values 0.09 and 0.008 respectively).

Conclusion: Aspirin may act as a modifier by enhancing the effect of MedDiet and ameliorating the effect of stress reduction interventions on placental-mediated diseases.