A Study to assess the effect of vitamin D_3 supplementation on iron status among the iron and 25(OH)D deficient pregnant women: An randomized placebo-controlled study

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By

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9. SUMMARY

Objective 1: Preparation of the antenatal card in order to standardize the antennal services received by the pregnant women (Govt. Head Quarters and Hospital, Udhagamandalam).

One of the most important benefits of ANC card usage is standardization of the ANC service provided by any health cadre it can also be used for quality assessment of the ANC services provided. Standardization of ANC services by using the ANC card is one of the important strategies in making pregnancy safer and quality assurance can be applied easily.

Objective 2: Retrospective survey to find the most recent prescribing pattern and most possible teratogenicity risk to foetus in pregnant women (Obstetrics and Gynecology clinic of Govt. Head Quarters and Hospital, Udhagamandalam).

The present study concludes that despite the fact that there is compliance to FDA safety drugs use in pregnancy, the mother and the fetus might be at the risk, as certain variables in this study with respect to maternal characteristics showed the odds of exposure to potentially harmful medications such as elderly pregnancy, co-morbid conditions and length of hospital. Thus there is a need for thorough description of patterns of pregnancy exposure to medicine with potential risk and also rate of exposure during different gestation period. The current study indicates that the drug use in pregnancy should be observed by treating physician and must be made aware of the potential risk to fetus in advance when prescribed. Also there is need of such studies periodically to update the therapeutic use of drugs during pregnancy and provide rational drug use.

Objective 3: To assess rise in hemoglobin and serum ferritin levels, when supplemented by vitamin D_3 in iron deficiency anemia (IDA) patients a systematic review and meta-analysis will be performed.

We could not find clinically and statistically effect which was significant of vitamin D supplementation in IDA patients and the meta-analysis yielded an inconclusive effect size. The included trials majorly consist of subjects with mild or moderate Iron deficiency. Apart from these observations, the added efficacy of Vitamin D supplementation in subjects with comorbidities where the outcomes may be attributed to the unjustifiable numbers of possible pathological and physiological pathways may not be related to Vitamin D administration. Further research is needed to clarify the issues including the pediatrics, pregnant women and subjects with comorbidities. More set of evidence is required for a conclusive meta-analysis before any definitive clinical recommendations are made.

Implications for research

As mentioned, more evidences from clinical trials are required for a conclusive meta-analysis. Furthermore, as mentioned above, the optimum levels of vitamin D supplementation and the circulatory 25(OH) D levels are yet not known and needs additional evidence

Objective 4: Evaluation and correlation of serum-25-hydroxyvitamin D and iron status in mild to moderate iron deficiency anemic pregnant women (Govt. Head Quarters and Hospital, Udhagamandalam).

These results support the fact that those pregnant women whose vitamin D levels were less, tend to have lesser levels of hemoglobin, RBC, iron, ferritin, hematocrit, mean cell volume and transferrin saturation. Further studies needs to be initiated to estimate whether there is a causal relationship of vitamin D deficiency and iron deficiency anemia.

Objective 5: Evaluation of vitamin D_3 supplementation efficacy in iron deficient anemic and serum-25-hydroxyvitamin deficient pregnant women (Govt. Head Quarters and Hospital, Udhagamandalam).

IDA is one of the major risk factor during pregnancy and has several adverse outcomes. It is necessary that during the antenatal care all the pregnant women should be evaluated for IDA and 25(OH)D deficiency. In this present study, supplementation of 1000 IU of vitamin D_3 along with routine medications for a period of 12 weeks among the iron and serum 25(OH)D deficient pregnant women showed significant increase in markers of s-iron and 25(OH)D levels from baseline to study conclusion visit. But there was no change in hematological parameters between intervention and the placebo groups except of increase in hematological level. Vitamin D_3 (1000) IU was well tolerated among the study participants, as few of them reported NSAEs and SAEs and it was determined as possible reaction by using Naranjo Causality scale. None of the study population experienced hypercalcemia and hypercalciuria. There is a need to conduct further studies, when there is co-existence of iron deficiency anaemia and vitamin D deficiency conditions in pregnant women.

10. CONCLUSIONS

Objective 1: Preparation of the antenatal card in order to standardize the antennal services received by the pregnant women (Govt. Head Quarters and Hospital, Udhagamandalam).

One of the most important benefits of ANC card usage is standardization of the ANC service provided by any health cadre it can also be used for quality assessment of the ANC services provided. Standardization of ANC services by using the ANC card is one of the important strategies in making pregnancy safer and quality assurance can be applied easily.

Objective 2: Retrospective survey to find the most recent prescribing pattern and most possible teratogenicity risk to foetus in pregnant women (Obstetrics and Gynecology clinic of Govt. Head Quarters and Hospital, Udhagamandalam).

The present study concludes that despite the fact that there is compliance to FDA safety drugs use in pregnancy, the mother and the fetus might be at the risk, as certain variables in this study with respect to maternal characteristics showed the odds of exposure to potentially harmful medications such as elderly pregnancy, co-morbid conditions and length of hospital. Thus there is a need for extensive description of prescription medication through pregnancy with potential risk to foetus and also rate of exposure at different gestation period. This study indicates that the drug use in pregnancy should be observed by treating physician and must be made aware of the potential risk to fetus in advance when prescribed. Also there is need of such studies periodically to update the therapeutic use of drugs during pregnancy and provide rational drug use.

Objective 3: To assess rise in hemoglobin and serum ferritin levels, when supplemented by vitamin D_3 in iron deficiency anemia (IDA) patients an systematic review and meta-analysis will be performed.

The included trials majorly consist of subjects with mild or moderate Iron deficiency. Apart from these observations, the beneficial effects of Vitamin D supplementation in subjects with comorbidities where the outcomes may be attributed to the unjustifiable numbers of possible pathological and physiological pathways may not be related to Vitamin D administration. Future research is required to clarify the concerns including the pediatrics, pregnant women and subjects with comorbidities. More set of evidence is required for a conclusive meta-analysis before any conclusive clinical recommendations are made.

Implications for research

As mentioned, more evidences from clinical trials are required for a conclusive meta-analysis. Furthermore, as mentioned above, the optimum concentrations of vitamin D supplementation and the circulatory 25(OH) D levels are yet not known and needs additional evidence

Objective 4: Evaluation and relation between serum-25-hydroxyvitamin D and iron status in mild to moderate iron deficiency anemic pregnant women (Govt. Head Quarters and Hospital, Udhagamandalam).

These results support the fact that those pregnant women whose vitamin D levels were less, tend to have lower levels of hemoglobin, red blood cells, iron, ferritin, hematocrit, mean cell volume and transferrin saturation. Further investigation needs to be conducted to evaluate whether there is a causal effect of vitamin D deficiency and iron deficiency anemia.

Objective 5: Evaluation of vitamin D_3 supplementation efficacy in iron deficient anemic and serum-25-hydroxyvitamin deficient pregnant women (Govt. Head Quarters and Hospital, Udhagamandalam).

IDA is one of the major risk factor during pregnancy and has several adverse outcomes. It is necessary that during the antenatal care all the pregnant women should be evaluated for IDA and 25(OH)D deficiency. In this present study, supplementation of 1000 IU of vitamin D_3 along with routine medications for a period of 12 weeks among the iron and serum 25(OH)D deficient pregnant women showed significant increase in markers of s-iron and 25(OH)D levels from baseline to study conclusion visit. The intervention and placebo group did not show significant difference except for increase in hematological level. Vitamin D_3 (1000) IU was well tolerated among the study participants, as few of them reported NSAEs and SAEs and it was determined as possible reaction by using Naranjo Causality scale. None of the study population experienced hypercalcemia and hypercalciuria. There is a need to conduct further studies, when there is co-existence of iron deficiency anaemia and vitamin D deficiency conditions in pregnant women.