Evaluation of the effect of melatonin drug on the course of treatment and complications of sepsis in infants

Abstract

Background: Septicemia is one of the most important causes of neonatal mortality in developing countries. Its prevalence varies in developed and developing countries, so that its incidence in developed countries is 1-8 cases per 1,000 live births have been reported, while studies in developing countries have estimated several times that number. Neonatal sepsis causes mortality and morbidity in infants and puts a lot of cost on the country's health system, especially in developing countries and especially in preterm infants is considered a public health problem. The use of antioxidants has recently been considered due to the body's defense mechanism in the process of sepsis. One of the antioxidants that can be used in the treatment of sepsis is melatonin. Melatonin is involved in the pathogenesis of many neonatal diseases. Studies on its therapeutic effects in neonatal free radical disease (including asphyxia), respiratory distress syndrome, surgery, and sepsis are ongoing. Melatonin has been shown to be safe even in high doses and to avoid toxicity in animal and human studies.

Aim: The aim of this study was to evaluate the effect of melatonin drug on the course of treatment and complications of sepsis in neonates.

Materials & Methods: This study was a clinical trial, phase 3 and without blinding. In this study, 50 infants under 28 days with sepsis based on Cochran's formula (25 infants in the intervention group and 25 infants in the control group) were randomly entered into the study. In the neonatal intervention group, in addition to antibiotics, they received melatonin tablets at a dose of 3 mg every 12 hours for 3 days. The effect of the drug was assessed based on WBC, CRP, interleukin-6 and ANC. These cases were assessed at the beginning of treatment and also 72 hours after the start of treatment in both groups.

Results: Fifty infants with sepsis were enrolled in the intervention and control groups. There were 13 males and 12 females in each group. Also, the mean age of participants in the intervention group was 11.32 days with a standard deviation of 5.75 days and in the control group was 10.96 days with a standard deviation of 5.16 days ($p = 0.82$). WBC changes in the study groups: As it is clear, there was no statistically significant difference in the control group before and after the study ($p = 0.13$), but in the intervention group, there was a statistically

significant difference between the beginning and the end of the study ($p = 0.02$). Changes in CRP, IL-6 and ANC in the study groups: There was no statistically significant difference in the control group before and after the study; Also, there was no statistically significant difference between the beginning and the end of the study in the intervention group. Also, according to the results of independent t-test, there was no significant difference in the length of hospitalization of the two groups.

Conclusion: Based on the results, co-administration of antibiotics and melatonin had no effect on length of hospitalization, mortality, CRP, Interleukin 6 and ANC in patients with sepsis, but the amount of WBC in patients was significantly reduced.

Keywords: melatonin-sepsis- neonatal sepsis