Introduction
Patients with β-thalassemia major receive regular blood transfusions. Non-invasive hemoglobin (Hb) estimation may simplify their care. Masimo Pronto-7 Pulse CO-oximetry device is used to non-invasively estimate the hemoglobin level but has not been previously validated in this group of patients. The primary objective of this study was to validate the pulse CO-oximetry based hemoglobin estimation in children and adults with thalassemia major.

Methods
We conducted a prospective observational study on 108 children and adults with thalassemia major attending the daycare thalassemia center of a tertiary care hospital over 6 weeks. We estimated a spot Hemoglobin (SpHb) level using Masimo Pronto-7 Pulse CO-oximetry device (two measurements per patient) and compared it to a venous sample Hb (Reference Hemoglobin; Ref Hb) measured using Abbott CELL-DYN Sapphire hematology analyzer. We calculated Pearson correlation coefficient and coefficient of determination (R2). The multivariable linear regression model of predicting the estimation differences included age, gender, weight, height, blood pressure and reference hemoglobin.

Results
We enrolled 108 patients (54 males, 54 females) with a mean age of 21.6 years (SD 7.3; 2.5–38). There were 156 estimation episodes. The mean Ref Hb and SpHb were 9.4 g/dL (SD 0.9; 7.1–12.3) and 11.1 g/dL (SD 1.2; 7.5–14.7) respectively. The correlation coefficient between the SpHb and Ref Hb was 0.49 (R2 = 24%) with a mean difference of 1.7 g/dL (SD 1.1; −1.2 to 4.3). In the multivariable model, Ref Hb level was the only statistically significant predictor of the difference in measurement (p =0.002). There was a strong correlation between the two CO-oximetry Hb measurements (correlation coefficient 0.70, R2 = 50%).

Conclusions
Our results indicate that Masimo Pronto-7 Pulse CO-oximetry device overestimates the hemoglobin level and it cannot be recommended for patients with thalassemia major. Larger prospective studies are needed to confirm these results.