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Title: Alpha-1-antitrypsin (A1AT) serum concentration in newborns is susceptible to diurnal variations

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Body: Laboratory evaluation of A1AT deficiency involves measurement of circulating A1AT protein (quantitation) and characterization of A1AT genetic polymorphisms. In contrast to adult and pediatric populations, there are no reliably documented A1AT serum reference ranges for newborns available. We evaluated blood samples from 145 children collected at 0-7 day after birth within the frame of on-going newborn A1AT deficiency screening program in Central Poland. A1AT and hsCRP serum concentration was measured by nephelometry, A1AT phenotyping performed by isoelectrofocusing. The median A1AT serum concentration for normal newborn population with the MM phenotype (n=135) was 172,0 mg/dL (123-331).Lower concentrations of A1AT correlated with heterozygosity for the S and Z alleles, respectively MS (n=3) 151,0 and MZ (n=3) 125,0 mg/dL. Considerable dynamics in A1AT blood level changes in the first days of life were observed with median A1AT concentration of 155,5 mg/dL at day 0, 158,5 at day1, 183,2 at day2, 169,0 at day 3, 175,5 at day 4, 154,0 at day 5, 154,0 at day 6 and 150,0 mg/dL at day 7. A1AT serum levels at day 1 vs. day 2 and day 2 vs day 5 were proven statistically different by the non-parametric Kruskal-Wallis one-way analysis on variance, respectively p=0,046 and p=0,004. Importantly, no significant day-to-day dynamics of serum hsCRP was observed. Median A1AT (179 mg/dL; 157-243) and hsCRP (0,2 mg/dL; 0,12-0,64) serum levels in premature newborns (n=9) were comparable to those delivered at full term (hsCRP-0,23 mg/dL; 0,1-7,92). Our data suggest that specific A1AT reference range for newborns allowing for the day-to-day variability might prove clinically relevant.