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Title:

**PROPORTION OF PATIENTS DETECTED WITH SUBCLINICAL
HYPOTHYROIDISM IS INDEPENDENT OF TIME OF BLOOD DRAW**

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Objective:

There are differences in clinical opinion regarding the benefit of treating subclinical hypothyroidism in infertile patients. However, for patients with a thyroid stimulating hormone (TSH) serum level > 2.5mIU/L it is recommended to continue monitoring or administer levothyroxine to reduce TSH serum levels <2.5mIU/L (ASRM guideline document 2015). TSH levels in adults, have a predictable circadian rhythm, with the highest levels produced between 2am and 4am; while the lowest levels occur between 4pm and 8pm. Whether there is a misdiagnosis of subclinical hypothyroidism and underlying normal circadian rhythm due to testing afternoon blood draw is a current clinical concern. Only one study has showed the potential for this misdiagnosis, albeit the study included a small sample size. [1] The objective of this study was to identify any differences in the mean TSH levels obtained from morning compared to afternoon blood draws in patients seeking infertility treatment.

Design:

Retrospective cohort analysis

Materials and Methods:



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This study examined patients having routine TSH levels tested for either cycle day 3 evaluations or as part of a new patient consultation from January 2018 and March 2019. Serum TSH concentrations were obtained via electrochemiluminescence immunoassay Elecsys for use on Cobas e601(Roche) Detection range of 0.005 – 100 mIU/L. Chi Square analysis was used to determine statistical significance with $p < 0.05$ considered significant.

Results:

Of the 8345 patients who had routine TSH testing performed, 5028 were drawn in the morning and 3281 were drawn in the afternoon. There was no significant difference in the mean (\pm SD) TSH levels, 2.10408 (4.30) for am blood draws and 2.10426 (4.31) for pm blood draws. There was also no differences in the in the percentage of TSH results showing >2.5 mIU/L in morning 25% compared to afternoon blood draw groups 26%.

Conclusion:

This study showed no shift in the mean or in percentage of patients with elevated TSH levels in the morning compared to afternoon blood draw group. This data shows that afternoon blood draws are just as likely to detect elevated TSH levels as blood samples drawn in the morning. The strength of this study is its ability to define risks of misdiagnosis of subclinical hypothyroidism due to potential underlying changes in TSH levels for the different times of blood draw using binomial sorting of patient data in a diverse population of patients seeking ART treatment. This study highlights how TSH fluctuations that may occur throughout the day are clinically insignificant and even with ultra-sensitive immunoassays not, detectable in a population of patients undergoing reproductive treatment.