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A-053 Poor Clinical Utility of Free and Bioavailable Testosterone is Underscored by Overutilization

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BACKGROUND: Symptomatic androgen deficiency has an estimate prevalence of 2%–12% in males over 40 years of age and is associated with several comorbidities such as hypertension, obesity, dyslipidemia, metabolic syndrome, diabetes, and COPD. Diagnosis relies heavily on the measurement of testosterone concentrations. While total testosterone (tT) is often sufficient to diagnose deficiency, free testosterone (fT) or bioavailable testosterone (baT; non-sex hormone binding globulin (SHBG)-bound) may be helpful in assessing patients with suspected hormone binding abnormalities. Consensus guidelines recommend relying on tT measurement and only using fT or baT testing when indicated. Despite these recommendations, requests for measured fT and baT account for a large percentage of testosterone orders in our institution. Here we examined the utilization of testosterone orders, assessed the clinical utility of measured fT and baT relative to tT alone, and devised a reflex algorithm to optimize fT and baT utilization.

METHODS: Testosterone data was collected over a 12 month period, September 2020–August 2021. Only data from adult males with established reference intervals was included in the final cohort; ≥20 and 20–69 years of age for fT and baT, respectively. Logistic regression was used to determine the probability of low fT and baT based on tT concentration. An algorithm based on initial tT concentration was established to reflex to fT/baT when most likely to provide additional benefit.

RESULTS: Of 9754 testosterone tests performed on male patients during the study period, 4514 (46%) included a measured fT and/or baT. After excluding data without established reference intervals, the final cohort consisted of 1851 fT and 2514 baT measurements. Overall concordance with tT was 70.0% and 74.8% for fT and baT, respectively. However, only 0.2% (3/1479) were found to have low fT and

8.4% (166/1988) low baT when tT was greater than the reference interval lower limit (i.e., normal or high). The probability of a patient having low fT or baT with normal tT peaked at 0.01 and 0.21, respectively, and was greatest at the tT reference interval lower limit (240 ng/dL). An algorithm was devised in which only samples with tT concentrations of 240–500 ng/dL would reflex to baT testing. In this cohort, 90% of discordant (low baT with normal tT) samples would have triggered the baT reflex while reducing the overall utilization of baT by 55%. Applying the same reflex algorithm would have also reflexed 100% of discordant fT samples.

CONCLUSIONS: Despite being performed with nearly half of all testosterone orders, baT, and especially fT, provided little additional clinical utility to tT alone. By determining the probability of a low baT or fT when Tt is above the reference interval lower limit, a reflex algorithm can be devised to help optimize baT and fT utilization. While this algorithmic approach has been proposed by others, the reflex values in our cohort differ significantly from previously published values suggesting that laboratories should determine limits based on their individual testosterone assays. The logistic regression method utilized here provides one such example laboratories can follow for undertaking such an analysis.