therapy. Research suggests that thyroidectomy may have a role in improving this. We investigated the change in Quality of Life (QoL), symptom burden and mental health from baseline to 1 year after total thyroidectomy in patients with underlying thyroiditis.

Methods: We conducted semi-structured interviews with 96 patients at baseline and 1 year to discuss their thyroid-related symptom burden. Patients utilized prompt cards to identify and rank the severity of their thyroid-related symptoms (3 being most bothersome and 0 being no effect at all). Individual symptom scores were added to calculate a Cumulative Symptom Score (CSS). Patients also completed the validated Short Form-12 (SF-12) questionnaire for mental and physical health (scored from 0-100; higher score attributing to better health) and ThyCa-QoL questionnaire (scored from 0-100; higher score attributing more complaints) at these 2 time-points.

Results: Of the 96 patients with available CSS data, there were 37 patients in the Hashimoto's group (97% had biopsy proven thyroiditis and 24% were on thyroid hormone at baseline) and 59 patients in the control group. At baseline, Hashimoto's patients had a higher CSS than the control group (9.94 vs. 7.13, p=0.05). Overall, mean CSS, in both groups, declined from baseline to 1 year (7.74 to 6.08, p=0.04), and over half of the individual patients, had a decline in their CSS at 1 year (56% in Hashimoto's and 54% in control). Although, the Hashimoto's group started higher at their baseline, they also had a slightly larger decline in CSS at 1 year than the control patients (-2.2, p=0.11 vs. -1.2, p=0.19). On the SF-12, Hashimoto's patients had a significant improvement in their mental health (+ 6.0 pts, CI 1.8-10.2, p value = 0.007) whereas the control patients did not (+2.4 pts, CI 0.3-5.2, p=0.08). On the ThyCa-QoL, Hashimoto's patients had worse scores at baseline as compared to the control patients (20.8 vs 16.7, p=0.11) and there was a slight but clinically significant improvement from baseline to 1 year (decrease in mean of 1.18 pts, p=0.5). Analysis of the qualitative data showed that of the 10 patients who were on thyroid hormone pre-operatively, 9 described significant symptom improvement at 1 year, with fatigue being the major symptom that was reported as improved.

Conclusion: Based on the data above, we see that patients with Hashimoto's do have a higher symptom burden at baseline and thyroidectomy may play a role in symptom alleviation as well as improving mental health and QoL. Our data supports recent findings that thyroidectomy may play a role in alleviating thyroid related symptoms in this patient population and further investigation to better understand this phenomenon is warranted.

Thyroid

FROM HYPO- TO HYPERTHYROIDISM

CDC Clinical Standardization Programs (CSP) for Free Thyroxine (FT4) to Improve the Accuracy and Reliability of FT4 Measurements in Patient Care and Clinical Research

Ashley Ribera, BS[1], Amonae Dabbs-Brown, MS[1], Krista Poynter, BS[1], Otoe Sugahara, BS[2], Li Zhang, PhD[3], Uliana Danilenko, PhD[1], Hubert W. Vesper, PhD[1].

[1]Centers for Disease Control and Prevention, Atlanta, GA, USA, [2]CDC, Marietta, GA, USA, [3]CDC, Atlanta, GA, USA.

Reliable FT4 measurement is critical to assess thyroid function and diagnose and treat thyroid disorders. The Partnership for the Accurate Testing of Hormones (PATH) categorizes FT4 as a biomarker in high need for standardization, and currently high inter-assay variability restricts the interpretation of FT4 results in patient care to assay-specific reference intervals. The CDC CSP has partnered with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and PATH to create a standardization program for FT4 to improve accuracy, reliability, and comparability of current methods and thus to improve diagnosis, treatment and prevention of thyroidal illnesses. Currently, there are no serum FT4 reference materials available to assess the accuracy and reliability of FT4 assays. CDC has developed an accurate and sensitive reference measurement procedure (RMP) to create commutable serum reference materials with FT4 target values. Assay manufacturers, research and clinical laboratories can use these reference materials to assess their calibration, certify the analytical performance of their measurements, and monitor performance over time by collaborating with CDC CSP. The CDC FT4 RMP uses equilibrium dialysis (ED) with LC-MS/MS based on an internationally recognized ED procedure[1] followed by solid-phase and solvent extractions. Certified primary reference material IRMM468 was used to prepare calibrators. Chromatographic separation is achieved with a gradient of methanol and water with 0.1% formic acid. FT4 is quantified using positive electrospray ionization in positive mode. The intra- and inter-day imprecision of the CDC RMP are 3.0% and 1.1%. A comparison among FT4 RMPs resulted in a +2.5% bias for the CDC RMP to the mean for all labs. The CDC RMP measurement range was 3.02-258 pmol/L and thus suitable for analysis of hypo- and hyperthyroid patients. The CDC FT4 RMP demonstrates good accuracy and precision, and can be used as a viable accuracy base to which routine methods can be compared. An initial comparison study of a commercially available FT4 immunoassay (IA) and the CDC RMP with 24 samples (7.98-109 pmol/L) indicated a mean bias of -37.7%, further indicating a need for standardization. Findings from an IFCC study suggest that alignment of IA measurements to a FT4 RMP can improve comparability and would allow for a uniform reference interval for FT4.[2] CDC CSP established a new standardization program for FT4 to address the needs of the community and assist with improving test comparability and reliability.1. *Clin. Chem. Lab. Med.* 2011, 49: 1275-81. 2. *Clin. Chem*. 2017, 63: 1642-52.

Thyroid

FROM HYPO- TO HYPERTHYROIDISM

Clinical Implication of TSH Screening in Venous Thromboembolism Patients

Siroj Dejhansathit, MD[1], Ana Marcella Rivas Mejia, MD[2], Kenneth Nugent, MD[1].

[1]TEXAS TECH University Health Science Center, Lubbock, TX, USA, [2]Cox Health, Springfield, MO, USA.