Impact of Laboratory assays on the diagnosis of Hyperparathyroidism

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OBJECTIVES

The diagnosis of primary hyperparathyroidism (pHPT) relies on elevated calcium levels together with inappropriately elevated Parathyroid Hormone (PTH) levels. The Alfred (tertiary university teaching hospital) changed a second generation PTH assay from Roche to Abbott Architect on 29.11.11 and back to Roche Elecsys on 20.2.14. Both assays are intact PTH assays with separately evaluated reference ranges, however, the Abbott assay measures significantly higher in the range below 30 pmol/L(1). We investigated the impact of the change in PTH assay on the number and quality of the diagnosis of hyperparathyroidism in discharged hospital patients.

Figure 1 Annual Number of Patients with a Diagnosis of Hyperparathyroidism at Alfred Health

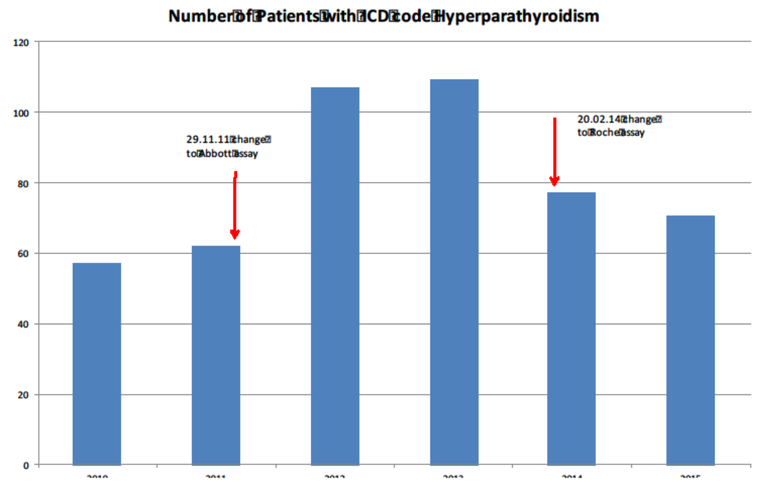
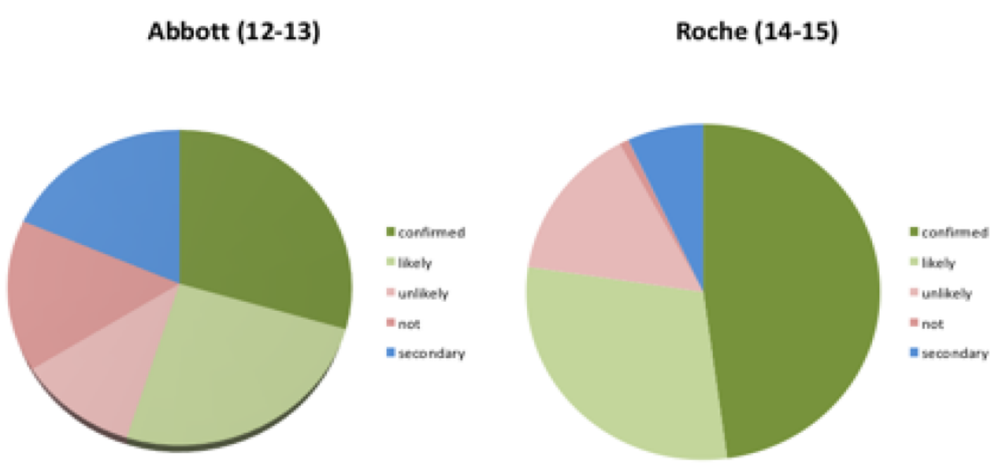


Figure 2 Percent of patients who are judged on audit to have confirmed, likely, unlikely, not or secondary HPT with the use of the Abbott or the Roche intact PTH assay



C-30, L-25, U-11, N-16, 2nd-18

C-48, L-30, U-15, N-1, 2nd-7

METHODS

We extracted information on all hospital patients discharged with the diagnosis of HPT (by ICD code) who were not on dialysis between 1.1. 2010 and 30.9.2015. Subsequently we audited the electronic medical record and laboratory results from 29.11.2011- 30.9.2015. We divided the diagnosis of HPT into categories (confirmed, likely, unlikely, not, secondary HPT) after clinical review of all available laboratory and clinical data. Ethics approval was obtained for the audit.

RESULTS

We retrieved 623 patient admissions of 460 individual patients between 2010- 2015. The number of discharge diagnosis hyperparathyroidism increased in the time that the Abbott assay was used (Fig. 1). The mean monthly number of patients diagnosed with hyperparathyroidism using the Abbott assay was 8.2 (median 8, [Interquartile range Q1, Q3] 5, 10) compared with 5 (median 5, IQR 4,7) with the Roche intact PTH assay (Mann-Whitney U-test $p < 0.01$.

We audited the records of **212** patients diagnosed using the Abbott assay (1.1.12- 20.02.14) and **120** patients diagnosed using the Roche assay (20.2.14- 30.9.15). The auditors agreed with the HPT diagnosis in 54.9% (113/206) of patients diagnosed with the Abbott assay and in 77.4% of patients diagnosed with the Roche assay (Fig. 2).

There were 55 patients considered to be unlikely to have pHPT with the Abbott assay and 18 patients with the Roche assay. None of these was referred for surgery. In these patients highest calcium was lower (2.6 mmol/L) and elevated PTH was only seen with normal calcium levels. Patients with secondary HPT we more frequently seen with the Abbott assay (38 patients vs 8 patients).

CONCLUSIONS

The choice of PTH assay might have a significant effect on the diagnosis of hyperparathyroidism especially with inexperienced junior medical officers. The new recognition of normocalcemic hyperparathyroidism makes it imperative that clinicians understand the limitations of the PTH assay used in their laboratory. Intact PTH assays that measure higher in comparison studies showed an increase in doubtful diagnosis of pHPT. While we did not see referral for surgery in our patients, in the outpatient setting (not investigated here) there might be direct referrals to surgery. Limitations of this study include the retrospective nature of the review and the relatively small number of patients. Clinicians should become aware of the type of PTH assay used in their laboratory and how it compares with other PTH assays.

REFERENCES:

La'ulu SL, **Roberts WL**. Performance characteristics of six intact parathyroid hormone assays. Am J Clin Pathol. 2010 Dec;134(6):930-8.