In search of perfect assay – prospective, multi-centre Clinical Validity study of novel, ultrafast IOPTH monitoring system.

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Introduction:

NBCL Connect is the first Analyser able to measure PTH in whole blood in 5 minutes but achieving precise measurements while maintaining speed and simplicity of IOPTH system is a significant challenge in real-time surgical environment.

Aim:

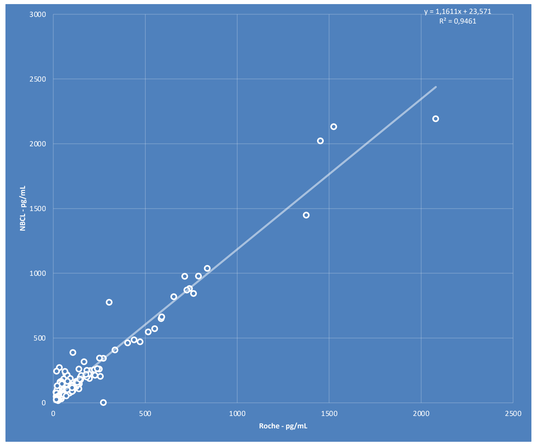
Prospective, multi-centre Clinical Validity study assessing NBCL performance during life surgery in London and Stuttgart with an aim of identifying and implementing incremental improvements in hardware, calibration, operating protocol and composition of assay.

Methods:

Patients undergoing parathyroidectomy had simultaneous IOPTH monitoring (Miami criteria) with NBCL and either Roche or Abbott (gold standards). Pearson coefficient was used for linear correlation and NBCL sensitivity/specificity/accuracy was calculated. Monitoring Committee regularly discussed results and implemented improvements in 3 stages.

Results

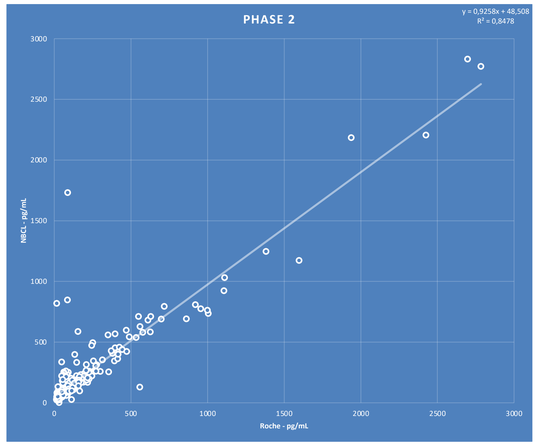
Phase 1. January 2022
PTH Kit lots: 2136, 2162,2243
PTH Protocols: 1497
60 patients, 246 samples



R = 0.98
Sensitivity 83.9%
Specificity 100%
Accuracy 84.8%

Improvements
Mechanical: packaging, pipetting
Callibration curve: high FN results due to flat curve and interference

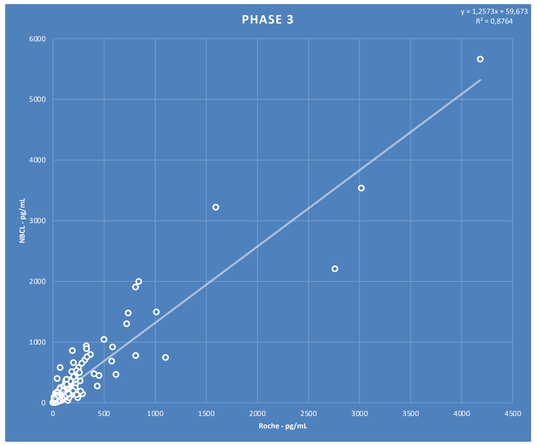
Phase 2 February to April 2022
PTH Kit lots: 2377,2415
PTH Protocols: 2112, 2201
97 patients, 348 samples



R= 0.92
Sensitivity 91.2%
Specificity 100%
Accuracy 91.3%

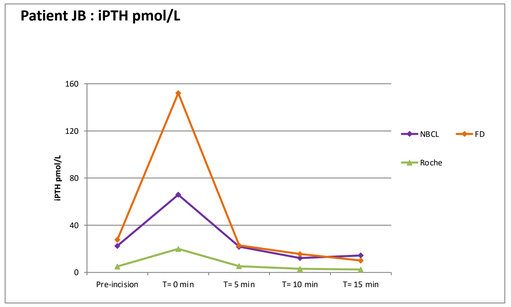
Improvements
Protocols: clot avoidance and detection
Calibration curve in low PTH range and less False Negative results

Phase 3 April to July 2022
PTH Kit lots: 2468
PTH Protocols: 2204, 2206, 2207
71 patients, 318 samples

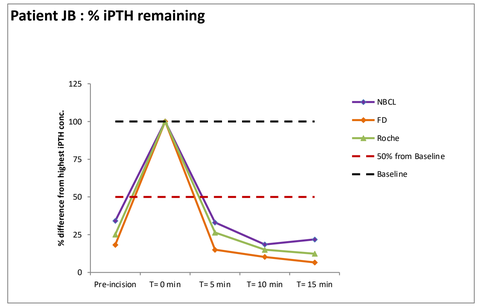


R = 0.93
Sensitivity 98.6%
Specificity 100%
Accuracy 98.6%

Improvements
Protocols:: reduced interference from heterophilic antibodies
Calibration curve stable and repeatable,
No False Negative results



Conclusions



- Close cooperation between surgeons, clinical scientists and engineers led to implementation of incremental improvements resulting in better clinical performance of NBCL Connect Analyser.
- Latest version of Analyser proved its ability to predict biochemical cure in patients undergoing surgery for PHPT and should be recommended for clinical use.
- Further multicentre clinical studies should be initiated to assess potential impact of this technology not only on improving outcome of parathyroid surgery but also on its cost effectiveness in reducing need for excessive and often unnecessary multiple preoperative localisation imaging.
- Please contact us if you would like to take part in future studies assessing clinical utility of this new technology (tom.kurzawinski@mac.com)