CASE REPORT

From Causatum to Erratum, all in a name

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SUMMARY

Background: This study highlights how a trivial mistake in collecting timed blood samples of parathyroid hormone (PTH) during parathyroidectomy (PTX) can potentially become a serious error affecting surgical closure. Methods: For the measurement of serum PTH, the intact PTH (iPTH) test was used to obtain baseline, preoperative, intraoperative, and postoperative samples of PTH, to guide the surgical team regarding adequacy of PTX. Results: Due to the lack of proper guidelines, all types of samples for PTH are labeled as iPTH by the Laboratory Information Services (LIS) software. Due to a human error in marking the PTH vacutainers generated for different time point samples by LIS, samples were swapped. The values in the lab revealed a spurious rise in PTH post-PTX. The laboratory physician carefully observed the tubes and identified the reason for this mistake. The timely action therefore led to surgical closure, otherwise it could have led to unwarranted extended PTX. Conclusions: In cases where timed samples are mandatory, having a common code for all requisitions can invariably lead to pre-analytical error, therefore proper discriminative measures need to be introduced to avoid these mistakes.

KEYWORDS

HIS, LIS, iPTH, ioPTH

LIST OF ABBREVIATIONS

HIS - Hospital Information System
LIS - Laboratory Information System
PTH - Parathyroid Hormone
PTX - Parathyroidectomy
iPTH - intact Parathyroid Hormone
ioPTH - Intraoperative Parathyroid Hormone

INTRODUCTION

Technology in the last few years has significantly improved the healthcare system in terms of quality of health care, patient safety, and operational efficiency. A significant contribution towards this improvement in the health care system has been made by advanced health information technology. Hospital services mainly utilize a hospital information system (HIS) for managing the
functions of different areas of the hospital such as patient registration, billing, pharmacy, inventory, radiology, medical record section, etc. [1]. In addition to this, a segment of the LIS, laboratory information system (LIS) has already been well-established in most of the advanced medical facilities worldwide. In some cases, LIS operates in isolation from HIS or may be integrated with the HIS via health level seven (HL-7). LIS helps the treating clinicians by managing, processing, reporting, and storing laboratory information thereby delivering results within a stipulated time frame. Undoubtedly both lab physicians and the treating clinicians are brought on a common platform in real-time by using LIS thereby integrating lab and bedside scenarios [2]. Despite the many benefits offered by the advancements in hospitals in the form of HIS and LIS it is very important to realize that all technology is human-operated and to err is human. Most of the mistakes usually arise out of sheer ignorance regarding the operational aspects of the technology being used. The hospital information system is used by one and all and hence owned by none in the hospital. Many users are therefore not familiar with the intricate details regarding the proper operating protocol of LIS. This ignorance may at times lead to serious errors affecting patient management. Therefore, it becomes important to realize that a little knowledge may prove dangerous resulting in diagnostic errors.

Parathyroid hormone (PTH) is secreted by the four parathyroid glands. The parathyroid gland secretes different fragments of PTH, namely 1 - 84 and 7 - 84 PTH fragments. Intact PTH (iPTH) is a widely used clinical investigation for the assessment of PTH levels in serum, which measures both 1 - 84 and 7 - 84 fragments [3]. Primary hyperparathyroidism (pHPT) is a clinical condition characterized by an unregulated excessive production of PTH, which in turn causes hypercalcemia and hypophosphatemia. pHPT arises mainly due to either benign adenoma or hyperplasia and is rarely due to parathyroid malignancy. Surgical intervention remains the mainstay of management which includes careful bilateral neck exploration (BNE) to access all parathyroid glands [4]. However, the increasing sensitivity of preoperative localization methods such as 99Tc-sestamibi scanning with or without ultrasound and the advent of intra-operative parathyroid hormone (ioPTH) monitoring assay have led to the use of minimally invasive procedures in parathyroid surgery [5,6]. Notably, ioPTH has emerged as one of the decisive factors that provide reassurance to operating surgeons during the peri-operative window regarding successful surgical removal evidenced by a sufficient fall in the levels of PTH [7]. This has ensured optimal surgical resection, decreased surgical time, reduced overly financial and health burdens on patients, and fewer complications of extended parathyroidectomy. A sufficient decrease of real-time PTH during surgery virtually indicates successful therapeutic parathyroidectomy. In 1993, Irvin et al. developed the rapid intraoperative PTH assay. The Quick intact intraoperative PTH assay is a technique that allows real-time monitoring of the decline in plasma PTH levels as the glands are removed during parathyroidectomy [8]. Numerous evidence-based models of the ioPTH fall have been proposed. Amongst these, the Rome criterion is followed globally which is based on a drop > 50% of ioPTH values compared to the highest pre-excision values and/or ioPTH value within the reference threshold at 20 minutes after excision, and/or ≤ 7.5 ng/L lower than the value at 10 minutes post-excision. Regardless of the surgical technique used, an insufficient drop in PTH levels in both 10 and 20 minutes sampling strongly supports continuing with the dissection and, in some cases, an extension of the surgical field to a conventional bilateral exploration [9].

What we aim to discuss through this article is not the surgical aspect of parathyroidectomy but the concerned pre-analytical and post-analytical framework involved with the raising of requests on HIS for multiple sample processing of iPTH at defined intervals during the surgical procedure. How knowledge regarding relatively simple HIS/LIS software-related applications can contribute to preventing major diagnostic errors is highlighted in this paper.

CASE REPORT

Case Presentation
A 16-year-old female presented with a history of trivial trauma leading to a pathological fracture of the right femur, abdominal discomfort, and a recent history of mood swings. She was evaluated and diagnosed with pHPT due to raised PTH at 1,455 pg/mL and normal serum calcium at 9.2 mg/dL. The ultrasonography of her neck revealed an enlarged left-sided parathyroid gland. A CECT of the neck and thorax revealed findings suggestive of left inferior parathyroid adenoma with multiple lytic lesions suggestive of bony lesions likely brown tumor of hyperparathyroidism. Given the above findings, she was referred to the surgical oncology department of our institute for further management. The patient was taken up for surgery and underwent a neck exploration with left-side superior and inferior parathyroidectomy. A baseline sample sent for iPTH estimation on the day of surgery revealed a value of > 2,000 pg/mL. This sample was collected at 9:12 am in the operating theatre, accepted in the lab at 11:11 am, and the report was generated at 11:34 am. The sample number was 230117C0372. A second sample post removal of the parathyroid gland was collected in the operation theatre (ioPTH) at 9:14 am and accepted in the lab at 11:03 am bearing a sample number 230117C0368. The report for this post-operative sample was generated at 12:20 pm with a value of PTH at 303 pg/mL. What is worth noticing here is that the first sample for iPTH estimation was received in the lab at 11:11 am while the second sample at 11:03 am which was technically not possible.
Flow of events leading to error generation

Barcoded tubes for two different samples of iPTH dispensed at APTL workstation bearing different sample numbers on barcode in order of time of dispersion.

Sample number 230117C0368 corresponding to time of collection of barcoded tube from APTL at 9:12 am and sample number 230117C0372 corresponding to time of collection of barcoded tube from APTL at 9:14 am is generated.

Preoperative sample for iPTH is received in the lab in the vacutainer bearing sample number 230117C0372 whereas postoperative sample is received in vacutainer bearing sample number 230117C0368.

Ideally the vacutainers are generated in increasing order of sample number. However clinicians are not aware of such small details and, hence, the postoperative sample was received in the vacutainer meant for pre-operative sample and vice versa.

Figure 1. The series of events post barcoding of vacutainers that led to incorrect PTH levels being reported.

Cause of error in the values of PTH
The patient was scheduled for elective parathyroidectomy on January 17th, 2023. The pre- and post-operative samples were collected in barcoded EDTA vacutainers generated on the same day through an automated phlebotomy tube labeler (APTL) machine. Sample collection time reflects the time of dispensing of the barcoded vacutainer from the APTL machine. As the requisition for both samples was initiated simultaneously with no provision for discrimination between the pre-operative, intraoperative, and post-operative samples on the HIS software, all these different time point samples for PTH would be read as iPTH only, irrespective of the time of draw. As both tests were initiated simultaneously, vacutainers were collected preoperatively outside the operation theatre (OT) at the location of the APTL machine and handed over to the resident doctor who would have been assisting with the procedure in the OT. It is very likely that due to the inability of the resident doctor in understanding the importance of the order of vacutainer generation in this case, an interchange of samples resulted. Consequently, the pre-operative sample was put in the vacutainer generated second in the line (230117 C0372) whereas the postoperative sample in earlier generated vacutainer (230117C0368). The sample numbers on our HIS are generated daily with changeover taking place at exactly midnight marking the beginning of a new day with a new series starting with C0001 (C designates all samples sent to Biochemistry wing) and preceded by the date in the sequence year/month/date. The pre-operative sample was accepted at 11:03 am in the vacutainer intended for the post-operative sample (230 117C0372) whereas the postoperative sample was sent in the vacutainer meant for the pre-operative sample (230117C0368), received in the lab at 11:11 am as per HIS records. Once the reports for both samples were generated which were contradictory, the laboratory in charge soon figured out the sample swap by looking at the opposite values and HIS entries for the vials. The case was urgently discussed by the laboratory in charge with the surgical team regarding this error while the patient was still on the OT table. Therefore, the surgery was closed and the correct report was uploaded on HIS. For ease of understanding, the entire events leading to the error are depicted in Figure 1.

DISCUSSION

Primary hyperparathyroidism is due to a single adenoma in 85% to 95% of cases which is often cured after adenoma removal. Several innovative minimally invasive surgical procedures have been introduced lately for the prevention of unnecessary near-total removal of the parathyroid gland, as was practiced in the past [10]. The introduction of ioPTH in conjunction with diagnostic imaging has been a cornerstone that adequately suggests surgeons to consider the excision adequate in the nick.
of time thereby preventing unnecessary excessive removal. Interestingly, ioPTH assay values when not falling to desired levels during non-extensive parathyroidectomy brings out the possibility of multiple adenoma and thereby timely ioPTH fall in these cases virtually eliminates the need for a repeated neck exploration [11]. This technique is helpful to surgeons and patients provided the laboratory can deliver the reports within the stipulated time frame. In our case the iPTH was performed on a chemiluminescence-based immunoassay analyzer (Siemens ADVIA CENTAUR XP) and due to effective communication between laboratory in-charge and surgeon, the assay was timely performed, and results were updated on HIS. However, a small mistake in not dispensing the sample in the right vacutainer could have led to serious consequences with the first value (pre-operative) sample being released with a lower iPTH value as compared to the second (post-operative) sample. This emphasizes the need for the understanding of the basic working of HIS by not only the laboratory personnel but also the clinicians involved in patient management [12]. Moreover, effective communication between the laboratory personnel and surgeon was very effective in preventing the catastrophe which would have otherwise occurred. As ioPTH is not a very commonly required test presently, all tests for PTH exist in HIS as iPTH and there is no possible obvious way of distinguishing sequential sampling. To avert future mistakes in this regard, it is suggested to design tests for iPTH with names like routine iPTH, pre-operative PTH, intraoperative PTH, and postoperative PTH.

What is worth commenting on here is that ioPTH processing is an emergency with prior information being conveyed to the lab from the operating surgeon regarding the urgency of sample processing as it may affect decision-making on the operation table. A simple mistake as discussed in the above case may lead to further delays and mismanagement.

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Declaration of Interest:
The authors have no relevant financial or non-financial interests to disclose.

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