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CASE REPORT

Fecal Contamination Leading to Falsely Elevated Urinary Amylase: Insights into Pre-analytical Quality Control

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SUMMARY

Background: **Elevated urinary amylase is usually associated with pancreatic disease, but non-pancreatic factors such as fecal contamination can also lead to false elevation.**
Methods: **The retrospective analysis of a 75-year-old patient with acute cerebral infarction identified fecal contamination as the cause of falsely elevated urinary amylase.**
Results: **Initial urine test showed amylase > 24,000 U/L, the level of which decreased to 164 U/L after standardized urine collection. Abdominal CT confirmed normal pancreatic morphology and uniform density.**
Conclusions: **Fecal contamination is the key source of falsely elevated urinary amylase. Strict pre-analytical quality control is the key to preventing laboratory errors.**
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KEYWORDS

urinary amylase, pre-analytical quality control, fecal contamination

INTRODUCTION

Acute cerebral infarction, a common cerebrovascular disorder, is characterized by abrupt neurological deficits such as aphasia, facial palsy, and limb weakness. Elevated urinary amylase levels are typically attributed to pancreatic pathologies (such as acute pancreatitis and pancreatic trauma). Zhang M et al. reported that hypertriglyceridemia may contribute to acute pancreatitis complicated by acute cerebral infarction [1]; however, to date, no documented cases have been reported in the literature describing acute pancreatitis developing during the treatment phase of acute cerebral infarction. This case report describes a 75-year-old patient with acute cerebral infarction who exhibited falsely elevated urinary amylase levels during hospitalization, illustrating the clinical mechanisms of fecal contamination and emphasizing the critical role of pre-analytical quality control. This case underscores that pre-analytical quality control is critical to enhancing test accuracy and reducing laboratory errors.

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CASE PRESENTATION

A 75-year-old female patient, presented by her husband, reported sudden-onset aphasia and left-sided limb weakness for 1 hour. Her medical history included uncontrolled hypertension without regular medication. No diabetes, coronary heart disease, smoking or alcohol history and no family history of similar conditions. Physical examination revealed clear consciousness, aphasia and reduced left-sided limb strength. Imaging findings: Cranial CT showed a suspected hypodense lesion in the right temporal lobe with age-related brain changes and bilateral subcortical ischemic foci; cranial MRI confirmed acute large-area infarction in the right cerebral hemisphere, age-related brain changes and bilateral subcortical ischemic foci. She was admitted for acute cerebral infarction treatment.

On day 10 of hospitalization, urinary amylase was measured. The urine sample appeared yellow and turbid. After centrifugation, the supernatant was analyzed. Initial testing was performed using the VITROS 5600 Integrated System (Ortho-Clinical Diagnostics, Inc., USA, linear range: 30 - 1,200 U/L). Due to the result exceeding the detection limit, the instrument automatically diluted the sample to its maximum dilution factor of 20 x, yielding a value of > 24,000 U/L (reference range: 32 - 641 U/L). To confirm accuracy, the sample was reanalyzed using the LABOSPECT008AS Automatic Analyzer (Hitachi High-Tech Corporation, Japan, linear range: 1.9 - 3,000 U/L), which reported 77,851 U/L (automatically diluted 50 x), exceeding the reference upper limit by 173-fold (reference range: 0 - 450 U/L). A review of the patient's electronic medical record showed that serum amylase on the same day was 48 U/L (reference range: 30 - 110 U/L), within the normal range. While elevated urinary amylase may persist during the convalescent phase of acute pancreatitis despite normalization of serum amylase, this case demonstrated an unusual discrepancy: urinary amylase was not only significantly higher than serum amylase but also exceeded the upper reference limit by 173-fold. Such an extreme elevation is unlikely solely attributable to pancreatitis, suggesting a non-pancreatic interfering factor. Microscopic examination of the urine sediment revealed suspected undigested food residues, raising the possibility of fecal contamination.

Consultation with the nursing staff in the ward revealed that the patient exhibited no clinical manifestations of acute pancreatitis, such as abdominal pain, nausea or vomiting. We communicated the abnormally elevated urinary amylase results and the suspicion of fecal contamination. Upon inquiry by the nurse, it was discovered that the urine sample had been collected using a bedpan (a hygiene device for patients with mobility impairments or bed confinement) and the family had inadvertently submitted urine contaminated with feces for testing. The nurse then instructed the patient to collect a clean-catch midstream urine sample. The re-collected urine appeared yellow and clear. After centrifugation, urinary amylase testing of the supernatant yielded a normal result of 164 U/L (reference range: 32 - 641 U/L) and urine sediment microscopy revealed no abnormalities. These results confirmed that the initial elevation in urinary amylase was artificially elevated due to fecal contamination.

Additionally, during the review of the patient's electronic medical record, we noted that an abdominal CT scan performed post-second urinalysis demonstrated normal pancreatic morphology and uniform density. These imaging findings further supported a non-pancreatic etiology (fecal contamination) for the elevated urinary amylase. The investigation and validation process for the falsely elevated urinary amylase due to fecal contamination is illustrated in the figure below.

DISCUSSION

Mechanistic analysis of fecal contamination causing falsely elevated amylase levels: The human gut contains pancreatic-type (P-type) and salivary-type (S-type) amylase [2], synthesized by the pancreas and salivary glands, respectively, and specific gut symbiotic bacteria [3-5] are also capable of secreting amylase, which is not fully degraded in the gastrointestinal tract and is excreted in feces while retaining enzymatic activity [6,7]. In this case, due to failure to follow midstream urine collection protocols, urine collected using a fecal-contaminated bedpan was submitted for testing, resulting in falsely elevated urinary amylase levels because fecal-derived amylases were erroneously detected.

The Critical Role of Pre-analytical Quality Control

The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) has indicated that preanalytical errors account for 60% - 70% of the total laboratory errors [8], with sample quality issues being the most common cause [9,10]. It is essential to standardize collection procedures and strengthen patient and family education on proper sample collection protocols. This is particularly important for elderly patients or those with mobility issues. Providing auxiliary tools such as sterile urine bags can help reduce the risk of sample contamination and prevent misjudgments in test results.

The Necessity of Multidisciplinary Collaboration

When laboratory inspectors identify abnormal test results, they need to check and evaluate the quality of samples and initiate the reinspection procedure. They should communicate promptly with clinical departments and make a comprehensive assessment on whether it is necessary to recollect samples for reexamination based on clinical manifestations and auxiliary tests, so as to ensure the accuracy of test results, provide a correct basis for clinical diagnosis, and avoid misdiagnosis and overmedication.

This case, though not a rare disease, underscores the risk of misdiagnosis attributable to inadequate preana-

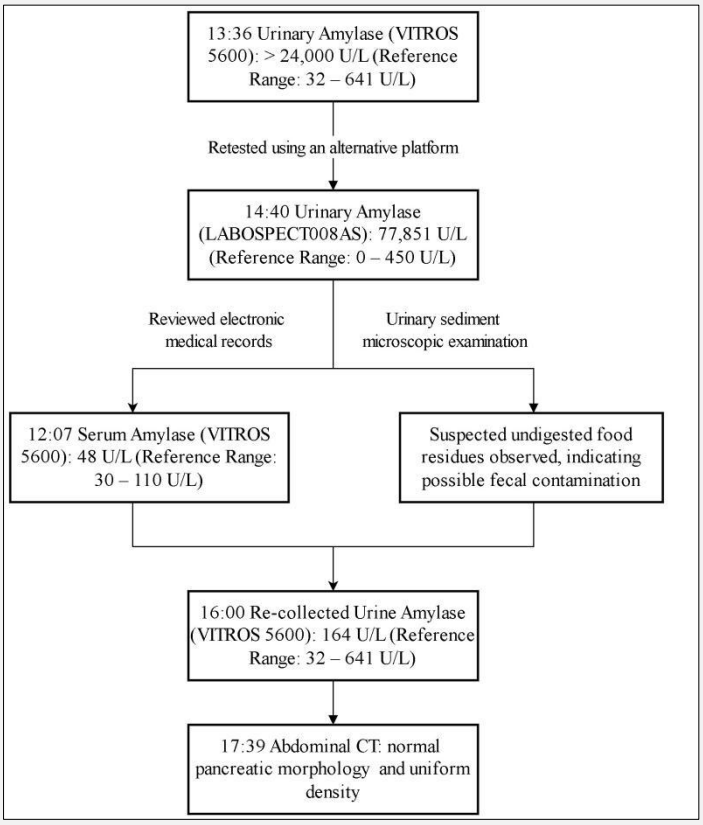

Figure 1. Diagnostic workflow for falsely elevated urinary amylase on day 10 of hospitalization.

lytical quality control. Through this case report, clinicians may be reminded to remain vigilant toward 'atypical elevations' and avoid misdiagnosis resulting from isolated abnormalities in single biomarkers. Despite its isolated nature, it offers practical guidance for identifying and addressing preanalytical quality issues in test samples, which is critical for enhancing medical quality and patient safety.

CONCLUSION

This case demonstrates that fecal amylase can lead to falsely elevated urinary amylase levels, emphasizing that pre-analytical quality control is the core component of laboratory error prevention and control. The accuracy of clinical test results can be improved by standardizing sample collection processes, strengthening patient and family education, implementing retest mechanisms, and multidisciplinary collaboration.

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Declaration of Interest:
No conflicts of interest to declare.

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