



Intrathecal Injection of Tranexamic Acid during Caesarean Section: Accidental Fatal Mistake

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Abstract

Objective: Draw attention for risk factors of drug error fatal mistakes that jeopardize patient life.

Case Presentation: In this study we presented a fatal drug error, intrathecal injection of tranexamic acid before caesarean section which led to neurotoxicity and repeated seizures, complicated by ventricular fibrillation and maternal mortality.

Conclusion: We should emphasize true drug for true patient by right method of administration especially in drugs that can easily endanger patient safety, legal rules should play a role to avoid repeated mistakes.

Keywords: Tranexamic acid; Spinal anesthesia, Patient safety

Introduction

High percent of drug error or confusing medication is due to similar packaging and labeling of drugs reach up to one third of cases, at the same time 50% of these cases is correlated with poor performance of qualified staff or lack of training and drug confirmation. Underlying reasons may be due to overly burdened staff and or psychological aspects like confirmation bias [1-3]. Other problems like translational problems and mistakable labeling errors were also described and discussed in the recent literature [4].

Tranexamic acid (TXA) is antifibrinolytic drug that is commonly used in patients with bleeding disorder. Its use is common in gynecologic and obstetric surgeries to overcome bleeding associated with the increased fibrinolytic activities [5].

In this case report, TXA was injected intrathecally during cesarean section instead of bupivacaine 0.5%, because both ampoules were having the same appearance resulting in a catastrophic fatal action.

Case Presentation

A 21 years old primigravida, presented to her obstetrician for elective caesarean section at 39 weeks gestation for obstetric indication (breech presentation).

Preoperative: She was vitally stable; her blood pressure was 110/75, pulse 82 bpm, BMI 20 kg/m². Her investigation preoperatively was normal including CBC, liver and renal function and coagulation study.

The anesthetist decided to give her spinal anesthesia, Spinal anesthesia was given while the patient in the sitting position at the L4-L5 interspace, using a 22-gauge needle. 8 mg (1.6 ml) of 0.5% hyperbaric bupivacaine, injected intrathecally, 50 second after injection the patient felt burning sensation at the site of injection associated with back and gluteal pain referred to lower extremities. No manifestations of sensory or motor block were noted, and the patient complained of severe intractable pain associated restlessness, she developed recurrent polymyoclonus and seizures about 2 minutes after intrathecal injection, emergency serum electrolytes was normal. The fits were continuous without stop except after intravenous thiopental injection. During the fit her vitals was blood pressure 170/110, pulse 120 bpm, respiratory rate 24/min. General anesthesia was induced by the infusion of propofol (200 mg) and celcurine (100 mg), and the patient's trachea was intubated. Anesthesia was maintained during surgery using propofol infusion (10 mg/kg/h) and Fentanyl (2 µg/kg/45 min) and surgery was continued. LSCS was done through Pfannenstiel incision; baby got out with apgar score 2 and 6 at one and five minutes.

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At the end of surgery and 5 min after the propofol infusion was discontinued, once she recovered from general anesthesia she passed again into recurrent polymyoclonus and seizures. Accidental intrathecal injection of the wrong drug was suspected. The anesthetist revised the medicine he gave and a used ampule of TXA was found in the trash. Neurological consultation was done who recommended continuous mechanical ventilation with continuous sedation.

Clonazepam (1 mg) and phenobarbital (800 mg) were given and continuous sedation using midazolam and fentanyl. The patient transferred to the ICU about 90 minutes after the injection and mechanical ventilation was maintained with volume controlled ventilation mode. Central venous and arterial lines were inserted to the patient. The first postoperative arterial blood gas analysis revealed metabolic acidosis (pH = 7.28, PaO₂ = 182, PaCO₂ = 36, HCO₃⁻ = 17.65). The blood analysis did not reveal any renal, hepatic, or hematological failure. The patient experienced tonico-clonic convulsions in the extremities 3h after admission to ICU, which were treated by an infusion of sodium thiopental (3-5 mg/kg/h). Gastric administration of Phenobarbital 200 mg/d was initiated. Cranial computed tomography was done showing no abnormalities.

In the first postoperative day, her blood pressure became 70/50 together with ECG pattern of tachyarrhythmia followed by ventricular fibrillation that couldn't be reversed by DC shock, patient arrested continuous CPR for one hour failed and finally the patient died after 14 hours of her operation.

Discussion

Tranexamic acid is a competitive inhibitor of plasminogen activation and a noncompetitive inhibitor of plasmin at higher concentrations [5,6,10]. Its use in humans is generally well tolerated, and its complications are minimal and include mainly gastrointestinal upsets. However, neurotoxicity and seizures have been reported in animal studies [6-8].

Some studies reported elevation of the systemic and intracranial pressure by direct cerebral application of TXA for treatment of ruptured intracranial aneurysm in animal models [8-10].

In 1988, Wong and colleagues [5] reported accidental intrathecal injection of 75 mg TXA in adult patient during appendectomy. The patient developed persistent sensory block of both lower extremities in addition to fever, myoclonus, and clonic convulsions that progressed to a generalized seizure that responded to intravenous diazepam, and the patient was fully recovered without any neurologic deficits.

Yeh et al. [7] reported inadvertent intrathecal injection of 500 mg of TXA. The patient developed generalized convulsions and hypertensive response followed by refractory ventricular fibrillation that ended the life of the patient.

The explanation of the sequelae is not definitely understood but may be attributed to massive sympathetic discharge induced by TXA that explained by suppression of the inhibitory gamma-amino butyric acid- (GABA)-A receptors in the cerebral cortex or lowering of cerebral blood flow with consequent cerebral ischemia [10-12].

Various recommendations on logistics to reduce medication errors as well considering LASA when ordering stocks & whenever feasible are mentioned:

1. Ideally, only one concentration of each substance should be available on wards, diverging concentrations should be ordered

according to individual cases only

2. LASA medication should carry warning labels, especially high risk medication with a narrow therapeutically margin, for example cardiovascular drugs, anesthetic drugs, cytostatics, high risk electrolyte carrying fluids.

3. a change to a barcode driven medication process can reduce the risk of confusing drugs significantly [13,14].

We recommend the following to minimize the drug errors encountered in our critical field of obstetrics

1. A standardized arrangement of drugs in the operating room;

2. Reading the drug label prior to drawing up the drug; 3) applying different shapes, size and colors of different ampoules;

3. Continuous review of medication errors in hospitals to identify causative associated factors and develop systematic interventions for prevention, similar packaging and presentation should be avoided where possible.

Also it is important to put in mind the 5 rules developed by WHO for patient safety Right Drug, route, time, dose and patient.

Finally all drug error must be revised, notified to the health care authority, documented and spread to all health care providers dealing with these medications together with increasing the availability of the clinical pharmacists to be involved in drug prescription and drug supply to the patient and health care providers.

Acknowledgement

No procedures performed in the study. It is just documentation of human error, but the research was approved by ethical committee it was in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent was obtained from the relative of the patient included in the study.

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