SAFETY ALERT

DRAP SAFTEY ALERT NO. 51

Safety Alert of Risk of Medication Errors resulting due to inadvertent intrathecal Tranexamic Acid Iniection.

Date: 28th of April, 2024.

Target Audience.

- Manufacturers and importers of tranexamic acid injection;
- Healthcare Commissions/ Provincial Health Departments; and
- Healthcare Professionals.

Background.

The WHO in its medical product alert on 16th March, 2022 informed healthcare professionals about the risk of administration errors that can potentially occur with tranexamic acid (TXA) injection. There have been reports of TXA being mistaken for obstetric spinal anaesthesia used for caesarean deliveries resulting in inadvertent intrathecal administration.

In TXA administered intrathecally, potent neurotoxin and neurological sequelae are manifested, with refractory seizures and 50% mortality. The profound toxicity of TXA administered intrathecally was described in 1980. A 2019 review identified 21 reported cases of inadvertent intrathecal injection of TXA since 1988, of which 20 were life-threatening and 10 fatal. Sixteen were reported between 2009 and 2018.

The WHO recommends early use of intravenous TXA within 3 hours of birth in addition to standard care for women with clinically diagnosed postpartum haemorrhage (PPH) following vaginal births or caesarean section. TXA should be administered at a fixed dose of 1g in 10 ml (100 mg/ml) IV at 1 ml per minute, with a second dose of 1g IV if bleeding continues after 30 minutes.

The WHO also informed that TXA is frequently stored in proximity to other medicines, including injectable local anaesthetics indicated for spinal analgesia (e.g., for caesarean section). The presentation of some of the local anaesthetics is similar to the TXA presentation (transparent ampoule containing transparent solution), which can erroneously be administered instead of the intended intrathecal anaesthetic resulting in serious undesirable adverse effects. Recently, obstetricians from several countries have reported inadvertent intrathecal TXA administration and related serious neurological injuries.

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Action in Pakistan.

The case was discussed in the 4th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) of the DRAP held on 26th of February, 2024 which decided the case as per Rule 10 (1) (b) and 10 (1)(h) (vi) of Pharmacovigilance Rules, 2022 and recommended National Pharmacovigilance Centre to issue safety alerts/ advisory related to the risk of medication errors due to inadvertent intrathecal tranexamic acid injection.

Therapeutic Good.

Name: Tranexamic acid (TXA) is used for the prevention and treatment of haemorrhages due to general or local fibrinolysis in adults and children from one year. Specific indication *inter-alia* includes gynaecological surgery or disorders of obstetric origin such as postpartum haemorrhage.

Advice for Healthcare Professionals.

Healthcare providers, particularly obstetricians and anesthesiologists, are urged to remain vigilant regarding the potential risk of unintended intrathecal administration of Tranexamic acid (TXA), leading to the development of potent neurotoxicity and subsequent neurological complications. It is recommended that healthcare professionals verify the labelling of Tranexamic acid (TXA) injections before administration. Instances have been documented where TXA has been mistaken for obstetric spinal anaesthesia during cesarean deliveries, resulting in inadvertent intrathecal administration. The similarity in presentation between some local anaesthetics and TXA (both typically packaged in transparent ampoules containing clear solutions) can lead to erroneous administration of the wrong medication instead of the intended intrathecal anaesthetic.

Tranexamic acid (TXA) is a lifesaving medicine; however, this potential clinical risk should be considered and addressed by all operating theatre staff. Reviewing of existing operating theatres' drug handling practices are required in order to decrease this risk, such as storage of TXA away from the anaesthetic drug trolley, preferably outside the theatre.

Guidelines for reporting Adverse Drug Reactions (ADRs).

Both healthcare professionals and patients are requested to report any adverse drug reaction with Tranexamic acid (TXA) injection to the National Pharmacovigilance Centre (NPC), Drug Regulatory Authority of Pakistan (DRAP) through the Med Vigilance E-Reporting System available on the DRAP website. Similarly, ADRs can also be reported through Med Safety App which is available through the App Store (for iOS devices) and Google Play (for Android devices).

References.

- Minutes of the 4th meeting of the Pharmacovigilance Risk Assessment Expert Committee.
- WHO statement on risk of medication errors with tranexamic acid injection resulting in inadvertent intrathecal injection.

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