MEDICINE SAFETY ALERT

IV Tranexamic acid – Administration error via the intrathecal route

21 December 2023

There have been several cases around the world in which Tranexamic acid has been administered intrathecally in error instead of the local anaesthetic agent, bupivacaine.(1)

Postpartum haemorrhage is the third most common cause of death in obstetric practice in developing countries. Tranexamic acid is life-saving in cases of severe postpartum haemorrhage(2) and, consequently, ampoules of Tranexamic acid are routinely kept in obstetric units for emergency use. Unfortunately, the ampoule packaging is similar to that of bupivacaine for spinal anaesthesia and fatal cases of this substitution error have been described in South Africa.(3, 4) This problem is recognised internationally and a recent review article and accompanying editorial published in Anaesthesia, 2019(5) delineates the issues. Publications in the South African literature contain illustrations of the similarity of the packaging ampoules of ampoules and the fact that these are frequently stored in obstetric units side-by-side. Catastrophic substitution errors are inevitable and there have been recent cases that have heightened the level of concern.

Alerts from WHO and the US FDA regarding Tranexamic acid are summarised in the table in reference 4, but further measures are required to minimise the risk of this lethal medication error. SAHPRA will urgently be engaging relevant industry partners on various risk minimisation measures in the mitigation of the highlighted risk.

Spinal anaesthesia for obstetrics is one of the most commonly performed procedures in South Africa. Given the life-saving nature of Tranexamic acid, it is not reasonable to require the withdrawal of Tranexamic acid from obstetric theatres. Whilst policies and systems can be put in place to make this kind of drug substitution error less common, it is essential that the packaging of Tranexamic acid is changed in such a way as to make these errors less likely.

All entities involved in obstetric anaesthesia including hospital managers, pharmacists, nursing staff and anaesthetic practitioners are urgently and cogently reminded of this potential hazard and that steps must be put in place to minimise the dangers.

A proposed inexpensive and quick-to-implement additional measure is to place a wrap-over warning tape on the snap-off end of the ampoule.

An urgent Dear Healthcare Practitioner (DHCP) letter drawing attention to this potential catastrophe, will be drawn up with the manufacturing companies and circulated. Further urgent regularity action, including a change in the packaging, an update to the professional information leaflet and a comprehensive risk management plan is being considered.

You are requested to urgently draw the attention of all involved personnel in your area of

responsibility to this very serious medication error and the steps available to prevent it.

Healthcare professionals are urged to report any adverse drug reactions (ADRs), or product quality problems to SAHPRA via the e-Reporting link available on the SAHPRA website (www.sahpra.org.za) or complete the ADR reporting form accessible via the SAHPRA website and email it to adr@sahpa.org.za. Alternatively, reporting can be done via the Med Safety App, downloadable through the Google Play or Apple App Store.

References:

1. Patel S, Robertson B, McConachie I. Catastrophic drug errors involving Tranexamic acid administered during spinal anaesthesia. Anaesthesia. 2019;74(7):904-14.
2. Collaborators WT. Effect of early Tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial. Lancet. 2017;389(10084):2105-16.
3. Bishop DG, Lundgren AC, Moran NF, Popov I, Moodley J. Intrathecal Tranexamic acid during spinal anaesthesia for caesarean delivery: A lethal drug error. South African Medical Journal. 2019;109(11).
4. Moran NF, Bishop DG, Fawcus S, Morris E, Shakur-Still H, Devall AJ, et al. Tranexamic acid at cesarean delivery: Drug-error deaths. Int J Gynaecol Obstet. 2023;160(1):49-52.
5. Palanisamy A, Kinsella SM. Spinal Tranexamic acid - a new killer in town. Anaesthesia. 2019;74(7):831-3.

About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965, as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.