



SCAN ME !

CASE REPORT : SINGLE-USE CRANIAL DRILLS, HIGH-RISK DEVICES !

Authors : A. BARUSSEAU¹, L. RUESCHE¹, L. GUENERET¹, Y. LURTON¹

¹Pharmacie, CHU de Rennes, 2 Rue Henri Le Guilloux, 35000 Rennes



Single-use cranial drills

- Used in neurosurgery to perforate cranial bones
- Connectors : Hudson chuck + motor
- Automatic disengagement



BACKGROUND & IMPORTANCE

From June 2018 to October 2020

ACCUMULATION OF ADVERSE EVENTS (AEs)

- 18 AEs recorded in our hospital :
✓ 7 of which resulted in a material safety declaration to the *Agence Nationale de Sécurité du Médicament et des produits de santé* for risk of cerebral damage

AIM & OBJECTIVES

- Analyse the causes of these AEs in order to propose corrective and preventive measures

MATERIALS & METHODS

- **Chronological analysis** of Material Safety (MS) data
- Contact and discussions with **the various people involved in the circuit** : the operating room, the biomedical engineering, the sterilisation department
- **Other healthcare establishments were questioned** to obtain feedback on the management of this type of AE
- Search of MS data *via the American MAUDE database* was carried out for the period, targeting the devices used in our centre
- **Causal analysis** using the 5M method : Ishikawa diagram

INTEGRA (CODMAN)
+ ANSPACH SYNTHES MOTOR

MOTOR CHANGE :
ELAN 4 BB BRAUN

INTEGRA (CODMAN)
REMOVAL FOR
MEDTRONIC

SHORTAGE
MEDTRONIC, CHANGE
FOR CMT WENGER
(EVONOS)

06/18

12/18

06/19

12/19

06/20

2018

2019

2020

From 06/2018 to 12/2018
5 MS declarations for non-disengagement

2019
1 MS declaration for non-disengagement

2020
Follow-up of AEs
1 MS declaration for non-disengagement

Figure 1 : Timeline showing AEs and equipment for cranial drills and engines at Rennes University Hospital

RESULTS

Machine : Cranial Drills/Motor

- Failure of the disengagement mechanism
- Types of material for the connection tip : plastic vs. metal
- Connection between chuck and motor may be loose

Manpower

- Sterilisation department :**
- Poor motor lubrication
- Operating room :**
- An added manual rotation movement
 - Non-perpendicular placement of the device
 - Inappropriate rotation speed

NON-DISENGAGEMENT OF CRANIAL DRILLS :
Risk of haemorrhage and risk of damage to the dura mater, haematomas

Material : Patient

- Pathological cranial bone
- Thickness of the cranial bone
- High intracranial pressure
- Adherence of dura mater

Medium : Operating Room

- Agitated environment
- Connection of equipment making it difficult to use

Method

- Inadequate training of the surgical team
- Faulty test procedure
- Unawareness of potential failure to disengage

Figure 2 : Ishikawa Diagram for non-disengagement of cranial drills

CORRECTIVE MEASURES

- ✓ Iterative change of supplier for cranial drills
- ✓ Training for the medical team : evidence of inappropriate motor rotation speed
- ✓ Monitoring of abnormal connection between chuck and motor nationally by the supplier
- ✓ Biomedical intervention: overhaul of motors, testing of a new Hudson chuck

PREVENTIVE MEASURES

- ✓ Integrate disengagement performance into cranial drills selection criteria

CONCLUSION & RELEVANCE

- Single-use cranial drills require **careful handling for optimum disengagement**
- The material causes have been identified, but **the human component cannot be ruled out**
- Corrective measures have been **implemented** to reduce the risk of these AEs
- Preventive measures also need to **be developed** such as revised selection criteria for the next call for tenders, or **best practices audits in the operating room**
- The impact of these corrective and preventive measures will be assessed through **AEs monitoring**

ID : NP-008

28TH EAHP CONGRESS : 20-21-22 MARCH 2024, Bordeaux

Contact author : alexandra.barousseau@gmail.com

