

MANAGEMENT OF MEDICATION ERROR REPORTS ASSOCIATED WITH THE INTRATHECAL ADMINISTRATION INSTEAD OF INTRAVENOUS ADMINISTRATION AT THE FRENCH NATIONAL DRUG AND HEALTH PRODUCTS SAFETY AGENCY

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AIM

The aim of this study is to qualify and analyse medications errors (ME) related to intrathecal administration of drugs instead of intravenous administration and establish recommendations to avoid this kind of error.

INTRODUCTION

Within the framework of the objectives set by the Public Health Law to reduce drug-related adverse events (adopted in 2004), the National Agency of Medicine and Health Product Safety (ANSM) has set up in 2005 a dedicated unit to collect and manage, in a single location, reports of medication errors or potential errors related to the packaging, labelling or names of medicinal products, and monitor the follow up of those likely to present a risk to Public Health. The "Medication errors Guichet" enables healthcare professionals to report directly to the agency medication errors without adverse reaction or near misses in addition of reports collected from the Pharmacovigilance System. In 2011 and 2012, respectively 1,734 and 1,589 medication errors have been collected.

Among medications errors reported, some were related to administration errors due to drugs administered by intrathecal route instead of intravenous route.

One way to intrathecal administration is to inject the drugs directly into the cerebrospinal fluid in the lower part of the spinal column. The other way is to inject by intracerebroventricular injection via an Ommaya reservoir, a dome-shaped container that is placed under the scalp during surgery.

Figure 1: Number of reports of ME collected by the dedicated unit of the french Agency since 2005

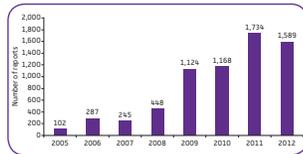
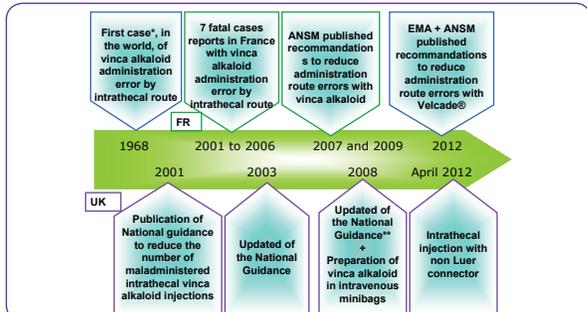


Figure 2: Background of errors related to the intrathecal route instead of the IV route



* Schochet and al: Neuronal changes induced by intrathecal vincristine sulphate. J Neuropathol Exp Neurol 1968; 27: 645-58
** HSC 2008/001 Updated national guidance on the safe administration of intrathecal chemotherapy

METHOD

To assess and analyse the number of medication errors (ME) cases reported in France to the agency, a wide request in the French Pharmacovigilance Database was performed on 11th April 2013 on all cases reporting a drug (suspect or interaction) administered by intrathecal route, during the period from January 1985 to 10th April 2013. Then, an analysis was made.

In France, in April 2013, 80 pharmaceutical products had a Marketing Authorisation with indication by intrathecal route. These drugs are analgesic, local anaesthetic, anti-neoplastic agent, antibiotic, non ionic contrast agent, corticosteroid and anti-spastic agent

In order to have information of European and international recommendations on errors related to the intrathecal route instead of IV route, a Non-Urgent Information (NUI) was sent to European Member States and an international literature review was conducted in march 2013.

RESULTS

FRENCH PHARMACOVIGILANCE DATABASE

981 cases were collected in our request but only 28 of them were included in our study. Those 28 reports of patent errors resulting in inadvertent administration by intrathecal route instead of intravenous route were reported including:

- 9 cases during a chemotherapy protocol;
- 6 during rachianesthesia;
- 6 during myelography;
- and 3 in patient with external ventricular drains;
- non information was available for the 4 remaining cases.

Figure 3 : Risk situation analysis

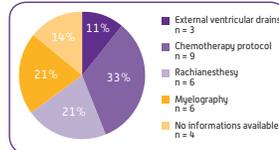
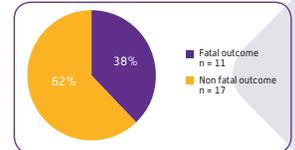


Figure 4 : Outcome of the 28 cases



All the cases lead to adverse effects (96% were serious and only 4% non serious). 11 cases had a fatal outcome. Among the 11 cases, 9 occurred during a chemotherapy protocol.

On the basis of those cases, three main situations were observed:



During chemotherapy, when an intravenous drug (vinca alkaloid for example) is associated with an intrathecal drug (methotrexate for example), the error generally occurs when intravenous drug (vinca alkaloid) is confused with therapeutic agents normally administered intrathecally, such as methotrexate.



Intravenous medication is administered by error into the intrathecal route. Among the 5 cases, 3 cases occurred with inadvertent administration of intravenous drugs in external ventricular drain and one of these cases had a fatal outcome.



Confusion between 2 drugs.

A drug has to be administered by intrathecal route but another drug without an indication by intrathecal route is administered by this route.

NUI

Regarding results of NUI, 16 countries answered: only United Kingdom introduced national guidance on the safe administration of intrathecal chemotherapy on 2001 and since 2001 no administration errors of IV chemotherapy by intrathecal route were observed. UK is the first country who introduced safer connector for intrathecal injection.

INTERNATIONAL LITERATURE REVIEW

Guidances have been identified:

- HSC 2008/001 Updated national guidance on the safe administration of intrathecal chemotherapy in UK;
- New-Zealand, Hong Kong, Scotland, Ireland, FDA and ISMP, OMS submitted guidance in the same way as UK.

CONCLUSION AND RECOMMANDATIONS

This analysis highlights that given the seriousness of inadvertent intrathecal administration including fatal cases, implementing general recommendations to minimize these medication errors is essential. Furthermore, this error belongs to the French "Never Events" list, i.e. avoidable serious adverse events, largely preventable patient safety incidents that should never occur in a healthcare if the appropriate preventive measures have been implemented*.

ANSM decided in accordance with its medication errors working group to set up minimization risk measures including:

- general recommendation for all intrathecal drugs in accordance with international guidance and in accordance with the experience of healthcare professionals of medication error working group ,
- communication(s) to healthcare professionals highlighting this risk of medication error.

*French "Never Events" list:

1. Error in management of patients treated with oral anticoagulants
2. Maladministration of potassium-containing solutions
3. Wrongly prepared injectable medication: method of preparation at risk
4. Intrathecal administration error instead of intravenous (IV) route
5. Wrong route administration of oral /enteral treatment
6. Chemotherapy overdose specially in pediatric population
7. Inappropriate administration of daily oral methotrexate (excluded cancerology)
8. Maladministration of Insulin
9. Maladministration of specialties used in anesthesiology in the surgery room
10. Wrong gas administered
11. Programming errors when using infusion pumps, electric syringes...
12. Error of administration related to the use of single-dose unit packaging (eg: single dose of saline liquid, antiseptic solution...), particularly in maternity care or pediatric