



Feedback from the report of an interventional radiology event at Strasbourg Hospital





2nd Priority - Control of optimization in Interventional Radiology

Background

- A new topic for ASN

ASN Inspection program really started in 2008 ; 2008 and 2009 Inspection national synthesis will be published in 2010 (mainly on occupational exposure)

Difficulty to delimit the number of facilities/practices of concerned: priorities to Interventional Neurology and Cardiology, and Radiology within Operational Wing (higher exposures for professional and patients)

Very few events reported to ASN

- Lessons learned after the notification of incident in the neurology service in Strasbourg Hospital

Contents

- Unexpected side effects in a neurology service in Strasbourg Hospital (One case in Lyon Hospital in cardiology)

- Main lessons learned

- On going works



Incident notified to ASN by Strasbourg Hospital

- 4 patients having received iterative treatments since the beginning of 2009 (for cerebral arteriovenous malformations) have developed unexpected side effects (alopecia, erythema) ... because of their “unusual” intensity
- 3 ASN inspections have been carried out with IRSN experts and a Radiologist (in collaboration with French Health Product Safety Agency and in presence of the manufacturer) ;
- Health consequences :
 - For only 8/26 patients, data for doses assessment were available
 - Calculated doses exceed values found in literature : 2 patients with severe alopecies received doses around 16-17 Gy (skin)
 - Possible neurological complication for 1 patient





Lessons learned after Strasbourg incident

No malfunction of the medical device has been found

First and routine settings were not optimized by the supplier

Organisational and Human Factors at the origin of the incident :

- **The training of the operators were inadequate (bad knowledge of the potentiality of the device in term of optimization)**
- **A real lack of safety culture : no written treatment procedure, no optimization approach, no follow-up of patients doses ...**

Failures :

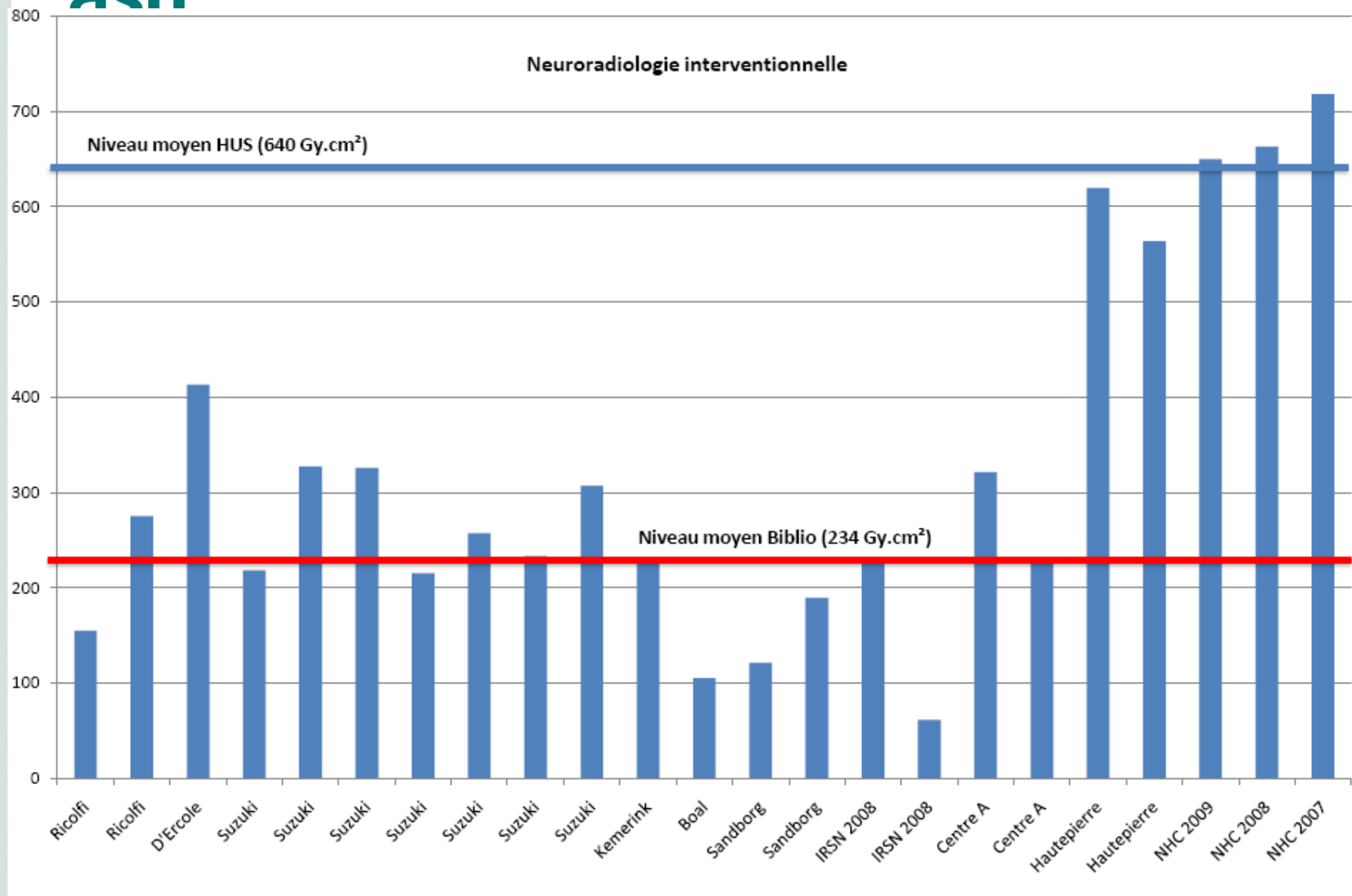
- in the organisation of Medical Physics (the medical physicist was not really associated and consulted) ;
 - in the organisation of maintenance (no traceability, no follow-up of modifications, of corrective actions, ...
- but in the organisation of care as well : the practitioner works in 2 centres, with 2 different devices and 2 groups of operators !**



A large scale action plan implemented by Strasbourg Hospital

- Actions are taking for better training of operators
- Device settings are optimised and managed
- Increased management of the manufacturer's maintenance and adjustment process
- A Structured procedure for optimisation of practices
 - Automatic retranscription of dosimetric data
 - Define reference level and evaluate practices
 - Changing in imaging practise
- In vivo dosimetry for therapeutic procedures
- Monitoring organised for patients liable to present lesions
 - Identification of patient at risk of complication
 - Implementation of patient follow-up
- Dosimetric data are archived in patients' records
- Consolidated organisational system for medical physics
- Consideration of possibilities for substituting procedures has been initiated

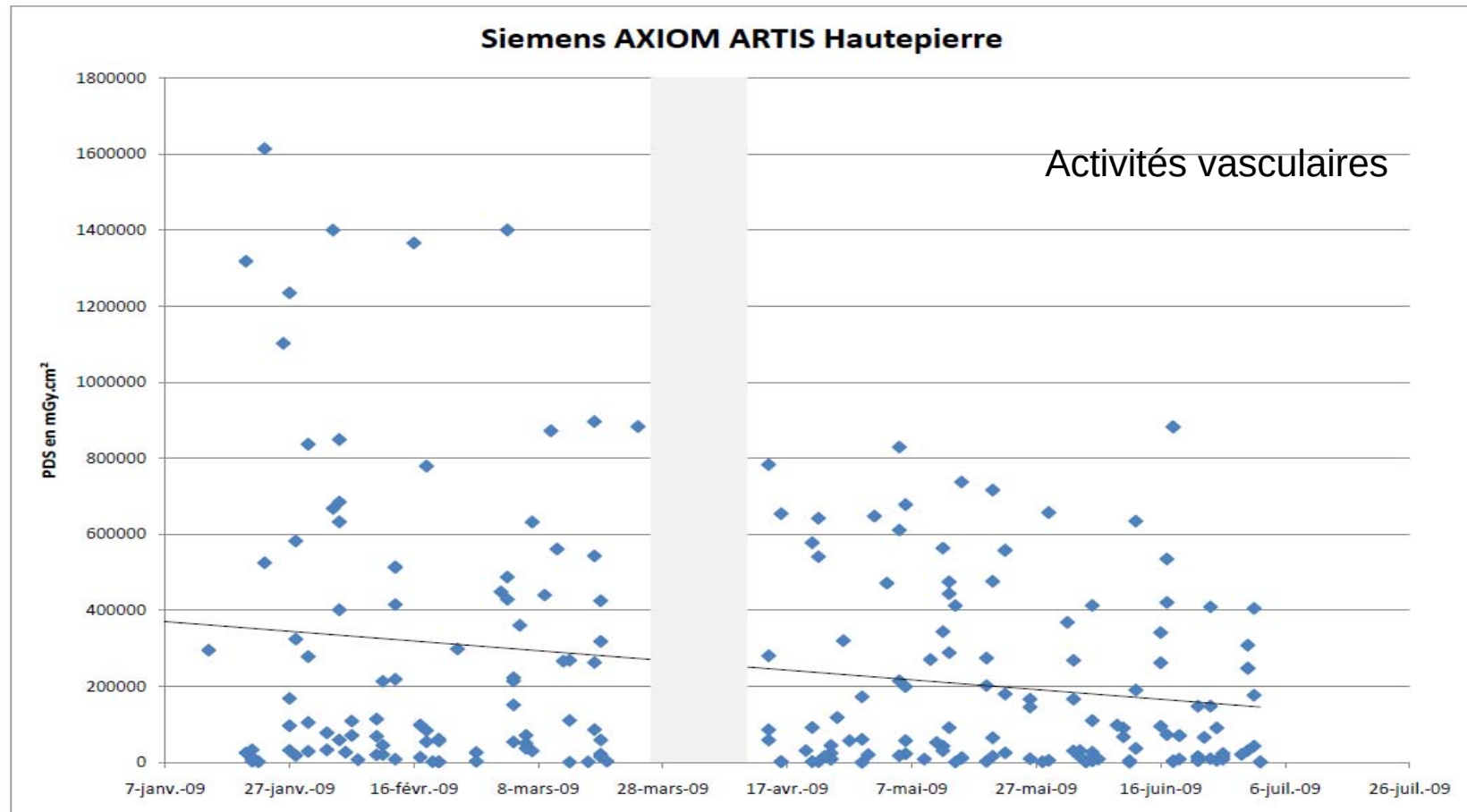
Setting optimization of the device and procedure and practical optimization have reduced the delivered doses respectively by 40% and from 30% to 50% !



Strasbourg Hospital data



Before and after optimisation



Doses divided par 2 /Strasbourg Hospital Data



On going works on this 2nd Priority - Control of optimization in Interventional Radiology

- Information and detailed and technical ASN report on this event are included on ASN website
- In collaboration with the French Society of Radiology (SFR), ASN has sent a 1st feedback experience towards interventional neurologist (recall of the national regulation, of the importance of optimization), toward Heads of hospital (about necessary means for training and Medical Physicist) and toward suppliers of devices (they supply training to operators and maintenance tasks as well).
- To be able to define generic actions in this field (ASN estimates that the situation at Strasbourg Hospital is not isolated), the Permanent Experts Group in medical radiation protection (GPMED) is preparing recommendations which will be submitted, for deliberation (2010), to ASN. On this base, as in radiotherapy, a national action plan on interventional radiology might be proposed to the Health Ministry next year.
- ASN inspections have to be improved considering both occupational exposures and patients exposures.

