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## Background

- ❖ Two techniques of ischemic stroke (IS) management
  - intravenous thrombolysis (IVT)
  - mechanical thrombectomy (MT)
- ❖ Haemorrhagic transformation (HT) is a complication occurring in 30-40% of patients.
- ❖ A pharmacovigilance (PV) and/or medical device vigilance (MDV) report should be done if this side effect potentially involves drugs or medical devices.

## Objectives

- ❖ To assess the percentage of HT after IS management with MT.
- ❖ To value declarations of MDV following HT post-MT.
- ❖ To draw a flowchart to help healthcare professionals better report side effects after IS management.



## Materials and methods

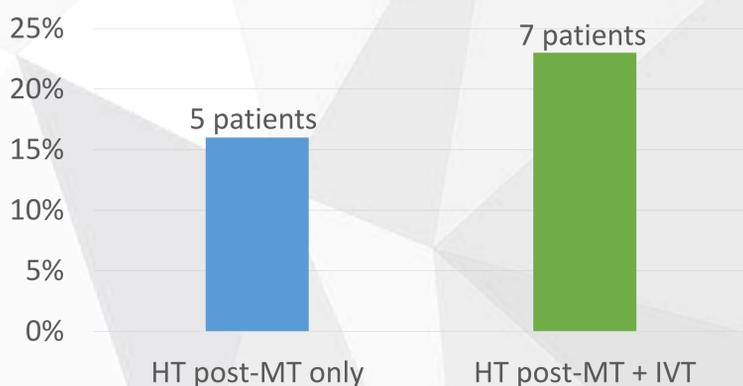
- ❖ A **retrospective study** was done over the period from May to July 2020 including patients with MT after IS. Demographic data, clinical data and techniques of management were collected.
- ❖ A flowchart was drawing with Microsoft Visio software.

## Results

### Over the study period, 31 patients were included

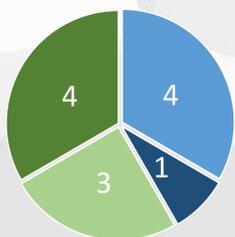
- sex ratio 1.07
- mean age 68±10 years
- mean BMI 25±4.42 kg/m<sup>2</sup>

### Percentage of haemorrhagic transformation



### Declarations done for the 12 patients with HT :

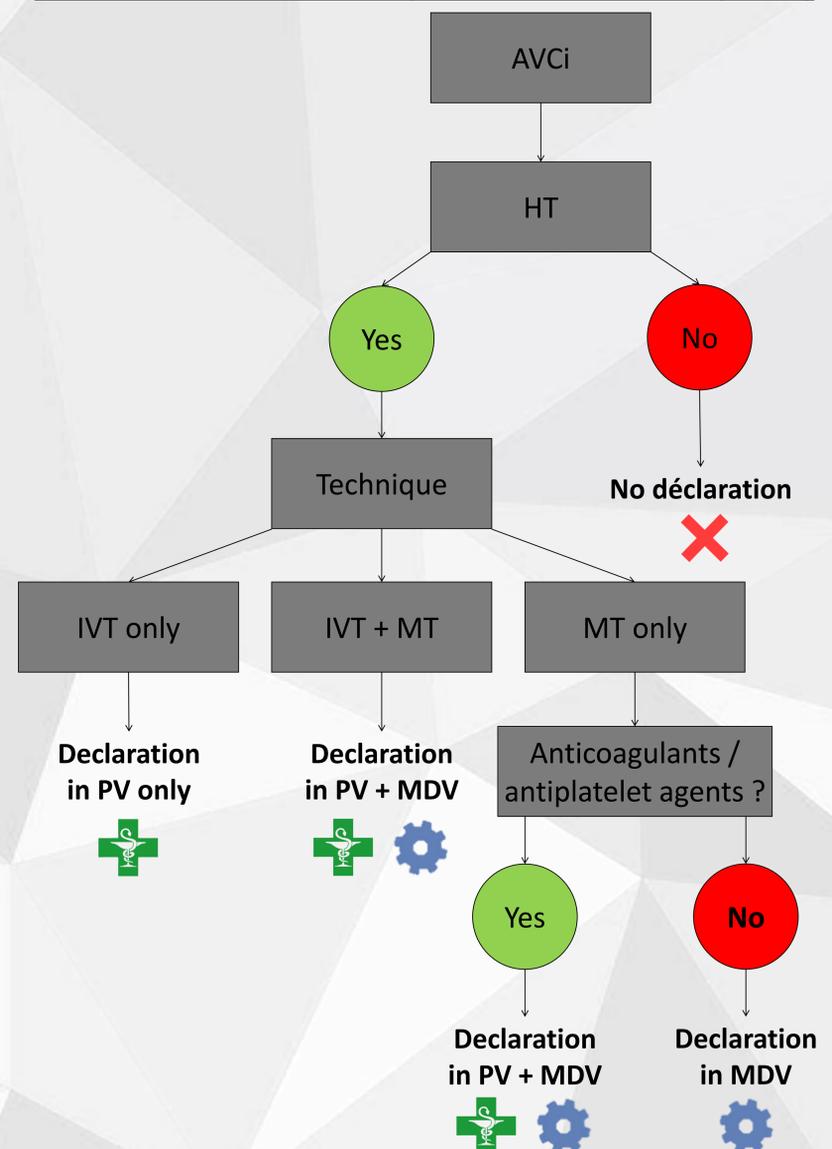
- ✗ Declaration to the wrong vigilance or no declaration
- ✓ Declaration to the good vigilance



→ 0/12 HT were reported in MDV. ✗

- ❖ According to French law, 12 patients should have been reported in MDV (patients with HT post-MT and patients with HT post-MT+IVT) and 7 in PV (patients with HT post MT+IVT).

### A flowchart has been developed to allow a better reporting



## Conclusion and relevance

- ❖ The percentage of haemorrhagic transformation post-mechanical thrombectomy is similar as in the literature. Haemorrhagic transformation is difficult to assess and may be the result of intravenous thrombolysis or mechanical thrombectomy, the natural history of stroke or influenced by risk factors.
- ❖ The number of reports done in medical device vigilance and pharmacovigilance after the ischemic stroke management post haemorrhagic transformation has been identified. There is a low rate of side effects reports and some are reported to the wrong vigilance.
- ❖ The flowchart will be validated and communicated to the hospital staff.