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“All authors have declared no conflict of interest”

Introduction

- ✓The majority of adverse reactions (ARs) induced by COVID-19 vaccines were considered as mild-to-moderate reactogenicity events.
- ✓But, despite the well proven efficacy and the safety of COVID-19 vaccines, some serious adverse have been emerging including neurological and thromboembolic complications (TEC) that are rare but life-threatening.

Method

- ✓We had included all patients with thromboembolic complications following COVID-19 vaccines notified the department of pharmacovigilance of the university hospital of Monastir
- ✓Imputability was assessed according to the French imputability causality assessment Scale.

Results:

1- Reported ADR related to Covid 19 vaccines

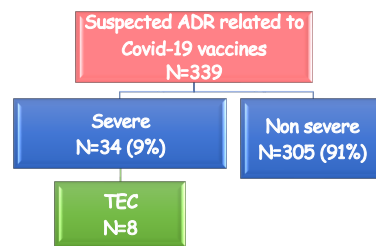


Figure 1: Reported ADR related to Covid-19 vaccin

2- Demographic and Clinical Characteristics of Patients

- ✓6 males / 2 females
- ✓ Median age: 68 years (31 - 82 years).

3-Pattern of TEC induced by COVID-19 vaccines

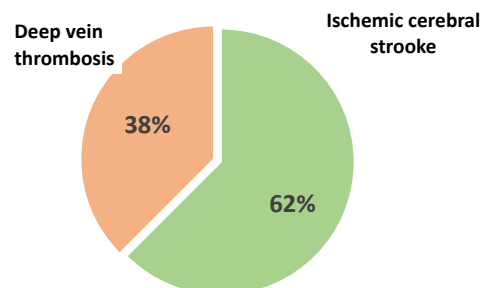


Figure 2: Pattern of TEC induced by Covid-19 vaccines

4-Chronological characteristics and outcomes of TEC

- Medium time to the onset of TEC was 13.3 days (1-30 days)
- In 7 patients: TEC were associated with the first dose of vaccine
- In 1 patient : TEC were associated with the second dose of vaccine

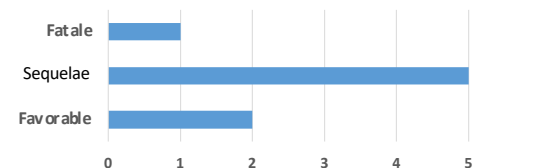


Figure 3: Outcomes of TEC

5- Incriminated vaccines:

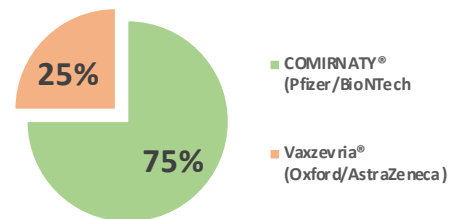


Figure 4: Culprit vaccines associated with TEC

6- Imputability assessment

- In 5 cases : Vaccine’s imputability was probable taking into consideration the clear temporal relationship between their administration and the onset of symptoms and the exclusion of other alternative causes after exhaustive investigations.

- 3 patients had predisposing factors for thrombosis and the imputability of the vaccines were uncertain.
- Since the gravity of these ARs, second dose of the related vaccine was contraindicated.
- An inactivated COVID-19 vaccine were recommended as an alternative to the second dose of vaccination.

Comments and conclusion

- In literature, reports of TEC had been increasingly described with mRNA and adenoviral vaccines with unproven causality.
- Vaccine’s benefits outweigh the risk of any adverse complications associated with its use.
- As causal association is still controversial, further study is, however, necessary to better prove it.