

Pregnancy safety outcomes in subcutaneous interferon-beta-exposed patients with multiple sclerosis: results from GCC region



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INTRODUCTION

- Women with multiple sclerosis (MS) are often diagnosed and treated at **childbearing age**.^{1,2}
- Therefore, **family planning** is an important consideration for female patients undergoing treatment.¹
- **Interferon beta (IFNβ)** has been recently approved for use during pregnancy and lactation.²
- Data from different registries have shown that **IFNβ exposure** before and/or during pregnancy **did not adversely affect pregnancy or infant outcomes**.^{2,3,4}
- The following sections present the **adverse events (AE) profile** of MS patients from **GCC region** (UAE, KSA, Oman, Qatar, Kuwait, Bahrain, Yemen) receiving subcutaneous (SC) IFNβ-1a prior to and/or during pregnancy, from 2015 till the end of 2019.



OBJECTIVE

- To carry out a **descriptive analysis of data** from Merck Serono Middle East FZ LTD Adverse Events safety database for pregnancy outcomes in patients receiving sc. IFNβ-1a from the GCC region.

METHODS

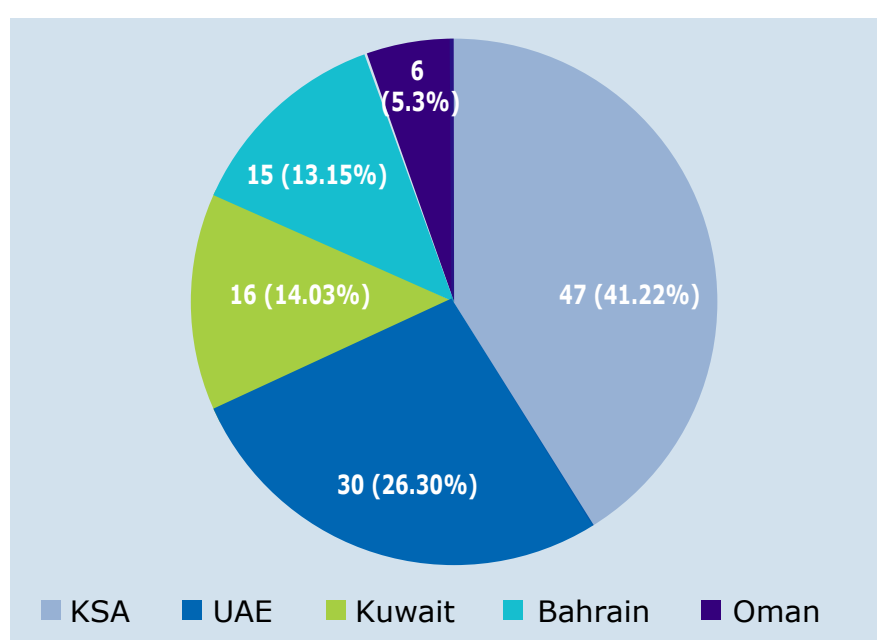
- We examined AE profiles from the Merck GCC local safety database containing individual case safety reports received during the post-marketing setting between **2015-2019**.



RESULTS

- During the period between 01-Jan-2015 to 31-Dec-2019, 224 AEs were identified in 114 cases (**Figure 1**).

Figure 1: Distribution of reported cases per country



- The average age was **30.9 years (21-46)**.
- Normal newborn outcome was identified with the **highest frequency**.
- AEs including premature baby, premature delivery, low birth weight baby accounted for **only 2.23% of all AEs** identified in GCC region (Table 1).
- The rate of spontaneous abortion was only **1.79%**; reporting rates for all other AEs were below 1% (Table 1).
- When compared with Merck Global Safety Database of all pregnancy cases with sc. IFNβ-1a reviewed cumulatively until 14-Dec-2018, **no abnormal AE trend was identified** for the GCC region.

Table 1: Serious AEs to pregnancy cases received during the reporting period

Serious AEs	Frequency	Percentage of all AEs
Premature baby	5	2.23
Premature delivery	5	2.23
Low birth weight baby	5	2.23
Abortion spontaneous	4	1.79
Neonatal hypoxia	2	0.89
Abortion	2	0.89
Jaundice neonatal	1	0.45
Pregnancy on contraceptive	1	0.45
Foetal death	1	0.45
Vaginal hemorrhage	1	0.45
Abdominal pain	1	0.45
Placenta accreta	1	0.45
Preterm premature rupture of membranes	1	0.45
Caesarean section	1	0.45
Rhesus incompatibility	1	0.45
Ectopic pregnancy with contraceptive device	1	0.45
Hemorrhage in pregnancy	1	0.45

Table 2: Key non-serious AEs to pregnancy cases received during the reporting period

Non-Serious AEs	Frequency	Percentage of all AEs
Fatigue	2	0.89
Pain	1	0.45
Somnolence	1	0.45
Pyrexia	1	0.45
Intentional dose omission	1	0.45
Anxiety	1	0.45
Breast engorgement	1	0.45
Urinary tract inflammation	1	0.45
Asthenia	1	0.45
Multiple sclerosis relapse	1	0.45

CONCLUSION

- **GCC data showed that exposure to IFNβ before and/or during pregnancy does not adversely affect pregnancy or infant outcomes.**



- **This is consistent with data collected from other registries and Merck Global safety database.**



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