

Descriptive Analysis of Adverse Events Reported Associated with the Use of Tigecycline or Minocycline Using the FDA Adverse Event Reporting System Database from 2008 to 2021

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INTRODUCTION

- The resistance rate to antimicrobials, specifically antibiotics, is rising and pose a challenge to public health due to their impact on morbidity and mortality rates.^{1,2}
- More potent antibiotics with a broader spectrum of activity are used including tigecycline, a minocycline derivative, to overcome bacterial resistance.³
- We aimed to explore the frequency and outcomes of adverse events associated with the use of minocycline and tigecycline using the FDA adverse event reporting system (FAERS) database from 2008 to 2021.

METHOD

- This was a retrospective study based on the FAERS database.
- All adverse events (AEs) and outcomes reports associated with the use of both generic and brand-name tigecycline or minocycline from first quarter 2008 to second quarter 2021 were extracted and analyzed.
- To calculate the total number of tigecycline and minocycline AEs and outcomes reports, we added all the data for each antibiotic (brand or generic) during the study time frame.
- Patient demographics were described (age, gender; etc.).
- Death reports as an outcome, were analyzed by age range, drug name, route of administration, and gender.

RESULTS

- We found 251,724 AEs reported from 2008 to 2021.
- The total number of patients was 12,929, where 2,687 patients used tigecycline (mean age 46.74 ±15.4 SD), and other patients used minocycline (mean age 48.04 ±16.5 SD).
- Total AEs were higher with minocycline use compared to tigecycline (figure2).

Figure 1: Percent of minocycline and tigecycline users by gender.

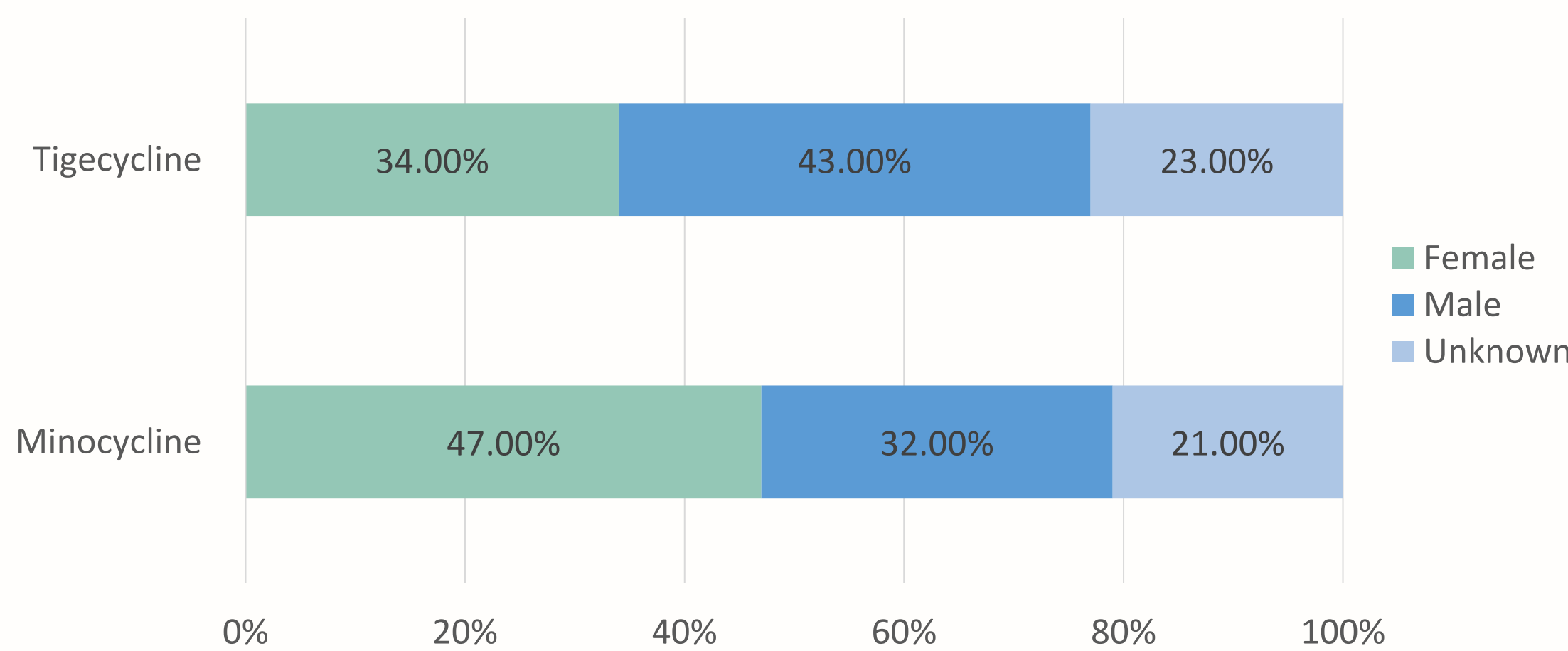


Figure 2: FAERS trends of tigecycline and minocycline AEs reported from 2008 to 2021

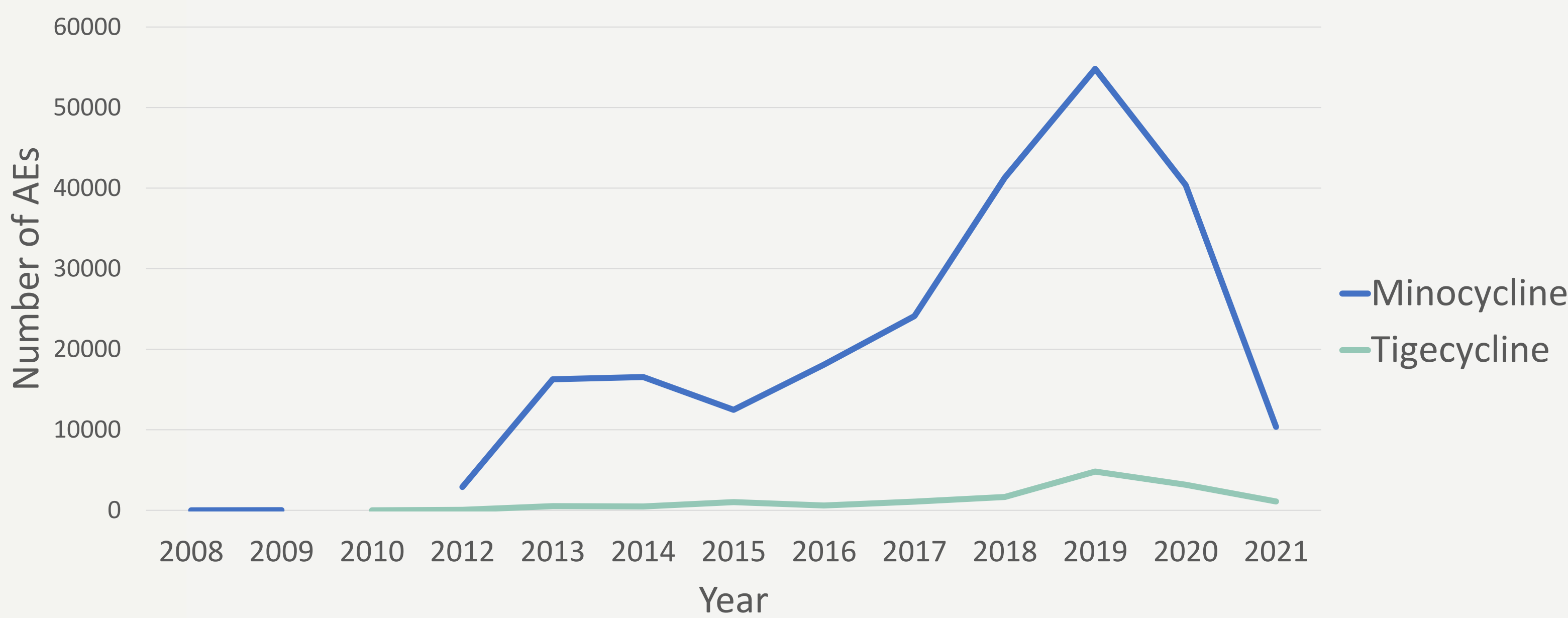


Table 1: Most frequent AEs reported for tigecycline or minocycline in FAERS.

	Number of AEs reports (%)			
Drug name	Minocycline	Tigecycline	Tygacil	Total
Drug related issues	18049 (9.24)	1135 (9.87)	130 (5.45)	19314 (9.23)
Musculoskeletal	18828 (9.64)	142 (1.23)	27 (1.13)	18997 (9.08)
Dermatological	13533 (6.93)	238 (2.07)	83 (3.48)	13854 (6.62)
Blood & coagulation	10541 (5.40)	1341 (11.66)	298 (12.48)	12180 (5.82)
Pain & discomfort	8465 (4.33)	232 (2.02)	44 (1.84)	8741 (4.18)

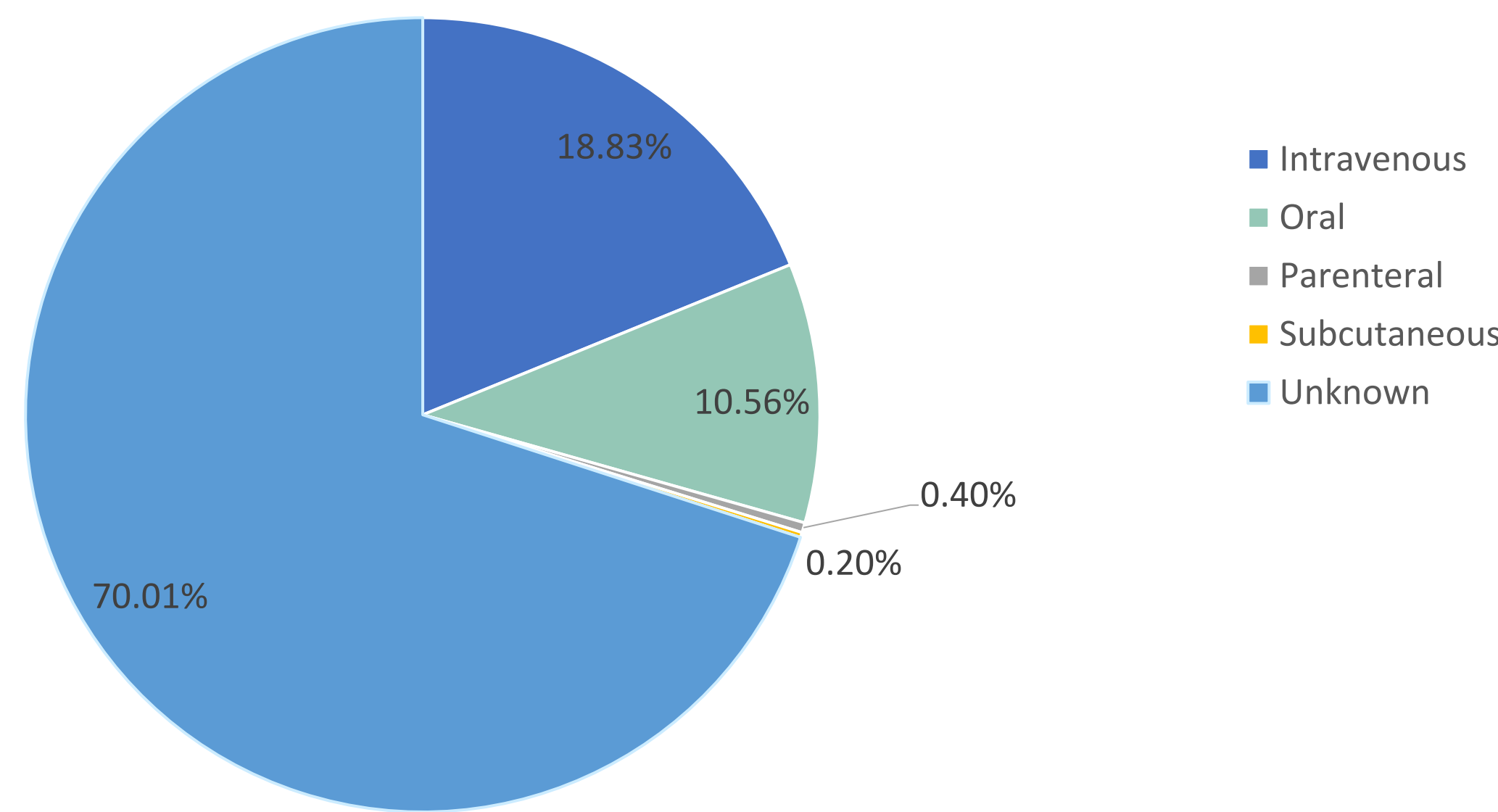
Table 2: Most frequent outcomes reported for tigecycline or minocycline in FAERS.

	Number of outcomes reports (%)			
Drug name	Minocycline	Tigecycline	Tygacil	Total *
Hospitalization - Initial or Prolonged	3122 (27.96)	872 (27.54)	271 (29.94)	4265 (27.99)
Death	671 (6.01)	611 (19.30)	207 (22.87)	1489 (9.77)
Life-Threatening	657 (5.88)	275 (8.69)	52 (5.75)	984 (6.46)
Disability	259 (2.32)	56 (1.77)	12 (1.33)	327 (2.15)
Required Intervention to Prevent Permanent Impairment/Damage	27 (0.24)	2 (0.06)	1 (0.11)	30 (0.20)
Congenital Anomaly	11 (0.1)	0	0	11 (0.07)

*The sum of percentages may exceed 100% as a submitter may report more than one outcome in each report.

- Males had the highest number of death reports with 47.5% of total 1,489 reported deaths.
- The age range of death reports was between one month to 98 years with mean of 56 years (±20.8 SD), however, for 321 deaths reports age was missing.

Figure 3: Analysis of death reports by drug administration route.



DISCUSSION & LIMITATIONS

- Regarding AEs, several studies were consistent with our findings like musculoskeletal AEs with minocycline and hematological AEs with tigecycline.⁽⁴⁻⁷⁾
- The percent of mortality with tigecycline use (brand & generic) was about 7 times higher than minocycline mortality.

Limitations:

- Underestimating or overestimating the number of AEs and outcomes reports.
- Prevalence and incidence rates of the reported AEs cannot be calculated.
- We cannot guarantee that death outcome is related to the use of minocycline or tigecycline.

CONCLUSIONS

- Drug-related issues and musculoskeletal AEs were the most reported AEs associated with tigecycline and minocycline use.
- Hospitalization and death were the highest reported outcome of utilizing the studied medication.
- Future cohort studies are needed to validate results.

REFERENCES

