**METHODS**

- Limited ongoing data regarding medications related to Osteonecrosis of the Jaw

**BACKGROUND**

- Osteonecrosis of the jaw (ONJ) is defined as the presence of exposed bone in the mouth, which failure to heal after appropriate intervention over a period of 6-8 weeks
- ONJ is a rare but serious adverse drug reaction (ADR) commonly associated with bisphosphonate and denosumab therapy
- FAERS is a large database of voluntarily reported adverse drug reactions associated with post-marked FDA-approved medications as well as natural substances, vaccines, and medical devices
- Prior research utilized the FAERS Database to explore this ADR
- Previously identified drug classes associated with ONJ included bisphosphonates, RANKL inhibitors, antiangiogenic agents, and m-TOR inhibitors
  - Proposed mechanism of action (MOA): antiresorptive properties and bone remodeling impairment via alterations in the formation of new blood vessels

**OBJECTIVE**

- Our study aims to build upon the prior findings, reporting trends of medication induced ONJ over time and identifying newly described medications

**METHODS**

- By May 2021, the FAERS database contained a total of 22,002,078 reported cases of ADRs
- We searched the FAERS database for all reported cases of medication related osteonecrosis of the jaw (MRONJ) from 2010-2021
- Cases lacking patient age or gender were excluded. Only adults (18+) and reports from Healthcare Professionals were included. Duplicate cases were removed
- The top 20 medications were identified and described for April 2010-December 2014 (“Time Period 1”) and April 2015-January 2021 (“Time Period 2”)
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**RESULTS**

- Between 2010-2014: 64.7% female, 35.3% male; average age was 66.1 +/- 11.1 years
- Between 2015-2021: 64.3% female, 35.7% male; average age was 69.2 +/- 11.5 years
- Novel drugs and classes described between 2010-2014:
  - Lenalidomide,
  - Corticosteroids (prednisolone and dexamethasone)
  - Docetaxel and paclitaxel
  - Letrozole
  - Methotrexate, Imatinib
  - Teriparatide
- Novel drugs and classes described between 2015-2021:
  - Palbociclib,
  - Pomalidomide
  - Radium-223
  - Nimulubum
  - Cabozantinib
- Zoledronic acid was the most frequently reported medication associated with ONJ during Time Period 1
- Denosumab was the most frequently reported medication associated with ONJ during Time Period 2

**Top 10 Drugs: 2010-2014**

1. Zoledronic Acid: 1903 cases; 60.8%
2. Alendronate: 576 cases; 18.4%
3. Denosumab: 506 cases; 16.2%
4. Pamidronate: 301 cases; 9.6%
5. Ibandronate: 112 cases; 3.6%
6. Lenalidomide: 82 cases; 2.6%
7. Risedronate: 81 cases; 2.6%
8. Sunitinib: 56 cases; 1.8%
9. Bevacizumab: 50 cases; 1.6%
10. Prednisolone: 42 cases; 1.3%

**Top 10 Drugs: 2015-2021**

1. Denosumab: 3148 cases; 54.5%
2. Zoledronic Acid: 2027 cases; 35.1%
3. Alendronate: 114 cases; 2.0%
4. Ibandronate: 112 cases; 2.0%
5. Ibandronate: 103 cases; 1.8%
6. Denosumab: 101 cases; 1.7%
7. Zoledronic Acid: 99 cases; 1.6%