Late Dosing of Leuprolide and Testosterone Levels >20 ng/dL in Prostate Cancer Patients

Przemyslaw Twardowski, MD1; Stuart N. Atkinson, MB, ChB2; Deborah M. Boldt-Houle, PhD2; Raoul S. Concepcion, MD3

1John Wayne Cancer Institute, Santa Monica, CA, USA; 2Tolmar Pharmaceuticals, Inc., Buffalo Grove, IL, USA; 3Integra Connect, West Palm Beach, FL, USA

OBJECTIVE

To determine the scope and impact of late injections of ADT in PCa patients, this study evaluated the:

- Timeliness of leuprolide injections
- Subsequent rate of T breakthroughs above 20 ng/dL
- Frequency of T/PSA tests prior to injections

METHODS

A retrospective review of electronic medical records from 1/1/07 to 6/30/16 of 78,464 leuprolide injections for PCa treatment was conducted to evaluate the percentage of late subsequent injections. T tests with T >20 ng/dL, and frequency of T/PSA testing prior to injections.

Injections and T tests were defined as "early-time" if on or prior to "late" if after day 32, 97, 128, or 184 for 1-, 3-, 4-, and 6-month formulations, respectively.

RESULTS

- For all leuprolide injections, 28.8% of injections were late: 14.4% were ≤1 week late (prior to day 40, 105, 136, 202 for 1-, 3-, 4-, and 6-month formulations, respectively), 3.2% were between 2- to 4-week late, and 9.1% were ≥2 weeks late (on or after day 47, 112, 143, 209 for 1-, 3-, 4-, and 6-month formulations, respectively) (Figure 2).
- Percent of late injections was high across all formulations: 46%, 20%, 26%, 27% for 1-, 3-, 4-, and 6-month formulations, respectively (Figure 3).

- 42% (32-48%) of formulations had T values exceeding 20 ng/dL when dosing was late (Figure 4).
- 83% of injections had a PSA value drawn prior to dosing; however, only 14% had a similarly timed T assessment (Figure 6).

CONCLUSIONS

Overall, greater than a quarter of injections were late

- Among late injections (26.8%), about half (12.4%) were ≥1 week late, and more than a third (9.1%) were ≥2 weeks late.
- Late injections were correlated with ineffective T suppression (above 20 ng/dL) (Figures 1 and 5).

For all injections, T levels were not monitored as frequently as PSA levels (Figures 2 and 3).

IMPLICATIONS

- Considering the clinical benefits of maintaining effective T suppression throughout the course of ADT, clinicians should
  - Administer treatments following labeled dosing instructions
  - Routinely monitor T levels

Future research evaluating differences between ADT agents on T suppression for late dosing would potentially be valuable.