ABSTRACT: RESULTS FROM A TIME AND MOTION STUDY OF DENOSUMAB SUBCUTANEOUS INJECTION AND ZOLEDRONIC ACID INTRAVENOUS INFUSION IN PATIENTS WITH METASTATIC BONE DISEASE FROM ITALIAN SITES

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Objectives:

Since 2011, denosumab (Dmb) subcutaneous (SC) injection is available as a superior treatment option in patients with bone metastases from solid tumours, compared with zoledronic acid (Zol) administered as an intravenous (IV) infusion. Although Zol was the mainstay treatment for skeletal-related events prevention, Dmb provides an alternative formulation to IV infusions. This Time and Motion study was conducted in Italy to estimate time endpoints associated with Dmb SC and Zol IV use.

Methods:

Patients with bone metastases from solid tumours scheduled to receive Dmb SC or Zol IV monotherapy in outpatient setting of 5 Italian hospitals were included in this study. The following pre-defined tasks were recorded in military time: patient registration, IV catheter installation, IV/SC drug administration (IV: infusion connection
until disconnection; SC: syringe filling and injection), and post-treatment monitoring. Active healthcare professional (HCP) time was recorded using a stopwatch. Time endpoints were total task time, total active HCP time, drug administration duration, and patient chair time. Data (mean) were analysed per site and pooled by country using a random intercept model.

**Results:**

A total of 85 observations were collected (50 Dmab SC and 35 Zol IV). Across sites, mean administration duration of Dmab SC injection was 3.4 minutes (min) and 15.9 min for Zol IV(-78%). The mean total task time was 9.9 min for Dmab SC and 31.2 min for Zol IV (-68%). Time savings associated with Dmab SC were also reflected in the total active HCP time (7.2 min vs. 12.1 min, -41%) and patient chair time (8.1 min vs. 23.3 min, -65%).

**Conclusions:**

Time savings associated with Dmab SC injection were seen for all outcome measures. Opting for Dmab SC administration instead of Zol IV infusion should increase the hospital capacity to treat more patients, and improve patients’ treatment experience in Italy.