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Comparative Assessment of Outcomes Using Two Different Intramuscular Testosterone Replacement Therapy Regimens

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Introduction: Hypogonadism is defined as serum total testosterone level < 300 ng/dL in combination with clinical signs or symptoms. Testosterone replacement therapy (TRT) aims to restore testosterone levels and reverse the signs and symptoms of hypogonadism. Several testosterone delivery systems, including intramuscular (IM) injections, are currently available. Nevertheless, side effect profile for the different dosing regimens of IM testosterone injections has not been investigated.

Objective: We sought to compare outcomes using two different commonly used IM TRT regimens.

Methods: We conducted a multi-institutional retrospective review of charts of men who presented to 4 different clinics between 2015 and 2019. Patients were included if they were 18 years or older and received one of the following TRT regimens: 100mg IM once weekly or 200mg IM once every other week. Patients were excluded if they received any additional non-TRT hormone replacement therapies in the last 6 months or had a diagnosis of prostate cancer. Primary outcomes were absolute and relative changes in Total Testosterone (TT), Free Testosterone (FT), Estradiol (E), Prostate Specific Antigen (PSA) and Hematocrit (Hct) at 3, 6 and 12 months after initiation of TRT. Secondary outcomes were any significant rises in E, Hct, PSA, and any other treatment related adverse events requiring cessation of TRT.

Results: There were 169 men who received 100mg IM once weekly and 94 men who received 200mg IM once every other week. At 3 months, increase in FT was more significant in the group receiving the 200mg ($p= 0.0269$), while increases in PSA and Hct were more significant in the group receiving 100mg ($p= 0.0003$ and $p< 0.0001$, respectively). At 6 months, increases in PSA and Hct were more significant in the 200mg group ($p= 0.0130$ and $p= 0.0130$ respectively). At 12 months, increases in all assessed laboratory values were more significant in the 100mg group ($p< 0.0001$). In men who had a baseline Hct below 54%, 1/102 (1.0%) of the 100mg group and 4/51 (7.8%) of the 200mg group had Hct levels rising above 54%, $p= 0.0262$. No patients, however, required a therapeutic phlebotomy. No differences were recorded in significant increases in E (>40 pg/mL) and PSA (>4 ng/mL) levels between both groups. There were no reported serious adverse events in this cohort, and 1 patient stopped TRT due to fertility concerns.

Conclusion: At 12 months after treatment initiation, IM TRT with 100mg weekly dosing appears to lead to higher rises in PSA, E and Hct, when compared to 200mg every other week. However, men who received 200mg IM every other week were more likely to have significant erythrocytosis (Hct > 54%). Further larger prospective studies are needed to validate these results.