

Restoring Erectile Function in Hypogonadal Elderly Patients who failed to respond to testosterone treatment alone, upon Combination with Vardenafil

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Objectives: This study was undertaken to investigate the efficacy and safety of Vardenafil in combination with testosterone, for the treatment of erectile dysfunction in hypogonadal patients who failed to respond to testosterone therapy (TT) alone.

Methods: This randomised prospective study in hypogonadal patients investigated non-responders to therapy with injectable long acting testosterone undecanoate 1000mg solely every 3months. 122 testosterone deficient patients with average age of 56 ± 3.9 years received initially this preparation. 71 responded well within 3 month. 51 subjects did not. They showed to have lower T-levels, smoking and higher rates of concomitant diseases such as diabetes, hypertension, hyperlipidaemia and drugs. 34/51 non-responders accepted the combination with 20mg Vardenafil on demand. Efficacy assessments were recorded by IIEF and partner self designed survey. Partner screening, i.e. answering 4 questions in terms of erectile quality/rigidity, duration of erection, successful intercourse completion and frequency at baseline and after 4-6 weeks with at least 6 PDE-5 inhibitors' attempts.

Results: 30 patients responded very well to this combination. IIEF-EF (questions 1-5 plus 15, 30 points) improved from 12 to 24. These subjects reported to feel again spontaneous or nocturnal and morning erections or tumescence. No changes in adverse effects were recorded. 10 patients who refrained from TT became Ed again, and got back to TT. Partner survey showed significantly higher satisfaction scale (1=poor, 2=fair, 3=good, 4=very good)

Conclusion: Data suggest that combination therapy of ED with testosterone and Vardenafil in hypogonadal patients is safe and effective in the subsets of hypogonadal patients who failed testosterone mono-therapy. TT is leading in a certain amount (54%) of patients to recovery process of erectile function, attributed to testosterone-induced remodelling of penile tissue structure and cellular function which may require 12 weeks or more to reach a significant improvement of erection. In non-responders to TT alone, combination therapy can enormously improve response.