جامعة الفيوم

كلية الطب

The English summary of the MD thesis

Optimization of intracavernosal pharmacotherapy in erectile dysfunction patients of various etiology.

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Summary and Conclusion

We did this study to determine the optimal effective dose combination of the Trimix (Tx) and the minimal effective dose in comparison to the standardized dose of PGE_1 20μg. Also, we want to evaluate the safety and side effects of ICI therapy with Tx.

The study included 180 patients seek a medical advice for their ED in the urology-out patient clinic in Suez Canal University Hospital, from 1/7/2000 – 31/12/2002. All patients came to us, complaining of failure to obtain or maintain penile erection sufficient to have coitus (for at least 6 months), with no history of priapism or sickle cell anemia.

The patients were classified randomly in nine groups (according to the dose of Tx). Each group contained 20 patients. In each group 10 patients were injected with PGE_1 (20μg) in the first session and the selected dose of the Tx in the second session, while the other 10 patients were injected by the same dose of

Tx in their first session and PGE_1 (20μg) in the second. This was done randomly and the patient was blind to the doses injected.

Each patient underwent, history taking physical examination, laboratory investigation, Duplex ultrasound examination of the penis, combined intra

cavernous injection (ICI) and stimulation test and efficacy assessment end points in the form of subjective assessment (patient satisfaction, compare to got to home, degree of erection by doctor), and objective assessment (Power Doppler study, axial rigidity, time to erection, time to detumescence and the incidence of priapism.

The mean age of the patients was 50.5y ±11.7y and the main duration of ED was 40.2 ±42.6 month. Ninety-eight patients (53.7%) had a disease affect their erectile status. There are no significant differences between the nine groups, except number of children, systolic and diastolic blood pressure.

When calculating the statistics, we pooled the representing response data to all Tx doses versus those of all PGE_1. Then we evaluate each group data for one Tx dose (regardless of order of administration) versus PGE_1. One patient was omitted because he developed priapism in the first visit and was treated by cavernospongiosal shunt after failed ICI of ephedrine and aspiration injection management.

We found there are no significant differences between both drugs for arterial dilatation response, peak systolic velocity (PSV) for Rt and Lt arteries, time to erection, degree of erection, patient satisfaction percent, BP after the injection, and average axial rigidity. Although there are a highly significant differences between both drugs in relation, to end diastolic velocity (EDV) Rt and Lt, and the duration of erection.

Tx induces better EDV than PGE_1 also it has a longer duration of action. This is due to that Tx acting on multiple level of action inducing more cavernous smooth muscle relaxation leading to better veno-occlusive response. Also, as papaverine is one of the components of Tx, it has a longer duration of action than PGE_1 alone.

As regard to the immediate complication there is no significant difference between both drugs in relation to pain, while Tx has a significant higher incidence to induce priapism.

While in assessing the different doses of Tx, the patient satisfaction percent for both drugs was equal**.**

In conclusion, the efficiency of Tx and PGE_1 is comparable with respect to erection and hemodynamic effect. Only the duration of erection was longer for Tx. These results indicate that regardless of its dose, Tx can replace PGE_1 from an efficacy point of view.

We can recommend the use of Tx especially for patient with mild and moderate veno-occlusive disease, as it induces more cavernous smooth muscle relaxation than PGE_1 alone.

Also Tx is an offer for patient searching for the cheaper and effective modality of treatment for their ED.