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STUDIES WITH TRIMIX GEL IN MEN WHO FAILED PHOSPHODIESTERASE INHIBITORS

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INTRODUCTION AND OBJECTIVE: Trimix (papaverine, phentolamine and PGE1) has been prepared by compounding pharmacists and used for intracavernous injections. After mixing, the shelf life is limited and refrigeration is recommended. As an alternative, topical Trimix gel seemed more stable and easier to use, but the results were poor due to limited absorption. Recently, we evaluated a new Trimix gel for administration at the urethral meatus. In this report, Erection Hardness Scores (EHS) and penile rigidity studies were recorded after the gel on 42 men with mixed morbidities who failed with PDE5 oral agents.

METHODS: Sixteen men were on anti hypertensive meds, 12 had type II diabetes, 8 had high cholesterol and 6 were post radical prostatectomy. Ten men had co morbidities. Prior to the gel, an (EHS) was recorded for the experience with oral agents. The Trimix active ingredients and 0.3 ml of gel were maintained in separate interlocking syringes at room temperature until the time of use. The final preparation was completed by vigorous mixing between the interlocking syringes. The mixed gel was inserted painlessly into the urethral meatus, and the patient massaged the outer glans for 2 minutes to promote absorption. There was no other form of stimulation. After the gel, an EHS was recorded for each patient. In addition, 9 had measurement of buckling pressures, and 7 had rigiscans.

RESULTS: For all 42 patients (mean age 55.2 yrs) the EHS was recorded as 1 for the oral agents (penis was larger but not hard), but 22 of these patients actually had no increase in size. After the gel, the mean EHS was 2.2, but 11 pts had an EHS of 3 (26.1%), and 6 had a 4 (16.6%). Thus, 40.4% of the study group had erections that were sufficient for penetration. In those with an ESH of 4, the buckling pressure was >90mm Hg. The 7 rigiscans provided real time information about the gel response and documented some tumescence in all cases. In a comparison of 3 and 4 scores, oral agents vs. gel, $X^2= 10.0$, $df 1$, $p<0.001$.

CONCLUSIONS: Trimix gel may have several advantages over oral agents and intracavernous injections. The active ingredients and gel may be carried by the patient at room temp. The shelf life is long because the active ingredients are mixed only at the time of use. The interlocking syringes permit thorough mixing. Administration is painless, and massage of the glans may enhance mucosal absorption. Even without stimulation by a partner or videos, these patients demonstrated statistically significant greater EHS with gel versus oral agents. These pilot data support the use of Trimix gel for ED, but more prospective trials are needed.