Regenerative Therapy in Erectile Dysfunction: A Survey on Current Global Practice Trends and G.A.F. Expert Recommendations

G.A.F. recommendation statements about RT in ED by Delphi Consensus questionnaire

Dear Colleagues:

Regenerative therapy (RT) for the treatment of erectile dysfunction (ED) is still an area of active research and development. Most of the available studies have shortages like are including small number of patients, short follow up data and heterogeneous protocols of applications. Although some studies have shown successful outcomes with the use of some modalities, the evidence is insufficient, and their use should be limited to clinical studies and ethical board approval.

Global andrology forum conducted a survey about RT in ED, and part of it is to establish experts' recommendations to guide the practitioner in this field for the best clinical practice.

This is an invitation to participate in Delph process to establish the experts' recommendations, and you have been selected to take part in this process based on your extensive clinical experience in dealing with patients with male sexual dysfunction. You can quit this survey, if you lack the required clinical experience and feel that you have received this invitation by mistake.

Delphi: The Delphi technique is a method of collecting opinions on a particular research question. It is based on the premise that pooled intelligence enhances individual judgement and captures the collective opinion of a group of experts without being physically assembled. The conventional Delphi uses a series of questionnaires to generate expert opinion in an anonymous fashion and takes place over a series of rounds.

Instructions on Scoring:

If you agree with the recommendation and do not want this recommendation to be changed, give it a score of 7-10 with 7 indicating you agree and no changes necessary and 10 indicating you strongly agree and no changes necessary. If you score a recommendation 7-10, no further action is required for this recommendation, and you may move forward to the next recommendation.

If you disagree with the recommendation (either entirely or part of it), give it a score of 1-6; with 1 indicating you strongly and completely disagree and you wish the entire recommendation to be changed, while 6 indicating you partly disagree and wish for some parts to be changed. If you do score a recommendation 1-6, you MUST write which parts you disagree with and provide an alternative recommendation. Write these alternatives in the space below the score for that recommendation.

Recommendations that score 7-10 by more than 70% of the participants will pass and be accepted as complete.

Recommendations that score 6 by more than 30% of the participants will fail. The proposed alternatives for these recommendations will be analyzed and these recommendations will be submitted to review by a group of core experts. Final versions of the new recommendations will be created. These will then undergo the second round of Delphi (another survey which is similar to this), by the same invited experts. After the second round, the recommendations that still do not pass will be subject to the third round of Delphi, which will be done via a Zoom meeting. A final consensus will be reached during the meeting.

Estimated time: 10-15 minutes.

First (Given) Name: Middle Name: Last (Family) name: Email:

- 1. "What is your profession?"
- 2. Are you involved in the management of male sexual dysfunction (MSD)?
- 3. How many years of experience in MSD?

The Recommendations

- Recommendation 1: Based on the currently available literature, RT should not be considered standard of care for treatment of ED and should be offered to patients with informed consent about its current limitations. (Rate between 1 – 10)
 - **Recommendation 1:** Please use this box to type any change in the above recommendation.
- Recommendation 2: RT appears to be more effective in patients with vasculogenic compared to other types of ED. (Rate between 1 10)
 - **Recommendation 2:** Please use this box to type any change in the above recommendation.

- 3. Recommendation 3: RT appears to be most effective in men with mild to moderate ED. (Rate between 1 10)
 - **Recommendation 3:** Please use this box to type any change in the above recommendation.
- 4. **Recommendation 4:** Young and middle-aged males appear to derive the most benefits from RT for the treatment of ED. (**Rate between 1 10**)
 - **Recommendation 4:** Please use this box to type any change in the above recommendation.
- 5. Recommendation 5: RT can be used in combination with other ED treatment modalities or as a solo treatment in men in whom standard treatments have failed, or who wish to try and regain natural erections. (Rate between 1 10)
- **6. Recommendation 5:** Please use this box to type any change in the above recommendation.
 - Recommendation 6. A reasonable proportion of patients treated with RT for ED report satisfaction with treatment. (Rate between 1 – 10)
- 7. **Recommendation 6:** Please use this box to type any change in the above recommendation.
 - Recommendation 7: Current evidence suggests that the improvement in erectile function after RT lasts approximately 6 to 12 months. (Rate between 1 10)
- 8. **Recommendation 7:** Please use this box to type any change in the above recommendation.
- 9. Recommendation 8: Although RT is associated with high short-term safety and minimum adverse effects, the long-term safety of RT is still unknown. (Rate between 1 10)
 - **Recommendation 8:** Please use this box to type any change in the above recommendation.
- 10. **Recommendation 9:** Currently, there is more evidence to support the efficacy of low intensity shock wave therapy compared to other modalities of RT. (**Rate between 1 10**)

• **Recommendation 9:** Please use this box to type any change in the above recommendation.