Global Survey on The Use of Regenerative Therapies in The Treatment of Male Erectile Dysfunction

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Dear Colleagues,

You are kindly requested to participate in this important global survey about the role of regenerative therapies in erectile dysfunction (ED). The regenerative therapies are growing modalities of treatment in erectile dysfunction but with large diversity in clinical practice. The scarcity of related large, randomized studies and the absence of clear guidelines account for more heterogeneity in recommendations and clinical applications of these therapies.

There is a growing interest in Regenerative Therapies (RT) for the treatment of erectile dysfunction (ED) since they offer the promise of reversal of the disease process and, possibly, a long-term, drug-free cure. RT include modalities like intracavernosal injection of stem cells or platelets-rich plasma (PRP), or the use of low-intensity shock wave therapy (LISWT). However, currently there are many limitations and controversies about the use of RT for ED:

- There is still a lack of large clinical trials with clear evidence about the short- and long-term efficacy and safety.

- There is no clear understanding of the mechanisms by which RT improve the erectile function.

- There is no clinical consensus on which type of ED, comorbidities, age groups and severity are most suited for RT.

- There is considerable variation in techniques, protocols, LIWST machines, PRP preparations, and the use of RT as sole or combined treatments.

- Hence, professional society guidelines still consider RT as experimental modalities of treatment.

- The scarcity of training and related educational activities, and absence of insurance cover for these treatments has further restricted the wider use of these therapies.

The purpose of this global survey is to throw some light on these controversies by understanding and comparing current clinical practices around the world.

ABOUT THE STUDY

This research project shall provide an understanding of the current practice of regenerative therapies in the treatment of male erectile dysfunction around the world. The results of this survey will also be used to craft expert recommendations on the use of these therapies.

WHY ME?

You are being asked to participate in this study because you are identified as a clinician/caregiver involved in the diagnosis and treatment of male ED.

PARTICIPATION

Your participation in this survey is voluntary and you may, anytime, refuse to take part in this research.

BENEFITS

You will not gain any material benefit from your participation in this research. However, your contribution will be valuable to get a consensus and possible recommendations for the best clinical practice from all the concerned clinical practitioners all over the world.

COSTS

Your participation in this project will not cost you anything.

RISKS

There are no known foreseeable risks involved in participating in this study.

CONFIDENTIALITY

The answers to the survey will be stored in safe folders. Access to the information is password protected and secured. We will not share your name, IP address, or any information that shall personally identify you. We assure you that any information we receive will be held in trust and confidence.

OUTCOMES OF THE STUDY

We will keep you posted on the outcomes of the study.

CONTACT

If you have questions, you may get in touch with us anytime: Dr. Manaf Al Hashimi (+971561104660), or via email at <u>manafhashimi@yahoo.com</u>.

Your contribution in this survey will help in exploring the real practice of these therapies by the medical experts around the world. We will be able to get more information about the indications, responses, patient's feedback and satisfaction, adverse effects and predictors of both good and poor responses of these therapies. All of this information will help all of us for better understanding and application of the best clinical practice and to answer many of current doubts and uncertainties about these therapies, in order to get a better clinical guidance and recommendations.

Most of the questions are about the most widely used regenerative therapies in erectile dysfunction which include but not limited to:

- Intra-cavernosal platelets rich plasma (PRP)
- Intra-cavernosal stem cell (SC)
- Penile shock wave therapy (SWT)

The survey may take between 15-20 minutes and by submitting your response, you consent to participate in this survey.

Important Notes:

(a) Please answer this survey only if you are involved in the management of men with ED.

(b) Please answer the survey even if you do not use any regenerative therapy for ED.

Survey Questions - Supplementary File

Global Survey on The Use of Regenerative Therapies

in The Treatment of Male Erectile Dysfunction

Q1: In which country do you practice?

Q2: How old are you? (years)

- o **25-34**
- o **35-44**
- o **45-54**
- o **55-64**
- o **65**

Q3: What is the nature of your profession?

- o Urologist with predominant practice in andrology and sexual health
- Urologist with some practice in andrology and sexual health
- Non-surgical andrologist and sexual health specialist
- Certified sexologist
- o Psychiatrist
- \circ Other: ...

Q4: What is your practice setting? (Please select all that apply)

- □ Academic
- □ Public
- Private
- □ Multiple

 \Box Other: ...

Q5: How many years have you been practicing (related to management of sexual

dysfunction)?

- Less than 2 years
- \circ 2-5 years
- \circ 6-10 years
- o 11-15 years
- More than 15 years

Q6: What is the percentage of ED patients in your daily clinical Practice?

- o **< 25%**
- o **25-50%**
- o **50-75%**
- o **75%**

Q7: What is the most common etiology of ED in your Patients? (Select all that apply)

- □ Psychogenic
- □ Endocrine abnormalities related to ED
- □ Vasculogenic
- □ Neurogenic
- □ Iatrogenic e.g. (Post-surgical, Post-radiation)
- \Box Combined etiology
- 🗆 Other: ...

Q8: What are the minimum steps of work-up you are using for the diagnosis of ED etiology?

- Medical history and examination.
- Medical history, examination, and hormonal testing.
- Medical history, examination, hormonal testing and penile doppler ultrasound.
- Medical history, examination, hormonal testing, penile doppler ultrasound and psychological evaluation.
- \circ Other: ...

Q9: Are you using any type of regenerative therapies in the management of male ED?

- o Yes
- \circ No

Q10: What is the most common cause of NOT using the regenerative therapies in male ED?

(Select all that apply)

- □ Non-availability
- □ Non-effective
- □ More costly
- □ Not recommended by guidelines
- □ Not allowed by institution because it is an experimental method
- □ Not covered by insurance
- □ More invasive
- □ No experience
- □ Not applicable: I am using regenerative therapies
- 🗆 Other: ...

Q11: In the future, would you be more likely to use regenerative therapies in the following:

(select all that apply)

- □ If endorsed by guidelines.
- \Box If covered by medical insurance
- □ If it is available in my institute
- □ If I have training to use
- □ If future studies showed more efficacy
- □ Not applicable: I am using regenerative therapies

Do you use regenerative therapies in managing ED?

- o Yes
- o No

Q12: How frequently do you recommend regenerative therapies as a treatment option for

erectile dysfunction?

- Only occasionally
- $\circ~$ Up to 25% of cases
- $\circ~$ 25% to 50% cases
- $\circ~$ 50% of cases

Q13: Regarding the use of regenerative therapies in erectile dysfunction, what are the

available options for use in your practice? (select all that apply)

□ Intra-cavernosal PRP

□ Intra-cavernosal stem cell

- □ Penile SWT
- □ None, I don't have any of them.

🗆 Other: ...

Q14: Regarding the use of regenerative therapies in erectile dysfunction, what is the most

common option used in your practice?

- Intra-cavernosal PRP
- o Intra-cavernosal stem cell
- o Penile SWT
- Combination of Intra-cavernosal PRP + Shock wave penile therapy
- Combination of Intra-cavernosal stem cells + Shock wave penile therapy
- \circ Other: ...

Q15: Regarding the use of regenerative therapies in erectile dysfunction, what is the second

most common option used in your practice?

- o Intra-cavernosal PRP
- o Intra-cavernosal stem cell
- \circ Penile SWT
- Combination of Intra-cavernosal PRP + Shock wave penile therapy
- $\circ~$ Combination of Intra-cavernosal stem cells + Shock wave penile therapy
- o I don't use another modality
- $\circ~$ Other: ...

Q16: Regarding the use of regenerative therapies in erectile dysfunction, what is the third

most common option used in your practice?

- Intra-cavernosal PRP
- o Intra-cavernosal stem cell
- o Penile SWT
- Combination of Intra-cavernosal PRP + Shock wave penile therapy
- Combination of Intra-cavernosal stem cells + Shock wave penile therapy
- I don't use another modality
- o **Other:** ...

Q17: Regarding the use of regenerative therapies in erectile dysfunction, do you offer

regenerative therapies as a first line of therapy?

- Yes, always.
- Yes, in selected patients.
- No, I always try established options like PDE5i, etc.

Q18: Regarding the use of regenerative therapies in erectile dysfunction, what is the most

common indication?

- Non- responders to other modalities
- Patients with adverse effects of other modalities
- o Patients request to try this new modality
- To have long-term cure
- \circ Other: ...

Q19: Regarding the use of regenerative therapies in erectile dysfunction, what is the second

most common indication?

- Non- responders to other modalities
- Adverse effects of other modalities
- Patients request to try this new modality
- To have long-term cure
- \circ Other: ...

Q20: Regarding the use of regenerative therapies in erectile dysfunction, what is the third

most common indication?

- Non- responders to other modalities
- Adverse effects of other modalities
- o Patients request to try this new modality
- $\circ~$ To have long-term cure
- $\circ~$ Other: ...

Q21: Regarding the use of regenerative therapies in erectile dysfunction, how is mostly used?

- \circ Sole treatment
- $\circ~$ Combination with others

Q22: If you are using regenerative therapy as a combination with other treatment, what is the

most common combination used?

o With PDE5I

- o With intra-urethral alprostadil
- With intra-cavernosal alprostadil
- With penile vacuum
- I am not using a combination.
- \circ Other: ...

Q23: What is the most common satisfaction feedback of patients after treatment with

regenerative treatment for ED?

- Highly satisfied
- Moderately satisfied
- Mildly satisfied
- \circ Unsatisfied
- $\circ~$ Other: ...

Q24: What proportion of your patients treated with regenerative therapies report significant improvement (good patient satisfaction with outcome; desired goal of treatment reached)

- Very few
- Up to 25% of cases
- $\circ~$ 25% to 50% cases
- $\circ~$ >50% of cases

Q25: After how long have your patients start to notice improvement in erectile function after regenerative therapy?

- \circ 1-3 Months
- o 3-6 Months
- \circ 6-9 Months
- \circ 9-12 Months
- o 1 year
- No improvements
- o Not sure
- \circ Other: ...

Q26: How long does the improvement of erectile function last after the use of regenerative

therapy?

- \circ 1-3 Months
- \circ 3-6 Months
- \circ 6-9 Months
- \circ 9-12 Months
- o 1 year
- No improvements
- \circ Not sure
- \circ Other: ...

Q27: What category of patients do you think benefit the most from regenerative therapies?

(Select all that apply)

□ Vasculogenic ED

- □ Endocrine abnormality related ED
- □ Iatrogenic ED (post prostatectomy, post radiation)
- □ Combined etiology
- □ Psychogenic
- 🗆 Other: ...

Q28: How do you rate the efficacy of regenerative therapies in erectile dysfunction compared

to PDE5I? (select all that apply)

- □ Better efficacy
- □ Less efficacy
- □ Less adverse effects
- □ More adverse effects
- □ Better long-term effects
- \Box More cost effective
- □ More expensive
- □ No advantages or disadvantages
- \Box Other:

Q29: What is the most used method for evaluation of the efficacy of regenerative therapy in

your practice? (Select all that apply)

- □ International Index of Erectile Function (IIEF)
- □ Overall patient satisfaction
- □ Penile doppler ultrasound

\Box Other:

Q30: In which severity category of patients with ED, you think the regenerative therapies are more effective? (Select all that apply)

□ Mild

□ Moderate

□ Severe

□ Other:

Q31: In which age group category of patients with ED, the regenerative therapies are more

effective? (Select all that apply)

□ Young

□ Middle age

Elderly

🗆 Other: ...

Q32: If the regenerative therapy for ED is covered completely by medical insurance, how

would affect the option of use? (Select all that apply)

□ I will recommend it to more percentage of ED patients.

- □ It will not affect my decision to use.
- □ More percentage of patients will agree or request it.
- \Box It will not affect the patient's decision to use.

 \Box Other:

Q33: Are there any specific regulations for the use of regenerative therapies for ED in your

country?

- o Yes
- **No**
- \circ Not sure

Q34: How would you present the regenerative therapies to your patients?

- Experimental modality
- Therapeutic modality
- Clinical Trial modality
- \circ Other: ...

Q35: How do you classify the currently available evidence that support the use of

regenerative therapies on the treatment of ED?

- Strong evidence and recommendation
- Moderate evidence and recommendation
- $\circ~$ Poor evidence and weak recommendation
- $\circ~$ No evidence at all
- Evidence against their use
- \circ Other: ...

Q36: What is the most common cause of patient refusal of regenerative therapy for ED?

- \circ The cost
- Being experimental
- Previous bad experience
- o Being invasive and more side effects
- \circ Other: ...

Q37: Do you believe the regenerative are truly effective or your choice to prescribe is based

on patient's request?

- Yes, I truly believe that is effective
- No, I do not believe it is effective, but I do prescribe on patient request.
- I do not know; I prescribe to improve my practice and knowledge.
- \circ Other: ...

Q38: Do you have any training to practice regenerative therapy?

- Yes. I have attended a formal training course.
- $\circ~$ No training but following the company manual instructions.
- \circ Other: ...

Q39: How would you rate the safety of regenerative therapies?

- Very safe
- o Generally safe
- May have significant side effects
- Not sure about long-term safety