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The Role of Different Modalities of Regenerative Therapies in the Treatment of Erectile Dysfunction: A Global Survey and Global Andrology Forum Expert Recommendations

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Purpose: There is increased interest in regenerative therapies (RTs) to treat erectile dysfunction (ED). However, the need for society's guidelines has led to varied practices. This study aims to investigate current global practices, address the heterogeneity in treatment protocols and evaluations, and establish expert recommendations in clinical practice.

Materials and Methods: Senior experts from the Global Andrology Forum (GAF) created a 32-question survey to evaluate the clinical aspects of various RT modalities and compare them with each other and with phosphodiesterase type 5 inhibitors (PDE5is). The survey was distributed worldwide to ED specialists through online Google Forms, the GAF website, international professional societies, and direct emails. The responses were analyzed and are presented as percentage frequencies. Additionally, an expert consensus on recommendations for RT use was reached at via a modified Delphi method.

Results: Out of 163 respondents from 39 countries, the majority (80.1%) were using low-intensity shockwave therapy (LISWT), followed by platelet-rich plasma (PRP) 61.3% and stem cell therapy (SCT) 17.8%. Efficacy comparisons revealed no perceived significant differences among RT modalities (p=0.124). Compared to PDE5is, the efficacy of LISWT and PRP was considered lower by the respondents, while SCT was rated better by almost half of those who used SCT. The duration of improvement varied (p=0.279), with most improvements lasting 1 to 6 months. The treatment protocols used for LISWT were mainly

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consistent but varied widely for PRP and SCT. Adverse effects were minimal, particularly for LISWT (p<0.001). The costs varied significantly (p<0.001), with SCT being the most expensive. The evidence for efficacy was rated as primarily moderate to strong for LISWT but poor for PRP and SCT (p=0.027).

Conclusions: Most respondents utilized LISWT, followed by PRP, with SCT being the least commonly utilized. The high break heterogeneity in treatment protocols and evaluation of RT underscores the need for further studies and guidelines to establish best practices.

Keywords: Erectile dysfunction; Extracorporeal shockwave therapy; Platelet-rich plasma; Regenerative medicine; Stem cells; Surveys and questionnaires

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INTRODUCTION

Erectile dysfunction (ED) is a commonly reported medical condition in men. It is defined as the consistent or recurrent inability of a man to attain and/or maintain a penile erection sufficient for sexual activity [1,2]. ED has been shown to have a profoundly negative impact on an individual's life and well-being [3]. Described risk factors for ED include age, smoking, dyslipidemia, diabetes, cardiovascular disease, obesity, depression, hypertension, hypogonadism, prior pelvic surgery, and spinal cord injury, in addition to psychological factors [2,4]. The workup for the evaluation of ED should include a thorough medical, sexual, and psychosocial history, physical examination, and selective laboratory testing [4,5]. Referral to a mental health professional should also be considered [5]. Beyond lifestyle changes and risk factor modifications, current treatment options for ED include oral medications, intracavernosal injections (ICIs), topical/intraurethral alprostadil suppositories, vacuum erection devices, and penile implants [4].

Oral phosphodiesterase type 5 inhibitors (PDE5is) are commonly used as the first-line treatment for ED, as they are the least invasive treatment [4,6,7]. However, PDE5is may not be appropriate for some patients who are either non-responders or prefer to avoid them due to contraindications or side effects. These patients might be interested in long-term or curative treatments for ED [8,9]. The 2018 American Urology Association guidelines on managing ED suggest that, through a shared decision-making model, patients no longer have to receive ED therapy from the least invasive to the most invasive treatments [5]. Even with the expansion of available ED treatments, some patients need help to achieve adequate performance. In such situations, regenerative therapy (RT), such as low-intensity shockwave therapy (LISWT), platelet-rich plasma (PRP), and stem cell therapy (SCT), has promising initial results and may be considered as monotherapy or combination treatment for men with ED [10-12]. RT, an alternative to standard therapies, can potentially reverse disease pathology rather than just treating symptoms. It is based on repairing or replacing diseased tissue by stimulating endogenous regenerative capabilities, leading to long-term improvement in erectile function. However, currently, there is no consensus on their use as standard care. These treatment modalities are still considered experimental or investigational and are used with conditional approval [4,13].

Globally, there is a significant degree of heterogeneity in the studies on RT for the management of EDs, necessitating conducting a comprehensive survey to investigate the current practices worldwide. In a cross-sectional, global online survey conducted by the Global Andrology Forum (GAF), which included 479 participants from 63 countries, the most common reasons for choosing RT for ED were adverse effects from other treatments, a desire to try this new approach, a lack of response to other treatments, and the hope for a long-term cure [14]. According to these respondents, middle-aged patients with moderate ED severity were considered the best candidates for RT. LISWT was the most commonly used treatment, followed by PRP and a combination of both. SCT was the least commonly reported modality for RT.

The current study investigated global practices in using RT to treat ED. By examining different modalities of RT, the study sought to clarify their effectiveness in managing ED, focusing on specific response patterns, outcomes, onset, and durations of effects. Additionally,

it endeavored to compare various RT methods with each other and with PDE5is, understand perceptions of existing evidence regarding RT for ED, and also offer expert recommendations to assist practitioners in optimizing clinical practice in this area.

MATERIALS AND METHODS

A cross-sectional, online survey for the global practice of RT in ED was developed and distributed according to the CHERRIES checklist (Supplement File 1) [15].

Questions were compiled by senior members of the GAF who had expertise in male sexual dysfunction (MSD), particularly in the realm of RT treatment. These questions underwent several rounds of refinement and were incorporated into a comprehensive questionnaire to obtain specific data regarding the clinical utilization of the most frequently employed RT modalities.

The survey was divided into four sections: the first section covered demographic information of the respondents (Q1–5), and the other three sections queried penile LISWT (Q6–14), PRP (Q15–23), and SCT (Q24–32). Each section comprised nine detailed questions that examined comparisons between each modality and other forms of RT and PDE5i, the application protocol, adverse effects, cost, and rating of available evidence supporting its clinical utilization.

The survey was generated and shared globally via the secure Google Form platform to safeguard the confidentiality of the responses. It was available for participation from May 27, 2023, to August 8, 2023. Clinicians worldwide who had experience with RT use in ED were invited to take part in this survey. Clinicians lacking prior experience or knowledge of RT in ED treatment were excluded. The first page of the questionnaire included an invitation letter, which outlined the survey's objectives and requested consent to participate. The invitation was sent by email to members of GAF and affiliated societies.

During the survey, the participants could review and adjust their answers before submitting them. Moreover, respondents could skip questions about specific RT modalities if they lacked experience, thereby avoiding potential bias in their responses.

The questionnaire was presented in English and used standard medical terminology. The GAF ethical committee (IR-02-23-116) approved this survey. The complete survey with the invitation letter is provided in Supplement File 2.

The data management and statistical analyses were performed using the Python programming language (Ver. 3.12, Python Software Foundation) utilizing the pandas (Ver. 2.2.2), NumPy (Ver. 1.2.6), and SciPy (Ver. 1.14.1) open-source libraries, in the JupyterLab (version 1.2.6) open-source coding environment.

The answers to the questionnaire were described as numbers and percentages of each choice. For questions where the participant might choose multiple answers, each response frequency was calculated from the total number of participants. The chi-square test was employed to compare categorical variables across different groups. If the assumptions of the chi-square test were invalid, the likelihood ratio was used for comparison.

The Spearman correlation test was utilized to determine the correlation between ordinal variables. A p-value less than 0.05 was considered to indicate the statistical significance for all of the employed statistical tests. Fig. 1 shows the overall study strategy and flow.

A set of expert recommendations was formulated through a collaborative effort involving senior members of the GAF with academic knowledge and clinical proficiency in treating ED with RT. These statements encapsulated the essential aspects of RT in ED treatment and were distributed among the experts to attain consensus using the Delphi method [16].

RESULTS

1. Demographics of the respondents

One hundred sixty-three individuals responded to the survey, all of whom utilized various RT modalities in ED and representing 39 countries. The highest participation rate (23/163, 14.1%) was from the United Arab Emirates, followed by Turkey (16/163, 9.8%) and Egypt (15/163, 9.2%), as shown in Fig. 2.

The most significant proportion of respondents (50/163, 30.7%) were aged 35 to 44 years, followed by 47 respondents (28.8%) aged 45 to 54 years, and 39 respondents (23.9%) aged 55 to 64 years. The vast majority of the respondents (143/163, 87.7%) were urologists, most of them (95/163, 58.3%) were urologists with predominant andrology practice, while the remaining (48/163, 29.4%) were urologists with some andrology practice. The remaining professionals were andrologists, sexologists, gynecologists, and general practitioners.

The World Journal of MEN's HEALTH

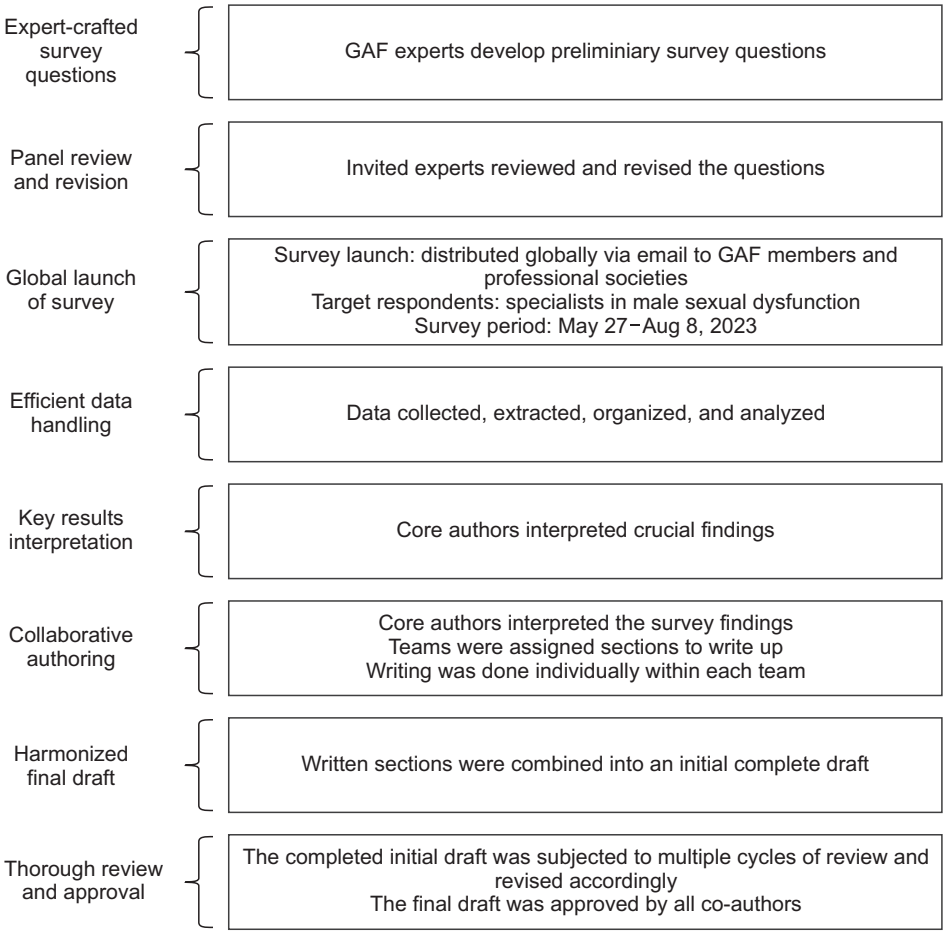


Fig. 1. Flow chart of the study. GAF: Global Andrology Forum.

The respondents had varied practice settings, with the majority (91/163, 55.8%) in private practice. Public and academic settings were equally represented, comprising 26/163 respondents (16.0%). The remaining respondents (20 out of 163, 12.2%) practiced across multiple settings.

Most participants (86/163, 52.8%) had over 15 years of experience. Additionally, 48/163 (29.4%) had between 6 to 15 years of experience, with the minority (29/163, 17.8%) having less than five years of experience.

2. The types of RT modalities used by respondents

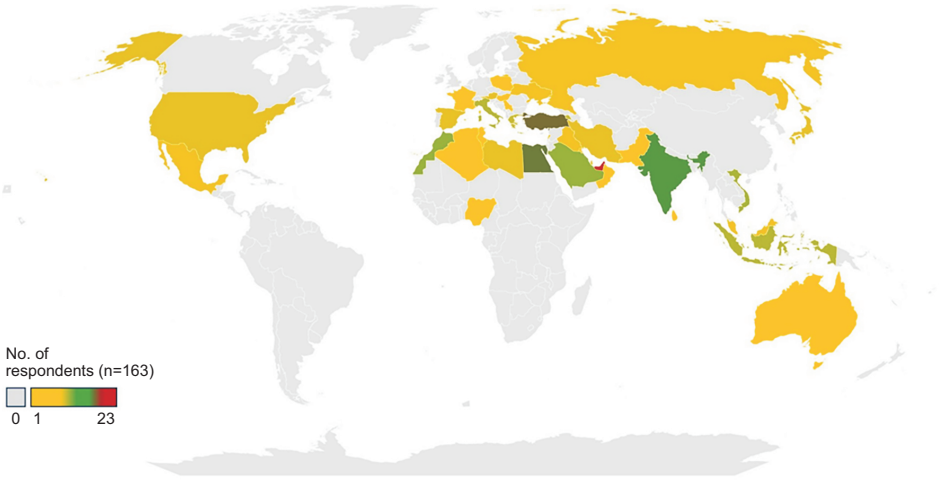
The respondents exhibited diversity in employing different modalities of RT for treating men with ED. A significant majority (132/163, 81.0%) utilized LISWT, followed by PRP (100/163, 61.3%) and SCT (29/163, 17.8%). Among the respondents, 23 out of 163 (14.1%) had experience using all three RT modalities.

3. Comparative analysis of the efficacy of different RT modalities

Participant responses varied in terms of rating the efficacy of various RT modalities for ED treatment.

1) LISWT

Approximately one-third of the LISWT users (42/132, 31.8%) believed that penile LISWT surpasses other RT modalities for treating ED. Conversely, an equivalent proportion (42/132, 31.8%) indicated uncertainty regarding this comparison. Additionally, some respondents (29/132, 22.0%) perceived penile LISWT to be equally effective as other RT modalities for ED treatment, while others (19/132, 14.4%) viewed it as being inferior.



	Country	Frequency	Percentage
1.	United Arab Emirates	23	14.1
2.	Türkiye	16	9.8
3.	Egypt	15	9.2
4.	India	13	8.0
5.	Morocco	8	4.9
6.	Saudi Arabia	8	4.9
7.	Vietnam	7	4.3
8.	Indonesia	6	3.7
9.	Italy	6	3.7
10.	Armenia	5	3.1
11.	Greece	5	3.1
12.	Austria	3	1.8
13.	Hong Kong	3	1.8
14.	Iran	3	1.8
15.	Japan	3	1.8
16.	Libya	3	1.8
17.	Qatar	3	1.8
18.	Spain	3	1.8
19.	United States	3	1.8
20.	Iraq	2	1.2

	Country	Frequency	Percentage
21.	Lebanon	2	1.2
22.	Malaysia	2	1.2
23.	Mexico	2	1.2
24.	Russia	2	1.2
25.	Singapore	2	1.2
26.	Ukraine	2	1.2
27.	Algeria	1	0.6
28.	Australia	1	0.6
29.	France	1	0.6
30.	Hungary	1	0.6
31.	Kuwait	1	0.6
32.	Nigeria	1	0.6
33.	Oman	1	0.6
34.	Pakistan	1	0.6
35.	Poland	1	0.6
36.	Serbia	1	0.6
37.	Sri Lanka	1	0.6
38.	Tunisia	1	0.6
39.	West Bank	1	0.6
	Total	163	100

Fig. 2. Geographical distribution of the respondents.

2) PRP

One-third of the participants assessed the efficacy of intracavernosal PRP similar to other RT methods (33/100, 33.0%), a slightly smaller number deemed it more effective (29/100, 29.0%), and one-fifth felt it to be less effective (20/100, 20.0%). A minority expressed uncertainty regarding its effectiveness (18/100, 18.0%).

3) SCT

Out of the only twenty-nine respondents claiming experience with SCT, a significant number (12/29, 41.4%) reported that intracavernosal injection of SCT was more effective than other RT modalities. Eight respondents (8/29, 27.6%) rated SCT as equivalent to other modalities, while four (4/29, 13.8%) considered it less effective. The remaining four respondents (5/29, 17.2%) expressed uncertainty regarding its efficacy.

Table 1. Comparisons of the efficacy of RT modalities[a]

	PRP	SCT	LISWT
Better than other RT	29 (29.0)	12 (41.4)	42 (31.8)
Same like the other RT	33 (33.0)	8 (27.6)	29 (22.0)
Less than other RT	20 (20.0)	4 (13.8)	19 (14.4)
Not sure	18 (18.0)	5 (17.2)	42 (31.8)

Values are presented as numbers (%).
RT: regenerative therapy, PRP: platelet-rich plasma, SCT: stem cell therapy, LISWT: low-intensity shockwave therapy.
[a]Chi-squared test (p=0.124).

Overall, Table 1 shows no significant statistical difference in the efficacy evaluations of each RT modality

The World Journal of MEN's HEALTH

compared to the other modalities (p=0.124).

4. Comparisons of the efficacy of different RT modalities to PDE5is

Respondents had varied assessments of RT modalities compared to PDE5is.

1) LISWT

A considerable number of participants (56/132, 42.5%) perceived LISWT as less effective than oral PDE5 did, following this, 39/132 (29.5%) rated its effectiveness nearly equal, while 30/132 (22.7%) considered it superior. A small minority (7/132, 5.3%) were uncertain about the comparison rate with PDE5is.

2) PRP

When comparing the effectiveness of intracavernosal PRP therapy with oral PDE5is, 44 out of 100 respondents (44.0%) perceived PRP therapy as less effective for treating men with ED. Conversely, (36/100, 36.0%) of respondents believed PRP therapy to be more effective, while 12 out of 100 (12.0%) thought its efficacy was nearly equal. Eight out of 100 respondents (8.0%) needed clarification about their rating.

3) SCT

When comparing SCT to PDE5is, the majority of participants indicated that they perceived the effectiveness of intracavernosal SCT in treating ED as superior (14/29, 48.3%), followed by nearly equivalent (7/29, 24.1%) and less effective (4/29, 13.8%). The minority of respondents (4/29, 13.8%) were uncertain about this comparison.

In general, a substantially more significant proportion of SCT users rated better efficacy compared to PDE5is than other RT modalities (p=0.0002), as shown in Table 2.

Table 2. Comparisons of the efficacy of RT modalities to phosphodiesterase type 5 inhibitors[a]

	PRP	SCT	LISWT
Less efficacy	44 (44.0)	4 (13.8)	56 (42.5)
Almost the same	12 (12.0)	7 (24.1)	39 (29.5)
Better efficacy	36 (36.0)	14 (48.3)	30 (22.7)
Not sure	8 (8.0)	4 (13.8)	7 (5.3)

Values are presented as numbers (%).
RT: regenerative therapy, PRP: platelet-rich plasma, SCT: stem cell therapy, LISWT: low-intensity shockwave therapy.
[a]Chi-squared test (p=0.0002).

5. Duration of improvement after RT treatment

The respondents noted different durations of enhancement of erectile function after the use of various modalities of RT.

1) LISWT

Regarding the duration of improved erectile function following penile LISWT, around one-third of the participants (40/132, 30.3%) noted that this enhancement endured for a period ranging from three to six months. The remaining respondents referred to variable improvement durations, as shown in Fig. 3.

2) PRP

Thirty-nine percent of respondents (39/100) reported that the enhancement in erectile function following intracavernosal PRP treatment endured for one to three months. The rest of the respondents reported other variable durations of time, as shown in Fig. 4.

3) SCT

One-fourth of respondents (7/29, 24.1%) indicated that the improvement in erectile function after undergoing treatment with SCT lasted between one and three months. The remaining respondents showed significant

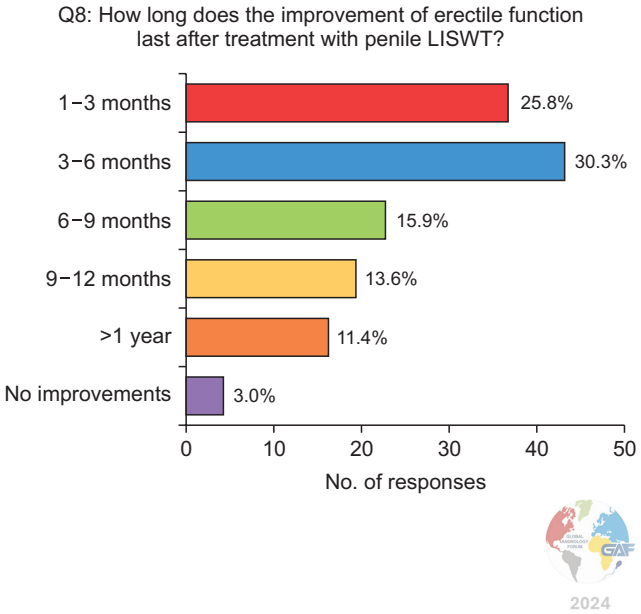


Fig. 3. Duration of improvement in erectile function after treatment with penile LISWT. LISWT: low-intensity shockwave therapy.

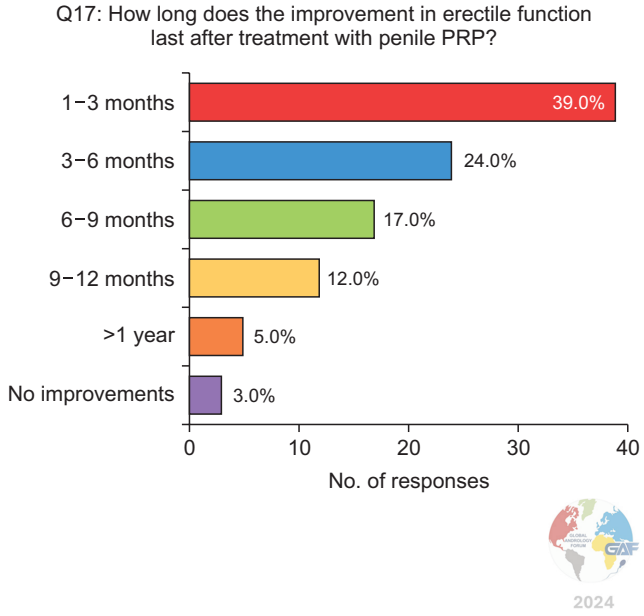


Fig. 4. Duration of improvement erectile dysfunction after treatment with PRP. PRP: platelet-rich plasma.

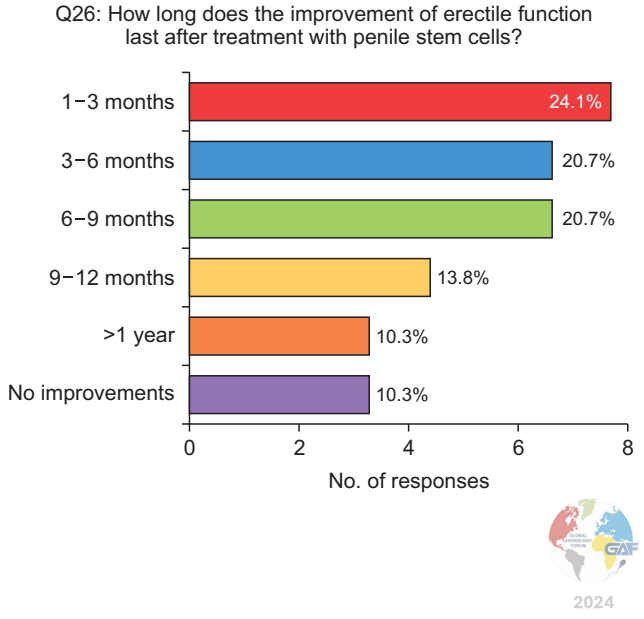


Fig. 5. Duration of improvement after SCT for erectile dysfunction treatment. SCT: stem cell therapy.

variability in their estimates (Fig. 5).

As in Table 3, there was no statistical difference among the various modalities of RT (p=0.279) in the respondents' estimate of whether the improvement in erectile function lasted less or more than six months.

Table 3. Comparisons of duration of improvement in RT[a]

	PRP	SCT	LISWT
1–6 months	63 (63.0)	13 (44.8)	74 (56.1)
>6 months	34 (34.0)	13 (44.8)	54 (40.9)
No improvements	3 (3.0)	3 (10.4)	4 (3.0)

Values are presented as number and percentage (%).
RT: regenerative therapy, PRP: platelet-rich plasma, SCT: stem cell therapy, LISWT: low-intensity shockwave therapy.
[a]Chi-squared test (p=0.279).

Table 4. Consistent versus variable protocols of RT[a]

	PRP	SCT	LISWT
Consistent	78 (78.0)	19 (65.5)	107 (81.1)
Variable	22 (22.0)	10 (34.5)	25 (18.9)

Values are presented as number and percentage (%).
RT: regenerative therapy, PRP: platelet-rich plasma, SCT: stem cell therapy, LISWT: low-intensity shockwave therapy.
[a]Chi-squared test (p=0.018).

6. Consistent versus variable protocol of RT applications

Most respondents consistently utilized RT modalities following the same protocol, whereas a minority employed them variably.

1) LISWT

When asked about their method of application, most of the respondents stated that they followed a consistent approach in their penile LISWT practice (107/132, 81.1%). The remaining reported using a variable approach (25/132, 18.9%).

2) PRP

Seventy-eight out of 100 respondents (78.0%) followed a consistent method and scheme of PRP application in their practices. In contrast, 22 out of 100 respondents (22.0%) did not adhere to a strict uniform practice and employed a variable protocol.

3) SCT

Most participants (19 out of 29, or 65.5%) adhered to a consistent application protocol. In contrast, the remaining respondents (10 out of 29, 34.5%) followed variable protocols.

There was a statistically significant difference between the consistent and variable protocols for different RT modalities, as it is more consistent with LISWT and PRP while more variable within SCT (p=0.018), as

The World Journal of MEN's HEALTH

shown in Table 4.

7. Protocols for RT applications in ED treatment

The respondents show considerable diversity in their use of RT applications.

1) LISWT

Various frequencies of LISWT are utilized for ED treatment, with the most common being six sessions over a month. However, some employed different frequency patterns, as shown in Fig. 6.

2) PRP

The application protocols for PRP vary widely. Most respondents (46/100, 46.0%) reported utilizing two sessions within three months. This practice was followed by more than two sessions per year, chosen by (22/100 respondents, 22.0%). Additionally, 20/100 respondents (20.0%), reported opting for a single session, while 5 out of 100 (5.0%) preferred two sessions per year. A small percentage of respondents, totaling 7 out of 100 (7.0%), provided miscellaneous responses, including scheduling 3 to 4 sessions per month, opting for three sessions one every 15 days, scheduling three sessions within three months, arranging four sessions weekly within one month, and varying between 1 and 3 sessions within a single month, as shown in Fig. 7.

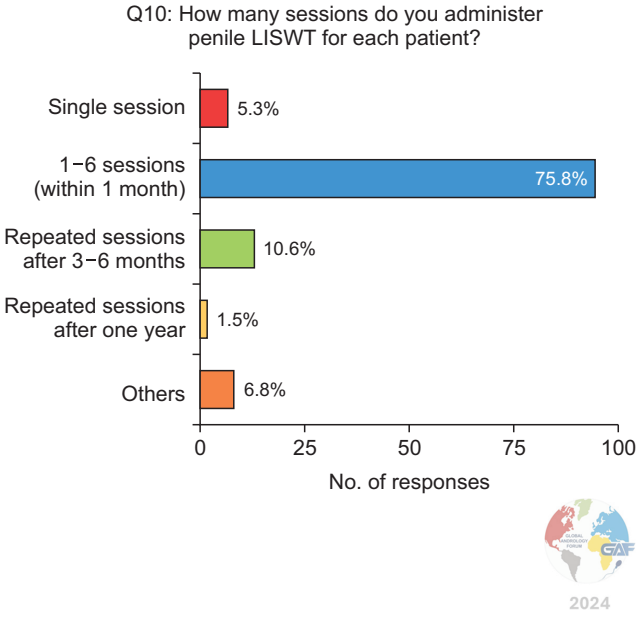


Fig. 6. Protocols of application patterns of LISWT in erectile dysfunction. LISWT: low-intensity shockwave therapy.

3) SCT

The respondents displayed a diverse range of protocols regarding the number of sessions for SCTs. The most significant proportion of respondents was evenly split between those who underwent single or two sessions within three months (8/29 respondents, 27.6% for each). The others were more variable in the number of

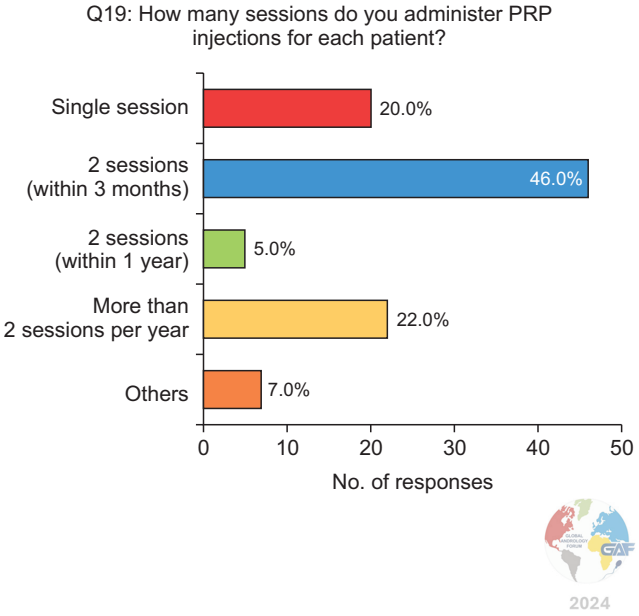


Fig. 7. Protocols of application patterns of PRP in erectile dysfunction treatment. PRP: platelet-rich plasma.

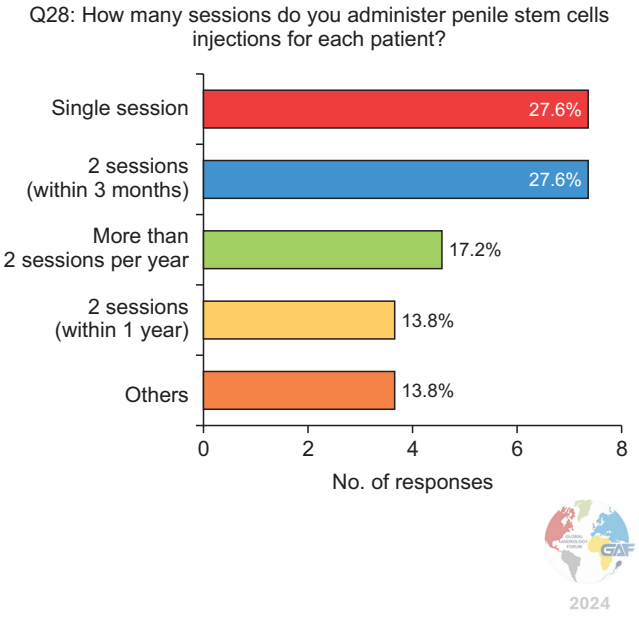


Fig. 8. Number of SCT sessions in the treatment of erectile dysfunction. SCT: stem cell therapy.

sessions and duration of treatment, as shown in Fig. 8.

Most LISWT users applied a nearly identical protocol over a month. In contrast, users of PRP and SCT offered sessions at variable intervals for up to a year. Statistical analysis revealed no significant differences between the protocols of both modalities (p=0.185), as shown in Table 5.

8. Combination of RT modalities for ED treatment

Respondents had a variable intention to combine different RT modalities.

1) LISWT

Interest existed in exploring the potential combined benefits of LISWT with other RT modalities to enhance its effectiveness. Over half of the respondents did not integrate penile LISWT with other RT modalities (75/132, 56.8%). However, 39.4% (52/132) did report utilizing penile LISWT in conjunction with PRP therapy. Only a tiny fraction of respondents combined SCT into their treatment protocol (4/132, 3.0%).

2) PRP

The respondents show diversity in their preferences regarding whether to use PRP alone or in conjunction with other RT modalities. More than half of the participants indicated that they utilized a combination of penile PRP and penile LISWT (61/100, 61.0%). This was followed by respondents who did not combine them (33/100, 33.0%) or those who combined with SCT (5/100, 5.0%), while one respondent did not mark a response.

3) SCT

The respondents differed in their usage of SCT, either on its own or in conjunction with other RT modalities. Most respondents (16/29, 55.2%) answered affirmatively and reported utilizing it along with penile LISWT. One-fifth of the respondents (6/29, 20.7%) used it alone, and an equal number (6/29, 20.7%) indicated its use along with penile PRP. One missed marking a response.

Given the p-value of <0.001, a noteworthy distinction exists in the treatment combination status. The SCT group was predominantly utilized alongside other treatment modalities, with a frequency of 22/29 cases (75.9%). Conversely, LISWT is predominantly administered as a standalone treatment in most cases, accounting for 75/132 cases (56.8%), as shown in Table 6.

Table 5. Variable protocol of application of PRP and SCT[a]

	PRP	SCT
Single session	20 (20.0)	8 (27.6)
Two sessions (within 3 months)	46 (46.0)	8 (27.6)
More than 2 sessions per year	22 (22.0)	5 (17.2)
Two sessions (within one year)	5 (5.0)	4 (13.8)
Others	7 (7.0)	4 (13.8)

Values are presented as number and percentage (%).
PRP: platelet-rich plasma, SCT: stem cell therapy.
[a]Chi-squared test (p=0.185).

Table 6. Combination or standalone of RT modalities[a]

	PRP	SCT	LISWT
Combination	66 (66.0)	22 (75.9)	56 (42.4)
No combination	33 (33.0)	6 (20.7)	75 (56.8)
Missing response	1 (1.0)	1 (3.4)	1 (0.8)

Values are presented as number (%).
RT: regenerative therapy, PRP: platelet-rich plasma, SCT: stem cell therapy, LISWT: low-intensity shockwave therapy.
[a]Chi-squared test (p<0.001).

9. Adverse effects of RT modalities

The majority of respondents confirmed the safety and low incidence of associated adverse effects of using RT to treat ED.

1) LISWT

Most survey participants (94/132, 71.2%) stated that they observed no adverse effects following the application of penile LISWT on their patients. However, the remaining respondents reported some adverse effects, as shown in Fig. 9.

2) PRP

Almost half of the respondents (46/100, 46.0%) experienced no adverse effects after undergoing penile PRP treatment. Conversely, the remaining respondents reported experiencing minor adverse effects, as shown in Fig. 10.

3) SCT

Most participants indicated experiencing no side effects and confirmed the procedure's safety. Specifically, nearly half of the respondents (15/29, 51.7%) reported no adverse effects. Among those who reported side effects, 8 out of 29 respondents (27.6%) mentioned minor

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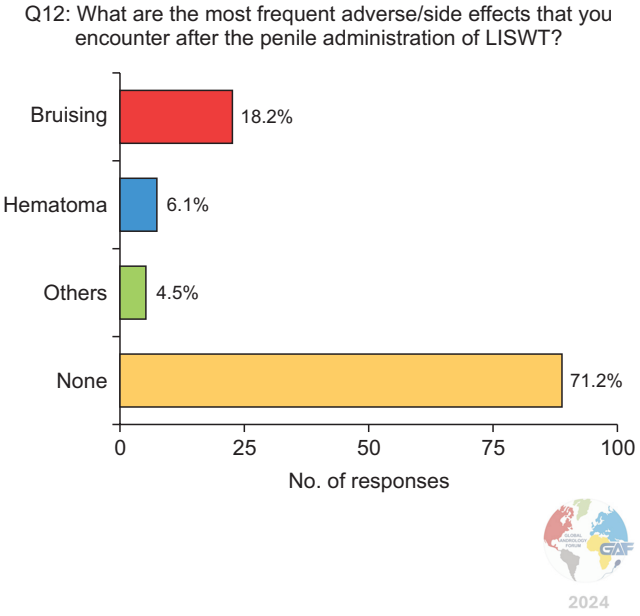


Fig. 9. Adverse effects of penile LISWT. LISWT: low-intensity shockwave therapy.

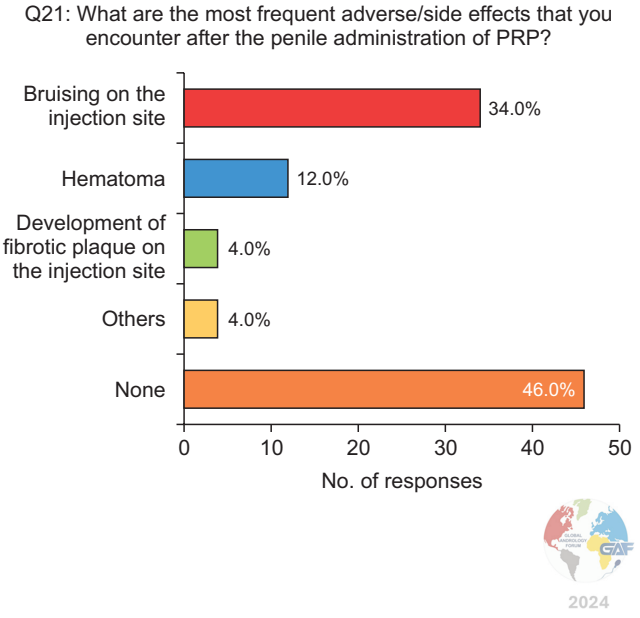


Fig. 10. Rates of adverse effects of PRP in erectile dysfunction. PRP: platelet-rich plasma.

effects such as bruising at the injection site, while 2 out of 29 (6.9%) reported local hematoma. Additionally, 1 out of 29 respondents (3.4%) reported the development of penile curvature and shortening, and 3 out of 29 (10.3%) reported other minor and different side effects, as shown in Fig. 11.

Overall, although most respondents affirmed the safety of RT modalities in treating ED since the p-

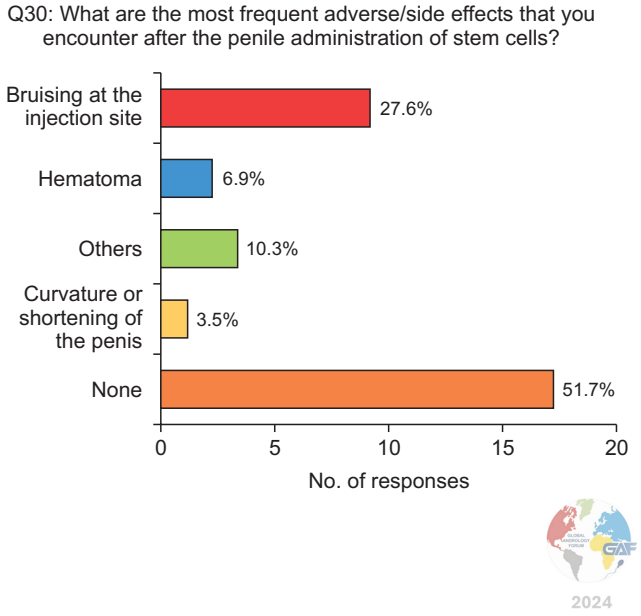


Fig. 11. Adverse effects of SCT in erectile dysfunction. SCT: stem cell therapy.

Table 7. The presence or the absence of adverse effects of RT modalities[a]

	PRP	SCT	LISWT
Present	55 (55.0)	14 (48.3)	38 (28.8)
None	45 (45.0)	15 (51.7)	94 (71.2)

Values are presented as number and percentage (%).
RT: regenerative therapy, PRP: platelet-rich plasma, SCT: stem cell therapy, LISWT: low-intensity shockwave therapy.
[a]Chi-squared test ($p<0.001$).

value is <0.001, there is a notable distinction in the perception of adverse effects. Individuals who use LISWT appear to perceive fewer adverse effects than the other two modalities, as in Table 7.

10. The cost of RT modalities

The respondents reported varying cost estimates of different RT modalities.

1) LISWT

The respondents reported variable estimates of the cost of LISWT in their practices within 300 USD to 500 USD, which was the most common estimate, as shown in Fig. 12.

2) PRP

Almost half the respondents (46 out of 100, 46.0%) stated that the typical PRP treatment cost falls within

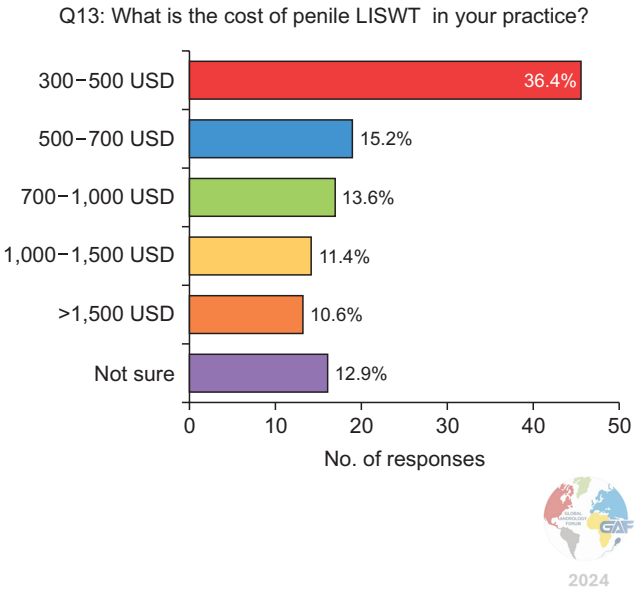


Fig. 12. The cost estimations of LISWT among the respondents. LISWT: low-intensity shockwave therapy.

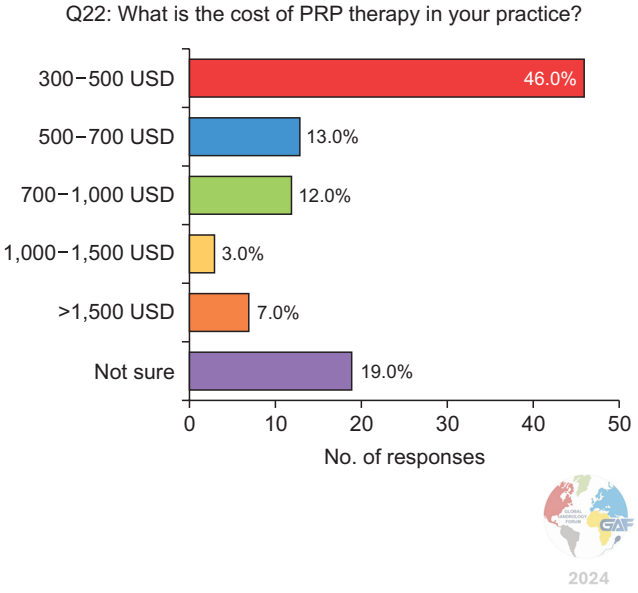


Fig. 13. Cost estimations of PRP among the respondents. PRP: platelet-rich plasma.

the range of $300 to $500, while others reported varying estimates, as shown in Fig. 13.

3) SCT

The cost of SCT was reported to be much higher, with almost half of the survey participants (13/29, 44.8%) indicating that the typical expense for this intervention exceeds $1,500. Other respondents offered varied estimations, suggesting a broader range of potential costs, as shown in Fig. 14.

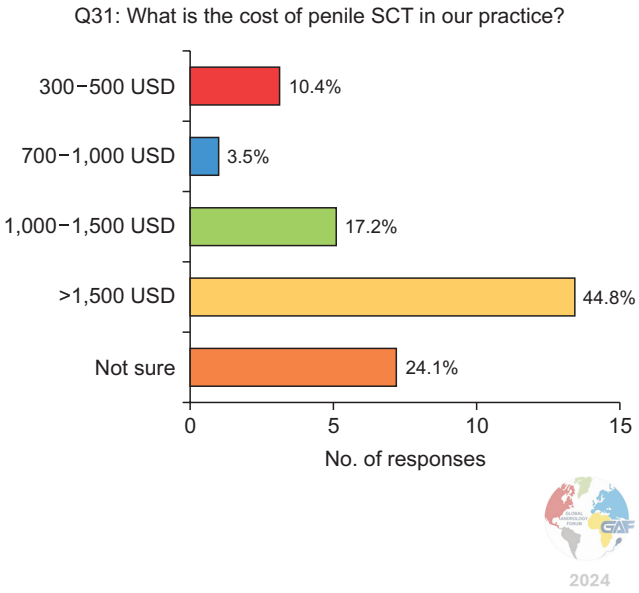


Fig. 14. Cost estimates of SCT in the treatment of erectile dysfunction. SCT: stem cell therapy.

Table 8. The cost estimates of RT modalities[a]

	PRP	SCT	LISWT
Not sure	19 (19.0)	7 (24.1)	17 (12.9)
300–500 USD	46 (46.0)	3 (10.3)	48 (36.4)
500–700 USD	13 (13.0)	0 (0.0)	20 (15.2)
700–1,000 USD	12 (12.0)	1 (3.4)	18 (13.6)
1,000–1,500 USD	3 (3.0)	5 (17.2)	15 (11.4)
>1,500 USD	7 (7.0)	13 (44.8)	14 (10.6)

Values are presented as number and percentage (%).
RT: regenerative therapy, PRP: platelet-rich plasma, SCT: stem cell therapy, LISWT: low-intensity shockwave therapy.
[a]Chi-squared test ($p<0.001$).

As shown in Table 8, the prices of the three RT methods are notably different, with SCT being the most costly option and PRP being the most economical.

11. Rating the supported evidence for RT modalities in ED

The respondents highlighted different perceptions of the available supporting evidence for RT in ED treatment.

1) LISWT

The participants showed a range of views in how they categorized the available evidence and recommendations on using penile LISWT as a treatment for ED. The majority (71/132, 53.8%) classified the existing evidence as moderate, while 15.2% (20/132) considered it

strong, and a quarter (34/132, 25.8%) considered it weak. A small proportion (5.2%) indicated no evidence.

2) PRP

The participants held varying perspectives on the existing evidence regarding PRP for ED. A significant proportion of them (42/100, 42.0%) expressed the view that the evidence supporting the efficacy of penile PRP therapy for treating ED is poor. Additionally, 8/100 respondents (8.0%) asserted that there was no evidence. Conversely, 38/100 (38.0%) believed in moderate evidence, while 10/100 (10.0%) advocated for the need for solid evidence and clear recommendations. Two of the 100 respondents needed clarification.

3) SCT

A significant portion of the participants expressed skepticism regarding the evidence supporting penile SCT. Among them, (10/29, 34.5%) perceived poor evidence, while (9/29, 31.0%) indicated moderate evidence and recommendation. Additionally, two groups, each consisting of 4 out of 29 participants (13.8%), reported contrasting views—one group recognized strong evidence and recommendations, while the other noted a lack of evidence. Only two respondents (6.9%) were uncertain about rating the available evidence.

A noteworthy contrast emerges in the perception of the available evidence among these treatment methods. The respondents seem to regard the evidence level for PRP and stem cells as lower, given that more than half indicated poor to no evidence available for these modalities, compared to 30% in the LISWT group (Table 9).

Table 9. The rating of the evidence about RT in erectile dysfunction[a]

	PRP	SCT	LISWT
No evidence at all	8 (8.0)	4 (13.8)	7 (5.2)
Poor evidence and weak recommendation	42 (42.0)	10 (34.5)	34 (25.8)
Moderate evidence and weak recommendation	38 (38.0)	9 (31.0)	71 (53.8)
Strong evidence and weak recommendation	10 (10.0)	4 (13.8)	20 (15.2)
Uncertain	2 (2.0)	2 (6.9)	0 (0)

Values are presented as number and percentage (%).
RT: regenerative therapy, PRP: platelet-rich plasma, SCT: stem cell therapy, LISWT: low-intensity shockwave therapy.
[a]Chi-squared test (p=0.027).

12. Societies guidelines about RT in ED treatment

The guidelines state that the absence of conclusive evidence regarding the efficacy of RT in treating ED underscores the need for further research and clinical trials to ascertain its true potential. While some studies suggest promising results, the current evidence must be more comprehensive and conclusive. Therefore, patients and healthcare providers should cautiously approach RT for ED until more robust evidence is available. A summary of these guidelines is shown in Table 10 [4,5,13,17-22].

13. GAF expert's recommendations

Presently, the current guidelines provided by pertinent societies lack detailed directives for practitioners concerning RT in ED, mainly because of scant research and its designation as having a low level of evidence. Consequently, the GAF has provided expert consensus statements and recommendations concerning various modalities of RT in ED, intending to offer practitioners guidance on the most contentious issues within this domain. Recommendations were formulated based on the survey outcomes, guidelines and recommendations from professional societies, existing literature evidence, and insights from clinical experts. The statements were then sent to experts for consensus using the Delphi method, and the whole process is illustrated in Fig. 15. These statements were subsequently sent to 47 experts in MSD and RT, who were members of GAF. Among them, two-thirds were urologists, and one-third were andrologists. Over two-thirds of the participating experts had more than ten years of experience in treating MSDs. The recommendations from GAF experts are summarized in Table 11.

DISCUSSION

Novel treatments for managing ED are focused on RT, which aims to reverse the pathogenesis of the disorder by restoring the structure and function of diseased erectile tissue and offer a "cure" as opposed to short-term treatment of symptoms [23]. These encouraging novel treatment strategies have been introduced into clinical practice in the last ten years but without adequate investigations and clear outcomes observed in clinical trials. Therefore, their use has been largely controversial despite the perception of their potential

Table 10. The societies guidelines about RT in ED treatment

Society	Recommendation
American Urology Association (AUA) Guidelines (2018) [5].	Penile LISWT and intracavernosal SCT should be considered investigational (conditional) recommendation (Grade C evidence level). Intracavernosal PRP therapy is regarded as an experimental (expert opinion).
Sexual Medicine Society of North America (SMSNA) Position Statement (2021) [13]	There is an absence of robust clinical data supporting the efficacy of RT for the treatment of ED. However, technologies such as LISWT have established relative safety.
The Asia-Pacific Society for Sexual Medicine Guidelines (2021) [17]	Supports the use of LISWT to improve penile erectile hemodynamics based on convincing basic science evidence (Level 2; Grade B). Correct patient selection is essential for treatment success; younger patients with mild-moderate ED, minimal cardiovascular comorbidities, and absence of diabetes or cavernous nerve injury are likely to have recovery and spontaneous erection (Level 2; Grade B). Adjunctive measures like combination with PDE5is may enhance LISWT effects and erectile function recovery (Level 2; Grade C). LISWT improves erectile function scores and penile hemodynamic parameters in men with vasculogenic ED (Level 1; Grade B). However, the long-term outcome is uncertain. Evidence suggests benefits up to 12 months after treatment (Level 2; Grade B). LISWT for treatment of ED should be restricted to men with mild-moderate vasculogenic ED, either responder or non-responders to PDE5is, and be performed in highly specialized centers (Level 2; Grade B). LISWT is a safe and well-tolerated procedure without clinically significant adverse events (Level 1; Grade A).
Canadian Urological Association (CUA) Guidelines (2021) [18]	Conditionally recommends against LISWT as a treatment for ED patients. Additional studies are required.
The Italian Society of Andrology and Sexual Medicine (SIAMS) Guidelines (2023) [19]	Suggest the use of LISWT in patients with mild vasculogenic ED not responding to PDE5is (weak recommendation, very low-quality evidence). No clear recommendations on the use of SCT and PRP therapies can be provided given the limited data.
European Association of Urology (EAU) Guidelines (2024) [4]	LISWT with/without PDE5is can be used in patients with mild vasculogenic ED or as an alternative first-line therapy in well-informed patients who do not wish or are not suitable for oral vasoactive therapy or desire a curable option (weak recommendations). LISWT with/without PDE5is may be used in vasculogenic ED patients who are poor responders to PDE5is (weak recommendations). Intracavernous injections of PRP have led to a mild improvement of EF among patients with organic ED, but the available evidence is still insufficient to provide a recommendation regarding its use. Its use should be limited to clinical trials (weak recommendations).
European Society for Sexual Medicine (ESSM) position statements [20,21]	LISWT is a safe and well-tolerated procedure, but its efficacy for the treatment of ED is doubtful and deserves more investigation Cell therapy (CT) for ED should be considered a treatment under investigation and not offered outside of clinical trials (Good Clinical Practice Statement). Patients should be informed regarding the limited evidence on the efficacy and safety of CT for ED (Level 3, Grade C).
Urological Society of Australia and New Zealand [22]	The use of LISWT regenerative technology and cellular-based therapy in ED should be cautioned due to unknown long-term outcomes and remains largely experimental (Level 3; Grade B) recommendation

RT: regenerative therapy, ED: erectile dysfunction, PRP: platelet-rich plasma, SCT: stem cell therapy, LISWT: low-intensity shockwave therapy, PDE5is: phosphodiesterase type 5 inhibitors.

to offer a durable and safe long-term solution to restore diseased erectile tissue [23].

We received 163 responses from various countries worldwide in our survey, and the demographic informations confirmed that there is geographic variability, both in the overall use of RT and specific modalities. The influence of nationality bias could be regarded as one of the limitations in any international or global research endeavor, including ours. A country's unique cultural, demographic, and healthcare environment can significantly impact RT results in ED treatment. The uneven nationality distribution of our survey respondents may skew the results due to cultural factors since views on sexuality and openness in talking about

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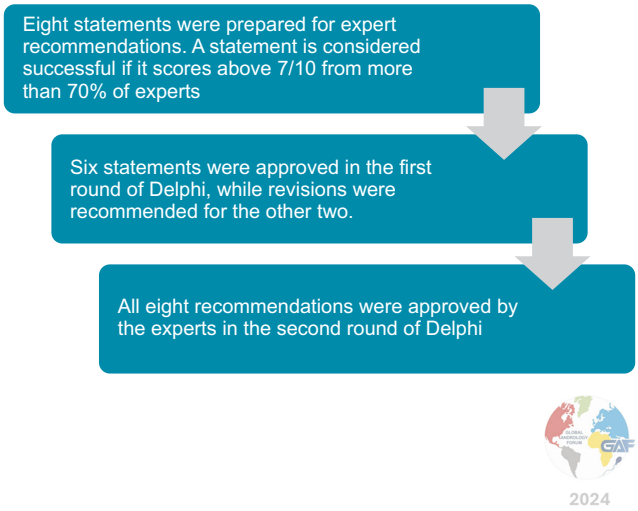


Fig. 15. Methodology of the Delphi method to reach a consensus for GAF expert's recommendations. GAF: Global Andrology Forum.

Table 11. Global Andrology Forum (GAF) expert's recommendations about RT for the treatment of ED

Currently, there is a lack of consensus regarding the effectiveness of RT in treating ED, and further large controlled studies are crucial to reach a definitive recommendation.
There is no consensus on the available data for making direct comparisons of effectiveness between RT and PDE5is.
Current data are uncertain about the expected duration of improvement of ED after treatment of each modality of RT.
There is severe diversity in protocols and applications of different modalities of RT
There are limited data about safety and better efficacy of combining different modalities of RT with each other or with PDE5is.
There is overall good short term safety data about using different modalities of RT, although the long term safety data is still lacking.
Despite limited studies demonstrating the effectiveness of LISWT in treating ED, further high-quality evidence is necessary to support its use as a routine therapeutic option.
Due to lack of current evidence, intracavernosal PRP or SCT should only be considered within the context of clinical trials or experimental treatments.

RT: regenerative therapy, ED: erectile dysfunction, PDE5is: phosphodiesterase type 5 inhibitors, LISWT: low-intensity shockwave therapy, PRP: platelet-rich plasma, SCT: stem cell therapy.

erectile disorders differ among different cultures. In cultures where sex is taboo, men may be less likely to admit to having ED or participate in clinical trials on RT. Demographics and ED prevalence, affected by age distribution and underlying medical conditions, definitely influence the results. Access to healthcare, insurance coverage, and healthcare quality can affect access to new and costly RT products and modalities. Lastly, regulatory approval processes for new treatments differ across countries. All these factors can affect the availability of RT for clinical trials and patient use and might eventually skew the results [12,24].

The results of our research emphasize the widespread adoption of LISWT as the most commonly used RT modality on a global scale. Our findings indicate that 81% of RT users who administer ED treatments incorporate LISWT into their clinical practice alone or in combination. This significant usage rate suggests strong acceptance and utilization of LISWT among healthcare professionals for addressing ED concerns. The prevalence of LISWT use aligns with the findings of Fode and colleagues, who surveyed 192 ED specialists in 2016. Their study reported that 75% of respondents were familiar with LISWT in ED treatment, with 14.1% having administered it [25]. The popularity of LISWT can be attributed to several factors. Firstly, numerous clinical studies have demonstrated its effectiveness in improving erectile function and penile hemodynamics in patients with ED, both as a standalone treatment and in combination with other modalities such as PDE5is and penile PRP therapy [26-28].

Additionally, the growing body of evidence supporting the regenerative effects of LISWT on penile tissue further contributes to its widespread adoption. Mechanistically, LISWT induces neovascularization, angiogenesis, and tissue remodeling in the corpora cavernosa, thereby improving erectile function and potentially reversing the underlying pathophysiology of ED [27,29]. More importantly, LISWT has been incorporated into the ED treatment pathway and is included in guidelines from certain societies, such as the European Association of Urology and the Asia-Pacific Society for Sexual Medicine [4,17], which further supports this treatment modality. Additionally, a significant study reviewed the literature on the most effective protocols for randomized, sham-controlled trials of LISWT for ED published in the last decade. A recommended protocol was proposed, which could serve as a reference for practitioners worldwide [30].

Several clinical studies have been conducted on intracavernosal PRP, but most of them have significant shortcomings. As a result, most medical societies recommend its use only within the context of clinical trials [4,18]. Despite these landmark recommendations, our survey revealed a wide spread of penile PRP use

(100/163) in 29 countries, which is consistent with the findings of other studies that confirmed the increasing trend of PRP use [31]. Scott et al [31] reported a consistent increase in the demand for PRP treatments for ED globally, with particular prominence in Australia, New Zealand, and the United States. They found 683 providers across 19 countries; most of them did not disclose the costs of penile PRP injections to potential patients through online platforms, and a significant portion of penile PRP providers lacked certification as urologists or andrologists in the countries where these injections were offered. The participants in our survey display significant diversity in how they rate the effectiveness of penile PRP treatment and the specific protocols they follow, including varying numbers of sessions and intervals between them. This notable variability is also evident in numerous other studies, where small sample sizes and differences in patient selection and treatment protocols have hindered consensus on the efficacy of penile PRP treatment [32,33].

Despite some recent interventional trials exploring the efficacy of intracavernosal SCT in treating ED, which have shown promising safety profiles and outcomes, the current body of research remains inadequate to establish a definitive treatment protocol, dosage, preferred cell type, or to elucidate the underlying mechanisms of action [34]. This limitation significantly hinders the widespread adoption of this treatment modality, compounded by its higher cost and limited availability. Consequently, intracavernosal SCT is the least utilized approach among our survey participants, with only 29 out of 163 indicating its usage. However, despite approximately half of the respondents expressing high confidence in the effectiveness of intracavernosal SCT and the majority confirming its safety, there exists notable diversity in both the application protocols and the evaluation of supporting evidence, and, given the small number of respondents, no recommendations can be offered.

In their recent study, Gutierrez et al [35] evaluated the variability in the criteria of RT in ED study trials, pointing out the substantial variability in the inclusion/exclusion criteria and outcome measures among these trials. LISWT trials most frequently utilized IIEF and had the strictest inclusion/exclusion criteria, suggesting more rigorous and functional outcome-based studies. Conversely, PRP/SCT trials, but not LISWT trials, had safety/tolerability as a primary outcome, likely due to the experimental nature of these therapies.

Based on the above discoveries, prospective randomized controlled research trials are required, characterized by consistent patient selection and procedural protocols, extended follow-up periods, and comprehensive assessment of both subjective and objective outcomes. Such studies could yield substantial evidence and direction for optimizing clinical practices. The recommendations from GAF experts represent crucial steps toward aligning heterogeneous practices with available evidence, thereby providing practitioners in the field with a supportive framework for optimal and safe clinical practice.

Our study offers ED treatment specialists an opportunity to explore the global use of RT in treating EDs, including the patterns of application protocols and current assessments of patient responses. However, it has some limitations, such as a small number of respondents, especially for SCT, a lack of standardized and objective measures for patient outcomes, and uneven geographical representation across the globe.

CONCLUSIONS

This extensive worldwide survey reveals widespread utilization of RT for the treatment of ED. The respondents predominantly employ LISWT and PRP, with SCT being the least utilized. While safety is largely affirmed, there is considerable divergence in perceptions regarding efficacy, application protocols, assessment of supporting evidence, and cost estimates for each modality. The notable heterogeneity and variations in RT utilization underscore the need for consensus on optimal protocols to enhance response and advocate for large-scale, randomized controlled studies.

Conflict of Interest

The authors have nothing to disclose.

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Author Contribution

Conceptualization: MAH, GMP. Statistical analysis: AH. Supervision: AA, R Shah. Writing – original draft: all authors. Writing – review & editing: all authors.

Supplementary Materials

Supplementary materials can be found via https://doi.org/10.5534/wjmh.240214.

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