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Shock Wave Therapy for Erectile Dysfunction: Marketing and Practice Trends in Major Metropolitan Areas in the United States

James M. Weinberger [1], Gary K. Shahinyan,[1] Shangyang C. Yang,[1] Robert H. Shahinyan,[1] Jesse N. Mills[1] and Sriram V. Eleswarapu[1]*

[1]*Division of Andrology, Department of Urology, David Geffen School of Medicine at UCLA, Los Angeles, California*

Abstract

Introduction: Due to the increasing prevalence of erectile dysfunction (ED) and pronounced distress for patients, a direct-to-consumer market for shock wave therapy (SWT) has emerged. We sought to evaluate trends in marketing and implementation of SWT as a restorative treatment for ED in large metropolitan areas by investigating cost to patients, provider credentials and treatment protocols.

Methods: SWT providers in 8 of the most populous metropolitan areas were identified using Google search. Search queries included: "Shockwave therapy for erectile dysfunction in [city];" "Shockwave therapy for ED in [city];" and "GAINSWave in [city]." All clinics advertising SWT for ED within the boundaries of the selected metropolitan area were included. Using a "secret shopper" methodology, clinics were contacted by telephone with the goal of identifying the pricing, duration and provider administering the treatment.

Results: Across 8 of the most populous cities in the U.S., 152 clinics offered SWT as a treatment for ED. Comprehensive information was available for 65% of the clinics; 25% of providers offering SWT were urologists while 13% were not physicians. The average price per treatment course was $3,338.28. Treatment duration was highly variable and ranged from 1 to indefinite courses based on individual patient circumstance.

Conclusions: SWT, as a restorative therapy for ED, is performed primarily by nonurologists and is not standardized. Direct-to-consumer marketing is used to target distressed men. This study highlights concerning trends in major metropolitan markets, given the substantial financial impact for patients and inconsistent credentials among providers. Further, these findings suggest that patients are frequently seeking care for ED from nonurologists.

Key Words: direct-to-consumer advertising, erectile dysfunction, marketing

Abbreviations and Acronyms

AUA = American Urological Association

DTC = direct-to-consumer

ED = erectile dysfunction

fSWT = focused shock wave therapy

rWT = radial wave therapy

SMSNA = Sexual Medicine Society of North America

SWT = shock wave therapy

The prevalence of erectile dysfunction (ED) is rising, with over 320 million individuals worldwide projected to suffer from ED by 2025.[1] Beginning with the introduction of oral phosphodiesterase-5 inhibitors in the late 1990s, the market for ED therapies has exploded. Previously characterized as a disease of aging, ED is now recognized to affect up to 30% of men younger than 40 years old.[2–4] The confluence of an increasing prevalence of sexual dysfunction in young men coupled with high rates of mental

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* Correspondence: Division of Andrology, David Geffen School of Medicine at UCLA, 10945 Le Conte Avenue, Suite 3361, Los Angeles, California 90095 (telephone: 310-794-3058; *email address*: SEleswarapu@mednet.ucla.edu).

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distress from ED[1] have led to the proliferation of direct-to-consumer (DTC) marketing platforms to meet the demand for ED therapies.[3] ED pharmaceuticals are expected to account for $7 billion in global health care costs by 2024,[5] with 1 popular DTC "men's health" platform, Hims (www.hims.com), commanding $250 million in annual subscription revenue.[6]

There is mounting interest in the DTC marketplace regarding regenerative therapies for ED, which seek to restore penile tissue to "cure" ED rather than simply treat it. Candidate therapies include platelet-rich plasma, low intensity shock wave therapy (SWT) and stem cell therapy.[7] While theoretical mechanisms and some early data support this as an area of research, there is a paucity of high-quality evidence supporting the broad use of any of these technologies in ED patients. Both the American Urological Association (AUA) and the Sexual Medicine Society of North America (SMSNA) designate SWT as "investigational."[8,9] Nonetheless, there is significant public interest and a flourishing market for SWT for ED.[10] Of note, the use of SWT for ED is not U.S. Food and Drug Administration approved.

The shock wave market segment has largely been dominated by GAINSWave, a practitioner database and DTC advertising platform that has promoted the efficacy of shock wave for ED despite limited evidence supporting its claim.[11] The DTC market landscape has emboldened many for-profit men's clinics to expand beyond prescribing testosterone therapy, phosphodiesterase-5 inhibitors and intracavernosal injections into offering restorative therapies such as SWT. We sought to evaluate trends in marketing and implementation of SWT as a restorative treatment for ED in large metropolitan areas by investigating cost, provider credentials and treatment protocols.

Materials and Methods

We utilized a "secret shopper" approach to perform a cross-sectional analysis of men's health clinics across 8 of the most populous metropolitan areas in the United States. The "secret shopper" method involves inquiring about services as a prospective patient. It has been widely used to characterize practice patterns in the health services literature.[12–14] We selected 8 of the 10 most populous metropolitan areas in the United States, aiming for geographical and socioeconomic diversity across the sample.[15] The metropolitan areas selected were Los Angeles, New York, Houston, Washington, D.C., Philadelphia, Atlanta, Boston and Dallas.

SWT providers across the metropolitan areas were identified using Google search (www.google.com) on September 21, 2021. An incognito browsing window was employed in order to avoid introducing individual search biases or software "cookies" that affect the search engine optimization algorithm. Search queries included: "Shockwave therapy for erectile dysfunction in [metropolitan area];" "Shockwave therapy for ED in [metropolitan area];" and "GAINSWave in [metropolitan area]." We examined results for each search term across the first 5 pages of Google search results. Across all metropolitan areas, 5 pages of search results were found to be exhaustive, with no new listings beyond page 4. Clinics met inclusion criteria if they utilized DTC advertising of SWT for ED and were located within the boundaries of the selected metropolitan areas.

All clinics identified from the search that met inclusion criteria were contacted by telephone. The calls, made by 4 of the authors (GKS, SCY, RHS, JMW), followed a standardized script; callers indicated interest in restorative ED treatments, asking about offerings for SWT and provider credentials. Specifically, callers requested information regarding the training of the provider administering the treatment (MD, DO, physician assistant, nurse practitioner and other) as well as the type of specialty training among providers who completed postgraduate residency. The secret shoppers then inquired about pricing, duration and protocol for SWT administration. Web sites for each clinic were utilized to fill in gaps from the telephone survey. Clinics were excluded after 3 failed contact attempts. Descriptive statistics were then used for analysis of the market for SWT across populous metropolitan areas in the United States.

Results

From the Google search, we identified 152 clinics that offer SWT as a treatment for ED across 8 of the most populous cities in the U.S. Comprehensive provider data were available for 140 (92%) clinics. Twenty-five percent of providers offering SWT were urologists, and 13% of providers were nonphysicians. Provider specialty training varied widely; among physicians, there were 18 different provider types. Physician assistants, nurse practitioners, chiropractors and naturopathic providers were also found to offer SWT for ED across the metropolitan areas. Figure 1 shows the diversity of specialty training for providers treating ED. In 3 of the 8 metropolitan areas, there were as many or more nonphysician providers than urologists offering SWT for ED. Provider types across the metropolitan areas are shown in figure 2.

Of the 152 clinics offering SWT for ED, 25 (16%) were excluded from cost analysis after 3 unsuccessful telephone contact attempts. Twenty-eight clinics (18%) indicated that a formal consultation with a provider was required before any information could be given about pricing and protocol for treatment. Information on pricing and treatment logistics was available for the remaining 99 (65%) clinics. The table highlights the average cost of SWT per session, the cost per treatment course and the range of costs across each metropolitan area. For the entire cohort, the average price per session of SWT for ED was $491.22. The corresponding average price per treatment course was $3,338.28. Notably,

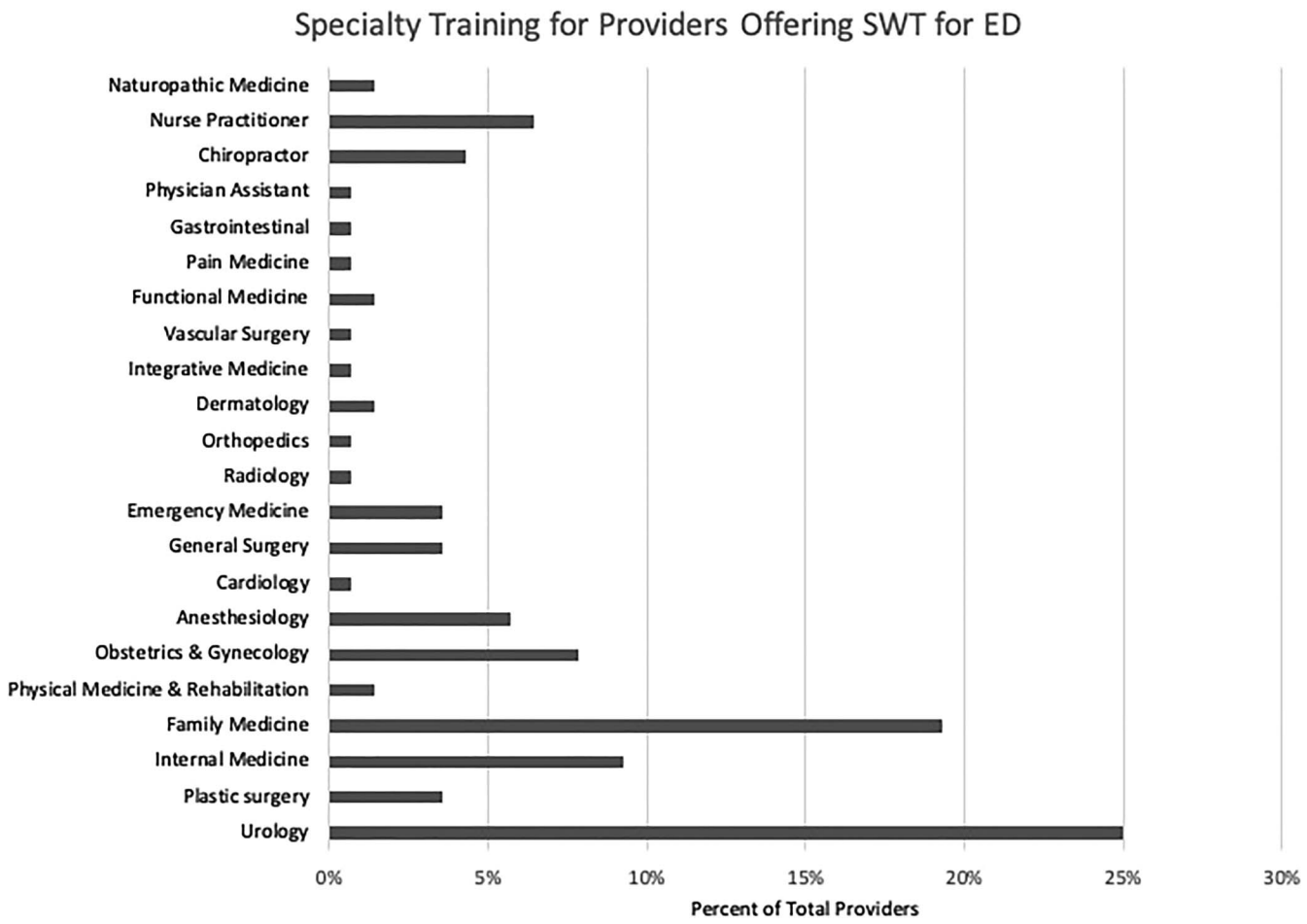

Figure 1. Histogram of types of specialty training for providers offering SWT for ED.

the range of costs varied by market; the most modest cost of a treatment course was $600 in the Atlanta metropolitan area, while the most expense treatment course cost $16,200 in the New York metropolitan area. Treatment duration was highly variable and ranged from 1 to indefinite courses based on individual patient circumstance. There was no standard across clinics regarding focused shock wave therapy (fSWT) vs acoustic or radial wave therapy (rWT), site of shock wave delivery (eg perineal, penile) or treatment protocol. The most common number of sessions in a treatment course was 6, however the number of shocks per session, type of device used, and energy and frequency settings varied widely.

Discussion

This study represents a cross-sectional analysis of providers and offerings for SWT for ED across 8 of the most populous metropolitan areas in the U.S. It is evident from this sample that SWT for ED is performed primarily by nonurologists; only a quarter of the providers in the cohort were trained in urology. Further, we found that 13% of providers offering SWT for ED were nonphysicians. Cost to the patient was considerable across the sample and there was no standardized protocol for treatment. This study highlights concerning trends in major metropolitan markets, given the substantial financial impact for patients and inconsistent credentials among providers.

The secret shopper approach has been used sparingly in the urological literature; Hsiang et al utilized this methodology to assess whether insurance status affects access to urological care at urgent care centers.[12] In this study, we similarly used a scenario-based approach to uncover real-world practice patterns. This approach is both novel and important in the sexual medicine literature; the "out-of-pocket" market for ED treatments is robust, as patients demonstrate inelastic demand for a cure. Out-of-pocket costs for intracavernosal stem cell therapy, another regenerative, nonguideline backed experimental regimen, has commanded upward of $20,000.[16] The DTC advertising approach leverages the distress caused by ED to demand such prices in a non-transparent market. Our secret shopper study highlights not only the wide discrepancy in provider training among those offering SWT for ED but also the burdensome cost for patients. Notably, given that SWT has not been shown in clinical trials to have durable, long-term efficacy, the AUA and SMSNA classify SWT

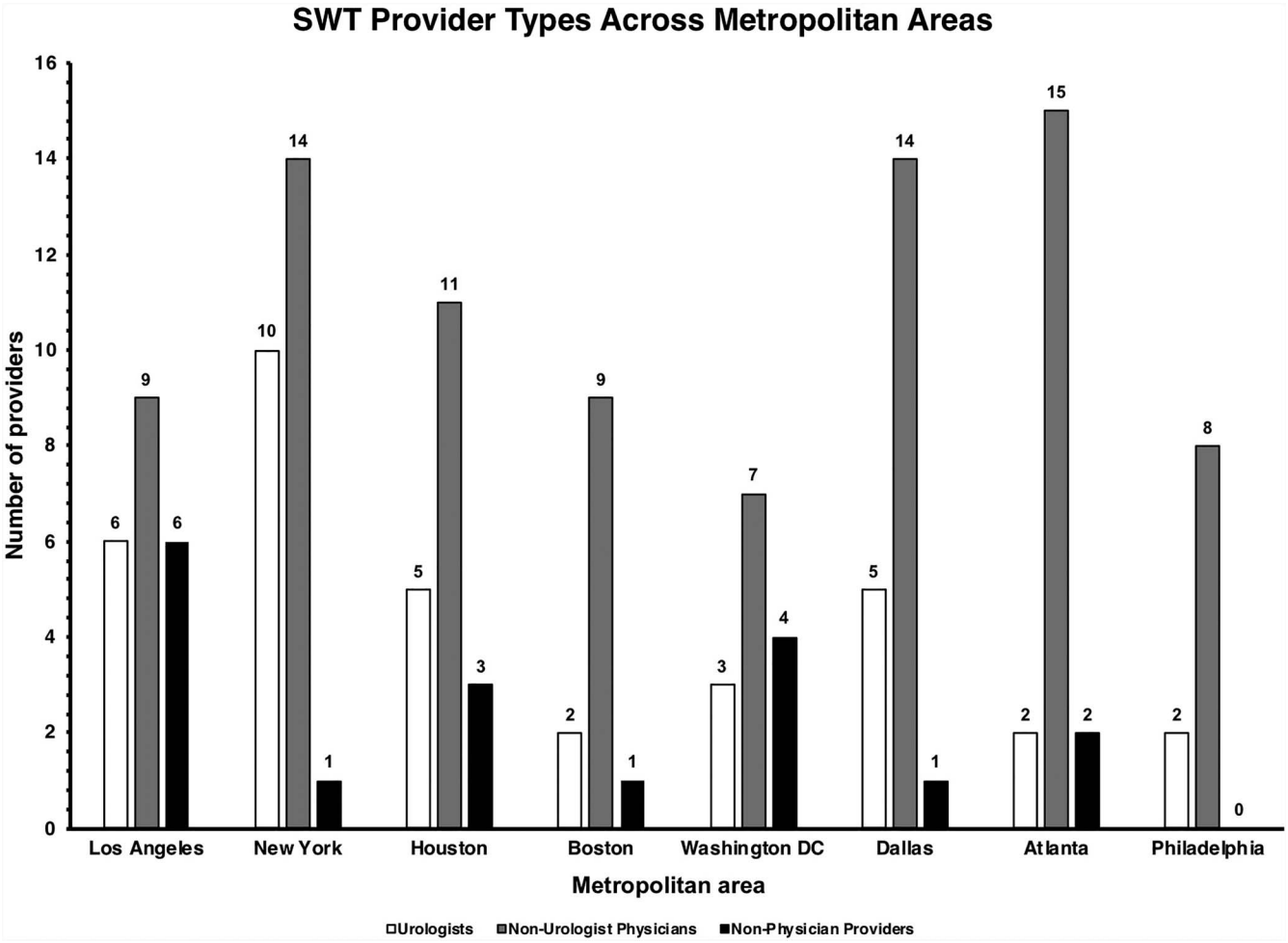

Figure 2. SWT provider types across metropolitan areas.

as an experimental therapy, indicating that patients should not be charged for receiving it.[7–9] Our results show that real-world practice does not adhere to these recommendations.

The findings in this study highlight the lack of a uniform treatment protocol in administering SWT for ED. The general protocol for SWT, as described by Vardi et al in the randomized controlled trial that established SWT as a promising therapeutic for ED, consists of 1–2 sessions of SWT per week for a duration of 5–10 weeks.[17] Importantly, the shock waves are delivered to the distal, mid and proximal shaft, as well as bilateral crura.[7] In this study of over 150 clinics across the country, there was wide variance in number of sessions per treatment course, site of delivery and type of SWT. Notably, fSWT differs from rWT in mechanism of wave generation and tissue penetration. Clinical and preclinical work in the literature has almost exclusively evaluated fSWT.[18–22] Despite categorical differences, and only preliminary studies comparing the two, fSWT and rWT, have

Table.
Average cost of SWT per session and per treatment course across metropolitan areas

City, State	Av $ Price of SWT per Session	Av $ Price of SWT per Treatment Course	Range of $ Prices for SWT Treatment Course
Atlanta, Georgia	372.5	2,625.00	600.00–4,500.00
Boston, Massachsetts	502.55	2,912.50	1,800.00–4,200.00
Dallas, Texas	489.00	3,292.31	1,800.00–6,900.00
Los Angeles, California	612.18	3,930.56	2,100.00–7,000.00
New York, New York	522.00	3,330.00	1,800.00–16,200.00
Philadelphia, Pennsylvania	458.25	3,623.75	3,000.00–4,500.00
Washington, D.C.	497.92	3,292.31	1,500.00–5,000.00
Houston, Texas	475.36	3,157.14	2,500.00–5,000.00
Overall av	491.22	3,338.28	600.00–16,200.00

been conflated by marketing platforms and transitively by patients; GAINSWave offers rWT, and yet both GAINSWave providers and other clinics in this cohort advertise SWT without specifying the discrepancy. The distinction between fSWT and rWT is clinically relevant. ED providers must reconcile the concern that the messaging of DTC advertising is reaching patients more effectually than Men's Health providers. Given the significant costs associated with these therapies, it is paramount that evidence-based messaging extends to patients.

The diversity in training of providers treating ED in this large cross-sectional analysis of metropolitan areas is striking. Urologists compose only a quarter of the cohort. Of note, providers trained in obstetrics and gynecology represent the fourth most common provider type. These physicians see no male patients throughout the entirety of their training, including no formal instruction in the pathogenesis and treatment of male sexual dysfunction. Per AUA guidelines, a diagnosis of ED in a patient should prompt a formal men's health evaluation, in part due to the demonstrable link between ED and later coronary events.[23,24] The findings here demonstrate that patients are seeking treatment for ED from providers who trained in dermatology, gynecology, physical medicine and rehabilitation, and chiropractic medicine, among others. As stewards of men's health, urologists are best positioned to take the lead on reaching and treating patients with ED.

This study is not without limitations. The 8 metropolitan areas were chosen among the 10 most populous in the nation with the goal of achieving geographical and socioeconomic diversity across the sample. We cannot be certain that the sample was therefore representative of other large metropolitan areas. Further, due to sampling, our results cannot necessarily be extrapolated to small metropolitan and rural areas. Another limitation to our secret shopper approach is that it excluded clinics that were not willing to provide information over the phone; this may have biased the sample toward clinics offering more of a "one-size-fits-all" approach. Despite these limitations, this study represents a novel characterization of a large segment of clinics and providers offering SWT for ED. Future directions include a formal cost effectiveness analysis of SWT for ED utilizing the real-world prices paid by patients.

Conclusions

SWT, as a restorative therapy for ED, is performed primarily by nonurologists and is not standardized. Across all clinics, DTC marketing is used to target symptomatic men, often with contradicting claims about the mechanism of therapy and the rates of cure. The AUA and SMSNA classify SWT as an experimental therapy, indicating that it is not ethical for providers to advertise or claim efficacy for treating SWT, pending further data. This study highlights concerning trends in major metropolitan markets, given the substantial financial impact for patients and inconsistent credentials among providers. SWT is proliferating in major metropolitan markets, clearly with market forces at work and money to be had. Level 1 evidence on SWT for ED is still pending—the therapy should not be marketed as having such. Further, these findings suggest that patients are frequently seeking care for ED from nonurologists. Importantly, ED can portend significant morbidities. If patients are exploring second-line therapy, they should be evaluated by urologists who are equipped to conduct a formal men's health evaluation and provide a data-driven and patient-centric discussion of treatment options.

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Editorial Commentary

"With great power comes great responsibility" is apropos to the practice of medicine even if offered initially to Peter Parker (Spider-Man) by his uncle Ben. We have all seen ads for therapies touting "a new revenue stream to increase profits" which can be enticing, especially as physicians are facing declining reimbursements and increasing regulations.[1,2] This article is a fascinating look at the current state of practice of shock wave therapy for erectile dysfunction (ED), which is considered experimental by the American Urological Association.[3] What is interesting (albeit not surprising, but somewhat concerning) is the high number of nonurologists (and even nonphysicians!) offering this therapy. Why would gynecologists and dermatologist and others care about ED? Is it because ED affects their patient populations so much? Unlikely. This finding only adds to the skepticism of this therapy despite some possible positive benefits in certain patients.

We all agree that urologists are best qualified to appropriately evaluate and treat patients with ED due to our advanced training and expertise in genitourinary physiology and pathophysiology. ED patients need experts with such training, especially due to the need for workup of potential underlying disorders[3] and access to potentially advanced diagnostic testing. We also provide patients with a full range of options, which is the only way of truly treating a patient, as anything less is inadequate. We must own this space. We must understand which patients may benefit from which therapies, and do everything we can to get patients into our offices for a proper evaluation and discussion of treatment options, even if it means offering alternative therapies. If we do, we must be honest with patient risks (including financial risks) and explain if a therapy is unlikely to work for them and not offer it to them if they are unlikely to benefit. We can't control if others do so, and we can't control if a patient ultimately seeks care elsewhere or does not follow our recommendations. However, at least we afforded them with the best possible medical advice and care based upon our expertise. Because with great power comes great responsibility.

Jonathan N. Rubenstein[1]
[1]*United Urology Group*
Baltimore, Maryland

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Reply by Authors

We appreciate the comments made by Dr. Rubenstein, as they reflect the sometimes subtle clash between the Hippocratic Oath and the consumerization of health care. Shockwave therapy (SWT) for erectile dysfunction (ED) may represent an edge case in the mind of some providers, as early studies demonstrate minimal adverse effects and notable response in certain patients.[1,2] This may allow some to feel that the do no harm precept is not being violated. However, this ignores the financial risk imposed on patients. None of this is to say that the use of SWT for ED is inappropriate, just that proper patient education, counseling on treatment options and setting of clear expectations should favor the evidence base. It is more likely that a provider trained in male sexual health can offer this type of data-driven and patient-centric discussion. We also agree with the highly astute point that the use of SWT for ED by nonurologists only adds damaging skepticism regarding its use, when early data suggest that there may in fact be a role for selected patients. An earlier era of sexual health consumerization led to widespread prescribing of testosterone from 2001 to 2011, often without appropriate indication,[3] which one can argue has contributed to a contemporary stigma around hormone evaluation and therapy. Urologists must be the shepherds of men's health and ensure that history doesn't repeat itself.

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