JCPM2024.10.22

The following is an edited transcript of the *Journal Club with Pearls & Marketing* (JCPM) of October 22, 2024, with Charles Runels, MD.

>-> The video of this live journal club can be seen here <-<

Topics Covered

- **Meta-analysis supports the P-Shot® Procedure**
- **Why Wait Until Medications are Needed Before Offering Disease-Slowing Regenerative Therapies?**
- **A New Algorithm for Treating Erectile Dysfunction**
- **The Politics of Changing the ED Treatment Algorithm**

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Transcript

Good evening. Tonight's Journal Club: I think we have an exciting paper that came out in the *Journal of Sexual Medicine* this month.

Meta-Analysis Supports P-Shot® Procedure

This is, I think, the third meta-analysis we've looked at that supports our P-Shot® procedure.[1]

We looked at one last week as well [that also supported our P-Shot® procedures].[2]

The one this week is, obviously, a super high-impact and respected journal, and once again, they show that PRP in the penis does, in fact, improve erectile function. They also talk about shockwaves and stem cells, and I'd like to give you a perspective of what I think about some of their observations and much of it I've gained from talking to the smart people in our group. This is not Charles as much talking as it is Charles reporting.

As best I can tell, I was the first to put PRP in a penis 15 years ago, in my own penis, but that doesn't really give me the credentials to talk about it so much, but 14 years of listening to you (the people in our group) and doing the procedure, and reading research, hopefully, I can put some perspective on what's said in this new paper.

The first thing is that we have support for what we're doing.

Then, if you look at this statement (from the study's discussion), it is loaded with implications: "While those conventional treatments have proven efficacy, there's a growing interest in the application of regenerative therapies for ED."

There are a couple of things about this statement.

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[1] Hinojosa-Gonzalez et al., "Regenerative Therapies for Erectile Dysfunction."

[2] Yogiswara, Rizaldi, and Soebadi, "The Potential Role of Intracavernosal Injection of Platelet-Rich Plasma for Treating Patients with Mild to Moderate Erectile Dysfunction."

One is that regenerative therapies, in general, were not a category of treatment when I did my training, and many of you did your training not so long ago. In my case, it was in the 80s, but even up to around ten years ago, talking about regenerative therapies was not so common.

I remember speaking with prominent people who didn't really understand what PRP even was. They might've heard of stem cells and playing around with that some, but the whole category of regenerative therapies with multiple possibilities within that category was not a thing, at least in the sexual medicine arena a decade ago.

Two decades ago, it became a thing in dentistry and orthopedics, and some outliers were doing it in plastic surgery; but only one or two in the thousands that I've spoken to, which is a small representation of the hundreds of thousands that take care of urethras and penises, so this is a new category. Regenerative therapies are a new category. I like to call it "cellular therapy", but I think regenerative therapy triggers some people. Whatever you want to call it, it's using cellular triggers to make things healthier.

But the loaded, unsaid thing that's between the lines there is this: "Conventional treatments have proven efficacy."

Well, ***that's true unless you're one of the 30,000 men per year who get a penile implant.***

It wasn't proven efficacy, at least at that endpoint in their life, so let's put it a different way. Over the course of 10, and that's been a steady number according to the published numbers by the various associations, over the course of 10 years, 30,000 men per year have had a penile implant, meaning that their therapy didn't work. Some of them had it for Peyronie's, but we treat that, too. So proven efficacy, yes, it's proven when it works, but when it doesn't, then what?

And then, the other thing that's between the lines here that I think needs to be said, they do bring it out later on in the paper, I think.

They say it in their discussion, which is a good place for it, that they talk about what PRP does, but *they never come right out and say what I'm about to tell you right now, which is that* ***none, not one, as they like to put it, the conventional proven with efficacy actually slow down the progression of the disease****, none of them.* They allude to it, but I think it should be said more plainly. The PDE5 inhibitors, your Trimix injections, of course, not the penile implant, don't slow down the progression of the disease, and of course, regenerative therapies do.

Why Wait Until Medications are Needed before offering Disease-Slowing Regenerative Therapies?

So you could make a case, and I make the case; I think if it were me, and my penis was now needing PDE5 inhibitors, I would ask, "Doctor, why didn't you give me regenerative therapies at the first sign of ED, or even before I started to need medications to help me slow down the progression of the neurovascular disease that's happening in the penis?"

So, not only do I think it's time to make this the standard of care, but I also think it should be offered as prophylaxis.

Now, that may be pushing it too big for most people to swallow, but I'm going to put it to you another way. You guys hear me talk about this almost every Journal Club; Faraday said it best: Michael Faraday, the great physicist, you never prove anything. You mount supporting evidence until someone disproves it, if it can be disproven, until eventually, it becomes the standard of care or widely accepted if you are a physicist, a mathematician, or a biologist.

So, when this becomes part of the official recommendation, this is the thing everybody should do, I don't know, but there are not the huge, literally billion-dollar budgets that go on with getting other sexual medicines approved because we're selling blood.

Obviously, the research is mounting, but we don't have the huge budget to make it acceptable, and there's never going to be a fancy, beautiful person, male or female, come into your office trying to get you to buy blood, because you don't buy it. The devices are useful, but they're becoming commoditized because there are so many devices that can help you prepare platelet-rich plasma now. I have my favorites. These days, I mostly use Regen, but others out there are excellent. Part of the reason I like Regen is they're dropping a lot of money doing research even though they know other people have kits, but the budgets can't compete with what goes on with Pfizer's of the world.

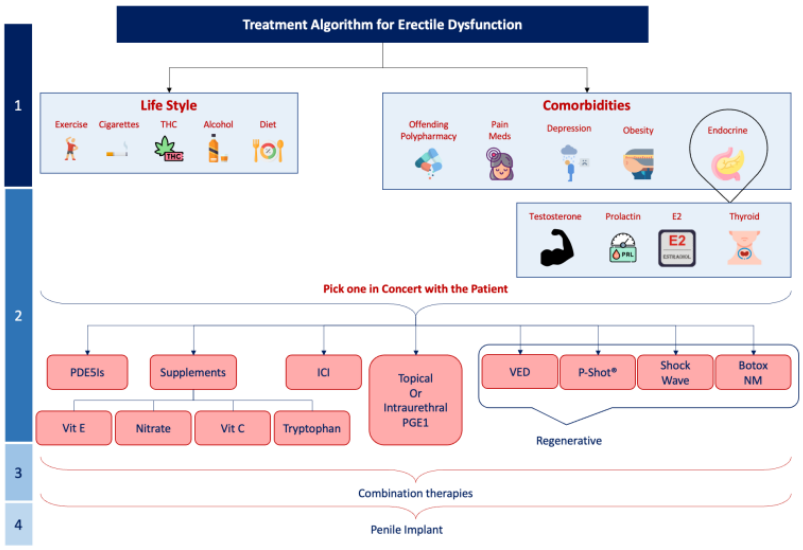
So, there are a couple of things, then I'll quit ranting about it, but a couple of things. I'm preaching to the choir because you offer these procedures. I put this in your handout section this suggested algorithm.

A New Algorithm for Treating Erectile Dysfunction

Let me pull it up for you to look at. I took the standard algorithm that's out there in the literature. Let me get where you can see it. There you go. I took the standard algorithm that's taught by the powers that be and added to it regenerative therapies.

So, you can see, someone comes in, they're having erectile problems. Obviously, you're going to think about lifestyle and comorbidities. If they're on pain medicines, I promise you, I worked in rehab clinics and have a special interest. If they're on opioids, their LH and FSH are reduced, and they have a low testosterone level, and unless someone's supplementing it, and all this you know.

You look at endocrine, then pick one in concert with the patient. That part, where it says the PDE5 inhibitors, the intracavernosal injections, and the topical or urethral PGE1s, is the standard part. And then, under the supplements, those are all things that have been shown to be helpful at high enough doses.



Then, I just added the regenerative therapies, a vacuum device that's been shown; now we have studies showing that using a penis pump increases transcutaneous oxygen levels throughout the day.[3] Another study showed that it enhanced the effectiveness of your PDE5 inhibitors.[4] [5]

Of course, our P-Shot® shockwave, and then recently, now we have three double-blind placebo-controlled studies looking at using botulinum toxin for ED,[6] [7] [8] [9] [10] (I need to change that, botulinum

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[3] Welliver et al., "A Pilot Study to Determine Penile Oxygen Saturation Before and After Vacuum Therapy in Patients with Erectile Dysfunction After Radical Prostatectomy."

[4] Lin and Wang, "The Science of Vacuum Erectile Device in Penile Rehabilitation after Radical Prostatectomy."

[5] Wang, "Is There Still a Role for Vacuum Erection Devices in Contemporary Sexual Medicine?"

[6] Abdelrahman et al., "Safety and Efficacy of Botulinum Neurotoxin in the Treatment of Erectile Dysfunction Refractory to Phosphodiesterase Inhibitors."

[7] El-Shaer et al., "Intra-Cavernous Injection of BOTOX® (50 and 100 Units) for Treatment of Vasculogenic Erectile Dysfunction."

[8] Giuliano, Denys, and Joussain, "Effectiveness and Safety of Intracavernosal IncobotulinumtoxinA (Xeomin®) 100 U as an Add-on Therapy to Standard Pharmacological Treatment for Difficult-to-Treat Erectile Dysfunction."

[9] Giuliano, Denys, and Joussain.

[10] Giuliano, Joussain, and Denys, "Safety and Efficacy of Intracavernosal Injections of AbobotulinumtoxinA (Dysport®) as Add on Therapy to Phosphosdiesterase Type 5 Inhibitors or Prostaglandin E1 for Erectile Dysfunction—Case Studies."

toxin, not "Botox" or neuromodulators. These days, I'm mostly using Xeomin. The study has been done with Dysport, Xeomin, and Botox.

The idea is that you get vasodilatation (and increased arterial blood flow) through smooth muscle relaxation, which is exactly what the PDE5 inhibitors do. However, the possible extra benefit is a relative increase in parasympathetic activity by an absolute attenuation of the sympathetic part of the autonomic nervous system.[11]

And, of course, parasympathetic is erection, which leads to a better erection, harder erection, a more easily obtained erection, and documented in the studies a larger flaccid penis, not a larger erection, but larger flaccid.[12]

And then the third step, if you look over the left, there's one, two, and then the third step is combining those therapies. The first step is to pick one and ask the patient which one. The next step is combination, and the third and the fourth are onto a penile implant.

So, I'd say that's the CMA protocol, which takes what's already standard of care and adds a reasonable menu of regenerative therapies.

Of course, many of you are combining all of that.

You're doing our Priapus Toxin® procedure with your shockwave, your P-Shot®, and vacuum device. And it'd be different if these were dangerous things, but shockwave and PRP and a penis pump, if done properly, have almost zero serious sequelae and lots of benefits.

So that's it. Use it however you want. Print it out, put it on the wall or in a notebook somewhere, or throw it away—whatever you think is good for it.

Let me go back to some more of the research.

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[11] Morris, Jobling, and Gibbins, "Botulinum Neurotoxin A Attenuates Release of Norepinephrine but Not NPY from Vasoconstrictor Neurons."

[12] Giuliano, Denys, and Joussain, "Effectiveness and Safety of Intracavernosal IncobotulinumtoxinA (Xeomin®) 100 U as an Add-on Therapy to Standard Pharmacological Treatment for Difficult-to-Treat Erectile Dysfunction."

Cross-linked vs. Non-Cross linked HA in the Anterior Vaginal Wall

There was a follow-up letter regarding using PRP with a human acellular dermal matrix, which we could be doing.[13] We do something similar when we use an HA, but you can't really use a non-cross-linked HA; you're good to go, but a cross-linked HA like your Juvederm and such in the anterior vaginal wall could be a problem and has been condemned by ACOG, but this is worth looking at.

It's just a further discussion about what we're doing and how the combination, I think, is to be worked out; the best way is to combine HA with PRP.

I know it's not yet FDA approved, but in Europe, Regen makes a non-cross-linked HA PRP kit that I think is going to be amazing for incontinence and can be put in the anterior vaginal wall, but it's off-label so far in the US. That is one of the other studies.

And the other one is another letter about using PRP for volumetric outcomes and reconstruction. We've talked about this like crazy, and I just wanted you to be up-to-date on the discussion. As you guys know, we've covered one of my favorite papers where they used PRP to treat the scar tissue resulting from the port in women who had breast cancer and then looked to see if treating that scar caused an increase in biopsy rates or recurrence rates, so high-risk women who had breast cancer and they did a placebo arm with saline. They showed a statistical decrease in biopsy and recurrence rates in the people who got the PRP.[14]

My guess about the mechanism is that it's changing the milieu, the bacterial milieu of the breast, which one study demonstrated to be different in women with breast cancer than in women without.[15] And of course, PRP is antibacterial,[16] [17] [18] but that's me guessing.

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[13] Kirch, "A Novel Technique Combining Human Acellular Dermal Matrix (HADM) and Enriched Platelet Therapy (EPT) for the Treatment of Vaginal Laxity."

[14] Eichler et al., "Platelet-Rich Plasma (PRP) in Breast Cancer Patients."

[15] Urbaniak et al., "The Microbiota of Breast Tissue and Its Association with Breast Cancer."

[16] Aggour and Gamil, "Antimicrobial Effects of Platelet-Rich Plasma against Selected Oral and Periodontal Pathogens."

[17] Sethi et al., "Systematic Literature Review Evaluating Evidence and Mechanisms of Action for Platelet-Rich Plasma as an Antibacterial Agent."

[18] Cieslik-Bielecka et al., "Microbicidal Properties of Leukocyte- and Platelet-Rich Plasma/Fibrin (L-PRP/L-PRF): New Perspectives."

However, the study showed that, at the very least, there was no demonstration of increased risk of breast cancer. It was the opposite, statistically decreasing it.

Obviously, I'm not saying it's inoculation or vaccination against breast cancer, but there was a statistical decrease. And so this is just an ongoing discussion.[19] I'm not sure why there seem to be challenges to the idea that PRP increases fat survival rate. That's been known for at least a decade with at least a dozen, well, 10 studies, give or take, that I know about.

But I do make an important point, and the main reason I brought it up is that it's being done. If we're going to talk about it, at least in a research setting, it may be useful so that we can compare apples to apples. "To list the platelet concentrations."

I see that done much more in Europe than in the US. In our studies, we'll talk about which kit we use, but to standardize it, we should discuss platelet concentrations. And I think that might be all I have. Let me be sure about that.

Oh, one other thing I just wanted to show you.

It's not a big stretch, but it's still interesting and the first time I've seen this talked about. They just showed that they used activated PRP, and they showed that, yeah, you can make the damaged urethra healthier with PRP.[20] They actually showed cell proliferation.

And that seems to me to be a helpful thing to know if, say if a woman just pushed out a 10-pound baby, and I think the time will come when doing some variation of our O-Shot® will be standard of care in the labor and delivery room at post vaginal delivery. We'll see. But this is another of many studies that support the idea of either repair or prophylaxis or improving healing immediately postpartum. So, I love this study. This is the first one I've seen talking about the urothelial cells.[21]

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[19] Kirch, "Breast Reconstruction—Developing a Volumetric Outcome Algorithm."

[20] Hu et al., "The Effect of Platelet-Rich Fibrin on the Biological Properties of Urothelial Cells."

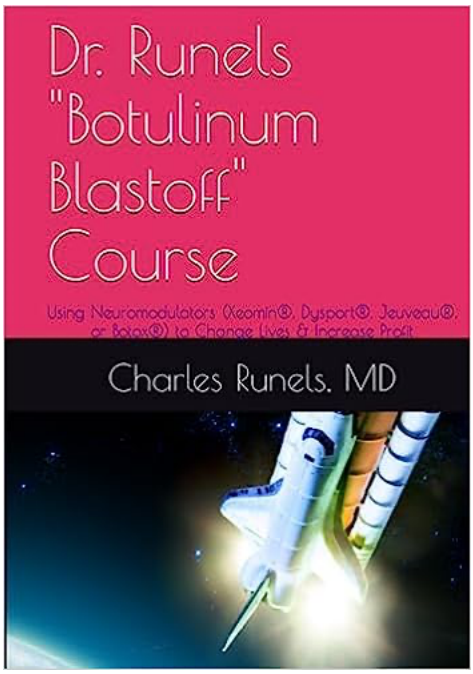
[21] Hu et al.

The Politics of Changing the ED Treatment Algorithm

I had one link I was going to give you. Let me put this in the chat box. This is just for more information about its politics. This is my response [22] to an article in JAMA[23], which did not mention much about science. They just did what they called "secret shopping" of people offering PRP to treat erectile dysfunction.

Their conclusion was that there was no standard protocol, no standardization of licensing required of people doing it, and that the advertisements were somehow offensive, as was the amount being charged.

They included in this article both people advertising generic PRP and those in our group advertising the P-Shot® (the people in our group who ***do*** have a standard protocol and a licensing standard). So we had a discussion that lasted a couple of months, involved attorneys, and eventually resulted in a correction, and I'll show you that correction.[24]



And I bring it up because let me show you the correction, and then I'll, there you go. There's the correction. Is that relative to the comments that were made with this meta-analysis?

I have come to appreciate a good and even an angry critic. I don't want somebody shooting a gun at me, but I've become appreciative of a good critic because it helps me think. People are just saying good things; then it makes me lazy.

And what has been pointed out is that there should be a standard way of doing it. Well, that's exactly what we have. And so part of the persuasion that went into securing this correction is that I actually demonstrated that the people in our group, that would be you guys, we have a protocol that's online, and if you log in to the Priapus Shot® website, the membership site, there's a place where you click and agree to follow the protocol or else drop out of the group and use your own name. And that click and agree is registered with your IP address and the time and date that you clicked it.

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[22] "Memo in Response to the JAMA Article."

[23] Shahinyan et al., "Analysis of Direct-to-Consumer Marketing of Platelet-Rich Plasma for Erectile Dysfunction in the US."

[24] "Errors in Text."

And so I said, "Here. Here it is right here. These are the names of the people. Here's the IP address and the time when they clicked, and here's the agreement that they clicked to follow this protocol."

Obviously, we have to alter what we're doing. The exact details might vary with patients, but the standardized idea behind it, and most of what's done, is the same from patient to patient. We do have a licensing requirement that means that we say no to a lot of people who try to be in our group, and we're careful about who we allow in, so it keeps our reputation high.

The other thing, of course, that goes into that is if the name is going to mean something, it means we have to make people stop using the name when they are not in our group. That has turned out to be our organization's most expensive and arduous task.

Unfortunately, we spend more on that than we do research, but we spend about a million a year. That's a million dollars, US dollars per year, not pesos, a million US dollars per year on attorneys, making people stop advertising our procedures who are not in our group, and this is exactly why.

So that we, patients, have some idea—there's never a guaranteed outcome—but they have an idea that they're dealing with someone who, at least someone, has looked at their license to practice medicine or nursing or nurse practitioner and that they have looked at a protocol and agreed to follow it. That's all that happens with your board exam.

Nobody's up in your business. You've just learned how to do something, and you've agreed to follow certain standards. So it's not on the same level as a board, but it is an agreement, and that's what we do.

We have more research coming. I'm not quite free yet to talk about all of it, but I think 2025 will be an amazing year, so you guys hang in there.

Let's see if there are any questions, and then let's call it tonight. Okay, thank you. Have a good night. Bye-bye.

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Tags

PRP, penile implants, erectile dysfunction, regenerative therapies, shockwave therapy, stem cells, sexual medicine, platelet-rich plasma, erectile function, cellular therapy, standard of care, P-Shot®, Priapus Shot®, botulinum toxin, vasodilatation, smooth muscle relaxation, parasympathetic activity, Peyronie's disease, neurovascular disease, platelet concentration, transcutaneous oxygen, vacuum device, O-Shot®, urethral repair, incontinence, non-cross-linked HA, JAMA, sexual medicine protocol, physician standards, Priapus Shot® group, Charles Runels

Helpful Links

=> Next Hands-On Workshops with Live Models <=

=> Dr. Runels *Botulinum Blastoff Course* <=

=> The Cellular Medicine Association (who we are) <=

=> Apply for *Online Training for Multiple PRP Procedures* <=

=> FSFI Online Administrator and Calculator <=

=> 5-Notes Expert System for Doctors <=

=> Help with *Logging into Membership Websites* <=

=> The software I use to send emails: ONTRAPORT (free trial) <=

=> Sell O-Shot® products: You make 10% with links you place; shipped by the manufacturer), this explains and here's where to apply <=