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Platelet-Rich Plasma for Erectile Dysfunction

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Sexual Medicine Society of North America, Inc. SMS

Introduction

Platelet-rich plasma (PRP) has been used for several decades across multiple disciplines including, pain medicine, wound care, dentistry, and orthopedics.

Countless clinical studies demonstrate that it is an effective medical procedure when healing and cellular regrowth are the treatment goals.

Today, specialists are finding many additional ways to use the tissue regenerating properties of PRP to treat male and female sexual dysfunction, urinary incontinence, non-invasive aesthetics, and hair regrowth.

There is limited clinical data for the application of PRP in the field of sexual medicine, specifically in conjunction with other forms of ED therapy.

Aim

- To review the charts of patients treated with PRP for their ED and report outcomes and safety concerns for this treatment modality.
- To examine if PRP, when used in conjunction with other treatments for ED, makes a significant difference in erectile function.
- To establish feasibility and justification for a larger clinical trial.
- To establish protocols for PRP use in urology and sexual medicine.
- We believe PRP can be used as a supplemental therapy for multiple urologic and sexual medicine concerns. Continued research will help inform patients and physicians so that its benefits are widely experienced.

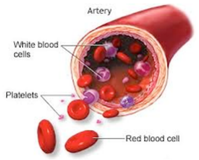
Method

- At Midwest Urological in Peoria, IL., eligible patients are routinely offered PRP as a adjunct to their ED therapy regimen of daily medication and vacuum pump.
- A retrospective chart review was performed.
- Charts were included in the review if they met the following criteria:
  - PRP treatment occurred between 8/1/2015 and 8/1/2016
  - Baseline and Post IIEF completed
  - No penile implant
  - Initial IIEF of moderate ED (10 - 20)
  - Patient received only 1 PRP treatment

TREATMENT PROTOCOLS

- Patient's own whole blood is drawn.
- Blood is spun down to isolate platelets and reduce RBCs.
- PRP is activated with calcium chloride.*
- Active platelet-rich fibrin matrix then injected into multiple sites along the penis.
- Patients are seen 2 weeks post-injection, and then every 4 weeks to monitor improvements.
- Patients complete International Index of Erectile Function (IIEF) prior to receiving PRP and then at each subsequent visit.

What is Platelet-Rich Plasma?

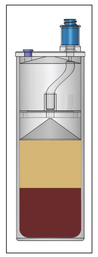


- Platelets are a type of white blood cell that contain alpha-granules.
- Each alpha-granule contains a high number of growth factors that play a fundamental role in healing, following tissue damage.

CELLULAR COMPONENTS

- Once platelets are activated, a platelet gel is formed containing the following:
  - Growth factors
  - Adhesive proteins
  - Fibrogen
  - Fibroectin
  - Vitronectin
  - Thrombospondin
- Present Study
  - 4-6 times the number of platelets and growth factors normally found in blood
  - Low RBCs and Granulocytes
  - High Monocyte concentrations

Not all PRP is Created Equal!



Our PRP solution underwent a double spin process, optimizing platelet cell count

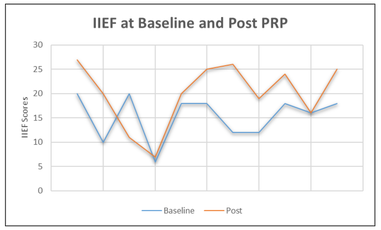
Results

N=11 patients met inclusion criteria

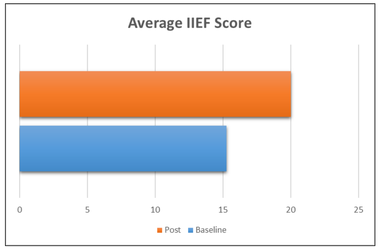
Patient Characteristics		Range
Age	58.09 (M)	46 - 66
Hypertension	3	
Hypogonadism	8	

IIEF Scores	M	Range
Baseline	15.27	6 - 20
Post-PRP	20	7 - 27

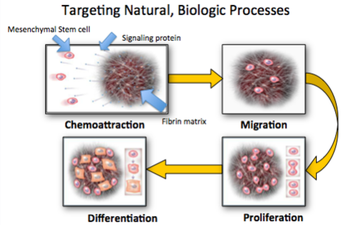
- Over 90% of patients improved or stayed the same
- A paired samples t-test revealed a significant difference between groups
  - t(10) = 2.58, **p = 0.027**
- The effect size was also calculated
  - *Cohen's d* = 0.85
- No adverse events were reported
- 100% of patients reported no side effects



Patient's IIEF scores displayed. Blue are scores at baseline. Orange are scores taken at least 4 weeks post PRP injection.

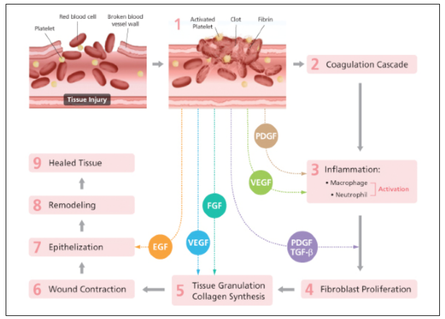


Mechanisms of Action



Platelet Growth Factor	Source
Platelet Derived (PDGF)	Platelets, osteoblasts, endothelial cells, macrophages, monocytes, smooth muscle cells
Transforming (TGF)	Platelets, extracellular maxtrix of bone, cartilage matrix, activated TH cells and natural killer cells, macrophages/ monocytes, neutrophils
Vascular endothelial (VEGF)	Platelets, endothelial cells
Epidermal (EGF)	Platelets, macrophages, monocytes
Fibroblast (FGF)	Platelets, macrophages, mesenchymal cells, chondrocytes, osteoblasts
Connective tissue (CTGF)	Platelets though endocytosis from extracellur environment in bone marrow
Insulin-like (IGF-1)	Plasma, epithelial cells, endothelial cells, fibroblasts, smooth muscle cells, osteoblasts, bone matrix

- Platelet aggregation and degranulation cause the release of biologically active proteins
- Growth factors bind platelet tyrosine kinase receptors on cell membrane
- Messenger proteins become activated in nucleus
- tRNA produced and triggers cascade
- Cascade provokes tissue repair and regeneration



Conclusion

- Adding PRP to an ED therapy regimen can have a significant impact on erectile function.
- PRP may be a safe and effective supplemental therapy for penile rehabilitation.
- Potential for zero side effects

Acknowledgements

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FOR ORGANIZATION USE ONLY

DETERMINE REGENERATION OF RESPONSE POTENTIAL TO PDE5 INHIBITOR CLASS OF MEDICATIONS POST PRP THERAPY

Purpose: The purpose of this study is to assess the efficacy of PRP therapy to restore effectiveness of the PDE5 inhibitor class of medications in men who no longer respond but who have previously responded with success to the PDE5 inhibitor class of medications in the past.

Inclusion criteria:

- Males over the age of 18
- Mild to moderate ED as determined by the IIEF
- Non responder to PDE5 Inhibitors when previously successfully responded for at least 3 years.

Exclusion criteria:

- No systemic anticoagulation
- No presence of cancer
- No systemic blood disorders
- No Peyronie's Disease

Participant "application" - details and application posted on BannoUrology.com

- Details of study inclusion and exclusion criteria
- Details of the study process and what is expected on the study subject
- Details of the specific date(s) subjects will be treated
- Online Application
    - Complete application with all inclusion and exclusion criteria data collected.
        - Medical intake form with study specific medical and medication questions.
        - IIEF Questionnaire

Study Protocol:

1. Recruitment
    - First 50 patients that meet study inclusion and exclusion study criteria are determined "1st level" eligible and will be asked to participate in a phone interview.
    - Phone interview to establish 2nd level of eligibility
        - Confirm Age
        - Confirm previous use of PDE5 inhibitor
        - Determine specific PDE5 inhibitor brand, dose, frequency and duration of use.
        - How long had they responded successfully to PDE5 inhibitors
        - How long have they been **non responders** of PDE5 inhibitors
        - Since non response, what different PDE5 inhibitor medications and doses have they tried and failed.

- Questionnaires Completed by verbal response
    - Procedure and study informed consent form
    - Androgen Deficiency in the Aging Male (qADAM)
    - International Index of Erectile Dysfunction (IIEF)
    - Sexual Satisfaction questionnaire

- Willingness to travel to study location on specific "study day"
- Willingness to complete and submit all study documents in a timely manner
- Willingness to submit a $500 preliminary fee that will be refunded entirely upon completion of all study (pre and post PRP procedure) documents, diagnostic labs and procedures.
- N=30 patients recruited

2. First appointment
    - Confirm and collect completed Informed Consent Form
    - Conduct a brief History and Physical Exam
    - Draw Lab work
        - Free and Total Testosterone
        - Estradiol
        - CBC with differential
        - PSA
    - Imaging
        - Duplex ultrasound
    - Other measures
        - Plethysmography - (Penile sensitivity measure)
3. Administer PRP per protocol
    a. Blood draw
    b. Centrifuge
    c. Injection
    d. Instruction of daily Cialis 5mg or Tadalafil 7mg and VED
5. Follow up 4 weeks
    a. IIEF
    b. Sexual satisfaction questionnaire
6. 12 weeks
    c. IIEF
    d. Sexual satisfaction questionnaire

The efficacy of platelet-rich plasma for the treatment of erectile dysfunction: initial outcomes

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Objective: Through past decades a variety of therapies have evolved for erectile dysfunction (ED). The effectiveness of these methods varies by individual and are often used in conjunction with each other for optimal penile rehabilitation. While the advent of platelet-rich plasma (PRP) is not new to medicine, there has been limited clinical data for its application in the field of sexual medicine, specifically in conjunction with other forms of ED therapy. Evidence suggests PRP promotes the body's natural healing process and therefore may help tissues in the penis better accept other therapies.

Materials and Methods: A retrospective chart review was conducted at Midwest Urological Group in Peoria, IL. At this site, patients are presented with the option of adding PRP to a medication and vacuum therapy regimen to treat their ED. Charts were included if 1) PRP treatment occurred between 8/1/2015 and 8/1/2016; 2) baseline and 4-week post International Index of Erectile Function (IIEF) complete; 3) no penile implant; and 4) initial IIEF indicated moderate ED (10-21). PRP was obtained using the patients' own blood and each patient received only one treatment.

PRP Preparation: Since not all PRP systems yield the same cellular components in their final product, we thought it important to include the cellular components of the specific PRP used in this study. The PRP system we used generates 4-6 times the number of platelets and growth factors normally found in the blood. The system is noted for its low RBC and Granulocytes as well as high Monocyte concentrations.

Results: N = 11 patients met the inclusion criteria. The mean age was 58.09 years with a range of 46-66 years. Three of the patients had hypertension; eight had hypogonadism. The average baseline IIEF score was 15.27 with a range of 6-20. The average post-PRP IIEF score was 20.00 with a range of 7-27. A paired samples t-test revealed that there was a significant difference between groups, $t(10) = 2.58$, $p = 0.027$. In light of the small sample size the effect size was also calculated and found to be large, *Cohen's d* = 0.85, $r = .439$. No adverse effects reported. 100% of patients reported no side effects.

Conclusions: PRP may be a safe and effective supplemental therapy for penile rehabilitation. Particularly notable is the prospect of zero side effects. Further investigation is required to assess how PRP works in conjunction with specific therapies and establish the fit within the physician's treatment protocol.

For questions, please contact:
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