AGENDA

State and Public School Life and Health Insurance Board
Benefits Sub-Committee

February 6, 2015

10:00 a.m.

EBD Board Room – 501 Building, Suite 500

I. Call to Order .............................................................. Shelby McCook, Chairman

II. Approval of January 9, 2015 Minutes.............................. Shelby McCook, Chairman

III. Stem Cell Review .... Chad Sulak, Morgan Pile, Janie Baltz, Harvest Technologies

IV. EBD Report.............................................................. Lori Eden, EBD Deputy Director

Upcoming Meetings
March 6th
April 10th

NOTE: All material for this meeting will be available by electronic means only asepse-board@dfa.arkansas.gov

Notice: Silence your cell phones. Keep your personal conversations to a minimum. Observe restrictions designating areas as “Members and Staff only”
The Benefits Sub-Committee of the State and Public School Life and Health Insurance Board (hereinafter called the Committee) met on February 6, 2015 at 10:00 a.m. in the EBD Board Room, 501 Woodlane, Suite 500, Little Rock, Arkansas.

**Members Present**

Janis Harrison  
Carla Wooley-Haugen  
Becky Walker  
Shelby McCook  
Jeff Altemus  
Angela Avery  
Claudia Moran  
Dan Honey

Lori Eden, Deputy Director, Employee Benefits Division (EBD)

**Others Present**

John Kirtley, David Keisner, Dwight Davis, UAMS; Lori Eden, Stella Greene, Ethel Whittaker, Leslie Smith, Janna Keathley, Marla Wallace, EBD; Kristi Jackson, Dale Branda, Jennifer Vaughn, ComPsych; Pam Lawrence, AHH; Mark Watts, Nicholas Poole, ASEA; BJ Himes, Andra Kaufman, Karen Langley, QualChoice; Wayne Whitley, Ronda Walthall, Larry Dickerson, AHTD; Treg Long, ACS; Andy Davis, Arkansas Democrat Gazette; Jackie Baker, ASP; Ro Summers, Gini Ingram, ACHI; Marlo James, AEA; Takisha Sanders, Health Advantage; Ashley Younger, Mitchell Williams; Margaret Zakrzewski, ASTA

**Call to Order**

The meeting was called to order by Shelby McCook, Chairman

**Approval of Minutes**

A request was made by McCook to approve the minutes from January 9, 2014. Walker made the motion to approve. Harrison seconded. All were in favor.
REGENERATIVE INJECTION THERAPY: by Dr. David Harshfield, Chad Sulak, Harvest

Regenerative Injection Therapy is known as Stem Cell Treatment. Platelet Rich Plasma Therapy was initially used over 20 years ago to enhance wound healing in cancer patient with jaw reconstruction and to increase the survival of bone grafts in dental procedures.

It’s also used in plastic surgery to enhance wound healing and to decrease the risk of infection. They began using it for professional athletics, and is now entering the mainstream medical centers with increasing indications for use.

Platelets release healing proteins called growth factors which stimulate stem cells accelerate tissue and wound healing. Stem cells can make exact copies of itself indefinitely, differentiate, and produce specialized cells for various tissues of the body.

There are two types of Stem Cells, Embryonic and Adult. There is no current approved treatment for Embryonic. It was used until October 2010 for spinal cord injuries. Adults have stem cell to maintain the normal turnover of regenerative organs, blood, skin and intestines.

The following are areas of investigation of stem cell treatment:

- Diabetes
- Rheumatoid arthritis
- Parkinson’s disease
- Osteoarthritis
- Stroke and traumatic brain injury
- Learning defects
- Heart attack
- Anti-cancer
- Baldness
- Repair tooth
- Repair hearing
- Restore vision
- Amyotrophic Lateral Sclerosis (ALS)
- Crohn's disease
- Wound Healing

The growth factors stimulate mesenchymal cells from body to site, and stimulate differentiation of stem cells to tissue specific cells.

A few of the Orthopedic Indications are as follows:
- Chronic lower back pain
- Tennis elbow
- Rotator cuff tears
- Knee Osteoarthritis
- Achilles Tendonitis
- Plantar Fasciitis
- Neck Pain
- Medical collateral ligament (MCL) tears
- Acute and chronic tendon problems
- Injuries to ligaments and muscles

The three phases of healing are (1) Inflammatory Phase, (2) Proliferative Phase, and (3) The Remodeling Phase. The timeframe for healing varies among the three.

Honey moved that Medical Directors of our carriers be invited to our next meeting to present their views on this process. Wooley-Haugen seconded. All were in favor.

**Motion Approved**

Harrison motioned to recommend to the board to revisit the decision for EBD Director to have the authority to make payroll deduction decisions for voluntary deductions. Wooley-Haugen seconded.

**Motion Approved**
EDB REPORT: by Lori Eden, EBD Deputy Director

Eden reported no additional information.

Meeting Adjourned
REGENERATIVE INJECTION THERAPY
Using the Body’s Natural Healing Process
Born in Little Rock, Arkansas

University of Arkansas for Medical Sciences

- Medical Doctorate in 1981, graduating with honors.
- Work in the Honor’s Program during medical school pertained to stem cell therapy for the treatment of Diabetes, and provided me with a Masters Degree in Physiology and Biophysics.
- Board certified in Radiology in 1981
Dr. David Harshfield

• Fellowship in Angiographic and Interventional Radiology
• Director of Special Procedures at UAMS upon completing my fellowship in 1982.
• Chairman of the Institutional Review Board (IRB) for the International Cellular Medicine Society (ICMS), as well on serving on the advisory board for the ICMS.
• Board of Directors for the American Association of Orthopedic Medicine (AAOM)
WHAT IS PRP?

Platelet Rich Plasma
History of Platelet Rich Plasma Therapy

Initially used over 20 years ago to enhance wound healing in cancer patient with jaw reconstruction and to increase the survival of bone grafts in dental procedures.

Also used in plastic surgery to enhance wound healing and to decrease the risk of infection.

Began being used in professional athletics and is now entering the mainstream medical centers with increasing indications for use.
Components of PRP

• Stem Cells
• Platelets
• Growth factors
• White blood cells
How does PRP work?

Platelets release healing proteins called growth factors which stimulate stem cells accelerate tissue and wound healing.
WHAT IS A STEM CELL?

- Cells which can make exact copies of itself indefinitely
- Can differentiate
- Produce specialized cells for various tissues of body
Two Types of Stem Cells

Embryonic
- no current approved treatment
- used until October 2010 for spinal cord injuries
- Currently a moratorium on use

Adult
- risk of rejection non-existent
- U.S. Government funding increasing
To maintain the normal turnover of regenerative organs, blood, skin and intestines.
### Stem Cell Treatment Investigation:

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<th>Benefits</th>
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<td>• Diabetes</td>
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<td>• Wound Healing</td>
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GROWTH FACTORS

Stimulate mesenchymal cells from body to site

Stimulate differentiation of stem cells to tissue specific cells
The Growth Factors And Other Cytokines Present In PRP Include:

- platelet-derived growth factor
- transforming growth factor beta
- fibroblast growth factor
- keratinocyte growth factor
- connective tissue growth factor
- insulin-like growth factor 1
- insulin-like growth factor 2
- vascular endothelial growth factor
- epidermal growth factor
- Interleukin 8
Adult Stem Cells

- Blood
- Adipose Tissue
- Bone Marrow
Orthopedic Indications

- Chronic lower back pain
- Tennis elbow
- Rotator cuff tears
- Knee Osteoarthritis
- Achilles Tendonitis
- Plantar Fasciitis
- Neck pain
- Medial collateral ligament (MCL) tears
- Acute and chronic tendon problems
- Injuries to ligaments and muscles
REGENERATIVE Treatment Options
1. Inflammatory Phase  2-5 days, platelet accumulation and clot formation
2. Proliferative Phase  - 2 days to 3 weeks.  
   Granulation contraction, epithelialization
3. Remodeling Phase  - 3 weeks to 2 years.  
   New collagen, scar not as strong as original tissue
OSTEOARTHRITIS
Platelet-rich Plasma (PRP) Treatment Shows Potential for Knee Osteoarthritis

New York—February 12, 2013

A study by researchers from Hospital for Special Surgery has shown that platelet-rich plasma (PRP) holds great promise for treating patients with knee osteoarthritis. The treatment improved pain and function, and in up to 73% of patients, appeared to delay the progression of osteoarthritis, which is a progressive disease. The study appears online, ahead of print, in the Clinical Journal of Sports Medicine.

"This is a very positive study," said Brian Halpern, M.D., chief of the Primary Care Sports Medicine Service at Hospital for Special Surgery, New York City, and lead author of the study.

Several treatments for osteoarthritis exist, including exercise, weight control, bracing, nonsteroidal anti-inflammatory agents, Tylenol, cortisone shots and viscosupplementation, a procedure that involves injecting a gel-like substance into the knee to supplement the natural lubricant in the joint. A new treatment that is being studied by a small number of doctors is PRP injections. PRP, which is produced from a patient’s own blood, delivers a high concentration of growth factors to arthritic cartilage that can potentially enhance healing.

"You take a person's blood, you spin it down, you concentrate the platelets, and you inject a person's knee with their own platelets in a concentrated form," said Dr. Halpern. "This then activates growth factors and stem cells to help repair the tissue, if possible, calm osteoarthritic symptoms and decrease inflammation."

In the new study, researchers at Hospital for Special Surgery enrolled patients with early osteoarthritis, gave
Clinical and MRI Outcomes After Platelet-Rich Plasma Treatment for Knee Osteoarthritis
Brian Halpem, MD, Salma Chaudhury, MD, PhD, MRC, Scott A. Rodeo, MD, Catherine Hayter, MD, Eric Bogner, MD, Hollis G. Potter, MD, Joseph Nguyen, MPH

Abstract and Introduction

Abstract

The purpose of this study was to investigate whether platelet-rich plasma therapy for early knee osteoarthritis is associated with good clinical outcomes and a change in magnetic resonance imaging (MRI) structural appearances. The design was a prospective cohort study following patients 1 year after platelet-rich plasma therapy for knee osteoarthritis. Twenty-two patients were treated with platelet-rich plasma for early osteoarthritis, confirmed with a baseline MRI. Inclusion criteria were Kellgren grade 0-II with knee pain in patients aged 30 to 70 years. All the patients received a 6-mL platelet-rich plasma injection using the Cascade system. Fifteen subjects underwent clinical assessments at baseline, 1 week, and 1, 3, 6, and 12 months, and MRIs at 1 year. Pain scores significantly decreased, whereas functional and clinical scores increased at 6 months and 1 year from baseline. Qualitative MRIs demonstrated no change per compartment in at least 73% of cases at 1 year.

Introduction

A number of approaches to managing early osteoarthritis have failed to reliably alleviate pain, restore normal knee function and anatomy, or to slow the progression of osteoarthritis. Biological therapies for focal knee osteoarthritis, such as platelet-rich plasma, have been proposed to improve clinical and structural outcomes by delivering a high concentration of growth factors that mediate healing and remodeling.[1,2]

This study aimed to investigate whether platelet-rich plasma therapy for early knee osteoarthritis is associated with changes in clinical outcomes and magnetic resonance imaging (MRI) over 1 year.

Case Report
Platelet-Rich Plasma Intra-Articular Injection Versus Hyaluronic Acid Viscosupplementation as Treatments for Cartilage Pathology: From Early Degeneration to Osteoarthritis

Elizaveta Kon, M.D., Bert Mandelbaum, M.D., Roberto Buda, M.D., Giuseppe Filardo, M.D., Marco Delcogliano, M.D., Antonio Timoncini, M.D., Pier Maria Fornasari, M.D., Sandro Giannini, M.D., and Maurilio Marcacci, M.D.

Purpose: The aim of our study is to compare the efficacy of platelet-rich plasma (PRP) and viscosupplementation (hyaluronic acid [HA]) intra-articular injections for the treatment of knee cartilage degenerative lesions and osteoarthritis (OA). Methods: The study involved 150 patients affected by cartilage degenerative lesions and early and severe OA. Fifty symptomatic patients were treated with 3 autologous PRP intra-articular injections and were evaluated prospectively at enrollment and at 2- and 6-month follow-up. The results obtained were compared with 2 homogeneous groups of patients treated with HA injections. One group was treated with injections of high-molecular weight HA; the other group was treated with low-molecular weight (LW) HA. International Knee Documentation Committee and EQ VAS scores were used for clinical evaluation; adverse events and patient satisfaction were also recorded. Results: At 2 months' follow-up, the PRP and LW HA groups showed a similar improvement, with higher results compared with the high-molecular weight HA group (P < .005). At 6 months' follow-up, better results were observed in the PRP group (P < .005). PRP and LW HA treatments offered similar results in patients aged over 50 years and in the treatment of advanced OA. PRP showed a better performance compared with HA in younger patients affected by cartilage lesions or early OA. Conclusions: Autologous PRP injections showed more and longer efficacy than HA injections in reducing pain and symptoms and recovering articular function. Better results were achieved in younger and more active patients with a low degree of cartilage degeneration, whereas a worse outcome was obtained in more degenerated joints and in older patients, in whom results similar to those of viscosupplementation have been observed. Level of Evidence: Level II, prospective comparative study.
Platelet-Rich Plasma Releasate Inhibits Inflammatory Processes in Osteoarthritic Chondrocytes

Gerben M. van Buul, MD.*,†, Wendy L.M. Koevoet, BSc‡, Nicole Kops, BSc*, P. Koen Bos, MD, PhD*, Jan A.N. Verhaar, MD, PhD*, Harrie Weinans, PhD*, Monique R. Bernsen, PhD† and Gerjo J.V.M. van Osch, PhD*,†§

Abstract

Background: Platelet-rich plasma (PRP) has recently been postulated as a treatment for osteoarthritis (OA). Although anabolic effects of PRP on chondrocytes are well documented, no reports are known addressing effects on cartilage degeneration. Since OA is characterized by a catabolic and inflammatory joint environment, the authors investigated whether PRP was able to counteract the effects of such an environment on human osteoarthritic chondrocytes.

Hypothesis: Platelet-rich plasma inhibits inflammatory effects of interleukin-1 (IL-1) beta on human osteoarthritic chondrocytes.

Study Design: Controlled laboratory study.

Methods: Human osteoarthritic chondrocytes were cultured in the presence of IL-1 beta to mimic an osteoarthritic environment. Medium was supplemented with 0%, 1%, or 10% PRP releasate (PRP r, the active releasate of PRP). After 48 hours, gene expression of collagen type II alpha 1 (COL2A1), aggrecan (ACAN), a disintegrin and metalloproteinase with thrombospondin motifs (ADAMTS)4, ADAMTS5, matrix metalloproteinase (MMP)13, and prostaglandin-endoperoxide synthase (PTGS)2 was analyzed. Additionally, glycosaminoglycan (GAG) content, nitric oxide (NO) production, and nuclear factor kappa B (NFKB) activation were studied.

Results: Platelet-rich plasma releasate diminished IL-1 beta-induced inhibition of COL2A1 and ACAN gene expression. The PRPr also reduced IL-1 beta-induced increase of ADAMTS4 and PTGS2 gene expression. ADAMTS5 gene expression and GAG content were not influenced by IL-1 beta or additional PRPr. Matrix metalloproteinase 13 gene expression and NO production were upregulated by IL-1 beta but not affected by added PRPr. Finally, PRPr reduced IL-1 beta-induced NFKB activation to control levels containing no IL-1 beta.

Conclusion: Platelet-rich plasma releasate diminished multiple inflammatory IL-1 beta-mediated effects on human osteoarthritic chondrocytes, including inhibition of NFKB activation.

Clinical Relevance: Platelet-rich plasma releasate counteracts effects of an inflammatory environment on genes regulating matrix degradation and formation in human chondrocytes. Platelet-rich plasma releasate decreases NFKB activation, a major pathway involved in the pathogenesis of OA. These results encourage further study of PRP as a treatment for OA.

Keywords:
Platelet-rich plasma: intra-articular knee injections produced favorable results on degenerative cartilage lesions

Elizaveta Kon · Roberto Buda · Giuseppe Filardo · Alessandro Di Martino · Antonio Timoneini · Annarita Cenaeci · Pier Maria Fornasari · Sandro Giannini · Maurilio Marcacci

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Abstract Platelet-rich plasma (PRP) is a natural concentrate of autologous blood growth factors experimented in different fields of medicine in order to test its potential to enhance tissue regeneration. The aim of our study is to explore this novel approach to treat degenerative lesions of articular cartilage of the knee. One hundred consecutive patients, affected by chronic degenerative condition of the knee, were treated with PRP intra-articular injections (115 knees treated). The procedure consisted of 150-ml of venous blood collected and twice centrifugated: 3 PRP units of 5 ml each were used for the injections. Patients were clinically prospectively evaluated before and at the end of the treatment, and at 6 and 12 months follow-up. IKDC, objective and subjective, and EQ VAS were used for clinical evaluation. Statistical analysis was performed to evaluate the significance of sex, age, grade of OA and BMI. A statistically significant improvement of all clinical scores was obtained from the basal evaluation to the end of the therapy and at 6–12 months follow-up ($P < 0.0005$). The results remained stable from the end of the therapy to 6 months follow up, whereas they became significantly worse at 12 months follow up ($P = 0.02$), even if still significantly higher respect to the basal level ($P < 0.0005$). The preliminary results indicate that the treatment with PRP injections is safe and has the potential to reduce pain and improve knee function and quality of live in younger patients with
Since 1999, Harvest has been a leader in multicellular processing technology. The company developed the first point-of-care, low-volume, whole blood processing system for the preparation of platelet rich plasma.
The Harvest Technologies PRP separation system is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care.
### Impact

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<th>Procedure</th>
<th>Est. #</th>
<th>Avg US Cost</th>
<th>Stem Cell Therapy Cost</th>
<th>Savings</th>
<th>Total Savings</th>
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<td>Stem Cells $3,000</td>
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