Qualitative aspects of treatment with prolotherapy for knee osteoarthritis in a multi-method study

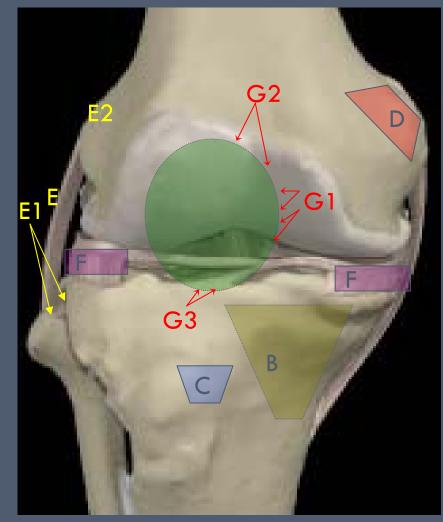
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Knee Osteoarthritis

- Age-related degenerative disease of joint cartilage
- Symptoms include pain, stiffness, decreased ability to perform activities of daily living (ADLs)
- Affects 6% of adults age 30 and above
- Limited options for treatment and pain-control
- No cure

Prolotherapy

- Injection-based therapy for chronic musculoskeletal pain
- hypertonic dextrose or sodium morrhuate
- Proposed mechanism of action:
 - osmotic rupture of cells
 - localized inflammation
 - stimulate release of growth factors
- Greater evidence for use of prolotherapy (PrT) for tendinopathies and osteoarthritis (OA) elsewhere, more needed for knee OA



Objective

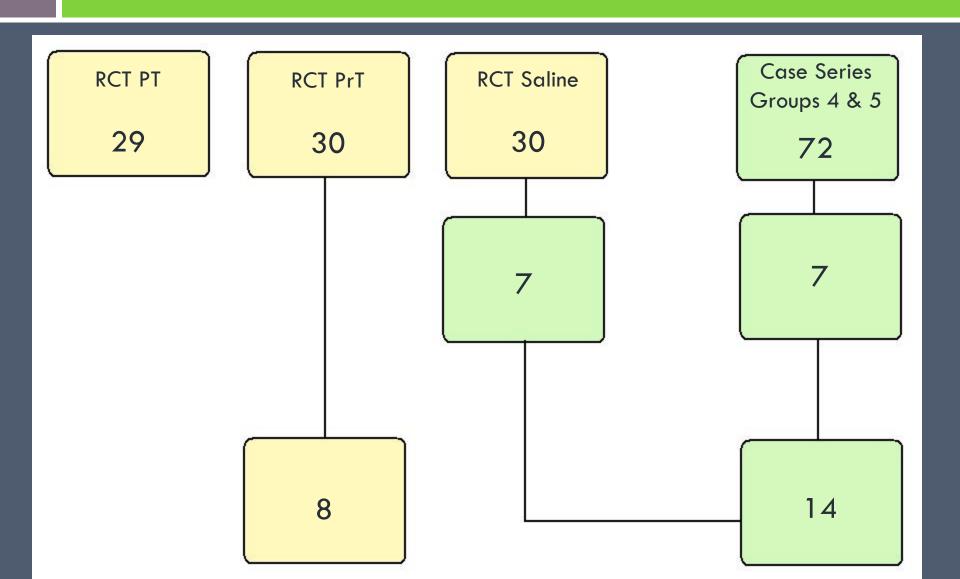
Assess the qualitative response of subjects who recently received PrT for knee OA in the parent study

Design

• 22 participants were randomly selected from 3 of 5 prior study arms

- RCT: PrT group (also placebo and physical therapy groups)
- Case series: groups 4 and 5
- Initially recruited from UW Family Medicine outpatient clinics
- Received 5 treatment sessions in 6 month period
- Telephone interviews:
 - •PrT's effectiveness and side effects
 - Initial and post therapy feelings towards PrT
- Discussed themes at weekly meetings
- Disagreements were resolved by consensus

Participants



Participants

• Inclusion criteria:

- 40-70 y.o. for RCT, 40-76 Group 4, 30-76 Group 5
- Knee OA pain for 3 months to 10 years

• Exclusion criteria:

• <u>RCT</u>: candidate for or had prior knee replacement, pregnancy, taking anticoagulants or narcotics, prior injection of PrT, steroids or hyaluronate, rheumatoid arthritis, prior intra-articular knee fracture, diabetes, chronic pain diagnosis, implanted medical device, nonferromagnetic metal electronically conductive wires or materials, referring physician thinks therapy will harm patient

- <u>Group 4</u>: all the above except will include patients with obesity, type 2 diabetes, prior ACL or PCL damage
- Group 5: same as group 4 except age range is 30-76

Results

• Parent study: 30-40% improvement in pain. Current study supports this positive effect for most participants

•Variability in subject outcomes

4 major themes emerged: most participants reported

 (1) Improvement in pain and ability to perform ADLs
 (2) Safety; there were no long-term side effects, few unexpected side effects

(3) Pre-treatment counseling enhanced treatment adherence and optimism

(4) Overall positive experience with PrT

Results

• 3 minor themes emerged:

(1) Confirmation of current PrT practices
(2) Functional improvement without pain reduction
(3) Prolotherapy has the potential to prolong surgery

Results

Participant Quotes

"Oh my gosh I can walk, especially I can get up and down stairs. I just feel so much better."

"I felt some benefit from it but now in the months since then I'm back to the same level of pain I was at before the study."

"the worst thing is the pain of the injections."

Conclusions

Major Themes:

• For most, PrT provides pain and ADL ability improvements that last at least 1 year. Large variability

•Prolotherapy is a safe treatment

• An initial informational session reduces uncertainty and anxiety, likely enhancing participant adherence. It also increases optimism towards PrT, possibly affecting treatment outcomes

• Recommendation of PrT to others and consideration of additional PrT regardless of treatment outcome indicates overall positive experience

Conclusions

Minor Themes:

• Participant reports confirm current use of multiple treatment sessions, post-treatment rest and use of oxycodone. Reports question use of lidocaine injections

 Most of those experiencing benefits have both pain and ADL ability improvements, however some experience improved functioning without pain reduction

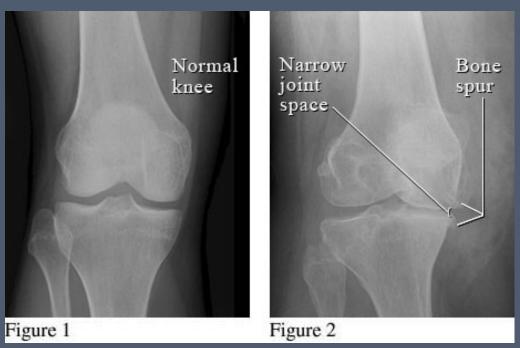
• When considering risks and benefits of knee surgery and PrT, PrT may be a worthwhile treatment to undergo before surgery

Limitations

- Not all participants blinded, study doctor not blinded
 - Expectation bias
- Recall bias
- Intention to treat analysis
 - Injury, additional therapy since last treatment, drop-out

Future Study

- Time frame of treatment benefits 3 year follow-up
- Ideal number of treatment sessions
- Relationship between knee OA severity and the effect of PrT



http://64.143.176.9/library/healthguide/en-us/images/media/medical/hw/h9991217.jpg

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Thank You!

Questions?

Updated Abstract

Qualitative aspects of treatment with prolotherapy for knee osteoarthritis in a multi-method study

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CONTEXT Prolotherapy is an injection-based treatment for chronic musculoskeletal pain consisting of an irritant solution injected on painful ligament and tendon attachments and in adjacent joint space. Objective results in the parent study suggest a 30-40% improvement in overall knee osteoarthritis (OA) related quality of life compared to baseline status. The qualitative response of patients receiving prolotherapy is not known.

OBJECTIVE To assess the qualitative response of subjects who recently received prolotherapy for knee OA in a clinical trial.

DESIGN We conducted semi-structured, in-depth telephone interviews. Transcribed responses were discussed by co-authors to identify major themes; disagreements were resolved by consensus.

SETTING Primary care, university based, outpatient Family Medicine clinic.

PARTICIPANTS Twenty-two participants randomly selected from three recent knee OA prolotherapy studies.

RESULTS Qualitative data reflected variability in subject outcomes; most had substantial symptom reduction and quality of life improvement. Four major themes emerged: most participants reported (1) improvement in pain and ability to perform activities of daily living; (2) safety; there were no long-term side effects; (3) pre-treatment counseling enhanced treatment adherence and optimism; (4) overall positive experience with prolotherapy. Three minor themes emerged: (1) confirmation of current prolotherapy practices; (2) functional improvement without pain reduction; (3) prolotherapy has the potential to prolong surgery.

CONCLUSIONS For most, prolotherapy improves pain and functioning without side effects. Clear, complete description of the study rationale and procedures may enhance optimism and adherence to treatment appointment. Regardless of clinical outcome, subjects reported that they would recommend prolotherapy to others and receive it again in the future for this or other indications, suggesting an overall positive clinical experience. Participant reports confirm the current use of multiple treatment sessions and recommendation of post-treatment rest. Prolotherapy may be a worthwhile treatment to prolong the need for surgery.