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Original Research Article

Comparing the Efficacy of Varied Dextrose Prolotherapy Concentrations in Treating Osteoarthritis of the Knee: A Double-Blind Randomized Trial

Shikha[1], Pooja Priyam[2], Vikas Kumar[3]

[1]Senior Resident, Department of Physical Medicine and Rehabilitation, Patna Medical College & Hospital, Patna, Bihar, India

[2]Senior Resident, Department of Physical Medicine and Rehabilitation, Patna Medical College & Hospital, Patna, Bihar, India

[3]Professor & Unit Heading, Department of Physical Medicine and Rehabilitation, Patna Medical College & Hospital, Patna, Bihar, India

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Corresponding Author: Dr. Vikas Kumar

Conflict of interest: Nil

Abstract:

Background: Osteoarthritis (OA) of the knee poses a significant burden due to its associated pain, stiffness, and decreased mobility. Traditional treatments often provide only temporary relief, prompting exploration of alternative therapies like dextrose prolotherapy. However, the optimal concentration of dextrose for maximal efficacy remains uncertain. The objective of the study is to compare the efficacy of varied dextrose prolotherapy concentrations in treating osteoarthritis of the knee, specifically evaluating their impact on pain reduction and functional improvement in affected individuals.

Methods: A double-blind randomized comparative study was conducted over two years. Sixty participants aged 40 to 70 with knee OA were randomized into two categories: Category A (12.5% dextrose) and Category B (25% dextrose). Pain scores and functional outcomes were calculated at baseline, 12 weeks, and follow-ups at 24 and 48 weeks.

Results: Baseline characteristics were comparable between categories. At 24 and 48 weeks, Category B exhibited significantly lower pain scores than Category A ($p = 0.049$, $p = 0.021$). Functional outcomes favored Category B at 48 weeks ($p = 0.028$). No significant adverse effects were reported.

Conclusion: Higher concentrations of hypertonic dextrose (25%) led to superior long-term pain reduction and functional improvement compared to 12.5% in knee OA. Hypertonic dextrose prolotherapy appears safe and effective, warranting further investigation for optimized treatment protocols.

Recommendations: Further research should explore the long-term effects and optimal dosing of hypertonic dextrose prolotherapy for knee OA management.

Keywords: Osteoarthritis, Dextrose prolotherapy, Concentration, Pain reduction, Functional improvement.

Introduction

Osteoarthritis (OA) of the knee is a degenerative joint disease described by the breakdown of cartilage, leading to pain, stiffness, and decreased mobility. Traditional treatment options include physical therapy, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroid injections. However, these treatments often provide only temporary relief and can have significant side effects. In recent years, dextrose prolotherapy has emerged as a promising alternative, offering a less invasive and potentially longer-lasting solution to knee OA management. This therapy involves the injection of a dextrose solution into the joint space or surrounding ligaments to encourage the body's healing response. The efficacy of dextrose prolotherapy, particularly how varying concentrations of dextrose affect outcomes, has become a subject of interest within the medical community.

Dextrose prolotherapy (DPT) works on the principle of inducing a mild inflammatory response. This response triggers the release of growth factors and stimulates the deposition of new collagen, leading to the strengthening of ligaments and tendons around the joint and potentially the regeneration of cartilage [1]. The concentration of dextrose used in prolotherapy is thought to play a crucial role in the therapy's effectiveness, with higher concentrations potentially leading to a more robust healing response.

Several studies have compared the efficacy of different dextrose concentrations in treating knee OA. A randomized controlled trial comparing the outcomes of knee OA patients administered with

prolotherapy using different dextrose concentrations. The study found that higher concentrations of dextrose were related with greater improvements in pain and function compared to lower concentrations [2]. Similarly, a systematic review evaluated the effectiveness of prolotherapy for knee OA across multiple studies and suggested that dextrose concentrations ranging from 10% to 25% were most effective in easing pain and improving joint function [3].

However, the optimal concentration of dextrose for maximizing therapeutic outcomes without increasing the risk of adverse effects remains a topic of debate. Some researchers argue that very high concentrations of dextrose may cause unnecessary discomfort and could potentially lead to tissue damage [4]. Therefore, finding the balance between efficacy and safety is crucial in the application of dextrose prolotherapy for knee OA.

DPT presents a promising treatment option for patients with OA of the knee, offering potential benefits over traditional therapies. The concentration of dextrose used in the treatment plays a significant role in its efficacy, with current evidence suggesting that moderate to high concentrations may offer the best balance between effectiveness and safety.

Therefore, the aim of this study is to compare the efficacy of varied dextrose prolotherapy concentrations in treating osteoarthritis of the knee, specifically evaluating their impact on pain reduction and functional improvement in affected individuals.

Methodology

Study Design: This study adopted a double-blind randomized comparative design.

Study Setting: The study was carried out at the Physical Medicine and Rehabilitation Department of Patna Medical College and Hospital over a period from March 2021 to February 2023.

Participants: A total of 60 participants diagnosed with osteoarthritis of the knee were recruited for this study.

Inclusion Criteria: Participants included individuals diagnosed with osteoarthritis of the knee, aged between 40 to 70 years, and willing to participate in the study.

Exclusion Criteria: Exclusion criteria comprised previous knee surgery within the last year, intra-articular steroid injection within the last three months, allergy to dextrose or any component of the prolotherapy solution, and severe comorbidities such as uncontrolled diabetes, cardiovascular diseases, or malignancy.

Bias: To minimize bias, both participants and assessors were blinded to the treatment allocation. Randomization was achieved using a computer-generated randomization table.

Variables: The independent variable was the concentration of hypertonic dextrose used in prolotherapy (12.5% for Category A and 25% for Category B), while the dependent variables included pain scores, functional outcomes, and adverse effects.

Data Collection: Baseline demographic data and clinical characteristics were recorded initially. Following randomization, participants received prolotherapy injections consisting of either 12.5% or 25% hypertonic dextrose solution at 0, 3rd, 6th, and 9th weeks. Follow-up assessments were conducted at regular intervals.

Procedure

1. Participants were randomly assigned to Category A (12.5% hypertonic dextrose) or Category B (25% hypertonic dextrose).
2. The injection site was prepared following universal precautions, and a lignocaine sensitivity test was performed before injecting 2% lignocaine followed by the hypertonic dextrose solution into the affected knee.
3. Ice massage and paracetamol were administered for pain management.
4. A standardized exercise program was prescribed starting from the 3rd day post-injection.
5. Participants were advised to avoid activities such as squatting, cross-leg sitting, and excessive stair use.

Statistical Analysis: Statistical analysis was accomplished using SPSS software version 18. Between-category comparisons were performed using appropriate parametric or non-parametric tests depending on the distribution of the data. p-values < 0.05 were regard as statistically considerable.

Ethical Considerations: The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

Result

Sixty participants diagnosed with osteoarthritis of the knee were involved in the study and randomized into two categories: Category A and Category B. Baseline characteristics including age, gender distribution, body mass index (BMI), and duration of osteoarthritis were comparable between the two categories (Table 1).

Table 1: Baseline Characteristics of Study Participants

Characteristics	Category A (n=30)	Category B (n=30)	p-value
Age (years), mean ± SD	58.3 ± 6.7	57.8 ± 7.1	0.732
Gender (M/F)	16/14	15/15	0.895
BMI (kg/m^2), mean ± SD	29.6 ± 3.2	30.1 ± 2.9	0.486
Duration of OA (months)	48.7 ± 12.5	47.2 ± 11.9	0.641

Outcome measures including pain scores and functional assessments were recorded at baseline, post-treatment (12 weeks), and at follow-up visits (24 weeks and 48 weeks). The pain scores, as measured by the Visual Analog Scale, were compared between Category A (12.5% Dextrose) and Category B (25% Dextrose) at different time points. At baseline, both categories exhibited comparable levels of pain, with Category A reporting a mean score of 7.2 ± 1.1 and Category B reporting 7.1 ± 1.0 (p = 0.754). Post-treatment (12 weeks), although Category B demonstrated a slightly lower mean pain score (4.0 ± 1.2) compared to Category A (4.5 ± 1.3), the difference was not statistically significant (p = 0.189).

However, at the 24-week follow-up, Category B showed a statistically significant reduction in pain scores (3.3 ± 1.1) compared to Category A (3.8 ± 1.2) (p = 0.049). This difference persisted at the 48-week follow-up, with Category B (3.0 ± 1.0) continuing to exhibit lower pain scores compared to Category A (3.6 ± 1.1) (p = 0.021).

The functional outcomes assessed at different time points for both categories. At baseline, the mean scores were similar between Category A (65.8 ± 8.5) and Category B (64.7 ± 7.9) (p = 0.621). Post-treatment (12 weeks), both categories showed improvements in functional outcomes, although the difference was not statistically substantial (p = 0.281).

However, at the 24-week follow-up, Category B demonstrated a trend towards greater improvement (40.2 ± 7.3) compared to Category A (42.6 ± 7.8), although this did not reach statistical relevant (p = 0.073). By the 48-week follow-up, Category B exhibited significantly better functional outcomes (36.1 ± 6.5) compared to Category A (38.5 ± 7.0) (p = 0.028).

These findings indicate that participants receiving 25% hypertonic dextrose experienced greater improvements in functional outcomes compared to those receiving 12.5% dextrose, particularly in the longer term. No significant adverse effects were reported in either category throughout the study duration.

Discussion

The study enrolled 60 participants diagnosed with osteoarthritis of the knee, randomly assigning them to Category A and Category B, with baseline characteristics, including age, gender distribution, BMI, and duration of osteoarthritis, being comparable between the two categories.

Pain scores, assessed via the Visual Analog Scale, showed no significant difference between the category post-treatment at 12 weeks. However, at the 24-week and 48-week follow-ups, Category B exhibited significantly lower pain scores compared to Category A (p = 0.049 and p = 0.021, respectively).

Functional outcomes demonstrated no significant variation between the categories at 12 weeks but showed a trend towards improvement favoring Category B at 24 weeks (p = 0.073) and significantly better outcomes at 48 weeks (p = 0.028).

These results suggest that participants receiving 25% hypertonic dextrose experienced greater improvements in both pain reduction and functional outcomes compared to those receiving 12.5% dextrose, with no significant adverse effects reported throughout the study duration.

The effectiveness and implications of hypertonic DPT in managing knee OA have been explored in various studies, highlighting its potential as a viable treatment option. A double-blind randomized comparative study emphasized the concentration-dependent symptomatic improvement in OA knee patients, suggesting a dose-response relationship with serial injections on the VAS [5]. Another study explored the early and longer-term analgesia effects of DPT in symptomatic Grade IV knee OA, noting significant analgesia and potentially favourable changes in synovial-fluid neurocytokine concentrations [6].

Comparative analysis across varied dextrose conc. found no statistically significant variance, suggesting the efficacy of DPT may not be strictly concentration-dependent [7]. Further research indicated that prolotherapy effectively enhances functional outcomes in all stages of knee OA [8]. The relationship between cartilage biomarker levels and functional outcomes in OA patients receiving DPT was also examined, indicating a potential for reduced cartilage degradation [9]. A study comparing the efficacy of DPT and ozone therapy in knee OA patients suggested that ozone therapy might offer more effective improvements in certain outcomes [10].

These studies collectively contribute to the increasing body of evidence supporting the use of

hypertonic dextrose prolotherapy in the management of knee osteoarthritis, highlighting its effectiveness, potential mechanisms of action, and comparative efficacy with other treatments.

Conclusion

The study compared the efficacy of different conc. of hypertonic DPT for knee osteoarthritis. It was found that participants receiving 25% hypertonic dextrose experienced significantly lower pain scores at 24 and 48 weeks compared to those receiving 12.5%. Additionally, functional outcomes favored the 25% dextrose category, with significant improvement at 48 weeks. No significant adverse effects were reported. These findings suggest that higher dextrose concentrations offer superior long-term pain reduction and functional improvement. Hypertonic DPT appears to be a safe and effective treatment option for knee osteoarthritis, warranting further research for optimized protocols.

Limitations: The limitations of this study include a small sample population who were included in this study. The findings of this study cannot be generalized for a larger sample population. Furthermore, the lack of comparison group also poses a limitation for this study's findings.

Recommendation: Further research should explore the long-term effects and optimal dosing of hypertonic dextrose prolotherapy for knee OA management.

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