

Clinical Outcomes of Hypertonic Dextrose Prolotherapy Injection in Obese Patients with Knee Osteoarthritis: A Quasi-Experimental Study

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Abstract

Background: Obesity is a major risk factor for knee osteoarthritis (KOA), contributing to pain, reduced joint function, and decreased quality of life. Hypertonic dextrose prolotherapy (HDP) has emerged as a potential treatment to lessen pain and improve function in KOA. This study aimed to observe the clinical outcomes of HDP injections in obese patients with KOA.

Methods: A quasi-experimental study was conducted in 2023, involved obese patients diagnosed with KOA. Participants were divided into two groups: an intervention group receiving HDP injections and a control group receiving normal saline (NS) injections. Clinical outcomes were assessed using the Numeric Rating Scale (NRS) for pain and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) before intervention, and at two and six weeks after intervention. Intergroup and intragroup mean differences were analyzed, with a significance value of $p<0.05$.

Results: A total of 38 participants were included, with 20 assigned to the HDP group and 18 to the control group. Intragroup analysis showed a significant reduction in NRS scores in both groups ($p<0.001$), whereas no significant intragroup change was observed in WOMAC scores. Intergroup analysis showed significantly greater improvement in both NRS and WOMAC scores in the HDP group compared with the control group at two and six weeks after intervention ($p<0.001$).

Conclusions: HDP injections improve clinical outcomes in obese patients with KOA, particularly in reducing pain intensity and improving functional status. Pain reduction may support participation in exercise and weight management programs, although persistent obesity may increase the risk of KOA recurrence.

Keywords: Hypertonic dextrose prolotherapy, knee osteoarthritis, obesity, numeric rating scale, WOMAC score.

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Introduction

Osteoarthritis (OA) is a degenerative joint disorder characterized by progressive destruction of the articular cartilage, which then extends to the subchondral bone and surrounding synovial structures. This process causes joint pain, stiffness, swelling, and limited function, making OA one of the leading cause of pain and disability.¹⁻³ Knee osteoarthritis (KOA) is the most common form of OA, and its development is strongly associated with several risk factors, including advanced age, gender, and a history of overweight or obesity.⁴

A meta-analysis of case-control and cohort studies revealed overweight or obesity, female sex, and age over 40 years as significant risk factors for KOA.⁵

Overweight and obesity increase the risk of OA through two potential mechanisms, including excessive mechanical loading on weight-bearing joints and systemic low-grade inflammation. OA affects approximately two out of every three individuals with obesity, and its frequency rises with elevated body mass index (BMI). Excess body weight contributes to increased joint loading, altered joint alignment, and muscular weakness, all of

which accelerate degenerative changes in the knee joint structure.⁶⁻⁸ Knee pain and obesity frequently coexist, and managing both can be challenging for various reasons.⁹

Current first-line management for KOA includes patient education, structured exercise program, and weight reduction, particularly in individuals with obesity. However, adherence to weight loss and physical activity recommendations is often poor, and many patients experience persistent pain despite conservative management. As a result, alternative non-surgical interventions are increasingly considered for symptom control and functional improvement.^{3,10}

Hypertonic dextrose prolotherapy (HDP) has emerged as a minimally invasive interventional treatment option for KOA and is recommended as an adjunctive therapy in the 2019 American College of Rheumatology/Arthritis Foundation guidelines for OA management.¹⁰ HDP is a non-surgical regenerative therapy involving the administration of an irritating solution, injected into painful or deteriorated tendon insertions, joints, ligaments, or surrounding joint spaces to stimulate tissue repair and reduce pain. HDP at a concentration of 12.5 to 25% is the most widely used prolotherapy solution, and several clinical trials have reported favorable outcomes. Injections of HDP infiltration across ligament and tendon insertions, administered intra- or extra-articularly, have been used for several decades to manage musculoskeletal pain, including knee

degeneration. Previous controlled studies and a recent meta-analysis have shown that HDP is effective in reducing pain and improving function in musculoskeletal disorders.^{11,12} Therefore, this quasi-experimental study aimed to evaluate clinical outcome of HDP injections in obese patients with KOA.

Methods

This quasi-experimental study involved patients with KOA and comorbid obesity. All participants were registered at the Department of Physical Medicine and Rehabilitation, Haji General Hospital of Surabaya, Indonesia, between May and August 2023. The inclusion criteria were patients with clinically diagnosed KOA, radiographic severity defined according to the Kellgren and Lawrence grading system, and comorbid obesity based on the Asia-Pacific body mass index (BMI) classification (BMI ≥ 25 kg/m²). Patients who met the eligibility criteria and provided written informed consent were included. Exclusion criteria comprised a history of knee surgery or knee replacement, previous knee injury, and prior intra-articular injections.

Participants were assigned into two groups: an intervention group and a control group. The intervention group received HDP injections administered in three components. The first component consisted of a 4 ml intra-articular injection of 25% hypertonic dextrose (HD). When joint effusion was present, aspiration was performed before injection (Figure 1).

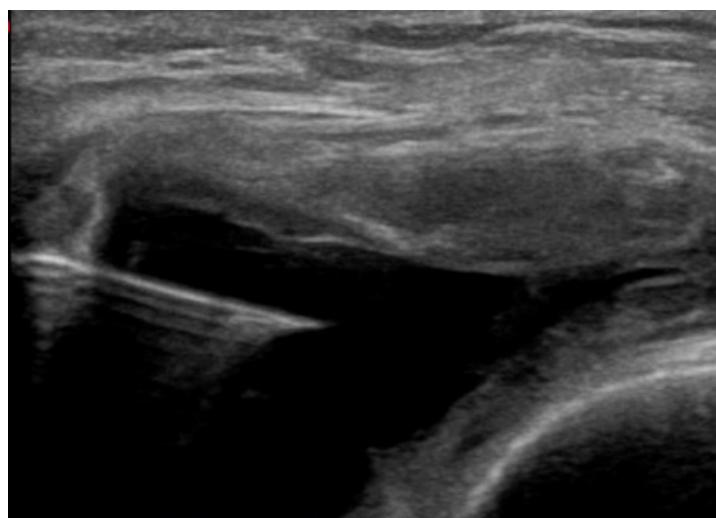


Figure 1 Ultrasound-Guided Aspiration of Knee Joint Effusion Before Intra-Articular Injection of 25% Hypertonic Dextrose



Figure 2 Ultrasound-guided Hypertonic Dextrose Injection at the Medial Collateral Ligament Insertion

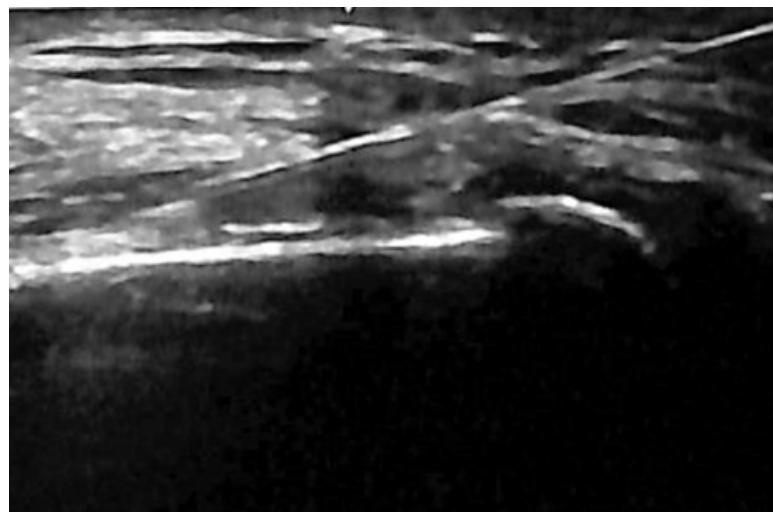


Figure 3 Ultrasound-guided Hypertonic Dextrose Injection at the Lateral Collateral Ligament Insertion

The second and third components involved injection of 15% HD at the insertion sites of medial collateral ligament (MCL) (Figure 2) and lateral collateral ligament (LCL) (Figure 3), respectively. The intervention group received injections on three occasions: at the first visit (week 0), second visit (week 2), and third visit (week 6).

The control group received intra-articular injections of normal saline (NS) combined with 1% lidocaine with volumes adjusted to individual patient need, administered at the same anatomical sites as the intervention group. The control group received a single

injection at the first visit (week 0). All intra-articular injections were performed under two-dimensional (2D) musculoskeletal ultrasound guidance using a Canon Xario 100 system equipped with an 18L7 linear transducer.

In addition to injection therapy, both groups underwent a standardized rehabilitation program consisting of short-wave diathermy (SWD), transcutaneous electrical nerve stimulation (TENS) twice weekly for six weeks, and quadriceps range-of-motion (ROM) exercises. Participants were trained to perform the exercises independently at home

on a daily basis for six weeks.

Baseline data, including age, gender, body weight, height, BMI (Asia-Pacific classification), and Kellgren and Lawrence grade, were recorded before the intervention. Radiographic severity was assessed using standard weight-bearing anteroposterior knee radiographs, with the Kellgren and Lawrence grades ranging from 0 to 4, where higher grades indicate more severe.

The primary outcomes were pain intensity assessed using the numeric rating scale (NRS) and functional status evaluated using the Western Ontario and McMaster Universities Arthritis Index (WOMAC). Outcomes were measured at three time points: before the intervention (week 0) and after the intervention (week 2 and week 6). The NRS measurement was carried out by direct patients interviews, with scores ranging from 0 (no pain) to 10 (very severe pain). WOMAC assessment was performed using the original 24-item English version of the questionnaire, covering pain, stiffness, and physical function. Participants completed the questionnaire independently; however, for those with difficulty reading or understanding English, trained interviewers administered the questionnaire verbally in Indonesian, maintaining the original wording to ensure consistency.

Descriptive data were summarized using Microsoft Excel 365 and presented as frequencies and percentages (%) or mean \pm standard deviation (SD). Normality testing demonstrated non-normal data distribution; therefore, non-parametric statistical analysis

were applied. The Mann-Whitney U test was performed for intergroup comparisons, whereas the Friedman test was used for intragroup comparisons across time points. Statistical analyses were performed using IBM SPSS version 26. Ethical approval for this study was obtained from the Medical Research Ethics Committee of Haji General Hospital of Surabaya, Indonesia (Approval No. 445/68/KOM.ETIK/2023).

Results

A total of 40 patients diagnosed with KOA and comorbid obesity who met the inclusion criteria were initially enrolled in this study. Participants were allocated into a control and an intervention (HDP) group. During the six-week follow-up period, two participants were lost to follow-up, thus the final analysis included 38 participants, comprising 20 patients in the HDP group and 18 patients in the control group. Baseline demographic and clinical characteristic, including age, gender, body weight, height, BMI, and Kellgren and Lawrence grade are presented in Table 1. No substantial baseline differences were observed between the two groups.

Both intragroup and intergroup analyses were performed, as shown in Table 2. Intragroup analysis showed significant improvements in the HDP group across all WOMAC domains (pain, stiffness, and physical function) from pre-intervention to week 2 and week 6 ($p<0.001$). In contrast, the control group did not show significant changes in

Table 1 Baseline Demographic and Clinical Characteristics of Participants

Variable	Control (n=18)	HDP (n=20)
Age (years), mean \pm SD	62.5 \pm 7.7	62.4 \pm 8.8
Gender (n, %)		
Male	3 (17%)	1 (5%)
Female	15 (83%)	19 (95%)
Body weight (kg), mean \pm SD	74.28 \pm 10.78	68.95 \pm 10.21
Height (cm), mean \pm SD	155.83 \pm 6.16	155.45 \pm 6.95
Asia-Pacific BMI Classification, n (%)		
Overweight (23–24.9 kg/m ²)	1 (5%)	1 (5%)
Obese I (25–29.9 kg/m ²)	8 (45%)	13 (65%)
Obese II (\geq 30 kg/m ²)	9 (50%)	6 (30%)
Kellgren-Lawrence grade, n (%)		
Grade 2	6 (33%)	3 (15%)
Grade 3	10 (56%)	13 (65%)
Grade 4	2 (11%)	4 (20%)

Note: BMI= Body mass index; SD= Standard deviation; HDP= Hypertonic dextrose prolotherapy

Table 2 Intragroup and Intergroup Comparisons of Numeric Rating Scale (NRS) and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) at Pre-intervention, Week 2, and Week 6

Variable	Control (n=18)	HDP (n=20)	p-value ^a
	Mean ± SD	Mean ± SD	
NRS			
Time point			
Pre-intervention	6.28 ± 0.82	6.55 ± 0.99	0.340
Week 2	5.44 ± 0.94	4.20 ± 1.05	0.001
Week 6	4.89 ± 1.02	1.90 ± 0.71	0.000*
Intragroup p-value ^b	0.000*	0.000*	
WOMAC pain			
Time point			
Pre-intervention	14.44 ± 2.91	14.5 ± 3.83	0.965
Week 2	13.94 ± 3.09	9.25 ± 3.93	0.001*
Week 6	13.27 ± 2.29	4.75 ± 3.17	0.000*
Intragroup p-value ^c	0.225	0.000*	
WOMAC stiffness			
Time point			
Pre-intervention	5.56 ± 1.24	5.60 ± 2.11	0.516
Week 2	5.25 ± 1.73	3.70 ± 1.72	0.009*
Week 6	5.00 ± 0.91	1.50 ± 1.00	0.000*
Intragroup p-value ^d	0.118	0.000*	
WOMAC physical function			
Time point			
Pre-intervention	50.22 ± 10.64	46.8 ± 14.76	0.558
Week 2	47.28 ± 11.28	27.2 ± 12.24	0.000*
Week 6	44.50 ± 11.96	9.65 ± 8.15	0.000*
Intragroup p-value ^e	0.526	0.000*	

Note: ^aIntergroup comparison (Mann-Whitney U test), ^{b-e}Intragroup comparison (Friedman test), *Statistically significant at $p<0.05$, NRS= Numeric rating scale, WOMAC= Western Ontario and McMaster Universities Arthritis Index; HDP= hypertonic dextrose prolotherapy.

WOMAC scores over the same period. Pain intensity assessed using the NRS evaluation showed significant reduction from pre-intervention to week 2 and week 6 in both groups ($p<0.001$).

Intergroup analysis showed no significant differences between group at pre-intervention. However, significant differences were observed at week 2 and week 6 in both NRS and WOMAC scores, favoring the HDP group ($p<0.001$). These findings indicate that HDP resulted in greater pain relief and functional improvement compared with the control intervention.

Discussion

This study evaluates the effectiveness of HDP in patients with KOA and comorbid obesity. KOA is a progressive degenerative joint disease that requires comprehensive management,

particularly in individuals with obesity, which is a primary risk factor accelerating disease progression.¹³ To our knowledge, this study is among the first to specifically examine the clinical effects of HDP injection in obese patients with KOA. Severe pain and restricted range of motion are the primary issues faced by KOA sufferers, significantly impairing daily activities, productivity, and quality of life.^{12,14,15} Therefore, clinical outcomes in this study were assessed using the NRS and the WOMAC at pre-intervention, two weeks and six weeks after intervention.

Both intergroup and intragroup analyses demonstrated significant changes in pain intensity measured by NRS. Intragroup analysis showed significant pain reduction over time in both the HDP and control groups. However, intergroup analysis showed significantly greater pain in the HDP groups at weeks two and six. These findings are consistent

with previous randomized controlled trial comparing intra-articular HDP with NS injections, which reported significantly greater pain reduction in the HDP group based on visual analog scale assessments.^{16,17}

This study also assesses functional outcomes using the WOMAC questionnaire, including pain, stiffness, and physical function categories, resulting significant improvement in the HDP group. Intergroup analysis showed significant differences favoring the HDP group at weeks two and six, meanwhile intragroup analysis showed significant improvements across all WOMAC categories in the HDP group. These findings align with other studies reporting superior WOMAC scores improvements in patients receiving HDP compared with NS control.^{16,18} A meta-analysis study further supports these results, showing that HDP is more effective than saline injections in improving WOMAC outcomes in patients with KOA.¹⁴

Hypertonic dextrose is an inexpensive, accessible, and minimally invasive treatment option that has gained attention as an alternative injection-based therapy for chronic musculoskeletal conditions. Evidence suggests that HDP is comparable to other therapy choices in enhancing pain, function, and quality of life, while maintaining a favorable safety profile. HDP has been recommended for KOA based on well-designed clinical trials, with a strength of recommendation level B.^{19,20} The positive effects of HDP were noted in the short-, medium-, and long-term benefits, including sustained clinical improvements up to one-year after treatment.¹⁵ The present findings are similar to these reports, showing the effectiveness of HDP at a shorter duration of 6 weeks after intervention. Additionally, a study evaluating HDP in advanced KOA have reported rapid analgesic effects and increase of synovial substance P levels shortly after injection.²¹

Reduction in collagen deposition and chondrocytes proliferation have been found in osteoarthritic joints, which has encouraged the development of therapies to regenerate cartilage.²² HDP is the most widely used of these treatments and produces a mild inflammatory state in response to cellular stress, leading to the cytokines release, thus boosting growth factors' activity and promoting the proliferation of tissue-specific healing cells. The findings suggest that treatment with HDP is more persistent and superior to corticosteroids in the mid-treatment follow-up. HDP injection for KOA has been shown to support tissue

repair or growth by increasing growth factors levels in the target tissues. HDP causes tissue repair by inducing inflammation, so that the effects appear more slowly, within a week or two, but are more stable and sometimes last for months.^{23,24} HDP has also been suggested as a soft tissue strengthener. Ligament laxity has been shown to improve with HDP injections. Tissue stability has also been proposed as a potential reason for pain reduction in injected joints.²⁵

This study has several limitations. First, the non-randomized design may introduce selection bias. Second, although NRS and WOMAC are validated instruments, they rely on subjective patient-reported outcomes. Third, the absence of a validated Indonesian version of the WOMAC questionnaire may introduce interpretation bias, although interviewer assistance was provided.

In conclusion, HDP improves clinical outcomes in obese patients with KOA, as reflected by reduction in pain intensity and improvements in function measured by NRS and WOMAC scores. HDP may serve as a potential bridge to break the KOA-obesity cycle. By reducing pain intensity, patients are able to engage in exercises and physical activity, thereby supporting weight loss and a healthier lifestyle. Consequently, addressing obesity may also lessen the KOA severity, and improve quality of life.

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Authors' Contributions

RV contributed to study conceptualization and design, methodology development, participant recruitment and data collection, data analysis and interpretation, manuscript drafting, and manuscript review. AZZAH contributed to data analysis and interpretation, manuscript drafting, and manuscript review.

Conflict of Interest

The authors declare no conflict of interest.

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