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STUDY TO COMPARE THE EFFECTIVENESS OF 25% DEXTROSE PROLOTHERAPY AND METHYL PREDNISOLONE IN PRIMARY OSTEOARTHRITIS OF KNEE IN TERMS OF PAIN AND IMPROVEMENT OF KNEE FUNCTION

Rheumatology

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ABSTRACT

Limited studies are available in management of primary osteoarthritis of knee with prolotherapy with 25% dextrose and methyl prednisolone. A prospective comparative study was conducted to see the effectiveness of 25% dextrose prolotherapy and methyl prednisolone in primary osteoarthritis of knee in terms of pain and improvement of knee function in sixty-six patients in age group of 50 to 70 yrs attending PMR department, RIMS, Imphal. The first group received 6 ml injections of 25% dextrose, 3 times at baseline, 1st month and 4th month and the second group received single dose of 80 mg of methyl prednisolone intra- articularly. In both the groups 50 mg of tramadol tablet and isometric strengthening exercise of quadriceps was given. Assessment was done at baseline, at 1st, 4th and 8th months by VAS and WOMAC. Statistically significant improvement was noted in VAS (5.91±0.82 to 2.65±0.94) and WOMAC score (45.25±6.68 to 20.25±7.67) at end of 8th month in first group. It was concluded that 25% dextrose was more effective than in management of primary osteoarthritis of knee.

KEYWORDS

WOMAC, VAS, KL grade, Prolotherapy

Introduction

Osteoarthritis (OA) is the commonest joint disease affecting the human body and is an important cause of disability. It is characterized by focal loss of cartilage with evidence of accompanying peri-articular response in the form of subchondral bone sclerosis and attempted new bone formation in the form of osteophytes. According to WHO, Osteoarthritis is the 2nd most common musculoskeletal problem in world population after back pain (Das, 2009).

Prolotherapy is also known as "proliferation therapy or regenerative injection therapy or proliferative injection therapy" It involves injecting an otherwise non-pharmacological and non-active irritant solution into the body, generally in the region of tendons or ligaments for the purpose of strengthening weakened connective tissue and alleviating musculoskeletal pain. The precise mechanism of action for prolotherapy is currently unclear. Prolotherapy, in clinical practice most commonly, hyperosmolar dextrose (a sugar) is the solution used. Lidocaine (a commonly used local anesthetic), phenol and sodium morrhuate (a derivative of cod liver oil extract) are other commonly used agents (Rabago, Slattengren & Zgierska, 2010; Baurer, 2015; Alderman, 2007).

Numerous studies have been conducted on corticosteroids, and its optimal dosing regimen for the intra-articular treatment of osteoarthritis. However, consensus has still not been established (Douglas, 2012).

Hence, this study was undertaken to compare the effectiveness of 25% dextrose prolotherapy and methyl prednisolone in primary osteoarthritis of knee in terms of pain and improvement of knee function"

Methods:

A prospective comparative study was conducted in the Department of Physical Medicine and Rehabilitation, RIMS, Imphal during October, 2015 to April, 2017. Sixty-four patients with primary knee osteoarthritis, in the age group of 50-70 years, with KL grade 2 and 3 and who gave informed consent were included in the study. The diagnosis of knee osteoarthritis was made on the basis of the results of clinical examination and antero-posterior standing radiography. All patients with inflammatory joint diseases, metabolic diseases of the bone, known blood diseases, systemic metabolic diseases including uncontrolled diabetes, immunodeficiency, Hepatitis B or C, systemic and local infections, severely moribund patients and KL grade 4 were excluded from the study.

Before the start of the study, the pain intensity was determined by using Visual Analogue Scale (VAS). In this scale, 0 indicated no pain and 10 indicated the worst pain. All patients also completed the Western Ontario and Mc Master University Arthritis index (WOMAC) assessment, which ranges from 0 to 100 and lower scores indicate better knee status.

The patients were randomized into two groups (dextrose group and methyl prednisolone group) by using block randomization.
Patients were made to lie down in supine position and the knee was kept in slightly flexed position.

The first group was injected with 6 ml of 25% of dextrose intra articularly through the supero-lateral approach. The second group was injected with single dose of 80 mg methyl prednisolone intra-articularly through the supero-lateral approach. Both group received 50 mg of tramadol tablet along with isometric strengthening of Quadriceps.

The injections were repeated three times for 25% dextrose, 0, 1st, 4th month. Follow ups were done at 1st, 4th, 8th month and the outcomes, i.e. pain intensity and function were determined by visual analogue scale (VAS) and Western Ontario McMaster University Osteoarthritis Index (WOMAC) scores.

Ethical Approval: All the participants were informed about the nature of the project and informed consent was taken. Ethical approval was taken from Institutional Ethics Committee, RIMS, Imphal.

Statistical analysis:

Statistical analyses were performed by SPSS statistical software version 21. The pre-treatment and post-treatment outcomes within the group were compared using paired t- test. Comparison between the two groups was done by independent samples t-test for quantitative data and chi-square test and Fisher exact test for qualitative data. P-value of <0.05 was taken as statistically significant.

Results:

The background characteristics of the study groups are presented in table 1 which shows no statistically significant difference between the

two groups. Before treatment, there is no significant difference in VAS and WOMAC score of both the groups (P>0.05). There was increase in VAS score from 5.91±0.82 at baseline to 6.47±0.57at first follow up. But reduced significantly to 2.65±0.947at end of 8th month (P<0.05) in 1st group. Among the methyl prednisolone group the VAS reduced maximum at 1st follow up 6.38±0.55 to 4.44±1.01 but at end of 8th month 5.91±0.82. The WOMAC score among dextrose group increased from 45.25±6.68 to 46.88±7.14 1st follow up, but significant reduction at the end of the study i.e. 20.25±7.67 (P<0.05). There was no significant reduction among the second group, 47.81±1.91 to 45.88±1.34 at end of the study.

Table1: Baseline characteristics of study group

Variables		1st group n(%) N=32	2nd group n(%) N=32	P value
Age	50-60	22(68.8)	21(65.6)	.762
	61-70	10(31.3)	11(34.4)	
Sex	M	25(78.1)	24(75)	.768
	F	7(21.9)	8(25)	
Duration(month)	<6 month	11(34.4)	13(40.6)	0.161
	6-12	13(40.6)	12(37.5)	
	12-24	2(6.3)	6(18.8)	
	24-48	4(12.5)	1(3.1)	
	>48	2(6.3)	0	
BMI(Kg/m^2)	25-30	32(100)	32(100)	0.576
KL-grade	Grade 2	16(50)	15(46.9)	0.802
	Grade 3	16(50)	17(53.1)	

Variables		Case group n(%) N=32	Control group n(%) N=32	P value
Occupation	Housewife	22(68.8)	23(71.9)	0.580
	Gov. employee	2(6.3)	3(9.4)	
	Self-business	2(6.3)	2(6.3)	
	Laborer	1(3.1)	3(9.4)	
	Shopkeeper	2(6.3)	1(3.1)	
	Actress	1(3.1)	0	
	Soldier	1(3.1)	0	
	Veg seller	1(3.1)	0	
Side of Affection	Both	3(9.4)	0	0.202
	Right	13(40.6)	17(53.1)	
	Left	16(50.0)	15(46.9)	
VAS		5.91±0.82	6.38±0.55	0.009
WOMAC		45.25±6.68	47.81±1.91	0.792

Significant p value <0.05 at 95 % confidence interval

1. VAS score
Table:2

VAS Score	1st group	2nd group	P value
Baseline	5.91±0.82	6.38±0.55	0.009
1st followup	6.47±0.57	4.44±1.01	<0.001
2nd followup	5.44±0.80	4.78±0.42	<0.001
3rd followup	2.65±0.94	5.91±0.82	<0.001
Difference			
• **1month**	-0.562	1.94	-
• **4 month**	0.468	1.59	-
• **8 month**	3.25	0.47	-

From above table it is clear that improvement in VAS score at 8th month in 1st group is 3.25(p<0.001) while in 2nd group 0.47.

2. WOMAC Score
Table:3

WOMAC	1st group	2nd group	P value
Baseline	45.25±6.68	47.81±1.91	0.792
1st followup	46.88±7.14	43.25±1.59	<0.001
2nd followup	33.81±7.66	43.38±1.48	<0.001
3rd followup	20.25±7.67	45.88±1.34	<0.001
Difference			
• **1month**	-1.37	4.56	-
• **4 month**	11.44	4.44	-
• **8 month**	25.0	1.94	-

Table 3 shows that at baseline WOMAC score in dextrose group was 45.25±6.68 and in 2nd group was 47.81±1.91 and the difference was not statistically significant. However, at 3rd follow up, the WOMAC score was significantly different between the two groups.

DISCUSSION

In this study, it was observed that there was significant improvement in functional disability at eight month of follow up. At baseline, the mean WOMAC score was 45.25±6.68 in the dextrose group and 47.81±1.91 in methyl prednisolone group. WOMAC score was 20.25±7.67 in the 1st group and 45.88±1.34 in the 2nd group at third follow up, i.e. at the end of eighth month. The improvement in WOMAC score was more in the first group with improvement in score of 25.0 as compared to with improvement of 1.94 from baseline.

A study on a total of 24 female patients (average age: 58.37 ± 11.8 years old). The patients received 3-monthly injection of 20% Detrose prolotherapy. Before the treatment mean VAS scale at was 8.83 ± 1.37. At the end of 24 week pain severity decreased to 4.87 ± 1.39, 45.86% (p < 0.001). (Eslamian & Amouzandeh, 2015)

In a study, 128 patients compared the effect of prolotherapy with 25% Dextrose intraarticular and 15% Dextrose extra-articular in osteoarthritis of knee. It was reported that there was significant improvement in WOMAC and VAS (p < 0.001). (Soliman, Sherif & Omar, 2016).

This study also shows that all subjects had some degree of improvement in pain and functional score in both the groups. Improvement in VAS score at 8th month in the dextrose group is 3.25(p<0.05).

This study also showed functional improvement as measured by WOMAC score in both the groups. The WOMAC score in the 1st group was 45.25±6.68 at baseline, which reduced to 20.25±7.67at 3rd follow up at eight month (p<0.001).

No adverse reaction occurred in any patient in both the groups, which suggests that 25% dextrose prolotherapy is safe in osteoarthritis knee, if not otherwise contraindicated.

Limitations of the study: Small sample size in each group, short period follow up period of only 8months, which is relatively short for a chronic disease like osteoarthritis of knee.

However, our study results are generally consistent with other studies on prolotherapy with 25% D and methyl prednisolone in subjects with osteoarthritis of knee. The results of this study introduce intervention therapies that resulted in significant reduction in pain and improvement in function, which is main focus in the treatment of osteoarthritis of knee. As such these interventions may be a possible treatment for patients with osteoarthritis of knee (OA).

Conclusion:

From the study it was found that 25% dextrose prolotherapy was better than methyl prednisolone in long term (8th month) for pain relief and functional improvement in patients of primary KL Grade 2 and 3 osteoarthritis of knee.

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