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Original Research Article

Comparison between 25% dextrose prolotherapy and single dose of platelet rich plasma in the management of pain and improvement of functional outcome in patients suffering from primary knee osteoarthritis: a randomized controlled trial

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ABSTRACT

Background: One of the most prevalent and disabling diseases worldwide, which decreases patients' quality of life (QoL) is knee osteoarthritis. However, pharmacological and non-pharmacological treatments, apart from complications, could not desirably control the disease. Limited studies are available in management of primary osteoarthritis of knee with prolotherapy with 25% dextrose and platelet rich plasma (PRP). Objective was to compare between 25% dextrose prolotherapy and single dose of PRP injection in the management of pain and improvement of functional outcome in patients suffering from primary knee osteoarthritis.
Methods: A comparative study was conducted to see the effectiveness of 25% dextrose prolotherapy and PRP in primary osteoarthritis (OA) of knee in the management of pain and improvement of functional outcome in sixty-six patients in age group of 50 to 70 years attending PMR department OPD, RIMS, Imphal between october2018 to April 2020. The first group received 6 ml injections of 25% dextrose 3 times at baseline, 1 month and 4th month, whereas the 2nd group received single dose of 5ml PRP at baseline.
Results: In both the groups 50 mg of tramadol tablet and isometric strengthening exercise of quadriceps was given. Assessment was done at baseline, at 1, 4 and 8 months by visual analogue scale (VAS) and western Ontario and McMaster university arthritis (WOMAC) index. 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 8 month in first group.
Conclusion: It was concluded that 25% dextrose was more effective than in management of primary osteoarthritis of knee.

Keywords- Prolotherapy, WOMAC, KL grading, PRP

INTRODUCTION

Osteoarthritis 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[1]. 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 anaesthetic), phenol and sodium morrhuate (a derivative

of cod liver oil extract) are other commonly used agents.[2,3] Numerous studies have been conducted on PRP, and its optimal dosing regimen for the intra-articular treatment of osteoarthritis. However, consensus has still not been established. Hence, this study was undertaken to compare the effectiveness of 25% dextrose prolotherapy and PRP 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 2018 to April 2020. 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 VAS. In this scale, 0 indicated no pain and 10 indicated the worst pain. All patients also completed the 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 PRP 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 particularly through the supero-lateral approach.

In PRP group 50 ml of blood was taken from an antecubital vein and placed in the centrifuge kit (standard kit) containing citrate phosphate dextrose (CPDA). Blood was centrifuged in standard kit at 1200 rpm for 15 minutes.[4] Then, the sediment (red blood cells) was placed in the first bag and the supernatant (plasma) in the second bag. It was centrifuged again at 2700 rpm for six minutes. After extraction of free platelet plasma, 5 ml of platelet-rich plasma was injected into the knee joint by supero-lateral approach. Both groups 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 1, 4, 8 month and the outcomes, i.e. pain intensity and function were determined by VAS and WOMAC scores.

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 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±0.57 at first follow up. But reduced significantly to 2.65±0.947 at end of 8th month (p<0.05) in 1st group.

Among the PRP group the VAS reduced maximum at 1st follow up 6.38±0.55 to 4.44±1.01 but at end of 8 month 5.91±0.82. The WOMAC score among dextrose group 1st increased from 45.25±6.68 to 46.88±7.14 1 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.

From table 2 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.

Table 3 shows that at baseline WOMAC score in 1st 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.

Table 1: Baseline characteristics of study group.

Variables		1st group, N=32 (%)	2nd group, N=32 (%)	P value
Age (Years)	50-60	22 (68.8)	21 (65.6)	0.762
	61-70	10 (31.3)	11 (34.4)	
Gender	Male	25 (78.1)	24 (75)	0.768
	Female	7 (21.9)	8 (25)	
Duration (Months)	<6	11 (34.4)	13 (40.6)	0.161
	6-12	13 (40.6)	12 (37.5)	

Continued.

Variables		1st group, N=32 (%)	2nd group, N=32 (%)	P value
	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)	
Occupation	Housewife	22 (68.8)	23 (71.9)	0.580
	Govt. employee	2 (6.3)	3 (9.4)	
	Businessman	2 (6.3)	2 (6.3)	
	Policeman	1 (3.1)	0	
	Labourer	1 (3.1)	3 (9.4)	
	Vegetable vendor	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		5.19±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

Table 2: VAS score comparison.

VAS score	1st group	2nd group	P value
Baseline	5.91±0.82	6.38±0.55	0.009
1st follow up	6.47±0.57	4.44±1.01	<0.001
2nd follow up	5.44±0.80	4.78±0.42	<0.001
3rd follow up	2.65±0.94	5.91±0.82	<0.001
Difference			
1 Month	-0.562	1.94	-
4 Months	0.468	1.59	-
8 Months	3.25	0.47	-

Table 3: WOMAC score comparison.

WOMAC score	1st group	2nd group	P value
Baseline	45.25±6.68	47.81±1.91	0.792
1st follow up	46.88±7.14	43.25±1.59	<0.001
2nd follow up	33.81±7.66	43.38±1.34	<0.001
3rd follow up	20.25±7.67	45.88±1.48	<0.001
Difference			
1 Month	-1.37	4.56	-
4 Months	11.44	4.44	-
8 Months	25	1.94	-

DISCUSSION

In this study, it was observed that there was significant improvement in functional disability at eight months of follow up. At baseline, the mean WOMAC score was 45.25±6.68 in the dextrose group (1st group) and 47.81±1.91 in PRP group (2nd 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% dextrose 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).[5] 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). 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 8 months in the dextrose group is 3.25 ($p<0.05$).[6]

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±7.67 at 3rd follow up at eight months ($p<0.001$).

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

Small sample size in each group, short period follows up period of only 8 months, 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% dextrose and PRP 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.

CONCLUSION

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

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REFERENCES

1. Das S. Manual of Rheumatology. Osteoarthritis. (3rd ed.). Mumbai: Indian Rheumatology Association. 2009;243-8.
2. Alderman D. A reasonable and conservative approach to knee tendonitis/tendonosis, sprain-strains, instability, diagnosis of meniscal tear, patellofemoral pain syndrome including chrondromalacia-patellae, degenerative joint disease, and osteoarthritis pain. Pract Pain Management. 2007;7:70-1.
3. Baurer B. Prolotherapy: solution to low back pain. Available from http://www.mayoclinic.org/prolotherapy/expert-answers/faq-20058347. Accessed on 20/7/2020.
4. Forogh B, Mianehsaz E, Shoaee S, Ahadi T, Raissi GR, Sajadi S. Effect of single injection of platelet-rich plasma in comparison with corticosteroid on knee osteoarthritis: a double-blind randomized clinical trial. J Sports Med Phys Fitness. 2016;56(7-8):901-8.
5. Eslamian F, Amouzandeh B. Therapeutic effects of prolotherapy with intraarticular dextrose injection in patients with moderate knee osteoarthritis: a single-arm study with 6 months follow up. Therap adv musculoskeletal dis. 2015;7(2):35-44.
6. Soliman DMI, Sherif NM, Omar OH, Zohiery EIAK. Healing effects of prolotherapy in treatment of knee osteoarthritis healing effects of prolotherapy in treatment of knee osteoarthritis. Egypt Rheumatol Rehabi. 2016;43(2):47-52.

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