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Original Article

Orthopaedics Section

Effectiveness of Short Form-36 Health Status Questionnaire Versus WOMAC Arthritis Index Questionnaire on Chronic Knee Osteoarthritis Patients

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ABSTRACT

Introduction: Osteoarthritis is a common disease of aged population and one of the leading causes of disability. Key causes include obesity or overweight along with ageing. Knee osteoarthritis can cause significant pain and functional loss. As the disease progresses, it can cause chronic knee joint pain, muscle weakness, joint deformity and functional deficiency which leads to decreased quality of life. The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) is a 24-item questionnaire with 3 sub-scales measuring pain (5 items), stiffness (2 items) and physical function (17 items). Health related quality of life is measured using Short Form-36, used to examine health status in following eight domains: bodily pain, physical function, role limitations due to social problems, physical problems, general health, vitality, social function, mental health, role limitation due to physical problems.

Aim: To find the effect of Short Form-36 Health Status Questionnaire versus WOMAC Arthritis Index Questionnaire to measure the pain, Range of Motion (ROM) and disability in subjects with chronic knee osteoarthritis patients treated with Contrast Bath and Knee Exercises.

Materials and Methods: This was a longitudinal cohort study. A total of 90 patients were divided into two groups of 45 each. Each patient was given treatment for four weeks. Each patient was treated with Contrast bath and Knee Exercises. Group A patients were instructed to fill the Short Form-36 Health Status Questionnaire and Group B patients were instructed to fill the WOMAC Arthritis Index Questionnaire and outcome measures were collected on day 1, at the end of 2nd week and at the end of 4th week. Data from study were analysed using the statistical package SPSS 19.0 (SPSS Inc., Chicago, IL) and level of significance was set at $p<0.05$.

Results: Group B shows a mean of the total score of WOMAC Arthritis Index Questionnaire which was 74.66 (SD 10.01) on Day 1; mean of 49.02 (SD 12.08) at the end of the 2nd week and a mean of 20.68 (SD 12.23) at the end of 4th week. The p-value was found to be 0.0001. The percentage disability evaluated by the WOMAC Arthritis Index Questionnaire shows a mean of 78 (SD 10) on Day 1; mean of 51 (SD 12) at the end of 2nd week and a mean of 22 (SD 13) at the end of 4th week. On day 1 Short Form-36 Questionnaire, total score of group A was 88.24 (SD 6.72) and at the end of 2nd week and 4th week, the mean score was 94.06 (SD 5.10) and 98.72 (SD 4.55), respectively with statistically significant difference p-value (0.0001).

Conclusion: The present study showed that the WOMAC Arthritis Index Questionnaire had superior sensitivity in reducing pain and increasing range of motion and thus by decreasing the disability.

Keywords: Contrast bath, Knee exercises, Range of motion, Visual analogue scale

INTRODUCTION

Osteoarthritis is the most common disease of aged population and one of the leading causes of disability [1]. It is characterised by loss of articular cartilage, hypertrophy of bones at the margins which include the subchondral sclerosis and decreased joint range of motion which in turn leads to biochemical and morphological alterations of the synovial membrane and joint capsule [2]. The proportion of people affected with knee osteoarthritis is due to obesity or overweight along with ageing [3]. In India, 8% of the total population are above 60 years in 2010 and is likely to rise by 21% by 2050 [4].

Osteoarthritis is due to strenuous physical activity like kneeling on the knees, squatting and prolonged standing as well as knee trauma and injury [5]. The risk factors in chronic knee osteoarthritis are multifactorial: female patients, elderly, obesity, knee injury, overuse of joints, reduced bone density, weakness of muscles and laxity of joints [6]. Previous knee trauma is 386 times prone to increase the risk of knee osteoarthritis [7].

Various researchers in several cross-sectional and longitudinal studies found the association between obesity and its prevalence of knee osteoarthritis [8]. Further, the obesity increases the risk of knee osteoarthritis by multiple mechanisms that are increased joint loading, change in body composition and behavioral factors such as diminished physical activity and subsequent loss of protective muscle strength [9].

Knee osteoarthritis can cause significant pain and functional loss. As the disease progresses, it can cause chronic knee joint pain, muscle weakness, joint deformity and functional deficiency which leads to decreased quality of patient life [10]. Patients may experience a serious impact to daily activities due to difficulty in walking, moving, climbing stairs, getting in and out of the car and sitting on a chair that is caused by instability or buckling of the joints together with the weakness of thigh muscles [11].

The prime objective of physical therapy in chronic knee osteoarthritis patients is to relieve knee joint pain, knee joint stiffness and maintaining or improving physical function to empower the patient to be an effective self-manager [12].

The intermittent application of superficial heat or cold is safe and cost-effective treatment. This can be recommended distinctly or along with other treatment. Contrast bath involves intervals of warm and cold application within a treatment session [13]. Warm may work by improving circulation and relaxing muscles so decreasing

pain, while a cold may numb the pain, decrease swelling, constrict blood vessels and block nerve impulses to the joint [14].

Followed to contrast bath treatment a highly recommended treatment for osteoarthritis is knee exercises which were well proved and has the beneficial effects on reducing pain, improving function and reducing disability in acute and chronic knee pain patients [15]. Exercise treatments can alter sensory input from the periphery by modification of muscle control and improved proprioception to enhance control of the affected joint, thus reducing nociceptor discharge and enhancing normal sensory input [16].

The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index Questionnaire is used for evaluation of patients functions in knee osteoarthritis. The WOMAC is a 24-item questionnaire with 3 sub scales measuring pain (5 items), stiffness (2 items) and physical functions (17 items) [17]. Health related quality of life is measured using Short Form-36, used to examine health status in following 8 domains: Bodily pain, physical function, role limitations due to social problems, physical problems, general health, vitality, social function, mental health, role limitation due to physical problems [10].

The main objective of this study was to compare the efficacy of Short Form-36 health status questionnaire with WOMAC Arthritis Index Questionnaire.

Null hypothesis: There will be no significant difference in Short Form-36 Health Status Questionnaire versus WOMAC Arthritis Index Questionnaire to measure the pain, ROM and disability in subjects with chronic knee osteoarthritis patients treated with Contrast Bath and Knee Exercises.

Alternative hypothesis: There will be significant difference in Short Form-36 Health Status Questionnaire versus WOMAC Arthritis Index Questionnaire to measure the pain, ROM and disability in subjects with chronic knee osteoarthritis patients treated with Contrast Bath and Knee Exercises.

MATERIALS AND METHODS

This was a longitudinal cohort study. The study duration for data collection was 12 months, April 2019 to April 2020. Chit method in simple random sampling method was used. IEC approval was done by the Institutional ethical committee (Ref No. KIPT/31/19-20 Dated 23/04/2019.) and informed consent was signed by all the patients participated in the study.

Inclusion criteria: Patients suffering with chronic knee osteoarthritis for at least six months, age group between 50-65 years, both male and female subjects, bilateral chronic knee osteoarthritis, X-ray: showing osteophytes, joint space narrowing at the knee joint Kellegren Lawrence Grade 2 and Grade 3 [18].

Exclusion criteria: Acute and sub-acute bilateral knee osteoarthritis patients, any old fracture at knee joint, ankylosing spondylitis, any previous knee pathology, any previous knee surgery; any post-surgical implant fixation at the knee region, tumours and cancer, any peripheral nerve lesions, any cardiopulmonary and renal condition.

Outcome Measures

Pain status, Range of Motion and Disability were measured by using Visual Analogue Scale, Universal Goniometer, Short Form-36 Health Status Questionnaire and WOMAC Arthritis Index Questionnaire. SF-36 Health status questionnaire and WOMAC Arthritis Index Questionnaire are available as a free tool on the internet and the scales were not modified by the researcher in the present study. The outcome measures were taken on the day before commencing the treatment, at the end of the 2nd week and finally at the end of the 4th week after the treatment.

The study was a hospital center based comparative follow up from day 1 to week 4. Sample for the study comprised of 90 chronic knee osteoarthritis patients aged between 50 to 65 selected by simple random sampling method. Samples of the study comprised of bilateral chronic knee osteoarthritis patients at Kempegowda Institute of Medical Sciences. The study was conducted, and outcome measures (VAS range of motion disability) were collected on day 1, at the end of 2nd week and at the end of 4th week. The study samples were selected based on inclusion and exclusion criteria. The 90 chronic knee osteoarthritis patients were divided into two groups having 45 samples in each group, group A patients were given contrast bath and knee exercises and were instructed to fill the Short Form- 36 Questionnaire on day 1, at the end of 2nd week and at the end of 4th week and group B patients were given contrast bath and knee exercises and were instructed to fill WOMAC Arthritis Index Questionnaire on day 1, at the end of 2nd week and at the end of 4th week.

In this study all the 90 subjects underwent exercise program as follows from 1st day to 4th week:

- Static exercises- static quads, static adductors, static abductors and SLR
- Range of Motion exercises- Knee mid flexion to end range extension and knee mid flexion to end range flexion.
- Strengthening exercise- Prone knee flexion and dynamic quadriceps with 1 kg weight
- Stretching exercises- Hamstring muscles stretch and quadriceps muscle stretch

The subjects were also given contrast bath on bilateral knee through packs of layers of towels. The total treatment time was 21 minutes which consist of four minutes of warm, followed by one minute of no treatment and then two minutes of cold. This cycle was repeated three times, in a total session of 21 minutes. All the subjects were given physiotherapy treatment for five visits per week for four weeks. The range of motion of right and left knee of all the 90 subjects was measured using a goniometer on day 1, end of the 2nd week and end of the 4th week.

STATISTICAL ANALYSIS

Data were analysed using the Statistical Package for Social Science (SPSS) version 19.0 (Chicago, IL) and level of significance was set at $p<0.05$. Descriptive statistics was performed to find out the mean and standard deviation of the respective groups. Normality of the test was assessed using Shapiro Wilkins test. ANOVA test followed by Post-hoc analysis was used within the groups to find out the statistical significance. Independent t-test was used between the groups to find out the significance.

RESULTS

Group A patients had a mean of 58.17 (SD 3.66). Group B patients had a mean of 58.15 (SD 4.29). Group A and Group B are almost similar with respect to the age of the participants. T-test shows significance between the groups and hence, the groups are comparable ($p>0.05$) [Table/Fig-1].

Groups	Mean	SD
Group A	58.17	3.66
Group B	58.15	4.29
p-value (t-test)	0.98	

[Table/Fig-1]: Age comparison.

Group A contains of 73.3% of females (33) and 26.7% of males (12). Group B participants are 57.8% females (26) and 42.2% of females (19) [Table/Fig-2].

Statistical analysis using Independent t-test between the groups showed significant difference of improvement at day 1, week 2 and week 4 in both the groups ($p<0.041$) [Table/Fig-3].

Statistical analysis using ANOVA and Post-hoc test between groups showed significant improvement in range of motion of

Groups	Gender	Number	Percentage
Group A	Male	12	26.7
	Female	33	73.3
Group B	Male	19	42.2
	Female	26	57.8

[Table/Fig-2]: Percentage distribution of males and females in Group A and Group B.

Column	Group A			Group B		
	Day 1	Week 2	Week 4	Day 1	Week 2	Week 4
Mean	7.66	4.88	2.35	8.06	5.06	2.15
SD	0.97	0.91	0.80	1.06	1.42	1.31
p-value (ANOVA)	0.0001*			0.0001*		
Day 1 Vs week 2 p-value	0.0001*			0.0001*		
Day 1 Vs week 4 p-value	0.0001*			0.0001*		
Week 2 Vs week 4 p-value (t-test)	0.0001*			0.0001*		
Day 1- week 4 Change (%)	69.3%			73.3%		

[Table/Fig-3]: Mean values and the standard deviation of the visual analogue scale for group A and group B.
*p<0.05 statistically significant

right knee at day 1, week 2 and week 4 in group A and group B (p<0.046). Post-hoc analysis also showed significant difference at all pair group comparison (p<0.05) in both group A and group B.

The percentage improvement of range of motion in right knee joint showed a better improvement with respect to Group B (28.4% vs 22.8%) compared to Group A [Table/Fig-4].

Column	Group A			Group B		
	Day 1	Week 2	Week 4	Day 1	Week 2	Week 4
Mean	93.37	105.2	114.66	114.66	114.66	110.53
SD	110.53	8.56	5.55	13.08	10.55	8.56
p-value (ANOVA)	0.0001*			0.0001*		
Day 1 Vs week 2 p-value	0.0001*			0.0001*		
Day 1 Vs week 4 p-value	0.0001*			0.0001*		
Week 2 Vs week 4 p-value (t-test)	0.0001*			0.0001*		
Day 1- week 4 Change (%)	22.8%			28.4%		

[Table/Fig-4]: Range of motion of right knee joint.
*p<0.05 statistically significant

Statistical analysis using ANOVA and Post-hoc test between groups showed significant improvement in range of motion of left knee at day 1, week 2 and week 4 in group A and group B (p<0.05). Post-hoc analysis also showed significant difference at all pair group comparison (p<0.05) in both group A and group B.

The percentage improvement of range of motion in left knee joint showed a better improvement with respect to Group B (23.1% vs 18.3%) compared to Group A [Table/Fig-5].

Group A shows a mean and the standard deviation of the total score of the Short Form-36 Questionnaire which was 88.24 (SD 6.27) on day 1; mean of 94.06 (SD 5.10) at the end of week 2 and a mean of 98.73 (SD 4.55) at the end of week 4. Statistical analysis using Independent t test within the group showed significant improvement at day 1, week 2 and week 4. Within group analysis using ANOVA followed by Post-Hoc test showed significant improvement at day 1, week 2 and week 4 [Table/Fig-6].

It shows a mean of 78 (SD 10) on day 1; mean of 51 (SD 12) at the end of week 2 and a mean of 22 (SD 13) at the end of week 4.

Column	Group A			Group B		
	Day 1	Week 2	Week 4	Day 1	Week 2	Week 4
Mean	97.24	106.48	115.08	92.17	102.64	113.48
SD	8.33	7.24	5.86	10.46	9.09	6.58
p-value (ANOVA)	0.0001*			0.0001*		
Day 1 Vs week 2 p-value	0.0001*			0.0001*		
Day 1 Vs week 4 p-value	0.0001*			0.0001*		
Week 2 Vs week 4 p-value (t-test)	0.0001*			0.0001*		
Day 1- week 4 Change (%)	18.3%			23.1%		

[Table/Fig-5]: Range of motion of left knee joint.
*p<0.05 statistically significant

Column	SF-36		
	Day 1	Week 2	Week 4
Mean	88.24	94.06	98.73
SD	6.72	5.10	4.55
p-value	0.0001*		
Day 1 Vs week 2 p-value	0.0001*		
Day 1 Vs week 4 p-value	0.0001*		
Week 2 Vs week 4 p-value (t-test)	0.0003*		
Day 1- Week 4 Change (%)	11.8%		

[Table/Fig-6]: Short Form-36 Questionnaire (Group A).
*p<0.05 statistically significant

Statistical analysis using Independent t-test within the group showed significant difference of improvement at day 1, week 2 and week 4 (p<0.05).

Within group analysis using ANOVA followed by Post-hoc Test showed significant improvement at day 1, week 2 and week 4 (p<0.05) in Group B [Table/Fig-7].

Column	WOMAC			% Disability		
	Day 1	Week 2	Week 4	Day 1	Week 2	Week 4
Mean	74.66	49.02	20.68	78	51	22
SD	10.01	12.08	12.23	10	12	13
p-value	0.0001*			0.0001*		
Day 1 Vs week 2 p-value	0.0001*			0.0001*		
Day 1 Vs week 4 p-value	0.0001*			0.0001*		
Week 2 Vs week 4 p-value (t-test)	0.0001*			0.0003*		
Day 1- week 4 Change (%)	72.30%			71.8%		

[Table/Fig-7]: WOMAC Arthritis Index Scale and % Disability (Group B).
*p<0.05 statistically significant

Statistical analysis using Independent t-test between the groups showed no significant difference of improvement at day 1, week 2 and week 4 intervals (p>0.05) [Table/Fig-8].

Groups	VAS scale		
	Day 1	Week 2	Week 4
Group A	7.66±0.97	4.88±0.91	2.35±0.80
Group B	8.06±1.06	5.06±1.42	2.15±1.31
p-value (Independent t-test)	0.06	0.54	0.88

[Table/Fig-8]: Between group comparison of visual analogue scale in Group A and Group B.

DISCUSSION

At the beginning, 145 patients were evaluated for eligibility to enter the study. Finally, 90 patients (for both WOMAC and SF-36) were included in the study. The study population, characteristics, samples,

age, gender and range of motion were consistent with the study which showed that there was a specific importance of contrast bath and knee exercises, which when implemented on patients showed significant improvement in the score of WOMAC questionnaire and SF-36. In present study, null hypothesis was rejected, and alternate hypothesis was accepted.

The mean age in the Group A was 58.17 and Group B was 58.15. The standard deviation of group A was 3.66 and group B was 4.29. Further, the present study was supported by Xie Y et al., who conducted a systematic review in 2018, which also had patients with the age group of above 50 years [18].

The present study showed significant improvement in VAS between Day 1- Week 4 ($p<0.05$) in group B compared to group A patients. The effectiveness of reducing knee pain was supported by Shehata AE and Fareed ME, which conducted a study in 2018 who concluded that contrast bath appears effective in treating chronic knee osteoarthritis patients [19]. Further the effectiveness of exercises in treating chronic knee osteoarthritis patients was supported by Deyle GD et al., who concluded that exercise yields functional benefits for patients with chronic knee osteoarthritis and may delay or prevent the need for surgical intervention [20].

The WOMAC Arthritis Index is a disease specific measure of disability associated with knee osteoarthritis that has demonstrated well to excellent reliability and validity. It is a 24 items questionnaire focusing on pain, stiffness and functional limitation. A higher score indicates worse pain, stiffness and physical function.

On the other hand, Short Form-36 is used to examine health status in the following 8 domains: bodily pain, physical function, role limitations due to social problems, physical problems, general health, vitality, social function, mental health, role limitation due to physical problems. The items contributing to a scale are scored so that a higher score represents better health, and they are averaged together to create the scale score. As both the scales are designed to evaluate disability and the quality of life, the researcher had chosen these two scales in the present study.

The within group analysis of SF-36 showed significant improvement between day 1 and week 4 ($p<0.05$). The use of SF-36 Questionnaire was supported by Laucis NC et al., at Los Angeles, CA, in 2015 who had concluded that SF-36 and its various versions are currently the most widely used health related Quality of Life measures in the United States [21]. This study was also supported by Srivastava SR who concluded that SF-36 is the gold standard to assess quality of life of people with knee osteoarthritis [22].

The present study showed that there is significant improvement in the scores of the WOMAC Arthritis Index Scale and its percent disability between the day 1 and week 4 ($p<0.5$) in group B patients. Further, this was supported by Basaran S et al., which conducted a study at Turkey, in the year 2010 where the researcher had reviewed various studies in which the WOMAC Arthritis Index Questionnaire was used as a valid tool [23].

Raeissadat SA et al., 2017 in his study concluded that there is a positive correlation between WOMAC and SF-36 in measuring health related quality of life in patients with knee osteoarthritis [24]. Previous evaluations of measurement characteristics of WOMAC and SF-36 in knee osteoarthritis patients have been done following joint replacement surgeries [25-28]. In such research, WOMAC performed better. In this study, while both WOMAC and SF-36 responded positively to the treatment, however, degree of responsiveness in WOMAC was far greater than SF-36. In line with the decrease in VAS scores, SF-36 also showed improvement, however, the degree of improvement was not so significant as compared to WOMAC. This was clearly demonstrated by rapid responsiveness and greater sustained increase in WOMAC scores following the commencement of treatment. SF-36 scores also reflected improvement but were not relatively rapid. This is because of the following key reasons: (a) The recall period in SF-36 is of one week. This is not a problem for WOMAC as the recall time is limited to 48 hours; (b) SF-36 is a generic health status instrument which is generally used to assess the social, mental and physical construct. Conceptually, improvement in physical construct could leads to social and mental improvements in future. However, the outcome measurements of such improvements cannot be assessed in short period. It is possible that the duration of the study was less to detect much improvement is SF-36 scores; (c) The lack of response in SF-36 scale may be due to lack of adequate and appropriate response categories for chronic knee osteoarthritis patients; (d) WOMAC on the other hand is a core functional assessment tool which eliminates some of the social and mental assessment outcomes in the treatment, thereby, leading to high responsiveness towards physical/functional assessment in chronic knee osteoarthritis patients.

From this study, it appears that WOMAC is more efficient than SF-36 in treatment of chronic knee osteoarthritis patients using contrast bath and knee exercises.

Limitation(s)

The study population was small. No long term follow up. The age group of patients limits the study. The frequency of male and female subjects was not equally distributed.

CONCLUSION(S)

The present study showed significant differences in the outcome measures of range of motion and also the visual analogue scale in Group A and Group B. There was significant difference in the pre and post total scores of Short Form-36 Questionnaire of Group A patients as well as significant differences in the pre and post total scores in the WOMAC Arthritis Index Questionnaire and its percent disability score. The present study also shows that the WOMAC Arthritis Index Questionnaire has shown superior sensitivity in the percentage wise improvement in the chronic knee osteoarthritis patients than the Short Form-36 Questionnaire.

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