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Research Article

ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE IN PATIENTS WITH KNEE OSTEOARTHRITIS: A COMPARISON OF TWO ANALGESIC COMBINATIONS

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Abstract

Objectives

Osteoarthritis (OA) is the most common form of degenerative joint disease and is a leading cause of chronic disability. The general well-being is affected significantly in OA patients resulting in poor quality of life. Health related quality of life (HRQOL) is stated as an individual's or a group's perceived physical and mental health over time. The main objective of our study is to compare the impact of two analgesic combinations on HRQOL in OA patients.

Methodology

This was a simple prospective observational cross-sectional study conducted in the Tertiary Care Hospital at Chittoor district for a period of 4 months (September 2017 – December 2017). The study population was divided randomly into two groups with each group consisting of 70 patients. Patients of both the groups were assessed for HRQOL using short form (SF)-36 questionnaire. HRQOL data was collected at R0 (baseline-before treatment), R1 (15 days after treatment).

Results

The mean (SD) age of the studied population was found to be 56 (10.6) years with a median age of 55 years. Scores of SF-36 domains were observed to be statistically increased in both the treatment groups. Group II patients' treatment was found to be comparatively more effective in increasing the quality of life (QOL) of OA patients than group I.

Conclusion

This study concludes that both lornoxicam and etodolac are effective in increasing the quality of life of knee OA patients. But etodolac has shown to be clinically more effective than lornoxicam after 15 days of treatment.

Key words: Etodolac, HRQOL, Lornoxicam, Osteoarthritis.

Introduction

Osteoarthritis (OA), also known as degenerative arthritis is the most common form of degenerative joint disease, and is a leading cause of chronic disability characterized by painful and stiff joints particularly in elderly population [1]. According to World Health Organization (WHO), 9.6% of men and 18.0% of women aged over 60 suffers with OA. Prevalence of knee and hip OA is high among other types of OA [2, 3]. When considering gender, OA prevalence is higher in women than men after the age of 45 years (yrs). The worldwide prevalence of knee OA and hip OA is 3.8% and 0.85% whereas in India it is 5.5% and 1.4% respectively [4, 5]. The general well-being is affected significantly in OA patients. WHO defines health related quality of life (HRQOL) as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". Thus, HRQOL is stated as an individual's or a group's perceived physical and mental health over time [6].

The main objective of HRQOL study is to compare two different treatment methods or to compare the impact of different drugs on same disease condition [7]. HRQOL scales are generally disease specific and generic. Disease specific scale drafts the patients attitude towards definitive aspects of health which gets affected by the specific disease and generic scale measures general health, physical, mental and social wellbeing of patients and how those affects their rapport with family and friends[8]. In this study, short form- 36 (SF-36) questionnaire was used to assess HRQOL.

It analyses the differences in health condition between male and female as well as among different social categories and measures the patient centered outcome which is useful to evaluate therapies [9]. The goals of OA treatment are alleviation of pain and improvement of functional status. The non-pharmacological options available for management of OA include appropriate footwear, knee bracing, weight loss, physical therapy, exercise,

hydrotherapy whereas pharmacological options include oral analgesics (acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), tramadol, opiates, duloxetine), topical/transdermal agents (capsaicin, lidocaine patches), intra-articular agents (corticosteroids, hyaluronic acid) and neutraceuticals (glucosamine, chondroitin) [10, 11]. Among the various drug options, NSAIDs are ubiquitous due to their analgesic and anti-inflammatory effects. In the class of NSAIDs, lornoxicam and etodolac combination with paracetamol were selected for the study. Lornoxicam is an oxicam derivative which acts by inhibiting prostaglandin biosynthesis [12]. Etodolac is a pyranocarboxylic acid derivative which acts by inhibiting the formation of prostaglandin endoperoxides from arachidonic acid [13]. It is equally effective as well as safe when compared with diclofenac, piroxicam, naproxen, and nabumetone [14]. This study is designed to assess the effect of combination of lornoxicam with paracetamol and etodolac with paracetamol on HRQOL in patients with knee OA.

Methodology

Study Design and Ethical Aspects

This was a simple prospective observational cross-sectional study conducted in the Tertiary Care Hospital for a period of 4 months (September 2017 – December 2017). The study protocol was approved by the institutional ethical committee (IEC/RVSIMS/2017/07). Consent from the hospital authorities were obtained before accessing data from the patients.

Written informed consents were obtained after explaining the study protocol to each individual patient. The study population was divided randomly into two groups as group I (treated with Lornoxicam+ Paracetamol- 8mg+325mg twice daily for 15 days) and group II (treated with Etodolac+ Paracetamol- 300mg+325mg twice daily for 15 days) with each group consisting of 70 patients.

Study Population

140 patients who fulfilled the inclusion criterion were documented from the case sheets and recorded in a separately designed case report form. Patients with knee OA of age greater than 40 years and either gender were included in the study. Patients with concomitant osteoarticular disorders, pregnant women and mentally retarded patients were excluded. A total of 140 patients were identified during ward rounds and through regular case record reviews during the study period.

Data Collection

Data including the patient demographics (age, gender, height, weight, BMI, marital status, occupation, food habit, substance abuse, and literacy background), allergy status, past medical history, surgical history and duration of OA were obtained by patient medical history interview and from medical records of the patients. Patients of both the groups were assessed for HRQOL using SF-36 questionnaire. HRQOL data was collected at R0 (baseline-before treatment), and R1 (15 days after treatment).

HRQOL Measurement Tool

The SF-36 [15] is a well-known, reliable and validated generic health status measure which encompasses 8 domains (physical function [PF], role limitation due to physical health [RP], role limitation due to emotional problems [RE], energy/fatigue [E/F], emotional wellbeing [EW], social functioning [SF], bodily pain [P], general health [GH]) related to daily life activities and consist of 36 items. Each domain scores from zero (lowest level of functioning) to hundred (highest level of functioning).

Statistical Analysis

The collected data were analyzed using Statistical Package for Social Science (SPSS) version 17 and Graph Pad Prism 7.0. Descriptive statistics was used to exhibit demographic details and SF-36 score. Continuous variables were reported using mean and standard deviation (SD). Categorical variables were reported by percentage and proportions. T- Test was used to analyze the difference in HRQOL of two groups at R0 and to analyze the difference in HRQOL between R0 and R1 of each group. Chi -square test was used to analyze the difference in some baseline demographic parameters of two groups. Wherever computed, a P value of less than 0.05 was considered significant, since the confidence interval (CI) was maintained at 95%. Pearson's correlation was used to determine an association of physical component summary with mental component summary.

Results

Patient Demographics

A total of 140 patients with knee OA were enrolled and randomized equally into two groups (70 each). The baseline characteristics of the subjects included in the study are shown in **Table 1**.

Table-1: Baseline Characteristics of Study Population.

Parameter	**Study Groups**		**P value**
	Group I	**Group II**	
Age(yrs)	56.4±10.03	56.5±11.22	0.9252*
Gender	Male- 13(18.6%)	Male- 19(27.1%)	0.2272**
	Female- 57(81.4%)	Female- 51(72.9%)	
Height (m^2)	2.75±0.177	2.73±0.165	0.2803*
Weight (kg)	55.52±4.13	55.8±2.88	0.6224*
BMI(kg/m^2)	20.2±1.52	20.52±1.17	0.1944*
Employment Status	Yes- 31(44.3%)	Yes- 38(54.3%)	0.2367**
	No- 39(55.7%)	No- 32(45.7%)	
Marital Status	Married- 62(88.6%)	Married- 64(91.4%)	0.5731**
	Unmarried- 8(11.4%)	Unmarried- 6(8.6%)	
Literacy Background	Literate- 28(40%)	Literate- 26(37.1%)	0.7284**
	Illiterate- 42(60%)	Illiterate- 44(62.9%)	
Food Habit	Veg- 4(5.7%)	Veg- 3(4.3%)	0.6982**
	Mixed- 66(94.3%)	Mixed- 67(95.7%)	
Allergy History	Yes- 1(1.4%)	Yes- 5(7.1%)	0.0951**
	No- 69(98.6%)	No- 65(92.9%)	
Social History	Yes- 10(14.3%)	Yes - 8(11.4%)	0.6136**
(Smoker/Alcoholic)	No- 60(85.7%)	No- 62(88.6%)	
Substance Abuse	Yes- 12(17.1%)	Yes- 9(12.9%)	0.4777**
	No- 58(82.9%)	No- 61(87.1%)	
Surgical History	Yes- 21(30%)	Yes- 27(38.6%)	0.2854**
	No- 49(70%)	No- 43(61.4%)	
Co-morbidities	Yes- 19(27.1%)	Yes- 23(32.9%)	0.4607**
	No- 51(72.9%)	No- 47(67.1%)	

Duration of OA			
1-6 months	58(82.8 %)	60(85.8%)	
6-12 months	7(10%)	4(5.7%)	0.2968*
>1 yr	2(2.9%)	5(7.1%)	
>2 yrs	3(4.3%)	1(1.4%)	

**Paired t test ** Chi-square test*

Statistically significant difference in the above parameters was not found between the groups. The mean (SD) age of the studied population was found to be 56 (10.6) years with a median age of 55 years which is shown in **Figure 1**. Patients with different co morbidities are shown in **Figure 2**.

Figure 1: Age Wise Distribution

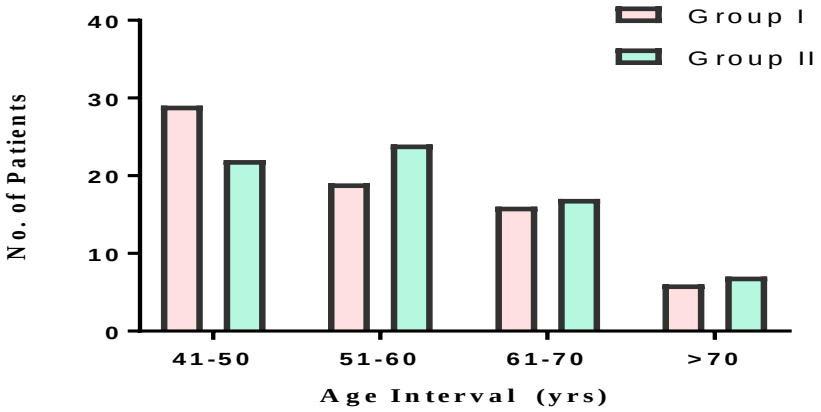
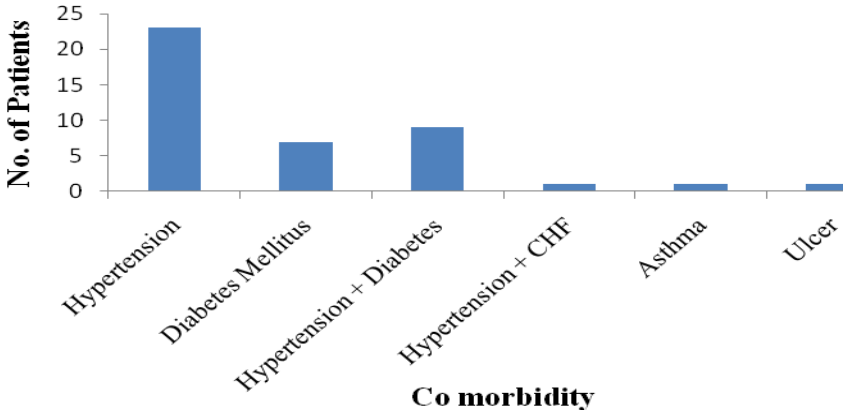


Figure 2: Comorbidity Wise Distribution

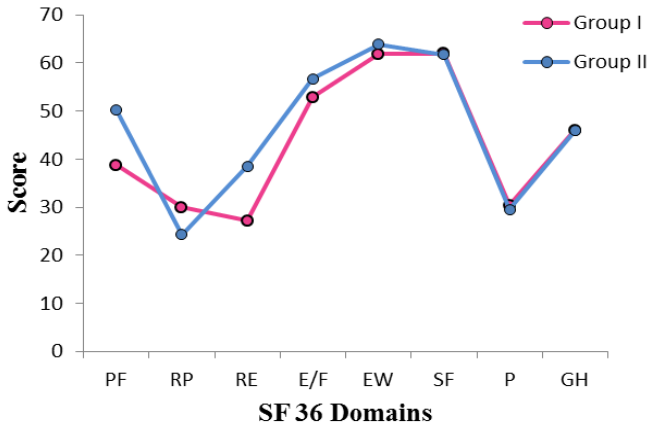


**CHF- Chronic Heart Failure*

Effect of Analgesic Combinations on HRQOL

Inter group comparison of baseline HRQOL showed no significant difference *(P value- 0.2419)* which is shown in **Figure 3**.

Figure 3: Comparison of Baseline (R0) Mean of SF 36 Domains



Scores of SF-36 domains were observed to be statistically increased in both the treatment groups except E/F domain. Group II patients' treatment was found to be comparatively more effective in increasing the quality of life (QOL) of OA patients by increasing the scores than group I patients' treatment as shown in **Table 2.**

Table 2: Intra Group Comparison of SF-36 Domains.

SF-36 Domains	Group I			Group II		
	R0	R1	P value	R0	R1	P value
PF	38.71±21.61	43.36±25.28	0.0141*	50.14±28.05	57±23.08	0.0053*
RP	30±46.16	42.86±42.86	0.0488*	24.29±43.19	42.86±49.84	0.0225*
RE	27.14±44.79	35.71±48.26	0.0329*	38.57±49.03	55.71±50.03	0.0132*
E/F	52.86±16.99	53.71±15.74	0.1816	56.75±19.36	58.25±17.84	0.1669
EW	61.83±13.6	62.27±13.52	0.0201*	63.83±15.46	65.7±13.81	0.0085*
SF	61.96±16.95	63.12±16.55	0.0056	61.79±19.37	65.56±16.48	0.0011*
P	30.43±23.97	33.61±25.82	0.0042*	29.5±25.66	37.57±21.81	<0.0001*
GH	46±15.22	48.07±14.95	<0.0001*	45.86±15.99	47.71±15.69	<0.0001*

**Paired t- test*

The profile of SF-36 physical and mental component summary of both the groups are shown in **Table 3 and 4**.

Table 3: Physical Component Summary.

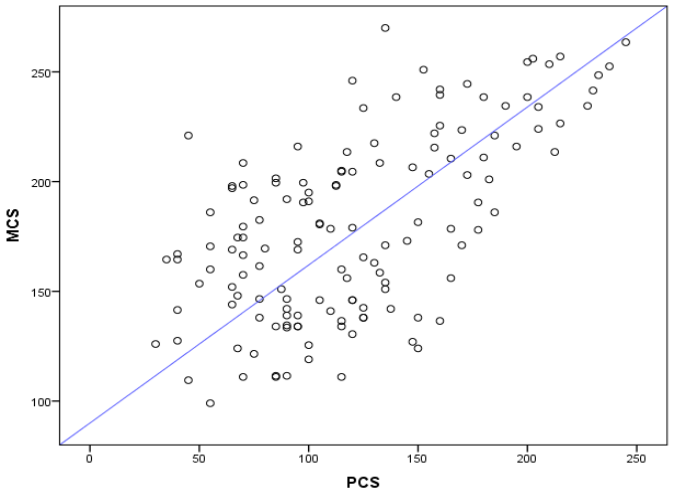
Descriptives	Group	Review	SF 36 Physical Component Domains			
			PF	**RP**	**P**	**GH**
Minimum	I	R0	10	0	0	20
		R1	10	0	0	20
	II	R0	10	0	0	15
		R1	15	0	0	25
Maximum	I	R0	85	100	100	75
		R1	100	100	87.5	75
	II	R0	100	100	100	80
		R1	100	100	77.5	80
Median	I	R0	40	0	30	42.5
		R1	42.5	0	35	42.5
	II	R0	50	0	32.5	40
		R1	50	0	37.5	45

Table 4: Mental Component Summary.

Descriptives	Group	Review	SF 36 Physical Component Domains			
			E/F	**SF**	**RE**	**MH**
Minimum	I	R0	15	36	37.5	0
		R1	20	44	37.5	0
	II	R0	25	32	25	0
		R1	30	36	32.5	0
Maximum	I	R0	95	92	100	100
		R1	95	92	100	100
	II	R0	100	100	100	100
		R1	100	100	100	100
Median	I	R0	50	60	62.5	0
		R1	50	60	62.5	0
	II	R0	55	68	62.5	0
		R1	55	68	63.4	100

Bivariate analysis was performed to determine the relationship between physical component score (PCS) and mental component score (MCS). PCS correlated positively with MCS suggesting that PCS and MCS are interlinked. Pearson correlation plot of PCS versus MCS is shown in Figure 4(a) & 4(b).

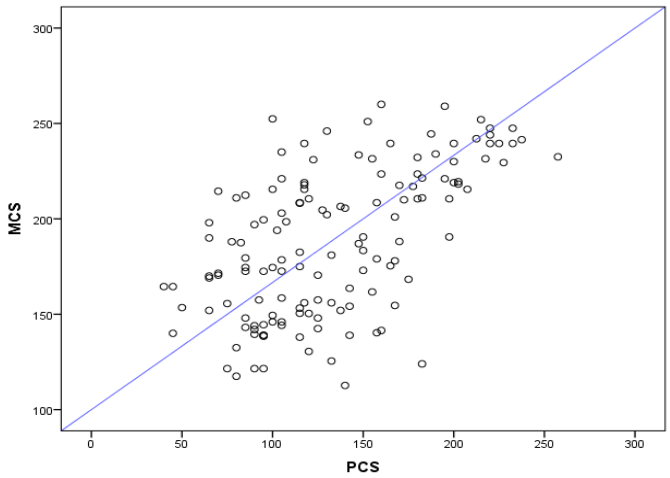
Figure 4(a): Correlation of PCS with MCS at R0



y=0.72 * x + 90

r = 0.615**

Figure 4(b): Correlation of PCS with MCS at R1.



y=0.6667 * x + 100

r = 0.573**

Discussion

OA is rare in women before the age of 45 years but its incidence increases significantly after menopause. In particular, OA of the hand or knee is about twice as common in women than men [16]. OA patients have low perception of their QOL. OA patients face chronic pain and functional limitations, which results in jobless and reduced quality of life. It has negative effects on mood, sleep, and participation in social as well as leisure activities [17]. Out of 291 conditions, knee OA was ranked as the eleventh highest contributor to disability in a global study [18]. The present study has collected the data of 140 patients with knee OA. The mean age of those included was 56 yrs, which complies with the findings of Elena L et al study [19]. Female patients were found to be more than men in both the study groups, similar to a study performed by Marcio MK et al [20]. The impact of OA may be worsened by the presence of co morbidities. Co morbidities which observed in this study population were hypertension, diabetes mellitus, CHF, asthma and ulcer as shown in Figure 2 ,which is similar to Alice AL et al study [21].The effect of OA on QOL is well known, particularly affecting the domains associated with physical health and general health. In this study, effectiveness of two analgesic combinations (lornoxicam with paracetamol and etodolac with paracetamol) has been comparatively evaluated using SF-36 questionnaire. Paracetamol has more of central effect and lornoxicam as well as etodolac have more of peripheral effect. Hence, a combination of lornoxicam and etodolac with paracetamol is preferred to give better therapeutic efficacy and also fastens pain

relief [22]. Many studies have suggested etodolac is as effective as other NSAIDS such as aspirin, piroxicam, lornoxicam etc. In the present study, both the combinations have found to be effective by increasing the score of SF- 36 and changes were not seen in E/F domain of both the groups as well as SF domain of group I. In addition, group II patients' treatment was assessed to be comparatively more effective than group I patients' treatment as shown in Table 2, which is similar to the study report of Gonzalo AP et al [23]. When compare to lornoxicam and other NSAIDs, etodolac has the potential advantage of not damaging articular cartilage, less gastro intestinal discomfort and possess more favorable therapeutic index. The half- life of etodolac (6.4 hours) is more than the half- life of lornoxicam (3-4 hours) [24]. Mental and physical health is fundamentally linked. This association has significant impact on QOL. In this study, statistically significant positive association was found between PCS and MCS in both the reviews as shown in Figure 4(a) and (b) which is analogous to Sepideh SF et al study findings [25].

Conclusion

This study concludes that both lornoxicam and etodolac are effective in increasing the quality of life of knee OA patients. But etodolac has shown to be clinically more effective than lornoxicam after 15 days of treatment. The main limitation of this study is that treatment is restricted only to the patients with knee OA. Hence, other types of OA patients should also be included in a future study to assess the efficacy of the above two analgesic combinations. Since OA affects daily activities of the patients, it is significant for the physicians to choose the best effective NSAID for each patient to improve their QOL.

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Conflict of Interest

The authors do not have any conflict of interest.

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