Promoting health and quality of life of patients with osteoarthritis of knee joint through non-pharmacological treatment strategies: A randomized controlled trial

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Abstract:
BACKGROUND AND OBJECTIVE: Osteoarthritis (OA) is a chronic degenerative disorder which primarily affects the articular cartilage of synovial joints followed by bony remodeling and overgrowth at the margins of these joints. The consequences of OA are pain, joint stiffness, decreased muscle performance, and decreased aerobic capacity, which eventually affect the quality of life (QOL) and increased risk for disability. The objective of the present study was to investigate the effectiveness of two nonpharmacological treatment regimens, that is, yoga and conventional physiotherapy, on QOL in patients suffering from OA of knee joint.

MATERIALS AND METHODS: A total of 83 patients with bilateral OA of knee joint, between the age group of 40 and 80 years, both males and females, were assigned into two groups using computer-generated scheme: 43 in the experimental group (yoga with conventional physiotherapy program) and 40 in control group (conventional physiotherapy program). Western Ontario and McMaster Universities OA index (WOMAC) and Short-Form 36 (SF-36) health survey were measured before, after 15 days, and after 30 days of treatment sessions, and the data were analyzed using paired and unpaired t-test.

RESULTS: The results of the study show significant improvement in both groups with regard to WOMAC and SF-36 at the end of 15 and 30 days of treatment regimen; however, when compared to the control group, experimental group had more significant improvement (P < 0.05) in WOMAC and SF-36 at the end of 15 and 30 days of treatment.

CONCLUSION: Yoga is more beneficial when added to conventional physiotherapy treatment regimen in promoting health and improving QOL in patients with OA of knee joint.

Keywords:
Health survey, knee, osteoarthritis, quality of life, yoga

Introduction

Osteoarthritis (OA) is a chronic degenerative ailment with multifactorial etiology. It is characterized by the synovial inflammation, loss of articular cartilage, hypertrophy of bone leading to osteophyte formation at the margins, subchondral sclerosis, and a range of biochemical and morphological changes in joint capsule and synovium. OA is the second most common rheumatologic problem, and it is the most frequent joint disease with a prevalence of 22%–39% in India. OA of the knee is a major cause of mobility impairment, particularly among females, and it was estimated to be the 10th leading cause of nonfatal burden.

Clinically, OA knee is characterized by variable degrees of inflammation at and...
around knee joint, pain during weight bearing, restriction of knee movement, crepitis, and effusion along with impaired proprioceptions. Reduced proprioceptions are also considered to be responsible for the initiation and perpetuation of degeneration of knee joint. Patients with knee OA often have poor neuromuscular control, slower walking speed, decreased functional ability, and increased risk of fall. Weaker quadriceps muscles often lead to buckling of knee, leading to higher susceptibility to fall among patients with knee OA.

As the disease advances, patients may suffer from pain even at rest or night due to synovitis and often have stiffness lasting for <30 min in the morning or following a period of inactivity. Deformities such as genu Varus or genu Valgus are also common in such patients.

Knee OA is one of the major contributors to the impairment of functional abilities. The disability can be extensive, including mobility limitation, difficulty with activities of daily living, and social isolation, ultimately resulting in reduced quality of life (QOL). The principal contributors to disability are believed to include pain, reduced range of joint movement, and muscle weakness.

QOL can be assessed by means of a generic instrument which identifies the impact of the disease on a patient’s general health or by means of a specific instrument which only measures the impact of the disease on the domains of QOL affected directly by the disease.

The Western Ontario and McMaster Universities OA Index (WOMAC) is generally recommended as the most sensitive condition-specific instrument to assess the intervention in patients with OA of lower limb, and The Medical Outcomes Study 36-Item Short-Form (SF-36) is now widely used as a generic health status measure.

Various measures are available for the treatment of OA knee such as conservative management including pharmacotherapy and various nonpharmacological treatment strategies, or surgical management in the form of resurfacing of joint or replacement surgeries.

Use of various nonpharmacological methods for the treatment of knee OA have been encouraged by the Osteoarthritis Research Society International including patient education, weight reduction, exercises, and other coping strategies.

Reduction in pain and stiffness, improved joint play and mobility, increased muscle strength, and to achieve greater functional independence in performing the activities of daily living are few objectives dealt by physiotherapy using various approaches, namely, exercises, electrotherapy, manual therapy techniques, taping, and by providing ergonomic advice to the patient.

Conventional exercises help in decreasing pain, improving strength and endurance, and improving range of motion and connective tissue elasticity, along with reduced functional limitations by improving walking speed, gait, and physical activity. It also helps alleviating depression and anxiety among these patients.

Yoga is a form of psycho-physical exercise which includes slow movements associated with muscle strengthening to improve physical and mental health.

Different schools of yoga (e.g., Iyengar yoga, IAYT, and hatha yoga) have developed therapeutic interventions for OA knee.

Hatha yoga, the physical form of yoga, incorporates poses, breathing techniques, and meditation, leading to reduce pain and stiffness associated with OA. It is also helpful in improving balance, strength, and flexibility and induces relaxation. Currently, yoga is one of the fitness programs recommended by the Arthritis Foundation for individuals with arthritis in general.

There is a substantial body of research suggesting the benefits of yoga on multiple medical conditions including improved control of hypertension, diabetes, and dyslipidemia and reduced anxiety, depression, and posttraumatic stress.

Many studies have compared yoga with different interventions such as stretching and strengthening exercises and showed functional changes and improvement in the QOL in traditional practice and yoga-based approach. The only randomized controlled trial conducted in India by Ebnezar et al. studied the effect of transcutaneous electrical stimulation and therapeutic ultrasound followed by yoga intervention for 40 min and reported that yoga therapy is better than physiotherapy exercises for reducing pain, morning stiffness, anxiety, pulse rate, and blood pressure in patients with OA, however was limited to numerical pain rating scale and anxiety (state and trait anxiety – STAI 1 and 2).

Some studies have focused on the effects of yoga on OA knee with positive outcomes reported on symptoms including pain, flexibility, functional disability, anxiety, and QOL, but have methodological issues related to their design.

Very few studies have investigated the effects of yoga on QOL in OA patients in India. Hence, the present study was undertaken to compare the effectiveness of yoga...
therapy with conventional physiotherapy treatment on QOL in patients with OA knee.

The objective of the present study was to investigate the effectiveness of two nonpharmacological treatment regimens, that is, yoga and conventional physiotherapy, on QOL in patients suffering from OA of knee joint.

Materials and Methods

Ethical clearance was obtained from the institutional ethics committee before initiating the trial (IEC/HMPCMCE/87/Faculty/9/24/18). The trial has been duly registered with Clinical Trial Registry - India (CTRI NUMBER (CTRI/2019/02/017422)).

Study design

This was a randomized controlled trial.

Sample size estimation

Given the absence of any baseline data, we assumed a moderate effect size of 0.4–0.5. A sample size of 45–50 is required per group with 5% type 1 error and 80% power for the effect size of 0.4–0.5. The sample size was further adjusted to 45 assuming 10% loss to follow-up.

Sample size

A total of 83 participants, diagnosed as having bilateral (B/L) OA of knee based on the clinical American College of Rheumatology (ACR) criteria, were divided into the following two groups [Figure 1]:

- Experimental group = 43 participants (n = 43)
- Control group = 40 participants (n = 40).

Inclusion criteria

1. Patients with B/L OA of knee according to the clinical ACR criteria
2. Age 40–80 years
3. Both genders
4. Patients who are functionally ambulatory
5. Patients who have not practiced any form of yoga or exercises in the past 2 months.

Exclusion criteria

1. Patients with unilateral knee OA, symptoms of locking or instability of knee, buckling, and shifting or “complain of giving way” in the past 3 months
2. Patients treated with corticosteroid injections within the past 2 months
3. Patients with total knee arthroplasty
4. Inflammatory arthritis
5. Any recent trauma of knee joint or lower limb
6. Patients who are taking analgesics.

Patients with B/L OA knee, referred for physiotherapy at Shree Krishna Hospital, Karamsad and from the nearby old-age homes/hospitals, were recruited for the study based on the inclusion and exclusion criteria after obtaining written informed consent.

All the eligible patients were divided into two groups using computer-generated scheme (WINPEPI software), and treatment allocation was carried out using concealed envelopes. Patients in the experimental group (n = 43 participants) were treated with conventional physiotherapy program along with yoga therapy, whereas patients in the control group (n = 40 participants) were provided only conventional physiotherapy treatment.

All the patients were assessed for their history, demographic details, and a detailed physical examination before taking any interventions. WOMAC and SF36 were assessed for all patients in both groups before initiating the treatment program.

The WOMAC scale consists of three dimensions, that is, pain, morning stiffness, and physical function associated with OA of the lower extremities. The SF-36 contains 36 questions aiming at the assessment of the participant’s health under the following eight major categories: physical functioning, role limitations due to physical health, role limitations due to mental health, energy or fatigue, emotional well-being, social functioning, pain, and general health.

Yoga therapy included six asanas, that is, Tadasana, Uttitha Trikonasana, Virbhadrasana, Dandasana, Sputa Padangustasana, and Baddha Konasana.[23,24] Each asana consisted of ten repetitions with short intervals of rest in between for a total of 30 min per session, three times per week for 4 weeks.

Conventional physiotherapy program included the following:

- Transelectrical nerve stimulation (10 min)
- Isometrics quadriceps exercise
- Straight leg-raising exercise in supine
- Terminal knee extension or vastus medialis oblique strengthening exercise in supine and high sitting
- Straight leg abduction exercise in side lying.

Each exercise was performed for a total of three sets, with each set made up of ten repetitions for 20 min, three times per week for 4 weeks.

All the patients were reassessed for WOMAC and SF-36 at the end of 15 days and 30 days of intervention in both groups.

Statistical analysis of the study was done using Stata 14.2 software (@copyright 1985-2015 StataCorp LLC, StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA).
Descriptive analysis was used to calculate the frequency and distribution of patients [Table 1]. All the descriptive data were analyzed to observe the homogeneity of groups for all the possible confounding factors.

Paired t-test was used to compare the difference of pre- and postintervention values of WOMAC score and SF-36 within the two groups. Unpaired t-test (two-sample test) was used to compare the differences between the two groups for same outcome measures. P < 0.05 was considered statistically significant.

Results

The mean age of the patients in the control group was 54.27 ± 8.44 years and in the experimental group was 56.58 ± 10.12 years.

Significant improvement was observed in all domains of WOMAC score in experimental group both at the end of 15 days and 30 days of treatment regimen (P < 0.05) [Table 2], however, maximum improvement was seen in the 3rd domain (physical function) and the total WOMAC score.

Comparing the score of SF-36 at baseline with postintervention score after 15 days and 30 days in the experimental group [Table 3], significant improvement was seen in all domains (P < 0.05).

Table 1: Distribution of patients in both groups

| Gender | Experimental group | Control group | Total |
|--------|-------------------|---------------|-------|
| Male   | 15                | 10            | 25    |
| Female | 28                | 30            | 58    |
| Total  | 43                | 40            | 83    |

Table 2: Comparison of Western Ontario and McMaster Universities Osteoarthritis Index at baseline, post 15 days, and post 30 days of intervention in the experimental group

| Variables | Pre, mean (SD) | Post_15, mean (SD) | P (pre-post 15) | Post_30, mean (SD) | P (pre-post 30) |
|-----------|---------------|--------------------|-----------------|-------------------|-----------------|
| WOMAC_D_1 | 13.16 (3.68)  | 7.51 (2.87)        | <0.001*         | 4.32 (1.93)       | <0.001*         |
| WOMAC_D_2 | 4.37 (1.79)   | 2.30 (1.28)        | <0.001*         | 1.20 (0.91)       | <0.001*         |
| WOMAC_D_3 | 42.32 (10.56) | 24.46 (8.36)       | <0.001*         | 13.79 (5.52)      | <0.001*         |
| WOMAC_T  | 59.86 (15.49) | 34.27 (11.48)      | <0.001*         | 19.32 (7.55)      | <0.001*         |

*P<0.05. WOMAC_D_1=WOMAC domain 1, WOMAC_D_2=WOMAC domain 2, WOMAC_D_3=WOMAC domain 3, WOMAC_T=WOMAC total. SD=Standard deviation, WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index

Table 3: Comparison of Short-Form-36 at baseline, post 15 days, and post 30 days of intervention in the experimental group

| Variables | Pre, mean (SD) | Post_15, mean (SD) | P (pre-post 15) | Post_30, mean (SD) | P (pre-post 30) |
|-----------|---------------|--------------------|-----------------|-------------------|-----------------|
| SF36_D_1  | 2.34 (0.48)   | 4.79 (1.12)        | <0.001*         | 7.60 (1.41)       | <0.001*         |
| SF36_D_2  | 16.39 (3.76)  | 24.51 (2.93)       | <0.001*         | 28.58 (1.34)      | <0.001*         |
| SF36_D_3  | 4.04 (0.21)   | 7.16 (0.87)        | <0.001*         | 7.79 (0.41)       | <0.001*         |
| SF36_D_4  | 6.88 (0.76)   | 9.60 (0.87)        | <0.001*         | 10.69 (0.46)      | <0.001*         |
| SF36_D_5  | 2.46 (0.54)   | 5.39 (1.09)        | <0.001*         | 8.55 (1.18)       | <0.001*         |
| SF36_D_6  | 48.60 (2.68)  | 41.30 (4.71)       | <0.001*         | 31.76 (5.35)      | <0.001*         |
| SF36_D_7  | 2.18 (0.54)   | 3.53 (0.50)        | <0.001*         | 4.67 (0.52)       | <0.001*         |
| SF36_D_8  | 13.48 (1.07)  | 15.59 (1.23)       | <0.001*         | 18.67 (0.91)      | <0.001*         |

*P<0.05. SF36_D_1 to SF36_D_8=SF-36 domain 1 to SF-36 domain 8. SD=Standard deviation, SF=Short Form

Maximum improvement was seen in the 6th domain of SF-36 score compared to other domains.

In the control group [Table 4], the results show significant improvement in patients over all the domains of WOMAC after conventional physiotherapy at the end of 15 days and 30 days (P < 0.05).

While comparing the score of SF-36 at baseline to postconventional physiotherapy after 15 days and 30 days in the control group [Table 5], there was a significant improvement in all domains (P < 0.05).

While comparing the results of WOMAC scale and SF-36 between the experimental and control groups, a significant improvement was observed in the experimental group (P < 0.05) at the end of 15 days and 30 days of treatment [Tables 6 and 7].

Discussion

The current study aimed to evaluate the effectiveness of yoga therapy over conventional physiotherapy treatment on QOL in patients with OA knee.

While comparing demographic data at baseline, it was found that the frequency of females (n = 58) with knee OA was high compared to that of males (n = 25), which is consistent with a study carried out by Venkatachalam et al., 2018, to find out the prevalence of OA of knee joint among adult population in a rural area of Kanchipuram, Tamilnadu, which suggested that female gender had 1.4 times more odds of having OA knee compared to male gender, which was statistically significant. [25]
A systemic review and meta-analysis of randomized controlled trials (2015) examined the effects of physiotherapy exercises on health-related QOL among patients with OA knee searching the four databases including PubMed, Cochrane Central Register of Controlled Trials, the Physiotherapy Evidence Database, and the Cumulative Index to Nursing and Allied Health Literature and provided a high-quality evidence that exercises improve the total summary score of SF-36, physical functioning score, and role-physical score of patients with OA knee. It also provided a moderate evidence for improvement in physical and mental components’ summary scores of SF-36 to a greater extent by exercises compared to controlled groups.[28]

Both groups in the present study showed clinically and statistically significant improvement in WOMAC and SF-36 scores, however, when compared with each other, patients receiving yoga therapy along with conventional physiotherapy had more significant improvement in both WOMAC and SF-36 scores compared to control group both at the end of 15 days and 30 days of treatment.

Abdel-Aziem et al., 2018, found the effectiveness of physiotherapy rehabilitation in knee OA patients with different pain intensities and stated pain as one of the prominent factors responsible for improvement in knee OA. Effects of physiotherapy rehabilitation including physical exercises and electrotherapeutic modalities are widely elaborated in literature, primarily reducing the pain intensity, improving knee mobility/range of motion, increasing quadriceps strength, and ultimately enhancing functional performance among OA knee patients, leading to improvement in visual analog scale for rating pain intensity and WOMAC.[22]

Table 4: Comparison of Western Ontario and McMaster Universities Osteoarthritis Index at baseline, post 15 days, and post 30 days of intervention in the control group

| Variables       | WOMAC_D_1 | WOMAC_D_2 | WOMAC_D_3 | WOMAC_T |
|-----------------|-----------|-----------|-----------|---------|
| Pre, mean (SD)  | 13.6 (2.46)| 4.52 (1.51)| 48.15 (9.96)| 66.25 (13.14) |
| Post_15, mean (SD) | 9.95 (2.41)| 3.25 (1.27)| 28.9 (7.08)| 42.1 (9.92) |
| P (pre-post 15) | <0.001*   | <0.001*   | <0.001*   | <0.001*   |
| Post_30, mean (SD) | 7.3 (2.13)| 2.05 (1.01)| 19.17 (7.02)| 29.02 (9.06) |
| P (pre-post 30) | <0.001*   | <0.001*   | <0.001*   | <0.001*   |

Table 5: Comparison of Short-Form-36 at baseline, post 15 days, and post 30 days of intervention in the control group

| Variables       | SF36_D_1 | SF36_D_2 | SF36_D_3 | SF36_D_4 | SF36_D_5 | SF36_D_6 | SF36_D_7 | SF36_D_8 |
|-----------------|----------|----------|----------|----------|----------|----------|----------|----------|
| Pre, mean (SD)  | 3.6 (1.3)| 17.62 (3.86)| 4.47 (0.71)| 6.42 (0.54)| 5.15 (1.16)| 42.32 (5.91)| 2.37 (0.54)| 13.45 (1.31) |
| Post_15, mean (SD) | 5.7 (1.22)| 20.92 (3.67)| 7.2 (0.60)| 6.325 (0.99)| 35.67 (7.89)| 3.32 (0.85)| 3.32 (0.85)| 14.97 (1.12) |
| P (pre-post 15) | <0.001* | <0.001* | <0.001* | <0.001* | <0.001* | <0.001* | <0.001* | <0.001* |
| Post_30, mean (SD) | 7.55 (1.10)| 26.85 (2.23)| 8.9 (0.84)| 7.575 (1.17)| 31.15 (8.61)| 3.35 (1.31)| 3.35 (1.31)| 17.42 (1.17) |
| P (pre-post 30) | <0.001* | <0.001* | <0.001* | <0.001* | <0.001* | <0.001* | <0.001* | <0.001* |

Table 6: Comparison of Western Ontario and McMaster Universities Osteoarthritis Index score between experimental and control groups at the end of 15 days and 30 days of treatment regimen

| Variables       | Experimental group | Control group |
|-----------------|--------------------|---------------|
| WOMAC_D_1 15 days | 5.65 (2.47) | 3.65 (1.45) |
| WOMAC_D_2 15 days | 2.06 (1.35) | 1.27 (0.78) |
| WOMAC_D_3 15 days | 17.86 (6.02) | 19.25 (5.29) |
| WOMAC_T 15 days | 25.58 (8.32) | 24.15 (6.20) |
| WOMAC_D_1 30 days | 8.83 (3.00) | 6.3 (1.82) |
| WOMAC_D_2 30 days | 3.16 (1.37) | 2.47 (1.06) |
| WOMAC_D_3 30 days | 28.53 (8.36) | 28.9 (7.58) |
| WOMAC_T_30 days | 40.53 (11.66) | 37.22 (10.48) |
| P               | <0.001*           | <0.001*       |

higher incidence of OA in females is thought to be more common after menopause, with estrogen deficiency playing a major role.[26]
cognitive errors by inputs at intellectual (jnana yoga) and emotional level (bhakti yoga).\cite{22}

A systemic review and meta-analysis on the integrative effect of yoga practice in patients with knee OA by Wang et al., 2018, suggested that the reason for reduction in pain and improvement in general health among patients with OA knee may be multifactorial. It may be local structure strengthening, proper positioning during yoga which reduces stress in specific area, systemic effect such as sympathetic and parasympathetic tone, etc. The good mental health may be jeopardized in patients suffering from arthritic pain. Yoga promotes the concepts of active mental awareness leading to reduction in pain and improvement in QOL in patients with OA.\cite{29}

Singh found the effect of yoga-based lifestyle intervention on patients with knee OA and suggested that yoga helps in reducing several psychological factors such as stress, anxiety, depression, and mood disturbances and enhances self-esteem and QOL in individuals with chronic pain and arthritic conditions. These effects are believed to be due to the prevention of synovial fluid volume deterioration by stretching and strengthening of different parts of the body; massaging and bringing fresh blood to the internal organs while rejuvenating the nervous system; and lubricating the joints, muscles, and ligaments. It is purported to have various effects on the nervous and circulatory systems, coordination and concentration, and calming effect on the body too.\cite{30}

Kan et al., reported that pain is a major symptom for OA. The cushioning between joints and cartilage wears away, and muscle weakness is considered the major cause of pain and disability. Yoga have been proved to have a positive effect in pain relief in all included studies, which provides strong evidence to support the application of yoga as an alternative therapeutic modality in pain management of patients with knee OA. Studies have demonstrated that people achieve better muscle strength and stamina as well as steadiness and flexibility with yoga exercise.\cite{30}

The current study reflected much more improvement in the domain 6 of SF-36 (Emotion/Energy), which is in consensus with a previous study carried out by Sharma et al., 2016, which studied the impact of anxiety and depression in patients with OA and found that psychological comorbidities (anxiety and depression) are highly prevalent among patients with OA and are frequently associated with higher pain and physical limitation and revealed that anxiety and depression can significantly impair the QOL of patients by altering pain perception and functional capacity.\cite{31}

Yoga offers a good value in addition as a nonpharmacological intervention in improving QOL and in reducing the anxiety in patients with OA knee joints.\cite{32}

Several factors would have contributed to the beneficial effects observed in both the groups during this study. As noted in several earlier studies, physiotherapy intervention may increase the blood flow. Better results in the yoga group could be due to the effect of yogasanas, Pranayama, relaxation, and its stress-reducing effect because yoga is meant to bring both physical and emotional stability.

Table 7: Comparison of Short-Form-36 score between experimental and control groups at the end of 15 days and 30 days of treatment regimen

| Variables | Mean difference (SD) | P       |
|-----------|----------------------|---------|
| SF36_D_1_15 days | 2.81 (1.54) | 1.85 (0.97) | <0.001* |
| SF36_D_2_15 days | 8.11 (4.68) | 3.3 (1.71) | <0.001* |
| SF36_D_3_15 days | 3.11 (0.87) | 1.22 (0.83) | <0.001* |
| SF36_D_4_15 days | 2.72 (1.00) | 0.77 (0.57) | <0.001* |
| SF36_D_5_15 days | 3.16 (1.34) | 1.25 (0.77) | <0.001* |
| SF36_D_6_15 days | 9.53 (4.40) | 4.52 (4.80) | <0.001* |
| SF36_D_7_15 days | 1.34 (0.68) | 0.95 (0.74) | 0.013* |
| SF36_D_8_15 days | 2.46 (1.20) | 1.52 (0.87) | <0.001* |
| SF36_D_1_30 days | 5.25 (1.54) | 3.95 (1.41) | 0.0001* |
| SF36_D_2_30 days | 12.18 (3.84) | 9.22 (2.86) | 0.0002* |
| SF36_D_3_30 days | 3.74 (0.44) | 2.87 (0.93) | <0.001* |
| SF36_D_4_30 days | 3.81 (0.73) | 2.47 (1.03) | <0.001* |
| SF36_D_5_30 days | 6.09 (1.25) | 2.42 (1.51) | <0.001* |
| SF36_D_6_30 days | 16.83 (5.14) | 11.17 (5.72) | <0.001* |
| SF36_D_7_30 days | 2.48 (0.82) | 0.97 (1.36) | <0.001* |
| SF36_D_8_30 days | 5.18 (1.41) | 3.97 (1.59) | 0.0004* |

*P<0.05. SF-36_D_1 to SF-36_D_8=SF-36 domain 1 to SF-36 domain 8. SF=Short Form, SD=Standard deviation
Conclusion

Yoga program is more effective when added to conventional exercise program in promoting overall health and improving the QOL in OA knee patients. Yoga would well be added to exercises to gain the additive effect in the treatment of OA knee patients.

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Conflicts of interest

There are no conflicts of interest.

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