

A Comparative Study between NSAID with McKenzie Exercise versus NSAID Treatment in Ankylosing Spondylitis

Dr. Iftakharul Alam^{1*}, Dr. Nusrat Neherin Khan², Dr. Suriya Shahaly³, Dr. Reshad Aldin Ahmed⁴, Prof. Dr. A K M Salek⁵, Prof. Dr. Taslim Uddin⁵

¹Consultant, Department of Physical Medicine and Rehabilitation, Anwar Khan Modern Medical College Hospital, Dhaka, Bangladesh

²RMO, Ibrahim Cardiac Hospital & Research Institute, Dhaka, Bangladesh

³Associate Consultant, Women and Child Hospital, Dhaka, Bangladesh

⁴SMO, Care Bridge Psychiatry and Drug Addiction Recovery Clinic, Dhaka, Bangladesh

⁵Professor, Department of Physical Medicine and Rehabilitation, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh

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*Corresponding author: Dr. Iftakharul Alam, Email: iftakhar23@gmail.com

Consultant, Department of Physical Medicine and Rehabilitation, Anwar Khan Modern Medical College Hospital, Dhaka, Bangladesh

Abstract

Original Research Article

Background: McKenzie method of mechanical diagnosis and therapy (MDT) is a technique primarily used in physical therapy. It was developed in the late 1950s by New Zealand physiotherapist Robin McKenzie. In 1981 he launched the concept which he called Mechanical Diagnosis and Therapy (MDT) a system encompassing assessment, diagnosis and treatment for the spine and extremities. On the other hand, Ankylosing spondylitis (AS) is a type of arthritis that causes lower back pain, hip pain and a stiff back which causes due to overtime work, vertebrae in the spinal column. In relieving pain and inflammation in AS patients, non-steroidal anti-inflammatory drugs (NSAIDs) are among the most commonly prescribed drugs in the world. **Aim of the Study:** The aim of this study was to compare between NSAID with McKenzie exercise versus NSAID treatment in Ankylosing spondylitis. **Methods:** This was a comparative experimental study which was conducted in the department of Physical Medicine and Rehabilitation, BSMMU, Dhaka, Bangladesh from October 2019 to September 2020. The study was approved by Institutional Review Board (IRB) of BSMMU. A total of 112 patients with ankylosing spondylitis were selected who were divided into two groups. 56 patients were allotted in group A (NSAID group) and another 56 were allotted in group B (NSAID with McKenzie exercise). All comparative data were analyzed and disseminated by using MS Excel and SPSS version 23.0. **Results:** The mean age was 28.02±5.86 years in group A whereas 28.8±5.94 years in group B and the difference was statistically not significant ($p>0.05$). The mean VAS score at baseline was 34.44±2.78 in group A and 34.03±2.23 in group B, at 4 weeks 28.89±3.67 in group A and 21.23±3.57 in group B, at 8 weeks 30.59±3.69 in group A and 16.95±3.62 in group B and at 12 weeks 28.08±3.34 in group A and 15.04±3.77 in group B. The mean BASFI at baseline was 3.19±0.15 in group A and 3.51±0.18 in group B, at 4 weeks 2.99±0.15 in group A and 2.15±0.05 in group B, at 8 weeks 1.99±0.09 in group A and 1.26±0.22 in group B and at 12 weeks 2.01±0.09 in group A and 1.25±0.2 in group B. The mean BASDAI at baseline was 5.01±0.39 in group A and 4.95±0.4 in group B, at 4 weeks 3.99±0.07 in group A and 3.43±0.09 in group B, at 8 weeks 3.97±0.09 in group A and 3.02±0.07 in group B and at 12 weeks 3.49±0.06 in group A and 1.98±0.09 in group B. The differences of VAS score, BASFI and BASDAI at 4, 8 and 12 weeks were statistically significant ($p<0.05$) between two groups. The mean BASDAI at baseline was 5.01±0.39 in group A and 4.95±0.4 in group B. At 4 weeks was 3.99±0.07 in group A and 3.43±0.09 in group B, at 8 weeks was 3.97±0.09 in group A and 3.02±0.07 in group B, at 12 weeks was 3.49±0.06 in group A and 1.98±0.09 in group B. The difference of BASDAI at 4, 8 and 12 weeks were statistically significant ($p<0.05$) between two groups. **Conclusion:** This study demonstrated the functional improvement of patients with AS in terms of pain, functional improvement and disease activity. However, as this study was done with a small sample size samples in a single center, we will recommend similar further studies in multiple centers with larger sample size. Ankylosing spondylitis (AS) causes pain and stiffness to affected joints as well as the spine and if the disease progresses, it can cause fusion of the joints, which can limit a person's mobility and flexibility.

Keywords: Ankylosing spondylitis, McKenzie exercise, Lower back pain, NSAIDs.

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INTRODUCTION

McKenzie method of mechanical diagnosis and therapy (MDT) is a technique primarily used in physical therapy. New Zealand physiotherapist Robin

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the spine and extremities in 1981. On the other hand, Ankylosing spondylitis (AS) is a type of arthritis that causes lower back pain, hip pain and a stiff back which causes due to overtime work, vertebrae in the spinal column. In relieving pain and inflammation in AS patients, non-steroidal anti-inflammatory drugs (NSAIDs) are among the most commonly prescribed drugs in the world. Vertebrae in the spinal column may fuse and becomes rigid (ankylosis) which may decrease in quality of life. The incidence rates of ankylosing spondylitis range from 0.2% to 1% of the adult population that affects the axial skeleton, causing characteristic inflammatory back pain, which can lead to functional and structural impairments and decrease in quality life [1]. The participation of other joints as the complex articulation of the hip may be present [2, 3]. Symptoms of the disease appear in average around 23 years of age and men are 2 to 3 times more likely to be affected than women [4]. AS involves inflammation and pain in many joints and spine. It causes physical outcomes like reduced physical activity, reduced spinal mobility, stiffness, fatigue, sleep disturbances. It is also impact psychological consequences such as depression [5]. Dagfinrud *et al.*, [6] and Ince *et al.*, [7], studies have reported beneficial effects of exercise on symptom severity, spinal mobility, muscle strength, functional capacity, cardiovascular capacity, and psychological status. Therefore, physical exercise is the cornerstone of the management program in AS. In physical therapy, the McKenzie method is a comprehensive method of care primarily used. In the late 1950s, this method by New Zealand physical therapist Robin McKenzie, OBE (1931-2013) [8, 9]. He launched the concept which he called Mechanical Diagnosis and Therapy (MDT) a system encompassing assessment, diagnosis and treatment for the spine and extremities, in 1981. MDT categorizes patients' complaints not on an anatomical basis [10, 11] but subgroups them by the clinical presentation of patients [12]. Although there is a lack of standardized or uniform physical therapy approach for patients with chronic low back pain, recent reports suggest that, the McKenzie exercise may improve pain and disability in such settings [13]. McKenzie method was developed by the physiotherapist with the same name and was intended for the management of acute as well as chronic low back pain related to various spine disorders. Furthermore, the McKenzie exercise emphasizes the importance of postural education and active involvement of the patient in the rehabilitation program, promoting the decrease of pain and restoring the flexibility of the spine [14]. In addition, McKenzie exercises support the auto-passive and active extension of the lumbar spine, with particular significance in regaining spine flexibility and invigorating the posterior structures, favoring a normal posture in lordosis of the lumbar segment [15, 16]. The advantages of McKenzie exercises are generally recognized for a broad spectrum of mechanical low back pain; conversely, limited data is currently available for inflammatory low back pain, particularly in patients with SpA [17]. As far we know,

until now no published studies of the effect of McKenzie exercises of ankylosing spondylitis have been carried out in a representative sample of Bangladeshi population. Therefore, it is clear that, there is a need to observe effect of prescribed McKenzie exercises on patients with AS having pain and disability of people in this country.

METHODOLOGY

This was a comparative experimental study. The study was conducted in the department of Physical Medicine and Rehabilitation, BSMMU, Dhaka, Bangladesh for the duration of the study was October 2019 to September 2020. The protocol of this study was approved by Institutional Review Board (IRB) of BSMMU. In total 112 patients with ankylosing spondylitis were selected in this study as study subjects. As per the inclusion criteria of this study, diagnosed case of axial ankylosing spondylitis according to ASAS criteria, patients with lack of regular exercise during the previous 6 months, able to understand the content of questionnaires and experimental schedules, patients with axial variety of ankylosing spondylitis, between the age of 18 and 60 years were included. On the other hand, according to the exclusion criteria of this study, patients with systemic organic involvement, severe comorbidity of heart, lung, liver or kidneys; patients who had been practicing regular exercises during the previous 6 months, had bamboo spine appearance on their X-ray spine, had no pain on movement on their spine or any joints and who got DMARD or biologics were excluded. All patients were divided into two groups. 56 patients were allotted in group A (NSAID group) and other 56 patients were allotted in group B (NSAID with McKenzie exercise). Indomethacin was used as NSAID. The slow-release capsules (75mg) were prescribed at night with meal and omeprazole (20 mg), as proton pump inhibitor were prescribed half hour before meal at morning and at night for twelve weeks. McKenzie extension exercises were performed for 50 minutes three times per week for 12 to 24 weeks. Baseline assessment was done at week-0 and outcome of exercise program were assessed on three consecutive follow up sessions at four weeks' interval by Bath Ankylosing Spondylitis Functional Index (BASFI) and BASDAI Bath Ankylosing Spondylitis Disease Activity Index (BASDAI). Before data collection, proper written consents were taken from all the participants. All comparative data were processed, analyzed and disseminated by using MS Excel and SPSS version 23.0 program as per necessity.

RESULTS

In this study, out of primarily selected 129 patients enrolled in this study, 112 patients were ultimately with us at the long run (control group 56 and intervention group 56). The mean age was 28.02 ± 5.86 years in group A and 28.8 ± 5.94 years in group B and the difference was statistically not significant ($p > 0.05$). It was observed that, majority (89.3%) of the patients in

each group were male. The mean BMI was 23.23±4.3 kg/m² in group A and 23.69±3.34 kg/m² in group B. The difference was statistically not significant (p>0.05) between two groups. It was observed that, half (50.0%) of the patients had fatigue in group A and 20 (35.7%) in group B. In all (100.0%) patients in each group had spinal pain. Almost two third (60.7%) patients had peripheral arthritis in group A and 34 (61.7%) in group B. Almost half (46.4%) of the patients had enthesitis in group A and 29 (51.8%) in group B. Almost half (48.2%) of the patients were current smoker in group A and 28 (50.0%) in group B. The mean VAS score at 4 weeks was 28.89 ±3.67 in group A and 21.23 ±3.57 in group B and the mean VAS score at 8 weeks was 30.59 ±3.69 in group A and 16.95 ±3.62 in group B. The mean VAS score at 12 weeks was 28.08 ±3.34 in group A and 15.04 ±3.77 in group B. The difference of VAS score at 4, 8 and 12 weeks were statistically significant

(p<0.05) between two groups. The mean BASFI at baseline was 3.19 ±0.15 in group A and 3.51 ±0.18 in group B, at 4 weeks it was 2.99 ±0.15 in group A and 2.15±0.05 in group B, at 8 weeks it was 1.99 ±0.09 in group A and 1.26 ±0.22 in group B and at 12 weeks it was 2.01 ±0.09 in group A and 1.25 ±0.2 in group B. The difference was statistically significant (p<0.05) between two groups. The mean BASDAI at baseline was 5.01 ±0.39 in group A and 4.95 ±0.4 in group B. The mean BASDAI at baseline was 5.01±0.39 in group A and 4.95±0.4 in group B. At 4 weeks was 3.99±0.07 in group A and 3.43±0.09 in group B, at 8 weeks was 3.97±0.09 in group A and 3.02±0.07 in group B, at 12 weeks was 3.49±0.06 in group A and 1.98±0.09 in group B. The difference of BASDAI at 4, 8 and 12 weeks were statistically significant (p<0.05) between two groups.

Table 1: Distribution of the study patients by age (N=112)

| Age (years) | Group A | | Group B | | P value |
|-----------------|------------|------|-----------|------|---------|
| | (n=56) | | (n=56) | | |
| | n | % | n | % | |
| <20 yrs. | 5 | 8.9 | 1 | 1.8 | 0.482 |
| 21-30 yrs. | 29 | 51.8 | 31 | 55.4 | |
| 31-40 yrs. | 22 | 39.3 | 24 | 42.8 | |
| Mean ±SD | 28.02±5.86 | | 28.8±5.94 | | |
| Range (min-max) | (18-40) | | (19-39) | | |

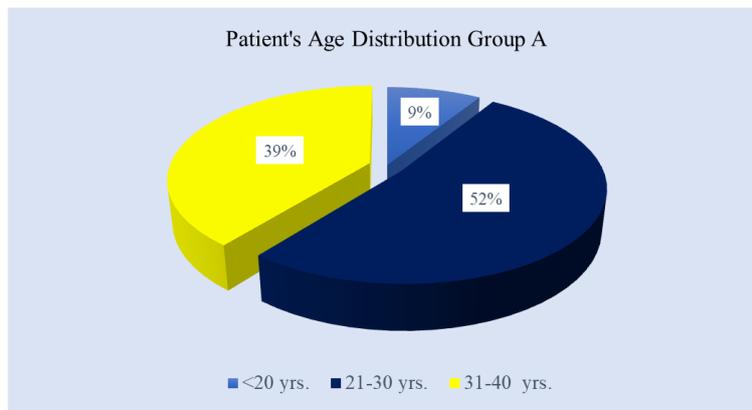


Figure I: Pie chart showed group wise patients by age (n=56)

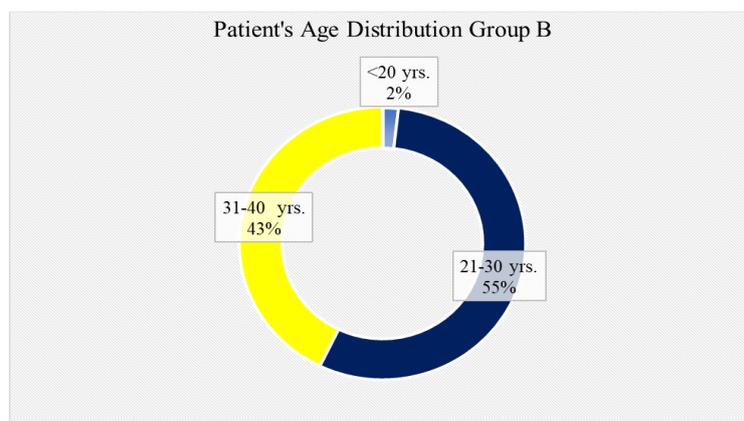


Figure II: Bar chart showed group wise patients by age (n=56)

Table 2: Distribution of the study patients by sex (N=112)

| Sex | Group A | | Group B | | p-Value |
|--------|---------|------|---------|------|---------|
| | (n=56) | | (n=56) | | |
| | n | % | n | % | |
| Male | 50 | 89.3 | 50 | 89.3 | 1.000 |
| Female | 6 | 10.7 | 6 | 10.7 | |

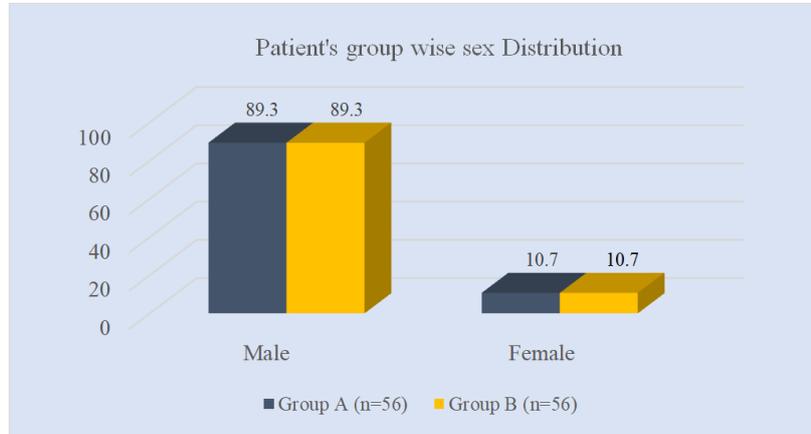


Figure III: Bar chart showed group wise patients by sex (N=112)

Table 3: Distribution of the study patients by anthropometric parameter (N=112)

| Anthropometric parameter | Group A | | Group B | | p-Value |
|--|------------|----------|------------|----------|---------|
| | (n=56) | | (n=56) | | |
| | Mean± SD | Mean ±SD | Mean ±SD | Mean ±SD | |
| Weight | 65.55±7.89 | | 66.11±8.37 | | 0.719 |
| Height | 1.67±0.07 | | 1.67±0.06 | | 0.955 |
| BMI (kg/m²) distribution of participants | | | | | |
| Underweight <18.5 | 5 | 8.9 | 2 | 3.6 | |
| Normal (18.5-24.9) | 33 | 58.9 | 36 | 64.2 | |
| Obese (25-30.9) | 18 | 32.2 | 18 | 32.2 | |
| Mean ± SD | 23.23±4.3 | | 23.69±3.34 | | 0.526 |

Table 4: Distribution of the study patients by past medical history (N=112)

| Past medical history | Group A | | Group B | | p- value |
|----------------------|---------|------|---------|------|----------|
| | (n=56) | | (n=56) | | |
| | n | % | n | % | |
| DM | 2 | 3.6 | 1 | 1.8 | 0.581 |
| Hypertension | 4 | 7.1 | 2 | 3.6 | |
| NSAIDs | 50 | 89.3 | 53 | 94.6 | |

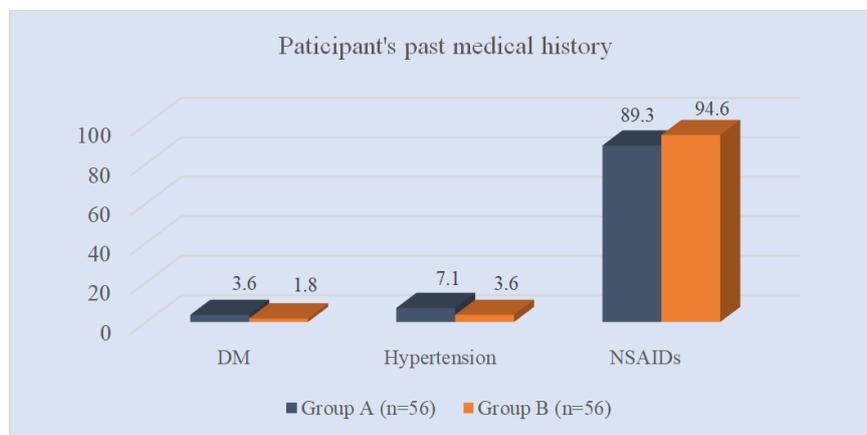


Figure IV: Bar chart showed group wise participants past medical history (N=112)

Table 5: Distribution of the study patients as BASDAI (N=112)

| BASDAI | Group A | Group B |
|--------------------|-----------|-----------|
| | (n=56) | (n=56) |
| | Mean ±SD | Mean ±SD |
| At baseline | | |
| Male | 5.01±0.37 | 5.17±0.37 |
| Female | 4.97±0.6 | 4.92±0.4 |
| p Value | 0.817 | 0.127 |
| At 4 weeks | | |
| Male | 4.12±0.07 | 3.53±0.09 |
| Female | 3.89±0.07 | 3.31±0.08 |
| p- Value | 0.001 | 0.001 |
| At 8 weeks | | |
| Male | 3.99±0.09 | 3.03±0.07 |
| Female | 3.82±0.09 | 2.89±0.07 |
| p- Value | 0.001 | 0.001 |
| At 12 weeks | | |
| Male | 3.59±0.06 | 2.08±0.08 |
| Female | 3.49±0.06 | 1.99±0.11 |
| p- Value | 0.001 | 0.015 |

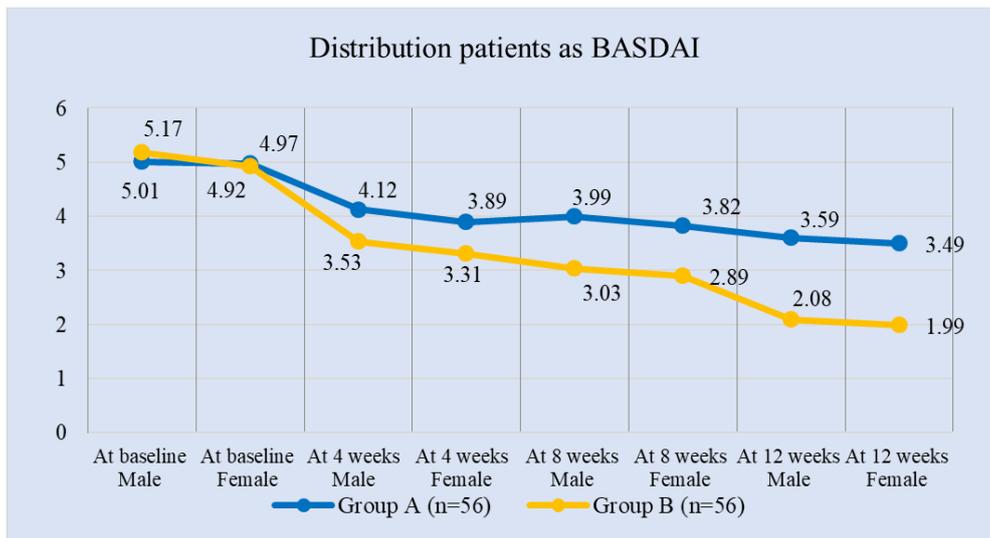


Figure V: Line chart showed group wise patients as BASDAI (N=112)

Table 6: Distribution of the study patients by BASFI (N=112)

| BASFI | Group A | Group B | P value |
|-------------|-----------|-----------|---------|
| | (n=56) | (n=56) | |
| | Mean ±SD | Mean ±SD | |
| At baseline | 3.19±0.15 | 3.51±0.18 | 0.001 |
| At 4 weeks | 2.99±0.15 | 2.15±0.05 | 0.001 |
| At 8 weeks | 1.99±0.09 | 1.26±0.22 | 0.001 |
| At 12 weeks | 2.01±0.09 | 1.25±0.2 | 0.001 |

Table 7: Distribution of the study patients by VAS score (N=112)

| VAS score | Group A | Group B | p- Value |
|-------------|------------|------------|----------|
| | (n=56) | (n=56) | |
| | Mean ±SD | Mean ±SD | |
| At baseline | 34.44±2.78 | 34.03±2.23 | 0.396 |
| At 4 weeks | 28.89±3.67 | 21.23±3.57 | 0.001 |
| At 8 weeks | 30.59±3.69 | 16.95±3.62 | 0.001 |
| At 12 weeks | 28.08±3.34 | 15.04±3.77 | 0.001 |

DISCUSSION

The aim of this study was to compare between NSAID with McKenzie exercise versus NSAID treatment in Ankylosing spondylitis. In this study, a total number of 112 patients with ankylosing spondylitis according to the Assessment of Spondylo-Arthritis International Society (ASAS) selection criteria aged 18–40 years were included in this study. All patients were divided into two groups. Among them, fifty-six (56) patients were allotted in Group-A (NSAID GROUP) and another 56 patients were allotted in Group-B (NSAID with McKenzie exercise). In this study, regarding the distribution of the study patients by age, it was observed that, more than half (51.8%) of the patients belonged to age between 21 and 30 years in group A and 31 (55.4%) in group B. The mean age was 28.02 ± 5.86 years in group A and 28.8 ± 5.94 years in group B. The difference was statistically not significant ($p > 0.05$) between two groups. In this study, regarding the distribution of the study patients by sex, it was observed that, in each of the groups 50 (89.3%) patients were male. The difference was statistically not significant ($p > 0.05$) between two groups. In a similar study, authors reported that, patients enrolled in their study were mainly young male, with a moderate disease activity as defined by BASDAI, which is closely resembled with the present study, where the current study found at 4 weeks the mean BASDAI was 4.12 ± 0.07 in male and 3.89 ± 0.07 in female in group A and BASDAI was 3.53 ± 0.09 in male and 3.31 ± 0.08 in female in group B. At 8 weeks, the mean BASDAI was 3.99 ± 0.09 in male and 3.82 ± 0.09 in female in group A and BASDAI 3.03 ± 0.07 in male and 2.89 ± 0.07 in female in group B. At 12 weeks, the mean BASDAI was 3.59 ± 0.06 in male and 3.49 ± 0.06 in female in group A and BASDAI 2.08 ± 0.08 in male and 1.99 ± 0.11 in female in group B. Exarchou *et al.*, [18] also reported that, the prevalence of clinically diagnosed AS increased linearly with age up to the age of 55 years, and then reached a plateau. For all age groups combined, the prevalence of AS was higher in men than in women (0.23% versus 0.14%; $P < 0.001$). The male-to-female ratio was highest after the age of 50; however, it was lower for younger age groups and the same pattern was observed for the prevalence of AS according to the strict case definition after age and sex stratification. The mean weight was 65.55 ± 7.89 in group A and 66.11 ± 8.37 in group B. The mean height was 1.67 ± 0.07 in group A and 1.67 ± 0.06 in group B. Almost one third (32.2%) of the patients belonged to BMI Obese (25-30.9 kg/m²) in group A and 18(32.2%) in group B. The mean BMI was 23.23 ± 4.3 kg/m² in group A and 23.69 ± 3.34 kg/m² in group B. The difference was statistically not significant ($p > 0.05$) between two groups. In this study, the distribution of the study patients by past medical history, it was observed that, fifty (89.3%) patients had NSAIDs in group A and 53(94.6%) in group B. The difference was statistically not significant ($p > 0.05$) between two groups. Authors stated that the rheumatoid arthritis

(RA) and ankylosing spondylitis (AS) are chronic progressive inflammatory diseases, leading to joint damage and reducing the physical fitness of patients [19]. Although their etiology and symptomatology are different, they were among the most common rheumatic diseases. Formerly, AS was often wrongly diagnosed as RA but cases of coexistence of RA with AS are rare. In this study, regarding the distribution of the study patients by duration of ankylosing spondylitis, it was observed that, more than three fourth (76.8%) of the patients belonged to duration of ankylosing spondylitis for >120 months in group A and 46 (82.1%) in group B. The mean duration of ankylosing spondylitis was 24.23 ± 14.71 months in group A and 23.64 ± 13.35 months in group B. The difference was statistically not significant ($p > 0.05$) between two groups. In current study, the mean VAS score at baseline was 34.44 ± 2.78 in group A and 34.03 ± 2.23 in group B. The study also showed that, the mean BASDAI at baseline was 5.01 ± 0.39 in group A and 4.95 ± 0.4 in group B. In accordance with our study, researchers observed that, all composite indices (BASDAI, BASFI, BASMI) showed statistically significant improvement at both visits in the McKenzie group and classical exercises group as well as compared to baseline ($P = 0.001$) [17]. Authors also emphasized that, rheumatologists must intervene in two crucial moments in the natural evolution of AS: on one hand, to diagnose early the disease and on the other hand to quantify and control its activity. In clinical practice, functional evaluation was done with the Bath Ankylosing Spondylitis Functional Index (BASFI), and disease activity was quantified with two score: an earlier one, containing only subjective clinical elements, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) [20]. However, the most important changes were proved in AS patients performing the McKenzie exercises: the decrease in BASDAI was particularly demonstrated in patients included in McKenzie group at 12 weeks ($P = 0.044$) and maintained after 24 weeks ($P = 0.001$); the same trend was seen with BASMI ($P = 0.001$) [21]. While, BASFI, the indicator of physical function in AS patients, did fall at the same magnitude after 12 weeks of physical therapy in all patients, the McKenzie intervention was reflected at the final visit as BASDAI changed more in patients belonging to group I than in controls ($P = 0.001$) [17]. At the end of their study, intergroup comparison demonstrated significant differences in all measurements including pain, lumbar spine motility (MST, FFD), BASFI, BASDAI and BASMI, favoring subjects with AS performing the specific McKenzie exercises ($P = 0.001$). Some studies detailed the Bath Ankylosing Spondylitis Metrology Index (BASMI), a 10-point scale, was used to measure the severity of trunk stiffness in the patients with AS; this index was combined with the results of cervical rotation, tragus-to-wall distance, lumbar side flexion, modified Schober and intermalleolar distance tests. Scores of 0 and 10 represent no limitation and most severe limitation; respectively [21-23] stated that, their meta-analysis

reported similar outcomes to those of prior study, evidencing significant effects regarding improvements in the BASMI, BASDAI and 6 MWT.

Limitation of the Study

During enrollment, 129 patients were selected, among them 6 patients were lost in first follow up at 4 weeks, another 6 patients were lost at second follow up and another 5 patients were lost in third follow up. Basically, this was a single centered study with small sized samples. Besides, the study was conducted at a very short period of time. That's why; the findings of this study may not reflect the exact scenario of the whole country.

CONCLUSION & RECOMMENDATION

McKenzie extension exercises may improve inflammatory pain and the range of motion of the lumbar spine in patients with early stages of axial ankylosing spondylitis. Therefore, it appears that, McKenzie method advances the basis of reeducation in patients with ankylosing spondylitis: a specific McKenzie exercise should be included in the standard of care aiming to improve pain, posture and function, especially in early axial disease subset. This comprises investigation of aspects of exercise programed design required to produce the largest effect, long-term adherence with exercise programs and the specific exercise requirements of sub-groups of people with AS most importantly. It can be inferred that, if the disease progresses, it can cause fusion of the joints, which can limit a person's mobility and flexibility. The treatment for AS to reduce symptoms, maintain the individual's flexibility and quality of life, and delay or prevent structural damage and possible complications of the disease.

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