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A comparative study on the effectiveness of centesimal and 50 millesimal potency of homoeopathic constitutional medicines in the management of osteoarthritis of knee joint

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Abstract
Objective: This study aimed to evaluate and compare the effectiveness of homoeopathic constitutional medicines in centesimal and 50 millesimal potencies for the treatment of knee osteoarthritis (OA). The primary focus was to assess changes in pain, stiffness, swelling, and functions of daily living in OA knee patients using these two potencies.
Methods: A non-randomized control trial was conducted with 40 patients diagnosed with OA of the knee, aged between 40-60 years, who attended the outpatient and inpatient departments of Government Homoeopathic Medical College, Thiruvananthapuram. Patients were alternately assigned to receive homoeopathic treatment in centesimal potency or 50 millesimal potency. The Knee Injury and Osteoarthritis Outcome Score (KOOS) was used to measure the improvement in symptoms, stiffness, pain, functions of daily living, recreational activities, and quality of life.
Results: The findings revealed a significant improvement in pain, swelling, stiffness, and daily function in both groups. However, the 50 millesimal potency group showed slightly greater improvements compared to the centesimal potency group, particularly in the total KOOS score and quality of life.
Conclusion: Homoeopathic constitutional medicines in both centesimal and 50 millesimal potencies demonstrated significant effectiveness in treating knee osteoarthritis. The 50 millesimal potency proved to be more effective, indicating its potential advantage in the management of OA knee joint pain and dysfunction.

Keywords: Osteoarthritis, knee joint, homoeopathy, centesimal potency, 50 millesimal potency, pain management, Knee Injury and Osteoarthritis Outcome Score (KOOS), swelling, stiffness, functional improvement

Introduction

Osteoarthritis (OA) is a long-lasting and chronic disorder affecting the synovial joints. It is marked by the gradual deterioration and breakdown of the articular cartilage, as well as the formation of cysts, bone spurs, and thickening of the bone beneath the cartilage which is known as subchondral sclerosis [1]. It is characterized by the progressive deterioration of articular cartilage and the degeneration of the joint's synovial membrane, meniscus (in the knee), surrounding ligaments, and subchondral bone, along with accompanying anatomical and functional changes.

Females in their peri-menopausal and post-menopausal years typically experience greater suffering than men, even though both sexes may experience it equally. The cause of it can be linked to the depletion of oestrogen at this age. The risk factors include genetic predispositions, obesity, inactivity, low bone density, poor dietary habits, trauma, and work environment conditions [2]. The current consensus is that Osteoarthritis (OA) is a biomechanical and inflammatory whole-organ disease that is influenced by various factors such as complement proteins, synovitis, obesity, innate immunity, systemic inflammatory mediators, low-grade inflammation caused by metabolic syndrome, and diabetes mellitus [3].

Pain, stiffness, and reduced function are the primary signs of Osteoarthritis (OA) in the knee. Cartilage loss results in bone-on-bone contact and this may eventually worsen into discomfort that is felt constantly. The stiffness associated with OA is described as "inactivity stiffness "which is experienced for five to ten minutes after the patient stands up and bears

weight following an extended period of immobility [4]. Physical examination of OA knee may show minor effusion with fluid bulge and cartilaginous crepitus or a crackling sensation. Range of motion is reduced in the affected knee joint, as osteoarthritis advances. Knee cartilage loss can cause the leg to become malaligned, resulting in a noticeable varus deformity or bow-legged posture. This knee angulation is associated with medial compartment Osteoarthritis (OA) of the knees. Patients might exhibit a valgus or knock-knee deformity, which is less frequent but suggests a more advanced condition in the lateral compartment of the knee. Following aspiration of an OA knee effusion, synovial fluid examination shows that the fluid is thick and viscous with a low number of synovial white blood cells, the majority of which are mononuclear cells [4].

According to the currently available researches, there is no known cure for Osteoarthritis (OA), and each person's degree of illness differs. As a result, a more general strategy for the present therapeutic approaches focuses on a mix of pharmacological and non-pharmacological therapy modalities [5]. For the past ten years, the main goals of therapy for treating Osteoarthritis (OA) have consistently been to improve physical function and relieve pain and stiffness. But while traditional OA medication therapy effectively reduces pain, it also has negative consequences on the gastrointestinal tract and heart, particularly when used over an extended period of time [6]. The treatment of chronic knee pain and impairment is thought to benefit from Total Knee Replacements (TKRs). However, a growing body of research employing patient-based outcome measures indicates that a sizable fraction of patients have persistent knee pain, functional impairment, a low quality of life, and discontent following total knee replacement [7].

According to recent studies, subjective pain, articular index, stiffness, and grip strength have all significantly improved in individuals receiving homoeopathic medications. Research on the impact of homoeopathic treatment on Activities of Daily Living (ADL) found that homoeopathic medications can be used safely as a comprehensive health care therapeutic to improve the ADL of patients with Osteoarthritis (OA) by lowering pain and stiffness and slowing the disease's progression [8].

Homoeopathy treats each disease in an individualistic manner by constructing totality of symptoms in each case which helps to differentiate one patient from another patient with a different totality of symptoms. Homoeopathy can surely give symptomatic relief and improve the quality of life of patients suffering from OA knee joint without any adverse side effects. It also prevents further progression of radiological damage by administering the constitutional medicine which corresponds to the totality of symptoms of the patient.

Centesimal potency was introduced by Dr. Samuel Hahnemann. Its mode of repetition is mentioned in aphorism 245-248 in 5th edition of Organon of Medicine. "Every perceptibly progressive and strikingly increasing ameioration in a transient or persistent disease precludes every repetition of administration of any medicine". The perfectly homoeopathic medicine given in minutest dose can be repeated at suitable intervals i.e. *"*at intervals of 14, 12, 10, 8, 7 days*"*, and, where rapidity is requisite, in chronic diseases resembling cases of acute disease, at still shorter intervals, but in acute diseases at very much shorter periods- every 24, 12, 8, 4 hours, in the very acutest every hour, up to as often as every 5 mins" [9].

50 millesimal potency was introduced by Dr. Samuel Hahnemann in the 6th edition of Organon of Medicine. Its mode of repetition is mentioned in aphorism 246-248 in the 6th edition of Organon of Medicine. For repetition, a single globule of medicine according to the 50 millesimal scale is dissolved in 7-8 tablespoons of water and vigorously shaken 8-10 times in a vial. From this mixture, one tablespoon is taken and added to a glass containing about 7-8 tablespoons of water, then stirred thoroughly. Afterward, an appropriate dose is given to the patient. In chronic conditions, the medicine is administered daily or every other day. In acute conditions, it is given every 2 to 6 hours, and in urgent cases, it may be repeated hourly or more frequently. The medicine is repeated by modifying the solution of each dose with vigorous shaking, thereby altering its potency and slightly increasing it [10].

The benefit of using 50 millesimal potency lies in its ability to cause minimal aggravation, making it safe for use even in the most severe cases. This potency has significantly reduced the treatment duration to half, a quarter, or even less. It allows for frequent repetition as needed. With this potency, a doctor can assess the suitability of the medicine within 2-4 days for chronic conditions and within 2-4 hours or even sooner for acute conditions [10].

This study is aimed to evaluate the effectiveness of homoeopathic constitutional medicines in centesimal potency and 50 millesimal potency in the treatment of osteoarthritis of knee joint. This study also aims to compare the effectiveness of homoeopathic constitutional medicine in centesimal and 50 millesimal potency in the management of osteoarthritis of knee joint.

Aim and objective

Aim

To compare the effectiveness of centesimal and 50 millesimal potency of homoeopathic constitutional medicines in the management of osteoarthritis of knee joint.

Objectives

1. To study the changes in pain, swelling, stiffness and functions of daily living in patients with OA knee after treatment with homoeopathic constitutional medicines in centesimal potency.
2. To study the changes in pain, swelling, stiffness and functions of daily living in patients with OA knee after treatment with homoeopathic constitutional medicines in 50 millesimal potency.
3. To compare the effect in Knee Injury and Osteoarthritis Outcome Score (KOOS Criteria) after treatment with homoeopathic constitutional medicines in centesimal and 50 millesimal potency in patients with OA knee.

Study design

The study was a non-randomised control trial. Every participant diagnosed with OA of knee joint who attended the outpatient and inpatient departments of Government Homoeopathic Medical College, Thiruvananthapuram was selected for the study. Participants were allocated in such a way that the first participant was given homoeopathic medicine in centesimal potency and the second one was given homoeopathic medicine in 50 millesimal potency. Every alternate participant was given homoeopathic

medicines in centesimal potency. Similarly, every alternate participant was given homoeopathic medicine in 50 millesimal potency. Hence, it was purposive sampling.
The study protocol was approved by the institutional ethical committee (Ethical clearance certificate number: 524/M1/GHMCT/2022/18) on 06/08/2022. Written informed consent was obtained from the patients for the evaluation of willingness to participate in this study.

Study settings
The study group includes cases from both from in-patient and out-patient section of Government Homoeopathic Medical College Hospital, Thiruvananthapuram.

Study duration
The duration of the study was 10 months.

Study population
The study was conducted on 40 cases with OA knee joint aged 40-60 years from both sexes satisfying the inclusion, exclusion and diagnostic criteria who consulted at the in-patient and out-patient section of Government Homoeopathic Medical College Hospital, Thiruvananthapuram.

Sampling
Sample size
A sample size of 40 cases with 20 cases in each group, satisfying the inclusion, exclusion and diagnostic criteria who consulted at the in-patient and out-patient section of Government Homoeopathic Medical College Hospital, Thiruvananthapuram.

Diagnostic criteria
1. Clinical signs and symptoms of OA knee joint.
2. Characteristic changes of osteoarthritis in X-Ray of knee joint.

Inclusion criteria
1. Age between 40-80 years.
2. Both sexes included.
3. Patients presenting with signs and symptoms of OA knee with characteristic X-Ray changes.

Exclusion criteria
1. Patients with serious complicated diseases such as heart diseases, severe lung diseases etc.
2. Cases of Rheumatoid arthritis, Psoriatic arthritis, raised serum uric acid levels and systemic diseases like SLE.
3. Cases with osteoporosis and bone tumors.
4. Severe osteoarthritis requiring surgical interventions.

Sampling procedure
The study was a prospective study and after the beginning of the study, a sample of 40 cases satisfying inclusion criteria were taken from the patients who consulted at the in-patient and out-patient department of Govt. Homoeopathic medical college Hospital, Thiruvananthapuram. Purposive sampling was used. Participants were allocated in such a way that the first participant was given homoeopathic medicine in centesimal potency and the second one was given homoeopathic medicine in 50 millesimal potency. Every alternate participant was given homoeopathic medicines in centesimal potency. Similarly, every alternate participant was given homoeopathic medicine in 50 millesimal potency.

Materials and methods of data collection
Patients who consulted at the out-patient Govt. Homoeopathic medical college Hospital, Thiruvananthapuram with sign and symptoms and characteristic radiographic changes of OA knee joint, satisfying the inclusion, exclusion and diagnostic criteria were subjected to detailed case taking in the standardized case taking format. The patients were administered homoeopathic constitutional medicine in such a way that the first participant was given homoeopathic medicine in centesimal potency and the second one was given homoeopathic medicine in 50 millesimal potency. The remedy was chosen according to the principles of homoeopathy. Repetition and change of both potency and remedy were done according to homoeopathic principles. The medicine was obtained from the hospital pharmacy, preferably medicines from HOMCO brand was used. A minimum number of 40 cases were selected for the study with 20 cases in each group. Each case was reviewed at an interval of 2-4 weeks.
A written informed consent was obtained from the participants prior to their enrollment into the study. The participants also had to undergo physical examination which included general examination as well as local examination of knee joint along with necessary laboratory investigations. The study subjects were briefed regarding the nature of study. The effectiveness of treatment was assessed based on the improvement of signs and symptoms before and after treatment which was assessed using the KOOS Questionnaire.

Outcome measurement
The effectiveness of treatment was assessed by comparing the KOO Score before and after treatment in both groups of patients who are using the homoeopathic constitutional medicines in centesimal and 50 millesimal potencies. Then the effectiveness of treatment in both these groups was compared with each other.

Plan of analysis
The total KOO score and score of symptoms; score of stiffness; score of pain; score of functions of daily living; score of functions, sports and recreational activities and score of quality of life in KOO scale during the last visit is compared with that of first visit, in order to evaluate the effectiveness of homoeopathic constitutional medicines in OA knee joint in both groups of patients who were given medicines in centesimal potency and 50 millesimal potency.
Final analysis of the study was done by means of appropriate statistical methods and confirmation was done by using the tests of significance.
In the group of OA knee joint patients who were given homoeopathic constitutional medicines in centesimal potency, the datas of score of stiffness; score of pain; score of functions, sports and recreational activities; score of quality of life in KOO scale and total KOO score does not follow normal distribution. Hence, a non-parametric test which is equivalent to paired t-test, called Wilcoxon signed rank test is applied for them. But, the datas of score of symptoms and score of functions of daily living follow normal distribution. Hence, a parametric test called paired t-test is applied.

In the group of OA knee joint patients who were given homoeopathic constitutional medicines in 50 millesimal potency, the datas of score of symptoms; score of stiffness; score of functions, sports and recreational activities; score of quality of life in KOO scale and total KOO score does not follow normal distribution. Hence, a non-parametric test which is equivalent to paired t-test, called Wilcoxon signed rank test is applied for them. But, the datas of score of pain and score of functions of daily living follow normal distribution. Hence, a parametric test called paired t-test is applied.

The difference between total KOO score before treatment and total KOO score after treatment was calculated in both groups of OA knee joint patients who were given homoeopathic constitutional medicines in centesimal potency and 5o millesimal potency. The mean difference in total KOO score before and after treatment follows normal distribution and it was tested by an independent t-test to compare the mean difference in total KOO score before and after treatment in both groups of OA knee joint patients who were given homoeopathic constitutional medicines in centesimal potency and 5o millesimal potency.

Statistics and interpretation

1. Score of symptoms in KOOS scale

Comparison of KOO symptoms score before and after treatment

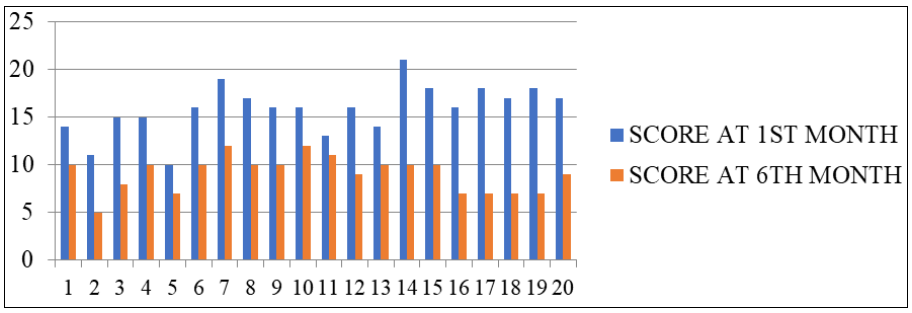

Fig 1: Graphical representation of symptoms score in KOO scale before and after treatment in centesimal group

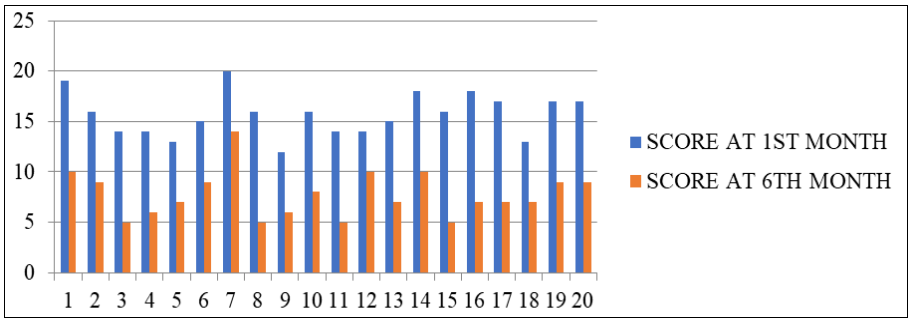

Fig 2: Graphical representation of symptoms score in KOO scale before and after treatment in 50 millesimal group

2. Score of stiffness in KOOS scale

Comparison of KOO stiffness score before and after treatment

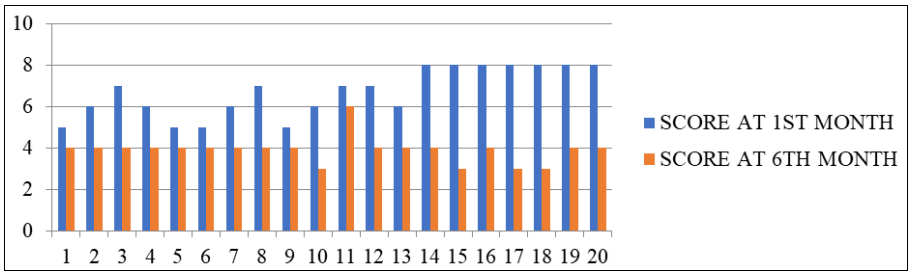

Fig 3: Graphical representation of stiffness score in KOO scale before and after treatment in centesimal group

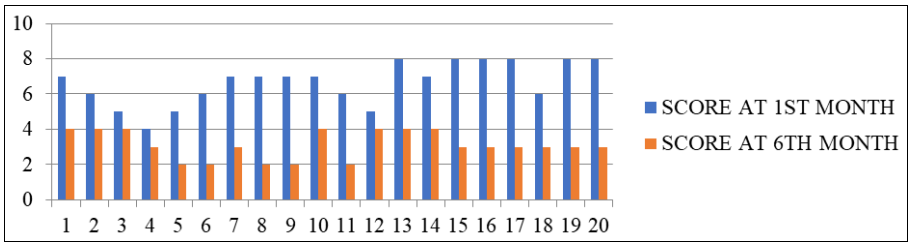

Fig 4: Graphical representation of stiffness score in KOO scale before and after treatment in 50 millesimal group

3. Score of pain in KOOS scale
Comparison of KOO pain score before and after treatment

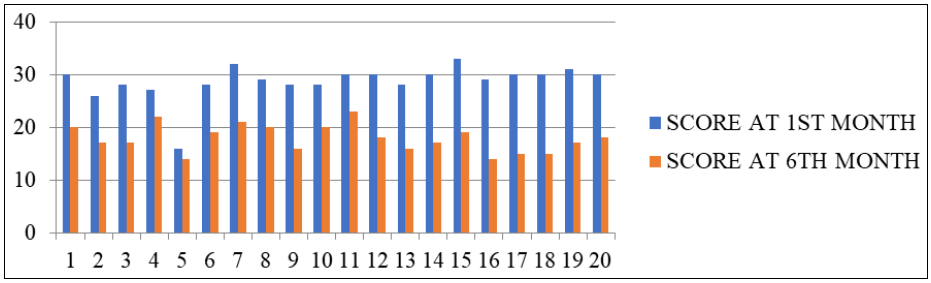

Fig 5: Graphical representation of pain score in KOO scale before and after treatment in centesimal group

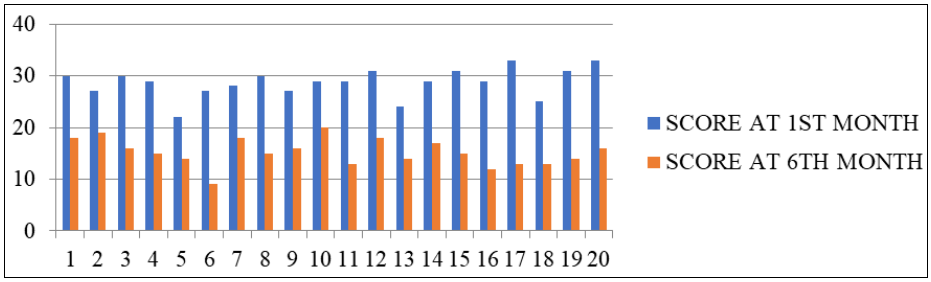

Fig 6: Graphical representation of pain score in KOO scale before and after treatment in 50 millesimal group

4. Score of functions of daily living in KOOS scale comparison of KOO functions of daily living score before and after treatment

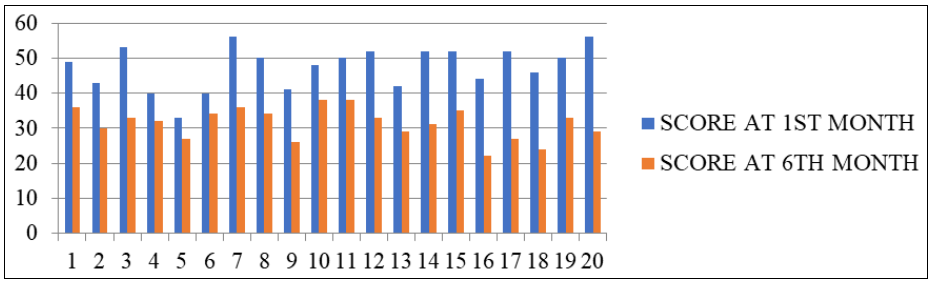

Fig 7: Graphical representation of functions of daily living score in KOO scale before and after treatment in centesimal group

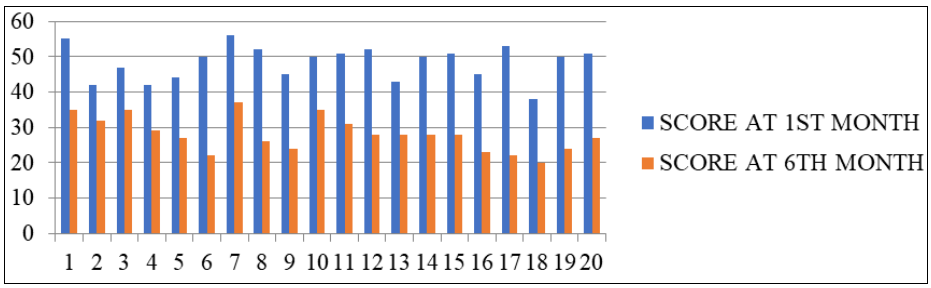

Fig 8: Graphical representation of functions of daily living score in KOO scale before and after treatment in 50 millesimal group

5. Score of functions, sports and recreational activities in KOOS scale
Comparison of KOO functions; sports and recreational activities score before and after treatment

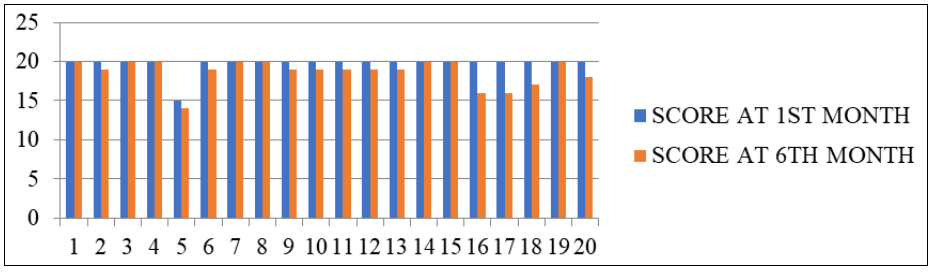

Fig 9: Graphical representation of functions, sports and recreational activities score in KOO scale before and after treatment in centesimal group

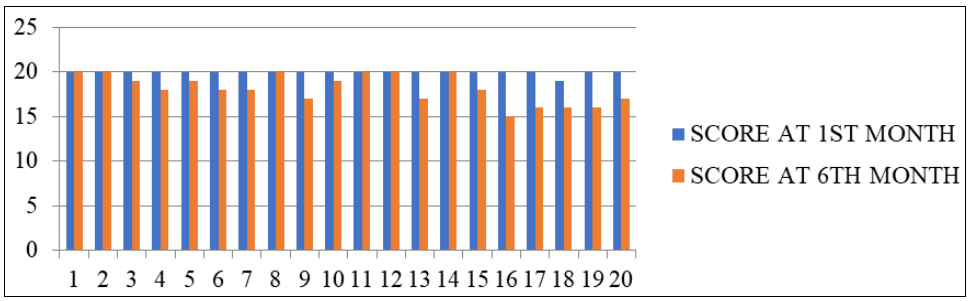

Fig 10: Graphical representation of functions, sports and recreational activities score in KOO scale before and after treatment in 50 millesimal group

6. Score of quality of life in KOOS scale
Comparison of KOO quality of life score before and after treatment

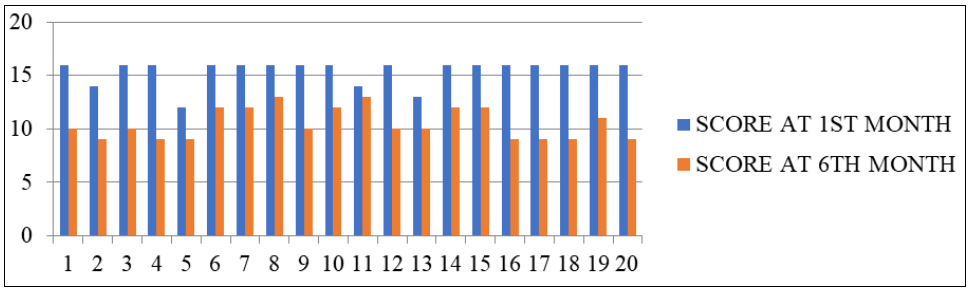

Fig 11: Graphical representation of quality of life score in KOO scale before and after treatment in centesimal group

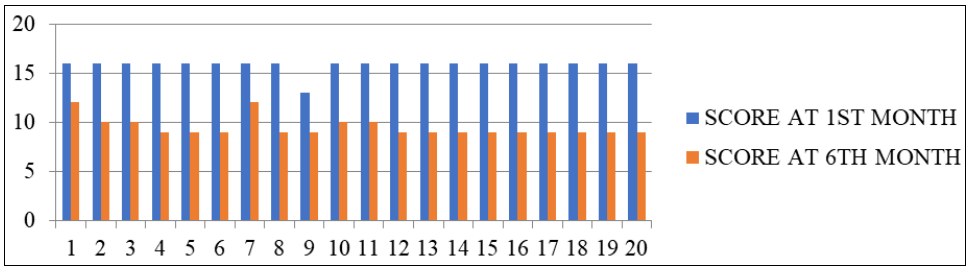

Fig 12: Graphical representation of quality of life score in KOO scale before and after treatment in 50 millesimal group

7. Total score in KOOS scale
Comparison of total KOO score before and after treatment

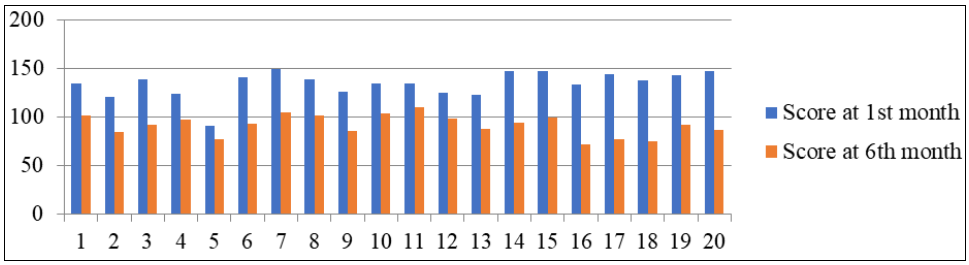

Fig 13: Graphical representation of total KOO score before and after treatment in centesimal group

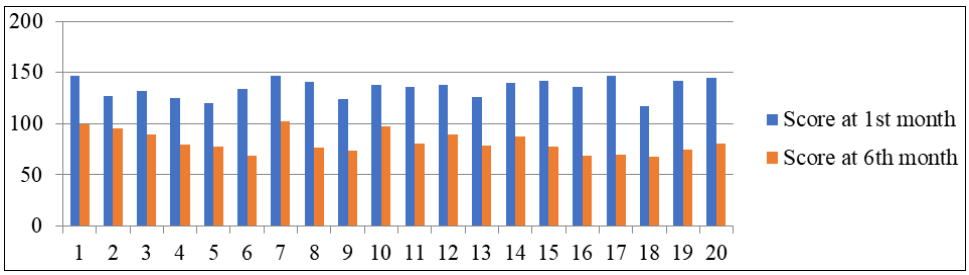

Fig 14: Graphical representation of total KOO score before and after treatment in 50 millesimal group

Result

This study was conducted with the intention to compare the effectiveness of homoeopathic constitutional medicine in centesimal and millesimal potency in the management of osteoarthritis of knee joint. The assessment was based on the variation in total KOO score and score of symptoms; score of stiffness; score of pain; score of functions of daily living; score of functions, sports and recreational activities and score of quality of life in KOO scale after treatment in both groups of patients with OA knee joint using medicines in centesimal potency and 50 millesimal potency.

On analyzing the changes in the scores of various sub-scales in Knee injury and osteoarthritis outcome score before and after treatment, we find that 17 (85%) patients had significant change and 3 (15%) patients had moderate change in score of symptoms in KOO scale in centesimal group. In 50 millesimal group, 19 (95%) patients had significant change and 1 (5%) patient had moderate change in the score of symptoms in KOO scale.

On considering the changes in score of stiffness in KOO scale, we find that 19 (95%) patients had significant change and 1 (5%) had moderate change in centesimal group and all 20 patients had significant change in 50 millesimal group.

On considering the changes in score of pain in KOO scale, we find that 12 (60%) patients had significant change and 8 (40%) had moderate change in centesimal group and 18 (90%) patients had significant change and 2 (10%) patients had moderate change in 50 millesimal group.

On considering the changes in score of functions of daily living in KOO scale, we find that 17 (85%) patients had significant change and 3 (15%) had moderate change in centesimal group and 16 (80%) patients had significant change and 4 (20%) patients had moderate change in 50 millesimal group.

On considering the changes in score of functions, sports and recreational activities in KOO scale, we find that 8 (40%) patients had no change and 12 (60%) had mild change in centesimal group and 6 (30%) patients had no change and 14 (70%) patients had mild change in 50 millesimal group.

On considering the changes in score of quality of life in KOO scale, we find that 7 (35%) patients had mild change and 13 (65%) had moderate change in centesimal group and 2 (10%) patients had mild change and 18 (90%) patients had moderate change in 50 millesimal group.

On considering the total KOO score, we find that 7 (35%) patients had very slight change, 5 (25%) patients had mild change and 4 (20%) patients had moderate change and 4 (20%) patients had significant change in centesimal group. In 50 millesimal group, 5 (25%) patients had very slight change, 8 (40%) patients had mild change and 3 (15%) patients had moderate change and 4 (20%) patients had significant change in total KOO score.

There is significant difference in total KOO score and score of symptoms; score of stiffness; score of pain; score of functions of daily living; score of functions, sports and recreational activities and score of quality of life in KOO scale after treatment in both groups of patients with OA knee joint using medicines in centesimal potency and 50 millesimal potency. The observed difference in KOO score after treatment in both groups of patients with OA knee joint using medicines in centesimal potency and 50 millesimal potency was found to be statistically significant and p-value was less than 0.05.

On comparing the effect in total KOO score after treatment with homoeopathic constitutional medicines in the group of OA knee joint patients using homoeopathic constitutional medicines in centesimal potency and 50 millesimal potency, we find that the mean difference in total KOO score before treatment and after treatment is greater in the group of OA knee joint patients using medicines in 50 millesimal potency when compared with that of the group of OA knee joint patients using medicines in centesimal potency.

Therefore, we find that, there is significant change in pain, swelling, stiffness and functions of daily living in patients with OA knee after treatment with homoeopathic constitutional medicines in centesimal potency and 50 millesimal potency. And, we also find that the mean difference in total KOO score before treatment and after treatment is greater in the group of OA knee joint patients using medicines in 50 millesimal potency when compared with that of the group of OA knee joint patients using medicines in centesimal potency.

Conclusion

This study has shown that, there is significant change in pain, swelling, stiffness and functions of daily living in patients with OA knee after treatment with homoeopathic constitutional medicines in centesimal potency and 50 millesimal potency.

This study has also shown that the mean difference in total KOO score before and after treatment, is greater in the group of OA knee joint patients using medicines in 50 millesimal potency when compared with that of the group of OA knee joint patients using medicines in centesimal potency. Thereby, the effectiveness of homoeopathic constitutional medicines in 50 millesimal potency is slightly more than that of homoeopathic constitutional medicines in centesimal potency, in the treatment of osteoarthritis of knee joint.

Limitations

- The sample size was very small when compared with the prevalence of OA knee joint in the population. Therefore, generalisation from the study should be made with care.
- OA knee joint is a chronic disease with slow progress. One year is very short study duration to assess the overall outcome.
- Patients with severe symptoms of pain, stiffness and functional disability suffering from OA knee joint will be in despair from long durations of previous treatments and they won't wait for sufficient time during the homoeopathic treatment.

Recommendations

- Study will be more scientific and its results will become more reliable when sample size is more.

In order to substantiate the results before scientific community, advanced images, investigations and scoring is necessary.

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