

AN OPEN, RANDOMIZED, COMPARATIVE CLINICAL STUDY TO ASSESS THE ANALGESIC & ANTI-INFLAMMATORY EFFICACY OF PAINMUKTI MJ TABLETS, PAINMUKTI CREAM AND PAINMUKTI-SANDHICAL TABLETS IN PATIENTS SUFFERING FROM CHRONIC PAIN

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ABSTRACT

Objective: To evaluate the comparative analgesic & anti-inflammatory efficacy and safety of Tab. Painmukti MJ tablets, Painmukti cream and Painmukti-sandhical tablets in patients suffering from chronic painful conditions. **Methods:** The study was initiated following Institutional Ethics Committee approval. Patients with chronic pain lasting more than 3 months were randomized to one of 3 groups and received either Tab. Painmukti-MJ+Painmukti cream [Group I], Tab. Painmukti-MJ + Tab.Painmukti-sandhical + Painmukti cream [Group II] or Oral placebo tablets + Diclofenac gel [Group III] for 3 months after obtaining written informed consent. Monthly assessments included pain relief using modified WOMAC and Visual Analog Scales (VAS), Quality of life using EQ-5D questionnaire and need for rescue analgesics. **Results:** 106 patients were enrolled of which 2 patients were withdrawn following adverse events. Significant reduction in the requirement of oral analgesics and/or anti-inflammatory agents was observed in Groups I & II as compared to the baseline (p <0.001). WOMAC score (p<0.05) and VAS scale (p <0.001) too reduced significantly while the overall Quality of Life improved significantly. **Conclusion:**, Painmukti tablets & cream and Sandhical tablets possess properties that enhance *agni*, pacify *ama* and vitiate *vata*dosh, thus proving useful in chronic painful conditions

Keywords: Tab. Painmukti, Tab. Painmukti-sandhical, arthritis, analgesic,

INTRODUCTION

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage as per International association for the study of Pain (IASP)[1]. Pain sensation can be of 2 main types: acute & chronic.

Traditionally, the distinction between acute and chronic pain has relied upon an arbitrary time interval from the onset; the two most commonly used markers being 3 months and 6 months since the initiation of pain[2]. Chronic pain conditions affect older adults mainly. Common chronic pain complaints include headache, low back pain, cancer pain, arthritic pain, neurogenic pain (pain resulting from damage to the peripheral nerves or to the central nervous system itself), psychogenic pain (pain not due to past disease or injury or any visible sign of damage inside or outside the nervous system). A person may have two or more co-existing chronic pain conditions [3]. Arthritis is a degenerative condition primarily affecting the articular cartilage. As the disease progresses, the underlying subchondral bone is exposed, later becoming hard and glossy. The bone at the margin of the joint then gets hypertrophied leading to formation of osteophytes. Pain makes it very difficult for individuals to be physically active and many become home bound [4,5]

Irrespective of the type of arthritis, the first line therapy mainly consists of oral, injectable and topical analgesic and anti-inflammatory drugs for the management of acute and

chronic pain, mainly the Non-steroidal anti-inflammatory agents (NSAIDs) [6]. As an outcome although these drugs offer symptomatic relief in patients of osteoarthritis, chronic use of these leads to adverse effects such as adverse effects on the kidney, and exacerbating asthma in some people, but the most important adverse effect of NSAIDs is that on the gastrointestinal tract. NSAIDs cause gastric erosions leading to ulcers which can be debilitating & in some cases have a fatal outcome. Additionally, in case of patients who do not respond to the primary line of treatment, intra-articular glucocorticoid injections is administered.

That is why search for safe and effective remedies continues from other alternative resources for their better management. Ayurveda has a tremendous potential to offer safer therapies for difficult to treat disorders such as arthritis. Several Ayurvedic medicinal plants used to treat pain in clinical practice demonstrated significant biological and immunomodulation effects in clinical drug trials [7,8] and experimental studies [9,10]

In Ayurveda, a combination of various herbal and herbo-mineral preparations has been mentioned for the management of *Sandhigataavata*. In this study we evaluated the potential analgesic & anti-inflammatory efficacy and safety of 3 proprietary Ayurvedic medications viz. Painmukti MJ tablets, Painmukti-sandhical tablets and Painmukti cream when administered for pain relief.

Table 1: The detailed composition of study medications are as follows:

Painmukti MJ Tablets		Painmukti - sandhical Tablets		Painmukti cream	
Ingredients	Quantity	Ingredients	Quantity	Ingredients	%
Nirgundhi Ghan (<i>Vitex nirgundo</i>)	50 mg	Guggul (<i>Commiphora mukul</i>)	150mg	Mahanarayan oil	10%
Rasna Ghan (<i>Pluchelanceolata</i>)	100mg	Asthishrunkhla ghan (<i>Cissus quadrangularis</i>)	100mg	Lavang oil (<i>Eugenia aromatica</i> oil)	0.5%
Shallaki Ghan (<i>Boswelliaserrata</i>)	100mg	Lajjalughana (<i>Mimosa Pudica</i>)	30mg	Twak oil (<i>Cinnamomum Zeylanicum</i> oil)	0.5%
Rakta Punarnava Ghan (<i>Boerhavia diffusa</i>)	40mg	Lakha (<i>Lacciferalacca</i>)	20mg	Pudinaphool (<i>Mentha spicata</i>)	5%,
Shunthi powder (<i>Zinziber officinalae</i>)	25mg	Aswagandha (<i>Withania sominfera</i>)	20mg	Shuddha Guggul (<i>Balsamodendron mukul</i>)	1%,
Musta powder (<i>Cyprus rotandus</i>)	75mg	Mukta	400mg	Marich ark (<i>Capsicum</i> extract)	0.1%
				Gandhapurapo oil (Winter green oil)	10%

Placebo: starch containing placebo tablets that were similar in appearance to the study medications were used in the study

Study design

This was a prospective, proof of concept, open, randomized, controlled, double blind, interventional, Phase IV study.

Ethical Considerations: The study was conducted after obtaining permission from the Institutional Ethics Committee in October 2011 at a tertiary care public hospital in a metropolitan city. Patients suffering from chronic joint pain including arthritis and attending the Orthopedics outpatient clinic (OPD) who fulfilled the study eligibility criteria were recruited into the study following written informed consent. This study was conducted as per the Indian GCP, Schedule Y

and other applicable government regulatory and ethical policies and procedures.

Study Population:

Eligibility criteria for the study included patients of either sex between the age group of 18-75 years (both years inclusive), who were suffering from chronic pain (continuous pain present for at least 3 months or more) due to different causes such as arthritis, frozen shoulder, tennis elbow, ankle sprain, low back pain, neurogenic pain (pain resulting from damage to the peripheral nerves or to the central nervous system itself), and who were willing to provide written, informed consent. Patients demonstrating signs and symptoms of complications such as bone and joint deformity, long term treatment of oral and/or injectable steroids or surgical intervention with signs and symptoms of other systemic

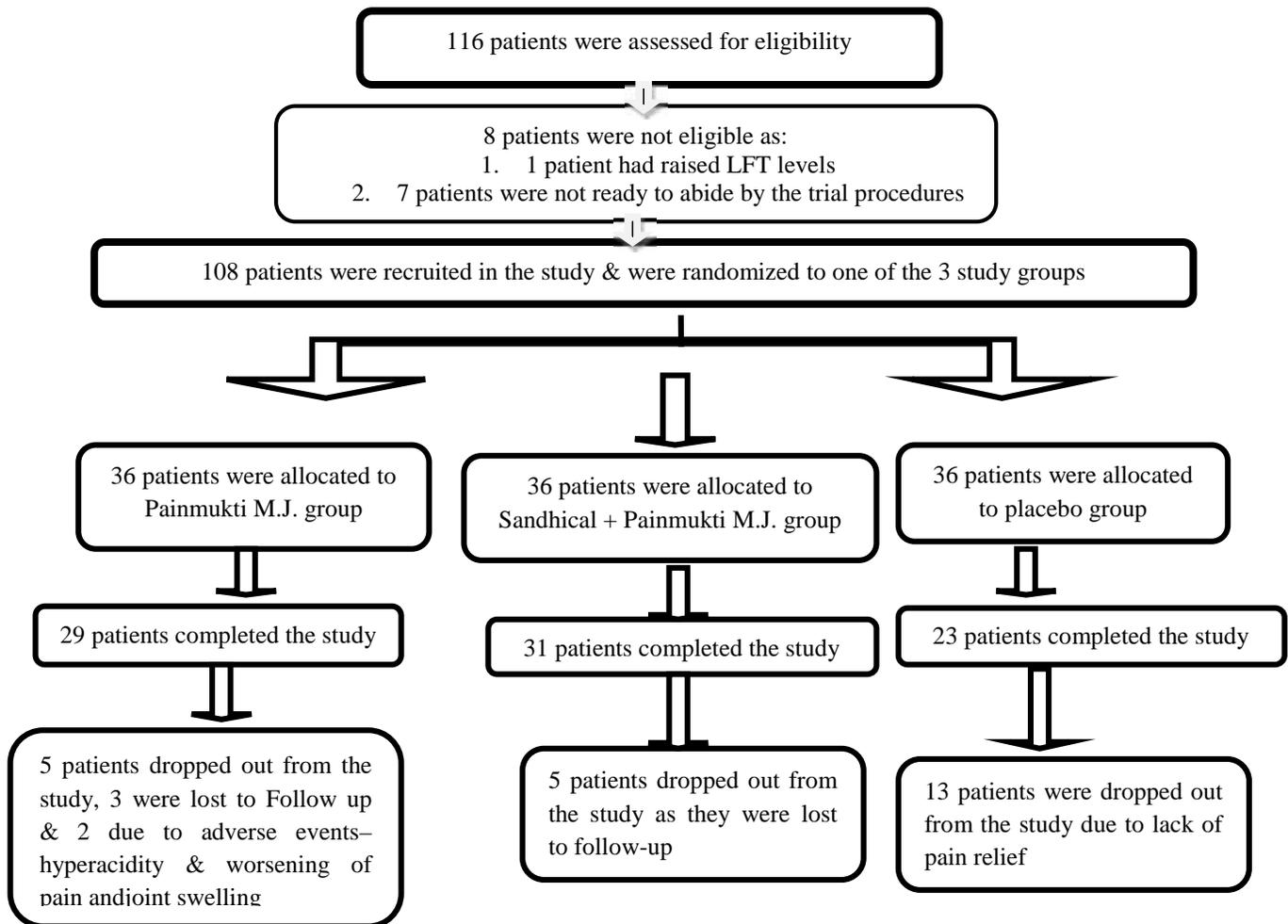
involvement were excluded including pregnant and lactating women. Potential participants were identified from Orthopedic OPD and were screened for the eligibility criteria after explaining the trial purpose and procedures.

Sample size calculation: The study was planned as a pilot comparative three arm study between 3 groups of a continuous response variable (pain relief) with equal number of patients in each group. As there was no previous literature available of similar studies with this study design using herbal formulations, the sample was calculated with a 10% expected difference in pain relief between the groups with standard deviation 15%. Thus, the sample size came to about 36 patients in each group so as to be able to reject

the null hypothesis that the population means between the 3 groups are equal with probability (power) of 80% and type I error probability associated with this test of this null hypothesis was 5%.

Study methodology: Eligible patients were randomized in 1:1:1 ratio using a computer generated randomization table to either one of the three groups. Patients randomized to Group I received Painmukti MJ tablets orally and Painmukti cream for local application, those in Group II received Painmukti MJ tablets and Painmukti-sandhical tablets orally while those patients randomized to Group III received oral placebo tablets and Diclofenac gel for local application. The study duration was 3 months.

Figure 1: Study Flow Chart



Study assessments were conducted at monthly intervals which included clinical history, physical examination, pain assessment using the modified WOMAC score and Visual Analog Scale (VAS) and assessment of Quality of life using the EQ-5D questionnaire. Need for additional analgesic/anti-inflammatory medications by the patients were also documented during the study period. Hematological and biochemical investigations (hemoglobin, CBC, ESR, LFT & RFT) and X-ray of the relevant body part were done at the baseline visit as well as after completion of the study *i.e.* after 3 months of the study medication. Safety was monitored by clinical assessment and laboratory investigations.

Statistical analysis: The data is expressed as Mean \pm SD (95 % Confidence Interval) for normally distributed data and Median (Range) for not normally distributed data. Kruskal Wallis/ANOVA followed by post hoc tests and Mann Whitney U test /unpaired 't' tests were used. A p value < 0.05 was considered as statistically significant for all the tests.

Results: 116 patients were screened to participate in the study to achieve a target of 90 patients who complete the study. Of these, 8 patients were screen failures and 108 were enrolled. 83 patients completed the study, 23 patients dropped out of the study at different time points mainly lost to follow-up while 2 patients were withdrawn from the study following development of adverse events. The study flow chart is shown in Figure 2.

Demographic distribution of patients:

Majority of the patients who enrolled in the study were women (n= 86; 81.13%). The average age of the participants was 49.94 ± 10.13

Distribution of patients according to disease condition: Majority of the patients in the study were those suffering from Osteoarthritis of the knee (80%) as can be seen from Fig 1- (Distribution of patients as per disease condition)

Requirement of oral analgesics and/or anti-inflammatory agents:

A significant reduction in the requirement of oral analgesics and/or anti-inflammatory agents was observed in Groups I & II as compared to Group III. The results are shown in Table 1.

Changes in the WOMAC and Visual Analogue scale (VAS) scores

A significant improvement in the WOMAC score was seen in Groups I & II at the end of 3 months. The results are shown in Table 2. Similar results were obtained in the VAS scoring with Groups I & II demonstrating significant improvement at the end of 3 months. The results are shown in Table 2 & 3.

Effect on Quality of Life:

An improvement in the overall Quality of life and Health Status was observed in groups I & II which was statistically significant for Group I following treatment for 3 months. Group III showed no improvement in the Quality of Life scores. The results are depicted in Tables 4&5.

Safety evaluation:

1 patient withdrew consent due to occurrence of a serious adverse event (patient was hospitalized due to increase in joint pain). One patient was withdrawn as she complained of hyperacidity after consumption of the study medications. No other major significant difference was observed in the laboratory parameters (hematology, liver and renal function tests).

Clinical Trail Registry:
CTRI/2013/03/003508 [Registered on:
21/03/2013] Trial Registered Retrospectively

DISCUSSION:

Treatment of pain may vary depending on the types of pain and it includes physical therapy, lifestyle management (including exercise and weight control) and medications. The most commonly prescribed medicines for its treatment include NSAIDs, Corticosteroids and Immunosuppressant drugs and variety of topical application but these drugs are associated with numerous short and long term side effects. In spite of so many advances in biomedical science, the management of pain still remains unsatisfactory and challenging. That is why majority of the patients were inclined towards alternative therapeutic modalities. In this regard, Ayurvedic herbal and herbo-mineral formulations have been found more effective and safer in comparison to NSAIDs and corticosteroids for long term use. [7]

The study results showed that treatment with the study medications decreased the

requirement of analgesics and anti-inflammatory agents, improved the pain scores (WOMAC & VAS) and also the Quality of Life scores. Also, there were no significant adverse effects on the lab-based safety parameters in the 3 months treatment period.

Probable mode of action of Painmukti Tab.

The primary constituent of Tab. Painmukti MJ is *Boswellia serrata* (Shallaki). The principal constituent of its gum resin is Boswellic acid, which is known to block the synthesis of pro-inflammatory chemomediators like 5-Lipoxygenase (including 5-hydroxy-eicosa tetraenoic acid) and leukotrienes. *Boswellia serrata* also reduces glycosaminoglycan degradation, which is essential to prevent articular damage [8, 11]. The principal constituents of *Rasna* (*Pluchea lanceolata*) are Heptacosane and Octocosanol, which have demonstrated anti-inflammatory activity [7]. The active constituents of *Ashwagandha* (*Withania somnifera*) are cuseohygrine, anahygrine and anaferine. These are helpful in reducing inflammation and stimulating the immune system. [8,12] *Shunthi* (*Zingiber officinale*) contains Zingiberene and Zingiberol which possess anti-inflammatory, anti-histaminic and anti-oxidant property [8, 13] *Rakta Punarnava Ghan* (*Boerhavia diffusa*) possesses. It contains alkaloid Punarnavine which block the synthesis of various pro-inflammatory chemo-mediators and reduces swelling.

Musta Powder (*Cyperus rotandus*) [14] is also claimed to have anti-inflammatory and analgesic properties. Its alcoholic extract

demonstrated significant anti-inflammatory activity against the exudative and proliferative phases of inflammation in two animal models (carrageenin induced oedema and formaldehyde induced arthritis in rats).

Seeing this fact, we proposed the Ayurvedic pharmacodynamic of Tab. Painmukti M.J., which is comprise of *Katu*, *Tikta rasa*, *Ushna virya*, *Katu Vipaka*, and *Vedanasthapaka* (analgesic) and *Shothahara* (anti-inflammatory) effect. Besides, it also imparts immune strength and improves the overall well being of the patient due to *Rasayana* (Immune enhancer) effect.

Probable mode of action of Painmukti cream:

Painmukti cream contains ingredients like *Mahanarayan oil* [15], *Pudinaphool (Mentha spicata)* [16] and *Gandhapura oil* (Wintergreen oil) [17, 18] which confer its analgesic and anti-inflammatory properties as the principle constituent of *Gandhpura Oil (G. fragrantissima)* is methyl salicylate.

Probable mode of action of painmukti-Sandhical Tablets:

Painmukti- Sandhical tablets are a combination of various herbs including *Guggul (Commiphora mukul)*, which is

claimed to reduce bone degeneration & increase bone density & promote calcium uptake in the bone [19]. *Cissus quadrangularis* builds up the chemical composition of the fractured bone viz. mucopolysaccharides, collagen, calcium, phosphorus and others as well as its functional efficiency [20, 21] and *Lajjalu (Mimosa Pudica)* which improves the process of regeneration of sciatica nerve [22]. The oleoresin fraction of *Guggul* possesses significant anti-arthritis and anti-inflammatory activities. *Lakha (Laccifera lacca)* resin acts as a tonic for muscles and bones [23]. *Ashwagandha (Withania sominifera)* act as tonic, nervine, sedative, nerve restorative anti-inflammatory, anti-arthritis and also prevent the damage of cartilages in osteoarthritis [24, 25]. *Mukta*, a type of sea shell being a rich source of calcium, helps in the bone remoulding process [23]. Most of the ingredients are *vatakaphanashaka*, *deepana*, *balya*, *rasayana*, *tridoshanashaka*, *pachana*, *shothaghna*, *vedanashamaka* & *shoolaprashamaka*. A compound preparation having these properties is claimed to halt the progress of disease conditions of *Sandhigatavata*.

Tables and Figures

Table 1: Requirement of oral analgesics and/or anti-inflammatory agents

Sr. No.	Requirement of analgesics	Day 0	Day 30	Day 60	Day 90
1.	Group I (n=29)	2 (0-5)	1 [@] (0-3)	0 [@] (0-4)	0 [@] (0-1)
2.	Group II (n=31)	2 (1-8)	1 [#] (0-5)	0 [@] (0-4)	0 [@] (0-1)
3.	Group III (n=23)	2 (1-4)	1 (0-4)	1* (0-4)	1 (0-4)

Result expressed as Mean ± SD (95 % Confidence Interval) for normally distributed data and Median (Range) for not normally

distributed data. *p <0.05, #p <0.01 and @p <0.001 as compared to V2 using Kruskal Wallis test

Table 2: Effect on WOMAC score

Study Groups	Day 0 (V2)	Day 30 (V3)	Day 60 (V4)	Day 90 (V5)
Group I (n=29)	34 (5-76)	36 (4-73)	27 (2-74)	21* (3-77)
Group II (n=31)	33 (6-69)	32 (3-60)	26* (6-77)	24 [@] (1-80)
Group III (n=23)	32.8± 12.9 (27.2-38.4)	31± 14 (25-36)	29± 14 (23-35)	26.5 ± 13.3 (20.6-32.4)

Result expressed as Median (Range) for not normally distributed data. *p <0.05 as compared to V2 using Friedman test

(Nonparametric Repeated Measures ANOVA); @p <0.01 as compared to V2 using Friedman test

Table 3: Effect on VAS score

Study Groups	Day 0 (V2)	Day 30 (V3)	Day 60(V4)	Day 90 (V5)
Group I (n=29)	7 (4-10)	6 (2-10)	4* [@] (1-10)	3 [@] (1-10)
Group II (n=31)	7 (5-10)	6 (2-10)	5 [@] (1-9)	4 ^{@#} (1-9)
Group III (n=23)	6 (3-10)	5 (2-9)	5 (2-10)	4 ^{\$} (1-10)

Result expressed as Median (Range) for not normally distributed data. *p <0.05 as compared to V2 and V3 using Friedman test (Nonparametric Repeated Measures

ANOVA); \$ p <0.01 as compared to V2 using Friedman test; @p <0.001 as compared to V2, V3 using Friedman test

Table 4: Effect on Quality of Life (EQ-5D score)

Study Groups	Day 0 (V2)	Day 90 (V5)
Group I (n=29)	10(5-12)	8*(1-11)
Group II (n=31)	9(5-14)	7*(5-10)
Group III (n=23)	9(5-12)	9(5-12)

Result expressed as Median (Range) for not normally distributed data. * p <0.01 as

compared to V2 using Wilcoxon matched-pairs signed-ranks test

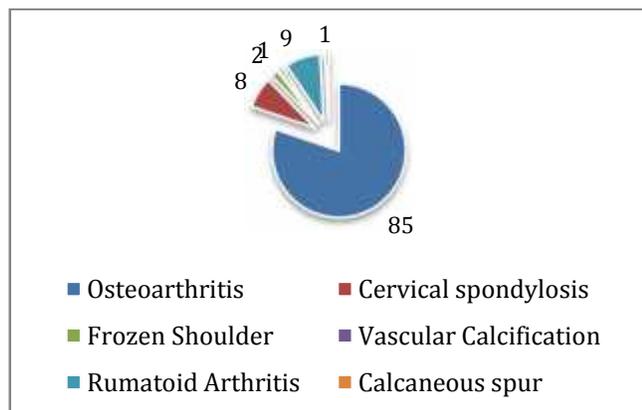
Table 5: Effect on Quality of Life (VAS - Health Status)

Study Groups	Day 0	Day 90
Group I (n=29)	50(10-90)	60*(10-95)
Group II (n=31)	60(20-90)	65*(40-90)
Group III (n=23)	50(10-90)	50(20-80)

Result expressed as Median (Range) for not normally distributed data. *p <0.05 as

compared to V2 using Kruskal-Wallis Test (Nonparametric ANOVA)

Fig. 2: Distribution of patients as per disease condition



CONCLUSION

In this study, there was a good relief in the joint pain and tenderness and stiffness in patients suffering from different arthritic problems with both Painmukti and Painmukti-sandhical tablets in addition to the local application of Painmukti cream. Thus Painmukti appears to be a moderately effective and safe medication in chronic pain conditions and can be given as an alternative to NSAIDs in these patients with minimal side-effects.

According to Ayurvedic philosophy any inflammatory condition *Ama* (reactive agent) plays a significant role in the occurrence of pain. The study medications have *Amapachana* (detoxifying), *Vedanahara* (analgesic), *Shothahara* (anti-inflammatory), *Vishaghna* (anti-allergic), *Jvarahara* (anti-pyretic) effects. Painmukti tab. & cream and Sandhical tab. have a good combination of herbal drugs that possess the desired qualities which pacify *Ama* and vitiate the *Vata Dosha*. By virtue of these properties these medications works as disease modifying, analgesic and

anti-inflammatory agents and will be helpful in the management of pain.

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