

CLINICAL TRIAL OF "V RELIEF" OINTMENT
Evaluation of the efficacy of "V RELIEF" in the management of
PAIN and other musculoskeletal complications"

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Reason: (HETU)

Ayurved is a science that considers any disease from its origin to its treatment. It is to prevent disease from its recurrence. This is the need of today's mankind suffering from various psychological and physical problems to get treated by natural way of healing. So is our step further to use modern technology, knowledge available, diagnostic help combine with Non Toxic, Non Narcotics, Non Metallic, Non Animal ingredient, purely Herbal Ayurvedic formulations to achieve this goal.

Vivechan (Introduction):

Pain is very common reason patients seek medical care. Pain has sensory and emotional components and is often classified as acute or chronic. Acute pain is frequently associated with anxiety and hyperactivity of the sympathetic nervous system. Chronic pain does not involve sympathetic hyperactivity but may be associated with vegetative signs and depressed mood and injury. People vary considerably in their tolerance for pain.

Pain is the most common reaction or lakshan of Vata. One such challenging Cause of PAIN is 'Vata-vyadhi'. Vata vyadhi is a special group of diseases first which appears in the Charak Samhita (Chapter 20). The Charak Samhita and its commentator Chakrapanidutt rightly emphasize the special importance of the group of diseases classified as Vata vyadhis viz-a-viz Pitta and Kapha diseases. This is primarily due to their severity of affliction and need of specific treatment for the control of the same

Utpatti (Metabolic transformation):

It is very important to evaluate the cause, severity, and nature of the pain and its effect on activities, mood, cognition, and sleep. Evaluation of the cause of acute pain (eg, back pain, chest pain etc, differs from that of chronic pain. The history should include the following information about the pain:

➤ **Quality**

- Burning,
- Cramping,
- Aching,
- Deep,
- Superficial
- Boring
- Shooting

- Severity
- Location
- Radiation pattern
- Duration
- Timing
- Pattern
- Degree
- Fluctuation
- Exacerbating Factor
- Relieving factors
- The patient's level of function
- Daily Activity
- Dressing
- Bathing
- Employment
- Avocations
- Personal habits
- Alcohol
- Working
- Psychological issues
- Depression
- Anxiety.

Pathogenesis: (SAMPRAPTI):

'Sroto-riktata' is an important feature in the 'Samprapti' (aetiology/pathogenesis) of all 'Vata vyadhis' according to the 'Charak Samhita'

It is reclassified that Vata Vyadhis narrated in the classical literature into eight subgroups. These are of great clinical relevance as they are organized as per their main presenting feature or Samprapti. They are as follows:

- Vata vyadhis with pain as predominant feature
- Vata vyadhis with pronounced movements as primary feature
- Vata vyadhis with loss of movements
- Vata vyadhis affecting the Ashayas (viscera)
- Vata vyadhis affecting the Indriyas (sense organs)
- Vata vyadhis caused by Avarana
- Vata vyadhis with Stambha (stiffness) as primary feature, and
- Vata vyadhis with Shosha (muscle atrophy).

Vata is the doer of all actions, the soul of all the happenings, possessor of all forms, chief of all living beings, the creator, the supporter and the controller of all; is omniscient, destroyer, lord of death and death itself. Hence all our efforts should be maintained to maintain it normally always.

Vayu i.e. Vata gets aggravated or increased from over indulgence in wrong foods i.e. Light, dry, rough, bitter, pungent and astringent, and activities i.e. Too much running, jumping, carrying heavy weights etc. This causes depletion of the tissues. Vata then fills up the empty channels left by the depletion of the tissues and moves or circulates greatly much more than

normal, and can become enveloped by the other doshas i.e. Pitta and kapha which have also filled up the empty spaces caused by depletion of the tissues.

Types of pain (Prakar)

Acute pain, which usually occurs in response to tissue injury, results from activation of peripheral pain receptors and their specific sensory nerve fibres.

Chronic pain related to ongoing tissue injury is presumably caused by persistent activation of fibers. However, the severity of tissue injury does not always predict the severity of chronic or acute pain. Chronic pain may also result from ongoing damage to or dysfunction of the peripheral or central nervous system.

Nociceptive pain may be somatic or visceral. Somatic pain receptors are located in skin, subcutaneous tissues, fascia, other connective tissues, and joint capsules. Stimulation of these receptors usually produces sharp or dull localized pain, burning if the skin or subcutaneous tissues are involved. Visceral pain receptors are located in most viscera and the surrounding connective tissue, causing obstruction and visceral pain. Which is deep, cramping, localized and sharp.

Psychotic Pain modulate intensity to a highly variable degree. Thoughts and emotions have an important role in the perception of pain. are defined by self-reported pain.

Pain impairs multiple cognitive domains including attention, memory, concentration, and content of thought, possibly by demanding cognitive resources.

Many pain syndromes are multi factorial. For example, chronic low back pain and most cancer pain syndromes have a prominent noniceptive component but may also involve neuropathic pain due to nerve damage.

Pain transmission and modulation

Pain fibres enter the spinal cord at the dorsal root ganglia and synapse in the dorsal horn. From there, fibers cross to the other side and travel up the lateral columns to the thalamus and then to the cerebral cortex.

Repetitive stimulation from a prolonged painful condition can sensitize neurons in the dorsal horn of the spinal cord so that a lesser peripheral stimulus causes pain . Peripheral nerves and nerves at other levels of the CNS may also be sensitized, producing long-term synaptic changes

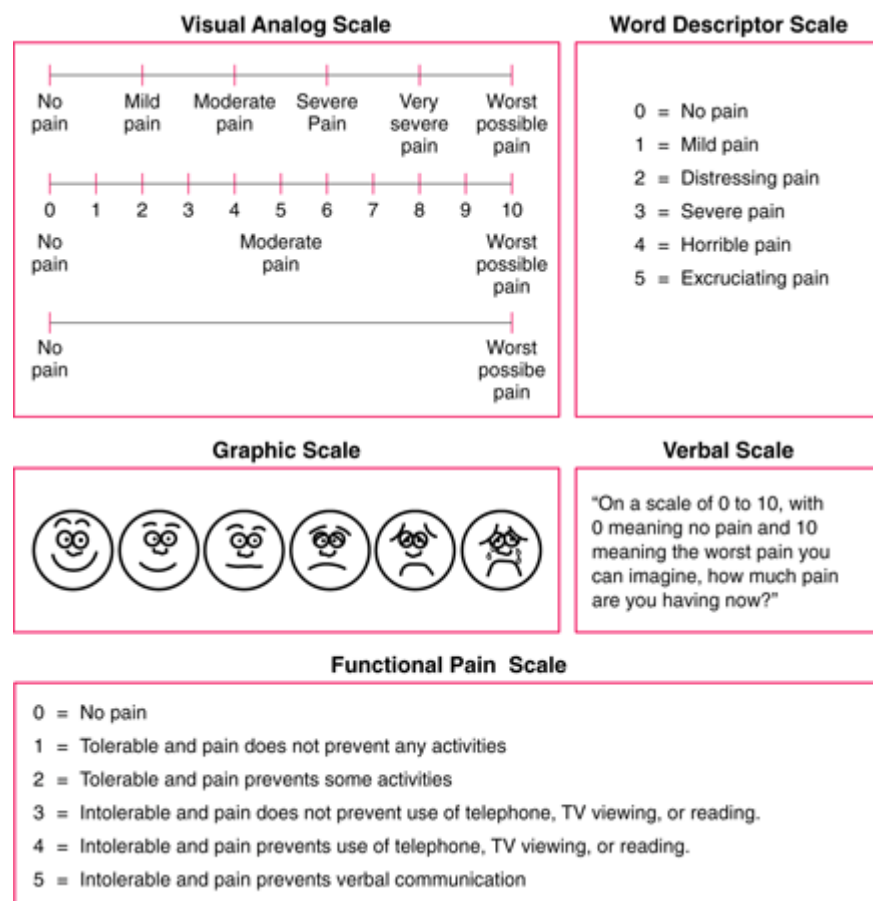
Psychologic factors are important modulators. They not only affect how patients speak about pain in a stoic, irritable or complaining way and how they behave in response to it, but they also generate neural output that modulates neurotransmission along pain pathways.

CRPS Complex regional pain syndrome is chronic neuropathic pain that follows soft-tissue or bone injury (type I) or nerve injury (type II) and lasts longer and is more sever.

Symptoms of Pain: (Lakshan)

Assessing pain by

- Affecting cognition
 - Speech
 - Facial grimacing
 - Frowning
 - Repetitive eye blinking
 - Irritability
 - Grimacing.
 - Pain severity
 - Crying
 - Wincing
 - Rocking
 - Mild
 - Moderate
 - Severe
-



Causes

In the elderly, the most common causes of pain are musculoskeletal disorders. However, pain is often chronic and multi factorial and the causes may not be clear.

Vayu (vata) gets aggravated or increased from over indulgence in wrong foods i.e. Light, dry, rough, bitter, pungent and astringent, and activities i.e. Too much running, jumping, carrying heavy weights etc. Which causes depletion of the tissues. Vata then fills up the empty channels left by the depletion of the tissues and moves or circulates greatly much more than normal, and can become enveloped by the other doshas i.e. Pitta and kapha which have also filled up the empty spaces caused by depletion of the tissues

Other Causes (Vishesh Karan)

Other Factors that may trigger pain include:

- Investigations: (PARIKSHAN)
- RADIOLOGY:
- X ray
- C T Scan
- M R I
- Bone Denxitomerty
- D X A
- PATHOLOGY:
- C B C
- E S R
- R A
- C R P
- A S O Titer
- A N A
- R A Antibodies
- Uric Acid

NIDAN: (Predisposing factors)

Affliction of 'Marma' is mentioned as a causative factor in the classic 'Charak Samhita'. A specific list of 28 'Marmas' (vital points) and the Vata vyadhis caused by trauma to each of them is mentioned in it.

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- There are two ways in which vata can be aggravated,
 1. By occupying the channels caused by the depletion of tissues and producing increased functioning in the channels so occupied.
 2. By becoming involved or enveloped by other doshas which have accumulated in the channels and producing disease and loss of functioning of the channels so affected. In the first type vata is the only dosha producing the effect and is hence very powerful. In the second type vata is associated with one or more of the other doshas and is regarded as not as powerful as the first type.

- In the bones vata causes pain in the thighs, joints and bones. In the marrow vata causes hollowness of bones, loss of sleep and constant pain.
- Vata in the tendons causes diseases like grdhrasi (sciatica), ayama (tetanus) and kubjata (kyphosis). Localised in the bony joints vata produces swelling , pain at the commencement of extending and flexing movements. Localised all over the body vata produces pain such as pricking, splitting throbbing and cutting etc. Stiffness, limitation in movements, contraction of the joints and tremors.

Carrying heavy load on the head, over indulgence in laughing, speaking, exertion of the face (by acts such as mimicking others, making faces, histrionic feats etc.) Sneezing, bending very hard bows, (iron bars, springs etc.) Use of irregular (uneven, hard) pillow while sleeping, chewing, biting very hard materials and other food and activities which aggravate vata, by which it gets localised pain

Symptoms (Lakshan):

- Acute pain
- Arthritis
- Rheumatism
- Gout
- Knee pain
- Sciatica
- Frozen shoulder
- Slip Disc
- Sprain
- Injury

Prevention: (NIDAN PARIVARJAN)

Diet & Lifestyle Advice

- Avoid consuming opposite foods.
- Do not control natural urges like vomiting, urination, bowels, etc.
- Do not take cold water bath immediately after a heavy workout, traveling, a long walk, etc.
- Take care not to consume foods which cause indigestion.
- Absolutely do not eat too much of salty, sour or acidic foods.

Avoid

- Sleeping in afternoons.
- Say no to Sour foods.
- Lifting excess weight
- Over exertion
- Sudden banding
- Long drives
- Sleeping under the fan or right opp to Air conditioner
- Lack of sleep

GENERAL TREATMENT: CHIKITSA

Pain treatment should be considered based on the degree, Location, Cause. Anti inflammatory, Tissue binders, Muscle relaxants, Healing, Analgesics herbs are used to treat the pain. Antidepressants, anticonvulsants, and other CNS-active drugs may also be used

for chronic or neuropathic pain and are first-line therapy for some conditions. Nerve stimulation, Ozone therapy, Bandages, Belts, Magnets, Acupressure, Acupuncture, Physiotherapy, Occupational therapy can also help to some selected patients. Cognitive-behavioural interventions, systematic use of relaxation techniques, hypnosis, or biofeedback may reduce pain and pain-related disability and help patients cope.

Treatment types : (Chikitsa prakar)

1. Daiva vyapashraya Chikitsa (Chanting of Mantras, Homas, Spiritual healing, Religious rites etc.)
2. Yukti vyapashraya Chikitsa (Medicines {Shodhana & Shamana } & Diet)
3. Satwaavajaya Chikitsa (Psychotherapy)

Yukti Vyapashraya:

(A) Antah Parimarjana-

- ✓ (a)Shodhana: Cleansing (Panchkarma as per the predominance of Doshas like Ghrita Pana & Mild purgation in Vataja type,
- ✓ therapeutic Emesis & Purgation in Pitta & Kaphja type).
- ✓ (b)Shamana:Palliative (Medhya Rasayanas,Diet etc.)

(B) Bahir Parimarjana

- ✓ Murdha Taila, Ahyanga, Shirodhara etc.
- ✓ Shastra Pranidhana-Use of Instruments & Surgical interventions.

Daivavyapashraya Chikitsa:

- ✓ Mantra- Chanting of Hymns.
- ✓ Aushadha- Sacred Herbs.
- ✓ Gems- Auspicious Stones.
- ✓ Mangala- Auspicious offerings.
- ✓ Homa- Yajna
- ✓ Niyama - Regulations.
- ✓ Prayaschita-Atonement.
- ✓ Upavasa-Fasting etc.

3. Satwaavajaya (Psychotherapy)

- ✓ When the underlying condition is treated the symptoms do not return
- ✓ Aachara Rasayana Physical & Mental Conduct.
- ✓ No involvement of Drugs.
- ✓ Maintains total life process.
- ✓ To speak truth, free from anger, abstains from alcohol & Over indulgence.

- ✓ Maintains Hygiene,
- ✓ Regular Sleep,
- ✓ Wholesome Diet.
- ✓ Controls over his Sense organs etc for Physical, Mental & Spiritual Wellbeing.
(Cha.Chi 1/30)

• **Medication:**

Ayurvedic treatment: (CHIKITSA)

Apart from various drugs available in Ayurved we have selected a patented Ayurvedic herbal medicine named "V RELIEF", manufactured by "Veer Health Care", Ahmedabad, India.

Drug review: (AUSHADHI VIVECHAN)

Contains of V RELIEF OINTMENT

| | | |
|-----------------|---------------------------|-----|
| GANDHPUDO OIL | Gaultheria fragrantissima | 16% |
| PUDINE KE PHOOL | Mentha Sylvestris | 3% |
| KAPOOR | Camphora Officinerum | 2% |
| NILGIRI OIL | Eucalyptus globulus | 1% |
| DEODAR OIL | Cedrus deodara | 1% |
| AJMA OIL | Apium Leptophyllum | 1% |

| Hindi Name | Weight | Botanical Name | Properties |
|-----------------|--------|---------------------------|--|
| GANDHPUDO OIL | 16% | Gaultheria fragrantissima | Gandhapura oil is aromatic, anti rheumatic, anti inflammatory, stimulator, repellents, pain reliever, antibacterial, antiseptic it is applied externally with success in acute rheumatism, sciatica and neuralgia. It is used in aches and pains |
| PUDINE KE PHOOL | 3% | Mentha Sylvestris | It is analgesic, anaesthetic, decongestant, emmenagogue, expectorant, febrifuge, antiseptic, antigalactagogue, antiphlogistic, antispasmodic, astringent, carminative, cephalic, cholagogue, cordial, decongestant, emmenagogue, expectorant, febrifuge, hepatic, Nervine, stimulant, stomachic, sudorific, vasoconstrictor and vermifuge. |
| KAPOOR | 2% | Camphora Officinerum | Camphor seems to stimulate nerve endings that relieve symptoms such as pain and |

| | | | |
|-------------|----|-----------------------|---|
| | | | itching when applied to the skin. Camphor is also active against fungi that cause infections in the toenails. Ant rheumatic, Anti-arthritic & Antiphlogistic: Being a detoxifier and a stimulant for circulatory system, camphor oil excites blood circulation and gives relief to rheumatic diseases, arthritis, and gout. It is also considered an antiphlogistic, that is, it reduces the swelling of body parts. This is yet another beneficial effect of proper circulation. |
| NILGIRI OIL | 1% | Eucalyptus globulus | It is Aperitif, antiseptic, antispasmodic, carminative, depurative, diuretic, emmenagogue, expectorant, galactagogue, laxative, stimulant, stomachic, splenic, tonic and vermifuge. |
| DEODAR OIL | 1% | Cedrus deodara | It proves to be a good remedy for sprains, pain, swelling, in remittent and intermittent fevers, diarrhea dysentery and ulcers, it is anti-fugal. It removes toxins from the bowel, alleviates coughing, and cures skin disorders, such as eczema and psoriasis, it is often used in aromatherapy. It is effectual in clearing the respiratory tract and reducing cough and cold. |
| AJMA OIL | 1% | Apium Leptophyllum | Ajma essential oil is one wonderful oil that has many interesting and benefiting qualities. It is quite famous all over for its strength in healing and curing diseases and injuries. Provides relief in heavy colds and migraine headaches, earaches. Body massage, spasmodic, colic and griping pains, asthma, muscle spasms, cramps, rheumatism, arthritis and oedema, relax the uterus and provide relief from menstrual cramps. |

Method:

The clinical study was planned by VAIDYA VINOD C MEHTA, BAMS (MUMBAI UNI) and DR MANAN V MEHTA, MBBS (MUMBAI UNI), in and around Mumbai and Ahmedabad.

Plan of Study:

The study was planned by the doctors and volunteers to evaluate the clinical efficacy of "V RELIEF" OINTMENT in the management of musculoskeletal ailments.

Inclusion criteria:

Patients suffering from one of the following symptoms of Acute pain, Arthritis, Rheumatism, Gout, Knee pain, Sciatica, Frozen shoulder, Slip Disc, Sprain, Injury, etc.

Exclusion criteria:

Patients with severe dehydration, Toxic symptoms, Renal failure, severe hypoglycaemia.

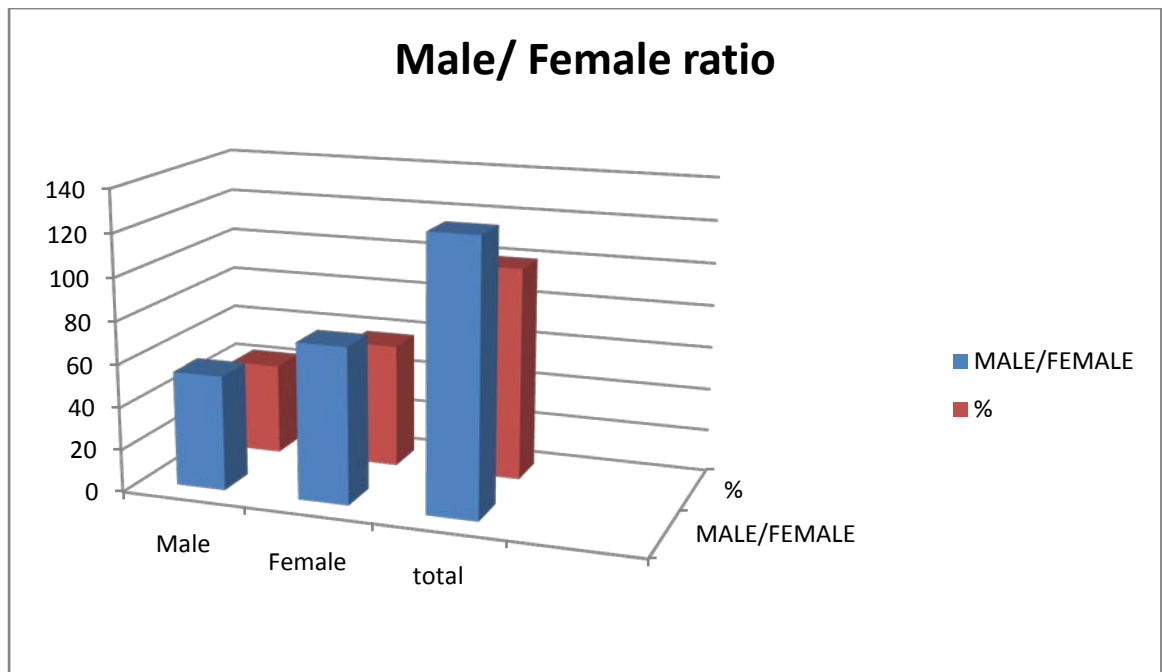
Study procedure:

Total 127 patients were selected for the study.

Each patient's complete medical history including personal data, a description of symptoms was taken. All the patients underwent a thorough clinical and pathological examination.

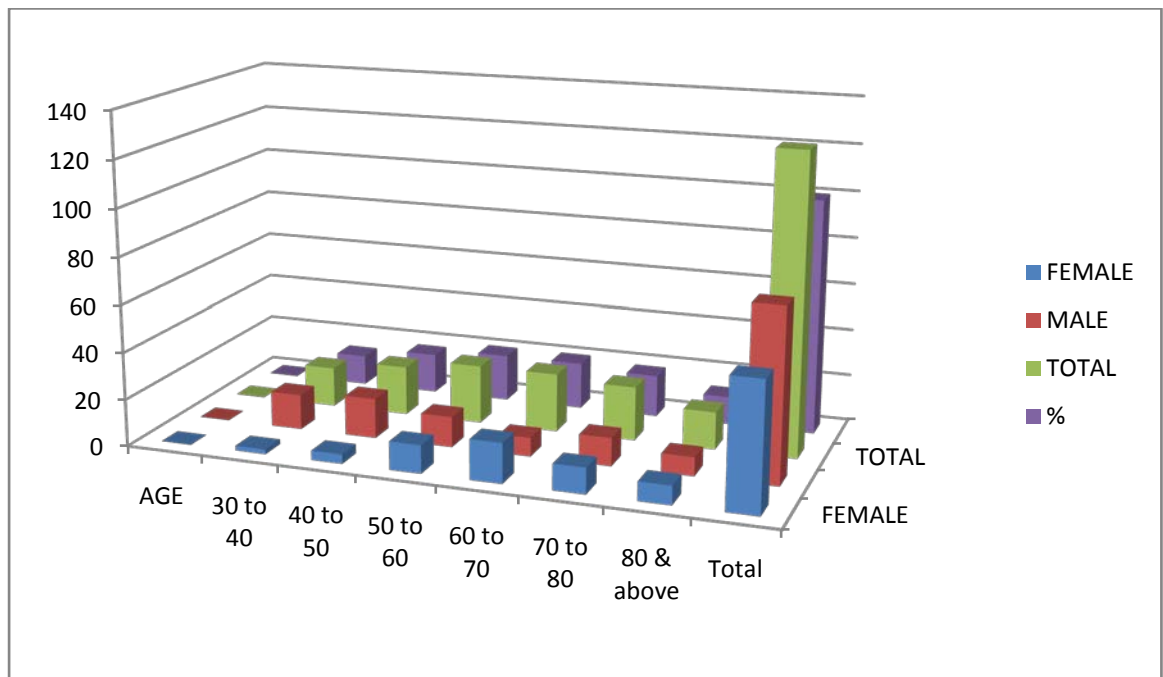
Gender:

| | |
|--------|-----|
| Male | 54 |
| Female | 73 |
| Total | 127 |



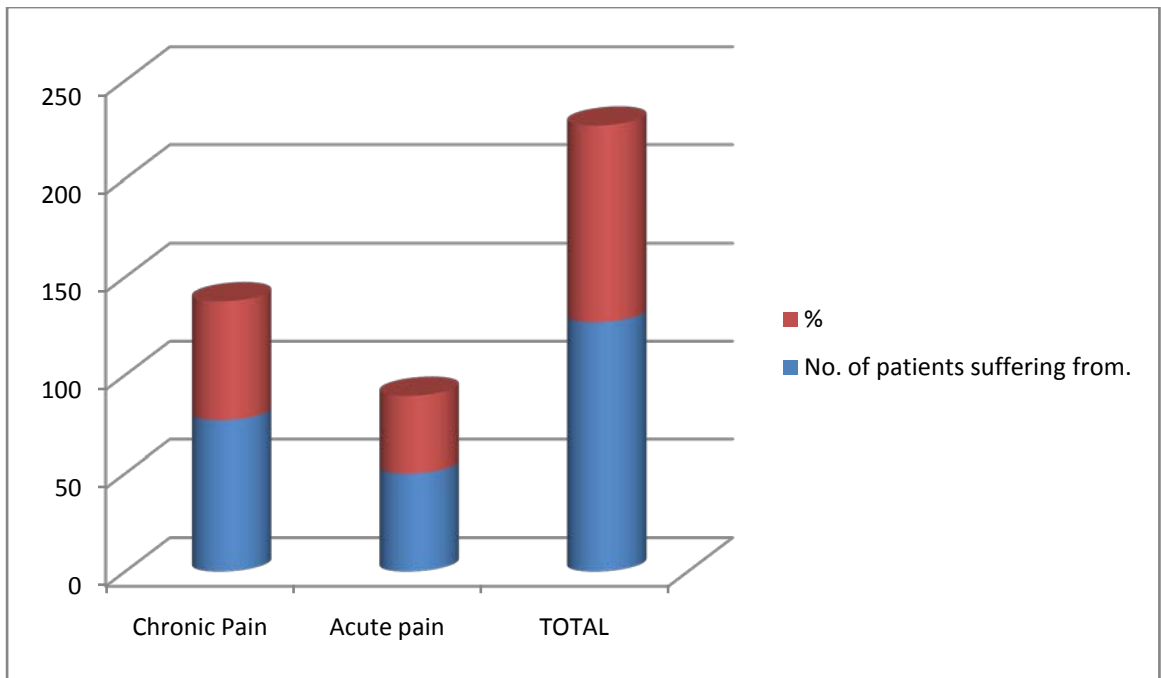
Age Ratio:

| AGE | MALE | FEMALE | TOTAL | % |
|------------|------|--------|-------|-----|
| 30 to 40 | 2 | 15 | 17 | 13 |
| 40 to 50 | 4 | 17 | 21 | 17 |
| 50 to 60 | 12 | 13 | 25 | 20 |
| 60 to 70 | 17 | 8 | 25 | 20 |
| 70 to 80 | 11 | 12 | 23 | 18 |
| 80 & above | 8 | 8 | 16 | 12 |
| Total | 54 | 73 | 127 | 100 |



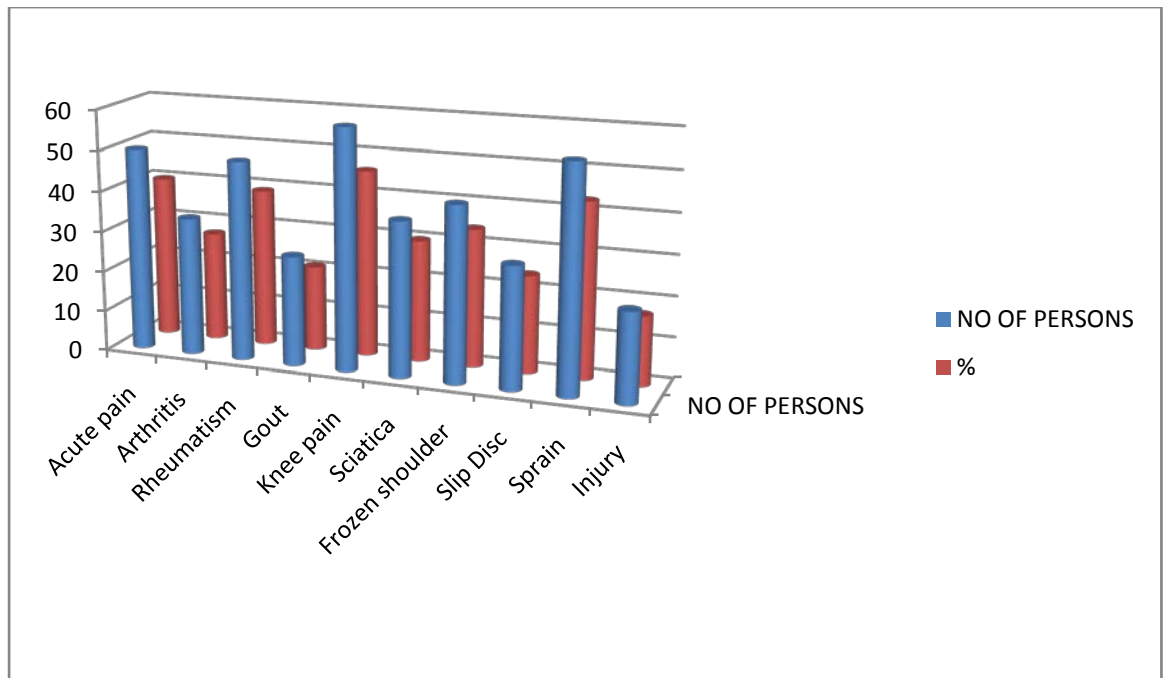
No. of patients suffering from

| Pain | No | % |
|--------------|-----|-------|
| Chronic Pain | 77 | 60.63 |
| Acute pain | 50 | 39.37 |
| TOTAL | 127 | 100 |



SYMPTOMS :

| SYMPTOMS | NO OF PERSONS | % |
|-----------------|---------------|----|
| Acute pain | 50 | 40 |
| Arthritis | 34 | 27 |
| Rheumatism | 49 | 39 |
| Gout | 27 | 21 |
| Knee pain | 59 | 46 |
| Sciatica | 38 | 30 |
| Frozen shoulder | 43 | 34 |
| Slip Disc | 30 | 24 |
| Sprain | 55 | 43 |
| Injury | 22 | 17 |



Dosage:

“V RELIEF” OINTMENT was given to every one to apply gently on effected area 3 times a day, or to apply as and when require.

Health Plan: (VIHAR)

- Physical activity Is crucial for a person with any psychological symptoms
- Swimming
- Regular exercise
- Increased water intake
- Proper meal timings
- Not to sleep in day time
- Proper counselling
- SHOIRO BASTI
- NASYA

(AHAR): To have: (PATHYA)

Three things were explained to patients.

- What they eat
- How much they eat
- When they eat
- A diet plan was tailored according to patients diet habit, working condition, daily routine, weight, age and gender.
- At the base there are foods rich in carbohydrates, such as grains, fruit and vegetables, Fibre, Dark green leafy vegetables was suggested.
- Amla, Dadimb, Black sesame seeds
- Milk, Curd, Butter milk
- Coconut, Dates, Almonds, Apricot
- Warm Milk at night. With Nutmeg or Pipramul.

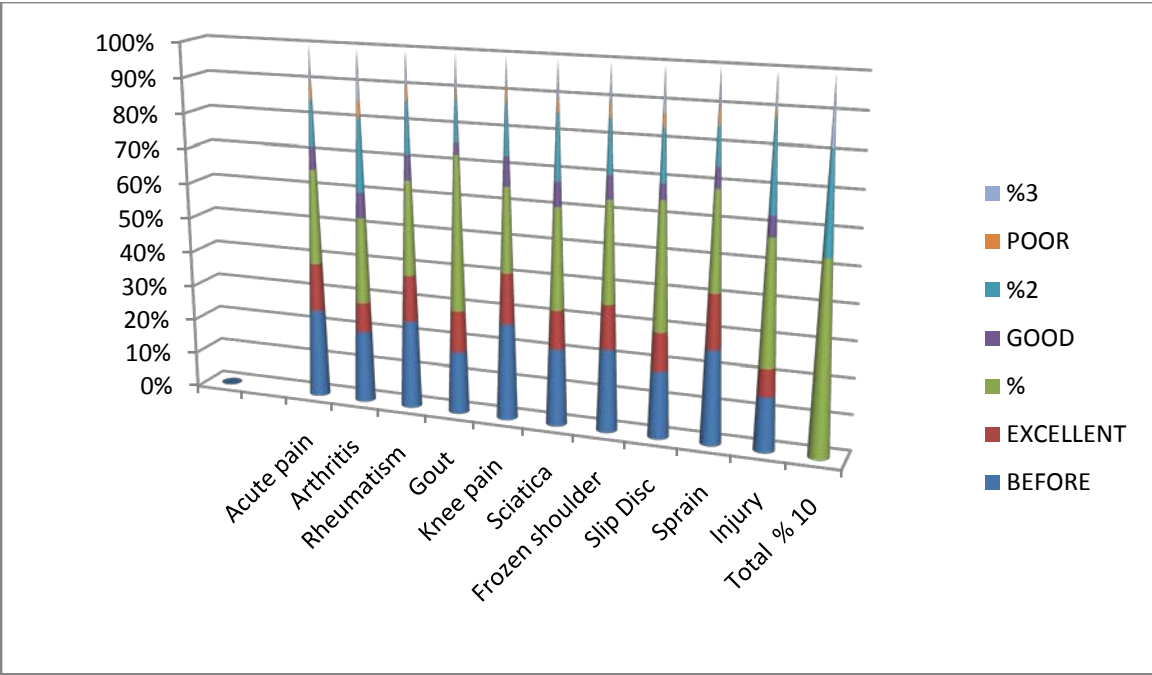
Diet not to have: (APATHYA)

- × Fried food
- × Excess chillies
- × No onion , garlic, green chillies
- × No Chutney, papad, Pickles
- × Lemon, Tamarind, Pineapple
- × Fried, stalled food
- × Outside eatables
- × Chole, Chana, Rajma, Kidney beans

Assessment of result: (UPSHAY) After administration of V RELIEF for 60 days, the following result was achieved.

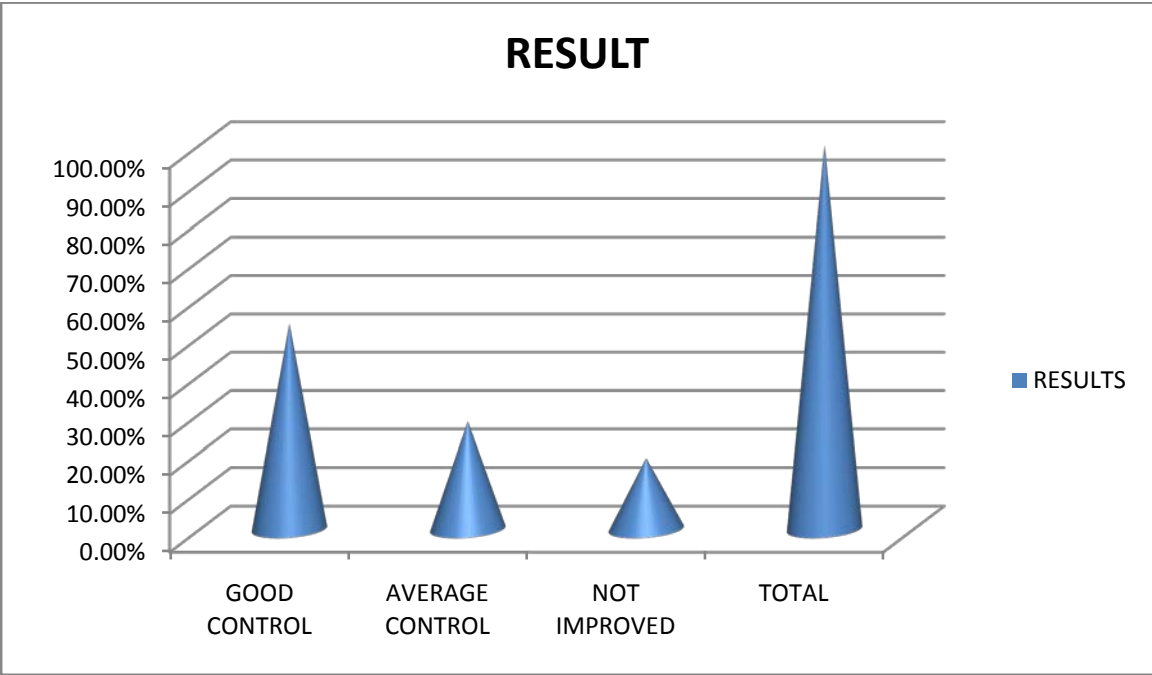
RESPONSE OF THE TREATMENT

| SYMPTOMS | BEFORE TREAT MENT | EXCELLENT | % | GOOD | % | POOR | % |
|-----------------|-------------------------|-----------|------|------|----|------|------|
| | | | | | | | |
| Acute pain | 50 | 27 | 54 | 13 | 26 | 10 | 20 |
| Arthritis | 34 | 14 | 41 | 12 | 35 | 8 | 24 |
| Rheumatism | 49 | 26 | 53 | 14 | 29 | 9 | 18 |
| Gout | 27 | 18 | 67 | 5 | 18 | 4 | 15 |
| Knee pain | 59 | 31 | 52 | 18 | 31 | 10 | 17 |
| Sciatica | 38 | 19 | 50 | 12 | 32 | 7 | 18 |
| Frozen shoulder | 43 | 23 | 53 | 12 | 28 | 8 | 19 |
| Slip Disc | 30 | 17 | 57 | 7 | 23 | 6 | 20 |
| Sprain | 55 | 32 | 58 | 12 | 22 | 11 | 20 |
| Injury | 22 | 11 | 50 | 8 | 36 | 3 | 14 |
| Total % 10 | | | 53.5 | | 28 | | 18.5 |



RESULT

| | |
|-----------------|--------|
| GOOD CONTROL | 53.5 % |
| AVERAGE CONTROL | 28 % |
| NOT IMPROVED | 18.5 % |
| Total | 100 % |



Conclusion:

According to result data it is established that "V RELIEF" OINTMENT

Is effective in curing neurological and Muscular disorders in 58.5 % of patients, shown average control in 28 % and was not found effective in 18.5 %

Reference:

Text Reference :

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Vanoaushadhi Gunadarsh. Purvardh

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| GANDHAPURNA OIL | 597 | 535 |
| PUDINE KA PHOOL | 390 | 390 |
| KAPOOR | 87 | 178 |
| NILGIRI OIL | | |
| DEODAR OIL | 305 | 340 |
| AJMA OIL | 11 | 99 |