



## Clinical Evaluation Report on Aswini Hiran Strong Pain Oil

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### ABSTRACT

*Aswini Hiran Strong Pain Oil is a topical Ayurvedic pain-relieving preparation used for knee pain, joint pain, muscular pain, shoulder pain, and backache. The product claims a rapid onset of relief within minutes of application and significant improvement within 14 days of regular use. A prospective, open-label, Phase 4 clinical study was conducted on adult subjects (n = 30) experiencing musculoskeletal pain. Pain severity was measured using a Visual Analogue Scale (VAS: 0–4) at baseline (Day 0) and after 14 days of regular application (Day 14). The study demonstrated significant improvement across all pain categories, with  $p < 0.001$  for every parameter evaluated through a two-tailed paired t-test analysis. Mean pain reduction at Day 14 was 81.25% for knee pain, 78.13% for back pain, 89.29% for shoulder pain, and 78.57% for calf/muscle pain. Onset-of-relief assessments showed 80% of participants experienced noticeable relief within 10 minutes, with 10% reporting relief as early as 3 minutes. No adverse reactions or tolerability issues were reported. These findings substantiate the claims of Aswini Hiran Strong Pain Oil and confirm its effectiveness as a topical remedy for musculoskeletal pain.*

**Keywords:** *Aswini Hiran Strong Pain Oil, Knee Pain, Back Pain, Shoulder Pain, Muscle Pain, Stiffness, Pain Reduction, VAS.*

### INTRODUCTION

Musculoskeletal pain is one of the most common health concerns affecting individuals across all age groups and occupations. Conditions such as knee pain, back pain, shoulder pain, joint pain, and muscle pain often arise due to strain, overuse, posture-related stress, or age-associated degenerative changes. These symptoms frequently lead to stiffness, reduced mobility, and compromised quality of life.

Topical Ayurvedic pain-relief oils have been widely used across India for generations, owing to their ability to provide localized relief, improve circulation, ease stiffness, and support joint flexibility. Their natural composition, rapid onset of action, and favourable safety profile have made them popular over-the-counter remedies for day-to-day musculoskeletal discomfort.

**Aswini Hiran Strong Pain Oil** is an **Ayurvedic Proprietary Medicine** formulated for external application to relieve knee pain, joint pain, backache, shoulder pain, and muscle pain. As per the product label, each 100 ml of oil is composed of:

- i. **Menthol – 10 g**
- ii. **Gandhapura Taila – 5 g**
- iii. **Tailaparna Taila – 2 g**
- iv. **Lavanga Taila – 1 g**
- v. **Tila Taila – q.s.**

Menthol provides a cooling counter-irritant effect leading to rapid sensory relief, whereas Gandhapura Taila (natural methyl salicylate source) offers analgesic and anti-inflammatory benefits. Tailaparna (Eucalyptus) and Lavanga (Clove) oils contribute additional soothing and circulation-enhancing effects. Tila Taila (Sesame oil) serves as the classical Ayurvedic base, supporting penetration, nourishment, and flexibility.

Aswini Hiran Strong Pain Oil is intended for external application only. The oil should be applied directly over the affected area and gently massaged until it is absorbed into the skin. For enhanced results, the use of a hot water bag or mild hot fomentation is recommended after application, as this may help improve penetration and relieve stiffness more effectively. The product should not be applied on open wounds, and care must be taken to avoid contact with the eyes. The oil must be kept out of the reach of children.

This clinical study was undertaken to substantiate the following product claims made for Aswini Hiran Strong Pain Oil:

- i. Noticeable pain relief in minutes
- ii. Significant reduction in pain within 14 days of regular use
- iii. Reduction in stiffness and improved joint movement
- iv. Effectiveness across knee pain, joint pain, back pain, shoulder pain, and muscle pain

A **Phase 4 (Post-Marketing) Clinical Study** was conducted to substantiate these therapeutic claims using structured evaluation tools, participant feedback, and statistical analysis of outcomes.

### MATERIAL AND METHODS

#### Study Design

A prospective, open-label, Phase 4 clinical evaluation was conducted using market samples of **Aswini Hiran Strong Pain Oil**. Thirty adult subjects (n = 30) aged 18–60 years with knee pain, back pain, shoulder pain, or muscular/calf pain were enrolled. Individuals with hypersensitivity, acute injuries requiring intervention, or dermatological conditions at the site of application were excluded.

### Study Duration

Each subject was evaluated at two timepoints:

- i. **Day 0 (baseline)**
- ii. **Day 14 (post-application)**

Subjects applied the oil as per package instructions:

*Apply sufficient quantity over the affected area and massage gently until absorbed.*

### Assessment Method

Pain severity was assessed using the **Visual Analogue Scale (VAS)**:

- i. 0 = Poor
- ii. 1 = Fair
- iii. 2 = Good
- iv. 3 = Very Good
- v. 4 = Excellent

Parameters evaluated:

- i. Knee Pain
- ii. Back Pain
- iii. Shoulder Pain
- iv. Calf/Muscular Pain

### Onset of Relief

Participants reported the approximate time at which they first felt noticeable relief:

- i. 3 minutes
- ii. 5 minutes
- iii. 10 minutes
- iv. 15 minutes

### Statistical Analysis

A paired two-tailed Student's t-test was used.

Significance was interpreted at:

- i. **p < 0.05** significant
- ii. **p < 0.01** highly significant
- iii. **p < 0.001** very highly significant

In this study, **all parameters achieved p < 0.001.**

## RESULTS

### Demographics

- i. Female: 15 (50%)
- ii. Male: 15 (50%)
- iii. Mean age: 42.9 years

### Occupation

- i. Service: 22 (73.33%)
- ii. Housewife: 5 (16.67%)
- iii. Business: 2 (6.67%)
- iv. Maid: 1 (3.33%)

### Baseline Pain Distribution

- i. Knee Pain: 8 (26.7%)
- ii. Back Pain: 8 (26.7%)
- iii. Shoulder Pain: 7 (23.3%)
- iv. Calf/Muscle Pain: 7 (23.3%)

### Efficacy Findings (Day 0 vs Day 14)

#### **Knee Pain**

- i. Day 0: 100% poor
- ii. Day 14: 87% very good/excellent
- iii. Mean reduction: **81.25%**,  $p < 0.001$

#### **Back Pain**

- i. Day 0: 100% poor
- ii. Day 14: 87% very good/excellent
- iii. Mean reduction: **78.13%**,  $p < 0.001$

#### **Shoulder Pain**

- i. Day 0: 100% poor
- ii. Day 14: 100% very good/excellent
- iii. Mean reduction: **89.29%**,  $p < 0.001$

#### **Calf/Muscle Pain**

- i. Day 0: 100% poor
- ii. Day 14: 85% very good/excellent
- iii. Mean reduction: **78.57%**,  $p < 0.001$

### Onset of Relief

- i. 3 minutes → 10%
- ii. 5 minutes → 16.7%

- iii. 10 minutes → 53.3%
- iv. 15 minutes → 20%

**Overall, 80% experienced noticeable relief within 10 minutes.**

#### Statistical Significance

All parameters demonstrated **very high statistical significance** ( $p < 0.001$ ).

#### DISCUSSION

The clinical findings demonstrate that **Aswini Hiran Strong Pain Oil** provides rapid and meaningful relief from musculoskeletal pain. A significant proportion of participants reported early relief within the first 3–10 minutes of application. This rapid onset aligns strongly with product claims and reflects the formulation's ability to act quickly on superficial musculoskeletal tissues.

Over 14 days of regular use, subjects experienced substantial reductions in pain scores in all evaluated categories. Shoulder pain showed the greatest improvement (89.29%), followed by knee and muscular pain. These improvements were consistently reflected in VAS scoring, where participants shifted from “poor” at baseline to “very good” and “excellent” after treatment.

Statistical validation confirmed **very high significance across all pain categories** ( $p < 0.001$ ). No adverse reactions were reported, indicating good tolerability and safety for repeated topical use.

These outcomes support the claims of rapid action, significant reduction in pain within 14 days, and overall improvement in joint and muscular comfort.

#### CONCLUSION

This Phase 4 clinical study confirms that **Aswini Hiran Strong Pain Oil** is effective and well-tolerated for relief from knee pain, joint pain, back pain, shoulder pain, and muscular pain. Rapid pain relief was observed within minutes, and continued use for 14 days resulted in substantial and statistically significant reductions in pain severity. No adverse reactions were observed.

The findings support the product's marketed claims and demonstrate its value as an effective Ayurvedic topical remedy for musculoskeletal discomfort.

#### OBSERVATIONS AND RESULTS

**Table 1: Age Distribution**

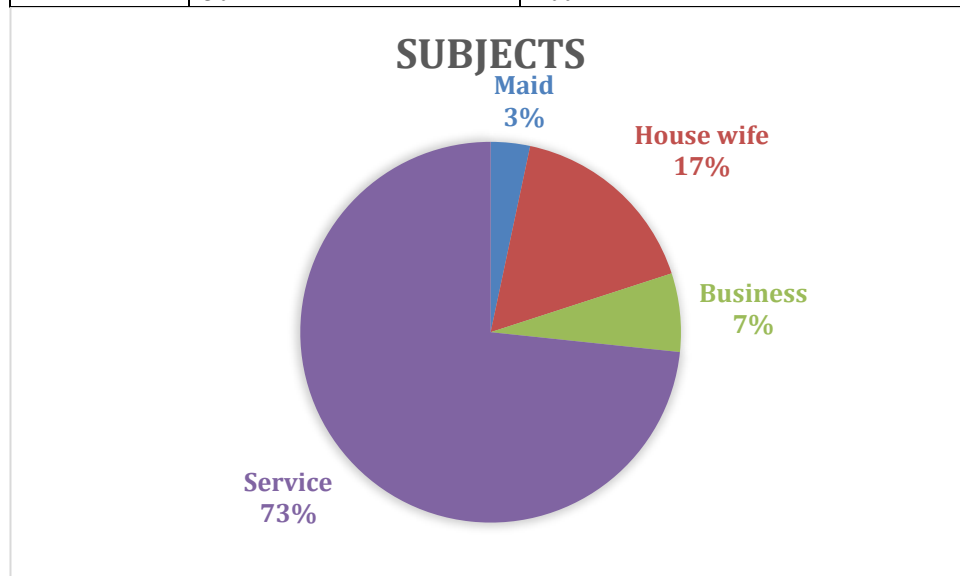
Gender	N (Average age)	Mean
Female	45.1	0.5
Male	40.7	0.5
Total	42.9	42.9

**Table 2: Gender Distribution**

Gender	N (number of people)	%
Female	15	50.0
Male	15	50.0
Total	30	100.0

**Table 3: Occupation**

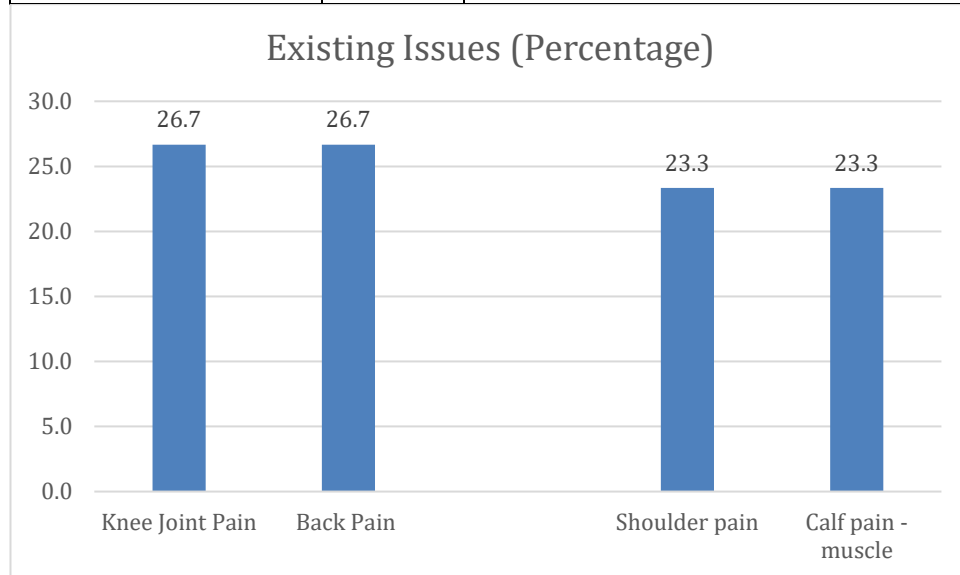
Occupation	Subjects	Percentage
Maid	1	3.33
House wife	5	16.67
Business	2	6.67
Service	22	73.33
Total	30	100



**Table 4:** Pain Distribution

Followed for 14 days for efficacy evaluation.

Existing problems	N	Percentage
Knee Joint Pain	8	26.7
Back Pain	8	26.7
Shoulder pain	7	23.3
Calf pain - muscle	7	23.3
Total	30	



**Table 5:** Knee Joint Pain

Efficacy	Before		After	
	N	Percentage	N	Percentage
Poor	8	100.00	0	0.00
Fair	0	0.00	0	0.00
Good	0	0.00	1	12.50
Very good	0	0.00	4	50.00
Excellent	0	0.00	3	37.50

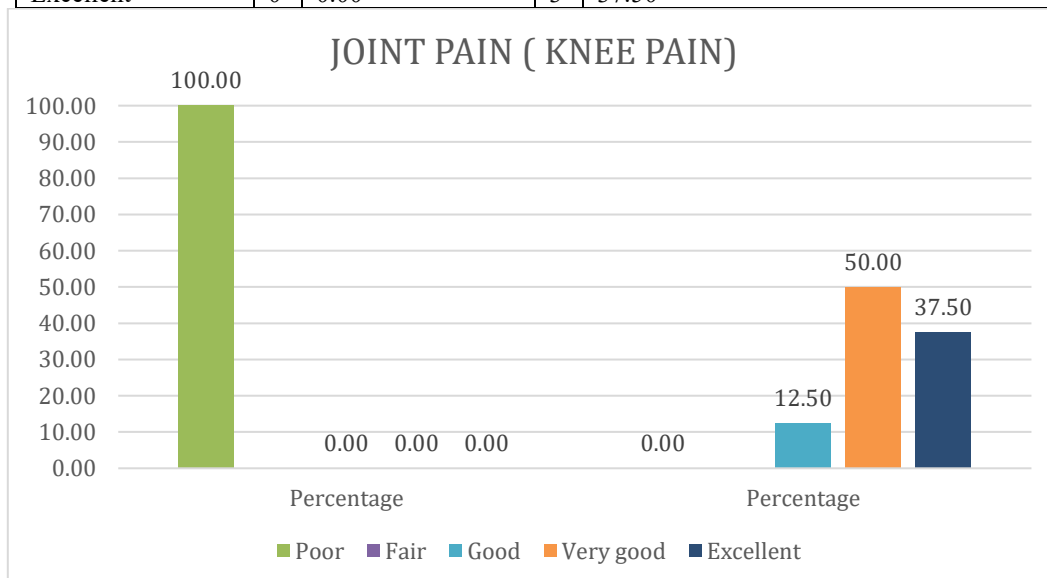


Table 6: Back Pain

Efficacy	Before		After	
	N	Percentage	N	Percentage
Poor	8	100.00	0	0.00
Fair	0	0.00	0	0.00
Good	0	0.00	1	12.50
Very good	0	0.00	5	62.50
Excellent	0	0.00	2	25.00

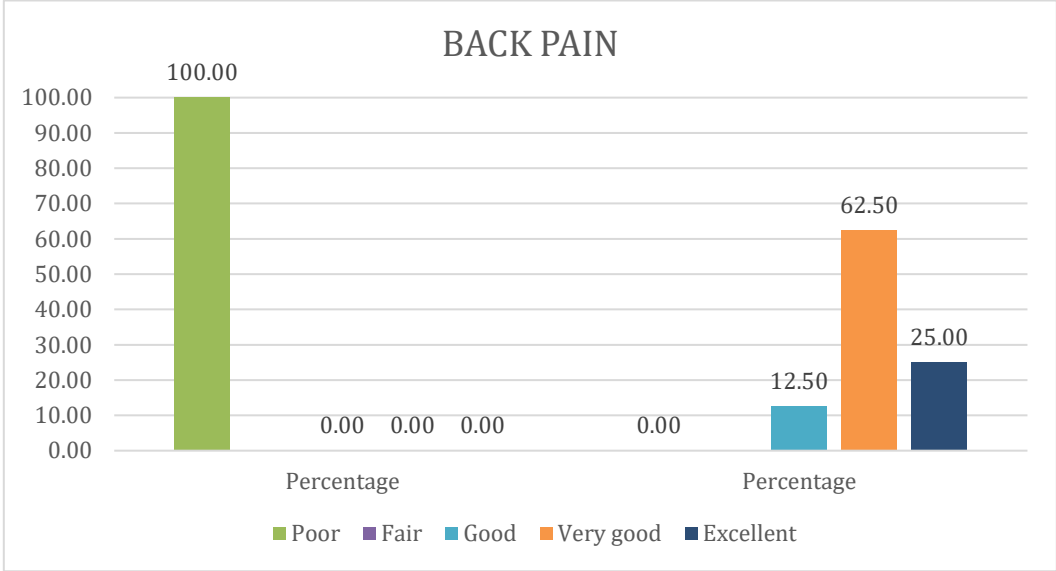
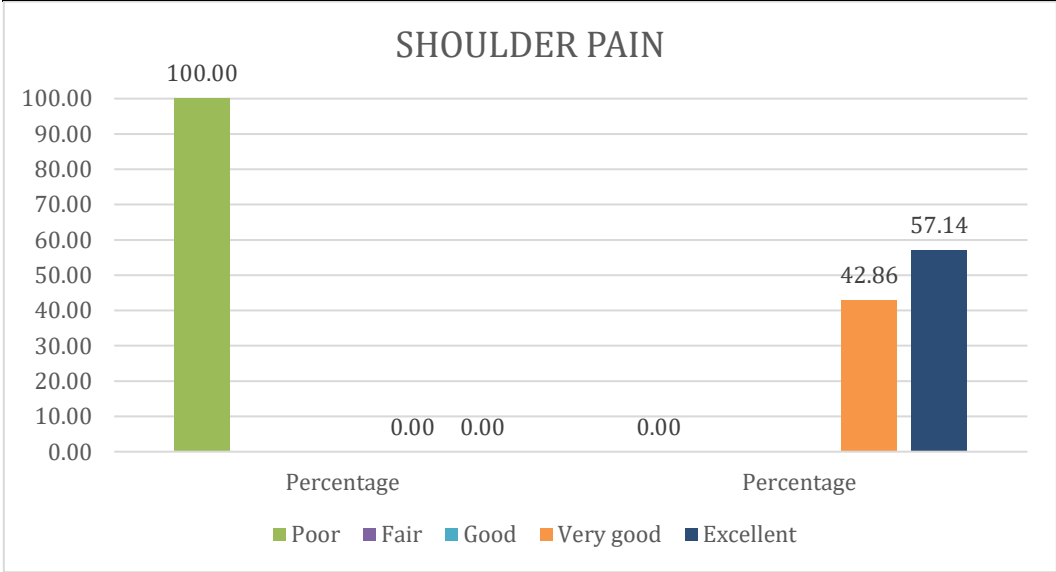


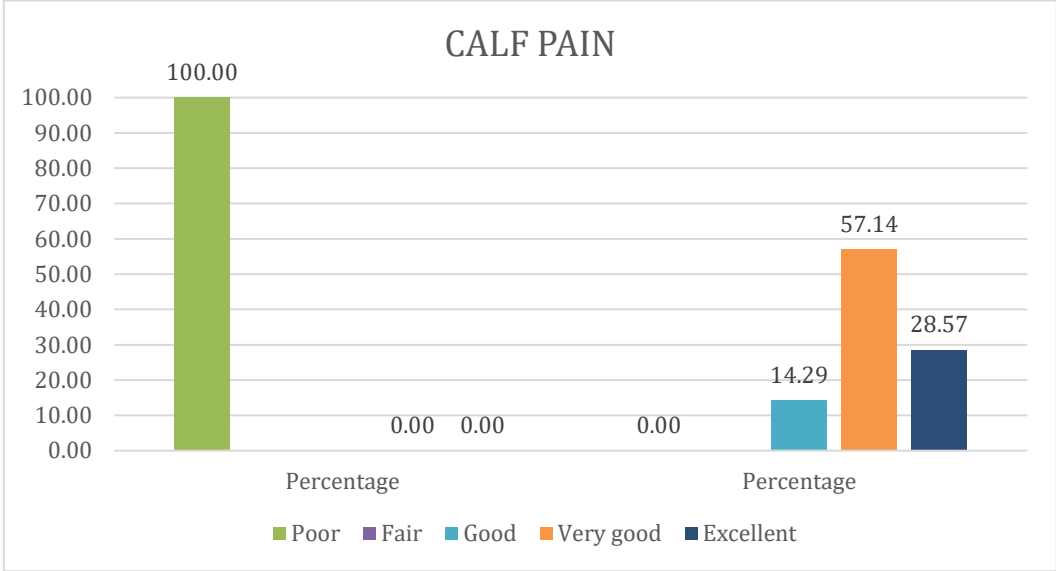
Table 7: Shoulder Pain

Efficacy	Before		After	
	N	Percentage	N	Percentage
Poor	7	100.00	0	0.00
Fair	0	0.00	0	0.00
Good	0	0.00	0	0.00
Very good	0	0.00	3	42.86
Excellent	0	0.00	4	57.14



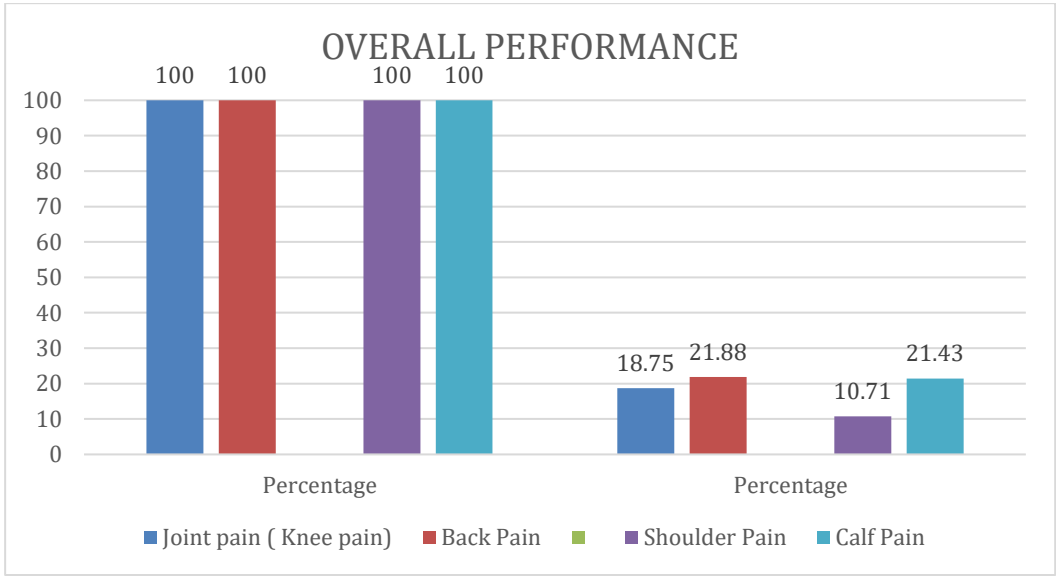
**Table 8:** Calf Muscle Pain

Efficacy	Before		After	
	N	Percentage	N	Percentage
Poor	7	100.00	0	0.00
Fair	0	0.00	0	0.00
Good	0	0.00	1	14.29
Very good	0	0.00	4	57.14
Excellent	0	0.00	2	28.57



**Table 9:** Overall Performance (Mean Pain Score): Day 0 vs Day 14

Efficacy parameters	Before		After		% Reduction
	N	Percentage	N	Percentage	
Joint pain (Knee pain)	4.00	100	0.75	18.75	81.25
Back Pain	4.00	100	0.88	21.88	78.13
Shoulder Pain	4.00	100	0.43	10.71	89.29
Calf Pain	4.00	100	0.86	21.43	78.57

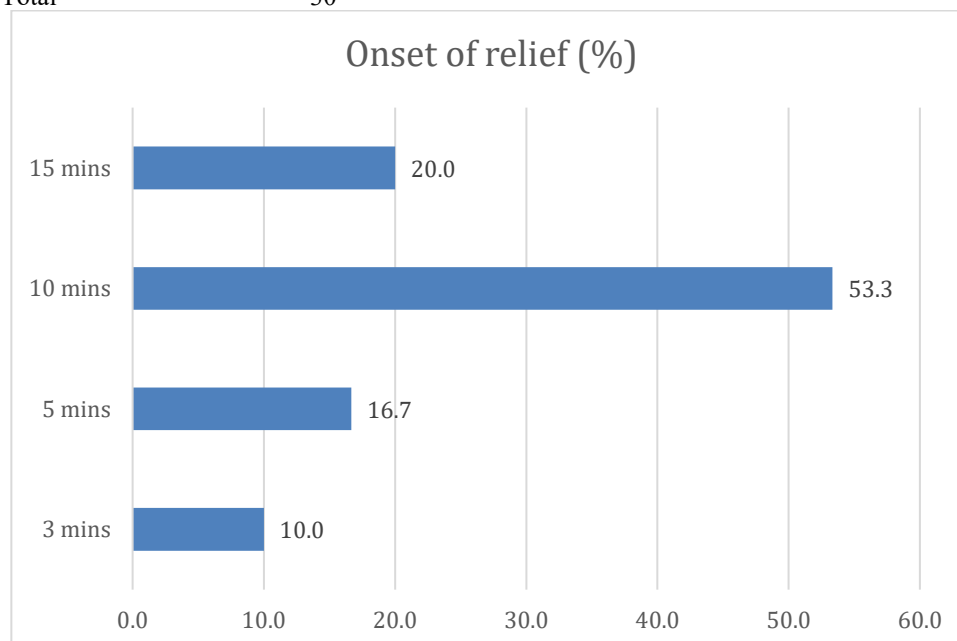


**Table 10: Onset Of Relief**

Onset of relief felt	Number	%
3 mins	3	10.0
5 mins	5	16.7
10 mins	16	53.3
15 mins	6	20.0

Total

30



**Note:** Immediate onset evaluation at first application; full efficacy assessed on Day 14.

## STATISTICAL ANALYSIS

**Table 11: T Test**

Paired t-test results comparing Day 0 and Day 14 pain scores.

	T value	Significance
<b>Knee Joint Pain</b>	$3.709 \times 10^{-6}$	$p < 0.001$
<b>Back Pain</b>	$2.486 \times 10^{-6}$	$p < 0.001$
<b>Shoulder pain</b>	$2.104 \times 10^{-6}$	$p < 0.001$
<b>Calf pain - muscle</b>	$1.983 \times 10^{-5}$	$p < 0.001$

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