

A Consumer Study on the Sensory Experience of new Herbal Topical Pain Relief Product in India

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ABSTRACT

Introduction: Pain management for musculoskeletal conditions often requires topical products to be used as adjuncts to oral analgesics. The acceptability of topical medication depends on including sensory characteristics, ease of application, after-feel, and residue, etc. This study was conducted to evaluate the consumer acceptability of the sensory parameters of a novel prototype topical pain relief gel containing boswellic acid, methyl salicylate, menthol, and capsaicin in adults who were regular body pain sufferers.

Methods: This was a prospective, quantitative, blinded, monadic-designed, consumer sensory home-use test (HUT), conducted in three cities in India. The study included 320 adults who had musculoskeletal pain or joint pain within the past six months leading up to the study, with the last pain occurring within the preceding four weeks. One group was given the gel formulation of the investigated topical pain relief gel and the other group was given the balm formulation. Participants used the assigned market sample at least three times in a 7-day study period, and then completed a web-based questionnaire on the sensorial aspects of the product.

Results: Over 90% of consumers agreed that the gel formulation provided fast cooling at the usual site of pain in 10 seconds, long-lasting cooling, and dual cooling and warming sensation. Furthermore, it was convenient and easy to use, was absorbed quickly, dried quickly, and had a pleasant smell without greasy after-feel, and left no residue. Significant findings were noted for the gel formulation versus the balm formulation for parameters of cooling.

Conclusion: The findings of the consumer sensory study demonstrate that a novel herbal gel formulation for pain relief has ideal properties of a topical pain relief formulation, and could be a useful adjunct to the pharmacological management of musculoskeletal pain, without adding to the burden of adverse effects.

KEYWORDS: musculoskeletal pain; topical analgesic; counterirritant; sensory

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INTRODUCTION

Pain is defined as “an unpleasant sensory and emotional experience associated with, or resembling that associated with actual or potential tissue damage”. Nociceptive pain is characterized by tissue damage and inflammation, responding to mechanical as well as inflammatory stimuli. A number of pathways transmit pain signals to the distinct areas of the brain.¹ Musculoskeletal pain is a common ailment across the world, and the burden increases with increasing age.² There are now reports of an increasing trend of pain even among general populations.¹ Pain has an impact on the quality of life (QoL) and independence levels of affected individuals.² Compared to individuals without chronic musculoskeletal

pain, those with chronic musculoskeletal pain report significantly lower mean total health-related quality of life scores, with sleep and general daily activities being most affected by pain, even if pain was graded as low or moderate.³ The common first-line approach to treating pain involves non-steroidal anti-inflammatory drugs (NSAIDs); however, the long-term safety is a limiting factor.^{1,4} In such situations, there is potential for the use of topical pain relief products, as they lack systemic side effects and drug-drug interactions. Topical pain relief products are thus a crucial part of multimodal therapy, and can even be used as first-line therapy for mild-to-moderate musculoskeletal pain. Herbal pain relievers with ingredients such as menthol, methyl salicylate

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and capsaicin, have gained attention for the management of chronic pain conditions with a good safety profile.¹ Their counterirritants properties further provide pain relief by desensitizing individuals to painful stimuli.^{5,6} Such counterirritants create hot or cold sensation which masks intense pain by interrupting the transmission of pain signals to the brain.¹

Patient acceptance of topical pain relief formulations depends on a variety of factors, including sensory characteristics (cooling, warming, etc), ease of application, after-feel, staining during and after use, greasiness, and intensity of odor. Consumer sensory studies help elucidate the acceptability of topical products, and thus, can guide the development of products that match the needs of the consumer, potentially improving treatment adherence and outcomes. Therefore, we conducted a consumer sensory study to compare a novel prototype of a gel formulation for musculoskeletal pain (marketed as Iodex Power Gel, referred to as Market Sample 1 in this study) with another commercially available topical pain relief formulation available in the Indian market (referred to as Market sample 2).

METHODS

Study design

This was a prospective, quantitative, blinded, monadic-designed, consumer sensory home-use test (HUT), conducted in three cities in India (Delhi, Mumbai, and Chennai). The study was conducted to evaluate the consumer acceptability of the sensory parameters of a novel prototype topical pain relief gel containing boswellic acid, methyl salicylate, menthol, and capsaicin in adults who were regular body pain sufferers.

Participants

A total of 320 participants were included in the study, comprising of adults who had musculoskeletal pain or joint pain within the past six months leading up to the study, with the last pain occurring within the preceding four weeks. Inclusion criteria were (i) use of pain relief balms, creams, gels, sprays, or a combination of these for previous pain occasions (ii) non-rejectors of the study (iii) users of gel formulations (iv) purchase decision maker (v) socioeconomic classification (SEC) A or B.⁷ Exclusion criteria were (i) pregnant or nursing women (ii) participants with open wounds/lesions (iii) participants with a medical condition that required hospitalization or medical supervision (iv) participants with a history of allergies to topical pain relief products (sprays, gels, and creams) (v) rejectors of cooling and warming sensation of topical products (vi) rejectors of herbal ingredients including clove, camphor, capsaicin, *Boswellia serrata* (vii) participants of market research projects for pain relief in the preceding three months (viii) healthcare professionals dealing with pain relief and pain management. All participants signed a written informed

consent document indicating their willingness to participate in the study.

Products tested

Iodex is a brand marketed by Haleon (earnstwhile GlaxoSmithKline Consumer Healthcare, Indian subcontinent). Iodex Power Gel was compared with a topical balm product, which is available in the Indian market. The formulations were referred to as Market Sample 1 and Market Sample 2, respectively. Market Sample 1 contains boswellic acid (65%) 3.85%, methyl salicylate 15%, *pudiva satva* (menthol) 3%, *kutuveera* (capsicum extract) 0.02%. Products were tested blind (unbranded) but respondents were provided information on the ingredients in the samples to ensure they were not allergic to any of those ingredients.

Protocol for product testing and survey

Participants received a survey kit containing a consent form (signed before taking the survey), instructions for the use of the product, instructions on disposal of the product after use, one market sample each, blinded and assigned with 3 digit-alphanumeric codes. The participants were divided into two cells or groups. One group (n=159) was given Market Sample 1 and the other group (n=161) was given Market Sample 2, to evaluate. The participant was to use the assigned market sample at least 3 times in a 7-day study period. The participants were instructed to apply the product on body parts where they typically apply similar topical pain relief products (e.g., knee joints, lower back, leg, etc).

After using the product, the participants completed a web-based questionnaire (approximately 15 minutes duration to complete the survey) on the sensorial aspects of the product. The primary outcome was product performance for sensory variables. The questionnaire collected data on pre-application characteristics, during application characteristics, and post-application characteristics. Broadly, the “pre-application” variables included color, smell or aroma of the product. The “during application” characteristics included texture, pleasant smell, ease of application, lack of messiness, fast absorption from the skin, and quick drying property. The “post-application” variables included soothing, cooling, and warming sensation within 10 seconds of application, rapid cooling sensation, long-lasting warm/cool sensation, dual cooling and warming action, relevance to the pain experienced, suitability for regular use, non-greasy/non-sticky after feel, lack of residue, lack of staining of clothes, and pleasant smell after application. The agreement rating scale included the responses “Yes, I agree”, “No, I don’t agree”, and “I don’t know”. The outcome of the study was the agreement of participants with the variables evaluated.

Data analysis

Data was collected by ConfirmIt, and exported to a Microsoft Excel database (Microsoft Corporation, Redmond, Washington, USA). Frequency and percentage was calculated for categorical variables, and results were presented as percentage. A two-tailed test was used for statistical analysis.

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RESULTS

Study participants

A total of 320 participants were included in this study. Demographic data of the study population are presented in Table 1.

Table 1. Demographic details of the study population

| Parameter | Topical Gel Formulation (n=159) | Topical Balm (n=161) |
|------------------------------|---------------------------------|----------------------|
| Gender | | |
| <i>Male</i> | 77 (48%) | 81 (50%) |
| <i>Female</i> | 82 (52%) | 80 (50%) |
| Age (years) | | |
| 30-45 | 57 (36%) | 55 (34%) |
| 46-55 | 52 (33%) | 53 (33%) |
| 56-65 | 50 (31%) | 53 (33%) |
| City | | |
| <i>Delhi</i> | 54 (34%) | 52 (32%) |
| <i>Mumbai</i> | 50 (31%) | 54 (34%) |
| <i>Chennai</i> | 55 (35%) | 55 (34%) |
| Socioeconomic classification | | |
| A | 80 (50%) | 82 (51%) |
| B | 79 (50%) | 79 (49%) |

Pre-application variables

Market Sample 1 gained positive responses from over 90% of participants to the pre-application variables of color and

smell. Table 2 describes the responses of patients who agreed to the claims

Table 2. Agreement of the participants with the pre-application variables for each of the products

| Variable | Market Sample 1 (Iodex Power Gel) | Market Sample 2 (Topical Balm) |
|----------------------|-----------------------------------|--------------------------------|
| Has the color I like | 96% | 94% |
| Has the smell I like | 92% | 91% |
| Smells natural | 91% | 91% |

During application variables

Market Sample 1 received high consumer agreement scores for the variables evaluated during application. All participants agreed with the claims related to texture, ease of application, and the lack of messiness in application, while 99% of participants opined that the formulation is quickly absorbed

from the skin, and dries quickly. Market Sample 1 (Iodex Power Gel) performed significantly better for lack of messiness in application, rapid absorption from the skin/surface, and quick-drying property, compared with Market Sample 2 (Topical Balm).

Table 3. Agreement of the participants with the variables evaluated during application for each of the products

| Variable | Market Sample 1 (Iodex Power Gel) | Market Sample 2 (Topical Balm) |
|---|-----------------------------------|--------------------------------|
| Has the texture I like | 100% | 99% |
| Has a pleasant smell I like | 94% | 94% |
| Is easy to apply | 100% | 100% |
| Is not messy to apply | 100%* | 96% |
| Gets absorbed from skin/surface quickly | 99%* | 95% |
| Dries quickly | 99%* | 94% |

*Statistically significant at 95% level of confidence; two-tailed test.

Post-application variables

Market Sample 1 received high consumer agreement scores (>90%) for most variables evaluated after application (except fast soothing sensation within 10 seconds and fast warming sensation within 10 seconds), as described in Table 4.

However, 94% of respondents agreed that the product provided a long-lasting warming sensation. Market Sample 1 performed significantly better for long-lasting cooling sensation and rapid cooling sensation within 10 seconds, compared with Market Sample 2

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Table 4. Agreement of the participants with the variables evaluated post-application for each of the products

| Variable | Market Sample 1 (Iodex Power Gel) | Market Sample 2 (Topical Balm) |
|---|-----------------------------------|--------------------------------|
| Fast soothing sensation within 10 seconds | 87% | 85% |
| Fast cooling sensation within 10 seconds | 91% [#] | 84% |
| Fast warming sensation within 10 seconds | 84% | 87% |
| Fast cooling sensation | 94% | 89% |
| Long-lasting warming sensation | 94% | 97% |
| Long-lasting cooling sensation | 94% [*] | 88% |
| Dual cooling and warming sensation | 91% | 89% |
| It will work fast for usual body pain | 94% | 95% |
| No greasy after-feel | 97% | 95% |
| No sticky after-feel | 97% | 95% |
| No residue | 99% | 97% |
| Does not stain clothing | 99% | 99% |
| Pleasant smell long after application | 91% | 91% |

*Statistically significant at 95% level of confidence; two-tailed test.
[#]Statistically significant at 90% level of confidence; two-tailed test.

Summary of the key benefits of Market Sample 1 (Iodex Power Gel)

At least 90% of consumers agreed that Market Sample 1 provides fast cooling at the usual site of pain in 10 seconds, provides long-lasting cooling, and provides dual cooling and warming sensation (Figure 1). At least 90% of consumers

agreed that the product is convenient and easy to use, gets absorbed quickly, dries quickly, has a pleasant smell, has no greasy after-feel, leaves no sticky after-feel, and leaves no residue. Figure 2 summarizes the sensory parameters for which Iodex Power Gel scored significantly higher than Topical Balm.

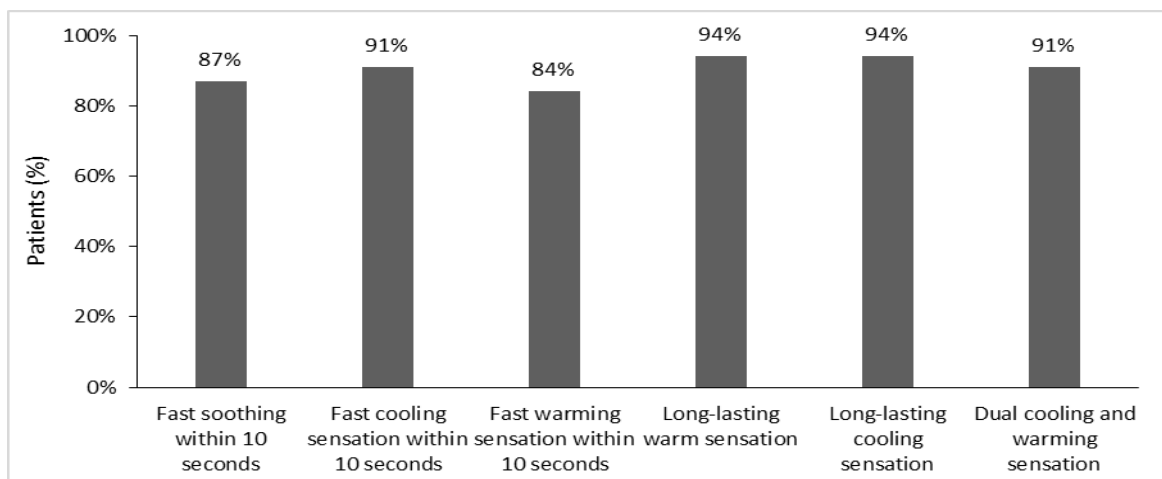


Figure 1. Key findings of sensory variables analyzed in the study

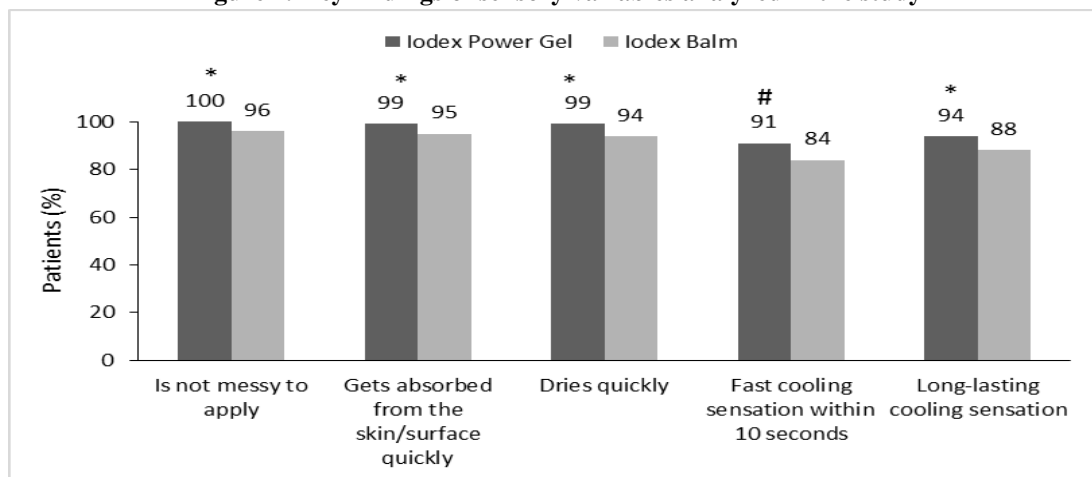


Figure 2. Sensory parameter comparison on select statistically significant findings

*Statistically significant at 95% level of confidence; two-tailed test; [#]Statistically significant at 90% level of confidence; two-tailed test.

DISCUSSION

The gel formulation scored higher over the balm formulation for long-lasting cooling sensation, rapid absorption from the skin, and rapid drying. These attributes of the formulation with a combination of ingredients with proven effectiveness in acute and chronic musculoskeletal conditions making it suitable for topical pain management. Counterirritants have received considerable support for the topical management of musculoskeletal pain. They act by inducing cutaneous irritation or pain so as to suppress subdermal pain (i.e., musculoskeletal pain). Counterirritants exert their effect through cooling or heating stimuli, or both.⁸ This consumer sensory study demonstrated that Market Sample 1, which is a combination of boswellic acid, menthol, methyl salicylate and capsicum extract, provides a rapid cooling sensation as well as a long-lasting cooling and a dual warming-cooling sensation. Furthermore, it leaves no residue, has an acceptable after-feel, dries easily, and is rapidly absorbed from the skin. These properties of counterirritant potential and high acceptability of the product among consumers indicate the potential for routine use of this product.

Menthol has been used for pain relief since ancient times. It activates Transient Receptor Potential Melastatin 8 (TRPM8), leading to increased nitric oxide production and subsequent vasodilation. This increased cutaneous blood flow is in contrast to traditional ice cooling, which reduces cutaneous blood flow. In addition, menthol is a weak sodium channel blocker, leading to a weak, localized anesthetic effect through reduced nociception. This desensitization of nociception occurs at low concentrations of menthol, while high concentrations cause irritation.^{9,10} Clinical studies have demonstrated that menthol gels provide a cooling effect on the skin for at least 40 minutes.¹¹ Another study demonstrated that topical menthol was more effective than ice application in relieving soreness at rest and during muscle contraction.¹² Combined with the favorable sensory variables noted in this study, menthol is a useful topical agent for the management of musculoskeletal pain.

Methyl salicylate exerts anti-inflammatory and analgesic effects through vasodilation and an increase of tissue temperature. It has the advantage of low systemic absorption. It interrupts the transmission of pain signals by modifying a cation channel in sensory neurons.¹³ It activates nociceptors but does not stimulate warm fibers, and therefore, the burning sensation lacks a thermal component. Topical preparations often combine methyl salicylate with menthol, so as to provide a warming sensation (through methyl salicylate) and a cooling sensation (through menthol).⁸ Methyl salicylate has the advantage of being a penetration enhancer, thus allowing better delivery of other herbal ingredients into the skin.¹⁴ Studies on the topical application of methyl salicylate plus menthol in patients with muscle strain demonstrated 40% greater pain relief with the combination as compared to placebo.¹³ Capsaicin activates a non-selective calcium-

permeable ion channel (transient receptor potential vanilloid 1; TRPV1) present at the terminals of nociceptors.^{15,16}

Extracts of the *Boswellia serrata* plant have analgesic and anti-inflammatory action. 3-O-acetyl-11-keto- β -boswellic acid (AKBA) and 5-Loxin decrease pro-inflammatory mediators and enzymatic degradation of cartilage. This regulation of inflammatory responses improves physical functioning and decreases pain in patients with osteoarthritis.¹⁷

Currently, several topical vehicles are available for drug delivery in the market. Gels provide stiffness to a solution or a colloidal dispersion and have the advantage of being non-greasy, and drying as a non-greasy film. In addition, gels can be applied on hairy areas and are cosmetically elegant.¹⁸ This study evaluated a gel formulation (market sample 1) and reported that over 90% of consumers accepted that it dries quickly, lacks a greasy after-feel, and does not leave a residue. This increases the acceptability of the formulation, as reflected by the fact that 94% of participants in this study agreed that the formulation was suitable for regular use and was relevant for the pain experienced.

The effectiveness of Iodex Power Gel formulation can be attributed to the science of each active ingredients discussed above, coupled with superior consumer sensorial experience. The combination of active ingredients in this formulation (i.e., *Boswellia serrata*, methyl salicylate, menthol, and capsaicin) results in a synergistic action against acute and chronic inflammatory conditions such as pain of musculoskeletal origin, muscle spasms/sprains, exertion soreness, lower back pain, and arthritic conditions. Formulation attributes (e.g., deep penetration [with permeation enhancement], long lasting relief, and faster action) along with ideal consumer sensorial experience accounts for the quick and superior alleviation of pain and impact on quality of life perspective (improved mobility and reduced stiffness/soreness). Furthermore, formulation features like fast drying, residue-free delivery of actives to the site of action, and superior application experience with no irritation of the skin encourage frequent use, thereby improving patient compliance and self-management of pain episodes.

CONCLUSION

Patient acceptability of topical pain relief formulations is a key driver of compliance and product effectiveness. The findings of the consumer sensory study demonstrate that a novel herbal gel formulation for pain relief has ideal properties of non-greasiness, lack of residue, quick-drying, ease of application, pleasant odor, rapid cooling sensation, dual cooling-warming sensation, and was suitable for regular use. This suggests that the investigated market sample 1 (Iodex Power Gel) could be a useful adjunct to the pharmacological management of musculoskeletal pain, without adding to the burden of adverse effects.

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DISCLOSURE

Asif Ali, Prashant Narang, Zee Alcasid are on payrolls of Haleon (erstwhile GlaxoSmithKline Consumer Healthcare). Thomas Thelemann is employed by MMR Research Worldwide Pte Limited

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