



Research Article

A CLINICAL TRIAL TO EVALUATE THE EFFICACY OF TOPICAL APPLICATION OF MODIFIED VIJAYA OIL IN THE MANAGEMENT OF VICHARCHIKA (ECZEMA)

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Article info	ABSTRACT
Article History:	Skin disorders have become a major threat in the present era due to the modern lifestyle and stressful living. References to skin diseases in Ayurveda are mostly seen under <i>Kushtha</i> .
Received: 18-03-2023	<i>Vicharchika</i> (Eczema) is one among them with <i>Kapha</i> predominance. The commonly used steroid therapy might lead to side effects. Thus, new topical treatments, such as Modified <i>Vijaya</i> oil, may be useful in reducing the requirement for chronic topical steroid therapy.
Revised: 05-04-2023	Aim: To assess the efficacy of topical application of modified <i>Vijaya</i> oil in the management of <i>Vicharchika</i> (Eczema). Materials and Methods: An open-label clinical trial was conducted on 40 patients clinically diagnosed with <i>Vicharchika</i> (Eczema) and the oil was given for topical application for 30 days. The efficacy was evaluated in terms of changes in parameters like EASI (Eczema Area Severity Index), SCORAD (Scoring of Atopic Dermatitis), VAS (Visual Analogue Scale), and SIGA (Static Investigator Global Assessment) before and after the intervention, between Day 0 and 30. The data were collected and analyzed with Wilcoxon Test. Results: The topical application of modified <i>Vijaya</i> oil was found to be highly effective in reducing the symptoms of <i>Vicharchika</i> (Eczema). Conclusion: Modified <i>Vijaya</i> oil could be used in symptomatic relief of <i>Vicharchika</i> (Eczema), and also repairs and enhances the damaged skin.
Accepted: 24-04-2023	
KEYWORDS:	
Eczema, Eczema	
Area Severity	
Index, Scoring of	
Atopic	
Dermatitis,	
Visual Analogue	
Scale, Static	
Investigator	
Global	
Assessment.	

INTRODUCTION

Skin is the largest organ of the body which provides the perfect barrier from physical, chemical, and biological external agents. Variations in the environmental stimuli and natural ability to deal with these factors result in specific reactions producing characteristic skin lesions in different parts of the body. The skin diseases in Ayurveda have been described under the heading of *Kushtha*, which are further divided into *Maha kushtha* and *Kshudra kushtha*.^[1] *Vicharchika* (Eczema), one among *Kshudra kushtha*, is described as a disease that coats or covers or causes injury to the skin in a distinguished manner, which so causes cracking of the skin in hands and

feet in *Shabdakalpadruma*.^[2] *Acharya Charaka* and *Acharya Vagbhata* have described it as a skin lesion with *Kapha* predominance.^[3] *Acharya Sushruta* mentioned it as *pitta* predominant with excessive itching, pain and dry lesions.^[4] Most of the Acharyas have presented it with symptoms like *Kandu* (pruritis), *Srava* (discharge), *Pidaka* (vesicles), and *Shyava varna* (discoloration). As per symptomatology and pathogenesis, *Vicharchika* is widely considered to be eczema in modern medicine.

Eczema is the common name given to Atopic dermatitis (AD), a chronic inflammatory skin condition that typically begins in the first few years of life. It can also develop for the first time at the later stages of age and now has become a common problem in all ages. Atopic dermatitis is characterized by cracked or scaly discoloured patches, erythema, papules, exudate and intense pruritus which can secondarily cause insomnia and diminished quality of life leading to psychological distress. A gradual increase in the prevalence of atopic dermatitis has been observed recently and it can be

Access this article online	
Quick Response Code	
	https://doi.org/10.47070/ijapr.v11i4.2728
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ascribed to environmental changes consequent to rapid development all over the world.^[5,6]

Although eczema is highly prevalent, there is no satisfactory treatment in Modern medicine. Usually, it is managed by antihistamines, oral and corticosteroids, topical immunomodulators, and UV phototherapy. As the disease recurs in most of the cases, treatment has to be done continuously which in turn leads to side effects. Prolonged use of topical steroids may lead to skin thinning, stretch marks, undesired hair development, and skin redness. Topical modulators may cause skin cancer, and even phototherapy can result in white skin and skin cancer.^[7] So, chronic steroid therapy may be replaced by other topical agents like modified *Vijaya* oil which relieves the irritation, rejuvenates the skin, and also which is not detrimental to the skin on continuous use.

This clinical study aimed to evaluate the effect of topical application of Modified *Vijaya* oil in patients suffering from *Vicharchika* w.s.r. to eczema.

MATERIALS AND METHODS

An open-label clinical trial was performed in subjects (≥ 12 to 75 years) diagnosed with *Vicharchika* (eczema), fulfilling inclusion criteria and willing to give consent. They were enrolled from OPD of the Department of Roga Nidana, National Institute of Ayurveda (NIA), Jaipur. The study was approved by the Institutional Ethics Committee of NIA (No. IEC/ACA/2019/ 2-16, Dated 15/10/19). The study has been registered in the Clinical Trial Registry, India

(CTRI/2020/06/034530), and the informed consent was taken from every patient before beginning the intervention.

Inclusion Criteria

1. Subjects (male or female) who belonged to the age group of 12 to 75 years (both inclusive).
2. Subjects without any history of significant diseases.
3. Subjects with no significant known allergies.
4. Subjects who were ready to follow the procedures as per the study protocol and could voluntarily sign an informed consent.

Exclusion Criteria

1. Subjects who underwent any laser dermatological procedure 4 weeks before screening in the study.
2. Subjects who were participating or participated 1 month prior to recruitment in any other clinical study.
3. Subjects with known hypersensitivity to any of the ingredients used in study drug.

Drug: The medicine used for intervention was modified *Vijaya* oil which was formulated, prepared, and sponsored by the Bombay Hemp Company Pvt. Ltd., Mumbai. The oil was modified into a cream form with Kokum butter and Shea butter as cream base. The ingredients were selected from various *Nigantus* and combined in such a way that, they pacify all the *Doshas* (especially *Kapha* and *Pitta*), relieve itching (*Kandughna*), cause healing (*Ropana*) and also improve complexion (*Varnya*) of the skin.

Table 1: Ingredients of Modified Vijaya Oil

S.No.	Ingredients	Botanical Name	Part used	Reference
1.	<i>Bhanga</i> leaf extract	<i>Cannabis sativa</i>	Leaf	BPN 141-145
2.	<i>Bhanga</i> seed oil	<i>Cannabis sativa</i>	Seed	BPN 141-145
3.	<i>Jhandu</i> (extract)	<i>Calendula officinalis</i>	Flower	SNB 389
4.	<i>Ushira</i> (oil)	<i>Vetiveria zizanoides</i>	Roots	NA 739-743
5.	<i>Damanaka</i> (oil)	<i>Artemisia vulgaris</i>	Seeds	BPN 510,511
6.	<i>Yashtimadhu</i> (extract)	<i>Glycyrrhiza glabra</i>	Roots	BPN 65,66
7.	<i>Kumari</i> (extract)	<i>Aloe vera</i>	Leaf	BPN 419,421

BPN: Bhava Prakasha Nigantu, SNB: Saligrama Nigantu Bhushan, NA: Nigantu Adarsh

Treatment

Subjects (≥ 12 to 75 years) diagnosed with *Vicharchika* (eczema), fulfilling inclusion criteria and willing to give consent were enrolled and evaluated on VAS (Visual Analogue Scale), EASI (Eczema Area and Severity Index), SCORAD (Severity Scoring of Atopic Dermatitis), SIGA (Static Investigator Global Assessment), and digital photographs on day 0. They were given modified *Vijaya* oil for topical application for 30 days, which was applied on the affected area twice a day viz., in the morning and evening. The evaluation was done based on the changes observed in the above said parameters on every visit (a total of 5

visits on 0, 7, 14, 21, 30 days). Discomforts or any kind of adverse reactions seen in the subjects were also noted.

Assessment Criteria

The efficacy of the trial product was evaluated based on the changes seen in the following parameters on every visit of the patient.

1. Eczema Area and Severity Index (EASI) score is a tool used to measure the severity and extent of atopic eczema. The intensity of redness (erythema), thickness (induration, papulation, edema), scratching (excoriation) and

lichenification (lined skin) of the eczema is assessed as none (0), mild (1), moderate (2), and severe (3). The four intensity scores are added up for each of the four body regions (head and neck, trunk, upper limb, and lower limb). The percentage area affected by eczema is evaluated in the four regions of the body. In each region, the area is expressed as nil (0), 1–9% (1), 10–29% (2), 30–49% (3), 50–69% (4), 70–89% (5) or 90–100% (6).^[8]

2. Scoring of Atopic Dermatitis (SCORAD) (objective) is a clinical tool used to assess the extent and severity of eczema. The rule of 9 is used to calculate the affected area, as a percentage of the whole body. The intensity of redness, swelling, oozing/crusting, scratch marks, lichenification and dryness is assessed as none (0), mild (1), moderate (2) or severe (3). Subjective symptoms like, itch and sleeplessness, are each scored by the patient or relative using a Visual Analog Scale (VAS) where 0 is no itch (or no sleeplessness) and 10 is the worst imaginable itch (or sleeplessness).^[9]
3. Static Investigator Global Assessment (SIGA) consists of a 6-point severity scale from clear to very severe disease (0 = clear, 1 = almost clear, 2 = mild disease, 3 = moderate disease, 4 = severe

disease, and 5 = very severe disease). The SIGA assessed clinical characteristics of erythema, infiltration, papulation, oozing, and crusting for the overall severity assessment.

4. For evaluation of eczematous lesion, digital photographs were taken on every visit by standard method for the evaluation of redness, thickness, scratching, lichenification of lesion and this were compared with baseline on graded scale.

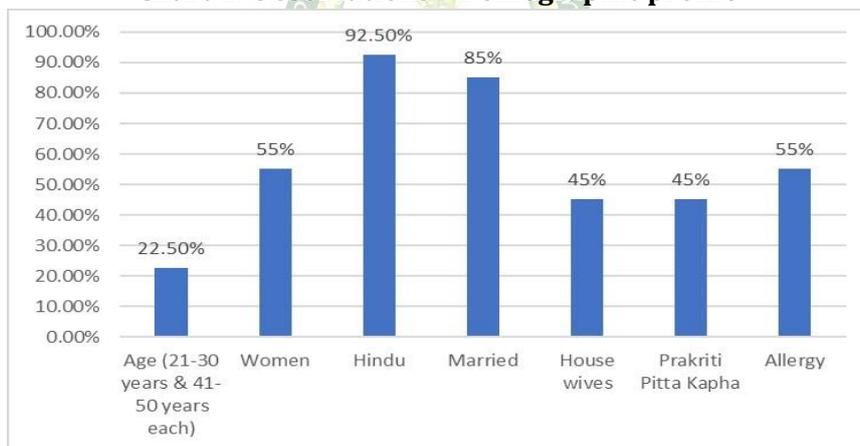
Statistical Analysis

Statistical analysis of the data collected were done with Wilcoxon test. Graphpad prism 9 was used for statistical analysis.

OBSERVATIONS

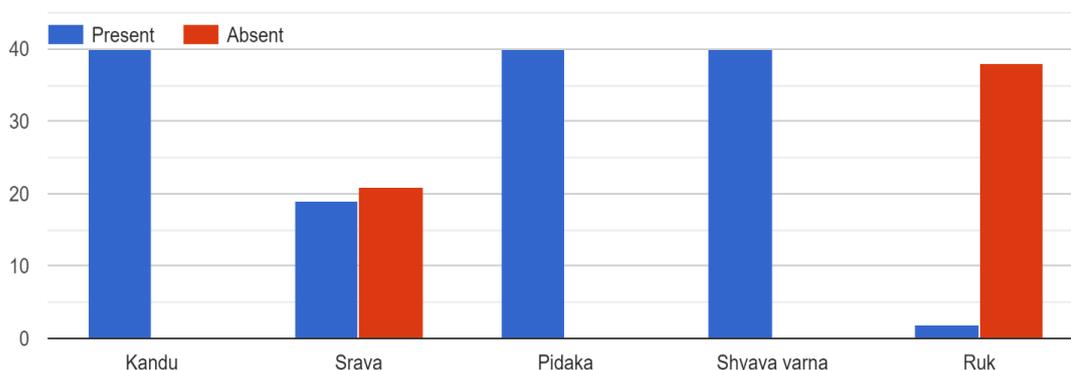
A total of 40 patients were enrolled in the trial. 37 patients had completed the course of treatment while 3 of them didn't follow the instructions regarding the trial medicine and failed to attend the visits, so they were considered as dropouts. Among the enrolled patients, majority of the patients (22.5% each) belonged to the age group of 21-30 years and 41-50 years, were women (55%), Hindu religion (92.5%), were married (85%), house wives (45%), *Pitta-kapha prakriti* (body constitution) (45%) and were allergic (55%) to dust, cold, soil etc. (Chart 1)

Chart 1: Observations - Demographic profile



Most of the symptoms of *Vicharchika* (eczema) mentioned by *Acharyas* were observed in patients. *Kandu* (pruritis), *Pidika* (vesicles) and *Shyava varna* (discoloration) were observed in all 40 patients. 47.5% of patients had *Srava* (discharge), whereas 52.5% patients had no *Srava* (discharge) due to attainment of chronicity. *Ruk* (pain), mentioned only by Acharya Sushruta was seen in 2 of the patients. (Chart 2)

Chart 2: Observations- Symptoms



RESULT

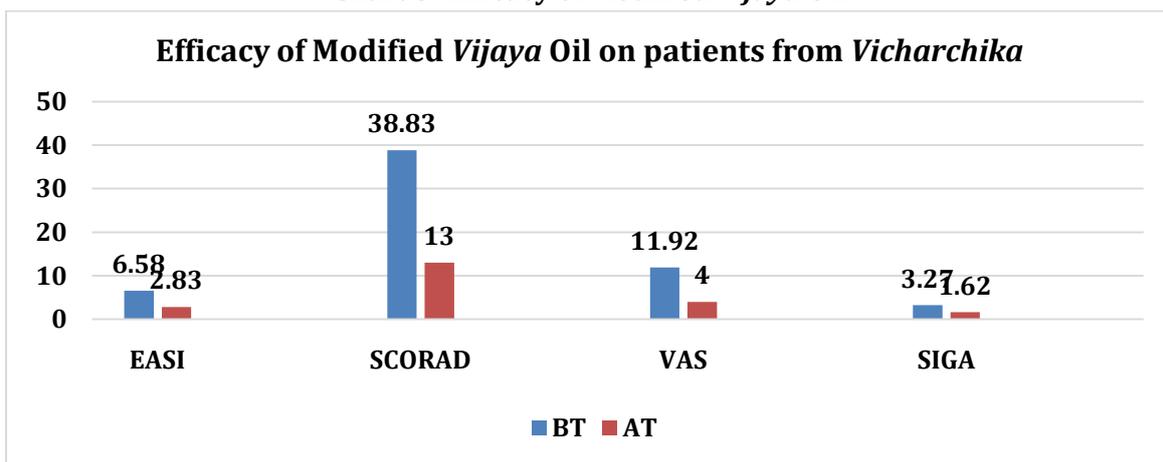
Highly significant results were obtained in patients after the intervention. The analysis was done based on the changes observed in EASI, SCORAD, VAS, SIGA and clinical photographs before (day 0) and after intervention (day 30). The total EASI score showed considerable reduction up to 57% ($p < 0.001$), the SCORAD (objective) significantly reduced by 66% ($p < 0.001$), VAS reduced by 66% ($p < 0.001$) and SIGA by 50% ($p < 0.001$). (Table 2) (Chart 3)

Table 2: Efficacy of Modified Vijaya Oil

Assessment Criteria	BT	AT	Diff.	% Relief	p-value	Significance
EASI	6.58	2.83	3.75	57%	<0.001	H.S
SCORAD	38.83	13	25.82	66%	<0.001	H.S
VAS	11.92	4	7.92	66%	<0.001	H.S
SIGA	3.27	1.62	1.65	50%	<0.001	H.S

BT- Before Treatment, AT- After Treatment, EASI- Eczema Area Severity Index, SCORAD- Scoring of Atopic Dermatitis, VAS- Visual Analogue Scale, SIGA- Static Investigator Global Assessment, HS- Highly Significant

Chart 3: Efficacy of Modified Vijaya Oil



A significant decrease was observed in mean values of EASI score when compared to baseline which implied that the oil was efficient in reducing redness, inflammation, itching and thickness of the skin. Reduction in mean values of SCORAD implied that it was efficient in reducing especially the dryness and lichenification if present (in chronicity), along with the other symptoms. The oil was efficient in diminishing itching to a very good extend, when observing

significant decrease in mean values of VAS. It was also noticed that (during the baseline visit) among 37 subjects, only 13 subjects had sleep disturbances due to itching etc., 50% decline was seen in SIGA also, which implied that the oil was efficient in making the skin clear. All these changes could be seen evidently while comparing the clinical photographs captured in the baseline visit and the last visit (5th visit) (Fig. 1 to 6).



Fig. 1: Subject no.3- Before Treatment



Fig. 2: Subject no.3: After treatment



Fig. 3: Subject no.29- Before treatment



Fig. 4: Subject no.29 - After Treatment



Fig. 5: Subject no.17 - Before treatment



Fig. 6: Subject no.17 - After treatment

DISCUSSION

In this study involving 40 patients, eczema was seen more prevalent in the age group of 21-30 and 41-50 years (middle age). Although eczema occurs at early ages of life, in childhood^[10], in this study no such pattern was observed. A higher prevalence (85%) was seen in married because maximum number of patients were above 21 years of age. Majority of patients were housewives (45%) which might have been due to continuous history of allergen exposure (dish wash bars) or a history of change in environment. A few of them were allergic to mud which they used for cleaning utensils. Disease prevalence was also seen in farmers (5%) which might have been due to allergens in plants or fertilizers or any other agents; and in industrial workers (2.5%), due to exposure to chemicals. Most of the patients (55%) had allergy on exposure to dust, cold and smoke; one of them was allergic to detergents and another had allergy on exposure to palak, paneer and eggs. Those people who had allergic sensitization was more prone to eczema.^[11] Majority of the patients had *Pitta Kapha Prakriti* (body constitution), also *Vicharchika* being *Kapha pitta* predominant disease these patients were more susceptible to develop the disease.

Vicharchika is a *Kapha* predominant disease (*Pitta* predominant according to *Sushruta*) that presents with *Kandu* (pruritis), *Pidaka* (vesicles), *Shyava varna* (discoloration) and *Bahu srava* (excessive discharge). It should be treated both by *Hetu viparita* (treatment against the cause) and *Vyadhi viparita* (against the disease) methods of treatment. By avoiding exposure to physical or chemical irritants, or *Nidana parivarjana*, *Hetu viparita chikitsa* could be begun. *Vyadhi Viparita chikitsa* could be employed by topical application of modified *Vijaya* oil.

After the intervention, there was 57% of relief of symptoms like itching, redness etc, with a significant reduction in the mean value of EASI when compared to baseline. On comparing the values of SCORAD, 66% relief was obtained, which implied dryness (criteria only assessed by SCORAD) also got reduced significantly. The mean values of VAS also reduced upto 66%. On assessing the skin through SIGA, 50% relief was obtained on comparison with the baseline. The oil was efficient in relieving itching, inflammation, oozing etc., thereby, making the skin clear. In some of the patients, the skin had become clear within 4th visit.

Although the results were highly significant, 2 of the patients developed dryness after initial relief. This might be due to chronicity or aggravated *Vata dosha* in the body. The oil was not seen much effective in very chronic conditions. In such conditions of chronicity or in patients where there is greater extend of *Dosha* vitiation (*Bahu doshavastha*), they have to be administered with *Shodhana* at first, followed by internal medications, so that once the body is cleansed, the medications act faster. Along with this, through external application, the *Doshas* at the skin could also be pacified. So a protocol involving both internal and external medication will be more effective in skin diseases.

Probable mode of action of Modified *Vijaya* oil

The cardinal symptoms of *Vicharchika* include *Kandu*, *Pidika*, *Shyava varna* and *Bahu srava*.

Kandu (pruritis) is seen mainly due to involvement of *Kapha* and *Pitta doshas*, most of the ingredients of the oil are *Kashaya* (astringent) and *Tikta rasa* (bitter taste) predominant which pacifies both of the *Doshas*.^[12] Moreover *Kashaya rasa* is *Kleda shoshana* and *Tvak prasadhana*. Thus it pacifies itching.

Pidaka (vesicles) may be of different varieties based on the *Dosha* predominance, it might be *Ama* (unripe) or *Pakva* (ripe) or even might get converted into *Vrana* (wound) as it progresses. In the early stages, there would be oozing out of fluid from the *Pidaka* (vesicles), later it gets dry and skin becomes thick. The ingredients like *Ushira* and *Yashti* in the oil acts on *Vrana* (wound) and is *Pachana* (digestive) too. *Kumari* further adds nourishment to the skin. *Srava* (discharge) occurs due to the combined vitiation of *Kapha* and *Pitta*. In *Vicharchika*, *Bahu srava* (discharge) is seen due to the vitiated *Udaka* (body water) situated in the *Tvak* (skin). *Vijaya* and *Damanaka* which have *Tikshna* (sharp) and *Ushna* (hot) properties act upon this. *Shyava varna* (discoloration) can be seen in *Vicharchika* based on the predominant *Dosha*. The disease occurs in *Tamra* layer of *Tvak* (skin) due to deranged *Brajaka pitta* and *Udana vayu*. In the oil, *Yashti* and *Kumari* which are *varnya* (enhances complexion) act upon this. Moreover *Vijaya* being *Vyavayi*, helps in quicker penetration of the medicine into the skin. The topical cannabinoids in *Vijaya* bind to cannabinoid receptors in sensory nerve fibres and inflammatory cells within the skin which leads to fast action of the medicine.

According to modern perspective, Cannabis seed oil contains potent anti-inflammatory compounds like cannabinoid which helps in skin conditions. In a study conducted in different animal models for acute and chronic contact dermatitis, the symptoms of skin inflammation were found markedly attenuated by cannabinoid receptor (CB₂) antagonists proving the above fact.^[13] Two percent licorice topical gel was found effective in reducing the scores for erythema, oedema and itching over two weeks in management of atopic dermatitis.^[14] *Calendula officinalis* helps in cure of cutaneous and internal inflammatory diseases of several origins. Topical formulations containing marigold extract (ME), evaluated in hairless mice against UV-B irradiation-induced photo damage, revealed that application of ME in gel formulation, were associated with a possible improvement in the collagen synthesis in the sub epidermal connective tissue.^[15] Skin care products containing *Artemisia princeps* extract (APE) are known to improve dry skin symptoms in atopic dermatitis. The antioxidant APE is an integral part of phytoextracts that upregulate FLG expression which is related to the pathology.^[16] Vetiver promote skin rejuvenation and strengthens connective tissue, assisting with wound healing of mature, irritated and inflamed skins.^[17] *Aloe vera* is best used for soothing itchiness or irritation.^[18]

Thus combination of these drugs, brings out excellent results with relief of symptoms of *Vicharchika* (Eczema) with 57% reduction in EASI

score, 66% reduction in SCORAD, 66% reduction in VAS and 50% reduction in SIGA ($p < 0.001$).

CONCLUSION

Thus it can be concluded that Modified *Vijaya* oil is highly effective in the management of *Vicharchika* (Eczema). Out of the 37 patients who have completed the trial, symptoms like itching, inflammation and redness got reduced significantly, after topical application of the cream for 30 days continuously. In patients with recent-onset and who had very less surface area affected, the skin became almost clear by third and fourth visit. *Vicharchika* being a *Pitta-kapha vyadhi*, the formulation as a whole was good enough to pacify these *Doshas*, thereby reducing the symptoms and also rejuvenating the skin. Also, no serious side effects were reported by the patients throughout the study. Thus the oil was efficacious in the relief of symptoms like redness, oozing, scratching, inflammation and lichenification on skin. Herbs have great potential to cure different kinds of skin diseases. Compared with conventional allopathic drugs, they have relatively low costs and can be used safely without any side effects.

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Cite this article as:

Manoj Vedhika, Godatwar Pawankumar, Sharma Reetu, Patel Neeraj Kumar, Peston Jamas Jahan, Dhuri Kalpana. A Clinical Trial to Evaluate the Efficacy of Topical Application of Modified Vijaya Oil in the Management of Vicharchika (Eczema). *International Journal of Ayurveda and Pharma Research*. 2023;11 (4):35-42.

<https://doi.org/10.47070/ijapr.v11i4.2728>

Source of support: Bombay Hemp Company Pvt. Ltd., Mumbai.

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