

CLINICAL VERIFICATION

Mentha piperita – A Multicentric Clinical Verification Study conducted by CCRH

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Mentha piperita has been used in Homoeopathy for many conditions like dry and spasmodic cough, hoarseness of voice, husky voice, productive cough, tendency to catch cold, headache, painful throat, infantile colic, pruritus vulvae, pain in neck, pimples on face, herpetic eruptions, etc as found in the literature. Besides these, pharyngitis, vertigo, coryza, tracheitis, gastritis, constipation and Urticaria were also relieved by this medicine and thus unfolding the hidden character of the medicine in there clinical conditions during the study.

A total of 6372 patients participated in this multicentric clinical verification study at various Units/Institutes under Central Council for Research in Homoeopathy to confirm the symptom of Mentha piperita, as mentioned in the homoeopathic Materia Medica.

Key words: homoeopathy; clinical verification; mentha piperita

Introduction

The clinical verification in Homoeopathy is one of the important steps for confirming the symptomatology of the drug generated during the proving of the drug on healthy human beings. The clinical confirmation of signs and symptoms, observed during proving is essential for validation of symptoms of the drug and its therapeutic application.

The Council had undertaken Clinical Verification study of *Mentha piperita* in order to validate its symptoms and signs mentioned in the literature^{1,2,3}

A partial proving of *Mentha piperita* was conducted by Demeures, who took a single drop of the tincture, the effect of which lasted till third month. The remarkable symptom of the drug is cough, which is generally dry, excited by air entering larynx, reading aloud, exposure to cold and shocks of any kind³. Demeures also used this drug in every case of influenza that came under his care in the winter of 1847 – 1848. He even advocates this medicine for the cough of consumptives. Hansen recommends it in bilious colic with great accumulation of gas, severe pain in herpes and as an external remedy in pruritus vulvae. Clarke J. H.2 mentions it's use in dry cough, headache, hoarseness, influenza, pruritus, sore throat and weakness of voice.

In our clinical verification programme, an effort has been made to explore its therapeutic utility by way of verification of the fragmentarily available data which formed the basis of prescribing the medicine.

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The Plant

Mentha piperita is a small herb and is cultivated in Indian gardens. Apart from India, it is distributed over Europe, Africa, North America and Japan.⁴ Its botanical name is *Mentha piperita* Linn and its synonyms are *Mentha hircine* and *Mentha officinalis*.⁴ This plant belongs to natural order *Labiatae*⁴, and its vernacular names⁴ are –

English – Peppermint
French – Menthe poivrée
German – Pfefferminze



The essential oil of plant is known for its antiseptic, stimulant and carminative properties. Its monoterpene content determined by gas chromatography is 1, 8-cineole (6-14%), limonene (1-5%), menthone (14-32%), menthofuran (1-9%), isomenthone (2-10%), menthyl acetate (3-5%), menthol (30-55%), pulegone (not more than 4.0%) and carvone (not more than 1.0%). The ratio of 1, 8-cineole to limonene should be greater than 2.0⁸

Pharmacological study of *Mentha piperita* reveals its antimicrobial activity inhibiting the growth of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Bacillus subtilis*, *Enterococcus faecalis* and *Escherichia coli*. However, *Mentha piperita* did not affect the growth of *Bacillus cereus*, *Penicillium cyclopium* and *Aspergillus aegyptiacus*. The essential oil inhibited the growth of *Trichophyton equinum* and *T. rubrum* (at a concentration of 0.4 ug/ml).⁸

Some Randomized Controlled Trials (RCT) in the past with *Mentha piperita* herbal extract reveals its effectiveness in Irritable Bowel Syndrome (IBS), Dyspepsia and as an Analgesic. In clinical pharmacology, its antispasmodic activity has been reported in IBS and dyspepsia. Its analgesic activity is indicated by its efficacy in induced muscular and mental relaxation. The clinical data shows its efficacy internally for symptomatic treatment of IBS and digestive disorders such as flatulence and gastritis and externally for the treatment of myalgia and headache. Its use described in Pharmacopoeias and traditional system of medicine indicate its efficacy for the symptomatic treatment of catarrh and coughs. Uses described in folk medicine but not supported by any experimental or clinical data indicate its ability to treat dysentery, diabetes, dysmenorrhoea, fevers, jaundice and urinary infections.⁸

In Homoeopathy, the whole plant excluding the root is used for the preparation of mother tincture⁴.

Methodology

Patients for the study were drawn from the OPDs of respective Institutes / Units of the Council. Their presenting symptoms and signs were recorded in the predefined case recording proforma to prescribe a medicine from the list of medicines assigned for clinical verification study. The medicine, which was found suitable for the patient on the basis of similarity was prescribed either in potency or in mother tincture and the changes in presenting symptoms and signs were recorded during the follow-up visits. If there was no change in symptoms and signs for a significant period, next higher potencies like 6c, 30c and 200c were prescribed and in case, no change was observed, even after change of potencies, the case was closed.

Study settings:

- Regional Research Institute (H), New Delhi
- Homoeopathic Drug Research Institute, Lucknow (U.P.)
- Homoeopathic Research Institute, Jaipur (Rajasthan)
- Clinical Research Unit, Jammu (J & K)
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In this multicentric trial of the medicine, 6372 cases (3493 males and 2879 females) were prescribed *Mentha piperita* during the period April 1980 - March 2004. The medicine was procured from the licensed pharmacy in various potencies viz. Q, 6c, 30c and 200c.

Results

The data of all the cases were collected, compiled and analyzed. The clinically verified symptoms are given in Table-1 alongwith the number of patients

prescribed on the basis of available symptoms and number of patients who got relieved. The symptoms superscripted with '1', '2' & '3' are in confirmation with the literature mentioned under reference.

Table 1: Clinically verified symptoms observed during the study

Location	Symptom(s)	Improvement Observed (% in brackets)
Head	Headache, frontal ^{2,3} from one temple to other ^{2,3}	83/ 66 (79.51%) 45/ 45 (100%)
Throat	Throat dry and painful on swallowing ^{2,3} Soreness of throat ¹ Throat painful to touch ^{2,3} Pain in throat ^{2,3} agg. on swallowing ^{2,3}	258/ 189 (73.25%) 98/ 59(60.20%) 49/ 43 (87.75%) 512/ 376 (73.43%) 400/ 299 (74.75%)
Abdomen	Infantile colic with flatulence ¹ Flatulence with bloated abdomen ¹	48/ 31(64.58%) 90 /64 (71.11%)
Female genitalia	Pruritus vulvae ^{1,2}	7/ 4 (57.14%)
Respiratory system	Dry cough ^{1,2,3} agg. from cold air ^{1,2} agg. from smoking ^{1,2} agg. from speaking ^{1,2,3} agg. inhaling cold air ^{1,2,3} with irritation in suprasternal fossa ^{1,2} , agg. at night agg.in evening agg. in morning agg. on laughing agg. on lying down with lachrymation with irritation in suprasternal fossa worse at night with tickling in throat worse at night with irritation in throat Spasmodic dry cough ² agg. on talking with hoarseness a voice ² Cough, productive, expectoration-thick white ² agg. from cold agg. from change of weather agg. by lying down Hoarseness of voice ² Husky voice ^{1,2,3} agg. from cold food	1782/ 1255 (70.42%) 613/ 524 (85.48%) 10/ 10 (100%) 407/ 296 (72.72%) 87/ 58 (66.66%) 6/ 3 (50%) 260/ 141 (54.23%) 14/ 14 (100%) 73/ 28 (38.35%) 94/ 65 (69.14%) 7/ 7 (100%) 2/ 2 (100%) 6/3 (50%) 639/ 551 (86.22%) 135/ 131(97.03%) 557/ 389 (69.83%) 7/4 (57.14%) 22/ 3 (13.63%) 753/ 466 (61.88%) 95/ 61 (64.21%) 3/ 1 (33.33%) 1/ 1 (100%) 454/ 328 (72.24%) 384/ 233 (60.67%) 24/16 (66.66%)
Back	Pain around neck ^{2,3}	38/ 34 (89.47%)
Skin	Every scratch becomes a sore ^{1,2,3} Small pimples on face ² with itching on left cheek with heat sensation Herpes zoster ¹ with intense pain agg. from touch with soreness of affected part after recovery	12/ 12 (100%) 49/ 31 (63.26%) 1/ 1 (100%) 1/ 1 (100%) 47/ 34 (72.34%) 3/2 (66.66%) 2/ 2 (100%)

Clinically verified symptoms of literature observed during the study Clinical symptoms

Following are the symptoms (Table-1) mentioned in the literature and verified clinically. These are superscripted with reference source. Moreover, during clinical verification, part of main symptom (modalities etc.) are also observed which are not mentioned in literature but relieved. These are mentioned in italics.

The following symptoms in Table-2, (totally new and not found in source literature) are the additional symptoms that were relieved either fully or partially. These, therefore, emerged as *clinical symptoms* not mentioned in the Homoeopathic Materia Medica on *Mentha piperita*.

Table 2: Clinical symptoms

Symptom(s)	Improvement Observed (% in bracket)
• Irritability in infants	1/ 1 (100%)
• Vertigo	45/ 45 (100%)
• Burning pain in head with heaviness, worse in evening	10/ 6 (60%)
• Pain in eyes with itching agg. from cold, better by warmth	5/ 5 (100%)
• Thin watery discharge from nose	331/ 209 (63.14%)
– with blockage of nose	8/ 1 (12.5%)
– with itching and irritation in nose and throat	43/ 25 (58.13%)
– worse from change of air	32/ 26 (81.25%)
– agg. from cold, at night and in winter	10/ 10 (100%)
– with redness of nostrils	2/ 2 (100%)
• Throat painful, agg. on swallowing liquid	38/ 20 (52.63%)
• Irritation in throat	9/ 5 (55.55%)
• Stitching pain in throat agg. on taking cold water and on coughing	59/ 28 (47.45%) 125/ 116 (92.8%)
• Pharyngitis	44/ 42 (95.45%)
• Hoarseness of voice, worse in morning	8/ 4 (50%)
– worse from cold	83/ 56 (67.46%)
– with sore throat	17/ 11 (64.70%)
– with cough	34/ 33 (97.05%)
• Pain in epigastrium	84/ 54 (64.28%)
– agg. from cold	9/ 9 (100%)
– with distension of abdomen	40/ 23 (57.5%)
– worse after eating	10/ 5 (50%)
– with flatulence	76/ 48 (63.15%)
• Colicky pain in abdomen in infants, worse after eating	10/5 (50%)
• Pain in abdomen	29/ 15 (51.72%)
• Flatulence with constipation	15/ 12 (80%)
• Pain in abdomen with nausea and vomiting, agg. from cold, better from warmth	25/ 25 (100%)
• Constipation with unsatisfactory stool and pain in epigastrium	16/ 9 (56.25%)
• Itching in anus	4/ 4 (100%)
• Dry cough with suffocative feeling and frontal headache, agg. at night, on sitting and from dust	133/ 130 (97.74%)

Table 2 (contd.)

Symptom(s)	Improvement Observed (% in bracket)
<ul style="list-style-type: none"> Paroxysmal cough worse in morning <ul style="list-style-type: none"> – with sensation of cold air inside nostrils in morning 	24/ 20 (83.33%) 1/ 1 (100%)
<ul style="list-style-type: none"> Spasmodic dry cough, agg. from cold air <ul style="list-style-type: none"> – agg. in evening – agg. at night – with irritation in throat – with breathlessness – with chest pain – with general weakness 	159/ 115 (72.32%) 9/ 3 (33.33%) 54/ 29 (53.70%) 21/ 12(57.14%) 56/ 38 (67.85%) 81/ 54 (66.66%) 11/ 6 (54.54%)
<ul style="list-style-type: none"> Cough, with whitish expectoration, with tickling in throat 	9/ 4 (44.44%)
<ul style="list-style-type: none"> Cough with dyspnoea, worse from cold air 	13/ 10 (76.92%)
<ul style="list-style-type: none"> Cough, productive, expectoration-thick white <ul style="list-style-type: none"> – agg. from cold – agg. from change of weather – agg. by lying down 	753/ 466 (61.88%) 95/ 61 (64.21%) 3/ 1 (33.33%) 1/ 1 (100%)
<ul style="list-style-type: none"> Pain in chest on coughing 	8/ 4 (50%)
<ul style="list-style-type: none"> Coldness of upper extremities 	1/ 1 (100%)
<ul style="list-style-type: none"> Small reddish eruptions on head with itching 	6/ 6 (100%)
<ul style="list-style-type: none"> Itching of arms and hands, better by scratching 	51/ 25 (49.01%)
<ul style="list-style-type: none"> Itching of arms and legs, worse from touch and scratching 	1/ 1(100%)
<ul style="list-style-type: none"> Urticarial rash, nodular, over skin <ul style="list-style-type: none"> – agg. after scratching – agg. from cold air – in thighs , groins and lower abdomen, agg. morning, evening and bathing 	7/ 6 (85.71%) 6/ 5 (83.33%) 1/ 1 (100%) 3/ 3 (100%)
<ul style="list-style-type: none"> Itching without eruption, with dryness of skin, worse on scratching, followed by bleeding 	10/ 6 (60%)
<ul style="list-style-type: none"> Feverish feeling, agg. in evening <ul style="list-style-type: none"> – with increased thirst – with bodyache 	20/ 15 (75%) 4/ 4 (100%) 3/ 3 (100%)
<ul style="list-style-type: none"> Tendency to catch cold 	31/ 24 (77.41%)
<ul style="list-style-type: none"> Oversensitive to cold weather and sour things 	6/ 6 (100%)
<ul style="list-style-type: none"> Pain in whole body 	6/ 4 (66.66%)

Discussion

The sphere of action of *Mentha piperita* is primarily on respiratory system.^{1,2,3} Its main indication is dry cough, agg. from cold air and the same symptom was verified in our study too in 85% of patients (Table-1). The other modalities mentioned for cough like agg. morning, smoking, talking, with irritation in throat and suprasternal fossa were also verified. Apart from the various modalities related to cough as mentioned above, 'cough aggravated at night, evening, morning, laughing, lying down' are also observed as additional

modalities relating to cough during the process of clinical verification.

In the Homoeopathic Materia Medica, *Mentha piperita* is mentioned for dry cough but in this study, 466 patients suffering from cough with white expectoration were relieved in various degrees, indicating its role in productive cough (Table-1).

The medicine relieved colicky pain in abdomen with flatulence (64.58%) and in adults, flatulence with bloated abdomen (71.11%) as mentioned in

homeopathic literature¹ which are thus verified. In 12 patients out of 15, constipation accompanied with flatulence was also relieved by this medicine indicating the scope of its action on intestinal complaints.

Design of study, i.e. to know the respective roles of experimental and observational studies in clinical verification, is still a topic of debate. However, this is an observational study which cannot be without bias⁵.

As large number of patients participated in this study and many symptoms were observed by more than one investigator and relieved in more than 30% of patients, thereby producing the reliability of the symptoms, especially so, when these symptoms were also observed during proving. So, it is rightly mentioned that clinical verification of drug pathogenesis is the much needed evidence based study for the homoeopathic therapy^{6,7}.

A medicine has many symptoms and signs. These can occur in different combinations in many clinical conditions. So it was practically difficult to carry out laboratory investigations for such a large number of patients which is a limitation of this study.

REPERTORY

A concise repertory of the verified symptoms, according to Jost Kunzli Von Fimmelsberg Kent's Repertorium Generale, has been compiled for the purpose of quick reference. Rubrics / sub rubrics in italics are new rubrics, i.e., not mentioned in the above referred repertory while rubrics / sub rubrics in Roman letters are the existing rubrics of the said repertory which were reconfirmed by this study.

Physicians may include these rubrics in their personal repertories for their day to day reference in practice.

MIND

IRRITABILITY
children, in

VERTIGO

HEAD

ERUPTION
RED
ITCHING
PAIN
evening
heaviness in head, with
Forehead, in
EXTENDING temples, to
BURNING

EYES

ITCHING
PAIN
cold application, agg.
warmth, amel.

NOSE

DISCHARGES
WATERY
night
change of climate, from
cold, from
itching and irritation in nose and throat, with
redness of nostrils, with
weather
OBSTRUCTION
discharge, with

FACE

ERUPTIONS
PIMPLES
cheek, left
heat sensation, with

THROAT

DRYNESS
INFLAMMATION
Pharynx
IRRITATION
PAIN
coughing, on
swallowing, on
liquids
touched, when
SORE
STITCHING

STOMACH

PAIN
cold after taking
distension of abdomen, with
flatulence, with
THIRST
chill during

ABDOMEN

ERUPTIONS
URTICARIA
Hypogastrium
nodular
morning
evening
air cold, in
bathing, after
scratching agg
FLATULENCE
flatus, with
constipation, during

PAIN

cold, from taking and as from taking cold
inspiration, during
deep
nausea, with
vomiting, with
warmth, amel.
CRAMPING, *infants in*
flatulence, with
eating, after

RECTUM

CONSTIPATION
insufficient, incomplete, unsatisfactory stools
pain in epigastrium, with
ITCHING

GENITALIA- FEMALE

ITCHING

LARYNX & TRACHEA

VOICE, hoarseness
morning
cold
cough, with
soreness in throat, with
husky
cold food, from

RESPIRATION

DIFFICULT
air in, cold
cough, with

COUGH

AIR, cold
LYING *agg.*
WEATHER, change of
DRY
morning
evening
night
air, from cold
lying, while
talking, on
irritation, suprasternal fossa, in
night
irritation in larynx
tickling in larynx, from
night
SUFFOCATIVE
dust, from
sitting, from
frontal headache, with
night

PAROXYSMAL

morning
with sensation of cold air inside nostrils

SPASMODIC

evening
night
cold air, from
talking, on
irritation in throat, with
hoarseness of voice, with
breathlessness, with
pain in chest, with
general weakness, with

EXPECTORATION

THICK
WHITE

CHEST

PAIN
cough, during

BACK

PAIN
cervical region

EXTREMITIES

COLDNESS, Upper Limbs
ERUPTIONS
Lower Limbs
Thigh

urticaria
nodular
morning
evening
air cold, in
bathing, after
scratching agg

ITCHING

Upper Limbs
Upper Arm
scratching
amel.
touch, on
Hand
scratching
amel.
touch on

CHILL

CHILLINESS
evening
increased thirst, with
pain, with



SKIN

ERUPTIONS

HERPETIC

burning
touch agg.

RED

URTICARIA

morning
evening
air cold, in
bathing, after
nodular
scratching , after

ITCHING

ERUPTION, without

SCRATCHING agg.
followed by bleeding
dryness of skin, with

SORE

of the affected part, herpis recovery after

SORE, becomes
scratch , after

GENERALITIES

COLD, tendency to take

PAIN

SENSITIVENESS

cold weather
sour things

WEAKNESS

cough, spasmodic from

Conclusion

Results obtained evidently prove that the sphere of action of *Mentha piperita* was more marked on respiratory system. A number of clinical symptoms also have been relieved by the medicine which were earlier not reported anywhere and shows its wider scope of therapeutic action. Further clinical trials with suitable study design are required to validate such conditions and to enhance the usefulness of this medicine.

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