Drug Proving in Homoeopathy, an essential component in Health Care Management

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Abstract:

'Drug Proving' is a method, unique to Homoeopathy where the pathogenesis of a drug is evolved through its trials on apparently Healthy Human Provers. Drug proving is the process of acquiring knowledge of instruments intended for the cure of natural disease (Aphorism - 105)5

Objective: To find out the pathogenetic effects of an Araucaria Columnaris on healthy human beings.

Methodology: Randomised double blind placebo controlled study. It is recommended to have at least 50 provers who can complete the total duration. The provers divided into 2 group one medicinal group (Araucaria Columnaris) which consist 25 provers and another placebo group with 25 provers. Record were maintained of both group, then the analysis was done and characteristic symptoms of Araucaria Columnaris were identified.

Result:Since only one prover from medicinal group experienced symptom out of 25 provers. Therefore, we rejected alternate hypothesis.

Conclusion:

As only 2 provers showed few symptoms, from which one prover was from placebo group and another one was from medicinal group which experienced few symptoms which were not so prominent to be considered as pathogenic symptoms of Araucaria columnaris 3X. So we concluded that Araucaria columnaris 3X does not give pathogenic symptoms on healthy human being of both sexes.

Key word: Drug proving, Araucaria Columnaris, Placebo, healthy human being

REVIEW OF LITERATURE: -

Introduction – **Drug Proving** is the systematic process of acquiring knowledge of the instruments intended for the cure of the natural diseases. In other wards we can say that it is the systematic process of investigating the pathogenetic power of drug by administering the same in to the healthy individuals of different age and both the sex.

Dr. Hahnemann established experimental human pharmacology by Proving Drugs on healthy human beings, obtained data on the pure effects of drugs which he recorded in his *'Chronic Diseases' and* in the '*Materia Medica Pura'.* He arranged all the datas according to a scheme of locations and presented in a systematic manner. He ensured complete objectivity by faithful recording the effects as experienced by the provers, retaining their language as far as possible. In his introductory remarks his personal comments and observations have been recorded separately. Even today his directions are rigidly adhered to in the Homoeopathic Pharmacopoeia.

Introduction – **The effects** of medicines can be ascertained from different sources, including: Proving on healthy human being, Toxicological studies in animals & Clinical experiences.

The human Drug-Proving could not be done to the extent of producing irreversible pathological changes. The pathological data owe their origin chiefly to clinical observations, supported by reports of accidental poisoning and a few animal provings that were conducted. Thus Homoeopathic Materia Medica is essentially a record of human functional pathology.

In Homoeopathic Drug Provings on healthy subjects, volunteers (provers) receive the medicinally active substances over a definite period of time. All striking changes and symptoms affecting the body or psyche are than carefully recorded and evaluated and described in detail e.g. intensity of individual symptoms, their variation at different times of day, associated circumstances and modifying influences. All newly occurring symptoms, in this context, are taken as symptoms, which systematically collected to form the picture of the drug substances being proved. Araucaria Columnaris is one of the ornamental plants. Common name is Christmas tree.

Description: - Araucaria Columnaris is a narrow columnar evergreen conifer with short mostly horizontal branches that grow in whorls around the slender, upright to slightly leaning trunk. The branches a lined with cord like, horizontal branch lets clad with small, green, incurved, spirally arranged, overlapping leaves. The Juvenile leaves are needle-like while the adult leaves are Scale-like and triangular. The bark is grey rough and resinous, exfoliating in the thin strips.
New Caledonian pine dioeciously, with the male and female cones on separate trees. The female cones up to 6 in. long (15 cm) are upright, scaly, egg shaped and located in the upper branches. The male cones up to 4 in. long (10 cm) are dropping, scaly, cylindrical and hang from the lower branches. Araucaria Columnaris is a popular garden tree in warm temperate climate. It is a magnificent focal point on alone and excellent Street tree [6]

As per Ayurvedic literature –
Veertaru (Christmas tree) is katu (bitter) in taste, ishana (hot), MutraKrichanashaka (diuretic), sandhishool (helps to treat joint pain), pathya (eatable), Agni deepak (increases appetite), destroys Vata Rog. Vellantra (Christmas tree) is ashmarihar (destroys stones), grahi (stops loose motion or diarrhoea), Vata and Kafahar, mutrakrichahar (diuretic). It's katu (bitter) when digested, laghu (light), Ruksha (Dry), Tikta-katu (bitter) taste, diuretic, excessive thirst, inflammation, uterine, eye, kidney disorders, diarrhea. It also has mentioned in sushrut Samhita – Veertarvadigana, Vatasanshamangana. Acharya Dalana mentioned it in – uttartantra 9/27.Ashtanga Hridya has mentioned it in Veertar vadigana. As various uses of this plant is already mentioned in Ayurveda there is a need to study the action of Homoeopathically prepared medicine from this plant Araucaria Columnaris.
Chemical properties: - Plants produce a diverse range of bioactive molecules making them rich source of diverse types of medicines. Chemical screening is performed to target isolation of new or useful type of constitutions having potential activity. The discovery of a potent remedy from plant origin will be a great achievement in bacterial infection therapies.
The resin was separately extracted with different solvents on its polarity, water, methanol, ethyl acetate and benzene. The extracts were screened for phytochemicals analysis; the result shows that methanolic extract involved in extraction of large number of phytochemicals when compared with others.
Various phytochemicals which are present in the plant are tannin, alkaloids, flavonoid, steroids, glycosides, cardiac glycosides, terpenoid, saponin, anthraquinone, protein, amino acid, carbohydrates, etc.
Phytochemicals properties of Araucaria Columnaris: -
TANNIN – A complex organic compound which are polyphenolic poly hydroxibenzoic acid derivative which is present in leaves bark and immature fruits which disappears after ripening antibacterial anti-diarrheal. Heavy metal poisoning hemostatic mild diuretic.

ALKALOIDS –is an organic compound of natural origin which contains nitrogen atom which is more or less basic, is of limited distribution and has at low doses marked pharmacological properties. Functions of alkaloids - Alkaloids are poisonous in nature but when used in small quantities they exert useful physiological effects on animals and human beings. Their exact role in plant is still a topic of research. Some of the predicted roles are: They are reserve substances which can supply nitrogen, they might be the defensive mechanism for plant growth in dry region to protect from grazing animals, herbivores and insects. They may be end product of detoxification mechanism in plant and by this way check formation of substance which may be prove to harmful to the plant. The possible role as growth regulatory factor in the plant. They are present normally in conjugation with plant acid like mercuric acid, cinchotannic acid etc. Therefore, alkaloids could be acting as carriers within plant for transportation of such acids.

FLAVONOID - compounds which gives plant Colour or responsible for pigmentation Flavonoids also act as enzyme inhibitor for example histidine decarboxylase inhibits the naringenin or quercitin. Flavonoids are also useful as anti-allergic, anti-inflammatory, hepatoprotective, maintains blood cholesterol level, diuretic, antispasmodic, antiviral or antibacterial. Some of them inhibit the growth of tumour or anticancer activity.

SAPONINS- are glycosides of triterpenes and sterols, occurs in more than seventy families of plants. They have soap like properties and act as surface active agents. They have the ability to haemolyse the blood cells.

Few examples of Saponins are hecogenin from Agave and yamogenin from Dioscorea species, saponins from alfalfa etc.

CARDIAC GLYCOSIDES- The last group of triperpenoids are cardiac glycosides or cardenolides. A typical cardiac glycoside is oleandrin (obtained from Nerium oleander, Apocynaceae). A considerable number of plants scattered throughout the plant kingdom contain C23 and C24 steroidal glycosides which exert on the failing heart a slowing and strengthening effect

TERPENOIDS- are the hydrocarbons of plant origin having general formula (C5H8) n. They are also oxygenated, hydrogenated and dehydrogenated derivatives. Basically terpenoids are volatile substances which give fragrance or aroma to plants. They are also known as essential oils because they represent essence. They are mainly found in leaves and fruits of plants like conifers, citrus and eucalyptus. The term ‘terpene’ was assigned to the compounds after isolation of volatile liquid turpentine from pine trees. They are easily oxidized nearly by all the oxidizing agents [7]

Material and methods:

This was a double-blind, randomly selected placebo control trial. The Motiwala National Homoeopathic College and Hospital served as the site of this investigation. This study, which included participants in both sexes between the ages of 18 and 60, lasted six months. The exclusion standards were Any illness or condition that may affect one or more of the following body systems: hematopoietic, renal, endocrine, pulmonary, central nervous, cardiovascular, immunological, dermatological, gastrointestinal Persons who are colour blind, those who have had surgery within the past two months, and The use of herbal or dietary supplements, treatments, or drugs that are likely to interfere with or significantly affect the responsiveness to the proving substance as part of planned medical or dental care throughout the period Volunteers using regular medications for any acute or chronic condition (Allopathy, Ayurveda, Homoeopathy, Naturopathy, etc.) disease, Participant must not be on any homeopathic remedy in the preceding one month and have had no significant change in health status in the last one month, Emotionally disturbed, hysterical or anxious person, Persons having no history of allergies food, hypersensitivity, etc., Women during pregnancy, puerperium and while breastfeeding and women who have undergone hysterectomy, Recent history of alcoholism/ drug

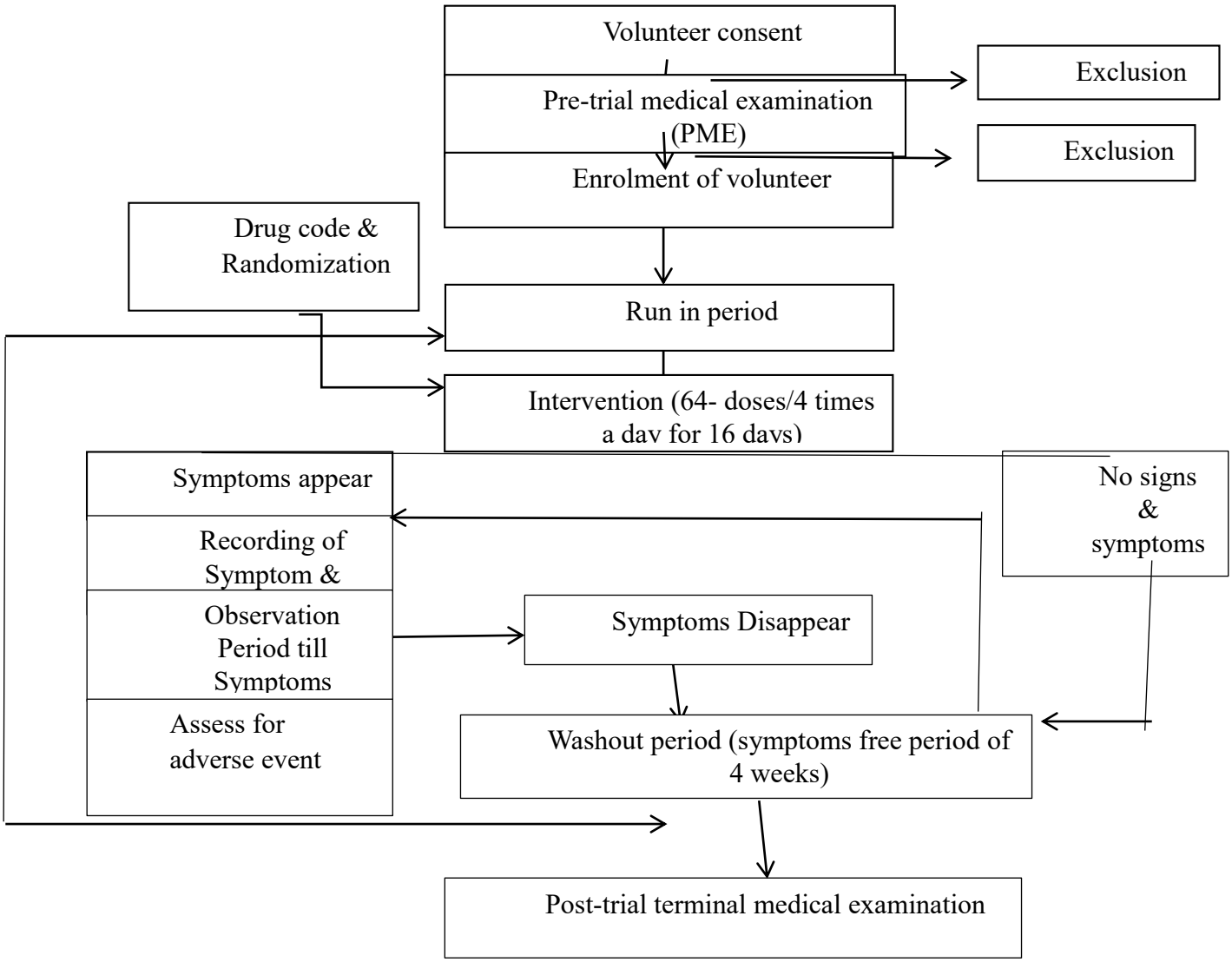
addiction or unlikely to refrain from excessive alcohol consumption/drug intake during the study period, Participation in another clinical or proving trial during the last 6 months
And inclusion criteria were Age- 18- 60 years,both male and female, Healthy individuals with no apparent disease, Intelligent enough to record carefully the facts, subject and objective symptoms generated by drug proving, those willing to give written consent. Around 50 healthy provers gave their consent and proving was conducted on them.

RESEARCH METHEDOLOGY SPECIFIED & EXPLAINED FOR DATA COLLECTION: -

Sample size taken from 50 volunteers by randomized double blind method.

Method of data collection relevant to objectives: -

Flow chart for proving cycle & study process:



Study instruments / data collection tools are: Consent form, Pre medical examination format, Day book.
Data management and analysis procedure [12]
During qualitative analysis Criteria for Symptom selection in Drug proving data is in the form of symptoms, where there is no measure of efficacy, but description of individual proving symptoms where qualitative research evaluation will be applied. The evaluation will be done by compilation of the proving symptoms in different categories, representing a certain probability to be associated with the remedy and therefore are the most important ones for further clinical verification.
Example: a symptom will belong to the remedy with great probability if at least one of the following criteria is met: Occurrence of the symptom in two or more volunteers, Objective, measurable signs corroborating with distinct intensity of the symptom, Occurrence of the symptom several times shortly after administration of the drug Recurrence of the symptom several times over the course of a number of days. Striking, seldom or paradox modalities and/or concomitants of the symptom However, all symptoms including those appearing in lesser number of provers, less distinct or common symptoms will all be included in the proving data. Symptoms, which are not thought to belong to the drug picture, would also be stated, but under separate headings, marked in a specific manner so they are not lost for clinical verification. Such symptoms may be compared with the clinical verification symptoms at a later stage if required

Characterizing features of proving symptoms:
All provers are to be included in the analyses. The symptoms obtained under verum or placebo must be listed separately. The proving symptoms are identified and their characterizing feature will be detailed:
New symptoms with marked severity, duration or frequency. Ongoing or recurring symptoms present during the proving that have been unexpectedly and markedly improved. Ongoing or recurring symptoms that have been unexpectedly and markedly worsened. Symptoms that recur from the past but have not occurred in the 12 months preceding the proving. Symptoms that display alteration with another symptom in a single volunteer in such a way that the alteration is strongly individualizing, Symptoms associated with modalities or concomitant symptoms occurring in other parts of the same prover. Symptoms that involve multiple body parts or organs in a similar manner or multiple symptoms within the same subject with a similar associated modality, forming an easily recognizable pattern of reaction. Similar symptoms occurring in multiple provers. Such symptoms may be related by similar sensation, modality, or body system and can be recognized through a qualitative analysis similar to red-line symptom reporting in homoeopathic literature.
Result: Since only one prover from medicinal group experienced symptom out of 25 provers. Therefore, we rejected alternate hypothesis.

DISCUSSION: Homoeopathic drug pictures are developed by recording the symptomatic effects of homoeopathic remedies given to healthy volunteer (a 'proving'). In a double-blind randomized controlled trial, we tested the hypothesis that individuals using an infinitesimal dilution of ARAUCARIA COLUMNARIS 3X. The main objective is to see the pathogenic effect of Araucaria Columnaris on healthy human being. For this drug proving we had prepared Araucaria columnaris by new method of preparation of mother tincture (maceration) with guideline from Text book of homeopathic pharmacy (homeopathic drug proving). We had prepared this drug in pharmacy department of M(N)HMC under guidance of Dr. Varsha Dharne. We had prepared mother tincture, then prepared further potency up to 3x by succussion. We had given 3x potency in globules form as 4 doses per day.Screening was done on 100 people as per their willing,Based on screening and inclusion

and exclusion criteria 50 provers were selected for the study. By double blind randomisation trail, we divided 2 groups of 25 provers each and segregated the provers as for one group i.e. placebo and second group i.e. Medicine group. Study duration was of 6 months, in which all the process of screening, case study, general examination was done of each provers.After case taking, those provers who were suitable for proving were given medicine which they had taken in 4 doses per day (1 dose = 4 globules) for 16 days. During proving all provers were told to maintain their daily diary to record symptoms. 30 days of washout period i.e. observational period after completion of 64 doses which was given, during observational period we observed any appearance of symptoms.In one of our prover Mr A.K. age 28-year-old male, started taking doses from 01/12/22, he experienced a lightning like pain on lower back extending to lower angle of scapula on 6/12/22 and symptom continued for 3 consecutive days better on 4th day. We had to stop dose from 7th of December till 13th of December and restarted taking dose from 14th of December. After that no symptom appeared. Washout period- 24/12/22 - 24/1/23 in this period also no significant symptom appeared. This symptom was from one prover of placebo group.The second prover Mr. H. H age 33-year-old male, started taking doses from 29/11/22, he experienced symptoms like sneezing and dry cough aggravated at waking up from bed, at night and symptom continued for 4 days' prover was feeling better on 5th day. Dose was stopped from 30/11/22 and restarted dose from 8/12/22 after that no symptoms appeared. Washout period – 22/12/22 to 22/1/23 in this period no symptoms appeared. This symptom appeared from one prover of medicinal group Our study doesn't show any specific symptoms proved of Araucaria Columnaris, which should not be considered as a significant symptom of this drug. Therefore, Null Hypothesis: - Araucaria Columnaris does not give pathogenic symptoms on healthy human beings of both sexes. Our study can be said as inconclusive.

Conclusion:

As only 2 provers showed few symptoms, from which one prover was from placebo group and another one was from medicinal group which experienced few symptoms which were not so prominent to be considered as pathogenic symptoms of Araucaria columnaris 3X. So we conclude that Araucaria columnaris 3X does not give pathogenic symptoms on healthy human being of both sexes.

Table no: 01 - STATISTICAL ANALYSIS:

AGE GROUPS	TOTAL NUMBER OF PROVERS
18 -25	37
26-30	06
31-35	03
36-40	01
41-45	00
46-50	02
51-55	00
56-60	01
Total	50

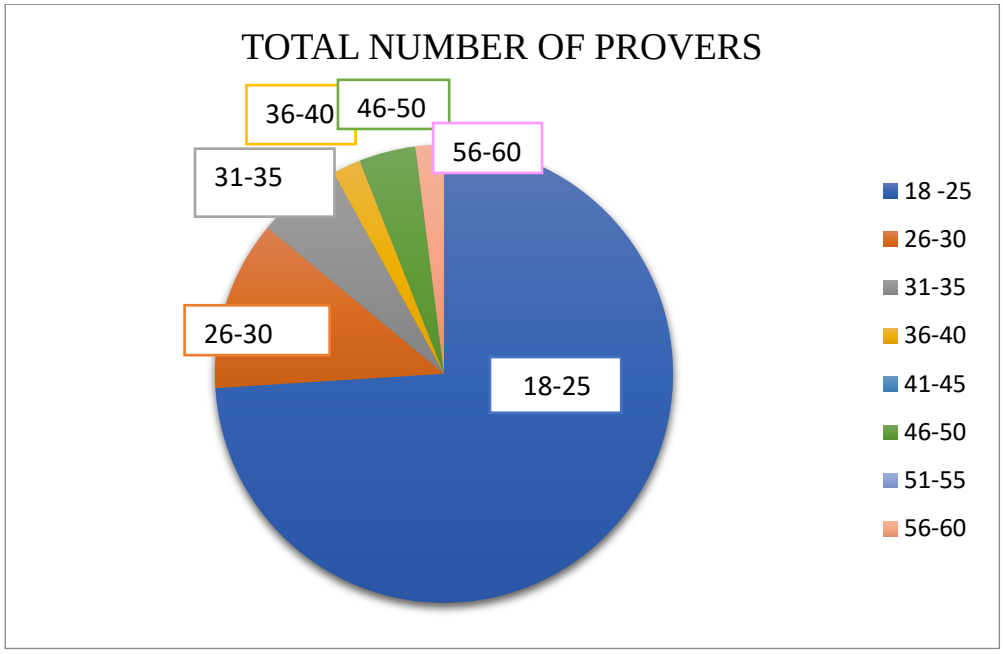


Table no 02 - GENDER DISTRIBUTION

GENDER OF PROVERS	TOTAL NUMBER
MALE	21
FEMALE	29
TOTAL	50

RESULTS OBTAINED

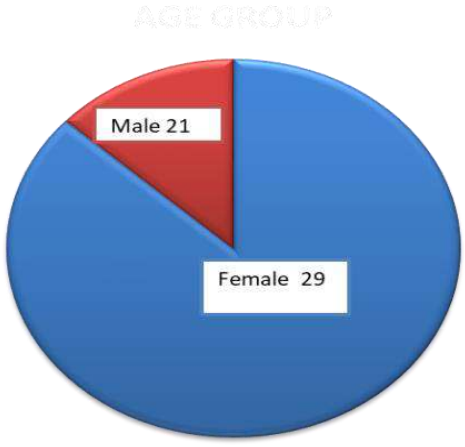
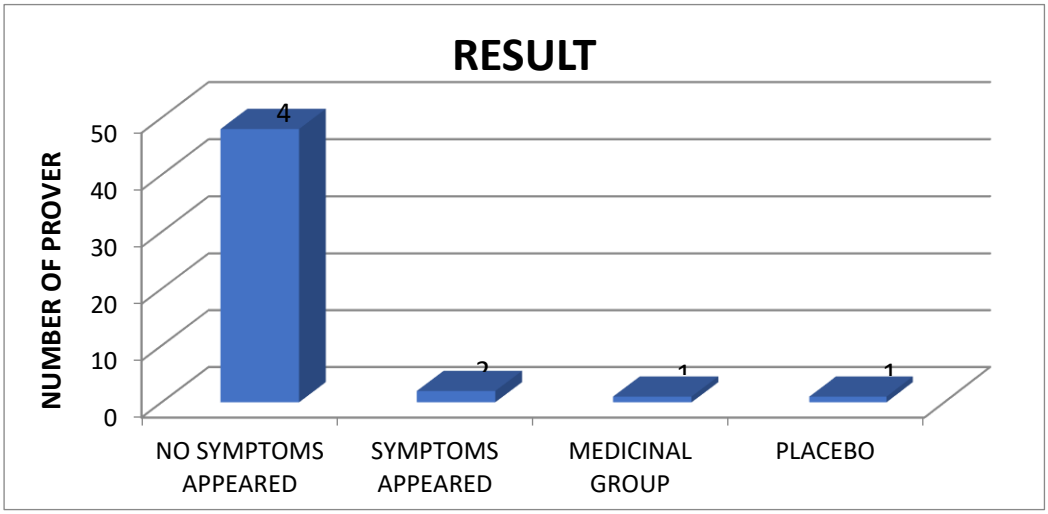


Table no :03

RESULT	NUMBER OF PROVER
SYMPTOMS APPEARED	2

NO SYMPTOMS APPEARED	48
MEDICINAL GROUP	1
PLACEBO GROUP	1
TOTAL	50



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