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To study efficacy of *Eschscholzia californica* mother tincture (*California poppy*) in treatment of migraine headaches

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Abstract

The aim of the study is to check efficacy of *Eschscholzia californica* Mother Tincture in treatment of migraine headaches. Sampling: Randomized Double Blind Placebo controlled trial, Patient-attending OPD with complaint of Headache. Sample size of 100 patients, Inclusion Criteria: Patient with complaint of Headache (Age: 15 to 65year). Exclusion: Patient suffering from Diabetes mellitus, hypertension, Hypothyroidism or taking any drug; Data Collection: Data collection is done through structured questioner; McGill Pain Questionnaire was used and pain severity was assessed on a linear 6 Grade -Verbal rating Scale (VRS). Data analysis: the data is analyzed using SPSS Version 21
Conclusion: It is found *Eschscholzia californica* Mother Tincture is found effective in treatment of migraine headaches.

Keywords: Headache, migraine, *Eschscholzia californica*

Introduction

Migraine headache is a common neurological complaint characterized with unilateral moderate to severe throbbing/ pulsating headache with nausea, vomiting, photophobia or photophobia. Migrain is caused due to spontaneous over activity of sensory pathways in the brainstem leading to abnormal amplification in pain.

Migraine Headache has been termed the seventh disabler due to its considerable impact on the quality of life (QOL) of patient. The prevalence of headache peaks in midlife, and is low among adolescents and after the age of 60 years. Women have 18% more risk of developing migraine compared to a 6% chance in men. (Brett R; 2015) [4].

Objective

To study efficacy of *Eschscholzia californica* Mother Tincture in treatment of migraine headaches.

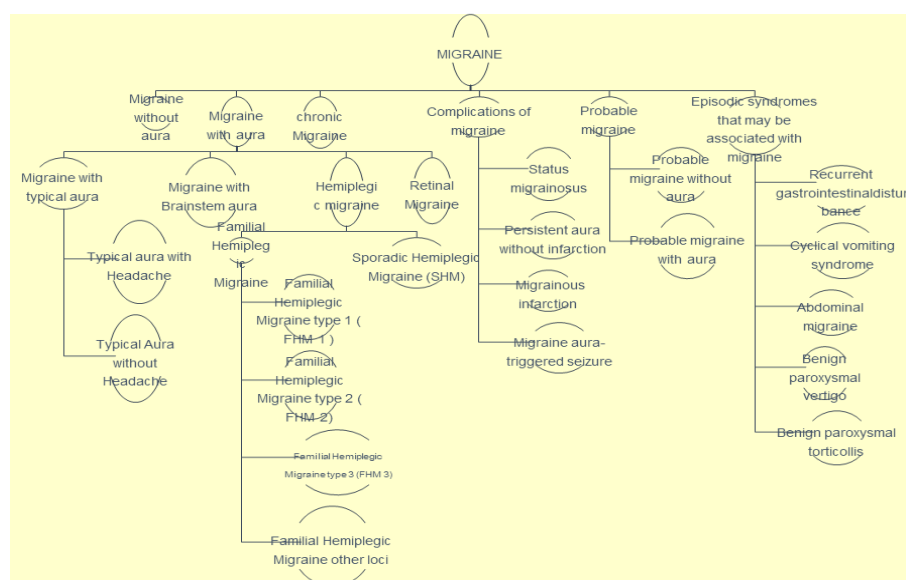


Fig 1: Classification of Migraine as per IHS Classification ICHD-3

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Homoeopathic medicines for Migraine

Eschscholzia californica

Eschscholzia californica (California poppy, golden poppy, California sunlight, cup of gold) is a spices of flowering plant in the Papaveraceae family which is found in California used for its medicinal values.

It is a perennial plant growing to 13-152 cm tall with alternately branching glucose blue green foliage. The leaves are alternately divided into round lobed segments, the flowers are solitary on long stems, silky textured with four petal long and broad, flower color ranges through yellow, orange and red.

Eschscholzia californica is known for its non-narcotic antispasmodic, sedative and analgesic quality. A soporific remedy used to promote relaxation and found useful for trouble sleeping (insomnia), aches, nervous agitation, nervous tension. Anxiety bed wetting in children, depression, long-term mental and physical tiredness (neurasthenia), nerve pain, various psychiatric conditions, blood vessel problems, sensitivity to weather changes, and sedation. It is commonly known for its therapeutic effects in relieving toothache and acts as tranquilizer.

Though this research study is conducted to study the efficacy of the *Eschscholzia californica* Mother Tincture in craniofacial neuralgia and migraine headache. Other Medicines which are known for their efficacy in Materia Medica for migraine are:

Belladonna characterized with intense throbbing, pulsating headache. *Glonoinum* an excellent medicine for congestive headaches of migraine triggered by sun exposure. *Spigelia* for left-sided migraine. *Sanguinaria canadensis* for right-sided migraine. *Iris versicolor* migraine associated with intense nausea, vomiting or acidity. *Nux Vomica* for migraine with gastric troubles. *Natrum Carbonicum* is suitable for sun headache migraine. *Natrum Muriaticum* migraine attacks that worsen around the menstrual cycle. *Sepia* migraine in women around menopause. *Kali Phos* for migraine due to stress.

Methodology

A randomized, double blind, placebo controlled trial enrolling 100 patients complaining of Headache. who met the selection criteria.

Sampling

Random sampling, Patient attending OPD with complaint of headache.

Duration of Study

1 March 2019 to 31 June 2019 (4 Month)

Dosage

20 drops of Mother Tincture twice a day. Morning and evening (Empty Stomach).

Inclusion Criteria

- Patient between age group 15 to 65 year visiting OPD with complaint of headache with no other serious physical abnormality and not taking any analgesics.
- Patient who has ability to understand the consent and is willing to comply with the requirement of the trial.

Exclusion

- Patient suffering from Diabetes mellitus, hypertension, Hypothyroidism, asthma or taking any allopathic. Homoeopathic or Ayurvedic treatment.
- Patient who had taken drugs for insomnia in past or present.
- Pregnant and lactation
- Previous participation in any clinical trial / proving in last 6 month
- Patient taking alcohol / smoking/ tobacco.
- Any contradiction to blood sampling.

Diagnostic Consideration

- In Routine Diagnostic imaging is not recommended for migraine, “Additional testing in patients without atypical symptoms or an abnormal neurologic examination is unlikely to be helpful” (Conicella 2008, Beithon 2013) [5]
- Case History and physical examination is sufficient to diagnose Migraine clinically.(Conicella 2008, Beithon 2013) [5]

Disposition

Drug A: *Eschscholzia californica* Q Mother Tincture (35 subjects)

Drug B: *Eschscholzia californica* Q Mother Tincture (35 subjects)

Drug C: Placebo Q Mother Tincture (30 subjects)

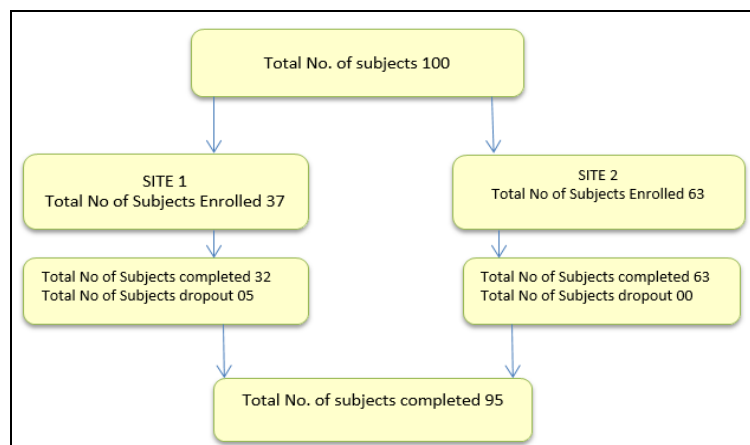


Fig 2: Disposition Flowchart

Data Collection

Data collection is done through structured questioner (McGill Pain Questionnaire) and pain severity was assessed on a linear 6 Grade -Verbal rating Scale (VRS) The enrollment day was considered as the base line data and subjects were asked to visit on: Day 10, Day 20, Day 30.

End Point

Fulfillment of primary study objectives.

In adverse event/ Incidence.

Statistical Analysis

The data is analyzed using SPSS Version 21. Significance level 5 %. The sample mean were assessed using paired t-test.

Result

Efficacy Analysis (For Drug A)

Table 1: Case Processing Summary (Drug A)

DRUG A	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
How strong is your pain after drug a	35	100.0%	0	0.0%	35	100.0%
How strong is your pain	35	100.0%	0	0.0%	35	100.0%

Table 2: Drug A-Descriptives

		Statistic	Std. Error	
how strong is your pain after drug a	Mean	1.3714	.11657	
	95% Confidence Interval for Mean	Lower Bound	1.1345	
		Upper Bound	1.6083	
	5% Trimmed Mean	1.3571		
	Median	1.0000		
	Variance	.476		
	Std. Deviation	.68966		
	Minimum	.00		
	Maximum	3.00		
	Range	3.00		
	Interquartile Range	1.00		
	Skewness	.493	.398	
	Kurtosis	.321	.778	
How Strong Is Your Pain	Mean	3.8857	.21604	
	95% Confidence Interval for Mean	Lower Bound	3.4467	
		Upper Bound	4.3248	
	5% Trimmed Mean	4.0397		
	Median	4.0000		
	Variance	1.634		
	Std. Deviation	1.27813		
	Minimum	.00		
	Maximum	5.00		
	Range	5.00		
	Interquartile Range	2.00		
	Skewness	-1.657	.398	
	Kurtosis	3.198	.778	

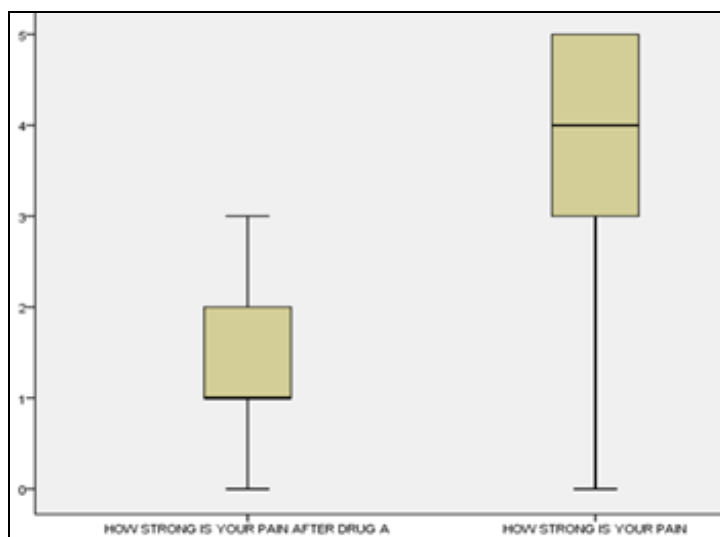


Fig 3: Efficacy Analysis (DRUG A)

Efficacy Analysis (For Drug B)

Table 3: Case Processing Summary (Drug B)

Drug B	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
How strong is your pain	35	100.0%	0	0.0%	35	100.0%
How strong is your pain after drug b	35	100.0%	0	0.0%	35	100.0%

Table 4: Drug B-Descriptive

		Statistic	Std. Error	
How strong is your pain	Mean		3.9429	.19204
	95% Confidence Interval for Mean	Lower Bound	3.5526	
		Upper Bound	4.3331	
	5% Trimmed Mean		4.1032	
	Median		4.0000	
	Variance		1.291	
	Std. Deviation		1.13611	
	Minimum		.00	
	Maximum		5.00	
	Range		5.00	
	Interquartile Range		1.00	
	Skewness		-2.435	.398
	Kurtosis		7.184	.778
	How strong is your pain after drug b	Mean		.9429
95% Confidence Interval for Mean		Lower Bound	.6431	
		Upper Bound	1.2426	
5% Trimmed Mean		.8810		
Median		1.0000		
Variance		.761		
Std. Deviation		.87255		
Minimum		.00		
Maximum		3.00		
Range		3.00		
Interquartile Range		1.00		
Skewness		.678	.398	
Kurtosis		-.088	.778	

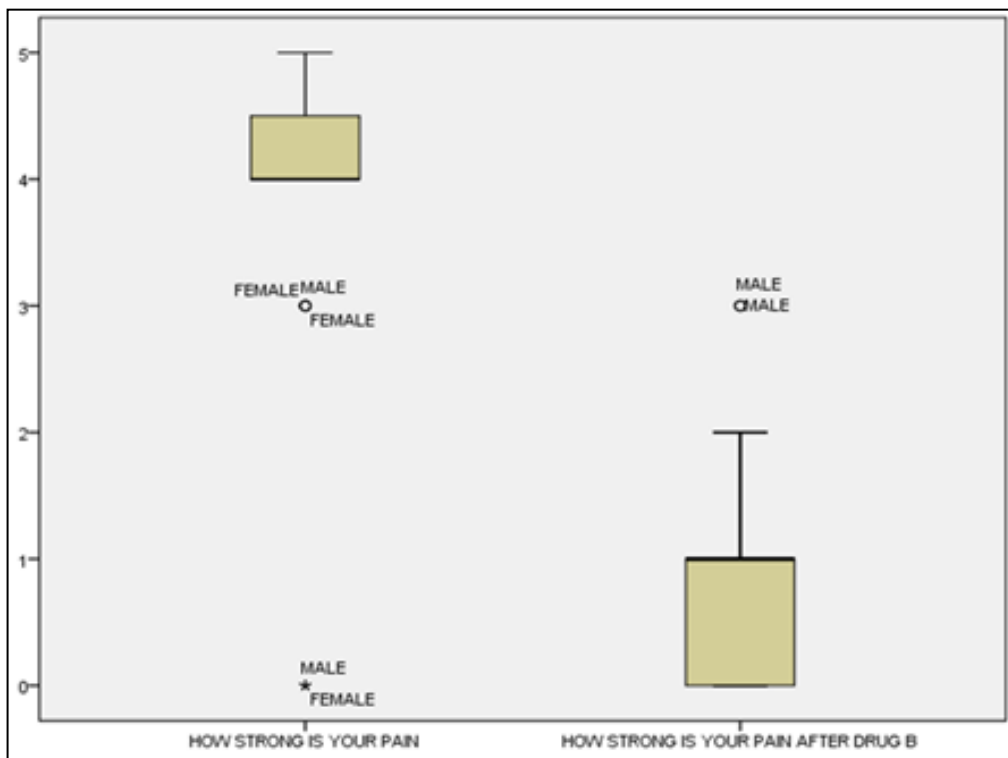


Fig 4: Efficacy Analysis (Drug B)

Efficacy Analysis (For Drug C)

Table 5: Case Processing Summary (Drug C)

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
How strong is your pain	30	85.7%	5	14.3%	35	100.0%
How strong is your pain after drug c	30	85.7%	5	14.3%	35	100.0%

Table 6: Drug C-Descriptives

		Statistic	Std. Error	
How strong is your pain	Mean	3.5333	.21832	
	95% Confidence Interval for Mean	Lower Bound	3.0868	
		Upper Bound	3.9798	
	5% Trimmed Mean	3.6481		
	Median	4.0000		
	Variance	1.430		
	Std. Deviation	1.19578		
	Minimum	.00		
	Maximum	5.00		
	Range	5.00		
	Interquartile Range	1.00		
	Skewness	-1.575	.427	
	Kurtosis	3.640	.833	
How strong is your pain after drug c	Mean	3.3000	.24518	
	95% Confidence Interval for Mean	Lower Bound	2.7985	
		Upper Bound	3.8015	
	5% Trimmed Mean	3.3889		
	Median	3.5000		
	Variance	1.803		
	Std. Deviation	1.34293		
	Minimum	.00		
	Maximum	5.00		
	Range	5.00		
	Interquartile Range	1.00		
	Skewness	-.959	.427	
	Kurtosis	.810	.833	

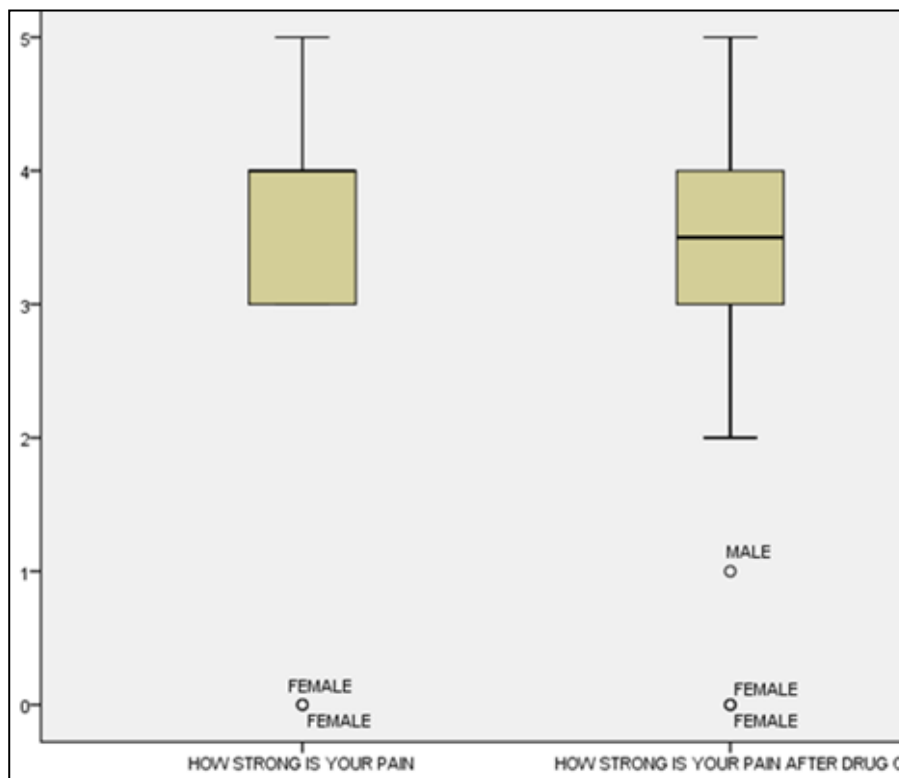


Fig 5: Efficacy Analysis (Drug C)

Paired Sample t Test: (Confidence Interval Percentage 95 %)

Table 7: Paired Sample Statistics

Paired Samples Statistics		Mean	N	Std. Deviation	Std. Error Mean
Drug A	How strong is your pain	3.8857	35	1.27813	.21604
	How strong is your pain after drug a	1.3714	35	.68966	.11657
Drug B	How strong is your pain	3.9429	35	1.13611	.19204
	How strong is your pain after drug b	.9429	35	.87255	.14749
Drug C	How strong is your pain	3.5333	30	1.19578	.21832
	How strong is your pain after drug c	3.3000	30	1.34293	.24518

Table 8: Paired Sample Correlation

Paired Samples Correlations		N	Correlation	Sig.
Drug A	How strong is your pain & how strong is your pain after drug a	35	.583	.000
Drug B	How strong is your pain & how strong is your pain after drug b	35	.234	.176
Drug C	How strong is your pain & how strong is your pain after drug c	30	.627	.000

The paired Sample correlational table adds the information that the intensity of pain before and after taking Drug A are significantly positively correlated (r =.583). Similarly for Drug B (r =.243) and for Drug C (r =.627).

Table 9: Paired Sample Test

Paired Samples Test		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Drug A	How strong is your pain - how strong is your pain after drug a	2.51429	1.03955	.17572	2.15719	2.87138	14.309	34	.000
Drug B	How strong is your pain - how strong is your pain after drug b	3.00000	1.26025	.21302	2.56709	3.43291	14.083	34	.000
Drug C	How strong is your pain - how strong is your pain after drug c	.23333	1.10433	.20162	-.17903	.64570	1.157	29	.257

Conclusion

Total number of subject analysed in the study is 100, of which 35 subjects were randomly assigned to drug A group, 35 were randomly assigned to the drug B group and 30 subjects to the drug C group, 5 subjects were drop out of the study. The subject were called for screening visit and were given the informed consent and screening procedure were started. Once the subjects were screen passed, eventually the subjects were randomized into Group A (*E. californica*), Group B (*E. californica*) and Group C (Placebo Group). The blind was broken after 30 Days when as per the protocol the trial ended.

The data obtained from the trial group was analyzed statistically using paired t test and the data was compared between the active and placebo group for the parameter including the palliation in the pain intensity. From the statistical analysis we conclude that

Drug A: *Eschscholzia californica* Q Mother Tincture There was a significant average difference between the intensity of pain before and after taking *Eschscholzia californica* Q Mother Tincture (t35 = 14.309. p<0.001). On average intensity of pain was 2.5 times less after taking *Eschscholzia californica* Q Mother Tincture.

Drug B: *Eschscholzia californica* Q Mother Tincture There was a significant average difference between the intensity of pain before and after taking *Eschscholzia californica* Q Mother Tincture (t35 = 14.083. p<0.001). On average intensity of pain was 3.0 times less after taking *Eschscholzia californica* Q Mother Tincture.

Drug C: Placebo There was a no significant average

difference between the intensity of pain before and after placebo (t30 = 1.157. p<0.001). On average intensity of pain was 0.2 times less after taking placebo thus not having any significant relief.

Thus it is concluded from this study that *E. californica* is possessing the therapeutic palliative effect in controlling and reducing the intensity of the migraine headache clinically.

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