

## Evaluation of Treatment Modality of Mandalidamsa with Ajitagada in Clinical Level

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**Abstract** Compare the efficacy of Group I received Vilwadi gulika with Sigrupunarnavadi yoga and Group II was given Ajitagada with Sigrupunarnavadi yoga in pit viper bites Vilwadi gulika and Ajitagada was administered internally where Shigrupunarnavadi yoga used as a Lepa applied externally in both group. 20 Patients of pit viper bite were selected as per the inclusion criteria from the Visha Chikitsa Kendra, Pappinisseri were divided randomly into two groups. Group I received Vilwadi gulika with Sigrupunarnavadi yoga and Group II was given Ajitagada with Sigrupunarnavadi yoga. Thorough clinical assessment was done before and after the treatment. The result was analysed statistically. Assessment was done before treatment and after treatment on 6<sup>th</sup> day, and the score for the cardinal symptoms were obtained. The data were statistically analysed and the comparison was done within the group by using student's paired t- test and in between the groups by using unpaired t- test.

**Keywords** *Visha; Agad*

### 1. Introduction

The fatal cases of poisoning are poisonous snakebites. In India it is believed that snakes bite about 2 lakh people annually, of which 15,000-30,000 cases prove fatal. There are around 3000 species of snakes in the world of which 200 are found in India. Colubridae and Viperidae families of venomous snakes are of medical importance in India and in Kerala. Numbers of incidence of bites are more from Viper and Pit viper bites are not rare. No antivenom is being made against Indian Pit vipers. Systemic

involvement has been hardly reported and symptomatic treatment is the existing mode in Modern system of medicine. Research is a scientific study to establish and analyse facts to contribute to the present knowledge.

### 1.1. Aim and Objective

Compare the efficacy of Group I received Vilwadi gulika with Shigrupunarnavadi yoga and Group II was given Ajitagada with Shigrupunarnavadi yoga in pit viper bites. Vilwadi gulika and Ajitagada was administered internally where Shigrupunarnavadi yoga used as a Lepa applied externally in both group.

### 1.2. Research Design

20 Patients of pit viper bite were selected as per the inclusion criteria from the Visha Chikitsa Kendra, Pappinisseri were divided randomly into two groups. Group I received Vilwadi gulika with Shigrupunarnavadi yoga and Group II was given Ajitagada with Shigrupunarnavadi yoga. Thorough clinical assessment was done before and after the treatment. The result was analysed statistically.

### 1.3. Selection of Subjects

Patients of pit viper bite from the Visha Chikitsa Kendra, Pappinisseri were selected as per the selection criteria for the study and randomly divided into two groups.

#### Inclusion Criteria

- Patients irrespective of sex, caste, religion and economic status having age between 16 to 70 years.
- Patients with diagnosed pit viper bite with a maximum duration of 6 hours.
- Patients with essential symptoms like oedema and pain due to pit viper bite.

#### Exclusion Criteria

- Patients who are not satisfying inclusion criteria
- Patients who are not willing to give consent
- Patients with systemic symptoms like respiratory failure, shock etc.
- Patients already had undergone other treatments
- Pregnant & lactating ladies
- Patients with history of diseases such as renal disease, diabetes mellitus, hypertension & cardiac diseases.

## 2. Research Techniques and Tools

Component of three Yoga, each Yoga has a literary back up. So details of each yoga have many drugs in this sequence.

- A) Shigrupunarnavadi yoga
- B) Vilwadi yoga
- C) Ajitagada yoga

**A) Shigrupunarnavadi Yoga (V.V. Jyo. 6/70)****Table 1: Ingredients of Shigrupunarnavadi Yoga**

S.N.	Drug	Malayalam name	Synonyms	Botanical name	English name
1.	Shigru	Muringa	Sobhanjana, Teekshna gandham, Mochaka	Moringa olifera Linn.	Horse radish tree
2.	Punarnava	Tavizhama	Svetamoola, Sophaghni, Deerghapatrika	Boerhavia diffusa Linn.	Hogweed
3.	Haridra	Manjal	Peetha, Nisa, Varavarninee, Haladhi	Curcuma longa Linn.	Turmeric
4.	Vacha	Vayambu	Ugra gandha, Golomi, Satha parvika, Kshudra patri, Mangalya, Lomasa.	Acorus calamus Linn.	Sweet flag
5.	Chandana	Chandhanam	Sree khanda, Chandana, Gandha sara, Malayaja.	Santalum album Linn.	Sandal tree
6.	Patha	Pata	Ambashta, Ambashtika, Padika, Kucheli.	Cyclia peltata Miers.	Pata root
7.	Eeswara mooli	Karalakam	Garalika, Eesvari, Sarpini, Garudi, Nakula priya.	Aristolochia indica Linn.	Indian birthwort
8.	Yashti	Eratti madhuram	Kleethaka, Kleethanaka, Madhulika	Glycyrrhiza glabra Linn.	Liquorice
9.	Shireesha	Nenmenivaka	Bhandila, Bhandi, Bhandira, Kapeetana, Sooka pushpa	Albizzia lebeck Benth	Siris tree
10.	Gokshura	Njerinjil	Gokandaka, Swadamshtra, Gokshuraka, Saranya	Tribulus terrestris Linn.	Land caltrops

Method of Preparation of the Drug: - All the drugs is taken in equal quantity and mix it properly. After thorough mixing, apply it with the help of rice water or water in affected area as lepa.

**B) Vilwadi Yoga (A.H.U.36/84-85)****Table 2: Ingredients of Vilwadi Yoga**

S.N.	Drug	Botanical Name	English Name	Part Used	Proportion
1.	Vilwa	Aegle marmelos Corr.	Bael tree	Moola, Twaka, Patra, Phala.	1 part
2.	Surasa	Ocimum sanctum Linn.	Indin Basil/ Holy basil/ Sacred basil.	Seeds, leaves and flower	1 part
3.	Karanja	Pongamia glabra Pierre	Indian beech.	Twak, Patra, Beeja	1 part
4.	Tagara	Valeriana wallichii DC.	Indian valerian.	Moola	1 part
5.	Surahwa	Cedrus deodara Roxb.	Himalayan cedar deodar.	Kand'asaar, Taila.	1 part
6.	Amalaki	Emblica officinalis Gaertn.	Indian goose berry.	Phala.	1/3 part
7.	Haritaki	Terminalia chebula Retz.	Chebulic myrobalan.	Phala.	1/3 part
8.	Vibhitaki	Terminalia belerica Roxb.	Belleric myrobalan.	Phala.	1/3 part
9.	Shunthi	Zingiber officinale Rosc.	Ginger.	Kanda	1/3 part
10.	Maricha	Piper nigrum Linn.	Black pepper.	seed	1/3 part
11.	Pippali	Piper longum Linn.	Long Pepper.	Phala, Moola.	1/3 part
12.	Haridra	Curcuma longa Linn.	Turmeric	Kanda.	1/2part
13.	Daruharidra	Cocinium fenestratum Gaertn & Colber	Indian berbery.	Moola, Kaand'a, Phala.	1/2part

## Preparation of the Drug

All the drugs are taken in equal quantity and goat's urine as per the requirement for Bhavana. After thorough mixing, Gutika are prepared weighing 1 gm each.

## Bhawana Drug

Goat's urine

### C) Ajitagada yoga (S.K.5/63-64)

*Table 3: Ingredients of Ajitagada [1-5]*

S. No.	Drug	Botanical Name	English Name	Part Used	Proportion
1.	Vidanga	Embelia ribes Burm.f.	Embelia	Fruit	1part
2.	Patha	Cyclea peltata Linn.	Pata root	Root	1part
3.	Amalaki	Embellica officinalis Gaertn.	Indian goose berry	Fruit	1/3part
4.	Haritaki	Terminalia chebula Retz.	Chebolic myrobalan	Fruit	1/3part
5.	Vibhitaki	Terminalia belerica Roxb.	Belleric myrobalan	Fruit	1/3part
6.	Ajamoda	Carum roxburghianum DC.	Bishop's weed	Fruit	1part
7.	Hingu	Ferula asafetida Boiss.	Asafoetida	Resin	1part
8.	Tagar	Weleriana wallichii DC.	Indian valerian	Root	1part
9.	Chitraka	Plumbago zeylanica Linn.	Leadwort	Root	1part
10.	Shunthi	Zingiber officinale Rosc.	Ginger	Rhizome	1/3part
11.	Maricha	Piper nigrum. Linn.	Black pepper	Fruit	1/3part
12.	Pippali	Piper longum Linn.	Long Pepper	Fruit	1/3part
13.	Saindhava lavana	-	Rock Salt	-	1/5part
14.	Sauvarchal lavana	-	Black Salt	-	1/5part
15.	Samudra lavana	-	Sea Salt	-	1/5part
16.	Vida lavana	-	Ammonium Chloride	-	1/5part
17.	Romaka lavana	-	Lack Salt	-	1/5part

## Preparation of the Drug

All Powder finely should be mixed with honey & stored in a cow's horn duly covered with a honey material for a fortnight. After that make small gutika (wt. Each gutika= 1gm).

## Bhawana Drug

Honey

A Performa was designed to collect and record the information. Proper grading was done to calculate the exact intensity of the cardinal symptoms like Oedema and Pain.

**Table 4:** Treatment Schedule in Group I and Group II

S No.	Details	Group I	Group II
1.	Sample size	10	10
2.	Drug (Internally)	Vilwadi gulika	Ajitagada
3.	Mode	Gulika of 1 gm.	Gulika of 1 gm.
4.	Dose	2 gm. bd with 12 hours interval.	2 gm. bd with 12 hours interval.
5.	Local application (Externally)	Sigrupunarnavadi Lepa	Sigrupunarnavadi Lepa
6.	No. of applications	4 times with 6 hrs. Interval	4 times with 6 hrs. Interval
7.	Medium	Riced washed water	Riced washed water
8.	Duration	5 days	5 days

The ingredients of study drug Ajitagada were purchased from Vaidyaratnam P.S. Varier's Arya Vaidya Sala, Kottakkal (450 gms). Then drug preparations done by myself in the dept. of Agadatantra laboratory under the guidance of Dr. K.V. Asha. Another drug Vilwadi gulikas were buy from the agency of Vaidyaratnam pharmaceutical, Kottakkal. One common external drug Sigrupunarnavadi choornas were buy from the Seetharam Ayurveda Pharmacy, Thrissur. The Sigrupunarnavadi powder is made into paste by mixing with riced washed water and applied over oedematous area. Lepa was washed off once it is dried. The first dose of medicine was started at the time of arrival.

### 3. Assessment & Statistical Analysis

Assessment was done before treatment and after treatment on 6<sup>th</sup> day, and the score for the cardinal symptoms were obtained. The data were statistically analysed and the comparison was done within the group by using student's paired t- test and in between the groups by using unpaired t- test.

#### Total Effect of Therapy

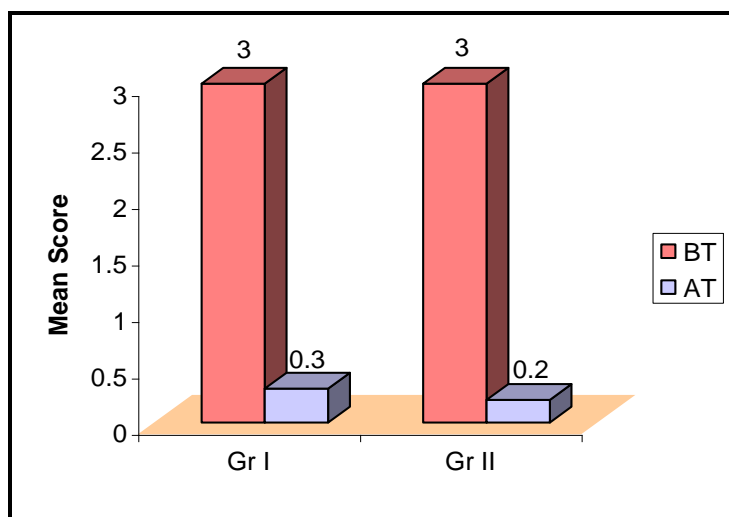
Total effect of therapy on 20 subjects of pit viper bite was given in percentage by calculating the mean difference of the scores, before and after the treatment.

- |    |               |     |                      |
|----|---------------|-----|----------------------|
| 1. | 100 % relief  |     | Cured                |
| 2. | >75 % to 99 % | --- | Marked improvement   |
| 3. | >50 % to 75%  |     | Moderate improvement |
| 4. | >25 % to 50 % | --- | Mild improvement     |
| 5. | 0 % to 25 %   |     | Unchanged            |

### 4. Observations and Analysis

**Table 5:** Effect of the Therapy on Oedema (Paired t - test)

Group	Mean Score		M. diff.	% Relief	SD	SE	t - value	P value
	BT	AT						
Group I	3	0.3	2.7	90	0.95	0.30	8.99	P< 0.001
Group II	3	0.2	2.8	93.33	0.78	0.246	11.34	P< 0.001



**Graph 1 of Table 5**

As seen in Table 5 which compares the effectiveness of the treatment on oedema, the mean score in group I was reduced from 3 to 0.3 after the treatment i.e. on 6<sup>th</sup> day, mean difference was 2.7 with SD  $\pm$  0.95. Percentage of relief obtained was 90%. t-value was found to be 8.99 which was statistically significant at the level of 0.001.

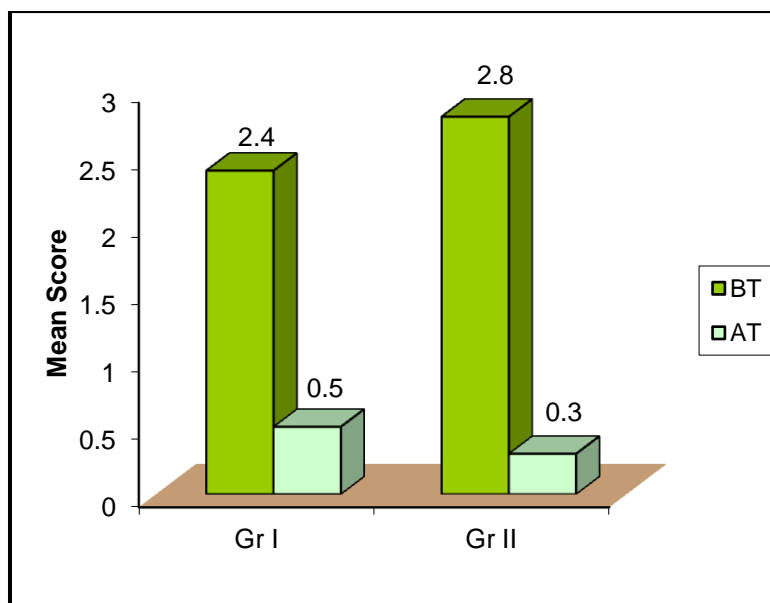
In group II the mean score was reduced from 3.7 to 0.2, mean difference was 2.8 with SD of  $\pm$  0.78. Percentage of relief obtained was 93.33%. 't' value was found to be 11.34 which was also statistically significant at the level of 0.001.

**Table 6: Effect of the Therapy on Pain (Paired t - test)**

Group	Mean Score		M. diff.	% Relief	SD	SE	t - value	P value
	BT	AT						
Group I	2.4	0.5	1.9	79.17	1.19	0.38	5.04	P<0.001
Group II	2.8	0.3	2.5	89.28	0.70	0.22	11.2	P<0.001

Table 6 shows, comparison of the efficacy of the treatment on Pain. In Group I mean score for the pain before the treatment was 2.4, which was later on reduced to 0.5 after the treatment. Mean difference was 1.9 with SD of  $\pm$ 1.19. Percentage of relief obtained was 79.17%. 't' value was found to be 5.04 which was statistically significant at the level of 0.001.

In group II the mean score was reduced from 2.8 to 0.3, mean difference was 2.5 with SD of  $\pm$  0.70. Percentage of relief obtained was 89.28% and 't' value was found to be 11.2 which was statistically significant at the level of 0.001.



Graph 2 of Table 6

Table 7: Comparison of Efficacy on Oedema in Between Two Groups (Unpaired T - Test)

Group	Mean Diff	SD	t - value	P value
Group I	2.7	0.95	1.45	P>0.05
Group II	2.8	.78		

On comparing the effect of the therapy on oedema, in between two groups, it was found that the mean difference of the Oedema score was 2.7 in Group I with SD  $\pm$  0.95, and 2.8 with SD of  $\pm$  0.78 in Group II. t-value was found 1.45 which was statistically insignificant, P>0.05.

Table 8: Comparison of Efficacy on Pain in between two groups (Unpaired t - test)

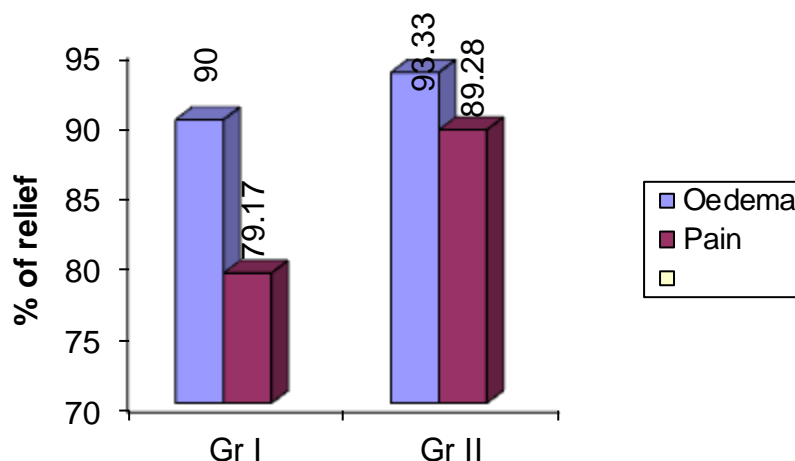
Group	Mean Diff	SD	t - value	P value
Group I	1.9	1.19	6.13	P>0.05
Group II	2.5	0.70		

While comparing the effect of the therapy on Pain in between two groups, it was found that the mean difference of the Pain score in Group I was 1.9 with SD of  $\pm$  1.19 and in Group II was 2.5 with SD of  $\pm$  0.70. t value was found to be 6.13 which was statistically significant, P>0.05.

Table 9: Percentage of Relief Obtained in Each Sign & Symptom

Symptom	Group I	Group II
	% Relief	% Relief
Oedema	90	93.33
Pain	79.17	89.28

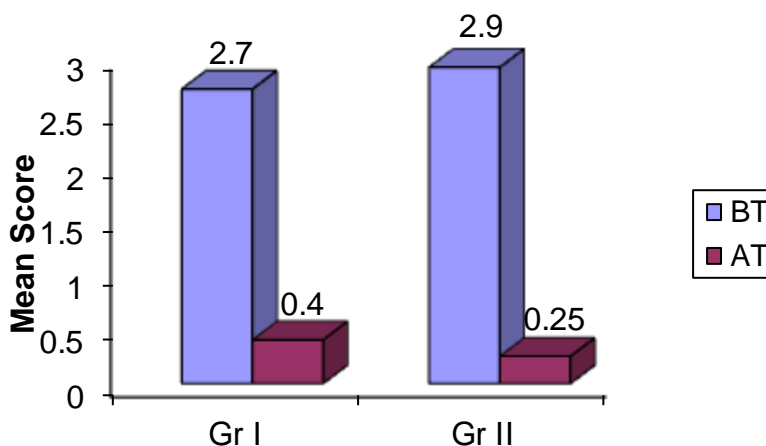
The above Table 9 shows the percentage of relief obtained in both groups for each sign and symptom. For Oedema in group I, 90% relief was seen and in group II 93.33%. For Pain in group I, 79.17% relief was seen and in group II 89.28%.



Graph 3 of Table 9

Table 10: Overall effect of the Therapies on two Cardinal symptoms

Group	Mean Score		M. diff.	% Relief	SD	SE	t - value	P value
	BT	AT						
Group I	2.7	0.4	2.3	85.18	1.07	0.34	7.015	P<0.001
Group II	2.9	0.25	2.65	91.37	0.74	0.235	11.27	P<0.001



Graph 4 of Table 10

The Above Table 10 shows the overall effect of the therapies on three cardinal symptoms together. In Group I total mean score before treatment was 2.7, which was reduced to 0.4 with mean difference 2.3. Standard deviation was  $\pm 1.07$  and the percentage of relief obtained was 85.18%. Here 't' value was 7.015, which was statistically highly significant at the level of 0.1% ( $P<0.001$ ).

In Group II total mean score before the treatment was 2.9 which was reduced to 0.25 after completion of the treatment with mean difference of 2.65 and Standard deviation of  $\pm 0.74$ . In this group 91.37% of relief was obtained. t-value was 11.27 which was statistically highly significant ( $P<0.001$ )



**Table 11:** Comparison of the Effect of the Two Therapies.

Group	Mean Diff	SD	t' Value	P Value
Group I	2.3	1.07	0.85	P>0.05
Group II	2.65	0.74		

When the effect of the two therapies was compared on the total mean score of all the three symptoms, it was found that the total mean difference in Group I was 2.3 with SD 1.07 and 2.65 with SD of 0.74 in Group II. t value was found 0.85, which was statistically insignificant (P>0.05).

**Table 12:** Haemogram values of Group I

Group I	Hb%	TLC	N	E	B	L	M	ESR
B.T	12.65	8220	49.2	3.2	0	47.6	0	14.5
A.T	12.48	8545	42.2	4.5	0	53.5	0	7.4

Table 12 shows that Mean Haemogram values before treatment was Hb % 12.65, TLC 8220, Neutrophil 49.2, Eosnophil 3.2, Basophil 0, Leucocytes 47.6, Monocytes 0 and ESR 14.5 and after treatment was Hb % 12.48, TLC 8545, Neutrophil 42.2, Eosnophil 4.5, Basophil 0, Leucocytes 53.5, and Monocytes 0 and ESR 7.4.

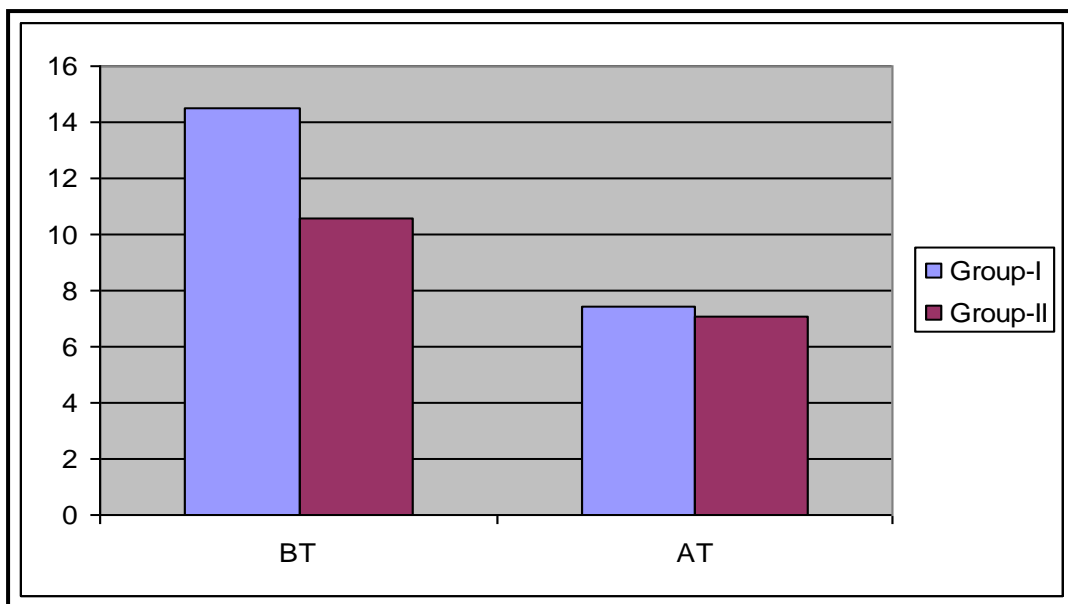
**Table 13:** Haemogram values of Group II

Group II	Hb%	TLC	N	E	B	L	M	ESR
B.T	12.45	7820	46.4	2.8	0	50.9	0	10.6
A.T	11.77	8305	47.6	4.2	0	48.6	0	7.1

Table 13 shows that Mean Haemogram values before treatment was Hb % 12.45, TLC 7820, Neutrophil 46.4, Eosnophil 2.8, Basophil 0, Leucocytes 50.9, Monocytes 0 and ESR 10.6 and after treatment was Hb % 11.77, TLC 8305, Neutrophil 47.6, Eosnophil 4.2, Basophil 0, Leucocytes 48.6, Monocytes 0 and ESR 7.1.

**Table 14:** Effect of Therapy on ESR

Group	BT	AT	M.Diff	S.D	S.E	t-Value	P
Group-I	14.5	7.4	7.1	7.6	2.40	2.9	<0.001
Group-II	10.6	7.1	3.5	8.6	2.72	1.28	<0.001



**Graph 5 of Table 14**

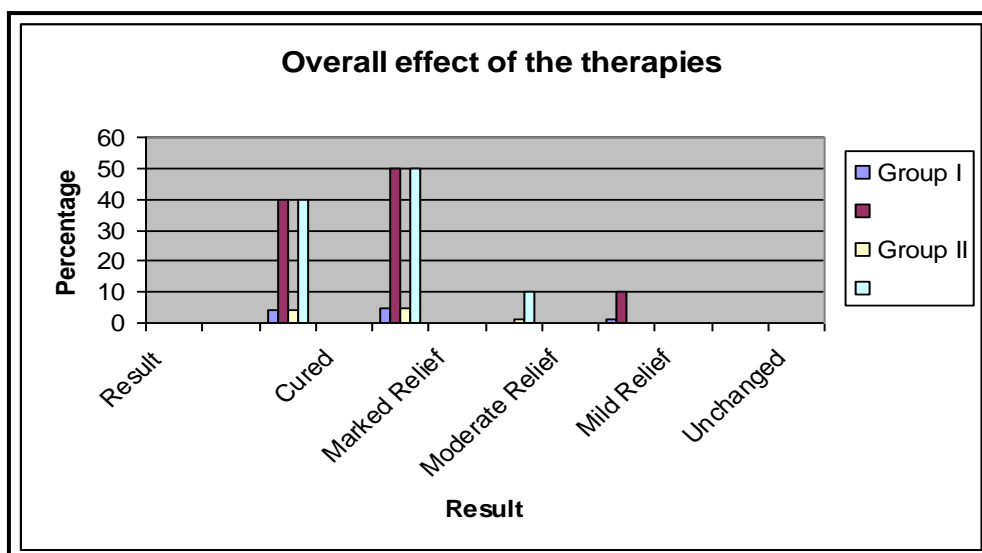
The above Table 14 shows that in Group I before treatment score was 14.5 and after treatment score was 7.4 with mean difference  $7.1 \pm 7.6$ , with t value 2.9 at  $p < 0.001$ , standard error for this Group is 2.40.

In Group II before treatment was 10.6 and after treatment score was 7.1 With mean difference  $3.5 \pm 8.6$ , with t value 1.28 at  $p < 0.001$ , standard error for this group is 2.72.

## 5. Results

**Table 15: Overall Result of the Therapies**

Result	Group I		Group II	
	No.	%	No.	%
Cured	4	40	4	40
Marked Relief	5	50	5	50
Moderate Relief	0	00	1	10
Mild Relief	1	10	0	00
Unchanged	0	00	0	00



Graph 6 of Table 15

The above Table 15 shows the overall effect of the therapy. In Group I 40% subjects were cured, 50% got marked relief, and 0% got moderate relief. 10% subjects showed mild relief and 0% got unchanged result. (n=10)

Group II shows that 40% subjects were cured, 50% got marked relief and 10% had a moderate relief. 0% subjects showed Mild relief and / or unchanged effect. (n=10)

## 6. Discussion

Mode of action of drugs depends on many factors like rasa, guna, veerya, vipaka, karma, doshaghna and ultimately prabhava. In Shigrupunarnavadi drug, among the 10 ingredients of yoga, most of the drugs having kapha vata hara property. Also 6 ingredients have specific mode of action in visha. Prabhava of yoga is very important. The combination of this yoga has prabhava as vishaghna. In the phalasaruti it is said that the usage of this yoga removes all the toxicity of Sarpa visha. In Vilwadi yoga, has the 13 ingredients of drug, most of the drugs having kapha vata hara property. Also three ingredients have Tridoshaghna property. Bhawana drug – Goat's urine has kapha vata hara property. Prabhava of yoga is very important. The combination of this yoga has special action as vishaghna in sarpa, luta, vruschika and undours visha as per the classical reference. In the phalasaruti it is said that the usage of this yoga removes all the toxicity of Sarpa visha. In Ajitagada yoga has the 17 ingredients of drug, most of the drugs having kapha vata hara property. Also 7 ingredients have Tridoshaghna property and 7 ingredients are same as Vilwadi yoga. Bhawana drug – Honey has kapha vata pitta hara property. Prabhava of yoga is very important. There are five types of salts in this yoga. So it has diuretic property. The combination of this yoga has special action as vishaghna in any visha (Jangama or Sthavara) as per the classical reference. In the phalasaruti it is said that the usage of this yoga removes all the toxicity of Sarpa visha.

In the present study it was found that both of the drugs, Ajitagada and Vilwadi are highly significant ( $P < 0.001$ ) in reducing the two cardinal symptoms selected for the study viz. Oedema and Pain. When the results were compared by unpaired t test, it was found that the efficacy of the drugs was comparatively insignificant ( $P > 0.05$ ). An account of percentage of relief in both had almost same effect 85.18% and 91.37% in the management of pit viper bite. Present study 'A comparative study on efficacy of Ajitagada yoga with Vilwadi yoga in Pit-viper bite' was conducted in two steps. The literary

work covered the literature works on two drugs and snakes and Pit-viper in modern and Ayurvedic parlance. The clinical study was conducted on 20 patients bitten by Pit-viper. The drugs were given for 5 days internally & common external drug -Shigrupunarnavadi. The effect of the medicines was evaluated on cardinal symptoms such as Oedema and Pain. In the present study, both the drugs, individually, showed highly significant results in reducing these symptoms ( $P < 0.001$ ). Comparatively, results were insignificant ( $P > 0.05$ ). Percentage of relief obtained after the treatment; on 6<sup>th</sup> day was 90% & 93.33% for Oedema and 79.17% & 89.28% for Pain in Group I and II respectively. Overall results show that comparatively drugs were insignificant ( $P > 0.05$ ) and on account of average percentage of relief obtained in all the two cardinal symptoms both groups have almost same value as 85.18% and 91.37% respectively. So an attempt was made by selecting the Trial Drug "Ajitagada" against the Control Drug "Vilwadi gutika" with common external drug Shigrupunarnavadi lepa for this clinical study and only "Ajitagada" for Experimental study.

## 7. Summary and Conclusion

In the present study it was found that both of the drugs, Ajitagada and Vilwadi are highly significant ( $P < 0.001$ ) in reducing the two cardinal symptoms selected for the study viz. Oedema and Pain.

When the results were compared by unpaired t-test, it was found that the efficacy of the drugs was comparatively insignificant ( $P > 0.05$ ). An account of percentage of relief in both had almost same effect 85.18% and 91.37% in the management of pit viper bite. Present study 'A comparative study on efficacy of Ajitagada yoga with Vilwadi yoga in Pit-viper bite' was conducted in two steps. The literary work covered the literature works on two drugs and snakes and Pit-viper in modern and Ayurvedic parlance. The clinical study was conducted on 20 patients bitten by Pit-viper. The drugs were given for 5 days internally & common external drug -Shigrupunarnavadi. The effect of the medicines was evaluated on cardinal symptoms such as Oedema and Pain. In the present study, both the drugs, individually, showed highly significant results in reducing these symptoms ( $P < 0.001$ ). Comparatively, results were insignificant ( $P > 0.05$ ). Percentage of relief obtained after the treatment; on 6<sup>th</sup> day was 90% & 93.33% for Oedema and 79.17% & 89.28% for Pain in Group I and II respectively. Overall results show that comparatively drugs were insignificant ( $P > 0.05$ ) and on account of average percentage of relief obtained in all the two cardinal symptoms both groups have almost same value as 85.18% and 91.37% respectively. So an attempt was made by selecting the Trial Drug "Ajitagada" against the Control Drug "Vilwadi gutika" with common external drug Shigrupunarnavadi lepa for this clinical study and only "Ajitagada" for Experimental study.

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