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# Studies on genesis of *Prameha* from *Amajirna* w.s.r. to biochemical parameters

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## ABSTRACT

**Background:** In classical text it had been highlighted that *Amajirna* is root cause to produce *Prameha*. *Musta* is drug which combat *Amajirna* and it also effective to cure *Prameha*. So, this gives reasons for need of the present study and also reason for selection of topic. **Aim:** To evaluate the pathogenesis of *Prameha* from *Amajirna* and the efficacy of *Musta* (*Cyperous rotundus*) in both *Amajirna* and *Prameha*. **Material and Methods:** This study is an open label, randomized, interventional, comparative, prospective, controlled clinical trial. In the present study the patient of *Prameha* were enrolled following the subjective criteria of *Prameha*. A total of 60 patients of *Prameha* were selected from the OPD and IPD of Shyamadas Vaidya Shastra Pith Hospital, Kolkata, West Bengal, and randomly allocated with a computerized randomization method into two groups. Those selected patients were subjected for a confirmatory biochemical analysis of FBS and PPBS. The prediabetic person was interrogated for *Amajirna* as a past history or present illness, by the subjective criteria of *Amajirna*. In group A (n= 30), *Musta Churna* was given for 90 days and in group B (n= 30), *Pippali Churna* was given for 90 days. Before treatment and after treatment data FBS, PPBS, HBA1C, SGOT, SGPT, serum amylase, serum lipase and alkaline phosphatase enzyme levels were recorded for statistical analysis. This record of assessment was taken at 0, 30, 60 and 90 days. Wilcoxon signed rank test; unpaired t-test were applied. **Result:** Both groups showed statistically significant (p<0.05) improvement in chief complaints of *Prameha*, *Amajirna*, FBS, PPBS, HBA1C, SGOT, SGPT, serum amylase, serum lipase and alkaline phosphatase. **Conclusion:** On percentage wise comparison, better relief was found in Group-A i.e., *Musta Churna* was found to be more effective in all the subjective and objective parameters than Group-B (*Pippali Churna*).

**Key words:** *Prameha*, *Amajirna*, *Musta*, *Pippali*

## INTRODUCTION

*Prameha*<sup>[1]</sup> is a disease existing from prehistoric era that is correlated with type 2 Diabetes mellitus, is affecting the 9.3% person of the world and 14% of India.<sup>[2]</sup> As of 2014, an estimated 387 million people

have diabetes worldwide, with type-2 diabetes making up about 90% of the cases. In classical text it had been highlighted that *Amajirna*<sup>[3]</sup> is the root cause to produce *Prameha*. In *Amajirna*<sup>[4]</sup> the incomplete or defective digestion caused due to influenced of vitiated *Kapha* within the stomach.<sup>[5]</sup> As a result, *Ama*<sup>[6]</sup> is formed which vitiated consistency of *Kapha* and vitiate *Meda*.<sup>[7]</sup> The sequence of *Meda Dushti* ultimately originates *Prameha*. *Acharya Sushruta* has considered the *Aparipakva* (raw/not fully formed) *Kapha* as cause of *Prameha* while describing its pathogenesis.<sup>[8]</sup> *Acharya Dalhana* has given the meaning of *Aparipakva* as *Ama* which proves that *Prameha* is caused by *Amajirana*.<sup>[9]</sup> *Acharya Charaka* has also mentioned *Prameha* is caused by *Amajirana* which inturn caused by *Kapha* aggravating factors in the body.<sup>[10]</sup> *Agnimandya* is caused due to the excess consumption of diet and lifestyle which aggravates *Kapha* which

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leads to *Ama* production in the body which is also called *Dushit* (impure) *Kapha*.<sup>[11,12]</sup> Till the time, *Dushit Kapha* remains in the abdominal area (*Koshtha*), is called *Amajirna*.

*Musta* (*Cyperous rotundus*) is drug which combat *Amajirna* and it is also effective to cure *Prameha*. Hence a study was proposed here to verify the hypothesis on genesis of *Prameha* from *Amajirna*<sup>[13]</sup> and also evaluate to efficacy of *Musta* (*Cyperous rotundus*) in both the disease. For this purpose, patients were selected from institute of post graduate ayurvedic education and research in a randomized form. Efficacy of *Musta* was evaluated through statistical analysis.

## AIM

To evaluate the pathogenesis of *Prameha* from *Amajirna* and the efficacy of *Musta* (*Cyperous rotundus*) in both *Amajirna* and *Prameha*.

## OBJECTIVES

1. To study the diagnostic approach of *Prameha*.
2. To explain the pathogenesis of *Prameha* from *Amajirna*.
3. To evaluate the efficacy of *Musta* (*Cyperous rotundus*) in both *Amajirna* and *Prameha*.

## MATERIALS AND METHODS

In the present study the patient of *Prameha* will be selected following the subjective criteria of *Prameha*. Those selected patients will be subjected for a confirmatory biochemical analysis of FBS and PPBS. The prediabetic state will be considered here, so the FBS and PPBS and HbA1c will range with in (100-125) mg/dl, (140-199) mg/dl, and (5.7-6.4)% respectively. The prediabetic person will be interrogated for *Amajirna* as a past history or present illness, by the subjective criteria of *Amajirna*. The objective criteria of *Agnimandya* i.e, hypo functioning. *Agni* will be verified through alkaline phosphatase etc. The selection of patients should do following the inclusion and exclusion criteria. The selected patient will be divided into two groups, Group A and Group B. Group A was

treated with *Musta* (*Cyperous rotundus*) and Group B was treated with *Pippali* (piper longum). Group B was treated as control. The both groups were administered by the powder drug. The drug was administered in both the groups in divided doses per day. Before treatment and after treatment data of blood sugar level and enzyme level were recorded for statistical analysis. A complete history sheet was furnished as case report file (CRF).

## Study type

Interventional, prospective, randomized, single blind, controlled clinical trial.

## Method of sampling

Computer Generated Simple Randomized Method were followed.

## Sample size

60 patients were taken for study (30 in each group).

## Study settings

The study was conducted in OPD and IPD of the institute I.P.G.A.E & R at S.V.S.P hospital. The patients of *Prameha* were selected from the OPD through verification of subjective criteria. The selected patients were subjected for verification of subjective criteria. The selected patients were subjected for verification of objective criteria of biochemical investigation. During selection of the patient inclusion and exclusion criteria were strictly followed.

All details of the patients were recorded and maintained in the specially prepared proforma.

Before registering patients informed consent was taken.

## Group Design

**Group A - *Musta Churna***

**Group B - *Pippali Churna*** (were treated as control)

Before treatment and after treatment data of blood sugar level and enzyme level were recorded for statistical analysis. A complete history sheet will be furnished as case report file (CRF).

## Posology

### Details of dosage of *Musta Churna* and *Pippali Churna*

**Table 1: Plan of treatment protocol in Group A**

SN	Name of Drug	Dosage Form	Dose & Frequency	Time of administration & Anupana	Duration
1.	<i>Musta Churna</i>	<i>Churna</i> (Powder)	3 gm twice a day	<i>Antebhakta</i> (after food) with luke warm water orally	3 months
<b>Total Duration of Therapy</b>					<b>3 months</b>

**Table 2: Plan of treatment Protocol in Group B**

SN	Name of Drug	Dosage Form	Dose & Frequency	Time of administration & Anupana	Duration
1.	<i>Pippali Churna</i>	<i>Churna</i> (Powder)	3 gm twice a day	<i>Antebhakta</i> (After food) with luke warm water orally	3 months
<b>Total Duration of Therapy</b>					<b>3 months</b>

### Place of study

Department of Roga Nidana Evum Vikriti Vigyana of Institute of Post Graduate Ayurvedic education and Research at Shyamadas Vaidya Sasthra Pith Hospital. 294/3/1, A.P.C. Rd, Kolkatta 09

### Study population

A small sample were taken from population those who are suffering from *Prameha* also presenting *Amajirna*, visiting the OPD and IPD, of I.P.G.A.E. & R at S.V.S.P Hospital.

### Sample size and design

Sampling was done with a method of simple random sampling. The study was conducted with a target of at least 30-40 completed cases in each group. Since the trial medication will be given to only one half of the

sample and the other will be treated as control group assuming maximum 30% drop out rate. This trans state will give a figure of approximately 80 subjects to recruit after screening to achieve the target sample size of not less than 0 in each group.

### Inclusion criteria

- Adult subjects of either sex between 40-80 years of age.
- Presence of cardinal signs and symptoms of *Prameha* and *Amajirna*.
- Patients showing pre- diabetic stage, with an elevated blood glucose level ranging between FBS  $\geq$  {100-125} mg/dl and PPBS  $\geq$  {140-199} mg/dl and HBA1C  $\geq$  {5.7-6.4}.
- Biochemical assessment showing altered level of serum amylase, Serum lipase, aminotransferase (SGOT & SGPT), alkaline phosphatase to interpret on status of Agni.
- Patient those are not taking any type of medicine except research drug.

### Exclusion criteria

- Diabetic stage.
- Pre-diabetic state with any complication.
- Dyspepsia due to any type of malignant condition.
- Dyspepsia where any type of surgical interference is necessary
- Pre-diabetic woman with pregnancy.

### Study variables

Respective relevant objective parameters of the disease are variables.

### Data collection & interpretation

The drug was administered for 90 consecutive days for each patient for both the groups and were assessed after 90 days after the date of registration. The case report form was filled up in both the groups & the baseline parameter should be recorded. In both the groups, the following laboratory investigations were conducted during baseline & final follow up.

**Schedule of data collection:**

In each group, the subject will be required at least 4 visits during studies.

**Visit 1** - Screening & enrolment

**Visit 2** - First follow up (Day 30)

**Visit 3** - Second follow up (Day 60)

**Visit 4** - Final follow up (Day 90)

**Laboratory investigations**

- FBS
- PPBS
- HBA1C
- Serum amylase
- Serum lipase
- SGOT
- SGPT
- Alkaline phosphatase

All above mentioned investigation were performed before commencement of the treatment and after completion of the treatment.

**Clinical parameters**

**Screening criteria for Prameha<sup>[14]</sup>**

- *Swedanga* - excessive sweating
- *Anga Gandha* - bad body odour
- *Shithila Anga* - Flabbiness of body
- *Sahyya Ashana Prasukhe* - sedentary lifestyle
- *Ratischa* - Ease of life
- *Hrt Upadeha* - heaviness in cardiac region
- *Netra Jiva Shravana Upadeha* - watering of eye tongue and ear
- *Ghanangta* - Obesity
- *Kesha Nakha Ativridhi* - excessive growth of hair and Feet
- *Shita Priyata* - preference to cold
- *Gala Talu Sosha* - dryness of throat and palate

- *Madhuryam Ashya* - sweetness of mouth
- *Kara Pada Daha* - burning sensation of hand and feet
- *Mutre Abhidhawanti Pippilika* - swarming of ants in urine

**Screening criteria for Amajirna<sup>[15]</sup>**

- *Shotho Gandakshi Kutaga* - swelling over eyes and cheeks
- *Yatha Bhuktam Avidagdham Udgara* - belching similar to those occurring soon after meal
- *Utkleda* - sensation of vomiting
- *Mala Vata Apravritti*
- *Gourvam* - heaviness in body/ abdomen

**Table 3: Screening criteria for Amajirna**

SN	Clinical Features	Finding	Score
1	<i>Shotho Gandakshi Kutaga</i>	None	0
		Mild	1
		Moderate	2
		Severe	3
2	<i>Yatha Bhuktam Avidagdham Udgara</i>	None	0
		Mild	1
		Moderate	2
		Severe	3
3	<i>Utkleda</i>	None	0
		Mild	1
		Moderate	2
		Severe	3
4	<i>Mala Vata Apravritti</i>	None	0
		Mild	1
		Moderate	2

		Severe	3
5	Gourvam	None	0
		Mild	1
		Moderate	2
		Severe	3

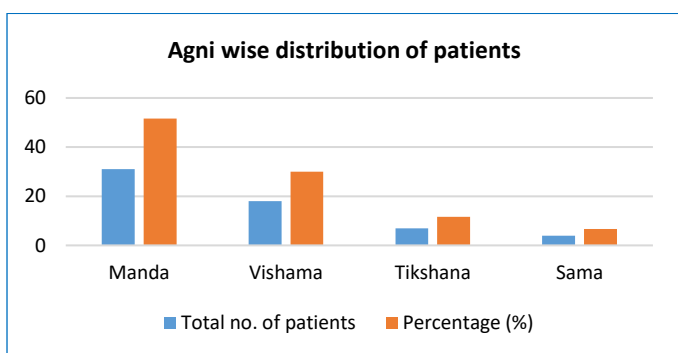
**OBSERVATION AND RESULTS**

**Table 4: Agni wise distribution of patients**

SN	Agni	Total number of patients (n)	Percentage (%)
1.	Manda	31	51.67
2.	Vishama	18	30.00
3.	Tikshana	07	11.67
4.	Sama	4	6.66
Total		60	100

It shows that 51.67% of patients had Mandagni, 34% of patients had Vishamagni, 11.67% patients had Tikshana Agni and 6.66% patients had Sama Agni.

**Figure 1: Showing Agni wise distribution of patients**



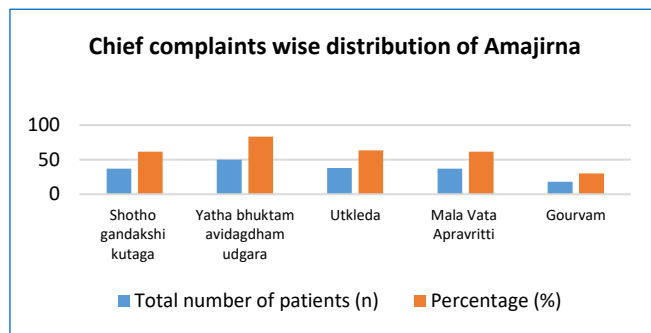
**Table 5: Chief complaints wise distribution of Amajirna patients**

SN	Chief complaints	Total number of patients (n)	Percentage (%)
1.	Shotho Gandakshi Kutaga	37	61.67
2.	YathaBhuktam Avidagdhham Udgara	50	83.33
3.	Utkleda	38	63.33

4.	Mala Vata Apravritti	37	61.67
5.	Gourvam	18	30.00

It shows that 83.33% of the patient had complaints of Yatha Bhuktam Avidagdhham Udgara, followed by Utkleda in 63.33%, Shotho Gandakshi Kutaga and Mala Vata Apravritti in 61.67% and Gourvama in 30% of patients.

**Figure 2: Showing chief complaints wise distribution of Amajirna patients**

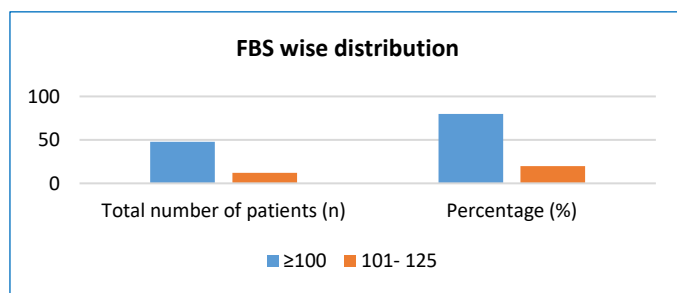


**Table 6: FBS wise distribution of patients**

SN	FBS (mmol/L)	Total number of patients (n)	Percentage (%)
1	≥100	48	80
2	101- 125	12	20
Total		60	100

It shows that FBS level was found up to ≥100 mmol/L in 80% followed by 101- 125 mmol/L in 20% of the patients.

**Figure 3: Showing FBS wise distribution**



**Table 7: PPBS wise distribution of patients**

SN	PPBS (mmol/L)	Total number of patients (n)	Percentage (%)
1	≥140	54	90.00

2	141- 150	4	6.67
3	151-199	2	3.33
Total		60	100

It shows that PPBS level was found up to  $\geq 140$  mmol/L in 90% followed by 141-150 mmol/L in 6.67% and 151-199 mmol/L in 3.33% of the patients.

Figure 4: Showing PPBS wise distribution of patients

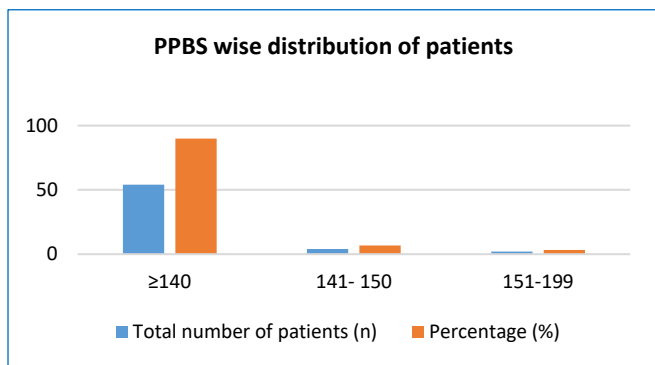


Table 8: HbA1c wise distribution of patients

SN	HbA1c (%)	Total number of patients (n)	Percentage (%)
1	$\geq 5.7$	46	76.67
2	5.7- 6.0	13	21.66
3	6.1-6.4	1	01.67
Total		60	100

It shows that HbA1c level was found up to  $\geq 5.7\%$  in 76.67% followed by 5.7- 6.0% in 21.66% and 6.1-6.4% in 01.67% of the patients.

Figure 5: Showing HbA1c wise distribution

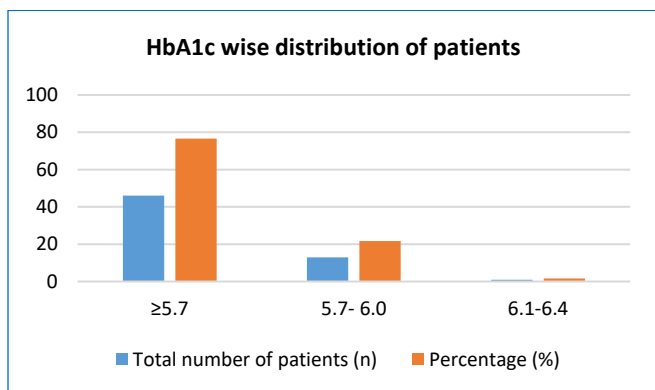


Table 9: Showing serum amylase wise distribution of patients

SN	Serum amylase (IU/L)	Total number of patients (n)	Percentage (%)
1	$\geq 100$	36	60.00
2	101 - 200	23	38.33
3	$>200$	1	01.67
Total		60	100

It shows that serum amylase level was found up to  $\geq 100$  IU/L in 60% followed by 101 – 200 in 38.33% and  $>200$  in 1.67% of the patients.

Figure 6: Showing serum amylase wise distribution

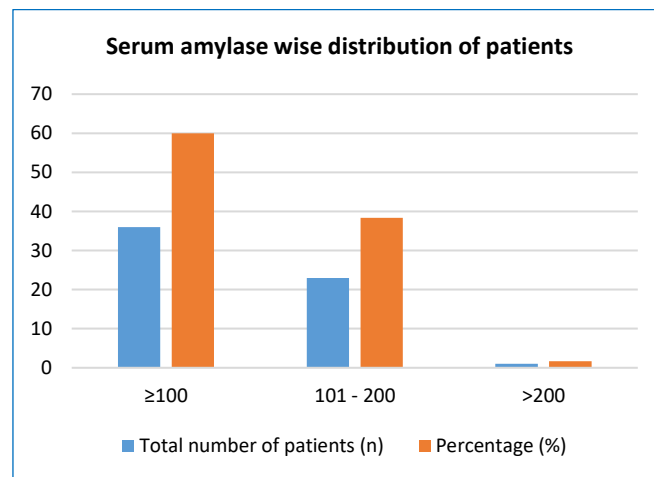


Table 10: Showing serum lipase wise distribution of patients

SN	Serum Lipase (IU/L)	Total number of patients (n)	Percentage (%)
1	$\geq 200$	48	80.00
2	201 - 300	11	18.33
3	$>300$	1	01.67
Total		60	100

It shows that serum lipase level was found up to  $\geq 200$  IU/L in 80% followed by 201 – 300 in 18.33% and  $>300$  in 1.67% of the patients.

Figure 7: Showing that Serum lipase wise distribution

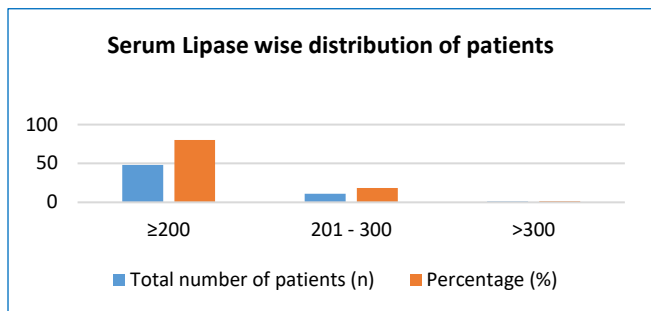


Table 11: Showing SGOT wise distribution of patients

SN	SGOT (units/liter of serum)	Total number of patients (n)	Percentage (%)
1	≥50	48	80.00
2	51 - 150	12	20.00
3	>150	00	00
Total		60	100

It shows that SGOT level was found up to >150 units/litre of serum in 80% followed by 51 – 150 units/litre of serum in 20% and ≥50 units/litre of serum in 0% of the patients.

Figure 8: Showing that SGOT wise distribution

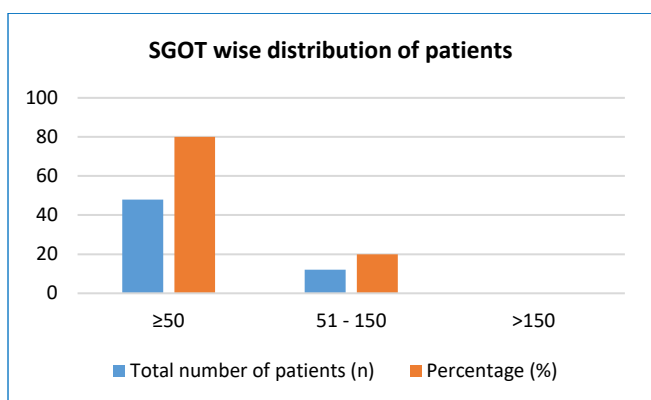


Table 12: Showing SGPT wise distribution of patients

SN	SGPT (units / litre of serum)	Total number of patients (n)	Percentage (%)
1	≥60	40	66.67
2	61 - 150	20	33.33

3	>150	00	00
Total		60	100

It shows that SGPT level was found up to >150 units/litre of serum in 66.67% followed by 61 – 150 units/litre of serum in 33.33% and ≥60 units/litre of serum in 00% of the patients.

Figure 9: Showing SGPT wise distribution

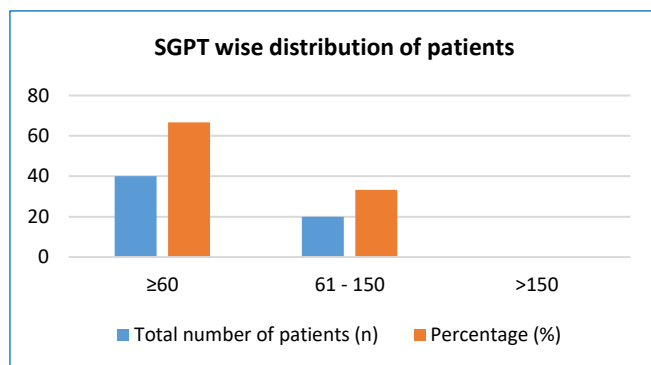
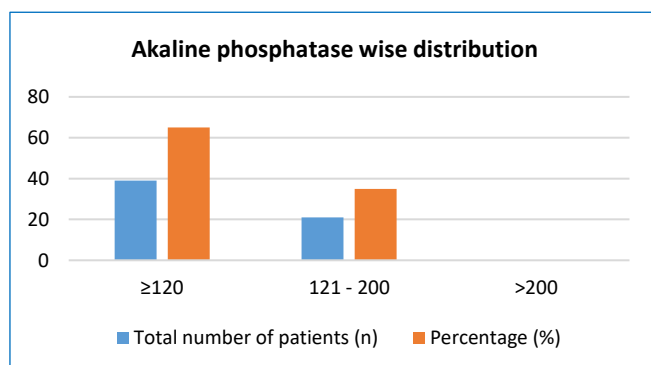


Table 13: Showing alkaline phosphatase wise distribution of patients

SN	ALP (U/L)	Total number of patients (n)	Percentage (%)
1	≥120	39	65.00
2	121 - 200	21	35.00
3	>200	00	00.00
Total		60	100

It shows that ALP level was found up to >200 (U/L) in 65% followed by 121 – 200 (U/L) in 35% and ≥120 (U/L) in 00% of the patients.

Figure 10: Showing alkaline phosphatase wise distribution





Effect of therapy on Objective criteria

FBS

Table 14: Effect of therapy on FBS

Group	Mean Value		Diff.	% Relief	Paired "t" test				
	BT	AT			S.D.	S.E.	"t"	p	Signi.
A	161.76	143.11	18.65	11.52	35.90	7.04	2.64	<0.01	HS
B	166.86	146.55	20.30	12.16	38.95	7.23	2.80	<0.05	S

It shows that, Group-A and Group-B showed 11.52% and 12.16% reduction in FBS respectively, which was statistically highly significant and significant respectively.

Table 15: Comparison of effect of therapy on FBS

Group	Difference in means	Unpaired "t" test				
		S.D.	S.E.	"t"	p	Significant
A	18.65	35.90	7.04	1.1	<0.05	S
B	20.31	38.95	7.23			

It shows that, on applying Un-paired "t" test, the difference of decrease in FBS levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on FBS levels.

PPBS

Table 16: Effect of therapy on PPBS

Group	Mean Value		Diff.	% Relief	Paired "t" test				
	BT	AT			S.D.	S.E.	"t"	p	Signi.
A	211.26	184.5	26.76	18.55	39.90	7.82	3.70	<0.01	HS
B	228.75	186.3	42.44	12.66	61.75	11.46	3.42	<0.05	S

It shows that Group-A and Group-B showed 18.55% and 12.66% reduction in PPBS respectively, which was statistically highly significant and significant respectively.

Table 17: Comparison of effect of therapy on PPBS

Group	Difference in means	Unpaired "t" test				
		S.D.	S.E.	"t"	p	Significant
A	26.76	39.9	7.82	2.6	<0.05	S
B	42.44	61.75	11.46			

It shows that on applying Un-paired "t" test, the difference of decrease in PPBS levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on PPBS levels.

HbA1c

Table 18: Effect of therapy on HbA1c

Group	Mean Value		Diff.	% Relief	Paired "t" test				
	BT	AT			S.D.	S.E.	"t"	p	Signi.
A	7.8	7.6	0.20	20.34	0.81	0.16	4.44	<0.001	HS
B	8.4	7.4	0.97	11.47	1.34	0.25	3.91	<0.05	S

It shows that Group-A and Group-B showed 20.34% and 11.47% reduction in HbA1c respectively, which was statistically highly significant and significant respectively.

Table 19: Comparison of effect of therapy on HbA1c

Group	Difference in means	Unpaired "t" test				
		S.D.	S.E.	"t"	p	Significant
A	0.22	0.80	0.15	2.4	<0.05	S
B	0.97	1.34	0.25			

It shows that on applying Un-paired "t" test, the difference of decrease in HbA1c levels in both groups

was statistically significant. This indicates that both the drugs provided similar effect on HbA1c levels.

**Serum amylase**

**Table 20: Effect of therapy on Serum amylase**

Group	Mean Value		Diff.	% Relief	Paired "t" test				
	BT	AT			S.D.	S.E.	"t"	p	Signi.
A	25.99	25.30	0.69	18.30	5.98	1.17	4.35	<0.001	HS
B	27.03	24.82	2.20	14.35	2.74	3.85	1.24	<0.05	S

It shows that Group-A and Group-B showed 18.30% and 14.35% reduction in serum amylase respectively, which was statistically highly significant and significant respectively.

**Table 21: Comparison of effect of therapy on Serum amylase**

Group	Difference in means	Unpaired "t" test				
		S.D.	S.E.	"t"	p	Significant
A	0.69	5.98	1.17	1.23	<0.05	S
B	0.41	2.74	1.52			

It shows that on applying Un-paired "t" test, the difference of decrease in serum amylase levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on serum amylase levels.

**Serum lipase**

**Table 22: Effect of therapy on Serum lipase**

Group	Mean Value		Diff.	% Relief	Paired "t" test				
	BT	AT			S.D.	S.E.	"t"	p	Signi.
A	7.71	6.98	0.19	12.72	0.47	0.09	2.08	<0.001	HS
B	7.09	7.02	0.06	10.98	0.41	0.07	1.34	<0.05	S

It shows that Group-A and Group-B showed 12.72% and 10.98% reduction in serum lipase respectively, which was statistically highly significant and significant respectively.

**Table 23: Comparison of effect of therapy on Serum lipase**

Group	Difference in means	Unpaired "t" test				
		S.D.	S.E.	"t"	p	Significant
A	0.19	0.47	0.09	1.04	<0.05	S
B	0.16	0.41	0.07			

It shows that on applying Un-paired "t" test, the difference of decrease in serum lipase levels in both groups was statistically highly significant. This indicates that both the drugs provided similar effect on serum lipase levels.

**SGOT**

**Table 24: Effect of therapy on SGOT**

Group	Mean Value		Diff.	% Relief	Paired "t" test				
	BT	AT			S.D.	S.E.	"t"	p	Signi.
A	41.38	33.13	8.23	19.8	41.09	8.05	4.45	<0.001	HS
B	27.03	24.82	2.20	8.13	20.74	3.85	2.02	<0.05	S

It shows that Group-A and Group-B showed 8.23% and 2.20% reduction in SGOT respectively, which was statistically highly significant and significant respectively.

**Table 25: Comparison of effect of therapy on SGOT**

Group	Difference in means	Unpaired "t" test				
		S.D.	S.E.	"t"	p	Significant
A	8.23	41.09	8.05	2.45	<0.05	S
B	2.13	20.72	3.84			

It shows that on applying Un-paired “t” test, the difference of decrease in SGOT levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on SGOT levels.

**SGPT**

**Table 26: Effect of therapy on SGPT**

Group	Mean Value		Diff.	% Relief	Paired “t” test				
	BT	AT			S.D	S.E	“t”	p	Signi.
A	3.16	2.5	0.33	24.86	1.15	0.66	2.39	<0.001	HS
B	1.44	0.65	0.79	10.44	1.78	0.33	1.34	<0.05	S

It shows that Group-A and Group-B showed 24.86% and 10.44% reduction in SGPT respectively, which was statistically highly significant and significant respectively.

**Table 27: Comparison of effect of therapy on SGPT**

Group	Difference in means	Unpaired “t” test				
		S.D.	S.E.	“t”	p	Significant
A	0.19	1.66	0.32	1.28	<0.05	S
B	0.79	1.78	0.34			

It shows that on applying Un-paired “t” test, the difference of decrease in SGPT levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on SGPT levels.

**Alkaline Phosphatase**

**Table 28: Effect of therapy on Alkaline Phosphatase**

Group	Mean Value		Diff.	% Relief	Paired “t” test				
	BT	AT			S.D	S.E	“t”	p	Signi.
A	7.8	7.6	0.20	20.34	0.81	0.16	4.44	<0.001	HS

B	8.4	7.4	0.97	11.47	1.34	0.25	3.91	<0.05	S
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It shows that Group-A and Group-B showed 20.34% and 11.47% reduction in alkaline phosphatase respectively, which was statistically highly significant and significant respectively.

**Table 29: Comparison of effect of therapy on Alkaline Phosphatase**

Group	Difference in means	Unpaired “t” test				
		S.D.	S.E.	“t”	p	Significant
A	0.22	0.80	0.15	2.4	<0.05	S
B	0.97	1.34	0.25			

It shows that on applying Un-paired “t” test, the difference of decrease in alkaline phosphatase levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on alkaline phosphatase levels.

**DISCUSSION**

The subjective & objective parameter were assessed with data compilation & statistical analysis. The obtained data of before & after treatment of experimental group were evaluated through 't' test. The before treatment and after treatment value of blood glucose level and gastrointestinal enzymes level were computed to achieve 't' test and 'p' value by paired 't' test. The comparative study between Group A and Group B were done through unpaired 't' test.

The obtained data of before treatment & after treatment were computed & analyzed statistically. The values are expressed as Mean ± SEM (Standard Error of Mean). The data were analyzed by paired 't' test. A level of p<0.001 was considered as statistically highly significant and p<0.05 was considered as statistically significant. Comparative study of both Group - A & Group - B was done, through analysis of the obtained data by unpaired 't' test. Level of significance was noted & interpreted accordingly.

### Chief complaints of Amajirna

It was observed that, 83.33% of the patient had complaints of *Yatha Bhuktam Avidagdhm Udgara*, followed by *Utkleda* in 63.33%, *Shotho Gandakshi Kutaga* and *Mala Vata Apravritti* in 61.67% and *Gourvam* in 30% of patients. The above data supports the hypothesis that *Amajirna* is *Kapha* dominance *Ajirna* and if we recognize *Amajirna* from other type of *Ajirna* we can treat the disease according (Table 2).

### Blood sugar levels

FBS level was found up to  $\geq 100$  mmol/L in 80% followed by 101- 125 mmol/L in 20% of the patients. PPBS level was found up to  $\geq 140$  mmol/L in 90% followed by 141-150 mmol/L in 6.67% and 151-199 mmol/L in 3.33% of the patients. HbA1c level was found up to  $\geq 5.7\%$  in 76.67% followed by 5.7- 6.0% in 21.66% and 6.1-6.4% in 1.67% of the patients (Table 3,4,5).

Serum amylase level was found up to  $\geq 100$  IU/L in 60% followed by 101 – 200 in 38.33% and  $>200$  in 6.67% of the patients. Serum lipase level was found up to  $\geq 200$  IU/L in 80% followed by 201 – 300 in 18.33% and  $>300$  in 1.67% of the patients. SGOT level was found up to  $>150$  units/litre of serum in 80% followed by 51 – 150 units/litre of serum in 20% and  $\geq 50$  units/litre of serum in 0.00% of the patients. SGPT level was found up to  $\geq 60$  units/litre of serum in 66.67% followed by 61 – 150 units/litre of serum in 33.33% and  $>150$  units/litre of serum in 0.00% of the patients. ALP level was found up to  $>200$  (U/L) in 65% followed by 121 – 200 (U/L) in 35% and  $\geq 120$  (U/L) in 0.00% of the patients (Table 6,7,8,9,10).

### Fasting Blood Sugar level

Group-A and Group-B showed 11.52% and 12.16% reduction in FBS respectively, which was statistically highly significant and significant respectively. In diabetic state, there is beta cell failure leading to reduced basal insulin secretion in fasting state, drug showed fasting blood sugar lowering effect which is statistically significant in both the groups. It shows possibility of beta cell protective or regenerative effect of drugs (Table 11).

### Post Prandial Blood Sugar level

Group-A and Group-B showed 18.55% and 12.66% reduction in PPBS respectively, which was statistically highly significant and significant respectively, this may be because of retarding the carbohydrate absorption from intestine,  $\alpha$ - glucosidase inhibitor action & improvement in peripheral glucose uptake (Table 13).

### Serum HbA1c

Group-A and Group-B showed 20.34% and 11.47% reduction in HbA1c respectively, which was statistically highly significant and significant respectively (Table 15).

On applying Un-paired “t” test, the difference of decrease in HbA1c levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on HbA1c levels (Table 16).

### Serum amylase

Group-A and Group-B showed 18.30% and 14.35% reduction in serum amylase respectively, which was statistically highly significant and significant respectively (Table 17).

On applying Un-paired “t” test, the difference of decrease in serum amylase levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on serum amylase levels (Table 18).

### Serum lipase

Group-A and Group-B showed 12.72% and 10.98% reduction in serum lipase respectively, which was statistically highly significant and significant respectively (Table 19).

On applying Un-paired “t” test, the difference of decrease in serum lipase levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on serum lipase levels (Table 20).

### SGOT

Group-A and Group-B showed 8.23% and 2.20% reduction in SGOT respectively, which was statistically

highly significant and significant respectively (Table 21).

On applying Un-paired “t” test, the difference of decrease in SGOT levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on SGOT levels (Table 22).

#### SGPT

Group-A and Group-B showed 24.86% and 10.44% reduction in SGPT respectively, which was statistically highly significant and significant respectively (Table 23).

On applying Un-paired “t” test, the difference of decrease in SGPT levels in both groups was statistically significant. This indicates that both the drugs provided similar effect on SGPT levels (Table 24)

#### Alkaline phosphatase

Group-A and Group-B showed 20.34% and 11.47% reduction in alkaline phosphatase respectively, which was statistically highly significant and significant respectively (Table 25).

This can be inferred that existing duration of therapy have significant role on FBS, PPBS, HbA1c, serum amylase, serum lipase, SGOT, SGPT, Alkaline phosphatase level.

#### Comparative Effect of Therapy

##### Effect on Chief complaints

In Group A, *Shotho Gandakshi Kutaga* was relieved by 76.50% which was statistically highly significant ( $p < 0.001$ ), while in Group B it was relieved by 58.82% which was statistically significant ( $p < 0.05$ )

In Group A, *Yatha Bhuktam Avidagdham Udgara* was relieved by 88.02% which was statistically highly significant ( $p < 0.001$ ), while in Group B it was relieved by 41.17% which was statistically significant ( $p < 0.05$ )

In Group A, *Utkleda* was relieved by 80.64% which was statistically highly significant ( $p < 0.001$ ), while in Group B it was relieved by 32.50% which was statistically significant ( $p < 0.05$ ).

In Group A, *Mala Vata Apravritti* was relieved by 80% which was statistically highly significant ( $p < 0.001$ ),

while in Group B it was relieved by 33.33% which was statistically significant ( $p < 0.05$ ).

In Group A, *Gouravam* was relieved by 78.37% which was statistically highly significant ( $p < 0.001$ ), while in Group B it was relieved by 55.10% which was statistically significant ( $p < 0.05$ ) (Table 6.29).

The above data supports the hypothesis that *Amajirna Prameha* is *Kapha* dominance *Ajirna* and if we recognize *Amajirna* from other type of *Ajirna* we can treat the disease according. *Musta churna* show good result because *Katu, Tikta and Kashya Rasa, Laghu* and *Ruksha Guna, Sheeta Virya* and *Katu Vipaka* gives *Kaphapitta Shamana* effect and as it is having *Katu Rasa, Laghu Guna*, it increases the *Agni* and also give *Kapha Shamana, Deepana, Pachana, Rochana, Amahara* and *Lekhana* properties. Hence the relief observed was higher and statistically highly significant. On the other hand, *Pippali Churna* due to its *Katu Rasa, Laghu Snigdha* and *Tikshna Guna, Anusha sheeta Virya, Madhura Vipaka* and *Vatakaphashamaka Doshaghnata*. Due to these qualities, it helps in relieving *Amajirna Prameha*. Hence the relief observed was statistically significant. Statistically all *Amajirna Prameha Lakshana* show highly significant result due to the *Agni Deepana, Ama Pachana Premehahara* action of, *Ama* was disappeared and hence the symptoms of *Amajirna Prameha* got relieved.

#### Overall effect of therapy

In Group A, marked improvement was observed in 83.33% of the patient, moderate improvement was observed in 16.67% of patients. In Group B, marked improvement was observed in 60% patients, moderate improvement was observed in 33.33% patients and mild improvement was observed in 6.67% patients. No patients were observed as complete cured and unchanged in both the groups.

#### CONCLUSION

*Amajirna Prameha* (Pre-Diabetes) with dominancy of *Kapha* among the *Doshas, Meda* among the *Dooshyas*. Both the groups were having statistically significant result in the parameters i.e., FBS, PPBS, HBA1C, SGOT, SGPT, serum amylase, serum lipase and alkaline

phosphatase. But in inter group comparison, *Musta Churna* was found to be more effective than *Pippali Churna*. There is further scope for new researchers to used formulation containing more drugs instead of single drug. The present work could be conducted with large sample size and more days of drug given which might give better results.

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