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The comparative and clinical study on *Khandamalki* and *Patoladi kwatha* in *Amlapitta* W.S.R to*"Amlapittai Pryoktavya Kapha pittaha rovidhi"*

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Abstract

***Amlapitta* is one among the commonest disorders prevalent in the society nowadays due to indulgence in incompatible food habits and activities. It is a very common disease affecting mostly the adults. *Acharya Vrinda* in *Vrind Madhav*has mentiond thatthe treatment of *Amlapitta*mainly depends upon *Kaphapittaharovidhi.*So the present study was planned to prove this principle.*Khandamalki and PatoladiKwatha,* very simple, safe and cost effective drugs,have been chosen to explore the efficacyin the management of *Amlapitta as Shaman* therapy.*shodhan* therapy is time consuming and not possible to execute in all the patients so the present study has been carried out to evalute the *Shamana* effect of *Khandamalki and PatoladiKwatha*. The results of the study are discussed in this paper.**

Key words: ***Amlapitta, Khandamalki, Patoladikwatha.***

Introduction

Ayurveda is a holistic way of living in which the mind, body, diet and exercise act together to contribute to one`s health. Any vitiation leads to imbalance which needs to be corrected through regulation of diet, exercises, mind and bodily functions. In recent years, health levels are decreasing due to changing of life style, diet pattern, behavioral pattern and mental stress and strain. Everyone is prone to various disease due to the against of our normal physiology of digestion. There have *been* extraordinary increases disorders incidences related to *Annavahastrotas* (Gastrointestinal system) related disorders. *Amlapitta* is such type of G.I. disorder which is the outcome of faulty dietetic habits, with disturbed function of *Agni* (digestive fire) is the valuable topic of concern in the present era. *Kashyapasamhita* was the first text that gave a detailed description of *Amlapitta* (Kashyap Samhita). *Kashyapasamhita* has accepted the involvement of all three *doshas* in *amlapitta* whereas *charakasamhita* and *madhavakara* has accepted the dominance of *pitta dosha* in this disease. The word *amlapitta* is comprised of two words *amla* and *pitta*. The term *amla* refers to a particular type of taste equated with sour taste which causes excessive salivarysecretions. *Pitta* is a bodily chemical substance which is mainly responsible for the maintenance of the process of digestion and transformation. *Amlapitta* is a pathological condition in which there is vitiation of *pitta dosha* in the body *pittadosha* possesses *katu rasa*, but after it gets vitiated the *katu rasa* of *pitta dosha* changes to *amla rasa* (Kashyap Samhita).

Aims and objectives

The Comparative and Clinical Study on *Khandamalki* and *PatoladiKwatha* in *Amlapitta*W.S.R to *"AmlapittaiPryoktavya Kaphapittaharovidhi"* was undertaken with the following aims and objectives

1. Conceptual study on *Amlapitta*
2. To evaluate the efficacy of *Khandamalki* in the management of *Amlapitta.*
3. To evaluate the efficacy of *PatoladiKwatha* in the management of *Amlapitta.*
4. To evaluate the combined efficacy of *Khandamalki* and *PatoladiKwatha* in the management of *Amlapitta*.

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Materials and Methods

Following materials and methods were adopted for the completion of present research project:

Design of study: Simple, randomized, opens three group comparative studies.

Selection of cases: For clinical study, patients of *Amlapitta*fulfilling the diagnostic criteria were registered from the OPD/IPD of NationalInstituteof *Ayurveda,* Jaipur (Agnivesha Charaka Samhita).

Diagnostic criteria were mainly based on the signs and symptoms of *Amlapitta*described in *Ayurvedic* classics. They include *Avipaka*, *Klama, Utklesha, Tikt-Amlodgara, Hrita-Kanthadaha, AruchiGaurav, Chhardi, Shira-shul.*

(a) Inclusion Criteria

i. Patient willing to undergo trial and ready to give written consent.
ii. Age : 16-60 years
iii. Sex- either sex.
iv. Patients presenting with classical features of *Amlapitta*.

(b) Exclusion Criteria

i. Patients not willing for trial.
ii. Patients below the age of 16 years and above 60 years.
iii. Chronicity more than 5 years.
iv. Patients having organic disease like gastric ulcer, duodenal ulcer etc.
v. Patients suffering from*Amlapitta* with any other chronic diseases like Asthma, Malignancies, Liver Cirrhosis, and Chronic renal failure, diabetes were excluded from the study.

Research protocol

Administration of drugs

For the present clinical study, 45 patients were enrolled and they were randomly divided into following three groups:-

GROUP A: 15 patients were registered in this group and they were given "*Khandamalki"* for 30 days.

GROUP B: 15 patients were registered in this group and they were given "*PatoladiKwatha"* for 30 days.

GROUP C: 15 patients were registered in this group and they were given *"Khandamalki"* and *"PatoladiKwatha"* for 30 days.

45 patients were selected for present study from *Arogyashala*outpatient department & in patient department, National Institute of *Ayurveda*, Jaipur filling the inclusion criteria set for this purpose. Follow up was taken after 7 days. All patients were divided into three groups-

Group A- 15 clinically diagnosed patients of *Amlapitta* were administered "*Khandamalki"* 5 gram twice in a day with milk for 30 days.

Group B- 15 clinically diagnosed patients of *Amlapitta* were administered "*Patoladikwatha"* 20 ml twice in a day (before meal) with honey for 30 days.

Group C- 15 clinically diagnosed patients of *Amlapitta* were administered "*Khandamalki"* 5 gram twice in a day with milk for 30 days and "*Patoladikwatha"* 20 ml twice in a day (before meal) with honey for 30 days.

TRIAL DRUGS

GROUP A

DRUG-*khandamalki*
Dose- 5 gram twice daily
Time of administration- after meal
Duration- 30 days
Anupana- milk

GROUP B

Drug -*PatoladiKwatha*
Dose- 20 gram twice daily
Time of administration- before meal
Duration- 30 days
Anupana- Honey

GROUP C

Drug -*Khandamalki* **+***PatoladiKwatha* both

Pathological investigations

Routine hematological, urinary examinations were done before and after treatment to rule out any other pathology.

Drugs

1. *Khandamalki*

Pharmacodynamic properties of *Khandamalki (B.R. Shuladhikarshloka 228-32)*

1. **PatoladiKwatha**
2. Pharmacodynamic properties of PatoladiKwatha (Amlapitta Nidana Chikitsa Prakrana Shloka 26)

Table 1.

SN	Drug	Botanical name	Rasa	Guna	Veerya	Vipaka	Karma
1	Kushmanda	BeninkasaHispida	Madhura	Laghu, snigdha	Sheeta	Madhura	Vata- pitta shamak,tridoshahar
2	Amalaki	Embilicaofficinalis	Pancharasa	Guru, ruksha	Sheeta	Madhura	Pitta shamak
3	Pipalli	Piper longum	Katu	Laghu, snigdha	Anushnasheeta	Madhura	Kapha- vatashamak
4	Jiraka (shweta)	Cuminamcyminum	Katu	Laghu, ruksha	Ushna	Katu	Kapha-vatashamak
5	Shunti	Zingiberofficinale	Katu	Laghu, snigdha	Ushna	Madhura	Kapha- vatashamak
6	Marich	Piprenigrum	Katu	Laghu, tikshna	Ushna	Katu	Kapha- Vatashamak
7	Tallish- patra	Abieswebbiana	Tikt- madhura	Laghu- tikshan	Ushna	Katu	Kapha- Vatashamak
8	Dhnyak	Coriandrumsativum	Tikt- madhura	Laghu- snigdha	Ushna	Madhura	Pitta- Shamak Tridoshhar
9	Dal-chini	Cinnamomnmzeylanicum	Katu- tikt	Laghu, ruksha	ushna	Katu	Kapha-Vatashamak, Pitta Vardhak
10	Tej- patra	Cinnamemmumtamala	Katu- tikt	Laghu, ruksha	Ushna	Katu	Kapha- Vatashamak, Pitta vardhak
11	Suksha- ela	Elettariacardamomum	Katu- madhura	Laghu, ruksha	Sheeta	Madhura	Tridoshahar
12	Nagkesar	Mesuaferrea	Tikt- kshya	Laghu, ruksha	Ushna	Katu	Kaphapittashamak
13	Mustak	Cyperusrotundus	Tikt, katu, kshya	Laghu, ruksha	Sheeta	Katu	Kapha- pitta shamak
14	Madhu	honey	madhura	Guru, ruksha	Sheeta	Katu	Kapha pitta shamak
15	Ghrit	Ghee	madhura	Guru, snigdha	Sheeta	Madhura	Pitta shamak
16	Khand	-	madhura	Snigdha, sheeta	Sheeta	Madhura	Pitta shamak

Table 2.

SN	Drug	Botanical name	Rasa	guna	Veerya	Vipaka	Karma
1.	Patola	Trichosanthesdicoica	Tikta	Laghu, Ruksha	Katu	Ushna	Kaphapittashamak
2.	Amalaki	Emblicaofficinalis	Pancha rasa	Guru, ruksha	Sheeta	Madhura	Pitta shamak
3.	Haritaki	TermanaliaChebula	Pancharasa	Laghu, ruksha	Ushna	Madhura	Tridoshharamainly vatashamak
4.	Vibhitak	Termanaliabellirica	Kashya	Ruksha, laghu	Ushna	Madhura	Kaphapittashamak
5.	Nimba	AzadiractaIndica	Tikta, kashya	Laghu	sheeta	Katu	Kaphapittashamak
6.	Madhu	Honey	Madhura	Guru, ruksha	Sheeta	Katu	Kapha pitta shamak

Criteria of assessment-

Scoring system was adopted for assessment of various subjective features and grades from zero to four were accorded to various features according to the severity. The symptoms were evaluated and response of drug was recorded in term of percentage relief of symptoms. Patients were grouped under following categories on the basis of their results of the clinical trial.

- Completely relieved -100% relief from symptoms
- Marked improvement-75-99% relief from symptoms
- Moderate improvement-50-74% relief from symptoms
- Mild improvement-25-50 % relief from symptoms
- No improvement-below 25 % or no relief

Statistical evaluation and result analysis

The entire data generated from clinical study was statistically analyzed. The results were made on the basis of grades of various variables compared between pre- trial and post- trial values in terms of percentage, based on mathematical means and its difference. Values between variables were compared with Wilcoxon Signed Ranks Test for dependent samples by using the degree of freedom p value. Intergroup comparison was also done with Kruskal-Wallis Test (Nonparametric ANOVA) and Dunn's Multiple Comparisons Test. The results were expressed in terms of mean, standard deviation (SD) and standard error (SE).

- $P < 0.001$ - highly significant
- $P < 0.01$ - significant
- $P > 0.05$ - non significant

Results and Discussion

Table 1 Effect of therapy on assessment criteria in group A

Symptoms	N[1]	Mean			Relief %	S.D.[5] (±)	S.E.[6] (±)	W & T[7] ±	P[8]	Results
		BT[2]	AT[3]	Diff.[4]						
Avipaka	11	1.80	0.93	0.86	48.14	0.639	0.165	6.500	.0005	HS
Klama	11	1.46	1.20	0.26	18.18	0.457	0.118	2.256	.0625	NS
Utklesha	12	2.00	1.33	0.67	33.33	0.488	0.126	5.292	.0020	HS
TiktAmlodgara	15	2.53	1.60	0.93	36.84	0.798	0.206	4.525	.0010	HS
Daha	15	2.13	1.46	0.66	31.25	0.617	0.159	4.183	.0020	HS
Chhardi	10	1.40	0.86	0.53	38.09	0.743	0.191	2.779	.0313	S
Shira-shul	06	0.60	0.26	0.33	55.55	0.488	0.126	2.646	.0625	NS
Gaurav	06	0.53	0.26	0.26	50.00	0.457	0.118	2.256	.0125	S
Aruchi	12	1.80	0.93	0.86	48.14	0.639	0.165	6.500	.0005	HS

[[1]No. of patients having symptoms, [2]Mean score before treatment, [3]Mean score after treatment, [4]Difference in mean, [5]Sandard deviation, [6]Standard error, [7]Wilcoxan Signed , [8]Degree of freedom]

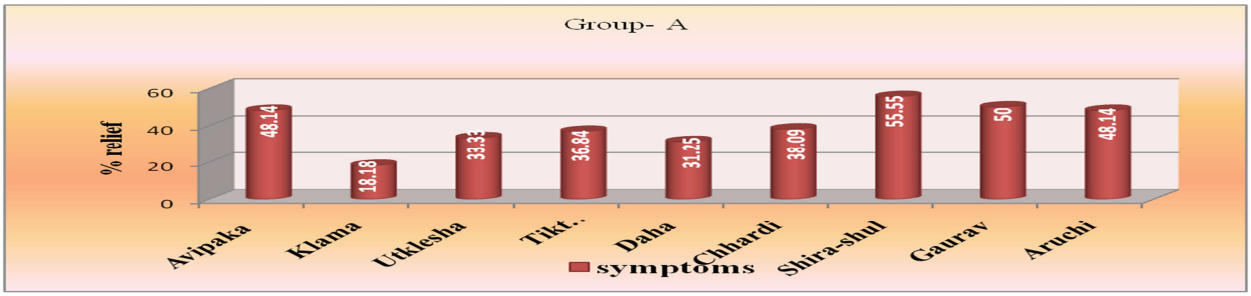

Fig 1.

Table 2 effect of therapy on assessment criteria in group B

Symptoms	N[1]	Mean			Relief %	S.D.[5] (±)	S.E.[6] (±)	W & T[7] ±	P[8]	Results
		BT[2]	AT[3]	Diff.[4]						
Avipaka	12	1.73	0.73	1.00	57.69	0.654	0.169	5.916	.0002	HS
Klama	10	1.33	1.06	0.26	20.00	0.457	0.118	2.256	.0625	NS
Utklesha	15	2.33	1.53	0.80	34.28	0.560	0.144	5.527	.0005	HS
TiktAmlodgara	15	2.33	1.60	0.73	31.42	0.703	0.181	4.036	.0039	HS
Daha	15	1.86	1.00	0.86	46.42	0.351	0.090	9.539	.0002	HS
Chhardi	12	1.26	0.46	0.80	66.66	0.560	0.144	5.527	.0010	HS
Shira-shul	05	0.60	0.20	0.40	66.66	0.632	0.163	2.449	.0625	NS
Gaurav	07	0.93	0.46	0.46	50.00	0.516	0.133	3.500	.0156	S
Aruchi	09	1.40	0.60	0.80	52.38	0.774	0.200	3.595	.0039	HS

[1]No. of patients having symptoms, [2]Mean score before treatment, [3]Mean score after treatment, [4]Difference in mean, [5]Sandard deviation, [6]Standard error, [7]Wilcoxan Signed, [8]Degree of freedom

After analysis of above data of group A, it was observed that the maximum relief in percentage was in *shira-shul* (55.55%), then in *Gaurav* (50.00%), then in *Aruchi* and Avipaka (48.14%), then in *Chhardi* (38.09%), then in *Tikt*-amlodgara (36.84%) , then in *Daha* (31.25%) and minimum relief in percentage was in *Klama* (18.18%). According to statistical analysis, *Avipaka, Utklesha, TiktAmlodgara,Daha, Aruchi* shows highly significant result,*Chhardi* and *Gaurav* show significant result, whereas *Klama* and *Shira-shul* show insignificant result (Agnivesha Charaka Samhita).After analysis of above data of group B, it was observed that the maximum relief in percentage was in *Chhardi* and *Shira*-shul (66.66%), then in *Avipaka* (57.69%), then in *Aruchi* (52.38%), then in *Gaurav* (50%), then in *Daha* (46.42%) , then in *Utklesha* (34.28%), then in *Tikt*-amlodgara (31.42%) and minimum relief in percentage was in *Klama* (20%). According to

statistical analysis, *Avipaka*, *Utklesha*, *TiktAmlodgara*, *Daha*, *Chhardi* and *Aruchi* shows highly significant result, *Gaurav* show significant result, whereas *Klama* and *Shira*-shul show insignificant result.

Table 3. Effect of therapy on assessment criteria in group C

Symptoms	N1	Mean			Relief %	S.D.5 (±)	S.E.6 (±)	W & T[7] ±	P8	Results
		BT[2]	AT[3]	Diff[4].						
Avipaka	14	2.46	0.73	1.73	70.27	0.961	0.248	6.985	.0001	HS
Klama	08	1.53	0.80	0.73	47.82	0.593	0.153	4.785	.0020	HS
Utklesha	13	2.20	1.20	1.00	45.45	0.645	0.169	5.916	.0005	HS
TiktAmlodgara	15	2.53	0.93	1.60	63.15	0.828	0.213	7.483	.0002	HS
Daha	15	2.33	0.93	1.40	60.00	0.632	0.163	8.573	.0001	HS
Chhardi	07	2.00	0.73	1.26	63.33	0.883	0.228	5.551	.0010	HS
Shira-shul	11	1.66	0.33	1.33	80.00	0.975	0.252	5.292	.0010	HS
Gaurav	09	1.46	0.40	1.06	72.72	0.961	0.248	4.298	.0039	HS
Aruchi	13	2.00	0.40	1.60	80.00	0.828	0.218	8.411	.0001	HS

[1]No. of patients having symptoms, [2]Mean score before treatment, [3]Mean score after treatment, [4]Difference in mean, [5]Sandard deviation, [6]Standard error, [7]Wilcoxan Signed, [8]Degree of freedom

After analysis of above data of group C, it was observed that the maximum relief in percentage was in*Shira*-shul and *Aruchi* (80%), then in *Gaurav* (72.72%), then in *Avipaka* (70.27%), then in *Chhardi* (63.33%), then in *Tikt-Amlodgara* (63.15%) , then in *Daha* (60%), then in *Klama* (47.82%) and minimum relief in percentage was in *Utklesha* (45.45%). According to statistical analysis, *Avipaka,klama, Utklesha, TiktAmlodgara,daha, Chhardi, Shira-shul, Gaurav*and *Aruchi* shows highly significant result.

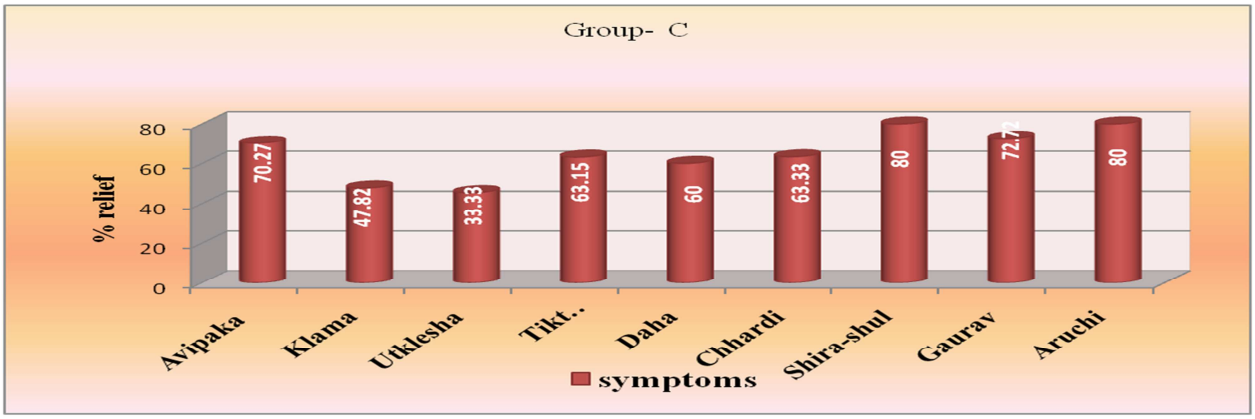

Fig 3.

Table 4 – Intergroup comparison by Kruskal-Wallis Test (Nonparametric ANOVA)

S.No.	Symptoms	KW Value	P Value	Results
1.	*Avipaka*	7.582	P<0.05	S
2.	*Klama*	7.013	P<0.05	S
3.	*Utklesha*	6.132	P<0.05	S
4.	*TiktAmlodgara*	9.107	P<0.05	S
5.	*Daha*	11.092	P<0.01	HS
6.	*Chhardi*	6.339	P<0.05	S
7.	*Shira-shul*	11.015	P<0.01	HS
8.	*Gaurav*	0.667	P<0.05	S
9.	*Aruchi*	9.833	P<0.01	S

Table 5 Dunn's Multiple Comparisons Test

S.No.	Symptoms	Dunn's Multiple Comparisons Test	Mean Rank Difference	P Value	Remarks
1.	*Avipaka*	Group A & Group B	-1.76	P>0.05	NS
		Group A & Group C	-11.63	P<0.05	S
		Group B& Group C	-9.86	P>0.05	NS
2.	*Klama*	Group A & Group B	-0.00	P>0.05	NS
		Group A & Group C	-9.40	P>0.05	NS
		Group B& Group C	-9.40	P>0.05	NS
3.	*Utklesha*	Group A & Group B	-2.33	P>0.05	NS
		Group A & Group C	-10.16	P>0.05	NS
		Group B& Group C	-7.83	P>0.05	NS
4.	*TiktAmlodgara*	Group A & Group B	2.53	P>0.05	NS
		Group A & Group C	-10.33	P>0.05	NS
		Group B& Group C	-12.86	P<0.05	S
5.	*Daha*	Group A & Group B	-3.73	P>0.05	NS
		Group A & Group C	-13.36	P<0.01	HS
		Group B& Group C	-9.63	P>0.05	NS
6.	*Chhardi*	Group A & Group B	-4.73	P>0.05	NS
		Group A & Group C	-11.26	P<0.05	S
		Group B& Group C	-6.53	P>0.05	NS
7.	*Shira-shul*	Group A & Group B	-0.66	P>0.05	NS
		Group A & Group C	-12.83	P<0.01	HS
		Group B& Group C	-12.16	P<0.05	S
8.	*Gaurav*	Group A & Group B	-3.80	P>0.05	NS
		Group A & Group C	-11.00	P<0.05	S
		Group B& Group C	-7.20	P>0.05	NS
9.	*Aruchi*	Group A & Group B	2.06	P>0.05	NS
		Group A & Group C	-11.06	P<0.05	S
		Group B& Group C	-13.13	P<0.05	S

Overall assessment of therapy

At the end of treatment each patient result were carefully observed to assess the overall effect of therapy

Grading	Group A	Group B	Group C
Complete relief	0 %	0 %	0 %
Marked relief	0 %	0 %	26.66 %
Moderate relief	20 %	46.67 %	60.00 %
Mild relief	53.33%	53.33 %	6.67 %
No relief	26.67 %	0 %	6.67 %

In group A, 26.67% patients achieved no relief, 53.33% patients achieved mild relief, 20% patients achieved moderate relief, no any patients achieved marked and complete relief.

In group B, 53.33% patients achieved mild relief, 46.67% patients achieved moderate relief, and no any patients achieved marked and complete relief.

In group C, 06.67% patients achieved no relief, 06.67% patients achieved mild relief, 60% patients achieved moderate relief, 26.66% patients achieved marked relief andno any patients achieved complete relief.

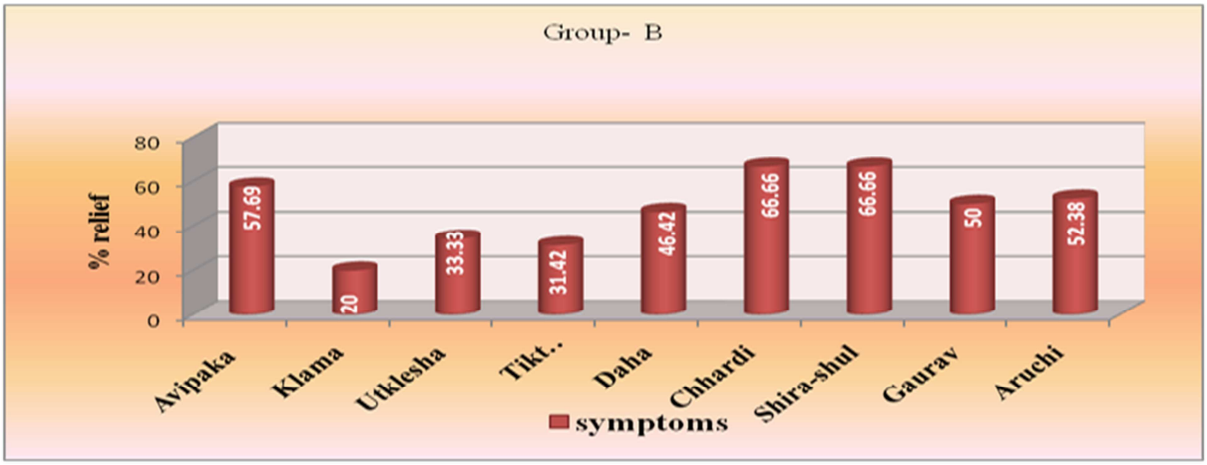

Fig 4.

Degradation by pathogenesis by formulated drugs-

Drug which is *Agnideepaka*, *Kaphashamaka* antagonist properties of *VidagdhaPitta*, *Srotoshodhaka* and *Vatanulomaka* is useful as palliative treatment of *Amlapitta* (Sushruta Sushruta Samhita). In Group A*Khandamalaki* with *Anupana* of luke warm milk was given. Main ingredients of *Khandamalki, Kushmanda* and *Amalaki*. The properties of *Kushmanda* are *Laghu*, *Snigdha*, *SheetaVirya*, *MadhuraRasa* and *Vipaka*. Due to its properties it suppresses *Ushna* and *Tikshna* properties of *Vidagdhapitta*. *Amlaki* is *AmlaRasa*dominant *Pancharasa*, *SheetaVeerya* and *MadhuraVipaka*, *Guru*, *Ruksha* and *Sheet*. It is *Pittashamak* due to *SeehtaVirya* and *MadhuraVipaka*. Madhuis *Pittakaphashamak* due to *Ruksha*, *Madhura* and *SheetVirya*. *Pippali*, *Jeeraka*, *Nagkeshar* are *Kaphavatshamak* due to *Ruksha*, *Laghu*, *UshanaVirya* and *Katu*, *TiktaRasa*. All of these drugs digest the *SamAnsha* of *AmaRasa*. There is a lot of importance of *Anupana* in increasing the activity of drug. There is *Anupana* of cow's milk which is also *SheetaVirya* and*MadhuraRasa* dominate and suppress the excess quantity of *Pitta* in *Amlapitta*. *Mishri*is also *Pittashamak* due to *MadhuraRasa*. *Medhya*effect of *Kushmanda* prevents its etiology due to psychological factor like *Klam*, *Anidra* etc.

PatoladiKwatha was given in group 'B' with *Prakshep* of *Madhu*. Ingredients of *PatoladiKwatha* are mostly *Ruksha*, *Laghu*,*Tikt*, *Kasaya*, *AnushnaSheetaVeerya*, *MadhuraVipaka*. *Ruksha*,*Laghu* properties and *TiktaRasa* dominant *Dravya* absorbs the *Dravansha* (liquid) of *VidgdhaPachakaPitta*. In formulated drug *Kashaya* rasa dominant *Dravyas* are *Haritaka*, *Vibhitaki* and *Nimba*. *TiktaKashyaRasas* are *Kaphapittashamak*.

*Triphala*is mild laxative and *Anulomna* due to its *Prabhava*. *Madhu* as a *PrakshepDravya*, due to *SheetaVirya*, *Ruksha*, *Kashaya* and *MaduraRasa* is also *Kaphapittashamak*. Due to *Sandhana* property of *Madhu* it is also effective in complication of *Amlapitta* like gastric ulcer etc. by the analysis of ingredients of *Patoladikwatha* it is found that most of its ingredients are *Kaphapittashamak* which is just antagonistic of causative factors of *Amlapitta* and increasing the *Agni*. Due to increase in *Agni* proper digestion of *Ahara* will be possible and *NiramaPitta* will be produced not *VidgdhaPitta*. As a result of it *Amalpitta*Vyadhi will not be produced.

Conclusion

Clinical study reveals that both drugs*Khandamalki* and *PatoladiKwatha* showed highly significant results. In group C the results were better than group A & B. Because the combination of both drugs had been proved more effective in patients than single one. Hence, it can be concluded that the *Amlapitta* is better managed by administration of both drug without any side effect and *"Kaphapittaharovidhi*" is beneficial in the management of*Amlapitta* disease.

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