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A CONCEPTUAL STUDY OF AUSHADHA SEVANA KAALA W.S.R. TO PRATISHYAYA IN APPLICATION OF VYOSHADHI VATI FOR COMPARISON OF ADHOBHAKTA AND NISHI KAALA

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ABSTRACT

The 21st century, with its continuous changing life styles, Environment and dietary habits has made man as main victim of many diseases. Among those pratishyaya is one of the most common urdhwa Jatrugatavyadhi. According to different Acharyas medicine should administer for urdhwa Jatrugata vyadhis at Nishi and Adhobhakta kaala. To know the drug delivery system depending upon time of administration,I wanted to be conduct clinical study in Nishi kaala and Adhobhakta kaala with drug Vyoshadhi vati in Pratishyaya.

This research study was planned to selected a urdhva jaturgatha vikara pratishyaya for which vyoshadi vati has been taken and effect of aushadha and aushashada sevana kala on pratishyaya was observed.

KEYWORDS: Kaala, Dominance of kaala, Bhesaja and Kaala relation

INTRODUCTION

Kaala is one of the nine kaarana Dravya, which are Responsible for the origin (initiation) and maintenance of universe and hence for human life. Every event in the nature and in human life is deeply affected by kaala. Ayrveda emphasis on the manifold affects of kaala on human life. Dominance of kaala is revealed in all the event; Such as birth, Growth, formation of the seasons, management of diseases, collection of the drugs Etcetera.

कालबुध्दीन्द्रियार्थानां योगो मिथ्या न चाति च।
द्वव्याश्रयाणां व्यधीनां त्रिविधो हेतु संग्रह:॥
(च.सू.१/५४)

The causes of the diseases relating to both (mind and Body) are 3 fold causes – Wrong utilization, non-utilization and excessive utilization of Time, Mental faculties and objects of sense organs.

The Bhesaja and Kaala relation is explored in various shades by the Ancient Acharyas Bhaisaiya kaala exemplify the applicability of concept of kaala in the management of diseases. Acharya Vagbhata has stated that-

कालो भैषज्ययोगकृत ।
(अ.सं.सू.१/४५)

Which means kaala fulfills the aim of administration of bhesaja. Aushada sevana kaala is the time for the administration of the drug. It is the type of Aavasthika kaala. It impacts on efficacy of the drug. Drug exhibits different action when administered in different Aushadha sevana kaala. In optimum digestion and metabolism in a healthy individual is attributed to Agni. The Hypo activity of Agni produces majority of disorders like Agimandhya, Jvara, Atisara and Grahani Etcetera. The rate of metabolism of Bhesaja by Agni is affected by factors – food, type

of bhesaja used, time of Administration and sarira avastha. Kaala and Agni both have been accorded the status of parinamakara bhavas by the Acharyas. Thus a thorough knowledge of Agni –Bhesaja interaction in the Bhesajya kaala will help in the quick action with reduced dose and prolonged duration of the medication used.

According to predominance of Dosha at the various stages of the disease, same drug can be administered in different aushadha sevana kaala to achieve desired effect. The medicines given at improper time are not useful.Actual aim of Aushadha sevana kaala is to provide the fulfillment towards desired action of drug administration in patient in order to produce Dhatusatmya.Proper times for the administration of medicines.

यञ्ज्यादन्नादौ मध्येऽन्ते कवलान्तरे।
ग्रासेग्रासे मुहुः सान्नं सामुद्गं निशिचौषधम॥
(अ.हृ.सू.१३/३७)

Number of Bhesaja kaala are ten as per Caraka, Susruta, Astangahrdaya and kasyapa; Eleven as per Astanga sangraha; Five as per sharangadhara and Bhava prakasha.

Method and material :

CLINICAL STUDY

The exponents of Ayurveda possessed keen intellect and applied theconcepts formulated, in the management and treatment of the diseased. Concept ofBhaisajya Kala is one of the gems of the treasure, which was utilised by them toachieve Bhaisajya Prayoga Paryapti. To recapitulate the concepts discussed, both theentities Kala and Agni are very important as far as Parinamana is concerned, formerbeing *non material* and the latter *material causes* of the same. A Bhisak is

atfreedom, to employ both Kala and Agni while establishing Dhatu Samya from thestate of Dhatu Vaismya so that they *symbiotically enhance* the activity of Bhesaja.

The time of administration of Bhesaja (Bhaisajya Kala) is appropriate for achievingthe target.

The main hypothesis was –

- Nishi Aushadha sevana kaala is more effective than Adhobhakta kaala in the management of disease pratishyaya.

To validate the hypothesis clinically, it was planned to selected a urdhva jaturgatha vikara pratishyaya for which vyoshadi vati has been taken and effect of aushadha and aushashada sevana kala on pratishyaya was observed.

OBJECTIVES :

- To study the concept of Aushadha sevana kaala and comparative study of Vyoshadhi Vati in Adhobhakta, Nishi kaala W.S.R. to Pratishyaya.
- To collect the all literary reviews of Aushadha sevana kaala, pratishyaya and vyoshadhivati
- To compare the effectiveness of vyoshadhivati in pratishyaya in Adhobhakta and Nishi kaala.

MATERIALS AND METHODS :

1. Compile the review of literature
   Patients : Patients attending OPD & IPD sections of BP dept. of our college , who fulfilled the diagnostic criteria of selection were included for this study.
2. Criteria for Selection of Patients :The patients having classical signs and symptoms of Pratishyaya and free from other associated complications were selected irrespective of Sex, Age, Caste etc.
4. Proforma :A special research proforma was prepared to maintain the records of findings during case taking.

5. The interventional Phase :All the selected patients were randomly divided into two groups, the groupswere made according to the time of administration of drug as follows:

Vyoshadhivati will be administered as per below given chart:

Details	Group – A	Group – B
Drug	Vyoshadhi vati	Vyoshadhi vati
Time of Administration	Adhobhakta kaala	Nishi kaala
Matra	3 gr.per day	3 gr.per day
Anupana	Luke Warm Water	Luke Warm Water
Number of patients	30	30

(Source:Primary Data)

6. Criteria for Assessment of Results

The results of treatment were assessed on the basis of classical signs and symptoms of the disease. For statistical analysis, multidimensional scoring system was adopted and was checked before and after treatment which was as below :

The Assessment of signs and Symptoms :

Signs and Symptoms	Grading				
	1	2	3	4	5
Kshavathu	No sneezing	1-10 sneezing	10-15 sneezing	15-20 sneezing	>20 sneezing
Nasavarodha	No Obstruction	Mild Obstruction	Moderate Obstruction.Inhalation and Exhalation to be supplemented with mouth breathing	Complete Blockage with total mouth Breathing	
Nasasrava	No Discharge	Feeling of running nose without visible fluid	Occasional running nose with visible fluid	Running nose which needs moping but controllable	Severe rhinorrhea with copious flui needs continuously moped
Kandu	No Itching	Mild	Moderate	Severe	
Kasa	No Cough	Occasional cough	Moderate cough	Complete loss of interest in food	Continuous cough with throt and chest pain
Sirah Shoola	No	Mild	Moderate	Severe patient restless and able to carry routine work with great difficulty	Severe cripping headache that redness patient bed ridden
Bhutwa bhutwa	No attacks	Period between attacks >2days	Period between attacks 1-2days	Period between attacks 12-24 hours	Attacks within 12 hours
Redness around nose	No	Mild	Moderate	Severe	

(Source:Primary Data)

Criteria for assessing total effects :

- Complete relief – 100%
- Markedly improvement – > 75% but < 100%
- Moderate improvement – Between 51 to 75%
- Mild improvement - Between 25 to 50%
- No relief - < 25%

OBSERVATIONS AND RESULTS

(In the clinical study of the patients of Pratishyaya)

1. **Incidence of Age:**

Sr. No.	Age Group	Group A		Group B		Total	
		Count	**%**	**Count**	**%**	**Count**	**%**
1	18 – 20	3	10.00%	4	13.33%	7	11.67%
2	21 – 25	10	33.33%	14	46.67%	24	40.00%
3	26 – 30	7	23.33%	7	23.33%	13	23.33%
4	31 – 35	7	23.33%	4	13.33%	11	18.33%
5	36 – 40	3	10.00%	1	3.33%	4	6.67%
	Total	**30**	**100%**	**30**	**100%**	**60**	**100%**

(Source:Primary Data)

In group A, 3 patients (10%) were having age between 18 – 20 years, 10 patients (33%) were having age between 21 – 25 years. There were 7 patients (23%) each from age group 26 – 30 years and 31 – 35 years while 3 patients (10%) belonged to age group 36 – 40 years.

In group B, 4 patients (13%) were with age between 18 - 20 years. In age group 21 - 25, there were maximum 17 patients (47%). 7 patients (23%) were from age group 26 – 30 years, 4 patients (13%) were from age group 31 – 35 while 1 patient (3%) was having age between 36 – 40 years.

2. Incidence of Sex

Sr.No.	Sex	Group A		Group B		Total	
		Count	%	Count	%	Count	%
1	Male	14	46.67%	12	40.00%	26	43.33%
2	Female	16	53.33%	18	60.00%	34	56.67%

(Source:Primary Data)

In group A, 14 patients (47%) were male while 16 patients (53%) were female. In group B, 12 patients (40%) were male while 18 patients (60%) were female.

3. Incidence of Marital status

Sr.No.	Marital status	Group A		Group B		Total	
		Count	%	Count	%	Count	%
1	Married	18	60.00%	14	46.67%	32	53.33%
2	Unmarried	12	40.00%	16	53.33%	28	46.67%

(Source:Primary Data)

In group A, 18 patients (60%) were married while 12 patients (40%) were unmarried. In group B, 14 patients (47%) were married while 16 patients (53%) were unmarried.

Statistical analysis of different parameters:-

As grading used for the parameters were ordinal in nature,"Wilcoxon Signed Rank test" is used for intra-group comparison. (i.e. before and after treatment of a group) while for inter-group comparison,(i.e. for comparing two groups with each other) "Mann-Whitney U test" is used.

We have tested hypothesis for each parameter and result is interpreted accordingly. The level of significance is kept at 0.05. Proper summary statistics like mean, median, S.D., IQR (Inter Quartile Range) are provided along with graphical and diagrams.

1. <u>Kshavathu</u>

Using one tailed Wilcoxon signed rank test, to test the hypothesis –

H0 : Median reduction in Kshavathu score after treatment is zero.

H1 : Median reduction in Kshavathu score after treatment is greater than zero.

Kshavathu	Mean score			Median diff.	IQR of diff. (Q3 - Q1)	Sample Size	Wilcoxon signed rank test (T+)	p-Value
	B.T	21st day	diff					
Group A	3.57	1.5	2.07	2	0 (2 – 2)	30	465	< 0.001
Group B	3.63	1.07	2.57	3	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in kshavathu score at 21st day of treatment (Mdn diff. = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant reduction in Kshavathu for Group A in 21 days.** For group B, the median reduction in kshavathu score (Mdn diff. = 3) at 21st day is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant reduction in kshavathu for Group B in 21 days.**

Kshavathu	Mean score			Median diff.	IQR of diff. (Q3 –Q1)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	B.T	A.T	diff					
Group A	3.57	1.17	2.40	2	1 (3 – 2)	30	465	< 0.001
Group B	3.63	1.0	2.56	3	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in kshavathu score after treatment (Mdn diff. = 2) is significant (P-value < 0.001) at 5% level of significance.**i.e. it can be said that There is significant reduction in Kshavathufor Group A.** For group B, the median reduction in kshavathu score (Mdn diff. = 3) after treatment is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant reduction in kshavathu for Group B.**

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H0: Reduction in kshavathu score for group A and group B are equal (equally distributed)

H1: Reduction in kshavathu score for group A and group B are not equal (not equally distributed)

B.T. - 21st Day	Median difference |BT–D21|	Mean of difference |BT–D21|	S.D. of difference |BT–D21|	Mann-Whitney U statistic	P- Value
Group A	2	2.07	0.520	250.5	< 0.001
Group B	3	2.57	0.504		

(Source:Primary Data)

At 21st day, Distribution of "reduction in kshavathu score" for group A and group B was significantly different. (p –value < 0.001) with reduction for group A (Mean = 2.07, S.D. = 0.520) and that for group B (Mean = 2.57, S.D. = 0.504) Thus over first 21 days, treatment B was observed to be more effective in reduction of kshavathu as compared to treatment A.

B.T – A.T.	Median difference |bef–aft|	Mean of difference |bef–aft|	Mann-Whitney U statistic	P- Value
Group A	2	2.4	375	0.203
Group B	3	2.57		

(Source:Primary Data)

Distribution of "reduction in kshavathu score" for group A and group B was not significantly different. (p –value = 0.203) with reduction for group A (Mean = 2.40, S.D. = 0.498) and that for group B (Mean = 2.57, S.D. = 0.504) Thus treatment A and treatment B can be considered as equally effective in reduction of kshavathu.

2. Nasavarodh

Nasavarodh	Mean score			Median diff.	IQR of diff. (Q3 – Q1)	Sample size	Wilcoxon rank test (T+)	P - Value
	B.T	21 st day	diff					
Group A	3.47	1.43	2.03	2	0 (2 – 2)	30	465	< 0.001
Group B	3.57	1.07	2.50	2.5	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

Using one tailed Wilcoxon signed rank test, to test the hypothesis –

H0: Median reduction in Nasavarodh score before and after treatment is zero.

H1: Median reduction in Nasavarodh score before and after treatment is greater than zero.

For group A, the median reduction in nasavarodh score (Mdn diff = 2) at 21st day is significant (P-value < 0.001) at 5% level of significance. i.e. it can be said that there is significant reduction in Nasavarodh for

Group A in 21 days. For group B, the median reduction in nasavarodh score (Mdn diff = 2.5) at 21st day is significant (P-value < 0.001) at 5% level of significance. i.e. it can be said that there is significant reduction in nasavarodh for Group B in 21 days.

Nasavarodh	Mean score			Median diff.	IQR of diff. (Q3 –Q1)	Sample size	Wilcoxon signed rank test (T+) B.T	P - Value A.T
	B.T	A.T	diff					
Group A	3.47	1.13	2.34	2	1 (3 – 2)	30	465	< 0.001
Group B	3.57	1.07	2.50	2.5	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

Using one tailed Wilcoxon signed rank test, to test the hypothesis –

H0: Median reduction in Nasavarodh score before and after treatment is zero.

H1: Median reduction in Nasavarodh score before and after treatment is greater than zero.

For group A, the median reduction in nasavarodh score (Mdn diff = 2) after treatment is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that there is significant reduction in Nasavarodh for Group A.** For group B, the median reduction in nasavarodh score (Mdn diff = 2.5) after treatment is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that there is significant reduction in nasavarodh for Group B.**

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H0 : Reduction in nasavarodh score for group A and group B are equal (equally distributed)

H1 : Reduction in nasavarodh score for group A and group B are not equal(not equally distributed)

B.T. –21st Day	Median difference |BT–D21|	Mean of difference |BT–D21|	S.D. of difference |BT–D21|	Mann- Whitney U statistic	P- Value
Group A	2	2.03	0.490	262.5	0.001
Group B	2.5	2.50	0.509		

(Source:Primary Data)

At 21st day, Distribution of "reduction in nasavarodh score" for group A and group B was significantly different (p –value = 0.001) with reduction in group A (Mean = 2.03, S.D. = 0.490) and that of group B (Mean = 2.50, S.D. = 0.509). Thus **treatment B can be considered as more effective in reduction of nasavarodh as compared to treatment over first 21 days.**

Group	Median difference |bef–aft|	Mean of difference |bef–aft|	S.D. of difference |bef–aft|	Mann-Whitney U statistic	P- Value
Group A	2	2.33	0.479	375	0.197
Group B	2.5	2.50	0.509		

(Source:Primary Data)

Distribution of "reduction in nasavarodh score" for group A and group B was not significantly different (p –value = 0.197) with reduction in group A (Mean = 2.33, S.D. = 0.479) and that of group B (Mean = 2.50, S.D. = 0.509). Thus both treatment A and treatment B can be considered as equally effective in reduction of nasavarodh.

3. Nasasrava

Using one tailed Wilcoxon signed rank test, to test the hypothesis –

H0 : Median reduction in Nasasrava score before and after treatment is zero.

H1 : Median reduction in Nasasrava score before and after treatment is greater than zero.

Nasasrava	Mean score			Median diff.	IQR of diff. (Q3 – Q1)	Sample size	Wilcoxon signed rank test (T+) B.T	P - Value
	B.T	21st day	diff					
Group A	3.50	1.43	2.07	2	0 (2 – 2)	30	465	< 0.001
Group B	3.53	1.10	2.43	2	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in nasasrava score (Mdn diff = 2) at 21st day is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant reduction in Nasasrava for Group A.** For group B, the median reduction in nasasrava score at 21st day (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant reduction in nasasrava for Group B.**

Nasavarodh	Mean score			Median diff.	IQR of diff. (Q3 –Q1)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	B.T	A.T	diff					
Group A	3.50	1.10	2.40	2	1 (3 – 2)	30	465	< 0.001
Group B	3.53	1.10	2.43	2	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in nasasrava score (Mdn diff = 2) after treatment is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant reduction in Nasasrava for Group A.** For group B, the median reduction in nasasrava score after treatment (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant reduction in nasasrava for Group B.**

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H0 : Reduction in nasasrava score for group A and group B are equal (equally distributed)

H1 : Reduction in nasasrava score for group A and group B are not equal(not equally distributed)

B.T. –21st Day	Median difference |BT–D21|	Mean of difference |BT–D21|	S.D. of difference |BT–D21|	Mann-Whitney U statistic	P- Value
Group A	2	2.07	0.520	304.5	0.001
Group B	2	2.43	0.504		

(Source:Primary Data)

At 21st day, Distribution of "reduction in nasasrava score" for group A (Mean = 2.07, S.D. = 0.520) and group B (Mean = 2.43, S.D. = 0.504) was significantly different (p –value = 0.010). Thus **over 21 days,treatment B can be considered as more effective in reduction of nasasrava as compared to treatment A.**

Group	Median difference |bef–aft|	Mean of difference |bef–aft|	S.D. of difference |bef–aft|	Mann-Whitney U statistic	P- Value
Group A	2	2.40	0.498	435	0.802
Group B	2	2.43	0.504		

(Source:Primary Data)

Distribution of "reduction in nasasrava score" for group A (Mean = 2.40, S.D. = 0.498) and group B (Mean = 2.43, S.D. = 0.504) was not significantly different (p –value = 0.802). Thus **both treatment A and treatment B can be considered as equally effective in reduction of nasasrava.**

4. <u>Kandu</u>

Using one tailed Wilcoxon signed rank test, to test the hypothesis –

H0 : Median reduction in Kandu score before and after treatment is zero.

H1 : Median reduction in Kandu score before and after treatment is greater than zero.

Kandu	Mean score			Median diff.	IQR of diff. (Q3 – Q1)	Sample size	Wilcoxon rank test (T+)	P - Value
	B.T	21 st day	diff					
Group A	3.60	1.40	2.20	2	0 (2 – 2)	30	465	< 0.001
Group B	3.60	1.10	2.50	2.5	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in kandu score (Mdn diff = 2) at 21st day is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant reduction in Kandu for Group A.**

For group B, the median reduction in kandu score (Mdn diff = 2.5) at 21st day is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant reduction in kandu for Group B.**

Kandu	Mean score			Median diff.	IQR of diff. (Q3 – Q1)	Sample size	Wilcoxon rank test (T+)	P - Value
	B.T	21 st day	diff					
Group A	3.60	1.13	2.47	2	1 (3 – 2)	30	465	< 0.001
Group B	3.60	1.10	2.50	2.5	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in kandu score (Mdn diff = 2) after treatment is significant (P-value < 0.001) at 5% level of significance. **i.e.it can be said that There is significant reduction in Kandu for Group A.** For group B, the median reduction in kandu score (Mdn diff = 2.5) after treatment is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant reduction in kandu for Group B.**

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H0 : Reduction in kandu score for group A and group B are equal (equally distributed)

H1 : Reduction in kandu score for group A and group B are not equal(not equally distributed)

Group	Median difference |bef–aft|	Mean of difference |bef–aft|	S.D. of difference |bef–aft|	Mann-Whitney U statistic	P- Value
Group A	2	2.20	0.484	322.5	0.027
Group B	2.5	2.50	0.509		

(Source:Primary Data)

At 21st day, Distribution of "reduction in kandu score" for group A (Mean= 2.20, S.D. = 0.484) and group B (Mean = 2.50, S.D. = 0.509) was significantly different. (p –value = 0.027) Thus **over 21 days, treatment B can be considered as more effective in reduction of kandu as compared to treatment A.**

Group	Median difference |bef–aft|	Mean of difference |bef–aft|	S.D. of difference |bef–aft|	Mann-Whitney U statistic	P- Value
Group A	2	2.47	0.507	435	0.804
Group B	2.5	2.50	0.509		

(Source:Primary Data)

Distribution of "reduction in kandu score" for group A (Mean = 2.47, S.D. = 0.507) and group B (Mean = 2.50, S.D. = 0.509) was not significantly different. (p –value = 0.804) Thus **both treatment A and treatment B can be considered as equally effective in reduction of kandu.**

Kasa

Using one tailed Wilcoxon signed rank test, to test the hypothesis –

H0: Median reduction in Kasa score before and after treatment is zero.

H1: Median reduction in Kasa score before and after treatment is greater than zero.

Kasa	Mean score			Median diff.	IQR of diff. (Q3 – Q1)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	B.T	21 st day	diff					
Group A	3.53	1.50	2.03	2	0 (2 – 2)	30	465	< 0.001
Group B	3.30	1.03	2.27	2	0.75 (2.75 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in kasa score at 21st day (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e it can be said that There is significant improvement in Kasa for Group A.**For group B, the median reduction in kasa score at 21st day (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant improvement in kasa for Group B.**

Kasa	Mean score			Median diff.	IQR of diff. (Q3 – Q1)	Sample size	Wilcoxon signed rank test (T+)	P - Value A.T
	B.T	A.T	diff					
Group A	3.53	1.13	2.40	2	1 (3 – 2)	30	465	< 0.001
Group B	3.30	1.03	2.27	2	0.75 (2.75 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in kasa score after treatment (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e it can be said that There is significant improvement in Kasa for Group A.** For group B, the median reduction in kasa score after treatment (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance.**i.e. it can be said that There is significant improvement in kasa for Group B.**

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H0: Reduction in kasa score for group A and group B are equal (equally distributed)

H1: Reduction in kasa score for group A and group B are not equal(not equally distributed)

B.T. –21st Day	Median difference |BT–D21|	Mean of difference |BT–D21|	S.D. of difference |BT–D21|	Mann-Whitney U statistic	P- Value
Group A	2	2.03	0.414	353	0.046
Group B	2	2.27	0.450		

(Source:Primary Data)

At 21st day, distribution of "reduction in kasa score" for group A and group B was significantly different (p –value = 0.046) with score reduction for group A (Mean = 2.03, S.D. = 0.414) and that of group B (Mean = 2.27, S.D. = 0.450). Thus, **over 21 days, treatment B can be considered as more effective in improvement of kasa as compared to treatment A.**

Group	Median difference |bef–aft|	Mean of difference |bef–aft|	S.D. of difference |bef–aft|	Mann-Whitney U statistic	P- Value
Group A	2	2.40	0.498	510	0.281
Group B	2	2.27	0.450		

(Source:Primary Data)

Distribution of "reduction in kasa score" for group A and group B was not significantly different (p –value = 0.281) with score reduction for group A (Mean = 2.40, S.D. = 0.498) and that of group B (Mean = 2.27, S.D. = 0.450). Thus, **treatment A and treatment B can be considered as equally effective in improvement of kasa.**

6. Sirahshoola

Using one tailed Wilcoxon signed rank test, to test the hypothesis –

H0: Median reduction in Sirahshoola score before and after treatment is zero.

H1: Median reduction in Sirahshoola score before and after treatment is greater than zero.

Sirahshoola	Mean score			Median diff.	IQR of diff. (Q3 – Q1)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	B.T	21 st day	diff					
Group A	3.50	1.57	1.93	2	0 (2 – 2)	30	465	< 0.001
Group B	3.40	1.03	2.37	2	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in sirahshoola score at 21st day (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e it can be said that There is significant improvement in Sirahshoola for Group A.** For group B, the median reduction in sirahshoola score at 21st day (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant improvement in sirahshoola for Group B.**

Sirahshoola	Mean score			Median diff.	IQR of diff. (Q3 –Q1)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	B.T	A.T	diff					
Group A	3.50	1.10	2.40	2	1 (3 – 2)	30	465	< 0.001
Group B	3.40	1.03	2.37	2	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in sirahshoola score after treatment (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance.**i.e it can be said that There is significant improvement in Sirahshoola for Group A.** For group B, the median reduction in

sirahshoola score after treatment (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant improvement in sirahshoola for Group B.**

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H0: Reduction in sirahshoola score for group A and group B are equal (equally distributed)

H1: Reduction in sirahshoola score for group A and group B are not equal(not equally distributed)

B.T. –21st Day	Median difference |BT–D21|	Mean of difference |BT–D21|	S.D. of difference |BT–D21|	Mann-Whitney U statistic	P- Value
Group A	2	1.93	0.254	266	< 0.001
Group B	2	2.37	0.490		

(Source:Primary Data)

At 21st day, distribution of "reduction in sirahshoola score" for group A and group B was significantly different (p –value < 0.001) with score reduction for group A (Mean = 1.93, S.D. = 0.254) and that of group B (Mean = 2.37, S.D. = 0.490). Thus, **over 21 days, treatment B can be considered as more effective in improvement of sirahshoola as compared to treatment A.**

Group	Median difference |bef–aft|	Mean of difference |bef–aft|	S.D. of difference |bef–aft|	Mann-Whitney U statistic	P- Value
Group A	2	2.40	0.563	470.5	0.731
Group B	2	2.37	0.490		

(Source:Primary Data)

Distribution of "reduction in sirahshoola score" for group A and group B was not significantly different (p –value = 0.731) with score reduction for group A (Mean = 2.40, S.D. = 0.563) and that of group B (Mean = 2.37, S.D. = 0.490). Thus, **treatment A and treatment B can be considered as equally effective in improvement of sirahshoola.**

7. <u>Bhutwa bhutwa</u>

Using one tailed Wilcoxon signed rank test, to test the hypothesis –

H0: Median reduction in Bhutwa bhutwa score before and after treatment is zero.

H1: Median reduction in Bhutwa bhutwa score before and after treatment is greater than zero.

Bhutwa bhutwa	Mean score			Median diff.	IQR of diff. (Q3 – Q1)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	B.T	21 st day	diff					
Group A	3.67	1.50	2.17	2	0 (2 – 2)	30	465	< 0.001
Group B	3.47	1.03	2.43	2	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in bhutwa bhutwa score at 21st day (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance **i.e it can be said that There is significant improvement in Bhutwa bhutwa for Group A.** For group B, the median reduction in bhutwa bhutwa score at 21st day (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant improvement in bhutwa bhutwa for Group B.**

Bhutwa bhutwa	Mean score			Median diff.	IQR of diff. (Q3 –Q1)	Sample size	Wilcoxon signed rank test (T+)	P - Value A.T
	B.T	A.T	diff					
Group A	3.67	1.10	2.57	2	1 (3 – 2)	30	465	< 0.001
Group B	3.47	1.03	2.43	2	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in bhutwa bhutwa score after treatment (Mdn diff = 3) is significant (P-value < 0.001) at 5% level of significance. **i.e it can be said that There is significant improvement in Bhutwa bhutwa for Group A.** For group B, the median reduction in bhutwa bhutwa score after treatment (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant improvement in bhutwa bhutwa for Group B.**

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H0: Reduction in bhutwa bhutwa score for group A and group B are equal (equally distributed)

H1: Reduction in bhutwa bhutwa score for group A and group B are not equal(not equally distributed)

B.T. –21st Day	Median difference |BT–D21|	Mean of difference |BT–D21|	S.D. of difference |BT–D21|	Mann-Whitney U statistic	P- Value
Group A	2	2.17	0.461	336.5	0.042
Group B	2	2.43	0.504		

(Source:Primary Data)

At 21st day, distribution of "reduction in bhutwa bhutwa score" for group A and group B was significantly different (p –value = 0.042) with score reduction for group A (Mean = 2.17, S.D. = 0.461) and that of group B (Mean = 2.43, S.D. = 0.504). Thus, **over 21 days, treatment B can be considered as more effective in reduction of bhutwa bhutwa as compared to treatment A.**

Group	Median difference |bef–aft|	Mean of difference |bef–aft|	S.D. of difference |bef–aft|	Mann-Whitney U statistic	P- Value
Group A	3	2.57	0.568	516.5	0.263

Group B	2	2.43	0.504		

(Source:Primary Data)

Distribution of "reduction in bhutwa bhutwa score" for group A and group B was not significantly different (p –value = 0.263) with score reduction for group A (Mean = 2.57, S.D. = 0.568) and that of group B (Mean = 2.43, S.D. = 0.504). Thus, **treatment A and treatment B can be considered as equally effective in reduction of bhutwa bhutwa.**

8. Redness around nose

Using one tailed Wilcoxon signed rank test, to test the hypothesis –

H0: Median reduction in Redness around nose score before and after treatment is zero.

H1: Median reduction in Redness around nose score before and after treatment is greater than zero.

Redness around nose	Mean score			Median diff.	IQR of diff. (Q3 – Q1)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	B.T	21 st day	diff					
Group A	3.57	1.40	2.17	2	0 (2 – 2)	30	465	< 0.001
Group B	3.43	1.00	2.43	2	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in redness around nose score at 21st day (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e it can be said that There is significant improvement in Redness around nose for Group A.** For group B, the median reduction in redness around nose score at 21st day (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant improvement in redness around nose for Group B.**

Redness around nose	Mean score			Median diff.	IQR of diff. (Q3 –Q1)	Sample size	Wilcoxon signed rank test (T+)	P - Value
	B.T	A.T	diff					
Group A	3.57	1.10	2.47	2	1 (3 – 2)	30	465	< 0.001
Group B	3.43	1.00	2.43	2	1 (3 – 2)	30	465	< 0.001

(Source:Primary Data)

For group A, the median reduction in redness around nose score after treatment (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e it can be said that There is significant improvement in Redness around nose for Group A.** For group B, the median reduction in redness around nose score after treatment (Mdn diff = 2) is significant (P-value < 0.001) at 5% level of significance. **i.e. it can be said that There is significant improvement in redness around nose for Group B.**

Comparative Analysis of Groups:

Using Mann-Whitney U test, to test the hypothesis –

H0: Reduction in redness around nose score for group A and group B are equal (equally distributed)

H1: Reduction in redness around nose score for group A and group B are not equal(not equally distributed)

B.T. –21st Day	Median difference |BT–D21|	Mean of difference |BT–D21|	S.D. of difference |BT–D21|	Mann-Whitney U statistic	P- Value
Group A	2	2.17	0.461	336.5	0.042
Group B	2	2.43	0.504		

(Source:Primary Data)

At 21 day, distribution of "reduction in redness around nose score" for group A and group B was significantly different (p –value = 0.042) with score reduction for group A (Mean = 2.17, S.D. = 0.461) being greater than that of group B (Mean = 2.43, S.D. = 0.504). Thus, **over 21 days,treatment B can be considered as more effective in reduction of redness around nose as compared to treatment A.**

Group	Median difference |bef–aft|	Mean of difference |bef–aft|	S.D. of difference |bef–aft|	Mann-Whitney U statistic	P- Value
Group A	2	2.47	0.507	465	0.804
Group B	2	2.43	0.504		

(Source:Primary Data)

Distribution of "reduction in redness around nose score" for group A and group B was not significantly different (p –value = 0.804) with score reduction for group A (Mean = 2.47, S.D. = 0.507) being greater than that of group B (Mean = 2.43, S.D. = 0.504). Thus, **treatment A and treatment B can be considered as equally effective in reduction of redness around nose.**

Parameter	Efficacy at 21st Day		Comparative efficacy
	Group A	**Group B**	
kshavathu	Significant	Significant	Group B
nasavarodha	Significant	Significant	Group B
nasasrava	Significant	Significant	Group B
kandu	Significant	Significant	Group B
kasa	Significant	Significant	Group B
sirahshoola	Significant	Significant	Group B
Bhutwa bhutwa	Significant	Significant	Group B
redness around nose	Significant	Significant	Group B

Parameter	Efficacy After treatment		Comparative efficacy
	Group A	**Group B**	
kshavathu	Significant	Significant	Equally Effective
nasavarodha	Significant	Significant	Equally Effective
nasasrava	Significant	Significant	Equally Effective
kandu	Significant	Significant	Equally Effective
kasa	Significant	Significant	Equally Effective
sirahshoola	Significant	Significant	Equally Effective
bhutwa bhutwa	Significant	Significant	Equally Effective
redness around nose	Significant	Significant	Equally Effective

(Source:Primary Data)

All 8 assessment parameters –were considered for evaluating overall effect of therapy. The criteria for assessment of overall effect of therapy are:-

Overall Effect (patient wise)	Criteria
Complete relief	100% relief (relief from all 8 signs & symptoms)
Marked improvement	75% - <100% relief (relief from 6 – 7 symptoms)
Moderate improvement	50% - < 75% relief (relief from 4 – 5 symptoms)
Mild improvement	25% - < 50% relief (relief from 2 – 3 symptoms)
No relief	< 25% relief in signs and symptoms (relief less than 2 symptoms)

(Source:Primary Data)

Distribution of patients according to relief:

AT 21ST Day Overall Effect (patient wise)	No. of patients			
	Group A		Group B	
	Count	%	Count	%
Complete relief	0	0.00%	23	76.67%
Marked improvement	6	20.00%	6	20.00%
Moderate improvement	15	50.00%	0	0.00%
Mild improvement	8	26.67%	1	3.33%
No relief	1	3.33%	0	0.00%

(Source:Primary Data)

At 21st day, For group A, Out of 30 patients, 6 patients (20%) were markedly improved, 15 patients (50%) showed moderate improvement 8 patient (27%) were mildly improved while 1 patient (3%) had no relief. In group B, 23 patients (77%) were observed with complete relief, 6 patients (20%) were markedly improved while 1 patient (3%) was mildly improved.

After treatment Overall Effect (patient wise)	No. of patients			
	Group A		Group B	
	Count	%	Count	%
Complete relief	15	50.00%	23	76.67%
Marked improvement	12	40.00%	6	20.00%
Moderate improvement	2	6.67%	0	0.00%
Mild improvement	1	3.33%	1	3.33%
No relief	0	0.00%	0	0.00%

(Source:Primary Data)

At the end of the study, for group A, Out of 30 patients, 15 patients (50%) were observed with complete relief, 12 patients (40%) were markedly improved, 2 patients (7%) showed moderate

improvement while 1 patient (3%) was mildly improved. In group B, 23 patients (77%) were observed with complete relief, 6 patients (20%) were markedly improved while 1 patient (3%) was mildly improved

DISCUSSION

In science, it is essential to prove a concept with methods, prior to its acceptance as truth. The ancient research methodology was designed to provide a demonstrative inference of truth with the help of syllogism (Pararthanumana). One of the limbs of the Pancavayava is Nigamana (conclusion), a step prior to the establishment of truth as conclusion, Upanaya (discussion) is mandatory. Discussion is the logical interpretation of the collected literary material and the obtained clinical findings in order to provide the vision of truth in totality. Convincing logically with the help of intellectual reasoning, is also exhalted by Acaryas because without reasoning, perception of truth could be a matter of chance.

Discussion regarding conceptual study:

Mentioned Bhaisajya Kala from the classics, one can very clearly understand that food related Bhaisajya Kala (61.54%) are described predominantly in contrast to Kala (23.08%) and frequency(15.39%) related Bhaisajyakala. According to the modern medicine, food is proved to affect the bioavailability of a drug. Thus a proper sequential arrangement of drug and food is essential in order to obtain optimum therapeutic results according to the allied sciences. Hence the use of the medicines either along with food, or on an empty stomach is advocated for enhancing the potency of the drug.

In Ayurveda, Pancamahabhuta Siddhanta is the basis for the majority of the concepts. According to the Siddhanta, pancabhutatamakedehe Hi Aharaha pancabhautikah (C. Su. 15), which means the Sarira is a conglomeration of the five protoelements and the food is meant to sustain the body is alsopancabhautic in composition. Bhesaja is not an exception so both Bhesaja and Ahara share the same basic elemental composition. Bhesaja act by virtue of their potency (Cakrapani on C. Su. 2/17) and Ahara act on the basis of the Rasa. Hence Bhesaja and Ahara are used by the Acarya by means of Yukti in order to achieve the expected therapeutic activity.

The potency of a Bhesaja given is not tolerated especially by the old, women, debilitated patients. In such cases it becomes a need to reduce the efficacy of the Bhesaja by giving it in the Adhobhaktakala, where Anna Bhesaja interaction will occur and the potency of the Bhesaja will be altered to a great extent and hence can be tolerated by the above mentioned patients.

Salient features of Bhaisajya Kala :

In all the Bhaisajya Kala, the Bhesaja is to be given orally. The time of intake of food is used as a variable in all the Kalas. The sequence of Anna and Bhesaja is used as Karana to achieve expected therapeutic activity (Karya) in a Vyadhita. The Udirana of Dosas, status of Agni i.e. Sariravastha at a particular Kala serves as a Nimitta Karana for Bhaisajya Prayoga Paryapti.

Bhaisajyakala and other factors :

To recapitalate, nine factors of Vyadhita - Dusya, Desa, Agni, Satva, Bala, Prakrti, Vaya, Linga and Ahara influence the choice of Bhaisajyakala directly. The significance of examination of these factors is pointed in Astangahrdaya (Su. 12/67that a physician who proceeds to Cikitsa Karma, after thorough observation of the factors, never goes astray from his aim of eradicating the diseae.

Bhaisajya Kala and **chronotherapy** are both based on rhythmicity (timed movements in human beings). In chronotherapy, the maximum blood level of the drug is optimised in such a manner that its peak activity will match the time of greatest discomfort in patients. The Bhaisajyakala, even though is governed by various factors, one of them is to administer the Bhesaja at the time of dominance of particular Dosa, which is aggravated so as to pacify it. The principles in both the concepts can thus be correlated.

The concept of chronobiology is inherent in Ayurveda. All the rhythms circadian, circamensual and circannual are recognized in Dosas both quantitatively and qualitatively. According to A. H. Su. 1/8, Vayohoratribhuktanam corresponds to the life rhythm (in the childhood, there is dominance of Kapha dosa), circadian rhythm (in the afternoon, there is aggravation of Pitta dosa) and dietary rhythm (at the end of digestion, Vata dosa is dominant). This rhythm is arranged by

the author in a definite sequence i.e. from infradian to ultradian i.e. cycles prevalent for more time to the rhythms of lesser period. In Ayurveda, all physiological and pathological phenomenon depend upon delicate balance of Dosas and to precisely regulate the Dosic biological clocks, regimens were suggested by Acaryas in the from of Dinacarya and Rtucarya. To brief, the chronotherapy could be considered as a part of the whole i.e. Sadaveksa Kala of Caraka. Time of administration of drugs in allied sciences : It is observed that the time of intake of medicine is determined by the symptoms present-emetic drugs are to be given repeatedly, quick action is expected - laxatives are given before breakfast, for prolonged action -antacids are given after meals, because of slow onset of action - Sucralfate is to be given before meal, for increased absorption - thyroxine should be given on empty stomach, to prevent gastric irritation-salicylates are given after food.

Discussion regarding Disease Pratishyaya:

The disease Pratishyaya considerably attracted the ancient physicions, who cited detailed descriptions classifications, symptomtology, complications and management,in the Samhitas. While dealing with the complications of Pratishyaya it has been considered as aprodromal sign of future disease entity. Though the disease in the initial phases is a curable disease but if it attains the chronic phase becomes difficult to treat because of its associated complications. In modern medical system a wide range of antibiotics and decongestants are available. But these drugs have nothing to do with such a chronic condition. (Hirschm JV Antibiotics for common respiratory tract infections in adults-162,256-264). The surgical procedures will lead a lot of complications ranging from bleeding, oro-antral fistula, infra orbital anesthesia to neuralgia and paraesthesia (KB Bhargava, A Short text book of ENT Diseases-188). So it is a matter of prime importance to derive a treatment protocol which helps the patients to overcome this pathetic condition. Although this condition i.e. Jeerna(Dushta) Pratishyaya is described as a poor diagnostic disease in Ayurvedic classics(Su.Ut.24/15) a lot of treatment protocols are described by various Acharyas. Unfortunately proper treatment documentation is not available today regarding this disease. So this problem was selected for the study taking all these points into effective consideration.

In Ayurvedic classics the term Pratishyaya cover a broad spectrum of nasal and Para nasal infections. This disease can occur as a separate entity, symptom of many systemic pathology or

as a complication of other diseases (Ma.Ni.Pur.27/18). Improper management will lead this simple disease to a dangerous and complicated stage called Dushta Pratishyaya (Su.Ut.24/16-17).

While explaining Nidana, Acharya clearly mentioned the allergic factors like dust, fumes, which cause paroxysmal sneezing and rhinorrhoea. Head injury, seasonal variations, suppression of natural urges etc. are other factors which can initiate pathology (Ch.Chi.26/104). The prodromal symptoms like sneezing, heaviness in head etc. are due to the initial body act of removing the pathogens so that a full disease manifestation can be prevented (Su.Ut.24/5).

An over view of Samprapti reveals that vata is the chief factor which initiate the disease manifestation (Su.Ut.24/14). Vitiation of vata can occur by specific Nidana or by Avarana of other Doshas (Ch.Chi.28/206). The disease passes through Amavastha, Pakwavastha and mismanagement of these stages leads to Dushta Pratishyaya (Su.Ut.24/18-20).

Discussion regarding drug Vyoshadi vati:

Drug vyoshadi vati has been taken based on astanga hrdaya and bhava prakasha as it is easily available ,easily preparable and effective incase of pratishyaya.

Discussion regarding materials and methods:

The 60 patients with disease Pratishyaya who are hemodynamically stable individuals of either gender, who fulfilling the inclusion criteria were divided in to 02 group's i. e. 30 in each group

(group-A,group-B).Both the groups treated with Vyoshadi vati but group- A in Adhobhakta kala,group-b in Nishi kala. Assessment was done based on subjective parameters .

Discussion regarding observations and results:

As grading used for the parameters were ordinal in nature,"Wilcoxon Signed Rank test" is used for intra-group comparison. (i.e. before and after treatment of a group) while for inter-group comparison,(i.e. for comparing two groups with each other) "Mann-Whitney U test" is used.

We have tested hypothesis for each parameter and result is interpreted accordingly. The level of significance is kept at 0.05.

Statistical analysis shows that all the symptoms kshavathu, nasavarodha, nasasrava,kandu, kasa, sirah shoola,bhuta bhutwa and redness around nose in all the patients in both the groups improved markedly and are statistically significant at $p<0.05$ after treatment and after follow up.

When compared between the group A and group B all the symptoms kshavathu, nasavarodha, nasasrava,kandu, kasa, sirah shoola,bhuta bhutwa and redness around nose in group B recovered fast than group A which is statically significant.

This change might be due to the effect of aushadha sevana kala the patient who have been under treatment in nishi kala recovered fast than adho bhakta kala.

The efficacy of the drug vyoshadi vati on pratishyaya is more in nishi kala than adho bhakta kala, as per the opinion of astanga hrdaya in urdwa jaturgata vikaras the medicine should be given in nishi kala holds good.

Definetly there is a role of time of administration of drug in particular disease at particular time and the reasons are to be elucidated by further research in changes at micro level observation and bio chemical level.

CONCLUSION

The conclusion of the present study is as under:

1.compiled all the available literature of Aushada sevana kala

2.compiled all the available literature of disease pratishyaya

3.compiled the literature of drug Vyoshadi vati

4.observed the Effect of drug Vyoshadi vati on disease Pratishyaya

5.observed the effectiveness of Adhobhakta kala and Nishi kala in disease Pratishyaya in application of drug Vyoshadi vati

6.observed the Vyoshadi vati was more effect in nishi kala than Adhobhakta kala in Pratishyaya .

7.concluded that Aushada sevana kala played an important role in treating disease Pratishyaya.

8.concluded that Aushada sevana kala played an important role in treating diseases.

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