International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

The Role of Daruharidra as Pramehaghna Karma with Special Reference to Madhumeha

Dr Ankur Saxena[1], Dr. Arun Kumar Pandey[2], Dr Shweta Yadav[3], Dr Shivanshu Agrawal[4], Dr Priya Gupta[5]

[1]Asst. Prof, Dept. of Rog Nidan Evum Vikriti Vijyan, Major S D Singh P G Ayurvedic College And Hospital, Farrukhabad, UP
[2]Assit. Prof. , Dept of Swasthavrita, Major S D Singh P G Ayurvedic Medical College & Hospital, Farrukhabad, UP
[3]Assit. Prof. , Dept of Prasuti Tantra Avun Sri Rog , Major S D Singh P G Ayurvedic Medical College & Hospital, Farrukhabad, UP
[4]Asst. Prof. Dept. of Rog Nidan Evum Vikriti Vijyan, Kalwati Ayurvedic Medical College & Hospital & Research Center, Goraha, Kasganj.UP
[5]Asst. Prof. Dept. of Dept. Of Kriya Sharir, Kalwati Ayurvedic Medical College & Hospital & Research Center, Goraha, Kasganj.UP

ABSTRACT

There are many drugs described in Ayurveda which can be used in the treatment of ,Madhumeha. Sometime different species of that particular drug is sold in market having no therapeutic use or having no record of therapeutic potential under same vernacular name. In this study the drug *Daruharidra* has been selected. The exact botanical source of *Daruharidra* is root of *Berberis aristata* D.C, but more than 13 species of berberis are available throughout Himalayan region ranging from 3,000-13,000ft height. One of it is *Berberis asiatica*, which is considered as a substitute of *B.aristata* but no such scientific work has been done to prove it. Secondly now days due to ban in uprooting of *Daruharidra*, physician has started using stem. So, in this studystem ofboth species is assessed for its efficacy in *Prameha*.

In *Berberis aristata* D.C group 14 patients completed the drug regime, highly significant (P<0.001 relief was seen in *Prabhutamutratrata*(83.47%), *Kar-pad-tal dah*(86.40%) and *Daurbalyata*(62.50%) and postprandial blood sugar was significantly reduced (P<0.05). In this group 14.28% patient markedly improved, 57.14% patients improved and 28.57% patients were in unchanged category.

In *B.asiatica* group 14 patients completed the drug schedule, highly significant(P<0.001) relief was observed in *prabhutamutrata* (59.02%) and *Kar-pad-tal dah*(62.71%) and post-prandial blood sugar level was significantly reduced (P<0.05).As overall effect of drug is concern 07.14% patients controlled,14.28% patients markedly improved,57.14% improved, and 21.42% in unchanged category.

No difference was observed in the therapeutical potential of *Berberis aristata* D.C. and *Berberis asiatica*Roxb.ex.D.C clinically.

As in pharmacological and Clinical study not much difference is observed in both the drugs, but the water soluble extractive and Berberine quantity is higher in *B.asiatica* groups so *B.asiatica* can be used in preparation of Rasanjan and other products.

Key words: Madhumeha, Daruharidra, B. aristate, B. asiatica, pharmacological, analytical and clinical study.

INTRODUCTION

As we move further into the new era, there is a growing fascination with the traditional wisdom of ancient India, perhaps this is because it is based on law of nature that are timeless. Hence it is as relevant to our well-being today as it was thousands of years ago. This is especially true for Ayurveda, the ancient and holistic healing system and the practice of it in India is for over 5000 years.

One of major stumbling block in the wider acceptance of medicinal plant drug is the lack of or inadequacy of standardization of raw drug and contracting forest area has led to the adulteration, substitute and spurious drugs to such extent that many times the correct identity of the original drug mentioned in the Ayurvedic literature has been found to be forgotten totally.

Sometime different species of that particular drug is sold in market having no therapeutic use or having no record of therapeutic potential under same vernacular name for e.g. *Rauwolfia serpentiana* replaced by *R.canescens,Cassia angustifolia* by *C.auriculata,S.Chirata* by *S.angustifolia.*

Keeping above view in mind, in this study the drug*Daruharidra* has been selected. The exact botanical source of *Daruharidra*[1] by various Ayurvedic scholar is root of *Berberis aristata* D.C, but more than 13 species of berberis are available throughout Himalayan region ranging from 3,000-13,000ft height. One of it is *Berberis asiatica*, which is considered as a substitute of *B.aristata* but no such scientific work has been done to prove it. Secondly now days due to ban in uprooting of *Daruharidra*, physician has started using stem. So, in this work both species stem is assessed for its efficacy in *Prameha*. *Daruharidra* has been mentioned or prescribed in *Prameha*since Charka[2]period to Raj Nighantu[3]andit is one of the most important ingredients of ant-diabetic formulation, so it's time to search whether the so-called recommended substitute has same efficacy as genuine drug, moreover to assess role of *Daruharidra*stem in diabetes mellitus, which will help in formatting new formulation for Diabetes. The aim of this study is to compare the efficacy of both species of Berberis (*Daruharidra*) in the management of Diabetes mellitus. And to evaluate the role of *Daruharidra* in *Pramehaghna* formulations.

MATERIALS AND METHOD

Criteria for Selection of Patients

The patients suffering from salient features of *Prameha* and Diabetes mellitus either attending the O.P.D. or admitted in the I.P.D. of Deptt of Dravya Guna and Kayachikitsa, Major S.D. Singh P.G. Ayurvedic Medical College and Hospital, Farrukhabad, U.P. were selected randomly for this present study irrespective of age, sex, caste, occupation, religion etc.

Diagnostic Criteria

Increase in Blood Sugar level either fasting or postprandial or both were the essential criteria for the selection. The known patients of Diabetes mellitus or the patients preliminary diagnosed on the basis of signs and symptoms of the diseases were confirmed by further investigation.

Exclusion Criteria

1) Patients of *Sahaja Madhumeha* (IDDM)
2) Patients complicated with any cardiac problems
3) Patients suffering from anorectal diseases

4) Diabetes mellitus due to other hormonal disturbances like Phaeochromocytoma, Acromegaly, Thyrotoxicosis etc.
5) Diabetes due to side effect of drugs:
    - Diuretics (Thiazide groups)
    - Steroids

Investigations

1) Routine Haematological Examination: Like T.L.C., D.L.C., Hb%, E.S.R. and P.C.V. – to rule out any other pathological condition.
2) Urine Analysis- Routine and Microscopic
3) Stool- Microscopic and Macroscopic
4) Biochemical Examination
    - *Blood Sugar* Fasting and Postprandial
    - *Serum cholesterol*

Drug Administration

Dose:

Group I: Ghan tablet (Stem) of *Berberis aristata*D.C 6gm/day in three divided doses i.e., 4 tablets of 500 mg each.

Group II: Ghan tablet(Stem) of *Berberis asiatica*Roxb.ex.D.C 6gm/day in three divided doses i.e., 4 tablet of 500 mg each.

Anupana: Lukewarm water

Drug Intake: 6 hourly with empty stomach

Duration: 6 weeks.

During this period the strict restriction was kept on regularizing the dietary habits of the patients.

CRITERIA FOR ASSESSMENT

After the completion of the treatment, the results were assessed by adopting the following criteria:

- Improvement in signs and symptoms of disease on the basis of the symptoms score.
- F.B.S. and P.P.B.S. levels
- Serum Cholesterol
- Urine sugar

The indoor patients were examined daily and the outdoor patients weekly and the changes observed in the signs and symptoms were assessed by adopting suitable scoring method and the objective signs by using appropriate clinical tools. The detail assessment of clinical signs and symptoms are discussed below:[4,5]

1) **PrabhutaMutrata (Polyuria)**

Frequency of urine	
▪ 3 – 6 times per day, rarely at night	0
▪ 6 – 9 times per day, 0 – 2 times per night	1
▪ 9 – 12 times per day, 2 – 4 times per night	2
▪ More than 12 times per day, more than 4 times per night	3

2) ipasa (Polydypsia)

▪ Feeling of thirst 7 – 9 times/24 hours, either/or Intake of water 5 – 7 times/24 hours with quantity 1.5 – 2.0 liter/24 hours	0
▪ Feeling of thirst 9 - 11 times/24 hours, either/or Intake of water 7 - 9 times/24 hours with quantity 2.0 - 2.50 liter/24 hours	1
▪ Feeling of thirst 11 – 13 times/24 hours, either/or Intake of water 9 – 11 times/24 hours with quantity 2.50 -3.00 liter/24 hours	2
▪ Feeling of thirst >13 times/24 hours, either/or Intake of water >11 times/24 hours with quantity >3.00 liter/24 hours	3

3) Kshudha (Appetite)

▪ 2 main meals + 1 breakfast	0
▪ Feeling of hunger after 6 hours of food	1
▪ Feeling of hunger after 4 hours of food	2
▪ Feeling of hunger after 2 hours of food	3

4) Abhyavaharana Shakti (Hunger)

▪ Person taking food in excessive quantity twice in a day	0
▪ Person taking food in normal quantity twice in a day	1
▪ Person taking food in moderate quantity twice in a day	2
▪ Person taking food in less quantity twice in a day	3
▪ Person taking food in less quantity once in a day	4
▪ Person not at all taking food	5

5) Kara-Pada-Tala-Daha/Supti (Neuropathy)

▪ No Daha	0
▪ Kara-pada-tala-daha/Suptiincontineous	1
▪ Kara-pada-tala-daha/Supticontineous but not severe	2
▪ Kara-pada-tala-daha/Supticontineous and severe	3

6) Avila Mutrata (Turbidity)

Absence of albumin in urea	0
Present with +	1
Present with ++	2
Present with +++	3

7) Mutramadhurya (Glycosuria)

▪ Absence of Glucose in urine	0
▪ <0.5% Glucose in urine	1
▪ 0.5 - 1.0% of Glucose in urine	2
▪ 1.0 – 2.0% of Glucose in urine	3
▪ >2.0% Glucose in urine	4

8) Dourbalyata (Weakness)

▪ Can do routine exercise/work	0
▪ Can do moderate exercise with hesitancy	1
▪ Can do mild exercise only, with difficulty	2
▪ Can not do mild exercise too	3

9) Alasya/Utsahahani (General Debility)

▪ No Alasya (doing satisfactory work with proper vigor and in time)	0
▪ Doing satisfactory work/late initiation, like to stand in comparison to walk	1
▪ Doing unsatisfactory work/late initiation, like to sit in comparison to stand	2
▪ Doing little work very slow, like to lie down in comparison to sit.	3
▪ Don't want to do work/no initiation, like to sleep in comparison to lie down	4

10) Shula (Joint Pain)

▪ No pain	0
▪ Pain in joint, routine movements normal	1
▪ Pain in joint, slight limitations of movements	2
▪ Pain in joint, limitations of movements with reduced activity.	3

11) Pindiko-udveshatan (Cramps)

▪ No cramps	0
▪ Cramps after walking more than 1 km.	1
▪ Cramps after walking	2
▪ Cramps after walking ½ km	3
▪ Inability in walking even ½ km	4

Statistical Analysis: Mean, percentage relief, S.D., S.E., 't' an 'p' values were calculated. Paired 't' test was used for calculating the 't' value in the paired data.

Assessment of Overall Effect of The Therapy

1) Control of the disease: The patient whose Fasting and Postprandial blood sugar level came down to normal limits and complete relief in all the signs and symptoms.
2) Markedly improved: Blood sugar relief percent above 50% and above 75% relief in signs and symptoms.
3) Improved: Blood sugar relief percent less than 50% and more than 25% relief in signs and symptoms.
4) Unchanged: No reduction in blood sugar level and less than 25% relief in signs and symptoms.

RESULT

A) ANALYTICAL STUDY

Both the tablet under taken for the present study were analyzed by employing various parameters as mentioned in materials and methods *B.aristata* and *B.asiatica* stem, the raw material were also estimated for berberine content and water soluble extract. Data evolved has been presented here. The analytical data of physio-chemical analysis of the ghana tablet samples has been presented in table 1.

Table –1 Analytical data of *Berberis aristata*&*Berberis asiatica* Ghana tablet

No.	Parameters	Sample	
		B.aristata	*B.asiatica*
1	Loss on drying at 110° C	9.84%w/w	9.18%w/w
2	Total Ash value	19.11%w/w	16.25%w/w
3	Water soluble extractive	69.57%w/w	69.50%w/w
4	Methanol soluble extractive	33.41%w/w	47.55%w/w
5	Hardness of Ghanatablet	3kg/cm2	3kg/cm2
7	Tablet disintegration time	30min	30min
8	Weight variation test of tablet.	Av.- 488.00mg Max- 502.00mg Min- 478.00mg	Av.-490.00 mg Max.504.00mg Min-470.00mg

As could be seen from the Table-1, the loss on drying of the sample was between 9-10%.This relates to the moisture content in the sample and the value is in higher side. The ash value of *B.aristata* was more (19.11%) as compared to that of *B.asiatica* indicating presence of more inorganic content in it. Both water and methanol soluble extractive of both the sample are quite high as expected since the tablet were prepared by using ghana i.e. water soluble extract, The methanol soluble extractive was about 50% higher in *B.asiatica* (47.55%) than *B.aristata* (33.41%).this can useful for differentiating between *B.aristata* and *B.asiatica* used as raw material.

The physico-chemical parameters mentioned in the Ayurvedic pharmacopoeia of India is for root and stem of Daruharidra (*Berberis aristata* D.C) in different monographs, foreign matters, total ash, acid insoluble ash, extractive values etc. Hence, the above-mentioned parameters were selected for the analysis of the Ghana tablet. The evolved data will be useful as reference for the analysis of Daruharidra tablet and can be used for its quality control.

Table-2 The water soluble extractive value and Berberine content of raw material, i.e. *B.aristata* and *B.asiatica* stem sample has been presented.

PARAMETER	*B.aristata*	*B.asiatica*
Water soluble extractive, %w/w	5.95	10.70
Berberine content, %w/w	0.40	0.67

The data presented indicate that both water soluble extractive and berberine content was much higher in *Berberis asiatica* 10.70% and 0.67% respectively, as compare to 5.95% and 0.40% in *B.aristata* respectively. Whereas According to Ayurvedic pharmacopeia of India (Vol-I Pg-33, First edition) the water soluble extractive value of *B.aristata* should not be less than 6%.

B) PHARMACOGNOSTICALSTUDY

Berberis aristata D.C and *Berberis asiatica*Roxb.ex.D.C belong to the Berberdiaceae family, they grow in Himalayan region. *Berberis aristata* is available at higher altitude whereas B.asiatica is available at lower altitude. Now days stem is used in medicine so it is necessary to study the stem of genuine drug and its substitute pharmacognostically. As plants morphology is concern, even though both belong to same family they can be differentiated by following their peculiar features (table -3).

	*B.aristata*D.C	*B.asiatica*Roxb.ex.D.C
1	Occurring at high altitude of Himalaya	Dry valley of Himalaya(Low Alt.)
2	Shrubs up to 4-5m in Height	Shrubs up to 2m in Height
3	Stem is around 20cm in diameter	Stem is around 10cm in diameter
4	Spines are not distinct in leaves	Spines are distinct in leaves
5	Leaves glossy dark green above	Leaves whiteness beneath, Coracious
6	Venation not prominent in leaves	Venation prominent in leaves
7	Corymbose raceme	Umbellate raceme

C) CLINICAL STUDY

EFFECT OF THERAPIES

GROUP 1 - *Berberis aristata* Group

In this group, 14 patients of *Prameha* completed their treatment so the results of these patients are shown.

Table–4 Effect of *Berberis aristata* stem ghana tablet on Chief Complaints.

Signs & Symptoms	**Mean Score**		**%**	**S.D.**	**S.E.**	**'t'**	**P**
	B.T.	**A.T.**	**Relief**	**(±)**	**(±)**		
PrabhutaMutrata (n=9)	1.33	0.22	83.47	0.52	0.17	8.32	<0 .001
Avila Mutrata (n=0)	-	-	-	-	-	-	
Kshudhadhikya (n=7)	1.43	0.86	39.86	0.53	0.20	2.85	<0.05
Trishnadhikya (n=9)	1.11	0.22	80.18	0.51	0.17	3.34	<0.05
Kara-Pada-Tala Daha	1.25	0.17	86.4	0.47	0.14	6.77	<0.001

(n=12)							
Daurbalyata(n=14)	1.71	0.64	62.5	0.61	0.16	6.51	<0.001

The above table reveals that *Berberis aristata* Ghana tablet group provided statistically highly significant (P<0.001) relief in *PrabhutaMutrata*(83.47%), *Kar-pad-tal-dah* (86.4%) and *Daurbalyata* (62.5%), whereas significant relief was obtained in *Kshudhadhikya* and *Trishnadhikya*.

Table – 5: Effect of *Berberis aristata* on associated Symptoms

Associated Signs & Symptoms	**Mean Score**		**% Relief**	**S.D. (±)**	**S.E. (±)**	**'t'**	**P**
	B.T.	**A.T.**					
Alasya (n=8)	1.25	0.25	80	0.73	0.26	2.78	<0.05
Sandhishool (n=5)	5	00	00				
Mutra-madhurya(n=6)	1.12	2.25	100.89	1.39	0.49	-1.31	>0.05
Ati-nidra (n=5)	1	0.6	40.00	0.38	0.17	0.95	>0.05
Weight loss(14)	61.67	60.58	1.76	1.16	0.31	3.48	<0.05
Sthaulya (n=10)	1.70	1.10	35.29	0.69	0.21	2.85	<0.05
Ati-sweda(n=3)	1	0	100	0	-	-	-
Jihwa-Talu-Kantha-shosha (3)	1.67	.67	59.88	0	-	-	-
Kar-pad-supti(0)	-	-	-	-	-	-	-
Pindiko-udveshatan (n=3)	03	00	100%	0	--	-	-
Libido (n=02)	2	2	0	0	-	-	-

Alasya : Before treatment mean score of *Alasya* was 1.25 which came down to 0.25 at the end of therapy with 80% relief which was statistically significant (P<0.05) .

Mutramadhurya: Initial mean score of *Mutramadhurya*was 1.12 which increased up to 2.25 after treatment with 100.89% increased (P>0.01).

Pindiko-udvestan: Complete Relief was Observed in 3 patients.

Sthaulya: Mean score of *Sthaulya* was 1.70 before treatment which reduced to 1.10 after treatment. The relief provided was 35.29% which was statistically significant (P<0.05).

Ati-nidra: Initial mean score of *Ati-nidra* was 1.00 which reduced to 0.60 after treatment with 40.00% relief which was statistically insignificant.

Libido: No change was seen.

Table–6: Effect of *Berberis aristata* stem ghana tablet on Biochemical values

Biochemical Values	**Mean Score**		**% Relief**	**S.D. (±)**	**S.E. (±)**	**'t'**	**P**
	B.T.	**A.T.**					
Blood Sugar							
Fasting (n=14)	176.28	175.57	0.40	41.49	11.09	0.06	>0.05
Postprandial (n=14)	269.5	237.5	11.87	48.66	13.10	2.45	<0.05
S. Cholesterol(n=14)	217.21	207.21	4.42	24.31	6.50	1.49	>0.05

Berberis aristata provided statistically insignificant reduction in Fasting blood sugar (0.40%) and Significant reduction in postprandial Blood sugar with 11.87% relief(P<0.05). It provided statistically insignificant reduction in the S. Cholesterol level with percentage reduction of 4.42%.

Table – 7: Effect of *Berberis aristata* on Hematological Values

Haematological Values	Mean Score		% Relief	S.D. (±)	S.E. (±)	't'	P
	B.T.	A.T.					
T.L.C. (n=14)	8335.71	8421.41	1.03↑	2090.22	558.89	0.15	>0.05
Hb gm% (n=14)	13.47	13.25	1.64↓	0.80	0.21	1.03	>0.05
E.S.R. (n=14)	22	21.43	2.60↓	13.80	3.47	0.16	>0.05

The *Berberis aristata* Ghana tablet therapy provided statistically insignificant increase in T.L.C (1.03%)whereas Hb% (1.64%) and E.S.R. (2.60%) decrease was statistically insignificant.

Table –8: Total effect of *Berberis aristata* in 14 patients of Madhumeha.

Results	No. of patients	Percentage
Controlled	00	00
Markedly Improved	02	14.28
Improved	08	57.14
Unchanged	04	28.57

In this group, no patients were under the control of the drug, 14.28% patients showed markedly improvement, 57.14% patients showed improvement. The remaining 28.57% patients were unchanged after treatment.

GROUP 2 - *Berberis asiatica*Roxb.ex.D.C.Group

In this group, 14 patients of Prameha completed their treatment.

Table –9: Effect of *Berberis asiatica* stem Ghana tablet on Chief Complaints

Signs & Symptoms	Mean Score		% Relief	S.D. (±)	S.E. (±)	't'	P
	B.T.	A.T.					
PrabhutaMutrata (n=9)	2.44	1	59.02	0.64	0.21	6.1	<0.001
Avila Mutrata (n=1)	2	1	50	0	-	-	
Kshudhadhikya (n=4)	1	0.5	50	0.57	0.28	1.78	>0.05
Trishnadhikya (n=7)	2.28	1.00	56.14	0.95	0.35	3.65	<0.05
Kara-Pada-Tala Daha (n=9)	1.77	0.66	62.71	0.60	0.20	5.55	<0.001
Daurbalyata(5)	1.40	0.80	42.85	0.54	0.24	2.50	>0.05

The above table depicts that *B.asiatica* tablet group provided statistically highly significant (P<0.001) relief in *PrabhutaMutrata* by 59.02% relief and in *Kar-pad tal-dah*(62.71%).Statistically significant relief was seen in *Trishnadhikya*(56.14%).Statistically insignificant relief was observed in *Kshudhadhikya*(50%) and *Dourbalyata* (42.85%).

Table – 10: Effect of *Berberis asiatica* on Associated Symptoms

Associated Signs & Symptoms	Mean Score		% Relief	S.D. (±)	S.E. (±)	't'	P
	B.T.	A.T.					
Alasya (n=07)	2.28	1.00	56.14	0.95	0.35	3.65	<0.05
Mutra-madhurya(9)	2	0.5	25	1.45	.48	2.29	<0.05
Ati-nidra (n=0)							
Sthaulya (n=06)	1.66	1.16	30.12	0.54	0.22	2.27	>0.05
Weight loss(14)	61.67	60.58	1.76	1.16	0.31	3.48	<0.05
Ati-sweda(3)	1	5	50	0			
Jihwa-Talu-Kantha-shosha(04)	1.75	1.00	42.85	0.50	0.25	3.00	<0.05
Kar-pad-supti	-	-	-	-	-		
Pindiko-udveshatan (n=07)	1.85	0.71	61.62	0.37	0.14	8.14	<0.001
Libido (n=05)	1	1	00				

Alasya : Before treatment mean score of *Alasya* was 2.28 which came down to 1.00 at the end of therapy with 56.14% relief which is statistically significant.

Pindiko-udvestan : Before treatment mean score of *Pindiko-udveshtan* was 1.85 which came down to 0.71 at the end of therapy with 61.620% relief which is statistically highly significant (P<0.001).

Weight loss: Mean score of weight was 61.67 before treatment which reduced to 60.58 after treatment. The relief provided was 1.76% which is statistically significant (P<0.05).

Jiwhatalu kantha sosha: Before treatment means score was 1.75 which reduced to 1.00 after treatment. The relief provided was 42.85% which is statistically significant.

Stastistically insignificant change was seen in *Sthaulya*whereas *mutrmadhurya* was increased significantly after treatment.

Table–11: Effect of *Berberis asiatica* stem Ghana tablet on Biochemical values

Biochemical Values	Mean Score		% Relief	S.D. (±)	S.E. (±)	't'	P
	B.T.	A.T.					
Blood Sugar							
Fasting (n=14)	178.5	169.71	4.92↓	37.52	21.69	0.40	>0.05
Postprandial (n=14)	271.50	227.00	16.39↓	70.22	20.29	2.19	<0.05
S. Cholesterol(n=14)	194.21	181.14	6.73	23.73	13.71	0.95	>0.05

Berberis asiatica provided statistically insignificant reduction (P>0.05) in Fasting blood sugar by 4.92% relief however in postprandial Blood sugar level the reduction was statistically significant(P<0.05) with 16.39% relief, The reduction in S. Cholesterol level is statistically insignificant(P>0.05)with percentage reduction of 6.73%.

Table –12: Effect of *Berberis asiatica* on Haematological Values

Haematological Values	Mean Score		% Relief	S.D. (±)	S.E. (±)	't'	P
	B.T.	A.T.					
T.L.C. (n=14)	9871.43	9250	6.29	2053.58	1187.04	0.52	>0.05
Hb gm% (n=14)	14.09	13.09	7.09	0.94	0.54	1.84	>0.05
E.S.R. (n=14)	21.83	18.33	24.80	5.38	1.44	3.76	<0.05

The *Berberis asiatica* group therapy provided statistically insignificant increase in Hb %(7.09%), Insignificant decrease was seen in T.L.C. (6.29%) and statistically significant(P<0.05) decrease was seen in E.S.R.(24.80%).

Table – 13: Total effect of *Berberis asiatica* in 14 patients of Madhumeha.

Results	No. of patients	Percentage
Controlled	01	07.14
Markedly Improved	02	14.28
Improved	08	57.14
Unchanged	03	21.42

In this group, 7.14% patients were under the control of the disease, 14.28% patients showed markedly improvement, 57.14% patients showed improvement. The remaining 21.42% patients were unchanged after treatment.

DISCUSSION

Effect on Signs & Symptoms:

Berberis aristata Ghana tablet group provided statistically highly significant (P<0.001) relief in *PrabhutaMutrata*(83.47%), *Kar-pad-tal-dah*(86.4%) and *Daurbalyata*(62.5%), whereas significant relief was obtained in *Kshudhadhikya* and *Trishnadhikya.*

B.asiatica tablet group provided statistically highly significant (P<0.001) relief in *PrabhutaMutrata* by 59.02% relief and in *Kar-pad-tal-dah*(62.71%).Statistically significant relief was seen in *Trishnadhikya*(56.14%).Statistically insignificant relief was observed in *Kshudhadhikya*(50%) and *Daurbalyta* (42.85%).

In chief complaints both group showing same results, *Prabhutamutrata* is greately reduced due to the *UshnaVeerya*, *Tikta* and *Katu rasa*, because *Tikta rasa* help in the depletion of *Kleda,Meda, Vasa, Majja, Lasika, Puya, Sweda, Mutra* and *Pitta, UshnaVeerya* and *Laghu, Rukshaguna* of the drug help in absorption of excessive fluid from the body moreover they stimulate *Agni*.

Kar-pad tal dah may be pacified by the *Sheeta* property of *Tikta rasa*. *Dourbalyata* might be reduced by proper formation of all *Dhatu* by the stimulation of *Agni* by *UshnaVeerya*, *Tikata* and *Katu rasa*. *Tikta rasa* also promote firmness of the skin(*Twak*) and muscles(*mansa*).

Effect on Hematological Values

The *Berberis aristata* Ghana tablet therapy provided increase in T.L.C by 1.03%, whereas Hb% was increased by 1.64% and E.S.R. was decreased by 2.60%, all are statistically insignificant. It indicates that, this group has no effect on hematological values.

Berberis asiatica group therapy provided statistically insignificant increase in Hb%(7.09%), Insignificant decrease was seen in T.L.C.(6.29%) and statistically significant (P<0.05) decrease seen in E.S.R. (24.80%).

The decrease in E.S.R in asiatica group might be due to the inhibitory action of berberine against various bacteria.

Effect on Blood Sugar

Berberis aristata provided statistically insignificant reduction in Fasting blood sugar (0.40%) and Significant reduction in postprandial Blood sugar with 11.87% relief (P<0.05). It provided statistically insignificant reduction in the S. Cholesterol level with percentage reduction of 4.42%.

Berberis asiatica provided statistically insignificant reduction (P>0.05) in Fasting blood sugar by 4.92% relief and in postprandial Blood sugar level the reduction is significantly decreased (P<0.05) with 16.39% relief, The reduction in S. Cholesterol level is statistically insignificant(P>0.05)with percentage reduction of 6.73%.

In both the groups the significant reduction is seen in post-prandial blood sugar, it coincides with the result in pharmacology where the both drugs were showing anti-hyperglycaemic action. This may be due to the presence of berberine alkaloid which helps in utilization of glucose and hampers absorption of glucose from gut.

PROBABLE MODE OF ACTION

The basic principles of Ayurvedic Pharmacology are capable to explain the mode of action in scientific way. Pharmacology of Ayurveda is based on the theory of *Rasa, Guna, Veerya, Vipaka* and *Prabhava* which were the simplest parameters in those days to ascertain the action of drug.

Acharya Charaka states that

किञ्चिद्रसेनकुरुतेकर्मवीर्येणचापरम्॥७१॥

द्रव्यंगुणेनपाकेनप्रभावेणचकिञ्चन। **(Cha. Su. 26/71)**

Certain drugs act through *Rasa*; some through *Veerya*, Some through their *Gunas*, Some through their *Vipaka* and some through their *Prabhav*.[6]

Here also the *Daruharidra* is acting by its *Raspanchaka*, The *Katu-Tikta rasa* pacify or balances the *bahudravakapha* and pitta moreover by its *Shoshan* properties it reduces excessive *meda, Kleda and Lasika* etc; *Laghu, Rukshaguna* helps to normalize *bahudravkapha* and indirectly stimulate *Jatharagni* and *Dhatwagni*; The *UshanaVeerya* further help to bring vitiated *Kapha* and *Vata Doshas* to normal condition and stimulate *Jatharagni* as well as *Dhatwagni*.So, in this way the *Ras panchak* of the *Daruharidra* normalizes the vitiated *Kapha-Pitta –vata, Dushya* and Destructs the *Samprapti*.

Modern View

Berberine present in the Daruharidra was found to effectively inhibit the activity of Diasacchaidases in Caco-2.It also decreased sucrase activity after preincubation with Caco-2 cells for 72 hours. However, Gluconeogenesis and glucose consumption of Caco-2 were not influenced. 2-Deoxyglucosetransporting through Caco-2 cell monolayers was decreased by berberine but the effect was not statistically significant. These results suggest that the anti-hyperglycemic activity of berberine is at least partly due to its ability to inhibit alpha-glucosidase and decrease glucose transport through the intestinal epithelium.[7]

CONCLUSION

The word *Daruharidra*is not found in Vedic periods but since Samhita Period it has been used in medicine. Ayurvedic Classics have described wide range of therapeutic properties of the plant and have indicated in *Vrana, Phiranga, Upadansha, Gandmala, Visarpa, Pravahika,Kamala, Aruchi, Bastishotha,*

Twakdosha, Atisaar, Prameha, Raktapitta, and especially in Eye, Ear, Nose, Throat diseases. (*Urdhajatru-gata-roga*). From Charka period to Nighantu period it has been mentioned in context of Prameha treatment.

Daruharidra has *Katu, Tikta rasa; Katuvipaka; Laghu, ruksha Guna; and UshnaVeerya.* Its property is similar to the *Haridra,* which is also considered as a substitute of *Daruharidra.*

Botanical source of *Daruharidra* is Roots of *Berberis aristata* D.C. but now days its stem is being used. Other species of Berberis are used in it place but *Berberis asiatica*Roxb.ex.D.C. is commonly used.

The root and stem of Berberis species are yellow due to presence of Berberine, which is therapeutically important alkaloid. Berberine possesses growth inhibitory activity against Giardiasis, Entamobea histolytic, Chlamydia trachomatis, and has shown good results in Cholera and Liver cirrhosis.

Pharmacognosy: Macroscopically both species can be differentiated on the bases of leaves and inflorescence. *B.aristata* leaves spines are not distinct, are glossy green, venation not prominent and corymbose raceme, whereas *B.asiatica* leaves spines are distinct, venation prominent and umbellate raceme. Stem is very difficult to differentiate but the yellow intensity of wood is less and bark is more blackish in *B.aristata* as compare to *B.asiatica*.

In microscopic study *B.asiatica* can be differentiated by the presence of rhytidoma, starch grains and large vessels which are not present in *B.aristata* however in case of *B.aristata* the prismatic crystal of calcium oxalate are more as compare to former and the medullary rays is wider.

Analytical Study: No significant difference was observed in most of the physio-chemical parameter between two drugs Ghana tablets, but the methanol extractive value was about 50% higher in *B.asiatica* as compare to *B.aristata*.

The water-soluble extractive of stem powder of *Berberis asiatica* (10.70%) was higher as compare to *Berberis aristata* (5.95%).

The berberine quantity by Gravimetric method was also higher in case of *Berberis asiatica* stem (0.67%) as compare to *Berberis aristata* stem (0.40%).

In TLC also similar spots were seen in both the drug's ghana but the intensity was more in *B.aristata*.

Ayurvedic Pharmacopoeia of India has not mentioned Berberis asiatica stem the Data evolved in the present study will be very useful and serve as reference for its routine analysis.

Clinical study: Age of onset of disease was maximum in age group of 41-50yrs, 52.77% patients have positive family history of diabetes mellitus. Most of the patients have Prabhutamutrata, Daurbalyata and Kar-pad-tal dah as chief complaints.

In *Berberis aristata* D.C group 14 patients completed the drug regime, highly significant ($P<0.001$ relief was seen in Prabhutamutratrata(83.47%), Kar-pad-tal dah(86.40%) and Daurbalyata(62.50%) and postprandial blood sugar was significantly reduced ($P<0.05$). In this group 14.28% patient markedly improved, 57.14% patients improved and 28.57% patients were in unchanged category.

In *B.asiatica* group 14 patients completed the drug schedule, highly significant($P<0.001$) relief was observed in prabhutamutrata (59.02%) and Kar-pad-tal dah(62.71%) and post-prandial blood sugar level was significantly reduced ($P<0.05$).As overalleffect of drug is concern 07.14% patients controled,14.28% patients markedly improved,57.14% improved, and 21.42% in unchanged category.

No difference was observed in the therapeutical potential of *Berberis aristata* D.C. and *Berberis asiatica*Roxb.ex.D.C clinically.

As in pharmacological and Clinical study not much difference is observed in both the drugs, but the water soluble extractive and Berberine quantity is higher in *B.asiatica* groups so *B.asiatica* can be used in preparation of Rasanjan and other products.

REFERENCES

1. Sharma PV (Reprint) DravyagunaVigyana, Vol II. Varanasi: Chaukhamba Bharati Academy; 2020. 694
2. Gaur BL, editor, (1st ed.). Commentary Ayurveda Dipika of Cakrapanidatta on Charaka Samhita of Agnivesha, Vol-III, Chikitsasthana; PramehaChikitsa: Chapter 6, Verse 26. Delhi: Rastriya Ayurveda Vidyapeeth; 2014. 428
3. https://niimh.nic.in/ebooks/e-Nighantu/rajanighantu/?mod=read&h=dAruharidra
4. Gaur BL, editor, (1st ed.). Commentary Ayurveda Dipika of Cakrapanidatta on Charaka Samhita of Agnivesha, Vol-III, Chikitsasthana; PramehaChikitsa: Chapter 6, Verse 13-14. Delhi: Rastriya Ayurveda Vidyapeeth; 2014. 423
5. Gaur BL, editor, (1st ed.). Commentary Ayurveda Dipika of Cakrapanidatta on Charaka Samhita of Agnivesha, Vol-II, Nidansthana; PramehaNidan: Chapter 4, Verse 47. Delhi: Rastriya Ayurveda Vidyapeeth; 2014. 131
6. Gaur BL, editor, (1st ed.). Commentary Ayurveda Dipika of Cakrapanidatta on Charaka Samhita of Agnivesha, Vol-I, Sutra sthana; AtreyabhadrakapiyaAdhyaya: Chapter 26, Verse 71-72. Delhi: Rastriya Ayurveda Vidyapeeth; 2014. 783
7. Pan, Guo-Yu et al. “The antihyperglycaemic activity of berberine arises from a decrease of glucose absorption.” *Planta medica* vol. 69,7 (2003): 632-6. doi:10.1055/s-2003-41121