Published online in http://ijam.co.in ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 15 (1), 2024; 198-205

A Randomised Active Controlled Clinical Trial to Evaluate the Efficacy of *Vyoshadi Yoga* versus Simethicone drop in *Udarshula* (Infantile Colic)

Research Article

Shruti Kapatkar[1*], Renu Rathi[2]

1. PG Scholar, 2. Professor and Head, Department of Kaumarbhritya,
Datta Meghe Institute of Higher Education and Research (Deemed to Be University),
Sawangi (M), Wardha, Maharashtra. India.

Abstract

Background: Infantile colic is said to be the most common complaint among few weeks to 6 months of age babies and is characterised by continual sobbing. Acharya Kashyapa has portrayed a disease named '*Udarshula*,' which shows the same clinical features as 'Infantile colic. The present study aimed to evaluate the efficacy of '*Vyoshadi Yoga* in *Udarshula*. Material and Methods- This study belongs to Randomized Active controlled clinical trial which comprises total 40 patients of *Udarshula* randomly divided into two equal groups. Group A (Trial group) was treated with *Vyoshadi Yoga* two times a day after feeding with Honey and Group B (Control group) was treated with Simethicone drop administered two times a day after feeding for 14 days. Assessment of *Udarshula* was done by using the parameters of the FLACC scale, Subjective Criteria and Parent Questionnaire on 0,3rd ,7th, and 14th day. Results- Positive results were seen in both groups. After application of Wilcoxon Sign Rank test, it has been observed that both the formulation of *Vyoshadi Yoga* and Simethicone were found to be equally significant P-value=0.01<0.05 in both groups. On the 28th day, post follow-up showed both the group were reduced the symptoms of Infantile colic and improvement was seen. Conclusion- Significant results were noted in both the interventions. No ADR was reported. Further large sample studies with standard control would render better evidence in results with justification.

Keywords: *Udarshula,* Infantile Colic, *Vyoshadi Yoga,* Simethicone, *Vedanadhyaya*, FLACC Scale.

Introduction

Ayurveda is the most scientifically based medicinal system. In the past, Ayurveda was separated into eight specialties. One of the most important *Ashtanga* branches is *Kaumarbhritya*, also known as *Kaumartantra* or *Balachikitsa*. *Kaumarbhritya* comprises prenatal and puerperium care, as well as pacification of children's disorders. The foetus relies on its mother for growth and development during its intrauterine life. After birth, the newborn undergoes a series of physiological changes in preparation for independent existence. The respiratory, circulatory, digestive, and urinary tracts are the most affected. The digestive system is inextricably linked to the anabolic, growth, and development processes that are critical throughout this stage of life. Many adaptive disruptions in the digestive system, like as flatulence, indigestion, and colic, affect the infant's growth and weight gain. *Acharya Kashyapa* wrote the *Kashyapa Samhita*, a unique contribution of *Kaumarbhritya Tantra*. *Vedanadhyaya* is found in *Sutra Sthana* (1). This chapter discusses the signs of diseases in children who have not developed speech. Because infants are unable to verbalise their suffering. *Vedanadhyaya* is critical in understanding the signs and symptoms associated with Balrog (2-3). *Prakupita Vayu* builds up in *Koshtha*, causing abdominal discomfort and prolonged crying in the infant. *Udarshula* (infantile colic) is one of the most painful problems of infancy. According to Ayurvedic science, it mainly seen from birth to *ksheerapa awastha* (6 months) and same has been described as Infantile colic in conventional science because during this time period, the gut flora is still developing, which leads to indigestion of milk and other foods. Colic develops when the baby cannot digest food properly due to immature gut.

Infantile colic is a strange and perplexing illness. Every year, it is estimated that 22.5% of all babies suffer with colic. Infantile colic is described as uncontrollable weeping in newborns aged 0-3 months for more than three hours per day, more than three days per week for three weeks or longer. It is most common in the afternoon and evening (4-5). Approximately 47 percent of infantile colic cases resolved by the age of three months, another 41 percent resolved by the age of six months, and the remaining 12 percent resolved between the ages of six and twelve months (6).

Therefore, there was need to check the effectiveness of Ayurvedic drug compositions over *Udarshula*, which will reduce the symptoms of colic without its regression, with negligible side effects and

*** Corresponding Author:**
Shruti Kapatkar
PG Scholar, Department of Kaumarbhritya,
Datta Meghe Institute of Higher Education and Research (Deemed to Be University),
Sawangi (M), Wardha, Maharashtra.
Email Id: shrutikapatkar50@gmail.com

financially affordable for all economical classes. The reason behind the selection of *Vyoshadi Yoga*, the ingredients of *Vyoshadi Yoga* are mentioned in Arogya Raksha Kalpadrumah (7) which is indicated for *Udarshula*, having main ingredients as depicted in table no.1 having eight main drugs with each 30 grams. standard drug Simethicone, showed proven results with Placebo for the treatment of *Udarshula*. (In 1994) (8).

Table 1: Ingredients of formulation and its properties

Drug name	*Rasa*	*Virya*	*Vipaka*	*Guna*	Action	*Gana*
Shunthi (Zingiber officinalis. Roxb, Roots) (9)	*Katu*	*Ushna*	*Madhura*	*Laghu & Snigdha*	*Dipana, Pachana, Shothaghna*	*Deepaniya, Shulaprashaman (Ch S.) Pippalyadee, Trikatu* (Su S.)
Maricha (Piper nigrum Linn, fruits*)* (10)	*Katu*	*Ushna*	*Katu*	*Laghu, Tikshna*	*Deepana, Pachana, Vatanulomana, Krimighna, Jwaraghna*	*Deepaniya, Shulaprashaman (Ch) Pippalyadee, tryushana (Su. S)*
Pippali (Piper longum Linn, fruits*)* (11)	*Katu*	*Anushna*	*Madhura*	*Laghu, Snigdha, Tikshna*	*Kaphavatashamak, Deepana, rasayana*	*Deepaniya, Shulaprashaman (Ch) Pippalyadee, Tryushana, Aamlakyadi (Su. S)*
Ajmoda (Carum roxburghianum. DC. Craib, fruits*)* (12)	*Katu, tikta*	*Ushna*	*Katu*	*Laghu, Tikshna, Snigdha*	*Deepani, hrudya bastirogarujapaha*	*Shulaprashaman, Deepaniya (Ch)*
Jiraka (Cuminum cyminum Linn, beeja*)* (13)	*Titkta , katu, madh ura*	*Ushna*	*Katu*	*Laghu, Tikshna, Snigdha*	*Pachana, Vedanasthapak, Grahi*	*Shulaprashaman (Ch) Pippalyadee (Su. S)*
Krishna jiraka (Carum bulbocastanum. , beeja*)* (14)	*Katu*	*Ushna*	*Katu*	*Laghu, Snigdha*	*Pachana, Vedanasthapak, Grahi*	-
Hingu (Ferula foetida syn, niryas*)* (15)	*Katu*	*Ushna*	*Katu*	*Laghu, Tikshna, Snigdha*	*Deepana, Pachana, Ruchi kara, Anulomana, jantughna*	*Deepaniya (Ch) Pippalyadee, Ushakadi (Su. S)*
Saindhava (Sodiichloridum, salt) (16)	*Lavan a*	*Ushna*	*Madhur or Katu*	*Guru, Snigdha, Tikshna*	*Trishoghna, Avidahi, Agnidipana*	-

This study aimed to evaluate the efficacy of *Vyoshadi Yoga* in the management of *Udarshula*. The objectives of the study were to compare the efficacy of *Vyoshadi yoga* and simethicone drop in the management of Infantile colic (*Udarshula*) individually by using the parameters like FLACC scale, subjective criteria, and parent questionnaire in the management of *Udarshula*. Also, to validate the concept of *Udarshula* in current clinical practice as described by acharya kashyapa in *Vedanaadhyaya* of kashyapa Samhita.

Methodology

This clinical trial was a parallel arm, Randomized clinical trial. After obtaining ethical approval from the Institutional Ethics Committee (IEC) and registering the trial with the Clinical Trials Registry of India (CTRI), a total of 40 patients in the age group of 2 months to 6 months were enrolled. These patients presented with complaints such as severe crying, aversion to breast milk, abdominal pain, and abdominal distension. The trial recruited participants from various sources, including the outpatient department (OPD), inpatient department (IPD), specialty health checkup camps, nearby hospitals in Wardha, and vaccination centres. Infant suffering from infectious diseases like Tuberculosis, HIV, and any other systemic diseases with acute abdomen were excluded from the study. The included infants were divided into two groups of 20 each following the random sampling and named as Group A (*Vyoshadi Yoga*) with honey and Group B (Simethicone drop) was open label and no blinding was done. The total duration of the trial for both the groups was on 0, 3rd, 7th, 14th day and 28th day of post follow up treatment period. The dosage of both groups was decided as per Fried's rule depicted in the dosage table no. 2 and 3 with same duration for both interventions.

Ethical Clearance

The research work was approved by Institutional Ethical Committee of Datta Meghe Institute of Higher Education and Research, Sawangi (Meghe), Wardha MGACHRC/IEC/Mar-2023/694 and C.T.R.I. registration (CTRI/ 2021/11/038202).

Withdrawal criteria

1. If the symptoms get aggravated during treatment such enrolled patients were withdrawn from clinical trial and suitable alternative treatment was delivered free of charge till it becomes alright.
2. If parents discontinue treatment in between study.

Posology

As per Age, medicine in the prescribed doses was packed in a plastic box and given to parents for administration as per the schedule.

Table 2: Shows interventions of both groups with posology

Group	Sample size	Intervention	Dose and frequency	*Anupana*	Duration	Review
Group A	20	*Vyoshadi Yoga*	0.16gm - 0.48gm BD orally	Honey (*madhu*)	14 days	Follow up after 28 days of treatment
Group B	20	Simethicone drops	0.5 ml per dose once a day in mild and twice a day in moderate condition orally	-	14 days	Follow up after 28 days of treatment

Table 3: Drug doses of both interventions by Fried's rule

AGE	Dose of Trial Drug	Dose of Simethicone
2 months	0.16 gm.	0.5 ml per dose once a day in mild and twice a day in moderate condition The total dose is 20 mg four times a day (17)
3 months	0.24 gm.	
4 months	0.32 gm.	
5 months	0.4 gm.	
6 months	0.48 gm.	

The dose of Vyoshadi yoga was calculated as per Sharangdhar as well as Fried's rule and the calculation is the same as depicted in table no. 3. Also, the dose of Simethicone is 20 mg/four times a day for children, so, it is calculated as per severity, in mild 0.5 ml once and in moderate and severe conditions; the same dose is repeated as per need.

Preparation of Research drug

Method of preparation of *Vyoshadi Yoga*

The process of preparing a powdered formulation of raw drugs adheres to Good Manufacturing Practice (GMP) standards. Initially, all ingredients are meticulously selected, taken in equal proportions, and finely crushed to ensure uniformity. As part of the process, asafoetida (*hingu*) undergoes purification, known as Hingu Shodhana, to remove impurities by frying in *go-ghrita*. Remanning mixture are then finely ground using a *khalva yantra* (grinder) and sieved through a mesh with a size of 80 to achieve a fine powder consistency. Subsequently, all ingredients are thoroughly mixed together and stored in dry, airtight containers to maintain quality and prevent moisture absorption. This meticulous process ensures the quality, safety, and efficacy of the final product, aligning with the standards of GMP for pharmaceutical preparations.

The effectiveness of therapy was evaluated based on improvements seen in both subjective and objective criteria. Subjective criteria were selected from the context of *Vedanadhyaya* in Ayurvedic classics such as *Stanyavyudasyate* (Aversion To breast milk), *Rodana* (cry), *UtanshchAvabhjyte* (Lying in supine position), *Udarstabhdata* (distension in abdomen), *Shaitya* (feeling of cold), *Mukhasweda* (perspiration over face) (1) which were assessed on the 0th, 3rd,7th,14th day and 28th day of post treatment follow up period of the trial and graded according to severity as 1 and 0 for present and absent respectively. On similar days objective criteria such as FLACC Scale (Face, Legs, Cry, Activity and Consolability) (18) were assessed on gradation according to severity such as 02,01 and 0 for severe, moderate, and absent respectively. Parent questionnaire was asked to parents, it was related to breast feed babies for proper digestion, burping, type of milk taken etc. (8) along with proper pathyas to mother and infant care is must. (19)

The obtained results were analysed based on above criteria with The Wilcoxon Sign Rank test showed comparative assessment of clinical features in group A before treatment 3.6 after 0.65 was found in group B there was 3.6 after treatment it is reduced into 0.7. with z-test -3.994 and P-value found <0.01 in both groups. Therefore, present study indicates that the role of *Vyoshadi yoga* & Simethicone both are equally efficient in the management of *Udarshula* (Infantile colic).

Observations and Results

In the present study, a total of 40 infants got enrolled in this study, 20 enrolled in each group, completed the study with zero dropouts as the administration of the formulation was much easier because of its sweet taste and solid consistency. Also, the parents were more concerned about the colic and they were getting positive responses in relieving the symptoms of their baby including excessive crying, they cooperated in the study and attended during and post-treatment follow-up visits from time to time with positive responses and enthusiasm. A maximum number of subjects 40% belonged to the age group of 6 months and 25% in group B. In group A 20% and 30% were of 3 months of age respectively. In group A 15% and 25% in group B were obtained of age 2 months. In Group Sample A, Male to Male-to-female ratio is 7:13 and in Group Sample B, Male to Female ratio is 9:11 with P value=0.519.

Table 4: Comparison of *Stanyavyudasyate* (Aversion To breast milk) distribution in (Group A vs Group B)

Clinical feature	Category	Group **Before treatment** (0 day)		Group **After treatment** (14 days)		Group Post follow up day t/t	
		A	B	A	B	A	B
Stanyavyudasyate (Aversion To breast milk)	Absent	3 (15.0%)	3 (15.0%)	19 (95.0%)	19 (95.0%)	20 (100%)	20 (100%)
	Present	17 (85.0%)	17 (85.0%)	1 (5%)	1 (5%)	0	0
Chi-square test statistics		Chi-square=0, P=1.00		Chi-square =0, P=1		Chi-square=0, P=0	

There was reduction in symptoms with 100% in both groups as shown in table no 4. As Vyoshadi yoga having *Deepana, Pachana, vatanulomana* properties which corrects *ama*(toxins) in the body. Also, *anupana* honey provides good palatability and Yogavahi in action.

Table 5: Comparison of *Rodana* (Cry) distribution in (Group A vs Group B).

Clinical feature	Category	Group		Group		Group	
		Before treatment (0day)		**After treatment** (14 days)		Post follow up day t/t	
Rodana (cry)		A	B	A	B	A	B
	Absent	0	0	20 (100.0%)	18 (90.0%)	20 (100.0%)	20 (100.0%)
	Present	20 (100.0%)	20 (100.0%)	1 (5%)	2 (10%)	0	0
Chi-square test statistics		Chi-square -Na, P=Na		Chi-square-2.105, P=0.147 NS*		Chi-square -0, P=0	

As in table no 5, *Rodana* (cry) was 100% present in both the group infants in all 40 children and at the end of the trial it was completely cured in both groups.

Table 6: Comparison of *Utanshchavabhjyte* (Lying in supine position) distribution in (Group A vs Group B)

Clinical feature	Category	Group		Group		Group	
		Before treatment (0day)		**After treatment** (14 days)		Post follow up day t/t	
Utanshchavabhjyte (Lying in supine position)		A	B	A	B	A	B
	Absent	5 (25.0%)	10 (50.0%)	19 (95.0%)	18 (90.0%)	20 (100.0%)	20 (100.0%)
	Present	15 (75.0%)	10 (50.0%)	1 (5%)	2 (10%)	0	0
Chi-square test statistics		Chi-square=2.667 P=0.102		Chi-square=0.36 P=0.548		Chi-square-0, P=0	

Utanshchavabhjyte (Lying in supine position) was present in 15 (75%) of infants in group A and in group B there was 10(50%) pre-treatment and 1% post-treatment in group A and 2(10%) in group B.

Table 7: Comparison of *Udarstabhdata* (distension in abdomen) distribution in (Group A vs Group B)

Clinical feature	Category	Group		Group		Group	
		Before treatment (0day)		**After treatment** (14 days)		Post follow up day t/t	
Udarstabhdata (distension in abdomen)		A	B	A	B	A	B
	Absent	5 (25.0%)	6 (30.0%)	20 (100.0%)	20 (100.0%)	17 (85%)	20 (100%)
	Present	15 (75.0%)	14 (70.0%)	0	0	3 (15.0%)	0 (0.0%)
Chi-square test statistics		Chi-square=0.125, P=0.723		Chi square=0, P=0		Chi square=3.243, P=0.072	

As shown in table no 7 there was reduction in symptoms in both groups but at post treatment follow up period there was 15% regression was seen due to improper dosage and not following proper pathyas in group A.

Table 8: Comparison of *Shaitya* (feeling of cold) distribution in (A vs Group B) At before treatment

Clinical feature	Category	Group		Group		Group	
		Before treatment (0day)		**After treatment** (14 days)		Post follow up day t/t	
Shaitya (feeling of cold)		A	B	A	B	A	B
	Absent	8 (60.0%)	7 (75.0%)	20 (100.0%)	20 (100.0%)	20 (100.0%)	20 (100.0%)
	Present	12 (40.0%)	13 (25.0%)	0	0	0	0
Chi-square test statistics		Chi square=0.107, P=0.744		Chi square=0, P=0		Chi square=0, P=0	

There was significant reduction was seen in symptom hence 100% cure was there as shown in table no 8.

Table 9: Comparison of *Mukhasweda* (perspiration over face) distribution in (A vs Group B)

Clinical feature	Category	Group		Group		Group	
		Before treatment (0day)		**After treatment** (14 days)		Post follow up day t/t	
Mukhasweda (perspiration over face)		A	B	A	B	A	B
	Absent	9 (45.0%)	9 (45.0%)	20 (100.0%)	20 (100.0%)	19 (95.0%)	20 (100.0%)
	Present	11 (55.0%)	11 (55.0%)	0	0	1(5.0%)	0 (0.0%)
Chi-square test statistics		Chi square=0, P=1		Chi square=0, P=0		Chi square=1.026, P=0.311	

There was present of symptoms in both the groups with 11(55%). After post treatment it was reduced to 100% in both groups but 1(5%) subject having perspiration over face because of dehydration due to summer season.

Table 10: Objective criteria- FLACC Scale comparison of clinical features distribution in (Group A vs Group B)

Clinical features in FLACC Scale		Group		Group		Group	
		Before treatment (0th day)		After treatment (14th day)		Post follow up treatment period	
		A	B	A	B	A	B
1. Face	Scale 0	1 (5.0%)	4 (20.0%)	20 (100.0%)	20 (100.0%)	20 (100.0%)	20 (100.0%)
	1	17 (85.0%)	15 (75.0%)	-	-	-	-
	2	2 (10.0%)	1 (5.0%)	-	-	-	-
Chi square test statistics		Chi square=2.258, P=0.323		Chi square=0, P=0		Chi square=0, P=0	
2. Legs	Scale 0	-	-	20 (100.0%)	20 (100.0%)	19 (95.0%)	18 (90.0%)
	1	16 (80.0%)	16 (80.0%)	-	-	1(5.0%)	2 (10.0%)
	2	4 (20.0%)	4 (20.0%)	-	-	-	-
Chi square test statistics		Chi square=0, P=1		Chi square=0, P=0		Chi-square=0.36 P=0.548	
3. Activity	Scale 0	0 (0.0%)	1 (5.0%)	20 (100.0%)	20 (100.0%)	19 (95.0%)	20 (100.0%)
	1	15 (75.0%)	16 (80.0%)	-	-	1 (5.0%)	0 (0.0%)
	2	5 (25.0%)	3 (15.0%)	-	-	-	-
Chi square test statistics		Chi square=1.532, P=0.465		Chi square=0, P=0		Chi square=1.026, P=0.311	
4. Cry	Scale 0	-	-	10 (50.0%)	19 (95.0%)	20 (100.0%)	19 (95.0%)
	1	3 (15.0%)	5 (25.0%)	10 (50.0%)	1 (5.0%)	0 (0.0%)	1 (5.0%)
	2	17 (85.0%)	15 (75.0%)	-	-	-	-
Chi square test statistics		Chi square=0.625, P=0.429		Chi square=10.157, P=0.001		Chi square=1.026, P=0.311	
5. Consolability	Scale 0	1 (5.0%)	0 (0.0%)	20 (100.0%)	20 (100.0%)	18 (90.0%)	18 (90.0%)
	1	11 (55.0%)	9 (45.0%)	-	-	2 (10.0%)	2 (10.0%)
	2	8 (40.0%)	11 (55.0%)	-	-	-	-
Chi square test statistics		Chi square=1.674, P=0.433		Chi square=0, P=0		Chi square=0, P=1	

FLACC scale was used to assess the pain grading during the colic. It scores on scale of 02,01,0 as severe, moderate and relief respectively as shown in table no 10. there was reduction in symptoms on both the groups was seen to 100%.

Table 11: Comparative assessment of Clinical features score of A group vs Group B group using Wilcoxon Sign Rank Test

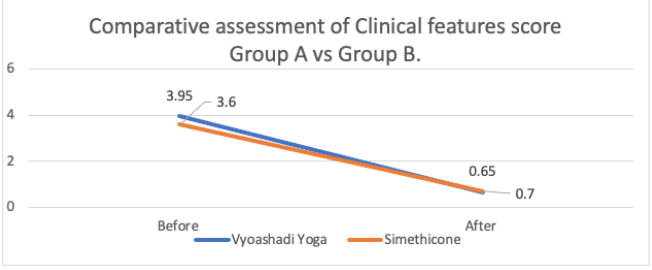
		Mean	Std. Deviation	Std. Error Mean	Z-test	P-value	Difference	(%)	Difference (%)
Group A	Before	3.95	0.75915	0.16975	-3.995	<0.01	3.3	83.5443	2.988748
	After	0.65	0.58714	0.13129					
Group B	Before	3.6	0.50262	0.11239	-3.994	<0.01	2.9	80.55556	
	After	0.7	0.57124	0.12773					

Prior to treatment, Group A had a mean score of 3.95 with a standard deviation of 0.75915. After treatment, the mean score significantly decreased to 0.65, with a standard deviation of 0.58714. In Group B, initial mean score was 3.6, with a standard deviation of 0.50262. Post-treatment, the mean score reduced to 0.7, and the standard deviation was 0.57124. Group A (*Vyoshadi Yoga*) displayed a mean difference of 3.3 and a percentage change of 83.54%, highlighting its substantial impact. Group B (Simethicone) mean difference was 2.9, with a percentage change of 80.56%. hence, the relief score was calculated to 2.988 as par the formulas was drawn in table no 11.

In graph 1 there was shown comparative assessment of clinical features in group A before treatment 3.6 after 0.65 was found in group B there was 3.6 after treatment it is reduced into 0.7. with z-test -3.994 and P-value found <0.01 in both groups.

Along with these subjective and objective criteria, parent questionnaire also asked to parents regarding the food habits of babies, if baby is being feed formula, which formula was currently using? If any solid food introduced or not? if yes then which type of food parents preferred to give?Does baby pass the gas/ burp after every feeding? stool habits etc these types of questions were during study. Significant results were obtained after post treatment due to following proper pathyas and skilled feeding with prescribed drug formulation.

Graph 1- Graphical Representation of Comparative assessment of Clinical features score A vs Group B.



Discussion

According to Ayurveda, Vata is the primary element that causes colic in infants (20). Infantile colic can be correlated with *Udarshula* based on similar clinical features. If *Mandagni* (lack of appetite) is present, it leads to ama (undigested toxic element) and Strotodushti (blockage in microchannels) (21). Also due to immature gut flora causes the improper digestion of milk or other liquid items, Intolerance to certain foods or ingredients in breast milk or formula. No or improper burping can also lead to severe pain in stomach (22). The analytical study of *Vyoshadi yoga* showed the absence of microbial contents and on a quality control test and no contamination. A total of 40 infants enrolled randomly in the trial received *Vyoshadi Yoga* and Simethicone as per the groups.

Probable mode of action of medication:

The probable mode of action and *rasapancahak* of *Vyoshadi yoga* have been interpreted in table no 1 also described role of each ingredient in detailed.

Properties of drugs

- ***Shunthi*** – Its *ushna virya* and *katu rasa* qualities stimulate the *Agni* (digestive fire), which relieves *Mandagni*. Due to its *ruchyam* characteristic, which delivers flavour to the mouth and relieves *arochaka* (anorexia), *katu* rasa and *agnideeptikara karma* perform *agnideepana*, and due to *katu* rasa and *Tikshna guna*, which performs *pachana* of *amadosha*, *strotoshodhana*, flatulence, and abdominal pain (carminative and stimulant) (23)
- ***Maricha*** - *Ushna* and *katu Vipaka* increases the *agni*, *tikshna guna* of *maricha* can expels the vitiated *doshas* which are in *sanchaya Avastha* in body, helps in *strotoshodhana*, useful in *agnimandya, ajirna, shula* and *adhamana.* (24)
- ***Pippali***- it helps in increases the *Deepana* action, *strotoshodhaka*, *rasayana* properties provides nourishment to *rasaadi dhatus* along with *shulaprashaman* property (25)
- ***Ajmoda***- Due to its *katu-tikta rasa* and *ushna virya* it acts as *vatanuloamana*, helps in relieving excessive gases from forms during digestion process, also it helps in *adhamana* (fullness of stomach) (26).
- ***Jeeraka***- Being *katu, tikta* and *Madhura rasa* it acts as a *deepana* and *ruchyam*, also due to the *katu-rasa* and *vipaka* acts as *Deepana* and *pachana* property, *anulomana* due to its *ushna* and *snigdha guna*, also acts as *shulaprashamana* and *Krimighna*. (27)
- ***Krishna jiraka***- Due to *katu rasa* and *katu vipaka* it acts as an *agnideepana* and *vatanulomana*. Therefore, it is used in *Agnimandya, ajirna, adhmana, aruchi* and in *charddi*. (28)
- ***Hingu*** -Being *katu, ushna* and *Tikshna* it acts as a *Deepana, pachana, ruchikara*, it is also used as a *krimihara* also should be used in Agnimandya, adhmana, Gulma (fullness of abdomen), *udarshula, krumi* and *vibandha.* (29)
- ***Saindhava*** – due to *lavana rasa* it acts as catalyst hence enhance the action of other drugs present in formula by helping them for deep penetration in the body also for easy digestion. Due to its hygroscopic nature, it forms a lubrication, which helps for digestion. (30)

Also having the properties of *Agni Deepana* (carminative) and *Pachana* (digestive), *shula prashamana* which enhanced the action of *pachakagni* and *dhatwagni* improves digestion and absorption of nutrients and alleviates *vata dosha* and helps to relieve colic pain. It is very cost effective that anyone can afford with more efficacy. There is only pure form *churna* which can be made palatable by giving with honey as an *Anupana*. As honey is the best *Anupana* for child due to its sweetness and having the properties of best *Yogavahi* substance; honey carries the effects of the medications added to it without changing its own properties. It implies that it improves the characteristics and functions of the substances it interacts with (31) along with Antiseptic, antibacterial, anti-inflammatory, sedative, mild laxative, healing, and cleansing characteristics according to modern science have been demonstrated by numerous experiments and studies on honey (32). Both the medications have shown significant efficacy in reducing symptoms of *Udarshula*. this study proved that *Vyoshadi Yoga* administered in the infants with *Udarshula* showed *agnideepana* (33) *amapachana, vatanulomana, krumighna* and *vatashamaka* effect due to synergistic action of trial drug ingredients. This intervention should be more studied in multi-centres with large sample size.

Conclusion

Udarshula (Infantile colic) is a condition characterized by excessive crying, fussiness, and irritability in otherwise healthy infants. It is a commonly seen in age group of 2-6 months of age due to immature gut flora and weaning period. In the age of contemporary science, there are very few medical treatments accessible to address this ailment. Evidence from the study showed that both the interventions *Vyoshadi Yoga* and Simethicone drop are safe to administer in the paediatric population without any adverse effect or aggravation of symptoms. So, it can be suggested in routine paediatric practice for colic as it is showed improvement of 83% and Simethicone drop with 80% respectively. hence, it found to be equally significant P-value=0.01<0.05 in both groups. It is established that patients who presented with complaints of *Udarshula* shared similarities with those listed in *Kashyapa Samhita's Vedic* Sciences, which was another goal of this study attempt to authenticate the symptoms and indications included in *Vedanadhyaya* hence, it must be utilised as a tool for detecting abdominal pain as it is validated in this study in current era also.

Conflict of interest: No any conflict of interest
Funding: Intramurally – None

Consent

As per the Institutional Ethical Committee and CONSORT protocol, written consent was taken from

the parents of patients and collected and preserved by the author.

Acknowledgment

DMIHER, deemed to be University, Sawangi Meghe, Wardha (MH), India for intramural funding to conduct the research

References

1. Vriddhajeevaka: Kashya Samhita, Tewari P.V.; Chowkhamba Vishwa Bharati publishers, Varanasi 1st edition reprint. 2002: Sutrasthan 25/15
2. Dattatray G. Parde, Avhale Sadhana, The Importance of Vedanadhyaya in Clinical Diagnosis of Childhood Diseases. International Journal of Ayurveda and Pharma Research. 2022;10(2):80-84
3. Rai Deepshikha, Kumar Amit. Vedanadhyaya: A Crucial Contribution of Kashyap Samhita in Paediatric Clinical Examination. International Journal of Ayurveda and Pharma Research. 2016;4(1):7-10
4. Wessel MA, Cobb JC, Jackson EB. Paroxysmal fussing in infancy, sometimes called “colic". Paediatric. 1954; 14:721.
5. Singh Meherban. Care of the New born: Sagar printers and publishers, New Delhi; 6th Edition 2004, page no.137
6. Savino F, Oggero R. Management of infantile colic’s, [Article in Italian]. Minerz’a Paediatric. 1996; 48(7.8): 313- 319
7. Kaikulangara Rama Warrier, Vriddhi Gulma Shoola Udara Chikitsa, Dr Lal Krishnan, Arogya Raksha Kalpadrumah, Chowkhamba Sanskrit Series; Varanasi, 31 December 2006, Third, 2019, ISBN: 81-7080-223-7.
8. Thomas J. Metcalf, Thomas G. Irons- simethicone in the treatment of infant colic: A randomized, Placebo-controlled, Multicentre trial, vol.94 No.1July1994
9. Deshpande A.P., Ranade Subhash, Dravyaguna Vijanan (Ayurvedic Medicinal Plants) part 1-2, Proficient Publishing House,2019, new edition April 2015page no.293
10. Deshpande A.P., Ranade Subhash, Dravyaguna Vijanan (Ayurvedic Medicinal Plants) part 1-2, Proficient Publishing House,2019, new edition April 2015page no.484
11. Deshpande A.P., Ranade Subhash, Dravyaguna Vijanan (Ayurvedic Medicinal Plants) part 1-2, Proficient Publishing House,2019, new edition April 2015page no.507
12. Deshpande A.P., Ranade Subhash, Dravya Guna Vijanan (Ayurvedic Medicinal Plants) part 1-2, Proficient Publishing House,2019, new edition April 2015page no.608
13. Deshpande A.P., Ranade Subhash, Dravya Guna Vijanan (Ayurvedic Medicinal Plants) part 1-2, Proficient Publishing House,2019, new edition April 2015page no.418
14. Deshpande A.P., Ranade Subhash, Dravya Guna Vijanan (Ayurvedic Medicinal Plants) part 1-2, Proficient Publishing House,2019, new edition April 2015page no.419
15. Deshpande A.P., Ranade Subhash, Dravya Guna Vijanan (Ayurvedic Medicinal Plants) part 1-2, Proficient Publishing House,2019, new edition April 2015page no.404
16. Deshpande A.P., Ranade Subhash, Dravya Guna Vijanan (Ayurvedic Medicinal Plants) part 1-2, Proficient Publishing House,2019, new edition April 2015.
17. Singh Meharban, Deorari Ashok, Drug Doses in children, chapter no. 17 Antispasmodics, CBS Publishers, 10th edition, New Delhi, 2019: p 119
18. Merkel S, Voepel-Lewis T, Shayevitz JR, et AL: The FLACC: A behavioural scale for Scoring postoperative pain in young children. Paediatric nursing 1997; 23:29379
19. Dash Durgaprasad, Jain C. M., Clinical Review on Infantile Colic, Ayu-vol. 30, no. 3 (July-September) 2009, pp. 323 - 326
20. Sharma P.V., Charak Samhita (Text with English translation), Chikitsasthana 28, Vatavyadhichikitisam adhyaya, Verse 15, VIth Edition, Chowkhamba Orientalia, Varanasi, 2000, Page No. 462-463.
21. Sharangadhara Samhita, Murthy Srikantha, 6thEdition, Chowkhamba Orientalia, Varanasi, 2006: p 44
22. Chinmay Mavinkurve et al: Ayurvedic Approach Towards Pain Management in Udarashoola W.S.R. To Infantile Colic – A Review Article. International Ayurvedic Medical Journal {online} 2019 http:// www.iamj.in/posts/images/upload/1927_1930.pdf
23. Byadgi PS, Kanashetti DS, Tiwari R et al. Shunthi (Zingiber officinale Rosc.): A Miraculous Medicinal Plant. Int J Adv Res Med Chem 2021; 3(1): 8-13.
24. Singh, Bhavna. (2016). Critical Review of Maricha (Piper Nigrum Linn) in Brihat Trayi with Special Reference to Nighantus. Dev Sanskriti Interdisciplinary International Journal. 7. 65-71. 10.36018/dsiij. v7i0.77.
25. Kumari M, Ashok BK, Ravishankar B, Pandya TN, Acharya R. Anti- inflammatory activity of two varieties of Pippali (Piper longum Linn.). Ayu. 2012 Apr;33(2):307-10. doi: 10.4103/0974-8520.105258. PMID: 23559810; PMCID: PMC3611634.
26. Sriwastava NK, Shreedhara CS, Aswatha Ram HN. Standardization of Ajmodadi churna, a polyherbal formulation. Pharmacognosy Res. 2010 Mar;2(2):98101. doi: 10.4103/0974-8490.62957. PMID: 21808548; PMCID: PMC3140114.
27. Jani, Dilip & Gujarathi, Jasmine. (2017). International Journal of Ayurveda and Pharma Research Review Article Pharmacological Appraisal of Cuminum Cyminum L. In Dysmenorrhoea: An Ayurvedic Approach in Consideration of Current Evidences. International Journal of Ayurveda and Pharma Research. 4. 29-35.

28. Kumar Bhupesh, Haldar Pronab. Critical Review on Krishna Jiraka Arka. Annals of RSCB [Internet]. 2020Nov.25 [cited 2023Aug.20];1201-5
29. Murali Megha, Kumari Ragini, Soni Kirti, Kumar Sujeet. Therapeutic Action of Hingu in Respiratory System: A Literary Review. International Journal of Ayurveda and Pharma Research. 2020;8(12):37-42.
30. Rout AK, Dwivedi RR. A clinical study of Haritaki and Saindhava Lavana in Kaphaja Kasa with special reference to Samyoga Guna. Ayu. 2011 Jul;32(3):357-60. doi: 10.4103/0974-8520.93914. PMID: 22736910; PMCID: PMC3326882.
31. Tripathi Brahmanand, Editor, Charak Chandrika (Hindi Commentary) on Charak Samhita, Chowkhamba surbharti prakashan, Sutrasthan, chapter 27, Ikshu Varga, Verse No.249, 531.
32. Manley MC, Calnan M, Sheiham A. A spoonful of sugar helps the medicine go down? Perspectives on the use of sugar in children's medicines. Soc Sci Med., 1994; 39(6): 833– 84
33. Rathi B, Rathi R. Principals of ethical Ayurveda prescription writing in clinical practice: A literature review. J Datta Meghe Inst Med Sci Univ 2019;14: S97-102.

*****