RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFECT OF SAINDHAVADI CHOORNA IN VATAJA UDARASHOOLA IN INFANTS W.S.R. TO INFANTILE COLIC

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ABSTRACT

Introduction: Infantile colic is a condition of excessive cry of unknown cause in otherwise well infants. It is one of the most common presentations to a pediatrician in early months of life. Colic can be particularly frustrating for parents because the baby gets distressed for no apparent reason and no amount of consoling seems to bring any relief. The prevalence rate of infantile colic in infants varies from 2%-73% worldwide. *Vataja udarashoola* line of treatment can be adopted while considering the nature of pain in infantile colic. *Vataja udarashoola* being acute in nature, the *Pachana aushadhi* acts on obstruction and facilitate *Prakruta vatanulomana*. *Saindhavadi choorna* is one such formulation having *Deepana, pachana* and *Vatanulomana* properties. **Objectives**: This study evaluated and compared the effect of *Saindhavadi choorna* and *Shatapushpa arka* in *Vataja udarashoola* in infants w.s.r to infantile colic based on neonatal infant pain scale (NIPS) and Ayurvedic assessment criteria. **Methodology**: In this Randomized controlled open label parallel clinical study 30 subjects were enrolled in 2 groups (15 subjects each) from OPD and

IPD of SSCASRH Banglore and was administered *Saindhavadi choorna* and *Shatapushpa Arka* respectively twice daily for a period of 3 days. Assessment was done before intervention, 1st hour, 3rd day and 5th day using NIPS and Ayurvedic assessment criteria. Analysis included descriptive statistics, Fisher exact test, Mann u Whitney Rank sum test and Friedman's test. **Results:** Statically significant results were obtained in both the groups after treatment and follow-up with P value <0. 001. No significant effect was observed in between the groups. When compared clinically Group A has given 89.01% and Group B has given 98% improvement. **Conclusion**: Both *Saindhavadi choorna* and *Shatapushpa arka* are equally effective in the management of *Vataja udarashoola* in infants' w.s.r to infantile colic.

KEYWORDS: Infantile colic, Vataja udarashoola, Saindhavadi choorna, Shatapushpa arka.

INTRODUCTION

Crying is an essential preverbal means of communication through which infants express their needs. However, excessive or prolonged crying may disturb sleep, impair mother–infant bonding, and cause significant anxiety to caregivers and physicians. Although crying is common in all infants, about 20% of babies below two months require medical attention due to excessive fussiness.[1]

Infantile colic is characterized by unexplained paroxysms of irritability, fussing, or crying, often attributed to abdominal discomfort.[2] It affects 2–73% of infants worldwide, and despite its high prevalence, the exact pathogenesis remains unclear.[3] Colic is considered a functional gastrointestinal disorder and has been associated with later development of migraine.

Anti-foaming agents are used in infantile colic which reduces the surface tension of mucus and promote the expulsion of intestinal air[4], but they may be associated with adverse effects like drowsiness, apnea, coma[5] etc. Based on clinical features, infantile colic can be correlated with Vataja Udarashoola described in Ayurvedic classics, where the use of Shoolahara drugs is indicated for pain relief.

Saindhavadi Choorna[6], described in Balarogadhikara of Yogaratnakara, is a unique formulation containing Bhojya dravyas with *Snigdha* and *Ushna* properties, specifically indicated for Vataja Udarashoola and Anaha in infants. The present randomized controlled clinical study evaluates the effect of *Saindhavadi Choorna* with *Shatapushpa Arka* in infants

with Vataja Udarashoola (with special reference to infantile colic), including both conceptual and clinical assessment, and draws relevant conclusions based on the results.

OBJECTIVES OF THE STUDY

Primary objective: To evaluate the effect of Saindhavadi Choorna in Vataja Udarashoola in infants w. s. r. to infantile colic by employing standard Validated scales (NIPS Scale).

Secondary objectives: To compare the effect of Saindhavadi Choorna and Shatapushpa Arka in Vataja Udarasoola in infants w. s. r. to infantile colic by employing standard validated scales (NIPS Scale).

MATERIALS AND METHODS

The study was a randomized controlled clinical study.30 Patients fulfilling the diagnostic criteria were selected irrespective of their sex and religion and grouped into two randomly. Informed consent was taken from all parents before inclusion into the trial. The study was approved by Institutional Ethics Committee SSIEC Protocol No-SSIEC/187/2021 and same was registered in CTERI(Registration number CTRI/2022/10/046805.

Saindhavadi choorna[6] and Shatapushpa arka[7] were administered orally in group A and group B respectively before feed (Pragbhaktha) twice a day for continuous 5 days and follow was done on 5th day.Shatapushpa arka was selected as the controlled drug.

Dose of Saidhavadi choorna & Shatapushpa arka **(Table 1)**
Dose of Saindhavadi choorna was calculated according to the reference from dosage calculation in of Yogaratnakara. Dose of Shatapushpa Arka was calculated according to Young's formula.

Ingredients of Saidhavadi choorna and Sathapushpa arka (Table2,3)
Preparation of Choorna[8]

Saindhavadi choorna was prepared at teaching pharmacy of Department of Rasa Shastra and Bhaishajya Kalpana, of the institute as per Sharagdhara referance.

Preparation of Shatapushpa Arka[9]

Shatapushpa Arka was prepared in the teaching pharmacy of Department of Rasa Shastra and Bhaishajya Kalpana, of the institute as per Ayurvedic Pharmacopeia of india.

INCLUSION CRITERIA

- Infant in the age group of 1 month to 6 months of age diagnosed with infantile colic will be included irrespective of their gender.
- Infants on various types of feeds like breastfeed, formula feed, and complimentary feeds.
- Infants whose parents are willing to sign the consent form will be included.

EXCLUSION CRITERIA

- Infants are below 1 month and above 6 months of age.
- For infants with congenital anomalies, serious systemic illness will be excluded.

DIAGNOSTIC AND ASSESSMENT CRITERIA
DIAGNOSTIC CRITERIA

Diagnosis was made based on the COLIQ QUESTIONNAIRE[10] (Crying and signs of digestive discomfort or stomach pain in infants) which consisted of questions related to the signs of infantile colic. This questionnaire measures the severity of infantile colic.

ASSESSMENT CRITERIA

NIPS[11] (Neonatal infant pain scale) was used to assess the subjects of infantile colic during the study. It consists of 6 variables with scores 0 and 1 which assess the behavior of an infant who is in pain.

• Ayurvedic assessment criteria was prepared based on the Samanya Udarashoola Lakshna in an infant and Vataja Udarashoola Lakshanas.[12] Scoring was done based on the presence and absence of the symptoms.

CRITERIA FOR WITHDRAWAL

- In infants whose parents were not willing to continue their participation in the study.
- In infants whom any emergency intervention were needed.
- None of the infants were withdrawn from the study as no such emergencies were observed.

RESEARCH PROFORMA

A specialized case proforma was prepared, which includes the details of patient and the disease. It consists of demographic data, presenting complaints, personal history, family history, Anti-natal, natal and post-natal history, Feeding history. NIPS scale was used for assessment.

STATISTICAL ANALYSIS

- The analysis was carried out using IBM SPSS software version 26 and SIGMASTAT version 3.1
- Within the group Friedman repeated measures of Anova, Between the groups- Fisher exact test was done to assess before and after treatment differences within the groups and between the groups.
- p value ≤0.05 was considered as statistically significant

OBSERVATION AND RESULTS

The present study was conducted to assess the efficacy of Saidhavai Choorna in infantile colic. Study was carried out with a specifically designed case proforma & assessment was done by NIPS Scale. Based on the data obtained the below conclusions were drawn.

In the present study, most infants were aged 1–2 months (37%), followed by 2–3 months (30%), 3–4 months (23%), 4–5 months (7%), and 5–6 months (3%). Male infants constituted 53% and females 47%. Socio-economic status showed that 40% belonged to the lower-middle class, 27% to the upper class, 20% to the upper-middle class, and 13% to the upper-lower class; none belonged to the lower class.

All subjects (100%) presented with Rodana with ghoravega (inconsolable cry), muhurmuhu prakopa–upasamana (paroxysmal cry), and irritability, while 53% showed stanavyudasya (aversion to breast milk). Cry duration exceeded 3 hours/day in 56.7% of infants, 2–3 hours/day in 33%, 1–2 hours/day in 6.7%, and less than 1 hour/day in 3%. Acute onset was observed in all cases, with no chronic episodes reported.

Associated features (Anubandha Vedana) included abdominal distension in all infants (100%), hardness of abdomen in 80%, discomfort in the supine position in 73%, sweating on the forehead in 50%, and peripheral hypothermia in 40%. Cry episodes commonly occurred between 6 am–12 pm, 4 pm–7 pm, and 7 pm–12 am (33% each), with no episodes reported between 12 pm–4 pm.

Abdominal tenderness was noted in 6.6% and constipation in 33.3% of infants. No cases of cow's milk allergy, gastro-esophageal reflux, or infections were reported. Consanguinity was present in 36.6% of parents. Most mothers were primi-gravida (63.3%). Maternal illnesses

included gestational diabetes mellitus (33.3%), pregnancy-induced hypertension (6.7%), and hyperemesis gravidarum (3.3%), with no other systemic illnesses.

Regarding perinatal history, 73.3% were term and 26.6% preterm babies. Normal vaginal delivery occurred in 40% and LSCS in 60%. All infants cried immediately after birth. Exclusive breastfeeding was practiced in 73%, while 28% received mixed feeding. Most mothers (70%) fed for 30–40 minutes per session, with 60% feeding every 1–2 hours. Improper burping was noted in 70% of cases, and all mothers used the cradle hold position.

Semisolid stools were observed in 77% and hard stools in 23%. Sound sleep was reported in 80% of infants. Most infants weighed between 4100–6000 g. Respiratory rate was 31–40/min in 57% and >40/min in 43%. Crying was frequent in 90% of infants, with prolonged cry or screaming with prolonged cry observed equally (50% each).

During colic episodes, common features included abdominal distension (93%), hard abdomen (83%), gaseous feeling (83%), flexion of legs (77%), clenched fists (73%), facial strain (67%), redness of face (53%), and restlessness (57%). Aggravation was commonly noted in the morning (67%), with relief achieved through swedana (37%), abhyanga (37%), feeding (23%), and mardana (3%).

DISCUSSION

The present study evaluated the effect of Saindhavadi Choorna (Group A) and Shatapushpa Arka (Group B) in managing infantile colic (Udarashoola) using the Neonatal Infant Pain Scale (NIPS). Both interventions produced statistically significant improvement in pain-related behaviors, indicating their effectiveness in reducing colicky pain.

Infantile colic was most prevalent in the 1–2 month age group, consistent with the period of gut immaturity and developing intestinal microbiota. Gender distribution was almost equal, suggesting no gender predilection. All infants presented with inconsolable and paroxysmal crying, confirming Rodana as the predominant manifestation of Vataja Udarashoola. More than half of the infants cried for over 3 hours/day, indicating severe pain intensity and a vicious cycle of air entrapment and discomfort.

Both treatment groups showed highly significant improvement (P < 0.001) in key NIPS parameters such as facial expression, cry, limb movements, breathing pattern, and state of arousal as early as 1 hour after administration, with sustained improvement on day 3 and day

5. Early facial relaxation and reduction in cry intensity indicate a rapid onset of analgesic and anticolic action. Although both groups were equally effective overall, Group B (Shatapushpa Arka) showed slightly faster relief at the end of the first hour.

Associated features like Udarastabhata (abdominal distension) and Uttanavabhanjana (discomfort in supine position) improved significantly in both groups, supporting the muscle relaxant and Vatanulomana properties of the formulations. Improvement in cold extremities (Shaitya) and forehead sweating (Mukhasweda) reflects normalization of circulation and reduction of stress-related autonomic responses following pain relief.

A significant reduction in Stanavyudasya (aversion to breastfeeding) was observed, particularly in Group B, suggesting that Shatapushpa Arka, with its Ushna, Deepana, and Shoolaghna properties, effectively corrected Vata-induced Agni disturbance and reduced feeding-related discomfort.

Both formulations were effective in reducing body rigidity (Prastabdhagatra), indicating alleviation of severe Vata aggravation and restoration of normal Vata gati. Although changes in difficulty of passing urine and stools were statistically insignificant due to a small sample size, clinical improvement was noted, supporting the role of both drugs in normalizing Apanavayu function.

Overall, the study demonstrates that Saindhavadi Choorna and Shatapushpa Arka are safe, fast-acting, and effective interventions for infantile colic, with Shatapushpa Arka showing slightly quicker symptomatic relief. The results validate the Ayurvedic approach of Vatanulomana, Shoolaghna, and Agnideepana in the management of infantile colic.

GROUP A

Saindhavadi Choorna, comprising Saindhava, Shunti, Ela, Hingu, and Bharangi, possesses analgesic, antispasmodic, carminative, and digestive properties, making it effective in the management of Vataja Udarashoola. The Teekshna and Sookshma Gunas of Saindhava Lavana facilitate Srotoshodhana and Srotovivarana, promoting Anulomagati of Vata and enhancing deeper tissue penetration of the formulation.

Shunti (Zingiber officinale) contains gingerol, linalool, and phenolic compounds that exhibit analgesic and antispasmodic effects by inhibiting muscarinic receptor–mediated acetylcholine action in gastrointestinal smooth muscles, thereby reducing spasms. Ela (Elettaria

cardamomum) contains flavonoids and 1,8-cineole, which exert analgesic and spasmolytic effects by inhibiting intracellular calcium influx and suppressing prostaglandin synthesis.

Hingu (Ferula asafoetida) contains ferulic acid and other bioactive compounds with proven antispasmodic and analgesic properties, acting through modulation of histamine, muscarinic receptors, and calcium channels. Its Ushna Veerya, Laghu, Snigdha, and Teekshna Gunas aid in relieving obstruction, facilitating Vatanulomana, and reducing Shoola.

Bharangi (Clerodendrum indicum) exhibits significant analgesic activity, contributing to the reduction of intestinal pain. Collectively, these pharmacological and Ayurvedic actions explain the rapid relief of colicky pain and abdominal spasm observed following administration of Saindhavadi Choorna.

GROUP B

B-phellandrene and alpha-pinene, which together helped in preventing gas formation and gas expulsion, which together helped in preventing gas formation and gas expulsion, were found in Shatapushpa (Anetham sowa)149. It has a distinct antispasmodic property also. Even though both the group are showing statistically significant, Group B (Satapushpa arka) is showed immediate effect comparing to Group A in reduction of all the symptoms of infantile colic and Vataja Udarashoola.

PROBABLE MODE OF ACTION

SAINDHAVADI CHOORNA

Vataja Udarashoola is a condition resulting from Sthanika Vata Sanchaya in Koshta due to Pratilomagati of Apanavayu and Samanavayu Vikriti. Atirodana, Vatadushta Stanyapana could be the prime causes for Vataja Udarashoola in infants. Shoola is an acute condition which requires immediate attention and relief. Here, all the drugs have analgesic and antispasmodic properties which mainly act on the acetylcholine receptors, which might have helped to reduce spasmodic in the intestine by decreasing smooth muscle contractions. Saindhavadi Choorna had Teekshna, Sookshma Guna and thus was effective in reaching the Sookshma Srotas instantaneously. Few drugs like Hingu, Shunti, Saindhava had Ushma Guna that could control Stambhana caused by Seeta Guna. The Snigdhata of Ghrita and Saindhava helped to bring in Mriduta of Srotas and further reduction of Kathinata and Stambha. Most of the drugs had Vatanulomana and Shoolaghna Karma i.e. they were Doshapratyaneeka and Vyadhi Pratyaneeka. Thus by its fast acting properties, Saindhavadi was effective in

correcting the Vikrita Vata instantaneously relieving the colicky pain and reducing the pain related behavioural changes in infants.

SHATAPUSHPA ARKA

Arka is a concentrated liquid containing the volatile substances and is sookshma, Teekshna and Vishada. Shatapushpa also is Teekshna and thus Shatapushpa Arka is fast acting and can reach the target site instantaneously. By its Ushna Guna it is Stambhaghna and thus reduces rigidity. It is Shoolaghna and is thus effective in reducing the muscular contractions of the intestine. Though both the groups had Vatahara and Shoolahara drugs, Shatapushpa Arka had instantaneous effect in reducing pain within few minutes (1-4 minutes) compared to Saindhava where the Choorna required slightly longer time (20-30 min)to reduce the pain effectively since its absorption was slower compared to Arka.

CONCLUSION

This study evaluated the clinical features of Vataja Udarashoola in infants and assessed the therapeutic efficacy of Saindhavadi Choorna, with Shatapushpa Arka as the control. Vataja Udarashoola, a disorder of the *Annavaha Srotas*, commonly presented with excessive crying, abdominal distension, and body rigidity, correlating with infantile colic. The condition was most prevalent in infants aged 1–3 months, with symptoms predominantly occurring in the evening, indicating Vata predominance.

Both Saindhavadi choorna and shatapushpa Arka showed statistically significant improvement in all clinical parameters, with overall clinical improvement of 89% in the Saindhavadi Choorna group and 98% in the Shatapushpa Arka group. Intergroup comparison revealed no statistically significant difference, indicating that both treatments were equally effective in managing Vataja Udarashoola (infantile colic) in infants.

LIMITATION OF THE STUDY

Small sample size.

SCOPE OF FURTHER STUDY

- The study can be carried out in larger sample size with shorter period of intervention for better significance in statistical analysis.

- Further studies can be conducted concentrating on specific causes of infantile colic.

- Further studies comparing Saindhavadi Choorna with other formulations effective in Vataja Udarashoola can be conducted.

- Further studies can be carried out by including Stanya Pareeksha to understand its role in infantile colic.

Table 1: Dose of medicine.

Age (Years)	Saindhavadi choorna	Satapushpa arka
1.1 - 2 months	250 mg	0.1 ml
2.1 – 3 months	375 mg	0.2 ml
3.1 – 4 months	500 mg	0.3 ml
4.1 – 5 months	625 mg	0.4 ml
5.1 – 6 months	750 mg	0.5 ml

Table 2: **Ingredients of Saindhavadi choorna.**

Drugs	Latin name
Saindhava lavana	Chloride of sodium
Bharangi	Clearodendrum serratum(Linn)
Shunti	Zingiber officinale Roxb.
Hingu	Ferula Northax. Bioss
Ela	Elettaria cardamomum (Maton)

Table 3: Ingredients of Shatapushpa Arka.

Drugs	Latin name
Shatapushpa	Anetham sowa. Kurz

Table no 4-Showing effect size difference on Facial expression-Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	Day 3	Day 5	1hr	D3	D5	1hr	D3	D5
Facial expression	A	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.21 Medium	0.25 Medium	0.2 Medium	0.14±0.364 Small	0.0±0.364 Nil	0.0±0.364 Nil
	B	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.24 Medium	0.25 Medium	0.2 Medium			
	@P<0.001 in comparison to D0(Friedman test)									

Table no. 5 - Showing effect size difference on Cry-Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	Day 3	Day 5	1hr	D3	D5	1hr	D3	D5
Cry	A	0.000(0.000-1.000)@	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.15 Small	0.28 Medium	0.25 Medium	0.0±0.364 Nil	0.0±0.364 Nil	0.182±0.364 Medium
	B	0.000(0.000-1.000)@*	0.000(0.000-0.000)@**	0.000(0.000-0.000)@	0.27 Medium	0.28 Medium	0.25 Medium			
	@P<0.001 in comparison to D0(Friedman test)									
	*P<0.001 in comparison to group A values and **P=0.036 in comparison to Group B values(Mann Whitney Rank sum test)									

Table no 6-Showing effect size difference on Movement of arm Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	Day 3	Day 5	1hr	D3	D5	1hr	D3	D5
Movement of Arms (Flexed/Extended)	A	1.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.12 Small	0.24 Medium	0.2 Medium	0.39±0.364 Large	0.182±0.364 Medium	0.0±0.364 Nil
	B	0.000(0.000-1.000)@ *	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.26 Medium	0.25 Medium	0.2 Medium			
	@P<0.001 in comparison to D0(Friedman test)									
	*P=0.033 in comparison to Group A values(Mann Whitney Rank sum test)									

Table no 7- Showing effect size difference on Movement of legs Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	Day 3	Day 5	1Hr	D3	D5	1Hr	D3	D5
Movement of Legs (Flexed/Extended)	A	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.24 Medium	0.24 Medium	0.2 Medium	0.07±0.364 Small	0.0±0.364 Nil	0.07±0.364 Small
	B	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.24 Medium	0.24 Medium	0.2 Medium			
	@P<0.001 in comparison to D0(Friedman test)									

Table no 8-Showing effect size difference on Breathing pattern Within the group &between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	Day 3	Day 5	1Hr	D3	D5	1Hr	D3	D5
Breathing pattern	A	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.14 Small	0.18 Medium	0.14 Medium	0.0±0.364 NIL	0.0±0.364 NIL	0.0±0.364 NIL
	B	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.12 Small	0.17 Medium	0.13 Small			
	@P<0.001 in comparison to D0(Friedman test)									

Table no 8-Showing effect size difference on State of arousal Within the group &between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	Day 3	Day 5	1Hr	D3	D5	1Hr	D3	D5
State of arousal	A	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.26 Medium	0.20 Medium	0.17 Medium	0.11±0.364 Small	0.19±0.364 Medium	0.0±0.364 Nil
	B	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.29 Large	0.22 Medium	0.17 Medium			
	@P<0.001 in comparison to D0(Friedman test)									

Table no 9-Showing effect size difference on *Stanavyudasya* (rejects breastmilk) Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	**Day 3**	**Day 5**	**1hr**	**D3**	**D5**	**1hr**	**D3**	**D5**
***Stanavyudasya* (Rejects breastmilk)**	A	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	NIL	NIL	NIL	0.0±0.364 Nil	0.0±0.364 Nil	0.26±0.364 Medium
	B	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.24 Medium	0.18 Medium	0.14 Medium			
	@P<0.001 in comparison to D0 (Friedman test)									

Table no 10-Showing effect size difference on *Routi* (cry) Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	**Day 3**	**Day 5**	**1Hr**	**D3**	**D5**	**1Hr**	**D3**	**D5**
***Routi* (cry)**	A	1.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-1.000)@	0.97 Large	0.97 Large	0.97 Large	0.27±0.364 Medium	0.26±0.364 Medium	0.39±0.364 Large
	B	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@*	0.19 Medium	0.25 Medium	0.2± Medium			
	@P<0.001 in comparison to D0 (Friedman test) *P=0.038 in comparison to Group A values (Whitney Rank sum test)									

Table no 11-Showing effect size difference on *Uttanavabhanjana* (discomfort in supine position) Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	**Day 3**	**Day 5**	**1Hr**	**D3**	**D5**	**1Hr**	**D3**	**D5**
***Uttanavabhanjana* (discomfort in supine position)**	A	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.19 Medium	0.14 Small	0.15 Small	0.18±0.364 Medium	0.0±0.364 Nil	0.33±0.364 Large
	B	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.21 Medium	0.22 Medium	0.17 Medium			
	@P<0.001 in comparison to D0 (Friedman test)									

Table no 12-Showing effect size difference on *Udarastabdhata* (Hardness of abdomen) Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	Day 3	Day 5	1Hr	D3	D5	1Hr	D3	D5
Udarastabdhata (Hardness of abdomen)	A	1.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.14 Small	0.18 Medium	0.20 Medium	0.13±0.364 medium	0.0±0.364 nil	0.26±0.364 medium
	B	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.19 Medium	0.24 Medium	0.18 Medium			
		@P<0.001 in comparison to D0 (Friedman test)								

Table no 13-Showing effect size difference on *Shaitya* (cold extremities) Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	Day 3	Day 5	1Hr	D3	D5	1Hr	D3	D5
Shaitya (cold extremities)	A	0.000(0.000-0.000)	0.000(0.000-0.000)	0.000(0.000-0.000)	0.093 Small	0.12 Small	0.12 Small	0.11±0.364 Medium	0.0±0.364 Nil	0.0±0.364 Nil
	B	0.000(0.000-0.000)	0.000(0.000-0.000)	0.000(0.000-0.000)	0.053 Small	0.068 Small	0.073 Small			
		@P<0.001 in comparison to D0 (Friedman test)								

Table no 14-Showing effect size difference on *Mukhasweda* (Sweating over forehead) Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	Day 3	Day 5	1Hr	D3	D5	1Hr	D3	D5
Mukhasweda (Sweating over forehead)	A	0.000(0.000-0.000)	0.000(0.000-0.000)	0.000(0.000-0.000)	0.093 Small	0.12 Small	0.14 Small	0.0±0.364 Nil	0.0±0.364 Nil	0.0±0.364 Nil
	B	0.000(0.000-0.000)	0.000(0.000-0.000)	0.000(0.000-0.000)	0.08 Small	0.10 Small	0.12 Small			
		@P<0.001 in comparison to D0 (Friedman test)								

Table no 15-Showing effect size difference on *Prastabdha gaatra* (body become rigid) Within the group & between the group.

Symptoms	Group	Median			Effect size (within the group)			Effect size (between the group) A&B		
		1hr	**Day 3**	**Day 5**	**1Hr**	**D3**	**D5**	**1Hr**	**D3**	**D5**
Prastabdha gaatra (body become rigid)	A	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.29 Large	0.24 Medium	0.18 Medium	0.21±0.364 Medium	0.182±0.364 Medium	0.182±0.364 Medium
	B	0.000(0.000-1.000)@	0.000(0.000-0.000)@	0.000(0.000-0.000)@	0.21 Medium	0.25 Medium	0.2 Medium			
	@P<0.001 in comparison to D0 (Friedman test)									

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