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An open labelled clinical trial to Evaluate the efficacy of Sauvarchaladi Churna in Udar Shula W.S.R to infantile colic

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Abstract
Udara Shoola seen in infancy is explained by *Kashyapa* which occurs due to various causes, which are hypothesized but exact cause is not known, it is a self limiting condition which affects infants between few weeks after birth to 6 month of age. Colic is defined as excessive crying in an otherwise healthy infants. Infantile colic Usually starts in the first few week of life & end by 4-5 month. 80% of babies are brought to clinics with the infantile colic.

Objective: the present study has done to evaluate effect of Sauvarchaladi Churna to treat Udarshula in infants.

Methods: An open clinical trial with 36 patients is done from KAHER's Shri B.M.K. Ayurveda Mahavidyalaya, Shahapur, Belagavi, Karnataka, 590003 OPD and IPD OF the department.

Results: There was significant in result of reducing the frequency of cry, status of legs, flushing of face, and reduction in refusal to feed. 36 Patients of Infantile colic were selected. Sauvarchaladi churna with honey in a dose of 1ratti, 2ratti, 3ratti, 4ratti, 5ratti, 6ratti in age group of 1month, 2months, 3months, 4months, 5months, 6months respectively. Assessment of parameter was done before treatment, at 10min, 20min, 30min, 40min, 50min, 60min, 80min, 100min, 120min, 150min and 180min of treatment.

Conclusion: Sauvarchaladi Churna is effective in the management of infantile colic.

Keywords: Udar Shoola, Dyclomine, Infantile colic, Sauvarchaladi churna

Introduction
Udara Shoola various types of Shoola are described. Those are like Eka doshaja, Dwandwaja, Sannipataja, Amaja, etc. the present study has been given importance towards Udara Shoola in children w.rs.t infantile colic. infantile colic is one which exhibits a symptom complex of paroxysmal abdominal pain presumably of intestinal origin associated with severe crying. It usually starts in the first few weeks of life and ends by 4-5 month. *Udarshoola* (Infantile colic) is considered to be the foremost complaint noticed in the infant which is expressed by incessant cry that disturb mother and whole family. If not attended to, it can impact on poor weight gain poor quality of life in infants, thus the major issue to be focused on for proper management. Infantile colic occurs at a very early phase of life and it is expressed by irritable incessant cry as infants are not able to express it in verbal form or other form. Cumulative incidence rates of colic vary from 5% to 25%. Crying associated with infantile colic can cause relationship stress, improper breast feeding, postpartum depression, excess visits to doctor, and child abuse such as "Shaken baby syndrome" [6]. Colicky symptoms have been linked to feeding problems and disturbed sleep [7]. An infantile colic may be related to long term a outcome which affects family stability, short term anxiety or depression in the mother, temper tantrums and altered sleep patterns. It may cause exhaustion and stress in the parents. To alleviate this burning problem from the routine pediatric practice Sauvarchaladi churna is chosen for study. Results has given the idea that, it could be one of the reasonable effective drug mentioned in the classics in alleviating pain Sauvarchaladi churna has taken for the study and administered once, and the features were assessed with the assessment criteria by providing suitable grading scales to screen the improvement of the clinical condition. The observations were recorded.

Methods
An open labelled clinical trial was carried out with the objective to study the effect of sauvarchaladi churna in infantile colic.

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Drug administration schedule- Sauvarchaladi churna was administered once with madhu.for 1 month old baby 1 ratti was given, for 2 month old baby 2 ratti was given and so on till 6 months.

Inclusion criteria
a. Babies in between the age group 1st week to 6months of either sex
b. Babies presenting with signs and symptoms of diagnostic criteria

Exclusion criteria
a. Children above 6months of age will be excluded.
b. Babies with known congenital anomalies or known chromosomal abnormalities contraindicating the inclusion into the study like diaphragmatic hernia etc.
c. Abdominal colicky necessitating emergency intervention will be excluded.
d. Abdominal colicky associated with any other systemic involvement or any other medical cause as found by the investigator at the time of examination necessitating the exclusion will be excluded

Table 1: Diagnostic Criteria

Major criteria (At least 1 with "intermittent Cry" as must)	Minor Criteria(At least 1)
Intermittent high pitched Cry	*Mukha sweda* or Flushing of face
Refusal of breast feed	*Uttanashayana*(feels comfortable when the baby is made to lie on abdomen
Udar sthabdhata	*Shaitya*
	Pulling of leg towards abdomen
	Touches the abdomen while crying

Results
A total number of 58 patients were screened in which 38 patients were enrolled among them 36 completed the trial. All patients were selected as per the inclusion and exclusion criteria and were assessed for the improvement of the clinical conditions.

Age: Among 36 patients maximum of 36.11% were of 2 months of age, followed by 19.44% were of 3 months of age, 13.89% of the children belongs to 1 months of age, 11.11% children belongs to 6 months of age group, 8.33% of the children belongs to <1 month & 5 months of age group and the minimum of 2.78% children belongs to 4 months of age group

Sex: Among 36 patients 58.33% of the patients were male and 41.67% were female

Socioeconomic status: Among 36 patients 47.22% of the patients were of upper middle class, 41.67% of the patients were of lower middle class, 11.11% of the patients were of upper class.

Feeding history: Among 36 patients, 66.67% of patients were on exclusive breast feed,25% of patients were Exclusive breast feed + top feed, 8.33% of patients were only on top feed.

Diva swapana: Among 36 mother of patients, 72.22% mothers had habit of diva swapana and 27.78% of mothers do not takes sleep during day time.

Abdominal distention: Among 36 patients, 80.56% of patients had abdominal distention and in 19.44% there were no abdominal distension noted.

Abdominal auscultation: Among all 36 patients i.e. in 100%

of the patients gurgling sound were noted.

Abdominal palpation: Among 97.22% of the patient's soft and non-tender abdomen were noted and in 2.78% of the patients were having tender abdomen

Prakruti: Among 36 patients, 47.22% of patients had VK prakruti, 22.22% of patients had PK prakruti, 19.44%, had VK prakruti and 11.11% of patients had K predominant prakruti

Kula vrittanta: Among 36 patients 61.11% of patients were first born, 33.33% of patients were second born and only 5.56% of patients were third born

Table 2: Observations based on assessment criteria- status of cry by Wilcoxon matched pairs test

Time points	Mean	Std. Dv.	Median	Mean Diff.	SD Diff.	% of change	Z-value	P-value
Before	3.6	0.5	4.0					
At 10min	3.6	0.5	4.0	0.0	--	0.00	--	--
Before	3.6	0.5	4.0					
At 20 min	3.4	0.5	3.0	0.2	0.4	5.38	2.3664	0.0180*
Before	3.6	0.5	4.0					
At 30 min	3.1	0.5	3.0	0.6	0.5	15.38	3.9199	0.0001*
Before	3.6	0.5	4.0					
At 40 min	2.8	0.5	3.0	0.8	0.6	22.31	4.4573	0.0001*
Before	3.6	0.5	4.0					
At 50 min	2.5	0.5	2.5	1.1	0.7	30.77	4.6226	0.0001*
Before	3.6	0.5	4.0					
At 60 min	2.4	0.6	2.0	1.3	0.8	34.62	4.6226	0.0001*
Before	3.6	0.5	4.0					
At 80 min	2.1	0.8	2.0	1.5	1.0	42.31	4.7030	0.0001*
Before	3.6	0.5	4.0					
At 100 min	1.6	1.0	1.0	2.0	1.1	55.38	4.9365	0.0001*
Before	3.6	0.5	4.0					
At 120 min	1.4	1.0	1.0	2.2	1.1	61.54	5.0862	0.0001*
Before	3.6	0.5	4.0					
At 150 min	1.1	1.2	1.0	2.5	1.4	69.23	5.0862	0.0001*
Before	3.6	0.5	4.0					
At 180 min	1.0	1.2	0.0	2.6	1.4	73.08	5.0862	0.0001*

Table 3: Comparison of different time points with baseline with respect to status of Legs by Wilcoxon matched pairs test

Time points	Mean	Std. Dv.	Median	Mean Diff.	SD Diff.	% of change	Z-value	P-value
Before	2.0	0.0	2.0					
At 10min	2.0	0.0	2.0	0.0	--	0.00	--	--
Before	2.0	0.0	2.0					
At 20 min	2.0	0.0	2.0	0.0	--	0.00	--	--
Before	2.0	0.0	2.0					
At 30 min	1.9	0.2	2.0	0.1	0.2	2.78	0.0001	0.9999
Before	2.0	0.0	2.0					
At 40 min	1.9	0.3	2.0	0.1	0.3	5.56	1.8257	0.0679
Before	2.0	0.0	2.0					
At 50 min	1.8	0.4	2.0	0.2	0.4	9.72	2.3664	0.0180*
Before	2.0	0.0	2.0					
At 60 min	1.6	0.5	2.0	0.4	0.5	20.83	3.4078	0.0007*
Before	2.0	0.0	2.0					
At 80 min	1.4	0.5	1.0	0.6	0.5	29.17	4.0145	0.0001*
Before	2.0	0.0	2.0					
At 100 min	1.4	0.5	1.0	0.6	0.5	29.17	4.0145	0.0001*
Before	2.0	0.0	2.0					
At 120 min	1.3	0.5	1.0	0.7	0.5	34.72	4.3724	0.0001*
Before	2.0	0.0	2.0					
At 150 min	1.3	0.5	1.0	0.7	0.5	36.11	4.4573	0.0001*
Before	2.0	0.0	2.0					
At 180 min	1.3	0.5	1.0	0.8	0.5	37.50	4.4573	0.0001*

Table 4: Comparison of different time points with baseline with respect to status of Refusal to feed by Wilcoxon matched pairs test

Time points	Mean	Std. Dv.	Median	Mean Diff.	SD Diff.	% of change	Z-value	P-value
Before	1.0	0.0	1.0					
At 10min	1.0	0.0	1.0	0.0	--	0.00	--	--
Before	1.0	0.0	1.0					
At 20 min	1.0	0.0	1.0	0.0	--	0.00	--	--
Before	1.0	0.0	1.0					
At 30 min	1.0	0.0	1.0	0.0	--	0.00	--	--
Before	1.0	0.0	1.0					
At 40 min	1.0	0.0	1.0	0.0	--	0.00	--	--
Before	1.0	0.0	1.0					
At 50 min	1.0	0.0	1.0	0.0	--	0.00	--	--
Before	1.0	0.0	1.0					
At 60 min	0.9	0.3	1.0	0.1	0.3	8.33	1.6036	0.1088
Before	1.0	0.0	1.0					
At 80 min	0.9	0.3	1.0	0.1	0.3	11.11	1.8257	0.0679
Before	1.0	0.0	1.0					
At 100 min	0.6	0.5	1.0	0.4	0.5	36.11	3.1798	0.0015*
Before	1.0	0.0	1.0					
At 120 min	0.5	0.5	0.0	0.5	0.5	52.78	3.8230	0.0001*
Before	1.0	0.0	1.0					
At 150 min	0.3	0.5	0.0	0.7	0.5	66.67	4.2857	0.0001*
Before	1.0	0.0	1.0					
At 180 min	0.3	0.5	0.0	0.7	0.5	66.67	4.2857	0.0001*

Table 5: Comparison of different time points with baseline with respect to status of Face by Wilcoxon matched pairs test

Time points	Mean	Std. Dv.	Median	Mean Diff.	SD Diff.	% of change	Z-value	P-value
Before	2.0	0.2	2.0					
At 10min	2.0	0.2	2.0	0.0	--	0.00	--	--
Before	2.0	0.2	2.0					
At 20 min	2.0	0.2	2.0	0.0	--	0.00	--	--
Before	2.0	0.2	2.0					
At 30 min	1.9	0.3	2.0	0.1	0.2	2.82	0.0001	0.9999
Before	2.0	0.2	2.0					
At 40 min	1.6	0.5	2.0	0.3	0.5	16.90	3.0594	0.0022*
Before	2.0	0.2	2.0					
At 50 min	1.5	0.5	2.0	0.4	0.5	22.54	3.5162	0.0004*
Before	2.0	0.2	2.0					
At 60 min	1.4	0.5	1.0	0.6	0.5	28.17	3.9199	0.0001*
Before	2.0	0.2	2.0					
At 80 min	1.3	0.6	1.0	0.7	0.6	33.80	4.1069	0.0001*

Before	2.0	0.2	2.0					
At 100 min	1.2	0.7	1.0	0.8	0.6	40.85	4.3724	0.0001*
Before	2.0	0.2	2.0					
At 120 min	1.0	0.8	1.0	1.0	0.8	50.70	4.4573	0.0001*
Before	2.0	0.2	2.0					
At 150 min	0.7	0.8	0.5	1.3	0.8	63.38	4.6226	0.0001*
Before	2.0	0.2	2.0					
At 180 min	0.6	0.8	0.0	1.4	0.8	70.42	4.6226	0.0001*

Table 6: Comparison of different time points with baseline with respect to status of flushing of face by Wilcoxon matched pairs test

Time points	Mean	Std. Dv.	Median	Mean Diff.	SD Diff.	% of change	Z-value	P-value
Before	1.0	0.0	1.0					
At 10min	1.0	0.0	1.0	0.0	--	0.00	--	--
Before	1.0	0.0	1.0					
At 20 min	1.0	0.2	1.0	0.0	0.2	2.78	0.0001	0.9999
Before	1.0	0.0	1.0					
At 30 min	0.9	0.3	1.0	0.1	0.3	8.33	1.6036	0.1088
Before	1.0	0.0	1.0					
At 40 min	0.7	0.5	1.0	0.3	0.5	33.33	3.0594	0.0022*
Before	1.0	0.0	1.0					
At 50 min	0.6	0.5	1.0	0.4	0.5	44.44	3.5162	0.0004*
Before	1.0	0.0	1.0					
At 60 min	0.4	0.5	0.0	0.6	0.5	63.89	4.1973	0.0001*
Before	1.0	0.0	1.0					
At 80 min	0.3	0.5	0.0	0.7	0.5	72.22	4.4573	0.0001*
Before	1.0	0.0	1.0					
At 100 min	0.2	0.4	0.0	0.8	0.4	83.33	4.7821	0.0001*
Before	1.0	0.0	1.0					
At 120 min	0.1	0.4	0.0	0.9	0.4	86.11	4.8599	0.0001*
Before	1.0	0.0	1.0					
At 150 min	0.1	0.2	0.0	0.9	0.2	94.44	5.0862	0.0001*
Before	1.0	0.0	1.0					
At 180 min	0.1	0.2	0.0	0.9	0.2	94.44	5.0862	0.0001*

Table 7: Comparison of different time points with baseline with respect to status of Pulling of legs towards abdomen by Wilcoxon matched pairs test

Time points	Mean	Std.Dv.	Median	Mean Diff.	SD Diff.	% of change	Z-value	P-value
Before	1.0	0.0	1.0					
At 10min	1.0	0.0	1.0	0.0	--	0.00	--	--
Before	1.0	0.0	1.0					
At 20 min	1.0	0.0	1.0	0.0	--	0.00	--	--
Before	1.0	0.0	1.0					
At 30 min	0.9	0.2	1.0	0.1	0.2	5.56	0.0002	0.9999
Before	1.0	0.0	1.0					
At 40 min	0.9	0.4	1.0	0.1	0.4	13.89	2.0226	0.0431*
Before	1.0	0.0	1.0					
At 50 min	0.8	0.4	1.0	0.2	0.4	19.44	2.3664	0.0180*
Before	1.0	0.0	1.0					
At 60 min	0.6	0.5	1.0	0.4	0.5	41.67	3.4078	0.0007*
Before	1.0	0.0	1.0					
At 80 min	0.5	0.5	0.5	0.5	0.5	50.00	3.7236	0.0002*
Before	1.0	0.0	1.0					
At 100 min	0.4	0.5	0.0	0.6	0.5	58.33	4.0145	0.0001*
Before	1.0	0.0	1.0					
At 120 min	0.3	0.5	0.0	0.7	0.5	69.44	4.3724	0.0001*
Before	1.0	0.0	1.0					
At 150 min	0.3	0.5	0.0	0.7	0.5	72.22	4.4573	0.0001*
Before	1.0	0.0	1.0					
At 180 min	0.3	0.5	0.0	0.7	0.5	72.22	4.4573	0.0001*

Discussion

The observations in the present study has done by giving emphasize in different assessment criteria's as follows.

Age wise distribution of the patients proceeds information that maximum of the colicky complaint patients are coming under 2 month age group category. Study discloses that maximum of the patients available were suffering from infantile colic. Sex wise distribution gives information that maximum of the colicky patients are Male children, moderns references also suggests that male patients are more prone for colicky pain. Evidence of study reveals about the availability male patients is more in this hospital during the study period.

Study reveals about the socio economic status of the patients that maximum 17 (47.22%) are coming under Upper middle class group. This is because the total strength of the middle class people is more than other socio economic groups. Study reveals about 100% of cases were having the gurgling sound, moderns references also suggests that hyper peristalsis & gurgling sound present in infantile colic. All 100% of cases in both the group were immunized as per national immunization schedule. In the present study 61.11% of the patients were first born, moderns references also suggests that first born are more prone to develop infantile colic. Recent study reveals on the status of diva swapna of mother that maximum i.e. 26 (72.22%) had habit of day sleep. Study reveals about the feeding habit of the individual patients that maximum 66.67% of patients were absolutely under breast feed, 25% were on breast feed plus top feed and 8.33% were only on top feed, modern references suggest that the incidence if disorder is equal among breast fed and formula fed infants.

Effect of sauvarchaladi churna on crying
1. Presence of azulene, ferulic acid, luteolin, valeric acid in Hingu having the antispasmodic action thus may causing the relieve in crying episodes. The major constituents of Zingiber officinale include volatile oils, oleoresin (gingerol), linoleic acids and trace elements such as magnesium, phosphorus and potassium. Most of the pharmacological activities of Ginger officinale can be attributed to the presence of gingerol and its analogues found in the rhizome extracts it contains a mixture of constituents like monoterpenes and sesquiterpenes which were reported to have anti-inflammatory and analgesic activities. So may be due to analgesic effect of sunthi reduction of pain occur & child had relieved from crying episodes. Along with this Sunthi also having the carminative property, as the accumulated gases passes out there was decrease in tension of abdominal muscles leads to decrease in colicky further leading to decrease in crying. Presence of alkaloid, saponins and tannins, in Vacha caused inhibition of muscular contraction, the spasmolytic effect is mediated through the presence of CCB like constituent(s) which is concentrated in the n hexane fraction and this study provides a strong mechanistic base for its traditional use in gastrointestinal disorders such as colic pain Due to Shoolaghana & vatanulomana karma of lavana it is also indicated in shoola.
2. Effect of sauvarchaladi on status of legs/pulling of legs towards abdomen Due to accumulation of gases in the abdomen there is increased tension in smooth muscles leading to pain due to pulling of legs infant tries to relax the tension, by the administration of sauvarchaladi churna due to action of Vatanulomana the tension got relieved & also shoola shamaka property of Shunthi & Hingu attribute to decrease in colic pain eventually the child relieved from this symptom and feels better.
3. Effect of sauvarchaladi on Refusal to feed
Refusal to feed is due to – Pain, fullness of abdomen, Agnimandhya. Presence of azulene, ferulic acid, luteolin, valeric acid in Hingu having the antispasmodic action thus cases reduction in pain. The major constituents of Zingiber officinale include volatile oils, oleoresin (gingerol), linoleic acids and trace elements such as magnesium, phosphorus and potassium. Most of the pharmacological activities of ginger can be attributed to

the presence of gingerol and its analogues found in the rhizome extracts it contains a mixture of constituents like monoterpenes and sesquiterpenes which were reported to have anti-inflammatory and analgesic activities. So may be due to analgesic effect of Sunthi reduction of pain occur & child may relived from pain. Due to Katu rasa, Ushna Virya & Snigdha & Laghu guna and properties like Agnideepana, pachana, rochana property Sunthi 152may have caused reduction in symptom of refusal to feed & child may showed the interest in feeding. Fullness of abdomen got relived from the vatanulomaka properties of Sauvarchaladi churna. Due to deepana -pachana effect of trikatu, indrajava, & sauvarchala lavana child got relived from refusal to feed at 100 min. with the mean value of 0.6 after the administration of sauvarchaladi churna & the infant shows interest in feeding.
4. Effect bof Sauvarchaladi churna on facial expression Sauvarchaladi churna predominantly consist of usha virya dravyas which causes relieve in pain and thus infants feel calmness resulting in reduction of facial expression.
5. Effect of sauvarchaladi churna on flushing of face
In udarshoola, aggravated vayu enters in kostha, flatulence in kostha causes todvata pida,simultaneously the infant feels anxiety leading to flushing of face, as the pain beyond the specific threshold of tolerance will cause horripillation, flushing, sweating as it's feedback mechanism to nervous system. The known cause of colic is gaseous accumulation in abdomen results in increased tension of smooth muscles leading to high threshold pain causing flushing of face, eventually by administration of sauvarchaladi churna due to vatanulomaka property the main culprit is removed.

Summary
36 patients have been enrolled having between 1 to 6 months. Assessment was done based on the graded assessment criteria using SSPS version 20. Observations were collected on basis of demographic data which includes age, sex, religion, socio-economic status, etc. The data related disease includes chief complaints, associate complains, Flushing of face etc. Sauvarchaladi churna shown to be highly significant in reducing the clinical manifestation of infantile colic. The study revealed that Sauvarchaladi churna was found to be better in relieving the acute manifestation of infantile colic. Sauvarchaladi churna shows antispasmodic effect and able to reduce frequency of pain, duration of pain and cry significantly. No side effect observed during and after its clinical trial. The drugs in Sauvarchaladi churna having Deepanaa, Pachana and Vatanulomak, Ruchya properties.

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