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Research Article

Anemia in Children

A comparative clinical study to evaluate the efficacy of Amalakyavaleha and Devdali Churna in Pandu Roga w.s.r. to Iron Deficiency Anemia in Children

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Background: Pandu Roga is a condition characterizes by skin discoloration resembling Haridra or a greenish tinge, along with symptoms such as Hridayaspandanam, Roukshyam, Swedabhava, Shrama and related complications. It reflects various underlying conditions caused by a deficiency in Rakta Dhatu, such as reduced hemoglobin or RBCs. Iron Deficiency Anemia (IDA), a prevalent nutritional disorder globally, affects over 40% of children, especially in developing nations like India. IDA impairs cognitive and physical development, immunity, and overall health. While iron supplements are commonly used, their side effects often limit adherence, highlighting the need for safer, holistic treatments.

Aim and Objectives: To evaluate, compare the efficacy and clinical safety of Amalakyavaleha and Devdali Churna drugs in children.

Materials and Methods: A randomized, comparative clinical trial was conducted on 40 pediatric patients for 4 weeks diagnosed with IDA. The patients were divided into two groups: Group I received Amalakyavaleha, while Group II was treated with Devdali Churna. The clinical efficacy of both interventions was assessed based on subjective and objective criteria, symptomatic relief, and overall improvement in nutritional status.

Results: The study revealed that both groups significantly improved clinical symptoms and hematological markers. The comparative analysis demonstrated the potential of Amalakyavaleha in addressing the underlying causes of Pandu Roga and effectively managing IDA.

Conclusion: This study seeks to provide evidence for using safe and effective Ayurvedic alternatives in addressing anemia in children, offering a holistic approach that goes beyond symptom management to target the root cause.

Keywords: Pandu Roga, Rakta Dhatu, IDA, Amalakyavaleha, Devdali Churna

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Introduction

In our classical texts, *Pandu Roga* is one among the diseases which occurs due to *Dhatu Vaishamyata* and the description is available in three forms; i.e. as a disease,**[1]** complication**[2,3,4]** and sign of certain diseases.**[5,6]** The disease condition in which the skin of the person is discolored like *Haridra* or greenish tinge and other peculiar signs and symptoms include *Hridayaspandanam*, *Roukshyam*, *Swedabhava*, *Shrama* and its consequences.**[7]** Considering *Panduta* (Pallor) as the predominant sign, the disease is termed as *Pandu Roga*. In *Charaka Samhita*, it is mentioned as *Pitta Pradhan Vyadhi* and the *Dosha Pitta Pradhanastu* mentioned as its basic cause and *Rasa Pradoshaja Vyadhi*.**[8]**

Anemia is derived from the Greek term 'bloodlessness'. It is defined as decreased red blood cell (RBC) volume (reflected by RBC count and Hb concentration per RBC and Hematocrit) or reduced Hb concentration below age-appropriate normal values. WHO defines "as a condition in which the number of RBCs is insufficient to meet the body's physiologic needs". It is not a disease entity but a manifestation of different diseases in which there is pallor on the skin due to a deficiency of blood tissue (*Rakta Dhatu)* either in the form of hemoglobin or red blood cells (RBCs).**[9]**

WHO (2011) estimated that the worldwide prevalence of anemia was 42% in children, 38% in pregnant woman and 29% in non-pregnant woman. Globally, it is estimated that 40% of all children aged 6–59 months, 37% of pregnant women and 30% of women 15–49 years of age are affected.**[10]**

Iron deficiency was the fourth and twelfth leading cause of years lived with disability in women and men observed by the Global Burden of Diseases Study in 2017. The percentage of years lived with disease has decreased over the past three decades from 17.3 to 12% in India.**[11]** The prevalence is significantly higher in developing countries as compared with developed countries. As per National Family Health Survey - 4 prevalence is highest in preschool children (>60%) followed by adolescents and young adults (30%).**[12]** IDA is most common and widespread nutritional deficiency anemia**[13]** in which reduction of iron stores precedes and is more severe condition in which low level of iron are associated with presence of microcytic hypochromic red cells in circulation,

The relative number of which reflects the severity of the iron deficiency. Iron helps to move oxygen from the lungs to the rest of the body and helps muscles store and use oxygen. In older children, it is usually caused by dietary deficiency, insufficient iron intake, poor gastrointestinal absorption or occult blood loss, intercurrent infections such as Hookworm infestation, Malaria, Infectious diseases, Tuberculosis, etc.

Pica also increases the risks of lead poisoning and helminthic infestation. Weakness, fatigue, shortness of breath, difficulty in concentrating and poor work productivity are non-specific symptoms attributed to low delivery of oxygen to body tissues and decreased activity of iron-containing enzymes. It has been reported to decrease cognitive performance and delay mental and motor development in children. Prematurity, living in poverty, a diet low in iron and certain long-term illnesses are the high-risk factors causing IDA in children.

Various formulations have been described in our classical texts, which are very effective in the prevention and management of *Pandu Raga.* Considering this, the present study "A Comparative Clinical Study to Evaluate the Efficacy of *Amalakyavaleha* and *Devdali Churna* in *Pandu Roga* w.s.r to Iron Deficiency Anemia in Children" has been focused on treatment of *Pandu Roga*.

Aims and Objectives

1. To analyze the etiopathogenesis of *Pandu Roga* and Iron Deficiency Anemia from *Ayurvedic* and Modern texts/ journals.
2. To evaluate the efficacy of *Amalakyavaleha* and *Devdali Churna.*
3. To compare the effects of *Amalakyavaleha* and *Devdali Churna*.
4. To evaluate the clinical safety of *Amalakyavaleha* and *Devdali Churna* drugs in children.

Materials and Methods

Total 40 patients were registered from the *Kaumarbhritya-Balroga* OPD/IPD, Rajiv Gandhi Government Post Graduate Ayurvedic College and Hospital, Paprola, randomly fulfilling the criteria of this study. A case proforma was filled with the data obtained by interrogation, physical examination, and collection of details of each child.

Inclusion Criteria

1. Patient between age group of 3-12 years.
2. Patient having Hb in between 7-10 gm%. (as per WHO classification)
3. Patients / Parents willing to participate in the trial.

Exclusion Criteria

1. Patients having age less than 3 years and above 12 years.
2. Patient having Hb levels below 7 gm% or above 10 gm%.
3. Patient suffering from the major systemic illness, Tuberculosis, Bleeding Disorders, etc.

Grouping of patients

In the present research work, a total of 40 patients were registered and studied under two groups.

Group I: In this group, 20 patients were managed with *Amalakyavaleha**.***

- Route of Administration: Oral
- Dosage: 500mg/kg/day in two divided doses.
- *Anupana*: Lukewarm Water.

Group II: 20 patients were managed with *Devdali Churna* in this group.

- Route of Administration: Oral
- Dosage: 80mg/kg/day in two divided doses.
- *Anupana*: Lukewarm milk or water.

Duration of the trial: 4 weeks

Follow up: 2nd week and at the time of completion.

Criteria of Assessment of Results

The assessment of the effect of trial drugs was done based on the subjective and objective criteria. All the patients were examined before initiation and after completion of the trial.

The improvement was assessed based on relief in the severity of the symptoms and changes in the laboratory investigations were also taken into consideration.

Subjective Criteria

Grading and scoring system were adopted for assessing each sign and symptom before the commencement and after completion of trial.

SN	Symptoms	Grade
1.	**Panduta -** Twacha(1), Nakha(2), Netra(3), Jihwa(4), Hastapada(5)	
	Absent	0
	Present at one site	1
	Present at two sites	2
	Present at three or more sites	3
2.	**Daurbalya (Weakness)**	
	Not present	0
	After Moderate work, relieved soon and tolerable	1
	After moderate work, relieved later and tolerable	2
	After little work, relieved later and beyond tolerable	3
3.	**Hridayaspandanam (Palpitation)**	
	Not present	0
	On doing routine physical activity	1
	On doing strenuous physical activity	2
4.	**Aruchi (Anorexia)**	
	Absent	0
	Present	1
5.	**Bhrama (Dizziness)**	
	No	0
	Mild	1
	Moderate	2
	Severe	3
6.	**Ayasaja Shwasa (Shortness of breath)**	
	No	0
	Mild	1
	Moderate	2
	Severe	3

7.	**Shirashoola (Headache)**	
	No	0
	Mild	1
	Moderate	2
	Severe	3
8.	**Pica**	
	Not present	0
	Present	1
9.	**Disturbed Sleep**	
	Not present	0
	Present	1
10.	**Pindikodweshtana (Calf Muscle Pain)**	
	Not Present	0
	Present	1

Objective Criteria

- Hb gm%
- Ferritin
- Peripheral Blood Smear

Laboratory investigations

- MCV, MCH, MCHC
- TLC
- ESR
- RFT (Blood Urea, S. Creatinine)
- LFT (SGOT, SGPT)

Statistical Analysis

Proposed research work was an open-label clinical trial. Data was statistically analysed by using appropriate tests "Student's paired 't' test" for individual group & "Unpaired 't' test" for intergroup comparison were used for parametric data.

For non-parametric data "Wilcoxon signed rank sum test" was used for individual group and "Mann Whitney 'U' test" was used for intergroup comparison.

The obtained results were interpreted as follows

- Highly significant $p<0.001$
- Significant $p<0.05$
- Insignificant $p>0.05$

Assessment of Results

Result is assessed based on overall effect of trial drug on subjective and objective parameters and categorized as

Marked Improvement	>75% Relief
Moderate Improvement	50%-74% Relief
Mild Improvement	25%-49% Relief
No Improvement	<25% Relief

Results

Assessment of the subjective parameters before and after treatment

Signs and symptoms	Groups	Mean		d	% Relief	SD±	SE±	W value	P value
		BT	AT						
Panduta	Group I	1.65	0.7	0.95	57.57%	0.604	0.135	-136	<0.001
	Group II	1.7	0.75	0.95	55.88%	0.223	0.05	-190	<0.001
Daurbalya	Group I	1.6	0.6	1	62.50%	0.458	0.102	-171	<0.001
	Group II	1.65	0.6	1.05	63.63%	0.223	0.05	-210	<0.001
Hridaya spandanam	Group I	1	0.45	0.55	55%	0.604	0.125	-55	0.002
	Group II	0.75	0.4	0.35	46.67%	0.489	0.109	-28	0.016
Aruchi	Group I	0.95	0.1	0.85	89.47%	0.366	0.081	-153	<0.001
	Group II	0.9	0.1	0.8	88.89%	0.410	0.091	-136	<0.001
Bhrama	Group I	1.05	0.4	0.65	61.90%	0.587	0.131	-78	<0.001
	Group II	1.2	0.55	0.65	54.17%	0.587	0.131	-78	<0.001
Ayasaja Shwasa	Group I	0.85	0.4	0.45	52.94%	0.510	0.114	-45	0.004
	Group II	0.65	0.35	0.3	46.15%	0.470	0.105	-21	0.031

Shirashoola	Group I	1.6	0.7	0.9	56.25%	0.447	0.1	-153	<0.001
	Group II	1.4	0.5	0.9	64.28%	0.307	0.068	-171	<0.001
Pica	Group I	0.9	0.1	0.8	88.88%	0.410	0.091	-136	<0.001
	Group II	1	0.35	0.65	65%	0.489	0.109	-91	<0.001
Disturbed sleep	Group I	0.95	0.1	0.85	89.47%	0.366	0.081	-153	<0.001
	Group II	0.6	0.25	0.35	58.33%	0.489	0.109	-28	0.016
Pindikodweshtana	Group I	0.75	0.3	0.45	60%	0.510	0.114	-45	0.004
	Group II	0.6	0.15	0.45	75%	0.510	0.114	-45	0.004

Intergroup comparison of sign and symptoms

Signs and symptoms	Mean diff. (BT-AT)		Diff. in % Relief	Mann Whitney Rank	p value
	Group I	Group II			
Panduta	0.95	0.95	1.69%	408.5	0.978
Daurbalya	1	1.05	-1.13%	392	0.634
Hridayaspandanam	0.55	0.35	8.33%	443.5	0.371
Aruchi	0.85	0.8	0.58%	420	0.796
Bhrama	0.65	0.65	7.73%	410	0.989
Ayasaja Shwasa	0.45	0.3	6.79%	440	0.423
Shirashoola	0.9	0.9	-8.03%	409	0.989
Pica	0.8	0.65	23.88%	440	0.423
Disturbed sleep	0.85	0.35	31.14%	510	0.007
Pindikodweshtana	0.45	0.45	-15%	410	0.989

Effect of Therapy on Objective Criteria

Investigations	Groups	Mean		d	% change	SD±	SE±	't' value	p value
		BT	AT						
Hb gm%	Group I	9.406	9.84	-0.434	-4.61%	0.852	0.191	-2.277	0.035
	Group II	9.415	9.56	-0.145	-1.54%	0.368	0.082	-1.763	0.094
S. Ferritin	Group I	32.574	34.335	-1.761	-5.41%	2.643	0.591	-2.980	0.008
	Group II	28.801	29.631	-0.831	-2.88%	2.904	0.649	-1.280	0.216

Intergroup comparison of Objective criteria

Investigations	Mean diff (BT-AT)		Diff. in % Relief	't'value	p value
	Group I	Group II			
Hb gm%	-0.434	-0.145	-3.07%	-1.392	0.172
S. Ferritin	-1.761	-0.831	-2.53%	-1.059	0.296

Intergroup Comparison for Peripheral Blood Smear

PBF	BT		AT	Percentage
	Mild Microcytic Hypochromic	Poikilocytosis and Anisocytosis	Normocytic Normochromic	
	No. of Pt.	No. of Pt.	No. of Pt.	
Group I	18	2	16	80.00%
Group II	20	0	13	65.00%

Effect of Therapy on Laboratory parameters

Investigations	Groups	Mean		d	% change	SD±	SE±	't' value	p value
		BT	AT						
TLC	Group I	7.158	6.163	0.995	13.90%	1.556	0.348	2.859	0.010
	Group II	5.97	5.816	0.154	2.58%	0.728	0.163	0.949	0.355
MCV	Group I	77.07	80.35	-3.3	-4.28%	2.473	0.553	5.968	<0.001
	Group II	75.65	77.5	-1.85	-2.45%	1.309	0.293	-6.321	<0.001
MCH	Group I	22.7	23.1	-0.4	-1.76%	0.995	0.222	-1.798	0.088
	Group II	22.85	23.05	-0.2	-0.88%	0.523	0.117	-1.710	0.104
MCHC	Group I	28.4	29.05	-0.65	-2.29%	0.587	0.131	-4.951	<0.001
	Group II	28.45	28.95	-0.5	-1.76%	0.513	0.115	-4.359	<0.001
ESR	Group I	14.25	12.45	1.8	12.63%	5.473	1.224	1.471	0.158
	Group II	15.65	14.45	1.2	7.67%	5.177	1.158	1.037	0.313

SGOT	Group I	26.25	25	1.25	4.76%	5.056	1.131	1.106	0.283
	Group II	29.5	28.05	1.45	4.92%	5.96	1.333	1.088	0.290
SGPT	Group I	19.1	19.7	-0.6	-3.14%	6.286	1.406	-0.427	0.674
	Group II	23.5	22.05	1.45	6.17%	7.03	1.572	0.922	0.368
S. Creatinine	Group I	0.705	0.605	0.1	14.18%	0.165	0.037	2.703	0.014
	Group II	0.66	0.585	0.075	11.36%	0.168	0.0376	1.994	0.061
B. Urea	Group I	24.3	21.35	2.95	12.14%	6.778	1.516	1.946	0.067
	Group II	25.3	22.85	2.45	9.68%	6.549	1.464	1.673	0.111

Intergroup comparison of laboratory investigations

Investigations	Mean diff (BT-AT)		Diff. in % Relief	't' value	p value
	Group I	Group II			
TLC	0.995	0.154	11.32%	2.188	0.035
MCV	-3.3	-1.85	1.83%	-2.318	0.026
MCH	-0.4	-0.2	-0.88%	-0.796	0.431
MCHC	-0.65	-0.5	-0.53%	-0.860	0.395
ESR	1.8	1.2	4.96%	0.356	0.724
SGOT	1.25	1.45	-0.16%	-0.0114	0.909
SGPT	-0.6	1.45	-9.31%	-0.972	0.337
S. Creatinine	0.1	0.075	2.82%	0.474	0.638
B. Urea	2.95	2.45	2.46%	0.237	0.814

Discussion

Subjective parameters

- The study revealed excellent results in Group I, where patients showed relief in symptoms such as *Panduta*, *Daurbalya*, *Aruchi*, *Bhrama*, *Shirashoola*, Pica and Disturbed sleep with highly significant statistical results ($p<0.001$). There were also significant improvements in *Hridayaspandanam*, *Ayasaja Shwasa* and *Pindikodweshtana* ($p<0.05$).
- Group II also showed satisfactory outcomes, with significant improvement in *Hridayaspandanam*, *Ayasaja Shwasa*, Disturbed sleep and *Pindikodweshtana*. However, highly significant relief was observed in symptoms of *Panduta*, *Daurbalya*, *Aruchi*, *Bhrama*, *Shirashoola* and Pica.
- When comparing the two groups, Group I exhibited superior improvement across all subjective assessment parameters.

Objective parameters

- The differences in mean values of the objective parameters like Hb, MCH, MCHC, ESR, SGOT, SGPT, S. Creatinine, B. Urea, S. Ferritin before and after treatment were not statistically significant, suggesting the possibility of chance occurrence. However, TLC and MCV showed statistically significant mean differences.

Probable Mode of Action of the Trial Drugs.

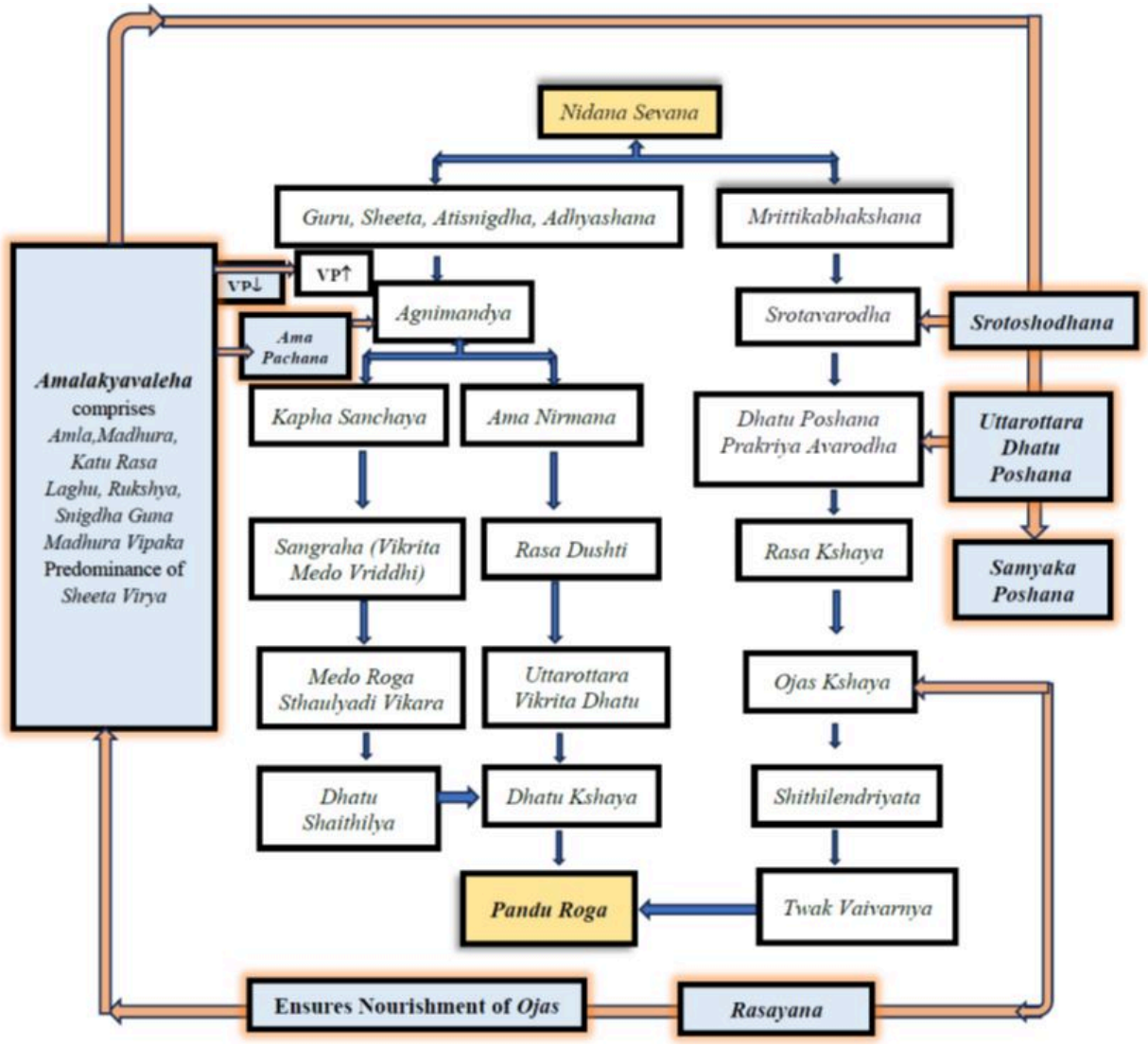
1. Amalakyavaleha

Pharmacological Actions

Ingredients	Karma	Action based on pharmacological studies
Amalaki	Raktavikara, Paittikavikara, Daurbalya, Rasayana, Deepana	Antioxidant, Anti-inflammatory Immunomodulator, Hepatoprotective, Intestinal disorders, Antibacterial, Cytoprotective
Pippali	Pandughna, Daurbalya, Aruchi, Deepana, Raktavardhaka, Rasayana	Antioxidant, Antibacterial, Antimicrobial and Anti-amoebic, Anthelmintic, Antiplatelet
Yashtimadhu	Vatapittashamaka, Raktavikara, Raktalpata, Rasayana, Balya	Antioxidant, Anti-inflammatory, Anti-microbial, Immunostimulatory, Hepatoprotective
Draksha	Pandughna, Hrida Daurbalya, Anulomana, Raktaprasadan	Antioxidant, Antimicrobial and Anti-viral, Hepatoprotective, Cardioprotective
Shringabera	Hridya, Deepana, Pachana, Vatanulomana, Daurbalya, Raktavardhaka	Antioxidant, Neuroprotective & cognitive-enhancing effects, Hepatic & renal-protective effect
Vamshalochan	Raktavikara, Raktasthambhaka, Balya	Antioxidant, Anti-inflammatory, Anthelmintic, Antibacterial
Sharkara	Pittashamaka, Raktavardhaka, Balya, Daha Prashamana, Balya, Deepana	Anti-inflammatory, Antipyretic, Digestive Aid
Madhu	Agni Deepaka, Balya, Lekhaniya, Shodhana, Krimivishaprashamana, Tridoshaprashamana	Anti-bacterial, Antioxidant property, source of Dietary fiber, Vit C, Vit.B6

Therapeutic Indication

SN	Therapeutic indication	Drug ingredients	Improvement in Clinical Features
1.	Pandughna	Draksha, Pippali, Amalaki	Paleness, Headache
2.	Daurbalya	Amalaki, Pippali, Shringabera	Fatigue, Weakness, Shortness of Breath, Dizziness
3.	Deepana-Pachana	Amalaki, Pippali, Sharkara, Madhu,	Anorexia, Disturbed Sleep
4.	Raktvardhaka	Amalaki, Pippali, Yashtimadhu, Draksha, Shringabera, Sharkara	Weakness, Palpitations, Calf muscle pain, Disturbed Sleep, Anorexia, Pica, Headache
5.	Hrida Daurbalya	Amalaki, Draksha, Pippali, Shringabera	Palpitations, Shortness of breath, Dizziness
6.	Vatanulomana	Draksha, Shringabera	Calf muscle pain, Headache, Disturbed Sleep
7.	Pittashamaka	Amalaki, Yashtimadhu, Shringabera, Sharkara, Madhu	Anorexia, Palpitations, Dizziness
8.	Balya	Yashtimadhu, Vamshalochana, Sharkara, Madhu	Weakness, Calf muscle pain, Dizziness
9.	Krimivishaprashamana	Pippali, Madhu	Pica, Anorexia
10.	Aruchi	Amalaki, Pippali, Shringabera, Madhu	Anorexia, Weakness



Flow chart 1: *Samprapti Vighatana* of *Pandu Roga* by *Amalakyavaleha*

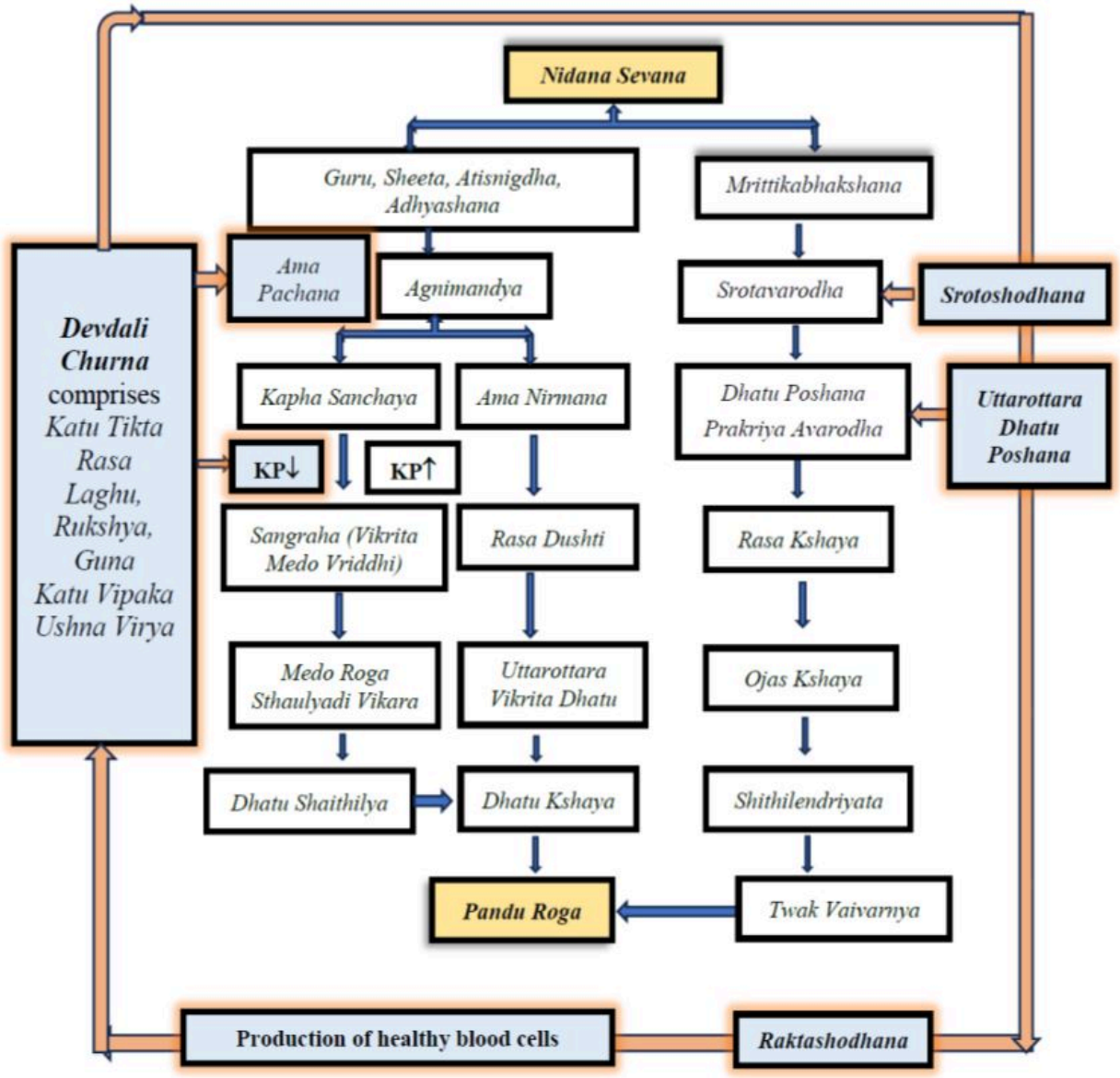
2. Devdali Churna

Pharmacological Actions

Ingredients	Karma	Action based on pharmacological studies
Devdali	Raktavikara, Paittikavikara, Daurbalya, Rasayana, Deepana	Antioxidant, Anti-inflammatory Immunomodulator, Hepatoprotective Intestinal disorders, Antibacterial Cytoprotective

Therapeutic Indication

SN	Therapeutic indication	Drug ingredient	Improvement in Clinical Features
1.	Raktavikara, Paittikavikara, Daurbalya, Rasayana, Deepana	Devdali	Pica, Disturbed Sleep, Anorexia, Headache, Dizziness



Flow chart 2: *Samprapti Vighatana* of *Pandu Roga* by *Devdali Churna*

- The selected formulations for the study i.e., *Amalakyavaleha* and *Devdali Churna* possess excellent *Pandughna Karma* with *Amla*, *Madhura*, *Katu, Tikta Rasa, Laghu, Ruksha, Snigdha Guna, Sheeta and Ushna Virya* with *Madhura* and *Katu Vipaka*
- The constituent herbs of both the formulations are collectively known to have Antioxidant, Anti-inflammatory, Anti-microbial, Immunomodulatory, Hepatoprotective, Antibacterial, Antimicrobial and Anti-amoebic, Anthelmintic, Antiplatelet, Cytoprotective, source of Dietary fiber, Vit C, Vit.B6, Digestive Aid effects based on pharmacological evidence-based studies, play a crucial role in Disrupting the pathogenesis of the disease.

Conclusion

Pandu Roga is a widespread nutritional disorder in children characterized by Fatigue, Paleness and General weakness. These symptoms can significantly hinder a child's growth and daily activities, presenting a challenge for parents who must balance their child's nutritional needs with frequent medical care, often leading to emotional stress.

Ayurvedic remedies have proven effective in reducing the severity of *Pandu Roga* in children. Whether it comes to alleviating the symptoms like *Panduta*, *Hridayaspandanam*, *Bhrama*, Pica, *Pindikodweshtana* as well as associated features like Weakness, Anorexia, Headache and Disturbed Sleep.

The study indicates that the *Amalakyavaleha* formulation administered in Group I had more satisfactory and significant results compared to the drug used for Group II. No adverse effects were reported during the trial, confirming the safety of both treatments.

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