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Research Article

Randomized Open-Label Trial Comparing Two *Ayurvedic Churna* Formulations for Hair Fall (*Keshapatana*) among Young Female Patients

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Abstract

Background: *Ayurveda* describes hair fall as *Keshapatana* or *Khalitya.* Increased physical and psychological stress negatively impacts the hair health. Telogen effluvium and female pattern hair loss are commonly prevalent in young females. *Ayurveda* considers *kesha* as *mala* of *Asthi dhatu,* suggesting that addressing pathology in *Asthi dhatu* may help manage hair fall. Aim: To assess the efficacy of Asthimajjapachak Churna (AMC) compared with Shwadamshtradi Rasayana Churna (SRC) for managing hair fall in young females. Methods: An open-label, randomized, parallel-group clinical trial was conducted on 60 females aged 21-30 years with hair fall. Group A (trial group) received AMC and group B (control group) received SRC, both administered at 1.5 g twice daily with ghee and honey on an empty stomach for 30 days. Assessments were performed using the classical symptoms, the hair pull test and the Ludwig test. Results: Most patients had *Pitta* dominant *prakruti* with excessive *Lavana* (salty) and *Katu* (spicy) *rasa* in their diets. *Asthivaha srotas dushti* was observed in 98.33% patients, whereas *Rasavaha srotas dushti* was noted in 53.33% patients. An overall therapeutic relief of 58.45% was observed in Group A, compared to 35.94% in Group B. Conclusion: A higher number of patients showing *Asthivaha srotas dushti*, indicates involvement of *Asthigata dosha* in hair fall. Alleviation of *Asthigata dosha* may promote the physiological formation of healthy hair, which is specially achieved in the present study in Group A. This result is highly significant than previous works conducted on hair fall.

Keywords: *Keshapatana,* Hair fall*, Asthimajjapachak Churna, Shwadamshtradi Rasayana Churna, Rasayana,* Hair regeneration

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Introduction

Background

Humans of 21st century live an accelerated life and not everyone is able to devote sufficient time to their own health in their daily routine leading to constant mental and physical stress. Contributing factors like excessive physical and mental stress, sedentary life style, pollution, excessive exposure to sunlight etc. are resulting in negative impact on health of hair leading to range of diseases like hair fall, greying of hair.

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According to *Ayurveda*, Hair fall is considered as *Keshapatana* or *Khalitya*, termed as morbid baldness referring to condition in which there is premature, gradual, total or partial hair loss especially from the scalp.(1) According to a recent survey conducted among individuals aged 18 to 35 years, 43.4% of men and 65.9% of women in India experience hair fall.(2) Condition of *Khalitya* is briefly mentioned in *Ayurveda Samhita* however the direct and clear description regarding causative factors is unavailable. However, by analysing the scattered references the indirect knowledge of aetiological factors such as negligence in the treatment of *Pratishyaya,* excessive use of *Kshara*, consumption of *Viruddha Aahara* like simultaneous intake of *Lavana* with milk, vitiation of *Asthivaha Srotas, Asthidhatu kshaya,* vitiation of *Rasa*, *Rakta* and *Swedavaha Srotas*, causes of *Shiroroga*, using excessive hot water for head bath, improper hair style or hair maintenance can be considered.(3,4,5,6)

According to *Charaka*, *Teja* with help of *doshas* scorches the scalp and produces *Khalitya* in a person. (7) *Sushruta Samhita* reads *Samprapti* of *Khalitya* by stating that the *Pitta Dosha*

provoked by its own factors penetrates into the *Romakoopa* where along with the *Vata* it hampers the hair growth process. The *Kapha Dosha* along with the *Shonita* creates an obstruction in the *Romakoopa* further preventing the growth of new hair at that site. (8) According to *Charaka* for the adequate treatment of *Khalitya*, *Samshodhana* should be subjected along with *Nasya*, *Shiroabhyanga* and *Shirolepa*.(9)

Considering the increasing incidence of hair fall in the community various research works are being conducted to address this issue even in the field of *Ayurveda*. Many studies focus on the usefulness of panchakarma procedures in management of hair fall. However, correcting the *Strotas* vitiation especially the *Asthivaha Strotas* is a new perspective to ponder upon. Hence the unexplored drug *Asthimajjapachak Churna* (AMC) mentioned in *Charaka Samhita* was chosen for the management of *Keshapatana*.(10) *Shwadamshtradi Rasayana Churna* (SRC) mentioned in *Ashtanga Hridaya* was chosen as comparative drug. (11) Previous two different clinical studies conducted using SRC in combination with *Madhukadi taila nasya* as well as with *Madhukadi lepa* have shown encouraging results in the management of hair fall.(12,13) Building upon these findings, the present study aims to compare the efficacy of AMC with SRC to evaluate and establish a potentially more effective intervention.

Objectives

The primary objective of this clinical study was to compare the efficacy of AMC and SRC in the management of *Keshapatana* in female patients of age group 21 to 30 years over a one-month period. The secondary objective of the study was to evaluate changes in clinical symptoms of *Keshapatana.*

Methodology

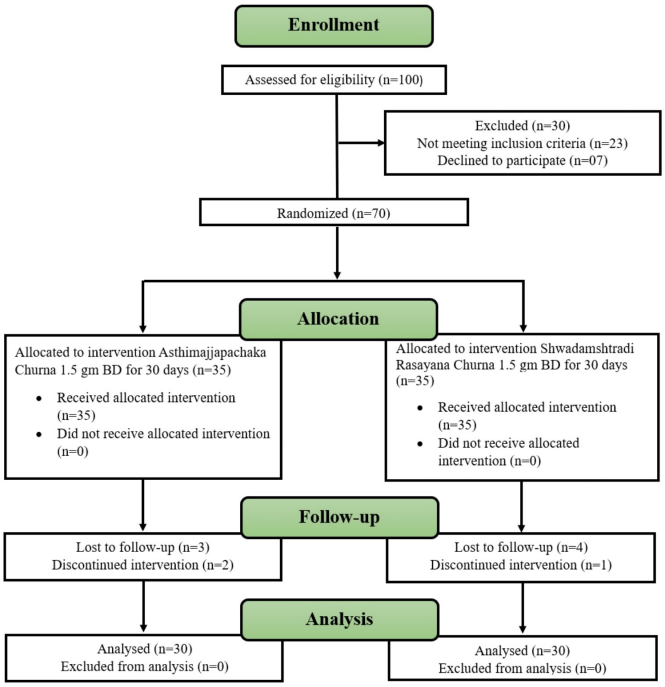
Trial Design: This trial was a randomized open-label parallel-group clinical trial with allocation ratio of 1:1. For this trial Ethical clearance was obtained from the IEC, Reference No. (Inward No.- AY/PG/441/2019-20 dated 07-10-2020) and the study was also registered prospectively on CTRI-Clinical trial registry of India (CTRI/2020/111029227 Registered on:19/11/2020). The study was conducted over one-year period.

Participants: 70 patients met the study's inclusion and exclusion criteria and were enrolled from an initial pool of 100 subjects screened via the Hair Pull Test. The enrolled patients were subsequently randomized into two equal groups: Group A (n=35) and Group B (n=35). In Group A, 3 participants were lost to follow-up and 2 discontinued the intervention. Similarly, in Group B, 2 participants were lost to follow-up and 3 discontinued the intervention. Thus, a total of 10 subjects dropped out of the study. Hence, statistical analysis was performed on the remaining 60 patients. (Figure 1).

Eligibility Criteria: Inclusion criteria: Female patients aged between 21 and 30 years, regardless of their socioeconomic status. Participants were required to exhibit significant active hair fall, defined as losing more than 5 strands of hair, as determined through the hair pull test. Additionally, only those who provided informed written consent were included in the study.

Exclusion criteria: Individuals with major or chronic systemic illnesses, such as Cancer, Tuberculosis etc. Patients suffering from specific hair disorders like Alopecia areata, Alopecia totalis, Tinea capitis, Folliculitis decalvans, and cicatricial alopecia were also excluded. Pregnant or lactating women were not considered for the study.

Figure 1 – CONSORT flow diagram



Study Setting: Patients were enrolled in this trial at *Kayachikitsa* OPD of the institute after receiving written informed consent.

Interventions: The study trial consisted of two groups. Treatment group A was prescribed with the AMC, while the control group B was prescribed with SRC.

Study Formulation: AMC and SRC are classical Ayurvedic formulations mentioned in Charak Samhita and Ashtanga Hridaya (classical Ayurveda texts) respectively. Formulation composition of both trial drugs that is AMC and SRC. [Table 1]

Table 1: Formulation composition of *Asthimajjapachak Churna* (AMC) and Shwadamshtradi Rasayana Churna (SRC) drugs

***Asthimajjapachak Churna* (AMC)**		
Composition	**Botanical name**	**Part used**
Guduchi (14)	*Tinospora cordifolia* (Willd.) Hook.f. & Thomson	Stem
Amalaki (15)	*Phyllanthus emblica* L.	Fruits
Musta (16)	*Cyperus rotundus* L.	Rhizome
***Shwadamshtradi Rasayana Churna* (SRC)**		
Composition	**Botanical Name**	**Part used**
Guduchi (14)	*Tinospora cordifolia* (Willd.) Hook.f. & Thomson	Stem
Amalaki (15)	*Phyllanthus emblica* L.	Fruits
Gokshura (17)	*Tribulus terrestris* L.	Roots

Identification and standardisation of raw materials of trial drugs was carried out in FDA approved pharmacy attached to the institution. Later both the *churna* formulation AMC and SRC were prepared according to classical methods. The prepared

formulations were then subjected to finished product standardization to ensure their quality. The raw materials and final products adhered to the guidelines outlined in the Ayurvedic Pharmacopeia of India (API) for the standardization of Ayurvedic medicines.

Drug regimen: Patients in both groups underwent a 30-day treatment regimen. The only variation between the groups was the specific drug administered: Group A received AMC, whereas Group B received SRC. For both groups, the drug was prepared as a *Churna* and administered orally at a dose of 3 g per day (divided into two equal doses of 1.5 g twice daily) before meals. The *Anupana* for both groups consisted of ghee and honey in unequal quantities.

Outcome Measures: Systemic and general physical examination of enrolled patients was done using a validated questionnaire and case record form. Subjective criteria such as *Kesharukshata, Shirokandu, Keshatanutwa, Keshajatilatwa,* presence of split ends was assessed twice by giving a score before and after the therapy according to the severity of the symptoms.

Local examination to assess the degree of hair loss was done using Pull test and Ludwig scale.

a) Pull test: Approximately 50 hair strands were taken using index finger, middle finger and thumb and gentle pull was applied. The shedding of more than 5 strands indicated significant hair fall and test was considered to be positive. (18)

b) Ludwig Scale- Used as a method of classifying female pattern baldness and grading of the same (stage 1 to stage 3). (19)

Randomization and Allocation: A total of 70 participants who met the inclusion criteria were enrolled and randomized into two groups using a computer-generated randomization sequence to ensure unbiased allocation. The participants were assigned to either the Intervention Group (AMC) or the Control Group (SRC) in a 1:1 ratio.

Allocation concealment was maintained through the use of sequentially numbered, opaque, sealed envelopes (SNOSE), prepared by an independent third party not involved in the conduct or assessment of the trial. The allocation sequence was implemented by a staff member who was not involved in the outcome evaluation or treatment administration.

This was an open-label study, and hence, both the investigators and participants were aware of the group assignments.

Participant Withdrawal: Patients were continuously monitored during each visit to record the adverse events if any. No withdrawals occurred due to severe adverse events, worsening of symptoms, development of intercurrent illness requiring treatment, or female participants becoming pregnant during the trial.

Statistical Methods: A p-value ≤ 0.05 was considered statistically significant. SPSS (IMB) statistics software was used to perform statistical analysis. Wilcoxon signed rank test was applied to the statistical data for Ludwig scale and evaluating the effect of treatment within the group. Mc Nemar's test was applied for evaluating the results of hair pull test. The Wilcoxon signed-rank test was applied to evaluate the statistical significance of changes in the Ludwig scale, as well as for all subjective parameters (such as *Keshapatana, Kesharukshata, Shirokandu, Keshatanutwa, Keshajatilatwa,* and split ends) before and after the therapy within each group.

Results

Descriptive Analysis of Study Participants based on Ayurvedic Diagnostics- Prakruti, **Rasa sevana**, **Aahara hetu**, **Srotoas dushti:** Among the enrolled patients, 25% exhibited a *Pitta-Vata Prakriti*, while 21.67% were identified with a *Pitta-Kapha Prakriti*. Most of patients had a predominant diet consisting of *Lavana Rasa* (65%) and *Katu Rasa* (58.33%). A significant involvement of *Asthivaha Srotas* (98.33%) and *Rasavaha Srotas dusti* (53.33%) was noted. In addition to the chief complaint of *Keshapatana*, patients also reported *Kesha Rukshata*, *Shirokandu*, *Kesha Tanutva* and split ends. Upon interrogation, patients also revealed the past history of *asthi-sandhi shoola* (25%) along with the complaints related to *amlapitta* and *jwara*.

Figure 2: Distribution of patients based on *Prakruti*

Figure 3: Distribution of patients based on *rasa sevana*

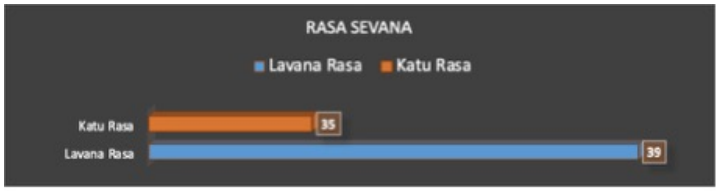


Figure 4: Distribution of patients based on *aahara hetu*

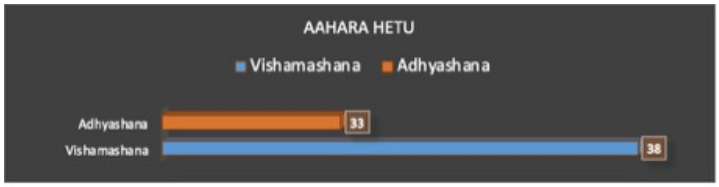


Figure 5: Distribution of patients based on *srotoas dushti*

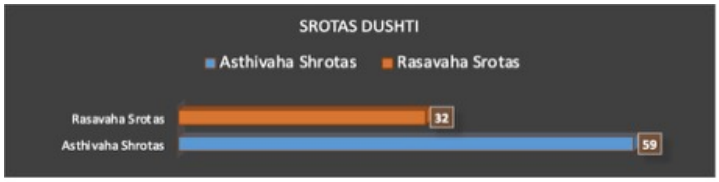


Figure 6: Distribution of patients based on *vyadhi lakshana*

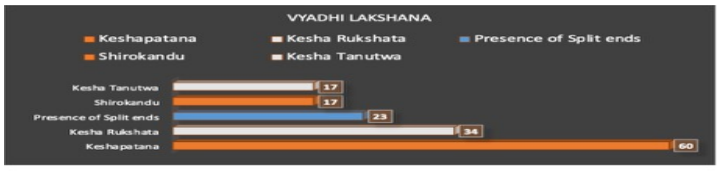
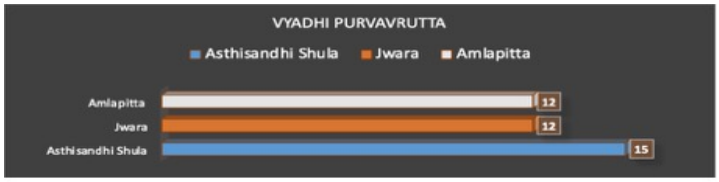


Figure 7: Distribution of patients based on *vyadhi purvavrutta*



Effect of treatment on hair pull test: Both groups were able to achieve statistically significant outcomes in hair pull test.

Table 2: Effect of treatment on hair pull test

Hair Pull test	Group A		Group B	
	BT	AT	BT	AT
Negative	0	30	0	27
Positive	30	0	30	3
Total	30	30	30	30
McNamar's value	56.008		45.814	
P value	0.00		0.00	
Result	Significant		Significant	

Effect of treatment on Ludwig scale: Both groups were unable to achieve statistically significant outcomes in Ludwig scale.

Table 3: Effect of treatment on Ludwig scale

Ludwig Scale		Mean	Median	SD	SE	Wilcoxon W	P value	Result
Group A	BT	1.03	1.00	0.18	0.03	0.00	1.00	Non-significant
	AT	1.03	1.00	0.18	0.03			
Group B	BT	1.00	0.00	0.00	0.00	0.00	1.00	Non-significant
	AT	1.00	0.00	0.00	0.00			

Effect of treatment on subjective parameters: Statistically significant improvements were observed in *Keshapatana*, *Kesha Rukshata*, and *Shirokandu* in both groups. In the parameters of *Kesha Tanutva* and *Kesha Jatilatva*, significant results were observed in the treatment group, whereas the control group showed non-significant outcomes. Both groups failed to demonstrate significant improvement in the condition of split ends.

Overall effect of therapy on subjective parameters: The overall percentage effect of therapy on subjective parameters was found to be higher in Group A, with an improvement of 58.45%, as compared to Group B, which showed an improvement of 35.94%.

Figure 8: Overall effect of therapy on subjective parameters in both the groups

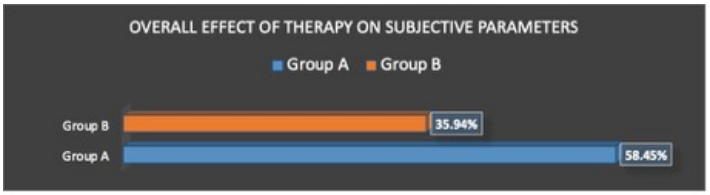


Table 4: Effect of treatment on subjective parameters

Sign	Grouping		Mean	Median	SD	SE	Wilcoxon W	p-value	% effect	Result
Keshapatana	Group A	BT	3.00	3.00	0.00	0.00	-5.066	0.0000004	88.89	Significant
		AT	3.36	0.00	0.55	0.10				
	Group B	BT	3.00	3.00	0.00	0.00	-4.894	0.000001	78.89	Significant
		AT	0.63	0.50	0.72	0.13				
Kesha rukshata	Group A	BT	0.63	0.00	0.81	0.15	-2.646	0.00815	36.8	Significant
		AT	0.40	0.00	0.62	0.11				
	Group B	BT	0.77	1.00	0.63	0.11	-2.236	0.02534	21.74	Significant
		AT	0.60	1.00	0.50	0.09				
Shirokandu	Group A	BT	0.57	0.00	1.14	0.21	-2.46	0.01387	100	Significant
		AT	0.00	0.00	0.00	0.00				
	Group B	BT	0.47	0.00	0.73	0.13	-3.035	0.002408	100	Significant
		AT	0.00	0.00	0.00	0.00				
Kesha Tanutwa	Group A	BT	0.53	0.00	0.73	0.13	-2.00	0.0455	25	Significant
		AT	0.40	0.00	0.67	0.12				
	Group B	BT	0.20	0.00	0.55	0.10	-1.633	0.1024	15	Non-Significant
		AT	0.07	0.00	0.25	0.05				
Kesha Jatilatwa	Group A	BT	0.20	0.00	0.48	0.90	-2.121	0.03389	100	Significant
		AT	0.00	0.00	0.00	0.00				
	Group B	BT	0.07	0.00	0.25	0.05	-1.414	0.15729	NA	Non-Significant
		AT	0.00	0.00	0.00	0.00				
Split Ends	Group A	BT	0.47	0.00	0.63	0.11	-1.633	0.10247	NA	Non-Significant
		AT	0.33	0.00	0.48	0.09				
	Group B	BT	0.43	0.00	0.58	0.10	-1.000	0.31731	NA	Non-Significant
		AT	0.40	0.00	0.50	0.09				

Discussion

Hair thinning or female pattern hair loss is cause of significant psychological and social distress especially in the young and middle-aged women and caters to greater demand for effective treatment in the age group of 21-30 years. (20) Therefore the population selected in the present study were young females of same age group. The genetics and positive maternal history for the complaint of hair thinning was however not observed in the present contrary to the findings of recent researches on the same. (21) Defective nutrition including the consumption of excessive *Lavana* and *Katu Rasa* was observed in most of the patients in the present study supporting the classical evidence from Samhita texts.(22) Dominance of *Pitta-Vata Prakriti* was observed in 25% patients which highlights the prominence of *Pitta* and *Vata Dosha* in hair degeneration.(23) Similarly the involvement of *Asthivaha Strotas* was found in almost all the patients probably indicating the low mineral density and decreased bone health resulting in premature balding (24). Inappropriate hair care including the use of chemical shampoos and inappropriate hairstyle was also seen in most of the patients resulting in cuticular damage and hair fall in the patients.(25) Although the complaint of *Keshapatana* was primarily observed; associated complaints like *Kesha Rukshata*, presence of split ends*, Shirokandu, Kesha Tanutwa* were observed in the patients indicating generalised ill hair health. The positive history of *Asthi Sandhi Shool* (25 %) indicating the presence of *Asthi Dhatu Dushti* and ill bone health while presence of *Jwara* also indicating the probable telogen effluvium associated with female pattern hair loss. (26)

Mode of Action of Drugs: Trial drug- *Asthimajjapachaka Choorna* (AMC): *Kesha* is considered as the *Mala* of *Asthi Dhatu* and when *Dosha* vitiate *Asthi Dhatu* it also affects the health of hair causing problems like *Keshapatana*. Similarly, in the *Samprapti* of *Keshapatana, Pitta* and *Vata dosha* have important role. Hence this aspect can be considered for treating *Keshapatana*. *Asthi Majja Pachaka churna* contains three drugs namely *Guduchi*, *Amalaki* and *Musta*. *Guduchi* is *Tridoshaghna*. It possesses *Rasayana Guna, Balya, Jwarahara, Deepana, Twak rogahara*. As it has *Madhura Vipaka* it alleviates *Vata Dosha*. (27) *Amalaki* alleviates *Vata Dosha* due to its *Amla rasa*; *Pitta Dosha* through the means of *Madhura Rasa* and *Sheeta Guna* and *Kapha Dosha* because of *Ruksha Guna* and *Kashaya Rasa*. *Amalaki* has properties like *Rasayana, Vayasthapana, Vrushya* etc. (28) *Musta* has *Sheeta Virya* and *Katu, Tikta* and *Kashaya Rasa* alleviates *Kapha* and *Pittadosha*. It has *Deepana* and *Pachana* properties and is useful in *Jwara*.(29) When we use these drugs in combination it alleviates mainly *Pitta Dosha* along with *Vata* and *Kapha Dosha*, and there by addressing the main *Samprapti* of *Keshapatana*. Similarly, because of *Deepana* and *Pachana* properties, it also results in *Dhatugata Dosha-Amapachana* and *Dhatwagni Deepena* thereby alleviating *Asthigata Alpa Bala Dosha*, it accelerates the process of formation of healthy *Asthidhatu* and *Kesha*. Premature hair fall is the sign of early ageing. In this combination two drugs have *Rasayana*, *Balya, Vrushya* and *Vayasthapana* properties, helping in addressing the aging process. The *Anupana* of *Goghrita* and *Madhu* makes it palatable. Due to *Rasayana Guna* of *Goghrita* and *Sukshma Srotas Vishodhana Guna* of *Madhu,* it increases the effectiveness of medicine. (30,31,32)

Control drug: *Shwadamshtradi Rasayana Churna* (SRC): *Ashtanga Hridaya* while explaining different *Rasayana* the combination of *Guduchi*, *Amalaki* and *Gokshura* is explained. It is clearly mentioned that, using it with Ghrita and *Madhu* results in long and healthy hair. In this combination first two drugs are same as AMC and third drug *Gokshura* has *Sheeta* and *Snigdha Guna*. (33) It alleviates the *Vata dosha*. Hence when these drugs are used in combination, it alleviates *Pitta* and *Vata dosha.* In this combination all three drugs have *Rasayana*, *Vrushya, Balya* and *Vayasthapana* properties. Hence this medicine mainly works on *Keshapatana* with its antiaging effect.

Overall effect of therapy: The overall effect of therapy was evaluated by taking relief in percentage of each patient. Moderate improvement was seen in 18 patients in group A while in 11 patients of group B. Wilcoxon sign test showed that significant relief was obtained in almost all the parameters in Group A except in split ends. While insignificant result was observed in complaints of *Kesha Tanutva*, *Kesha Jatilatva* and split ends in the group B. The administration of AMC showed 58.45% average relief and by SRC, 35.94% relief was seen in group A and B respectively. The results of the present study were found to be comparatively more effective than previously published works. In studies conducted in 2015 and 2019 involving 20 patients each, SRC was used as the internal medicine in combination with *Madhukadi Taila Nasya* and *Madhukadi Churna Lepa* respectively, showing percentage improvements of 31.43% and 18.42% in subjective parameters. (12,13) In contrast, the present intervention demonstrated a higher overall efficacy, indicating a potentially more promising therapeutic approach. Both groups showed significant improvements in the hair pull test, indicating that 30 days of treatment with either AMC or SRC effectively halts acute hair shedding. (18) However, outcomes on the Ludwig scale remained non-significant. Because visible changes in hair density and the hair growth cycle require a longer physiological timeframe—typically several months—the 30-day duration was likely insufficient to register structural improvements. (20) This suggests that while the interventions quickly stop active hair loss, prolonged treatment is needed for visible structural regrowth.

Limitations of the study: The study was conducted as an open-label trial rather than a double-blind trial. This trial was conducted on a limited number of patients, which may not fully represent the broader population experiencing hair fall. The trial exclusively focused on female patients within a specific age group, which limits the generalizability of the findings. Hair fall affects both genders and various age groups, and the results of this study cannot be extrapolated to men or to women outside of the age range studied.

Future scope: Future large-scale, multicentre studies focusing on patients with *Keshapatana* associated with *asthivaha srotodusti* and a history of *jwara* can be planned using more robust assessment methods to enhance accuracy and generalizability. In *Ayurveda*, treatment is individualized based on *Prakriti*, and the status of *Dosha, Dushya*, and *Mala*. Hence, future research may also explore treatment outcomes across different *Prakriti* types, considering variations in *Dosha, Dushya*, and *Mala* involvement, to observe differences in treatment outcomes. Minoxidil, a widely recognized and clinically validated treatment for hair fall, has shown significant efficacy in hair regrowth. (34) Comparative studies between AMC and Minoxidil are warranted to evaluate differences in efficacy, safety, and patient satisfaction. Integrating sophisticated diagnostic tools such as trichoscopy, densitometry, scalp biopsy, bone mineral density assessment, and serum Vitamin D levels in future trials with larger sample sizes can yield more definitive and insightful results, potentially validating AMC as a viable component of integrated hair fall management.

Conclusion

This study evaluated the comparative effect of *Asthimaja Pachak Churna* (AMC) and *Shwadamshtradi Rasayana Churna* (SRC) in the management of hair fall. A higher number of participants exhibited *Asthivaha Srotas Dushti*, indicating the involvement of *Asthigata Dosha*. The administration of AMC helped in correcting this problem, thereby promoting the proper formation of *Asthi Dhatu* and consequently formation of healthy *Kesha.* The effect of AMC was significantly more effective than SRC in managing hair fall and associated symptoms. The overall improvement of 58.45% was noted in the AMC treated group whereas the SRC group showed only 35.94% improvement. Furthermore, the therapeutic outcome of AMC surpassed the results of earlier studies (2015 and 2019), which reported lower percentage improvements 31.43% and 18.42% respectively, when SRC was used in combination with *Madhukadi Nasya* or *Lepa*. Thus, AMC appears to provide the promising and holistic therapeutic approach for the management of hair fall.

Data availability statement: Trial data is available with corresponding author.

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