A Study to Evaluate the Efficacy of Baicapil Formulations in Treatment of Telogen Effluvium

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Abstract

Introduction: *The changes in lifestyle and food habits have resulted in a steady increase in number of people presenting with hair loss and poses quite a challenge for dermatologists. Baicalin is an active flavonoid which activates dermal papilla cells & induces the mRNA expression of growth factors, such as insulin like growth factor 1 (IGF1) and vascular endothelial growth factor (VEGF). This action can clinically transform the telogen phase to anagen phase due to which there is good scope of using this product in telogen effluvium.*

Materials & Methods: *This was a pilot study on 30 subjects who had persistent hair loss for more than 3 months. Subjects were directed to apply 1ml (6 sprays) of the anti hair loss serum containing Baicapil in the morning after bath & once before bed time for 2 months. Efficacy of the hair serum was assessed using subjective scale and objective method at baseline, day 30 and day 60.*

Results: *In our study 63.3% of subjects had persistent hair loss of more than 6 months duration. Majority of our subjects belonged to the age group of 21 to 25 years with mean age of 26.33 ± 8.7 years and 46.7% were students. In the study median subjective score at 1st visit was 7, at 2nd visit score reduced to 6 and at 60th day score reduced to 4 which is statistically significant (p=<0.001). With respect to objective assessment at Point A, median number of thin hairs at 1st visit was 6, at 2nd visit it reduced to 4 and at 3rd visit reduced to 3. With respect to Objective assessment in Point B, median number of thin hairs at 1st visit was 5, at 2nd visit reduced to 3 and at 3rd visit reduced to 2 which was also statistically significant(p=<0.001).*

Conclusion: *Baicapil formulations are effective in decreasing hair loss and promoting hair growth in case of patients with telogen effluvium.*

Keywords: Telogen Effluvium, Baicapil, Hairloss

Introduction

The physical as well as psychological well being is reflected through one's hair. However, the incidence of patients presenting with hair loss has been rising steadily and poses quite a challenge for dermatologists. The condition has several causes and the most common ones being Telogen effluvium and androgenic alopecia [1]. Rapid urbanisation, changing food fads coupled with higher stress levels are some of the common causes of telogen effluvium.

Dermal papilla has a central role in maintenance of follicular epithelial differentiation. It is believed that the volume of the dermal papilla may be proportional to the size of the hair follicle, and that of the hair fibre. And it is the dermal papilla, which is the primary site for androgen action [2].

WNT/β-catenin pathway positively regulates hair follicle initiation. Normally, the β-catenin pathway is inactive in the adult epidermis, but it has been shown that hair follicles may develop de novo if β-catenin pathway is activated in epidermal basal cells of adult transgenic mice [3]. Baicapil has been shown to act on this pathway [4].

Material and Methods

30 subjects with persistent hair loss for more than 3 months who consulted in dermatology out-patient department in Belgaum Institute of Medical Sciences, Belagavi between February 2017 and July 2017 were enrolled in this study. This study was approved by the institutional Ethics Committee (BIMS-IEC/79/2015-16). A written informed consent was taken from each subject before commencement of the study.

Inclusion criteria

1. Female patients with hair loss for more than 3 months
2. Those willing to participate in the study

Exclusion criteria
1. Pregnant and lactating women.
2. Those with systemic diseases and chronic illness.
3. Patients on drugs responsible for hair loss or hematinics.
4. Family h/o androgenic alopecia or female pattern hair loss
5. Family h/o thyroid disorders
6. Women with menstrual irregularities
7. Suspected cases of alopecia areata or scarring alopecias

Diagnosis of diffuse hair loss was ascertained based on detailed history and clinical examination. Participants were directed to apply 1ml (6 sprays) of the anti hair loss serum containing Baicapil in the morning after bath & once before bed time for 2 months. Subjective scale was assessed by asking them to grade their hair loss from 0-10, with 8-10 being severe hair loss, 5-7 being moderate hair loss and 1-4 classified as minimal hair loss, 0 being no hair loss at the beginning of study, day 30 and day 60. Objective assessment was done by taking photographs of scalp using Instascope (a portable device attached to the camera of a mobile phone; the same mobile phone was used throughout the study) before, during and after treatment. The photos were captured at the highest point of mid frontal hairline (point A) and 10cms posteriorly from the first point (point B). The number of thin hair at point A and point B were noted at baseline, day 30 and day 60.

Statistical analysis
Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of frequencies and proportions. Continuous data was represented as mean and standard deviation. **Wilcoxon Signed rank test** to assess the test of significance for paired data such as baseline and after treatment for qualitative data was used. **Graphical representation of data:** MS Excel and MS word was used to obtain various types of graphs such as bar diagram. **P value** (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Results
The study population comprised of 30 subjects with hair loss for more than 3 months. In the study majority of subjects were in the age group 21 to 25 years (33.3%), 46.7% were students and majority of them had hair loss for more than 6 months (63.3%) as depicted in Table 1. Mean age of subjects was 26.33 ± 8.7 years and mean duration of hair loss was 5.7 ± 7.1 months.

Table 1: Profile of subjects in the study

		Count	%
Age	<20 years	6	20.0%
	21 to 25 years	10	33.3%
	26 to 30 years	7	23.3%
	> 30 years	7	23.3%
Occupation	Agriculture	3	10.0%
	Asha Worker	2	6.7%
	Bank Accountant	1	3.3%
	Hospital Group D	4	13.3%
	Housewife	6	20.0%
	Student	14	46.7%
Duration of Hair loss	<6 months	11	36.7%
	>6 months	19	63.3%

Five subjects were lost to follow up at the end of one month while the remaining 25 subjects completed the study. None of the subjects reported any adverse events during the study period.

Subjective assessment
In the study, median subjective score at 1st visit was 7, at 2nd visit score reduced to 6 and at 60th day score reduced to 4. There was significant decrease in median subjective score at 30th day and 60th day in comparison with baseline as depicted in Table 2 and Fig 1.

Table 2: Subjective Assessment of Hair loss among subjects at difference intervals of followup

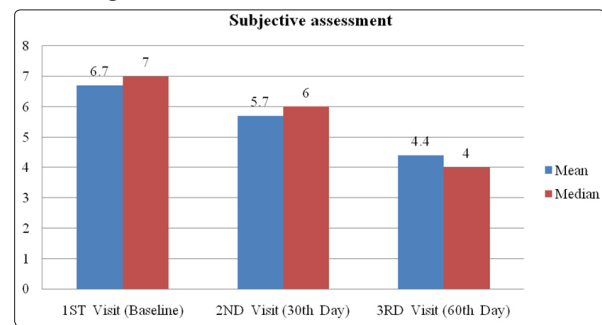|	Mean	SD	Minimum	Median	Maximum	P value
1ST Visit (Baseline)	6.7	1.0	5	7	9	
2ND Visit (30th Day)	5.7	1.3	4	6	9	<0.001*
3RD Visit (60th Day)	4.4	1.9	2	4	9	<0.001*

*Wilcoxon signed rank test

Figure 1: Bar diagram showing Subjective Assessment of hair loss

Objective assessment to assess the of number of thin hair
At Point A the median number of thin hair at 1st visit was 6, at 2nd visit it reduced to 4 and at 3rd visit reduced to 3. There was significant decrease in median number of thin hair from baseline to 60th day as depicted in Table 3 and Fig 2, 3.

Table 3: Objective assessment in terms of thin hair at Point A

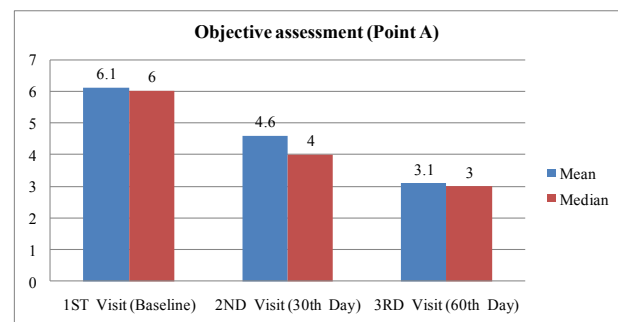|		Mean	SD	Minimum	Median	Maximum	P value
Point A	1ST Visit (Baseline)	6.1	1.9	2	6	10	
	2ND Visit (30th Day)	4.6	2.0	1	4	8	<0.001*
	3RD Visit (60th Day)	3.1	2.0	0	3	8	<0.001*

*Wilcoxon signed rank test

Figure 2: Bar diagram showing Objective assessment in terms of thin hair at Point A

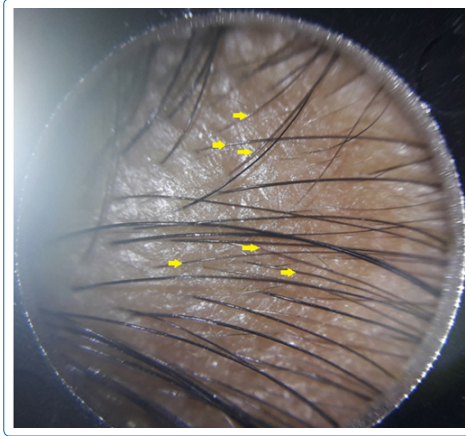**Photographs:**

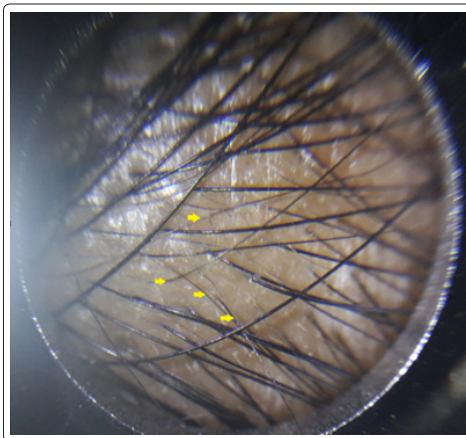**Photo 1:** Number of thin hair at point A at 1st visit - 6

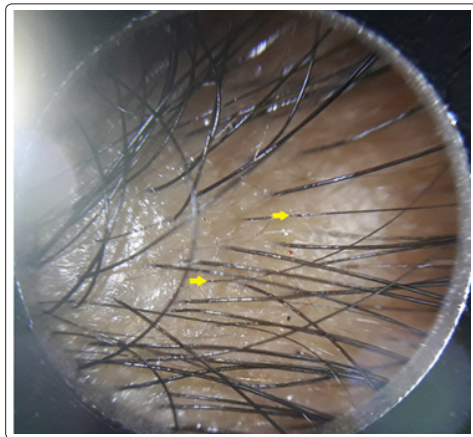**Photo 2:** Number of thin hair at point A at 2nd visit - 4

Photo 3: Number of thin hair at point A at 3rd visit - 2

With respect to Objective assessment in Point B, median number of thin hairs at 1st visit was 5, at 2nd visit 3 and at 3rd visit 2. There was significant decrease in median number of thin hairs at 30th day and 60th day in comparison with baseline as evident from Table 4 and fig 4,5.

Table 4: Objective assessment in terms of thin hair at Point B

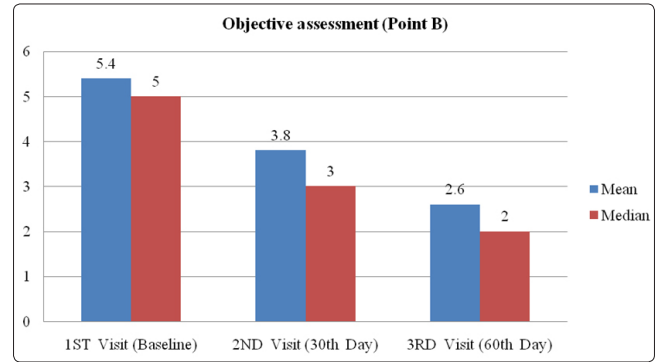|		Mean	SD	Minimum	Median	Maximum	P value
Point A	1st Visit (Baseline)	5.4	1.9	2	5	10	
	2nd Visit (30th Day)	3.8	1.6	1	3	6	<0.001*
	3rd Visit (60th Day)	2.6	1.7	0	2	6	<0.001*

Figure 4: Bar diagram showing Objective assessment in terms of thin hair at Point B
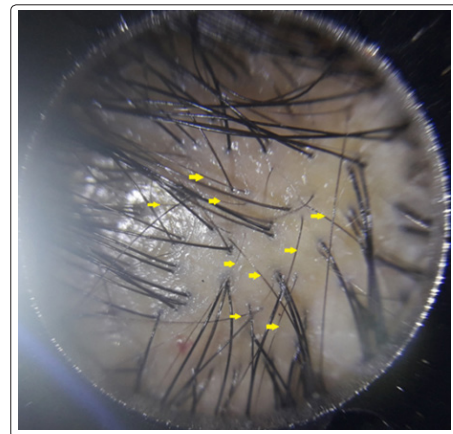

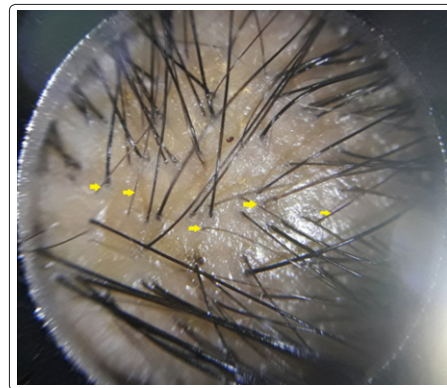**Photo 4:** Number of thin hair at point B at 1st visit - 9

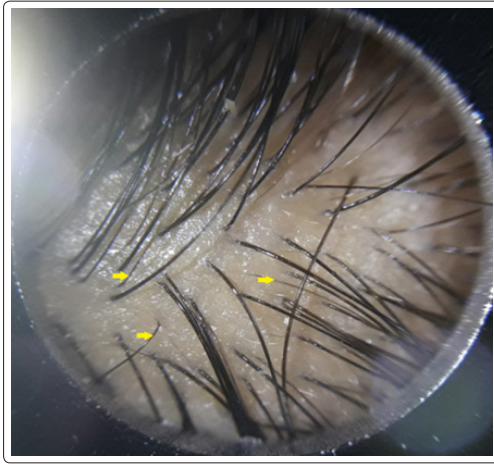**Photo 5:** Number of thin hair at point B at 2nd visit - 5

Photo 6: Number of thin hair at point B at 3rd visit - 3

Discussion

Telogen effluvium (TE) is defined as increased shedding of telogen club hair due to premature termination of the anagen phase of the hair cycle. Acute telogen effluvium is an acute onset scalp hair loss that occurs 2–3 months after a stressful event and shedding usually ceases in 3–6 months [2]. Sometimes persistent telogen effluvium can lead to female pattern baldness or androgenetic alopecia [6].

Chronic diffuse telogen effluvium refers to persistent shedding of hair for longer than 6 months. It can be a result of an idiopathic change in hair cycle dynamics (primary chronic telogen effluvium) or be secondary to a variety of causes including female pattern hair loss [2]. The primary insult is to the dermal papillae of the anagen follicle, which induces an early shunt to telogen.

Telogen Effluvium (TE) is generally considered to be the most common type of alopecia in females followed by Female Pattern Hair Loss (FPHL) [7]. Telogen effluvium is reported to be 28% - 92% depending upon the age group studied [8-10].

Baicapil is a combination of 3 plant extracts, namely Scutellaria baicalensis, Triticum vulgare (soy) sprout and Glycine max (wheat) sprout. Scutellaria baicalensis Georgi is a traditional oriental natural herb and Baicalin is an active flavonoid isolated from it. It has many pharmaceutical actions such as anti-inflammatory action, antibiotic action, antioxidant properties, and antiproliferative effects on prostate cancer cells. Further, Baicalin antagonises the androgen receptor by suppressing the dihydrotestosterone dependent activation cascade and also promotes proliferation of the human papillary dermal cells [5]. Baicalin activates Wnt/βcatenin signaling in a dose dependent manner in human dermal papilla cells. It can also induce the mRNA expression of growth factors, such as insulin like growth factor 1 (IGF1) and vascular endothelial growth factor (VEGF) and hence convert telogen hair to anagen [4].

Though the number of people complaining of hair loss is rising at an alarming rate, there are very few molecules in the market to address this issue. Minoxidil has remained the gold standard for treatment of hair loss for a very long time. It causes premature entry of follicles into anagen, and probably prolongs anagen and increases hair follicle size. A number of in vitro effects of minoxidil have been described in monocultures of various skin and hair follicle cell types including stimulation of cell proliferation, inhibition of collagen synthesis, and stimulation of vascular endothelial growth factor and prostaglandin synthesis.

Clinical trials of topical minoxidil in male and female hair loss all show a remarkably rapid increase in hair growth, measured by hair counts or hair weight. The increase is evident within 6–8 weeks of starting treatment and has generally peaked by 12–16 weeks [11]. However, it is sometimes associated with adverse effects such as headache, light headedness, unwanted facial hair growth and sensitivity to the molecule [12].

Newer molecules which would improve circulation, inhibit perifollicular fibrosis and also inhibit 5 alpha reductase activities have been continuously researched. Though many products are currently available in the market, there are very few in vivo studies to prove their efficacy and our study is one such in vivo study done to know the efficacy of Baicapil formulations in the treatment of hair loss. This study throws light on the effect of newer molecule like Baicalin in controlling hair loss without any untoward effects on the subjects.

In our study 63.3% subjects had hair loss persisting for more than 6 months and hence would be categorised under chronic diffuse telogen hair loss. Similar finding is reported in a study by Fatani M I et al where 79.2% of telogen effluvium patients had hair loss persisting for more than 6 months and only 20.8% of patients had acute telogen effluvium [13]. Chronic diffuse telogen hair loss can be idiopathic, nutritional or even female pattern hair loss. The most common triggering event in our study was change in their food habits as a result of migration to a different place.

The subjective and objective assessment showed a statistically significant (p=<0.001) decrease in the hair loss after treatment with Baicapil formulations.

Conclusion

Baicapil formulations are effective in decreasing hair loss and promoting hair growth in telogen effluvium.

Limitations

The sample size was small and follow-up period was short. Only women were included in this study.

Disclosure

Anti hair loss serum containing Baicapil formulations was provided by Brinton pharmaceutical Ltd. Authors did not receive any financial support for conducting this study and they do not have any financial interest in the product or in the company.

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