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Effect of *Kshoudradi Aschyotana* in *Arjuna* w.s.r to Sub-Conjunctival Haemorrhage: A Randomised Clinical Trial

Research Article

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Abstract

Introduction: Subconjunctival haemorrhage (SCH) is a frequent eye condition marked by bleeding beneath the conjunctiva, which causes noticeable discoloration and generally disturbs the affected person. There is currently no specific treatment for SCH in contemporary medical practices. According to Ayurveda, it correlates with *Arjuna*. It is a *rakta pradoshaj vikara* (disease caused by vitiated blood) and primarily a *pitta*-predominant disease manifesting in the *Shukla mandala* of *netra.* Objectives: The objective of the study was to compare the efficacy of *Kshoudradi Aschyotana* with Flurbiprofen Eye Drops in *Arjuna* with special reference to sub-conjunctival haemorrhage. Materials and Methods: After securing ethical clearance and registering the trial with the CTRI, twenty patients satisfying the inclusion criteria and diagnosed with *arjuna* were randomised into two groups(10 in each group). The trial group and the control group received *Kshoudradi Aschyotana* and Flurbiprofen eye drops for 5 days respectively. Objective parameters were assessed using Slit-Lamp photography and the area of the lesions was recorded on the baseline, 5th, and 7th days. The statistical analysis of the area of haemorrhage was conducted using independent and paired t-test for between and within-group analysis respectively. Results: *Kshaudraadi Aschyotana* has exhibited better results in reducing the area of subconjunctival haemorrhage as compared with flurbiprofen eye drops within five days(P <0.05). Conclusion: The study concludes that *Kshaudraadi Aschyotana* has beneficial effects in the management of *Arjuna* as compared with the flurbiprofen eyedrops.

Keywords: *Arjuna,* Flurbiprofen eyedrops, *Kshaudraadi Aschyotana,* Subconjunctival hemorrhage.

Introduction

Subconjunctival haemorrhage (SCH) is a painless, abrupt appearance of a sharply defined redness of bleeding beneath the conjunctiva (1). The prevalence of SCH is three out of every thousand people per year (2). The vast majority of cases are typically regarded as idiopathic. However, acute conjunctivitis, systemic hypertension, local trauma, and diabetes mellitus are the main risk factors linked to the development of SCH (3). In modern science, there is no specific treatment for SCH other than symptomatic care and it takes at least two to three weeks to resolve the condition. Identifying the source of bleeding, cold compresses, astringent eye drops, lubricant eye drops, and NSAIDs are all part of the current management (4).

Ayurveda classics correlate SCH with *Arjuna*, one among the *Shukalagata rogas* (diseases of sclera). Ayurveda classics mention *Arjuna* as a *Nirukh* (painless) condition and the conjunctiva resembles *Sasa rudhira* (rabbits' blood), *or Lohita Bindu (*red dot*)* (5). Ayurveda has outlined diverse treatment approaches, including *Aschyotana, Seka, Anjana,* and others. Keeping in mind the above-said treatment principles in managing *Arjuna*, *Kshaudraadi Aschyotana* was specifically used as a treatment (6).

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Objectives

The objective of the study was to compare the efficacy of *Kshoudradi Aschyotana* with Flurbiprofen Eye Drops in *Arjuna* with special reference to sub-conjunctival haemorrhage.

Material and Methods

The study included participants from *Shalakyatantra* department (OPD and IPD) of KLE Ayurveda Hospital Shahapur, Belagavi, Karnataka.

Drugs

Kshoudra and *Khanda Sharkara* were procured from GMP Certified KLE Ayurveda Pharmacy, Khasbag, Belagavi, in sachets containing 2.5gm each and *Dadhimastu* were prepared freshly in the *Kriyakalpa* unit of *Shalakyatantra* department of KLE Ayurveda Hospital, Shahapur, Belagavi, Karnataka.

Method of Preparation of Drugs

Kshaudraadi Aschyotana

Equal amounts(2.5 grams) each of *Sharkara* (sugar), *Dadhimastu* (curd water), and *Kshoudra* (honey) are mixed in a sterile *Khalva yantra* (mortar and pestle) and thoroughly triturated until the sugar is fully dissolved and the resulting mixture is transferred into a 10 ml sterile bottle.

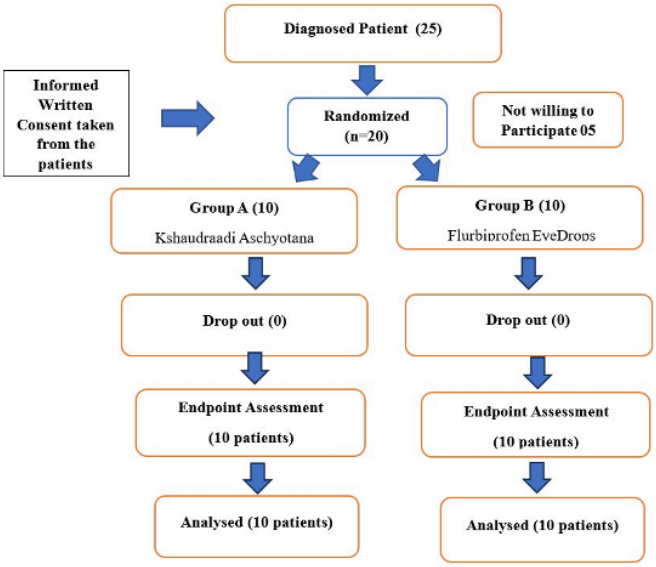
Flurbiprofen Drops

Flurbiprofen drops were purchased from a licensed pharmacy.

Research Study Design

The clinical trial consists of two groups with 10 participants in each group. **Figure** 1 depicts the CONSORT flow diagram of the study.

Figure 1: CONSORT flow chart of the study



Participants

A total of 20 patients diagnosed with *Arjuna* were recruited from the *Shalakyatantra* OPD and IPD of the KLE Ayurveda Hospital, Shahapur, Belagavi, Karnataka.

Inclusion Criteria

Individuals aged 18 to 80 years having ocular illnesses with idiopathic and traumatic sub-conjunctival haemorrhage without epithelial defect were included in the study regardless of gender or occupation.

Exclusion Criteria

Exclusion criteria encompassed systemic ailments such as uncontrolled diabetes mellitus, hypertension, chronic obstructive pulmonary disease, and renal pathologies. Patients having iatrogenic subconjunctival haemorrhage after surgical procedures, those experiencing vicarious bleeding associated with menstruation, and those presenting with prevalent causes of red eye like conjunctivitis, episcleritis, scleritis, keratitis, corneal ulcers, iritis, and glaucoma, were excluded from the study. Common conditions such as dry eye and blepharitis were also part of the exclusion criteria.

Intervention

The trial commenced after obtaining approval from the Institutional Ethics Committee, (Protocol ID BMK/20/PG/SKT/01) and CTRI registration (CTRI/ 2021/11/037840).

Treatment Protocol

The detailed study protocol is given in Table 1.

Table 1: Study Protocol

Groups	Sample	Interventions	Assessment Days
Group A	10	*Kshoudradi Aschyotana* one drop hourly twelve times daily for five days	Baseline, 5th day & 7th day
Group B	10	Flurbiprofen eye drops One drop twice daily for five days	Baseline, 5th day & 7th day

Outcomes

Objective Parameter

Slit Lamp Photography was performed using a mobile camera attached to a slit lamp adapter to capture images. Measurements of the dimensions of the lesion were taken on baseline, 5th day, and 7th day. An online Photoshop application was utilized to select the haemorrhage area using the magnetic lasso selection tool. The length and width of the lesion were recorded and the obtained value was divided by 10 due to the 10x magnification power of the slit lamp. These original pixel values were then converted to millimeters, and the area was computed (7).

Randomisation

The randomisation plan chart for the current study was provided by the medical research centre of our institute (reference ID: KLE/BMK/MRC/837/22). The 20 participants were randomised into two groups by using computerised randomisation techniques with seed number 12065 (http://www.randomization.com).

Statistical Analysis

Statistical analysis was performed using SPSS software version 20 (Statistical Package for Social Science, IBM, Armonk, New York, USA). The statistical analysis area of haemorrhage was conducted using independent and paired t-test for between and within group analysis respectively on the baseline, 5th day, and 7th day. The *P*-value less than 0.05 was considered to be statistically significant.

Results

The research adhered to the guidelines outlined in the CONSORT statement for recording and documenting the study results.

Recruitment

The informed consent was taken from all the participants and data collection was done between

January 2022 and July 2023. Throughout the trial, participants were required to visit the outpatient department (OPD) for assessment and documentation. Additionally, participants were instructed to inform the investigators promptly if they experienced any adverse effects.

Baseline Data

Characteristics of the Subject

Age

Among 20 subjects enrolled for the study majority of the population (30%) were under the category of 50 to 60 years of age, 25% of subjects were under the category of 60 to 70 years, 15% of each subject was under the category of 20 to 30 years and 30 to 40 years, 05% of each subject were under the category of 10 to 20 years, 40 to 50 years and 70 to 80 years.

Sex Incidence

Among 20 subjects enrolled in the study, 60% of the (i.e. twelve subjects)were males and 40% (i.e. eight subjects) were females.

Outcomes and Estimation

Objective Parameters

The effect of the treatments was evaluated by statistically analysing changes in the haemorrhage area. There was a statistical difference (P<0.05) between the groups on the 5th and 7th days. In Group A, there was a statistically significant improvement ($P < 0.05$) in the reduction of haemorrhage area from the baseline measures to 94.01% on the fifth day and 99.25% on the seventh day. Likewise, in Group B, there was a statistically significant improvement ($P < 0.05$) in the reduction of haemorrhage area from baseline measures to 35.60% on the fifth day and 39.91% on the seventh day. (**Tables** 2 and 3) (**Figure** 2)

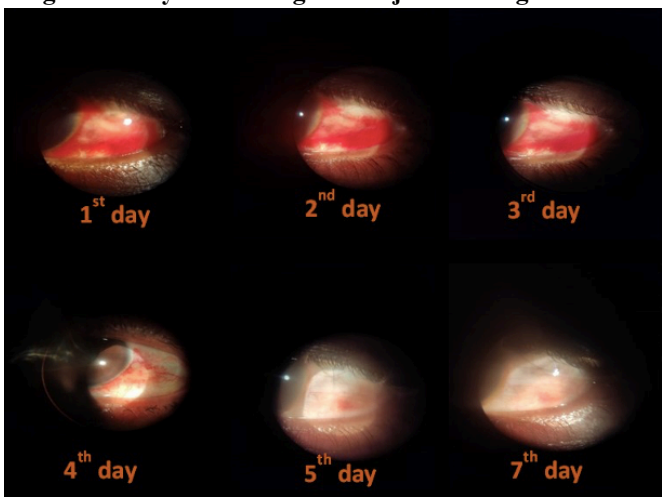
Table 2: Statistical analysis of the area of *arjuna* between the group using Independent t test

Variable	Group	Number	Mean ±Standard Deviation	t Value	P Value
Area Day 1	Group1	10	82.42±49.28	2.00	0.060
	Group2	10	46.75±27.23		
Area Day 5	Group1	10	4.93±3.08	-3.85	0.001
	Group2	10	30.10±20.46		
Area Day 7	Group1	10	0.61±0.69	-4.4587	0.000
	Group2	10	28.09±19.48		
Area Day 1st & 5th	Group1	10	77.48±47.45	4.217	0.001
	Group2	10	13.25±8.31		
Area Day 1st & 7th	Group1	10	81.81±48.86	4.007	0.001
	Group2	10	18.67±9.80		
Area Day 5th & 7th	Group1	10	4.32±2.51	2.391	0.028
	Group2	10	2.02±1.72		

Table 3: Statistical analysis of the area of *arjuna* within the group using paired t test

Variable	Day	Mean	Percentage change	P value
Group 1 Area	1st day	82.42	94.01%	0.001*
	5th day	4.93		
	1st day	82.42	99.25%	0.000*
	7th day	0.61		
	5th day	4.93	87.63%	0.000*
	7th day	0.61		
Group 2 Area	1st day	46.75	35.60%	0.000*
	5th day	30.11		
	1st day	46.75	39.91%	0.000*
	7th day	28.09		
	5th day	30.11	6.71%	0.005*
	7th day	28.09		

Figure 2: Day wise changes in Arjuna during treatment



Harms

We have not come across any adverse or unintended effects in the study.

Discussion

The studies conducted on the management of *Arjuna* is very limited. Subconjunctival hemorrhage (SCH) is a common ocular condition often managed conservatively, with spontaneous resolution occurring within two weeks (8). Moreover, contemporary medicine does not have a specific treatment modality for this condition(9). This randomized clinical study investigated the efficacy of *Kshoudradi Aschyotana* as an alternative intervention for SCH, aiming to explore their potential benefits in accelerating resolution and improving patient outcomes. In this study, participants were randomized into two groups: Group A received trial drug, while Group B received Flurbiprofen eye drops which were known for their anti-inflammatory and reducing conjunctival hyperemia (10).

The primary outcomes assessed included area, time to resolution of SCH and patient-reported discomfort. The findings of this study suggest that *Kshoudradi Aschyotana* may offer a promising therapeutic option for SCH. Participants in Group A exhibited faster resolution times and reported reduced

discomfort compared to those in Group B. Also there was no adverse event observed during the entire course of the treatment. These results align with previous research highlighting the anti-inflammatory and healing properties of Ayurvedic formulations, which are believed to promote tissue repair and hasten the absorption of blood beneath the conjunctiva. A previous study compared *Vasadi Ghrita Aschyotana* with Carboxymethyl Cellulose eye drops and found that Vasadi Ghrita yielded better results (11). In comparison, *Ksoudradi Ashyotana* is freshly prepared daily and administered as drops, making it simpler than preparing *Ghrita*.

Another study utilized a *kriyakalpa protocol*, including *seka* with *yastimadhu ksheerapaka*, *bidalaka* with *triphala yastimadhu*, *netra pichu* with *triphala ghrita*, and internal treatment with *Vasa Guduchyadi Kashaya*. This approach showed good results, resolving hemorrhage within 5 days(12). In our study, however, a single therapy of *aschyotana* achieved significant results within the same 5-day period, proving to be more effective compared to the *kriyakalpa* protocol.

Probable Mode of action of the drugs

Effect of *Kshoudra*

Honey is recognized for properties like *Chakshushya* (enhancing vision), *Prasadana* (providing nourishment), *Sodhana* (facilitating purification), *Ropana* (promoting healing), *Sandhana* (fostering union), and *Sukshma margaanusari* (effectively permeating minute channels). *Madhura rasa* (sweet taste) with a *kashaya anurasa* (underlying astringent note), along with its inherent *pichilla guna* (sliminess), *yogavahi* property (synergistic effect), and *pitta prasamana* (balance *pitta*) qualities collectively render honey a useful drug in the management of *Arjuna*. The inherent qualities of *Chakshushya* and *Prasadana* play a crucial role in not only nourishing and revitalising but also in soothing and rejuvenating the delicate ocular structures. This collective impact ultimately facilitates optimal clarity of vision and a revitalisation of the eye's tissues, thereby yielding comprehensive enhancements in ocular health(13). *Madhura rasa* might help in nourishing and strengthening the ocular tissues. The combined actions of *Sodhana* (purification), *Ropana* (healing), and *Sandhana* (union), coupled with the notable influence of the *Kashaya anurasa*, synergistically contribute to the purification of the blood and the expedited healing of tissues. As *Arjuna*, being a *rakta* and *pitta pradana vyadhi*, due to *Sukshma marga anusari* guna of *Madhu,* it will be able to navigate to subtle channels, thereby slowing down the progression of the disease (14).

The presence of anti-coagulation proteins in honey, such as PLA2 and melittin, may aid in the dissolution of blood clots (15). Furthermore, the iron content of honey may aid in the resolution of bleeding by encouraging natural healing processes and tissue repair (16). The anti-inflammatory properties of honey combat inflammation by reducing oxidative stress in lesions (17). Additionally, its capability to counteract free radicals and its flavonoid content might accelerate healing and haemorrhage resolution by safeguarding cells against oxidative damage (18). Honey's notable concentration of sugars and its elevated osmolarity can potentially accelerate the healing process of lesions. Within honey, enzyme inhibitors and serine proteases also play a pivotal role in wound healing. Honey serves to enhance the activity of hydrogen peroxide, which in turn activates these beneficial inhibitors (19). The fundamental constituents of honey, encompassing glucose, fructose, sucrose, and maltose, are thought to bear a pivotal role in the resolution of Subconjunctival Hemorrhage (SCH) (20). The presence of vitamin C within honey offers a significant advantage, as it substantially supports tissue regeneration and repair (21). Furthermore, honey's content of B vitamins could potentially expedite the overall healing process (22). Honey contains characteristics that aid in both vascular and corneal absorption, working synergistically to ensure quick and effective action, potentially helping in the resolution of Subconjunctival haemorrhage (SCH) (23).

Effect of *Khanda Sharkara*

Chakshushya guna of *Khanda Sharkara* might help to nourish and improve the health of the eyes (24). *Sharkara* possesses *Madhura rasa* (sweet taste) and is *Akshaprasadanam* in nature. D-003 and policosanols found in *Saccharum officinarum* have antithrombotic effects by inhibiting platelet aggregation, which may potentially lead to the resolution of haemorrhage (25). The flavonoids present in *Saccharum officinarum* protect cells from oxidative damage (26). Moreover, the presence of resveratrol might contribute to the resolution of subconjunctival haemorrhage (27). Sugar also possesses wound-healing activity which might help in the reversal of pathology (28).

Effect of *Dadhimastu*

Dadhimastu, possesses *Madhura rasa, Ropana, Sandhana,* and *Sheeta guna* which could be beneficial in resolving the haemorrhage. *Amla rasa* (sour taste) has the ability of *Indriya Dradhikartawa (*strengthen sense organs*)*, which might be helpful in enhancing the strength and functioning of the sensory organs (29). The *Kashaya rasa* possesses *Rakta Vishodhana* (blood purifying) and *Ropana* (tissue healing) properties which may help in resolving haemorrhage (30). *Dadhimastu* possesses *Rakta and Pittahara* properties, and since *Arjuna* is primarily a *Rakta* and P*itta* disorder, it may help in the *Samprapti Vighatana*. The *Srodhoshodhakara karma* of *Dadhimastu* facilitates its passage in tiny channels, which may help in the resolution of haemorrhages in minute capillaries (31). The presence of hydrophobic and aromatic amino acids in *Dadhimastu* contributes to its antioxidant effects. Additionally, when combined with hydrolysed collagen, it may exhibit an additive antioxidant effect (32). Proline of curd water (*Dadhimastu*) stimulates a series of complex wound healing processes, including fibroplasia, collagen production, wound contraction, and epithelialisation. The peptide-based hydrogel also

helps in tissue regeneration and repair which might promote the resolution of the lesion (33).

Effect of *Aschyotana*

The initial treatment approach in *Arjuna* is *Aschyotana* as *Raga* (redness)is the main symptom. *Arjuna* being a *Pitta* and *Rakta pradhana vyadhi*, all three ingredients used for *Aschyotana* have *Madhura rasa* and *sheeta gunas* which may help in combating the pathogenesis of the diseases. The *Ropana* type of *Aschyotana* might be helpful in the quicker resolution of haemorrhage (34). Water-soluble drugs are absorbed through the vascularity and permeability of the vessel wall in transcorneal and transconjunctival/sclera absorption, facilitated by the trabecular meshwork pathway. This efficient absorption process may allow for the quick resolution of haemorrhage (35).

Limitations of this study include its relatively small sample size and short-term follow-up period. Future research could benefit from larger, multicenter trials with longer observation periods to further elucidate the efficacy and safety profile of Ayurveda eye drops in SCH management. Additionally, exploring the mechanisms underlying the therapeutic effects of specific herbal extracts could provide valuable insights into their potential pharmacological actions and optimize treatment protocols.

Conclusion

The study concludes that *Kshaudraadi Aschyotana* one drop hourly has beneficial effects in the management of *Arjuna* as compared with the flurbiprofen eyedrops one drop twice daily for five days So, *Kshaudraadi Aschyotana* can be used as a safer and effective treatment modality in the management of *Arjuna*.

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