Optimization of *Parisheka kriyakalpa* (procedure for closed eye irrigation) 3: A clinical study on acute conjunctivitis with *Triphala* decoction

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Received 26 November 2015, revised 11 July 2016

Scientific validation of any drug, therapy, protocol or procedure requires a standardized procedure of manufacturing process, execution of the protocol or therapeutic procedure for standardization if the formulation protocol or procedure has variables in literature and practice; they need to be optimized first following a systematic approach with prospective clinical application for further validation of the optimized data. *Netra Parisheka/Seka* foremost topical ocular therapeutic procedure had similar prevalence of variability in literature and practice. To meet the above criteria and to achieve the objective of standardization; optimization of SOP of *Netra Parisheka* procedure was thought to be the pre-requisite. Using all adopted parameters, total 51 (68 eyes) patients were enrolled out of which 50 (67 eyes) patients completed the study. Highly significant result with P value > 0.001 of *Netra Parisheka* procedure for a period of four days in dose of 750 ml, 500 ml & 250 ml for *Vata, Pitta* & *Kaphaja Netra roga*, respectively, temperature 37.2–37.7 °C, height 6-6.5 cm, duration 5–15 min, width 1.5-2.0 mm in *Aamavastha* of *Netra roga* (acute inflammatory condition of the eye) and shows its definite role of the procedure in the conversion of *Aamavastha* to *Niraamavastha* (remission of acute inflammatory sign) after 4th day. In some cases complete remission of symptoms was observed, i.e., 40%, while more than 70 % patients were having improvement in their signs and symptoms.

**Keywords:** *Netra Seka/Parisheka, Kriyakalpa, Optimization, SOP, Shalakya Tantra, Topical ocular therapeutics.*

**IPC Int. Cl.:** A01D 1/00, A01D 1/01, A01D 1/39, A61K 36/00, A01D 27/00, A01D 27/02, A01D 27/04

Science life knowledge treasure emerged with the dawn of civilization on this Indian subcontinent. Observation, inferences and practices continuously refined the knowledge and it ultimately was documented in *Ashtanga Ayurveda* format. Among the 8 branches supraclavicular body part treatment branched as Shalakya Tantra1 which deals mainly in sense organ’s health and disease. More than 80% available literature on this specialty is on *Netra Roga* (Ophthalmology) which itself signifies its importance. A separate chapter on topical ocular therapeutics procedure exists in the literature since the documentation which remained in a continuous phase of development. These topical ocular therapeutic procedures, i.e., *Seka* (closed eye irrigation), *Ashchyotana* (eye drops), *Pindi* (poultice application), *Bidalaka* (lid ointing), *Tarpana* (satiation), *Putpaka* [retention of medicinal decoction along with *Mansrasa* (serum like material) on eyes], *Anjana* (collyrum/eye ointment) are the 7 procedures in order of their clinical application2. The role of this procedure has been evaluated in different disease conditions at postgraduate center of *Netra Chikitsa* (treatment of eye disease which is subdivision of department of Shalakya)3-6 but question of optimization and standardization has not been addressed so far anywhere. These procedures are practiced by Ayurvedic physicians as such and at many centers they have their modification/alterations as well. Scientific validation of any drug, therapy, protocol or procedure requires a standardized procedure of manufacturing process, execution of the protocol or therapeutic procedure for standardization if the formulation protocol or procedure has variables in literature and practice; they need to be optimized first following a systematic approach with prospective clinical application for further validation of the optimized data. *Netra Parisheka/Seka* the foremost
topical ocular therapeutic procedure had the similar prevalence of variability in literature and practice. To meet the above criteria and to achieve the objective of standardization; optimization of SOP of Netra Parisheka procedure was thought to be the pre-requisite. The study was planned in three steps, viz. survey study, response factor study in healthy individuals thus to further refine/moderate them and finally testing the refined SOP clinically.

While analyzing the signs and symptoms of Aamavastha (acute inflammatory conditions of eye), it possess the quality of Kaphaanurupi. So, one can adopt Lekhana (Ruksha and Ushna guna pradhana) (predominantly having dry and hot properties) Netra Parisheka in Aamavastha by which Aama Shoshana can be achieved. The Ushna guna of Lekhana Parisheka help in Amapachana and parimarjana.

On the basis of this concept, here in this study Lekhana Parisheka with Triphala decoction was adopted, which was the drug of choice and first and foremost procedure by our Aacharyas in all Abhishyanda Rogas.

Meanwhile the assessment of Pharmacodynamics of Triphala too shows 40% Kashaya and Amla Rasa pradhana, 67% Ushna Virya, 100% Madhura Vipaka, 43% Laghu and 28% Ruksha in Guna, 33% Tridoshasamaka and 34% Vatamasamaka properties (Fig. 1).

Objectives
2. To assess the clinical efficacy of adopted SOP in Aamavastha of Netra roga (acute conjunctival inflammation).
3. To make the adopted SOP as baseline for standardization of the procedure.

Methodology
The patients of Aamavastha of Netra roga (acute conjunctival inflammation) coming to the OPD and IPD of Department of Shalakya; IPGT & RA; GAU Jamnagar were selected for the clinical trial and subjected to Parisheka Kriyakalpa with Triphala decoction.

Registration
The study has been registered in the Clinical Trail Registry of India (CTRI) Reg. No CTRI/2013/05/03647.

Criteria of selection of patients
Patients presenting with classical symptoms and signs of Aamavastha of Netra Roga (acute conjunctival inflammation) were taken into this study. Following points are taken in to consideration; Udirna vedhana (intense pain), Ragata (redness), Shopha (swelling), Nistoda (needling pain), Shula (pricking pain), Gharsana (FB sensation), Asrusrava (watering & discharge), Daha (burning sensation), Kandu (itching), Netra gaurava (heaviness), matting of lashes, follicles, pre-auricular lymph adenopathy.

Exclusion criteria
1. Patients not willing for attending the hospital for the procedure daily and registration.
2. Complicated conjunctivitis, e.g., with glaucoma, uveitis, corneal ulcer, panophthalmitis/ endophthalmitis, dacycystitis, episcleritis, scleritis, dry eye, ocular trauma, etc.
3. Patients presenting after 7 days of ocular complaints.
4. Specific conjunctivitis (tuberculous, lepromatous conjunctivitis, etc.)
5. Uncontrolled diabetes mellitus.

Drug
Triphala Choorna: Haritaki Phala (Terminalia chebula Retz.) 1 part, Vibhitaka Phala [Terminalia bellerica (Gaertn) Roxb.] 2 part, Amalaki Phala (Phyllanthus emblica L. syn Emblica officinalis Gaertn) 4 part.
Form: Kwatha (Decoction)

Dose: As developed through SOP.

Duration: Twice daily for 4 days.

Follow up: After completion of the trial patients were managed further till asymptomatic phase and followed 7 more days for any reoccurrence of the symptoms.

Pathyapathya: Advised Laghu ahara- To take light food when he/she gets hunger and matra to be half of his/her hunger. To follow Samyak Nidracharya and advised to avoid Diwaswapna.

Investigations
1. Routine blood and urine examination (wherever required) to rule out systemic diseases.
2. Fasting and PP blood sugar (wherever required).

Criteria for assessment
For the assessment of effect of the therapy, a clinical Performa was prepared. Scoring system was developed for the assessment of the chief signs and symptoms of Aamavastha of Netra roga (acute conjunctival inflammation). Assessment was done on the basis of changes in the subjective as well as the objective parameters after the procedure.

Number of patients: 51 patients

Statistical analysis: The final conclusion was drawn on the basis of the statistical evaluation by subjecting the findings with Students paired t test.

Overall assessment of the therapy
Complete remission of symptoms: 100% relief of the complaints and no recurrence during the follow up.
Markedly improved: 75% and up to 100% relief in the complaints.
Moderately improved: 50% and up to 75% relief in the complaints.
Mild Improved: 25% and up to 50% relief in the complaints.
Unchanged: less than 25% relief in the complaints

Clinical assessment criteria
Assessment was done on the basis of improvement in clinical features, i.e., subjective and objective parameters of the patients before and after treatment by using a standardized grading scale as per the WHO guidelines for Clinical Research Methodology in Ayurveda developed by IPGT & RA, Jamnagar, the details are given as follows:

Total 51 patients were registered in the trial group, amongst them 50 patients had completed the course of treatment and 01 patients did not complete the treatment. 100 % of patients were suffering from Ragata and Shopha, 91.17% patients from Ashru srava, 88.23% from Udirna vedhana, 80.88% of the patients from Netra gaurava, 57.35% patients from Gharsana, 29.41% patients from Kandu, 26.47% patients from Nistoda, 19.11% patient from Shula and 8.80% patients were suffering from Daha.

Results
In the present clinical study, total 51 (68 eyes) patients having the features of Aamavastha of Netra roga (acute conjunctival inflammation) were registered. Amongst these 50 (67 eyes) patients completed the course of treatment and one patient discontinued the course of treatment. The effects of therapy on subjective as well as objective parameters on eyes are as follows:

Statistically insignificant result in right eye was observed in right eye therapy with complaints of Udirna vedhana, Ragata, Shopha, Nistoda, Shula, Gharsana, Ashru srava, Daha, Kandu, and Netra gaurava at the end of 1st day procedure of Netra Parisheka. Same observation was seen in left eye for the same complaints. Statistically highly significant results in right eye were observed in the relief of Ashru srava, Udirna vedhana, Shopha, Gharsana, Netra gaurava, Ragata, Nistoda, Shula and Kandu at the end of 2nd day procedure of Netra Parisheka and statistically highly significant results in left eye were observed in the relief of Ashru srava, Udirna vedhana, Shopha, Gharsana, Netra gaurava, Ragata, Nistoda, Shula and Kandu at the end of 2nd day procedure of Netra Parisheka.

Analysis of Table 1 reveals statistically highly significant results in right eye in the relief of Gharsana, Netra gaurava, Udirna vedhana, Ragata, Ashru srava, Shopha while statistically insignificant results were observed in the relief of Nistoda, Shula and Kandu at the end of 3rd day procedure of Netra Parisheka. Analysis of Table 2 reveals statistically highly significant results left eye were observed in Ragata, Netra gaurava, Kandu, Ashru srava, Udirna vedhana, Gharsana, Shopha, while insignificant results were observed in the relief of Nistoda, Shula and Daha at the end of 3rd day procedure of Netra Parisheka. Analysis of Table 3 reveals highly significant in right eye clinical improvement was observed in Udirna vedhana, Gharsana, Netra
gaurava, Shopha, Ashru srava, Ragata. Statistically significant results were observed in the relief of Nistoda, Shula and Daha at the end of 4th day procedure of Netra Parisheka. Analysis of Table 4 reveals statistically highly significant results in left eye were observed in the relief of Udirna vedhana, Netra gaurava, Ashru srava, Gharsana, Shopha, and Ragata. Statistically significant results were observed in the relief of Nistoda, Shula, Kandu and Daha at the end of 4th day procedure of Netra Parisheka.

Table 5 which shows the overall effect, it is evident that 46% patients got cured, 30% patients got markedly improved, 20% patients were moderately improved and 4% patients got mild improvement. After completion of the clinical trial of 4 days, the patients were followed up for seven more days. During this period, none of the patients had reported the recurrence or aggravation of the symptoms.

**Discussion**

The comprehensive knowledge of the science of life has emerged as the final result of constant observations, inferences and moreover nurturing by imbibing ideas from other experts. Acharya Charaka has provided the means of proper learning of Ayurveda, viz. learning, teaching and discussion and has provided elaborate description for the conduct of discussion and the benefits of the same. Professional discussion indeed promotes the power of application of knowledge leading to enlightenment and wisdom.
Modern research methodology also lays emphasis on the interpretation of collected facts and observed data, which helps to the establishment of explanatory concepts linking observations and results.

**Selection of the problem**

To highlight the importance of local ocular therapeutic measures and consumer driven quality procedure in eye care, it was felt necessary to optimize SOP for these *Kriyakalpa* 14, so that it can be followed universally and thus, can be subjected for standardization after validation of the SOPs.

Technique to conduct *Netra Parisheka* procedure differs in different centers. It has been observed in case of height and width of the *dhara* (stream) (Fig. 2) as well as in methods of pouring of *Kwatha* (decoction) (Fig. 3). Some surgeons/attendant do it with close eyes and some with open eyes (Fig. 4) also there was irregular flow *dhara* of decoction in some centers (Fig. 5). Therefore, streamlining and development of standard operational procedure for these measures is found to be need of the hour. The validated SOP will further draw a roadmap for the standardization of the procedure.

**Day one:** First day sitting of *Netra Parisheka* procedure itself showed good relief in pain, watering and heaviness (P<0.01). The *Pachana* property of *Seka* would help in *Aama Pachana* which in turn removed *Srotorodha* and *anila mudata*.

**Day two & three:** Though there was no much significant improvement in other symptoms except pain as that of first day but the clinical condition had

**Table 4—Effect of therapy on LE chief complaints (Day four of *Netra Parisheka* procedure)**

<table>
<thead>
<tr>
<th>Features</th>
<th>n (Number of eyes)</th>
<th>BT</th>
<th>AT % of relief</th>
<th>SD</th>
<th>SE</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Udhrna vedhana</em> (Intense raising pain)</td>
<td>33</td>
<td>0.24</td>
<td>1.39</td>
<td>83.63</td>
<td>0.609</td>
<td>0.106</td>
<td>13.14</td>
</tr>
<tr>
<td><em>Ragata</em> (Redness)</td>
<td>37</td>
<td>0.39</td>
<td>1.10</td>
<td>67.21</td>
<td>0.657</td>
<td>0.108</td>
<td>10.25</td>
</tr>
<tr>
<td><em>Shopha</em> (Swelling)</td>
<td>37</td>
<td>0.37</td>
<td>1.13</td>
<td>73.68</td>
<td>0.585</td>
<td>0.961</td>
<td>11.80</td>
</tr>
<tr>
<td><em>Nistoda</em> (Needling pain)</td>
<td>10</td>
<td>0.3</td>
<td>1.3</td>
<td>81.25</td>
<td>0.483</td>
<td>0.152</td>
<td>8.51</td>
</tr>
<tr>
<td><em>Shula</em> (Pricking pain)</td>
<td>06</td>
<td>0.33</td>
<td>1.33</td>
<td>77.77</td>
<td>0.516</td>
<td>0.210</td>
<td>6.32</td>
</tr>
<tr>
<td><em>Gharsana</em> (FB sensation)</td>
<td>19</td>
<td>0.36</td>
<td>1.15</td>
<td>73.33</td>
<td>0.374</td>
<td>0.085</td>
<td>13.47</td>
</tr>
<tr>
<td><em>Ashrasava</em> (Watering &amp; discharge)</td>
<td>34</td>
<td>0.17</td>
<td>1.17</td>
<td>81.63</td>
<td>0.458</td>
<td>0.078</td>
<td>14.95</td>
</tr>
<tr>
<td><em>Doha</em> (Burning sensation)</td>
<td>03</td>
<td>0.41</td>
<td>0.91</td>
<td>68.75</td>
<td>0.288</td>
<td>0.083</td>
<td>11</td>
</tr>
<tr>
<td><em>Kandu</em> (Itching)</td>
<td>12</td>
<td>0.36</td>
<td>1.1</td>
<td>82.69</td>
<td>0.504</td>
<td>0.092</td>
<td>15.57</td>
</tr>
</tbody>
</table>

**Table 5—Overall effect of therapy**

<table>
<thead>
<tr>
<th>Total effect</th>
<th>Number of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete remission</td>
<td>23</td>
<td>46</td>
</tr>
<tr>
<td>Marked improvement</td>
<td>15</td>
<td>30</td>
</tr>
<tr>
<td>Moderate improvement</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Mild improvement</td>
<td>02</td>
<td>04</td>
</tr>
<tr>
<td>Unchanged</td>
<td>00</td>
<td>00</td>
</tr>
</tbody>
</table>

Fig. 2—The picture clearly shows the height & width of *Netra dhara*, here the same *Kwatha* is used for seven times except in infectious conditions with maximum quantity of 100-150ml.

Fig. 3—Here the pictures different method of practicing the procedure between the physicians of the same institute.

Fig. 4—Here the picture shows, the subject is forced to open the eyes during the procedure and the vessels used for *dhara*.

Fig. 5—Here the picture clearly shows the *dhara patra*, which is causing irregular flow of *dhara*.
not aggravated. This clearly indicates complete Aama Pachana process requires little time. Meanwhile in some of the cases Niramalakshana were getting evident on the third day (p<0.001).

**Day four:** At the end of 4th day, Niramalakshana were clearly evident. In some cases complete remission of symptoms (40%) was also observed (P<0.001). After 4th day, nearly 60% of the patients required further treatment for complete remission. The treatment was given according to the doshic predominance. An average of 5 more days had taken for complete remission of symptoms. All the patients’, i.e., 100% had good compliance with Netra Parisheka procedure. Result of Triphala eye drop in conjunctivitis was observed in another study with Triphala eye drops in Conjunctivitis15 also the antimicrobial action of Triphala mashi was established in another study16.

**Follow up**
After completion of the clinical trial of four days, the patients were followed up for seven more days. No adverse drug reaction observed during the study.

**Conclusion**
Study clearly shows the importance of streamlining and development of standard operational procedures of kriyakalpa is need of the hour. Aama condition can be formed at any level of Agni samskara, i.e., Jataragni, bhutagni and dhatwagni level due to its hypo functioning. Achakshusya ahara (food articles having ill effect on eye) and Vihara plays a vital role in the Drishti vaha srotovaigunya and Dhatwagnimandya. From above points, the importance of normal functioning of Pachaka Pitta in the maintenance of Netra swasthya (ocular health) is evident. Triphala’s tridoshara & Aama Pachana property proves the Aacharyas drug of choice in all Abhishyandha Netraroga. Since Netra Parisheka procedure is Apatarpana in nature, it is the best suitable procedure for Aama Pachana and Bahir-parimarjana of doshas in Aamavastha of Netra roga. In view of this pathophysiology of Aamavastha, concentration of Parisheka drug should not be too high. Hence, in this study only 1/4th part of the Kwatha used for Parisheka is reduced. This part of the study authenticates the observation of survey study (part two) by showing the clinical efficacy of Netra Parisheka procedure in the Aamavastha of Netra roga (acute conjunctival inflammation). Highly significant result with Netra Parisheka procedure for a period of four days in Aamavastha of Netra roga shows its definite role of the procedure in the conversion of Aamavastha to Niraamavastha. Thus this procedure decreases the work load on Jataragni thereby transforming the Aama (unwanted material in the local tissue) to nearly normal state and also enhancing the excretion of the abnormal end product through Bhrajaka pitta (cutaneous metabolism). Since, it is an economical and safe procedure, development of the procedure can contribute to the public health.

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