Technical Note

Physico-chemical analysis of Commiphora wightii and borax coated herbal seton

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Background: Herbal seton (Kṣārasūtra) is a cost effective para-surgical technique employed in the management of anorectal conditions like fistula and hemorrhoids without causing much complications. Perennial non-availability raw materials, severe pain and allergic reactions are the major demerits of standard Kṣārasūtra demanding for its better options. Guggulu (Commiphora wightii) and Tānkana (Borax) coated Kṣārasūtra (GTK) a modified variant of the standard is being used in the Anorectal Clinic under the Department of Shalyatantra (Surgery), Amrita School of Ayurveda since last 6 years. It has been observed for good patient tolerance, cutting and healing properties.

Methods: The physico-chemical evaluation of GTK was conducted in the Quality Control (QC) lab of Amrita School of Ayurveda. The parameters assessed were length, weight, thickness, tensile strength, loss on drying, water soluble extractive, sulphated ash, pH and macroscopic appearance following the methodology elaborated in Ayurvedic Pharmacopoeia of India (API). Those were compared with the corresponding values of standard Kṣārasūtra prescribed by Indian Council for Medical Research (ICMR).

Results: The final results on each parameters were length – 39.44 cm, weight – 0.19934 g, thickness – 0.7147 mm, tensile strength – not less than 6.25 kg, loss on drying – 18.73%, water soluble extractive – 39.79%, sulphated ash – 12.89%, pH – 7.94 and macroscopic appearance – blackish brown.

Conclusion: GTK was found less alkaline, higher in tensile strength, more in moisture content and less brittle in nature suggesting it as a safe choice in anorectal practice compared to the ICMR standard.

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Introduction

Kṣārasūtra is a medicated thread impregnated with Kshara, a caustic alkali of herbal or mineral origin. Description of Kṣārasūtra is available in Suṣruta Samhita the surgical treatise of Ayurveda under the context of Sinus, and in Caraka Samhita in the context of management of Inflammation. The method of preparation and indications are mentioned in Caradutta. Ayurvedic Surgeons widely use it to manage conditions like anal fistula, piles, rectal polyp, and pilonidal sinus. The clinical trial executed by ICMR at multiple centres has set Apamarga Kṣārasūtra (Seton coated with Euphorbia nerifolia, Achyranthes aspera Linn and Curcuma longa) developed by Banaras Hindu University as standard in practice. Unfortunately, very few GMP (Good Manufacturing Practice) certified companies do manufacture it on commercial basis rather than some Kṣārasūtra practitioners owing to its potential limitations.

Commiphora wightii (Guggulu) has proven antibacterial and anti-inflammatory properties and Borax (Tankana) has established wound healing property. Hence the combination was chosen to modify the standard one. Guggulu and Tankana Kṣārasūtra (GTK) is prepared with surgical linen number 20, as base by smearing it with the 11 coats of Guggulu, 7 coats of Tankana and 3 coats of Haridra (powdered Curcuma longa). Here, the Snuhi (latex of Euphorbia nerifolia) base coat is replaced using Guggulu resin. Instead of Apamarga Kshara, fine powder of fried Borax is used. The thread and number of coatings are the same as the standard mentioned in API. It is being used in the Anorectal Clinic, under the Dept. of Shalya Tantra, Amrita School of Ayurveda. According to the Minor Operation Theatre Records, 391 patients were treated with GTK, for fistula-in-ano during 2015 to 2017 and the effect was found satisfactory with a better patient compliance.

Aim

It was to find the physico-chemical characteristics of GTK in comparison with the ICMR standards of Apamarga Kṣārasūtra.

Materials & Methods

Materials required for preparation

Surgical linen no.20 Q.S.(Quantity Sufficient), purified Guggulu 50 g (Commiphora wightii resin), Tankana Kshara 50 g (fried and powdered Borax), Curcuma longa rhizome powdered, 25 g, Gomutra (fresh cow’s urine) Q.S.
Preparation

1. Surgical thread was spread across the breadth of the metallic frames of Kṣārasūtra cabinet.
2. It was smeared with paste of Guggulu (soaked in Gomutra), evenly all around the thread, with the help of a gauze piece and gloved hands.
3. After smearing all the threads on the hangers, those were kept in airight Kṣārasūtra cabinets for drying.
4. The cabinet was closed properly to prevent entry of moisture into the cabinet.
5. The temperature inside the cabinet was maintained warm overnight.
6. Eleven such coatings were completed with the above-mentioned paste, and after applying the 12th coat the moist thread was passed through heaped Borax powder immediately.
7. On completion of coating all the threads with Kshara, the frames were shaken gently making the excess Kshara to fall off.
8. The hangers were again kept in the cabinet for drying. This process was repeated till seven coatings of Guggulu and Tankana Kshara were done. Total 18 coats were applied on the thread.
9. The following 3 coats were done with Guggulu paste, and fine powder of Turmeric, thus making a total of 21 coatings on the thread.
10. The threads were cut at a uniform length for packing purpose.
11. It was transferred to glass tubes with lid and then autoclaved.

Later the tests were carried out in the QC Lab attached to the Rasashastra and Bhaishajya Kalpana (Medicinal Chemistry and Pharmacy) Dept. by following the methodology enumerated in API, under the context of Physico chemical characteristics of Apamarga Kṣārasūtra following the appendices provided for each characteristic.

Observation

A dark brown to black thread, with a dry coat of intact medicated material, smooth to touch was obtained after coating and drying for 21 days. The physico-chemical characteristics of the thread were tabulated in the table given below in comparison with the ICMR standard of Apamarga Kṣārasūtra. For each parameter to be tested Kṣārasūtras prepared from the same batch were taken as per the prescribed count or quantity, assessed individually and the average of the readings was recorded as the final result.

Methods for physical tests

- **Length**: Length of each thread was measured using a standard scale.
- **Weight**: Each thread used in the test was weighed, on a balance of 0.1 mg (0.0001 g) sensitivity.
- **Thickness**: It was measured with the help of a screw-gauge.

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Tensile strength: The Kṣārasūtra under test was attached to a hook suspended from a stand. A weighing pan of 250 g was tied to the other end of the Kṣārasūtra, and a weight of 2 kg was kept on the pan. Blocks of weight were kept on the pan in increment of 50 g, with a gap of 5 s between each addition. At the time, the Kṣārasūtra broke, the total weight of the pan and weights in it was recorded as the breaking load of the Kṣārasūtra. In case of breakage of thread within 1 cm from two ends the test was repeated on a fresh sample. The average of five tests conducted was noted as the breaking load of the sample.

Methods of chemical tests

- **Loss on drying (LOD)** at 105 °C: Was assessed using a hot air oven.
- **Water soluble extractive**: The test material was weighed accurately, macerated with water (1:40 w/v) at room temperature for 5 min, refluxed for a period of 5 min on steam bath, cooled to room temperature and filtered into a tube with graduation. It was made up to original volume with water. The water was evaporated, and it was dried to a constant weight at 100°–105 °C.
- **pH (Alkalinity)**: 0.1 g of material used for coating was taken and 10 mL of CO₂ free water was added to it. The mixture was vortexed for a minute, kept aside for 15 min, again vortexed for one minute and filtered. The pH of supernatant was assessed using digital pH analyzer.
- **Sulphated ash**: A silica crucible was made red-hot for 10 min and kept for cooling in a desiccator. It was weighed. 3 Kṣārasūtras were taken in the crucible and weighed accurately. It was ignited, initially in a gentle manner until it was totally charred. The residue was kept for cooling and added with 1ml of concentrated sulphuric acid, heated gently till white fumes were no longer emitted. It was ignited protecting from air currents at 800 °C until all black particles have disappeared. The crucible was kept to cool and weight was noted.

Results

The results are present in Table 1.
Discussion

Physical parameters

Length: The average length of the thread was found to be 39.44 cm which was more than the standard ranges in API (29–31 cm). As the length of anal canal is 15 cm, a thread with a minimum of 30 cm was sufficient to be used in fistula management. The length was also dependent on that of frames used for drying purpose. Unlike the standard, GTK requires more number of knots to prevent slippage due to the soapy nature of Guggulu resin. Hence the increased length was beneficial.

Weight: The average weight was found to be 0.19934 g which was much lesser than the standard (0.9 to 1 g). When the weight of thread is less, lesser would be the foreign body sensation felt by the patient. Pressure effect would be much lesser and as a result the pain would also be less.

Diameter/thickness: The average thickness of threads was found to be 0.7147 mm against the standard of 1.75–2.0 mm. In Apamarga Kṣarasūtra the base coat made of Euphorbia nerifolia latex which coagulated on exposure to atmosphere. It could contribute an uneven nature to the thread which would irritate the tissue causing pain. Here, GTK was found smooth, even and with less thickness implies it causes less foreign body sensation and tissue reaction.

Tensile strength: It is the breaking load expressed in kilograms. It was found to be 6.25 kg against 5 kg standard. The more the tensile strength more would be the knot security and there would be much less chance of breaking of thread while securing the knot or thread changing.

Chemical parameters tested

Loss On Drying (LOD) at 105 °C: Following the method in API, 18.73% was the calculated as LOD. It was very much more than the standard of 5%. More moisture content implies more disintegration of medicament in the tract.

Water-soluble extractive: Average extractive value derived was 39.79% against the standard value of 85%.

 pH (Alkalinity): As the result was 7.94 which was near to neutral, GTK was found to be less less irritant to tissue.

Sulphated ash: The sulphated ash percentage was found out as 12.89% which was less than the standard of 80%–82%.

Conclusion

It was found that the physico-chemical characteristics of GTK showed varied results in almost all the parameters tested when compared with standard Apamarga Kṣarasūtra. The results were lesser with respect to weight, thickness, LOD, water soluble extractive, Sulphated ash and pH. It was on the higher side higher with respect to length, moisture content and tensile strength. Counting its advantages like less irritant to tissue, producing less foreign body sensation and lesser chances of breakage of thread it can be considered as a safe alternative in Anorectal practise. The preparation is much easier owing to the perennial availability of raw materials also.

Scopes and limitations of the study

Broad perspective studies need to be planned with more sensitive parameters within sophisticated laboratory set up. The clinical information for the current study was taken from hospital records. So more clinical parameters can be assessed and Randomized Controlled Trials with large sample size need to be carried out.

Conflicts of interest

The authors declare no conflicts of interest.

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