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# A clinical trial to evaluate the efficacy of *Katupila Arka* in post operative fistulotomy wound

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## ABSTRACT

Post-operative fistulotomy wound is a surgically created wound for the better healing of fistulous tract. It is considered as the standard treatment modality for fistula in ano and is the most widely performed procedure. The healing of the fistulotomy wound is a challenging task as the chances of infection is more because of its contaminated nature. This can be related to *Vrana* in *Ayurveda* and can be managed. There is a need for drugs which have *Vrana Shodhaka* and *Vrana Ropaka* properties. *Katupila* (*Securinega leucopyrus* (Wild.) Muell) has all the above said properties due to the presence of various phytochemical agents. It's having a broad spectrum anti-microbial activity. References from a previous work done on *Katupila Kalka* indicate that, it is effective for the management of diabetic wound. Keeping the practical difficulty in the preparation of *Kalka* on daily basis, *Arka Kalpana* is adopted as an alternate method here. *Katupila Arka* showed marked ulcer regression during the course of treatment than Povidone Iodine which could be attributed to *Vrana Shodana* and *Ropana* property. It renders *Shodhana* (Cleansing/Purification) action by virtue of its *Kashaya* and *Tikta Rasas*, *Laghu*, *Ruksha*, *Tikshna Gunas*, *Ushna Veerya* and *Katu Vipaka*. *Ropana* (Tissue healing / Regeneration) by virtue of its *Kashaya* and *Madhura Anurasa* and overall, by *Prabhava*. Tannins, Flavonoids, Phenol, Saponins and Alkaloids are present in the trial drug which enhances the wound healing property.

**Key words:** *Vrana Sodhana*, *Vrana Ropana*, *Katupila*, *Securinega leucopyrus*, *Arka*

## INTRODUCTION

Post-operative fistulotomy wound is a surgically created wound for the better healing of fistulous tract. Fistulotomy is considered as the standard treatment modality for fistula in ano and is the most widely performed procedure about an average of 55.6% cases.<sup>[1]</sup> It is the classic method, where the track of the fistula being laid widely open and the resulting wound is allowed to heal by granulation. Fistulotomy has a

complete healing rate over 90% of low inter-sphincteric and Trans sphincteric fistula.<sup>[2]</sup>

The wound is more prone to contamination due to its anatomical position and the less resting period. This can be related to *Vrana* in *Ayurveda*.<sup>[3]</sup> *Acharya Susruta* has quoted *Vrana* in an elaborate manner, from his keen observations. He has proposed Sixty *Upakramas* for the management of *Vrana*. Major emphasis is given for the essentiality of adopting the principle of *Vrana Shodana* and *Vrana Ropana*. So, a drug which possess *Vrana Shodhana* and *Vrana Ropana* property is needed for the better management.<sup>[4]</sup>

*Katupila* (*Securinega leucopyrus* (Wild.) Muell) is a folklore medicine widely used in Sri Lanka for the management of acute, chronic and non-healing wounds. *Katupila* extract have a broad spectrum anti-microbial activity. The pharmacognostic study of *Katupila* shows the presence of tannins, calcium oxalate and other essential oils which promote wound healing. References from a previous work done on

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*Katupila Kalka* indicate that, it is effective for the management of diabetic wound.<sup>[5]</sup>

Keeping the practical difficulty in the preparation of *Kalka* on daily basis, *Arka Kalpana* is adopted as an alternate method here.<sup>[6]</sup> *Arka* is a liquid preparation obtained by distillation of certain liquids or drugs soaked in water using the *Arkayantra* or any convenient modern distillation apparatus.<sup>[7]</sup> The increased potency, easy absorption and applicability make it special. And even can be expected to have a better result as the drug possess active principles in it.

Povidone-iodine have remained popular after decades of use for antiseptis and wound healing property. Its broad spectrum of activity, ability to penetrate biofilms, lack of associated resistance, anti-inflammatory, good tolerability has been cited as important factor and no negative effect on wound healing. It's expected to remain a highly effective treatment for acute and chronic wound.<sup>[8]</sup>

*Katupila Arka* is taken as a trial drug as it possesses an antimicrobial action along with its inherent property to directly facilitate wound healing process. Thus, analyse and evaluate the efficacy of drug in post-operative fistulotomy wound.

## MATERIALS AND METHODS

### Preparation of *Katupila Arka*

**Ingredients:** *Katupila* (stem course powder) - 200ml

Water - 2000ml

**Procedure:** *Katupila* is taken and made into course powder. 200ml (66gm) of the drug is taken and soaked in 10 parts of water i.e., 2000ml and it's kept for a day. Then it was transferred into distillation apparatus with condenser attached to it and closed properly. Temperature was maintained at 60° throughout the procedure. *Arka* started draining out of the receiver after 45 to 50 minutes. The collected *Arka* was stored in amber air tight glass bottle. About 800 ml is collected in 7 hours.

### Research design and study population

Thirty subjects who were diagnosed with post-operative fistulotomy wound were selected fulfilling the inclusion criteria from Out Patient and In Patients

of department of *Shalya tantra*, SSCAS&RH, Bengaluru and were randomly distributed into 2 groups of 15 each using simple randomization method (lottery method).

During the course of treatment, subjects from both the group were allowed to continue with their regular medications which did not interfere with the study.

### Diagnostic criteria

Subject who underwent fistulotomy were taken for the study.

### Inclusion criteria

- Subjects who have a post-operative fistulotomy wound were included in the study.
- Subjects of either gender.
- Subjects whose age was in between 21-60.
- Subjects who fulfilled the diagnostic criteria.

### Exclusion criteria

- Wounds other than fistulotomy wound were excluded from the study.
- Subjects with signs and symptoms of septicemia.
- Subjects diagnosed with HIV, HbsAg, leprosy, tuberculosis, malignancy.
- Subjects suffering from nephrotic syndrome, auto immune disorders.

### Intervention

#### Group A (Control Group)

Fifteen subjects of group A were allotted for dressing with sterile gauze soaked in Povidone-iodine twice daily for fourteen days.

#### Group B (Trial Group)

Fifteen subjects of group B were allotted for dressing with sterile gauze soaked in *Katupila Arka* twice daily for fourteen days.

### Assessment Criteria

Subjective parameters which include pain and burning sensation, pain was assessed in Visual Analog Scale and burning sensation by grading from 0 to 3. Objective parameter was assessed by Bates Jensen Wound

Assessment tool.<sup>[9]</sup> It serves to assess the progression of wound healing.

#### Duration of study

- Total duration of study was 28 days.
- Duration of treatment - 14 days (observations were made on 0<sup>th</sup>, 7<sup>th</sup>, 14<sup>th</sup> day).
- Follow up period - 14 days.

### OBSERVATION AND RESULTS

#### Observation during intervention

- Both Povidone iodine and *Katupila Arka* were easy to apply.
- *Katupila Arka* was non-irritant; But povidone iodine caused mild irritation.
- Protected the ulcer from further damage.
- Maintained adequate moisture.
- Promoted exude drainage.
- No signs of infection manifested during intervention.

### RESULTS

**Table 1: Between the group comparison (BT) and (AT) for Pain**

Assessment of Pain	0 <sup>th</sup> day	7 <sup>th</sup> day	14 <sup>th</sup> day	28 <sup>th</sup> day (follow up)	p value
Group A	5.67 ± 0.55	4.80 ± 0.55	4.07 ± 0.53	3.00 ± 0.53	** p 0.019 ***p 0.005
Group B	6.13 ± 0.40	4.47 ± 0.46	2.53 ± 0.41**	1.00 ± 0.35***	

**Table 2: Between the group comparison (BT) and (AT) for Burning Sensation**

Assessment of Burning Sensation	0 <sup>th</sup> day	7 <sup>th</sup> day	14 <sup>th</sup> day	28 <sup>th</sup> day (follow up)	p value
Group A	2.40 ± 0.19	2.13 ± 0.19	2.13 ± 0.19	1.53 ± 0.17	**p<0.007

Group B	2.60 ± 0.13	2.13 ± 0.13	1.60 ± 0.13	0.80 ± 0.11**	
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**Table 3: Between the group comparison (BT) and (AT) for BWAT**

Assessment of BWAT	0 <sup>th</sup> day	7 <sup>th</sup> day	14 <sup>th</sup> day	28 <sup>th</sup> day (follow up)	p value
Group A	2.33 ± 0.25	2.27 ± 0.27	2.20 ± 0.28	2.00 ± 0.24	**p<0.023
Group B	2.27 ± 0.18	1.93 ± 0.18	1.60 ± 0.19	1.20 ± 0.11**	

Total duration of the study was 28 days including follow up. Assessment was made on 0<sup>th</sup>, 7<sup>th</sup>, 14<sup>th</sup>, 28<sup>th</sup> day. On assessment of pain, it was found a significant reduction observed on 14<sup>th</sup> day and 28<sup>th</sup> day in Group B (trial group) compared to Group A (control group). In burning sensation also, the p value is significant in Group B compared to Group A.

In the total assessment of wound was done with Bates-Jensen Wound Assessment Tool Score, there was highly significant decrease (p<0.023) was observed in Group B in comparison to Group A i.e., remarkable improvement in wound regression in Group B.

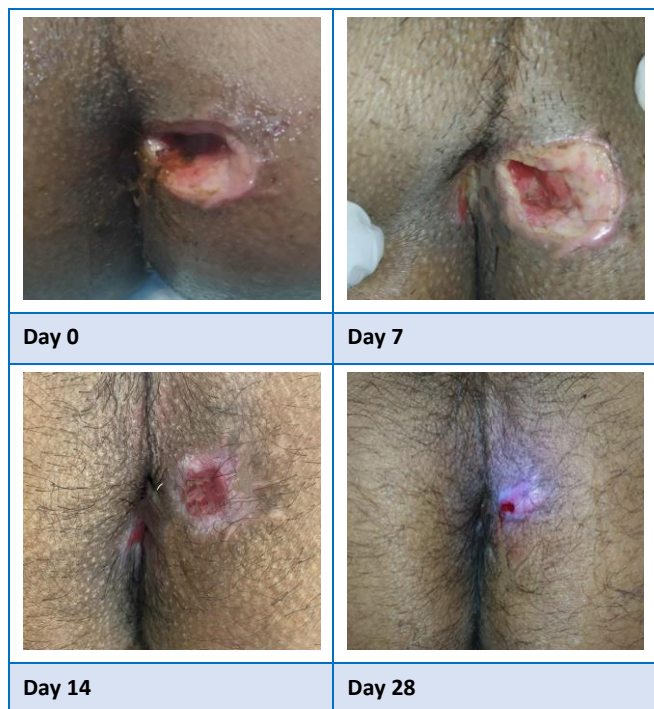
### DISCUSSION

There was significant difference in pain between the groups (p value<0.05), within the group. Group B showed marked reduction in pain during the course of treatment unlike Group A, which could be due to the presence of Alkaloids, Flavonoids, Saponins, Tannins and can be ascribed as the *Vatahara* effect of the drug (*Snigdha, Guru-Guna*). In terms of burning sensation, Significant reduction in burning sensation in Group B may be due to *Pittahara* and *Kashaya Rasa* properties which can be attributed as the *Dahasamana* property of *Katupila*. Ulcer regression was observed in Group A was due to the antimicrobial and anti-inflammatory action of povidone iodine. Whereas Group B has showed marked ulcer regression during the course of

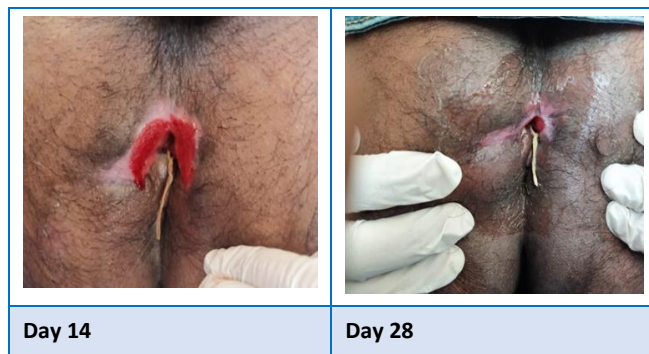
treatment than Group A, which could be attributed to *Vrana Shodana* and *Ropana* property. It renders *Shodhana* (Cleansing/ Purification) action by virtue of its *Kashaya* and *Tikta Rasas*, *Laghu*, *Ruksha*, *Tikshna Gunas*, *Ushna Veerya* and *Katu Vipaka*. *Ropana* (Tissue healing / Regeneration) by virtue of its *Kashaya* and *Madhura Anu-Rasa* and overall, by *Prabhava*.<sup>[10]</sup>

Tannins, Flavonoids, Phenol, Saponins, Alkaloids are present in the *Katupila Arka* which enhances the wound healing property by virtue of its antioxidant, anti-inflammatory, antimicrobial property and the direct effect of tannins and flavanoids in promoting healing process by wound contraction with increased capillary formation and fibroblast proliferation, followed by enhanced rate of epithelialization.<sup>[11-13]</sup>

**Control Group**



**Trial Group**



**LIMITATION**

Undermining, surrounding skin colour change, peripheral tissue oedema and induration criteria of BWAT was inessential as it is not the characteristic feature of post operative fistulotomy wound. Hence, insignificant results in both the groups.

**CONCLUSION**

Fistulotomy is the surgical procedure, where the fistulous tract being laid widely open and the resulting wound is allowed to heal by granulation. In this clinical trial on 30 subjects. All inclusive, Group B (Trial group) rendered significantly better results over Group A (Control group) ( $p < 0.05$ ). The trial drug *Katupila Arka* showed immense range of chemical constituents which could be attributed to its rapid wound healing property. It is cost effective due to requirement of lesser amount of drugs and better healing, and can be applied in any group of subjects due to its better acceptability and safety. Hence, from the study it was concluded that, the drug *Katupila Arka* possesses high qualitative efficacy in "*Vrana Ropana*" with minimal scarring without producing any adverse effects.

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