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Clinical Evaluation of Katupila Nirudhhalepa in Management of Dusta Vrana

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Abstract

Context: Dustavraa is combination of two Sanskrit word meaning Dusta as contaminated/ infected/chronic/non-healing and Vrana as Ulcer/wound. Chronic/ non-healing/ contaminated ulcer is a frequently encountered problem in present era commonly as a complication of trauma or pathological insult. Ayurveda mentions Vrana Shodhana (wound cleansing) and Vrana Ropna (wound healing) as treatment modalities under the Shasti Upkramas (60 specific treatment modalities for wound). "No plant is devoid of medicinal values on this globe" as per Ayurvedic literature. Katupila shrub (Securinega leucopyrus linn), even though doesn't find its specific mention in Ayurvedic classics but as per above statement of "all plants are with medicinal properties", is better used as folklore medicine for wound management.

Aims: Aim of present study was to evaluate efficacy of folklore drug name Katupila over Dusta vrana.

Methods and Material: This study includes efficacy analysis of Katupila drug as a Nirudhhalepa (smeared paste of Securinegaleucopyrus mixed with honey) for the management of DustaVrana over 30 numbers of patients who were fulfilling inclusion criteria. Daily application of Nirudhhalepa over Dustavrana was done with proper aseptic precautions until complete healing or 28 days whichever is earlier. During the study, weekly assessment according to assessment parameter was done and results were drawn accordingly.

Statistical analysis used: obtained data Analysis was done using SPSS version 23 (IBM SPSS Statistics Inc., Chicago, Illinois, USA) Windows software program. The data were checked for normality before statistical analysis using Shapiro–Wilk test. Friedman test was applied for repeated measures.

Results and conclusion: The data has shown encouraging results of wound healing to revalidate its use in wound management. All observation and results showed that Katupila Nirudhhalepa is promoting agent in wound healing process.

Keywords: DustaVrana; Katupila; Nirudhhalepa; Non-healing ulcer; Securinegaleucopyrus; Shasti Upkrama; Wound.

Key messages: Present study validates data regarding wound healing effect of folklore drug named 'Katupila'.

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INTRODUCTION

Ayurveda India's own medical science traces its root from pre-vedic periods (to be validated more than 5000 years). Since then its utility is proved to be healing science as it is valid in the present condition also. Ayurveda validates even those folklore medicines that are not edited in its classics as of medicinal properties and allows to

use newer drugs with the acceptable concept of "Anuktadravya". Anuktadravya concept supports the concepts of ethno botany which conduct "the scientific study of the traditional knowledge and customs of a people concerning plants and their medical, religious, and other uses". Katupila (Securinegaleucopyrus) being used as folklore medicine since century for wound management needs to be revalidated with scientific approach and medical statistics. Considering this layout, evaluationof Katupila as therapeutic agent in the form of paste prepared by mixing its fine powder with Honey as a topical application in wound management specifically unhealthy and non -healing wounds is carried out in present study on Total Number of 30 patients. The study was taken up with the objective of cost effectiveness, reduction in wound healing period, easy accessibility of the drug, as a day care procedure and with good quality life style for the patients. The aim was to utilise medicinal value of Katupila to avoid functional and structural damage to body parts due to wounds.

METHODOLOGY

A. Source of data:

A.1 *Clinical source:*

Patients were selected from the OPD and IPD department of Shayla Tantra irrespective of gender and socioeconomic status.

A.2 *Drug source:*

Raw drugs required for Katupila Nirudhhalepa, that is Katupila plant were collected from the farms in and around of Bhavnagar, Gujarat State of India and Honey from Zandu pharmacy. Katupila drug authentication was done by Department of Dravya Guna (Department of Herbal Medicine/Ayurvedic Materia medica), assuring the quality, final drug was prepared in pharmaceutical unit of Parul institute of Ayurveda.

B. Methods of collection of data

B.1 *Research design:* Open Clinical Trial Study

B.2 *Sample size:* Minimum 30 Patient

B.3 *Inclusion criteria:*

- Vrana having signs and symptoms of classical Dusta Vrana like Atisamvritta–Ativivritta, Atikathina–Atimridu, Utsanna-Avsanna, Atishita-Atiushna[1] etc.
- Modern Parameter of Chronic Wound
- Patient Having the age between the 16 years to 70 years, Irrespective of gender

B.4 *Exclusion criteria:*

- Patient having Uncontrolled Diabetes mellitus
- Patient who is HIV, HBsAG, VDRL Positive
- Patient having Malignancy or tuberculosis
- Patient having Septicemia
- Anaemic patient

B.5 *Diagnostic criteria:* As per classical symptoms of Dusta vrana and modern parameter for chronic and Non-healing wound.

B.6 *Composition of trial drug:* Katupila fine powder (leaf) and Honey.

B.7 *Posology (Table no. 1)*

Table 1: Posology of drug

Drug	Duration	Sitting	Dose
Katupilla Nirudhhalepa (Katupila fine powderand Honey)	28 days	Maximum. 28	Topical dose According to Wound size

B.8 *Investigation:*

- Blood: CBC, HIV, HBsAg, RBS, VDRL, ESR
- Pus: for culture (if required)
- Sputum: AFB (if required)
- Radiology: as per requirement
- Biopsy: if required

B. 9 *Method:*

a. PURVAKARMA (Pre-procedure)

- Informed and written consent was taken
- *Debridement (SOS):* There was not requirement of debridement throughout study
- *Prakshalan:* Application of distilled water to clean wound

b. PRADHAN KARMA(Procedure)

- Nirudhhalepa application: Application of Katupila Fine powder with Madhu(honey) on Wounddaily locally.
- Bandaging

c. ***PASCHAAT KARMA (Post-procedure)***

- Relavant Vranitopasaniya regimen (Precaution for wound care)

B.10 *Assessment criteria:* Improvement in sign and symptoms was assessed at weekly interval i.e. 7th,

14th, 21th, 28th day by Subjective criteria (Table No. 2) and Objective criteria (Table No. 3).

Table 2: Subjective criteria

Criteria	Grade 0	Grade 1	Grade 2	Grade 3
Vedana (Pain -VAS scale)	Absent	Mild (1-3)	Moderate (4-6)	Severe (7-10)
Kandu (Itching)	No itching	Slight localized itching	More localizes itching but not disturbing sleep	Continuous itching, disturbing sleep
Daha (Burning sensation)	No burning sensation	Intermittent burning sensation	Continuous burning sensation, not disturbing sleep	Continuous burning sensation, disturbing sleep

Table 3: Objective criteria

Criteria	Grade 0	Grade 1	Grade 2	Grade 3
Gandh (Odour)	None	Present when dressing removed	Present, when patient was approached	Patient distressed by odor
Varna (Peri wound skin)	Healthy	Erythema (red)	Macerated (white)	Excoriated (red and wet)
Sravaa (Exudate type)	Absent	Serous (clear)	Seropurulent	Purulent
Sravaa matra (Exudate level)	Absent	Dressing marked	Dressing wet	Dressing soaked
Akruti (Wound measurement)	≤ 5 cm^2	> 5 cm^2 but <10 cm^2	>10 cm^2 but <20 cm^2	>20 cm^2
Puti puya mansa (Slough tissue)	No slough	Up to 25% covered with slough	25-50% covered with slough	More than 50% covered with slough
Jihvatalabh (Granulation)	More than 50% covered with Granulation tissue	25 to 50% covered with Granulation tissue	Up to 25% covered with Granulation tissue	No Granulation

C. Drug Katupila (Table 4) (Fig. 1 Preparation of Katupila powder):

Table 4: Details of drug Katupila

Latin name	English name	Regional name (Gujarati)	Rasa	Guna	Virya	Vipaka	Prabhav
Securinega lecupyrous (Euphorbiacea)	Water caltrop	Humari / Sheenvi	Kashay, Tikta	Ruksha, laghu, tikshna	Ushna	Katu	Tridoshahara

Collected *Katupila* plant | Dried leaves of plant, leaves shed off from its branches itself | Filtration of powder from No. 120 sieve

Fig. 1: Preparation of Katupila Powder.

C. 1 Drug analytical study:

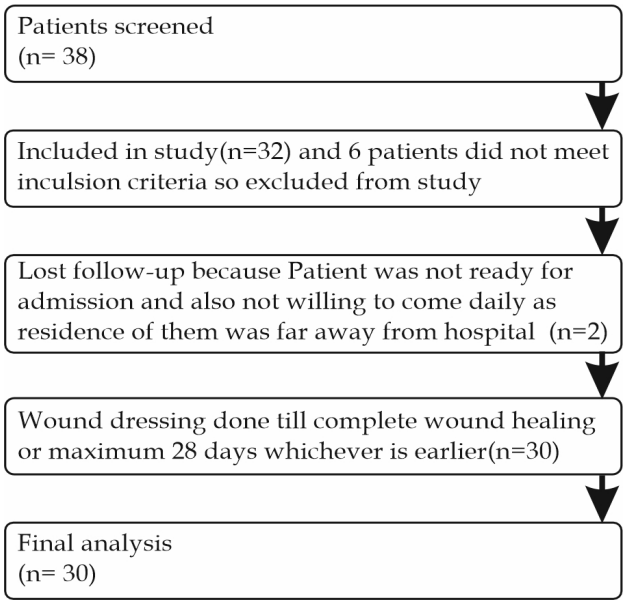
Analytical study of Katupila Churna was done in QC lab. It is rich of various alkaloids, terpenoids, triterpenoids, Glycosides, Saponin, Tannins, and Carbohydrates. Also Katupila is Acidic by nature.

C.2 Antibacterial assay of drug:

Drug acted as a broad spectrum antibacterial agent in Agar well diffusion method conducted at Department of Science, Shree Dineshbhai Shamjibhai Ravani Science College, Maharaja Krushnakumarsinhji Bhavnagar University. (Ref no: DSRB.Sc/2018/-19/123).

OBSERVATION

A total number of 38 patients were screened for study, but among them, 6 patients (with uncontrolled diabetes) were not meeting inclusion criteria so excluded from study. Total 32 patients were registered irrespective of religion, caste or sex. Among these 32 patients, 2 patients had not completed treatment due their inconvenience for admission in hospital. Other than this 2, all 30 numbers of patients completed the due course of study hence, with no any major adverse event. So, final data analysis was done over total 30 numbers of patients.



Observation on demographic data (Table no. 5) (Fig. 2 Observation on Demographic data on 30 patients)

Table 5: Maximum number of Demographic Data observed in study

Criteria of data	Maximum found in study	Percentage	Number of patients
Age	20-19 year	33.30%	10
Gender	Male and female	Both 50%	Each were 15
Religion	Hindu	96.7%	29
Marital status	Married	66.7%	20
Education	Uneducated	53.3%	16
Occupation	Student	30.0%	9
Socio-economic group	Middle class	70%	21
Habitat	Rural	53.3%	16

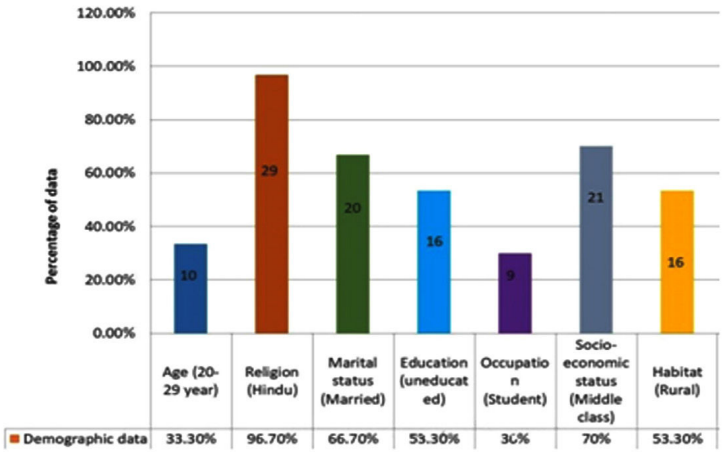


Fig. 2: Observation on demographic data

Observation over maximum clinical findings in study (Table no. 6) (fig. 3 Observation on Clinical Symptoms

Table 6: Maximum clinical findings found in study

Criteria of data	Maximum found in study	Percentage	Number of patients
Wound chronicity	0-1 month	76.6%	23
Wound number	Single	90%	27
Onset of wound	Traumatic	76.6%	23
VranaSraava/ Pramana/ consistency	Sero-purulent/ dressing marked/ thin	50%/ 50%/ 76.6%	15/15/23
Gandha	Absent	93.3%	28
Pain/Type of pain/Periodicity of pain/ intensity	Present/Pricking/continuous/ moderate	93.3%/73.3%/56.6%/73.3%	28/22/17/22
Kandu	Absent	90%	27
Jwar	Absent	90%	27

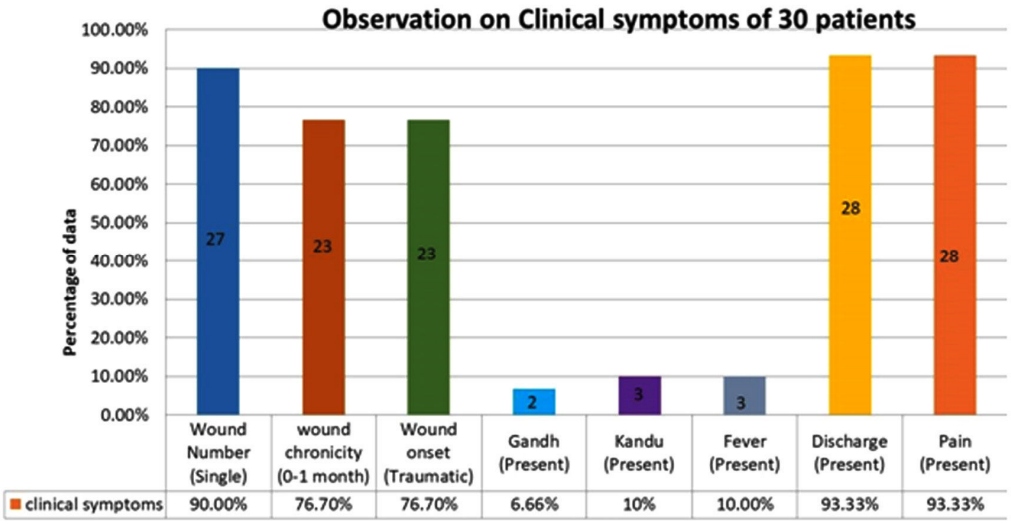


Fig. 3: Observation on Clinical Symptoms

of 30 Patients):

A. *Observation on healing time:* Average wound healing time: 0.297 cm x cm

Table 7: Observation on average unit healing time on wound chronicity

Wound chronicity	Average healing time
0-1 month	1.5 cm x cm
1-2 month	0.71 cm x cm
2-3 month	0.37 cm x cm
Greater than 3 month	0.1 cm x cm

A.1 Observation over unit wound healing time according to wound chronicity (Table no. 7):

According to wound chronicity, observation indicates that greater chronicity had lesser unit healing time compared to lesser wound chronicity.

A.2 Observation on average unit wound healing time on age group (Table no. 8):

Table 8: Observation on average unit healing time on age group

Age group	Average Healing time
20-29 year	0.57 cm x cm
30-39 year	0.35 cm x cm
40-49 year	0.31 cm x cm
50-59 year	0.25 cm x cm
60-69 year	0.21 cm x cm

Table no. 8 Observation of average unit healing time of wound according age group is indicating that age is affecting factor for wound healing. As observation showed greater healing time in younger age group and lesser unit healing time in older age group.

Table 9: Observation on average unit healing time of different type of ulcer

Type of non-healing ulcer/wound	Number of patient	Percentage	Average unit healing time
Post-Traumatic Infected wound	20	66.66%	0.266 cm x cm
Infected ulcer after boils	3	10%	0.473 cm x cm
Varicose ulcer	4	13.33%	0.485 cm x cm
Pressure ulcer	1	3.33%	0.23 cm x cm
Diabetic ulcer	1	3.33%	0.08 cm x cm
Arterial ulcer	1	3.33%	0.21 cm x cm

A.3 Observation on average unit healing time in different type of wound (Table no. 9):

In present study, wound healing was observed in various type of non-healing or contaminated wounds, among them drug possessed great unit healing time i.e. 0.485 cm x cm and very lower unit healing time in diabetic ulcers i.e. 0.08 cmx cm.

A.4 Observation on Rescue medicine: Tab. Paracetamol 500 mg 1 tab SOS (maximum 3 tablet / day) was given as a rescue medicine in 3 patient for fever. (In 2 patients rescue medicine was given for 3 days, In 1 patient rescue medicine was given for single dose only.)

RESULTS

Analysis was done using SPSS version 23 (IBM SPSS Statistics Inc., Chicago, Illinois, USA) Windows software program. The data were checked for normality before statistical analysis using Shapiro–Wilk test. Friedman test was applied for repeated measures.

In this study *Dusta vrana* treated with *Katupila Nirudhhalepa* found very effective clinically as well as statistically.

- Total 90.0% patients were completely cured that is complete healing was observed within 28 days.

Table 10: Result of complete study by appropriate statistical test

Parameters	Mean rank					N	Chi-square	Df	Asymp. sig.	Statistical status
	BT	7th day	14th day	21st day	28th day					
Vedana (Pain)	4.80	3.75	2.60	2.05	1.80	30	98.260	4	0.000	Significant
Daha (Burning)	3.52	3.17	2.87	2.77	2.68	30	27.129	4	0.000	Significant
Kandu (Itching)	3.13	2.97	2.97	2.97	2.97	30	8.000	4	0.092	Not significant
Gandha (Odor)	3.13	2.97	2.97	2.97	2.97	30	8.000	4	0.092	Not significant
Varna (Peripheral Skin)	4.72	3.90	2.70	2.08	1.60	30	99.089	4	0.000	Significant
Sraava Matra (Exudate)	4.48	3.50	3.00	2.18	1.83	30	86.7171	4	0.000	Significant
Sraavabheda (Exudate Type)	4.62	3.53	2.90	2.15	1.80	30	78.262	4	0.000	Significant
Puti-Puya Mansa (Slough)	4.88	3.72	2.37	2.08	1.95	30	101.345	4	0.000	Significant
Jihvatalabhvat (Granulation)	4.93	3.72	2.45	1.95	1.95	30	104.879	4	0.000	Significant
Aakruti (Size)	4.95	3.95	2.77	1.80	1.57	30	111.547	4	0.000	Significant

- In 10% cases moderate improvement was seen because complete wound healing required more than 28 days.
- Average wound healing days: 19.36

DISCUSSION

Dusta Vrana observed during study were mostly loaded with slough and having horror look which

is main classical symptom mentioned as "*Bhairava*" and "*Puti-puyamansa*"[2] accordingly indicative of dead soft tissue within it. And also wound found with sero-purulent discharge which is suggestive of presence of infective organism causing delaying wound healing.

Vrutta (Round)**:** *Aayat* (Vertical ovale) are shape of *Sukhsadhya* (easy to treat) wound.[3] In present study above mentioned wound shape were also observed, though wounds were clinically non-healing or contaminated considered as difficult to treat. So this concept of wound shape is not justifiable in this study.

A. Probable action of Katupila in wound healing:

Anti-inflammatory action[4] will prevent the prostaglandins from ever being synthesized, reducing or eliminating the pain. sAlso, accelerate the process of wound healing by regulation of inflammatory cytokines.

The high *antioxidant capacity*[5] will lower oxidative stress of tissue and wards off any free-radicals through the scavenging activity locally. This in turn facilitates micro and macro debridement of wounds and ulcers exposing and cleaning the wound base.

Broad spectrum antimicrobial activity had provoked the wound healing by reduction of the pathogens in wounds. By other hand it had also assisted in management of the foul smell in the wounds and dressings even after 24 hours (since the dressing was changed once daily). Tannins increase the availability of nitric oxide in hypoxic tissue and defend against the endothelial dysfunction. Hence vasodilatation of the constricted blood vessels increased the blood flow providing nutrition and oxygen to tissues. This triggers neogenesis (regeneration of biological tissue) and vasculogenesis forming neovascularization and resulting in fresh epithelialization and granulation assisted in wound healing.

Saponin boosted epidermal cell and collagen synthesis in skin tissue which in turned assisted in early wound closure with *minimal scar formation*.

Other *nutritional factors* i.e. carbohydrate, protein and ascorbic acid had acted as an energy supplement for enhancement of wound healing.

By the above combined activities the non-healing ulcers and wounds were rapidly healed.

B. Probable action of Honeyin wound healing:[6]

Wound healing activity of honey is mainly attributed to its *Madhura* (Sweet), *Kashaya Rasa* (Astringenttaste) and *Pichhila* (Slimy), *Sheeta* (cool), *Laghu* (light) *Guna*.

- *Madhura Rasa* being *Sarvadhatuposhaka* and *Bruhana* by its karma, it will enhance repair procedure by regeneration of tissue. Also honey's *Madhur Rasa* is indicative of wide range of amino acids, vitamins, and trace elements in addition to large quantities of readily assimilable sugars which will provide direct nutrition to tissue.
- *Kashaya Rasa* deterges the wound surface by *Shodhan Karma* and eliminates foul smell from wounds by *Tikshna Guna* which destroys the bacteria which produce ammonia.
- *Sheeta Guna* is identical mark of its anti-inflammatory action, which did reduction in pain by soothing and anti-inflammatory action.
- *Pichhila Guna* having *lepana Karma* acts as moist retentive and moist wound environment favorable for wound healing promotion. Moist wound dressing is also useful for better cosmetic results with less pain and fewer dressing changes.

Honey acts as an *oxidative media*, because when comes in contact with wound, the glucose oxidase enzyme introduced to the honey by the bee slowly releases the anti-septic hydrogen peroxide (H_2O_2). This H_2O_2 released at sufficient levels so even though it is effective against bacteria, it does not cause tissue damaging and fibroblast growth which is stimulated by H_2O_2.

Honey being *acidic* in nature, it helps in release of more oxygen. So honey will act like insulin, which is providing oxygen to functioning cell for better growth and stimulation of immune response.

By summarizing all activity of honey, it promotes rapid healing with minimal scaring.

Adverse drug reaction: No any type of adverse drug reaction was noted throughout the study period.

CONCLUSION

Shodhana property of *Katupilla Nirudhhalepa* is established by absence of necessity of mechanical debridement in all the 30 patients, though they have reported with different grading of slough. Ropana property is indicated by pharmacological evaluation, that it consists many of ingredient i.e. Alkaloids, Terpenoids, Flavonoids etc and also antibacterial activity which are promoting factors for wound healing process. So, all observation and results showed that *Katupila Nirudhhalepa* is

promoting agent in wound healing process.

Merits and demerits of Katupila Nirudhhalepa:

- **Merits:**
  - Katupila Nirudhhalepa is patch like dressing material which did not stick to wound site, so it is easy to remove on next dressing.
  - Honey as a wound dressing base is more effective compared to other, because honey persists its healing effects even though after exudative dilution.
  - The mode of treatment was found to be cost-effective, safe, and easy to implement.
- **Demerit:**
  - As Katupila proved to be effective in diabetic ulcer, in this study Katupilla Nirudhhalepa had too low unit healing rate in diabetic ulcers.

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