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ORIGINAL RESEARCH ARTICLE

STUDY OF ADVERSE REACTIONS OF INDIGENOUS OINTMENT AS LOCAL APPLICATION IN WOUND MANAGEMENT

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Abstract

Background: The past decade has seen an explosive growth of wound healing research that promises to facilitate clinical wound repair. Present study was aimed to study adverse reactions of indigenous ointment as local application in wound management. **Material and Methods:** Present study was prospective, observational study. Patients aged between 18-65 years, either gender, had wound, willing to participate in present study & complete follow-up were included for study. Every time, wound was cleaned with normal saline, dried with gauze & a thin film of ointment covering entire wound surface was applied. **Results:** In present study, 50 patients with various types of wounds, was carried out to evaluate the efficacy of indigenous topical agent produced from barks of 5 trees. Majority patients were from 26-50 years of age (48 %), were male (63 %) & of non-diabetic aetiology (76 %). In present study, majority wounds were ulcers (40 %) followed by burns (18 %), post-op wounds (16 %), amputation stumps (14 %) & pressure sores (12 %). In majority of the patient's wound closure was achieved with split skin grafting (74 5). Common organisms isolated were Pseudomonas Aeruginosa (24 %), Staphylococcus Aureus (20 %) & Proteus Mirablis (10 %). In 80 % patients, systemic antibiotics used in conjunction with local agent. Only local itching was observed as a adverse reaction (2 %) in present study. No local (redness, burning sensation & pain) or systemic (itching, fever & allergic reactions) were noted in present study. No any significant complications were observed during trial or after trial (during follow up). **Conclusion:** Indigenous agent is effective and safe for us in the management of various wounds encountered in surgical practice. It had no adverse reactions and patient compliance and acceptance was good.

Keywords: wound management, Indian medicine, indigenous agent, wound healing

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Introduction

Wounds and their management are fundamental to the practice of surgery and all surgeons depend on wound repair process.[1] For a prolonged duration of human history, incomplete or complicated wound healing was the rule and not an exception. The basic principles of wound care and antisepsis introduced during past century aided / eased the surgeon's job considerably.

The past decade has seen an explosive growth of wound healing research that promises to facilitate clinical wound repair. For centuries people are using various topical agents for healing of wounds and have improvised the agents according to the need. In India history goes back more than 5000 years B.C. where in Ayurveda use of turmeric (Haldi) as a topical antimicrobial agent was shown to be effective and emphasized.[2] Plants and tree extracts have played a crucial role in India for centuries, as topical preparations for management of wounds. [2]

In last decade a large number of effective topical agents for prevention of burn wound sepsis have come upon the scene. Until recently all these methods of topical therapy of burn wound had fallen into dispute because of toxicity & microbial resistance of the substance applied either local or systemic or failure to show any beneficial results of both.[3,4] In quest for alternative sources of antimicrobials we have turned back towards. Ayurveda, the ancient system of medicine in India. Present study was aimed to study adverse reactions of indigenous ointment as local application in wound management.

Material And Methods

Present study was prospective, observational study, conducted in department of general surgery, at XXX medical college & hospital, XXX, India. Study duration was of 6 months (December 2001 to Jun 2002). Study approval was obtained from institutional ethical committee.

Patients aged between 18-65 years, either gender, had wound, willing to participate in present study & complete follow-up were included for study. While Pregnant females, patients with leprosy, severe systemic disease & peripheral neuropathy were excluded Study was explained to patients in local language & written consent was taken for participation & study. Decision for premature *discontinuation* trail protocol

- Voluntary election to leave study.
- Discontinuation due to experiencing adverse effects.
- Development of an intercurrent disease for which we warrant study termination for particular patient.
- The patient showed no sign of wound improvement within 2 weeks of treatment.

Present study was an open labelled trial using an indigenous product ointment on 50 patients, with various types of wounds, as a topical agent for dressing, from time of admission till complete wound cover is achieved. Evaluation of wound status by using special study proforma and photographs at regular intervals was employed for charting the changes in wound status.

This ointment is an extract of barks of 5 trees having antibacterial activity. namely Ficus bengalensis (Vad), Ficus glomerata (Udumbar), Ficus religiosa (Pipal), Ficus infecturia

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(Pakar) & Azadirachta Indica (Neem). The study has been conducted as per the research guidelines for evaluating the safety and efficacy of herbal medicines set down by World Health Organization (1993)[5]

Basic data regarding patient's history and other parameters was recorded. Baseline blood investigations and wound swab for culture and sensitivity were sent prior to ointment application. Wound evaluation was scored in a tabulated format as in case record forms (CRFs). Every time, wound was cleaned with normal saline, dried with gauze & a thin film of ointment covering entire wound surface was applied. Wound surface was covered with dry gauze or autoclaved banana leaves (Burn wounds) & bandage applied. Change of dressing was done every 24 hours.

On Day 3, wound evaluation was done and score was recorded. Wound swab for culture and sensitivity was sent. On Day 7, wound evaluation was scored. Wound swab sent for Culture and sensitivity. On Day 10, wound evaluation was scored. Wound swab sent for Culture and sensitivity. On follow up, wound examined (healed wound or graft taken or scar maturation). Final photograph was taken depending on patient compliance.

During study we observed any local (itching, redness, burning sensation & pain) or systemic (itching, fever & allergic reactions) adverse effects or any complications noted trial or after trial (during follow up). After completion of the study, the data obtained was analysed and interpreted. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Statistical analysis was done using descriptive statistics.

Results

In present study, 50 patients with various types of wounds, was carried out to evaluate the efficacy of indigenous topical agent produced from barks of 5 trees. Majority patients were from 26-50 years of age (48 %), were male (63 %) & of non-diabetic aetiology (76 %). In present study, majority wounds were ulcers (40 %) followed by burns (18 %), post-op wounds (16 %), amputation stumps (14 %) & pressure sores (12 %). In majority of the patient's wound closure was achieved with split skin grafting (74 5).

Table 1: General characteristics

	No. of patients	**Percentage**
Age groups (in years)		
12-25	12	24
26-50	24	48
51-65	14	28
Gender		
Male	31	62
Female	19	38
Aetiology		
Diabetic	12 (24%)	24
Non-diabetic	38 (76%)	76
Wound Type		
Ulcers	20	40

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Burns (BURNT AREA)	9	18
Post-op wounds	8	16
Amputation stumps	7	14
Pressure sores	6	12
Type of wound cover		
Split skin grafting	37	74
Wound contraction	7	14
Epithelisation	4	8
Secondary suturing	1	2
Stump closure	1	2

26% of the wounds were sterile at the inclusion in the study while rest grew various organisms at inclusion but were sterile at completion. Common organisms isolated were Pseudomonas Aeruginosa (24 %), Staphylococcus Aureus (20 %) & Proteus Mirablis (10 %).

Table 2: Microbiological flora isolated from various wounds

Microbiological flora	No. of patients	Percentage
Pseudomonas Aeruginosa	12	24
Staphylococcus Aureus	10	20
Proteus Mirablis	5	10
Klebsiella	3	6
Eishcherechia Coli	3	6
Acinetabacter	2	4
Staphylococcus Aureus (MRSA)	1	2
Citobacter	1	2
No growth	13	26

In 80 % patients, systemic antibiotics used in conjunction with local agent. The mean number of days required to achieve the desired end point remained same (14 days) irrespective of use/non-use of systemic antibiotics.

Table 3: Use of systemic antibiotics

Antibiotics Used	No. of patients	Percentage
Systemic antibiotics used in conjunction with local agent	40	80
Only local agent used	10	20

Only local itching was observed as a adverse reaction (2 %) in present study. No local (redness, burning sensation & pain) or systemic (itching, fever & allergic reactions) were noted in present study. No any significant complications were observed during trial or after trial (during follow up).

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Table 6: Adverse reactions

	No. of patients	Percentage
Adverse reactions		
A) Local		
Itching	1	2
Redness	0	0
Burning sensation	0	0
Pain	0	0
B) Systemic		
Itching	0	0
Fever	0	0
Allergic reactions	0	0
COMPLICATIONS		
During trial	0	0
After trial (during follow up)	0	0

CASE 4

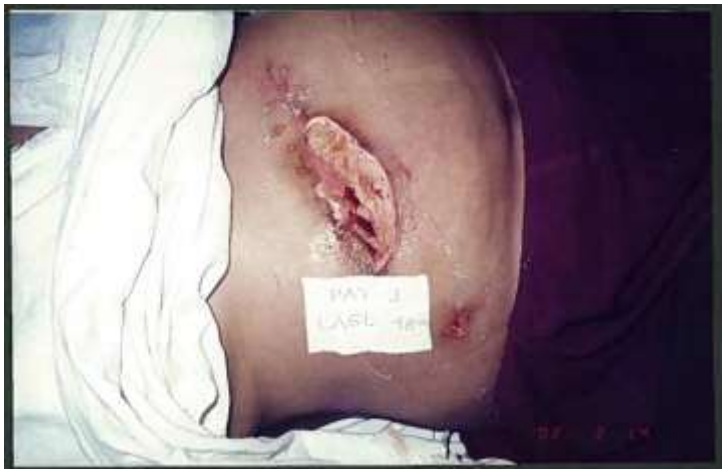

Photo 1: Post Cholecystectomy infected and gaped wound- Day 1

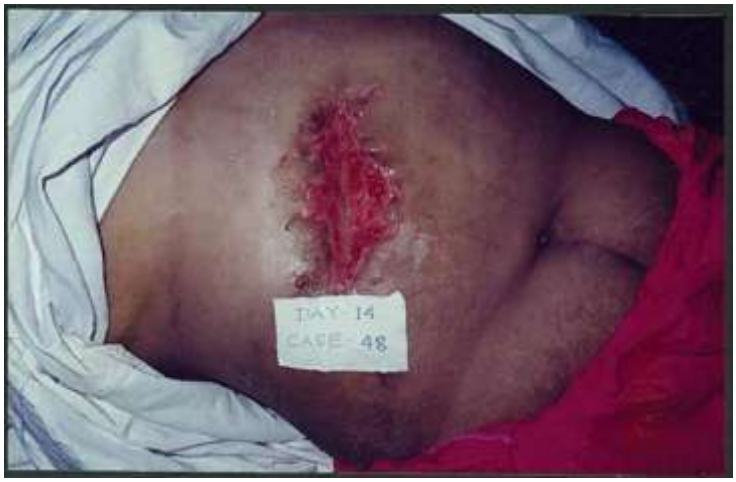

Photo 2: Day-14 of wound, 1. Healthy red granulation tissue, 2. No discharge 3. No slough

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Photo 3: Post-SSG-Da-7-Wound closed

Discussion

Through experience, trials and errors knowledge about medicinal properties of different plants was developed. As tribal culture developed and job specialization commenced, certain people developed a more detail understanding of wound healing and qualities of local plants a topical agent.[6,7] In time three jobs developed into the skills of surgeons. The knowledge and experience were passed on to next generations most often verbally. In India, medical system, Ayurveda, promotes the knowledge and use of medicinal plant extracts as topical agents in wound management.[8,9]

In this study, the day of achieving 'zero' slough i.e. no macroscopic evidence of any dead tissue ranges between 7 to 28 days with a mode of 14 days. This suggests that this agent has desloughing activity when applied locally over wounds. In this study, the day of achieving zero discharge also ranges between 7 to 28 days with a mode of 14 days. At the end point the wounds showed no evidence of any visible serous / purulent / sero-purulent / sanginous discharge from the wound bed indicated a healthy wound bed ready to receive a split skin graft. A healthy granulation tissue i.e. the wound floor covered by a pink, pin-point, velvety tissue that bleeds on touch was observed in the wounds by 14th days (mode) with a range of 7 to 28 days. This indicated clinical end point of the trial.

Epithelisation was seen in burns patients with partial thickness wounds extending over 15%- 30% of total body surface area. In this study the earliest epithelisation observed was on 21^ day and in all other patients of burns epithelisation was completed by 28 days. In this study, the day of achieving zero inflammation in wound was between range 7 and 28 days with a mode of 14 days. Clinically zero inflammation was defined as disappearance of peri- wound oedema and absence of any discharge from wound floor and development of a healthy granulation tissue. Haematologically it was confirmed by reduction in the total WBC counts. The range is 7 to 28 days with a mode of 14 days.

In this study, no side effects have been noticed both during the trial as well as during regular follow up. The common side effects of itching, allergic reactions were also not detected in this study with this product thus making it a very acceptable product as local

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agent in management of wounds. No local or systemic adverse reactions were detected in 49 patients in this trial. Only 1 patient experienced mild itching for 2 days in the beginning but it disappeared without any treatment from 3'[d] day onwards. Thus, this product was observed to be free from local and / or systemic adverse reactions when applied locally over wounds.

Rapid control of wound slough and stimulation of development of healthy wound bed led to early wound closure and helped to decreases the hospital stay of patient.[10,11] Scar is the visible residual mark of the wound. This parameter is particularly important in burns patients and indicates a process of healthy wound healing. In this study the patients of bums responded well to this product and produced healthy scar without any hypertrophic scars and keloid formation upto to 3 months of follow up. This needs further study to detect the possible effect of this product on the process of wound healing and scar maturation when used as a local application.

This agent was observed to have beneficial effects on the process of wound healing and cleansing.[12] It has reduced the overall duration of the wound healing irrespective of the age group and sex. This agent was observed to be free from any adverse reactions and it had antibacterial action on the wound flora. The scar formation of all these wounds was without any hypertrophy or keloid formation. Thus, this indigenous agent is an effective and safe alternative available to the surgeons for local management of various types of wounds.

Conclusion

From this prospective study of over 50 patients, it can be concluded that this indigenous agent is effective and safe for us in the management of various wounds encountered in surgical practice. It had no adverse reactions and patient compliance and acceptance was good.

Conflict of Interest: None to declare
Source of funding: Nil

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