Journal of Cardiovascular Disease Research

ISSN: 0975-3583,0976-2833 VOL05, ISSUE 01, 2014

ORIGINAL RESEARCH ARTICLE

STUDY TO EVALUATE THE EFFICACY OF INDIGENOUS OINTMENT IN ACHIEVING BENEFICIAL EFFECTS ON WOUND CONDITIONS

Dnyanesh Madhukar Belekar[1], Madhuri Anant Gore[2]

[1]MBBS, MS, FCPS, DNB, MNAMS, FAIS, FMAS, Associate Professor & Unit Head, Department of Surgery, K J Somaiya Medical College, Hospital & Research Centre, Sion, Mumbai, Maharashtra – 400022, India.

[2]MBBS, MS, Ex- Professor & HOD, Department of Surgery, L. T. M. M. C. G. H., Sion, Mumbai, Maharashtra – 400022, India.

Received Date: 05/01/2014 Acceptance Date: 29/01/2014

Corresponding Author:

Dr. Dnyanesh Madhukar Belekar, MBBS, MS, FCPS, DNB, MNAMS, FAIS, FMAS, Associate Professor & Unit Head, Department of Surgery, K J Somaiya Medical College, Hospital & Research Centre, Sion, Mumbai, Maharashtra – 400022, India.

Email: dnyaneshbelekar@yahoo.co.in

Abstract

Background: Wounds and their management are fundamental to the practice of surgery and all surgeons depend on wound repair process. Introduction of clinically effective antimicrobial agent has regularly followed by the rapid emergence of strains of bacteria resistant to them. Present study was aimed to evaluate the efficacy of indigenous ointment in achieving beneficial effects on wound conditions. **Material and Methods:** Present study was prospective, observational study, conducted in patients aged between 18-65 years, either gender, had wound. An indigenous product ointment was used as a topical agent for dressing, from time of admission till complete wound cover is achieved. **Results:** This open labelled study involving 50 patients, 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 %). The mean day of achieving zero slough was 14 days. 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 %). In 80 % patients, systemic antibiotics used in conjunction with local agent. In majority of the patient's wound closure was achieved with split skin grafting (74 5). Only local itching was observed as an adverse reaction (2 %) in present study. **Conclusion:** This indigenous product is efficient as local agent in achieving beneficial effects on wound healing, highly effective against large spectrum of microbiological flora of wounds, effective in achieving good scar quality.

Keywords: wound healing**,** indigenous product, microbiological flora, scar quality.

ISSN: 0975-3583,0976-2833 VOL05, ISSUE 01, 2014

Introduction

Wounds and their management are fundamental to the practice of surgery and all surgeons depend on wound repair process[1]. Any surgical intervention will result in a wound in order to gain access to and deal with the underlying pathology. In both situations the surgeon's task is to minimize the adverse effects of wound, remove and / or repair damaged structures and harness the process of wound healing to restore function.[1,2]

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. In last decade a large number of effective topical agents for prevention of burn wound sepsis have come upon the scene. Among the substances available for effective topical antimicrobial use are silver nitrate, mafenide acetate, silver sulfadiazine and gentamicin.[3]

Introduction of clinically effective antimicrobial agent has regularly followed by the rapid emergence of strains of bacteria resistant to them. This has seriously reduced the therapeutic value of many potent antibiotics. Indiscriminate use of these antibiotics has further complicated the problem of nosocomial infections, particularly due to survival and multiplication of resistant microorganisms in hospital environment.[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 evaluate the efficacy of indigenous ointment in achieving beneficial effects on wound conditions.

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.

Inclusion criteria

- Patients aged between 18-65 years, either gender, had wound (e.g. infected wounds, clean wounds, 15% to 30% burn wounds, diabetic ulcers, amputation stumps, pressure sores & post-operative wounds), willing to participate in present study

Exclusion criteria

- Pregnant females.
- Leprosy.
- Severe systemic disease.
- Peripheral neuropathy.

Study was explained to patients in local language & written consent was taken for participation & study. This is 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

ISSN: 0975-3583,0976-2833 VOL05, ISSUE 01, 2014

(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).

Wound care method -

- Clean the wound with normal saline Make wound dry with gauze
- Apply a thin film of ointment covering entire wound surface
- Cover wound surface with dry gauze or autoclaved banana leaves (Burn wounds)
- Apply bandage
- Change of dressing 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.

Following parameters were analysed to assess the efficacy of the product

- Wound status.
- Patient's self-evaluation score using visual analog scale for pain.
- Wound culture and sensitivity.
- Scar evaluation.

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

This open labelled study involving 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 etiology (76 %).

Table 1: General characteristics

Characteristics	**Males**	**Females**	**Total (%)**
Age Group (in years)			
12-25	7	5	12 (24 %)
26-50	12	12	24 (48 %)
51-65	12	2	14 (28 %)
Total	31	19	
Aetiology			
Diabetic	10	2	12 (24%)
Non-diabetic	21	17	38 (76%)

In present study, majority wounds were ulcers (40 %) followed by burns (18 %), post-

ISSN: 0975-3583,0976-2833 VOL05, ISSUE 01, 2014

op wounds (16 %), amputation stumps (14 %) & pressure sores (12 %). The size of the wound ranged from 4cm^2 to 1250cm^2. In this study wound of 13 patients was observed to be in the range of 100cm* to 196cm^2. The mean day of achieving zero slough was 14 days. The mean day of achieving zero discharge was 14 days. The mean day of achieving zero inflammation was 14 days. Total white blood cell count ranged from 5000/cumm to 27,000/cumm. In the beginning on an average the WBC count was »15,000/cumm and in the end on an average it was <7,500/cumm.

Table 2: Types of wound

Type	No. of patients	Percentage
Ulcers	20	40
Burns (BURNT AREA)	9	18
• 15 % to 20 %	6	12
• 21% to 25 %	1	2
• 26 % to 35 %	2	4
Post-op wounds	8	16
Amputation stumps	7	14
Pressure sores	6	12

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 %), Klebsiella (6 %), Eishcherechia Coli (6 %), Acinetabacter (4 %), Staphylococcus Aureus (MRSA) (2 %) & Citobacter (2 %). 13 wounds were sterile at inclusion and remained sterile at completion.

Table 3: 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

ISSN: 0975-3583,0976-2833 VOL05, ISSUE 01, 2014

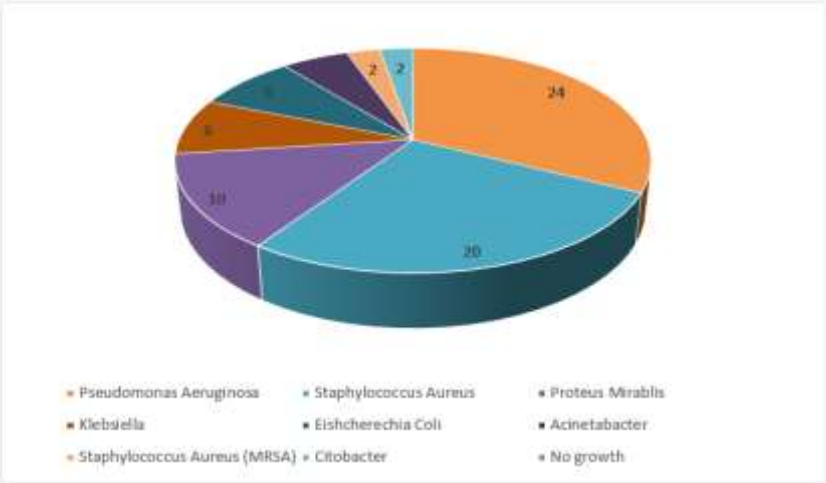

Figure 1

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 4: 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

In majority of the patient's wound closure was achieved with split skin grafting (74 5).

Table 5: Modalities of wound cover

Type of wound cover	No. of patients	Percentage
Split skin grafting	37	74
Wound contraction	7	14
Epithelisation	4	8
Secondary suturing	1	2
Stump closure	1	2

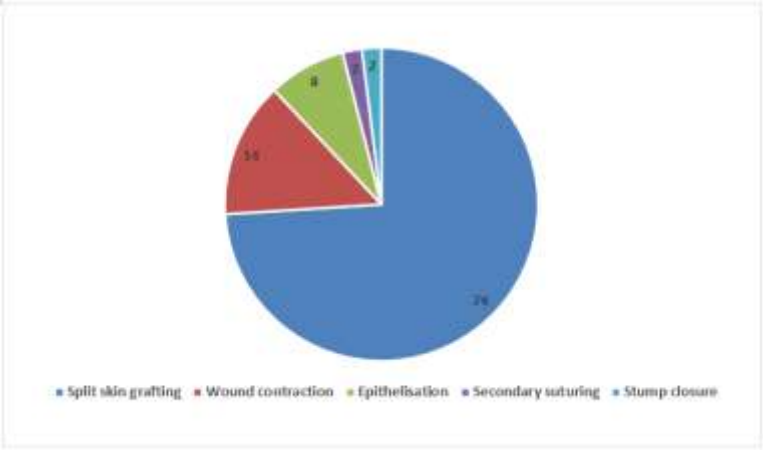

Figure 4

ISSN: 0975-3583,0976-2833 VOL05, ISSUE 01, 2014

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).

Table 6: Adverse reactions

ADVERSE REACTIONS	No. of patients	Percentage
Local Itching	1	2

CASE 3

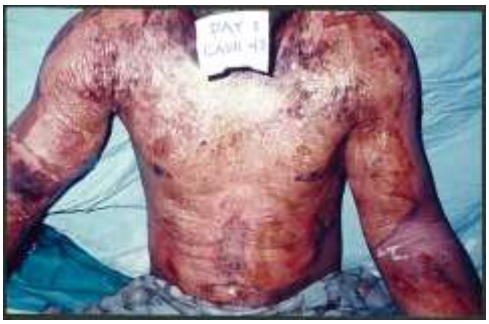
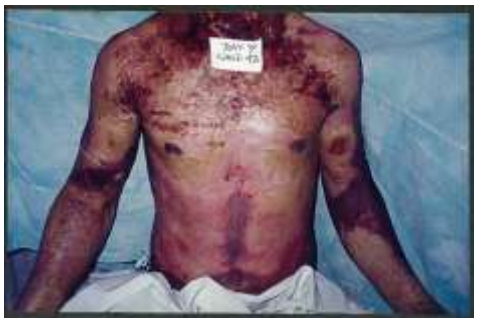

Photo 1: ≈30% Partial thickness burns; Photo 2: ≈30% Day -7 of wound

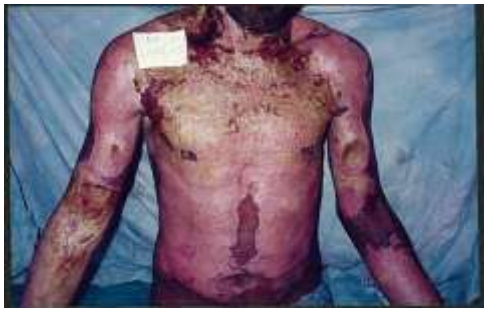
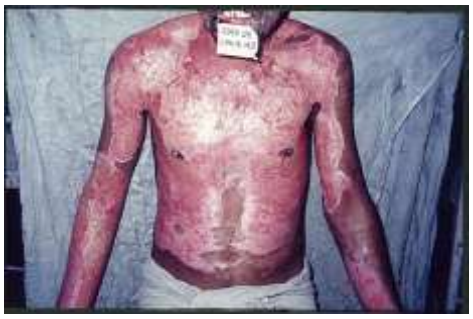

Photo 3: ≈30%% Day-14 of wound; Photo 4: ≈30%% Day 21 of wound

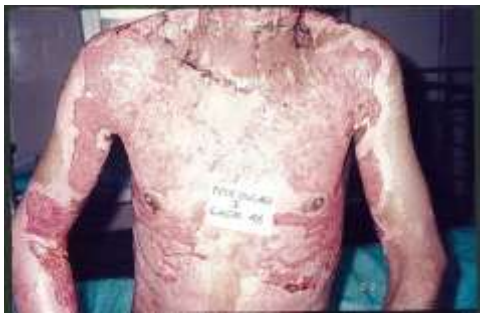
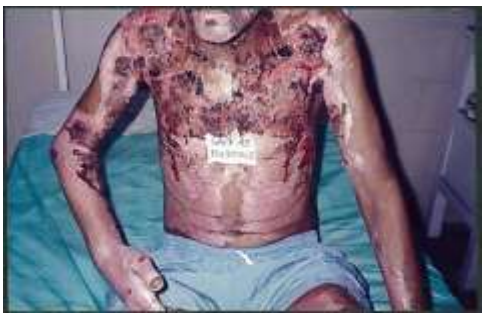

Photo 5: Wound closure achieved by SSG Post- SSG-I-Day-3; Photo 6: Wound closure achieved by SSG Post-SSG-II-Day-5

Discussion

The use of plants and trees extracts as topical agents in management of wounds in a culture such as lndia9 and China had been greater than that of nomadic tribes of the desert due to wider variety of plant life and the settled nature of cuIture.[6] The developing use of plants and their natural substances is clearly identified in historical records.[7] In India, medical system,

ISSN: 0975-3583,0976-2833 VOL05, ISSUE 01, 2014

Ayurveda, promotes the knowledge and use of medicinal plant extracts as topical agents in wound management.[8]

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 21st 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.[9] 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, a wide spectrum of micro-biological flora was detected in wounds of 37 patients. Wounds of 13 patients did not grow any micro- organisms on the wound culture and remained sterile throughout the study, tilt the end point. 37 wounds which grew micro-organisms in the beginning but were sterile at the end point. This observation suggests that the agent under study has anti-bacterial action. In 40 patients, systemic antibiotics were used due to presence of systemic infection, in conjunction with this product that was applied locally over wounds. The desired end point was observed with a mode of 14 days in these 40 patients.

In 10 patients, systemic antibiotics were not used due to absence of any evidence of systemic infection, in conjunction with this product that was applied locally. The desired end point was observed at mode of 14 days in these 10 patients so the use or non-use of systemic antibiotic was not observed to affect the efficacy of the agent under study.

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.[10,11] In this study the patients of bums responded well to this product and produced healthy scar without any hypertrophic scars and keloid formation up 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.

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.

Indigenous ointment used in present study, multiple similar local agents are in use at present, but the literature review has failed to reveal similar evaluation of any of these products hence comparison between these and this new product could not be done. An open controlled trial between this agent and other established products is needed to evaluate these issues.

Conclusion

This indigenous product is efficient as local agent in achieving beneficial effects on wound healing, highly effective against large spectrum of microbiological flora of wounds, effective

ISSN: 0975-3583,0976-2833 VOL05, ISSUE 01, 2014

in achieving good scar quality. The scars formed were not hypertrophic and keloid formation was not detected in any. It had no adverse reactions and patient compliance and acceptance was good.

Conflict of Interest: None to declare

Source of funding: Nil

References

1. N. Scott Adzick. Wound healing: Biologic and clinical features, Sabiston textbook of surgery: The biological basis of modern surgical practice, 15th ed. 1997, pages: 207-220.
2. Chopra R.N., Nayar S.L and Chopra I.C. (1956) Glossary of Indian Medicinal Plants. C.S.I.R., New Delhi.
3. Basil A Pruitt Jr, Scott K Pruitt. Cleon W. Godwin Bums, surgery scientific principles and practice, 2nd ed. Chapter 13, 1997, pg. 221-24S.
4. David J. Coleman, Burns, Bailey and Love's short practice of surgery, 23’* ed. 2000, pg. 188-199.
5. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines World Health Organisation, Regional office for the Western Pacific, Manila (1993).
6. Weishia H and Tsi-siang S (1984) treatment of Burns, P-106. Edited by chih-chun, Yang, Wei-Shia, Hsu and Tsi-siang Shih-shanghai Scientific and technical Publishers. Spriger-Verlag, Berlin-New York.
7. Nadkarni A.K. (1976) Indian Materia Medica P-60, 543-552, 776 Popular Prakashan Pvt. Ltd., Mumbai.
8. Satyavati G.V, Raina M.K and Sharma M (1976). Medicinal Plants of India. I : 36 115 438 - 441.
9. Chopra R.N. Chopra I.C. Handa K.L. and Kapur L.D. (1958). Indigenous drugs of India., pg. 496, 508. U.N. Dhur and Sons Pvt. Ltd., Calcutta.
10. David J. Coleman, Wounds. Tissue repair and scars, Bailey and Love’s short practice of surgery, 23’d ed. 2000, pg. 29-39.
11. Neil A Fine, Thomas A. Mustoe. Wound healing, surgery: Scientific principles and practice, 2’d ed. Chapter 3, 1997, pg. 67-83.