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Original Research Paper

General Surgery

USE OF PAPAIN-UREA BASED PREPARATION IN THE MANAGEMENT OF DIABETIC FOOT ULCERS, A RANDOMISED CONTROLLED TRIAL

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ABSTRACT

Background: Diabetic foot ulcer is a very common condition encountered in surgical practise. Wound management pose a good challenge for a treating surgeon due to its physical, mental and social implications. The devitalised necrotic tissue present in ulcer does not favour the wound healing as it increases the chance of infection and delays appearance of granulation tissue. Hence debriding of devitalised tissue plays a key role in wound care. In present study ,we used papain urea based preparation in dressings which is a autolytic agent. This study was conducted to evaluate the effectiveness of use of papain urea based preparations compared with regular conventional dressing in diabetic foot ulcer management.

Methods: This was a prospective study conducted in Kore Hospital and Medical Research Centre, Belgaum, India. 60 eligible subjects with diabetic foot ulcers were selected and subjects were randomly allocated into two groups Group A and Group B with 30 subjects in each group. Subjects in Group A underwent dressing with Superoxidised solution and in Group B underwent regular Papain urea. Results were assessed with respect to percentage decrease in necrotic tissue, incidence of infection, appearance of granulation and hospital stay.

Results: Among Group A subjects percentage reduction of necrotic tissue was more, granulation appeared early and the hospital stay was less compared to Group B subjects which were statistically significant. However, there was no significant difference with respect to incidence of infection in both groups.

Conclusions: Papain urea based preparation is effective in diabetic foot ulcer care.

KEYWORDS : Autolytic, Debridement, Papain urea

INTRODUCTION

Diabetes mellitus is a chronic and disabling disease which has reached an epidemic proportion in many parts of the world It is a major and growing concern to global public health. Diabetes results in long term damage, dysfunction of various organs especially the eyes, kidneys, nerves, heart and blood vessels.

Diabetic foot problems are the common causes for hospitalization (nearly 30%) with 20% of the total health-care costs which is more than all other diabetic complication One-third of all diabetic patients have significant peripheral neuropathy and/or peripheral vascular disease (PVD) Also it increases with duration of diabetes that is, 15% at duration of 10 years and 45% after the duration of 20 yearsThe management of diabetic foot ulcers needs a multidisciplinary approach The successful management of diabetic foot ulcers prompts offloading the wound by using appropriate therapeutic footwear, daily saline or similar dressings so as to provide a moist wound environment, debridement, antibiotic therapy Many modalities of debridement are now available as surgical/sharp, mechanical, autolytic, enzymatic and biologic with major emphasis on enzymatic wound debridement A well-known and widely used enzymatic system is the papain-urea (PU) combination. In this system, papain is used to attack and breakdown any protein contaning cysteine residues The combination of papain and urea is probably twice as effective in protein digestion as papain alone. An advantage of the PU combination may be nonspecific bulk debridement within a broad pH range 3.0–12.0 As, superoxidised solution(SOS) contains no cysteine residues, are elelctrochemically processed aqueous solutions manufactured from pure solutions which is rich in reactive oxygen species with neutral pH Considering the burden of diabetic foot ulcer and limited data on the effectiveness of PU based preparation vs SOS in debridement of diabetic foot ulcers The present study was undertaken to compare effectiveness of PU based preparation vs SOS in debridement of grade 2 diabetic foot ulcers, as assessed by the appearance of granulation tissue on the end of day 21.

Epidemiology:

In 2014,diabetescaused4.9 million deaths and death is noted in a person every 7 seconds. Based on the estimates from International Diabetes Association, worldwide 387 million people have diabetes. This number is expected to rise to 582 million by 2035.

Diabetes is potential epidemic in India with more than 62 million diabetic individuals. It is predicted that, by 2030, it may afflict upto 79.4 million individuals

Need of the study:

To find the effectiveness of Papain-urea based preparation in the management of Grade-ll diabetic foot ulcers

AIM AND OBJECTIVE

- To compare the effectiveness
- Papainurea V/S Superoxidised solution
- Grade 2 diabetic foot ulcers management
- Granulation tissue
- End of day 21

METHODS AND MATERIALS

This study was conducted in the Department of Obstetrics and Department of General Surgery , Kore Hospital and Medical Research Centre, Belgaum from January 2015 to December 2015.

Patients were divided into 2 groups:

- Group A –Superoxidised solution (SOS)-30 pts
- Group B- Papain-Urea based preparation-30 pts

Patients taking insulin or oral hyperglycaemic both are included in this study.

Exclusion criteria:

- Diabetes Mellitus with gangrenous changes
- Vascular insufficiency
- Osteomyelitis
- Patient receiving

- Corticosteroid
- Immunosuppressive agents
- Radiation or chemotherapy
- Condition like renal failure, generalized debility and other factors which affects wound healing

Technique:

Application of ointment in both groups was done once daily in the following manner:

- Wound was washed with normal saline, and later ointment/spray was applied
- Use of ointment was terminated, when granulation tissue appears or till 21 days.

Outcome variables

- Granulation tissue appearance
- Reduction in slough
- Decreased ulcer size
- Decreased odor of discharge
- Decrease induration around ulcer

- **Size of an ulcer measured using sterile gauze:**
- Area of an ulcer assessed at the beginning 05th/10th/21st day

Stages of wound healing using Papain-urea based preparation

Photograph Day- 0

Day- 21

Stages of wound healing using Superoxidised solution based preparation Photograph

Day- 0

Day- 21

RESULTS

Table 1: Sex distribution

Sex	Group-A (Superoxidised solution) [n=30]		Group-B (Papain urea) [n=30]	
	Number	%	Number	%
Male	24	80.00	26	86.67
Female	06	20.00	04	13.33

Table 2: Comparison of ulcer characteristics

Variables	Findings	Group-A (Superoxidised solution) [n=30]		Group-B (Papain urea) [n=30]		p value
		No	%	No	%	
Mode	Traumatic	17	56.67	18	60.00	0.684
	Spontaneous	12	40.00	9	30.00	
	Pressure	1	3.33	2	6.67	
	Others	0	0.00	1	3.33	
Duration (Months)	1 or less	16	53.33	19	63.33	0.792
	2 to 12	13	43.33	10	33.33	
	> 12	1	3.33	1	3.33	
				30	100.00	
Discharge	Present	5	16.67	2	6.67	0.212
	Absent	25	83.33	28	93.33	
Site	Left	9	30.00	11	36.67	0.584
	Right	21	70.00	19	63.33	
Shape	Oval	6	20.00	11	36.67	0.348
	Circular	16	53.33	12	40.00	
	Irregular	8	26.67	7	23.33	

Table 3: Comparison of Floor

Intervals	Findings	Group-A (Superoxidised solution) [n=30]		Group-B (Papain urea) [n=30]		p value
		No	%	No	%	
Day 10	Granulation tissue	1	3.33	2	6.67	0.612
	Slough	29	96.67	28	93.33	
Day 21	Granulation tissue	14	46.67	22	73.33	0.035

Table 4: Comparison of Ulcer area

Intervals	Group-A (Superoxidised solution) [n=30]		Group-B (Papain urea) [n=30]		P value
	Mean	SD	Mean	SD	
Before dressing	32.15	25.63	29.71	24.34	0.583
Day 5	23.96	15.51	20.76	17.63	0.318
Day 10	21.10	13.84	14.20	10.65	0.052
Reduction ulcer Area	11.10	16.24	15.40	16.63	0.149

Table 5: Comparison of wound culture

Intervals	Group-A (Superoxidised solution) [n=30]		Group-B (Papain urea) [n=30]		P value
	Mean	SD	Mean	SD	
Before dressing	32.15	25.63	29.71	24.34	0.583
Day 5	23.96	15.51	20.76	17.63	0.318
Day 10	21.10	13.84	14.20	10.65	0.052
Reduction ulcer Area	11.10	16.24	15.40	16.63	0.149

DISCUSSION

Alvarez et al. (2000) proved, papain-urea is more effective than collagenase for pressure ulcer debridement and in promoting granulation tissue.

Anand.A. et al, compared efficacy of SOS Hosmath V. et al in Bangalore compared the effectiveness of collagenase v/s papain–urea for debridement of chronic non-healing ulcers/wounds and to evaluate their role in promoting ulcer healing by granulation and reduction in ulcer/wound size.

Overall this study shows more favourable results with debridement with papain-urea based preparation as compared to debridement with superoxidised solution.

Limitations:

- Smaller sample size
- Further multicentric studies with large sample size are required to confirm these observations

CONCLUSIONS

Debridement with papain-urea based preparation significantly influences granulation tissue and thereby promotes early healing compared to debridement with superoxidised solution Furthermore it is equally efficacious to that of superoxidised solution equally effective method in the prevention of infection Hence Papain-urea is a better enzymatic debriding agent promotes faster

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