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RESEARCH ARTICLE

COMPARE THE EFFECT OF WOUND HEALING AND COST OF DRESSING SOLUTION BETWEEN CITRIC ACID AND CONVENTIONAL METHOD OF DRESSING AMONG THE PATIENTS WITH DIABETIC FOOT ULCER IN TERTIARY HOSPITAL

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ABSTRACT

Background: Diabetic foot ulcers are sores or wounds on the foot and are often a strong indicator of advanced diabetes. Local application of citric acid is most effective in the treatment of various wounds, including wounds for which there are no alternative options available.
Objective: The study objective to compare the effect of wound healing and cost of dressing solution between citric acid and conventional method of dressing among the patients with diabetic foot ulcer in a tertiary hospital in India.
Methods: Totally, 120 Patients with diabetic foot ulcer were recruited for the study. The researcher had chosen the first sixty patients for conventional method of dressing after that next sixty patients allotted for 3% citric acid dressing. The pre assessment was carried out before applied dressing the wound status was assessed on 1st day and post assessment was done on 8th day, 15th day and 22nd day for both groups. The clinical data were gathered by using the interview method in regional language and some clinical data collected from patients' case sheet. For assessing the wound, the Modified Bates Jensen's Wound Assessment tool was used.
Results: The wound healing status was much better among the patients who received citric acid dressing than patients who received conventional dressing that was 53 patients in the citric acid dressing and 26 patients in the conventional dressing group had mild level wound - almost double the time. The significant 'p' value inferred that the difference in improvement in wound healing status among the patients in the citric acid dressing and conventional dressing groups after the intervention was statistically significant ($p<0.0001$).
Conclusion: The health care providers used citric acid solution for dressing it will reduce the cost of dressing and reduce economic burden to the patient.

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INTRODUCTION

Diabetes is a chronic, lifelong condition that affects the body's ability to use the energy found in food. Diabetes is a group of metabolic disease in which a person has high blood sugar levels over a prolonged period (Williams and Hopper, 2015). International Diabetes Federation (2015) reported that worldwide 415 million people with diabetes, it will increase as 642 million in 2040. South East Asia, 78.3 million people with diabetes in 2015, it will increase 140.2 million in 2040. One in 11 adults has diabetes in 2015. It will became one in 10 adults have diabetes in 2040.

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Every six seconds one person dies from diabetes. Three fourth of the people with diabetes live in low and middle income Counties. Worldwide, 12% of global health expenditure is spending on diabetes (International diabetes federation, 2015). Diabetes can mean double trouble for the feet. Diabetic foot ulcers are sores or wounds on the foot and are often a strong indicator of advanced diabetes. When the patient can't feel cuts and blisters, they are more likely to get sores and infections. If the patient don't notice or treat the sores, they can become deeply infected, and lead to amputation (Diabetic nerve pain). Shah, vascular surgeon, said "up to 25% of patients with diabetes develop a foot ulcer. More than half of all foot ulcers become infected, requiring hospitalization and 20% of infections result in amputation. Diabetes contributes approximately 80% of all non-traumatic amputations

performed every year. After a major amputation, 50% of people will have another other limb amputated in two years. People with a history of a diabetic foot ulcer have a 40% greater 10-year death rate than people with diabetes alone (The Times of India City Ahmedbad). In India, Diabetic foot problems are the commonest reason for hospitalization of diabetic patients (about 30% of admissions) and absorb some 20% of the total health-care costs of the disease more than all other diabetic complication. In India, prevalence of foot ulcers in diabetic patients in clinic population is 3%, which is much lower than reported in the western world. A possible reasoning for the low prevalence in Indians is younger age and shorter duration of diabetes (Gupta, 2012). A newer approach for effective treatment of chronic bacterial wound infections not responding to conventional therapy is using citric acid as a sole topical agent. Local application of citric acid to a variety of chronic infected wounds such as diabetic foot infections, chronic traumatic wound/non-healing ulcers, lepromatous ulcers, healing in more than 95% of chronic infected wounds indicating that the citric acid is most effective in the treatment of various wounds, including wounds for which there are no alternative options available (Nagoba *et al.,* 2008). Most of the hospital using conventional method of dressing to treat the diabetic foot ulcer and other methods of dressing tissue plasminogen activator, insulin, papaya, hyperbaric oxygen therapy, bio-engineering technique etc (Velmurugan *et al.,* 2008). These all the methods are using totreat the wound but it's expensive, unable to afford by all the patients because most of the patients in lower economic status. So the investigator had interest to find newer approach with low cost at the same time it should show the effective wound healing also.

MATERIALS AND METHODS

The study aim was to compare the effect of wound healing and cost of dressing solution between citric acid and conventional method of dressing among the patients with diabetic foot ulcer. The study adopted quasi-experimental research design. It was conducted in Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry. It is one of territory Super-specialty hospitals in India. Inclusion criteria for the study was patients those who were diagnosed as type I and type II, with or without co-morbid illness, above the age of 18 in both gender and admitted in general surgical wards were included for the study. Totally, 120 Patients with diabetic foot ulcer were recruited for the study. The researcher had chosen the first sixty patients for conventional method of dressing after that next sixty patients allotted for 3% citric acid dressing. The pre assessment was carried out before applied dressing the wound status was assessed on 1st day and post assessment was done on 8th day, 15th day and 22nd day for both groups. The patients who were sensitive to citric acid and critically ill were excluded from the study. The clinical data were gathered by using the interview method in regional language and some clinical data collected from patients' case sheet. For assessing the wound, the Modified Bates Jensen's Wound Assessment tool was used. It is a comprehensive tool which gives adequate information of diabetic foot wound like size, depth, edges, undermining, necrotic tissue types, necrotic tissue amount, exudates type, exudates amount, skin colour surrounding the wound, peripheral tissue edema, peripheral tissue indurations, granulation tissue, epithelization and assessment of bio-burden. Modified Bates Jensen's wound assessment tool was used to assess the diabetic foot ulcer healing process by direct observation method. The tool evaluates fourteen wound characteristics on a five point rating scale, with lower scores indicating greater desirability of wound healing process. Each parameter was marked with scores based on the severity of the wound. Total scores ranged from fourteen (skin intact but at risk for further damage) to 70 (profound tissue degeneration). The continuum had two extreme ends of wound condition spectrum. They were wound regeneration and wound degeneration. Each parameter was marked with scores based on the severity of the wound. Total scores ranged from fourteen (skin intact but at risk for further damage) to 70 (profound tissue degeneration). (Velmurugan, 2008) The wound severity was classified as 14 - 22 was mentioned as minimal wound, 23- 33 noted as mild wound, 34 - 44 were stated as moderate wound and 45 - 70 were classified as critical wound. Ethical approval was obtained from Institute Ethical Committee (Human Studies). The reliability of the Modified Bates Jensen's wound assessment scale was found 0.88 by inter-rater method, which showed a highly positive correlation of the intervention. Descriptive and inferential statistics were used for analyzing the data. The mean, standard deviation, percentages, paired 't' test and chi-square' test were used to express the data.

Conventional method of dressing

The wound status was assessed before starting conventional method of dressing (pre assessment) was carried out on the first day. The sample recruited for the conventional dressing after debridement. The wound was irrigated with normal saline and slough was removed with hydrogen peroxide then Betadine soaked gauze pieces were applied over the wound and dressed. Each dressing required approximately, 60 - 100 ml of normal saline, 10 - 30 ml of hydrogen peroxide and 20 - 40 ml Betadine approximately. The dressing was carried once in daily continuously upto 21 days. The post assessment was carried out to evaluate the wound every week end that was on 8th day, 15th day and 22nd day.

Citric Acid dressing

Citric acid was added in distilled water in the ratio of 3gm/100ml (3%).Citric acid solution was prepared in pharmacy preparation wing by the pharmacist. Commercially available citric acid is used for pharmaceutical purpose. Citric acid solution is stored in a sterile container and closed with air tight cap. The wound status was assessed before starting citric acid dressing (pre assessment) was carried out on the first day. The wound was cleaned with 3% citric acid and then the citric acid soaked gauzes were spread the over wound and dressing applied without using any other solution. For each dressing, approximately 50 to 100 ml of citric acid solution was needed. Initially wound size was large so more solution was required and gradually wound size became small after healing which required less solution. The citric acid dressing was carried out upto 21days daily once. The wound healing status was assessed on 8th day, 15th day and 22nd day. The study was approved by the JIPMER Scientific Advisory Committee. Ethical approval was obtained from Institute Ethical Committee (Human Studies), JIPMER, Puducherry. Informed written consent was obtained individually from the patients who participated in the study. Confidentiality was maintained throughout study. The dressing procedure was done under aseptic technique for all the patients. The descriptive statistics like mean, standard deviation and percentages were used to express the data. Inferential statists such as paired independent 't' test between groups, paired 't' test within group (pre and post-test), repeated ANOVA and 'chi-square' test were used for data analysis.

Table 1. Clinical Variables of the Patients with Diabetic Foot Ulcer in the Citric Acid and Conventional method of dressing Groups

Clinical variables		Citric acid dressing group(n=60)		Conventional dressing group(n=60)		X^2	'P' value
		No.	%	No.	%		
Type of DM	Type I	3	5	2	3.3	0.20	0.648 (NS)
	Type II	57	95	58	96.7		
Duration of illness	1-5 years	7	11.7	18	30	7.30	0.026* (S)
	6-10 years	23	38.3	23	38.3		
	>10 years	30	50	19	31.7		
Fasting blood sugar level	Normal (70-120mg/dl)	1	1.7	4	6.7	4.68	0.096 (NS)
	Below normal(<70mg/dl)	3	5	8	13.3		
	Abnormal (>110mg/dl)	56	93.3	48	80		
HbA1c level	Good control (6-7%)	0	0	2	3.3	3.35	0.187 (NS)
	Fair control (7-8%)	6	10	10	16.7		
	Poor control (>8%)	54	90	48	80		
BMI (kg/m²)	Underweight (<18.5)	15	25	8	13.3	3.01	0.390 (NS)
	Normal (18.5-24.9)	10	16.7	13	21.7		
	Overweight (25-29.9)	27	45	32	53.3		
	Obese (>30)	8	13.3	7	11.7		
Diet control	Regular	17	28.3	20	33.3	2.50	0.286 (NS)
	Sometimes	42	70	36	60		
	Nil	1	1.7	4	6.7		
Compliance of treatment	Compliance	12	20	12	20	0.00	1.00 (NS)
	Non-compliance	48	80	48	80		
Co-morbid illness	Nil	15	25	15	25	13.57	0.482 (NS)
	CVS disorder	25	41.7	17	28.3		
	CNS disorder	1	1.7	0	0		
	Renal disorder	1	1.7	0	0		
	Eye disorder	2	3.3	2	3.3		
	Others	0	0	1	1.7		
	>one disorder	16	26.6	25	41.66		
History of previous DFU	Yes	46	76.7	43	71.7	0.39	0.532 (NS)
	No	14	23.3	17	28.3		
History of digital amputation	Yes	10	16.7	10	16.7	0.00	1.00 (NS)
	No	50	83.3	50	83.3		
Cause of foot ulcer	Injury	18	30	20	33.3	15.44	0.218 (NS)
	Corns & callus	2	3.3	1	1.7		
	Loss of sensation (neuropathy)	4	6.7	9	15		
	Blister (ischemic)	7	11.7	9	15		
	Others	10	16.7	6	10		
	>one cause	19	31.6	15	25		
Site of diabetic foot ulcer	Right foot	46	76.7	34	56.7	5.40	0.067 (NS)
	Left foot	13	21.7	24	40		
	Both	1	1.7	2	3.3		
Diabetic foot ulcer grade	Grade III	43	71.7	37	61.7	1.35	0.245 (NS)
	Grade IV	17	28.3	23	38.3		

S – Significant (*P<0.05) NS – Non significant

Table 2. Compare the Mean and Standard Deviation of Wound Healing Status of the Patients with Diabetic Foot Ulcer in the Citric Acid and Conventional dressing Groups

Wound Healing Assessment	Citric acid dressing (n=60)		Conventional Dressing (n=60)		't'-Test	'P' – value
	Standard deviation	Mean	Standard deviation	Mean		
1st day assessment (pre assessment)	66.23	1.995	66.80	1.505	1.757	0.082 (NS)
On 8th day (post assessment I)	55.58	3.903	60.67	5.115	6.120	0.000 (S)
On 15th day (Post assessment II)	41.85	4.595	48.33	6.008	6.640	0.000 (S)
On 22nd day (Post assessment III)	28.03	5.734	36.18	8.752	6.034	0.000 (S)

S – Significant (P<0.001) NS – Non significant

RESULTS

The comparison of wound healing status among the patients with diabetic foot ulcer in the citric acid dressing and conventional dressing groups before and after the intervention. On the 15th day (post-assessment II), nine (15%) patients had critical wound status and 51 (85%) had moderate level wound healing status in the citric acid dressing group. In the conventional dressing group, 37 (61.7%) patients had critical wound status and 23 (38.3%) had moderate level wound healing status. The data show the point that critical and moderate wound level was found markedly more decreased in the citric acid group than in the conventional dressing group. On the 22nd day (post-assessment III), two (3.3%) patients had critical wound status, four (6.7%) had moderate level wound, 53 (88.3%) had mild level wound and one (1.7%) patient had minimal level wound in citric acid dressing group. In the conventional dressing group, five (8.3%) patients had critical wound status, 29 (48.3%) had moderate level wound, 26 (43.3%) patients had mild level wound and none of them had minimal level wound. The table 1 'chi-square' test was applied to find out the statistical difference between the clinical variables among these two groups. There was no significant difference found among the clinical variables of both groups except duration of illness (p<.026). Since the difference in clinical variable - duration of illness was found to be statistically significant (p value 0.026), it was used as one of the covariate in the independent 't' test analysis to compare the post mean values of both groups. The table 2 shows independent 't' test was carried out to find the difference in

Table 3. Compare the Cost of Citric Acid Dressing and Conventional Dressing

Dressing solutions	Cost of solution in Rupees &paisa				
	1000 ml	100 ml	50 ml	Single dressing (in ml)	Cost for single dressing
3% Citric acid	4.82	0.48	0.24	50 – 100	0.24 – 0.48Paisa
Conventional dressing solution:					
• Normal saline	32	3.20	1.6	60 – 100	
• H_2O_2	150	15	7.5	10 – 30	Rs.5.66 - 12.18
• Betadin	112	11.20	5.6	20 – 40	

Note: costs mentioned in the study at the time of data collection period from 2012 to 2013. Initially the wound size was large so required more solution and gradually the wound size was became small after healing which required less solution.

- 1000gm Citric acid cost was Rs.160/-.
- 1kg is required to prepare 33.200 liter of citric acid solution
- Cost of 1 liter 3%citric acid solution = 160/33.200=Rs 4.82 Paisa
- 30gm of citric acid is needed to prepare 1000 ml (1 Liter) of citric acid solution.
- 100 ml of 3%citric acid cost =4.82/10=0.48 Paisa
- 50 ml of 3%citric acid cost = 0.48 / 2=0.24 Paisa.
- Normal saline 1000 ml cost – Rs.32/-
- 60 ml Normal saline costs Rs. 1.92 paisa (0.32 X 6=1.92) to 100 ml Rs.3.20 paisa. (10ml costs-0.32paisa)
- Hydrogen peroxide (H_2O_2) 1000ml cost – Rs. 150/-
- 100 ml hydrogen peroxide costs Rs.15
- 10 ml Hydrogen peroxide cost Rs. 1.50 paisa to 30 ml costs Rs.4.50 paisa.
- Betadine 1000ml cost – Rs.112/-
- 100 ml Betadin costs Rs. 11.20 paisa
- 20 ml Betadine solution cost Rs.2.24 paisa to 40 ml costs Rs.4.48 paisa.

wound healing status existed between the citric acid and conventional dressing groups. The significant 'p' value inferred that the difference in improvement in wound healing status among the patients in the citric acid dressing and conventional dressing groups after the intervention was statistically significant ($p<0.0001$). So, it is proved that there was better wound healing in the citric acid dressing group than the conventional dressing group. The Table 3 shows the comparison of cost of dressing solution between the citric acid solution and conventional dressing solution reported that citric acid was highly economical than the conventional dressing solutions.

DISCUSSION

In both groups there was improvement in wound healing status during all the three assessments. But, the table 2 data revealed the fact that the wound healing status was much better among the patients who received citric acid dressing than patients who received conventional dressing that was 53 patients in the citric acid dressing and 26 patients in the conventional dressing group had mild level wound - almost double the time. The following study finding is also supported the present study findings. Nagoba, did a study on treatment of lepromatous ulcers using citric acid as a sole antimicrobial agent in India. Thirty-four known cases of lepromatous ulcers not responding to conventional antibiotic therapies for long duration were investigated for culture and susceptibility. Topical application of citric acid ointment resulted in complete healing in 25 (73.52%) cases. In eight cases (26.48%), there was elimination of infective agent from ulcer site and formation of healthy granulation, but no complete healing of ulcer was seen. Results indicated that citric acid is the best alternative for the effective management of lepromatous ulcers when other therapies are exhausted (Nagoba *et al.,* 2012). The table 3 finding revealed that citric acid solution was cheaper and affordable by all the patientsthan the conventional dressing solutions. At the same time patients with diabetic foot ulcer who received citric acid dressing had significantly better wound healing in the post-assessments than the patients in the conventional dressing group. The present study finding supported by Nagoba, conducted a study on simple, effective and affordable approach for the treatment of burns infections. The aim of the study was to develop a simple and effective treatment modality using citric acid as a sole antimicrobial agent to control infections in burns patients not responding to conventional treatment. Citric acid treatment was found effective in the control of burns infections as compared to conventional therapy. Complete healing in 86.95% cases as compared to 45% in a control group indicated that citric acid is nontoxic, economical and quite effective in the management of burns infections (Nagoba *et al.,* 2010).

Conclusion

Diabetic wound would not heal soon and it become chronic when compared to other wounds. In India, most of the diabetic foot ulcer patients were belong to low economic status. They were spending significantly higher proportion of their income on treatment than those without foot complications which leads to heavy economic burden to their family. The patients were unable to spend high cost treatment also. 3%Citric acid solution is cheap and better solution to treat wound. So the health care providers may consider using 3% citric acid solution to dress the diabetic wound. If, the health team members used 3% citric acid solution for dressing it will reduce the cost of dressing and reduce economic burden to the patient.

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