

**Original Research Article**

Role of Bovine Colostrum in Healing of Chronic Non-Healing Ulcers – A Clinical Study

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Email: sahooranjanarkl@gmail.com, Mob No. 8763147949**Abstract**

This study was conducted to compare the efficacy of colostrum powder as an add on dressing with that of conventional dressing in the healing of chronic non-healing ulcer. Sixty patients with non-healing ulcer were treated with conventional dressing (povidone iodine, hydrogen peroxide) (Group 1) and another 60 patients were treated with add-on Bovine Colostrum (Group 2) for a period of 3 weeks. The healing of ulcer in both groups was determined by using Resvech Ulcer Healing Score (which utilizes 9 ulcer parameters) at weekly intervals for 3 weeks. There was highly significant increase in wound healing in the Bovine Colostrum treated group in comparison to the conventionally treated group, starting from first week upto third week. Bovine colostrum has significant wound healing property.

Keywords: Resvech Score, Conventional dressing, Diabetic Ulcer.

Introduction

Non healing ulcer have a significant impact on the health and quality of life of patients and their families, causing pain, loss of function and mobility, depression, distress and anxiety, embarrassment and social isolation, financial burden, prolonged hospital stays and chronic morbidity or even death^[1]. Chronic non-healing ulcers could be due to systemic conditions such as diabetes mellitus, tuberculosis, leprosy, venous ulcers, pressure sores, atherosclerosis, and traumatic vasculitis^[2]. Complications of chronic ulcer include infection such as cellulitis and

infective venous eczema, gangrene, haemorrhage and lower-extremity amputations. Chronic ulcer lead to disability and disability worsens ulcer outcomes resulting in a vicious cycle^[3].

The art of suitable and appropriate management of non-healing ulcer remains a major hurdle in medical science. In spite of recent advances in aseptic techniques, antimicrobial chemotherapy and ulcer management, several types of ulcer have proved recalcitrant. Conventionally dressing techniques using povidone iodine, hydrogen peroxide, normal saline, debridement of dead and devitalized necrotic slough and tissues, control of

infections by antibiotics, rest, skin care have remained the mainstay of management. But many ulcers take too long to heal with these modalities esp. diabetes mellitus, sickle cell disease, leprosy, Buerger's disease, deep vein thrombosis, atherosclerosis, etc.

Newer biological dressings like PDGF, stem cell and bovine colostrums (BC) dressings which are enriched with growth and immune factors for formation of healthy granulation tissue and early epithelialisation; are recently known to have revolutionized ulcer healing^[4].

Thus this study is conducted to compare the efficacy of colostrum powder as an add on dressing with that of conventional dressing in the healing of chronic non-healing ulcer.

Patients and Method

This was an open label quasi experimental study conducted in our tertiary care teaching hospital between 2015 to Oct 2017.

All adult Patients of both gender attending the OPD or admitted to Indoor wards for treatment of their non-healing ulcers were included in the study. The ulcer was of three months duration or longer duration^[5] and were of any aetiology. The patients who were hypersensitive to colostrums or having history of lactose intolerance were excluded from the study. Also patients suffering from concurrent illness that may interfere with treatment like carcinoma, tuberculosis, Hansen's disease, connective tissue diseases, severe anaemia, or with ulcers with clinical signs of heavy infection were excluded.

The study protocol, study questionnaire and case record form was designed and approved by the Institutional Ethics Committee before the start of the study. Patients satisfying the inclusion and exclusion criteria were explained about the nature of the study and informed consent was taken from them before enrolment. Data was collected from the study subjects through interview and physical observation regarding their demographic profile, underlying diseases, duration of wound, past history of medication or allergy and drug history.

Details regarding the baseline physical examination findings like type of ulcer, site, mode of onset and symptomatology were recorded in the Case Record Form (CRF). The enrolled patients were given either conventional treatment or add on treatment with Bovine Colostrum by the treating physician.

- **Group 1** – Conventional Dressing (cleansing with Normal Saline and wound debridement followed by toileting with various topical agents like Povidone Iodine, Hydrogen Peroxide, Silver Sulfadiazine and Rectified spirit on daily basis.
- **Group 2** – Conventional Dressing with Add-on Bovine Colostrum Oral Capsules and Powder (Alchemist, Solan, Himachal Pradesh) applied to margins, edges, floor and base of ulcer and wound area covered by a normal saline soaked gauze.

Assessment of Wound Healing : Healing of ulcer was determined by using a Ulcer Healing Score designed by RESVECH SCALE V1.0(5) (Resvech score) utilizing 9 parameters (area, depth, edges, perilesional maceration, tunneling, type of tissue in wound bed, exudates, infection and pain (using VAS score) measured at baseline and at weekly follow-up intervals for 3 weeks.

Statistical analysis: Categorical data was calculated by Pearson's chi square test and continuous data calculated by Student's unpaired t- test using SPSS 21.

Result

A total of 120 patients with chronic non-healing ulcers were enrolled into the study out of which 96 were males and 24 were females; most of these patients were between 31 - 50 years. (Table 1)

These patients had chronic ulcers due to various etiology and were assigned to two treatment groups (Conventional Treatment (Group-1) and Add On Bovine Colostrum (Group-2)) (Table 2)

Resvech Score was measured in all the patients in both groups at baseline and weekly for 3 weeks and the Mean Score in all the 60 patients was calculated and compared statistically. (Table 3)

Table 1 Age and Sex Distribution of Patients with Chronic Non Healing Ulcer

Age	Male	Female	Total
21-30	15	3	18
31-40	28	10	38
41-50	26	4	30
51-60	19	3	22
61-70	8	4	12
Total	96	24	120

Table 2 Type of Chronic Ulcer in Each Treatment Group

Sr no	Type of Ulcer	Group-1 (Conventional Dressing) n=60	Group-2 (Bovine Colostrum Add On Dressing) n=60
1	Diabetic foot ulcer	32	32
2	Trophic ulcer	10	12
3	Sickle cell disease ulcer	8	9
4	Venous ulcer	5	5
5	Necrotising fasciitis	2	0
6	Fournier gangrene	1	1
7	Post burn	1	1
8	Buerger’s disease ulcer	1	0
	Total	60	60

Table 3 Mean Resvech Score at Baseline and Follow-Up (max. score = 40)

Groups	Parameter	Baseline	After 1 st Week	After 2 nd Week	After 3 rd Week
Group 1 (n = 60)	Mean Resvech Score ± SEM	27.87±3.549	25.07±4.133	21.53±4.424	16.88±4.826
	% of Healing from Baseline	-	37.35%	46.18%	57.8%
Group 2 (n = 60)	Mean Resvech Score ± SEM	25.47±4.268	15.78±5.663	9.50±3.981	4.83±2.895
	% of Healing from Baseline	-	60.55%	76.25%	87.93%
Group1 vs Group 2	P value (chi-sq)	0.001	0.000	0.000	0.000

Discussion

Non-healing ulcers that are difficult to treat, includes venous ulcers, diabetic ulcers, trophic ulcers, pressure sores, sickle cell disease ulcer and necrotizing fasciitis. The effect of different topical agents on the healing of the abovementioned ulcers has been subject of extensive research but only few have been properly controlled. Bovine colostrum has attracted the attention of a lot of contemporary research due to immense untapped potential they possess towards healing many recalcitrant ulcers. Colostrum contains many immune and growth factors like EGF (epidermal growth factor), TGF (transforming growth factor), IGF(insulin like growth factor), FGF(fibroblast growth factor), stimulate skin growth, cellular

growth, and repair by direct action on DNA and RNA^[6].

Few researchers have conducted studies on bovine colostrums on wound healing. Thapa (2005) observed bovine colostrum to have chemical debridement action, deodorization of offensive wounds, absorption of edematous fluid around ulcers, antibacterial and anti-inflammatory actions which were of greatest clinical advantage in diabetic ulcers, trophic ulcers, sickle cell disease ulcer, Fournier gangrene and necrotizing fasciitis^[7]. According to study by Khirsagar Y et al in 2015 the anti-inflammatory, anti-viral and anti-bacterial properties of bovine colostrums makes it suitable for oral/ topical applications^[6].

In our study most commonly affected age group of non healing ulcer is 31 to 50 yr of age and males are more affected compared to females which is corroborated by study of Chaterjee et al (2015)^[8] and Khirsagar Y et al (2015)^[6].

In our study there was highly significant ($p < 0.001$) improvement in healing rate in bovine colostrum add on group at the end of first, second and third week of treatment as evident from Resvech score. The healing rate improved from 60.55% at end of first week to 87.93% in third week of treatment in bovine colostrum add on group in comparison to conventional dressing group which showed healing rate from 37.35% to 57.8% in same time period. Studies by Chaterjee et al (2015) and Khirsagar Y et al in 2015 confirmed that bovine colostrum improves healing rate appreciably in non healing ulcers in comparison to conventional dressing^{[8][6]}.

Conclusion

Bovine colostrum produces very significant increase in healing of chronic non-healing ulcers due to varying aetiology and has a remarkable potential in revolutionizing management of non healing ulcers.

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