

# A Comparative Study of the Efficacy of Antibiotic Impregnated Collagen Granule Dressings Vs Conventional Dressings for Treatment of Diabetic Ulcers

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## I. Introduction

In An Era Where Diabetes Has Become A Major Health Problem With Increasing Prevalence In Both Developed And Developing Countries, Management Of Complications Especially The Diabetic Ulcers Has Imposed A Huge Challenge For The Health Care Systems. The Incidence Of Foot Ulcers Is About 25% Of Which 50% Become Infected Requiring Hospitalization. These Contribute To Approximately 80% Of All Non-Traumatic Amputations In India, Annually (1) Patients With A History Of Diabetic Foot Ulcers Have 40% Higher 10 -Year Death Rate, Than Those Without.

Hence, Successful Treatment Of Diabetic Foot Ulcer Becomes Mandatory And Requires Multidisciplinary Management Including Attention To: Wound Care, Revascularisation, Offloading And Management Of Metabolic Abnormalities, Anti-Microbial Therapy And Surgery.

As A Result Many Auxiliary Techniques Have Been Combined With Systemic Antibiotic Therapy With Adjunctive Local Antiseptic Usage, Hence We Would Like To Explore The Advantages Of Modern Bioactive dressing (2) Techniques Mainly By Using Collagen Granules As A Part Of Wound Care. Collagen Dressings Have Gained An Undeniable Progress In Attaining Early And Higher Rate Of Cure (3). It Has The Advantages Of Being Impermeable As Well As Physiological That Creates An Interface Between The Wound And Environment Apart From Being Non-Immunogenic, Non-Pyrogenic, Hypo Allergenic And Pain Free. (4)(6)

The Present Study Aims At Comparing The Efficacy Of Antibiotic Impregnated Collagen Granules [2% Mupirocin And 1% Metronidazole] With That Of Conventional Dressings Using Povidone Iodine, In The Treatment Of Diabetic Foot Ulcers.

## II. Materials And Methods

The Diagnosis Of A Diabetic Foot Ulcer Infection Is Based On IDSA Foot Infection Guidelines (5):

-> 2 Manifestations Of Inflammation

### -Mild-

Grade 1- (Local swelling, induration, Erythema, Tenderness, Pain, Warmth, Purulent Discharge Thick Opaque To White Or Sanguineous Discharge)

### -Moderate Infection

Grade 2- A Local Diabetic Foot With Surrounding Erythema >2 Cm Or Ulcer With Involvement Of Structures Deeper Than Skin and Subcutaneous Tissues

Grade 3- Abscess, Osteomyelitis, Septic Arthritis, Fasciitis With No Evidence Of Systemic Inflammatory Response Syndrome.

### -Severe Infection

Grade 4- A Local Diabetic Foot Ulcer Accompanied By >2 Signs Of Systemic Inflammatory Response Syndrome (SIRS)

### III. Inclusion Criteria

- \*Males And Females In Between The Age Of 30-60 Years With A Prior History Of Diabetes And On Regular Medication (Oral Hypoglycaemic Drugs Or Insulin Therapy).
- \*A Diagnosis Of Diabetic Foot Ulcer Infection Based On Idsa Guidelines-That Includes Grade 1 And 2 Of International Working Group On Diabetic Foot **Iwgd** classification.
- \*Wound Swab Culture That Shows Positive And Predominant Gram-Positive Bacteria Along With Anaerobic Culture At The First Visit,With No Prior History Of Antibiotic Usage In The Past 4 Weeks, And Wounds With Mild To Moderate Soakage.

### IV. Exclusion Criteria

- \*Pregnant And Lactating Women,Non Insulin Dependent Diabetes Mellitus.
- \*Diabetes With Associated Comorbidities Such As Hypertension,Chronic Liver Disease,Renal Failure,Cardiac Or Cerebro Vascular Diseases.
- \*Grade 3 And 4 Foot Ulcers In Iwgd Classification.
- \*Patients With History Of Hypersensitivity To Metronidazole And Mupirocin.
- \*Patients With Acute Limb Ischemia,Venous Disease.

The Present Study Is A Hospital Based Retrospective Comparative Study Where A Total Of 114 Diabetic Patients Records Who Were Admitted In The Department Of General Surgery At Government General Hospital,Vijayawada Between July 2018 And March 2019 Were Studied And The Records Of 60 Of Those Strictly Fulfilling The Inclusion Criteria Were Selected And Divided Into 2 Categories {Collagen Group And Conventional Group}For The Sake Of Analysis Of The Results.

### V. Objectives

#### To Study:

- Total Number Of Patients Who Attained A Negative Wound Culture At The End Of Second And Fourth Week Of Treatment.
  - Average Time Of Treatment To Obtain Healthy Granulation Tissue.
  - Total Number Of Patients Attained 75%Of Total Wound Closure At The End Of 6 Weeks.
- Endpoints To Determine Cure Of Diabetic Foot Ulcer Infection (Dfui):
- Absence Of Microbiologicaland Clinical Evidence Of Original Infection
  - Improvement In Wound Score And Decrease In Number Of Manifestations Of Inflammation,However Without Complete Resolution.

Before Applying The Dressing,Foot Ulcer Was Thoroughly Debrided And Treated With U-Sol Solution And A Wound Swab For Culture Was Collected For Both The Groups,Followed By A Conventional Dressing With Povidone Iodine In The Conventional Group And Application Of Antibiotic Impregnated(Mupirocin 2% W/V, Metronidazole 1% W/V)Collagen Granules Over The Wound With A Thickness Of 2 Mm And An Occlusive Dressing In The Collagen Group. Wound Dressing Was Changed Every 3<sup>rd</sup> Day In The Collagen Group And Accordingly For The Conventional Counterpart. Wound Swab Culture Was Taken Weekly.

### VI. Results

Out Of Total 60 Patients, 28 Were Female And 32 Were Maleswith 26 Between The Age Of 40-50 Yrs. And 34of 50-60yrs. There Was No Significant Difference In The Sex Distribution Of Patients And The Healing Process.

### VII. Response To Treatment

Category	Collagen Group{N-30}	Conventional Group{N-30}	P-Value
Sterile Wound Culture At 2 Weeks	18 {60%}	13{42%}	0.03*
Sterile Wound Culture At 4 Weeks	27{90%}	24{80%}	0.04
Average Time For Healthy Granulation Tissue	8 Days	14 Days	0.03**
75%Of Wound Closure At 6 Weeks	21{70%}	19{63%}	0.21*

\*- Mann-Whitney Test,\*\*Pearson Chi-Square Test.

-60% Of Collagen Group Had Attained A Negative Wound Swab Culture At The End Of 2 Weeks Compared To 42% Of Its Conventional Counterpart,Which Had Increased To 90% By The End Of 4 Weeks Of Treatment.

-Collagen Group Has Attained A Healthy Pink And Well Vascularised Wound Base With Granulation Tissue At A Mean Of 8 Days

- 70% Of Collagen Group Showed 75% (3/4th) Wound Closure At The End Of 6 Weeks Of Treatment.

Our Study Can Surely Relate A Significant Rate In Attaining A Negative Wound Swab Culture With In 2 Weeks Of Collagen Granule Dressings With Only 42 % Result In The Conventional Dressing Group(P=0.03),Which Increased To 90% With 6 Weeks Of Treatment Compared To 80% With Conventional Dressings(P=0.04),Where The Mean Time For Appearance Of A Healthy Granulation Tissue Was Reduced To 8 Days (P=0.03).Though 70% Of Collagen Groups Could Attain 75% Of Wound Closure By 6 Weeks,It Was Statistically Insignificant As No Correlation Or Benefit Was Demonstrable From Attaining An Early Healthy Wound.(P=0.22),That Could Lead To An Early And Complete Wound Closure ,As Most Of The Wounds (80% In Collagen Group And 88% In Conventional Group) Required Split Skin Grafting. Time Required For Complete Healing Did Not Have A Linear Relationship With A Sterile And Clinically Healthy Appearing Wound.

### **VIII. Discussion**

Any Chronic Wound Would Have Elevated Levels Of Metalloproteinaseswhich Have High Proteolytic Activity,The Use Of Collagen Has Been Found To Inhibit The Action Of Proteinases And Promote Wound Healing By Deposition And Organisation Of Freshly Formed Fibres And Granulation Tissue In The Wound Bed. Metronidazole Has Been Found To Be Highly Effective Against Anaerobic Bacteria Which Are Proven To Be A Part Of Predominant Culture In A Diabetic Ulcer Co Existing With Gram Positive And Gram Negative Bacteria. IwgdF Recommends Wound Culture Results From A Diabetic Ulcer Infection That Are Often Polymicrobial;While Virulent Pathogens(Staphylococcus Aureus Or Beta Hemolytic Streptococci)That Are Isolated Should Be Treated ,Some Less Virulent Isolates(Corynebacterium Or Coagulase Negative Staphylococci)Are Often Contaminants Or Colonizers That May Not Need Targeted Antibiotic Treatment.(3).

Topical Mupirocin Has Been In Use For Skin Infections Such As Impetigo And Folliculitis Caused By Gram Positive Bacteria And Even Has An Effective Action Over Methicillin Resistant Staphylococcus Aureus. Metronidazole Has Strong Action Against Obligate Anaerobicbacteria Which Is Predominantly Found In Diabetic Foot Ulcer Infections Associated With Ischemia Or A Foul Smelling Discharge.Though Has A Low Bioavailability Of 20% On Topical Application,It Has Better Local Activity With Minimised Systemic Toxicity.

As Such There Are Limited Studies That Prove The Efficacy Of Antibiotic Incorporated Collagen Granules In Treating Diabetic Ulcers Our Study Lags In Proven Data,Gentamicin Impregnated Collagen Sponge Was Used By Jin-Sol Et Al In A Study For Treating Surgical Site Infections ,That Showed Significant Results.Donaghue Et Al.,In 75 Patients Had Compared The Efficacy Of Collagen Alginate Topical Wound Dressing With That Of Regular Wound Dressing With Gauze And Normal Saline In Diabetic Foot Ulcer Patients.There Was 80.6% Of Reduction In Mean Wound Area,Observed In Collagen -Alginate Dressing Group Compared To 61.1% In Gauze Dressing Group

### **IX. Conclusion**

Mupirocin And Metronidazole Impregnated Collagen Granules Does Not Offer Significant Better Results Over Conventional Dressings In Terms Of Completeness Of Healing .However,It May Decrease The Duration Of Oral Or Systemic Antibiotic Therapy To Attain Culture Negative, Non-Infected And Healthy Wound Which Could Be Taken For Other Methods Of Wound Closure,With Lessened Duration Of Hospital Stay And The Morbidity Of Dressings.These Collagen Particles Has An Application Methodology That Is Easier When Compared To Other Kind Of Hydrocolloid Or Conventional Adhesive Dressings .

Disadvantages Are This Is Not A Cost Effective Treatment When Used For Bigger Wounds.But The Use Of These Mupirocin And Metronidazole Impregnated Collagen Particles Can Increase The Potentials In Wound Healing While Also Further Studies Are Needed To Prove The Efficacy.

### **References**

- [1]. L.N.Mc Ewen ,K.R. Ylitalo,W.H.Herman And J.S.Wrabel,Prevalence And Risk Factors For Diabetes -Related Foot Complications In Translating Research Into Action For Diabetes[Triad],Journal Of Diabetes And Its Complications,Vol.27,No.6,Pp.588-592,2013.
- [2]. R.R.Yotsu,N.M.Pham,M.Oe Et Al.,Comparison Of Characteristics And Healing Course Of Diabetic Foot Ulcers By Etiological Classification:Neuropathic ,Ischemic And Neuro-Ischemic Type,"Journalof Diabetes And Its Complications,Vol.28,No.4,Pp-528-535,2014.
- [3]. Steedl.Wound-Healing Trajectories.Surgclin North Am.,2003;83:547-555.
- [4]. Kevinr.Knox,Ramazio.Datiashvili,Marks.Granick.Surgical Wound Bed Preparation Of Chronic And Acute Wounds.Clin Plastic Surg.,2007;32:633-641.
- [5]. IwgdF Guideline On The Diagnosis And Treatment Of Foot Infection In Persons With Diabetes.2019.
- [6]. Lazaro-Martinez JI,Garcia -Morales E,Beneit-MontesinosJV,Martinez-De-Jesus Fr,Aragon-Sanchez FJ.Randomized Comparative Trial Of A Collagen/Oxidized Regenerated Cellulose Dressing In The Treatment Of Neuropathic Diabetic Foot Ulcers.Ciresp 2007;82:27-31.