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ABSTRACT BOOK

Fragments of Collagens I-III Useful in Regenerative Medicine

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Background

Materials useful in dressing non-healing wounds, including DFU should be consistent with a uniform concept of chronic wound healing - TIME strategy. The goal of TIME is to restore optimal conditions by removing barriers, correcting disorders affecting the lack of healing and strengthening the potential of natural wound healing processes [1-2].

Objectives

The main goal of our research is designing, manufacturing and checking the usability of complex, biocompatible, hybrid materials useful in dressing non-healing wounds, including DFU. Final materials should have a positive effect on healing process at all stages: hemostasis, inflammation, proliferation and tissue remodeling.

Methods

Libraries of immobilized peptide fragments covering the whole collagens I-III were synthesized using SPOT technique with DMT/NMM/TosO⁻ as a coupling reagent [3]. The dot-blot technique using polyclonal antibodies has allowed to select of fragments reproducing the outer sphere of the native protein.

Results

Based on screening, 33 fragments derived from collagen I, 26 fragments from collagen II and 52 fragments of collagen III were selected. Their re-synthesis under SPPS conditions allowed to obtain a set of collagen fragments I-III that reproduce the outer sphere of proteins

Conclusion

Selected fragments of collagens I-III reproduce the outer sphere of native proteins and they form stable spatial structures that mimic the triple helix of native collagen.

Acknowledgments

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[2] F. Gelain et al., *Int. J. Nanomed.* **2008**, 3, 415-424.

[3] Fraczyk et al., *J. Pep. Sci.* **2018**, 24, e3063.

Bidimensional Network Meta-Analysis on the Efficacy and Safety of the Diabetic Foot Treatments

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Background:

Foot infection is the most common cause of non-traumatic amputation in people with diabetes. Most diabetic foot infections require systemic antibiotic therapy. Since there are many antibiotics available for the diabetic foot infections. We investigated which are the safest and most effective.

Objective:

This network meta-analysis (NMA) is aimed to give a quantitative and systemic evaluation of safety and efficacy for the following diabetic foot treatments: *Antipseudomonal-penicillins, Carbapenems, Fluoroquinolones, Broad-spectrum-penicillins, Cephalosporins and other antibiotics.*

Methods:

The article's research was constructed from PubMed. Odds ratios were calculated to evaluate binary outcomes. Forest plots were conducted to reveal the performance of pair-wise comparison of above treatments in each outcome. The outcomes highlighted are Clinical resolution, Adverse events and Serious complications of the infections.

To organize the treatments, we used P-scores for the frequentist method and surface under the cumulative ranking curves (SUCRA) for Bayesian method.

Results:

Carbapenems are the most recommended therapy according to our NMA; *Fluoroquinolones* has high efficacy but should be applied with caution since it revealed poor performance in safety outcomes and finally *Tigecyclin* reduces the risk of amputation better than any other antibiotics.

Conclusion:

This network meta-analysis has reached new conclusions on the efficacy and safety evaluation of diabetic foot treatments that the older studies could not have reached. Results allowed a suitable classification of antibiotic treatments for diabetic foot according to their efficacy and safety unlike other studies which have been focusing on a two by two comparison.

Peptides Derived From Growth Factors as a Potential Drug in Regenerative Medicine

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Background

Growth factors like epidermal growth factor (EGF), vascular endothelial growth factor A or transforming growth factor α are essential molecules responsible for regeneration due to their ability to promote cell proliferation, what may induce tissue regeneration.

Objectives

The aim of the studies was to find short fragments of growth factors with maintained biological activity of whole polypeptides. Application of proteins in therapy has limitations because of their unfavorable pharmacokinetic and pharmacodynamic parameters, susceptibility to enzymatic degradation and immunogenicity. All these disadvantages can be eliminated by using short peptides derived from native proteins, assuming that they retain the biological activity of the original protein.

Methods

Libraries of peptide fragments covering the whole selected proteins were synthesized using SPOT technique with DMT/NMM/TosO⁻ as a coupling reagent [1]. Dot blot technique allowed to select fragments reproducing the outer sphere of the native protein and active fragments were found. The method was also applied to find cross-reactions between peptides derived from other growth factors.

Results

Set of peptides constituting the outer sphere of growth factors was found. For EGF the results were overlapping with binding sites of EGF-EGFR complex [2].

Conclusion

Selection of short fragments of growth factors may enter the opportunities to design novel drugs based on short peptides with the same biological function as the native protein.

Acknowledgments

Financial support, project UMO-2018/31/B/ST8/02760.

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Swiss Interprofessional Guidance of Good Practice of Acute and Complicated Diabetic Foot Syndromes – A National Project

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Background: Diabetic foot syndromes (DFS) have multiple negative outcomes in a patient population marked with co-morbidities and frailty. Their management requires a quality of care consisting of evidence-based, practical guidance tools for primary care providers together with the implementation of an interprofessional care system including nationally standardized diagnose-relevant best practice recommendations.

Objective: Provision of national best practice guidances for timely and qualitative care of patients with DFS.

Methods: Under the umbrella of the national non-profit association QualiCCare, an interprofessional and comprehensive Swiss practical guidance for the timely and standardized quality of care management of acute DFS and diabetic foot ulcers (DFU) was elaborated in a multi-stakeholder approach including all relevant professions. Before the nation-wide implementation of the primary care triage and treatment guidance and indication-specific recommendations for interprofessional networks and footcare centers, three Swiss regions will pilot the implementation in different primary care settings in collaboration with the respective interprofessional footcare centers.

Results: Twenty experienced stakeholders from 12 different professions issued four protocols for various aspects of DFS between March 2018 and January 2020 and defined criteria for the triage and treatment in primary care as well as the timely referral of patients with DFS and DFU to interprofessional footcare centers. All invited professional societies agreed to contribute and have a representative in the working group. The resulting guidances were endorsed by all national professional societies.

We propose a framework for primary care, specialized footcare networks as well as interprofessional footcare centers. The piloting of the proposed concepts is in preparation.

Conclusions: We provide evidence-based tools for Swiss primary care providers and specialists while increasing the accessibility for patients to specialized care of DFS.

The Contribution of Transcutaneous Oximetry in the Determination of Amputation Height in Diabetic Foot Syndrome

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Introduction: The dramatic rise in the prevalence of diabetes mellitus, has led to an increase in its chronic complications. One of them is diabetic foot syndrome. The transcutaneous oximetry provides valuable information for the correct determination of the amputation line.

Patients and methods: We investigated 22 patients suffering from DM type 2 (9 men and 13 women), mean age 70.5 years, with finding of diabetic foot syndrome with gangrene (grade IV or V according to Wagner classification). Using the Oxykapnomonitor SMK 365, Hellige, Germany equipment for transcutaneous oximetry, we determined the amputation height. As a minimum value of transcutaneous partial pressure of oxygen (TcPO₂) for amputation line, we determined 25 mmHg in accordance with international recommendations of professional societies. 9 members of our group underwent low and 13 members high amputation.

Results: Healing per primam occurred in 15 patients (68 %), 4 patients (18 %) had surgical wounds healing per secundam. In 3 patients (14 %) amputation wound healing did not occur and reamputation was necessary. Reamputation was required in patients with the lowest TcPO₂ values (25 - 29 mmHg) at the amputation line level.

Conclusion: Our results confirm, that the minimum TcPO₂ value for stump healing per primam is 30 mmHg. This value is also consistent with the updated international recommendations for transcutaneous oximetry. The issue of diabetic foot syndrome requires interdisciplinary cooperation, patient education, and improved pre- and postgraduate education.

Altrazeal Dressing in Diabetic Foot Ulcers

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Wound healing depends on multiple factors that play a major role in healing. Trauma, ischemia and neuropathy lead to debilitating ulcers in feet of these patients with long standing diabetes. This study has been undertaken in Burn and Plastic Surgery department of AIIMS Rishikesh in patients of diabetic foot ulcers with a new powder based dressing.

Altrazeal powder dressing is composed of 14.9% poly (2-hydroxypropyl methacrylate) (pHPMA), 84.8% poly (2-hydroxyethyl methacrylate) (pHEMA), and 0.3% sodium deoxycholate. When the powder is applied to a moist wound, the sterile powder interacts with the exudates within the wound, forming a flexible moist layer dressing. This powder can be used in superficial acute wounds, surgical wounds, and chronic wounds, including pressure ulcers, leg ulcers, and diabetic foot ulcers. This case series outlines the role of powder in recalcitrant diabetic foot ulcers for a speedy healing time, early weight-bearing, and better quality of life.

Using a Large Administrative Healthcare Database to Identify Opportunities for Service Development in Lower Extremity Amputation in Ireland.

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Ireland, along-side the rest of the world, is facing a rapid growth in the incidence of diabetes. Among the most troublesome complications is diabetic foot ulcer (DFU) which frequently results in lower extremity amputation (LEA). In addition to the patient disability, this complication consumes enormous amounts of healthcare resources.

The objective of this study is to describe the current extent of healthcare resource utilisation (in terms of bed days) among patients undergoing LEAs in Ireland, to determine the average length of stay (LOS) and to assess potential for savings in bed days used.

We used a national administrative health database Hospital Inpatient Enquiry system (HIPE) to identify adult inpatients (aged 16) who underwent a minor or major LEA between 2015-2018, including number of procedures, length of stay (LOS), and bed days utilisation (BDU).

A total of 2646 procedures were performed over the 4 years (660/year), 65% of whom had diabetes. Among patients with diabetes undergoing minor LEA, the total number of admissions was 1,219, the average LOS was 18 days and the total BDU was 21,942. In the diabetes cohort, there were 502 major LEAs, with an average LOS of 50 days and a total BDU utilisation of 25,100.

Patients undergoing LEA amputation account for a significant proportion of inpatient bed utilisation in Ireland. Better management of diabetes, ulcer prevention, early effective management of DFU and prompt access to rehabilitation may help mitigate this and large administrative databases like HIPE can provide relevant data to support prioritisation and service re-orientation.

Engineering a Diabetic Foot Lesion Predictor to Stop Walking in Time

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Background Diabetic foot prevention standard of care includes education, regular evaluation, therapeutic shoes and customized insoles. Contrary to the usual praxis, clinical wish lists long for the possibility to anticipate lesions, and therefore to avoid them.

Objectives To establish the feasibility of a precursor instrument for diabetic foot lesions by monitoring physical foot magnitudes in healthy adults.

Methods Five physical magnitudes were selected as a first step to engineer a lesion predictor because of their possible link with early signs of a diabetic foot lesion.

Results Physical magnitudes of the normal and ulcerated foot have significant disparities. *Plantar pressure*, peak absolute pressure values (healthy 142-564KPa, diabetic patient 80-300KPa) and “integral absolute pressure time” (healthy 34-153KPa, diabetic patient 32-54KPa). *Skin temperature* (healthy 27-37°C, diabetic 18-29°C, asymmetry 2.2°C) increases with inflammation and decreases in absence of neuropathic or vascular activity and depends upon ambient temperature. *Humidity* defines microclimates (20, 60 and 75% RH); experiments have recorded 96.6% and 91% RH in polymer and leather footwear respectively. *Bioimpedance*, foot-to-foot resistance (men 500-467Ω and women 631-549Ω). *Electromyography* (amplitude 1.5-3.4 μV, latency to onset 4.7-5.1ms and to peak 5.3-6.1ms) on medial plantar sural nerve action potential.

Conclusion Electromyography and bioimpedance may be combined to establish a possible threshold to distinguish normal from ulcerated foot. These five parameters are good candidates in the prediction of foot lesions during gait. Emphasis is placed on the combination of physical magnitudes to estimate dissipated energy during gait to eventually trigger alerts for the diabetic patient.

Clanging Tuning Fork Test is Superior to the 10-g Monofilament in Testing for Diabetic Peripheral Neuropathy and for Assessing the Risk of Diabetic Foot Ulcers

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ADA guidelines recommend testing for diabetic peripheral neuropathy (DPN) by clinical criteria, combined with qualitative testing (reduced/absent) of ankle reflexes, vibration, 10-g monofilament, proprioception, and thermal or pinprick sensation. They recommend using the monofilament on the plantar surface to detect the “high-risk foot”. We have compared the timed Clanging Tuning Fork (CTF) test to the 10-g monofilament on the plantar surface, with 8 out of 8 sites correct considered normal. The CTF test was described by Oyer et al in *Endocrine Practice*, Vol 12, p.6-12 in 2007. The 128-Hz tuning fork is struck so the tines clang together to give a reproducible stimulus. It is applied to the dorsum of the great toe, proximal to the nail, and the time until the patient is “not sure” they feel vibration is noted. Scores from both great toes were averaged. The result in seconds was reproducible with a SD of 1 second. Results were compared in 150 diabetic patients. When the CTF score was 5-8 seconds, the monofilament was normal in 100% of patients. When the CTF score was 1-4 seconds, 68% had a normal monofilament. At 0 seconds, 37% had a normal monofilament. Sixteen patients had a history of diabetic foot ulcers. CTF scores were 4 seconds or less in all patients. Monofilament sensitivity was absent in 5, reduced in 4, but normal in 7 of the patients with ulcers. A CTF score of 4 seconds or less correlates with risk of diabetic foot ulcer better than the 10-g monofilament test.

Treatment of Diabetic Foot Ulceras Using Technology with a C-Boot Device

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Introduction- It is known that the application of Radiofrequency in wounds, improves vascularization and oxygenation of tissues, it has also been shown to increase the Epidermal and Vascular Growth Factors. It is known to be a safe and well tolerated treatment by the patient. In order to know the effect of this treatment on the Diabetic Foot Ulcers, this study was carried out, incorporating a C-Boot, designed to apply the radiofrequency treatment with a C 100 CAPENERGY for application in the foot ulcers.

Methodology- Four patients were treated with one or several ulcers where 10 minutes of capacitive electrode treatment was first applied in the area of the ulcer at a power of 50% of that delivered by the team. Then it was applied 20 minutes using the C-Boot with active and passive plate. The treatment was applied once a week. Ecosonography was performed to evaluate subcutaneous edema and a Visual Analogue Pain Scale.

Results- All patients noticed a decrease in the symptoms of edema and a decrease in pain from the first weeks, at the end of the treatment the ulcers were closed, improving the quality of life of these patients.

Conclusions- The application of Tecarterapia with the use of C-Boot has proven to be an effective treatment for the treatment of ulcer in the Diabetic Foot.

The Development of Appropriate Footwear for Prevention and Management of Diabetic Foot Problems

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Background: The incidence and prevalence rates of diabetes in Nigeria and globally are increasing and foot complications are equally rising. There is however lack of adequate knowledge about the role of footwear in the prevention and management of foot related problems among diabetic patients in Nigeria.

Objectives: the purpose of this study is 2-fold namely; (1) To determine the perceived role of therapeutic footwear in the prevention and management of foot problems among patients with diabetes, (2) To develop appropriate footwear for diabetic patients.

Methods: This study was carried out among diabetic patients in Kaduna State, Nigeria. Pre-tested structured questionnaires were used to collect data. Simple descriptive statistics were used; frequency with percentage distribution for categorized variables. Trial prototypes were developed based on clinical perspective and an in-depth understanding of patients' expectations and perceptions of footwear.

Results: It was discovered that up to 53% females and 37% males of diabetic patients were wearing most often inappropriate footwear like slippers or slip-on footwear with no fastening mechanism. The outcome of fit and comfort assessment of the trial prototypes has showed that 86%, 84% and 92% of the patients were comfortable with the top line, agreed that the fastening mechanism aligned properly and alright with the depth of the instep respectively.

Conclusion: It was concluded that the high rate of amputation reported amongst diabetic patients in developing countries like Nigeria could be drastically reduced through appropriate design, development and wearing of 'correct' footwear.

Examination of Granulation Tissue Using OASIS® □ Extra Matrix

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Background

OASIS® extra matrix (OASIS) was used in wound therapy from 2015 in Japan. It's one of the first products of regenerative wound therapy products. OASIS have functions of signal and scaffold. There isn't clinical research for tissue examination of using OASIS in Japan. □ So OASIS and control (traditional therapy) were compared by tissue examination.

Objective

6 cases of diabetic foot ulcers (included chronic limb threatening ischemia) were examined. They did half side tests, one side is OASIS and another side is normal dressing after the first debridement.

Method

Half side test was performed after the debridement, and get granulation tissue by punch biopsy (φ3mm) from diabetic foot ulcer included ischemic wound. Tissue biopsy was performed after 1 week of the debridement and reconstructive operation. Tissue was examined of cell counts by Hematoxylin and eosin-stained.

Results

OASIS have more cell counts than control after 1 week of the debridement. OASIS have no significance to control in reconstructive. The cure rate isn't different between OASIS and control.

Conclusions

OASIS have a function of growing good granulation and reduce wound therapy term. Long-term observation needs to know the cured matured area after the wound is cured.

Do Podiatric Appointment Intervals Influence Re-ulceration Rates in Diabetes Patients?

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Background

The recurrence rates of diabetes foot ulceration vary between studies but are generally high. Maciejewski (et al 2004) reported up to 59.3% one year recurrence and no conclusive effect from therapeutic footwear in keeping with similar studies of specialist interventions.

Objectives

This study was designed to determine if podiatric visit intervals altered the rate of foot ulceration recurrence in high risk diabetes patients in a specialist foot service.

Methods

Randomised prospective parallel group study comparing 2, 4 and 8 week appointment intervals on the recurrence of diabetes foot ulceration over one year. The study was powered for a sample size of 97.

Results

103 patients, 75 male. 82% Type 2 DM, median diabetes duration 18.2 years.

Primary outcome measures - There was no significant difference in foot ulceration recurrence rates between groups - 2 week 67%, 4 week 63% and 8 week 77%, $p=0.37$, or time to ulceration median 66.5 vs 71.5 vs 84 days, $p=0.22$. One major amputation per group.

Secondary outcome measures - 15 patients withdrew in total ($p=0.33$ between groups). One year outcomes, 49% had an active ulcer and 42% were alive and ulcer free (both $p=0.85$ between groups), mortality rate 4% ($p=0.20$ between groups).

Conclusion

Follow up appointment intervals of 8 weeks do not adversely affect outcomes but may significantly improve resource allocation with a growing diabetes population.

References

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C Reactive Protein Predicts Adverse Outcomes in Diabetes Foot Infections

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Background

Diabetic foot infections are serious, expensive and associated with adverse outcomes.

Objectives/Methods

To determine outcomes we audited 54 admissions for clinically diagnosed diabetes foot infections in 35 patients (25 males) over 6 months. Their median age was 56.6 (range 21.8-89.2) years.

Results

Median admission duration 13 (range 1-191) days, 19 patients had osteomyelitis and 11 ischaemia.

Admission microbiology - 22 *S.aureus* (2 MRSA), 6 other Staphylococci, 16 Streptococci, 12 *Enterococcus faecalis* (4 vancomycin resistant), 3 other Enterobacter, 13 Coliforms, 5 *Pseudomonas aeruginosa* and 10 others. One *S.aureus* bacteraemia.

Ten had mono cultures, the others - median 2 (range 2-6) organisms. No individual or polymicrobial culture predicted outcome.

Ischaemia patients had polymicrobial cultures (10/11 versus 15/24 neuropathic, p0.05), were older (62.2 versus 50.2 years), with longer lengths of stay (14.5 versus 10.0 days) but not statistically significant.

Osteomyelitis patients had similar age and lengths of stay to patients without osteomyelitis.

The median C reactive protein (CRP) on admission 79 (range 1-315) mg/l, on discharge 10.5 (1-158) mg/l. Three patients had admission CRP 10 mg/l. In 2 rising after admission.

Three patients died. Two had major amputations. Fourteen patients were readmitted after "clinical resolution" of infection, 4 more than once.

Failure to suppress CRP 10mg/l had positive predictive value 81.3, specificity 86.4 p0.005 for readmission or serious adverse outcome.

Conclusion

We recommend that patients don't stop antibiotics and are not discharged until the CRP is 10 mg/l.