DFSG 2021 Virtual

Diabetic Foot Study Group

of the EASD

17th Scientific Meeting

24th-25th September 2021
Virtual meeting

Abstracts

Paul Brand Award Oral 2021

CONTINUOUS, DAILY MONITORING OF PLANTAR PRESSURES IN HIGH-RISK DIABETIC PATIENTS: A UNIQUE INSIGHT INTO HIGH PRESSURE LEVELS DURING THE 3 MONTHS PRECEDING NEW FOOT ULCERATION.

Katie Chatwin, Caroline Abbott, Prabhav Nadipi Reddy, Satyan Rajbhandari, Frank Bowling, Andrew Boulton, Neil Reeves

Aim: High plantar pressure is strongly associated with diabetic foot ulcer (DFU) occurrence; however, previous studies are limited to a 'snapshot' measurement of plantar pressure taken at study onset or following DFU healing. The aim of this study was to provide a unique insight into plantar pressures experienced in the three months preceding a DFU.

Method: Forty-six patients with diabetes, peripheral neuropathy and a previous DFU wore an intelligent insole system[1] that continuously assessed plantar pressure during all daily activity for 18-months or until DFU development. Sustained high-pressure parameters (minutes of high-pressure/hour and number of 'bouts'/hour (a bout was defined as a group of continuous high-pressure readings)) in the three months preceding a DFU were compared between feet that developed DFU and those remaining ulcer-free, using multilevel binary logistic regression analysis. Pressure analysis was conducted for the whole foot and the forefoot.

Results: Twelve feet ulcerated during the study: all DFUs were under the forefoot area. Those feet developing new ulcers experienced significantly more minutes of high pressure [19(95% CI, 0.86-37, *P*=0.04)] and higher number of 'bouts' of high pressure [0.64(0.024-1.3, *P*=0.042)] at the forefoot (Figure 1) during the three months leading up to DFU development, compared to a comparable three months of data for those feet which did not ulcerate.

Conclusion: For the first time, plantar pressures occurring during daily activities have been measured continuously in the months leading up to a DFU, using an intelligent insole system. Sustained high plantar pressures were found at the forefoot throughout the 3-month period preceding forefoot DFU development compared with the forefeet that did not ulcerate. Daily monitoring of sustained high-pressure areas, using insole systems, may prove useful for preventing DFU development.

[1]SurroSenseRx, Orpyx Medical Technologies Inc., Calgary, Canada

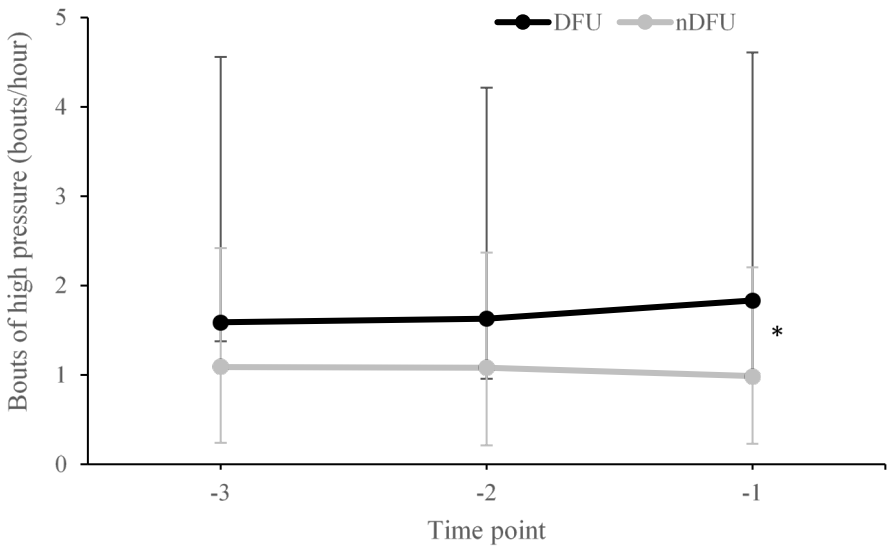


Figure 1. Average number of bouts of high pressure at the forefoot, comparing feet that ulcerated during the study (DFU) to feet that remained ulcer-free (nDFU). For DFU group, data were compared at month -3, month -2 and month -1 time points before DFU occurrence. For nDFU group, three consecutive months of comparable data were selected. Data are mean, error bars are 95% CI. *Significance between groups (P<0.05).

Top 5 Oral 1

COST-EFFECTIVENESS AND COST-UTILITY OF FOOT TEMPERATURE MONITORING FOR PREVENTION OF DIABETIC FOOT ULCER RECURRENCE: A RANDOMIZED CONTROLLED TRIAL

Jaap van Netten, Marcel Dijkgraaf, Wouter Aan de Stegge, Sicco Bus

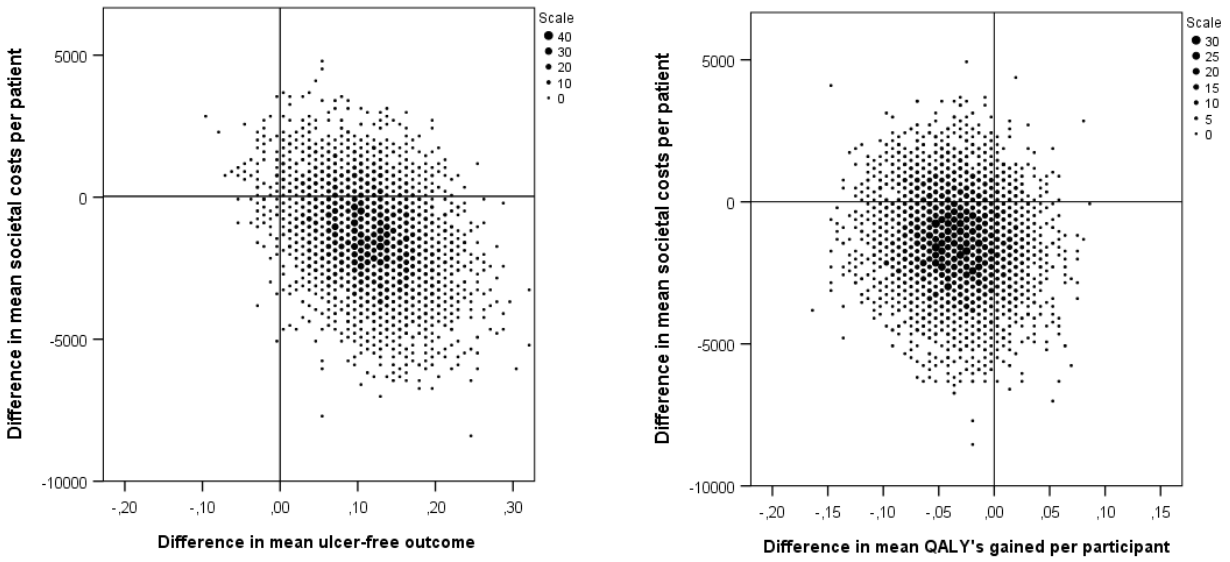
Aim: The skin of people with diabetic foot disease is thought to heat up from weight-bearing activity before it breaks down into ulceration. We assessed cost-effectiveness and cost-utility of at-home foot skin temperature monitoring for the prevention of diabetic foot ulcer recurrence.

Method: In this outcome-assessor-blinded multicenter RCT, we randomly assigned people at high risk of ulceration to usual care (i.e. podiatric treatment, education, and therapeutic footwear) or usual care plus measuring skin temperatures at 6-8 plantar sites per foot each day (enhanced therapy). Foot care costs from a societal perspective were obtained via questionnaires and electronic health records. Utilities were calculated based on EQ-5D-3L scores. Primary outcome for effectiveness was foot ulcer recurrence in 18 months. Group differences were assessed by calculating 95% confidence intervals, corrected for bias with accelerated non-parametric bootstrapping. Incremental cost-effectiveness ratios (ICER) and incremental cost-utility ratios (ICUR) were calculated as the ratio between costs and effect/utility differences between enhanced therapy and usual care.

Results/Discussion: Total foot care costs per participant during 18-months follow-up were lower in enhanced therapy (n=151; €6,067 (SD:€13,778)) compared to usual care (n=153; €7,376 (SD:€15,790); p=0.450). Enhanced therapy was cheaper and more effective in 78% of the cost-effect pairs (Fig.1). Enhanced therapy had 79% probability of being cost-effective at a willingness-to-pay of €0 per participant who remains ulcer-free. Quality-adjusted life years were lower in enhanced therapy (1.085 (SD:0.33)) than in usual care (1.119 (SD:0.31); p=0.348). Enhanced therapy was cheaper but with lower quality of life in 68% of cost-utility pairs (Fig.1). Enhanced therapy had 45% probability of achieving cost-utility at a willingness-to-pay of €50,000 per QALY gained.

Conclusion: In this first-ever societal-perspective cost-effectiveness RCT in the field of diabetic foot disease, we found temperature monitoring cost-effective in foot ulcer prevention, at the expense of lower quality of life.

ICER (left) and ICUR (right) of temperature monitoring for the prevention of diabetic foot ulcer recurrence



Legend: Differences between enhanced therapy and usual care are shown, with "enhanced therapy minus usual care" – i.e.: pairs in bottom-right part indicate enhanced therapy is cheaper and with better outcomes; Costs in Euros, effects in percentage ulcer-free, utilities in quality-adjusted life years (QALY); ICER and ICUR show outcomes of non-parametric bootstrapping of cost-effect and cost-utility pairs with 5000 replications.

Top 5 Oral 2

Safety and efficacy of several versus isolated prophylactic flexor tenotomies: A 1-year prospective study

Mateo López Moral, Aroa Tardáguila García, Irene Sanz Corbalán, Raúl Molines Barroso, Yolanda García Álvarez, José Luis Lázaro Martínez

Aim: International Working Group (IWGDF) guidelines recommend digital flexor tenotomies in high-risk patients to prevent ulcers. To our knowledge no previous research have analyzed long term outcomes after this surgical procedure. Therefore, the principal aim of this study was to assess the long-term clinical outcomes of patients who underwent isolated versus several percutaneous flexor tenotomies.

Method: Twenty-three patients who underwent percutaneous flexor tenotomies secondary to tip-toe ulcers were included in this 1-year prospective study between April 2019 and January 2021. Reulceration, toe deformities, minor lesions, hiperquerathosis and barefoot pressures were analyzed after a 1-year follow-up period. Patients were divided into two different groups: 1) isolated tenotomies, 2) several tenotomies (2 or more tenotomies).

Results / Discussion: During the follow-up period 99 tenotomies in 31 feet were performed. Patients with isolated tenotomies (n=11, 35.48%) showed higher rate of reulceration (n=8, 72.7%) secondary to transfer lesions in the adjacent toes (p <.001, CI[0.05-0.44]). In addition, we found more prevalence of hiperquerathosis (n=11, 100%) and minor lesions (n=9, 81%) in the adjacent toes (p <.001, CI[0.8-1.09] and p <.001, CI[0.02-0.39] respectively). Adjacent hammer toes were found in the group of patients who underwent isolated tenotomies (n= 11, 100%) (p<.001, CI[0.7-1.1]). Barefoot peak pressure (1.42 [IQR-1.23-1.61] N/cm^2, p=.003) and integral pressure time (0.78 [IQR-0.75-0.88] N/cm^2/s, p=.003) in the non-tenotomy toes were higher in the group of patients who underwent isolated tenotomies. Finally, in the group of patients who underwent several tenotomies (n=20, 64.52%) we found higher rate of floating toes (n=16, 80%) in comparison with isolated tenotomies patients (p=.001, CI[0.18-0.77]).

Conclusion: Patients who underwent several tenotomies resulted in better clinical outcomes after a 1-year follow-up period in comparison with isolated tenotomies. When indicated, clinicians should consider performing several tenotomies in patients with toe ulcers in order to reduce complications.

Top 5 Oral 3

EFFECT OF PERCUTANEOUS NEEDLE FLEXOR TENDON TENOTOMY ON BAREFOOT PEAK PLANTAR PRESSURE DURING WALKING

Tessa Busch-Westbroek, Marieke Mens, Jaap van Netten, Sicco Bus, Max Nieuwdorp, Sjoerd Stufkens

Aim: People with diabetes and polyneuropathy often develop toe deformities that result in ulcers or pre-ulcerative lesions on the toe apex. International guidelines recommend considering a flexor tendon tenotomy to treat these deformities. The purpose here is to reduce mechanical pressure on the toe apex. However, this has never been quantitatively demonstrated. Our aim was to investigate outcomes of this surgical technique by means of dynamic barefoot pressure measurements and clinical follow-up.

Method: Barefoot plantar pressure measurements were prospectively collected as part of usual care before and after treatment with needle flexor tenotomy of hammer toes in people with diabetes and a recently healed toe ulcer. Pressure was measured during walking with an EMED platform (Novel GmbH), prior to and 2-4 weeks after surgery. Primary outcome was mean peak plantar pressure for each toe. Clinical outcomes were collected via follow-up visits. We used student's t-tests for statistical analysis.

Results/Discussion: In 14 patients (29% female; 86% type diabetes; mean age 68 years), a total of 50 toes of 19 feet were operated (mean 3.6 toes/patient), most frequently the second (38%) and third (30%) toe. Barefoot pressures on the toes decreased from an average of 432 kPa (SD: 256) to 153 kPa (SD: 100); this 278 kPa decrease (95% confidence interval: 204-353) was statistically significant ($p<0.001$). During an average follow-up of 8.5 months, no recurrent ulcers and one complication (hyperextension) as a result of the operation were seen.

Conclusion: This is the first-ever quantitative demonstration that percutaneous needle flexor tendon tenotomy provides a statistically significant, more than 50% decrease of dynamic barefoot peak plantar pressures at the operated toes and no recurrent toe ulcers at medium-long follow-up. The technique is easy to perform and seems safe with almost no side effects. However, further RCTs should prove long-term clinical and biomechanical efficacy.

Top 5 Oral 4

Top 5 Oral 4 THE NATURAL HISTORY OF CHARCOT NEUROARTHROPATHY: ASSESSMENT OF THE CLINICAL OUTCOMES IN THE FIRST DECADE AFTER A NEW CHARCOT EVENT.

Karanjeet Sagoo, Raju Ahluwalia, Ines Reichert, Michael Edmonds, Sze Ping Tan

Aim: Charcot Neuroarthropathy (CN) is a debilitating condition characterised by progressive tissue destruction. Following off-loading, we assess the long-term implications of a CN episode to a better understanding of its risks.

Method: We identified 98-patients seen at a specialist diabetic foot clinic, diagnosed with a unilateral acute CN between 2009-11. Data extracted included demographics, medical-conditions, development of CN, foot deformity; vascular or complications; orthopaedic procedures and mobility. Outcomes of interest included foot issues, co-existing morbidities, and mortality rates.

Results: At diagnosis, 98.0% had diabetes (45.8% type 1, 54.1% type 2, M:F 1:1.13). Mean age at diagnosis was 53.4 years. Most patients were affected on the right foot 3:4. 44.9% had hypertension, 80.6% diagnosed with large fibre neuropathy, 41.8% nephropathy and 62.2% had retinopathy. 9.2% had a transplant (2 renal, 2 pancreatic and 5 renal and pancreatic), 8.2% had an MI, 4.1% had a DVT, 6.1% had PVD requiring intervention and 5.1% developed gastroparesis. The mean CRP was 13.21 (2-70), mean ESR was 29.12 (2-83) and mean HbA1C was 8.28% (6-11.6) at diagnosis.

Over the subsequent decade, 56.1% developed a foot ulcer, 16.3% required minor amputation at a mean of 2.33 years (0-6). A further 14.3% developed a contralateral CN at a mean of 3.5yrs (0-9), and 6.1% underwent foot reconstruction. 35.7% developed complications of vascular disease, and 17.4% required intervention. At the time of last foot clinic review 72.4% were ambulating without casts. Mean length of foot clinic follow up was 4.9 years (3-10.3 years), at a mean of 2.33yrs (0-6). The overall 10-year mortality was 28.6%, and greater with bilateral foot disease (19.4 vs. 25%); mean time to death was 19.2 months (0-75).

Conclusion: Within 5yrs of an acute-CN episode a high incidence of foot complications, including a contralateral CN, but mortality at 10yrs is <30%.

Top 5 Oral 5

SMALL ARTERY DISEASE AND ITS POSSIBLE IMPACT ON DIABETIC FOOT ULCERS OUTCOMES AND MICROCIRCULATION - A PILOT STUDY.

Radka Jarosikova, Veronika Woskova, Jitka Husakova, Vladimíra Fejfarová, Michal Dubský, Alexandra Jirkovská, Robert Bem, Věra Lánská

We occasionally observe an insufficient effect of revascularization procedures in patients with diabetic foot ulcers (DFU) and peripheral arterial disease (PAD). Treatment failure could be associated with small artery disease (SAD) which correlates with medial arterial calcification (MAC).

Aim: The aim of our study was to confirm the hypothesis that more advanced MAC increase amputation rates and alter microcirculation in patients with DFU even after successful revascularization.

Methods: We enrolled in the retrospective study 45 patients with DFU (mean age 66.4±10.1 years) after percutaneous transluminal angioplasty (PTA) performed between 2018-2020. MAC quantified using a 3 level score based on foot radiographs and microcirculation status assessed by transcutaneous oxygen pressure ($TcPO_2$) were evaluated in all study subjects before PTA. Patients were divided into three study groups according to MAC score into group O–no MAC (n=14), group M–moderate MAC (n=17) and group S–severe MAC (n=14). DFU outcomes (healed DFU, non-healed DFU, minor or major amputations, death) as well as $TcPO_2$ values were followed till 3 months after revascularization.

Results: Due to a small study cohort a trend to lower $TcPO_2$ values before PTA (23.2±13.5 vs. 19.6±13.5 vs. 29.6±13.8 mmHg; p=0.1) more frequent minor and major amputations (61.5 vs. 58.8 vs. 42.9%; p=0.09) and higher mortality (14.3 vs. 11.8 vs. 0%; p= 0.16) were only observed in group S and M in contrast to group O. The $TcPO_2$ increase after successful PTA was the same in patients in group O as well as in groups M and S. MAC score significantly correlated with age (r=0.31; p=0.04), other parameters including renal function didn´t correlate with MAC score.

Conclusion: Our study suggests increased risk of amputation rates in patients with moderate or severe MAC/SAD. Further research is needed to fully confirm the relationship between SAD/MAC and DFU prognosis.

Supported by *NU20-01-00078 and VZ0002301.*

OP01

PLANTAR PRESSURE DURING DIFFERENT WALKING SPEEDS AND ACTIVITIES OF DAILY LIVING IN PEOPLE WITH DIABETES AT HIGH RISK OF ULCERATION

Chantal Hulshof, Jaap van Netten, Maartje Dekker, Mirjam Pijnappels, Sicco Bus

Aim: In evaluating the biomechanical properties of therapeutic footwear, most often in-shoe plantar pressures are obtained during mid-gait steps at preferred speed in a laboratory setting. However, this may not represent plantar pressures or indicate the cumulative stress experienced in daily life, where people obtain different walking speeds and weight-bearing activities. We investigated plantar pressure during different walking speeds and activities of daily living in people with diabetes at high risk of ulceration.

Method: We assessed in-shoe plantar pressure (Pedar-X; Novel GmbH) during three standardized walking speeds: 0.8, 0.6 and 0.4 m/s and seven activities: walking at preferred speed (reference condition), standing, accelerating, decelerating, Timed Up and Go test (TUG) and stair ascending and descending. Peak pressure (PP) and pressure time integral (PTI) were determined for four foot regions: hallux, metatarsal 1, metatarsal 2-3 and metatarsal 4-5. For statistical analyses we used linear mixed models ($\alpha<0.05$) with Bonferroni correction.

Results / Discussion: We included 39 feet of 20 participants (4 female, age: 63.7±8.2 years, 100% IWGDF risk 3). Results are shown in Figure 1, and described for metatarsal 1: PP increased and PTI decreased significantly with increasing walking speed (ΔPP: 38.3±23.7 kPa, ΔPTI: -11.1±12.4 kPa·s). Standing (42.0±12.3 kPa), TUG (127.4±47.8 kPa) and decelerating (93.7±38.6 kPa) showed significantly lower PP than walking at preferred speed (160.8±51.9 kPa). Stair ascending (79.4±31.3 kPa·s) and descending (82.3±32.6 kPa·s) showed significantly higher PTI than walking at preferred speed (55.9±17.3 kPa·s). PP and PTI in acceleration were most similar to walking at preferred speed (PP: 150.7±43.7 kPa, PTI: 53.2±17.6 kPa·s).

Conclusion: To analyze the cumulative stress on the foot in shod conditions during daily life in people at high risk of diabetic foot ulceration, plantar pressures (both PP and PTI) during different walking speeds and activities of daily living should be taken into account.

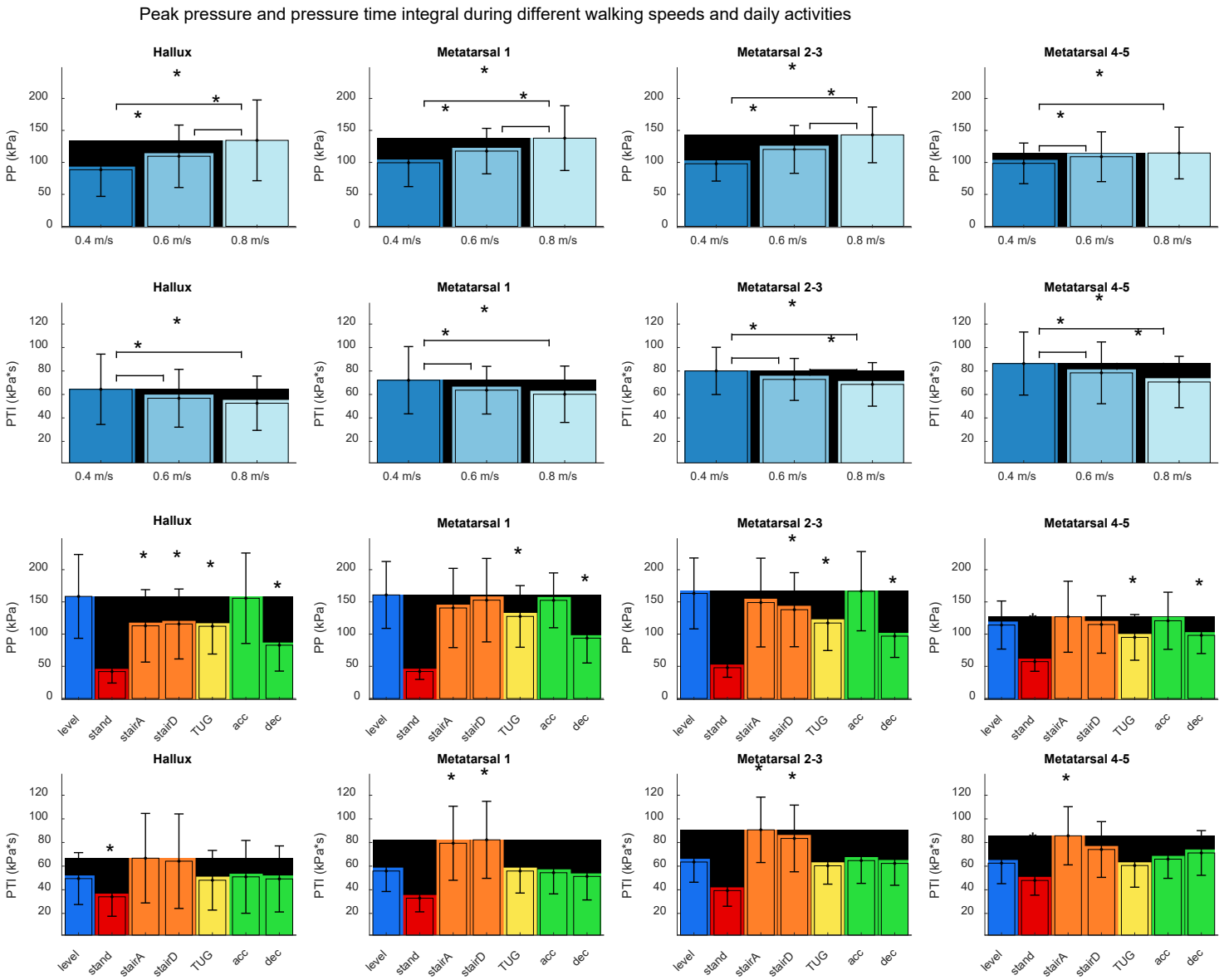


Figure 1 – Peak pressure (PP) and pressure time integral (PTI) (mean ± standard deviation) of the different walking speeds and daily activities. Top two rows: * = significantly different from each other. Bottom two rows: * = significantly different from level. (level = walking at preferred speed, stairA = stair ascending, stairD = stair descending, TUG = Timed Up and Go test, acc = accelerating, dec = decelerating)

OP02

CAN CLUSTERING BE USED TO STRATIFY PATIENTS BASED ON THEIR RISK OF DIABETIC FOOT COMPLICATION?

Roozbeh Naemi, Nachiappan Chockalingam, janet lutale, Zulfiqarali G. Abbas

Aim: The aim of this study was to assess if the patients can be divided into different strata and if those correspond to the risk of diabetic foot complications.

Methods: Data from 2284 (M/F:1310/974) patients, with diabetes, were included in this study. The data included a set of 28 parameters relating to the demographic, vascular, neurological and biomechanical status of patients. A two-step cluster analysis technique was used to divide the patients into sub-groups where patients in each sub-group show similar characteristics.

Results and Discussion: The analyses resulted in two distinct subgroups of patients: Group 1=1199(M/F:669/530) patients and Group 2=1072(M/F:636/436) patients.

From categorical parameters, only impaired sensation to touch was found to have importance at the highest levels: 87.4% of those with Normal sensation were in Group 1; whereas Group 2 compromised 95.1%, 99.3% and 90.5% of those with decreased, highly-decreased and absent sensation to touch (Fig 1).

From continuous parameters, the predictors of grouping with highest importance Group-1(Mean ± SD) vs Group-2 (Mean±SD) were: Ankle Vibration Perception Threshold-VPT (16.9 ±4.1V-vs-31.9±7.4V); Hallux VPT (16.1 ±4.7V-vs-33.1±7.9V) (Fig 2); Knee VPT(18.2±5.1V-vs-30.1±6.5V); Average Temperature Sensation Threshold to cold and hot stimuli at the foot (29.2±1.1°C-vs-26.7±0.7°C) and (35.4±1.8°C-vs-39.5±1.0°C) respectively and Average Temperature Tolerance Threshold to hot stimuli at the foot (43.4±0.9°C vs 46.6±1.3°C).

In addition, neuropathy (monofilament) was moderately important predictor (importance level= 0.52) of grouping with 26.2% of participants with neuropathy in Group-1 vs 73.5% of participants with Neuropathy in Group-2.

Furthermore, history of ulceration, current foot ulcer, and future foot ulceration were identified as parameters that contribute to grouping with more than 80% of ulcers associations in Group-2.

Conclusion: Only two distinct clusters were identified. Group 2 showed distinctive measures related to a higher level of neuropathy and associated with higher risk of diabetic foot ulceration.

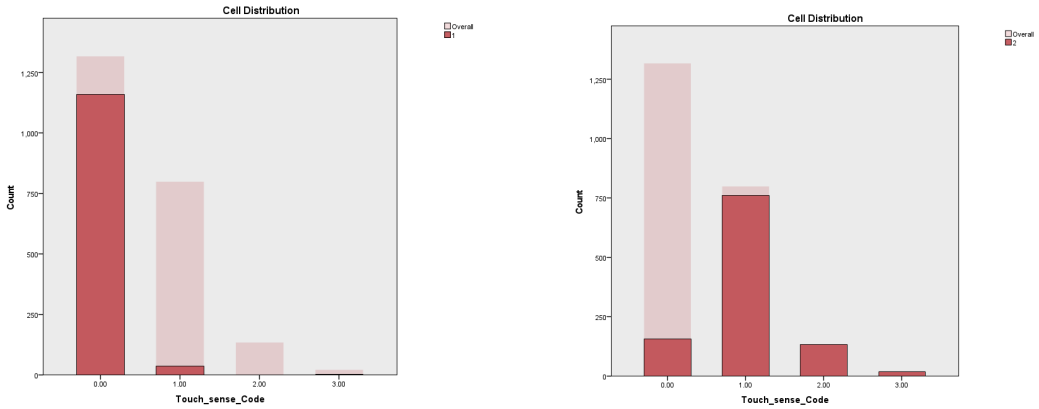


Figure 1: Distribution of participants across fours different levels of sensations: Normal (0); decreased (1), highly decreased(2) and absent (3) for Group 1 in solid vs total shaded (left) and Group 2 solid vs total shaded (Right)

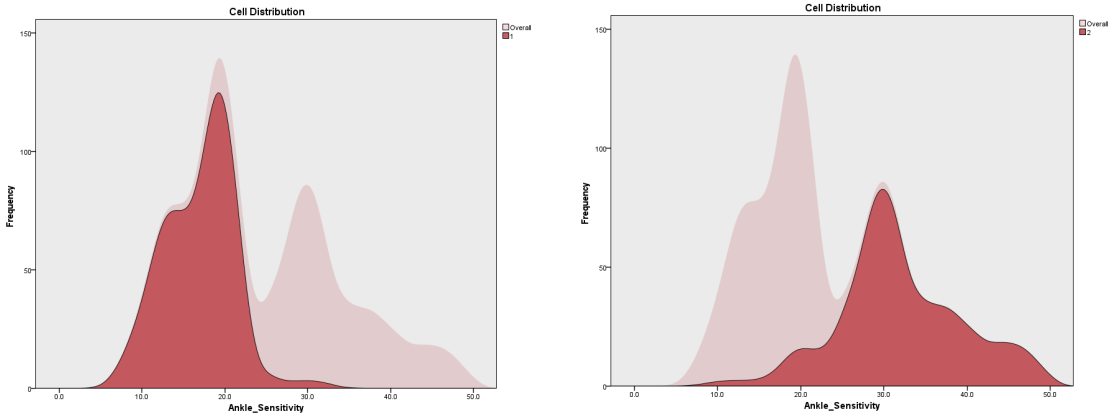


Figure 2: Distribution of Vibration Perception Threshold at Ankle (in Volts) for Group 1 solid vs total shaded (left) and Group 2 solid vs total shaded (Right)

OP03

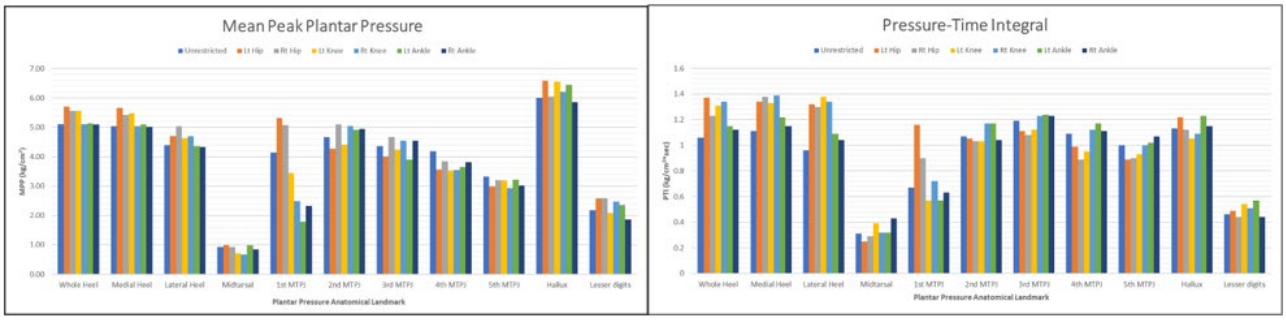
LOWER LIMB JOINT CONSIDERATIONS IN PLANTAR PRESSURE ANALYSIS

Erica Bartolo, Claudia Giacomozzi, David V Coppini, Alfred Gatt

Aim: Although there is substantial evidence that altered joint kinematics may occur in the presence of diabetic peripheral neuropathy, it is still unclear whether there is a direct influence to plantar pressure distribution resulting in ulceration. The aim of this study was to evaluate the influence of induced lower limb joint restriction on mean peak plantar pressure (MPP) and pressure-time integral (PTI) during gait.

Method: Ten adults, having no neurological, musculoskeletal or systemic conditions, which might act as confounding variables apart from induced joint restriction, were recruited. Participants were instructed to walk barefoot over a pressure mat system, where five correct trials were recorded. This procedure was repeated whilst restricting the hip joints using a hip ROM splint, the knee joints using inelastic bandaging and the ankle joints using white zinc oxide tape. MPP and PTI analysis was performed, from eleven pre-established anatomical locations in the foot.

Results / Discussion: MPP and PTI in the first MTPJ were significantly increased during hip joint restriction, indicative of a higher toe-off duration. MPP in the first MTPJ was significantly decreased with knee and ankle joint restriction, due to the possible adoption of a hip strategy as compensation to improve gait efficiency. Finally, PTI in the contralateral rearfoot regions was significantly increased during hip and knee joint restriction, suggestive of a shift in weight to the contralateral limb during heel-strike, especially since the ankle joint was not restricted.



Conclusion: Results from this study show that, apart from applying offloading techniques in the presence of ulceration, clinicians should evaluate joint kinematics, hence redistributing plantar pressures during gait and more patient-specific management strategies are developed. Moreover, along with MPP analysis, PTI changes should also be considered, since the duration of the load on a region of the foot may be equally damaging.

OP04

IMPACT OF GLOBAL LIMB ANATOMIC STAGING SYSTEM ON THE INDICATION OF CELL THERAPY IN DIABETIC PATIENTS WITH NO-OPTION CHRONIC LIMB-THREATENING ISCHEMIA

Michal Dubsky, Jitka Husakova, Robert Bem, Vladimíra Fejfarová, Alexandra Jirkovská, Radka Jarosikova, Veronika Woskova

Aim: Autologous cell therapy is an alternative treatment method for diabetic patients with no-option chronic limb-threatening ischemia (NO-CLTI). Global Vascular Guidelines presented new classification of angiograms Global Limb Anatomic Staging System (GLASS). The aim of our study was to assess the impact of GLASS grade on the indication and outcomes of cell therapy in patients with NO-CLTI and diabetes.

Method: One-hundred eight patients with NO-CLTI persisting after unsuccessful standard revascularization treated by cell therapy in our foot clinic over 11 years were enrolled in the study and followed 24 months after the procedure. ACT was injected intramuscularily into the muscles of the calf and foot. GLASS grades included femoro-popliteal (FP GLASS, grade 0-4), infrapopliteal (IP GLASS, grade 0-4) and pedal (P GLASS, grade 0-2) vascular disease. All GLASS grades were compared between amputated and non-amputated patients.

Results/Discussion: Of 108 patients treated by cell therapy 22 (20.4%) died without a causal link with cell treatment during the follow-up, major amputation was necessary to perform in 30/86 (34.8%) of surviving patients. FP GLASS grades 3-4 were present in 16/30 (53.3%) of amputated patients and in 10/56 (17.9%) of non-amputated patients ($p<0.001$). On the other hand IP GLASS grade 4 (57.2 vs 66.6%; NS) and P GLASS grade 2 (41.1 vs 40%, NS) were without a significant difference between both groups.

Conclusion: Our study proved that severe femoro-popliteal vascular disease had a negative impact on the outcome of cell therapy of NO-CLTI and confirmed the need of appropriate indication of cell therapy to treat mainly the infrapopliteal leasions.

Supported by MZO00023001.

OP05

RADIOGRAPHIC PREDICTIVE VALUES FOR VARUS AND VALGUS MIDFOOT DEFORMITY IN CHARCOT NEUROARTHROPATHY

Raúl Molines Barroso, Francisco Javier Álvaro Afonso, Yolanda García Álvarez, Esther Garcia Morales, Mateo López-Moral, José Luis Lázaro Martínez

Aim: We aimed to identify the optimal diagnostic cut-off point on the scale of radiographic measurements in the weight-bearing lateral x-ray to predict the probability of ulceration in patients with midfoot Charcot foot differentiated by varus and valgus deformities.

Method: A longitudinal prospective study was performed in a specialized diabetic foot unit between November 2018 and February 2020. Thirty-five patients with chronic Charcot neuroarthropathy midfoot deformity were included. We evaluated the following 3 radiographic measurements in a lateral view: Calcaneal pitch, lateral Meary's angle and cuboid height. Charcot feet were stratified according to varus or valgus deformity. Patients were followed for one year to identify a new event of midfoot ulceration.

Results / Discussion: Fifteen (43%) patients showed a valgus deformity, and 20 (57%) patients showed a varus deformity. Sixteen (46%) patients developed a midfoot ulceration during the following period. Lateral Meary's angle and calcaneal pith showed association with ulcer occurrence both medial ($p<0.001$ CI[5.733-11.540]; $p=0.025$ CI[1.271-15.729]) and lateral deformity ($p=0.015$ CI[0.854-6.896]; $p<0.001$ CI[5.035-8.215]). Cuboid head was associated with ulceration in those patients with a lateral pattern ($p<0.001$ CI[3.131-5.286]). All patients with valgus deformity, that developed a midfoot ulcer had a lateral talar first metatarsal angle greater (more negative) than -27.5 degrees (Sensitivity = 100, Specificity = 100%). All patients with varus deformity that developed a midfoot ulcer had a calcaneal pitch greater (more negative) than -5 degrees and a cuboid height greater (more negative) than -1.5 degrees (Sensitivity = 100%, Specificity = 100%).

Conclusion: Lateral Meary's angle is the greatest angular prediction of ulceration, with greater than -27.5º measurement correlating with ulceration occurrence in patients with Charcot midfoot deformity in valgus position. While calcaneal pitch and cuboid height are the greatest angular predictors with greater than -5º and -1.5º respectively in patients with Charcot varus deformity.

OP06

METABOLOMIC RISK PREDICTORS OF DIABETIC FOOT ULCERS

Jonas Hedegaard Andersen, Tommi Suvitaival, Kajetan Trost, Simone Theilade, Ismo Mattila, Anne Rasmussen, Marie Frimodt-Moeller, Peter Rossing, Cristina Legido-Quigly, Tarunveer Singh Ahluwalia

Aim: In this study, we investigated the association between circulating plasma metabolites and DFUs in subjects with type 1 diabetes (T1D).

Method: Plasma metabolites (n=75) and clinical characteristics from 637 individuals with T1D recruited from Steno Diabetes Center Copenhagen as part of a cross-sectional study were assessed. Baseline characteristics, DFU diagnoses at baseline and longitudinal data on development of DFU were retrieved from electronic patient journals.

Associations between single metabolites and DFU were evaluated by linear regression analyses at baseline and by Cox proportional hazards model at follow-up. Models were fitted with and without adjustments (age, gender, body mass index, systolic blood pressure, cholesterol, HbA_{1c}, smoking, statin, triglycerides, eGFR and urinary albumin excretion) and corrected for multiple testing.

Results / Discussion: Participants had a mean age of 54 (IQR 46, 62) years, 55% were male (n=348), diabetes duration 35 (25, 44) years, HbA_{1c} 64 (56, 72) mmol/mol and eGFR 85 (64, 102) ml/min/1.73m^2. In total 19 participants had DFU at baseline, and a further 108 developed DFU during a median follow-up of 10 years. In the crude model, 11 metabolites at baseline were associated with future risk of DFU. After adjustment, higher levels of ribonic acid exhibited a significantly elevated risk of future DFUs (HR 1.38(1.06-1.8) *$p<0.05$)*. Figure 1 shows DFU-free survival of participants stratified by ribonic acid at baseline measurement.

Conclusion: In this study, we identified several circulating metabolites associated with future risk of DFU in individuals with T1D. After adjustment for potential confounders and multiple testing, a sugar derivate (i.e. ribonic acid) retained significant association to future development of DFUs. Previous studies have demonstrated that ribonic acid is related to other complications (i.e. kidney disease and retinopathy) and this study adds to these findings as well as the growing evidence of predicting DFUs via measurements of plasma metabolites.

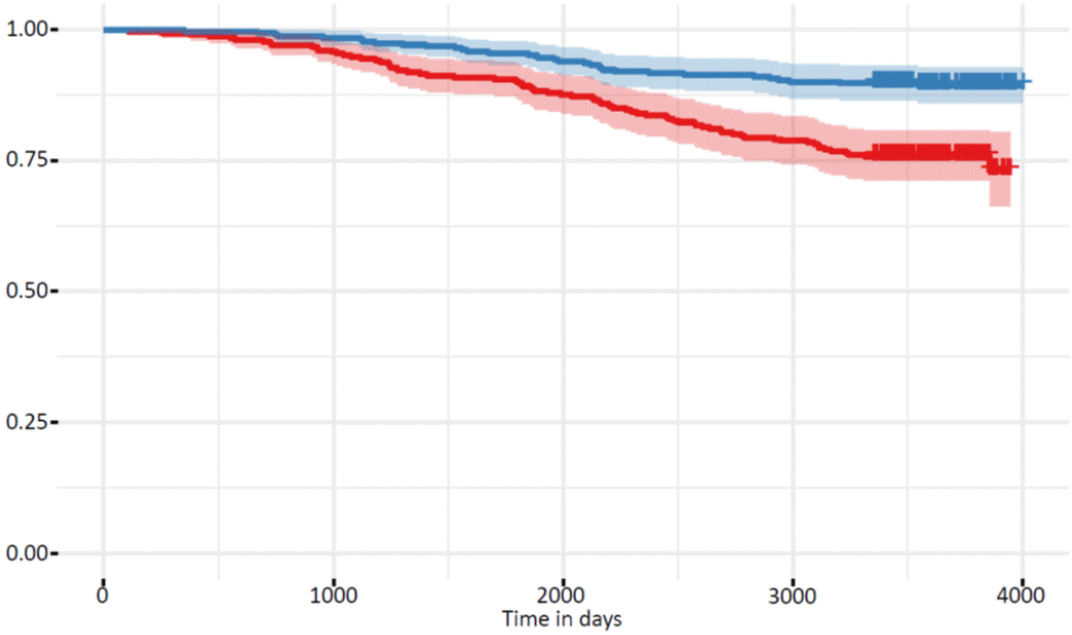


Fig.1 Kaplan-Meier estimate of DFU free days divided in 50% with highest and lowest levels of Ribonic acid

Ribonic acid >50%

Ribonic acid <50%

OP07

ARE DIGITAL ARTHRODESIS OR DIGITAL ARTHROPLASTY USEFUL AND SAFETY SURGICAL TECHNIQUES FOR THE MANAGEMENT OF DIABETIC FOOT PATIENTS?

Aroa Tardáguila García, Irene Sanz, Raúl Molines Barroso, Francisco Javier Álvaro Afonso, Esther Garcia Morales, José Luis Lázaro Martínez

Aim: To analyse the development of short-term and long-term complications in diabetic foot patients after digital arthroplasty or arthrodesis as elective, prophylactic, curative or emergent surgery.

Method: A retrospective study was carried out between January.2017-March.2020, reviewed patient´s records at specialized Diabetic Foot Unit. All patients were treated by digital arthroplasty or arthrodesis to correct deformity (elective/prophylactic surgery), achieve ulcer healing (curative surgery) or osteomyelitis management (emergent surgery). A total of 53 patients were included in the study from surgical intervention until 1-year follow-up. We registered short-term complications (dehiscence, hematoma, infection and minor amputation); and long-term complications (digital deformity, reulceration, osteomyelitis, ulcer recurrence, residual osteomyelitis and dead). We analyzed the association between the type of surgery and the development of complications.

Results/Discussion: Forty-one (77.4%) patients were men, with an average age of 66.5±9.9 years. Forty-four (83.0%) received artrophasty, and 9(17.0%) received arthrodesis. Type of surgery was distributed as follows: 1(1.9%) elective, 6(11.3%) prophylactic, 17(32,1%) curative and 29(54.7%) emergent. The mean time until healing from ulcers was 5.2±5.2 weeks. Thirty (56,6%) patients suffered short-term complications [20(37.7%) dehiscence, 15(28.3%) hematoma, 5(9.4%) infection, 1(1.9%) minor amputation] and 25(47.2%) long-term complications [18(34.0%) reulceration, 4(7.5%) osteomyelitis, 3(5.7%) digital deformity, 2(3.8%) ulcer recurrence, 2(3.8%) residual osteomyelitis, 1(1.9%) dead]. Significant differences were observed between arthrodesis and the development of long-term complications p=0.044; OR 5.1 [IC 0.9-27.2], but no differences were observed between type of surgery and short-term or long-term complications. Moreover, we observed that short-term complications were related to more time until healing p<0.001 (7.6±6.0 versus 2.1±0.5 weeks) as well, as more time until healing, 6.3±6.2 versus 4.2±4.0 weeks were related to the development of long-term complications p=0.039.

Conclusion: Digital arthroplasty or arthrodesis are good options for the management of diabetic foot patients that require digital deformity correction, achieve digital ulcer healing or management of osteomyelitis in phalanges.

OP08

AUDIT OF ACTIVE CHARCOT FEET: CHARACTERISTICS, TREATMENT OUTCOMES AND COMPLICATIONS

Robert Bem, Veronika Woskova, Vladimíra Fejfarová, Petr Teyssler, Radka Jarosikova, Jitka Husakova, Karol Sutoris, Bedrich Sixta, Michal Dubský

Aim: The diabetic Charcot foot (CF) is a serious complication of diabetes that can often lead to major amputation. The aim of our study was to review the characteristics, treatment outcomes and complications in patients with diabetes related CF treated at our foot clinic.

Method: A total of 279 Charcot feet in 231 patients (mean age 60.6±11.9 years, 70% men) treated in our foot clinic were included in the study between 2014-2021 and retrospectively analysed. Diabetes and foot related characteristics, type of treatment, bilateral CF involvement, ulcer and amputation rates were recorded.

Results / Discussion: Of 231, 184 CF patients were treated conservatively, 20.3% of patients underwent orthopaedic surgery. 20.8% of all CF patients had bilateral involvement. Major amputation-free survival was achieved in 98.2% feet after a mean follow-up of 3.7 years. Foot ulcers were present in 40.1% of feet, 19% of feet required minor amputations and 15.1% of feet needed other foot surgery.

Conclusion: Conservative and orthopaedic treatment led to increased number of saved limbs in patients with CF in our centre. A common complication of CF treatment is the occurrence of foot ulcers and the associated need for surgery.

This study was supported by MHCR IN 00023001.

OP09

OP09 MANAGEMENT OF SEVERE DIABETIC FOOT INFECTION: A SYSTEMATIC REVIEW OF SURGICAL MANAGEMENT AND OUTCOMES

Raju Ahluwalia, Ines Reichert, Michael Edmonds, Sze Ping Tan

Introduction

The 'diabetic-foot-attack' (DFA) is a limb-threatening presentation of severe diabetic foot infection (DFI) presenting as rapidly progressive skin and tissue necrosis. This systematic review of providers aims to analyse and recommend evidence-based best-practice management for patients presenting with severe DFI (IWGDF/IDSA 3 and 4).

Methods

A systematic review following PRISMA guidelines by 2 independent reviewers up to Feb 2021. All identified guidelines, full-text articles on diagnostic including clinical assessment and treatment modalities including surgical techniques utilized in the management of 'severe' DFI included for qualitative analyses. (PROSPERO Registration Number: CRD42021238249).

Results

1168 reports were identified, 86 were included (21 guidelines on general management, 23 assessing bacterial composition/antibiotic choice, 8 focusing on vascular assessment, 14 assessing local antibiotic application and 14 surgical techniques, and 6 wound care).

Clear consensus is reached on positive PTB test, ulcer area >2cm squared or >3mm in depth as suggestive of osteomyelitis and a percutaneous bone biopsy recommended for definitive diagnosis after MR imaging .. Urgent referral to a specialist foot care team within 24 hours for intravenous broad-spectrum antibiotics, protocolised surgical debridement to reduce length-of-stay and gentamicin-impregnated beads were recommended. Deep tissue cultures and non-invasive vascular studies (for revascularisation) should be obtained after surgical debridement. Certain bacteria are more commonly reported e.g., Haemolytic Strep. Staged reconstruction to restore stability in the foot and wound closure with split thickness skin grafting/pedicle flaps are recommended. Limb salvage is achievable, but outcomes are affected by age, presentation, and comorbidities e.g., PVD.

Conclusion

There is a paucity of literature on specific surgical approaches in severe DFI. Standardised treatment including resuscitation for systemic stabilisation, and microbial assessment, is well defined. Anatomical understanding of infection spread, with protocolised surgical resection of devitalised tissue is mandated. Application of local antibiotic carriers, systemic antibiotic duration, and staged reconstruction policies need further evaluation.

OP10

OP10 PROGNOSTIC FACTORS IN SEVERE DIABETIC FOOT INFECTION: A SURVIVORSHIP ANALYSIS.

Raju Ahluwalia, Julie Whitehouse, Abraham Bashir, Aditya Bitla, Aizaz Tabish, Michael Edmonds, Amine Dincer

Background/introduction: The typical Diabetic Foot Attack (DFA) is an acute presentation of diabetic foot disease involving severe infection and an inflammatory response, which can be systemic. Infection can affect both bone and joint tissue and spread through the soft tissue planes leading to necrosis and a surgical emergency. We determine prognostic or risk factors that influence 5-year survival and major limb amputation in patients with a DFA.

Methods: Prospective data was collected of patients presenting with a neuropathic, non-ischaemic infected foot, to a MDFT from May 2014 – May 2016. All patients were followed up for 5 years. 94 patients presented with diabetic foot ulcers (DFUs) classified as IDSA/ IWGDF Grade 3: infection in a patient without systemic inflammatory response signs; and 30 presented with DFUs classified IDSA/ IWGDF Grade 4: infection in a patient with systemic toxicity. 114 pooled-patient-samples were included in final analysis using SPSS Statistics (version 26).

Results: Overall, 5-predictors were associated with an increased likelihood of 5-year mortality; age ($p<0.001$); CRP(>100) on admission ($p<0.05$), both minor ($p<0.05$)/major amputation ($p<0.05$); and on-going soft tissue wound care requiring a day case debridement ($p<0.05$). These 5 variables correctly classified 5-yr mortality in 76.1% of cases, with a specificity of 91.0% and NPV of 78.0%. The number of debridement's which a patient received in the index admission was statistically significant in predicting future readmission to hospital ($p<0.02$). Adjusting for initial severity, the subsequent development of treatable-PVD was a marker for amputation and mortality in the grade 4 presentations.

Discussion: Following protocolised treatment; age and admission CRP (>100) can be used in a risk-stratification tool rationalising more aggressive patient management. Multiple debridement predicts further in-patient readmission, whilst minor/major amputation, and increased duration of post episode wound care, subsequent development of treatable-PVD increased mortality. These indicators can be used in disease stratification and treatment strategies.

OP11

THE COVID-19 PANDEMIC STRONGLY REDUCED THE PRESENTATION RATE OF DIABETIC FOOT ULCERS IN BELGIUM, BUT THE IMPACT ON SEVERITY WAS LIMITED TO SLIGHTLY LARGER LESIONS

An-Sofie Vanherwegen, Frank Nobels, Kris Doggen, Eveline Dirinck, Patrick Lauwers, the IQED-Foot COVID-19 Working Group

Aim: The Belgian government introduced a national COVID-19 lockdown from 14/03 until 03/05/2020. Free movement was restricted and only urgent medical care was allowed. Although diabetic foot clinics (DFC) were advised to treat all foot problems as urgent, patients were reluctant to visit the hospital. This study investigates the impact of the lockdown on presentation rate and diabetic foot ulcer (DFU) severity at presentation.

Method: Within the ongoing national care quality improvement initiative (IQED-Foot), a prospective cohort study was conducted among 22 DFC. 887 consecutive patients with DFU of Wagner grade ≥ 2 were included. Patients were divided based on their first contact: pre-lockdown group (A, first contact between 01/01 and 13/03/2020, n=322) or (post-)lockdown group (B, first contact between 14/03 and 30/09/2020, n=565).

Results: All DFC, except one, remained open for active foot problems with implementation of COVID-19 measures. During lockdown, the average weekly presentation rate was strongly reduced (0.6 vs. 1.4 patients/week/DFC in 2018; p<0.001). However, median patient-reported presentation delay did not increase (A: 3 [1-8] vs. B: 3 [1-7] weeks; p=0,81). Demographic data such as gender, age, diabetes type and duration were not different. Patients that presented during/after lockdown had less frequently a prior DFU (B: 50% vs. A: 60%; p=0,005). Regarding DFU severity, patients seen during/after lockdown had less frequently critical ischemia (B: 11% vs. A: 18%; p=0.0103) and presented with slightly larger lesions (< 1cm^2 B: 32% vs. A: 38%; p=0.0003, 1-3cm^2 B: 45% vs. A: 40%; p=0.0152). No differences in depth, infection or loss of protective sensation were observed.

Conclusion: DFC in Belgium remained accessible to patients with foot problems. Although patient inclusion was strongly reduced, overall presentation delay did not increase. The impact on DFU severity was limited to slightly larger lesions. Follow-up is ongoing and outcome data will be available by September.

OP12

THE IMPACT OF COVID-19 PANDEMIC ON LOWER EXTREMITY AMPUTATIONS

Amanda Killeen, Michael Siah, Javier La Fontaine, Matthew Malone, Lawrence Lavery

Aim: To compare the total lower extremity amputations, and level of amputation, during one year of the COVID-19 pandemic to total lower extremity amputations for three years prior.

Method: All lower extremity amputation current procedural terminology (CPT) codes were queried from the electronic medical record between the dates of March 1, 2017 and February 29, 2021 at one site. Parkland Hospital is a public health system serving needy, underserved, and indigent population in Dallas County. Amputation levels were defined as "knee or above" which includes knee disarticulation, all transfemoral amputations, hip disarticulation, and interpelviabdominal amputation; "below knee" which includes ankle disarticulation and all transtibial amputations; or "foot." Forefoot amputations are defined as amputation at the interphalangeal joints, metatarsophalangeal joint, or amputation of the toe with distal metatarsal head resection.

Amputation totals for the three years prior to COVID-19 (March 1, 2017-February 28, 2020) were included in one group and compared to amputation totals during one year of COVID-19 (March 1, 2020-February 29, 2021). Proportional comparison was performed with chi square.

Results / Discussion:

Table 1. Level of Amputation – Parkland Hospital

	3 Years Prior to COVID-19 N=3050	**1 Year of COVID-19** N=1111	**p-value**
Knee or above	336 (11.0%)	112 (10.1%)	0.39
Below knee	700 (23.0%)	301 (27.1%)	**0.005**
Foot	2014 (66.0%)	698 (62.8%)	0.055
Lisfranc/Chopart	23 (1.1%)	29 (4.2%)	**<0.001**
Transmetatarsal	620 (30.8%)	220 (31.5%)	0.72
Forefoot	1371 (44%)	449 (64.3%)	0.07

Conclusion: The COVID-19 pandemic resulted in significantly increased below knee amputations. Of the limbs that were salvaged, there were significantly more amputations at the Lisfranc/Chopart level.

OP13

THE CHANGES OF OUT-PATIENT CLINIC ORGANISATION AND DIABETIC FOOT MANAGEMENT DURING THE COVID-19 EPIDEMIC IN 2020

Vilma Urbancic-Rovan, Mojca Lunder

Background and aims: Continuous structured care is essential for prevention of diabetic foot complications. COVID-19 epidemic significantly influenced the organization of work at the out-patient foot clinic at our University hospital in 2020. We aimed to evaluate the changes in diabetic foot management during the epidemic.

Methods: The data on cumulative patient visits, foot screening, number of patients with foot ulcers and referrals to other specialists in the years 2019 and 2020 were collected. The data from the COVID-19 lock-down periods (March 12 – May 14, and October 19 – December 31, 2020) were compared to non-lock-down periods in 2019 and 2020. One-way analysis of variance (ANOVA) was used.

Results / Discussion: Cumulative number of patient visits in 2020 was significantly lower than in 2019 (4471 vs. 5610; P=0.05) due to the lock-down periods (table, P<0.01) when significantly less screening procedures were performed, the number of other activities remained almost unchanged (table).

It is important to emphasize that throughout the epidemic, including lock-down periods, the clinic remained open for all patients with foot ulcers or other acute foot problems without suspected COVID-19. Telephone and e-mail consultations were also available.

Table: Summary of the clinic activities

	Average N/month ± SEM		
	2019	**2020 (non-lock-down)**	**2020 (lock-down)**
Clinic visits	467.5±17.3	443.0±22.3	274.2±23.5 **
Foot screening	234.3±27.1	224.4±15.3	79.4±10.5 ***
Foot ulcer management	274.0±7.9	264.7±7.9	214.8±15.0
Emergency visits	25.5±1.5	25.1±1.5	24.2±1.3
Referrals: imaging procedures	11.4±0.9	12.8±2.6	10.9±1.3
Referrals: vascular procedures	9.0±1.1	6.2±1.0	7.6±1.4

** P<0.01 and *** P<0.001 vs. non-lock down and 2019

Conclusion: The COVID-19 epidemic outbreak influenced the organization of work at our foot clinic. The average monthly number of visits decreased significantly during the lock-down periods, mainly due to reduced preventative activities. Importantly, foot ulcer management, referrals to imaging and vascular procedures remained stable, indicating good accessibility of the emergency foot care services.

OP14

LOWER LIMB AMPUTATION RATE AND PREDICTIVE FACTORS IN IN DIABETIC FOOT PATIENTS DURING PANDEMIC COVID 19

Carolina Chaves, Guilherme Vaz de Assunção, João Diogo Castro, Pedro Cantista, Lia Ferreira, Cláudia Amaral, Cláudia Freitas, Helena Neto, Joana Martins, Luís Loureiro, Luís Costa, Miguel Abreu, André Gomes, Sara Pinto, Joel Pereira, Rosa Guimarães, André Carvalho, Rui Carvalho

Aim: COVID19 pandemic limited the provision of health care during lockdown period. Despite that, our Diabetic Foot Unit (DFU) maintained in-person care to at-risk patients.

Method: Evaluate clinical and demographic characteristics, predictive factors of and amputation rate in a population with foot ulcers (FU) hospitalized during lockdown period (2020) and up to 3 months after it, compared with a population admitted in the same conditions in the first 6 months of 2019. To assess predictive factors for amputation in 2020, a control population with ulcers, but without amputation, was considered.

Results / Discussion: During 2020 period, 101 patients were admitted (males: 75.2%) with a median age of 69 years (min-max: 44-90), 91.9% with type 2 diabetes mellitus (DM2), of which 63% underwent amputation (minor: 51; major: 13). Amputee patients (males: 75%) had median age of 68 years (min-max: 44-88), 92.2% had DM2 with a median duration of 20 years (min-max: 5-32). Amputee patients had longer time ulcers (median: 2 months vs 1 month, p=0.73) and severe infection (PEDIS4 64.1% vs 10.8%,p<0.001) than non-amputee counterparts. Amputation was significantly more frequent in: patients admitted from the emergency department (ED) than those from the FU clinic (61% vs 29.4%, p=0.021); patients with peripheral arterial disease (92.1% vs 81,1%, p=0.023), forefoot ulcers (93.7% vs 64.9%, p<0.001) or gangrene (54.7%vs 2.9%,p<0.001). The total number of amputations in 2020 compared with 2019 did not rise (n=64 vs n=66), nor major amputations (n=13 vs n=15). Amputee patients had a significant increase in hospitalization from the ED in 2020 vs 2019 (56% vs 36%, p=0.007) and an increase of severity of infection at admission (PEDIS 4: 64% vs 48%, p=0.13).

Conclusion: The maintenance of FU consultations maintained the number of amputations stable during lockdown period, although patients were hospitalized preferentially from the ED, with more severe infection.

OP15

THE NOVEL USE OF A SMARTPHONE APPLICATION TO ENABLE RAPID COMMUNICATION BETWEEN COMMUNITY FOOT HEALTH SERVICES AND AN ACUTE HOSPITAL MULTIDISCIPLINARY FOOT TEAM IN COVID-19.

Daina Walton, Elsa Ahrens, Sara Vautier, Maureen Bates, Jennifer Tremlett, Michael Edmonds

Aim: In response to Covid-19, a hospital based multidisciplinary foot team (MDFT), which remained open during the pandemic, collaborated with the local community podiatry service to offer select patients shared care. Our aim was to investigate the use of a novel smartphone application to support shared care of high-risk foot complications in persons with diabetes and foot ulceration between these services.

Method: Data was collected from the smartphone application and electronic patient records during the first three-months using the application to summarise patient demographics, wound characteristics and frequency of care.

Results / Discussion: 30 patients received shared care. Within this cohort, 83% were male, 93% had Type 2 Diabetes, age (mean ± SD) 73 ± 12 years, HbA1c (mean ± SD) 8.3 ± 2.7%, 71.1 ± 32.1 mmol/mol and 33% had chronic kidney disease. On initial consultation, 63% presented with SINBAD score of 3 or more. 53% identified as an ethnic minority group.

110 remote consultations discussing their shared care took place. The average response time by the MDFT to a message sent from community podiatry was 17 minutes.

Reasons for remote consultations were: 11% required an appointment to be expedited to the MDFT, 20% required review of wound progress and antibiotic plan, 27% required virtual MDFT consultations due to their individual concerns attending hospital during the pandemic and 41% were for a podiatric led wound review.

During these three-months, six patients were admitted to hospital, but only three were admitted directly for an acute foot complication. Four received angioplasty and one had minor amputation. There were no major amputations or deaths. No patients contracted Covid-19.

Conclusion: The increased frequency of review by community podiatry and rapid communication relayed to the MDFT via a smartphone application ensured the safe continuation of shared care for those with foot ulceration during Covid-19.

OP16

PREDICTIVE FACTORS FOR MAJOR AMPUTATION IN HOSPITALIZED PATIENTS WITH NEUROISCHEMIC DIABETIC FOOT INFECTION

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Aim: Diabetic foot ulcers are one of the most disabling complications of diabetes. The presence of infection is a common complication, leading frequently to hospitalization and potentiates major amputation. The aim of this study was to determine predictive factors for early major amputation in hospitalized patients with neuroischemic diabetic foot infection.

Method: We conducted a retrospective and observational study of patients admitted in our center with neuroischemic diabetic foot infection between January 2010 and December 2017. The predictive value of relevant demographic and clinical variables for major amputation at 30 days was evaluated.

Results / Discussion: During the study period, 322 patients were hospitalized with neuroischemic diabetic foot infection. Thirty days after admission 13.0% (n=42) of the patients had been submitted to a major amputation. The hindfoot location of the ulcer was associated with a higher rate of amputation (25.0% vs 10.9%, p=0.017), as well as absent/unsuccessful lower-limb revascularization (17.7% vs 6.2%, p=0.004). The amputation group was older, had a lower level of hemoglobin, albumin and pre-albumin at admission, as well as a higher level of platelets, leukocytes and C-reactive protein. After multivariate analysis, we confirmed that age [OR 1.04 (years), p=0.018], hindfoot location (OR 2.39, p=0.034), revascularization (OR 0.31, p=0.006), hemoglobin [OR 0.75 (g/dL), p=0.010], platelets [OR 1.01 (x10^3/μL), p=0.001], leukocytes [OR 1.15 (x10^3/μL), p=0.001], C-reactive protein [OR 1.01 (mg/L), p=0.037] and albumin levels [OR 0.09 (g/dL), p <0.001] were independently associated to major amputation. No association was found regarding sex, type, duration or other complications of diabetes, other cardiovascular risk factors, previous amputation or microbiological isolation.

Conclusion: Age, hindfoot location, absent/unsuccessful lower-limb revascularization, as well as hemoglobin, platelets, inflammatory parameters and albumin levels are predictive factors for early major amputation in hospitalized patients with neuroischemic diabetic foot infection.

OP17

WEIGHT-BEARING ACTIVITY IN PEOPLE WITH DIABETIC FOOT DISEASE: A SYSTEMATIC REVIEW

Vera Fijen, Jaap van Netten, Sicco Bus

Aim: Despite the importance of promoting weight-bearing activity for people with diabetic foot disease, it may also contribute to an increased risk of ulceration or delay in ulcer healing. However, whether a difference exists in weight-bearing activity between people at different stages of foot disease is unknown. We aimed to investigate quantitatively-measured daily activity level in people with various stages of diabetic foot disease.

Method: We systematically searched the peer-reviewed literature for studies reporting objectively-measured weight-bearing activity in people with diabetes at risk of or with a foot ulcer. Step or stride count was extracted from included publications. Means (over studies) and weighted-means (over total number of participants) were calculated for comparison between different IWGDF-strata. Comparisons were also made between activity indoors and outdoors, and between different climates.

Results: From a total 1130 publications found, 23 were included. People with IWGDF risk category 1 and 2 were found to take a mean 6,782 steps/day (11 studies; 320 participants; weighted mean: 5,445), people in IWGDF risk category 3 a mean 6,575 (7 studies; 261 participants; weighted mean: 6,334), and those with a foot ulcer a mean 4,343 (5 studies; 156 participants; weighted mean 4,620). People who lived in a temperate oceanic climate were more active compared to people who lived in hotter or more humid climates (mean steps/day for no ulcer: 7,712 vs 5,266 [16 studies]; for ulcer: 6,819 vs. 2,669 [5 studies], respectively). Three studies that separated indoor and outdoor activity showed that people were more active indoors (mean 4,047 vs. 2,514).

Conclusion: Weight-bearing activity in people with diabetes who are at risk of ulceration seems to be similar between the various IWGDF ulcer risk strata, but is lower for those with a foot ulcer. Weight-bearing activity differs depending on the climatological environment, and is higher indoors then outdoors.

OP18

RELATIONSHIP BETWEEN THE ACE I/D POLYMORPHISM AND CIRCULATING LEVELS AND RISK OF LOWER-EXTREMITY AMPUTATION IN PATIENTS WITH TYPE 1 DIABETES

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Aim: The insertion/deletion (I/D) polymorphism in the angiotensin-converting-enzyme (*ACE*) gene has been widely studied in people with diabetes, but not with respect to lower-extremity amputation (LEA). We examined the associations between *ACE* I/D genotype, plasma ACE concentrations and LEA in people with type 1 diabetes.

Method: *ACE* I/D genotype and plasma ACE concentrations were assessed in 3 prospective cohorts of participants with type 1 diabetes. LEA was defined as a limb removal above the metatarsophalangeal joint resulting from nontraumatic causes. Linear, logistic and Cox proportional hazard regression models were computed to evaluate the likelihood of LEA at baseline and during follow-up according to *ACE* genotype (XD [ID or ID] versus II) and plasma concentrations, after adjusting for confounders.

Results/Discussion: Among 1301 participants (male 54%, age 41±13 years, diabetes duration 24±11 years), 90 (6.9%) participants had a baseline history of LEA. Baseline LEA was more prevalent in XD (7.4%) than in II genotype (4.5%): OR 2.17 (95%CI, 1.03–4.60, p=0.04). Incident LEA occurred in 53 individuals during a median duration of follow-up of 14 (25^{th}-75^{th} percentiles, 6-19) years. The incidence was higher in XD *versus* II carriers (4.3 [3.2–5.7] versus 1.7 [0.6–4.5] per 1000 person-years): HR 3.26 [1.16–13.67], p=0.02. The D-allele was also associated with more prevalent LEA at the end of study (OR 2.48 [1.33–4.65], p=0.004). LEA was associated with high ACE concentrations among II carriers (449 [360 – 539] versus 354 [286–423] ng/ml, mean [95%CI], p=0.03), but not in XD carriers (512 [454–570] versus 537 [488–586], p=0.27).

Conclusion: We reported the first independent association between the D-allele of the *ACE* I/D polymorphism and excess risk of LEA in patients with type 1 diabetes. Further studies are needed to investigate the role of ACE in the pathophysiology of lower-limb complications in people with diabetes.

OP19

A NEW TOOL TO DIAGNOSE LOCAL WOUND INFECTION: THE TILI SCORE (THERAPEUTIC INDEX FOR LOCAL INFECTION)

Eric Senneville

Aim: An important pathophysiological characteristic of diabetic foot ulcers (DFUs) is a reduced immune response, and as a result, opportunistic pathogens may colonize and lead to infected DFUs, with a risk of osteomyelitis, amputation and death. Diagnosis of local infection in chronic wounds, such as DFUs, may be difficult for non-expert health care providers. We report herein a specific diagnostic tool of local infection in chronic wounds which aims to start early antimicrobial treatment.

Method: An interdisciplinary panel of wound experts from seven European countries was brought together to discuss how to diagnose local wound infection and developed a new therapeutic index for local infection (TILI Score). This score has been assessed and validated through a study conducted in 6 European countries.

Results / Discussion: Six indicative parameters were selected to diagnose local wound infection: erythema, heat, edema, induration/swelling, spontaneous or pressure pain, stalled wound healing and increase and/or change in color or smell of exudate. The study performed in 307 patients with non-DFU wounds suggested that the presence of at least 5 of these 6 parameters indicates the use of a local antimicrobial treatment. In DFUs, local antimicrobial therapy being currently not recommended, systemic antibiotic therapy should be discussed in case of such clinical signs, noting that diabetes may minimize the inflammatory signs.

Conclusion: The TILI Score can be used by any caregiver in daily practice to early diagnose local infection and seems adapted for use in patients with a suspicion of DFU and to discuss the indication of a systemic antibiotic therapy given the high risks of bad outcome in these settings.

OP20

INCIDENCE AND RISK FACTORS OF DIABETIC FOOT DISEASE IN PATIENTS EARLY AFTER PANCREAS OR SIMULTANEOUS PANCREAS AND KIDNEY TRANSPLANTATION

Vladimíra Fejfarová, Eliška Vrátná, Jitka Husakova, Simona Kratochvilova, Peter Girman, František Saudek, Michal Dubský, Robert Bem, Veronika Woskova, Alexandra Jirkovská, Radka Jarosikova, Věra Lánská

Diabetic foot (DF) can develop in diabetic patients after organ transplantation (Tx) due to several factors including peripheral arterial disease (PAD), diabetic neuropathy and insufficient DF prevention.

Aim: To assess the occurrence of DF and associated risk factors in transplant patients.

Methods: Fifty-seven diabetic patients were enrolled as part of this prospective study. All patients underwent organ Tx (01/2013-12/2015) and were followed up on average for 32.7±10.6 months. Over the study period we evaluated DF incidence and identified number of factors DF development, including organ function, presence of late complications, PAD, history of DF, levels of physical activity before and after Tx, patient education and standards of DF prevention.

Results: DF developed in 31.6% (18/57) of patients after organ Tx within 10.7±8 months. The following factors significantly correlated with DF development: diabetes control before Tx (p=0.007), PAD (p<0.0001), transcutaneous oxygen pressure ($TcPO_2$; p=0.0003), history of DF (p=0.003), presence of deformities (p=0.002) and increased leisure-time physical activity before Tx (p=0.037). However, based on stepwise logistic regression analysis, the only factors significantly associated with DF during the post-transplant period were: PAD (OR 47.19; 95% CI=6.55–623.7; p< 0,0001), deformities (OR 11.5; 95% CI=2.27–75.2; p=0.003) and increased leisure-time physical activity (OR 3.1; 95% CI=1.09–11.15; p=0.034). Education was provided to patients periodically (2.6±2.5 times) during the observation period. Although 94.7% of patients regularly inspected their feet (4.5±2.9 times/week), only 26.3% of transplant patients used appropriate footwear.

Conclusion: Incidence of DF was relatively high, affecting almost 1/3 of pancreas and kidney/pancreas recipients. The predominant risk factors were: presence of PAD, foot deformities and higher leisure-time physical activity before Tx. Therefore, we recommend a programme involving more detailed vascular and physical examinations and more intensive education focusing on physical activity and DF prevention in high-risk patients before Tx.

GAUK 546417, SVV260466, UK Progress Q41, IN 00023001, NU20-01-00078

OP21

HEALTH LITERACY AND COGNITION INDEPENDENTLY PREDICT INCIDENT FOOT ULCERS AFTER 4 YEARS – THE SOUTHERN TASMANIAN HEALTH LITERACY AND FOOT ULCER DEVELOPMENT IN DIABETES (SHELLED) COHORT STUDY

Pam Chen, Tania Winzenberg, Karen Wills, Michele Callisaya, Tim Greenaway

Aim: Poor health literacy (HL) is associated with poorer health outcomes in diabetes but little is known about its effects on foot disease. This study aimed to determine the associations between HL and index diabetic foot ulcer development over 4 years.

Method: This is a 4-year prospective study of incident foot ulcer development in people with diabetes from a tertiary hospital diabetes outpatient clinic. 222 individuals aged over 40 years and without a history of foot disease, psychotic disorders or dementia we recruited. The primary outcome measure was development of a first foot ulcer. Key exposure measures included HL, measured using the short form Test of Functional Health Literacy in Adults (s-TOFHLA) and the Health Literacy Questionnaire (HLQ). Baseline risk factors for diabetic foot disease of peripheral neuropathy, peripheral arterial disease and foot deformity were assessed according to published guidelines. Covariates included cognition, diabetes and foot care self-efficacy, depression, diabetes distress, diabetes knowledge and foot care behaviour.

Results / Discussion: Of 222 participants, 191 (86.0%) completed the study, with 178 (80.1%) ulcer free and 13 had developed an incident ulcer. Every unit increase in S-TOFHLA score and HLQ score reduced the odds of foot ulcer development by 6% (OR 0.94, 95% CI 0.88, 0.99) and 4% (OR 0.96, 95% CI 0.94, 0.99) respectively. Every unit increase in cognition scores reduced the odds for foot ulcer development by as much as 23% (OR 0.77, 95% CI 0.63, 0.94). These findings were independent of category of risk for foot disease at baseline.

Conclusion: These data provide novel evidence that health literacy and cognitive deficits may be significant clinical risk factors for index foot ulceration. Healthcare policymakers and providers should identify and target people with these deficits, and tailor educational programs for diabetic foot disease prevention to meet their needs.

OP22

OP22 STAGE 0 CHARCOT NEUROPATHY: A SYSTEMATIC REVIEW OF DIAGNOSTIC MODALITIES AND OUTCOMES.

Amine Dincer, Raju Ahluwalia, Michael Edmonds

Introduction: Stage 0 Charcot Neuroarthropathy (CN) refers to pre-radiological detection of the CN process thus providing an opportunity to halt disease progression with offloading. We aim to identify imaging modalities with the highest diagnostic value(s) in Stage 0 CN.

Methods: A systematic review following PRISMA guidelines by 2 independent reviewers to February 2021 Observational studies and reviews that evaluated a diagnostic modality in Stage 0 CN i.e., imaging or microbiological studies, clinical assessment(s) were included for qualitative analyses.

Results: 89 studies were identified including eight studies assessing six diagnostic modalities (MRI, SPECT/CT, bone-scintography, 18F-FDG PET/CT, ultrasound and histological analysis). Three studies singularly reported detailed MRI diagnostic findings of Stage 0 CN, which included subchondral bone marrow oedema/cysts, adjacent soft tissue oedema and closed subcortical trabecular micro-fractures. 18F-FDG-PET/CT, assessed the range of foot metabolic activity which correlated with MRI findings, occasionally predating them. SPECT/CT localised tracer uptake of bone scintigraphy, and osteoblastic repair activity to subchondral location of ligaments or tendon insertions in Stage 0 CN. CT-findings demonstrated cortical disruption, periosteal reaction and intraosseous fractures. Ultrasonography detected active soft tissue inflammation and revealed joint effusions, synovitis, and bone-erosions. Furthermore, MRI and 18F-FDG-PET/CT scanning provided an objective measure of the inflammatory process which can be useful for monitoring the disease process. Two studies assessed CN progression to deformity after identification of stage 0, recording deformity development as 16.5% (8-25%) of cases even with standard off-loading.

Conclusion: Today, no standardised guidelines exist for the diagnosis of Stage 0 CN. Each diagnostic modality reports discrete but different functional-anatomic changes, with uncertain diagnostic value in Stage 0 CN. Future validation and consensus on diagnostic pathway(s) for Stage 0 CN are required, as the combination of early recognition and immobilisation/off-loading has been shown to prevent disease progression to major deformity.

OP23

SCREENING FOR DEPRESSIVE SYMPTOMS AMONGST PATIENTS WITH DIABETIC PERIPHERAL NEUROPATHY

Cynthia Formosa, Nikolaos Papanas, rahab alghafri, Alfred Gatt

Aim: Depression is a growing concern in the 21st century. The study aimed to determine the relationship between having diabetic peripheral neuropathy and the development of depressive symptoms in patient with type 2 diabetes mellitus (T2DM).

Method: A comparative non-experimental study was conducted. Ninety five T2DM individuals aged 65 years and more were recruited. The sample was divided into two groups; 50 participants with T2DM only and 45 participants with DPN. The Patient Health Questionnaire-9 (PHQ-9) was used to collect information about low mood/depression symptoms in the recruited subjects.

Results / Discussion: Participants with DPN recorded higher scores of PHQ-9 than those with T2DM only. The mean PHQ 9 score for the Diabetic Peripheral Neuropathy group (6.09) was significantly higher than the mean PHQ 9 score for the T2DM group (2.24) ($p<0.001$). Participants with DPN were more likely to have a mild/moderate or moderately severe low mood/depression symptoms, when compared to Type 2 DM participants who exhibited minimal to no low mood/depressive symptoms. Based on our data, this study demonstrates that depression and anxiety disorders exist more frequently in patients with diabetes and DPN. We aim to alert clinicians to the fact that low mood and depression are common in patients with diabetes presenting with DPN and that these conditions can complicate matters and impair positive outcomes if both are overlooked and not addressed simaltaneosly in the clinical scenario.

Conclusion: The association between diabetic neuropathy and depression is confirmed, with significant depressive symptoms found in patients with neuropathy when compared to patients with diabetes with no complications. Complaints caused by DPN and emotional problems associated with DPN should be addressed in the management of DPN in order to prevent depressive symptoms. A call for change in screening practices to help identify patients with DM and depressive symptoms is warranted.

OP24

THE ROLE OF THE CORRECT EXECUTION OF EXERCISES IN THE PREVENTION OF THE DIABETIC FOOT

Piergiorgio Francia, Alessandra De Bellis, Giulia Iannone, Roberto Anichini

Aim: It is well known that exercise therapy (ET) can play an important role in the prevention of diabetic foot ulcers. The aim of this work was to verify how the quality in the execution of exercises affects the results obtained by ET in patients with diabetes.

Method: Fourteen sedentary subjects with diabetes at low risk of foot ulceration, mean age 59.9±9.0 yrs, gender (m/f : 10/4), BMI 27.6±3.7 kg / m2, yrs of disease 22.9±11.4 years, followed an ET of 12 weeks (twice a week). The program consisted of 11 exercises aimed at improving joint mobility of the lower limbs and balance. Before and at the end of the training, parameters relating to gait speed (15 m), Borg rating of perceived exertion (RPE), ankle joint mobility, ankle muscle strength, and quality of execution of the exercises were evaluated (1: correct; 2 not properly executed; 3 not performed).

Results / Discussion: The quality of exercise execution recorded was not correlated with the other parameters investigated. Toe mobilization and balance exercises were the most difficult to perform correctly (scores: 1.86 and 1.71 respectively). Blood glucose, joint mobility, muscle strength and walking speed improved significantly after the training period ($p < 0.01$). After the training period, walking speed was instead correlated with joint mobility ($r = -0.57$; $p = 0.035$), muscle strength ($r = -0.67$; $p = 0.009$) and blood glucose ($r = 1$; $p < 0.001$).

Conclusion: The initial sedentary condition of the patients may justify the significant improvements in the parameters studied and the lack of relationship found between the quality of the execution of the exercises and the other parameters investigated. However, avoiding exercise execution errors, in addition to be able to achieved better results, appear to be important in order to reduce the risk of injury and ulceration.

OP25

EFFECT OF TLC-NOSF DRESSINGS IN NEURO-ISCHAEMIC DFUS CONSIDERING THEIR LEVEL OF ISCHAEMIA: POST-HOC ANALYSIS OF THE EXPLORER RCT

José Luis Lazaro Martinez, Mike Edmonds, Jacques Martini, Ralf Lobmann, Alberto Piaggesi, Serge Bohbot

Aim: The Explorer trial, a European double-blind, randomised controlled trial (RCT), published in 2028, has established that introducing a TLC-NOSF dressing into a good local standard of care (SoC) significantly improves the clinical outcomes (wound closure - 48% vs 30% at Week 20 - and healing time) of neuroischaemic diabetic foot ulcers (NI DFUs). Considering the impairment of the vascular network of those NI DFUs may explain the poor prognosis of these wounds. We aimed to evaluate the effect of the TLC-NOSF dressing in the subgroups of patients categorised by the level of ischemia

Method: A descriptive post-hoc analysis of the Explorer data, based on ITT population (240 patients) were performed. To be eligible, a patient's Ankle Brachial Pressure Index (ABPI) score had to be 0.9 or less and Toe Pressure of at least 50 mm Hg (or Ankle Pressure at least 70 mm Hg if toe pressure could not be measured). In case of ABPI greater than 0.9, a Toe Brachial Pressure Index (TBPI) score of 0.7 or less and toe pressure of at least 50 mm Hg were mandatory. To answer the issue, we divided the treated population between Mild ischaemia (ABPI 0.7-0.9 and TBPI 0.5-0.7. N=159) and Moderate ischemia (ABPI <0.7 or TBPI <0.5. N=81).

Results / Discussion: In the global population (well balanced between groups), amputation history and revascularisation history were 61% and 48%, respectively. After 20 weeks of treatment, clinical outcomes were always in favour of the TLC-NOSF treatment, with very consistent closure rates ranging between 47% and 49% within the TLC-NOSF group and between 27% and 36% within the control group, when respectively considering the mild and moderate ischaemia groups.

Conclusion: This clinical evidence supports that treating DFUs with TLC-NOSF dressings (and good SoC) results in higher wound closure rates whatever level of ischaemia.

OP26

PERFORMANCES OF TLC-NOSF POLY-ABSORBENT DRESSINGS ON DIABETIC FOOT ULCERS: RESULTS OF A MULTICENTRE, PROSPECTIVE, OBSERVATIONAL STUDY

Ralf Lobmann

Aim: This clinical evaluation aimed to assess the performances of TLC-NOSF dressings with poly-absorbent fibres in the local management of diabetic foot ulcers (DFUs) in an unselected patient population under real-life settings.

Method: A large, prospective, multicentre observational study with three different TLC-NOSF poly-absorbent dressings* was conducted in 55 centres across Germany between January 2019 and June 2020. The main endpoints included wound healing rate and progression, health-related quality-of-life (HRQoL) improvement, and tolerability and acceptability of the dressings.

Results/Discussion: Altogether 217 patients with a DFU were treated with the evaluated dressings for a mean duration of 63±30 days. By the final visit, 57.6% of the ulcers healed, 32.3% improved, 4.1% were stabilized, and 4.1% worsened. A clear improvement was reported in the majority of the patients on all HRQoL parameters, in particular regarding disturbing discharge (73.9%), fears of wound deterioration (71.0%), frustration due to long-healing time (65.2%), pain (68.1%), patients' mobility: moving troubles (69.6%), difficulties in climbing stairs (65.2%), limitation of leisure activities (66.7%), and dependency of help from others (65.2%). The dressings were 'very well' tolerated (88.9%) and 'very well' accepted (83.4%) by a large majority of the patients.

Conclusion: These results show the good performance of the TLC-NOSF dressings in improving wound healing and HRQoL of patients treated in real-life, and support the current guidelines recommending their use in the local management of DFUs.
*UrgoStart Plus Pad, UrgoStart Plus and UrgoStart Plus Border, Laboratoires URGO, France

OP27

USE OF HUMAN PLACENTAL DERIVED PRODUCTS IN THE TREATMENT OF DIABETIC FOOT ULCERS: A SYSTEMATIC REVIEW & META-ANALYSIS OF RANDOMISED CONTROLLED TRIALS

Yashvini Khambhatya, Amar Sethi, Prash Vas

Aim: Diabetic-foot-ulcerations (DFUs) can lead to significant morbidity and health-economic costs. Human placental-derived-products (hPDP) contain a cocktail of growth factors, anti-inflammatory cytokines and pro-angiogenic factors with potential to kick-start healing in chronic-DFUs which are frequently unresponsive to standard-of-care (SOC). Given the increasing focus on this technology, we undertook a systematic-review and meta-analysis on the efficacy of hPDM in promoting DFU-healing.

Method: Ovid-MEDLINE, Embase and Cochrane Central Register of Controlled Trials (CENTRAL) were searched until 01 March 2021. Trials comparing hPDP + SOC vs SOC alone or advanced placental product were screened and selected. Primary outcome was the proportion of wound-healing at 6,12 and 24-weeks. As a secondary outcome we evaluated cost-effectiveness of adjuvant hPDP treatment

Results: From 1069 citations, 13 studies met the inclusion criteria for our review. 11 RCTs covering a total of 749 participants (397 patients, 352 controls) were included in the meta-analysis. Proportion of complete wound-healing in hPDP + SOC cohort was 4.01 times higher than SOC alone (RR: 4.01, [95% CI, 2.54, 6,35) at 6-weeks and 1.84 times higher (RR: 1.84, [95% CI, 1.58, 2.15) at 12-weeks. No data for sustained wound healing at 24-weeks was reported. Only 6 studies reported cost of hPDP-allograft use with an estimated cost of $2925 (range $306 - $12, 394) per healed ulcer at 12-weeks. Significant heterogeneity of patients and DFUs between studies was noted and overall, the risk of bias of was found to be high.

Conclusion: Adjuvant hPDP DFU-treatment increases the likelihood of DFU healing at 6 and 12-weeks but the high risk of bias in studies was a significant limitation. Future studies need to include more homogenous recruitment criteria and equilibrate SOC provision between centres. Only then can the various health economies evaluate the clinical and cost-effectiveness of this promising technology.

OP28

FACTORS INFLUENCING THE RISK OF MAJOR AMPUTATION OF PATIENTS WITH DIABETIC FOOT SYNDROME AFTER AUTOLOGOUS CELL THERAPY

Jitka Husakova, Robert Bem, Vladimíra Fejfarová, Alexandra Jirkovská, Veronika Woskova, Radka Jarosikova, Michal Dubský

Aim: Autologous cell therapy (ACT) is currently the last option for limb salvage in the patients with chronic limb-threatening ischemia (CLTI) and diabetic foot disease (DFD). However, in some patients it is still necessary to perform a major amputation even after ACT. The aim of our study was to assess the risk factors for the major amputation during 2 years follow-up after ACT in patients with CLTI and DFD.

Method: One-hundred thirteen patients were included into our study and divided into the group with major amputation (AMP; n= 37) and group without amputation (nAMP, n = 76). The major amputation risk factors were evaluated before ACT and included factors relating to the patient, to DFD and to the cell product.

Results / Discussion: The AMP group had significantly higher C-reactive protein (CRP) levels compared to the nAMP group (22.7 vs. 10.7mg/l, p=0.024). In stepwise logistic regression independent predictors for major amputation were mutation of the gene for methylenetetrahydrofolate reductase with polymorphism 1298 (MTHFR A1298C) (OR 4.33 [95% CI 1.05-17.6]), smoking (OR 3.83 [95% CI 1.18-12.5]) and CRP >10 mg/l (OR 2.76 [95% CI 0.93-8.21]). Lower transcutaneous oxygen pressure ($TcPO_2$) values were observed in AMP patients compared to the nAMP group at one month (24.5 vs. 33.2, p=0.012) and at 3 months (31.1 vs. 40.92, p=0.011) after ACT.

Conclusion: Our study showed that the risk of major amputation after ACT in diabetic patients with CLTI is increased by MTHFR gene mutations, smoking and higher CRP at baseline. Lower $TcPO_2$ one and 3 months after ACT may also have a predictive value. Therefore, it is necessary to stop smoking before ACT, treat any infection and, above all, indicate anti-aggregation or anticoagulant treatment after the procedure.
Supported by MZO 00023001 and by GAUK No. 304321.

OP29

HOW INDEPENDENT, BASED ON THE IADL SCORE, ARE PATIENTS ADMITTED FOR A DIABETIC FOOT ULCER?

Marianne Bertels, Asma Benkheil, Noor Gerets, Christophe De Block, Jeroen Hendriks, Saskia Van Bouwel, Eveline Dirinck, Patrick Lauwers

Aim: Diabetic foot ulcers (DFU) are an invalidating complication of diabetes mellitus. Functional status can be assessed by the Instrumental Activities in Daily Living (IADL) questionnaire. The IADL has not been studied extensively in DFU patients.

To determine IADL score in DFU patients, and to evaluate the relation between IADL score and DFU severity and outcome.

Method: This is an observational prospective cohort study at the Antwerp University Hospital (30/6/2019-31/8/2020). The IADL scale scores 8 items, and was assessed at admission and after six months. A higher score indicates independent functioning. The patient population was subdivided in two groups: IADL score ≤ 6/8 versus > 6/8. Outcome was determined as healing, non-healing, minor or major amputation, or death.

Results: 45 patients were included, predominantly male (89%), with a mean age of 70 years.

IADL score at admission was 5.8/8. Men scored less (5.6/8) compared to women (7/8) ($p=0.113$). Age showed a negative correlation ($r = -0.411$, $p < 0.05$) with IADL score. No significant differences were found between IADL score at admission and DFU severity or outcome at discharge.

After six months, 18 patients (47%) had a stable IADL score. 15 patients (39%) declined while 5 (13%) improved. IADL score was comparable for men and women (5.1/8 versus 5.2/8). More amputations were performed in the group with a higher IADL score at admission ($p=0.022$). Patients who had a major amputation had a steady or deteriorating IADL score ($p=0.005$). The outcome after six months did not differ according to the IADL score at admission.

Conclusion: At admission, a negative correlation between age and IADL score is found. The IADL score is reduced after six months. Outcome after six months does not differ according to IADL score at admission. More amputations are performed in the group with the high IADL score.

OP30

DISEASE KNOWLEDGE ABOUT DIABETIC FOOT AMONG PERSONS WITH DIFFERENT RISK OF ULCER OCCURRENCE ACCORDING TO THE INTERNATIONAL WORKING GROUP GUIDELINES

Marta García-Madrid Martín de Almagro, Mateo López Moral, Aroa Tardáguila García, Irene Sanz, Francisco Javier Alvaro Afonso, José Luis Lázaro Martínez

Aim: To analyze levels of understanding about diabetic foot care and prevention in persons with diabetes according to International Working Group (IWGDF) risk stratification system.

Method: A descriptive study was conducted in 80 persons (20 each group) with diabetes at different level of risk for foot ulceration (IWGDF risk 0-3). A previously validated questionnaire, the PIN Questionnaire, was used to analyze their levels of understanding of foot complications and pathophysiology. Participants were asked to indicate on a 5-point response scale, ranging from 1 = strongly disagree to 5 = strongly agree.

Results / Discussion: IWGDF-3 risk patients identified that good circulation and absence of polyneuropathy in their feet were related to healthy feet in comparison with the rest of the groups (19.6 ± 2.7, $p<.001$ and 14.2 ± 0.7, $p<.001$ respectively). IWGDF-3 risk patients found to know that a foot ulcer (DFU) on their feet will not get pain on their feet in comparison with the rest of the groups (6.6 ± 2.8, $p<.001$). Additionally, IWGDF-3 risk patients found to know which physical causes could affect the development of a DFU (18 ± 1.4, $p<.001$) and that foot self-care and medical control could prevent DFU appearance (23.4 ± 2.15, $p<.001$ and 13.9 ± 0.9, $p<.001$ respectively). Regarding the capability to anticipate complications and the worry about them we did not find any difference between groups. Finally, IWGDF-3 risk patients of DFU occurrence found to be the group of patients with a lower anger against practitioners (2.65 ± 1.12, $p<.001$).

Conclusion: IWGDF-3 patients found to know the natural progression of diabetes foot complications and how to prevent them. Clinicians and diabetes educators should focus on their efforts to educate persons with diabetes at lower risk of foot ulcer (IWGDF 0-2) to prevent further complications.

OP31

OBESITY AND DECREASED VIBRATION PERCEPTION ASSOCIATED WITH PREMATURE CARDIOVASCULAR MORTALITY IN A SINGLE CENTRE PROSPECTIVE OF STUDY OF PEOPLE WITH DIABETES

Dragan Tesic, Dragica Tesic, Miroslav Tomic, Stefan Andric, Mirjana Tomic

Aim: The aim of this prospective, single centre study was to define factors associated with early cardiovascular mortality in diabetes.

Method: 1345 patients under age 75 were included who were undergoing assessment of their diabetes between January 2008 and May 2010. Peripheral artery disease (PAD), peripheral neuropathy and diabetic retinopathy (DR) were assessed. Data on micro- and macro- vascular complications were collected. Outcome was determined in 2021 and baseline characteristics were compared between those who had and had not suffered cardiovascular death under age 75 years within 10 years of review in two casually selected cohorts.

Results / Discussion: Those who died (n2=70) were more frequently male (60 vs. 45.3%, p=0.08), younger (66.4±7.4 vs. 79.9±3.4, p<0.000) when compared to those still alive (n1=75). Those who died were also significantly (p<0.01) more likely to have had TEA/CVI (34.3 vs. 10.7%), HF (21.4 vs. 1.3%), MI (44.3 vs. 20%), PAD (48.6 vs. 9.3%), DFU (25.7 vs. 9.3%), mAMP (17.1 vs. 1.3%) at baseline. Minor amputations were significantly more likely (8.6 vs. 1.3%, p<0.04). Following multivariable logistic regression analysis significant differences between groups remained for only creatinine (123±45 vs. 88.9±16.9 mmol/L, p<0.003) and VPT <5 (7.8 [95% CI: 3.7-16.4)], p=0.008), cholesterol >6.2 mmol/l (2.0 [95% CI: 1.0-4.0)], p<0.05), estimated maximum lifetime BMI (3.4 [95% CI: 1.7-6.8)], p<0.000), alcohol usage (4.7 [95% CI: 1.5-14.7)], p=0.005), smoking habit (2.2 [95% CI: 1.1-4.3)], p<0.03) and earlier age of diabetes onset (43.4±12.5 vs. 49.2±9.9, p=0.0029).

Conclusion: Decreased VPT, the presence of PAD on clinical testing and higher maximum estimated lifetime BMI are strongly associated with premature cardiovascular death. These measures may be independent markers of greater risk of reduced life expectancy.

OP32

ADHERENCE TO WEARING THERAPEUTIC FOOTWEAR DURING WEIGHT-BEARING ACTIVITIES IN ADULT AMBULATORY PEOPLE WITH DIABETES AND LOSS OF PROTECTIVE SENSATION

Kim Tijhuis, Chantal Hulshof, Jaap van Netten, Mirjam Pijnappels, Sicco Bus

Aim: Adherence to wearing therapeutic footwear helps prevent diabetic foot ulcers. Few studies have measured adherence objectively, while those who did only used walked steps to determine adherence. We aimed to investigate footwear adherence during a variety of weight-bearing activities in people with diabetes and loss of protective sensation.

Method: Wearing time of all therapeutic footwear worn by each of 14 participants (3 female, Age 62.9±8.7, BMI 29.0±4.1, 100% IWGDF risk 3) was measured for seven consecutive days with a temperature-based sensor placed in the shoe insole. Wearing time was the time that prescribed footwear was worn. Daily-life physical activity behavior was simultaneously measured with a tri-axial accelerometer. Adherence was calculated as the proportion of wearing time during weight-bearing activities or daily steps. Weight-bearing activities included walking, standing, shuffling and stair walking.

Results / Discussion: Adherence during all weight-bearing activities was 69.7±19.3%, during standing 69.2±19.8% and daily steps 71.1±19.1%. Time spent standing was significantly higher than for walking, shuffling and stair walking (2.1±0.8h/day, 1.4±0.6h/day, 0.4±0.1h/day, 0.1±0.04h/day, respectively, $p<0.025$). We found a high correlation between wearing time and adherence during all weight-bearing activities ($r=0.904$, $p<0.001$). During the morning and afternoon hours participants were significantly more adherent (77.4±20.6%, 77.3±23.1%) than night and evening hours (Figure 1). Participants were more adherent outside than inside their house (77.4±24.8 vs. 63.3±22.0%, $p=0.019$). Four participants were classified as adherent (≥80%) and had compared to those who were not, a higher number of steps per day (8831±2599 vs. 4033±2138, $p=0.024$) and higher adherence during walking (87.7±3.9% vs. 64.2±18.7%) (Figure 1).

Conclusion: Adherence to wearing therapeutic footwear during weight-bearing activities is insufficient in this high-risk population. Furthermore, adherence should be assessed during more weight-bearing activities than just walking, as people spend longer times standing during which adherence may be different. A personalized plan for adherence improvement is desirable.

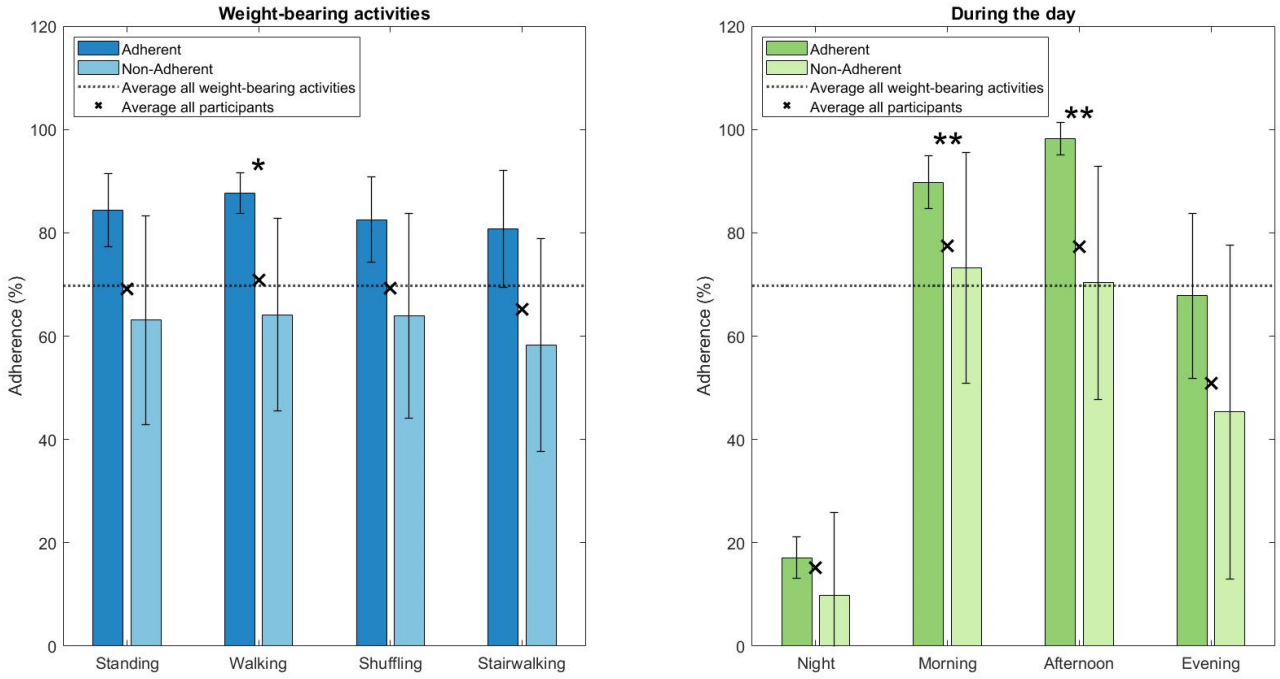

Figure 1 – Adherence (mean and standard deviation) of different weight-bearing activities (left figure) and during the day (right figure), compared between adherent (≥80%) and non-adherent participants. *Significant different between adherent (≥80%) and non-adherent group (p=0.031). **Significantly different compared to night (p<0.001) and evening (p<0.026).

EP01

IN-SHOE DIAGNOSTIC TECHNOLOGIES FOR ULCER PREVENTION OF THE DIABETIC FOOT

Claire Saliba Thorne, Alfred Gatt, Clifford DeRaffaele, Abduarahman Bazena

Aim: To provide rigorous analysis of literature related on technologies that measure in-shoe plantar pressures and skin temperatures simultaneously. In addition to this, this review looked into the validity, reliability and responsiveness of such devices.

Method: Literature related to the topic was searched in database sources. Outcome measures of interest included validity, reliability and responsiveness of in-shoe temperature/pressure mapping device used, quantity of sensors used, anatomical landmarks. Quality of evidence and risk of bias was evaluated using the QUADAS-2.

Results/Discussion: Nineteen studies were identified and included. The majority of studies used a small sample size of healthy participants. All studies have shown excellent validity but only 6 tested for the reliability of the device. None of the studies tested for responsiveness. Quality assessment results scored high-risk in view of 'patient selection', 'use of reference standard', 'applicability', and low-risk in view of 'use if index test' and 'flow/timing'. Despite the fact that these studies focused on diabetes, we expected them to investigate the validity and reliability of their device on participants living with diabetes mellitus rather than on healthy individuals. We had also expected to find more studies that have utilized devices that are able to measure in-shoe pressure and in-shoe temperature simultaneously. Current evidence of a newly developed cost-effective device that is able to measure in-shoe temperature and pressure simultaneously, is not robust enough to confirm the reliability and validity of such a device.

Conclusion: This review provides a comprehensive understanding of the available technologies that simultaneously measure in-shoe plantar pressures/temperature. This review confirms that further reliability testing and clinical validation these devices is required. Information gathered from this review, can be useful in identifying functioning characteristics of mentioned devices to develop a reliable and valid, in-shoe pressure and temperature device that can be used to predict ulceration.

EP02

GAIT ALTERATION AND FOOT DEFORMITIES IN CHILDREN LIVING WITH TYPE 1 DIABETES

Alfred Gatt, Roxanne Agius, Tiziana Mifsud, Darren Sillato, John Gerard Torpiano, Cynthia Formosa

Aim: This study aimed to determine if T1DM children aged between 10-16 years exhibit altered foot pathologies and gait parameters when compared with same-aged children without any medical conditions.

Method: This quantitative research study employed a non-experimental, case-control study design. Thirty-four (η=34) participants were recruited and divided into Group A, healthy children (η=16) and Group B (η=18), T1DM children. All participants underwent a clinical biomechanical examination followed by instrumented gait analysis using the Oxford Foot Model in order to investigate foot segment motion.

Results / Discussion: T1DM children demonstrated more dermatological lesions such as hyperkeratosis (33.3%) and in-growing toenails (22%) and structural foot abnormalities including claw toes (33.3%), hammer toes (22.2%) and hallux abducto-valgus (11.1%) than their healthy counterparts. 72.2% of T1DM children live with a pronated foot type as compared to 50% of heathy children. Gait analysis results indicate a significant difference between the two groups at the hindfoot to tibia angle at heel strike and toe-off, suggesting limited ankle joint motion. Dynamic ankle range of motion correlated well with the static clinical findings of the ankle joint in the T1DM children population. Reduced ankle dorsiflexion range of motion is a significant foot type that is known to affect foot function and can lead to deformity, thus illustrating the aetiology of the clinical findings.

Conclusion: Children with T1DM demonstrated a higher frequency of structural foot pathologies than non-diabetic children possibly associated with limited ankle sagittal plane movement. Screening is warranted to identify and manage these conditions early in order to reduce their risk of more significant foot problems associated with DM in adulthood.

EP03

CORRELATION OF SKIN ADVANCED GLYCATION END PRODUCTS WITH PARAMETERS OF DISTAL SENSORIMOTOR POLYNEUROPATHY IN SUBJECTS WITH TYPE 2 DIABETES MELLITUS

Stella Papachristou, Grigorios Trypsianis, Kalliopi Pafili, Dimitrios Papazoglou, Konstantinos Vadikolias, Nikolaos Papanas

INTRODUCTION: Skin advanced glycation end products (AGEs) may be increased in diabetes mellitus.

AIM OF THE STUDY: To examine the correlation between skin AGEs and parameters of distal sensorimotor polyneuropathy (DSPN) in subjects with type 2 diabetes mellitus (T2DM).

MATERIALS AND METHODS: Overall, 132 subjects (88 men, 44 women) with a mean age of 64.57±8.21 years and median T2DM duration of 14.50 years were included. Skin AGEs were measured with AGE reader mu connect (Diagnoptics) on the dominant arm. Single and triplicate measurements were performed. Diagnosis of DSPN was based on the neuropathy disability score (NDS). Small nerve fibre function was evaluated by temperature and pinprick sensation on the foot. Vibration perception threshold (VPT) on the hallux was measured with a neurothesiometer (Horwell Scientific Laboratory Supplies).

RESULTS: Simple AGEs measurement was positively correlated with their triplicate measurement (Pearson's Correlation Coefficient r=0.991, 95% CI=0.987-0.994, p<0.001). In simple measurement, AGEs were higher among subjects with vs. those without DSPN (3.31±0.73 vs. 2.55±0.56, p<0.001). Furthermore, they were higher among subjects with reduced vs. normal temperature sensation (3.18±0.72 vs. 2.51±0.56, p<0.001), among subjects with reduced vs. normal pinprick sensation (3.86±0.32 vs. 2.84±0.72, p=0.002), as well as among those with abnormal vs. normal VPT (3.45±0.69 vs. 2.74±0.68, p<0.001). The same significant differences were observed in triplicate measurement.
CONCLUSIONS: In T2DM, skin AGEs are increased in the presence of DSPN. Moreover, they are increased, when there is small nerve fibre impairment or abnormal VPT.

EP04

UTILITY OF SUDOMOTOR FUNCTION TEST TO DETECT THE FIRST DIABETIC FOOT ULCER DEVELOPMENT.

Irene Sanz Corbalán, Raúl Molines Barroso, Francisco Javier Alvaro Afonso, Yolanda García Álvarez, Esther Garcia Morales, José Luis Lázaro Martínez

Aim: to evaluate the diagnostic accuracy of sudomotor function test (SFT) in the first ulcer development in patients with risk 0 by the International Working Group of Diabetic Foot (IWGDF) risk stratification system in a follow-up of 10 years.

Method: Follow-up prospective study with 92 patients from the Diabetic Foot Unit enrolled consecutively between July 2011 and April 2015 and follow up to January 2021. Diabetic patients without active foot ulcer were classified with 0 risk IWGDF risk stratification system (without neuropathy, arterial vascular disease, foot deformity and history of ulceration and amputation). The patients were divided in two groups according to diabetic neuropathy examination: Group A, had Semmes-Weinstein Monofilament (SWM)/Biothensiometer not affected and SFT affected, and Group B, had all the tests not affected.

Results / Discussion: Forty-eight (52.2%) of the patients were men and the mean age of the sample was 73±9.8 years. Fifty-eight patients were included in the Group A and 6 of them (10.3%) developed diabetic foot ulcer. Thirty-four patients were included in the Group B and 1 (2.9%) of them developed diabetic foot ulcer. The patients were follow-up for 10 years and the ulcer was developed with a mean follow-up of 45.5 ± 35.4 months.

The sensitivity of SFT was 0.85, the specificity was 0.38, positive predictive value was 0.10 and negative predictive value was 0.97.

The risk stratification systems in the literature evaluate diabetic neuropathy by SWM/Biothesiometer, but these tests do not detect the patients without risk to develop the first foot ulcer. SFT has high sensitivity to detect patients with diabetic neuropathy and consider the patient in a higher level of risk.

Conclusion: The SFT has more diagnostic accuracy to detect patients with risk to develop the first diabetic foot ulcer for 10 years follow-up.

EP05

MANAGEMENT OF NEW DIABETIC FOOT ULCER DURING COVID-19 PANDEMIC

Cesare Miranda, giorgio zanette, silvia grazioli, maurizio tonizzo, andrea da porto, roberto da ros

Aim: Diabetic foot ulcer (DFU) is a major cause of morbidity and mortality in the world Early referral to multidisciplinary diabetic foot clinics can decrease progression of disease, but Covid-19 Pandemic is changing our approaches and our health care organization.The aim of this study was to evaluate the clinical characteristics and outcomes for subjects with new diabetic foot ulcer admitted at our clinic during year 2020

Method: We analized retrospectively 199 patients with diabetitc foot ulcer presenting at diabetic foot visit from February 2020 to December 2020.We identified 59 patients with new diabetic foot ulcer, but 6 patients were excluded from study because lost to follow-up.All participants after the first outpatient visit or hospitalization had regular clinical follow-up.Healing, major amputation, death and rate of COVID-19 infection were evaluated.

Results / Discussion: The mean age was 75.8 ±11.9 years, 40.7% patients were over 80 years,63% were male and 93% had type 2 diabetes,mean HbA1c was 7.68±1.8%.Among patients included, 35.6% were admitted for emergency and 72.9% reported previous ulcers. The mean ulcer duration was 29.9 ± 30.4 days. Most DFUs were infected (61.2%), deep to muscle, tendon or bone and over half (52.5%) were ischemic.Hypertension (74.6%), end-stage renal disease (47.7%) and ischemic heart disease (34.5%) were the most frequent comorbidities.Thirty-three (62.2%) patients healed, 10 (18.9%) had a minor amputation, while 2 (3.8%) had a major amputation and 9 (15%) patients died due to cardiac complications.

Conclusion: The spread of SARS-CoV-2 in Italy has changed the organization of health care systems dramatically, but our data show that patients with new lesions are elderly and unfortunately 30.5% of them had an ulcer for over a month.DFU cannot wait and even during the COVID-19 pandemic we must treat the ulcer early if we are to increase the likelihood of healing and reduce the rate of amputation.

EP06

LOWER LIMB AMPUTATIONS IN SWEDEN: INCIDENCE, TIME TRENDS, AND REGIONAL VARIATIONS

Gustav Jarl, Ayako Hiyoshi, Michael Carlberg, Anton Johannesson, Stefan Jansson

Aim: Epidemiological studies on temporal changes in incidence of lower limb amputations (LLA) and their regional variation in Sweden are scarce. Previous reports have either excluded partial foot amputations or not distinguished between amputations above and below the knee. The aim of the study was to examine the national time trend and regional variation in incidence of LLA in Sweden over the recent 10 years.

Method: Data on all incident (lifetime first) LLA on people 18 years and older were identified using relevant procedure codes recorded in the national inpatient register between 2008 and 2017. Amputations were categorized into three levels: 1) high proximal (through or above the knee), 2) low proximal (below the knee), and 3) partial foot amputations (excluding toe amputations). Poisson regression models were fitted to estimate amputation incidence rates and their annual changes with adjustment for age (10-year groups) and sex. Regional variation was examined at county-level, which divides Sweden into 21 regions. Rates are shown by per 100,000 inhabitants.

Results / Discussion: The LLA incidence (all levels combined) significantly decreased annually by 1.6% during the period, and this trend appeared to be driven by decreases of high proximal and low proximal amputations (Table 1). No significant change of partial foot amputations incidence was observed. The decline in the incidence of all LLA were, however, not shared by all regions; 9 regions showed declines, but 12 regions showed stable trends. The ratio of the highest to lowest amputation incidence among regions was 1.9 for all LLA levels combined, 2.6 for high proximal amputations, 3.2 for low proximal amputations, and 27.0 for partial foot amputations.

Conclusion: Amputation incidence has decreased in Sweden but regional variations in incidence, time trends, and amputation levels call for more research.

Table 1. Amputation incidence (per 100,000 inhabitants), regional variation and time trends.

Amputation levels	N (%)	National incidence	Regional variation, min – max	Incidence change/year, (95% CI)
All amputations	16,941 (100)	22.1	17.6 – 34.3	0.984 (0.973 – 0.994)
High proximal	7,051 (41.6)	9.2	6.4 – 16.6	0.985 (0.974 – 0.995)
Low proximal	8,207 (48.4)	10.7	5.2 – 16.4	0.973 (0.962 – 0.984)
Partial foot	1,683 (9.9)	2.2	0.2 – 5.4	0.994 (0.974 – 1.014)

EP07

MULTIDISCIPLINARY DIABETIC FOOT CLINIC: 12-MONTH OUTCOMES AND RECOMMENDATIONS

Morwan Bahi

Aim: Diabetic foot disease is a common presentation in patients with poorly controlled diabetes resulting in high rates of infection, limb loss or death. There has been a move towards establishment of multidisciplinary diabetic foot clinics (MDFC) to identify high risk patients with diabetic foot ulcers in an attempt to provide best outcomes and minimise morbidity and mortality. We present 12-month outcomes from our local MDFC.

Method: We conducted a retrospective, single-centre study reporting outcomes of patients seen in the multidisciplinary DFC in a large tertiary hospital over a 12-month period between 1 January 2019 and 31 December 2019.

Results: Between 1 January 2019 and 31 December 2019, 52 patients were seen in our MDFC with a mean age 58.6 +/- 12.8 years and a male predominance of 60%. Common co-morbidities were renal disease (57%) and ischaemic heart disease (23%). Outcomes for these patients were observed over the subsequent 12-month period. There was a total of 19 hospital admission events for diabetic foot infection involving 17 patients (32.7%); 14 of those 17 patients (82%) had evidence of underlying peripheral vascular disease requiring revascularization. There was a total of 14 minor amputation events and 6 major-limb amputations (11%). Seven patients out of the 52 seen in clinic had passed away at 12 months. The initial ulcer/wound reviewed in clinic was healed in 28 (54%) of patients at 12 months.

Conclusion: The establishment of MDFC has allowed identification of high-risk diabetic ulcer patients early and provided an avenue for diagnosis of underlying peripheral vascular disease at an earlier stage. We believe this has led to an increase in the rate of minor amputations and a subsequent reduction in the rate of major-limb amputations. We report an over 50% rate of wound healing in the 12 months following the initial appointment.

EP08

PERSONS WITH DIABETES EXPERIENCE USING GAIT-ANALYSIS AND EFFICACY OF OFFLOADING.

Mette Guldbæk, Klaus Kirketerp-Møller, Anne Mette Rosenfalck, Anne Rasmussen

Aim: The aim of this pilot study was to evaluate the educational guidance, and persons with diabetes ability to understand the importance of offloading, by using gait-analysis insoles and interviews.

Method: Twenty high risk persons with foot ulcer, previous foot ulcer or Charcot foot was included, for gait-analysis. They walk 20 meters 4 times in prescribed footwear with insoles and therapeutic sandals with rigid rocker bottom without insoles (New Feet® Denmark). Elastic sensor insole Pedar X (Novel® Munich, Germany) was used to measure plantar pressure. A high-risk area, Point of Interest (POI), was chosen for comparison between the two types of footwear.

Person experience was evaluated with short semi-structured questions after performing the gait-analysis and one months after by phone. Diabetes related data was collected from our electronic patient record.

Results / Discussion: Mean age 58,5 years (range 46-77 years), 11 (55%) Type2 diabetes, 17 (85%) males, diabetes duration were 27,3 years (range 2-66 years), HbA1c 66 mmol (range 32-105 mmol), BMI 28,9 (range 15,9-43,1) and 20 (100%) had peripheral neuropathy (vibration threshold > 25 V). Twelve (60%) with foot ulcer, 16 (89%) with previous foot ulcer, 7 (35%) Charcot foot, and 5 (25%) had toe-amputations. ΔPOI in prescribed footwear had a range from 72 – 210 kPa and ΔPOI in the therapeutic sandal had a range 39 – 243 kPa.

After gait-analysis all participants expressed better understanding for offloading and use of prescribed/therapeutic footwear. After one month 18 (90%) had a more positive approach of use of prescribed/therapeutic footwear.

Conclusion: The positive feedback from the participants showed that gait-analysis could be useful for the educational guidance the daily footclinic. Result did not unequivocally show which footwear was best. This pilot study provides an opportunity to evaluate our educational guidance and select which target groups will benefit from a gait analysis.

EP09

EVALUATION OF THE KNOWLEDGE, AWARENESS, ATTITUDES AND PRACTICES OF PATIENTS WITH DIABETIC FOOT SYNDROME AND ACTIVE ULCERATION.

María del Sol Tejeda Ramírez, Marta García-Madrid Martín de Almagro, Mateo López-Moral, Aroa Tardáguila García, Raúl Molines Barroso, José Luis Lázaro Martínez

Aim: To describe data on the knowledge, awareness, attitudes, and practices of diabetic foot syndrome (DFS) patients with diabetic foot ulcers (DFU).

Method: The evaluation of 50 surveys targeting DFS patients with DFU in a Specialized Diabetic Foot Unit was conducted by a single researcher between January and March 2021. The survey was composed of a total of 40 questions. Thirty-three questions were regarding the patient with ulcers knowledge, awareness, attitudes and practices and 7 questions were completed by the researcher responsible for evaluating the patient's care.

Results/Discussion: Forty-three (86%) patients were men, with an average age of 65.10±9.7 years. Most patients interviewed, 45 (90%), recognized the association between the onset of DFU and high blood sugar levels, despite these claims, 27(54%) did not know the data or HbA1c level as a predictor of the evolution of DFU. With regard to the practices described, 39 (78%) patients claimed they were wearing adequate footwear; however, this was confirmed only to be correct on 29 (58%) occasions by the researcher. This evaluation showed among other results that 42 (84%) patients had calluses despite 47(94%) stressing the importance of going to the podiatrist as often as patients deemed appropriate. Forty-four (87%) patients considered it important to perform the indicated rest, but 25 (50%) patients lifted weight frequently, 23 (46%) ascended and descended stairs and 19 (38%) had no help in their basic daily activities. Forty-six (92%) considered that knowing about their condition can help avoid complications, although, 31 (62%) had never received DFS education and 49 (98%) stated education on a regular basis would be welcomed.

Conclusion: Educational actions should be increased to improve DFS awareness and practices in patients with DFU.

EP10

PREVALENCE AND EPIDEMIOLOGY FACTORS INVOLVED IN CELLULITIS WITH LYMPHANGITIS AMONG PATIENTS WITH DIABETIC FOOT ULCER SEEN IN TANZANIA

Zulfiqarali G. Abbas, Janet Lutale, Lennox Archibald

Aim: Among patients attending a large diabetes clinic, cellulitis has been a well-recognized problem in those with foot complications. Patients with poorer outcomes appear to have concomitant lymphangitis with cellulitis. However, the epidemiology and clinical implications of lymphangitis have not been characterized in Africa.
We carried out this study to (i) characterize the epidemiology of lymphangitis in a large patient cohort; (ii) identify risk factors associated with lymphangitis; and (iii) ascertain the effect of lymphangitis on outcome in this patient population.

Method: This was a retrospective cohort study of all patients who attended the diabetes clinic in Dar es Salaam during January 2017 to December 2019 (study period). Following informed consent, we recorded history and epidemiologic details followed by physical examination. Data were entered in a standardized questionnaire and analyzed with Epi Info statistical software (CDC, Atlanta, GA). Relative Risk (RR) and 95% confidence intervals (CI) were calculated.

Results / Discussion: During the study period, 1698 patients participated in the study; 1084 (64%) were male, and 457 (27%) had lymphangitis and cellulitis. Median age: 58 (range 17-97) years; median BMI: 26 (range 13-60) kg/m^2. Lymphangitis was significantly associated with non-healing of ulcers (RR: 1.4; CI: 1.1-1.7, P<0.01) or having to undergo lower limb amputation (RR: 1.8; CI: 1.4-2.2, P<0.001). Although patients with lymphangitis were more likely to die (RR=1.4), the difference was not statistically significant. Of note, patients without peripheral arterial disease were significantly more likely to acquire lymphangitis (RR: 1.5; CI: 1.2-1.8, P <0.001).

Conclusion: The prevalence of lymphangitis complicating diabetic foot ulcer disease in Tanzania is 27%. Moreover, patients with lymphangitis were more likely to have worse outcomes, such as amputation or death. The association of lymphangitis with delayed healing suggests infections are playing a greater role in the pathogenesis of foot ulcer disease and remains underappreciated.

EP11

ANTIMICROBIAL RESISTANCES INCIDENCE AND PATTERNS IN DIABETIC FOOT: AN EPIDEMIOLOGICAL SURVEY OF DIABETIC FOOT INFECTIONS IN NORTHEASTERN ITALY

Giovanni Boschetti, Enrico Brocco, Marino Bruseghin, Christine Whisstock, Michela Pinfi, Mariagrazia Marin

Aim: This paper is a retrospective epidemiological assessment of bacterial species isolated in all out-patients with clinically infect foot ulcers referring to our diabetic foot unit within one year, with particular attention to index pathogens as identified by the European Antimicrobial Resistance Surveillance Network.

Method: 426 microbiological reports were collected between november 2018 and 2019 from outpatients referring to our clinic for a Diabetic Foot Infection. All outpatients who underwent a microbiological examination in our ambulatory were included in the study. Clinically infected lesions underwent cleaning with povidone-jodine and saline solution then debrided. Punch biopsy of deep tissues were collected by trained Nurses or Podiatrist.

Results: Of the 426 cultures 241 (56·5%) showed growth of a single strain of bacteria, 146 (34·3%) two, 15 (3·5%) three and 7 (1·6%) fungal growth. *S. aureus* and *P. aeruginosa* accounted for 33.5% and 11.4% of the cases and showed widespread resistances to the recommended empiric antimicrobial therapy. For *S. aureus* MRSA was isolated in 27,1% while 14,06% showed resistance to 3 antimicrobial classes without methicillin resistance; MLSb pattern was present in 28 cases and more than half *S. aureus* were resistant to at least 2 different classes of antibiotic with penicillin resistance being almost ubiquitous. *P. aeruginosa* presented extensive resistance to fluoroquinolones (57.3%) frequently associated with resistance to penicillin (17,6%) or carbapenems (23,5%). *S. Epidermidis* showed MLSb pattern associated to Methicillin resistance in 45.5% of cases, all (21) *M. morganii* were resistant to at least 3 different classes of antibiotic; the only isolated Enterococcus faecium showed VRE pattern.

Bacteria	No resistances		R to 1 class		R >= 2 classes		Total	
	n	%	n	%	n	%	n	%
E. faecium	0	0	0	0	1	100	1	0·17
E. faecalis	20	55·6	9	25	7	19·4	36	6·2
S. coagulase -	6	16·2	5	13·5	26	70·3	37	6·4
S. aureus	30[(2)]	15·7	64	33·3	98	51	192[(2)]	33·5
Streptococci	10	27	18	48·6	9	24.4	37	6·4
S. epidermidis	0	0	2	9·1	20	90·9	22	3·9
Other gram +	3	30	2	20	5	50	10	1·8
E. coli	6	18·75	1	3·125	25	78·125	32	5·6
K. pneumoniae	0	0	0	0	8[(1)]	100	8[(1)]	1·4
Acinetobacter spp	3	50	0	0	3	50	6	1·03
P. aeruginosa	23	33·8	16	23·6	29	42·6	68	11·9
E. cloacae	0	0	3	11·5	23	88·5	26	4·5
M. morganii	0	0	0	0	21	100	21	3·8
S. marcescens	0	0	0	0	19[(2)]	100	19[(2)]	3·3
P. mirabilis	0	0	1	6·7	14	93·3	15	2·6
K. oxytoca	1	11·1	5	55·6	3	33·3	9	1·6
Other gram -	8	23·5	5	14.7	21	61·8	34	5·9
Total	110	19·2	131	22·9	332	57·9	573[(5)]	100

Conclusion: an empiric, single-agent, antimicrobial therapy must face an army of pathogens that resist at least 2 different antibiotic classes in more than 50% of the cases; assuming a monomicrobial infection, more than half of the times antimicrobial empiric therapy will most likely prove uncorrect.

EP12

EVALUATING ANTIBIOTIC SENSITIVITY OF DEFINITE PATHOGENS IN DIABETIC FOOT INFECTIONS IN A NORTH EAST ENGLAND POPULATION

Igor Kubelka, Daniel Wall, Solim Muzammil Nahaboo, Emma Scott, Nazhrah Haji Mostapha, Daniel Betchetti, Mavin Macauley

The infected diabetic foot ulcer is complex milieu, containing colonizing and pathogenic bacteria. Targeting pathogenic bacteria presents a challenge. To address this, we classified bacterial species according to pathogenic potential: Red Group – Definite pathogens, Yellow Group – Likely pathogens and Green Group – Commensals. Antibiotic sensitivity of pathogens in the Red Group was evaluated.

A retrospective analysis of 75 participants (61 males; 14 females), 14 (18.7%) type 1 diabetes and 61 (81.3%) type 2 diabetes participants who had tissue sampling between January 2019 - July 2020 was conducted. Red Group organisms were: anaerobes, β haemolytic streptococci, Enterobacteriaceae, and Staphylococcus aureus.

17% (n=18) of tissue samples were monomicrobial, 83% (n=86) polymicrobial. Microbial distribution: Enterobacteriaceae 48.4% (n=54) [E.coli (n=13), Klebsiella (n=7), Entorobacter (n=7), Citrobacter (n=6), Morganella (n=6), Proteus (n=16), MSSA 32% (n=39), β haemolytic streptococci 10.7% (n=13), anaerobes 6.6% (n=8), MRSA 2.5% (n=3) species.

All ***Enterobacteriaceae*** were sensitive to carbapenems and gentamicin. 2 of 13 E. coli isolates were resistant to piperacillin / tazobactam; and 1 of 16 Proteus isolates was resistant to ciprofloxacin. 53% Enterobacteriaceae were resistant to co-amoxiclav [a third were E.coli, and two-thirds were AMP C producing organisms].

All ***β haemolytic streptococci (group A, B, C, G)*** were sensitive to penicillin and teicoplanin. Resistance to clindamycin was observed in 3 of 13 isolates. Group B (S. agalactiae) resistance to doxycycline was observed in 7 of 8 isolates.

All ***anaerobes*** were sensitive to metronidazole.

MSSA was fully sensitive to flucloxacillin, trimethoprim, rifampicin, and linezolid. Resistance to doxycycline was observed in 2 of 38, clindamycin 5 of 38 and clarithromycin 8 of 38 isolates respectively.

All ***MRSA*** isolates were sensitive to doxycycline, trimethoprim, and linezolid.

Resistance to co-amoxiclav was mostly seen with Enterobacteriaceae. Targeted anti-microbial therapy supported by tissue sampling and antibiotic stewardship is vital in the management of diabetic foot infections.

EP13

INFECTION WITH LOW-PATHOGENIC BACTERIA IS ASSOCIATED WITH A HIGHER DIABETIC FOOT AMPUTATION RISK IN THE TOOL COHORT

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Background: Some bacteria seem associated with aggressive manifestations of diabetic foot infection. Other bacteria present in diabetic foot wounds are considered low-pathogenic. We assessed amputation risk among bacterial species.

Methods/ materials: We included patients (>18 years) with diabetic foot infection (DFI) in a retrospective cohort study (March 2011- January 2020, TOOL cohort) at a Dutch tertiary care hospital. We retrieved culture results and used best available type of cultures for further analysis: percutaneous bone biopsy in case of osteomyelitis, ulcer bed biopsy in case of soft tissue infection and osteomyelitis (if no bone biopsy was performed), and ulcer swab if no other cultures were obtained. If repeated cultures were taken from the same location of a patient in three months' time, we pooled results into a composite determinant with only unique bacteria. We clustered bacteria into 5 groups:1 *Streptococcus* and *Staphylococcus aureus*;2 coagulase-negative *Staphylococcus*,*Cutibacterium*,*Corynebacterium* and *Enterococcus*;3 gram-negative bacteria;4 anaerobic bacteria;5 less common gram-positive bacteria (e.g., *Actinomyces*,*Lactococcuslactis*). We used time dependent Cox regression to analyse the association between time to first amputation and bacterial groups. We used infection with one group as the exposure and infection with at least one of the other groups as the comparator. We corrected for history of amputation.

Results: We extracted data from 138 patients, with 311 infective episodes. Incidence rates for infection per group per person year for group 1-5 were:1.10; 0.48; 0.99; 0.37; 0.085, respectively. The risk of amputation was highest for infection with group 2 (HR 2.8*, CI 1.7-4.8, followed by group 5 4,3 and 1 (HR 1.9, CI 0.67-5.3; HR 1.5, CI 0.89-2.6; HR 1.3, CI 0.79-2.2; HR 0.61, CI 0.37-1.04, respectively).

Conclusions: Infection with bacteria that are usually considered low-pathogenic was associated with a higher risk of amputation, while infection with pathogenic gram-positive bacteria was associated with a lower amputation risk.

EP14

META-ANALYSIS: OUTCOMES OF SURGICAL VERSUS MEDICAL MANAGEMENT OF DIABETIC FOOT OSTEOMYELITIS

David Truong, Matthew Malone, Javier La Fontaine, Dane Wukich, Lawrence Lavery

Aim: To evaluate the quality of current literature on medical versus surgical management of diabetic foot osteomyelitis.

Methods: A PubMed and Google Scholar search of articles relating to osteomyelitis in the feet of persons with diabetes mellitus (DM) was performed over the dates of January 1931 to January 2020. Articles that involved Charcot Arthropathy, case reports, small case series, review articles, commentaries, non-human studies, and articles that were not in English were excluded. QUADAS-2 was used to rate the bias of each study. A meta-analysis was performed using random effects, inverse variance methods.

Results: The search yielded a total of 1192 articles. After further reviewed and removal of articles that did not meet inclusion criteria, 28 articles remained. 18 articles related to the medical management of diabetic foot osteomyelitis (DFO) and 13 articles related to surgical management. Three articles looked at a combination of medical and surgical managements and were included in both groups. Heterogeneity was evaluated using Cochran's Q, I^2, τ^2 and τ. The I^2 value for the medical management of DFO was 86.46%, whereas for surgical management, it was 90.78%. Since I^2 values were high, publication bias could not accurately be calculated. τ^2 and τ for medical and surgical management were as follows: 1.04, 1.02 and 0.97 and 0.98, respectively.

Conclusion: We identified significant differences in the definitions for criteria for diagnosing DFO. There is also no uniform consensus on defining what is a successful treatment outcome. This restricts the ability to compare studies and to draw conclusions on any differences between treatments with regards to outcomes. The meta-analysis suggested that surgical treatment is more favorable over medical management of DFO. All of the studies with surgical intervention resulted in significant findings with a predication interval suggesting that all future studies will share the same positive results.

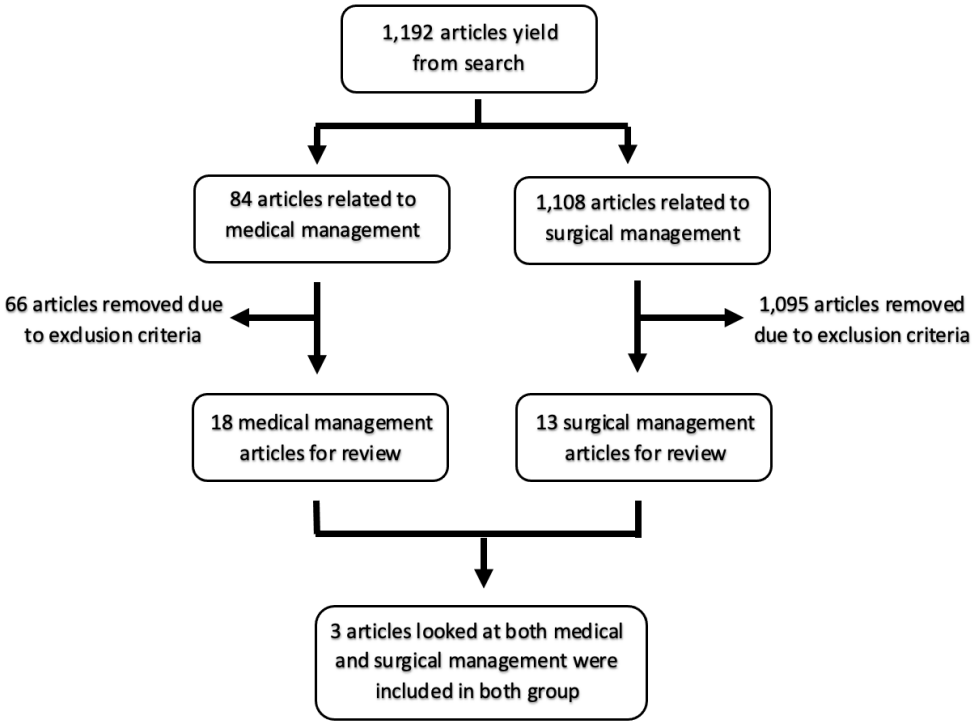


Fig 6: Result of search analysis. 31 articles qualified for review at the end after exclusion criteria were applied.

Q	125.58
p_Q	0.000
I^2	86.46%
τ^2 (Odds Ratio)	1.04
τ (Odds Ratio)	1.02

Table 3: Heterogeneity of medical management of OM. Q=Cochran's Q; p_Q = Q *p*-value; τ = tau.

Font

Q	130.20
p_Q	0.000
I^2	90.78%
τ^2 (Odds Ratio)	0.97
τ (Odds Ratio)	0.98

Table 4: Heterogeneity of surgical management of OM. Q=Cochran's Q; p_Q = Q *p*-value; τ = tau.

#	Reference	OR	95% CI	Weight
1	Mauler	0.04	0.01-0.25	4.02%
2	Lesens*	93.84	25.06-351.37	4.99%
3	Tone	3.45	1.36-8.77	5.87%
4	Larzo-Martinez*	14.44	3.45-60.39	4.79%
5	Acharya	4.09	2.44-6.88	6.66%
6	Mutluoglu	1296	74.36-22586.51	2.39%
7	Valabhji	9.47	3.87-23.18	5.95%
8	Jeffcoate	1.97	1.16-3.36	6.64%
9	Senneville 2008	3.16	1.38-7.23	6.09%
10	Embril	16.70	8.74-31.94	6.44%
11	Tice	4.99	3.37-7.37	6.85%
12	Yadlapalli	14.69	5.93-36.44	5.92%
13	Senneville 2001	10.56	2.03-54.84	4.37%
14	Pittet	2.66	1.18-6.03	6.11%
15	Ha Van*	1.72	0.86-3.42	6.37%
16	Venkatesan	11.56	2.71-49.38	4.75%
17	Peterson	3.31	1.14-9.56	5.60%
18	Bamberger	1.27	0.58-2.78	6.18%
	Combined Effect	5.25	2.26-12.17	100%

Table 5: The ORs and study weight of medical management of OM

#	Reference	OR	95% CI	Weight
1	Niazi	81	26.59246.79	7.80%
2	Akkurt	110.25	13.38-908.60	4.77%
3	Lesens*	15.47	6.89-34.72	8.90%
4	Larzo-Martinez*	4.59	1.24-16.96	7.20%
5	Beieler	245.44	46.15-1305.44	5.91%
6	Gauland	39.06	23.01-66.31	9.76%
7	Kowalski	3.41	1.96-5.93	9.70%
8	Aragon-Sanchez 2011	841.00	163.33-4330.31	5.98%
9	Aragon-Sanchez 2011	6400.00	385.18-106339.01	3.25%
10	Aragon-Sanchez 2009	220.03	67.83-713.68	7.57%
11	Aragon-Sanchez 2008	19.72	11.63-33.44	9.77%
12	Henke	16	15.52-16.49	10.54%
13	Ha Van*	12.02	5.29-27.28	8.86%
	Combined Effect	41.19	13.47-125.90	100%

Table 6: The ORs and study weight of surgical management of OM

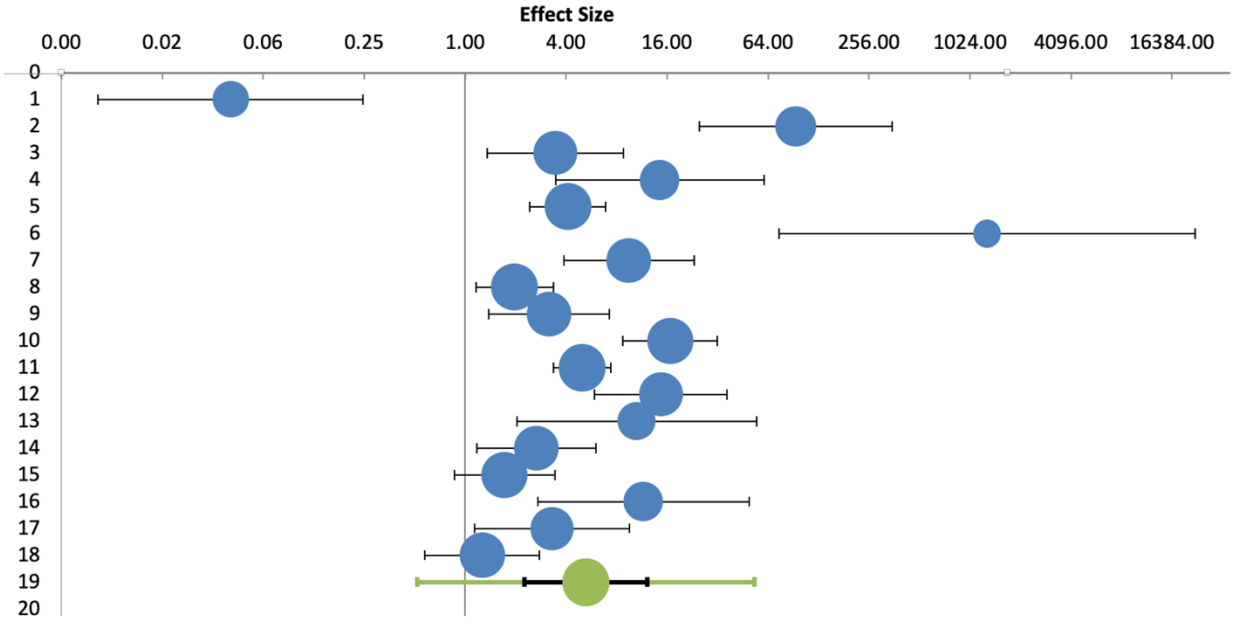


Fig 1: Forest Plot of Medical management of OM

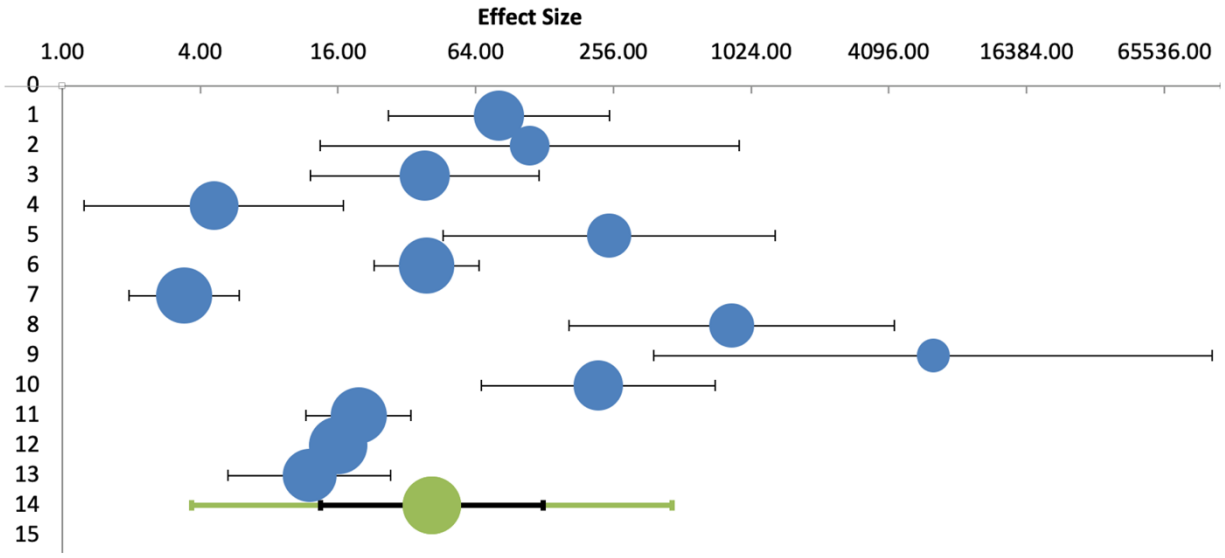


Fig 2: Forest Plot of Surgical management of OM

EP15

A RETROSPECTIVE ANALYSIS OF THE BACTERIOLOGICAL PROFILE OF INFECTED DIABETIC FOOT IN RELATION TO THE METHOD OF MATERIAL COLLECTION AND SELECTED CLINICAL PARAMETERS

Przemyslaw Witek, Sebastian Borys, Jerzy Hohendorff, Teresa Koblik, Maciej Małecki

Aim: A retrospective analysis of the bacteriological profile of diabetic foot infections (DFI) treated at a Polish tertiary hospital depending on the method of sample collection and selected clinical parameters.

Method: 206 patients (141, 68 % men) hospitalized in our department were analysed. In the first two years a swab and in the next two years a tissue slice from the bottom of the ulceration was taken for microbiological assessment. Differences in the prevalence of GRAM(+) and GRAM(-) flora were assessed depending on the method of collection (swab, tissue slice), the presence of critical lower limb ischaemia (CLI), gender, e-GFR level, age, HbA1c, CRP.

Results / Discussion: 398 bacterial strains were isolated (average 1.93 strains/patient), 193 (48.5 %) Gram(+) and 205 (51.5 %) Gram(-). 82 samples (39.8 %) were monoculture, 124 (60.2 %) multiculture. In patients without CLI compared to patients with CLI, the GRAM(+) flora was significantly more frequent irrespective of the method of culture collection (swab: 48 (58.5 %), p=0.005; slice: 73 (57.9 %), p=0.003). In patients with GFR < 60 ml/min, GRAM(+) flora was significantly more frequent in slice cultures 56 (59.6 %) than in swab cultures 26 (40.0 %), p=0.015 and also compared to slice cultures of patients with GFR ≥ 60 ml/min 61 (42.1 %), p=0.008. Significantly more GRAM(-) flora was found in the swabs of patients ≥ 65 years of age as compared to those < 65 years: 39 (63.9 %) and 44 (44.9 %), respectively. Moreover, significantly more GRAM(-) flora also was found In patients with HbA1c below vs above median (8,4 %) irrespective of the method of culture collection.

Conclusion: In our study we found significant differences in the prevalence of Gram(+) and Gram(-) bacterial flora in some groups of patients with DFI depending on clinical characteristics and the method of collection.

EP16

DIABETIC MUSCLE INFARCTION: - A RARE BUT IMPORTANT COMPLICATION OF DIABETES

Elizabeth Pendry, Prash Vas, Chris Manu, Michael Edmonds

Diabetic muscle infarction is a rare complication of diabetes and in the literature associated with poor blood glucose control.

Aim/Method: We report 4 cases of diabetic muscle infarction to raise awareness of this condition and prevent the diagnosis being missed.

Results: The patients complained of unilateral acute pain in the lower leg, with 3 /4 cases affecting the posterior compartment and one affecting the anterior compartment. One patient also had pain the thigh; 3/4 patients were on haemodialysis.

Three patients had palpable pedal pulses but one had severe peripheral arterial disease (PAD) with occluded popliteal to dorsalis pedis graft.

Mean values of blood results with ranges were: -

White cell count 13.6 (4.98-41.04 10*9/L), Neutrophil count 13.2 (3.08-35.70 10*9/L), Creatinine 440.2 (101-762 umol/L), C Reactive Protein 209 (37.6 – 434.8mmol/L), eGFR 22.7 (6-67mL/min), Glycated haemoglobin 7.5 (6.5-8.0 % DCCT), 58 (44-60 mmol/mol IFCC).

Creatinine Kinase (CK) was 1637 (78-4824 IU/L) but was normal in two patients.

All patients had MRI scans which demonstrated muscle oedema and diffuse subcutaneous oedema. In one patient there was evidence of haematoma which aspiration under ultrasound revealed altered blood.

The patient with thigh pain underwent a PET scan which showed diffuse metabolic activity in the thigh muscles This patient underwent surgical exploration and histology revealed muscle necrosis.

The patient with PAD had the occluded graft recanalized and fasciotomies performed. Muscle biopsy showed coagulated necrosis.

In three patients, the muscle infarction resolved but recurred in one. The patient with PAD eventually came to major amputation.

Discussion: Acute unilateral muscle pain especially in dialysis patients may be due to muscle infarction and should be diagnosed urgently by MRI. Recurrences may occur. Be aware that blood glucose control may be reasonable, CK may be normal and there may be coexistent PAD – requiring a low threshold of suspicion.

EP17

ESTROGEN REPLACEMENT THERAPY CAN IMPORVE DIABETIC NEUROPATHY AND PREVENTE AMPUTATIONS IN POSTMENOPAUSAL WOMEN

Tatiana Zelenina, Aleksandr Zemlianoi, Vladimir Salukhov

Aim: Early treatment the neuropathy alteration could avoid and reduce the number of foot amputations. The estrogen deficiency in postmenopausal women with diabetes can deteriorate nerve dysfunction. We hypothesized that ERT would prevent of progression of nerves disorders in these women.

Method: We examined 61 postmenopausal women with type 2 diabetes, sensorimotor neuropathy (DSN) and history of diabetic foot amputations. We excluded women with contraindications to ERT. Clinical neurological examination (Neuropathic Disability Score (NDS)), sural nerves conduction study (SNCS) and cardiovascular autonomic reflex tests (CARTs) were performed.

The first group (27 patients) had received estradiol valerate 2 mg per day plus dienogest, the second one (18 women) had received 1 mg 17-β estradiol per day plus dydrogesterone, the third group (16 patients) had received placebo during 12 months. All examinations were repeated after 12 months of treatment. After 9 years of treatment, we assessed the number of new foot amputations.

Results / Discussion: The patients of the three groups had same age, duration of diabetes, anthropometric and metabolic parameters. We found moderate or severe SMN in all patients. Moreover confirmed/severe CAN were observed quiet often (71.2, 77.8 and 69.8 % respectively; χ^2=0.57; p=0.24). ERT resulted in improvement of NDS (9.0±0.92 at baseline and 7.1±0.58 after treatment, p=0.04) as well as SNCS for women in the first group. No changes in the neurological examination were found for other participants. Moreover restorations of CAN stages were detected for treatment groups (70 and 57% cases confirmed/severe CAN respectively). Were did not find any new cases of foot amputations after 9 years of observation in the treatment groups.

Conclusion: The ERT were followed by restoration of SNCS parameters and CARTs. The effect of ERT may depend on the dose of estrogen. This preventive effect of ERT should be profoundly investigated.

EP18

ORTHOPEDIC SURGERY IN THE MANAGEMENT OF THE DIABETIC FOOT – A FIVE-YEAR EXPERIENCE

Veronika Woskova, Alexandra Jirkovská, Robert Bem, Michal Dubský, Vladimíra Fejfarová, Jitka Husakova, Radka Jarosikova, Petr Teyssler, Karol Sutoris

Background and aim: Surgical treatment of deformities, especially severe bone changes due to Charcot neuro-osteoarthropathy (CN) complicated by ulcer and subsequent osteomyelitis (OM), shows favorable results in terms of ulcer healing, ability to walk and limb salvage. The aim of our study was to present the results of five-year collaboration with an orthopedic surgeon in the management of selected diabetic foot patients.
Methods: The study included 47 patients treated at a diabetic foot clinic, who underwent orthopedic surgery between Apr 2015 and Oct 2020; the median follow-up period was 24 (6–60) months. Indications for surgery were severe deformities and/or instability based on CN. Non-healing or recurrent wounds were present in most cases (91%). OM was confirmed in 31 patients (66%). In 13 (28%) patients revascularization was performed prior to surgery.
Results: Of the 47 included patients, 40 were analyzed per-protocol, 7 patient died from a non-foot related cause. Orthopedic surgery included 18 (45%) procedures of the midfoot and 22 (55%) hindfoot and ankle procedures. External fixation (EF) was performed in 33 patients (82%). Ulcer healing was achieved in 28/36 (78%), ulcer recurrence after weight-bearing activities occurred in 8/40 (20%) patients. During follow-up, 6 patients underwent major amputation (5 of uncontrolled infection). No serious surgery-related complication was observed. Additional surgery was required in 11 (28%) patients; of these, 7 (18%) had further orthopedic corrections. At the end of the follow-up period, 29 (73%) patients had functional limb and were able to walk using accommodative devices (footwear or orthoses).
Conclusion: Orthopedic surgeon plays an important role in the management of the diabetic foot, especially in patients with Charcot foot deformities complicated by ulcers and infection. In our study we observed a limb preservation in 73 % patients. Long-term follow-up and further analysis of ulcer recurrence is needed.

Supported by MZO 00023001.

EP19

LESSONS LEARNED FROM COMPLEX DEFORMITIES OF CHARCOT DIABETIC HINDFOOT AND ANKLE RECONSTRUCTIVE SURGERY

Iozefina Botezatu, dan laptoiu, andrei bunea, sorina romanescu, gilbertina stefan, eduard catrina

Aim: To present the organizational and medical barriers in the management of severe hindfoot deformities (with instability and infected) in diabetic patients, with lack of funding, deficiency of Charcot foot clinical recognition and screening, absence of a multidisciplinary team, lack of professional training in order to avoid amputation. Despite medical and non-medical difficulties, we tried to assemble a team and improve our surgical technique in order to improve the quality of life of patients proposed for limb amputation.

Method: We operated between 2016-2019, 13 patients with deformed, unstable ankles (secondary to loss of talus), as sequelae of an insufficiently treated Charcot diabetic foot. Five cases presented with osteomyelitis for which reconstruction was performed in 2 stages; 4 cases had superficial ulcers. All patients had comorbidities (diabetic nephropathy, retinopathy, chronic antiplatelet treatment). For the first patients, tibio-calcaneal fusion was performed only with retrograde nail; in the last 2 years we applied tibio-calcaneal arthrodesis with Phoenix nail (TM Zimmer Biomet) supplemented with contoured antero-medial plate for stability: in 3 cases tantalum cones were used to replace the talus. In all cases vancomycin-impregnated peroneal malleolus autograft and morselized allograft were used.

Results / Discussion: In the short and medium term the follow-up results were encouraging, in accordance with the specialized literature. No immediate septic complications were noted, with only one infected case at 1 year (probably reactivation of the infection) that was amputated in another service. We agree that tantalum cones require longer follow-up (plus 1 year).

Conclusion: The lack of a dedicated medical team and a multidisciplinary center in the treatment of patients with diabetic foot does not make it impossible to save from amputation a pelvic limb. The deformities associated with ankle/hindfoot Charcot are often multiplanar, highly prone to ulceration and raise several challenges in the surgical reconstruction.

EP20

IMPACT OF UTILISING A NOVEL MHEALTH APPLICATION ON CLINICAL OUTCOMES IN THE MANAGEMENT OF PEOPLE WITH DIABETES WHO HAVE EXPERIENCED A RECENTLY HEALED FOOT ULCERATION: AN EVALUATION OF THE INTELLIN™ PLATFORM

Paul Chadwick, Rory Cameron, Mark Edge, Samantha Haycocks

Aim: Faster and more appropriate referral to a specialist clinic after symptom onset has been linked to a reduced risk of patients developing severe diabetic foot ulcers (DFUs) and improved outcomes. The INTELLIN platform provides support and health education for patients with a recently healed DFU, with the aim of improving ulcer self-detection and to prompt individuals to take timely action in case of recurrence. This feasibility study assessed the acceptability, suitability and usability of the INTELLIN platform, as reported by patients and clinic staff.

Method: Patients from Salford Royal NHS Foundation Trust completed a medical questionnaire to create their profile. At baseline, all patients completed their 8 care processes. Follow-ups were scheduled at Weeks 1, 4, 16, 28 and 40. Patients and staff assessed platform usability on a 5-point scale (strongly agree [5] to strongly disagree [1]) at Weeks 1, 16 and 52. Time until reulceration was measured through Week 52. The proportion of patients who self-referred for recurrence was also assessed.

Results / Discussion: One hundred and ninety-seven patients were assessed for eligibility and 15 entered the full analysis set (FAS) (see Haycock *et al.* for full analysis of patient disposition). Baseline characteristics are summarised in Table 1. Up to Week 52, 8/15 patients in the FAS experienced a recurrence, with a mean Site, Ischaemia, Neuropathy, Bacterial Infection, and Depth (SINBAD) score of 2.1 and a mean duration of 2.6 days. Mean time from last DFU to recurrence during follow-up was 273.0 days. No patients self-referred during the study. In the qualitative assessment, 12/15 patients and 11/15 staff rated the platform 4–5/5 for ease of use, and 13/15 patients and 10/15 staff gave a rating of 4–5/5 for likelihood of continuing the platform after the study.

Conclusion: Despite the small sample size, initial qualitative data shows high INTELLIN platform acceptability and usability for patients and clinicians, with high likelihood of recommendation for future use. There were no instances of self-referral reported, though this finding is likely to be associated with the prospective visits already scheduled within the study and patient familiarity with the appointment service provided by Salford Royal. The number of ulcer-free days reported in this study is high compared to previous reports. Future studies may explore the potential for increased time to reulceration vs published data.

Table 1: Baseline characteristics

Baseline characteristic	Patients in the FAS (n=15)
Diabetes mellitus	
T1DM, n (%)	3 (20)
T2DM, n (%)	12 (80)
Mean time from diabetes diagnosis, years (SD)	17.9 (10.1)
Most recent DFU prior to study entry	
Mean time since healing of last DFU, days (SD)	45.9 (23.9)
Mean (SD) SINBAD score of last DFU	2.1 (1.0)
Cases where last DFU was severe, n (%)	4 (27)
Patients receiving insulin, n (%)	6 (40)
Mean basal insulin dose per day, units (SD)	16.9 (20.1)
Mean bolus insulin dose per day, units (SD)	5.7 (10.0)
Number of patients overdue their annual 8 care processes, n (%)	2 (13.3)

DFU, diabetic foot ulcer; FAS, full analysis set; SD, standard deviation; SINBAD, Site, Ischaemia, Neuropathy, Bacterial Infection, and Depth; T1/2DM, type 1/2 diabetes mellitus.

EP21

SOCIO-ECONOMIC AND PATIENT DEMOGRAPHIC CHALLENGES ARISING DURING THE RECRUITMENT AND ENROLMENT PROCESS FOR A FEASIBILITY STUDY EXPLORING THE IMPLEMENTATION AND ACCEPTANCE OF THE INTELLIN™ PLATFORM IN PATIENTS WITH A PREVIOUS HISTORY OF DIABETIC FOOT ULCERS

Samantha Haycocks, Rory Cameron, Mark Edge, Paul Chadwick

Aim: Diabetic foot ulcers (DFUs) are common in patients with diabetes and can result in high rates of amputation, morbidity and mortality. A feasibility study was carried out to assess implementation and acceptance of the INTELLIN platform — a novel mHealth application for the management of patients who have experienced a recently healed DFU. Here we discuss the socio-economic and patient demographic challenges that arose during the recruitment and enrolment process, and how such challenges may impact future mHealth studies.

Method: Patients from the Salford Royal NHS Foundation Trust completed a medical questionnaire to create their INTELLIN profile. Eligible patients were adults with type 1/2 diabetes and a history of a recent DFU, defined as being eligible for the National Diabetes Foot Care Audit and classified as healed for ≥4 weeks but no more than 12 weeks. Participants must also have owned a smartphone on study enrolment (see Chadwick *et al.* for full methodology).

Results / Discussion: One hundred and ninety-seven patients were assessed for eligibility, 19 patients were enrolled and 15 entered the full analysis set (FAS). At baseline, 3/15 FAS patients were female, with a mean (standard deviation [SD]) age of 60.8 (9.3) years and a mean (SD) body mass index of 32.94 (6.13). Reasons underlying enrolment failure are summarised in Table 1. App accessibility issues predominated (69/178; 38.8%), driven by a lack of smartphone access (58/178; 32.6%), which was the most important barrier to enrolment, with subsequent patient discussion highlighting concerns over use of mobile data packages and phone memory. Cognitive impairment (3/178 patients; 1.7%) and eyesight problems (5/178 patients; 2.8%) were also identified as barriers to smartphone use and enrolment. Medical/compliance issues (63/178; 35.4%) and personal reasons for non-participation (46/178; 25.8%) were identified as additional major barriers. Of those patients that entered the FAS, 2 completed the study.

Conclusion: The substantial barriers to enrolment encountered in this feasibility study demonstrate the considerable impact of socio-economic factors on mHealth studies, specifically this study in patients with diabetes. The diabetes demographic often includes older patients and those with comorbidities, which may also result in a high burden of technology accessibility issues. These issues may have been compounded by the relatively low-income demographic of the Salford ward. Future studies should consider appropriate measures and additional support required for increased study accessibility.

Table 1: Reasons for patient non-participation in the study

Reason for non-participation	Patients (N=178), n (%)
App accessibility issues	69 (38.8)
Language	3 (1.7)
Cognitive impairment	3 (1.7)
Eyesight *(limiting use of smartphone)*	5 (2.8)
No smartphone	58 (32.6)
Medical/compliance issues	63 (35.4)
Reulcerated	28 (15.7)
Deceased	2 (1.1)
Awaiting other surgery *(not necessarily foot or diabetes related)*	2 (1.1)
Outside 12-week rule *(history of a recent DFU defined as eligible for the NDFA and classified as healed for ≥4 weeks but no more than 12 weeks)*	20 (11.2)
Future appointments already planned *(not necessarily foot or diabetes related)*	4 (2.2)
In another study	2 (1.1)
Compliance issues *(patients unlikely to be able to attend all visits necessary for study inclusion)*	5 (2.8)
Personal issues	46 (25.8)
No interest	9 (5.0)
No contact	24 (13.5)
Moved area	3 (1.7)
Domiciliary *(patients requiring home-based care)*	6 (3.4)
Work	3 (1.7)
Personal reasons (other)	1 (0.6)

DFU, diabetic foot ulcer; NDFA, National Diabetes Foot Care Audit.

EP22

AUTOLOGOUS PUNCH-GRAFTING FOR THE MANAGEMENT OF HARD TO HEAL DIABETIC FOOT ULCERS IN THE REARFOOT: A PROSPECTIVE CASE SERIES

Yolanda García Álvarez, Esther Garcia Morales, Marta García-Madrid Martín de Almagro, Mateo López-Moral, Irene Sanz Corbalán, José Luis Lázaro Martínez

Aim: To evaluate clinical outcomes of Ultrasonic Assisted Wound Debridement and autologous Punch Grafting as a treatment for hard to heal diabetic foot ulcers (DFU) in rearfoot.

Method: A prospective case series involving a total of 6 patients with hard to heal DFU´s treated with punch grafting was conducted during May 2017 to December 2020 in a specialized diabetic foot unit. DFUs had more than 6 months of evolution, not responding to conventional treatment and did not present local clinical infection based, untreated osteomyelitis and critical limb ischaemia (Median area surface at day 0: 5,9cm^2). Median evolution time was 204 [interquartile range 32 – 344] weeks. This suggests that DFU included in the present study are complicated wounds that have not responded to other treatments previously. Wound bed preparation was performed by ultrasonic assisted wound debridement (UAW) (Söring GmbH, Germany) to obtain the optimal tissue as possible at wound bed. After that, 4-6 mm punch was taken from the thigh and grafted in the ulcer area with a distance between 2 to 6 millimeters. A non-adherent, non-occlusive dressing was used to cover the grafted ulcer. In the other hand, negative wound therapy pressure (NWTP) was applied in conjunction with punch grafting in cases of high exudate level. Ulcers were revised once a week. Removable knee-high walkers were used to offload.

Results / Discussion: We obtained higher healing rate in a shorter time, 50% of patients healed in a mean time of 5.67 ± 2.88 weeks and 83,3% of healing in a mean time of 14.60 ± 12.72 weeks.

Conclusion: Autologous punch graft is an easy procedure that promotes healing, achieving wound closure in chronic DFU´s. It represents an alternative of treatment for hard to heal DFU´s in which conservative treatment has been unsuccessful.

EP23

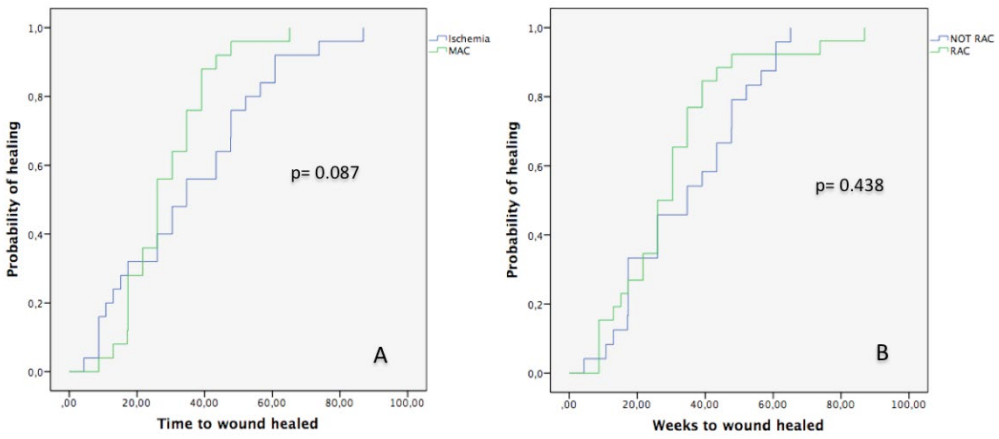
COMPARATIVE CLINICAL OUTCOMES OF PATIENTS WITH DIABETIC FOOT ULCERS (DFUS) AND ISCHEMIA VERSUS PATIENTS WITH DFU AND MEDIAL ARTERY CALCIFICATION (MAC)

Francisco Javier Álvaro Afonso, Yolanda García Álvarez, ESTHER ALICIA GARCIA MORALES, Marta García-Madrid Martín de Almagro, Aroa Tardáguila García, José Luis Lázaro Martínez

Aim: To compare the clinical outcomes among outpatients with diabetic foot ulcers (DFUs) and ischemia versus outpatients with DFU and medial artery calcification (MAC).

Method: We have performed an observational retrospective cohort study including 50 patients divided in two groups (25 with mild or moderate ischemia and 25 with MAC according to the ankle-brachial index (ABI) and/or toe-brachial index (TBI) values. Clinical outcomes between two groups were analysed. In addition, for each patient anteroposterior XR-plains were reviewed to evaluate the presence of radiographic arterial calcification (RAC) and a second analysis was performed dividing the study population in patients with RAC or not RAC.

Results / Discussion: Significance differences in mean healing time (35.6±22.3 versus 28.8 ±12.5 weeks, p=0,191) were not observed among groups according to the ABI and/or TBI values or according to the presence or not of RAC (30.1 ±18.5 versus 34.4±18.0 weeks, p=0,411). Figure depicts the time to wound healing Kaplan-Meir survival curve for the presence of ischemic/MAC (A) or RAC/NOT RAC (B) respectively. Patients without RAC were significantly associated with higher levels of total cholesterol (155.58±39.8 versus 130.73±25.2 mg/dl, p=0,013), HDL (49.54 ±20.0 versus 38.18± 10.7 mg/dl, p=0.005), LDL (82.08±25.7 versus 65.34±18.3 mg/dl, p=0.010), hematocrit (42.16 ±4.55 % versus 38.85±5.95 %, p=0.033) and hemoglobin (13.73 ±1.6 versus 12.69 ±1.91 g/dL, p=0.044). Moreover, patients with RAC were significantly associated with higher number of minor amputations until wound healing [RAC 30,8% (8/26) versus NOT RAC 4%, (1/24), OR 10.22, 95% CI 1.12-89.39, p=0,014].



Conclusion: Patients with DFU and MAC had not significance differences in mean healing time comparing with patients with DFU and ischemia. The presence of RAC were significantly associated with higher number of minor amputations until wound healing and the absence of RAC were significantly associated with higher total cholesterol, HDL, LDL, hematocrit and hemoglobin level.

EP24

SAFETY OF DIABETIC FOOT ULCER TREATMENT WITH A NOVEL TOPICALLY APPLIED MESENCHYMAL STEM CELL PRODUCT

Jonas Hedegaard Andersen, Anne Rasmussen, Marie Frimodt-Moeller, Esther Steeneveld, Steven Elliman, Timothy O'Brien, Klaus Kirketerp-Møller, Peter Rossing

Aim: To investigate safety of treating diabetic foot ulcers (DFU) with a topically administered mesenchymal stem cell (MSC) product.

Method: Individuals with diabetes, peripheral neuropathy, toe blood pressure >40 mmHg and non-infected below ankle DFU with duration of four to fifty-two weeks before inclusion were screened.

In addition to standard care and offloading devices, participants were treated once with a topically applied allogeneic cellular product containing CD362 enriched MSCs acquired from bone marrow of healthy non-related and leukocyte antigen (HLA)-unmatched donors suspended in a collagen solution.

Participants were subsequently followed for seven months to gather information on adverse event (AE) and serious advents (SAE).

Results / Discussion: Of sixteen screened individuals two were included. Participants incurred a total of seven AEs and one SAE during the follow-up. Increased exudation from DFU was observed by both participants and was suspected to be associated with the investigated medical product (IMP). In both cases the exudation was resolved within one week without any worsening of index ulcer or reoccurrence. The SAE consisted of a hospital admission due to neurological symptoms which were assumed to be caused by hypoglycemia, no relation to the IMP was suspected. The other AEs were mild and no relation to IMP was suspected.

None of the treated ulcers healed during the follow-up.

Conclusion: This study presents data from two individuals with DFU treated with a novel topical MSC treatment. We found one AE suspected to be associated to the IMP i.e. increased exudation from the DFU. This potentially detrimental AE was resolved within one week and can easily be remedied by choosing other bandages with higher absorption capacity or with more frequent change of bandages the first week after application of IMP.

This study lays the groundwork for further large scale randomized clinical studies using this novel MSC treatment.