SOPATE 2022

Endorsed by EFIC

The 4th European Congress on Clinical Trials in Pain

7-8 December 2022 | Vienna, Austria

Bioevents
Sharing Biomed Knowledge

Abstract Book

Poster 1

Acute Pain

The immediate effect of Progressive Muscle Relaxation on the pain and well-being of garment workers

Munira Hoosain[1], Sanda Dwayi[1], Aqeelah Ganie[1], Zita Jacobs[1], Dominique Prince[1], Yonela Sokomani[1], Sonya Marais[1], Nicola Plastow[1]

Occupational Therapy, Stellenbosch University, South Africa

Background:

Musculoskeletal pain is prevalent amongst garment workers as a result of awkward postures, as well as repetitive or forceful movements. Musculoskeletal pain can have a negative impact on the mental health and quality of life of workers, subsequently leading to a decrease in productivity. Progressive Muscle Relaxation is a time efficient, cost-effective and simple technique that could be used by workers while at their workstations.

Objectives:

The aim of this study is to determine the immediate effect of PMR on the pain and mental well-being of garment workers with musculoskeletal pain.

Methods:

A pre-experimental, single-group pretest-posttest design was used. Data were collected in two sessions with the workers, individually (n=24). During the first session, consent was obtained, an intake interview was done to determine eligibility for the study, and the Patient Health Questionnaire-9 was administered. During the second session, the pain Visual Analogue Scale and Stellenbosch Mood Scale were administered before and immediately after the PMR intervention. Data were recorded and tracked on spreadsheets and analysed using SPSS.

Results:

24 workers participated, with a mean age of 40,67 years and average length of employment of 10.26 years. PHQ-9 scores showed that most (n=9) participants presented with minimal depression, followed by (n=15) participants presenting with mild, moderate and moderately severe depression. Pain VAS scores indicated that PMR effectively decreased musculoskeletal pain with a mean difference of 2.67 (p .001, effect size 1.74). Results from the STEMS showed an improvement in mood after the PMR intervention (effect sizes 0.5).

Conclusion:

PMR was effective at immediately reducing musculoskeletal pain and improving the mood of garment workers with musculoskeletal pain. We recommend further research using a control group and assessing long term effects of PMR.

Poster 2

Acute Pain

Nebulized Ketamine at 3 Different Dosing Regimens for Painful Conditions in the Emergency Department

Daniel Dove[1], Catsim Fassassi[1], Ashley Davis[1], Jefferson Drapkin[1], Mahlaqa Butt[1], Rukhsana Hossain[1], Sarah Kabariti[1], Antonios Likourezos[1], John Marshall[1], **Sergey Motov**[1]
Emergency Medicine, Maimonides Medical Center, USA

Background: Ketamine is a non-competitive N-methyl-D-aspartate (NMDA)/glutamate-receptor complex antagonist that decreases pain by diminishing central sensitization, hyperalgesia, and "wind-up" phenomenon at the level of the spinal cord (dorsal ganglion) and central nervous system. The anti-hyperalgesic, anti-allodynic, anti-tolerance, and anti-sensitization properties of ketamine allow this medication to be used for pain control of various chronic pain syndromes.

Objective: Assess and compare the analgesic efficacy and rates of adverse effects of ketamine administered via breath-actuated nebulizer at three different dosing regimens for Emergency Department patients presenting with acute and chronic painful conditions.

Methods: This was a prospective, randomized, double-blinded trial comparing three doses of nebulized ketamine (0.75mg/kg, 1 mg/kg and 1.5 mg/kg) administered via breath-actuated nebulizer, in adult Emergency Department patients aged 18 years and older with moderate to severe acute and chronic pain. Primary outcome included the difference in pain scores between all three groups at 30 minutes. Secondary outcomes included a need for a second or third dose of ketamine, need for rescue analgesia, and adverse events in each group at 30 and 60 minutes.

Results: We enrolled 120 subjects (40 per group). Difference in mean pain scores at 30 minutes between the 0.75 mg/kg and 1 mg/kg groups was 0.25 (95% confidence interval [CI]: -1.28 to 1.78), between the 1 mg/kg and 1.5 mg/kg groups was -0.225 (95% CI: -1.76 to 1.31), and between the 0.75 mg/kg and 1.5 mg/kg groups was 0.025 (95% CI: -1.51 to 1.56). No clinically concerning changes in vital signs were observed. No serious adverse events occurred in any of the groups.

Conclusions: Nebulized ketamine administered at the 1.5 mg/kg dose via breath-actuated nebulizer did not provide superior analgesia to nebulized ketamine at the 0.75 mg/kg and the 1 mg/kg for short-term treatment of moderate to severe pain in the Emergency Department and resulted in slightly higher rates of dizziness and fatigue.

Poster 3

Acute Pain

Analgesic Efficacy of Oral VTS-Aspirin/Ketamine for Management of Acute Musculoskeletal Pain in the Emergency Department - A Proof of Concept Pilot Study

Ashley Davis[1], Catsim Fassassi[1], Daniel Dove[1], Jefferson Drapkin[1], Antonios Likourezos[1], Ankit Gohel[2], Patrizia Favale[2], Rukhsana Hossain[1], Mahlaqa Butt[1], Louis Gerges[1], **Sergey Motov**[1]

[1]*Emergency Medicine, Maimonides Medical Center, USA*

[2]*Pharmacy, Maimonides Medical Center, USA*

Background: A combination of ketamine and aspirin could lead to a more effective analgesia for musculoskeletal pain than each medication alone, a theory proposed by Vitalis Analgesics (New York, NY) even though aspirin potentiates and increases the number of NMDA receptors with resultant reduction in analgesic efficacy of ketamine.

Objective: We aimed to assess the analgesic efficacy and safety of a combination of oral VTS-Aspirin® and Ketamine (VTS-K) in managing acute Musculoskeletal (MSK) pain in adult Emergency Department (ED) patients.

Methods: This was a prospective, proof-of-concept, single-arm, clinical trial evaluating the efficacy and safety of a single dose of oral VTS-K in adult ED patients with acute moderate-to-severe MSK pain. The primary outcome included the difference in pain scores, on an 11-point numeric pain rating scale, at 60 minutes. Secondary outcomes included the need for rescue analgesia, the occurrence of adverse events at 60 minutes, and a change in pain scores at 120 minutes.

Results: We enrolled 25 patients to the study. The mean baseline pain score was 8.6 and the mean pain score at 60 minutes decreased to 4.8. The oral ketamine dose ranged from 24 mg to 50 mg with a mean dose of 37.8mg. No clinically concerning changes in vital signs were noted. No serious adverse events occurred in any of the subjects. All adverse effects were transient and weak in intensity.

Conclusion: We demonstrated that administration of VTS-K to adult ED patients with acute MSK pain resulted in clinically significant pain relief in 80% of enrolled subjects.

Poster 4

Acute Pain

Oral VTS-Aspirin/Ketamine versus Oral Ketamine for Emergency Department patients with acute musculoskeletal pain

Louis Gerges[1], Catsim Fassassi[1], Carla Barberan[1], Sophia Correa-Bravo[1], Ashley Davis[1], Jefferson Drapkin[1], Antonios Likourezos[1], Michael Silver[1], Rukhsana Hossain[1], Patrizia Favale[2], Ankit Gohel[2], **Sergey Motov**[1]

[1]*Emergency Medicine, Maimonides Medical Center, USA*

[2]*Pharmacy, Maimonides Medical Center, USA*

Background: Aspirin is a non-selective and irreversible NSAID that inhibits the activity of both cyclooxygenase-1 and 2 and blocks the synthesis of prostaglandins and thromboxanes. It is predominantly used for the treatment of headache but has limited use in the Emergency Department (ED) as an analgesic. A combination of ketamine and aspirin for the treatment of acute musculoskeletal pain in the ED could result in greater pain relief in comparison to each analgesic alone even though aspirin potentiates and increases the number of NMDA receptors, which could lead to a reduced analgesic efficacy of ketamine.

Objective: To investigate if an orally administered combination of VTS-Aspirin ™ and ketamine will provide better analgesia than a ketamine alone in adult patients presenting to the ED with acute musculoskeletal pain.

Methods: A prospective, randomized, open-label trial of ED patients aged 18 and older presenting with moderate to severe acute musculoskeletal pain as defined by an 11-point numeric rating scale (NRS) with an initial score of ≥5. Patients were randomized to receive either 324 mg of VTS-Aspirin and 0.5 mg/kg of oral ketamine (AOK) or 0.5 mg/kg of oral ketamine (OK) alone. Patients were assessed at baseline, 30, 60, 90, and 120 minutes. Primary outcome was a difference in pain scores between the two groups at 60 minutes post-administration. Secondary outcomes included adverse events and the need for rescue analgesia.

Results: We enrolled 60 patients in the study (30 per group). The difference in mean pain scores at 60 mins between the AOK and OK groups was 2.6 [95% CI: 1.38 - 3.77] showing a lower mean pain score in the OK group. At 60 minutes, the AOK group had a change in mean pain score from 8.4 to 6.3 (difference 2.1; 95% CI: 1.35 - 3.00). The OK group had a change in mean pain score from 7.8 to 3.7 (difference 4.1, 95% CI: 3.25 -4.90). No clinically concerning changes in vital signs were observed. No serious adverse events occurred in either group. The most commonly reported adverse effects were dizziness and fatigue. None of the participants required rescue analgesia at 60 minutes post-medications administration.

Conclusion: Administration of an oral combination of VTS-Aspirin ™ and ketamine resulted in less analgesia compared to oral ketamine alone, for the short-term treatment of moderate to severe acute musculoskeletal pain in the ED

Poster 5

Acute Pain

Predictive Factors for Favorable Short-term Response to Interlaminar Epidural Block for Cervical Radiculopathy

Sung Hyun Shin[1], Daeseok Oh[1]
Department of Anesthesia & Pain Medicine, Inje University
Haeundae Paik Hospital, South Korea

Background: Predictive factors for the short-term efficacy of epidural injection in cervical radiculopathy have been explored in a limited number of studies, and these have not shown concordant results.

Objectives: The objective of this study was to identify the clinical factors that predict short-term outcomes of cervical interlaminar epidural injection (CIEI) for management of cervical radiculopathy.

Methods: We analyzed the clinical data of 72 patients who received fluoroscopic-guided CIEI using the paramedian approach for cervical radiculopathy in order to identify the predictive factors for short-term outcomes of CIEI. Demographic characteristics, history of neck surgery, diagnosis, initial numeric rating score, duration of symptoms, Douleur Neuropathique 4 (DN4) questions, painDETECT questionnaire, neck disability index, and ventral epidural spread of contrast medium were assessed. Treatment success was defined as at least a 50% reduction in the numeric rating score after CIEI and was designated as a good response.

Results: The short-term success rate of CIEI for cervical radiculopathy was 55.56%. Multivariate logistic regression analysis established that spinal stenosis (odds ratio, 0.183; $p = 0.012$), a longer duration of 24 weeks of symptoms (odds ratio, 0.206; $p = 0.026$), and combined positive results for the DN4 and painDETECT (odds ratio, 0.019; $p = 0.008$) decreased the odds ratio of a good response, 2–3 weeks after CIEI.

Conclusions: CIEI provides a significant short-term outcome in patients with cervical radiculopathy. However, CIEI efficacy may be negatively affected in patients with spinal stenosis, the presence of a chronic state, and a possible neuropathic pain component.

Table 1. Univariate and multivariate logistic regression results of variable.

Variable	Category	Univariate		Multivariate	
		OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Sex	Female	0.897 (0.341 - 2.359)	0.826	-	-
Age		1.017 (0.971 - 1.066)	0.470	-	-
BMI		1.190 (0.978 - 1.449)	0.083	-	-
DM	Yes	0.778 (0.179 - 3.387)	0.738	-	-
Hx. of neck surgery	Yes	1.667 (0.285 - 9.738)	0.571	-	-
Diagnosis	Spinal stenosis	0.224 (0.083 - 0.607)	0.003	0.183 (0.049 - 0.684)	0.012
Initial NRS neck		0.990 (0.971 - 1.010)	0.326	-	-
Initial NRS arm		0.970 (0.942 - 0.998)	0.037	0.976 (0.935 - 1.019)	0.269
Duration	Chronic	0.137 (0.045 - 0.418)	<.001	0.206 (0.051 - 0.832)	0.026
Neuropathic component	Positive	0.143 (0.041 - 0.497)	0.002	0.119 (0.025 - 0.571)	0.008
NDI score		0.929 (0.876 - 0.985)	0.013	0.983 (0.900 - 1.075)	0.710
Ventral epidural spread	Positive	1.615 (0.444 - 5.873)	0.466	-	-

Estimated Odds Ratio (OR) Abbreviations: BMI, body mass index; DM, diabetes mellitus; NRS, numerical rating scale; NDI, neck dysfunction index; CI, confidence interval. The neuropathic component refers to the combination of positive results for DN4 plus painDETECT.

Poster 6

Acute Pain

Efficacy of Pregabalin and Duloxetine in Patients with Painful Diabetic Peripheral Neuropathy (PDPN): a Multi-center, Phase 4 Clinical Trial Blossom

Martin Rakusa[1], Sandra Vuckovic Rebrina[2], Iris Marolt[3], Adam Stepien[4]

[1]*Divison of Neurology, University Medical Centre Maribor, Slovenia*
[2]*Merkur University Hospital, Vuk Vrhovac University Clinic, Croatia*
[3]*., Healthcare Center, Slovenia*
[4]*Neurological Clinic, Military Institute of Medicine, Poland*
[5]*Clinic of Neurology, University Clinical Center of Serbia, Serbia*

Introduction: Our trial evaluated the efficacy of two generic medications in treating pain in patients with PDPN – pregabalin (Pregabalin Krka) and duloxetine (Dulsevia®).

Methods: Patients were randomised to the pregabalin (99) or duloxetine (102) arm. The pain was evaluated using the DN-4 questionnaire and visual analogue scales (VAS, 0-100 mm) to measure average pain intensity (API), worst pain intensity (WPI) in the last 24 hours and current pain intensity (CPI).

Results: After 12 weeks, CPI, API and WPI decreased from 57.3 ± 16.5 to 22.0 ± 19.8, 60.5 ± 14.0 to 23.5 ± 18.0, and 69.2 ± 16.7 to 27.7 ± 20.6 in the pregabalin arm and 54.9 ± 14.1 to 20.0 ± 17.5, 58.7 ± 15.0 to 21.9 ± 18.8, and 67.4 ± 16.0 to 27.4 ± 21.0 in the duloxetine arm (all in mm, all p0.001). The DN-4 questionnaire score significantly decreased from 6.9 ± 1.6 (both arms) to 3.6 ± 2.4 (pregabalin, p0.001) and 3.6 ± 2.5 (duloxetine, p0.001).

The proportion of patients with a clinically significant improvement of API (≥ 30% improvement from baseline and/or ≤ 30 mm on VAS) at week 12 was 88.3% [CI 81.7%, 94.8%] in the pregabalin arm and 86.9% [CI 76.7%, 97.1%] in the duloxetine arm. API at week 2 was reduced by 28.1% in the pregabalin and 31.6% in the duloxetine arm.

Conclusion: Our results demonstrate that Dulsevia® and Pregabalin Krka are effective medications for treating pain in PDPN in more than 86% of all randomised patients.

Poster 7

Alternate Trial Design Approaches

An Alternative Design for Cancer Pain Trial: Positive Run-in with Randomized Withdrawal

Guang-Liang Jiang[1], Feng Xu[1]
Clinical Development, Xgene Pharmaceutical Inc., China

Background: Worldwide, an estimated 19.3 million new cancer cases with 10 million death occurred in 2020. Pain prevalence is 66.4% in advanced, metastatic, or terminal disease. Cancer pain has a severe impact on quality of life and is associated with numerous psychosocial consequences. However, the conventional placebo-controlled, parallel-group randomized design for cancer pain has faced enrollment challenge, dropouts (up to 44% even in short duration of trials), low compliance and ethical issues in this palliative-care population heavily loaded with anti-cancer treatments.

Objectives: To discuss the advantage of positive run-in with randomized withdrawal enrichment design for cancer pain trial.

Methods: Use model drug XG005, a prodrug conjugate of naproxen and pregabalin, to collect estimated effect size from literature and compare two cancer pain trial designs.

Results: Under placebo-controlled, parallel-group randomized design, with 90% power and two-tailed $\alpha = 0.05$, 150 subjects/arm would be needed to demonstrate superiority over placebo, with placebo exposure lasting the entire follow-up period (e.g., 4 weeks). While use positive run-in, randomize responders at the end of run-in period, and allow withdrawal once pain relapses, only 24 responders/arm (resulted from 48-75 subjects for run-in) would be randomized for the above power. The estimated median placebo exposure would be 5 days (5 times t1/2) before withdrawal.

Conclusion: The alternative cancer pain trial design will need fewer subjects and minimize the exposing time to ineffective treatment and thus avoid patient suffering. Its yet unpopularity in cancer pain trial requires discussion among scholars and regulatory agencies.

Poster 8

Alternative Outcome Measure

Validation of a simple bedside-Quantitative Sensory Testing battery for chronic neuropathic pain.

Juliane Sachau[1], Christina Appel[1], Maren Reimer[1], Manon Sendel[1], **Julia Forstenpointner**[1], Jan Vollert[1,2,3,4], Philipp Hüllemann[1], Ralf Baron[1]

[1]*Division of Neurological Pain Research and Therapy, Department of Neurology, University Hospital Schleswig-Holstein, Campus Kiel, Germany*

[2]*Pain Research, MSk Lab, Department of Surgery and Cancer, Faculty of Medicine, Imperial College London, UK*

[3]*Department of Anaesthesiology, Intensive Care and Pain Medicine, University Hospital Muenster, Germany*

[4]*Neurophysiology, Mannheim Center of Translational Neuroscience (MCTN), Medical Faculty Mannheim, Heidelberg University, Germany*

The assessment of sensory phenotypes in patients with neuropathic pain provides important information of the underlying pathophysiological mechanisms. In order to evaluate sensory function standardized quantitative sensory testing (laboratory-QST) protocols are used. The feasibility of such protocols however is limited due to high expenditures of time and costs. Thus, a simple bedside-QST battery was recently developed indicating good agreement in comparison to laboratory-QST. In the current approach we aimed to validate and improve the initial bedside-QST protocol. Patients suffering from chronic neuropathic pain (n= 60) attended three consecutive visits. The baseline and longterm (after 3 weeks) visit, included laboratory-QST and bedside-QST assessment, whereas 3 hours after the initial visit only bedside-QST was repeated to assess test-retest reliability. Additionally, patients completed questionnaires regarding their pain (intensity, quality), depression, anxiety and quality of life to assess convergent/divergent validity. Results indicated a moderate to excellent test-retest reliability for most bedside-QST parameters. Overall, results for short-term reliability and interval-scaled parameters were slightly better. Most of the bedside-QST parameters did not correlate with the depression and anxiety score suggesting a good divergent validity.Thus, bedside-QST has good concurrent criterion and divergent validity as well as reliability. Importantly, this battery consists of only five low-cost devices, that can be quickly and easily used to characterize the sensory phenotype of patients with neuropathic pain. Moreover, we propose different combinations of bedside-QST parameters for an improved mechanism-based examination of patients' subgroups and to identify treatment responders.

Poster 9

Alternative Outcome Measure

Abnormal autonomic phenomenon provoked by noxious muscle stimulation as a possible sign of mixed syndrome among chronic sciatica patients

Elzbieta Skorupska[1], Daria Wotzka[2], Tomasz Dybek[3], Michał Rychlik[4], Marta Jokiel[1,5], Mariusz Konieczny[3], Przemysław Domaszewski[6], Paweł Pakosz[3], Paweł Dobrakowski[7]

[1]*Department of Physiotherapy, Poznan University of Medical Sciences, Poland*

[2]*Faculty of Electrical Engineering, Automatic Control and Informatics, Opole University of Technology, Poland*

[3]*Faculty of Physical Education and Physiotherapy, Opole University of Technology, Poland*

[4]*Department of Virtual Engineering, Poznan University of Technology, Poland*

[5]*Department of Traumatology, Orthopedics and Hand Surgery, Poznan University of Medical Sciences, Poland*

[6]*Department of Health Sciences, University of Opole, Poland*

[7]*Psychology Institute, Humanitas University in Sosnowiec, Poland*

Background: Sciatic pain can possibly persist due to neuropathic, nociplastic, or mixed syndrome pain pathomechanism. Referred pain is considered a possible sign of nociplastic pain, thus the abnormal activity of the immune and autonomic nervous systems can be possible. To confirm abnormal autonomic reactivity within the referred pain zone of active trigger points, a new diagnostic tool that uses noxious muscle stimulation under infrared camera control – the Skorupska Protocol® test (the SP test®) – was applied. The SP test® is considered positive if the size of the noxiously provoked vasomotor response in the lower leg is bigger than 3%. Healthy subjects, who undergo the SP test®, are characterized by the absence of vasomotor reactivity.

Objectives: The study aims at examining if chronic sciatica subjects with/without co-morbidity can develop an abnormal autonomic response to the SP test® spreading down to the lower leg in the sciatic pain zone.

Methods: Two groups of chronic sciatica patients: group A (with referred pain (n=20)) and group B (without referred pain (n=20)) were examined using the SP test®.

Results: The SP test provoked an abnormal vasomotor response, that covered the lower leg, sized: A 20.4 ± 19.9% vs B 3.77 ± 9.14%; p = 0.000; CI (0.347,0.348).

Conclusions: The chronic sciatica patients who present with muscle referred pain co-morbidities can be objectively distinguished by abnormal autonomic nervous system activity confirmed by the SP test®. The observed phenomenon can possibly be applied to confirm the mixed syndrome/nociplastic pain involvement in chronic sciatica.

Poster 10

Back Pain

Is increased dose of triamcinolone for lumbar medial branch block associated with superior efficacy?

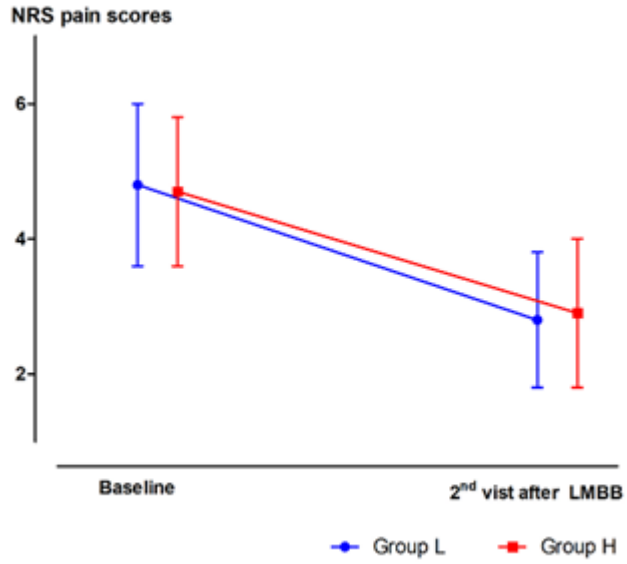
Jae Ni Jang[1], Sukhee Park[1], Ji-hoon Park[1]
Department of Anesthesiology, 1Catholic Kwandong University School of Medicine, South Korea

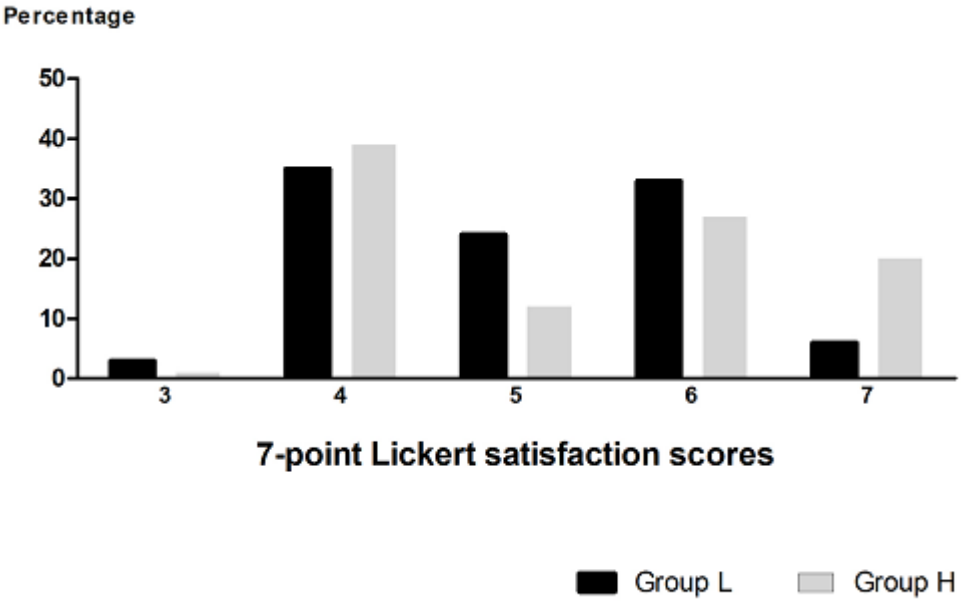
Background: Although the beneficial effects of steroids for lumbar medial branch block (LMBB) have been demonstrated, there are no guidelines for selecting an appropriate steroid dose for LMBB. The study objective is to retrospectively compare the analgesic effect of different doses of triamcinolone in combination with local anesthetics to determine the lowest possible dose of triamcinolone for lumbar medial branch block in lumbar facet joint pain.

Methods: A total of 223 patients with clinical features of lumbar facet joint syndrome who underwent LMBB were retrospectively divided into 3 groups according to the triamcinolone doses, (1) 10-mg triamcinolone (T10 group, n = 121); (2) 20-mg triamcinolone (T20 group, n = 87); (3) 40-mg triamcinolone (T40 group, n = 15). The outcome measurements were the numeric rating scale (NRS) pain scores, the 7-point Likert satisfaction scale, and the proportion of responder (reduction in NRS pain score 50% or 7-point Likert scale of ≥ 6) at 2nd visit after lumbar medial branch block.

Results: The change in NRS pain score at 2nd visit (25.6 ± 14.0 days) after LMBB showed no statistical difference between the three groups. The 7-point Likert scale at 2nd visit after the LMBB also did not show significant difference between the three groups. The proportion of responder was comparable among groups.

Conclusions: The increased dose of triamcinolone for LMBB did not show superior analgesic efficacy.


NRS pain scores
6
4
2
Baseline
2nd vist after LMBB
Group L
Group H


Percentage
50
40
30
20
10
0
3
4
5
6
7
7-point Lickert satisfaction scores
Group L
Group H

Poster 11

Back Pain

Safety and Tolerability of STA363 in Patients with Degenerative Disc Disease

Anders Lehmann[1], Andreas Gerward[1], Björn Strömqvist[2], Douglas Beall[3]

[1]*Clinical Development, Stayble Therapeutics, Sweden*

[2]*Department of Orthopedics, University Hospital Malmö/Lund, Sweden*

[3]*Interventonal Radiology, Comprehensive Specialty Care, USA*

Background

Patients suffering from degenerative disc disease (DDD) not responding to conservative therapy are left with few therapeutic options. Intradiscal injection of lactic acid (STA363) in pigs has been shown to transform the nucleus pulposus into fibrotic tissue and thereby render the motion segment less mobile. It is hypothesized that this effect affords therapeutic benefits to DDD patients.

Objectives

To evaluate STA363 with regard to efficacy (primary objective) and safety/tolerability (one of the secondary objectives) in patients with DDD.

Methods

In a double-blinded, randomized, placebo-controlled phase 2b study, 110 patients were recruited in 3 countries. The patients were randomized into one of 3 groups: Placebo (Omnipaque) and STA363 at 90 or 180 mg in Omnipaque. A single intradiscal injection (1.5 mL) was done and patients will be followed for 12 months. Primary endpoint is change from baseline in low back pain (Numerical Rating Scale) and one secondary endpoint is incidence of adverse events (AEs).

Results

Two discs were treated in 38% of the patients, and all injected discs were of Pfirrmann grade 3. The study has not yet been unblinded but overall, safety and tolerability data collected so far suggest that the treatment is safe and tolerable. A total of 58 AEs has been reported and with two exceptions of severe AEs unlikely to be related to the treatment, all AEs were mild or moderate.

Conclusion

Preliminary results indicate that intradiscal injection of STA363 is safe and tolerable.

Poster 12

Back Pain

Diagnosis of C4 radiculopathy

Yasuhisa Tanaka[1], Eduardo Yoshizaki[2]
[1]*Department of Orthopaedics, Tohoku Central Hospital, Japan*
[2]*Department of Orthopaedics, National University of Asuncion, Paraguay*

Introduction:

Cervical nerve root compression causes neck and scapular pain, and its location indicates the affected root. Furthermore, C5 to C8 radiculopathy is usually accompanied by specific neurologies. However, features of C4 radiculopathy are not well-known.

Material and Methods:

We retrospectively studied patients who underwent posterior foraminotomy of the unilateral C3-4 intervertebral level between 2012 and 2020 and showed improvements within 1 month after surgery. We collected data on symptom duration, site of neck pain, Spurling test, imaging findings, selective root block (SRB) effect, and surgical results using a cervical radiculopathy scoring system (normal=20 points).

Results:

In total, 13 patients were included, with mean age of 70 (range, 53-82) years, and mean follow-up of 2 years. Symptom durations were 3 months to 5 years and exceeded 1 year in five patients. All patients reported unilateral nape pain of the suboccipital and upper trapezius region. Spurling test elicited reproduction or increase of nape pain in every patient. Plain radiographs showed facet joint hypertrophy and foraminal stenosis at C3-4 level on the symptomatic side in every case. Those findings were also clear on magnetic resonance imaging and computed tomography scans. In 7 patients who underwent SRB, pain reproduction and its temporary relief were obtained. Cervical radiculopathy scores ranged from 9 to 15 points before surgery, and from 16 to 20 after surgery. Mean improvement rate was 90%.

Conclusion:

Unilateral nape pain, long-standing, especially elderly, indicates C4 radiculopathy. Positive Spurling test and facet joint hypertrophy can confirm the diagnosis.

Poster 13

Chronic Pain

Mindfulness Combined with Exercise Online (MOVE) Compared with a Self-Management Guide for Adults with Chronic Pain: A Feasibility Randomised Controlled Trial.

Orla Deegan[1], Brona Fullen[1], Maire-Brid Casey[3], Ricardo Segurado[1], Conor Hearty[2], Catherine Doody[1]
[1]*School of Public Health Physiotherapy and Sports Science, University College Dublin, Ireland*
[2]*Department of Pain Medicine, Mater Misericordiae University Hospital, Ireland*
[3]*School of Medicine, Trinity College Dublin, Ireland*

Background
Mindfulness-based stress reduction (MBSR)[1] and exercise[2] are recommended in the management of chronic pain (CP). Limited studies exist combining these interventions in an online pain management programme (PMP).

Objectives
This study explored the acceptability and feasibility of a combined MBSR and exercise online PMP for adults with CP, and examined the feasibility of conducting a Randomised Controlled Trial (RCT) comparing MBSR and exercise online with an online self-management guide.[3]

Methods
A feasibility RCT was conducted with participants randomised into Group A (8-week MBSR and exercise live online) and Group B (8-week online self-management guide). Primary outcomes included recruitment, attrition, intervention adherence, and satisfaction. Participants wore a Fitbit watch during the study and completed patient reported outcome measures at baseline, post-intervention and 12-week follow-up.

Results
96 participants were randomised and 80 (83.3%) completed the interventions. 76.3% (n=73) of participants adhered to wearing the Fitbit for 8-weeks. Higher mean satisfaction (Client Satisfaction Questionnaire-8) was reported in group A 26.2(±5.5) than group B 19.4(±5.6). The Patient Global Impression of Change scale showed favourable changes in both groups; 65.1% of group A, 42.3% of Group B reporting improvement. Comparable improvements post-intervention and at a 12-week follow-up were noted within both groups for Brief Pain Inventory, Pain Self Efficacy Questionnaire, Pain Disability Index, Pain Catastrophising Scale, Fear Avoidance Belief Questionnaire and Short Form-36 Health Survey.

Conclusion
The findings suggest both online intervention formats explored in this study are feasible and a fully powered RCT of mindfulness combined with exercise, delivered live online is warranted.

References:

1. Turner J, Anderson M, Balderson B et al. Mindfulness-based stress reduction and cognitive behavioral therapy for chronic low back pain: similar effects on

mindfulness, catastrophizing, self-efficacy, and acceptance in a randomized controlled trial. Pain 2016;157:2434-2444. doi:10.1097/j.pain.0000000000000635

2. National Institute for Health and Care Excellence (NICE) (2021) Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain. NG193. Available at: https://www.nice.org.uk/guidance/ng193 (Accessed 18th July 2021)

3. Deegan O, Fullen B, Casey M, Segurado R, Hearty C, Doody C. Combined online interactive mindfulness and exercise programme (MOVE-Online) compared with a self-management guide for adults with chronic pain: protocol for a randomised controlled feasibility trial. BMJ Open. 2022;12(2):e058265

Poster 14

Chronic Pain

Pain Prevalence in an Irish University

Orla Flynn[1,2], Brona M Fullen[1,2], Catherine Blake[1,2]
[1]*School of Public Health, Physiotherapy and Sports Science, University College Dublin, Ireland*
[2]*Centre for Translational Pain Research, University College Dublin, Ireland*

Introduction

Chronic pain is prevalent in young people, with pooled prevalence estimated at 12% (Murray et al., 2022). To date, pain prevalence has not yet been comprehensively explored in an Irish university context.

Aims

This study aimed to determine pain prevalence in students attending University College Dublin.

Methods

Ethical approval was obtained (Flynn-Blake-LS-19-90). A cross-sectional anonymous online survey was designed and made available (Survey Monkey). Participant demographics, regional pain location (7 regions), pain severity (1-10 NRS) and duration were collected. The responses were imported to SPSS-27 and analysed.

Results

Four hundred and ninety-nine of 609 students (82%) reported pain. Most of the students were 18-30 years old (n=441, 88%), female (n=359, 72%), and undergraduates (n=358, 80%). Pain severity scores (NRS) were highest (mean±SD) in the head/face (4.59±3.1), neck/shoulders (4.81±2.8) and mid/low back (4.48±2.6). Pain duration was distributed between acute (n=293, 59%) and chronic pain (n=206, 41%). Out of 449 respondents, pain impacted students in a range of areas including sports participation (n=255, 57%), sleep quality (n=248, 55%) and ability to attend college (n=137, 30.5%).

Conclusions

Pain is prevalent and burdensome in a cross-section of one Irish university. Raising awareness of pain in young people is important. Both to prevent pain progression from acute to chronic and to mitigate the burden of chronic pain.

Poster 15

Chronic Pain

Mu-Positive NK Cells Expression as Putative Biomarker for Chronic Pain Diagnosis, in Fibromyalgia and Osteoarthritis Patients

Valentina Malafoglia[1], Sara Ilari[2], Michael Tenti[1], Carolina Muscoli[2], William Raffaeli[1]

[1]*Institute for Research on Pain, Isal-Foundation, Italy*

[2]*Department of Health Sciences, University "Magna Graecia" of Catanzaro, Institute of Research for Food Safety & Health (IRC_FSH), Italy*

Background

Chronic pain diagnosis is arduous because of affective-motivational, cognitive-evaluative and sensory-discriminative pain characteristics. Moreover, the lack of specific biomarkers makes chronic pain diagnosis and therapy sometimes useless. Recently, we identified Mu opioid receptor positive (Mu+) B cells percentage as a candidate marker for chronic pain, in fibromyalgia (FM) and in osteoarthritis (OA) patients.

Objectives

Here we propose Mu+ Natural Killer (NK) cells as a new immune cell type being part of a biological markers pool for chronic pain patients.

Methods

We enrolled three groups of patients: FM patients, OA patients and Pain-Free subjects (negative control group). We collected blood samples to apply immunophenotyping analysis and study the expression of Mu opioid receptor on NK cells surface. Western blot analysis has been performed in order to detect NK cells functional status. Biological data were statistically analyzed.

Results

Final results showed that the percentage of Mu+ NK cells were statistically lower in FM and OA patients than in pain-free subjects. NK cells activation status appeared diverse between chronic pain patients and pain-free subjects.

Conclusions

We identified Mu+ NK cells expression as another possible component of biological markers pool for chronic pain diagnosis, in FM and OA patients, as well as for Mu+ B cells. This finding could help the management of chronic pain, leading to tailored therapies and personalized rehabilitation programs, for FM and OA patients. Future studies will help us to understand whether the modulation of Mu+ B and NK cells is a common mechanism in other chronic pain conditions.

Poster 16

Chronic Pain

Medical Need and Barriers of Adequate Pain Management of End of Life Cancer Patients - Georgian Experience

Tamari Rukhadze[1,2], Zaza Khachiperadze[1,2], Ketevan Meladze[1,2], Salome Kordzaia[1,2], Tamar Lekashvili[1,2]

[1]*Oncology and Palliative Medicine, Iv. Javakhishvili Tbilisi State University, Faculty of Medicine, Georgia*

[2]*Clinical Oncology, Acad. Todua Clinic, Georgia*

Background and aims - the goal of the study – Improve quality of life of patients with cancer chronic pain in Georgia through evaluation of needs, availability and accessibility of opioids.

Questionnaire survey, analysis of patients, medical professionals, patients medical records and patients care givers were applied in the study.

Results - The several problems associated with caregivers and difficulties with respect to clinical groups, problems with opioids prescription, dose selection, their availability and administration forms of opioids were assessed and included in data base along with medical problems. The 234 questioners were analyzed: 148 (63.2%) patients, 57 (24.4%) caregivers and 29 (12.4%) medical professionals. In accordance with the obtained material comparative analysis was performed, study results reliability was evaluated based thereof, wherein p value indicator was considered to be statistically reliable.

Conclusions:

Application of clinical groups in medical practice is provisional. Clinical group creates a barrier in adequate pain management, makes impossible to prescribe opioids to patients with medical means during anti-cancer radical treatment in case of strong pain;

Clinical group fails to provide complete information on general condition of patient, quality of life. It is nor applied in accordance with international clinical guidelines and is maintained only in the countries of post-soviet region;

The main barriers of non-adequate pain control and challenges in opioids availability in Georgia are: lack of the opioids, limited knowledge of medical professionals, opioid phobia between medical professionals, patients and whole population, incompliance of normative bases, legislation and regulations.

Poster 17

Chronic pain

Tobacco Smoke Exposure Predicts Physical Pain among U.S. Children

Ashley L. Merianos[1], E. Melinda Mahabee-Gittens[2], Matthew Lee Smith[3]

[1] *University of Cincinnati, USA*
[2] *Cincinnati Children's Hospital Medical Center, USA*
[3] *Texas A&M University, USA*

Background: Tobacco smoke exposure and physical pain are significant public health problems that are independently associated with many health consequences among children. However, less is known about whether exposure to thirdhand tobacco smoke (THS) and secondhand tobacco smoke (SHS) in children's homes is associated with physical pain.

Objectives: We examined whether home tobacco smoke exposure was associated with physical pain among U.S. children.

Methods: We conducted a secondary analysis of 2019-2020 National Survey of Children's Health data including 70,330 U.S. children ages 0-17 years. Home tobacco smoke exposure status included: no home TSE (did not live with smokers); home THS exposure only (lived with ≥1 smoker who did not smoke indoors); and home SHS+THS exposure (lived with ≥1 smoker who smoked indoors). We fitted a weighted adjusted logistic regression model to assess home tobacco smoke exposure status with physical pain while adjusting for: child age, sex, race/ethnicity, health status, emotional/developmental/behavioral problem; caregiver education level; and family household structure and federal poverty level.

Results: The mean (SE) age of children was 8.67 (0.04) years. Approximately 7% of children experienced physical pain in the past 12-months. Adjusted model results indicated that children who were exposed to home THS exposure only (adjusted odds ratio [AOR]=1.27, 95% confidence interval [CI]=1.02-1.58) and home SHS+THS exposure (AOR=1.71, 95%CI=1.11-2.63) were at increased odds of experiencing physical pain compared to children with no home TSE.

Conclusion: Promoting household tobacco cessation efforts in interventions for chronic pain treatment and management may be beneficial for the physical health of children.

Poster 18

Chronic Pain

Influence of Chronic Pain on Social Disconnectedness among Older Adults in the United States

Matthew Lee Smith[1], Oluyomi Oloruntoba[1], Matthew E. Barrett[1], Leigh Ann Eagle[2], Sue Lachenmayr[2], Ashley L. Merianos[3]

[1] *Texas A&M University, College Station, TX, USA*

[2] *Maryland Living Well Center of Excellence, Salisbury, MD, USA*

[3] *University of Cincinnati, Cincinnati, OH, USA*

Background. Chronic pain impacts millions of older Americans and can impede opportunities for social interaction because of disease symptomatology, mobility impairments, and/or withdrawal due to depression or mental distress.

Objectives. This study examined the influence of chronic pain on social disconnectedness among older adults in the United States.

Methods. Using an internet-delivered survey, data were analyzed from a national sample of 4,082 adults ages 60 years and older. Chi-square tests were used to compare characteristics between older adults with and without chronic pain. An ordinary least squares regression model was fitted to assess the influence of chronic pain on social disconnectedness, controlling for sociodemographics, other chronic conditions, and depressive symptomatology. Theta scores for the 13-item Upstream Social Interaction Risk Scale (U-SIRS) served as the dependent variable, which were generated using Item Response Theory. Higher U-SIRS theta scores indicated higher risk.

Results. Participants' average age was 69.6 (±5.2) years. About 59% were female and 23% self-reported chronic pain. A significantly larger proportion of older adults with chronic pain reported clinical depression (χ^2=125.97, P<0.001), felt a low sense of community belonging (χ^2=18.87, P<0.001), lacked companionship (χ^2=58.21, P<0.001), and had no contact with friends in the past two weeks (χ^2=4.25, P=0.039). In the adjusted model, higher U-SIRS theta scores were reported among older adults with chronic pain (β=0.12, P<0.001).

Conclusion. Effective chronic pain management may alleviate barriers to social engagement and improve social connectedness. Clinical trials are needed to objectively assess the directionality of the association between chronic pain and social disconnectedness.

Poster 19

Fibromyalgia

Health-related Quality of Life in Fibromyalgia: The Role of Pain – A Case Control Study

Ines Genrinho[1,2], Sofia Azevedo[1], Joana Saldanha[3], Graça Costa[1], Maria Ceu Morais[1], **Ines Cunha**[1]

[1]*Rheumatology, Centro Hospitalar Baixo Vouga, Portugal*

[2]*Rheumatology, Centro Hospitalar Tondela Viseu, Portugal*

[3]*Physical medicine and rehabilitation, Centro Hospitalar Baixo Vouga, Portugal*

Introduction:Fibromyalgia(FM) is one of the leading causes of chronic widespread pain in the world. This condition has a negative impact in health-related quality of life(HRQoL). The aim of this study was to determine the impact of pain in HRQoL and its relation with other clinical domains in FM.

Methods:A single-centre, case-control study was conducted enrolling FM patients that fulfilled ACR2016 criteria and a healthy control group. All patients answered to the Functional Assessment of Chronic Illness Therapy – Fatigue(FACIT-F), Hospital Anxiety and Depression Scale(HADS), Fibromyalgia Impact Questionnaire(FIQ-P, not in control group) and Visual Analogic Scale(VAS) for pain and fatigue. HRQoL was assessed by the European Quality of Life-5 Dimensions(EQ5D) questionnaire. Social-demographic and clinical data were collected. General descriptive analysis was performed using SPSS Statisticsv26.

Results:Sixty-six patients were included (47 FM, 19 controls), all female, with mean age 48.7±9.9 and 44.8±2.8 years old, respectively. Pain VAS, EQ5D_pain, EQ5D_general health and total EQ5D were higher in FM patients (p0.05). Depression and anxiety were more frequent in FM patients (p=0.02), having also higher rates of antidepressants, muscle relaxants, neuromodulators, opioids, paracetamol and NSAIDs use. It was found a moderate correlation between pain VAS and EQ5D_pain (r2=-0.40), EQ5D_general health (r2=-0.49), total EQ5D (r2=-0.45) and FIQ-P (r2=0.40).

Conclusion: FM patients presented worsts pain scales compared to control group and required more medications for pain control. Highest pain indices were negatively correlated with HRQoL and associated to higher depression and anxiety rates. This study highlights the relevance of pain screening and control once impaired the HRQoL.

Poster 20

Fibromyalgia

How Sleep Disturbances Impair Health Quality in Fibromyalgia Patients? – A Case Control Study

Ines Genrinho[1,2], Sofia Azevedo[1], Joana Saldanha[3], Graça Costa[1], Maria Ceu Portelada[1], **Ines Cunha**[1]

[1]*Rheumatology, Centro Hospitalar Baixo Vouga, Portugal*

[2]*Rheumatology, Centro Hospitalar Tondela Viseu, Portugal*

[3]*Physical medicine and rehabilitation, Centro Hospitalar Baixo Vouga, Portugal*

Introduction:Poor sleep quality in Fibromyalgia(FM) affects the majority of patients and can lower pain threshold, resulting in significant impairment on health-related quality of life(HRQoL). The aim of this study was to determine the prevalence of sleep disturbances in FM patients and its impact on HRQoL.

Methods:A single-centre, case-control study was conducted enrolling FM patients that fulfilled ACR2016 criteria and an healthy control group. All patients answer Functional Assessment of Chronic Illness Therapy–Fatigue(FACIT-F), Hospital Anxiety and Depression Scale(HADS), Fibromyalgia Impact Questionnaire validated for Portuguese(FIQ-P, not in control group) and Visual Analogic Scale(VAS) for pain and fatigue. HRQoL was assessed by the European Quality of Life-5 Dimensions(EQ5D). Pittsburgh Sleep Quality Index(PSQI), with a total of≥5 were indicative of poor sleep quality. Social-demographic and clinical data were collected. General descriptive analysis was performed using SPSS Statisticsv26.

Results:Sixty-six patients were included (47FM, 19 controls), all female, mean age 48.7±9.9 and 44.8±2.8 years old, respectively. All FM patients presented poor sleep quality with higher PSQI(p=0.00). Excluding the sleep duration, all the other domains were higher in FM patients. Almost one half of FM patients were under anxiolytics, 6.4%tricyclic antidepressants, 53.3%muscle relaxants and 22.5%neuromodulators. It was found a moderate correlation between sleep disturbances and FIQ-P(r2=0.43), FACIT(r2=-0.52) and total EQ5D(r2=-0.41).

Conclusion:This study permitted an objective assessment of the most affected sleep domains in FM. Despite the algic component being the main complaint of the patients, sleep disorders should not be neglected as they are associated with severe disease, worst fatigue and negative functional impact on HRQoL.

Poster 21

Fibromyalgia

Sarcopenia vs Dynapenia in patients with Fibromyalgia: which of these is present? What is its impact on pain and functional prognosis? – A case-control study

Joana Saldanha[1], Inês Genrinho[2], Sofia Azevedo[2], Maria Morais[2], Graça Costa[2], **Inês Cunha**[2]

[1]*Physical Medicine and Rehabilitation, Centro Hospitalar do Baixo Vouga, Portugal*

[2]*Rheumatology, Centro Hospitalar do Baixo Vouga, Portugal*

Background: Patients with Fibromyalgia(FM) often present loss of strength, physical performance and muscular mass. Sarcopenia is the reduction of skeletal muscle function and mass; severe if poor physical performance. Dynapenia is the reduction of muscle function without decrease in muscular mass.

Objectives: Determine the prevalence of sarcopenia in FM and its correlation with functional prognosis.

Methods: Single-center, case-control study enrolled FM patients (ACR 2016 criteria) and healthy controls. Participants answered SCAR-F, Hospital Anxiety and Depression Scale(HADS), European Quality of Life-5Dimensions(EQ5D), Pain/Fatigue Visual Analogue Scale(VAS), Fibromyalgia Impact Questionnaire(FIQ) (only in FM). Sociodemographic and clinical data were collected. Muscle mass/body and visceral fat were assessed by bioimpedance analysis; muscle strength by handgrip test; physical performance by gait speed, balance and stand up tests. Data were analyzed using SPSSv26.

Results: Forty-seven women with FM (mean age: 48.7(±9.9); 48.9% practiced physical exercise; mean BMI: 27.6 (±4.52) Kg/m2) and 19 healthy controls were enrolled. FM had significant higher(p0.03) SARC-F and visceral fat; lower skeletal muscle and strength; worst tandem stand and stand up tests. Sarcopenia was diagnosed in 21.3% of FM and dynapenia in 31.9%, showing higher prevalence(p=0.016). FM with sarcopenia had significantly higher(p0,03): HADS for anxiety; pain, activity and total in EQ5D; BMI. FM with dynapenia had higher care, activity and total in EQ5D(p0.04).

Conclusion: Our study demonstrated significant loss of muscle function and mass in FM, confirming higher sarcopenia prevalence, which was associated with anxiety, higher pain/ BMI, worst quality of life/ physical performance (related to severe sarcopenia). Screening is crucial, since it seems to influence functional prognosis.

Poster 22

Fibromyalgia

Cognitive Dysfunction in Fibromyalgia and its Relationship with Pain- A Case-control Study

Sofia Ferreira Azevedo[1,2], Inês Genrinho[1,2,3], Joana Saldanha[2,4], Maria Céu Portelada[1,2], Graça Costa[1,2], **Inês Cunha**[1,2]

[1]*Rheumatology Department, Centro Hospitalar Do Baixo Vouga, Portugal*

[2]*Centro Académico Clinico Egas Moniz, Health Alliance, Portugal*

[3]*Rheumatology Department, Centro Hospitalar Tondela- Viseu, Portugal*

[4]*Physical Medicine and Rehabilitation, Centro Hospitalar Do Baixo Vouga, Portugal*

Introduction

Fibromyalgia (FM) is one of the leading causes of chronic widespread pain, although many other symptoms may be present.

Objectives

Our study aims to compare the prevalence of cognitive impairment in patients with FM and healthy controls and evaluate its correlation with pain and disease severity.

Methods

Single-centre, case-control study in Portuguese patients diagnosed with FM according to ACR 2016 criteria and a matched healthy control group.

Sociodemographic, chronic medication, and clinical data were collected. The Montreal cognitive assessment test (MoCA), pain visual analogic scale (VAS), and other disease activity scales were applied. Cognitive impairment was defined as a MoCA score 26 points.

Statistical analysis was performed using SPSS software. The significance level was set at p0.05.

Results

Sixty-six participants were included (47 FM patients, 19 controls). All were women; the mean age was 47.56 (SD10.68 years). Groups were comparable regarding educational level.

We found lower MoCA Scores, higher prevalence of cognitive impairment, and higher pain VAS scores in FM patients (p-value0.001).

Comparing patients with and without cognitive impairment, we found higher VAS pain scores (p=0.03) in the first group. We also found a negative linear correlation between MoCA and pain VAS scores (r=-0.334; p=0.02).

Discussion

Our study suggests an association between pain and cognitive dysfunction in FM patients, suggesting that severe disease is associated with higher levels of cognitive impairment. Whether there is a bidirectional relation between pain and cognition is still uncertain, and more studies are paramount.

Poster 23

Headache

Migraine Prevalence, Triggers and Impacts in an Irish University

Orla Flynn[1,2], Brona M Fullen[1,2], Catherine Blake[1,2]
[1]*School of Public Health, Physiotherapy and Sports Science, University College Dublin, Ireland*
[2]*Centre for Translational Pain Research, University College Dublin, Ireland*

Background

As a complex neurobiological disorder, migraine carries many personal and societal impacts in the general population and demonstrates equivalent student burdens.

Objectives

Whilst global pooled migraine prevalence has been previously demonstrated [16%] (Wang et al., 2016), regional prevalence has not yet been comprehensively explored in an Irish university. Thus this study aimed to ascertain migraine prevalence and associated characteristics at University College Dublin.

Methods

Ethical approval was obtained (Flynn-Blake-LS-19-90). A cross-sectional anonymous online survey was designed and made available (Survey Monkey). Participant demographics, migraine prevalence [ICHD-III criteria] and associated factors were collected and analysed (SPSS-27).

Results

Of 494 students, n=124 (25%) reported migraine [95% CI 21-29%; P0.05]. Females demonstrated an 85% prevalence (n=102) and males 14% (n=18). Migraine was highest in those between 18-30 years old (n=93, 75%) and undergraduates (n=75, 60.5%). Migraine demonstrated a 50% (n=62) prevalence in those with a physical health condition and a 31% (n=39) prevalence in those with a mental health condition [ICD-11]. The main migraine triggers were physiological and behavioural (life stress; lack of sleep), reported by 88% (n=108) of migraineurs respectively, alongside academic stress (82%, n=102). The main migraine treatments were sleep (n=119, 97.5%), hydration (n=118, 96.7%) and darkroom resting (n=115, 94%). Headache impact assessment [HIT-6] provided a mean score of (64±9.1), indicative of severe impact.

Conclusions

Migraine is prevalent and burdensome in a cross-section of one Irish university. Since students will be moving into the workforce upon graduation, mitigating migraine at the university level is important.

Poster 24

Headache

Association of Body Mass Index, Blood Pressure and Interictal Serum Levels of Cytokines in Migraine with and without Aura

Pēteris Tretjakovs[1], Aelita Plinta[1], Simons Svirskis[1], Inara Logina[1], Gita Gersone[1], Antra Jurka[1], Indra Mikelsone[1], Leons Blumfelds[1], Vitolds Mackevics[1], Guntis Bahs[1]
Faculty of Medicine, Riga Stradins University, Latvia

Background. Cytokines can act on neuronal receptors and cause neurovascular inflammation and contribute to pain.

The aim of the study was to clarify correlations among body mass index (BMI), blood pressure (BP) and serum levels of cytokines in migraine female patients.

Methods. 14 migraineurs with aura, and 12 – without aura during their interictal period were compared with 25 controls. Interleukin-8 (IL-8), soluble intercellular adhesion molecule-1 (sICAM-1), soluble vascular cell adhesion molecule-1 (sVCAM-1), matrix metalloproteinase-9 (MMP-9), interferon gamma (IFN-γ), monocyte chemoattractant protein-1 (MCP-1), transforming growth factor alpha (TGF-α) and plasminogen activator inhibitor-1 (PAI-1) were measured in serum by ELISA method.

Results. Migraineurs had significantly increased levels of IL-8, but decreased serum levels of PAI-1 and sICAM-1 during the interictal period, regardless of aura. BMI correlated with BP, and also with IFN-γ and MMP-9 only in patients with aura.

Conclusion. There were three correlations in migraine patients with aura that were absent in patients without aura: between IL-8 and PAI-1; MMP-9 and IL-8; IL-8 and sICAM-1. Migraineurs without aura, on the other hand, had correlations that patients with aura did not have (between PAI-1 and MCP-1, sICAM-1; between MMP-9 and sICAM-1, MCP-1; between TGF-α and PAI-1, MMP-9, sICAM-1; between sICAM-1 and MMP-9, PAI-1, MCP-1; as well as between sVCAM-1 and MCP-1). PAI-1, TGF and MMP-9 could be used as biomarkers to distinguish migraineurs from healthy individuals.

Poster 25

Methodology and Evidence

A comparison of methods for estimating dichotomous treatment effects in clinical trials: a simulation study

Jacqueline Thompson[1], Samuel Watson[1], Lee Middleton[1], Karla Hemming[1]
Institute of Applied Health Research, College of Medicine and Dentistry, University of Birmingham, UK

Introduction

The odds ratio (estimated via logistic regression) is a well-established and common approach for estimating covariate-adjusted binary treatment effects when comparing a treatment and control group with dichotomous outcomes. Its popularity is primarily because of its stability and robustness to model mis-specification. However, the situation is different for the relative risk and risk difference, arguably easier to interpret and better suited to specific designs such as non-inferiority studies. So far, there is no equivalent, widely acceptable approach to estimate an adjusted relative risk and risk difference when conducting clinical trials, in part, due to the lack of a comprehensive evaluation of available candidate methods.

Methods/Approach

A simulation study is designed to evaluate the performance of relevant candidate methods to estimate relative risks to represent conditional and marginal estimation approaches. We consider the log-binomial, generalised linear models (GLM) with iteratively weighted least-squares (IWLS) and model-based standard errors (SE); log-binomial GLM with convex optimisation and model-based SEs; log-binomial GLM with convex optimisation and permutation tests; modified-Poisson GLM IWLS and robust SEs; log-binomial generalised estimation equations (GEE) and robust SEs; marginal standardisation and delta method SEs; and marginal standardisation and permutation test SEs.

Independent and identically distributed datasets are simulated from a randomised controlled trial to evaluate these candidate methods. Simulations are replicated 10000 times for each scenario across all possible combinations of sample sizes (200, 1000, and 5000), outcomes (10%, 50% and 80%), and covariates (ranging from -0.05 to 0.7) representing weak, moderate or strong relationships. Treatment effects (ranging from 0, -0.5, 1; on the log-scale) will consider null (H0) and alternative (H1) hypotheses to evaluate coverage and power in realistic scenarios. Performance measures (bias, mean square error (MSE), relative efficiency and convergence rates) are considered across scenarios covering a range of sample sizes, event rates, covariate prognostic strength and model mis-specifications.

Potential Results, Relevance & Impact

There are several methods for estimating unadjusted and adjusted relative risks. However, it is unclear which method(s) is the most efficient, preserves type-I error rate, is robust to model mis-specification or is the most powerful when adjusting for

non-prognostic and prognostic covariates. GEE estimations may be biased when the outcome distributions are not from marginal binary data. Also, it seems that marginal standardisation and convex optimisation may perform better than GLM IWLS log-binomial.

Poster 26

Neuropathic Pain

Mindful SensoriMotor Therapy with brain modulation for the treatment of pain in individuals with disarticulation or nerve injuries

Shahrzad Damercheli[1], Max Ortiz-Catalan[1,2,3]
[1]*Electrical Engineering, Chalmers University of Technology, Sweden*
[2]*Operational Area 3, Sahlgrenska University Hospital, Sweden*
[3]*Department of Orthopaedics, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Sweden*

Background
Neuropathic pain due to sensorimotor impairment, such as Phantom Limb Pain (PLP), is a complex medical condition that is difficult to treat. Phantom Motor Execution (PME) is a plasticity-guided therapy that has shown promising results in the treatment of PLP. PME is based on the stochastic entanglement hypothesis that stipulates such pain arises due to sensorimotor impairment, and therefore can be alleviated by re-engaging the affected neural circuitry and exploiting competitive plasticity. Furthermore, neural re-engagement of the affected neural circuitry can be facilitated by integration with sensory training and non-invasive brain modulation, such as transcranial Direct Current Stimulation (tDCS).

Objective
The aim is to present the method of a single-arm clinical trial applied for the treatment of neuropathic pain caused by sensorimotor impairment.

Method
We are conducting a single-arm clinical trial in eight participants suffering from PLP due to a high amputation (i.e., disarticulation) or peripheral nerve injuries. We further developed PME to integrate phantom motor imagery and sensory feedback in a new concept called Mindful SensoriMotor Therapy (MiSMT), which we further enhanced with tDCS. We utilize tDCS to facilitate phantom movement, sensory discrimination, and thus plasticity.

This study is registered at ClinicalTrials.gov (2020-07147) and consists of 10 interventions where participants mindfully perform sensory, motor, and sensorimotor training while receiving anodal tDCS over the primary motor cortex. Pre- and post-therapy assessments including questionnaires and functional assessments are conducted to track the changes in pain, phantom limb movement, and sensory acuity.

Results
The protocol of the proposed treatment, MiSMT enhanced with tDCS, will be presented at the conference.

Poster 27

Neuropathic Pain

Effects of Interdisciplinary Pain Rehabilitation Programs on Neuropathic and non-Neuropathic Chronic Pain Conditions – A Registry-Based Cohort Study from Swedish Quality Registry for Pain Rehabilitation

Nazdar Ghafouri[1], Emmanuel Bäckryd[1], Elena Dragioti[1], Marcelo Rivano Fischer[2,3], Åsa Ringqvist[2], Björn Gerdle[1]

[1]*Department of Health, Medicine and Caring Sciences, Linköping University, Pain and Rehabilitation Centre, Sweden*

[2]*Department of Neurosurgery and Pain Rehabilitation,, Skåne University Hospital, Sweden*

[3]*Department of Clinical Sciences, Faculty of Medicine, Lund University, Sweden*

Background: Neuropathic pain arises as a direct consequence of a lesion or disease affecting the somatosensory system. Pharmacological treatments for neuropathic pain often fail despite following guidelines. Interdisciplinary Pain Rehabilitation Programs (IPRP) are an effective intervention for chronic pain conditions. Little research has investigated whether IPRP can benefit patients with chronic neuropathic pain compared to other chronic pain conditions. This study assesses effects of IPRP on patients with chronic neuropathic pain compared to non-neuropathic patients using Patient-Reported Outcome Measures. Methods: A neuropathic group of patients (n = 1,654) was compared to a non-neuropathic group (n = 14,355) composed of common diagnosis (low back pain, fibromyalgia, whiplash associated disorders, and Ehlers-Danlos Syndrome) in relation to background variables, three overall outcome variables, and 22 mandatory outcome variables. Of these patients 43–44% participated in IPRP. Results: At assessment, the neuropathic group reported significantly (small effect sizes (ES)) more physician visits the previous year, older age, shorter pain durations, and less spatial extent of the pain (moderate ES). For the 22 mandatory outcome variables, we found only clinically insignificant differences according to ESs between the groups. For those participating in IPRP, the neuropathic group displayed equal or in some cases slightly superior results compared to the non-neuropathic group. Discussion: This large study found that neuropathic pain patients can benefit from IPRP intervention. Both registry studies and RCTs are needed to better understand which patients with neuropathic pain are most suitable for IPRP and to what extent special considerations need to be made for these patients.

Poster 28

What predicts painful polyneuropathy? An analysis of symptoms and signs in patients with painful and painless polyneuropathy using machine learning

Janne Gierthmühlen[1], Nadine Attal[2], David Bennett[3], Didier Bouhassira[2], Troels Staehelin Jensen[4], Kristine Bennedsgaard[4], Nanna B. Finnerup[4], Lieven Nils Kennes[5], Helen Laycock[6], Andrew SC Rice[6], Yelena Granovsky[7], Leah Shafran-Topaz7, David Yarnitsky[7], Ralf Baron[1]

[1] Division of Neurological Pain Research and Therapy, Department of Neurology, University Hospital of Schleswig-Holstein, Campus Kiel, Germany;

[2] Inserm U987, APHP, UVSQ, Paris-Saclay University, CHU Ambroise Pare, 92100 Boulogne-Billancourt, France;

[3]University of Oxford, Nuffield Department of Clinical Neurosciences, John Radcliffe Hospital, Oxford, UK

4 Danish Pain Research Center, Department of Clinical Medicine, Aarhus University, and Department of Neurology, Aarhus University Hospital, Aarhus, Denmark

[5]Department of Economics and Business Administration, University of Applied Sciences Stralsund, Stralsund, Germany

[6] Pain Research, Department of Surgery and Cancer, Faculty of Medicine, Imperial College, London, UK

[7] Department of Neurology, Rambam Health Care Campus, and Faculty of Medicine, Technion, Haifa, Israel

Background and Objectives: It is still unclear why some patients develop painful and others painless polyneuropathy. The aim was to identify risk factors for a painful polyneuropathy.

Methods: 1181 patients of the multi-center DOLORISK-database with painful (probable or definite NeuP) or painless (unlikely NeuP) probable or confirmed neuropathy were investigated clinically, with questionnaires and QST. Multivariate logistic regression (MLR) including all potential variables (demographics, medical history, psychological symptoms, personality items, pain catastrophizing, life-style factors as well as results from clinical examination and quantitative sensory testing) and machine learning was used for the identification of meaningful predictors and final risk prediction of painful neuropathy.

Results: MLR demonstrated that severity (TTS) and idiopathic etiology, presence of chronic pain in family, PROMIS Fatigue and Depression T-Score, PCS total score and alcohol misuse are important predictors for the presence of pain in neuropathy. Machine learning (random forest) identified almost the same variables. MLR archived an accuracy above 78 %, random forest of 76 %, thus almost four out of five subjects can be identified correctly.

Conclusion: This multi-center analysis shows that personality, emotional well-being, life-style and clinical phenotype as associated factors for risk of painful neuropathy. Results may help in the future to identify patients at risk for development of painful neuropathy.

Poster 29

Neuropathic Pain

Evaluation of the Platelet-Rich Plasma (PRP) Gel Action of Unresponsive Healing on Diabetic Foot Ulcers and Neuropathic Pain

Krissia Leme[1], Guilherme Neri[1], Gabriel Biscaro[1], Andreia Bulgareli[4], Nelson Duran[2,3], Maria Candida Parisi[4], Ângela Luzo[1,2]

[1]*Transfusion Medicine Service, Stem Cell Processing Laboratory, Umbilical Cord Blood Bank, Haematology Hemotherapy Center, University of Campinas (UNICAMP), Brazil*

[2]*Laboratory of Urogenital Carcinogenesis and Immunotherapy, Department of Structural and Functional Biology, Institute of Biology University of Campinas (UNICAMP), Brazil*

[3]*Nanomedicine Research Unit (Nanomed), Center for Natural and Human Sciences (CCNH), Federal University of ABC (UFABC), Brazil*

[4]*Department of Internal Medicine, Faculty of Medical Sciences. University of Campinas (UNICAMP), Brazil*

Background: Diabetic foot ulcer is a chronic complication of Diabetes Mellitus, difficult to manage and of great impact on the quality of life of patients. Platelet-rich Plasma (PRP) could be beneficial for healing processes and pain management due to its active biomolecules that promotes immunomodulation, angiogenesis, cell proliferation and analgesia.

Objectives: Evaluation of the PRP gel action on diabetic foot ulcers in a patient who was not responsive to any of the conventional treatments for non-healing ulcers.

Methods: Compassionate use of PRP gel for healing diabetic ulcers, in a patient of the Endocrinology outpatient clinic of Hospital de Clínicas da UNICAMP, who was not responsive to conventional treatments. The PRP gel dressing was changed weekly for a period of 8 weeks.

Results: The Diabetic foot ulcers treated with PRP gel exhibited healing without fibrosis and with excellent skin quality. The patient was followed up for 4 years and he did not show pain remission and ulcers treated with PRP gel.

Conclusion: The PRP gel was effective in the healing of chronic diabetic ulcers, in addition to resulting in total pain remission. The observed outcomes can be attributed to the release of bioactive factors from the α-granules that acted in the healing and regeneration of the tissue.

Poster 30

Neuropathic Pain

Increased TRPA1 Functionality in Patients with Chemotherapy-Induced Peripheral Neuropathy: Proof-of-Concept for TRPA1-based Analgesics?

Heleen Marynissen[1], Filip Van Herpe[2], Jeroen Dekervel[2], Eric Van Cutsem[2], Jan de Hoon[1]

[1]*Center for Clinical Pharmacology, KU Leuven, Belgium*

[2]*Gastrointestinal and Liver Diseases, University Hospitals Leuven, Belgium*

Background

Preclinical research has correlated the symptomatology of chemotherapy-induced peripheral neuropathy (CIPN) to an altered functionality of Transient Receptor Potential Ankyrin 1 ($TRPA_1$) and TRP Vanilloid 1 ($TRPV_1$)[1].

Objectives

$TRPA_1$ and $TRPV_1$ functionality *in vivo* in patients with chronic CIPN after oxaliplatin.

Methods

Patients with a grade ≥1 neuropathy (total neuropathy score [TNS_c]), 1-12 months after oxaliplatin treatment, are included. Thermal and mechanical pain thresholds are assessed using quantitative sensory testing (QST). $TRPA_1$ and $TRPV_1$ functionality is evaluated by measuring the dermal blood flow (DBF) response to topical application of their agonists, cinnamaldehyde (10%) and capsaicin (1,000µg/20µL), respectively, during 60 minutes. The DBF is quantified in Perfusion Units (PUs), using laser speckle contrast imaging. Pain thresholds and maximal DBF changes are compared to a control group, matched for sex, age and BMI. Interim analysis is performed in GraphPad Prism (unpaired t-test or Mann-Whitney U-test, α=0.05). Data are presented as mean±SEM.

Results

So far, 31 patients (48% male, 59±2 years, BMI 25.1±0.7 kg/m²) and 25 healthy controls (48% male, 61±2 years, BMI 24.7±0.7 kg/m²) were included. Respectively 17 and 14 patients displayed a grade 1 ($TNS_c \leq 7$) and 2 (7 TNS_c 15) neuropathy. QST revealed mechanical allodynia in patients (Figure 1). Cinnamaldehyde application resulted in higher DBF changes in patients compared to controls, whereas capsaicin-induced DBF changes were similar in both groups (Figure 2).

Conclusion

Displaying an increased $TRPA_1$ functionality, patients with CIPN after oxaliplatin might truly benefit from $TRPA_1$-based analgesics.

References

[1]Sisignano M. et al. Nat.Rev.Neurol. 10;694-707 (2014)

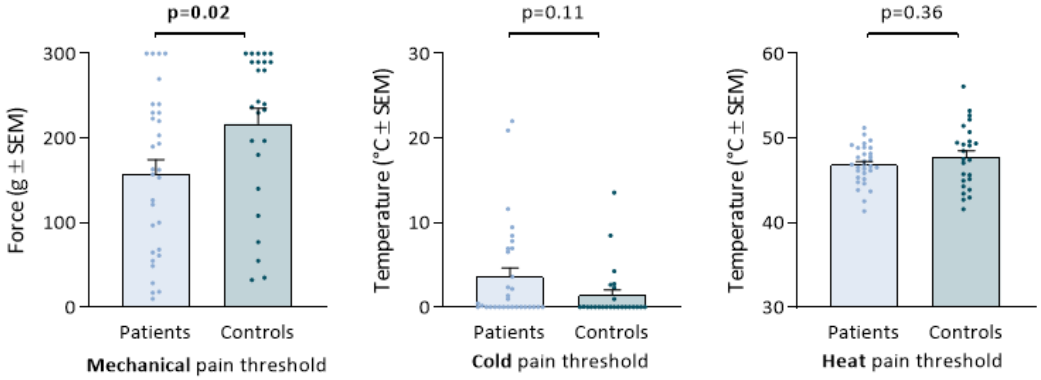


Figure 1. Quantitative sensory profile.

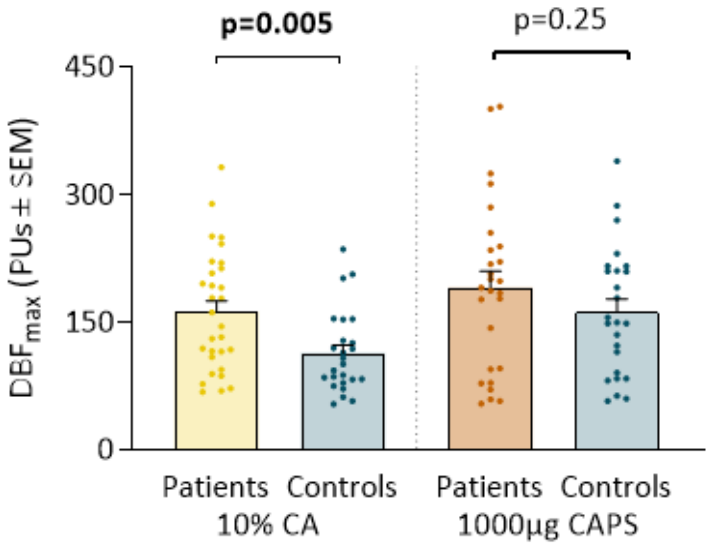


Figure 2. DBF_{max} upon $TRPA_1$ and $TRPV_1$ activation by topical cinnamaldehyde (CA) and capsaicin (CAPS) application, respectively.

Poster 31

Neuropathic Pain

Neuronal activation of CREB, a transcription factor, in experimental autoimmune encephalomyelitis: A mechanism of pain in multiple sclerosis ?

Taekyun Shin[1]
Department of Veterinary Medicine, Jeju National University, College of Veterinary Medicine, South Korea

Background: Pain is a common disabling symptom of multiple sclerosis. Multiple sclerosis-associated neuropathic pain would be attributed to the demyelinating lesions in the spinal cords and brains.

Objectives: The aim of this study was to investigate whether a pain related transcription factor, CREB (cyclic AMP response element-binding protein), is activated in sensory neurons in the spinal cords with experimental autoimmune encephalomyelitis (EAE), an animal model of multiple sclerosis.

Methods: EAE was induced in rats with immunization myelin basic protein with complete Freund's adjuvants. The activation of CREB was evaluated in the spinal cords by immunohistochemistry and Western blot analysis.

Results: Western blot analysis revealed that EAE caused up-regulation of phospho-CREB in the spinal cords at the peak stage. Immunohistochemistry showed that phospho-CREB positive sensory neurons increased compared with those of normal control. While inflammation subsided at the 21 days post-immunization, phospho-CREB-positive neurons were still found with decreased density. At the peak stage of EAE, phospho-CREB-immunoreactivity was also detected in reactive astrocytes and some macrophages.

Conclusion: Neuroplastic changes, through the activation of CREB, occur in sensory neurons as well as in glial cells in the course of EAE. Neuronal activation of CREB in the spinal cords in EAE may facilitate the persistence or recurrence of pain.

*This research was supported by the National Research Foundation of Korea (Grant number: NRF- 2019R1A2C1087753).

Poster 32

Pain in Rheumatoid Arthritis

Psychological Characteristics, Clinical Pain and Quality of Life Among Women Diagnosed with Rheumatoid Arthritis

Keren Grinberg
Ruppin Academic Center, Israel

Background:

Pain and disability are prevalent complaints in rheumatoid arthritis (RA). In addition to the chronic pain and the physical disabilities, patients also report psychological, spiritual and social restrictions. It is known that higher self-efficacy could help cope with chronic illness. However, so far, psychological aspects such as depression and anxiety in the context of self-efficacy, clinical pain and quality of life among RA patients have not been examined.

Objectives: (1) To examine the levels of depression, anxiety, self-efficacy and quality of life among women diagnosed with RA, compared to healthy women; (2) To examine the relationship between psychological characteristics, quality of life and clinical pain among women diagnosed with RA.

Methods:

The sample included 104 women diagnosed with RA and 144 healthy women. Tools included sociodemographic questions, Beck Depression Inventory (BDI), State-Trait Anxiety Inventory (STAI), Short-form McGill Pain Questionnaire (SF-MPQ), quality of life (SF-12), and self-efficacy questionnaires.

Results:

Both self-efficacy (t (186.075) =8.189, p0.05) and quality of life t (201.067) = 5.331 , p0.05) were lower among women in the RA group than in the control group. Among women with RA, low quality of life was significantly related to severe clinical pain (r=0.341, p0.05). Furthermore, a negative relationship was found between depression and quality of life, and between depression and anxiety, and self-efficacy.

Conclusion:

The findings shed light on the complexity of RA, and the importance of managing the disease from a multidisciplinary approach that includes attention to personality and mental aspects among RA patients.

Poster 33

General/Other

Women's Experiences of Seeking Care for Pelvic Organ Prolapse

Louise Carroll[1,2,3], Cliona O' Sullivan[2], Catherine Doody[1,2], Carla Perrotta[2], Brona Fullen[1,2]

[1]*UCD Centre for Translational Pain Research, UCD School of Public Health, Physiotherapy and Sports Science, Ireland*

[2]*UCD School of Public Health, Physiotherapy and Sports Science, University College Dublin, Ireland*

[3]*Physiotherapy Department, Tipperary University Hospital, Ireland*

Background: Approximately 50% of women develop pelvic organ prolapse (POP) over their lifetime[1]. Symptoms include pain, bulge, urinary, bowel and sexual symptoms affecting all aspects of a woman's life.

Barriers to seeking help for pelvic floor dysfunction (PFD) include low levels of knowledge, societal culture of acceptance, embarrassment, feeling dismissed by healthcare professionals (HCPs), trivialising their impairment and de-prioritizing their own health[2,3].

Women with POP symptoms generally present first to primary care after which they may be referred to gynaecologists and/or physiotherapists specialising in women's health.

Objectives: To explore experiences of women seeking treatment for POP.

Methods: Qualitative research methods were employed. Women with POP were recruited from an online support group (n=930 members). Inclusion criteria: adult women, diagnosed with POP and aware of POP stage. Following informed consent, a demographic questionnaire, interview questions and the Central Sensitisation Inventory (CSI) were forwarded. Semi-structured zoom audio-recorded interviews were conducted. Thematic analysis was undertaken; transcripts coded, and themes identified. Ethics approval was obtained (LS-21-01-Carroll-Ful).

Results: Fourteen women age 32-41 years, parity 1-3, with POP Stage 1-3 participated. Having overcome barriers to seeking care, women often encountered HCPs they perceived as dismissive or not appreciative of the impact of POP. Others reported positive interactions and appreciated access to HCPs who they felt listened, understood the impact of POP, gave explanations, a positive prognosis and outlined a treatment plan. This type of interaction fostered hope, empowerment and self-efficacy.

Conclusions: Increased focus on person centred care, particularly emotional support, information and education may improve women's experiences when seeking care for POP.

Poster 34

General/Other

PROMPT NIT-1: Setting up and implementing a multiple languages, multi-center PROMs survey

Claudia Weinmann, Marcus Komann, **Winfried Meissner**
Jena University Hospital, Germany

Background:

Within the IMI-PainCare project (www.imi-paincare.eu), we needed to plan and implement a large non-interventional patient survey – PROMPT NIT-1. Aim of PROMPT NIT-1 is to find out which PROMs work best for post-operative pain assessment. Based on a structured consensus process[1], the NIT-1 survey consisted of several established tools. We planned to include 4,000 patients and collect data at 7 timepoints: baseline, POD1, POD3, POD7, M1, M3 and M6.

Tasks:

For implementing a study that uses various questionnaires in 18 hospitals in 8 different languages/countries, many prerequisites are necessary. Tasks before and during the study were: obtaining all copyright permissions for the selected tools, translating the questionnaires into 8 languages according to an elaborated, standardized translation process , implementing the survey technically in all languages, obtaining ethics approval and GDPR clearance in all 18 data collecting sites, recruiting study sites, concluding cooperation contracts, developing the study protocol, SOPs, training materials, and patient informed consent forms for all sites, registering the study, training, supporting and closely monitoring the data collectors, and remunerating them.

Results:

6 consortium and 12 non-consortium hospitals included 3,303 patients. 6 out of 18 sites included considerably fewer patients than planned. However, sufficient case numbers were reached and follow-up rates on M1, M3 and M6 are very good (70-80%).

Conclusion:

Set-up and implementation of a large, international, multiple languages data collection is challenging and ambitious but feasible if sufficient resources (project management and technical/IT expertise, qualified staff, funding, commitment) are available and the time schedule for preparing the study is generously calculated.

---

[1] Pogatzki-Zahn EM, Liedgens H, Hummelshoj L, Meissner W, Weinmann C, Treede RD, Vincent K, Zahn P, Kaiser U; IMI-PainCare PROMPT consensus panel. Developing consensus on core outcome domains for assessing effectiveness in perioperative pain management: results of the PROMPT/IMI-PainCare Delphi Meeting. Pain. 2021 Nov 1;162(11):2717-2736. doi: 10.1097/j.pain.0000000000002254. PMID: 34181367.

Poster 35

General/Other

The risk of polypharmacy and compliance in the treatment of pain in patients in palliative oncology care - the nurse's mission and tasks.

Dagmar Svecova[1,2], Hana Havlickova[1,2], Adela Zelbova[3]
[1] *Department of Oncology and Radiotherapy, Faculty Hospital; Sokolska 548, 50005 Hradec Kralove, Czech Republic*
[2] *Outpatient Ambulance of Palliative Oncological Care, Faculty Hospital; Sokolska 548, 50005 Hraqdec Kralove, Cech Republic*
[3] *Department of Social Care, Faculty Hospital; Sokolska 548, 50005 Hradec Kralove, Czech Republic*

Background. Currently, the treatment of oncological patients is associated with the use of new highly effective drugs for the treatment of pain. In the management of pain treatment and its prevention, nursing care is of great importance. Proper and targeted education of the patient in managing symptoms associated with pain is aimed at revealing the risk of polypharmacy and compliance. Good cooperation between the patient, the nurse and the patient's family is a condition.
Objectives. The aim of the pilot study is to analyze the risks brought by polypharmacy and compliance in the treatment of pain in patients in palliative oncology care.
Methods. 62 patients were included in the pilot study as part of the palliative oncology care program at the FNHK. A specific questionnaire based on the analysis of polypragmatism and co-compliance was used for the evaluation. The questionnaire was filled out by the patient during regular outpatient check-ups.
Results. In the monitored group of patients (n=62), in whom 3 or more medicinal products (n=54) were recorded in the treatment of pain, there was at least one serious event associated with an adverse effect of an inappropriate combination of drugs. Of these, 19 (35.2%) had repeated drug interactions associated with the need to change and adjust treatment, and 5 (9.2%) patients had serious drug interactions associated with hospitalization, when pain was not under control.
Conclusion. Timely analysis of the risks of polypharmacy and compliance during analgesic treatment fundamentally affects the quality of health care. The nurse's educational work is an integral part of care and has an important place in the creation of a care plan. It significantly affects the quality of life and subsequently the "benefit cost" of patients in palliative oncology care.

The work was supported by the project Ministry of Health Czech Republic; NU20-0900045.