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INFILTRATION OF LIPOSOMAL BUPIVACAINE (LB) DECREASES LENGTH OF HOSPITALIZATION FOLLOWING TOTAL KNEE ARTHROPLASTY (TKA)

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OBJECTIVES: Perioperative pain management is an important aspect of recovery from TKA, as severe pain can delay ambulation and hospital discharge. The objective of this study was to determine the impact of local infiltration analgesia using LB when compared to continuous femoral nerve catheter (FNC) following TKA. **METHODS:** This study enrolled consecutive patients who received a TKA between April 2011 and September 2014 into three study groups, excluding bilateral and revision TKA. Study Group A received adductor canal infiltration with bupivacaine and knee infiltration with LB. Study Group B received adductor canal infiltration with LB and knee infiltration with LB. The control group received a continuous FNC with an OnQ pump and ropivacaine. Numeric pain rating scores (NPRS), distance walked, and length of stay (LOS) were the primary outcomes. **RESULTS:** A total of 237 participants were enrolled in this study, including 98 in Group A, 34 in Group B, and 105 controls. On postoperative day (POD) 0, mean NPRS were similar between Group A (1.8±1.7), Group B (2.7±1.8), and the control group (2.3±2.4). Significantly ($p < 0.05$) more patients in Group A (58%) and Group B (44%) walked on POD 0 than in the control group (0%); almost all patients walked on POD1. The mean distance walked was also significantly greater ($p < 0.05$) on POD0 and on POD1 in Group A (33±42 feet; 193±203 feet) and Group B (42±82 feet; 211±144 feet) than in the control group (0 feet; 46.3±73 feet). LOS was significantly ($p < 0.05$) shorter in Group B (2.2±1.7 days), than in the control group (3.2±0.7 days) and Group A (3.0±1.7 days). **CONCLUSIONS:** Local infiltration analgesia using LB improved ambulation and LOS following TKA when compared to continuous FNC with an OnQ pump and ropivacaine. The one-day decrease of hospitalization suggests an estimated cost savings to an Illinois hospital of \$2,158 per patient.

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PATIENT-REPORTED PHYSICAL FUNCTION OUTCOME MEASURE FOR ADULTS WITH FIBRODYSPLASIA OSSIFICANS PROGRESSIVA: INTELLIGENT TEST DESIGN BASED ON PROMIS ITEM BANKS

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OBJECTIVES: Fibrodysplasia Ossificans Progressiva (FOP) is a rare and disabling genetic condition of progressive extraskeletal bone formation. Physical functioning declines as FOP progresses. The objective was to develop a measure of physical function (PF) in adults with FOP. **METHODS:** We reviewed the PROMIS PF item bank for relevant items for FOP, and 44 PF items were identified. We then conducted concept elicitation (CE) interviews in 21 patients diagnosed with FOP (with varying levels of disease severity) who attended the International FOP Association meeting. The selected PF items were administered after the CE interviews. Interview data were analyzed to identify categories of physical functioning that were impacted by FOP. Based on the CE findings and PF item data, 26 items were initially selected for the new measure. Clinical experts in FOP reviewed the proposed set of items. Five additional items were incorporated into the draft measure, and cognitive interviews (CIs) were conducted in 10 patients, and revisions were made to the final FOP-PF Questionnaire (FOP-PFQ; 28 items). **RESULTS:** For the CE interviews, mean age was 30 years (range 16–54) and 58% were female. For the CIs, mean age was 31 years (range 16–57) and 50% were female. CE interviews demonstrated substantial impacts of FOP on mobility, upper extremity function, and related activities. The CE findings, PROMIS PF item descriptive data, and discussion with clinical experts resulted in 31 relevant items which were included in the draft FOP-PFQ. Based on the CIs, the majority of patients understood the instructions, questions, and response scales; three items were deleted due to redundancy or item removal from the original PROMIS item bank. **CONCLUSIONS:** This qualitative research supports the content validity of the FOP-PFQ and illustrates the application of PROMIS item banks for efficient new instrument development in an ultra-rare and disabling genetic disease.

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RAPID ACQUISITION OF DATA ON THE PATIENT PERSPECTIVE IN RHEUMATOID ARTHRITIS THROUGH A DIGITAL PORTAL

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OBJECTIVES: Rheumatoid arthritis (RA) is an autoimmune disease characterized by significant morbidity related to systemic and joint inflammation. With the availability of more targeted therapeutic approaches and the potential of disease remission, there is increased focus on utilizing patient reported outcomes to better evaluate RA treatment impact. Collecting such data efficiently, i.e., with relatively low cost and time expenditures, can be challenging. Our objective was to implement digital direct-to-patient methodology to collect and incorporate United States (US) RA patient data into the Outcome Measures in Rheumatoid Arthritis Clinical Trials (OMERACT) project to study the patient perspective on remission. **METHODS:** Leveraging a known community (MediGuard.org) of approximately 40,000 US RA patients with pre-existing consent to contact for research purposes, patients were contacted in December 2014 to obtain 50 responses to the OMERACT survey through a direct-to-patient digital communications platform. Patients did not receive any honoraria for survey completion. **RESULTS:** The first survey was completed within seven minutes of initial digital outreach and the fiftieth within three hours. RA patients from 23 continental US states were represented. Of the 50 patients, 82% were female, mean age 54.8 years; male patients were older, mean age 61.7 years. RA diagnosis duration was 11.3 years average (range 1–40). Comorbidities including other autoimmune and musculoskeletal conditions, diabetes, cardiovascular disease, malignancies were reported by 70%; 76% reported synthetic (72%) and/or

targeted (44%) disease-modifying antirheumatic drug use; 84% reported current RA disease activity. Additional usable data were obtained including those on education, employment, health insurance, income, remission state, health assessment questionnaire, and patient global for the project. **CONCLUSIONS:** This analysis documents the feasibility of gaining rapid and relevant responses from a representative community RA patient population regarding their perspective on RA remission through our digital direct to patient portal.

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CONTENT VALIDITY EVALUATION OF A NEW DIARY DEVELOPED TO EVALUATE SYMPTOMS IMPORTANT TO PATIENTS WITH MODERATE TO SEVERE RHEUMATOID ARTHRITIS

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OBJECTIVES: Patient-reported outcome instruments are used in clinical trials of rheumatoid arthritis (RA) treatments to evaluate treatment benefits. A growing body of evidence suggests that joint pain, tiredness, and morning joint stiffness are among the most important symptoms for RA patients. A 7-item electronic daily diary was developed to assess these key symptom concerns of patients with RA for use as efficacy endpoints in clinical trials. The aim of this study was to evaluate the content of the diary and to ascertain whether patients with RA found items in the diary interpretable and relevant through concept elicitation and cognitive interviews. **METHODS:** A cross-sectional qualitative interview study was conducted in adults with moderate-severe RA in the US and UK. Interviews were conducted using a standardized interview guide to elicit information about ways patients with RA experience and talk about their symptoms followed by a cognitive interview on the diary. Data were analyzed utilizing a qualitative analysis software program, Atlas.ti. **RESULTS:** The study sample included 28 participants (US n=22, UK n=6; 29% male; mean age 58.41 years; RA mean duration 13.92 years). Total HAQ-DI mean scores were 0.84 (US) and 1.50 (UK). Morning joint stiffness (n=19), joint pain (n=28), and tiredness (n=7) were among the most commonly experienced and reported symptoms; saturation of these concepts was achieved in the second interview. These results demonstrated that the diary includes appropriate content and terminology. Cognitive interviews indicated that participants found the diary items and response options clear, easy to understand and relevant to their RA experiences. No differences in qualitative results were noted between the two country samples. **CONCLUSIONS:** Results of this qualitative study suggest that the 7-item electronic daily diary includes content relevant to patients and is suitable for assessing RA symptoms in clinical studies of patients with moderate to severe RA.

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DOES ORAL CHOLECALCIFEROL SUPPLEMENTATION IMPROVE PAIN INTENSITY AND DISABILITY IN PATIENTS WITH CHRONIC LOW BACK PAIN?

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OBJECTIVES: In the past decade many studies established relationship between vitamin D deficiency and chronic musculoskeletal pain including low back pain. Present study aimed to examine the effect of vitamin D3 supplementation in patients with chronic low back pain with low level of vitamin D. **METHODS:** This single arm, open label study was conducted in a public tertiary care teaching hospital in India after obtaining approval from the Ethics Review Board of the hospital. Adult patients of either gender, aged 18 to 65 years, with a diagnosis of CLBP and low serum 25(OH) D3 levels (<30 ng/mL) and not responding to medications and physical therapies, having a pain score of at least 50 as assessed on 0–100 Visual Analogue scale (VAS) at baseline were eligible for study recruitment. Cholecalciferol (active vitamin D3) in a dose of 60,000 IU/week for a period of 8 weeks was given to the enrolled subjects according to standard guidelines. Study endpoints include change in pain score and disability as measured by modified Oswestry disability questionnaire (MODQ). Patient information and outcome measures were collected at baseline, 2, 3 and 6 months. **RESULTS:** A total of 68 chronic low back patients were included in the trial. Mean baseline vitamin D level is found to be 12.80±5.73 ng/ml. After treatment it significantly ($P < 0.01$) increased to 36.07±12.51. VAS (81.03±18.57) and MODQ (44.83±15.47) were high at baseline. Pain intensity has significantly reduced to 44.71±18.96 (< 0.05) and 35.74±17.75 (< 0.05) at 3 and 6 months respectively. Disability has significantly reduced to 30.94±12.48 (< 0.05) and 26.10±10.03 (< 0.05) at 3 and 6 months respectively. **CONCLUSIONS:** Present study shows that vitamin D supplementation can improve the pain and disability in patients with CLBP. Study results should be carefully interpreted as it is a single arm open label study and concomitant medication usage was not assessed.

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MINIMALLY IMPORTANT DIFFERENCES FOR PATIENT-REPORTED OUTCOMES MEASUREMENT INFORMATION SYSTEM (PROMIS) FATIGUE AND PAIN INTERFERENCE SCORES

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OBJECTIVES: Interpretation of patient-reported outcomes (PROs) requires some definition of an important or meaningful difference. This study aimed to estimate minimally important differences (MIDs) for the Patient-Reported Outcomes Measurement Information System (PROMIS®) Fatigue and Pain Interference scale scores in rheumatoid arthritis (RA). **METHODS:** The responsiveness of several PROs was assessed in an observational cohort of 521 RA patients in the Arthritis, Rheumatism and Aging Medical Information Systems (ARAMIS) cohorts. PROMIS Fatigue and Pain Interference instruments were administered at baseline, 6 months, and 12 months. Self-reported retrospective changes in fatigue and pain over the previous 6 months were obtained at