University Hospitals Bristol NHS
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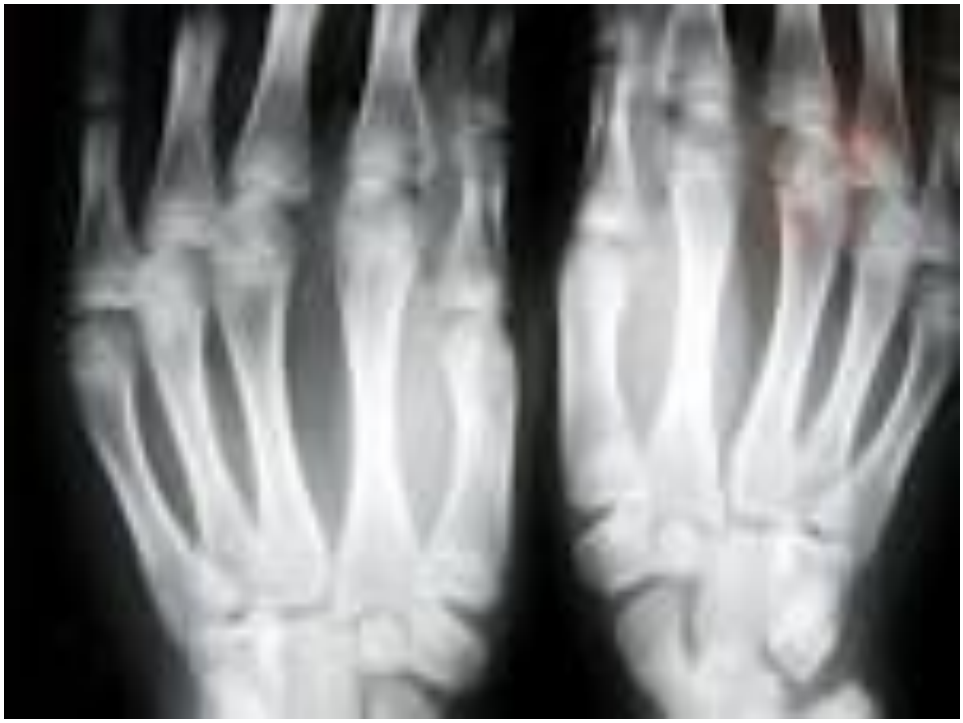
Rheumatology

Evidence Update

September 2017 (Quarterly)



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Training Sessions 2017

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September (13.00-14.00)

Fri 1st	Literature Searching
Mon 4th	Critical Appraisal
Tue 12th	Interpreting Statistics
Wed 20th	Literature Searching
Thu 28th	Critical Appraisal

October (12.00-13.00)

Fri 6th	Interpreting Statistics
Mon 9th	Literature Searching
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Wed 25th	Interpreting Statistics

November (13.00-14.00)

Thu 2nd	Literature searching
Fri 10th	Critical Appraisal
Mon 13th	Statistics
Tue 21st	Literature searching

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NICE National Institute for Health and Care Excellence

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18 September 2017 - Publisher: BMJ Open Read Summary

Malignant Neoplasms in Patients With Rheumatoid Arthritis Treated With Tumor Necrosis Factor Inhibitors, Tocilizumab, Abatacept, or Rituximab in Clinical Practice: A Nationwide Cohort Study From Sweden
18 September 2017 - Publisher: JAMA Internal Medicine Read Summary

NHS England commissioning framework for biosimiliar medicines [PDF]
Source: NHS England - 12 September 2017 - Publisher: NHS England Read Summary

A Phase III Study Evaluating Continuation, Tapering, and Withdrawal of Certolizumab Pegol After One Year of Therapy in Patients With Early Rheumatoid Arthritis
12 September 2017 - Publisher: Arthritis & Rheumatology Read Summary

Two deaths reported in phase III trial investigating upadacitinib for rheumatoid arthritis
11 September 2017 - Publisher: Biospace Inc. Read Summary

Cochrane Library

Highlighted Cochrane Review

Pregabalin for pain in fibromyalgia in adults
Sheena Derry, Malene Cording, Philip J Wiffen, Simon Law, Tudor Phillips, R Andrew Moore

Certolizumab pegol (CDP870) for rheumatoid arthritis in adults
Vicente Ruiz Garcia, Amanda Burls, Juan B Cabello, Paloma Vela Casasempere, Sylvia Bort-Marti, José A Bernal
Online Publication Date: September 2017

Non-steroidal anti-inflammatory drugs (NSAIDS) for trigger finger
Mabel Qi He Leow, Qishi Zheng, Luming Shi, Shian Chao Tay, Edwin SY Chan
Online Publication Date: September 2017

Back Schools for chronic non-specific low back pain
Patrícia Parreira, Martijn W Heymans, Maurits W van Tulder, Rosmin Esmail, Bart W Koes, Nolwenn Poquet, Chung-Wei Christine Lin, Christopher G Maher
Online Publication Date: August 2017

Methotrexate for psoriatic arthritis

Tom D Wilsdon, Samuel L Whittle, Tilenka RJ Thynne, Arduino A Mangoni
Online Publication Date: July 2017

Pharmacological interventions for preventing bone density loss in critically ill people
David JW Evans, Sharon R Lewis, Andrew F Smith
Online Publication Date: July 2017

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What's new in rheumatology

- Intraocular fluocinolone implant for uveitis (August 2017)
- Adverse events with short-term oral glucocorticoid use in adults (April 2017)

Diagnosis and differential diagnosis of systemic lupus erythematosus in adults

- Definite SLE
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Polyarticular juvenile idiopathic arthritis: Treatment

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Biologic Therapies

Different effect of biologics vs. metho-trexate on bone turnover in active rheumatoid arthritis: 1-year follow-up

Author(s): Killinger Z.; Sterancakova L.; Kuzma M.; Jackuliak P.; Payer J.; Tomkova S.; Vanuga P.

Source: Osteoporosis International; 2017; vol. 28

Abstract: Introduction: It was shown, that anti-TNFalpha agents may reduce circulating RANKL, resulting from favorable change in OPG/RANKL ratio and thus increases bone formation and decreases bone resorption markers. In addition, the role of glucocorticoids (GC) use (and their reduction during anti-TNF therapy) and menopause status on bone turnover markers (BTM) remains unexplained. Objective: Comparison of the biological disease-modifying antirheumatic drugs (bDMARDs) and conventional synthetic DMARDs effect on BTM after one year of active rheumatoid arthritis (RA) treatment and with regard to GC use and menopause status. Patients and methods: A 12-month prospective follow-up in 105 patients with active RA (Disease Activity Score-DAS 28 > 5. 1) was performed. This cohort was divided in two groups: group 1 (n=84, mean age 54 yrs) treated with bDMARDs (anti TNF blockers) and group 2 (n=21, mean age 53 yrs) treated with non-biological DMARDs (Methotrexate) with equivalent GC dose (6. 2 mg vs. 6. 6 mg), respectively. From group 1, also a subset of patients without GC treatment (n=29) was analysed. BTM, osteocalcin (OC) and CTx were measured at baseline and after 1 year of treatment using conventional electrochemiluminescence immunoassay. Results: During follow up, a significant increase in serum levels of osteocalcin in patients within group 1 (19,8 ug/l at baseline vs. 27,1 ug/l at month 12; p<0. 001) and increase of OC in the subset of pts without GC treatment (20,3 ug/l at baseline vs. 27,4 ug/l at month 12; p<0. 001) was observed. In group 2 the levels of OC remained unchanged. In both groups, no treatment effect on CTx or menopause status influence was observed. Conclusion: Significant increase of OC levels, but not CTx levels was observed only in group treated with bDMARDs. In addition, sustained OC increase was observed in patients without GC treatment, which supports theory that bDMARDs may have beneficial effect on BTM.

Identification of factors that may influence the selection of first-line biological therapy for people with psoriasis: A prospective, multicentre cohort study

Author(s): Davison N.J.; Payne K.; Mason K.J.; Mcelhone K.; Warren R.B.; Griffiths C.E.M.; Kirby B.

Source: British Journal of Dermatology; 2017

Publication Type(s): Article In Press

Abstract: Background: The Psoriasis Stratification to Optimise Relevant Therapy (PSORT) consortium has a collective aim to develop a prescribing algorithm to help stratify eligible patients with psoriasis

to the most appropriate biological treatment. To facilitate the adoption of a stratified approach, it is necessary to first understand the factors driving the choice of first-line biological therapy. Objectives: To identify and quantify factors that influence the selection of the first-line biological therapy for people with psoriasis. Methods: Multinomial logistic regression was used to determine the factors that influenced the probability of treatment selection, using data from the British Association of Dermatologists Biologic Interventions Register from January 2012 to December 2015. Sensitivity analyses were performed to assess the robustness of the findings to key assumptions. Results: The main analysis was based on a dataset comprising 3040 people with psoriasis. The identified factors affecting first-line biological selection within the available therapies were: presence of psoriatic arthritis; patient weight; employment status; country of registration; and baseline disease severity. Importantly, the analysis showed a general shift in prescribing behaviour over time. These results were robust to sensitivity analysis. Conclusions: This study offers important insights into the factors influencing current prescribing practice for first-line biological therapies for people with psoriasis. It provides baseline data to inform the evaluation of future potential changes that may affect prescribing behaviour, such as stratified medicine.

Systematic Literature Review and Meta-analysis of Tumor Necrosis Factor-Alpha Experienced Rheumatoid Arthritis

Author(s): Wells A.F.; Curtis J.R.; Betts K.A.; Du E.X.; Douglas K.; Ganguli A.

Source: Clinical Therapeutics; 2017

Publication Type(s): Article In Press

Abstract: Purpose: The goal of this study was to compile all available evidence regarding the efficacy of tumor necrosis factor-alpha (TNF) inhibitors, non-TNF biologics, and tofacitinib for TNF-experienced patients who have rheumatoid arthritis (RA). Methods: A systematic literature review of MEDLINE, EMBASE, and rheumatology conference abstracts was performed to identify observational studies and randomized controlled trials (RCTs) reporting American College of Rheumatology response rates (ACR 20/50/70) for adult patients with RA who switched from at least 1 TNF to another TNF or a non-TNF therapy. A direct random effects meta-analysis was performed to evaluate ACR 20/50/70 response rates for TNF and non-TNF therapies. Separate analyses were conducted among 3-, 6-, and 12-month observational studies and for 6-month RCTs. Findings: A total of 18 observational studies and 6 RCTs were selected. Among 3-month observational studies, the percentages of ACR20/50/70 responders switching to another TNF were similar to those switching to a non-TNF biologic (ACR20, 54.5% vs 58.6%; ACR50, 33.3% vs 33.3%; and ACR70, 13.0% vs 14.6%, respectively). Among 6-month observational studies, the percentages of TNF ACR20/50/70 responders were higher than those of non-TNF responders (ACR20, 67.7% vs 50.4%; ACR50, 50.4% vs 26.6%; and ACR70, 24.9% vs 11.6%). Among 6-month RCTs, the percentages of non-TNF biologic ACR20/50/70 responders were similar to those in the 6-month non-TNF observational studies (ACR20, 50.7% vs 50.4%; ACR50, 27.5% vs 26.6%; and ACR70, 11.9% vs 11.6%). For 12-month observational studies, TNF biologic ACR20/50/70 percentages were higher than those of non-TNF therapies (ACR20, 72.2% vs 57.0%; ACR50, 42.1% vs 28.9%; and ACR70, 22.9% vs 10.0%). Implications: For TNF-experienced patients with RA, subsequent TNF therapy and non-TNF biologic therapy have comparable efficacy.

Second-line biologic therapy optimization in rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis

Author(s): Cantini F.; Niccoli L.; Nannini C.; Cassara E.; Kaloudi O.; Giulio Favalli E.; Becciolini A.; Benucci M.; Gobbi F.L.; Guiducci S.; Foti R.; Mosca M.; Goletti D.

Source: Seminars in Arthritis and Rheumatism; 2017

Publication Date: 2017

Publication Type(s): Article In Press

Abstract: Objective: The Italian board for the TAilored BIOlogic therapy (ITABIO) reviewed the most consistent literature to indicate the best strategy for the second-line biologic choice in patients with rheumatoid arthritis (RA), spondyloarthritis (SpA), and psoriatic arthritis (PsA). Methods: Systematic review of the literature to identify English-language articles on efficacy of second-line biologic choice in RA, PsA, and ankylosing spondylitis (AS). Data were extracted from available randomized, controlled trials, national biologic registries, national healthcare databases, post-marketing surveys, and open-label observational studies. Results: Some previously stated variables, including the patient's preference, the indication for anti-tumor necrosis factor (TNF) monotherapy in potential childbearing women, and the intravenous route with dose titration in obese subjects resulted valid for all the three rheumatic conditions. In RA, golimumab as second-line biologic has the highest level of evidence in anti-TNF failure. The switching strategy is preferable for responder patients who experience an adverse event, whereas serious or class-specific side effects should be managed by the choice of a differently targeted drug. Secondary inadequate response to etanercept (ETN) should be treated with a biologic agent other than anti-TNF. After two or more anti-TNF failures, the swapping to a different mode of action is recommended. Among non-anti-TNF targeted biologics, to date rituximab (RTX) and tocilizumab (TCZ) have the strongest evidence of efficacy in the treatment of anti-TNF failures. In PsA and AS patients failing the first anti-TNF, the switch strategy to a second is advisable, taking in account the evidence of adalimumab efficacy in patients with uveitis. The severity of psoriasis, of articular involvement, and the predominance of enthesitis and/or dactylitis may drive the choice toward ustekinumab or secukinumab in PsA, and the latter in AS. Conclusion: Taking in account the paucity of controlled trials, second-line biologic therapy may be reasonably optimized in patients with RA, SpA, and PsA.

Efficacy and Safety of Vaccination in Pediatric Patients with Systemic Inflammatory Rheumatic Diseases: a systematic review of the literature.

Author(s): Sousa, Sandra; Duarte, Ana Catarina; Cordeiro, Inês; Ferreira, Joana

Source: Acta reumatologica portuguesa; 2017; vol. 42 (no. 1); p. 8-16

Publication Type(s): Journal Article

Available in full text at Acta reumatologica portuguesa [Acta Reumatol Port] NLMUID: 0431702 - from EBSCOhost

Abstract:INTRODUCTIONChildren and adolescents with systemic rheumatic diseases have an increased risk of infections. Although some infections are vaccine-preventable, immunization among patients with juvenile rheumatic diseases is suboptimal, partly due to some doubts that still persist regarding its efficacy and safety in this patient population.OBJECTIVESTo review the available evidence regarding the immunological response and the safety of vaccination in children and adolescents with systemic inflammatory rheumatic diseases (SIRD).METHODSA systematic review of the current literature until December 2014 using MEDLINE, EMBASE and abstracts from the American College of Rheumatology and European League Against Rheumatism congresses (2011-2014), complemented by hand search was performed. Eligible studies were identified and efficacy (seroprotection and/or seroconversion) and safety (reactions to vaccine and relapse of rheumatic disease) outcomes were extracted and summarized according to the type of vaccine.RESULTSTwenty-eight articles concerning vaccination in pediatric patients with SIRDs were found, that included almost 2100 children and adolescents, comprising nearly all standard

vaccinations of the recommended immunization schedule. Children with SIRDs generally achieved seroprotection and seroconversion; nevertheless, the antibody levels were often lower when compared with healthy children. Glucocorticoids and conventional disease-modifying anti-rheumatic drugs do not seem to significantly hamper the immune responses, whereas TNF inhibitors may reduce antibody production, particularly in response to pneumococcal conjugate, influenza, meningococcal C and hepatitis A vaccine. There were no serious adverse events, nor evidence of a relevant worsening of the underlying rheumatic disease. Concerning live attenuated vaccines, the evidence is scarce, but no episodes of overt disease were reported, even in patients under biological therapy.CONCLUSIONSExisting literature demonstrates that vaccines are generally well tolerated and effective in stable SIRD patients, yet antibody titers are frequently lower than in healthy controls. There is some evidence that biological therapy could hamper the immune response. Data on safety of live attenuated vaccines is limited. Although the available literature covers most vaccines included in the national immunization plan, there is a need for more information regarding new vaccines and new anti-rheumatic therapies.

What could we learn from the sub-analysis of a single nation cohort in a worldwide study? Lessons from the results observed in the Italian cohort of the GO-MORE trial.

Author(s): Giacomelli, Roberto; Ruscitti, Piero; Bombardieri, Stefano; Cuomo, Giovanna

Source: Clinical and experimental rheumatology; 2017; vol. 35 (no. 4); p. 623-629

Publication Type(s): Journal Article

Abstract:OBJECTIVESGO-MORE Trial investigated the use of Golimumab (GLM) in 3280 rheumatoid arthritis (RA) patients worldwide. At present, the burden of arthritis is greater in poorer countries than in developed countries due to socioeconomic disparities, thus suggesting the usefulness of subgroup investigations. We aimed to evaluate GLM as add-on therapy for RA patients in the Italian cohort of GO-MORE trial and compared the clinical characteristics between Italian patients and the enrolled patients worldwide.METHODSNinety-eight Italian patients with active RA, fulfilling the 1987 ACR criteria were enrolled. Statistical analyses were performed to assess: i. the differences in baseline characteristics; ii. the efficacy after 6 months; between Italian and Rest of the World GO-MORE populations.RESULTSCompared to the worldwide population, Italian patients showed a lower value of disease activity and a significantly short disease duration. Unlike the worldwide patients, the large majority of Italian patients received biologic therapy after the failure of the first synthetic DMARD and were not treated by high methotrexate dosage. After 6 months of GLM treatment, no differences were observed in the therapeutic response. Italian patients reported a positive autoinjection experience mirroring the worldwide results.CONCLUSIONSThe analysis of the Italian GO-MORE subset confirms that differences among patients may be shown, depending on different approaches in different health systems. GLM in the Italian patients showed a favourable benefit/risk profile and the positive autoinjection experience may help with patient's compliance and survival of the treatment.

Serious adverse events and the risk of stroke in patients with rheumatoid arthritis: results from the German RABBIT cohort

Author(s): Meissner Y.; Richter A.; Listing J.; Zink A.; Strangfeld A.; Manger B.; Tony H.P.; Wilden E.

Source: Annals of the rheumatic diseases; Sep 2017; vol. 76 (no. 9); p. 1583-1590

Publication Type(s): Article

Available in full text at Annals of the Rheumatic Diseases - from Highwire Press

Abstract:OBJECTIVE: In the general population, the incidence of stroke is increased following other serious events and hospitalisation. We investigated the impact of serious adverse events on the risk of stroke in patients with rheumatoid arthritis (RA), taking risk factors and treatment into

account.METHODS: Using data of the German biologics register RABBIT (Rheumatoid Arthritis: Observation of Biologic Therapy) with 12354 patients with RA, incidence rates (IRs) and risk factors for stroke were investigated using multi-state and Cox proportional hazard models. In addition, in a nested case-control study, all patients with stroke were matched 1:2 to patients with identical baseline risk profile and analysed using a shared frailty model.RESULTS: During follow-up, 166 strokes were reported. The overall IR was 3.2/1000 patient-years (PY) (95%CI 2.7 to 3.7). It was higher after a serious adverse event (IR: 9.0 (7.3 to 11.0)), particularly within 30 days after the event (IR: 94.9 (72.6 to 121.9)). The adjusted Cox model showed increased risks of age per 5 years (HR: 1.4 (1.3 to 1.5)), hyperlipoproteinaemia (HR: 1.6 (1.0 to 2.5)) and smoking (HR: 1.9 (1.3 to 2.6)). The risk decreased with better physical function (HR: 0.9 (0.8 to 0.96)). In the case-control study, 163 patients were matched to 326 controls. Major risk factors for stroke were untreated cardiovascular disease (HR: 3.3 (1.5 to 7.2)) and serious infections (HR:4.4 (1.6 to 12.5)) or other serious adverse events (HR: 2.6 (1.4 to 4.8)).CONCLUSIONS: Incident adverse events, in particular serious infections, and insufficient treatment of cardiovascular diseases are independent drivers of the risk of stroke. Physicians should be aware that patients who experience a serious event are at increased risk of subsequent stroke.

Efficacy, Safety and Pharmacokinetics of Up to Two Courses of the Rituximab Biosimilar CT-P10 Versus Innovator Rituximab in Patients with Rheumatoid Arthritis: Results up to Week 72 of a Phase I Randomized Controlled Trial

Author(s): Yoo D.H.; Suh C.-H.; Shim S.C.; Jeka S.; Molina F.F.C.; Hrycaj P.; Wiland P.; Lee E.Y.

Source: BioDrugs; Aug 2017; vol. 31 (no. 4); p. 357-367

Publication Type(s): Article

Abstract: Background: CT-P10 is a biosimilar of innovator rituximab (RTX), a biological therapy used to treat patients with rheumatoid arthritis (RA) who have responded inadequately to anti-tumor necrosis factor agents. Objective: Our objective was to compare the clinical profile of CT-P10 versus RTX in patients with RA who received up to two courses of treatment and were followed for up to 72 weeks. Methods: In this multicenter double-blind phase I study, patients were randomized 2:1 to receive CT-P10 1000 mg or RTX 1000 mg at weeks 0 and 2. Based on disease activity, patients could receive a second course of treatment between weeks 24 and 48. Efficacy endpoints, including mean change from baseline in Disease Activity Score using 28 joints (DAS28), safety, immunogenicity, pharmacokinetics, and pharmacodynamics were evaluated. Results: In total, 154 patients were randomized to CT-P10 or RTX (n = 103 and 51, respectively); 137 (n = 92 and 45) completed the first course of treatment, of whom 83 (n = 60 and 23) were re-treated. Improvements from baseline in all efficacy endpoints were highly similar between the CT-P10 and RTX groups over both treatment courses. At week 24 after the second course, mean change from week 0 of the first course in DAS28 erythrocyte sedimentation rate was -2.47 and -2.04 for CT-P10 and RTX, respectively, (p = 0.1866) and in DAS28 C-reactive protein was -2.32 and -2.00, respectively (p = 0.3268). The proportion of patients positive for antidrug antibodies at week 24 after the second treatment course was 20.0% and 21.7% in the CT-P10 and RTX groups, respectively. The safety profile of CT-P10 was comparable to that of RTX, and pharmacokinetic and pharmacodynamic properties were similar. Conclusions: In patients with RA, efficacy, safety, and other clinical data were comparable between CT-P10 and RTX after up to two courses of treatment over 72 weeks. (ClinicalTrials.gov identifier NCT01534884).

Delayed anti-TNF therapy increases the risk of total knee replacement in patients with severe rheumatoid arthritis

Author(s): Chen Y.-C.; Chiu W.-C.; Cheng T.-T.; Lai H.-M.; Yu S.-F.; Su B.Y.-J.; Hsu C.-Y.; Ko C.-H.

Source: BMC Musculoskeletal Disorders; Aug 2017; vol. 18 (no. 1)

Publication Type(s): Article

Available in full text at BMC Musculoskeletal Disorders - from BioMed Central

Abstract: Background: This study evaluated the effect of early anti-tumor necrosis factor (TNF) therapy in patients with severe rheumatoid arthritis (RA) on the subsequent risk of total knee replacement (TKR) surgery. Methods: This retrospective observational study included a hospital-based cohort of 200 patients diagnosed with severe RA who received treatment with anti-TNF therapy between 2003 and 2014. Clinical parameters including age, sex, body mass index, and the time from the diagnosis of RA to the initiation of anti-TNF therapy were analyzed. Results: Of the 200 enrolled patients, 84 underwent an early intervention (3 years from the diagnosis of RA to the initiation of anti-TNF therapy). Five (6.0%) patients in the early intervention group underwent TKR compared to 31 (26.7%) in the late intervention group (p = 0.023). After adjusting for confounding factors, the late intervention group still had a significantly higher risk of TKR (p = 0.004; odds ratio, 5.572; 95% confidence interval, 1.933-16.062). Those receiving treatment including methotrexate had a lower risk of TKR (p = 0.004; odds ratio, 0.287; 95% confidence interval, 0.122-0.672). Conclusions: Delayed initiation of anti-TNF therapy in the treatment of severe RA was associated with an increased risk of TKR surgery. Adding methotrexate treatment decreased the risk of future TKR.

Patterns of care for biologic-dosing outliers and nonoutliers in biologic-naive patients with rheumatoid arthritis

Author(s): Delate T.; Jenkins D.; Meyer R.

Source: Journal of Managed Care and Specialty Pharmacy; Aug 2017; vol. 23 (no. 8); p. 798-808

Publication Type(s): Article

Abstract:BACKGROUND: Although most biologic medications for patients with rheumatoid arthritis (RA) have recommended fixed dosing, actual biologic dosing may vary among real-world patients, since some patients can receive higher (high-dose outliers) or lower (low-dose outliers) doses than what is recommended in medication package inserts. OBJECTIVE: To describe the patterns of care for biologic-dosing outliers and nonoutliers in biologic-naive patients with RA. METHODS: This was a retrospective, longitudinal cohort study of patients with RA who were not pregnant and were aged = 18 and 110[%] of the approved dose in the package insert at any time during the study period. Baseline patient profiles, treatment exposures, and outcomes were collected during the 180 days before and up to 2 years after biologic initiation and compared across index biologic outlier groups. Patients were followed for at least 1 year, with a subanalysis of those patients who remained as members for 2 years. RESULTS: This study included 434 RA patients with 1 year of follow-up and 372 RA patients with 2 years of follow-up. Overall, the vast majority of patients were female (~ 75[%]) and had similar baseline characteristics. Approximately 10[%] of patients were outliers in both follow-up cohorts. ETN patients were least likely to become outliers, and ADA patients were most likely to become outliers. Of all outliers during the 1-year follow-up, patients were more likely to be a high-dose outlier (55[%]) than a low-dose outlier (45[%]). Median 1- and 2-year adjusted total biologic costs (based on wholesale acquisition costs) were higher for ADA and ETA nonoutliers than for IFX nonoutliers. Biologic persistence was highest for IFX patients. Charlson Comorbidity Index score, ETN and IFX index biologic, and treatment with a nonbiologic disease-modifying antirheumatic drug (DMARD) before biologic initiation were associated with becoming high- or low-dose outliers (c-statistic = 0.79). CONCLUSIONS: Approximately 1 in 10 study patients with RA was identified as a biologic-dosing outlier. Dosing outliers did not appear to have better clinical outcomes compared with nonoutliers. Before initiating outlier biologic dosing, health care providers may better serve

their RA patients by prescribing alternate DMARD therapy.

A reduced 12-joint ultrasound examination predicts lack of X-ray progression better than clinical remission criteria in patients with rheumatoid arthritis

Author(s): de Miguel E.; Pecondon-Espanol A.; Castano-Sanchez M.; Corrales A.; Gutierrez-Polo R.

Source: Rheumatology International; Aug 2017; vol. 37 (no. 8); p. 1347-1356

Publication Type(s): Article

Abstract: To study the predictive value of clinical remission definitions and ultrasound (US) examination on X-ray progression in rheumatoid arthritis (RA). This was an observational prospective multicenter 1-year follow-up cohort of RA patients with moderate disease activity (3.2 1 and no progression was defined as

Rituximab biosimilar and reference rituximab in patients with previously untreated advanced follicular lymphoma (ASSIST-FL): primary results from a confirmatory phase 3, double-blind, randomised, controlled study

Author(s): Jurczak W.; Moreira I.; Kanakasetty G.B.; Munhoz E.; Echeveste M.A.; Giri P.; Castro N

Source: The Lancet Haematology; Aug 2017; vol. 4 (no. 8)

Publication Type(s): Article

Abstract: Background GP2013 is a rituximab biosimilar developed to stringent development guidelines, including non-clinical and preclinical investigations and clinical trials in rheumatoid arthritis and follicular lymphoma. We aimed to compare the efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics of GP2013 plus cyclophosphamide, vincristine, and prednisone (GP2013-CVP) with rituximab-CVP (R-CVP) in patients with follicular lymphoma. Methods In this phase 3, multinational, double-blind, randomised, controlled trial, adults (aged 18 years or older) with previously untreated, advanced stage (Ann Arbor stage III or IV) follicular lymphoma of WHO histological grades 1, 2, or 3a were randomly assigned (1:1) using interactive response technology to eight cycles of GP2013-CVP or R-CVP (combination phase), followed by monotherapy maintenance in responders for a 2-year period. Randomisation was stratified by Follicular Lymphoma International Prognostic Index risk group and geographic region. The primary endpoint was comparability in overall response, with equivalence concluded if the entire 95% CI was within a margin of -12% to 12%. The primary endpoint was analysed using the per-protocol set, which included all patients who received at least one (partial or complete) dose of investigational treatment and who did not have any major protocol deviations. The trial is registered with ClinicalTrials.gov, number NCT01419665, and is ongoing. Findings Between Dec 1, 2011, and Jan 15, 2015, 858 patients were screened for eligibility. 314 patients were randomly assigned to GP2013, of whom 312 were given GP2013, and 315 were assigned to reference rituximab. Median follow-up was 11.6 months (IQR 5.8-18.2) for the primary analysis. The primary endpoint, equivalence of overall response, was met (271 [87%] of 311 patients with GP2013 and 274 [88%] of 313 patients with reference rituximab achieved an overall response; difference -0.40% [95% CI -5.94 to 5.14]). Occurrence of adverse events and serious adverse events was similar between the treatment groups (289 [93%] of 312 patients in the GP2013-CVP group had an adverse event and 71 [23%] of 312 patients had a serious adverse event; 288 [91%] of 315 patients in the R-CVP group had an adverse event and 63 [20%] had a serious adverse event). The most common adverse event was neutropenia (80 [26%] of 312 patients in the GP2013-CVP group and 93 [30%] of 315 patients in the R-CVP group in the combination phase and 23 [10%] of 231 patients in the GP2013-CVP group and 13 [6%] of 231 patients in the R-CVP group in the maintenance phase). The most common grade 3 or 4 adverse event during the combination and maintenance phase was neutropenia (55 [18%] of 312 patients in

the GP2013-CVP group and 65 [21%] of 315 patients in the R-CVP group in the combination phase and 17 [7%] of 231 patients in the GP2013-CVP group and nine [4%] of 231 patients in the R-CVP group in the maintenance phase). The occurrence of anti-drug antibodies was similar in the treatment groups (five [2%] of 268 patients in the GP2013-CVP; three [1%] in the R-CVP group). Interpretation Our results show that GP2013 represents a viable rituximab biosimilar candidate for patients with previously untreated advanced follicular lymphoma. The introduction of biosimilars provides additional therapeutic options with potential to increase access to effective and life-saving biological therapies such as rituximab. Funding Hexal.

Predictors of work disability after start of anti-TNF therapy in a national cohort of Swedish patients with rheumatoid arthritis: Does early anti-TNF therapy bring patients back to work?

Author(s): Olofsson T.; Nilsson J.A.; Geborek P.; Lindqvist E.; Turesson C.; Petersson I.F.; Englund M

Source: Annals of the Rheumatic Diseases; Jul 2017; vol. 76 (no. 7); p. 1245-1252

Publication Type(s): Article

Available in full text at Annals of the Rheumatic Diseases - from Highwire Press

Abstract: Objectives: To examine predictors of work ability gain and loss after anti-tumour necrosis factor (TNF) start, respectively, in working-age patients with rheumatoid arthritis (RA) with a special focus on disease duration. Methods: Patients with RA, aged 19-62 years, starting their first TNF inhibitor 2006-2009 with full work ability (0 sick leave/disability pension days during 3 months before bio-start; n=1048) or no work ability (90 days; n=753) were identified in the Swedish biologics register (Anti-Rheumatic Treatment In Sweden, ARTIS) and sick leave/disability pension days retrieved from the Social Insurance Agency. Outcome was defined as work ability gain >=50% for patients without work ability at bio-start and work ability loss >=50% for patients with full work ability, and survival analyses conducted. Baseline predictors including disease duration, age, sex, education level, employment, Health Assessment Questionnaire, Disease Activity Score 28 and relevant comorbidities were estimated using Cox regression. Results: During 3 years after anti-TNF start, the probability of regaining work ability for totally work-disabled patients was 35% for those with disease duration =5 years (adjusted HR 2.1 (95% CI 1.4 to 3.2)). For patients with full work ability at bio-start, disease duration did not predict work ability loss. Baseline disability pension was also a strong predictor of work ability gain after treatment start. Conclusions: A substantial proportion of work-disabled patients with RA who start anti-TNF therapy regain work ability. Those initiating treatment within 5 years of symptom onset have a more than doubled 3-year probability of regaining work ability compared with later treatment starts. This effect seems largely due to the impact of disease duration on disability pension status.

Biologic injections for osteoarthritis and articular cartilage damage: can we modify disease?

Author(s): Shi W.J.; Tjoumakaris F.P.; Lendner M.; Freedman K.B.

Source: Physician and Sportsmedicine; Jul 2017 ; p. 1-21

Publication Type(s): Article In Press

Abstract: Objective: The purpose of the present investigation is to conduct a systematic review of the literature to review the clinical results of platelet rich plasma (PRP) and mesenchymal stem cell treatments (MSC) (biologics) for articular cartilage lesions and osteoarthritis of the knee. Methods: A search of the PubMed, EMBASE, and Cochrane databases was performed to identify studies involving biologic therapy for osteoarthritis or osteochondral defects. Only Level I-III clinical trials with at least 3-month follow-up were included. Outcome data was gathered on any patient-completed surveys, 2nd look arthroscopy, follow-up imaging, biopsy/histology results, and any adverse effects of treatment. Results: Thirty-three articles met our inclusion criteria. There was a

total of 21 PRP studies in the study. All PRP studies showed clinical improvement with PRP therapies in outcomes surveys measuring patient satisfaction, pain, and function. Two studies reported no significant difference in improvement compared to hyaluronic acid (HA). Similarly, the 7/9 MSC studies showed improvement. One study found BM-MSC implantation was not significantly superior to matrix assisted chondrocyte implantation (MACI), while one reported peripheral blood stem cells (PBSC) did not significantly improve outcomes over HA. Of the three studies looking at a combination of MSC/PRP, two found MSC/PRP combination did not improve outcomes compared to MSC or PRP therapy alone. The one PRP study that had a 2nd look arthroscopy reported increases cartilage regeneration with PRP. All 8 MSC studies with follow-up MRI and all 7 MSC studies with 2nd look arthroscopy showed improvement in cartilage regeneration in terms of coverage, fill of the defect, and/or firmness of the new cartilage. Conclusion: Current data suggests that, of the two treatments, MSC provides more significant disease modifying effect; however, further research needs to be done to compare these two treatments and determine if there is a synergetic effect when combined.

Risk of Cancer Recurrence Among Individuals Exposed to Antitumor Necrosis Factor Therapy: A Systematic Review and Meta-Analysis of Observational Studies

Author(s): Micic D.; Komaki Y.; Alavanja A.; Rubin D.T.; Sakuraba A.

Source: Journal of Clinical Gastroenterology; Jul 2017

Publication Type(s): Article In Press

Abstract:BACKGROUND:: Patients with immune-mediated disorders such as ankylosing spondylitis, inflammatory bowel disease, psoriasis and rheumatoid arthritis are increasingly treated with tumor necrosis factor (TNF) inhibitors. The safety of anti-TNF therapy in patients with a history of cancer requires further evaluation. We conducted a systematic review and a meta-analysis of observational studies including patients with a history of cancer exposed to anti-TNF therapy assessing for a risk of new cancer or cancer recurrence. MATERIALS AND METHODS:: A computerized literature search of MEDLINE, Google scholar, and Cochrane Database of Systematic Reviews was performed through September 1, 2015. Study characteristics, quality, and risk of bias were assessed. Random-effects model meta-analyses were used to estimate the risk of new cancer development or cancer recurrence. RESULTS:: Nine English-language observational studies including patients with a history of cancer and exposed to anti-TNF therapy were idenitifed. The pooled incidence rate ratio of new or recurrent cancer among individuals with a history of cancer exposed to anti-TNF therapy was not significantly different compared with control therapies (incidence rate ratio, 0.90; 95% confidence interval, 0.59-1.37). Subgroup analyses were performed according to disease type, underlying cancer diagnosis, time to initiation of anti-TNF therapy and study quality. Heterogeneity of study populations, heterogeneity of the included cancer subtypes and utilization of observational studies limits the study quality. CONCLUSIONS:: The risk of new cancer or cancer recurrence among patients with a history of cancer and use of anti-TNF therapy is similar to the risk with nonbiological disease modifying therapies. These results support the use of anti-TNF medications in select populations despite prior diagnosis of cancer.

Clinical characteristics of importance to outcome in patients with axial spondyloarthritis: Protocol for a prospective descriptive and exploratory cohort study

Author(s): Andreasen R.A.; Emamifar A.; Duerlund B.; Fischer L.; Hansen I.M.J.; Kristensen L.E.

Source: BMJ Open; Jul 2017; vol. 7 (no. 7)

Publication Type(s): Article

Abstract: Introduction Spondyloarthritis (SpA) is a heterogeneous spectrum of rheumatic diseases with either predominantly axial inflammatory symptoms of the spine and sacroiliac joints or predominantly peripheral arthritis. The two main entities of axial SpA (axSpA) are ankylosing spondylitis or non-radiographic axSpA (nr-axSpA). Tumour necrosis factor-alpha inhibitors have revolutionised the treatment of patients with axSpA who failed to respond to non-steroidal anti-inflammatory drugs and physical therapy. Chronic pain is common in patients with SpA and may still persist despite the lack of signs of inflammation. This has led researchers to hypothesise that central pain sensitisation may play a role in the generation of chronic pain in SpA. The painDETECT Questionnaire (PDQ) is a screening tool developed to detect neuropathic pain components. The primary objective is to explore the prognostic value of the PDQ regarding treatment response in patients with axSpA 3 months after initiating a biological agent. Secondary aim is to evaluate the impact of extra-articular manifestations, comorbidities and patient-reported outcomes and elucidate if these factors influence treatment response. Method and analysis We will include 60 participants (>=18 years of age) diagnosed with axSpA independent of main entity, who initiate or switch treatment of a biologic. Data will be collected at baseline and at endpoint following Danish clinical practice (>=3 months) of treatment with biologics. We will explore whether the PDQ and other phenotypical patient characteristics are prognostically important for response to biological therapy according to established response criteria like 50% improvement in the Bath Ankylosing Spondylitis Disease Activity Index (50%) and Ankylosing Spondylitis Disease Activity Score. Ethics and dissemination The study is approved by the Region of Southern Denmark's Ethics committee (S-20160094) and has been designed in cooperation with patient representatives. The study is registered at clinicaltrials.gov (NCT02948608, pre-results). Dissemination will occur through publication(s) in international peer-reviewed journal(s).

Impact of adherence to biological agents on health care resource utilization for patients over the age of 65 years with rheumatoid arthritis

Author(s): Lathia U.; Ewara E.M.; Nantel F.

Source: Patient Preference and Adherence; Jul 2017; vol. 11 ; p. 1133-1142

Publication Type(s): Article

Available in full text at Patient preference and adherence - from National Library of Medicine

Abstract: Objective: Poor adherence to therapy increases the patient and societal burden and complexity of chronic diseases such as rheumatoid arthritis (RA). In the past 15 years, biologic disease-modifying anti-rheumatic drugs (DMARDs) have revolutionized the treatment of RA. However, little data are available on the impact of adherence to biologics on health care resources. The objective of the study was to determine the long-term health care resource utilization patterns of RA patients who were adherent to biologic DMARD therapy compared to RA patients who were non-adherent to biologic DMARD therapy in an Ontario population and to determine factors influencing adherence. Methods: Patients were identified from the Ontario RA Database that contains all RA patients in Ontario, Canada, identified since 1991. The study population included RA patients, aged 65+ years, with a prescription for a biologic DMARD between 2003 and 2013. Exclusion criteria included diagnosis of inflammatory bowel disease, psoriatic arthritis or psoriasis in the 5 years prior to the index date and discontinuation of biologic DMARD, defined as no subsequent prescription during the 12 months after the index date. Adherence was defined as a medication possession ratio of >=0.8 measured as the proportion of days for which a patient had biologic treatment(s) over a defined follow-up period. Adherent patients were matched to non-adherent patients by propensity score matching. Results: A total of 4,666 RA patients were identified, of whom 2,749 were deemed adherent and 1,917 non-adherent. The age (standard deviation) was 69.9 (5.46) years and 75% were female. Relative rates for resource use (physician visits, emergency visits,

hospitalization, home care and rehabilitation) for the matched cohort were significantly lower (PCopyright © 2017 Lathia et al.

Triple therapy versus biologic therapy for Active Rheumatoid Arthritis a cost-effectiveness analysis

Author(s): Bansback N.; Anis A.H.; Phibbs C.; Sun H.; O'Dell J.R.; Brophy M.; Keystone E.C.

Source: Annals of Internal Medicine; Jul 2017; vol. 167 (no. 1); p. 8-16

Publication Type(s): Article

Available in full text at Annals of internal medicine [Ann Intern Med] NLMUID: 0372351 - from EBSCOhost

Abstract: Background: The RACAT (Rheumatoid Arthritis Comparison of Active Therapies) trial found triple therapy to be noninferior to etanercept-methotrexate in patients with active rheumatoid arthritis (RA). Objective: To determine the cost-effectiveness of etanercept-methotrexate versus triple therapy as a first-line strategy. Design: A within-trial analysis based on the 353 participants in the RACAT trial and a lifetime analysis that extrapolated costs and outcomes by using a decision analytic cohort model. Data Sources: The RACAT trial and sources from the literature. Target Population: Patients with active RA despite at least 12 weeks of methotrexate therapy. Time Horizon: 24 weeks and lifetime. Perspective: Societal and Medicare. Intervention: Etanercept-methotrexate first versus triple therapy first. Outcome Measures: Incremental costs, quality-adjusted lifeyears (QALYs), and incremental cost-effectiveness ratios (ICERs). Results of Base-Case Analysis: The within-trial analysis found that etanercept-methotrexate as first-line therapy provided marginally more QALYs but accumulated substantially higher drug costs. Differences in other costs between strategies were negligible. The ICERs for first-line etanercept-methotrexate and triple therapy were $2.7 million per QALY and $0.98 million per QALY over 24 and 48 weeks, respectively. The lifetime analysis suggested that first-line etanercept-methotrexate would result in 0.15 additional lifetime QALY, but this gain would cost an incremental $77 290, leading to an ICER of $521 520 per QALY per patient. Results of Sensitivity Analysis: Considering a long-term perspective, an initial strategy of etanercept-methotrexate and biologics with similar cost and efficacy is unlikely to be cost-effective compared with using triple therapy first, even under optimistic assumptions. Limitation: Data on the long-term benefit of triple therapy are uncertain. Conclusion: Initiating biologic therapy without trying triple therapy first increases costs while providing minimal incremental benefit. Primary Funding Source: The Cooperative Studies Program, Department of Veterans Affairs Office of Research and Development, Canadian Institutes for Health Research, and an interagency agreement with the National Institutes of Health-American Recovery and Reinvestment Act.Copyright © 2017 American College of Physicians.

Anti-TNF Treatment for Extraintestinal Manifestations of Inflammatory Bowel Disease in the Swiss IBD Cohort Study

Author(s): Vavricka S.R.; Gubler M.; Gantenbein C.; Spoerri M.; Biedermann L.; Zeitz J.; Misselwitz B.

Source: Inflammatory Bowel Diseases; Jul 2017; vol. 23 (no. 7); p. 1174-1181

Publication Type(s): Article

Abstract: Background: Extraintestinal manifestations (EIMs) in patients with inflammatory bowel disease (IBD) are frequently observed. Little is known about the efficacy of anti-tumor necrosis factor (TNF) in EIM management. We assessed the effect of 3 anti-TNF agents (infliximab, adalimumab, and certolizumab pegol) on EIM evolution. Methods: Data on 1249 patients from the Swiss IBD Cohort Study (SIBDCS) were analyzed. All EIMs were diagnosed by relevant specialists. Response was classified into improvement, stable disease, and clinical worsening based on the physician's interpretation. Results: Of the 366 patients with at least 1 EIM, 213 (58.2%) were ever treated with an anti-TNF. A total of 299 treatments were started for 355 EIMs. Patients with EIM

were significantly more often treated with anti-TNF compared with those without EIM (58.2% versus 21.0%, P

Safety and efficacy of ocrelizumab in rheumatoid arthritis patients with an inadequate response to methotrexate or tumor necrosis factor inhibitors: a systematic review and meta-analysis

Author(s): Abushouk A.I.; Ismail A.; Elmaraezy A.; Ahmed H.; Badr A.S.; Gadelkarim M.; Elnenny M.

Source: Rheumatology International; Jul 2017; vol. 37 (no. 7); p. 1053-1064

Publication Type(s): Article

Abstract: We conducted this systematic reviews and meta-analysis to investigate the safety and efficacy of ocrelizumab in patients with active rheumatoid arthritis (RA) who exhibited resistance or intolerance to methotrexate or biological therapy. We performed a web-based literature search of PubMed, Google Scholar, EBSCO, Scopus, Embase, and Web of science for studies that compared ocrelizumab plus methotrexate versus methotrexate plus placebo in RA patients. Data were extracted from eligible studies and pooled as risk ratios (RR), using RevMan software. Pooling data from four RCTs (2230 patients) showed that ocrelizumab plus methotrexate were superior to methotrexate plus placebo at 24 weeks in terms of improvement on the American college of rheumatology (ACR20, ACR50, and ACR70) criteria (p

Infectious risk associated to orthopaedic surgery for rheumatoid arthritis patients treated by anti-TNFalpha

Author(s): Mabille C.; Degboe Y.; Constantin A.; Cantagrel A.; Ruyssen-Witrand A.; Barnetche T.

Source: Joint Bone Spine; Jul 2017; vol. 84 (no. 4); p. 441-445

Publication Type(s): Article

Abstract: Introduction Although biotherapy has greatly improved the prognosis of RA many patients have still recourse to an orthopaedic surgery. The current recommendation for scheduled surgery is to discontinue administration of the biological agent two to six weeks before surgery. Reinitiating anti-TNF therapy is proposed when the patient has healed. We wanted to know whether patients treated with anti-TNFalpha were exposed to an infectious risk undergoing a surgical procedure and if discontinuation of anti-TNFalpha therapy altered the risk of surgical infection. Methods We conducted a systematic review of the literature in PubMed, Embase and Cochrane until March 2014. We selected studies that reported post-operative infections by comparing patients treated with anti-TNFalpha to patients treated with csDMARD without biological treatment, or patients who continued anti-TNFalpha therapy to the patients who discontinued treatment prior to surgery. Results A first meta-analysis of 12 studies evaluating postoperative infection risk in patients treated with anti-TNFalpha showed that the postoperative infection risk doubled (RR = 1.81 [1.31-2.50]). Seven studies were grouped into a second meta-analysis to evaluate the benefit of the preventive discontinuation of anti-TNFalpha. Discontinuation of treatment did not alter the post-operative infection risk significantly: RR = 0.69 [0.39-1.21]. Conclusion This study showed that patients treated with anti-TNFalpha were more at risk of post-operative infection undergoing orthopaedic surgery. Preventive discontinuation of anti-TNFalpha does not seem to change this risk.

Clinical effectiveness and safety of leflunomide in inflammatory arthritis: a report from the RAPPORT database with supporting patient survey

Author(s): Schultz M.; Keeling S.O.; Katz S.J.; Maksymowych W.P.; Eurich D.T.; Hall J.J.

Source: Clinical Rheumatology; Jul 2017; vol. 36 (no. 7); p. 1471-1478

Publication Type(s): Article

Abstract: Leflunomide is indicated for the treatment of adults with rheumatoid arthritis, yet is underutilized. Given the cost of biologic therapy, understanding real-life effectiveness, safety, and sustainability of leflunomide, particularly in patients who have failed methotrexate, would be of value. The primary objective was to assess the proportion of patients achieving clinically meaningful benefit following an adequate trial of leflunomide. A retrospective analysis of a cohort supplemented with patient self-reported data using a standardized questionnaire. Data were analyzed using descriptive statistics, with a database multivariate logistic regression analysis to determine predictors of leflunomide response. Of the cohort available (N = 2591), 1671 patients with confirmed leflunomide use were included in the retrospective analysis, of whom 249 were incident users. Low disease activity (DAS-28 =1.2) at 3 months. Adverse effects (AE) were reported by 29% of incident users and after 1 year, 45% remained on leflunomide. Achievement of "minimal or no joint symptoms" was reported by 34% in the 661 analyzable survey responses (39% response rate). AE were reported by 55%, with nuisance (hair loss, nausea, stomach pain) AE and diarrhea being most common. Leflunomide was discontinued by 67% of responders within 1 year. An important proportion of patients, the majority of whom had previously failed methotrexate, achieved disease response with leflunomide with a low risk of serious adverse effects, suggesting that a trial of leflunomide may be a reasonable and cost-effective strategy prior to biologic therapy.

Risk of Cancer in Patients with Psoriasis on Biologic Therapies: A Systematic Review.

Author(s): Peleva, E; Exton, L S; Kelley, K; Mason, K J; Smith, C H

Source: The British journal of dermatology; Jul 2017

Publication Type(s): Journal Article Review

Abstract: Biologic therapies are highly effective in psoriasis, but have profound effects on innate and adaptive immune pathways that may negatively impact on cancer immunosurveillance mechanisms. To investigate the risk of cancer in psoriasis patients treated with biologic therapy we searched Medline, Embase, and the Cochrane Library (up to August 2016) for randomized control trials, prospective cohort studies and systematic reviews that reported cancer incidence in people exposed to biologic therapy for psoriasis compared to a control population. Eight prospective cohort studies met our inclusion criteria. All the evidence reviewed related to tumour necrosis factor inhibitors (TNFi) with the exception of one study on ustekinumab. An increased risk of non-melanoma skin cancer (NMSC), particularly squamous cell carcinoma, was reported with TNFi compared to both a general United States population and a rheumatoid arthritis population treated with TNFi. No evidence for increased risk of cancers (reported as all cancers, lymphoma, melanoma, prostate, colorectal and breast cancer) other than NMSC was identified. There were important limitations to the studies identified including choice of comparator arms, inadequate adjustment for confounding factors and failure to account for latency periods of cancer. There remains a need for ongoing pharmacovigilance in relation to cancer risk and biologic therapy; to determine whether the NMSC signal is specifically attributable to TNFi, further investigation is required using prospectively-collected data with adjustment for known NMSC risk factors. Systematic review registration number: PROSPERO; 2015:CRD42015017538.

Incidence of tuberculosis among patients with rheumatoid arthritis using TNF blockers in Brazil: data from the Brazilian Registry of Biological Therapies in Rheumatic Diseases (Registro Brasileiro de Monitoração de Terapias Biológicas - BiobadaBrasil).

Author(s): Yonekura, Claudia Leiko; Oliveira, Rene Donizeti Ribeiro; Titton, David C; Ranza, Roberto

Source: Revista brasileira de reumatologia; Jul 2017

Publication Type(s): Journal Article

Abstract:OBJECTIVESTo assess the incidence of tuberculosis and to screen for latent tuberculosis infection among Brazilians with rheumatoid arthritis using biologics in clinical practice.PATIENTS AND METHODSThis cohort study used data from the Brazilian Registry of Biological Therapies in Rheumatic Diseases (Registro Brasileiro de Monitoração de Terapias Biológicas - BiobadaBrasil), from 01/2009 to 05/2013, encompassing 1552 treatments, including 415 with only synthetic disease-modifying anti-rheumatic drugs, 942 synthetic DMARDs combined with anti-tumor necrosis factor (etanercept, infliximab, adalimumab) and 195 synthetic DMARDs combined with other biologics (abatacept, rituximab and tocilizumab). The occurrence of tuberculosis and the drug exposure time were assessed, and screening for tuberculosis was performed.STATISTICAL ANALYSISUnpaired t-test and Fisher's two-tailed test; p<0.05.RESULTSThe exposure times were 981 patient-years in the controls, 1744 patient-years in the anti-TNF group (adalimumab=676, infliximab=547 and etanercept=521 patient-years) and 336 patient-years in the other biologics group. The incidence rates of tuberculosis were 1.01/1000 patient-years in the controls and 2.87 patient-years among anti-TNF users (adalimumab=4.43/1000 patient-years; etanercept=1.92/1000 patient-years and infliximab=1.82/1000 patient-years). No cases of tuberculosis occurred in the other biologics group. The mean drug exposure time until the occurrence of tuberculosis was 27(11) months for the anti-TNF group.CONCLUSIONSThe incidence of tuberculosis was higher among users of synthetic DMARDs and anti-TNF than among users of synthetic DMARDs and synthetic DMARDs and non-anti-TNF biologics and also occurred later, suggesting infection during treatment and no screening failure.

Personalized Biologic Therapy for Large Vessel Vasculitis: Comment on the Articles by Langford et al...Langford CA, Cuthbertson D, Ytterberg SR, Khalidi N, Monach PA, Carette S, et al. A randomized, double-blind trial of abatacept (CTLA4-Ig) for the treatment of Takayasu arteritis. Arthritis Rheumatol 2017;69:846–53.

Author(s): Moiseev, Sergey; Novikov, Pavel; Smitienko, Ilya

Source: Arthritis & Rheumatology; Jul 2017; vol. 69 (no. 7); p. 1504-1505

Publication Type(s): Academic Journal

Rehabilitation and Therapies

Early High-Intensity Versus Low-Intensity Rehabilitation After Total Knee Arthroplasty: A Randomized Controlled Trial

Author(s): Bade M.J.; Struessel T.; Dayton M.; Wolfe P.; Foran J.; Kim R.H.; Miner T.; Dennis D.

Source: Arthritis Care and Research; 2017

Publication Type(s): Article In Press

Abstract: Objective: To examine the safety and efficacy of a high-intensity (HI) progressive rehabilitation protocol beginning 4 days after total knee arthroplasty (TKA) compared to a low-intensity (LI) rehabilitation protocol. Methods: A total of 162 participants (mean+/-SD ages 63+/-7 years; 89 women) were randomized to either the HI group or LI group after TKA. Key components of the HI intervention were the use of progressive resistance exercises and a rapid progression to weight-bearing exercises and activities. Both groups were treated in an outpatient setting 2 to 3 times per week for 11 weeks (26 total sessions). Outcomes included the stair climbing test (SCT; primary outcome), timed-up-and-go (TUG) test, 6-minute walk (6MW) test, the Western Ontario and

McMaster Universities Osteoarthritis Index (WOMAC), 12-item Short Form health survey (SF-12), knee range of motion (ROM), quadriceps and hamstring strength, and quadriceps activation. Outcomes were assessed preoperatively and at 1, 2, 3 (primary end point), 6, and 12 months postoperatively. Results: There were no significant differences between groups at 3 or 12 months in SCT, TUG, 6MW, WOMAC scores, knee ROM, quadriceps and hamstrings strength, quadriceps activation, or adverse event rates. By 12 months, outcomes on the 6MW, TUG, WOMAC, SF-12, quadriceps and hamstring strength, and quadriceps activation had improved beyond baseline performance in both groups. Conclusion: Both the HI and LI interventions were effective in improving strength and function after TKA. HI progressive rehabilitation is safe for individuals after TKA. However, its effectiveness may be limited by arthrogenic muscular inhibition in the early postoperative period.

Mindfulness Is Associated With Treatment Response From Nonpharmacologic Exercise Interventions in Knee Osteoarthritis

Author(s): Lee A.C.; Harvey W.F.; Han X.; Driban J.B.; McAlindon T.E.; Wang C.; Price L.L.; Wong J.B.

Source: Archives of Physical Medicine and Rehabilitation; 2017

Publication Type(s): Article In Press

Abstract: Objective: To examine the association between baseline mindfulness and response from exercise interventions in knee osteoarthritis (OA). Design: Cohort study; responder analysis of a clinical trial subset. Setting: Urban tertiary care academic hospital. Participants: Participants with symptomatic, radiographic knee OA (N=86; mean age, 60y; 74% female; 48% white). Interventions: Twelve weeks (twice per week) of Tai Chi or physical therapy exercise. Main Outcome Measures: Treatment response was defined using Osteoarthritis Research Society International criteria indicating meaningful improvements in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain, WOMAC function, or Patient Global Assessment scores. At baseline, participants completed the Five Facet Mindfulness Questionnaire (mean total score, 142+/-17) and were grouped into 3 categories of total mindfulness: higher, medium, or lower. Relative risk (RR) ratios were used to compare treatment response across groups. Results: Participants with higher total mindfulness were 38% (95% confidence interval [CI], 1.05-1.83) more likely to meet responder criteria than those with lower mindfulness. We found no significant difference between medium and lower mindfulness groups (RR=1.0; 95% CI, 0.69-1.44). Among the 5 mindfulness facets, medium acting-with-awareness was 46% (95% CI, 1.09-1.96) more likely to respond than lower acting-with-awareness, and higher acting-with-awareness was 34% more likely to respond, but this did not reach significance (95% CI, 0.97-1.86). Conclusions: In this study, higher mindfulness, primarily driven by its acting-with-awareness facet, was significantly associated with a greater likelihood of response to nonpharmacologic exercise interventions in knee OA. This suggests that mindfulness-cultivating interventions may increase the likelihood of response from exercise.

Formal physical therapy after total hip arthroplasty is not required: A randomized controlled trial

Author(s): Austin M.S.; Urbani B.T.; Fleischman A.N.; Purtill J.J.; Hozack W.J.; Parvizi J.; Rothman R.H.

Source: Journal of Bone and Joint Surgery - American Volume; 2017; vol. 99 (no. 8); p. 648-655

Publication Type(s): Review

Available in full text at Journal of Bone and Joint Surgery - American Volume - from Ovid

Abstract: Background: The value of formal physical therapy after total hip arthroplasty is unknown. With substantial changes that have occurred in surgical and anesthesia techniques, self-directed therapy may be efficacious in restoring function to patients undergoing total hip arthroplasty. Methods: We conducted a single-center, randomized trial of 120 patients undergoing primary,

unilateral total hip arthroplasty who were eligible for direct home discharge. The experimental group followed a self-directed home exercise program for 10 weeks. The control group received the standard protocol for physical therapy that included in-home visits with a physical therapist for the first 2 weeks followed by formal outpatient physical therapy for 8 weeks. Functional outcomes were measured using validated instruments including the Harris hip score (HHS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the Short Form-36 Health Survey (SF-36) preoperatively, at 1 month postoperatively, and at 6 to 12 months postoperatively. Results: Of 120 randomized patients, 108 were included in the final analysis. Ten patients (19%) were randomized to unsupervised home exercise and 20 patients (37%) were randomized to formal outpatient therapy crossed over between groups. There was no significant difference in any of the measured functional outcomes between patients receiving formal therapy (n = 54) and those participating in unsupervised home exercise (n = 54) at any time point (HHS, p = 0.82; WOMAC, p = 0.80; and SF-36 physical health, p = 0.90). Conclusions: This randomized trial suggests that unsupervised home exercise is both safe and efficacious for a majority of patients undergoing total hip arthroplasty, and formal physical therapy may not be required. Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Telemedicine for patients with rheumatic diseases: Systematic review and proposal for research agenda

Author(s): Piga M.; Cangemi I.; Mathieu A.; Cauli A.

Source: Seminars in Arthritis and Rheumatism; 2017

Publication Type(s): Article In Press

Abstract: Objective: To systematically review the scientific literature regarding tele-rheumatology and draw conclusions about feasibility, effectiveness, and patient satisfaction. Methods: PubMed, Scopus, and Cochrane database searches were performed (April 2016) using relevant MeSH and keyword terms for telemedicine and rheumatic diseases. Articles were selected if reporting outcomes for feasibility, effectiveness, and patient satisfaction and methodologically appraised using the Cochrane Collaboration's tool for assessing risk of bias and a modified version of CONSORT 2010 Statement. Results: A total of 177 articles were screened, 23 were selected for the present review but only 9 were RCTs. Five studies reported on feasibility, 14 effectiveness, and 9 satisfaction rates for different tele-rheumatology interventions grouped in synchronous (remotely delivered consultation) and asynchronous (remote disease activity assessment; tele-monitoring of treatment strategies or rehabilitation; and remotely delivered self-management programs). Seven studies (30.4%) were on rheumatoid arthritis, 2 (8.7%) were on systemic sclerosis (1 including also rheumatoid arthritis patients), 5 (21.7%) on fibromyalgia, 2 (8.7%) on osteoarthritis, 3 (13.0%) on juvenile idiopathic arthritis and 4 (17.4%) on mixed disease cohorts. Interventions and outcomes heterogeneity prevented meta-analysis of results. Overall, feasibility and patient satisfaction rates were high or very high across intervention types. Effectiveness was equal or higher than standard face-to-face approach in controlled trials which, however, were affected by small sample size and lack of blinding participants according to appraisal tools. Conclusion: Telemedicine may provide a well-accepted way to remotely deliver consultation, treatment and monitoring disease activity in rheumatology. Higher quality RCTs demonstrating effectiveness of different tele-rheumatology interventions are needed.

Clinical use of stem cells in orthopaedics

Author(s): Im G.-I.

Source: European Cells and Materials; 2017; vol. 33 ; p. 183-196

Publication Type(s): Article

Abstract: Stem cell research arose from the need to explore new therapeutic possibilities for intractable and lethal diseases. Although musculoskeletal disorders are basically nonlethal, their high prevalence and relative ease of performing clinical trials have facilitated the clinical application of stem cells in this field. However, few reliable clinical studies have been published, despite the plethora of in vitro and preclinical studies in stem cell research for regenerative medicine in the musculoskeletal system. Stem cell therapy can be applied locally for bone, cartilage and tendon regeneration. Candidate disease modalities in bone regeneration include large bone defects, nonunion of fractures, and osteonecrosis. Focal osteochondral defect and osteoarthritis are current targets for cartilage regeneration. For tendon regeneration, bone-tendon junction problems such as rotator cuff tears are hot topics in clinical research. To date, the literature supporting stem cell-based therapies comprises mostly case reports or case series. Therefore, high-quality evidence, including from randomised clinical trials, is necessary to define the role of cell-based therapies in the treatment of musculoskeletal disorders. It is imperative that clinicians who adopt stem cell treatment into their practices possess a good understanding of the natural course of the disease. It is also highly recommended that treating physicians do not thrust aside the concomitant use of established measures until stem cell therapy is evidently proved worthy in terms of efficacy and cost. The purpose of this review is to summarise on the current status of stem cell application in the orthopaedic field along with the author's view of future prospects.

Effectiveness of Periosteal Stimulation Therapy and Home Exercise Program in the Rehabilitation of Patients with Advanced Knee Osteoarthritis

Author(s): Elbadawy M.A.

Source: Clinical Journal of Pain; 2017; vol. 33 (no. 3); p. 254-263

Publication Type(s): Article

Abstract: Background: Osteoarthritis (OA) of the knee is the most common form of joint disease. It is one of the major causes of impaired function that reduces quality of life in older people worldwide. Periosteal Stimulation Therapy (PST) with boosters in combination with home exercises may be a suitable treatment option for such patients. Objectives: To examine the effectiveness of PST with boosters in addition to a home-based exercise program as compared with Transcutaneous Electrical Nerve Stimulation (TENS) combined with the same home-based exercise program in the management of chronic pain and functional impairments associated with advanced knee OA. Design: The study was a randomized controlled trial. Materials and Methods: Sixty patients with Kellgren-Lawrence grade 3 or 4 knee OA were randomized to receive PST or TENS once a week for 10 weeks, followed by boosters for 6 months in addition to a home exercise program. Visual Analogue Scale (VAS) and the Knee Injury and Osteoarthritis Outcome Score (KOOS) subscales were assessed at baseline, after the last PST session, and 6 months later. Results: Pain VAS and KOOS subscales were improved in both PST and TENS groups at 10 weeks and 6 months after intervention, with a statistically significant difference between the groups at both follow-up periods. Reduced pain VAS and increased KOOS subscales in the PST group were statistically significantly different from the TENS group during both follow-up periods. Conclusion: PST with boosters combined with a home exercise program was shown to be beneficial for improving subjective knee pain and functional performance of older patients with advanced knee OA.

Serious adverse events and the risk of stroke in patients with rheumatoid arthritis: results from the German RABBIT cohort

Author(s): Meissner Y.; Richter A.; Listing J.; Zink A.; Strangfeld A.; Manger B.; Tony H.P.; Wilden E.

Source: Annals of the rheumatic diseases; Sep 2017; vol. 76 (no. 9); p. 1583-1590

Publication Type(s): Article

Available in full text at Annals of the Rheumatic Diseases - from Highwire Press

Abstract:OBJECTIVE: In the general population, the incidence of stroke is increased following other serious events and hospitalisation. We investigated the impact of serious adverse events on the risk of stroke in patients with rheumatoid arthritis (RA), taking risk factors and treatment into account.METHODS: Using data of the German biologics register RABBIT (Rheumatoid Arthritis: Observation of Biologic Therapy) with 12354 patients with RA, incidence rates (IRs) and risk factors for stroke were investigated using multi-state and Cox proportional hazard models. In addition, in a nested case-control study, all patients with stroke were matched 1:2 to patients with identical baseline risk profile and analysed using a shared frailty model.RESULTS: During follow-up, 166 strokes were reported. The overall IR was 3.2/1000 patient-years (PY) (95%CI 2.7 to 3.7). It was higher after a serious adverse event (IR: 9.0 (7.3 to 11.0)), particularly within 30 days after the event (IR: 94.9 (72.6 to 121.9)). The adjusted Cox model showed increased risks of age per 5 years (HR: 1.4 (1.3 to 1.5)), hyperlipoproteinaemia (HR: 1.6 (1.0 to 2.5)) and smoking (HR: 1.9 (1.3 to 2.6)). The risk decreased with better physical function (HR: 0.9 (0.8 to 0.96)). In the case-control study, 163 patients were matched to 326 controls. Major risk factors for stroke were untreated cardiovascular disease (HR: 3.3 (1.5 to 7.2)) and serious infections (HR:4.4 (1.6 to 12.5)) or other serious adverse events (HR: 2.6 (1.4 to 4.8)).CONCLUSIONS: Incident adverse events, in particular serious infections, and insufficient treatment of cardiovascular diseases are independent drivers of the risk of stroke. Physicians should be aware that patients who experience a serious event are at increased risk of subsequent stroke.

International consensus: What else can we do to improve diagnosis and therapeutic strategies in patients affected by autoimmune rheumatic diseases (rheumatoid arthritis, spondyloarthritides, systemic sclerosis, systemic lupus erythematosus, antiphospholipid syndrome and Sjogren's syndrome)?: The unmet needs and the clinical grey zone in autoimmune disease management

Author(s): Giacomelli R.; Berardicurti O.; Carubbi F.; Cipriani P.; Di Benedetto P.; Liakouli V.

Source: Autoimmunity Reviews; Sep 2017; vol. 16 (no. 9); p. 911-924

Publication Type(s): Review

Abstract: Autoimmune diseases are a complex set of diseases characterized by immune system activation and, although many progresses have been done in the last 15 years, several unmet needs in the management of these patients may be still identified. Recently, a panel of international Experts, divided in different working groups according to their clinical and scientific expertise, were asked to identify, debate and formulate a list of key unmet needs within the field of rheumatology, serving as a roadmap for research as well as support for clinicians. After a systematic review of the literature, the results and the discussions from each working group were summarised in different statements. Due to the differences among the diseases and their heterogeneity, a large number of statements was produced and voted by the Experts to reach a consensus in a plenary session. At all the steps of this process, including the initial discussions by the steering committee, the identification of the unmet needs, the expansion of the working group and finally the development of statements, a large agreement was attained. This work confirmed that several unmet needs may be identified and despite the development of new therapeutic strategies as well as a better understanding of the effects of existing therapies, many open questions still remain in this field, suggesting a research agenda for the future and specific clinical suggestions which may allow

physicians to better manage those clinical conditions still lacking of scientific clarity.

Exercise in knee osteoarthritis: do treatment outcomes relate to bone marrow lesions? A randomized trial.

Author(s): Beckwée, David; Vaes, Peter; Raeymaeckers, Steven; Shahabpour, Maryam

Publication Date: Sep 2017

Publication Type(s): Academic Journal

Abstract: Purpose:Exercise is effective for reducing knee osteoarthritis (OA) pain but effect sizes vary widely. Moreover, not all knee OA patients perceive beneficial effects. Tailoring specific exercises to subgroups of knee OA patients may increase effectivity. Bone marrow lesions (BMLs) have been suggested as a criterion to define such subgroups. This study aimed to investigate whether BMLs' presence/absence is related to treatment outcomes in a group of knee OA patients who exercised for 18 weeks. Methods: Subjects with symptomatic knee OA started a strength or walking exercise program. BMLs' presence at baseline was assessed. Pain was assessed before and after the intervention with the intermittent and constant osteoarthritis pain (ICOAP) questionnaire. Also the global perceived effect (GPE) on the patient's complaints was rated. Results: Thirty-five patients (strength (N = 17) and walking (N = 18)) were analyzed for BMLs. BMLs were present in 25 (71%) knees. Five (14%) patients dropped out and 19 (54%) improved (GPE ≥5). All dropouts had BMLs, but no difference was seen between dropouts and retainers ($p > 0.05$). Pain scores did not differ between intervention groups ($p > 0.05$) or between patients with BMLs and without BMLs ($p > 0.05$). Conclusions: Pain scores and GPE was not different between knee OA patients with and without baseline BMLs in this sample.Implications for RehabilitationBoth walking and strengthening exercises are effective means of improving pain in patients with knee osteoarthritis.In a relatively small sample, this study shows that the presence or absence of subchondral bone marrow lesions, as seen on magnetic resonance images, is not related to treatment outcomes.

A longitudinal, qualitative study exploring sustained adherence to a hand exercise programme for rheumatoid arthritis evaluated in the SARAH trial.

Author(s): Nichols, Vivien P.; Williamson, Esther; Toye, Francine; Lamb, Sarah E.

Source: Disability & Rehabilitation; Sep 2017; vol. 39 (no. 18); p. 1856-1863

Publication Type(s): Academic Journal

Abstract: Purpose:This study explores the experience of participants taking part in a hand exercise programme for people with rheumatoid arthritis with a focus on adherence. The exercise programme was tested in a randomised controlled trial. This parallel qualitative study will inform future implementation into clinical practice. Method:Twenty-seven semi-structured interviews from 14 participants were undertaken at two time points (4 and 12 months after randomisation). We collected data of participants' experiences over time. This was guided by an interview schedule. Interview data were analysed using interpretative phenomenological analysis which is informed by phenomenological and hermeneutic theory. We recruited participants from National Health Service rheumatology and therapy departments. Results:At 4 months, 11/14 participants reported continuing with the exercises. By 12 months, 7/13 participants still reported exercising. The ability to establish a routine determined whether participants adhered to the exercise programme. This was sometimes influenced by practical issues. We also identified facilitators and barriers to regular exercise in the themes of the following: the therapeutic encounter, perceived benefit of exercises, attitude of mind, confidence, and unpredictability. Conclusions:Establishing a routine was an important step towards participants being able to exercise independently. Therapists provided participants with skills to continue to exercise while dealing with changes in symptoms and

schedules. Potential barriers to long-term exercise adherence need to be taken into account and addressed for successful implementation of this programme.Implications for RehabilitationBehavioural change components such as the use of an exercise planner (stating intentions of where, when and how), daily diary sheets, and joint goal setting enhance adherence to a hand exercise programme for RA by helping to establish routines.Exercise routines need to be flexible enough to fit in with life and symptom changes whilst delivering a sufficient dosage.Therapists facilitate this process by using behavioural components alongside more commonly used aspects of care (assessment, education, advice, and encouragement) to enable people with RA to become independent exercisers.

Physiotherapy for ankylosing spondylitis: Systematic review and a proposed rehabilitation protocol

Author(s): Sharan D.; Rajkumar J.S.

Source: Current Rheumatology Reviews; Aug 2017; vol. 13 (no. 2); p. 121-125

Publication Type(s): Review

Abstract: Ankylosing Spondylitis (AS) is a chronic inflammatory disease with gradual onset, largely affecting the axial skeleton. As leads to varying degrees of restricted spinal mobility, pain and loss of functional capacity. Rehabilitation, especially physiotherapy and exercises, are considered integral components of its management. Various rehabilitation modalities are available for the benefit of individuals with AS, but a sequenced protocol has not been reported. A scientific review was performed using the following search engines: MEDLINE (Pubmed), COCHRANE Library and Physiotherapy Evidence Database (PEDro). Studies, which had at least one of the groups receiving rehabilitation, and the major outcomes studied including pain, stiffness, mobility (spine and chest wall) and physical function (disease activity, ADL, QOL and global function) were selected. A total of 28 studies were shortlisted for the review which included a total of 1926 subjects with AS. The review of literature showed that individuals with AS had beneficial effects from exercise programmes compared to no exercise. Patient education, active involvement and motivation of individuals with AS played an important role in the overall treatment outcomes. Based on the review, a four-phase sequenced rehabilitation protocol has been laid down for the benefit of individuals with AS.

ORM2 and APOA2 serum levels can predict OA patient response to chondroitin sulfate/ glucosamine hydrochloride: Results from the moves study

Author(s): Calamia V.; Camacho M.; Gonzalez L.; Fernandez-Puente P.; Rego-Perez I.

Source: Basic and Clinical Pharmacology and Toxicology; Aug 2017; vol. 121 ; p. 75

Publication Type(s): Conference Abstract

Abstract: Background: A shotgun proteomic analysis performed on sera from patients enrolled in the Multicentre Osteoarthritis interVEntion trial with Sysadoa(MOVES) led to the discovery of a panel of predictive protein biomarkers useful to stratify osteoarthritis(OA) patients into responders and non-responders, either to Chondroitin sulfate/ glucosamine hydrochloride(Droglican, Bioiberica S.A., Barcelona, Spain) or Celecoxib. Objectives: To validate the sensitivity and specificity of a panel of six serum proteins useful to predict the patient response to Droglican treatment. Methods: We analyzed the serum levels of:APOA2, APOA4, APOH, C4BPa, ITIH1 and ORM2 by enzyme-linked immunosorbent assays (ELISAs).All the subjects studied belonged to the MOVES cohort at baseline(Droglican sub-cohort, n = 260).Non-parametric and multivariate analysis were performed to test the effects of the clinical variables gender, age, BMI, radiologic Kellgren/Lawrence(K/L) grade and WOMAC score at baseline, as well as the biomarker serum levels, on the response to Droglican treatment according to the OMERACTOARSI criteria and the WOMAC pain score(20%,30%,50% and

70% reduction) recorded at the end of the trial (after 6 months of treatment). Results: We found decreased serum levels of ORM2 at baseline in responders to Droglican according to the OMERACT-OARSI criteria vs. non-responders (76,11 +/- 53,25vs104,25 +/- 84,93; n = 171 vs 46; P = 0.047).APOA2 appeared statistically increased in responders with a 50% reduction in WOMAC pain score compared to non-responders (79,95 +/- 58,53vs66,05 +/- 46,49; n = 129vs112; P = 0.028).Patients with lower levels of ORM2 (median concentration= 69.8 ?g/ml) and higher level of APOA2 (median concentration= 63.8 ?g/ml) responded better to pharmacotherapy. Statistical interactions between ORM2 and APOA2 levels and radiologic K/L grade were also detected (P = 0.048 and P = 0.002, respectively).No statistically significant differences were found for the other four proteins. Conclusion: Our results show that ORM2 and APOA2 levels significantly correlates with patients response to Droglican suggesting the possibility of their use in predictive assays in order to optimize therapeutic outcomes in OA. Validation studies in different cohorts are needed to identify and validate a cut-off point for these biomarkers.

Impact of a patient support program on patient adherence to adalimumab and direct medical costs in Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriasis, psoriatic arthritis, and ankylosing spondylitis

Author(s): Rubin D.T.; Mittal M.; Chao J.; Skup M.; Davis M.; Johnson S.

Source: Journal of Managed Care and Specialty Pharmacy; Aug 2017; vol. 23 (no. 8); p. 859-867

Publication Type(s): Article

Abstract:BACKGROUND: AbbVie provides a free-to-patient patient support program (PSP) to assist adalimumab-treated patients with medication costs, nurse support, injection training, pen disposal, and medication reminders. The impact of these services on patient adherence to adalimumab and direct medical costs associated with autoimmune disease has not been assessed. OBJECTIVE: To quantify the relationship between participation in a PSP and outcomes (adalimumab adherence, persistence, and direct medical costs) in patients initiating adalimumab treatment. METHODS: A longitudinal, retrospective, cohort study was conducted using patient-level data from the PSP combined with Symphony Health Solutions administrative claims data for patients initiating adalimumab between January 2008 and June 2014. The sample included patients aged = 18 years with a diagnosis of Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriasis, psoriatic arthritis, or ankylosing spondylitis who were biologicnaive before initiation of adalimumab. Patients who enrolled in the PSP (PSP cohort) were matched to those who did not enroll (non-PSP cohort) based on age, sex, year of treatment initiation, comorbidities, diagnosis, and initiation at a specialty pharmacy. For the PSP cohort, the index date was assigned as the earliest date of PSP enrollment, and time to enrollment following adalimumab initiation was used to assign index dates for the non-PSP cohort. All patients were required to have evidence of medical and pharmacy coverage for at least 6 months before and after their first adalimumab claim and at least 12 months after their index date. Adherence (proportion of days covered during the 12 months following PSP opt-in [[]index date]) was compared between cohorts using t-tests. Persistence was assessed using survival analysis of discontinuation rates. Medical costs for emergency department, inpatient, physician, and outpatient visits (all-cause and disease-related) and total costs (medical plus drug costs) were compared at 12 months following the index date using t-tests. RESULTS: A total of 2,386 patients were included in the study and were allocated to the PSP (n = 1,199) and non-PSP (n = 1,187) cohorts. Baseline characteristics were similar between cohorts. During the follow-up period, adalimumab adherence was 14[%] greater in the PSP cohort than for the non-PSP cohort (67.0[%] vs. 58.8[%]; P

Impact of Traumatic Lower Extremity Injuries beyond Acute Care: Movement-Based Considerations for Resultant Longer Term Secondary Health Conditions

Author(s): Butowicz C.M.; Dearth C.L.; Hendershot B.D.

Source: Advances in Wound Care; Aug 2017; vol. 6 (no. 8); p. 269-278

Publication Type(s): Article

Abstract: Significance: Advances in field-based trauma care, surgical techniques, and protective equipment have collectively facilitated the survival of a historically large number of service members (SMs) following combat trauma, although many sustained significant composite tissue injuries to the extremities, including limb loss (LL) and limb salvage (LS). Beyond the acute surgical and rehabilitative efforts that focus primarily on wound care and restoring mobility, traumatic LL and LS are associated with several debilitating longer term secondary health conditions (e.g., low back pain [LBP], osteoarthritis [OA], and cardiovascular disease [CVD]) that can adversely impact physical function and quality of life. Recent Advances: Despite recent advancements in prosthetic and orthotic devices, altered movement and mechanical loading patterns have been identified among persons with LL and salvage, which are purported risk factors for the development of longer term secondary musculoskeletal conditions and may limit functional outcomes and/or concomitantly impact cardiovascular health. Critical Issues: The increased prevalence of and risk for LBP, OA, and CVD among the relatively young cohort of SMs with LL and LS significantly impact physiological and psychological well-being, particularly over the next several decades of their lives. Future Directions: Longitudinal studies are needed to characterize the onset, progression, and recurrence of health conditions secondary to LL and salvage. While not a focus of the current review, detailed characterization of physiological biomarkers throughout the rehabilitation process may provide additional insight into the current understanding of disease processes of the musculoskeletal and cardiovascular systems.

Frequency and Duration of Adrenal Suppression Following Glucocorticoid Therapy in Children With Rheumatic Diseases

Author(s): Ahmet A.; Lemieux J.; Aglipay M.; Barrowman N.; Duffy C.; Roth J.; Jurencak R.; Brienza V.

Source: Arthritis Care and Research; Aug 2017; vol. 69 (no. 8); p. 1224-1230

Publication Type(s): Article

Abstract: Objective: Adrenal suppression (AS), a glucocorticoid (GC) side effect with potentially significant morbidity, is poorly understood. The purpose of our study was to determine frequency, duration, and predictors of AS following a gradual taper of GC in children with rheumatic conditions. Methods: A prospective, observational cohort study was conducted. All patients ages 4 weeks of therapy were included. Morning cortisol was tested 4 weeks after GC taper to physiologic doses and then repeatedly until normalization. GCs were subsequently discontinued and a low-dose adrenocorticotropic hormone stimulation test was performed. Results: The study was completed by 31 of 39 patients. The median age was 12.9 years and median duration of GC therapy was 39.6 weeks. Seventeen patients (54.8%) had AS. Of the patients with AS, 50% showed recovery by 7 months. Two patients had persistent AS at 12 months and 1 patient at 2 years. A higher maximum GC dose was a significant predictor for the development of AS. Conclusion: More than 50% of our patients had AS after GC discontinuation, despite a gradual taper of GC. Stress steroids should be considered in children treated with long-term GC, even after steroid discontinuation, to prevent possible adrenal crisis.

Patients' perceived health service needs for osteoarthritis (OA) care: A scoping systematic review

Author(s): Papandony M.C.; Chou L.; Seneviwickrama M.; Cicuttini F.M.; Teichtahl A.J.; Wang Y.

Source: Osteoarthritis and Cartilage; Aug 2017

Publication Type(s): Article In Press

Abstract: Objective: To identify and synthesise evidence regarding patients' perceived health service needs related to osteoarthritis (OA). Design: A comprehensive systematic scoping review of MEDLINE, PsycINFO, EMBASE and CINAHL (1990-2016) was performed to capture information regarding patient perceived health service needs related to OA. Risk of bias and quality of included articles were assessed. Relevant data were extracted and collated to provide a systematic review of the existing literature. Results: Of the 1384 identified manuscripts, 21 were relevant to areas of patient perceived need, including needs related to medical care, pharmacologic therapy, physiotherapy and exercise therapy and alternative medicine. Key findings included (1) Symptom control drove the need for both conventional and complementary services. (2) An individualized relationship was sought with a practitioner knowledgeable in OA care and who adopted a holistic approach, whether providing conventional or alternative therapies. (3) Medications were required to obtain symptomatic relief, with use tempered by recognition of potential side effects and financial cost. (4) The need for allied health services was recognised, although patient and system issues were barriers to uptake. (5) Patient's attitudes towards joint replacement, orthoses and physical aids were influenced by patient preferences and previous healthcare experiences. Conclusion: Patient perceived needs are similar to those suggested by clinical guideline recommendations. Better aligning patient perceived needs with healthcare requirements may improve OA outcomes and optimise healthcare system utilisation.

Inflammation and post-operative recovery in patients undergoing total knee arthroplasty-secondary analysis of a randomized controlled trial

Author(s): Langkilde A.; Jakobsen T.L.; Bandholm T.Q.; Eugen-Olsen J.; Petersen J.; Andersen O.; Blauenfeldt T.

Source: Osteoarthritis and Cartilage; Aug 2017

Publication Type(s): Article In Press

Abstract: Objective: Reduced function persists for many patients after total knee arthroplasty (TKA). Inflammation is part of osteoarthritis' pathophysiology, and surgery induces a marked inflammatory response. We therefore wanted to explore the role of inflammation in long-term recovery after TKA, and thus conducted this secondary analysis of our randomized controlled trial (RCT) of physical rehabilitation +/- progressive strength training (PST). We aimed to investigate whether (1) inflammation is associated with functional performance, knee-extension strength, and knee pain before TKA; (2) PST affects inflammation, and the inflammatory state over time; (3) baseline or surgery-induced inflammation modifies the effect of rehabilitation +/- PST on change in 6-min walk test (delta6MWT); and (4) baseline or surgery-induced inflammation is associated with delta6MWT following TKA. Design: In the primary trial report's per-protocol analysis, 72/82 patients were included. Sixty had >=1 blood sample before and after TKA, and were included in this secondary analysis. Inflammation was measured by interferon gamma-inducible protein (IP)-10, soluble urokinase plasminogen activator receptor (suPAR), interleukin (IL)-6, IL-10, and tumor necrosis factor (TNF)-alpha at baseline; day 1, week 4, 8, and 26 after TKA. Results: At baseline, suPAR (P = 006) was negatively associated with 6MWT. Neither baseline nor surgery-induced inflammation modified the response to rehabilitation +/- PST. Only surgery-induced IL-10 was associated with delta6MWT26 weeks-baseline (P = 0.001), also adjusted for 6MWTbaseline, age, sex and body mass index (BMI). Conclusion: In this secondary analysis, only increased surgery-induced IL-10 response was associated with decreased long-term functional performance after TKA. The importance of controlling the surgery-induced immune response remains to be investigated further. Trial Identification: NCT01351831.

Long-Term Effectiveness of Adalimumab in Patients with Rheumatoid Arthritis: An Observational Analysis from the Corrona Rheumatoid Arthritis Registry.

Author(s): Pappas, Dimitrios A; Kremer, Joel M; Griffith, Jenny; Reed, George; Salim, Bob

Source: Rheumatology and therapy; Aug 2017

Publication Type(s): Journal Article

Available in full text at Rheumatology and Therapy - from ProQuest

Abstract:INTRODUCTIONCurrent recommendations for the management of rheumatoid arthritis (RA) focus on a treat-to-target approach with the objective of maximizing long-term health-related quality-of-life in patients with RA. Published studies from randomized clinical trials have reported limited data regarding the long-term efficacy and safety of adalimumab in patients with RA. This study aims to evaluate the long-term (10+ years) persistency and effectiveness of adalimumab in patients with RA in a real-world setting.METHODSIncluded in this study were biologic-naïve adults with RA initiating adalimumab during follow-up enrolled in the Corrona RA registry. More than 10 years of data on persistency of adalimumab and rheumatologist-supplied reasons for discontinuation were examined. Among patients who persisted on adalimumab over the years, clinical [e.g., clinical disease activity index scores (CDAI), physician global assessment, tender joint count, and swollen joint count] and patient-reported outcomes (PRO), such as physical function, pain, fatigue, and morning stiffness, were examined.RESULTSOf 1791 biologic-naive patients treated with adalimumab who had ≥1 follow-up registry visit, 64.1% were still on therapy at 1 year and 10.2% were still on therapy by the end of year 12. Among patients who persisted on adalimumab for at least 1 year (77.1% female, mean age 53.9 years), 67.0% were in low disease activity (LDA)/remission (CDAI ≤10) and had clinically meaningful improvements from baseline in all clinical assessments and PROs. Initial improvements in LDA/remission and in clinical and PRO assessments observed at year 1 were sustained in those patients who remained on adalimumab over 10 years of follow-up. Among patients who discontinued adalimumab, 61.6% were not in LDA/remission and 41.9% switched to another biologic within 12 months after discontinuing adalimumab.CONCLUSIONSReal-world data demonstrate a sustained effectiveness of adalimumab in the treatment of RA for patients who remained on therapy for 10 years.FUNDINGCorrona, LLC and AbbVie.

Cupping therapy for treating knee osteoarthritis: The evidence from systematic review and meta-analysis.

Author(s): Li, Jin-Quan; Guo, Wen; Sun, Ze-Gan; Huang, Qing-Song; Lee, En Yeong; Wang, Ying; Yao, Xiao-Dong

Source: Complementary therapies in clinical practice; Aug 2017; vol. 28 ; p. 152-160

Publication Type(s): Journal Article Review

Abstract:OBJECTIVECupping therapy is widely used in East Asia, the Middle East, or Central and North Europe to manage the symptom of knee osteoarthritis (KOA). The purpose of this systematic review was to evaluate the available evidence from randomized controlled trials (RCTs) of cupping therapy for treating patients with KOA.METHODSThe following databases were searched from their inception until January 2017: PubMed, Embase, the Cochrane Central Register of Controlled Trials and four Chinese databases [WanFang Med Database, Chinese BioMedical Database, Chinese WeiPu Database, and China National Knowledge Infrastructure (CNKI)]. Only the RCTs related to the effects of cupping therapy on KOA were included in this systematic review. A quantitative synthesis of RCTs will be conducted using RevMan 5.3 software. Study selection, data extraction, and validation was performed independently by two reviewers. Cochrane criteria for risk-of-bias were used to assess the methodological quality of the trials.RESULTSSeven RCTs met the inclusion criteria, and most were of low methodological quality. Study participants in the dry cupping therapy plus the Western

medicine therapy group showed significantly greater improvements in the pain [MD = -1.01, 95%CI (-1.61, -0.41), p < 0.01], stiffness [MD = -0.81, 95%CI (-1.14, -0.48), p < 0.01] and physical function [MD = -5.53, 95%CI (-8.58, -2.47), p < 0.01] domains of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) compared to participants in the Western medicine therapy group, with low heterogeneity (Chi2 = 0.00 p = 1.00, I2 = 0% in pain; Chi2 = 0.45 p = 0.50, I2 = 0% in stiffness; Chi2 = 1.09 p = 0.30, I2 = 9% in physical function). However, it failed to do so on a Visual Analog Scale (VAS) [MD = -0.32, 95%CI (-0.70, 0.05), p = 0.09]. In addition, when compared with Western medicine therapy alone, meta-analysis of four RCTs suggested favorable statistically significant effects of wet cupping therapy plus western medicine on response rate [MD = 1.06, 95%CI (1.01, 1.12), p = 0.03; heterogeneity: Chi2 = 1.13, p = 0.77, I2 = 0%] and Lequesne Algofunctional Index (LAI) [MD = -2.74, 95%CI (-3.41, -2.07), p < 0.01; heterogeneity: Chi2 = 2.03, p = 0.57, I2 = 0%].CONCLUSIONOnly weak evidence can support the hypothesis that cupping therapy can effectively improve the treatment efficacy and physical function in patients with KOA.

Clinical relevance commentary in response to: Effectiveness of a fine motor skills rehabilitation program on upper limb disability, manual dexterity, pinch strength, range of finger motion, performance in activities of daily living, functional independence, and general self-efficacy in hand osteoarthritis: A randomized clinical trial

Author(s): Beasley J.

Source: Journal of Hand Therapy; Jul 2017; vol. 30 (no. 3); p. 274-275

Publication Type(s): Note

Available in full text at Journal of Hand Therapy - from ProQuest

Effectiveness of a fine motor skills rehabilitation program on upper limb disability, manual dexterity, pinch strength, range of fingers motion, performance in activities of daily living, functional independency, and general self-efficacy in hand osteoarthritis: A randomized clinical trial

Author(s): Perez-Marmol J.M.; Garcia-Rios M.C.; Ortega-Valdivieso M.A.; Cano-Deltell E.E.

Source: Journal of Hand Therapy; Jul 2017; vol. 30 (no. 3); p. 262-273

Publication Type(s): Article

Available in full text at Journal of Hand Therapy - from ProQuest

Abstract: Study Design A randomized clinical trial. Introduction Rehabilitation treatments for improving fine motor skills (FMS) in hand osteoarthritis (HOA) have not been well explored yet. Purpose of the Study To assess the effectiveness of a rehabilitation program on upper limb disability, independence of activities of daily living (ADLs), fine motor abilities, functional independency, and general self-efficacy in older adults with HOA. Methods About 45 adults (74-86 years) with HOA were assigned to an experimental group for completing an FMS intervention or a control group receiving conventional occupational therapy. Both interventions were performed 3 times/wk, 45 minutes each session, during 8 weeks. Upper limb disability, performance in ADLs, pinch strength, manual dexterity, range of fingers motion, functional independency, and general self-efficacy were assessed at baseline, immediately after treatment, and after 2 months of follow-up. Results FMS group showed significant improvements with a small effect size on manual dexterity (P = 0.48) and a moderate-high effect on range of index (P = 0.58) and thumb (P = 0.39) motion. The control group showed a significant worse range of motion over time in some joints at the index (P = 0.36) finger and thumb (P = 0.55). Conclusions A rehabilitation intervention for FMS may improve manual dexterity and range of fingers motion in HOA, but its effects on upper limb disability, performance in ADLs, pinch strength, functionality, and self-efficacy remain uncertain. Specific interventions of the

hand are needed to prevent a worsening in range of finger motion. Level of Evidence 1b.

A new systematic reviewand network meta-analysis of long-term trials of pharmacological treatments in knee osteoarthritis

Author(s): Rovati L.C.; Giacovelli G.; Barbetta B.; Gualtieri F.; Vaghi P.; Minto C.; Azzolina D

Source: Osteoporosis International; Jul 2017; vol. 28 (no. 1)

Publication Type(s): Conference Abstract

Abstract: Objective: Osteoarthritis (OA) is a chronic and progressive degenerative disease. Most clinical trials of pharmacological agents for the treatment of OA assess their efficacy over shortterm periods. This is the first systematic review and metaanalysis of trials investigating the effects of available medications over long-term treatment courses on symptoms and joint structure changes in knee OA. Material and Methods: The Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, Embase, Scopus and Web of Science were searched for randomized controlled trials (RCTs) of pharmacological interventions in knee. Reference lists of retrieved articles were also screened for additional trials. Only RCTs with treatment/follow-up of at least 1 year were eligible. The primary outcome was knee OA pain change from baseline to the endpoint (>=12 months) on a validated scale. Secondary outcomes were changes in physical function and joint structure expressed as radiologic medial tibiofemoral joint space narrowing (JSN). We performed a random-effects network meta-analysis within a Bayesian framework. Imputation methods for mean changes and variability measures were adopted to include papers with incomplete data. Results: A total of 5992 articles for RCTs of drug therapy in knee OA were retrieved and 38 RCTs involving 18833 patients met the long-term eligibility criteria. All available pharmacological intervention categories were represented, including acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, bone acting agents, Slow Acting Drugs in OA and putative disease-modifying drugs. Overall, there were 27 interventions including placebo studied for long-term pain control, 13 for physical function and 17 for JSN, with trial duration ranging between 1 and 3 years. There was no evidence of efficacy for most interventions vs. placebo, with the exception of prescription glucosamine sulfate that was significant on pain (Figure) and physical function, with a Glass' Delta Effect Size (ES) of -0.29 [95% credibility interval: -0.49; -0.10] and -0.32 [-0.52, -0.12], respectively. Glucosamine sulfate, chondroitin sulfate and strontium ranelate were the only interventions able to significantly reduce radiologic JSN (ES 0.42 [0.20; 0.64], 0.20 [0.08; 0.31] and 0.20 [0.06; 0.35], respectively). Conclusions: This network meta-analysis shows no evidence of efficacy in the long-term management (at least 1 year) of knee OA for available medications. The only exception is prescription glucosamine sulfate, that is consistently effective on symptoms and joint structure changes, while chondroitin sulfate and strontium ranelate are effective only on structure. Additional long-term RCTs of available and new medications are needed in OA.

Job retention vocational rehabilitation for employed people with inflammatory arthritis (WORK-IA): A feasibility randomized controlled trial

Author(s): Hammond A.; O'Brien R.; Woodbridge S.; Bradshaw L.; Prior Y.; Radford K.; Culley J.

Source: BMC Musculoskeletal Disorders; Jul 2017; vol. 18 (no. 1)

Publication Type(s): Article

Available in full text at BMC Musculoskeletal Disorders - from BioMed Central

Abstract: Background: Inflammatory arthritis leads to work disability, absenteeism and presenteeism (i.e. at-work productivity loss) at high cost to individuals, employers and society. A trial of job retention vocational rehabilitation (VR) in the United States identified this helped people keep working. The effectiveness of this VR in countries with different socioeconomic policies and

conditions, and its impact on absenteeism, presenteeism and health, are unknown. This feasibility study tested the acceptability of this VR, modified for the United Kingdom, compared to written advice about managing work problems. To help plan a randomized controlled trial, we tested screening, recruitment, intervention delivery, response rates, applicability of the control intervention and identified the relevant primary outcome. Methods: A feasibility randomized controlled trial with rheumatoid, psoriatic or inflammatory arthritis patients randomized to receive either job retention VR or written information only (the WORK-IA trial). Following three days VR training, rheumatology occupational therapists provided individualised VR on a one to one basis. VR included work assessment, activity diaries and action planning, and (as applicable) arthritis self-management in the workplace, ergonomics, fatigue and stress management, orthoses, employment rights and support services, assistive technology, work modifications, psychological and disclosure support, workplace visits and employer liaison. Results: Fifty five (10%) people were recruited from 539 screened. Follow-up response rates were acceptable at 80%. VR was delivered with fidelity. VR was more acceptable than written advice only (7.8 versus 6.7). VR took on average 4 h at a cost of 135 per person. Outcome assessment indicated VR was better than written advice in reducing presenteeism (Work Limitations Questionnaire (WLQ) change score mean: VR = -12.4 (SD 13.2); control = -2.5 (SD 15.9), absenteeism, perceived risk of job loss and improving pain and health status, indicating proof of concept. The preferred primary outcome measure was the WLQ, a presenteeism measure. Conclusions: This brief job retention VR is a credible and acceptable intervention for people with inflammatory arthritis with concerns about continuing to work due to arthritis. Trial registration: ISRCTN 76777720. Registered 21.9.12.

Effect of omega-3 polyunsaturated fatty acids on arthritic pain: A systematic review

Author(s): Abdulrazaq M.; Innes J.K.; Calder P.C.

Source: Nutrition; Jul 2017 ; p. 57-66

Publication Type(s): Review

Available in full text at Nutrition - from ProQuest

Abstract: Objectives Pain is a significant problem in rheumatoid arthritis (RA) and is associated with prostaglandins derived from the omega-6 polyunsaturated fatty acid (PUFA) arachidonic acid. The omega-3 PUFAs eicosapentaenoic acid and docosahexaenoic acid have been shown to reduce inflammation, with some studies showing clinical improvements in RA. The aim of this systematic review was to investigate the effect of omega-3 PUFAs on arthritic pain. Method A systematic literature review of omega-3 PUFAs and pain associated with RA was performed up to December 2015. Randomized controlled trials (RCTs) investigating the effect of omega-3 PUFAs (>2 g/d) on patient or physician assessment of pain, or assessment by both patient and physician, were included. The Cochrane Collaboration's tool for assessing risk for bias was employed. Data for outcomes of interest were extracted and collated for interpretation. Results Eighteen RCTs published between 1985 and 2013 involving 1143 patients were included. Dosage of omega-3 PUFAs used was 2.1 to 9.1 g/d, with study durations of 12 to 52 wk. Ten studies supported the hypothesis that there is a reduction in patient or physician assessment of pain associated with RA after intake of omega-3 PUFAs. Eight studies found no statistically significant effect of omega-3 PUFAs on arthritic pain. Conclusions omega-3 PUFAs may have a therapeutic role in decreasing pain associated with RA, with doses of 3 to 6 g/d appearing to have a greater effect. Due to the limitations identified in the RCTs included in this review, more research is needed to investigate omega-3 PUFAs in larger populations and over extended periods of time.

Clinical characteristics of importance to outcome in patients with axial spondyloarthritis: Protocol for a prospective descriptive and exploratory cohort study

Author(s): Andreasen R.A.; Emamifar A.; Duerlund B.; Fischer L.; Hansen I.M.J.; Kristensen L.E.

Source: BMJ Open; Jul 2017; vol. 7 (no. 7)

Publication Type(s): Article

Available in full text at BMJ Open - from ProQuest

Abstract: Introduction Spondyloarthritis (SpA) is a heterogeneous spectrum of rheumatic diseases with either predominantly axial inflammatory symptoms of the spine and sacroiliac joints or predominantly peripheral arthritis. The two main entities of axial SpA (axSpA) are ankylosing spondylitis or non-radiographic axSpA (nr-axSpA). Tumour necrosis factor-alpha inhibitors have revolutionised the treatment of patients with axSpA who failed to respond to non-steroidal anti-inflammatory drugs and physical therapy. Chronic pain is common in patients with SpA and may still persist despite the lack of signs of inflammation. This has led researchers to hypothesise that central pain sensitisation may play a role in the generation of chronic pain in SpA. The painDETECT Questionnaire (PDQ) is a screening tool developed to detect neuropathic pain components. The primary objective is to explore the prognostic value of the PDQ regarding treatment response in patients with axSpA 3 months after initiating a biological agent. Secondary aim is to evaluate the impact of extra-articular manifestations, comorbidities and patient-reported outcomes and elucidate if these factors influence treatment response. Method and analysis We will include 60 participants (>=18 years of age) diagnosed with axSpA independent of main entity, who initiate or switch treatment of a biologic. Data will be collected at baseline and at endpoint following Danish clinical practice (>=3 months) of treatment with biologics. We will explore whether the PDQ and other phenotypical patient characteristics are prognostically important for response to biological therapy according to established response criteria like 50% improvement in the Bath Ankylosing Spondylitis Disease Activity Index (50%) and Ankylosing Spondylitis Disease Activity Score. Ethics and dissemination The study is approved by the Region of Southern Denmark's Ethics committee (S-20160094) and has been designed in cooperation with patient representatives. The study is registered at clinicaltrials.gov (NCT02948608, pre-results). Dissemination will occur through publication(s) in international peer-reviewed journal(s).

Impact of adherence to biological agents on health care resource utilization for patients over the age of 65 years with rheumatoid arthritis

Author(s): Lathia U.; Ewara E.M.; Nantel F.

Source: Patient Preference and Adherence; Jul 2017; vol. 11 ; p. 1133-1142

Publication Type(s): Article

Available in full text at Patient preference and adherence - from National Library of Medicine

Abstract: Objective: Poor adherence to therapy increases the patient and societal burden and complexity of chronic diseases such as rheumatoid arthritis (RA). In the past 15 years, biologic disease-modifying anti-rheumatic drugs (DMARDs) have revolutionized the treatment of RA. However, little data are available on the impact of adherence to biologics on health care resources. The objective of the study was to determine the long-term health care resource utilization patterns of RA patients who were adherent to biologic DMARD therapy compared to RA patients who were non-adherent to biologic DMARD therapy in an Ontario population and to determine factors influencing adherence. Methods: Patients were identified from the Ontario RA Database that contains all RA patients in Ontario, Canada, identified since 1991. The study population included RA patients, aged 65+ years, with a prescription for a biologic DMARD between 2003 and 2013. Exclusion criteria included diagnosis of inflammatory bowel disease, psoriatic arthritis or psoriasis in the 5 years prior to the index date and discontinuation of biologic DMARD, defined as no subsequent prescription during the 12 months after the index date. Adherence was defined as a medication

possession ratio of >=0.8 measured as the proportion of days for which a patient had biologic treatment(s) over a defined follow-up period. Adherent patients were matched to non-adherent patients by propensity score matching. Results: A total of 4,666 RA patients were identified, of whom 2,749 were deemed adherent and 1,917 non-adherent. The age (standard deviation) was 69.9 (5.46) years and 75% were female. Relative rates for resource use (physician visits, emergency visits, hospitalization, home care and rehabilitation) for the matched cohort were significantly lower (PCopyright © 2017 Lathia et al.

Effect of aquatic physical therapy on pain perception, functional capacity and quality of life in older people with knee osteoarthritis: Study protocol for a randomized controlled trial

Author(s): Alcalde G.E.; Fonseca A.C.; Boscoa T.F.; Goncalves M.R.; Bernardo G.C.; Pianna B.

Publication Type(s): Article

Available in full text at Trials - from BioMed Central

Abstract: Background: Aquatic therapy promotes short-term benefits for patients with knee osteoarthritis (OA), and it may be the first therapeutic option for this pathological condition. The objective of this study was to investigate the effects of an aquatic therapy program on pain intensity, functional ability, and quality of life in older people with knee OA. Methods/design: This is a parallel, two-arm, open, randomized controlled clinical trial with older people with knee OA. Volunteers will be allocated to an aquatic intervention group (WG), subjected to the intervention, or to a control group, not be subjected to any kind of intervention. Data collection pre- and postintervention will be composed of the evaluation of the perception of pain by visual analogue scale with application of nociceptive stimuli in four anatomical points of the knee, functional fitness tests, and application of the World Health Organization Quality of Life Scale abbreviated version and Western Ontario and McMaster Universities Osteoarthritis Index. The program will last 12 weeks, consisting of aerobic and functional exercises in the form of circuit training. Discussion: The objective of this clinical trial is to evaluate the effect of aquatic therapy in elderly patients with knee OA. The study is guided by practice-based scientific evidence for the use of aquatic rehabilitation exercises. It is expected that the WG volunteers will show reduced pain intensity, increased flexibility, and improved functional capacity and quality of life. It is believed that the desired results can be attributed to physical and physiological effects of immersion in warm water associated with the exercise protocol proposed. The data will be published after completion of the study. Trial registration: Brazilian Registry of Clinical Trials (ReBEC) registration number: RBR-78h48d. Registered on 19 August 2015.Copyright © 2017 The Author(s).

The effectiveness of the use of a digital activity coaching system in addition to a two-week home-based exercise program in patients after total knee arthroplasty: Study protocol for a randomized controlled trial

Author(s): Harmelink K.E.M.; Nijhuis-Van Der Sanden M.W.G.; Staal J.B.; Zeegers A.V.C.M.

Source: BMC Musculoskeletal Disorders; Jul 2017; vol. 18 (no. 1)

Publication Type(s): Article

Available in full text at BMC Musculoskeletal Disorders - from BioMed Central

Abstract: Background: There is consistent evidence that supervised programs are not superior to home-based programs after total knee arthroplasty (TKA), especially in patients without complications. Home-based exercise programs are effective, but we hypothesize that their effectiveness can be improved by increasing the adherence to physical therapy advice to reach an adequate exercise level during the program and thereafter. Our hypothesis is that an activity coaching system (accelerometer-based activity sensor), alongside a home-based exercise program, will increase adherence to exercises and the activity level, thereby improving physical functioning

and recovery. The objective of this study is to determine the effectiveness of an activity coaching system in addition to a home-based exercise program after a TKA compared to only the home-based exercise program with physical functioning as outcome. Methods: This study is a single-blind randomized controlled trial. Both the intervention (n = 55) and the control group (n = 55) receive a two-week home-based exercise program, and the intervention group receives an additional activity coaching system. This is a hand-held electronic device together with an app on a smartphone providing information and advice on exercise behavior during the day. The primary outcome is physical functioning, measured with the Timed Up and Go test (TUG) after two weeks, six weeks and three months. Secondary outcomes are 1) adherence to the activity level (activity diary); 2) physical functioning, measured with the 2-Minute Walk Test (2MWT) and the Knee Osteoarthritis Outcome Score; 3) quality of life (SF-36); 4) healthcare use up to one year postoperatively and 5) cost-effectiveness. Data are collected preoperatively, three days, two and six weeks, three months and one year postoperatively. Discussion: The strengths of the study are the use of both performance-based tests and self-reported questionnaires and the personalized tailored program after TKA given by specialized physical therapists. Its weakness is the lack of blinding of the participants to treatment allocation. Outcomes are generalizable to uncomplicated patients as defined in the inclusion criteria. Trial registration: The trial is registered in the Dutch Trial Register (www.trialregister.nl, NTR 5109) (March 22, 2015).

Differential impact of systemic lupus erythematosus and rheumatoid arthritis on health-related quality of life

Author(s): Chaigne B.; Chizzolini C.; Finckh A.; Alpizar-Rodriguez D.; Courvoisier D.; Ribi C.

Source: Quality of Life Research; Jul 2017; vol. 26 (no. 7); p. 1767-1775

Publication Type(s): Article

Abstract: Purpose: This study examined and compared health-related quality of life (QoL) in systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA). Methods: We included patients from two multicentric cohorts, the Swiss SLE cohort study (SSCS) and the Swiss Clinical Quality Management Program for RA (SCQM-RA). Patients were matched by age, sex and disease duration using the propensity score. Disease activity was assessed by SELENA-SLEDAI in SLE and by DAS-28 in RA. QoL was captured by the short-form 36 (SF-36). The primary outcomes were physical component summary (PCS) and mental component summary (MCS) of the SF-36. Generalized estimating equation models were used to assess evolution over time. Results: We analyzed 267 SLE patients and 267 matched RA patients. More patients with RA had active disease and more patients with SLE had immunosuppressant therapies at baseline. The median [interquartile range (IQR)] MCS and PCS scores were 45.1 [33.7-52.6] and 45.6 [38.0-53.0] in SLE and 48.8 [37.6-56.7] and 34.7 [26.8-43.0] in RA, respectively (ps

Appropriate Use Criteria for Hyaluronic Acid in the Treatment of Knee Osteoarthritis in the United States

Author(s): Bhadra A.K.; Altman R.; Dasa V.; Myrick K.; Rosen J.; Vad V.; Vitanzo P.; Bruno M.

Source: Cartilage; Jul 2017; vol. 8 (no. 3); p. 234-254

Publication Type(s): Article

Abstract: Objective: A workgroup of clinical experts has developed an Appropriate Use Criteria (AUC) for the use of hyaluronic acid (HA) in the treatment of osteoarthritis (OA) of the knee. The increasingly broad and varied use of HA injections, lack of published clinical guidance, and limited coverage for their use has created the imperative to establish appropriateness criteria. Methods: The experts of this workgroup represent rheumatology, orthopedic surgery, physiatry, sports medicine, and nursing clinicians with substantive knowledge of intra-articular HA therapy. This

workgroup utilized the results of a systematic review of evidence, expert clinical opinion, and current evidence-based clinical practice guidelines to develop appropriateness criteria for the use of intra-articular HA for knee OA in 17 real-world clinical scenarios. Results: The workgroup scored the appropriateness of treatment of each patient scenario using a 9-point scale to designate a treatment as appropriate (7-9), uncertain (4-6), or inappropriate (1-3). Six scenarios were scored as appropriate, 10 scenarios were scored as uncertain, and 1 scenario was scored as inappropriate. Conclusion: This article can assist clinicians in shared decision-making by providing best practices in considering HA injections for knee OA treatment. Moreover, this AUC article can aid payers and policy makers in determining reimbursement and preauthorization policies and more appropriately managing health care resources. It is clear that further research is still necessary-particularly in patient populations differentiated by OA severity-that may benefit the greatest from the use of HA injections for the treatment of knee OA.

Exercise Therapy in Juvenile Idiopathic Arthritis: A Systematic Review and Meta-Analysis.

Author(s): Kuntze, Gregor; Nesbitt, Colleen; Whittaker, Jackie L; Nettel-Aguirre, Alberto

Source: Archives of physical medicine and rehabilitation; Jul 2017

Publication Type(s): Journal Article Review

Abstract:OBJECTIVETo conduct a systematic review to evaluate the efficacy of exercise interventions in improving outcomes across domains of functioning and disability in children and adolescents with juvenile idiopathic arthritis (JIA).DATA SOURCESSeven electronic databases were systematically searched up to November 16, 2016.STUDY SELECTIONOriginal data, analytic prospective design, physical therapy-led exercise intervention evaluation, children and adolescents with JIA, and assessment of functional, structural, activity, participation, or quality of life outcomes.DATA EXTRACTIONTwo authors screened search results, and discrepancies were resolved by consensus. Of 5037 potentially relevant studies, 9 randomized controlled trials and 1 cohort study were included and scored.DATA SYNTHESISStudy quality (Downs and Black quality assessment tool) and level of evidence (Oxford Centre of Evidence-Based Medicine model) were assessed and meta-analysis conducted where appropriate. Alternatively, a descriptive summary approach was chosen. All randomized controlled trials were moderate-quality intervention studies (level 2b evidence; median Downs and Black score, 20 out of 32; range, 15-27). Interventions included aquatic, strengthening, proprioceptive, aerobic, and Pilates exercises. Pediatric activity capacity (Child Health Assessment Questionnaire) improved with exercise (mean difference, .45; 95% confidence interval, .05-.76). Furthermore, descriptive summaries indicated improved activity capacity, body function and structure (pain and muscle strength), and quality of life outcomes.CONCLUSIONSExercise therapy appears to be well tolerated and beneficial across clinically relevant outcomes in patients with JIA. The paucity of high-quality evidence and study heterogeneity limited the ability to provide conclusive, generalizing evidence for the efficacy of exercise therapy and to provide specific recommendations for clinical practice at this time. Future research evaluating exercise program implementation using validated outcomes and detailed adherence and safety assessment is needed to optimize clinical decision pathways in patients with JIA.

Physical Exercise and Physical Activity for Children and Adolescents With Juvenile Idiopathic Arthritis: A Literature Review.

Author(s): Catania, Hilenia; Fortini, Viola; Cimaz, Rolando

Source: Pediatric physical therapy : the official publication of the Section on Pediatrics of the American Physical Therapy Association; Jul 2017; vol. 29 (no. 3); p. 256-260

Publication Type(s): Journal Article

Abstract:PURPOSEThis is a review of studies that investigate the efficacy of exercise therapy and physical activity for children with juvenile idiopathic arthritis since the 2008 Cochrane Review.METHODStudies were identified that investigated the use of physical activity and exercise therapy in the treatment of children and adolescents with juvenile idiopathic arthritis, excluding the Cochrane Review. Two reviewers individually analyzed the results of the search to determine the eligibility of studies. The randomized controlled trial study designs were evaluated using PEDro scales.CONCLUSIONS AND RECOMMENDATIONS FOR CLINICAL PRACTICERecent literature supports the importance of the combination of strengthening, stretching, proprioceptive, and balance exercises and activities in water. Many of the reviewed studies proposed an intensive program of physical activity and exercise therapy, conducted 3 times a week for 12 weeks.

Physical and mechanical therapies for lower limb problems in juvenile idiopathic arthritis: a systematic review with meta- analysis.

Author(s): Fellas, Antoni; Coda, Andrea; Hawke, Fiona

Source: Journal of the American Podiatric Medical Association; Jul 2017

Publication Type(s): Journal Article

Abstract:BACKGROUNDJuvenile Idiopathic Arthritis (JIA) is a chronic, autoimmune, inflammatory joint disease and is the most common arthritis affecting children under 16 years of age. Children with JIA commonly experience lower limb dysfunction and disability.OBJECTIVETo systematically review the effectiveness of physical and mechanical therapies for lower limb problems JIA.METHODSRandomised control trials (RCT) of physical and mechanical interventions for lower limb problems in children with JIA were included. Primary outcome was pain. Secondary outcomes include but not limited to disability, functional ability and health-related quality of life. MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, PUBMED and CINAHL were searched for eligible studies. Authors of included studies and researchers in the field were contacted to identify additional studies.RESULTSTwo studies were included. Both studies evaluated the effectiveness of customised/custom foot orthoses in treating foot and ankle pain in children with JIA. One study also evaluated simple cushioned inserts. A total of 100 participants were included. Meta-analyses for comparisons between custom/customised foot orthoses and a control intervention after 3 months were not statistically significant for the outcomes of pain (mean difference -8.97; 95%CI: -18.01 to 0.07); child rated health-related quality of life (mean difference 4.38; 95%CI: [-3.68 to 12.44); and parent rated health-related quality of life (mean difference 1.77; 95%CI: -6.35 to 9.90). Meta-analyses were supported by sensitivity analyses.CONCLUSIONSConclusions: There is a paucity of research evaluating physical and mechanical therapies for lower limb problems in JIA. No physical therapy has been evaluated in RCT and mechanical therapy evaluation is limited to foot orthoses and shoe inserts for foot and ankle pain. The existing research is hampered by small sample sizes. Until further research is conducted, the effectiveness of mechanical and physical therapies for lower limb problems in JIA remains unclear. Systematic Review Registration: PROSPERO (identification record: CRD42015019996).

Financial incentives and health coaching to improve physical activity following total knee replacement: a randomized controlled trial.

Author(s): Losina, Elena; Collins, Jamie E; Deshpande, Bhushan R; Smith, Savannah R; Michl, Griffin L

Source: Arthritis care & research; Jul 2017

Publication Type(s): Journal Article

Abstract:OBJECTIVEMost persons who undergo total knee replacement (TKR) do not increase their physical activity following surgery. We assessed whether financial incentives and health coaching would improve physical activity in persons undergoing TKR.METHODSWe designed a factorial

randomized controlled trial among persons undergoing TKR for osteoarthritis. Subjects underwent normal perioperative procedures, including post-operative physical therapy, and were assigned to one of four arms: attention control, telephonic health coaching (THC), financial incentives (FI), or THC+FI. We objectively measured step counts and minutes of physical activity with a commercial accelerometer (Fitbit Zip) and compared the changes from pre-TKR to 6 months post-TKR across the four study arms.RESULTSOf the 202 randomized subjects, 150 (74%) provided both pre-TKR and 6 months post-TKR accelerometer data. Among completers, the average daily step count at 6 months ranged from 5619 (SD 381) in the THC arm to 7152 (SD 407) in the THC+FI arm (adjusting for baseline values). Daily step count 6 months post-TKR increased by 680 (95% CI: -94 - 1,454) in the control arm, 274 (95% CI: -473 - 1021) in the THC arm, 826 (95% CI: 89 - 1563) in the FI arm, and 1808 (95% CI: 1010 - 2606) in the THC+FI arm. Physical activity increased by 14 (SD 10), 14 (SD 10), 16 (SD 10), and 39 (SD 11) minutes in the control, THC, FI, and THC+FI arms, respectively.CONCLUSIONSA dual THC+FI intervention led to substantial improvements in step count and physical activity following TKR.

Analysis of effectiveness, safety and optimization of tocilizumab in a cohort of patients with rheumatoid arthritis in clinical practice.

Author(s): Mena-Vázquez, Natalia; Manrique-Arija, Sara; Rojas-Giménez, Marta

Source: Reumatologia clinica; Jul 2017

Publication Type(s): Journal Article

Available in full text at Reumatologia clinica [Reumatol Clin] NLMUID: 101293923 - from EBSCOhost

Abstract:OBJECTIVETo evaluate the effectiveness and safety of tocilizumab (TCZ) in patients with rheumatoid arthritis (RA) in clinical practice, establishing the optimized regimen and switching from intravenous (IV) to subcutaneous (SC) therapy.MATERIAL AND METHODSRetrospective observational study. We included 53 RA patients treated with TCZ. The main outcome was TCZ effectiveness at week 24. Secondary outcome variables included effectiveness at week 52, therapeutic maintenance, physical function and safety. The effectiveness of optimization and the switch from IV to SC was evaluated at 3 and 6 months. The efficacy was measured with the Disease Activity Score. Paired t-tests or Wilcoxon were used to evaluate effectiveness and survival time using Kaplan-Meier.RESULTSThe proportion of patients who achieved remission or low disease activity at weeks 24 and 52 was 75.5% and 87.3%, respectively. The mean retention time (95% confidence interval [95% CI] was 81.7 months [76.6-86.7]). Twenty-one of 53 patients (39.6%) optimized the TCZ dose and 35 patients switched from IV TCZ to SC, with no changes in effectiveness. The adverse event rate was 13.6 events/100 patient-years.CONCLUSIONSTocilizumab appears to be effective and safe in RA in clinical practice. The optimized regimen appears to be effective in most patients in remission, even when they change from IV to SC.

Functional Gain and Pain Relief After Total Joint Replacement According to Obesity Status.

Author(s): Li, Wenjun; Ayers, David C; Lewis, Courtland G; Bowen, Thomas R; Allison, Jeroan J

Source: The Journal of bone and joint surgery. American volume; Jul 2017; vol. 99 (no. 14); p. 1183-1189

Publication Type(s): Journal Article

Available in full text at Journal of Bone and Joint Surgery - American Volume - from Ovid

Abstract:BACKGROUNDObesity has been associated with lower function and more pain before and after total hip or knee replacement (THR or TKR). We examined the changes between preoperative and postoperative function and pain in a large representative U.S. cohort to determine if there was a relationship to obesity status.METHODSPreoperative and 6-month postoperative data on function

(Short Form-36 Physical Component Summary [PCS] score), joint pain (Hip disability and Osteoarthritis Outcome Score and Knee injury and Osteoarthritis Outcome Score), and body mass index (BMI) were collected from a national sample of 2,040 patients who had undergone THR and 2,964 who had undergone TKR from May 2011 to March 2013. Preoperative and postoperative function and pain were evaluated according to BMI status, defined as under or of normal weight, overweight, obese, severely obese, or morbidly obese.RESULTSPatients undergoing THR were an average of 65 years of age; 59% were women, 94% were white, and 14% were severely or morbidly obese. A greater obesity level was associated with a lower (worse) PCS score at baseline and 6 months postoperatively. Severely and morbidly obese patients had less postoperative functional gain than the other BMI groups. A greater obesity level was associated with more pain at baseline but greater postoperative pain relief, so the average postoperative pain scores did not differ significantly according to BMI status. Patients undergoing TKR had an average age of 69 years; 61% were women, 93% were white, and 25% were severely or morbidly obese. A greater obesity level was associated with a lower PCS score at baseline and 6 months. The postoperative gain in PCS score did not differ by BMI level. A greater obesity level was associated with worse pain at baseline but greater pain relief at 6 months, so the average pain scores at 6 month were similar across the BMI levels.CONCLUSIONSSix months after total joint replacement (TJR), severely or morbidly obese patients reported excellent pain relief and substantial functional gain that was similar to the findings in other patients. While obesity is associated with a greater risk of early complications, obesity in itself should not be a deterrent to undergoing TJR to relieve symptoms.LEVEL OF EVIDENCETherapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

The effectiveness of supplementary arm and upper body exercises following total hip arthroplasty for osteoarthritis in the elderly: a randomized controlled trial.

Author(s): Mitrovic, Dragica; Davidovic, Mladen; Erceg, Predrag; Marinkovic, Jelena

Source: Clinical Rehabilitation; Jul 2017; vol. 31 (no. 7); p. 881-890

Publication Type(s): Academic Journal

Abstract: Objective: To determine whether arm and upper body exercises in addition to the standard rehabilitation programme improve outcomes after hip arthroplasty. Design: Prospective, parallel, randomized, controlled trial. Setting: Orthopaedic and rehabilitation departments. Subjects: A total of 70 patients >60 years of age, who underwent hip replacement, out of 98 eligible candidates after exclusion criteria were implemented. Interventions: The study group took part in the supplementary arm and upper body exercise programme to be compared with the standard rehabilitation programme group. Main outcome: The primary outcome was a Harris Hip Score. Secondary outcomes were: Hand grip strength and Medical Outcomes Study 36-Item Short-Form Health Survey. Outcomes were assessed preoperatively, two weeks after surgery and at I2 weeks follow-up. Results: In the intervention group, significant improvements were found: in functional ability - Harris Hip Score after two (mean difference = 4.7 points) and I2 (mean difference = 5.85 points) weeks; in muscle strength - handgrip for both hands (mean difference for dominant hand = 4.I6 and for the other hand = 2.8) after I2 weeks; and in role-physical dimension SF-36 Health Survey (mean difference = 6.42 points) after I2 weeks. Conclusion: Results of this study indicate that arm and upper body exercises in addition to the standard rehabilitation programme improve outcomes I2 weeks after hip arthroplasty.

Physical Exercise and Physical Activity for Children and Adolescents With Juvenile Idiopathic Arthritis: A Literature Review... [including commentary by Patrick van der Torre].

Author(s): Catania, Hilenia; Fortini, Viola; Cimaz, Rolando

Source: Pediatric Physical Therapy; Jul 2017; vol. 29 (no. 3); p. 256-261

Publication Type(s): Academic Journal

Abstract: Purpose: This is a review of studies that investigate the efficacy of exercise therapy and physical activity for children with juvenile idiopathic arthritis since the 2008 Cochrane Review. Method: Studies were identified that investigated the use of physical activity and exercise therapy in the treatment of children and adolescents with juvenile idiopathic arthritis, excluding the Cochrane Review. Two reviewers individually analyzed the results of the search to determine the eligibility of studies. The randomized controlled trial study designs were evaluated using PEDro scales. Conclusions and Recommendations for Clinical Practice: Recent literature supports the importance of the combination of strengthening, stretching, proprioceptive, and balance exercises and activities in water. Many of the reviewed studies proposed an intensive program of physical activity and exercise therapy, conducted 3 times a week for 12 weeks.

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Rheumatology

September 2017, Volume 56, Issue 9

Annals of Rheumatic Disease

October 2017 - Volume 76 - 10

Arthritis & Rheumatology

September 2017, Volume 69, Issue 9

Journal of Rheumatology

August 1 2017, Volume 44, Issue 8

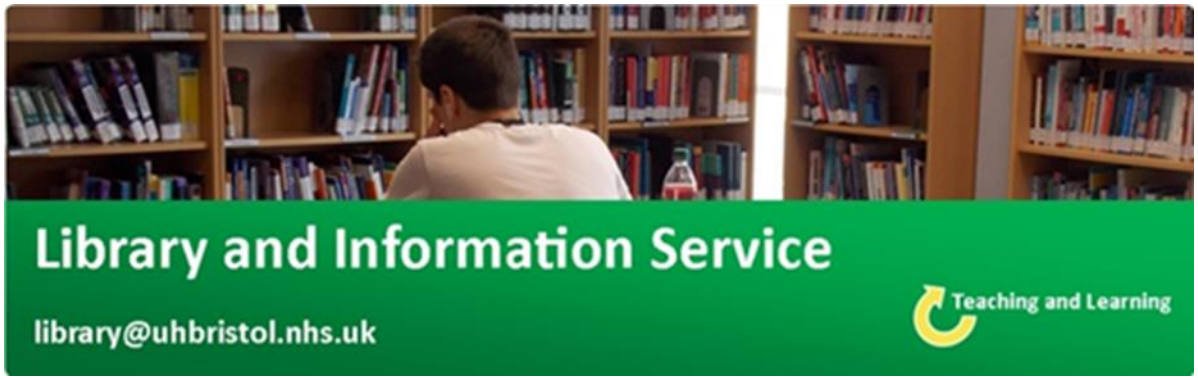
Osteoporosis International

September 2017, Volume 28, Issue 9

Exercise: Outcome Reliability

Looks at the level of agreement between assessments by *one rater* of the same material at two or more different times.	
Refers to the level of agreement between the initial test results and the results of repeated measurements made at a later date.	
This measures the level of agreement between assessments made by *two or more raters* at the same time.	

Inter-rater reliability	**Intra-rater reliability**	**Test retest reliability**



Library Opening Times

Staffed hours: 8am-5pm, Monday to Friday

Swipe-card access: 7am-11pm, seven days a week

Level 5, Education and Research Centre

University Hospitals Bristol

Contact your Outreach Librarian:

Jo Hooper

library@uhbristol.nhs.uk

Ext. 20105