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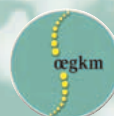
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News-Screen Rheumatologie

R. Lunzer

■ Relation of Nonsteroidal Anti-Inflammatory Drugs to Serious Bleeding and Thromboembolism Risk in Patients With Atrial Fibrillation Receiving Antithrombotic Therapy: A Nationwide Cohort Study

Lamberts M, et al. *Ann Intern Med* 2014; 161: 690–8.

Abstract

Background: Nonsteroidal anti-inflammatory drugs (NSAIDs) are assumed to increase bleeding risk, but their actual relation to serious bleeding in patients with atrial fibrillation (AF) who are receiving antithrombotic medication is unknown. **Objective:** To investigate the risk for serious bleeding and thromboembolism associated with ongoing NSAID and antithrombotic therapy. **Design:** Observational cohort study. **Setting:** Nationwide registries. **Patients:** Danish patients with AF hospitalized between 1997 and 2011. **Measurements:** Absolute risk for serious bleeding and thromboembolism with ongoing NSAID and antithrombotic therapy, assessed by using Cox models. **Results:** Of 150 900 patients with AF (median age, 75 years [interquartile range, 65 to 83 years]; 47 % female), 53 732 (35.6 %) were prescribed an NSAID during a median follow-up of 6.2 years (interquartile range, 2.1 to 14.0 years). There were 17 187 (11.4 %) and 19 561 (13.0 %) occurrences of serious bleeding and thromboembolism, respectively. At 3 months, the absolute risk for serious bleeding within 14 days of NSAID exposure was 3.5 events per 1000 patients compared with 1.5 events per 1000 patients without NSAID exposure. The risk difference was 1.9 events per 1000 patients. In patients selected for oral anticoagulant therapy, the absolute risk difference was 2.5 events per 1000 patients. Use of NSAIDs was associated with increased absolute risks for serious bleeding and thromboembolism across all antithrombotic regimens and NSAID types. An NSAID dosage above the recommended minimum was associated with a substantially increased hazard ratio for bleeding. **Limitation:** Observational design and unmeasured confounders. **Conclusion:** Use of NSAIDs was associated with an independent risk for serious bleeding and thromboembolism in patients with AF. Short-term NSAID exposure was associated with increased bleeding risk. Physicians should exercise caution with NSAIDs in patients with AF.

Kommentar

NSAR sind bei Patienten mit Vorhofflimmern unter oraler Antikoagulation mit einem vaskulären Risiko verbunden! Obwohl die Erkenntnis nicht wirklich neu ist, überrascht doch die Höhe des absoluten Risikos für Blutungen von 3,5 und das bereits nach 14 Tagen NSAR – dies nicht nur für schwere Blutungsereignisse, sondern ebenso, wenn auch geringer, für thromboembolische Geschehen. Auch wurde kein Unterschied zwischen selektiven und nichtselektiven NSAR gefunden. Somit bleibt als Alternative gerade bei entzündlicher Aktivität

im Alter, bei RA oder z. B. auch Gicht, die Glukokortikoidtherapie, idealerweise lokal.

■ Intraarticular Hip Injection and Early Revision Surgery Following Total Hip Arthroplasty: A Retrospective Cohort Study

Ravi B, et al. *Arthritis Rheumatol* 2015; 67: 162–8.

Abstract

Objective: Therapeutic intraarticular injections are used in the management of hip osteoarthritis (OA). Some studies suggest that their use increases the risk of infection and subsequent revision surgery after primary total hip arthroplasty (THA), while others do not. We undertook this study to clarify the relationship between prior intraarticular injection and the risk of complication in a subsequent primary THA. **Methods:** In a cohort of patients with hip OA who underwent a primary elective THA between 2002 and 2009, we identified those who received ≥ 1 intraarticular injection performed by a radiologist in the 5 years preceding their THA. Multivariable Cox proportional hazards models were used to determine the relationship between receipt of a presurgical injection (no injection, 1–5 years prior to THA, or < 1 year prior to THA) and the occurrence of post-surgical joint infection and revision THA in the following 2 years, while controlling for confounders. **Results:** Of 37,881 eligible THA recipients, 2,468 (6.5 %) received an intraarticular injection performed by a radiologist within 5 years of their THA (1,691 at < 1 year, 777 at 1–5 years). Controlling for age, sex, comorbidity, frailty, income, and provider volume, those who had an injection in the year preceding surgery were at increased risk of infection (adjusted hazard ratio [HR] 1.37, $P = 0.03$) and revision THA (adjusted HR 1.53, $P = 0.03$) within 2 years of the primary THA, relative to patients who did not. The association between prior injection and revision arthroplasty was attenuated and became nonsignificant (adjusted HR 1.41, $P = 0.13$) after occurrence of postoperative infection was controlled for in the regression model. No effect was found for injection 1–5 years prior to surgery. **Conclusion:** Intraarticular injection in the year preceding THA independently predicted increased risk of infection leading to early revision surgery. Further studies are warranted to elucidate explanations for these findings.

Kommentar

Auch wenn im oben angeführten Kommentar die Lokalthherapie als gute Option angeführt wird, sollte die Indikation zur Hüftgelenkspunktion sehr streng gestellt werden. Wie diese Arbeit zeigt, ist die Erfolgsrate gering und mit einem erhöhten Infektions- und Revisionsrisiko verbunden. Dass die Behandlung von Radiologen durchgeführt wurde, wird angemerkt.

■ Methotrexate in Combination with Other DMARDs Is Not Superior to Methotrexate Alone for Remission Induction with Moderate-to-High-Dose Glucocorticoid Bridging in Early Rheumatoid Arthritis After 16 Weeks of Treatment: The CareRA Trial

Verschueren P, et al. *Ann Rheum Dis* 2015; 74: 27–34.

Abstract

Objectives: To compare the efficacy and safety of intensive combination strategies with glucocorticoids (GCs) in the first 16 weeks (W) of early rheumatoid arthritis (eRA) treatment, focusing on high-risk patients, in the Care in early RA trial. **Methods:** 400 disease-modifying antirheumatic drugs (DMARD)-naïve patients with eRA were recruited and stratified into high risk or low risk according to classical prognostic markers. High-risk patients ($n = 290$) were randomised to 1/3 treatment strategies: combination therapy for early rheumatoid arthritis (COBRA) Classic (methotrexate (MTX) + sulfasalazine + 60 mg prednisone tapered to 7.5 mg daily from W7), COBRA Slim (MTX + 30 mg prednisone tapered to 5 mg from W6) and COBRA Avant-Garde (MTX + leflunomide + 30 mg prednisone tapered to 5 mg from W6). Treatment modifications to target low-disease activity were mandatory from W8, if desirable and feasible according to the rheumatologist. The primary outcome was remission (28 joint disease activity score calculated with C-reactive protein < 2.6) at W16 (intention-to-treat analysis). Secondary endpoints were good European League Against Rheumatism response, clinically meaningful health assessment questionnaire (HAQ) response and HAQ equal to zero. Adverse events (AEs) were registered. **Results:** Data from 98 Classic, 98 Slim and 94 Avant-Garde patients were analysed. At W16, remission was reached in 70.4 % Classic, 73.6 % Slim and 68.1 % Avant-Garde patients ($p = 0.713$). Likewise, no significant differences were shown in other secondary endpoints. However, therapy-related AEs were reported in 61.2 % of Classic, in 46.9 % of Slim and in 69.1 % of Avant-Garde patients ($p = 0.006$). **Conclusions:** For high-risk eRA, MTX associated with a moderate step-down dose of GCs was as effective in inducing remission at W16 as DMARD combination therapies with moderate or high step-down GC doses and it showed a more favourable short-term safety profile.

Kommentar

Die DMARD-Kombinationstherapien (z. B. Methotrexat/Salazopyrin, Leflunomid etc.) werden in den Empfehlungen zur Behandlung der RA immer wieder angegeben, wenngleich die Nebenwirkungen zunehmen. Auch ist anzunehmen, dass in der Praxis die Compliance schlechter sein wird. Dieser Artikel zeigt doch die gute Wirksamkeit von MTX mit einer Glukokortikoidtherapie zu Beginn der RA, mit einer Remissionsrate von etwa 70 % nach 16 Wochen. In dieser Arbeit führt die „Mehrfach-DMARD“-Kombination zu keinem weiteren Benefit.

■ Tumour Necrosis Factor Inhibitor Therapy and Infection Risk in Axial Spondyloarthritis: Results from a Longitudinal Observational Cohort

Wallis D, et al. *Rheumatology (Oxford)* 2015; 54: 152–6.

Abstract

Objectives: Long-term data on infection risk in axial SpA (axSpA) are sparse. TNF inhibitors (TNFis) are increasingly being used in axSpA, with infection being the most important adverse event. We aimed to investigate the frequency of infections in axSpA and to identify factors predisposing to infection. **Methods:** Data were extracted from a longitudinal observational cohort of patients with axSpA. Infection rates were calculated and multivariate analysis was performed to investigate the association of independent variables with infection. **Results:** Data were analysed for 440 patients followed for a total of 1712 patient-years (pys). A total of 259 infections, of which 23 were serious, were recorded in 185 patients. The overall rate of any infection was 15 (95 % CI 13, 17)/100 pys and the serious infection rate was 1.3 (95 % CI 0.9, 2.0)/100 pys. There was no significant difference in the rate of any infection or serious infection in patients on TNFis compared with patients never on biologic agents. In the multivariate analysis, DMARD treatment, but not TNFi treatment, was associated with risk of infection. Age, disease duration, smoking status, BASFI, BASDAI, co-morbidity score and hospitalization were not associated with an increased risk of infection. **Conclusion:** The serious infection rate in axSpA in this observational cohort is low when compared with rates reported in other rheumatic diseases. Biologic use was not a significant risk factor for serious infection.

Kommentar

Aus theoretischen Überlegungen hinsichtlich Sorge einer Unterdrückung der Immunabwehr ist bei Patienten unter einer Biologikatherapie besonders an Infektionen zu denken. Aber die SAE-Raten für schwere Infektionen sind bei SpA-Patienten (Mb. Bechterew) niedrig: 1,3/100 Patientenjahre.

■ Benefits and Risks of Low-Dose Glucocorticoid Treatment in the Patient with Rheumatoid Arthritis

Kavanaugh A, et al. *Rheumatology (Oxford)* 2014; 53: 1742–51.

Abstract

Glucocorticosteroids (GCs) have been employed extensively for the treatment of rheumatoid arthritis (RA) and other autoimmune and systemic inflammatory disorders. Their use is supported by extensive literature and their utility is reflected in their incorporation into current treatment guidelines for RA and other conditions. Nevertheless, there is still some concern regarding the long-term use

of GCs because of their potential for clinically important adverse events, particularly with an extended duration of treatment and the use of high doses. This article systematically reviews the efficacy for radiological and clinical outcomes for low-dose GCs (defined as 410 mg/day prednisone equivalent) in the treatment of RA. Results reviewed indicated that low-dose GCs, usually administered in combination with synthetic DMARDs, most often MTX, significantly improve structural outcomes and decrease symptom severity in patients with RA. Safety data indicate that GC-associated adverse events are dose related, but still occur in patients receiving low doses of these agents. Concerns about side effects associated with GCs have prompted the development of new strategies aimed at improving safety without compromising efficacy. These include altering the structure of existing GCs and the development of delayed-release GC formulations so that drug delivery is timed to match greatest symptom severity. Optimal use of low-dose GCs has the potential to improve long-term outcomes for patients with RA.

Kommentar

Schöne Übersichtsarbeit über die in Zukunft – trotz moderner Biologika – wahrscheinlich weiterhin notwendige Glukokortikoidtherapie. Diese Glukokortikoidtherapie ideal zu ergänzen, erfordert sicherlich eine gewisse Erfahrung. Aber ein optimaler Einsatz hat das Potenzial, den „Outcome“ für die Patienten entscheidend zu verbessern.

In der Arbeit ist auch das Nebenwirkungsprofil der Glukokortikoidtherapie von Huscher et al. [1] angeführt.

■ Comparative Effectiveness of Pharmacologic Interventions for Knee Osteoarthritis: A Systematic Review and Network Meta-analysis

Bannuru RR, et al. *Ann Intern Med* 2015; 162: 46–54.

Abstract

Background: The relative efficacy of available treatments of knee osteoarthritis (OA) must be determined for rational treatment algorithms to be formulated. **Purpose:** To examine the efficacy of treatments of primary knee OA using a network meta-analysis design, which estimates relative effects of all treatments against each other. **Data Sources:** MEDLINE, EMBASE, Web of Science, Google Scholar, Cochrane Central Register of Controlled Trials from inception through 15 August 2014, and unpublished data. **Study Selection:** Randomized trials of adults with knee OA comparing 2 or more of the following: acetaminophen, diclofenac, ibuprofen, naproxen, celecoxib, intra-articular (IA) corticosteroids, IA hyaluronic acid, oral placebo, and IA placebo. **Data Extraction:** Two reviewers independently

abstracted study data and assessed study quality. Standardized mean differences were calculated for pain, function, and stiffness at 3-month follow-up. **Data Synthesis:** Network meta-analysis was performed using a Bayesian random-effects model; 137 studies comprising 33 243 participants were identified. For pain, all interventions significantly outperformed oral placebo, with effect sizes from 0.63 (95 % credible interval [CrI], 0.39 to 0.88) for the most efficacious treatment (hyaluronic acid) to 0.18 (CrI, 0.04 to 0.33) for the least efficacious treatment (acetaminophen). For function, all interventions except IA corticosteroids were significantly superior to oral placebo. For stiffness, most of the treatments did not significantly differ from one another. **Limitation:** Lack of long-term data, inadequate reporting of safety data, possible publication bias, and few head-to-head comparisons. **Conclusion:** This method allowed comparison of common treatments of knee OA according to their relative efficacy. Intra-articular treatments were superior to nonsteroidal anti-inflammatory drugs, possibly because of the integrated IA placebo effect. Small but robust differences were observed between active treatments. All treatments except acetaminophen showed clinically significant improvement from baseline pain. This information, along with the safety profiles and relative costs of included treatments, will be helpful for individualized patient care decisions.

Kommentar

Diese Metaanalyse von doch 137 Studien mit 33.243 Patienten zeigte einige überraschende Ergebnisse: Acetaminophen (in Österreich: z. B. Parkemed®) konnte klinisch keine signifikante Verbesserung der Schmerzen gegenüber NSAR zeigen. Überlegen war aber die intraartikuläre Hyaluronsäure als wirksames Mittel gegen Schmerzen. Diese Studie weist darauf hin, dass Paracetamol „überverschrieben“ wird und die Hyaluronsäure nicht voll genutzt würde. Fairerweise wird auch auf den Placebo-Effekt von intraartikulären Injektionen verwiesen, außerdem sind Hyaluronsäure-Injektionen teuer.

Anmerkung: In den OARSI-Guidelines USA [2], an denen auch der Autor dieser Analyse maßgeblich beteiligt war, findet sich die intraartikuläre Hyaluronsäure-Therapie aber in der Kategorie „uncertain appropriateness“!

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1. Huscher D, Thiele K, Gromnica-Ihle E, et al. Dose-related patterns of glucocorticoid-induced side effects. *Ann Rheum Dis* 2009; 68: 1119–24.
2. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage* 2014; 22: 363–88.

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