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Full search strategy | Page 10
1. A systematic review and meta-analysis for the adverse effects, immunogenicity and efficacy of Lyme disease vaccines: Guiding novel vaccine development.

**Authors**
Badawi, Ala; Shering, Maria; Rahman, Shusmita; Lindsay, L Robin

**Source**
Canadian journal of public health = Revue canadienne de sante publique; Apr 2017; vol. 108 (no. 1); p. e62

**Publication Date**
Apr 2017

**Publication Type(s)**
Meta-analysis Journal Article Review

**PubMedID**
28425901

**Database**
Medline

**Abstract**
BACKGROUND Lyme borreliosis (LB) is the most prevalent arthropod-borne infectious disease in North America. Currently, no vaccine is available to prevent LB in humans, although monovalent and multivalent vaccines have been developed in the past. OBJECTIVE The aim of the current study is to conduct a systematic review and meta-analysis to evaluate and compare the findings from these two classes of vaccines for their reactivity, immunogenicity and efficacy, in the hope this may assist in the development of future vaccines. METHODS A search strategy was developed for online databases (PubMed, Ovid MEDLINE, and Embase). Search terms used were "vaccine/vaccination", "Lyme disease/Borreliosis", "clinical trial[s]" and "efficacy". Only seven clinical trials were included to compare the results of the monovalent vaccines to those of the multivalent one. Meta-analyses were conducted to evaluate the reactivity and immunogenicity of the two vaccine classes. Odds ratio (OR) for LB (and 95% confidence intervals; 95% CI) were calculated for the efficiency of the monovalent vaccine from three different clinical trials at different dose schedules. RESULTS Incidence of redness (local adverse effect) and fever (systemic side effect) were, respectively, 6.8- and 2.9-fold significantly lower (p < 0.05) in individuals who received multivalent vaccines compared to those receiving the monovalent one. Incidences of all other local and systemic adverse effects were non-significantly lower in the multivalent vaccine compared to the monovalent vaccines. Seroprotection was comparable among individuals who received the two vaccine classes at the 30 μg dose level. Efficacy in the prevention of LB was only evaluated for the monovalent vaccines. OR of LB ranged from 0.49 (95% CI: 0.14-0.70; p < 0.005, vs. placebo) to 0.31 (95% CI: 0.26-0.63; p < 0.005) for the initial and final doses respectively, with an overall OR of 0.4 (95% CI: 0.26-0.63, p < 0.001). CONCLUSION The current study further validates that the monovalent and multivalent LB vaccines result in mild local side effects and self-limiting systemic adverse effects, with the multivalent vaccine slightly more tolerable than the monovalent one. Both vaccine classes were similarly highly immunogenic. A new vaccine with high safety standards, better efficacy, low cost, and public acceptance is yet to be developed. Meanwhile, personal protection limiting exposure to ticks is recommended.

2. Alginate therapy is effective treatment for GERD symptoms: A systematic review and meta-analysis

**Authors**
Leiman D.A.; Riff B.P.; Morgan S.; French B.; Umscheid C.A.; Metz D.C.; Falk G.W.; Lewis J.D.

**Source**
Diseases of the Esophagus; May 2017; vol. 30 (no. 5); p. 1-9

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EMBASE

**Abstract**
In patients with gastroesophageal reflux disease (GERD) and erosive esophagitis, treatment with proton pump inhibitors (PPIs) is highly effective. However, in some patients, especially those with nonerosive reflux disease or atypical GERD symptoms, acid-suppressive therapy with PPIs is not as successful. Alginates are medications that work through an alternative mechanism by displacing the postprandial gastric acid pocket. This study performed a systematic review and meta-analysis to examine the benefit of alginate-containing compounds in the treatment of patients with symptoms of GERD. PubMed/MEDLINE, Embase, and the Cochrane library electronic databases were searched through October 2015 for randomized controlled trials comparing alginate-containing compounds to placebo, antacids, histamine-2 receptor antagonists (H2RAs), or PPIs for the treatment of GERD symptoms. Additional studies were identified through a bibliography review. Non-English studies and those with pediatric patients were excluded. Meta-analyses were performed using random-effect models to calculate odds ratios (OR). Heterogeneity between studies was estimated using the I² statistic. Analyses were stratified by type of comparator. The search strategy yielded 665 studies and 15 (2.3%) met inclusion criteria. Fourteen were included in the metaanalysis (N = 2095 subjects). Alginate-based therapies increased the odds of resolution of GERD symptoms when compared to placebo or antacids (OR: 4.42; 95% CI 2.45-7.97) with a moderate degree of heterogeneity between studies (I² = 71%, P = .001). Compared to PPIs or H2RAs, alginates appear less effective but the pooled estimate was not statistically significant (OR: 0.58; 95% CI 0.27-1.22). Alginates are more effective than placebo or antacids for treating GERD symptoms.

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3. Certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease-modifying antirheumatic drugs: A systematic review and economic evaluation

Authors
Corbett M.; Biswas M.; Moe-Byrne T.; Walton M.; Harden M.; Woolacott N.; Chehadah F.; Palmer S.; Soares M.; Laura B.; Ho P.

Source
Health Technology Assessment; Oct 2017; vol. 21 (no. 56); p. 1-326

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Oct 2017

Publication Type(s)
Article

Database
EMBASE

Abstract
Background: Several biologic therapies are approved by the National Institute for Health and Care Excellence (NICE) for psoriatic arthritis (PsA) patients who have had an inadequate response to two or more synthetic disease-modifying antirheumatic drugs (DMARDs). NICE does not specifically recommend switching from one biologic to another, and only ustekinumab (UST; STELARA, Janssen Pharmaceuticals, Inc., Horsham, PA, USA) is recommended after anti-tumour necrosis factor failure. Secukinumab (SEC; COSENTYX, Novartis International AG, Basel, Switzerland) and certolizumab pegol (CZP; CIMZIA, UCB Pharma, Brussels, Belgium) have not previously been appraisal by NICE. Objective: To determine the clinical effectiveness and cost-effectiveness of CZP and SEC for treating active PsA in adults in whom DMARDs have been inadequately effective. Design: Systematic review and economic model. Data sources: Fourteen databases (including MEDLINE and EMBASE) were searched for relevant studies from inception to April 2016 for CZP and SEC studies; update searches were run to identify new comparator studies. Review methods: Clinical effectiveness data from randomised controlled trials (RCTs) were synthesised using Bayesian network meta-analysis (NMA) methods to investigate the relative efficacy of SEC and CZP compared with comparator therapies. A de novo model was developed to assess the cost-effectiveness of SEC and CZP compared with the other relevant comparators. The model was specified for three subpopulations, in accordance with the NICE scope (patients who have taken one prior DMARD, patients who have taken two or more prior DMARDs and biologic-experienced patients). The models were further classified according to the level of concomitant psoriasis. Results: Nineteen eligible RCTs were included in the systematic review of short-term efficacy. Most studies were well conducted and were rated as being at low risk of bias. Trials of SEC and CZP demonstrated clinically important efficacy in all key clinical outcomes. At 3 months, patients taking 150 mg of SEC [relative risk (RR) 6.27, 95% confidence interval (CI) 2.55 to 15.43] or CZP (RR 3.29, 95% CI 1.94 to 5.56) were more likely to be responders than patients taking placebo. The NMA results for the biologic-naive subpopulations indicated that the effectiveness of SEC and CZP relative to other biologics and each other was uncertain. Limited data were available for the biologic-experienced subpopulation. Longer-term evidence suggested that these newer biologics reduced disease progression, with the benefits being similar to those seen for older biologics. The de novo model generated incremental cost-effectiveness ratios (ICERs) for three subpopulations and three psoriasis subgroups. In subpopulation 1 (biologic-naive patients who had taken one prior DMARD), CZP was the optimal treatment in the moderate-severe psoriasis subgroup and 150 mg of SEC was optimal in the subgroups of patients with mild-moderate psoriasis or no concomitant psoriasis. In subpopulation 2 (biologic-naive patients who had taken two or more prior DMARDs), etanercept (ETN; ENBREL, Pfizer Inc., New York City, NY, USA) is likely to be the optimal treatment in all subgroups. The ICERs for SEC and CZP versus best supportive care are in the region of 20,000-30,000 per quality-adjusted life-year (QALY). In subpopulation 3 (biologic-experienced patients or patients in whom biologics are contraindicated), UST is likely to be the optimal treatment (ICERs are in the region of 21,000-27,000 per QALY). The optimal treatment in subpopulation 2 was sensitive to the choice of evidence synthesis model. In subpopulation 3, results were sensitive to the algorithm for Health Assessment Questionnaire-Disability Index costs. The optimal treatment is not sensitive to the use of biosimilar prices for ETN and infliximab (REMICADE, Merck Sharp & Dohme, Kenilworth, NJ, USA). Conclusions: SEC and CZP may be an effective use of NHS resources, depending on the subpopulation and subgroup of psoriasis severity. There are a number of limitations to this assessment, driven mainly by data availability.

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4. Clozapine augmentation with antiepileptic drugs for treatment-resistant schizophrenia: A meta-analysis of randomized controlled trials

Authors
Zheng W.; Yang X.-H.; Xiang Y.-T.; Xiang Y.-Q.; De Leon J.

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May 2017

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Article

PubMedID
28355041

Database
EMBASE
Abstract
Objective: To meta-analyze randomized controlled trials (RCTs) for the efficacy and safety of adjunctive antiepileptic drugs (AEDs) to augment clozapine therapy for treatment-resistant schizophrenia. Data Sources: The search included databases in English (PubMed, PsycINFO, Embase, and Cochrane Library databases and the Cochrane Controlled Trials Register) and in Chinese (China Journal Net [CJN], WanFang, and China Biology Medicine [CBM]) and references from retrieved articles. The databases were searched using dates inclusive from their onset until January 1, 2016, for terms reflecting (a) schizophrenia, (b) clozapine, and (c) adjunctive drugs. Study Selection: From 1,969 potentially relevant articles, 21 articles describing 22 RCTs were selected. Data Extraction: Two independent investigators extracted data for a random-effects meta-analysis and assessed the quality of the studies using risk of bias and the Jadad scale. Standard mean difference, risk ratio (RR) +/- } 95% confidence intervals (CIs), and the number needed to harm (NNH) were used. Results: A total of 22 RCTs (N = 1,227) with 4 AEDs (topiramate [5 RCTs, n = 270], lamotrigine [8 RCTs, n = 299], sodium valproate [6 RCTs, n = 430], and magnesium valproate [3 RCTs, n = 228]) were analyzed. The means weighted by sample size were 12.1 weeks for treatment duration, 36.2 years for age, and 61% for male frequency. Significant superiority in total psychopathology was observed for topiramate (P < .0001), lamotrigine (P = .05), and sodium valproate (P = .002), compared to clozapine monotherapy. After removing outliers, the positive effect of sodium valproate remained, but the positive effect of lamotrigine disappeared (P = .40). Significantly improved efficacy in positive and general symptom severity was observed for topiramate (P < .0001), lamotrigine (P = .05), and sodium valproate (P = .002), compared to clozapine monotherapy. After removing outliers, the positive effect of sodium valproate remained, but the positive effect of lamotrigine disappeared (P = .40). Significantly improved efficacy in positive and general symptom severity was observed for topiramate (P = .04 and P = .02, respectively) and sodium valproate (P = .009 and P = .003, respectively). There were no significant differences regarding adverse drug reactions and all-cause discontinuations except for topiramate, which was associated with more all-cause discontinuations (RR = 1.99; 95% CI, 1.16 to 3.39; P = .01; I^2 = 0%; NNH = 7). Conclusions: Sodium valproate augmentation was efficacious and safe. Topiramate augmentation had a too-high discontinuation rate. High-quality RCTs are needed to inform clinical recommendations.

5. The effects of parathyroid hormone peptides on the peripheral skeleton of postmenopausal women. A systematic review

Authors Metcalfe L.M.; McCloskey E.V.; Aspray T.J.
Source Bone; Jun 2017; vol. 99; p. 39-46
Publication Date Jun 2017
Publication Type(s) Review
Database EMBASE
Abstract Given current developments in anabolic therapy for bone, we wished to document the effects of the only currently available anabolic therapy, parathyroid hormone (PTH) peptides, on the peripheral skeleton of postmenopausal women. We undertook a systematic review of English articles using MEDLINE, Scopus and the Cochrane Controlled Trials Register (final update 28th March 2016). Additional studies were identified through searches of bibliographies. Studies included those comparing PTH peptides with placebo, with anti-osteoporotic treatments and in combination therapies. Participants had to be postmenopausal women and outcomes included areal or volumetric bone mineral density (BMD) and measurements of bone microarchitecture at peripheral sites, such as the forearm and tibia. Data were extracted independently and reviewed by EVM and LMM. Data on study design were also collected for methodological risk of bias assessment. The heterogeneity between studies, regarding the drug dose and duration, and the site measured, prevented grouped meta-analysis. There were no significant differences in areal BMD between PTH peptides and placebo at peripheral skeletal sites at 12 months. A decrease in aBMD occurred with PTH(1-34) (larger dose) and PTH(1-84) treatment at 18 months follow-up in comparison to the placebo arms. Anti-resorptives seemed to attenuate losses of aBMD at peripheral sites when compared to PTH peptides monotherapy, likely mediated by lower cortical porosity. Finally, PTH peptides combined with bisphosphonates or denosumab attenuated peripheral BMD losses in comparison to PTH peptide monotherapy, with evidence of increased BMD at ultradistal peripheral sites when PTH(1-34) was combined with denosumab or hormone replacement therapy. This summary should act as a reference point for the comparison of new anabolic therapies, specifically in comparison to PTH(1-34).

6. Synthetic growth hormone-releasing peptides (GHRPs): A historical appraisal of the evidences supporting their cytoprotective effects

Authors Berlanga-Acosta J.; Garcia-del Barco Herrera D.; Mendoza-Mari Y.; Rodriguez-Ulloa A.; Garcia-Ojalvo A.; Falcon-Cama V.; Hernandez-Bernal F.; Guillen-Nieto G.; Abreu-Cruz A.; Beichen Q.
Source Clinical Medicine Insights: Cardiology; Mar 2017; vol. 11
Publication Date Mar 2017
Publication Type(s) Article
Database EMBASE
Available at Clinical Medicine Insights: Cardiology from Europe PubMed Central - Open Access
Abstract

Background: Growth hormone-releasing peptides (GHRPs) constitute a group of small synthetic peptides that stimulate the growth hormone secretion and the downstream axis activity. Mounting evidences since the early 1980s delineated unexpected pharmacological cardioprotective and cytoprotective properties for the GHRPs. However, despite intense basic pharmacological research, alternatives to prevent cell and tissue demise before lethal insults have remained as an empty niche in the clinical armamentarium. Here, we have rigorously reviewed the investigational development of GHRPs and their clinical niching perspectives.

Methodology: PubMed/MEDLINE databases, including original research and review articles, were explored. The search design was date escalated from 1980 and included articles in English only. Results and conclusions: GHRPs bind to two different receptors (GHS-R1a and CD36), which redundantly or independently exert relevant biological effects. GHRPs' binding to CD36 activates prosurvival pathways such as PI-3K/AKT1, thus reducing cellular death. Furthermore, GHRPs decrease reactive oxygen species (ROS) spillover, enhance the antioxidant defenses, and reduce inflammation. These cytoprotective abilities have been revealed in cardiac, neuronal, gastrointestinal, and hepatic cells, representing a comprehensive spectrum of protection of parenchymal organs. Antifibrotic effects have been attributed to some of the GHRPs by counteracting fibrogenic cytokines. In addition, GHRP family members have shown a potent myotropic effect by promoting anabolia and inhibiting catabolia. Finally, GHRPs exhibit a broad safety profile in preclinical and clinical settings. Despite these fragmented lines incite to envision multiple pharmacological uses for GHRPs, especially as a myocardial reperfusion damage-attenuating candidate, this family of "drugable" peptides awaits for a definitive clinical niche.

7. Assessment and simulation of costs and qol for sublingual immunotherapy in paediatric asthma vs placebo: Preliminary data

Authors: Trieste L.; Turchetti G.; Silvestri M.; Tosca M.A.
Source: Value in Health; 2017; vol. 20 (no. 9)
Publication Date: 2017
Publication Type(s): Conference Abstract
Database: EMBASE

Abstract: Objectives: Specific immunotherapy (SIT), either subcutaneous (SCIT) or sublingual (SLIT), is an allergen-oriented immunomodulation. It consists in administrating increasing doses of the sensitizing allergen, to induce tolerance or "desensitization". Nonetheless, the usefulness of SLIT in paediatric asthma is still matter of debate due to sporadic studies, a non-rigorous methodology, the lack of a real assessment of costs associated. The aim of our study was to evaluate the efficacy of SLIT vs Placebo in term of QoL and the related costs in children with allergic asthma measured under the usual circumstances of health care practice.

Methods: A 24-month, multicentre, prospective, randomized, double-blind, placebo-controlled, parallelgroup study evaluated the efficacy, safety, and tolerability, and cost-effectiveness of SLIT in combination with asthma SoC in children and adolescents in 8 Italian Centres. The NHS, the patient and the society perspectives have been considered. QoL has been assessed considering activity limitation; emotional problems and the global PACQLQ score. QALY has not been assessed since results from mapping disease specific and generic questionnaires’ were still not available.

Simulation considered: a 1,000 patient cohort, assessed unit costs and a time discrete Markov model with a discount rate of 3.5%. Transition probabilities come from transition rates by assessing the exponential matrix of a Kolmogorov model of patient condition evolution. Results: Total costs from the NHS, patient, and society perspectives of 1,000 patients are 1,201,534.12, 1,030.42, 1,880,004.15 respectively for the control group, and 1,316,556.09; 0.00; 1,399,226.49 for the study group. QoL shows a higher mean in the study than in the control group. Differences of emotional problem and PACQL scores assessed before and after randomization are not statistically different in the two groups.

Conclusions: With comparable QoL, SLIT induces an increasing of direct costs but a reduction of societal costs because of a reduction in out-of-pocket expenses and indirect costs.

8. Approval rating and opinion of outpatients and general practitioners toward generic drugs: A questionnaire-based real-world study

Authors: Mattioli F.; Castelli F.; Zuccoli M.L.; Martelli A.; Siri G.; Puntoni M.; Stimamiglio A.
Source: Patient Preference and Adherence; Aug 2017; vol. 11; p. 1423-1433
Publication Date: Aug 2017
Publication Type(s): Article
Database: EMBASE

Available at Patient Preference and Adherence from Europe PubMed Central - Open Access
Abstract

Purpose: Generic drugs use in the Liguria region is higher than the Italian average, but lower than in other European countries. No data exist about real-life prescription and level of awareness of generic drugs. In this study, we analyzed demographic, social, economic and cultural factors that may affect the level of awareness of generic drugs and their effective use. Methods: We conducted a population survey using a structured questionnaire, administered to a sample of 8 outpatient clinics of general practitioners located in different districts of Genoa (Liguria, Italy). Multivariate logistic modeling was adopted to study the relationship between awareness/use of generic drugs and characteristics of subjects. Results: Out of 2,000 outpatients surveyed, 95% were aware of generic drugs: these were mostly females (OR =2.2, 95% CI: 1.4-3.6), 35 years old (OR 6.0 vs 18-35 years), with a high level of education (OR 4.4 vs "elementary sch"), living in the west side of the city (OR =1.9 vs center); of these, only 59% declared that they effectively use generic drugs. Users were younger (OR =3.1, 18-35 years vs.65 years), with a high level of education (high school/university degree vs no title/elementary/secondary school OR =1.7), and were aware of the lower cost compared with branded drugs, and were mainly informed by pharmacists and physicians. Conclusions: Although subjects were substantially aware of the existence of generic drugs, ~40% still did not use them; doubts about their efficacy seem to be mainly driven by the idea that cheaper drugs lead to lower product quality, in terms of efficacy, safety and tolerability. New education policies on generic drugs are needed.

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9. Prescribing quality improvement: reducing high-dose antipsychotic use

Authors
Prajapati A.R.; Johnston E.; Ugochukwu U.; Solomka B.

Source
Progress in Neurology and Psychiatry; Jul 2017; vol. 21 (no. 3); p. 18-21

Publication Date
Jul 2017

Publication Type(s)
Article

Database
EMBASE

Abstract
Evidence of efficacy for high-dose antipsychotic therapy (HDAT) and antipsychotic combinations (AC) is lacking, while evidence of harm is compelling. Significantly higher proportions of Norfolk and Suffolk NHS Foundation Trust (NSFT) patients were being prescribed HDAT and AC compared with the national averages. Here, the authors describe a quality improvement program to rationalise and reduce HDAT and AC prescribing in NSFT, to bring it in line with, or below, the national average. The initiative demonstrates that prescribing culture can be improved through a sustained multi-professional team approach involving education and training, a targeted campaign, a proactive clinical pharmacy team and pharmacists' support.

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10. Newer generation antidepressants for young people: Real-life evidence needed: Commentary on... cochrane corner

Authors
Hussain H.; Wilkinson P.; Dubicka B.

Source
BJ Psych Advances; 2017; vol. 23 (no. 2); p. 75-80

Publication Date
2017

Publication Type(s)
Article

Database
EMBASE

Abstract
Major depressive disorder in children and adolescents is common and associated with significant morbidity and mortality. This 2012 meta-analysis by Hetrick et al shows statistically significant, but small, improvements in depressive symptom scores and probability of remission with second-generation antidepressants (SGAs) compared with placebo. SGAs lead to a small, but significant, increase in risk of suicidal thoughts/attempts compared with placebo. Patients included in the primary studies had milder depression, less psychiatric comorbidity and less suicidality than those normally seen in clinical practice in the UK’s National Health Service. However, primary studies had significant methodological shortcomings. Therefore, caution is needed when trying to generalise results to clinical practice.

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11. Probiotics in Helicobacter pylori eradication therapy: Systematic review and network meta-analysis

Authors
Wang F.; Feng J.; Chen P.; Zhou R.; Chang Y.; Liu J.; Li J.; Zhao Q.; Liu X.; Ma M.

Source
Clinics and Research in Hepatology and Gastroenterology; Sep 2017; vol. 41 (no. 4); p. 466-475

Publication Date
Sep 2017

Publication Type(s)
Article

Database
EMBASE
12. Thalidomide in relapsed lymphoma: 5 years of experience from Southend University Hospital NHS Foundation Trust

Abstract
Introduction: Thalidomide is an immunomodulatory and anti-inflammatory drug with well-documented efficacy in the treatment of multiple myeloma, both as initial therapy and in relapsed disease. Known side effects include venous thrombosis, fatigue, peripheral neuropathy and constipation. However as an oral drug with minimal myelosuppression, thalidomide is suitable for patients unable to tolerate more conventional chemotherapy or for whom regular hospital attendances are too demanding. Data from clinical trials and case series in a range of both B- and T-lymphoproliferative disorders show broad efficacy of thalidomide. The unusual and multiple modes of action of thalidomide suggest potential in treating disease resistant or refractory to conventional chemotherapy. This is further supported by exceptional case studies such as a refractory AITL patient achieving CR with thalidomide/dexamethasone and a post-allograft DLBCL patient achieving CR on thalidomide/rituximab. We have been using thalidomide in relapsed and frail lymphoma patients at Southend for a number of years with anecdotally good outcomes. We decided to conduct a retrospective study of lymphoma patients treated with thalidomide to assess the rates of response and overall survival, as well as examining the side effect profile. Methods: Data from 2012 to 2016 were collected retrospectively from pharmacy records for all lymphoma patients treated with thalidomide. The majority of these patients were multiply relapsed. Patients were all started on 50 mg daily, with dose escalation to 200 mg daily as tolerated, in addition to pulsed dexamethasone. Results: 27 patients were treated: - 11 DLBCL (2 transformed low grade) - 3 Follicular lymphoma - 2 B-NHL unspecified - 3 Hodgkin’s disease - 2 Waldenstrom’s macroglobulinaemia - 1 mantle cell - 5 angioimmunoblastic T cell - Age range of patients 52-58 (median age 75) - Line of treatment was 1-5 (median 2) - 17/27 patients were treated for >4 weeks (others stopped due to SEs or early relapse/death) - 7 of those 17 achieved disease control for >6 months. Conclusion: The patients examined in this study were all multiply relapsed and/or too frail for conventional chemotherapy. Prognosis in such a cohort is very poor and, unsurprisingly, many of the cases we looked at died shortly after starting treatment. However, a subset of these patients achieved long disease control—one patient is still alive 5 years after starting thalidomide. Thalidomide has a variety of mechanisms including immunomodulatory and anti-angiogenic properties so it is a logical choice of treatment in chemotherapy-resistant cases. Given the generally well-tolerated side effect profile and low cost of thalidomide not to mention the ease of administration, a trial of thalidomide is worth considering when no other options remain, where it may buy precious months, or even years, of life.

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13. Cost-effectiveness analysis in the Spanish setting of the PEAK trial of panitumumab plus mFOLFOX6 compared with bevacizumab plus mFOLFOX6 for first-line treatment of patients with wild-type RAS metastatic colorectal cancer

Abstract
Background Several probiotics were effective in the eradication treatment for Helicobacter pylori (Hp), but their comparative efficacy was unknown. Aim To compare the efficacy of different probiotics when supplemented in Hp eradication therapy. Methods A comprehensive search was conducted to identify all relevant studies in multiple databases and previous meta-analyses. Bayesian network meta-analysis was performed to combine direct and indirect evidence and estimate the relative effects. Results One hundred and forty studies (44 English and 96 Chinese) were identified with a total of 20,215 patients, and more than 10 probiotic strategies were supplemented in Hp eradication therapy. The rates of eradication and adverse events were 84.1 and 14.4% in probiotic group, while 70.5 and 30.1% in the control group. In general, supplementary probiotics were effective in improving the efficacy of Hp eradication and decreasing the incidence of adverse events, despite of few ineffective subtypes. In triple eradication therapy, there was no significant difference among the effective probiotics, and combined probiotics did not show a better efficacy and tolerance than single use. In triple therapy of 7 days and 14 days, Lactobacillus acidophilus was a slightly better choice, while Saccharomyces boulardii was more applicable for 10-day triple therapy. Conclusions Compared to placebo, most probiotic strategies were effective when supplemented in Hp eradication therapy. In triple eradication therapy, no probiotic showed a superior efficacy to the others. Compared to single use, combined probiotics could not improve the efficacy or tolerance significantly.

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Objective: To assess the cost-effectiveness of panitumumab in combination with mFOLFOX6 (oxaliplatin, 5-fluorouracil, and leucovorin) vs bevacizumab in combination with mFOLFOX6 as first-line treatment of patients with wild-type RAS metastatic colorectal cancer (mCRC) in Spain. Methods: A semi-Markov model was developed including the following health states: Progression free; Progressive disease: Treat with best supportive care; Progressive disease: Treat with subsequent active therapy; Attempted resection of metastases; Disease free after metastases resection; Progressive disease: after resection and relapse; and Death. Parametric survival analyses of patient-level progression free survival and overall survival data from the PEAK Phase II clinical trial were used to estimate health state transitions. Additional data from the PEAK trial were considered for the dose and duration of therapy, the use of subsequent therapy, the occurrence of adverse events, and the incidence and probability of time to metastasis resection. Utility weightings were calculated from patient-level data from panitumumab trials evaluating first-, second-, and third-line treatments. The study was performed from the Spanish National Health System (NHS) perspective including only direct costs. A lifetime horizon was applied. Probabilistic sensitivity analyses and scenario sensitivity analyses were performed to assess the robustness of the model. Results: Based on the PEAK trial, which demonstrated greater efficacy of panitumumab vs bevacizumab, both in combination with mFOLFOX6 first-line in wild-type RAS mCRC patients, the estimated incremental cost per life-year gained was 16,567 and the estimated incremental cost per quality-adjusted life year gained was 22,794. The sensitivity analyses showed the model was robust to alternative parameters and assumptions. Limitations: The analysis was based on a simulation model and, therefore, the results should be interpreted cautiously. Conclusions: Based on the PEAK Phase II clinical trial and taking into account Spanish costs, the results of the analysis showed that first-line treatment of mCRC with panitumumab + mFOLFOX6 could be considered a cost-effective option compared with bevacizumab + mFOLFOX6 for the Spanish NHS.

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