Gulácsi L.: Systematic review and analysis of evidences on clinical efficacy and cost-effectiveness of biological drugs for the treatment of adult Ulcerative Colitis

Appendix 8.8

Results of the health economic literature search (references and abstracts)

Ovid MEDLINE(R) 1946 to Present with Daily Update (22 hits)

EXCLUDED / NOT COST-UTILITY ANALYSIS

1.

Early patient stratification and predictive biomarkers in drug discovery and development: a case study of ulcerative colitis anti-TNF therapy.

Laifenfeld D. Drubin DA. Catlett NL. Park JS. Van Hooser AA. Frushour BP. de Graaf D. Fryburg DA. Deehan R.

Advances in Experimental Medicine & Biology. 736:645-53, 2012.

[Journal Article]

UI: 22161357

The current drug discovery paradigm is long, costly, and prone to failure. For projects in early development, lack of efficacy in Phase II is a major contributor to the overall failure rate. Efficacy failures often occur from one of two major reasons: either the investigational agent did not achieve the required pharmacology or the mechanism targeted by the investigational agent did not significantly contribute to the disease in the tested patient population. The latter scenario can arise due to insufficient study power stemming from patient heterogeneity. If the subset of disease patients driven by the mechanism that is likely to respond to the drug can be identified and selected before enrollment begins, efficacy and response rates should improve. This will not only augment drug approval percentages, but will also minimize the number of patients at risk of side effects in the face of a suboptimal response to treatment. Here we describe a systems biology approach using molecular profiling data from patients at baseline for the development of predictive biomarker content to identify potential responders to a molecular targeted therapy before the drug is tested in humans. A case study is presented where a classifier to predict response to a TNF targeted therapy for ulcerative colitis is developed a priori and verified against a test set of patients where clinical outcomes are known. This approach will promote the tandem development of drugs with predictive response, patient selection biomarkers.

Status

MEDLINE

Authors Full Name

Laifenfeld, Daphna. Drubin, David A. Catlett, Natalie L. Park, Jennifer S. Van Hooser, Aaron A. Frushour, Brian P. de Graaf, David. Fryburg, David A. Deehan, Renee.

Institution

Selventa, One Alewife Center, Cambridge, MA 02140, USA. dlaifenfeld@selventa.com

Date Created

20111213

Year of Publication

2012

EXCLUDED / NOT COST-UTILITY ANALYSIS

2.

Direct medical cost of managing IBD patients: a Canadian population-based study.

Bernstein CN. Longobardi T. Finlayson G. Blanchard JF.

Inflammatory Bowel Diseases. 18(8):1498-508, 2012 Aug.

[Comparative Study. Journal Article. Research Support, Non-U.S. Gov't]

UI: 22109958

BACKGROUND: This study aimed to quantify the direct medical cost of treating inflammatory bowel disease (IBD) in Manitoba in 2005/2006.

METHODS: In all, 7375 individuals with IBD recorded in the University of Manitoba IBD Epidemiology Database were matched on age, gender, and geography to up to 10 non-IBD controls. Data for cases and controls were extracted from Manitoba Health databases in fiscal 2005/2006 for pharmaceutical, physician

claims, and hospital abstracts. The mean and median expenditure were computed for the annual cost of pharmaceuticals, hospitalizations (day surgery and inpatient), and physician office visits. We assessed costs based on age, gender, type of IBD, disease duration, and level of care provided.
RESULTS: In 2005/2006 the mean direct cost of an IBD case was $3896 (standard error [SE] = $90) which was twice that of controls (P < 0.05). Crohn's disease (CD; n = 3735) was significantly more costly on average than ulcerative colitis (UC; n = 3640) ($4232; SE = $137 and $3552; SE = $117, respectively, P < 0.001). The most costly cases included those within 1 year of diagnosis ($6611; SE = $593), those hospitalized overnight (15%) ($13,495, SE = $416; max = $130,332), those who had a surgical stay (2% of IBD cases) ($18,749, range = $13,413-$125,912), and those using infliximab (0.7%) ($31,440, SE = $2311; max = $96,328). For individuals using infliximab their direct annual average healthcare cost was $9683 (SE = $1745, Max = $55,208) prior to using infliximab.
CONCLUSIONS: In Manitoba the direct average annual healthcare cost of CD is greater than UC and that of a patient using infliximab tends to be greater than one incurring a surgical stay. Copyright 2011 Crohn's & Colitis Foundation of America, Inc.
Status
MEDLINE
Authors Full Name
Bernstein, Charles N. Longobardi, Teresa. Finlayson, Greg. Blanchard, James F.
Institution
Department of Medicine, University of Manitoba, Winnipeg, Canada. cbernst@cc.umanitoba.ca
Date Created
20120718
Year of Publication
2012

INCLUDED
3.
Cost-effectiveness of early colectomy with ileal pouch-anal anastamosis versus standard medical therapy in severe ulcerative colitis.
Park KT. Tsai R. Perez F. Cipriano LE. Bass D. Garber AM.
Annals of Surgery. 256(1):117-24, 2012 Jul.
[Journal Article]
UI: 22270693
B 13 Raktari jelzet: A 52 (Ann Surg); USA, Philadelphia, ISSN 0003-4932; 1902:36 - 1903:42, 1907:45, 1909:50 - 1913:58, 1921:73 - 1921:74, 1924:79 -
BACKGROUND: Inflammatory bowel diseases are costly chronic gastrointestinal diseases. We aimed to determine whether immediate colectomy with ileal pouch-anal anastamosis (IPAA) after diagnosis of severe ulcerative colitis (UC) was cost-effective compared to the standard medical therapy.
METHODS: We created a Markov model simulating 2 cohorts of 21-year-old patients with severe UC, following them until 100 years of age or death, comparing early colectomy with IPAA strategy to the standard medical therapy strategy. Deterministic and probabilistic analyses were performed.
RESULTS: Standard medical care accrued a discounted lifetime cost of $236,370 per patient. In contrast, early colectomy with IPAA accrued a discounted lifetime cost of $147,763 per patient. Lifetime quality-adjusted life-years gained (QALY-gained) for standard medical therapy was 20.78, while QALY-gained for early colectomy with IPAA was 20.72. The resulting incremental cost-effectiveness ratio (costs/QALY) was approximately $1.5 million per QALY-gained. Results were robust to one-way sensitivity analyses for all variables in the model. Quality-of-life after colectomy with IPAA was the most sensitive variable impacting cost-effectiveness. A low utility value of less than 0.7 after colectomy with IPAA was necessary for the colectomy with IPAA strategy to be cost-ineffective.
CONCLUSIONS: Under the appropriate clinical settings, early colectomy with IPAA after diagnosis of severe UC reduces health care expenditures and provides comparable quality of life compared to exhaustive standard medical therapy.
Status
MEDLINE
Authors Full Name
Park, K T. Tsai, Raymond. Perez, Felipe. Cipriano, Lauren E. Bass, Dorsey. Garber, Alan M.
Institution
Stanford University Medical Center, Lucile Packard Children's Hospital, Division of Pediatric Gastroenterology, Hepatology, and Nutrition, Palo Alto, CA 94304, USA.
Date Created

20120703
Year of Publication
2012

EXCLUDED / NOT COST-UTILITY ANALYSIS
4.
Annual costs of tumor necrosis factor inhibitors using real-world data in a commercially insured population in the United States.
Schabert VF. Watson C. Gandra SR. Goodman S. Fox KM. Harrison DJ.
Journal of Medical Economics. 15(2):264-75, 2012.
[Journal Article. Research Support, Non-U.S. Gov't]
UI: 22115327
OBJECTIVE: To calculate annual cost per treated patient of tumor necrosis factor (TNF) inhibitors etanercept, adalimumab, and infliximab for common approved indications, based on actual TNF-inhibitor use in clinical practice.
METHODS: Adults with >=1 claim for etanercept, adalimumab, or infliximab between January 2005 and March 2009 were identified from the IMS LifeLinkTM Health Plan Claims Database. Patients new to therapy or continuing therapy (i.e., a prior claim for a TNF-inhibitor) were analyzed separately. Included patients had been enrolled from 180 days before the first TNF-inhibitor claim (index date) through 360 days after the index date and had a diagnosis during the pre-index period for rheumatoid arthritis, psoriasis, psoriatic arthritis, or ankylosing spondylitis. Patients with Crohn's disease, ulcerative colitis, or juvenile idiopathic arthritis were excluded. Annual costs were calculated using wholesale acquisition costs for the TNF-inhibitor and Medicare Physician Fee Schedule for drug administration. Costs from restarting or switching TNF-inhibitor therapy during the first year were included.
RESULTS: A total of 27,704 patients (11,528 new, 16,176 continuing) had claims for etanercept, adalimumab, or infliximab, most commonly (65%) for treatment of rheumatoid arthritis. The most commonly used agent was etanercept (14,777 patients; 53%), followed by adalimumab (6862 patients; 25%) and infliximab (6065 patients; 22%). Annual cost per treated patient was etanercept $14,873, adalimumab $17,766, and infliximab $21,256 across all indications. Annual cost per treated patient by disease was (etanercept/adalimumab/infliximab): rheumatoid arthritis ($14,314/$17,700/$20,390), psoriasis ($17,182/$17,682/$23,935), psoriatic arthritis ($15,030/$18,483/$24,974), and ankylosing spondylitis ($14,254/$16,925/$23,056). New and continuing patients showed similar results, with etanercept having the lowest costs.
LIMITATIONS: This analysis is limited to three TNF-inhibitors and a US managed-care population.
CONCLUSIONS: Based on this analysis of real-world use of TNF-inhibitors among patients in nationwide clinical practice settings, the annual TNF-inhibitor cost per treated patient was lowest for etanercept across all indications.
Status
MEDLINE
Authors Full Name
Schabert, Vernon F. Watson, Crystal. Gandra, Shravanthi R. Goodman, Seth. Fox, Kathleen M. Harrison, David J.
Institution
IMS Health, Inc., Alexandria, VA 22314, USA. vschabert@imscg.com
Date Created
20120309
Year of Publication
2012

EXCLUDED / NOT COST-UTILITY ANALYSIS
5.
Resource utilization before and during infliximab therapy in patients with inflammatory bowel disease.
Waters HC. Vanderpoel JE. Nejadnik B. McKenzie RS. Lunacsek OE. Lennert BJ. Goff J. Augustyn DH.
Journal of Medical Economics. 15(1):45-52, 2012.
[Journal Article. Research Support, Non-U.S. Gov't]
UI: 22023068
OBJECTIVE: Although Remicade (infliximab) is costly relative to non-biologic therapy, its impact on healthcare resource utilization and mucosal healing may make it a cost-effective option. This study aimed to compare gastrointestinal (GI)-related healthcare resource utilization and severity of mucosal damage before and during infliximab therapy in Crohn's disease (CD) or ulcerative colitis (UC) patients.
METHODS: A retrospective chart review was conducted at 14 gastroenterology practices from across the

country, which varied in practice sizes and types. Patients were aged >=18 years, diagnosed with CD or UC, and had an infliximab index date between January 1, 2005 and September 30, 2007. GI-related utilization 12 months before and 12 months after the index date was compared. Endoscopic disease severity was categorized based on blinded review of abstracted reports.
RESULTS: Results from 268 patients indicated significantly lower rates of surgery (29.7% to 9.9%, p<0.0001, CD; 24.4% to 12.8%, p=0.042, UC) and colonoscopy (54.4% to 17.6%, p<0.0001, CD; 50.0% to 22.1%, p=0.0007, UC) during infliximab therapy. The rates of hospitalizations in UC (15.1% to 3.5%, p=0.0124) and radiology assessments in CD (23.1% to 10.4%, p=0.006) also decreased. Based on severity data from 183 procedures, greater proportions of patients had normal or mild ratings during infliximab treatment compared with pre-treatment.
LIMITATIONS: This retrospective descriptive study is limited by the type and quantity of information available in patient charts from 14 gastroenterology clinics during the first year of infliximab treatment. In addition, the number of patients with pre-treatment and post-treatment disease severity information was too small to make comparisons among disease severity groups. Further information about the severity of disease and the extent of mucosal healing could be helpful in determining the effect of therapy on resource utilization in future research.
CONCLUSIONS: GI-related resource utilization was significantly lower and attenuation of mucosal damage severity was observed during infliximab treatment compared with the pre-treatment period.
Status
MEDLINE
Authors Full Name
Waters, Heidi C. Vanderpoel, Julie E. Nejadnik, Bijan. McKenzie, R Scott. Lunacsek, Orsolya E. Lennert, Barbara J. Goff, John. Augustyn, Damian H.
Institution
Janssen Scientific Affairs, LLC, Horsham, PA 19044, USA.
Date Created
20120119
Year of Publication
2012

EXCLUDED / PEDIATRIC ULCERATIVE COLITIS
6.
Cost-effectiveness analysis of adjunct VSL#3 therapy versus standard medical therapy in pediatric ulcerative colitis. [Review]
Park KT. Perez F. Tsai R. Honkanen A. Bass D. Garber A.
Journal of Pediatric Gastroenterology & Nutrition. 53(5):489-96, 2011 Nov.
[Comparative Study. Journal Article. Research Support, Non-U.S. Gov't. Review]
UI: 21694634
BACKGROUND: Inflammatory bowel diseases (IBDs) are costly chronic gastrointestinal diseases, with pediatric IBD representing increased costs per patient compared to adult disease. Health care expenditures for ulcerative colitis (UC) are >$2 billion annually. It is not clear whether the addition of VSL#3 to standard medical therapy in UC induction and maintenance of remission is a cost-effective strategy.
PATIENTS AND METHODS: We performed a systematic review of the literature and created a Markov model simulating a cohort of 10-year-old patients with severe UC, studying them until 100 years of age or death. We compared 2 strategies: standard medical therapy versus medical therapy + VSL#3. For both strategies, we assumed that patients progressed through escalating therapies--mesalamine, azathioprine, and infliximab--before receiving a colectomy + ileal pouch anal anastamosis (IPAA) if the 3 medical therapy options were exhausted. The primary outcome measure was the incremental cost-effectiveness ratio (ICER), defined as the difference of costs between strategies for each quality-adjusted life-year (QALY) gained. One-way sensitivity analyses were performed on variables to determine the key variables affecting cost-effectiveness.
RESULTS: Standard medical care accrued a lifetime cost of $203,317 per patient, compared to $212,582 per patient for medical therapy + VSL#3. Lifetime QALYs gained was comparable for standard medical therapy and medical therapy + VSL#3 at 24.93 versus 25.05, respectively. Using the definition of ICER <50,000/QALY as a cost-effective intervention, medical therapy + VSL#3 produced an ICER of $79,910 per QALY gained, making this strategy cost-ineffective. Sensitivity analyses showed that 4 key parameters could affect the cost-effectiveness of the 2 strategies: cost of colectomy + IPAA, maintenance cost after surgery, probability of developing pouchitis after surgery, and the quality of life after a colectomy + IPAA. High surgical and postsurgical costs, a high probability of developing pouchitis, and a low quality of life after a colectomy + IPAA could make adjunct VSL#3 use a cost-effective strategy.
CONCLUSIONS: Given present data, adjunct VSL#3 use for pediatric UC induction and maintenance of

remission is not cost-effective, although several key parameters could make this strategy cost-effective. The quality of life after an IPAA is the single most important variable predicting whether this procedure benefits patients over escalating standard medical therapy.
Status
MEDLINE
Authors Full Name
Park, K T. Perez, Felipe. Tsai, Raymond. Honkanen, Anita. Bass, Dorsey. Garber, Alan.
Institution
Division of Pediatric Gastroenterology, Hepatology, and Nutrition, Packard Children's Hospital, Stanford University Medical Center, Palo Alto, CA 94304, USA. ktpark@stanford.edu
Comments
Comment in: J Pediatr Gastroenterol Nutr. 2011 Nov;53(5):473; PMID: 21768884
Date Created
20111024
Year of Publication
2011

EXCLUDED / REVIEW
7.
Optimal use and cost-effectiveness of biologic therapies in inflammatory bowel disease. [Review]
Di Sabatino A. Liberato L. Marchetti M. Biancheri P. Corazza GR.
Internal & Emergency Medicine. 6 Suppl 1:17-27, 2011 Oct.
[Journal Article. Review]
UI: 22009609
Inflammatory bowel diseases (IBD), namely Crohn's disease and ulcerative colitis, are burdened by high medical costs which are mostly dependent on hospital inpatient treatment. New biologic therapies, which target specific cytokines in the inflammatory cascade leading to the intestinal lesions, including tumor necrosis factor (TNF)-, have revolutionized the management of IBD by offering a therapeutic chance to patients in whom conventional therapies failed. However, the relatively high costs of biologic drugs, together with their potential toxicity due to infections and malignancies, have led to debate regarding their indiscriminate use in IBD patients. The purpose of this review is to deal with the optimal use and cost-effectiveness of the two main monoclonal anti-TNF- agents currently used in the management of IBD patients, i.e. the chimeric human/murine antibody infliximab and the fully human antibody adalimumab.
Status
MEDLINE
Authors Full Name
Di Sabatino, Antonio. Liberato, Lucio. Marchetti, Monia. Biancheri, Paolo. Corazza, Gino R.
Institution
First Department of Medicine, Centro per lo Studio e la Cura delle Malattie Infiammatorie Croniche intestinali, Fondazione IRCCS Policlinico S. Matteo, University of Pavia, Pavia, Italy. a.disabatino@smatteo.pv.it
Date Created
20111019
Year of Publication
2011

EXCLUDED / NOT COST-UTILITY ANALYSIS
8.
Impact of persistence with infliximab on hospitalizations in ulcerative colitis.
Carter CT. Leher H. Smith P. Smith DB. Waters HC.
American Journal of Managed Care. 17(6):385-92, 2011 Jun.
[Journal Article. Research Support, Non-U.S. Gov't]
UI: 21756009
OBJECTIVES: To assess infliximab infusion patterns in ulcerative colitis (UC) and assess the impact of persistence with infliximab maintenance therapy on UC-related hospitalizations, lengths of stay, and inpatient costs.
STUDY DESIGN: Retrospective analysis of medical claims for UC patients newly initiating infliximab treatment.
METHODS: Patients were aged >18 years and had 2 UC diagnosis codes, an infliximab index date between September 1, 2005, and January 31, 2008, and continuous enrollment for >12 months before and >14 months after the index date. Infliximab induction (first 56 days postindex) and maintenance (>56 days and <12 months

postinduction) patterns were evaluated. Of patients with maintenance treatment, persistence was defined as a medication possession ratio (MPR) of >80%, and this group was compared with those without persistence (<80% MPR).
RESULTS: Overall, 420 patients were included in the analysis; 84.3% (n = 354) continued to maintenance therapy. Maintenance infusion patterns were consistent with recommended prescribing information. A smaller proportion of patients with maintenance therapy persistence required hospitalization compared with patients without persistence (3.0% vs 20.4%; P <.001). Hospitalized patients with maintenance therapy persistence had significantly lower mean inpatient costs ($14,243 vs $32,745; P = .046), with a trend toward shorter mean lengths of stay (6.67 vs 9.71 days; P = .147) than patients without persistence.
CONCLUSIONS: Infliximab maintenance therapy persistence in UC was associated with significantly fewer hospitalizations. Once hospitalized, patients with therapeutic persistence had significantly decreased inpatient costs.
Status
MEDLINE
Authors Full Name
Carter, Chureen T. Leher, Henry. Smith, Paula. Smith, Daniel B. Waters, Heidi C.
Institution
Centocor Ortho Biotech Services, LLC, 800 Ridgeview Dr., Horsham, PA 19044, USA. ccarte10@its.jnj.com
Date Created
20110715
Year of Publication
2011

INCLUDED
9.
Infliximab for the treatment of acute exacerbations of ulcerative colitis. [Review]
Bryan S. Andronis L. Hyde C. Connock M. Fry-Smith A. Wang D.
Health Technology Assessment (Winchester, England). 14 Suppl 1:9-15, 2010 May.
[Journal Article. Research Support, Non-U.S. Gov't. Review]
UI: 20507798
This paper presents a summary of the evidence review group (ERG) report into the clinical effectiveness and cost-effectiveness of infliximab for the treatment of acute exacerbations of ulcerative colitis, in accordance with the licensed indication, based upon the manufacturer's submission to the National Institute for Health and Clinical Excellence (NICE) as part of the single technology appraisal process. The submitted clinical evidence included four randomised controlled trials (RCTs), two comparing infliximab with placebo in patients not responsive to initial treatment with intravenous corticosteroids and one comparing ciclosporin with placebo. A fourth RCT compared ciclosporin with intravenous corticosteroids as the initial treatment after hospitalisation. The manufacturer's submission concluded that infliximab provides clinical benefit to patients with acute severe, steroid-refractory ulcerative colitis and is well tolerated; it also provides additional clinical benefits over ciclosporin, particularly avoidance of colectomy. A decision tree model was built to compare infliximab with strategies involving ciclosporin, standard care and surgery. After correcting a small number of errors in the model, the revised base-case incremental cost-effectiveness ratio (ICER) for infliximab compared with standard care was 20,000 pounds. However, sensitivity analyses revealed considerable uncertainty emanating from the weight of the patient, the timeframe considered and, most importantly, the colectomy rates used. When a more appropriate mix of trials were included in the estimation of colectomy rates, the ICER for infliximab rose to 48,000 pounds. The guidance issued by NICE on 31 October 2008 states that infliximab is recommended as an option for the treatment of acute exacerbations of severely active ulcerative colitis only in patients in whom ciclosporin is contraindicated or clinically inappropriate, based on a careful assessment of the risks and benefits of treatment in the individual patient; for people who do not meet this criterion, infliximab should only be used for the treatment of acute exacerbations of severely active ulcerative colitis in clinical trials.
Status
MEDLINE
Authors Full Name
Bryan, S. Andronis, L. Hyde, C. Connock, M. Fry-Smith, A. Wang, D.
Institution
West Midlands Health Technology Assessment Collaboration, Department of Public Health and Epidemiology, University of Birmingham, Edgbaston, Birmingham, UK.
Date Created
20100528
Year of Publication

2010

INCLUDED

10.
Cost-effectiveness of infliximab for the treatment of acute exacerbations of ulcerative colitis.
Punekar YS. Hawkins N.
European Journal of Health Economics. 11(1):67-76, 2010 Feb.
[Journal Article. Research Support, Non-U.S. Gov't]
UI: 19844750
BACKGROUND: Infliximab has been shown to be efficacious in acute exacerbations of ulcerative colitis (UC).
AIM: To evaluate the cost-effectiveness of infliximab treatment in patients hospitalised with acute exacerbations of UC.
METHODS: A decision analysis model was constructed to simulate the progression of acute UC patients treated with infliximab induction regimen over 1 year. Infliximab treatment was compared with standard care, ciclosporin and surgery using transitions derived from infliximab and ciclosporin randomised trials. Costs and outcomes were discounted at 3.5%. Intermediate outcomes of colectomy and post-surgery complications were translated into the primary effectiveness measurement, which was quality-adjusted life years (QALYs) estimated using EQ-5D. One-way and probabilistic sensitivity analyses were performed to estimate the uncertainty around the results.
RESULTS: The incremental cost effectiveness ratio (ICER) for infliximab was pound19,545 per QALY compared to ciclosporin, which in turn dominated standard care. Sensitivity analysis indicated patient body weight, utility estimates and treatment effect of alternative treatment strategies to be the most important factors affecting cost-effectiveness.
CONCLUSION: Infliximab induction regimen appears to be a cost-effective treatment option for UC patients hospitalised with an acute exacerbation.
Status
MEDLINE
Authors Full Name
Punekar, Yogesh Suresh. Hawkins, Neil.
Institution
Schering-Plough Ltd, Welwyn Garden City, AL7 1TW, UK. Yogesh.punekar@spcorp.com
Date Created
20100204
Year of Publication
2010

EXCLUDED / NOT COST-UTILITY ANALYSIS

11.
Inflammatory bowel disease in the United States from 1998 to 2005: has infliximab affected surgical rates?.
Cannom RR. Kaiser AM. Ault GT. Beart RW Jr. Etzioni DA.
American Surgeon. 75(10):976-80, 2009 Oct.
[Journal Article]
UI: 19886148
B13 Raktari jelzet: A 243 (Am Surg); USA, Baltimore-Philadelphia, ISSN 0003-1348; 1953:19, 1960:26 - 1965:31, 1967:33 -
The treatment costs for patients in the United States with inflammatory bowel disease (IBD) exceed 1.7 billion dollars/year. Infliximab, an antibody to tumor necrosis factor-alpha has been extensively used to treat IBD, with 390,000 IBD patients receiving the drug since its FDA approval in 1998. We sought to determine the impact of infliximab on population-based rates of hospitalizations and surgical care for patients with IBD in the United States. We used data from the Nationwide Inpatient Sample to analyze patterns of hospital-based treatment provided to patients with IBD between 1998 and 2005. Data from this analysis were combined with census data to calculate trends in population-based rates of treatment. Overall rates of hospitalization for patients with Crohn's disease and ulcerative colitis increased significantly between 1998 and 2005 (5.1%/year and 3.4%/year respectively, $P < 0.001$ for each). During the same time period there were no changes in the overall rates of surgical care. The expanding use of infliximab has not significantly impacted the use of surgical procedures for patients with either ulcerative colitis or Crohn's disease, and rates of nonsurgical hospitalizations have actually increased. Even in the era of infliximab, surgical care remains a mainstay in the treatment of IBD.
Status
MEDLINE

Authors Full Name
Cannom, Rebecca R. Kaiser, Andreas M. Ault, Glenn T. Beart, Robert W Jr. Etzioni, David A.
Institution
Department of Colorectal Surgery, Keck School of Medicine, University of Southern California, Los Angeles, California 90033, USA. rcannom@surgery.usc.edu
Date Created
20091104
Year of Publication
2009

INCLUDED
12.
Infliximab for the treatment of ulcerative colitis. [Review] [2 refs]
Hyde C. Bryan S. Juarez-Garcia A. Andronis L. Fry-Smith A.
Health Technology Assessment (Winchester, England). 13 Suppl 3:7-11, 2009 Oct.
[Journal Article. Research Support, Non-U.S. Gov't. Review]
UI: 19846023
This paper presents a summary of the evidence review group (ERG) report into the clinical effectiveness and cost-effectiveness of infliximab for moderately to severely active ulcerative colitis (UC) based upon a review of the manufacturer's submission to the National Institute for Health and Clinical Excellent (NICE) as part of the single technology appraisal (STA) process. The submission indicated that the efficacy of infliximab (5 mg/kg) had been demonstrated in terms of higher response rates and a sustained response in health-related quality of life. For the cost-effectiveness analysis, the manufacturer built a Markov model to compare infliximab with standard care. It estimated the incremental cost per quality-adjusted life-year (QALY) gained was between 25,044 pounds and 33,866 pounds depending on the strategy used. The ERG report generally agreed with the evidence on effectiveness of infliximab for subacute exacerbations of UC. However, there were several areas of uncertainty, of which the interpretation of the importance of the quality of life changes in the subacute situation and the assessment of the adequacy of the evidence of effectiveness of infliximab in the acute hospital-based situation were considered pre-eminent by the ERG. This challenged the estimates of cost-effectiveness offered and suggested that there should be a separate assessment of infliximab for acute exacerbations of moderately to severely active UC. The summary of the NICE guidance issued in April 2008 as a result of the STA states that: infliximab is not recommended for the treatment of subacute manifestations of moderately to severely active UC. [References: 2]
Status
MEDLINE
Authors Full Name
Hyde, C. Bryan, S. Juarez-Garcia, A. Andronis, L. Fry-Smith, A.
Institution
West Midlands Health Technology Assessment Collaboration, Department of Public Health and Epidemiology, University of Birmingham, UK. c.j.hyde@bham.ac.uk
Date Created
20091022
Year of Publication
2009

EXCLUDED / NOT COST-UTILITY ANALYSIS
13.
Biologics for inflammatory bowel diseases in the Asia-Pacific: can we afford to use them, can we afford not to?.
Gearry RB. Irving PM.
Journal of Gastroenterology & Hepatology. 24(7):1160-2, 2009 Jul.
[Comment. Editorial]
UI: 19682189
Status
MEDLINE
Authors Full Name
Gearry, Richard B. Irving, Peter M.
Comments
Comment on: J Gastroenterol Hepatol. 2009 Jul;24(7):1252-7; PMID: 19220669
Date Created

20090817
Year of Publication
2009
EXCLUDED / NOT COST-UTILITY ANALYSIS
14.
Selecting appropriate anti-TNF agents in inflammatory bowel disease. [Review] [59 refs]
Yun L. Hanauer S.
Expert review of gastroenterology & hepatology. 3(3):235-48, 2009 Jun.
[Journal Article. Review]
UI: 19485806
Infliximab was the first anti-TNF agent to be approved by the US FDA for the treatment of Crohn's disease (CD) in 1998. In the past 10 years, two other agents, adalimumab and certolizumab pegol, have also been approved for the treatment of CD. In the absence of head-to-head comparisons, the efficacy of these agents appear to be similar for the treatment of luminal CD. There are also prospective, randomized, controlled data to support the use of infliximab for the treatment of fistulizing CD and ulcerative colitis, and supportive post hoc data for the use of adalimumab and certolizumab pegol for the treatment of fistulizing CD. Practical matters, such as patient preference regarding the mode of administration, approval by third-party payers and residual patient cost, may actually play a larger role in choosing a particular anti-TNF agent, as efficacy and safety issues are similar for all three. Unfortunately, many patients do not respond, lose response or develop intolerance to anti-TNF treatment. Thus, new therapies are needed. Natalizumab, the first biologic that is not an anti-TNF agent, was FDA-approved in January 2008 for the treatment of CD patients who have failed conventional treatment, including anti-TNF therapy. As we continue to learn more about the pathogenesis of inflammatory bowel disease, novel targets for drug therapy are being developed. [References: 59]
Status
MEDLINE
Authors Full Name
Yun, Laura. Hanauer, Stephen.
Institution
Division of Gastroenterology, Department of Medicine, University of Chicago Hospitals, Chicago, IL 60637, USA.
Date Created
20090602
Year of Publication
2009

15.
Cost-effectiveness of 5-aminosalicylic acid therapy for maintenance of remission in ulcerative colitis.
Yen EF. Kane SV. Ladabaum U.
American Journal of Gastroenterology. 103(12):3094-105, 2008 Dec.
[Journal Article. Research Support, Non-U.S. Gov't]
UI: 18775007
B13 Raktari jelzet: A 181 (Am J Gastroenterol); USA, Baltimore, ISSN 0002-9270; 1954:21 -
OBJECTIVES: Oral 5-aminosalicylic acid (5-ASA, mesalamine) is effective in inducing and maintaining remission in ulcerative colitis (UC). The relative benefits and costs of maintenance 5-ASA therapy are uncertain. Our aims were to evaluate this strategy's potential cost-effectiveness.
METHODS: We constructed a Markov model to compare two strategies over 2 yr: (a) no maintenance 5-ASA, with 5-ASA 4.8 g/day given for flares, (b) maintenance 5-ASA 2.4 g/day, escalated and maintained at 4.8 g/day after the first flare. In both arms, the failure to induce remission led to other treatments, as needed: prednisone, parenteral corticosteroids, cyclosporine, 6-mercaptopurine, infliximab, and colectomy.
RESULTS: Without maintenance 5-ASA, the mean flares per person were 1.92, and the mean cost per person was $3,402. With maintenance 5-ASA providing a relative risk of flare of 0.7 at 5-ASA cost of $198/month, flares per person decreased to 1.38 at a cost of $8,810/flare prevented. Maintenance 5-ASA increased discounted quality-adjusted life-years per person (QALYs per person) from 1.75 to 1.77 at a discounted cost of $224,000/QALY gained. The results were most sensitive to the flare risk reduction and cost of 5-ASA, the utilities of being in remission without or with 5-ASA, and the colectomy rates. At $15/month (the cost of sulfasalazine), maintenance 5-ASA cost $640/flare prevented and $16,300/QALY gained.
CONCLUSION: Maintenance 5-ASA therapy decreases UC flares, but its cost may be substantial, depending on society's willingness to pay. If sulfasalazine can be tolerated and yields comparable benefits, sulfasalazine maintenance therapy is likely to be cost-effective. The cost per QALY gained by 5-ASA maintenance is highly

dependent on the quality of life while taking versus not taking maintenance 5-ASA, highlighting the importance of patients' preferences.
Status
MEDLINE
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Date Created
20081217
Year of Publication
2008

EXCLUDED / NOT COST-UTILITY ANALYSIS
16.
How expensive is inflammatory bowel disease? A critical analysis. [Review] [38 refs]
Odes S.
World Journal of Gastroenterology. 14(43):6641-7, 2008 Nov 21.
[Journal Article. Review]
UI: 19034966
Economic analysis of chronic diseases is required for proper allocation of resources and understanding cost-effectiveness studies of new therapies. Studies on health care cost of ulcerative colitis (UC) and Crohn's disease (CD) are reviewed here. These studies were carried out in various countries with disparate health care systems. In the United States, data were often modeled or retrieved from large insurance schemes. Surgery and in-patient hospitalization accounted for over half the outlay on UC and CD. Fistulous disease in CD and parenteral nutrition were very costly. In Canada, overall charges were lower than in the United States, but there too, surgical costs were relatively high. In European studies, economic data were abstracted directly from patients' files. One pan-European study examined the outlay on UC and CD in a community-based prospective inception cohort followed for 10 years. Overall costs in Europe were lower than in the United States. Surgery, hospitalization, year of follow-up, disease phenotype in CD and ASCA-positivity impacted significantly on costs. In all studies, the cost data were right skewed, aminosalicylates were expensive drugs, and biological agents the most expensive; moreover indirect costs were not calculated. Infliximab raised costs considerably in CD, but there were no long-term follow-up studies, so that the cost-benefit of biological agents remains unknown. In conclusion, costs of managing UC and CD vary by country, surgery, genotype and several other factors. The most important question for further research is whether the biological therapies are cost-effective in the long-term. [References: 38]
Status
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Other ID
Source: NLM. PMC2773305
Date Created
20081126
Year of Publication
2008

INCLUDED
17.
A model of the long-term cost effectiveness of scheduled maintenance treatment with infliximab for moderate-to-severe ulcerative colitis.
Tsai HH. Punekar YS. Morris J. Fortun P.
Alimentary Pharmacology & Therapeutics. 28(10):1230-9, 2008 Nov 15.
[Journal Article. Research Support, Non-U.S. Gov't]
UI: 18729845
B13 Raktari jelzet: A 305 (Aliment Pharm Ther); GBR, Oxford, ISSN 0269-2813; 1990:4 -

BACKGROUND: Infliximab (IFX) has been shown to be efficacious in moderate-severe ulcerative colitis (UC). Aim To evaluate the cost-effectiveness of a scheduled maintenance treatment (SMT) with IFX in moderate-severe UC patients.
METHODS: A Markov model was constructed to simulate the progression of a cohort of moderate-severe UC patients treated with IFX (5 mg/kg) SMT. Transitions were estimated from two phase III trials of IFX (ACT I and ACT II). Standard care, comprising immunomodulators and/or corticosteroids was used as a comparator. Two separate treatment strategies were evaluated - continued treatment in IFX responders and continued treatment in IFX patients achieving remission. The dose of IFX was estimated for a 73 kg typical UC patient in the UK. The results were calculated over 10 years using a discount rate of 3.5% for costs and outcomes. The outcome measure was quality-adjusted life years (QALYs) estimated using EQ-5D. Sensitivity analyses explored the uncertainty around the results.
RESULTS: The incremental cost effectiveness ratio (ICER) for IFX was 27,424 pounds in the responder strategy and 19,696 pounds in the remission strategy at 10 years. In sensitivity analysis, the ICER for IFX in the responder strategy ranged from 21,066 pounds to 86,322 pounds and in the remission strategy ranged from 14,728 pounds to 46,765 pounds. The model time horizon and patient body weight were important factors affecting results.
CONCLUSION: Eight-week SMT with IFX appears to be a cost-effective treatment option for adult patients suffering from moderate to severe UC.
Status
MEDLINE
Authors Full Name
Tsai, H H. Punekar, Y S. Morris, J. Fortun, P.
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Date Created
20081030
Year of Publication
2008

EXCLUDED / NOT COST-UTILITY ANALYSIS
18.
Impact of preoperative infliximab use on postoperative infectious complications in ulcerative colitis: the price we have to pay?.
Shen B.
Inflammatory Bowel Diseases. 14(7):1019-21, 2008 Jul.
[Journal Article]
UI: 18300280
Status
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Date Created
20080612
Year of Publication
2008

EXCLUDED / NOT COST-UTILITY ANALYSIS
19.
A review of infliximab use in ulcerative colitis. [Review] [20 refs]
Wilhelm SM. McKenney KA. Rivait KN. Kale-Pradhan PB.
Clinical Therapeutics. 30(2):223-30, 2008 Feb.
[Journal Article. Review]
UI: 18343261
BACKGROUND: Infliximab is a chimeric immunoglobulin G1kappa monoclonal antibody that binds with high affinity and specificity to the soluble form of tumor necrosis factor (TNF)-alpha, preventing it from binding to cellular receptors. Infliximab also binds to membranebound TNF-alpha found on inflammatory cell surfaces,

inducing apoptosis. Currently, infliximab is used for the induction and maintenance of remission in Crohn's disease (CD), with documented success. Infliximab's efficacy in the treatment of ulcerative colitis (UC) is now being investigated due to the similarities in the pathophysiology of CD and UC.
OBJECTIVE: The aim of this study was to review and evaluate the current literature of infliximab use in steroid-refractory UC to assess its role in treatment.
METHODS: A search of MEDLINE was conducted (1950-November 2007). Key terms included, but were not limited to, infliximab, inflammatory bowel disease, ulcerative colitis, cost, and quality of life. Studies included for review were limited to English-language, full-text, randomized, double-blind, placebo-controlled trials. Clinical trials were reviewed and summarized.
RESULTS: Four controlled clinical trials of infliximab in the treatment of steroid-refractory UC were found and assessed. In a double-blind, randomized, controlled trial in 43 patients with moderately severe, glucocorticoid-resistant UC, infliximab and placebo were not significantly different with respect to clinical and sigmoidoscopic remission or quality of life 2 and 6 weeks after infliximab treatment. In a multicenter, randomized, double-blind, placebo-controlled study in 45 patients with moderately severe to severe glucocorticoid-resistant UC, infliximab was associated with a significantly reduced need for colectomy compared with placebo (29% vs 67%; P=0.017). The Active Ulcerative Colitis Trials (ACT) 1 and 2 together included 728 patients with moderate to severe glucocorticoid-resistant UC. The primary outcome, the rate of clinical response at 8 weeks, was significantly higher with infliximab compared with placebo (5 mg/kg: ACT 1, 69.4%, ACT 2, 64.5%; 10 mg/kg: ACT 1, 61.5%, ACT 2, 69.2%; placebo: ACT 1, 37.2%;, ACT 2, 29.3%; all, P < 0.001 vs placebo). Based on the data from ACT 1 and 2, infliximab was associated with improved health-related quality-of-life (HRQOL) scores based on the Inflammatory Bowel Disease Questionnaire and the 36-item Short Form Health Survey.
CONCLUSIONS: Current data suggest that infliximab is an effective alternative treatment option for patients with moderate to severe UC with an inadequate response to conventional glucocorticoid treatment. Further trials are needed to assess infliximab's impact on the treatment and progression of UC, the HRQL of patients with UC, and the economic impact on the health care system. [References: 20]
Status
MEDLINE
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Date Created
20080317
Year of Publication
2008

EXCLUDED / NOT COST-UTILITY ANALYSIS
20.
Careful patient selection may improve response rates to infliximab in inflammatory bowel disease.
Pearce CB. Lawrance IC.
Journal of Gastroenterology & Hepatology. 22(10):1671-7, 2007 Oct.
[Journal Article]
UI: 17845695
BACKGROUND AND AIM: The use of infliximab in the treatment of Crohn's disease (CD) is acceptable and appears to be effective in ulcerative colitis (UC). Careful patient selection, resulting in infliximab only for truly refractory inflammatory bowel disease (IBD), may improve its efficacy. The present study aimed to determine if careful patient selection improved infliximab efficacy in IBD.
METHODS: CD or UC/IBD unclassified patients (Montreal classification) were considered for infliximab treatment only after failure of disease control with conventional therapies and confirmation of active disease. Patients with purely luminal IBD received a single infliximab dose. Patients with fistulizing disease (with or without luminal disease) received infliximab at 0, 2 and 6 weeks. Changes to Harvey Bradshaw (HBI) for inflammatory CD and Colitis Activity Index (CAI) for UC/IBDU were used to determine the response and remission rates. In fistulizing CD, a remission was sustained cessation of drainage and resolution of the fistula. Response was correlated to inflammatory marker levels.
RESULTS: Seventy IBD patients were treated. In CD, 85.2% (46/54) had active luminal and 40.7% (22/54) had fistulizing disease. In luminal CD, at 8 weeks a single infliximab dose induced remission in 75% (24/32) of patients compared to 92.9% (13/14) after infliximab at 0, 2 and 6 weeks. Fistulizing disease responded in 77.2% (17/22) and remitted in 50% (11/22) of patients at 8 weeks. In UC/IBDU, 75% (12/16) responded and 43.8% (7/16) of patients were in remission at 8 weeks.

CONCLUSION: Careful patient selection may improve infliximab's efficacy and clinical remission appears greater after induction with three infliximab doses in CD. Clinical efficacy is suggested for UC/IBDU.
Status
MEDLINE
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Comments
Comment in: J Gastroenterol Hepatol. 2007 Oct;22(10):1559-61; PMID: 17845681
Date Created
20070911
Year of Publication
2007

EXCLUDED / NOT COST-UTILITY ANALYSIS
21.
Inflammatory bowel disease: current therapeutic options. [Review] [43 refs]
Domenech E.
Digestion. 73 Suppl 1:67-76, 2006.
[Journal Article. Review]
UI: 16498254
B 13 Raktari jelzet: A 116; CHE, Basel, ISSN 0012-2823; 1968:1 - ; Elobb: Gastroenterologia
Medical management of inflammatory bowel diseases (IBD) includes two treatment strategies: induction and maintenance of remission. 5-Aminosalicylates are mostly used for mild active IBD and for maintenance treatment in ulcerative colitis (UC). Glucocorticoids remain, despite their frequent (and occasionally severe) side effects, as the mainstay for induction of remission in moderate to severe active IBD, both UC and Crohn's disease (CD). Cyclosporine and infliximab have emerged as the main, rapid-acting, alternatives in steroid-refractory UC and CD, respectively. Thiopurines (azathioprine and 6-mercaptopurine) are the most efficient and used immunomodulators in IBD; steroid refractoriness, steroid dependency, and long-term maintenance of remission for both UC and CD are their main indications. Methotrexate and infliximab may be used in the same clinical settings as thiopurines in CD, but not in UC; however, these drugs are a second-line treatment because of safety profile and economic costs. Copyright 2006 S. Karger AG, Basel. [References: 43]
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20060224
Year of Publication
2006

EXCLUDED / NOT COST-UTILITY ANALYSIS
22.
Cyclosporine A for induction of remission in severe ulcerative colitis. [Review] [54 refs]
Shibolet O. Regushevskaya E. Brezis M. Soares-Weiser K.
Cochrane Database of Systematic Reviews. (1):CD004277, 2005.
[Journal Article. Review]
UI: 15674937
BACKGROUND: Ulcerative colitis (UC) is characterized by a life-long chronic course with remissions and exacerbations. Approximately 15% of patients have a severe attack requiring hospitalization at some time during their illness. These patients are traditionally treated with intravenous corticosteroids, with a response rate of approximately 60%. The patients who do not respond to steroid treatment usually require surgical removal of the large bowel (proctocolectomy or colectomy with an anal pouch). This surgical procedure essentially cures the patient from the disease but is associated with complications such as pouchitis. Few alternative treatments exist for severe ulcerative colitis: immunosuppressive medications (such as azathioprine) have a slow onset of action and are therefore usually ineffective. Antibiotics are not proven to be effective and biological treatments

such as infliximab are still under investigation. The introduction of cyclosporine-A (CsA) for use in patients with severe ulcerative colitis (UC) has provided an alternative to patients previously facing only surgical options. Cyclosporine acts mainly by inhibiting T lymphocyte function, which is essential for the propagation of inflammation. Unlike most other immunosuppressive agents, CsA does not suppress the activity of other hematopoietic cells, does not cause bone marrow suppression and has a rapid onset of action. This reviews aims to systematically assess the effectiveness and safety of CsA for severe UC.
OBJECTIVES: This review aimed to evaluate the effectiveness of cyclosporine A for patients with severe ulcerative colitis.
SEARCH STRATEGY: Electronic searches of The Cochrane Library (Issue 1, 2004), EMBASE (1980-2004), and MEDLINE (1966-2004); hand searching the references of all identified studies; contacting the first author of each included trial.
SELECTION CRITERIA: Randomised clinical trials comparing cyclosporine A with placebo or no intervention to obtain and maintain remission of idiopathic ulcerative colitis.
DATA COLLECTION AND ANALYSIS: Two reviewers independently appraised the quality of each trial and extracted the data from the included trials. Relative risks (RR) with 95% confidence intervals (CI) were estimated. The reviewers assumed an intention to treat analysis for the outcome measures.
MAIN RESULTS: Only two randomized controlled trials were identified that satisfied the inclusion criteria. These two trials could not be pooled for analysis because of major differences in design and patient populations. In the first trial, 11 patients received intravenous cyclosporine (4 mg/kg) and 9 received placebo. Two of 11 in the treatment group failed to respond to therapy compared with nine of nine in the placebo group (RR 0.18, 95% CI 0.05 - 0.64). However, 3/11 and 4/9 eventually underwent colectomy in the treatment and placebo groups respectively and follow-up was less than a month. In the second trial 15 patients were treated with intravenous cyclosporine and 15 with intravenous methylprednisolone. Five of 15 patients in the cyclosporine group failed to respond to therapy as compared to 7/15 in the methylprednisolone group (RR 0.71, 95% CI 0.29 - 1.75). After 1 year 7/9 responders in the cyclosporine group were still in remission compared with 4/8 in the steroid group ($p > 0.05$) and the colectomy rate was similar in both groups. The mean time to response in the cyclosporine group in the 2 trials was short (7 days and 5.2 days). These results should be interpreted with caution given the small numbers of trials and patients evaluated for comparison, and limited follow-up (few weeks in one trial to a year in the other). The precise assessment of the occurrence of adverse events was difficult because the trials described different adverse reactions, which reversed after discontinuation of cyclosporine. There was no evidence in the trials reviewed that cyclosporine was more effective than standard treatment for preventing colectomy but this effect cannot be excluded due to the small sample size and rarity of this outcome. Additional limitations of current research include lack of data on quality of life, costs and long-term results of cyclosporine therapy.
AUTHORS' CONCLUSIONS: There is limited evidence that cyclosporine is more effective than standard treatment alone for severe ulcerative colitis. The relatively quick response makes the short-term use of cyclosporine potentially attractive, but the long-term benefit is unclear, when adverse events such as cyclosporine-induced nephrotoxicity may become more obvious. There is a need for additional research on quality of life, costs and long-term results from cyclosporine therapy in severe ulcerative colitis. [References: 54]
Status
MEDLINE
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Date Created
20050127
Year of Publication
2005

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations (5 hits)

EXCLUDED / NOT COST-UTILITY ANALYSIS

1.

Immunosuppressive and biologic therapy for ulcerative colitis.

Ardizzone S. Cassinotti A. de Franchis R.

Expert Opinion on Emerging Drugs. 17(4):449-67, 2012 Dec.

[Journal Article. Research Support, Non-U.S. Gov't]

UI: 23163556

INTRODUCTIon: Recent insight into the pathogenesis of ulcerative colitis have led to the development of new treatment options. A better understanding of IBD pathophysiology has progressively led to a more frequent use of immunosuppressants and biologics. AREAS COVERED: The use of the conventional immunomodulators, such as azathioprine, 6-mercaptopurine, methotrexate, cyclosporine and tacrolimus, and anti-TNF- agents, such as infliximab and adalimumab, in the treatment of ulcerative colitis are reviewed. Moreover, the ongoing studies evaluating the efficacy of emerging immunosuppressants in treating patients with ulcerative colitis are discussed. An effort is made to explore some critical areas in which early and more diffuse use of these agents may be advocated. EXPERT OPINION: Ulcerative colitis is a chronic condition mainly affecting young people in their more productive age, and determining high indirect costs to the patient and to society. Thus, there is a need for optimizing and renewing our traditional therapeutic approach to UC, and new therapies beyond conventional treatment options possibly aiming to change the poor clinical course of many patients with ulcerative colitis. Keeping in mind this potentially new therapeutic scenario, there are some critical areas in which early and more diffuse use of conventional and emerging new immunomodulators is advocated.

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Date Created

20121128

Year of Publication

2012

EXCLUDED / NOT COST-UTILITY ANALYSIS

2.

Mucosal healing in inflammatory bowel disease-a true paradigm of success?.

Dave M. Loftus EV Jr.

Gastroenterology & Hepatology. 8(1):29-38, 2012 Jan.

[Journal Article]

UI: 22347830

Mucosal healing is gaining more acceptance as a measure of disease activity in Crohn's disease and ulcerative colitis, and it is also gaining acceptance as an endpoint in clinical trials. Recent publications have correlated achievement of mucosal healing with good outcomes. Currently, there is no validated definition of what constitutes mucosal healing in inflammatory bowel disease. In clinical trials of ulcerative colitis, mucosal healing has been achieved with 5-aminosalicylates, corticosteroids, azathioprine, and infliximab. For Crohn's disease, mucosal healing has been achieved with corticosteroids, infliximab, and adalimumab, and mucosal healing has been maintained with infliximab. Achievement of long-term mucosal healing has been associated with a decreased risk of colectomy and colorectal cancer in ulcerative colitis patients, a decreased need for cortico-steroid treatment in Crohn's disease patients, and a trend toward a decreased need for hospitalization in Crohn's disease patients. Unfortunately, assessment of mucosal healing requires regular use of endoscopy, which is associated with increased costs, patient discomfort, and side effects. Biomarkers such as fecal calprotec-tin, fecal lactoferrin, serum C-reactive protein, and fecal S1 00A1 2 have been shown to correlate with disease activity in ulcerative colitis and Crohn's disease; in the future, these biomarkers might be used as surrogate markers for mucosal healing. Newer clinical trials are incorporating mucosal healing as an endpoint for evaluation of efficacy. However, before mucosal healing will be sufficient to guide therapy, clinicians need a standard definition of mucosal healing and a consistently used, prospectively validated scale with good interobserver agreement.

Status

PubMed-not-MEDLINE

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Other ID
Source: NLM. PMC3277196
Date Created
20120220
Year of Publication
2012

EXCLUDED / NOT COST-UTILITY ANALYSIS
3.
The impact of biologics on health-related quality of life in patients with inflammatory bowel disease.
Vogelaar L. Spijker AV. van der Woude CJ.
Clinical & Experimental Gastroenterology. 2:101-9, 2009.
[Journal Article]
UI: 21694833
BACKGROUND: Inflammatory bowel disease (IBD) is characterized by a chronic relapsing inflammation of the gastrointestinal tract. Adult IBD patients suffer from a disabling disease which greatly affects health-related quality of life (HRQoL). A worse HRQoL in these patients may result in a defensive and ineffective use of medical attention and thus higher medical costs. Because of its chronic nature, IBD may also cause psychological problems in many patients which may also influence HRQoL and care-seeking behavior. An important factor reducing HRQoL is disease activity. Induction of remission and long-term remission are important goals for improving HRQoL. Furthermore, remission is associated with a decreased need for hospitalization and surgery and increased employment, which in turn improve HRQoL. Treatment strategies available for many years are corticosteroids, 5-aminosalicylates and immunnosuppressants, but these treatments did not show significant long-term improvement on HRQoL. The biologics, which induce rapid and sustained remission, may improve HRQoL.
OBJECTIVE: To review and evaluate the current literature on the effect of biologics on HRQoL of IBD patients.
METHODS: We performed a MEDLINE search and reviewed the effect of different biologics on HRQoL. The following subjects and synonyms of these terms were used: inflammatory bowel disease, Crohn's disease, ulcerative colitis, quality of life, health-related quality of life, fatigue, different anti-TNF medication, and biologicals/biologics (MESH). Studies included were limited to English-language, adult population, full-text, randomized, double-blind, placebo-controlled in which HRQoL was measured.
RESULTS: Out of 202 identified articles, 8 randomized controlled trials (RCT) met the inclusion criteria. Two RCTs on infliximab showed significant improvement of HRQoL compared to placebo which was sustained over the long term. One RCT on adalimumab showed a significant and sustained improvement of HRQoL compared to placebo. This study showed also significant decrease of fatigue in the adalimumab-treated patients. Three RCTs on certolizumab showed a significant improvement of HRQoL in the intervention group compared to placebo. Two RCTs of natalizumab treatment were found. One study showed significant and sustained improvement compared to placebo, and also scores of HRQoL comparable to that in the general population, but in the other no significant results were found.
CONCLUSION: The biologics infliximab, adalimumab, certolizumab, and natalizumab demonstrated significant improvement of HRQoL of IBD patients compared with placebo. However, we found differences in improvement of HRQoL between the different biologics.
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PubMed-not-MEDLINE
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Source: NLM. PMC3108643
Date Created
20110622
Year of Publication
2009

INCLUDED

4.
An economic evaluation comparing concomitant oral and topical mesalazine versus oral mesalazine alone in mild-to-moderately active ulcerative colitis based on results from randomised controlled trial.
Connolly MP. Nielsen SK. Currie CJ. Marteau P. Probert CS. Travis SP.
Journal of Crohn's & colitis. 3(3):168-74, 2009 Sep.
[Journal Article]
UI: 21172266
INTRODUCTION: A previous randomised controlled trial has demonstrated that oral plus topical mesalazine enema is more effective than oral mesalazine alone for achieving clinical remission in mild-to-moderately active extensive ulcerative colitis (UC). To evaluate whether this strategy is cost-effective we conducted an economic evaluation comparing 1g topical mesalazine in combination with 4g oral mesalazine compared to 4g mesalazine monotherapy in mild-to-moderately active UC.
METHODS: The economic evaluation was based on the ability to achieve remission using changes from baseline in the ulcerative colitis disease activity instrument (UCDAI). A cost-utility analysis was used where the main outcome was quality-adjusted life years to reflect improved quality of life associated with achieving remission compared with active disease. A simulated Markov model with five health states was constructed to model cost and outcome changes over time: (1) active UC; (2) mesalazine-refractory active UC; (3) steroid-refractory active UC; (4) infliximab-responsive active UC; and (5) remission. To reflect parameter uncertainty in the cost-effectiveness analysis probabilistic sensitivity analysis (PSA) was conducted by varying relevant clinical parameters.
RESULTS: Average treatment costs required to transition a patient from active UC to remission using oral and topical mesalazine compared with oral alone were 1812 and 2390, respectively. Improved remission rates attributed to oral and topical mesalazine resulted in moderate improvements in quality-adjusted life years (QALYs) compared to oral mesalazine alone. Disaggregation of medical costs indicated that medical consultations and diagnostic costs were similar for both treatment arms. An abbreviated analysis which considered costs up to steroid-refractory patients in subacute UC indicated that combination therapy offered a cost-savings of 285 over 16weeks of therapy compared with monotherapy.
CONCLUSIONS: The results indicate that the addition of 1g topical mesalazine results in significant cost-savings and moderate quality of life improvements. We have also shown that irrespective of which treatment modality is used in steroid-refractory patients (eg, infliximab, azathioprine, ciclosporine) that topical mesalazine is cost-saving.
Status
PubMed-not-MEDLINE
Authors Full Name
Connolly, Mark P. Nielsen, Sandy K. Currie, Craig J. Marteau, Philippe. Probert, Chris S J. Travis, Simon P L.
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Date Created
20101221
Year of Publication
2009

INCLUDED
5.
Cost-utility analysis of infliximab and adalimumab for refractory ulcerative colitis.
Xie F. Blackhouse G. Assasi N. Gaebel K. Robertson D. Goeree R.
Cost Effectiveness & Resource Allocation. 7:20, 2009.
[Journal Article]
UI: 20003364
OBJECTIVE: To evaluate cost-utility of infliximab and adalimumab for the treatment of moderate-to-severe ulcerative colitis (UC) refractory to conventional therapies in Canada.
METHODS: A Markov model was constructed to evaluate incremental cost-utility ratios (ICUR) of 5 mg/kg and 10 mg/kg infliximab and adalimumab therapies compared to 'usual care' in treating a hypothetical cohort of patients (aged 40 years and weighing 80 kg) over a five-year time horizon from the perspective of a publicly-funded health care system. Clinical parameters were derived from the Active Ulcerative Colitis Trials 1 and 2. Costs were obtained through provincial drug benefit plans. ICUR was the main outcome measure and both deterministic and probabilistic sensitivity analyses were conducted.
RESULTS: Compared to the strategy A ('usual care') in the base case analysis, the ICURs were CA$358,088/QALY for the strategy B ('5 mg/kg infliximab + adalimumab') and CA$575,540/QALY for the

strategy C ('5 mg/kg and 10 mg/kg infliximab + adalimumab'). The results were sensitive to: the remission rates maintained in responders to 'usual care' and to 5 mg/kg infliximab, the rate of remission induced by adalimumab in non-responders to 5 mg/kg infliximab, early surgery rate, and utility values. When the willingness to pay (WTP) was less than CA$150,000/QALY, the probability of 'usual care' being the optimal strategy was 1.0. The probability of strategy B being optimal was 0.5 when the WTP approximated CA$400,000/QALY.
CONCLUSIONS: The ICURs of anti-TNF-alpha drugs were not satisfactory in treating patients with moderate-to-severe refractory UC. Future research could be aimed at the long-term clinical benefits of these drugs, especially adalimumab for patients intolerant or unresponsive to infliximab treatment.
Status
PubMed-not-MEDLINE
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Source: NLM. PMC2797497
Date Created
20091224
Year of Publication
2009

Web of knowledge (93 hits)

EXCLUDED / NOT COST-UTILITY ANALYSIS

FN Thomson Reuters Web of Knowledge

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PT J

AU Ardizzone, S
Cassinotti, A
de Franchis, R

AF Ardizzone, Sandro
Cassinotti, Andrea
de Franchis, Roberto

TI Immunosuppressive and biologic therapy for ulcerative colitis

SO EXPERT OPINION ON EMERGING DRUGS

AB Introduction: Recent insight into the pathogenesis of ulcerative colitis have led to the development of new treatment options. A better understanding of IBD pathophysiology has progressively led to a more frequent use of immunosuppressants and biologics.
Areas covered: The use of the conventional immunomodulators, such as azathioprine, 6-mercaptopurine, methotrexate, cyclosporine and tacrolimus, and anti-TNF-alpha agents, such as infliximab and adalimumab, in the treatment of ulcerative colitis are reviewed. Moreover, the ongoing studies evaluating the efficacy of emerging immunosuppressants in treating patients with ulcerative colitis are discussed. An effort is made to explore some critical areas in which early and more diffuse use of these agents may be advocated.
Expert opinion: Ulcerative colitis is a chronic condition mainly affecting young people in their more productive age, and determining high indirect costs to the patient and to society. Thus, there is a need for optimizing and renewing our traditional therapeutic approach to UC, and new therapies beyond conventional treatment options possibly aiming to change the poor clinical course of many patients with ulcerative colitis. Keeping in mind this potentially new therapeutic scenario, there are some critical areas in which early and more diffuse use of conventional and emerging new immunomodulators is advocated.

TC 0

Z9 0

SN 1472-8214

PD DEC

PY 2012

VL 17

IS 4

BP 449

EP 467

DI 10.1517/14728214.2012.744820

UT WOS:000311631100003

ER

6

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Stone, CD

AF Stone, Christian D.

TI The Economic Burden of Inflammatory Bowel Disease: Clear Problem, Unclear Solution

SO DIGESTIVE DISEASES AND SCIENCES

TC 0

Z9 0

SN 0163-2116

PD DEC

PY 2012

VL 57

IS 12
BP 3042
EP 3044
DI 10.1007/s10620-012-2417-8
UT WOS:000311513900002
ER

7

EXLUDED / ABSTRACT

PT J
AU Holubar, S
Piazik, B
Xu, K
Dulai, P
Tosteson, A
Siegel, C
Finlayson, S
AF Holubar, Stefan
Piazik, Breanne
Xu, Kathleen
Dulai, Parambir
Tosteson, Anne
Siegel, Corey
Finlayson, Samuel
TI Cost-Effectiveness of Infliximab versus Colectomy for Severe Ulcerative Colitis: A Markov Analysis
SO INFLAMMATORY BOWEL DISEASES
CT Crohn's-and-Colitis-Foundation's-National-Clinical-and-Research Conference on Advances in Inflammatory Bowel Diseases
CY DEC 13-15, 2012
CL Hollywood, FL
SP Crohns & Colitis Fdn, Natl Clin & Res
TC 0
Z9 0
SN 1078-0998
PD DEC
PY 2012
VL 18
SU 1
BP S57
EP S58
UT WOS:000311172600142
ER

8

INCLUDED

PT J
AU Saini, SD
Waljee, AK
Higgins, PDR
AF Saini, Sameer D.
Waljee, Akbar K.
Higgins, Peter D. R.
TI Cost Utility of Inflammation-Targeted Therapy for Patients With Ulcerative Colitis
SO CLINICAL GASTROENTEROLOGY AND HEPATOLOGY

AB BACKGROUND & AIMS: Oral mesalamine drugs are frequently used to treat patients with mild-to-moderate ulcerative colitis (UC). However, these drugs are costly, and long-term adherence is poor. We compared the cost utility of inflammation-targeted, intermittent therapy with that of universal, continuous maintenance therapy with mesalamine agents for patients with mild-to-moderate UC. METHODS: We developed a Markov cohort model that simulated a population of adult patients with newly diagnosed, quiescent UC after induction of remission with mesalamine agents. We obtained model inputs from the literature. The perspective taken was that of a short-term payer (health insurance provider) during a 5-year time period. We modeled 3 treatment strategies: symptom-targeted treatment (treatment for symptomatic disease flares only, SYMPT), continuous mesalamine maintenance for all patients (CONT, the current standard of care), and inflammation-targeted treatment (mesalamine therapy for only patients with a stool sample positive for an inflammatory marker, INFLAM). We measured disease flares, quality-adjusted life years (QALYs), costs (2009 U. S. dollars), and incremental cost-effectiveness ratios. RESULTS: INFLAM was the least costly strategy (cumulative per-patient cost of $22,798), compared with $24,378 for the SYMPT and $25,621 for the CONT strategies. Despite the lower cost, INFLAM was comparable to SYMPT and CONT in effectiveness (4.4986 vs 4.5014 QALYs, respectively), making INFLAM the optimal strategy. Several variables were found to be important in sensitivity analysis; the CONT strategy was optimal only if the cost of mesalamine drugs was markedly reduced. CONCLUSIONS: Inflammation-targeted treatment of patients with UC is effective and costs less than continuous treatment of all patients with mesalamine, the current standard of care. Prospective trials of inflammation-targeted treatment are warranted.

RI | Waljee, Akbar | G-2067-2010 |

TC 0

Z9 0

SN 1542-3565

PD OCT

PY 2012

VL 10

IS 10

BP 1143

EP 1151

DI 10.1016/j.cgh.2012.05.003

UT WOS:000309826200018

ER

9

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Thomson, ABR
Gupta, M
Freeman, HJ

AF Thomson, Alan B. R.
Gupta, Milli
Freeman, Hugh J.

TI Use of the tumor necrosis factor-blockers for Crohn's disease

SO WORLD JOURNAL OF GASTROENTEROLOGY

AB The use of anti-tumor necrosis factor-a therapy for inflammatory bowel disease represents the most important advance in the care of these patients since the publication of the National Co-operative Crohn's disease study thirty years ago. The recommendations of numerous consensus groups worldwide are now supported by a wealth of clinical trials and several meta-analyses. In general, it is suggested that tumor necrosis factor-alpha blockers (TNFBs) are indicated (1) for persons with moderately-severe Crohn's disease or ulcerative colitis (UC) who have failed two or more causes of glucocorticosteroids and an acceptably long cause (8 wk to 12 wk) of an immune modulator such as azathioprine or methotrexate; (2) non-responsive perianal disease; and (3) severe UC not responding to a 3-d to 5-d course of steroids. Once TNFBs have been introduced and the patient is responsive, therapy given by the IV and SC rate must be continued. It remains open to definitive evidence if concomitant immune modulators are required with TNFB maintenance therapy, and when or if TNFB may be weaned and discontinued. The supportive evidence from

a single study on the role of early versus later introduction of TNFB in the course of a patient's illness needs to be confirmed. The risk/benefit profile of TNFB appears to be acceptable as long as the patient is immunized and tested for tuberculosis and viral hepatitis before the initiation of TNFB, and as long as the long-term adverse effects on the development of lymphoma and other tumors do not prone to be problematic. Because the rates of benefits to TNFB are modest from a population perspective and the cost of therapy is very high, the ultimate application of use of TNFBs will likely be established by cost/benefit studies.

TC 0

Z9 0

SN 1007-9327

PD SEP 21

PY 2012

VL 18

IS 35

BP 4823

EP 4854

DI 10.3748/wjg.v18.i35.4823

UT WOS:000309099500003

ER

10

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Mesko, B
Zahuczky, G
Nagy, L

AF Mesko, Bertalan
Zahuczky, Gabor
Nagy, Laszlo

TI The triad of success in personalised medicine: pharmacogenomics, biotechnology and regulatory issues from a Central European perspective

SO NEW BIOTECHNOLOGY

AB The population of the world has recently passed the 7 billion milestone and as the cost of human genome sequencing is rapidly declining, sequence data of billions of people should be accessible much sooner than anyone would have predicted 10 years ago. This will form the basis of personalised medicine. However it is still not clear, even in principle, whether these data, combined with data of the expression of one's genome in various cells and tissues relevant to different diseases, could be used effectively in clinical medicine and healthcare, or in predicting responses to different therapies. Therefore this is an important issue which needs to be addressed before more resources are wasted on less than informative studies and surveys simply because technologies exist.
As a typical example, we have selected and summarise here key studies from the biomedical literature that focus on gene expression profiling of the response to biologic therapies in peripheral blood and biopsy samples in autoimmune diseases such as rheumatoid arthritis, spondylarthropathy, inflammatory bowel diseases and psoriasis.
We also present the state of the biotechnology market from a European perspective, discuss how spin-offs leverage the power of genomic technologies and describe how they might contribute to personalised medicine.
As ethical, legal and social issues are essential in the area of genomics, we analysed these aspects and present here the European situation with a special focus on Hungary.
We propose that the synergy of these three issues: pharmacogenomics, biotechnology and regulatory issues should be considered a triad necessary to succeed in personalised medicine.

RI

Nagy, Laszlo	A-3814-2008

TC 0

Z9 0

SN 1871-6784
PD SEP 15
PY 2012
VL 29
IS 6
BP 741
EP 750
DI 10.1016/j.nbt.2012.02.004
UT WOS:000307994100015
ER

11

EXCLUDED / NOT UCERATIVE COLITIS

PT J

AU Doherty, GA
Miksad, RA
Cheifetz, AS
Moss, AC

AF Doherty, Glen A.
Miksad, Rebecca A.
Cheifetz, Adam S.
Moss, Alan C.

TI Comparative cost-effectiveness of strategies to prevent postoperative clinical recurrence of Crohn's disease

SO INFLAMMATORY BOWEL DISEASES

AB Background: A number of treatments have been shown to reduce the risk of postoperative recurrence of Crohn's disease (CD). The optimal strategy is unknown. The aim was to evaluate the comparative cost-effectiveness of postoperative strategies to prevent clinical recurrence of CD. Methods: Three prophylactic strategies were compared to no prophylaxis; mesalamine, azathioprine (AZA) / 6-mercaptopurine (6-MP), and infliximab. The probability of clinical recurrence, endoscopic recurrence, and therapy discontinuation due to adverse drug reactions (ADRs) were extracted from randomized controlled trials (RCTs). Quality-of-life scores and treatment costs were derived from published data. The primary model evaluated quality-adjusted life years (QALYs) and cost-effectiveness at 1 year after surgery. Sensitivity analysis assessed the impact of a range of recurrence rates on cost-effectiveness. An exploratory analysis evaluated cost-effectiveness outcomes 5 years after surgery. Results: A strategy of no prophylaxis was the least expensive one at 1 and 5 years after surgery. Compared to this approach, AZA/6-MP had the most favorable incremental cost-effectiveness ratio (ICER) ($299,188/QALY gained), and yielded the highest net health benefits of the medication strategies at 1 year. Sensitivity analysis determined that the ICER of AZA/6-MP was preferable to mesalamine up to a recurrence rate of 52%, but mesalamine dominated at higher rates. In the 5-year exploratory analysis, mesalamine had the most favorable ICER over 5 years ($244,177/QALY gained). Conclusions: Compared to no prophylactic treatment, AZA/6-MP has the most favorable ICER in the prevention of clinical recurrence of postoperative CD up to 1 year. At 5 years, mesalamine had the most favorable ICER in this model. (Inflamm Bowel Dis 2012;)

TC 0
Z9 0
SN 1078-0998
PD SEP
PY 2012
VL 18
IS 9
BP 1608
EP 1616
DI 10.1002/ibd.21904
UT WOS:000307383100002
ER

12

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Bernstein, CN
Longobardi, T
Finlayson, G
Blanchard, JF

AF Bernstein, Charles N.
Longobardi, Teresa
Finlayson, Greg
Blanchard, James F.

TI Direct medical cost of managing IBD patients: A Canadian population-based study

SO INFLAMMATORY BOWEL DISEASES

AB Background: This study aimed to quantify the direct medical cost of treating inflammatory bowel disease (IBD) in Manitoba in 2005/2006. Methods: In all, 7375 individuals with IBD recorded in the University of Manitoba IBD Epidemiology Database were matched on age, gender, and geography to up to 10 non-IBD controls. Data for cases and controls were extracted from Manitoba Health databases in fiscal 2005/2006 for pharmaceutical, physician claims, and hospital abstracts. The mean and median expenditure were computed for the annual cost of pharmaceuticals, hospitalizations (day surgery and inpatient), and physician office visits. We assessed costs based on age, gender, type of IBD, disease duration, and level of care provided. Results: In 2005/2006 the mean direct cost of an IBD case was $3896 (standard error [SE] = $90) which was twice that of controls ($P < 0.05$). Crohn's disease (CD; n = 3735) was significantly more costly on average than ulcerative colitis (UC; n = 3640) ($4232; SE = $137 and $3552; SE = $117, respectively, $P < 0.001$). The most costly cases included those within 1 year of diagnosis ($6611; SE = $593), those hospitalized overnight (15%) ($13,495, SE = $416; max = $130,332), those who had a surgical stay (2% of IBD cases) ($18,749, range = $13,413$125,912), and those using infliximab (0.7%) ($31,440, SE = $2311; max = $96,328). For individuals using infliximab their direct annual average healthcare cost was $9683 (SE = $1745, Max = $55,208) prior to using infliximab. Conclusions: In Manitoba the direct average annual healthcare cost of CD is greater than UC and that of a patient using infliximab tends to be greater than one incurring a surgical stay. (Inflamm Bowel Dis 2012)

TC 0

Z9 0

SN 1078-0998

PD AUG

PY 2012

VL 18

IS 8

BP 1498

EP 1508

DI 10.1002/ibd.21878

UT WOS:000306403300011

ER

13

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Corte, C
Saxena, P
Tattersall, S
Selinger, C
Leong, RW

AF Corte, Crispin
Saxena, Payal
Tattersall, Stephen
Selinger, Christian

Leong, Rupert W.

TI When to use biological agents in inflammatory bowel disease

SO JOURNAL OF GASTROENTEROLOGY AND HEPATOLOGY

AB The use of biological agents in inflammatory bowel diseases across the Asia-Pacific region is increasing. As new molecules and targets are identified, knowledge regarding the indications, utility, optimization and adverse effects of biological agents grows. Careful patient selection, attention to communication and patient education will maximize the benefit of these drugs. Tertiary referral centers with specific interest in inflammatory bowel diseases and experience play an important role in their use. There is enormous opportunity for patients to benefit from biological agents in the therapy of Crohn's disease and ulcerative colitis. Use of these agents has been studied across a variety of indications and populations, and at different stages in the disease course. Failure to respond or loss of response can result from different causes, and can be medically managed in many cases. More research on the pleiotropic effects, safety of biological agents and biomarkers in the prediction of response will provide a sounder basis for individually directing therapy. Adverse events such as opportunistic infection and malignancy can occur, and screening prior to therapy and discussion on risk-benefit of the various management options are important. Cost of these medications especially with maintenance therapy remains an important issue in many Asia-Pacific countries. New and more specific agents will better target therapy and minimize adverse events.

TC 2

Z9 2

SN 0815-9319

PD JUL

PY 2012

VL 27

IS 7

BP 1141

EP 1149

DI 10.1111/j.1440-1746.2011.07056.x

UT WOS:000305453100006

ER

14

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Cohen, BL
Torres, J
Colombel, JF

AF Cohen, Benjamin L.
Torres, Joana
Colombel, Jean-Frederic

TI Immunosuppression in inflammatory bowel disease: how much is too much?

SO CURRENT OPINION IN GASTROENTEROLOGY

AB Purpose of review
Current treatment approaches favor the early introduction of immunomodulators and/or antitumor necrosis factor (TNF) agents. There is now strong evidence showing that combination therapy appears to be more effective than monotherapy in both ulcerative colitis and Crohn's disease. However, there are concerns associated with this strategy, and eventually the following questions will emerge when discussing therapeutic options with our patients: is it safe to maintain these therapies for the long-term?; how long should we maintain therapy?; and if we decide to stop or de-escalate therapy, what strategy should we use?
Recent findings
During the past year new evidence regarding safety of long-term therapy with anti-TNF and immunomodulators, and predictors of relapse following therapy discontinuation have become available.
Summary
In this review we aim to discuss some of the safety concerns related to the use of immunosuppressive drugs used in inflammatory bowel disease, as well as the possible strategy for de-escalation or discontinuation therapy. Eventually, choosing to stop either the anti-TNF or the immunomodulator is a case by case decision

based on the estimated risk-benefit ratio. In addition to the identified predictors of relapse after therapy discontinuation, other considerations such as long-term safety, cost, and natural history of the disease must be brought into this discussion.

TC 1

Z9 1

SN 0267-1379

PD JUL

PY 2012

VL 28

IS 4

BP 341

EP 348

DI 10.1097/MOG.0b013e328354567f

UT WOS:000305329800008

ER

15

EXCLUDED / REVIEW

PT J

AU Strong, SA

AF Strong, Scott A.

TI Inflammatory bowel disease surgery in the biologic therapy era

SO CURRENT OPINION IN GASTROENTEROLOGY

AB Purpose of review
The relationship between surgery and biologic agents in the management of patients with inflammatory bowel disease continues to be a source of interest for both surgeons and clinicians. Recent findings
The role of biologic agents in patients with varying presentations of Crohn's disease or ulcerative colitis continues to evolve. However, the currently available biologic therapies are clearly not the panacea we have desired because they have only marginally decreased the frequency with which operative intervention is required and may have increased the risk for infectious postoperative complications in the nonelective setting. Compared to surgery, biologic agents are also significantly more costly and may not provide any greater gain in quality of life. Summary
Future studies must focus on the use of surgery and emerging biologic agents as complementary therapies designed to safely control inflammatory disease while providing objective value.

TC 1

Z9 1

SN 0267-1379

PD JUL

PY 2012

VL 28

IS 4

BP 349

EP 353

DI 10.1097/MOG.0b013e328354d832

UT WOS:000305329800009

ER

16

EXCLUDED / ABSTRACT

PT J

AU Black, CM

Fan, T
Jakopin, Z
Draskovic, J

AF Black, C. M.
Fan, T.
Jakopin, Z.
Draskovic, J.

TI BUDGET IMPACT MODEL OF INFLIXIMAB FOR THE TREATMENT OF STEROID-DEPENDENT, STEROID-REFRACTORY AND ACUTE ULCERATIVE COLITIS IN THE REPUBLIC OF CROATIA

SO VALUE IN HEALTH

TC 0

Z9 0

SN 1098-3015

PD JUN

PY 2012

VL 15

IS 4

BP A136

EP A136

UT WOS:000304468200706

ER

17

EXCLUDED / ABSTRACT

PT J

AU Odes, SH
Vardi, H
Greenberg, D
Friger, M
Stockbrugger, RW
O'Morain, CA
Tsianos, EV
Politi, P
Clofent, J
Moum, B
Freitas, J
Langholz, E
Munkholm, PS

AF Odes, Selwyn H.
Vardi, Hillel
Greenberg, Dan
Friger, Michael
Stockbrugger, Reinhold W.
O'Morain, Colm A.
Tsianos, Epameinondas V.
Politi, Patrizia
Clofent, Juan
Moum, Bjorn
Freitas, Joao
Langholz, Ebbe
Munkholm, Pia S.

TI Cost-Effectiveness of Episodic or Maintenance Infliximab Treatment Versus Standard Treatment in a Community-Based Incidence Cohort of Adult Ulcerative Colitis Patients With 10-Years Follow-up

SO GASTROENTEROLOGY

CT Digestive Disease Week (DDW)

CY MAY 19-22, 2012
CL San Diego, CA
TC 0
Z9 0
SN 0016-5085
PD MAY
PY 2012
VL 142
IS 5
SU 1
BP S256
EP S256
UT WOS:000306994301309
ER

18

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Kohn, A
Fano, V
Monterubbianesi, R
Davoli, M
Marrollo, M
Stasi, E
Perucci, C
Prantera, C

AF Kohn, Anna
Fano, Valeria
Monterubbianesi, Rita
Davoli, Marina
Marrollo, Marzia
Stasi, Elisa
Perucci, Carlo
Prantera, Cosimo

TI Surgical and nonsurgical hospitalization rates and charges for patients with ulcerative colitis in Italy: A 10-year cohort study

SO DIGESTIVE AND LIVER DISEASE

AB Background: Today we are observing an increasing incidence of ulcerative colitis associated with an improved survival of patients.
Aim: To analyse current rates, outcomes, and costs of inpatient care for ulcerative colitis patients of central Italy.
Methods: The cohort included 644 ulcerative colitis patients, living in the Lazio region, with diagnosis made or confirmed by the staff of a single tertiary referral centre in Rome (1997-2006). Follow-up data on hospitalization rates, costs, and colectomy rates were collected from the Regional Hospital Information System.
Results: Overall hospitalization rates were 3 times higher than those of the region's general population, reflecting excess admissions for digestive or infectious diseases (standardized hospitalizations rates for digestive-tract: 15.9; for infectious diseases: 3.5). The overall cumulative risk for colectomy was 7.5%. On the average, hospitalizations for ulcerative colitis lasted 10 days. The mean reimbursement for a ulcerative colitis-related hospitalization was EUR 5120 (is an element of 4609 for nonsurgical admissions, is an element of 8655 for surgical hospitalizations).
Conclusion: Ulcerative colitis patients are 3 times more likely to be hospitalized than the general population. Colectomy rates in Italian ulcerative colitis patients resemble those of northern Europe, but most hospital admissions are for diagnostic procedures or medical therapy. Hospitalizations are almost twice as long as those reported in the United States although their mean cost is considerably lower.

TC 2
Z9 2
SN 1590-8658
PD MAY
PY 2012
VL 44
IS 5
BP 369
EP 374
DI 10.1016/j.dld.2011.11.009
UT WOS:000303644400004
ER

19

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Biondi, A
Zoccali, M
Costa, S
Troci, A
Contessini-Avesani, E
Fichera, A

AF Biondi, Alberto
Zoccali, Marco
Costa, Stefano
Troci, Albert
Contessini-Avesani, Ettore
Fichera, Alessandro

TI Surgical treatment of ulcerative colitis in the biologic therapy era

SO WORLD JOURNAL OF GASTROENTEROLOGY

AB Recently introduced in the treatment algorithms and guidelines for the treatment of ulcerative colitis, biological therapy is an effective treatment option for patients with an acute severe flare not responsive to conventional treatments and for patients with steroid dependent disease. The reduction in hospitalization and surgical intervention for patients affected by ulcerative colitis after the introduction of biologic treatment remains to be proven. Furthermore, these agents seem to be associated with increase in cost of treatment and risk for serious postoperative complications. Restorative proctocolectomy with ileal pouch-anal anastomosis is the surgical treatment of choice in ulcerative colitis patients. Surgery is traditionally recommended as salvage therapy when medical management fails, and, despite advances in medical therapy, colectomy rates remain unchanged between 20% and 30%. To overcome the reported increase in postoperative complications in patients on biologic therapies, several surgical strategies have been developed to maintain long-term pouch failure rate around 10%, as previously reported. Surgical staging along with the development of minimally invasive surgery are among the most promising advances in this field.

TC 0
Z9 0
SN 1007-9327
PD APR 28
PY 2012
VL 18
IS 16
BP 1861
EP 1870
DI 10.3748/wjg.v18.i16.1861

UT WOS:000303349900002

ER

20

EXCLUDED / PEDIATRIC INFLAMMATORY BOWEL DISEASE

PT J

AU Heaton, PC
Tundia, NL
Schmidt, N
Wigle, PR
Kelton, CML

AF Heaton, Pamela C.
Tundia, Namita L.
Schmidt, Nicole
Wigle, Patricia R.
Kelton, Christina M. L.

TI National Burden of Pediatric Hospitalizations for Inflammatory Bowel Disease: Results From the 2006 Kids' Inpatient Database

SO JOURNAL OF PEDIATRIC GASTROENTEROLOGY AND NUTRITION

AB Objectives: The objective of the present study was to quantify the national pediatric inpatient inflammatory bowel disease (IBD) burden in terms of the number of IBD-related hospitalizations, the number of days spent in the hospital, and hospitalization costs. Methods: Hospitalizations for children and adolescents 20 years and younger with a primary diagnosis of either Crohn disease (CD) or ulcerative colitis (UC) were selected from the 2006 Kids' Inpatient Database (KID). Length of the hospital stay in days (LOS) and charges for the hospitalization were found directly in the Kids' Inpatient Database, and cost was calculated using the hospital's cost-to-charge ratio. Predictor variables included patient characteristics, such as age and severity of illness, and hospital characteristics. Ordinary-least-squares regressions were developed and estimated to explain hospitalization costs. Results: In 2006, there were 10,777 IBD-related hospitalizations. The total and mean costs for CD were $66.3 million and $10,176 (95% confidence interval [CI] $9647-$10,705), and for UC were $48.6 million and $11,836 (95% CI $10,760-$12,912). For CD, 0-to 5-year-old patients had the highest mean LOS (8.10, 95% CI 5.53-10.67, days) and mean cost ($13,894, 95% CI $9053-$18,735), whereas, for UC, 11-to 15-year-old patients had the highest mean LOS (7.49, 95% CI 6.88-8.10, 95% CI 5.53-10.67, days) and mean cost ($13,407, 95% CI $11,704-$15,110). Conclusions: For a pediatric disease with a rather low prevalence rate, the estimated annual inpatient pediatric burden of IBD is a sizeable $152.4 million (2010 US$) and 64,985 days spent in the hospital. As medications and outpatient treatments improve for the treatment of IBD, there is an opportunity for significant reduction in inpatient burden.

TC 2

Z9 2

SN 0277-2116

PD APR

PY 2012

VL 54

IS 4

BP 477

EP 485

DI 10.1097/MPG.0b013e318239bc79

UT WOS:000302171800008

ER

21

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Hanauer, SB
Kirsner, JB

AF Hanauer, Stephen B.
Kirsner, Joseph B.

TI Treat the Patient or Treat the Disease?

SO DIGESTIVE DISEASES

AB Our therapeutic goals for the treatment of ulcerative colitis and Crohn's disease are evolving. Until the last decade the goals were primarily the treatment of symptoms. Regulatory approval for ulcerative colitis therapies have been based on short-term improvements in clinical indices and, most recently, the ability to heal the colonic mucosa, whereas approval for Crohn's disease therapies have been based on reductions in the CDAI (Crohn's Disease Activity Index). Over the past decade there has been increasing evidence in favor of more 'objective' measures of biologic disease activity including biomarkers such as C-reactive protein and mucosal healing in Crohn's disease and the histologic resolution of active inflammation in ulcerative colitis. The objective changes have provided expanded therapeutic goals based on longer-term maintenance therapies with the potential to modify the chronic disease behavior and to reduce pharmacoeconomic costs (reductions in hospitalizations, surgeries and neoplasia). Copyright (C) 2012 S. Karger AG, Basel

TC 0

Z9 0

SN 0257-2753

PY 2012

VL 30

IS 4

BP 400

EP 403

DI 10.1159/000338139

UT WOS:000306404500015

ER

22

EXCLUDED / NOT ULCERATIVE COLITIS

PT J

AU Carter, CT
Waters, HC
Smith, DB

AF Carter, Chureen T.
Waters, Heidi C.
Smith, Daniel B.

TI Effect of a continuous measure of adherence with infliximab maintenance treatment on inpatient outcomes in Crohn's disease

SO PATIENT PREFERENCE AND ADHERENCE

AB Background: To assess the impact of a continuous measure of adherence with infliximab maintenance treatment in Crohn's disease (CD) during the first year of treatment on CD-related health care utilization, CD-related hospitalizations, inpatient costs, and length of hospital stay.
Patients and methods: A retrospective claims analysis using the IMS LifeLink Health Plan Claims Database (September 1, 2004, to June 30, 2009) was conducted. Continuous enrollment for 12 months before and 12 months after the index date was required. Patients were required to have at least two claims with an International Classification of Diseases, 9th Revision, Clinical Modification diagnosis code for CD (555. xx) pre-index and be aged >= 18 years at index. Patients with three infusions during the first 56 days post-index and at least one infusion following day 56 post-index were considered to have maintenance therapy. Adherence and nonadherence were defined as a medication possession ratio of >= 80% and, 80%, respectively.
Results: Four hundred forty-eight patients were included in the analysis (mean age, 42.6 years; 56% female; mean +/- standard deviation [SD] and median number of infliximab infusions, 7.35 +/- 1.60 and 8). The number of patients who met the definition of adherence was 344 (77%). CD-related health care utilization was not significantly impacted by adherence except for ancillary services and radiology. Fewer adherent patients were hospitalized compared with nonadherent patients (9% versus 16%; P = 0.03). Adherent patients had fewer mean +/- SD and median days in the hospital (5.5 +/- 3.4 and 5 days) compared with

nonadherent patients (13.1 +/- 14.2 and 8 days; P = 0.01). Mean +/- SD and median hospital costs were significantly greater for nonadherent patients ($40,822 +/- $49,238 and $28,864) compared with adherent patients ($13,704 +/- $10,816 and $ 9938; P = 0.002). Conclusion: Adherence with maintenance infliximab over 12 months was associated with lower rates of CD-related hospitalizations and inpatient costs and a shorter length of hospital stay.

TC 0

Z9 0

SN 1177-889X

PY 2012

VL 6

BP 417

EP 426

DI 10.2147/PPA.S31115

UT WOS:000305011900001

ER

23

EXCLUDED / PEDIATRIC ULCERATIVE COLITIS

PT J

AU Park, KT
Perez, F
Tsai, R
Honkanen, A
Bass, D
Garber, A

AF Park, K. T.
Perez, Felipe
Tsai, Raymond
Honkanen, Anita
Bass, Dorsey
Garber, Alan

TI Cost-effectiveness Analysis of Adjunct VSL#3 Therapy Versus Standard Medical Therapy in Pediatric Ulcerative Colitis

SO JOURNAL OF PEDIATRIC GASTROENTEROLOGY AND NUTRITION

AB Background: Inflammatory bowel diseases (IBDs) are costly chronic gastrointestinal diseases, with pediatric IBD representing increased costs per patient compared to adult disease. Health care expenditures for ulcerative colitis (UC) are >$2 billion annually. It is not clear whether the addition of VSL#3 to standard medical therapy in UC induction and maintenance of remission is a cost-effective strategy. Patients and Methods: We performed a systematic review of the literature and created a Markov model simulating a cohort of 10-year-old patients with severe UC, studying them until 100 years of age or death. We compared 2 strategies: standard medical therapy versus medical therapy + VSL#3. For both strategies, we assumed that patients progressed through escalating therapies-mesalamine, azathioprine, and infliximab-before receiving a colectomy + ileal pouch anal anastamosis (IPAA) if the 3 medical therapy options were exhausted. The primary outcome measure was the incremental cost-effectiveness ratio (ICER), defined as the difference of costs between strategies for each quality-adjusted life-year (QALY) gained. One-way sensitivity analyses were performed on variables to determine the key variables affecting cost-effectiveness. Results: Standard medical care accrued a lifetime cost of $203,317 per patient, compared to $212,582 per patient for medical therapy + VSL#3. Lifetime QALYs gained was comparable for standard medical therapy and medical therapy + VSL#3 at 24.93 versus 25.05, respectively. Using the definition of ICER <50,000/QALY as a cost-effective intervention, medical therapy + VSL#3 produced an ICER of $79,910 per QALY gained, making this strategy cost-ineffective. Sensitivity analyses showed that 4 key parameters could affect the cost-effectiveness of the 2 strategies: cost of colectomy + IPAA, maintenance cost after surgery, probability of developing pouchitis after surgery, and the quality of life after a colectomy + IPAA. High surgical and postsurgical costs, a high probability of developing pouchitis, and a low quality of life after a colectomy + IPAA could make adjunct VSL#3 use a cost-effective strategy. Conclusions: Given present data, adjunct VSL#3 use for pediatric UC induction and maintenance of remission is not cost-effective, although several key parameters could make this strategy cost-effective. The

quality of life after an IPAA is the single most important variable predicting whether this procedure benefits patients over escalating standard medical therapy.

TC 1
Z9 1
SN 0277-2116
PD NOV
PY 2011
VL 53
IS 5
BP 489
EP 496
DI 10.1097/MPG.0b013e3182293a5e
UT WOS:000296383000007
ER

24

EXCLUDED / ABSTRACT

PT J
AU Lofland, J
Gunnarsson, C
Mallow, P
Rizzo, J
Feagan, B
AF Lofland, J.
Gunnarsson, C.
Mallow, P.
Rizzo, J.
Feagan, Brian
TI Cost-per-Responder Analysis of Infliximab Compared to Adalimumab Among Individuals with Moderate to Severe Ulcerative Colitis
SO AMERICAN JOURNAL OF GASTROENTEROLOGY
CT 76th Annual Scientific Meeting of the American-College-of-Gastroenterology
CY OCT 28-NOV 02, 2011
CL Washington, DC
SP Amer Coll Gastroenterol
TC 0
Z9 0
SN 0002-9270
PD OCT
PY 2011
VL 106
SU 2
MA 1121
BP S418
EP S418
UT WOS:000299772001683
ER

25

EXCLUDED / REVIEW

PT J
AU Di Sabatino, A

Liberato, L
Marchetti, M
Biancheri, P
Corazza, GR

AF Di Sabatino, Antonio
Liberato, Lucio
Marchetti, Monia
Biancheri, Paolo
Corazza, Gino R.

TI Optimal use and cost-effectiveness of biologic therapies in inflammatory bowel disease

SO INTERNAL AND EMERGENCY MEDICINE

CT 112th National Congress of the Italian-Society-of-Internal-Medicine

CY OCT 22-25, 2011

CL Rome, ITALY

SP Italian Soc Internal Med

AB Inflammatory bowel diseases (IBD), namely Crohn's disease and ulcerative colitis, are burdened by high medical costs which are mostly dependent on hospital inpatient treatment. New biologic therapies, which target specific cytokines in the inflammatory cascade leading to the intestinal lesions, including tumor necrosis factor (TNF)-alpha, have revolutionized the management of IBD by offering a therapeutic chance to patients in whom conventional therapies failed. However, the relatively high costs of biologic drugs, together with their potential toxicity due to infections and malignancies, have led to debate regarding their indiscriminate use in IBD patients. The purpose of this review is to deal with the optimal use and cost-effectiveness of the two main monoclonal anti-TNF-alpha agents currently used in the management of IBD patients, i.e. the chimeric human/murine antibody infliximab and the fully human antibody adalimumab.

TC 2

Z9 2

SN 1828-0447

PD OCT

PY 2011

VL 6

SU 1

BP 17

EP 27

DI 10.1007/s11739-011-0673-9

UT WOS:000296013000003

ER

26

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Gu, J
Stocchi, L
Geisler, DP
Kiran, RP

AF Gu, Jinyu
Stocchi, Luca
Geisler, Daniel P.
Kiran, Ravi P.

TI Staged restorative proctocolectomy: laparoscopic or open completion proctectomy after laparoscopic subtotal colectomy?

SO SURGICAL ENDOSCOPY AND OTHER INTERVENTIONAL TECHNIQUES

AB Background The aim of this study was to compare outcomes of laparoscopic and open completion proctectomy (CP) and ileal-pouch anal anastomosis (IPAA) after a previous laparoscopic subtotal colectomy (STC).

AB Methods From a prospectively maintained ileal pouch database, outcomes for patients who underwent laparoscopic CP after laparoscopic STC (LSTC-LCP group) for ulcerative or indeterminate colitis were compared to those for patients who underwent open CP (LSTC-OCP group). A control group of open CP after open STC (OSTC-OCP group) was case-matched to LSTC-OCP at a ratio of 1:2 for age at surgery, gender, body mass index (BMI), year of operation, and American Society of Anesthesiologists (ASA) classification. Demographics, perioperative data, and pouch function were compared. Quality of life was evaluated using the Cleveland Global Quality of Life Scale (CGQL). Results Between 1997 and 2009, 47 patients underwent LSTC followed by LCP (LSTC-LCP), and 48 patients underwent OCP after LSTC (LSTC-OCP); the latter group was matched to 96 open-open patients (OSTC-OCP). There were no significant differences in demographic and preoperative data among the three groups, except that the OSTC-OCP group patients were younger. Postoperative morbidity, pouch function, and CGQL were similar. LSTC-LCP patients had lower estimated blood loss (EBL) ($p < 0.001$), less commonly described intraoperative adhesiolysis ($p < 0.001$), reduced length of hospital stay (LOS) ($p = 0.002$) but longer operating time ($p = 0.001$) at CP/IPAA when compared with open-open patients. For patients with previous LSTC, LCP was associated with less commonly described intraoperative adhesiolysis ($p = 0.003$) and shorter LOS ($p = 0.003$) than OCP but a longer operating time ($p = 0.036$). Conclusions Laparoscopic CP and IPAA can be performed with safety comparable to that of open surgery after previous laparoscopic STC. The laparoscopic approach is associated with advantages including reduced intraoperative blood loss and earlier recovery as demonstrated by shorter length of hospital stay.

TC 1

Z9 2

SN 0930-2794

PD OCT

PY 2011

VL 25

IS 10

BP 3294

EP 3299

DI 10.1007/s00464-011-1707-0

UT WOS:000294964600024

ER

27

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Walsh, A
Mabee, J
Trivedi, K

AF Walsh, Anne
Mabee, John
Trivedi, Kashyap

TI Inflammatory Bowel Disease

SO PRIMARY CARE

AB Crohn disease and ulcerative colitis are the most common forms of inflammatory bowel disease (IBD) likely to be encountered in primary care. Patient-centered care is essential for positive outcomes, and should include long-term continuity with an empathetic primary care provider who can provide skillful coordination of the requisite multidisciplinary approach. Early suspicion of the diagnosis and referral to expert gastroenterologists for confirmation and medical management is essential. Coordinating interdisciplinary consultations, including colorectal surgeons, radiologists, stoma therapists, psychologists, and rheumatologists, in combination with comprehensive patient education, is key to decreasing overall morbidity, mortality, and health care costs associated with IBD.

TC 2

Z9 2

SN 0095-4543

PD SEP

PY 2011
VL 38
IS 3
BP 415
EP +
DI 10.1016/j.pop.2011.06.001
UT WOS:000295385800005
ER

28

EXCLUDED / NOT ULCERATIVE COLITIS

PT J

AU Carter, CT
Waters, HC
Smith, DB

AF Carter, Chureen T.
Waters, Heidi C.
Smith, Daniel B.

TI Impact of infliximab adherence on Crohn's disease-related healthcare utilization and inpatient costs

SO ADVANCES IN THERAPY

AB Few published reports have described the impact of adherence with biologic agents on hospitalizations and inpatient costs in Crohn's disease (CD).
A retrospective claims analysis using the IMS LifeLink Health Plan Claims Database between September 1, 2004 and June 30, 2009 was conducted. Continuous enrollment for 12 months before and 12 months after the index date was required. Patients were required to have a parts per thousand yen2 claims with an International Classification of Diseases, 9th Edition, Clinical Modification diagnosis code for CD (555.xx) preindex, be a parts per thousand yen18 years of age at index, and have a parts per thousand yen4 infliximab infusions with a gap no greater than 12 weeks between each infusion. Patients with 7-9 infliximab infusions (12 months postindex) were considered adherent; patients with 4-6 infliximab infusions were considered nonadherent.
In total, 638 patients were included in the analyses (mean age, 43 years; 58% female in the adherent group and 53% in the nonadherent group). The number of patients who met the definition of adherence was 466 (73%). A smaller proportion of adherent patients had a CD-related emergency room visit, compared with nonadherent patients (11% vs. 17%, P=0.029). A smaller proportion of adherent patients required CD-related hospitalization, compared with nonadherent patients (8% vs. 12%, P=0.117). Among those hospitalized, adherent patients had fewer mean [median] days in the hospital (5.9 [5] days), compared with nonadherent patients (12.8 [8] days, P=0.015). Mean [median] hospital costs were significantly lower for adherent patients ($13,427 [$9,352]), compared with nonadherent patients ($37,783 [$28,864], P=0.001). Multivariate analyses confirmed lower inpatient (P < 0.001) costs for adherent versus nonadherent patients. Adherence with infliximab therapy during the first year of treatment in patients with CD was associated with a shorter hospital length of stay and lower inpatient costs compared with nonadherent patients. Strategies for increasing adherence rates to infliximab maintenance therapy may be valuable in reducing hospitalizations and inpatient costs in patients with CD.

TC 0
Z9 0
SN 0741-238X
PD AUG
PY 2011
VL 28
IS 8
BP 671
EP 683
DI 10.1007/s12325-011-0048-7
UT WOS:000294069200006

ER

29

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Buchanan, J
Wordsworth, S
Ahmad, T
Perrin, A
Vermeire, S
Sans, M
Taylor, J
Jewell, D

AF Buchanan, James
Wordsworth, Sarah
Ahmad, Tariq
Perrin, Angela
Vermeire, Severine
Sans, Miguel
Taylor, Jenny
Jewell, Derek

TI Managing the long term care of inflammatory bowel disease patients: The cost to European health care providers

SO JOURNAL OF CROHNS & COLITIS

AB Background and aims: Inflammatory Bowel Disease (which includes Crohn's Disease and Ulcerative Colitis), is a chronic condition characterised by substantial morbidity. Inflammatory Bowel Disease patients are considered expensive to manage, hence accurate estimates of care costs are crucial to help healthcare providers plan clinical management. The aim of this study is to estimate the cost of care for Crohn's Disease and Ulcerative Colitis patients in the United Kingdom and Western mainland Europe. Methods: Decision models were built to simulate the natural disease history of Crohn's Disease and Ulcerative Colitis, informed by United Kingdom and European clinical pathways. A healthcare provider perspective was adopted, model inputs were informed by published sources and expert opinion, and UK healthcare costs were used (2008 prices). Cohorts of 25 year old patients presenting with symptoms of varying severity were modelled over ten years, and annual treatment costs calculated per patient. Results: The average annual cost of care per Crohn's Disease/Ulcerative Colitis patient was 631 pound/762 pound (United Kingdom) and 838 pound/796 pound (Europe). Most costs were incurred immediately following diagnosis, particularly in European Crohn's patients, reflecting the earlier use of more aggressive treatments. Surgery, hospitalisation, and the use of biological therapies and mesalazine (in Ulcerative Colitis) were key cost drivers. The total annual cost to the United Kingdom National Health Service of caring for Inflammatory Bowel Disease patients was estimated to be 31 pound million. Conclusions: This study confirms that Inflammatory Bowel Disease patients are expensive to manage and illustrates the importance of differentiating between alternative clinical management scenarios.

TC 2

Z9 2

SN 1873-9946

PD AUG

PY 2011

VL 5

IS 4

BP 301

EP 316

DI 10.1016/j.crohns.2011.02.005

UT WOS:000292786000004

ER

30

EXCLUDED / REVIEW

PT J

AU Park, KT
Bass, D

AF Park, K. T.
Bass, Dorsey

TI Inflammatory Bowel Disease-Attributable Costs and Cost-effective Strategies in the United States: A Review

SO INFLAMMATORY BOWEL DISEASES

AB The United States spends more for healthcare than any other country in the world. With the rising prevalence of both Crohn's disease and ulcerative colitis, inflammatory bowel disease (IBD). represents the leading chronic gastrointestinal disease with increasing healthcare expenditures in the US. IBD costs have shifted from inpatient to outpatient care since the introduction of biologic therapies as the standard of care. Gastroenterologists need to be aware of the national cost burden of IBD and clinical practices that optimize cost-efficiency. This investigation offers a systematic review of the economics of IBD and evidence-based strategies for cost-effective management.

TC 4

Z9 4

SN 1078-0998

PD JUL

PY 2011

VL 17

IS 7

BP 1603

EP 1609

DI 10.1002/ibd.21488

UT WOS:000292415200017

ER

31

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Carter, CT
Leher, H
Smith, P
Smith, DB
Waters, HC

AF Carter, Chureen T.
Leher, Henry
Smith, Paula
Smith, Daniel B.
Waters, Heidi C.

TI Impact of Persistence With Infliximab on Hospitalizations in Ulcerative Colitis

SO AMERICAN JOURNAL OF MANAGED CARE

AB Objectives: To assess infliximab infusion patterns in ulcerative colitis (UC) and assess the impact of persistence with infliximab maintenance therapy on UC-related hospitalizations, lengths of stay, and inpatient costs.
Study Design: Retrospective analysis of medical claims for UC patients newly initiating infliximab treatment.
Methods: Patients were aged >= 18 years and had 2 UC diagnosis codes, an infliximab index date between September 1, 2005, and January 31, 2008, and continuous enrollment for >= 12 months before and >= 14 months after the index date. Infliximab induction (first 56 days postindex) and maintenance (>56 days and <12 months postinduction) patterns were evaluated. Of patients with maintenance treatment, persistence was defined as a medication possession ratio (MPR) of >= 80%, and this group was compared with those without

persistence (<80% MPR). Results: Overall, 420 patients were included in the analysis; 84.3% (n = 354) continued to maintenance therapy. Maintenance infusion patterns were consistent with recommended prescribing information. A smaller proportion of patients with maintenance therapy persistence required hospitalization compared with patients without persistence (3.0% vs 20.4%; P < .001). Hospitalized patients with maintenance therapy persistence had significantly lower mean inpatient costs ($ 14,243 vs $ 32,745; P = .046), with a trend toward shorter mean lengths of stay (6.67 vs 9.71 days; P = .147) than patients without persistence. Conclusions: Infliximab maintenance therapy persistence in UC was associated with significantly fewer hospitalizations. Once hospitalized, patients with therapeutic persistence had significantly decreased inpatient costs. (Am J Manag Care. 2011;17(6):385-392)

TC 1

Z9 1

SN 1088-0224

PD JUN

PY 2011

VL 17

IS 6

BP 385

EP 392

UT WOS:000292257100006

ER

32

EXCLUDED / ABSTRACT

PT J

AU Ung, V
Lee, TW
Wang, HL
Kroeker, KI
Nguyen, TX
Ohinmaa, A
Jacobs, P
Wong, K
Fedorak, RN

AF Ung, Victoria
Lee, Thomas W.
Wang, Haili
Kroeker, Karen I.
Thanh X. Nguyen
Ohinmaa, Arto
Jacobs, Philip
Wong, Karen
Fedorak, Richard N.

TI Long-Term Cost-Effectiveness Analysis of Infliximab in the Management of Ulcerative Colitis

SO GASTROENTEROLOGY

CT Conference on Digestive Disease Week 2011

CY MAY 07-10, 2011

CL Chicago, IL

TC 0

Z9 0

SN 0016-5085

PD MAY

PY 2011

VL 140

IS 5

SU 1

BP S201

EP S201

UT WOS:000290167300814

ER

33

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT B

AU Hanauer, SB

AF Hanauer, Stephen B.

BE Chen, CW
Cheng, J
Gines, P
Ouyang, Q
Scholmerich, J

TI What Should We Expect from Future Therapies for Inflammatory Bowel Disease?

SO GUT AND LIVER

SE Falk Symposium

CT Falk Symposium on Gut and Liver

CY AUG 27-28, 2010

CL Beijing, PEOPLES R CHINA

AB Current therapies for inflammatory bowel disease are directed to the clinical goals of induction and maintenance of clinical remissions. However, as our therapeutic armamentarium has increased, we have recognized the lack of correlation between clinical symptoms of Crohn's disease and ulcerative colitis with mucosal inflammation, either endoscopically visible or histological. Similar observations have been made in the field of rheumatoid arthritis where there has been an evolution of goals from the treatment of signs and symptoms of rheumatoid arthritis to the prevention of structural damage and the definition of disease modification. There is evolving evidence in the field of inflammatory bowel disease that early, aggressive therapy with combinations of biologics and immune suppressants, particularly when administered early in the course of Crohn's disease can impact on both clinical signs and symptoms, but also on mucosal healing which has correlated with longer term pharmacoeconomic outcomes such as reductions in hospitalizations and surgeries. Our expectations of future therapies will, henceforth be, both the resolution of clinical signs and symptoms, but also a more personalized approach based on predictive factors to alter the long-term course with the goal of disease modification until ultimate causation, prevention and cures are identified.

TC 0

Z9 0

BN 978-3-8055-9672-5

PY 2011

VL 174

BP 68

EP 71

DI 10.1159/000322446

UT WOS:000293715500012

ER

34

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Meder, A
Swiatkowski, M
Meder, G

Koza, J
Szamocka, M

AF Meder, Agnieszka
Swiatkowski, Maciej
Meder, Grzegorz
Koza, Jaroslaw
Szamocka, Malgorzata

TI Treatment costs for the group of patients with non-specific inflammatory bowel disease during acute exacerbation and further annual observation

SO PRZEGLAD GASTROENTEROLOGICZNY

AB Introduction: The problem of costs related to health care services is particularly important in the case of chronic diseases, among which non-specific inflammatory bowel diseases (IBD) are classified. Aim: To analyse the costs of health care services determined by the National Health Fund (NFZ) during annual medical care for patients with IBD from the moment of inception of treatment of acute exacerbation. Material and methods: The study was conducted in 20042007 in 41 patients diagnosed with Crohn's disease (CD) (14 people) or ulcerative colitis (UC) (27 people). The study was initiated during an acute exacerbation. At the beginning of the study and during the final visit the history data concerning the occupational activity of the sick person was taken. During the observation the duration of inability to work because of IBD was noted. After a year, information about the amount of health care services and their costs incurred by the NFZ funds was obtained from the hospital database. The study protocol was approved by the Bioethics Committee at the Collegium Medicum of Bydgoszcz. Results: The average annual cost of treating a patient with IBD calculated on the basis of the income of the Hospital from the NFZ for provided health care services amounted to 10 298 PLN (in CD - 12 623 PLN and in UC - 9 092 PLN). Hospitalizations generated 95.8% of total costs. Costs of surgical treatment constituted 34.8% of the costs of hospitalization, and costs of biological treatment 14.5%. The cost of biological and surgical treatment per patient using health care services was comparable and amounted to 20 121 PLN (for surgical treatment) and 19 500 PLN (for biological treatment). The highest unit cost concerned the treatment of a patient with acute exacerbation of ulcerative colitis resistant to conventional therapy and was mainly associated with surgical treatment and postoperative complications. Conclusions: The main direct costs in IBD are associated with hospitalizations, with a high percentage related to surgical and biological treatment. Factors that will reduce the need for hospitalization or shorten its duration are economically beneficial. An alternative to current surgical treatment of patients with non-specific inflammatory bowel disease is biological therapy, which has many advantages. This method of treatment requires careful assessment over time of its application because of the short time since its introduction. In Poland, patients with non-specific inflammatory bowel disease, despite generally low financial outlays for health care and financial underestimation of the health services provided to patients, are treated in accordance with applicable standards.

TC 0

Z9 0

SN 1895-5770

PY 2011

VL 6

IS 1

BP 36

EP 44

DI 10.5114/pg.2011.20106

UT WOS:000290697400005

ER

35

EXCLUDED / ABSTRACT

PT J

AU Malone, D
Hurwitz, J
Lofland, J
Nejadnik, B

Vanderpoel, J
Waters, H

AF Malone, D.
Hurwitz, J.
Lofland, J.
Nejadnik, B.
Vanderpoel, J.
Waters, H.

TI Cost-effectiveness of immunomodulators versus infliximab for adults with moderate-to-severe ulcerative colitis.

SO INFLAMMATORY BOWEL DISEASES

CT Advances in Inflammatory Bowel Diseases Crohns and Colitis Foundations National Clinical and Research Conference

CY DEC 09-12, 2010

CL Hollywood, FL

TC 0

Z9 0

SN 1078-0998

PD JAN

PY 2011

VL 17

SU 1

BP S53

EP S54

UT WOS:000285256300175

ER

36

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Orlando, A
Armuzzi, A
Papi, C
Annese, V
Ardizzone, S
Biancone, L
Bortoli, A
Castiglione, F
D'Inca, R
Gionchetti, P
Kohn, A
Poggioli, G
Rizzello, F
Vecchi, M
Cottone, M

AF Orlando, Ambrogio
Armuzzi, Alessandro
Papi, Claudio
Annese, Vito
Ardizzone, Sandro
Biancone, Livia
Bortoli, Aurora
Castiglione, Fabiana
D'Inca, Renata
Gionchetti, Paolo
Kohn, Anna

Poggioli, Gilberto
Rizzello, Fernando
Vecchi, Maurizio
Cottone, Mario

TI The Italian Society of Gastroenterology (SIGE) and the Italian Group for the study of Inflammatory Bowel Disease (IG-IBD) Clinical Practice Guidelines: The use of tumor necrosis factor-alpha antagonist therapy in Inflammatory Bowel Disease

SO DIGESTIVE AND LIVER DISEASE

AB Biological therapies are an important step in the management of Inflammatory Bowel Diseases. In consideration of high cost and safety issues there is the need to have clear recommendations for their use. Despite the American Gastroenterological Association and the European Crohn's and Colitis Organisation have published exhaustive Inflammatory Bowel Disease guidelines, national guidelines may be necessary as cultural values, economical and legal issues may differ between countries. For these reasons the Italian Society of Gastroenterology and the Italian Group for the study of Inflammatory Bowel Disease have decided to elaborate the Italian guidelines on the use of biologics in Inflammatory Bowel Disease. The following items have been chosen: definitions of active, inactive, steroid dependent and resistant disease; measures of activity; anti-tumor necrosis factor alpha therapy use in active steroid dependent and refractory luminal Crohn's Disease, in fistulising Crohn's Disease, in steroid dependent and resistant active Ulcerative Colitis; risk of cancer; risk of infections during anti-tumor necrosis factor alpha therapy; special situations. These guidelines are based on evidence from relevant medical literature and clinical experience of a national working group.

TC 21

Z9 22

SN 1590-8658

PD JAN

PY 2011

VL 43

IS 1

BP 1

EP 20

DI 10.1016/j.dld.2010.07.010

UT WOS:000289661300001

ER

37

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Nguyen, GC
LaVeist, TA
Harris, ML
Wang, MH
Datta, LW
Brant, SR

AF Nguyen, Geoffrey C.
LaVeist, Thomas A.
Harris, Mary L.
Wang, Ming-Hsi
Datta, Lisa W.
Brant, Steven R.

TI Racial Disparities in Utilization of Specialist Care and Medications in Inflammatory Bowel Disease

SO AMERICAN JOURNAL OF GASTROENTEROLOGY

AB OBJECTIVES: Optimization of medical therapy and specialist care for inflammatory bowel disease (IBD) may reduce morbidity. We sought to characterize racial disparities in utilization of healthcare and medical therapy for IBD.

METHODS: We performed a cross-sectional study of black (n=137) and white (n=149) IBD patients recruited from an outpatient IBD clinic and through medical record review and telephone interview, compared utilization of IBD specialist services, emergency department (ED) services, and medications. We adjusted racial comparisons for demographic, socioeconomic, and clinical factors. RESULTS: After adjustment for confounders, blacks were less likely than whites to be under the regular care (defined as at least annual visit) of a gastroenterologist (adjusted odds ratio (aOR) 0.43; 95% confidence interval (CI): 0.25-0.75) or IBD specialist (aOR 0.37; 95% CI: 0.22-0.61). Follow-up with a primary care provider was, however, similar between blacks and whites. Over the preceding 12 months, blacks were more likely than whites to have at least one visit to the ED (aOR 2.02; 95% CI: 1.22-3.35), but there was no difference in hospitalization. Among CD patients with prolonged steroid use, blacks were less likely than whites to have been on infliximab (aOR 0.41; 95% CI: 0.21-0.77), but there were no racial differences in the use of immunomodulators (aOR 0.87; 95% CI: 0.48-1.60). CONCLUSIONS: There are racial differences in utilization of IBD-related specialist services, ED visits, and infliximab that are independent of income and education. Modifiable barriers to health-care access may have a role in these disparities.

TC 3

Z9 3

SN 0002-9270

PD OCT

PY 2010

VL 105

IS 10

BP 2202

EP 2208

DI 10.1038/ajg.2010.202

UT WOS:000282593000014

ER

38

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Scaldaferri, F
Correale, C
Gasbarrini, A
Danese, S

AF Scaldaferri, Franco
Correale, Carmen
Gasbarrini, Antonio
Danese, Silvio

TI Mucosal biomarkers in inflammatory bowel disease: Key pathogenic players or disease predictors?

SO WORLD JOURNAL OF GASTROENTEROLOGY

AB Inflammatory bowel diseases (IBDs) are chronic inflammatory disorders of the bowel, including ulcerative colitis and Crohn's disease. A single etiology has not been identified, but rather the pathogenesis of IBD is very complex and involves several major and minor contributors, employing different inflammatory pathways which have different roles in different patients. Although new and powerful medical treatments are available, many are biological drugs or immunosuppressants, which are associated with significant side effects and elevated costs. As a result, the need for predicting disease course and response to therapy is essential. Major attempts have been made at identifying clinical characteristics, concurrent medical therapy, and serological and genetic markers as predictors of response to biological agents. Only few reports exist on how mucosal/tissue markers are able to predict clinical behavior of the disease or its response to therapy. The aim of this paper therefore is to review the little information available regarding tissue markers as predictors of response to therapy, and reevaluate the role of tissue factors associated with disease severity, which can eventually be ranked as "tissue factor predictors". Five main categories are assessed, including mucosal cytokines and chemokines, adhesion molecules and markers of activation, immune and non-immune cells, and other mucosal components. Improvement in the design and specificity of clinical studies are mandatory to be able to classify tissue markers as predictors of disease course and response to specific

therapy, obtain the goal of achieving "personalized pathogenesis-oriented therapy" in IBD. (C) 2010 Baishideng. All rights reserved.

TC 12

Z9 13

SN 1007-9327

PD JUN 7

PY 2010

VL 16

IS 21

BP 2616

EP 2625

DI 10.3748/wjg.v16.i21.2616

UT WOS:000278519300007

ER

39

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Ducharme, J
Pelletier, C
Zacharias, R

AF Ducharme, James
Pelletier, Cindy
Zacharias, Ramesh

TI The safety of infliximab infusions in the community setting

SO CANADIAN JOURNAL OF GASTROENTEROLOGY

AB BACKGROUND: Tumour necrosis factor-alpha (TNF alpha) has an important role in the pathogenesis of inflammatory conditions such as rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriasis. Infliximab, a chimeric anti-TNF alpha monoclonal antibody, has been shown to reduce the severity of symptoms or induces remission of active disease. Infusions have generally been limited to the hospital setting due to cost and concerns for patient safety. Studies defining its efficacy and safety have, therefore, originated almost exclusively from hospital settings.
OBJECTIVE: To evaluate the safety of infliximab in a community clinic environment, across all types of patients.
METHODS: A retrospective chart review of 3161 patients who received a combined 20,976 infusions at a network of community clinics over 16.5 months was conducted. Adverse drug reaction (ADR) information was retrieved and coded for time of onset, severity and outcome. Only ADRs that occurred during or within the first 24 11 of the infusion were included.
RESULTS: A total of 524 (2.5% of all infusions) acute ADRs in 353 patients (11.2%) were recorded. Most reactions (ie, ADRs) were mild (n=263 [50.2%, 1.3% of all infusions]) or moderate (n=233 [44.5%, 1.1% of all infusions]). Twenty-eight reactions (5.3%, 0.1% of all infusions) were severe. Emergency medical services were called to transport patients to hospital for seven of the severe reactions, of which none required admission. As per pre-established medical directives, adrenaline was administered three times.
CONCLUSIONS: Infliximab infusions are safe in the community setting. Severe ADRs were rare. None required active physician intervention; nurses were able to treat all reactions by following standardized medical directives.

TC 6

Z9 6

SN 0835-7900

PD MAY

PY 2010

VL 24

IS 5

BP 307

EP 311

UT WOS:000277667800006

ER

40

INCLUDED

PT J

AU Bryan, S
Andronis, L
Hyde, C
Connock, M
Fry-Smith, A
Wang, D

AF Bryan, S.
Andronis, L.
Hyde, C.
Connock, M.
Fry-Smith, A.
Wang, D.

TI Infliximab for the treatment of acute exacerbations of ulcerative colitis

SO HEALTH TECHNOLOGY ASSESSMENT

AB This paper presents a summary of the evidence review group (ERG) report into the clinical effectiveness and cost-effectiveness of infliximab for the treatment of acute exacerbations of ulcerative colitis, in accordance with the licensed indication, based upon the manufacturer's submission to the National Institute for Health and Clinical Excellence (NICE) as part of the single technology appraisal process. The submitted clinical evidence included four randomised controlled trials (RCTs), two comparing infliximab with placebo in patients not responsive to initial treatment with intravenous corticosteroids and one comparing ciclosporin with placebo. A fourth RCT compared ciclosporin with intravenous corticosteroids as the initial treatment after hospitalisation. The manufacturer's submission concluded that infliximab provides clinical benefit to patients with acute severe, steroid-refractory ulcerative colitis and is well tolerated; it also provides additional clinical benefits over ciclosporin, particularly avoidance of colectomy. A decision tree model was built to compare infliximab with strategies involving ciclosporin, standard care and surgery. After correcting a small number of errors in the model, the revised base-case incremental cost-effectiveness ratio (ICER) for infliximab compared with standard care was (sic)20,000. However, sensitivity analyses revealed considerable uncertainty emanating from the weight of the patient, the timeframe considered and, most importantly, the colectomy rates used. When a more appropriate mix of trials were included in the estimation of colectomy rates, the ICER for infliximab rose to (sin)48,000. The guidance issued by NICE on 31 October 2008 states that infliximab is recommended as an option for the treatment of acute exacerbations of severely active ulcerative colitis only in patients in whom ciclosporin is contraindicated or clinically inappropriate, based on a careful assessment of the risks and benefits of treatment in the individual patient; for people who do not meet this criterion, infliximab should only be used for the treatment of acute exacerbations of severely active ulcerative colitis in clinical trials.

TC 1

Z9 1

SN 1366-5278

PD MAY

PY 2010

VL 14

SU 1

BP 9

EP 15

DI 10.3310/hta14suppl1/02

UT WOS:000279234300003

ER

41

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Kiran, RP
Moreira, AD
Remzi, FH
Church, JM
Lavery, I
Hammel, J
Fazio, VW

AF Kiran, Ravi P.
Moreira, Andre da Luz
Remzi, Feza H.
Church, James M.
Lavery, Ian
Hammel, Jeffery
Fazio, Victor W.

TI Factors Associated With Septic Complications After Restorative Proctocolectomy

SO ANNALS OF SURGERY

AB Objective: Few studies have evaluated factors that may be associated with the development of septic complications after restorative proctocolectomy. Therefore, the aim of this study is to evaluate preoperative and operative factors that might be associated with septic complications after restorative proctocolectomy. Methods: Patients developing abdominal and pelvic septic complications after restorative proctocolectomy were identified from a prospective database. Patients with subclinical leaks and ileostomy closure leak were not included in the septic complication group. A multivariable logistic regression model for sepsis was constructed using a forward stepwise selection with entry criterion of $P < 0.05$. Results: From 1983 to 2007, 3233 patients (56% male) were included in the database. Eight-four percent (2597) of patients underwent proximal diversion. Two hundred patients (6.2%) developed septic complications within 3 months of restorative proctocolectomy or within 3 months of ileostomy closure. On multivariate analysis, body mass index > 30 ($P = 0.02$, OR = 1.77), final pathologic diagnosis of ulcerative/indeterminate colitis ($P = 0.02$, OR = 2) or Crohn's disease ($P = 0.02$, OR = 3.6), intraoperative ($P = 0.02$, OR = 1.6), and postoperative transfusions ($P = 0.01$, OR = 1.9) were all independently associated with septic complications. We also demonstrated an independent association among individual surgeons ($P = 0.04$) with decreased septic complications. Conclusions: Body mass index greater than 30, final pathologic diagnosis of ulcerative/indeterminate colitis or Crohn's disease, intraoperative and postoperative transfusions, and surgeon were all independent factors associated with septic complications after restorative proctocolectomy.

TC 10

Z9 10

SN 0003-4932

PD MAR

PY 2010

VL 251

IS 3

BP 436

EP 440

DI 10.1097/SLA.0b013e3181cf8814

UT WOS:000275060800009

ER

42

INCLUDED

PT J

AU Punekar, YS
Hawkins, N

AF Punekar, Yogesh Suresh

Hawkins, Neil

TI Cost-effectiveness of infliximab for the treatment of acute exacerbations of ulcerative colitis

SO EUROPEAN JOURNAL OF HEALTH ECONOMICS

AB Background Infliximab has been shown to be efficacious in acute exacerbations of ulcerative colitis (UC). Aim To evaluate the cost-effectiveness of infliximab treatment in patients hospitalised with acute exacerbations of UC.
Methods A decision analysis model was constructed to simulate the progression of acute UC patients treated with infliximab induction regimen over 1 year. Infliximab treatment was compared with standard care, ciclosporin and surgery using transitions derived from infliximab and ciclosporin randomised trials. Costs and outcomes were discounted at 3.5%. Intermediate outcomes of colectomy and post-surgery complications were translated into the primary effectiveness measurement, which was quality-adjusted life years (QALYs) estimated using EQ-5D. One-way and probabilistic sensitivity analyses were performed to estimate the uncertainty around the results.
Results The incremental cost effectiveness ratio (ICER) for infliximab was 19,545 pound per QALY compared to ciclosporin, which in turn dominated standard care. Sensitivity analysis indicated patient body weight, utility estimates and treatment effect of alternative treatment strategies to be the most important factors affecting cost-effectiveness.
Conclusion Infliximab induction regimen appears to be a cost-effective treatment option for UC patients hospitalised with an acute exacerbation.

TC 1

Z9 2

SN 1618-7598

PD FEB

PY 2010

VL 11

IS 1

SI SI

BP 67

EP 76

DI 10.1007/s10198-009-0199-5

UT WOS:000275170000008

ER

43

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Cross, RK
Finkelstein, J

AF Cross, Raymond K.
Finkelstein, Joseph

TI Challenges in the design of a Home Telemanagement Trial for patients with ulcerative colitis

SO CLINICAL TRIALS

AB Background Nonadherence, inadequate monitoring, and side-effects result in suboptimal outcomes in ulcerative colitis (UC). We hypothesize that telemanagement for UC will improve symptoms, quality of life, adherence, and decrease costs.
Purpose This article describes the challenges encountered in the design of the home telemanagement in patients with UC trial.
Methods In a randomized trial to assess the effectiveness of telemanagement for UC compared to best available care, 100 patients will be enrolled. Subjects in the intervention arm will complete self-testing with telemanagement weekly; best available care subjects will receive scheduled follow up, educational fact sheets, and written action plans. Telemanagement consists of a home-unit, decision support server, and web-based clinician portal. The home-unit includes a scale and laptop. Subjects will respond to questions about symptoms, side-effects, adherence, and knowledge weekly; subjects will receive action plans after self-testing. Outcome variables to be assessed every 4 months include: disease activity, using the Seo index; quality of life, using the Inflammatory Bowel Disease Questionnaire; adherence, using pharmacy refill data

and the Morisky Medication Adherence Scale; utilization of healthcare resources, using urgent care visits and hospitalizations.
Results We encountered several challenges during design and implementation of our trial. First, we selected a randomized controlled trial design. We could have selected a quasiexperimental design to decrease the sample size needed and costs. Second, identification of a control group was challenging. Telemanagement patients received self-care plans and an educational curriculum. Since controls would not receive these interventions, we thought our results would be biased in favor of telemanagement. In addition, we wanted to evaluate the mode of delivery of these components of care. Therefore, we included written action plans and educational materials for patients in the control group ('best available care'). Third, we could not blind subjects to group assignment. In an attempt to decrease bias, staff was masked to group assignment to decrease measurement bias. Fourth, we selected outcome measures that were not invasive to decrease risks to subjects and to enhance recruitment.
Limitations Our results may not be generalizable as our program is a tertiary center. Further, subjects are not blinded to the intervention potentially resulting in bias; we attempt to minimize this bias by having staff masked to treatment group at the time of assessment of outcome measures.
Conclusions To the best of our knowledge, our trial will be the first randomized controlled trial to evaluate telemedicine in subjects with gastrointestinal disease. We describe several issues encountered in design and implementation of our trial that will aid investigators when planning telemedicine trials in inflammatory bowel disease. Clinical Trials 2009; 6: 649-657. http://ctj.sagepub.com.

TC 5
Z9 5
SN 1740-7745
PD DEC
PY 2009
VL 6
IS 6
BP 649
EP 657
DI 10.1177/1740774509346978
UT WOS:000272678800009
ER

44

EXCLUDED / ABSTRACT

PT J
AU Siegel, CA
AF Siegel, Corey A.
TI Accidentally ASCENDing Into Comparative Effective Research for Inflammatory Bowel Disease
SO GASTROENTEROLOGY
TC 3
Z9 3
SN 0016-5085
PD DEC
PY 2009
VL 137
IS 6
BP 1880
EP 1882
DI 10.1053/j.gastro.2009.10.014
UT WOS:000272539900007
ER

45

ABSTRACT

PT J

AU Holubar, SD
Long, KH
Loftus, EV
Wolff, BG
Pemberton, JH
Cima, RR

AF Holubar, Stefan D.
Long, Kirsten Hall
Loftus, Edward V., Jr.
Wolff, Bruce G.
Pemberton, John H.
Cima, Robert R.

TI Long-Term Direct Costs Before and After Proctocolectomy for Ulcerative Colitis: A Population-Based Study in Olmsted County, Minnesota

SO DISEASES OF THE COLON & RECTUM

CT Annual Meeting of the American-Society-of-Colon-and-Rectal-Surgeons

CY MAY 02-06, 2009

CL Hollywood, FL

SP Amer Soc Colon & Rectal Surg

AB PURPOSE: This study was designed to test the hypothesis that patients undergoing definitive surgery for chronic ulcerative colitis have reduced direct medical costs after, as compared with before, total proctocolectomy.
METHODS: A population-based cohort of patients who underwent proctocolectomy for ulcerative colitis from 1988 to 2007 was identified using the Rochester Epidemiology Project. Total direct healthcare costs were estimated from an administrative database. The primary outcome was the observed cost difference between the two-year period before surgery and the two-year period after a surgery/recovery period (surgery + 180 days). Statistical significance was assessed using paired t-tests and bootstrapping methods. Demographic data were presented as median (interquartile range) or frequency (proportion). Mean costs are reported in 2007 constant dollars.
RESULTS: Sixty patients were Olmsted County, Minnesota, residents at the time of surgery and for the entire period of observation. Overall 40 patients (66%) were men, median age was 42 (range, 31-52) years, and duration of median colitis was four (range, 1-11) years. Operations included ileal pouch-anal anastomosis (n = 45, mean cost of surgery/recovery period = $50,530) and total proctocolectomy with Brooke ileostomy (n = 15, mean cost of surgery/recovery period = $39,309). In the pouch subgroup, direct medical costs on average were reduced by $9,296 (P < 0.001, bootstrapped 95% confidence interval: $324-$15,628) during the two years after recovery. In the Brooke ileostomy subgroup, direct medical costs on average were reduced by $12,529 (P < 0.001, bootstrapped 95% confidence interval: $6,467-$18,688) in the two years after recovery.
CONCLUSION: Surgery for chronic ulcerative colitis resulted in reduced direct costs in the two years after surgical recovery. These observations suggest that surgical intervention for ulcerative colitis is associated with long-term economic benefit.

RI

Loftus, Edward	E-8304-2011
Holubar, Stefan	I-5002-2012

TC 6

Z9 6

SN 0012-3706

PD NOV

PY 2009

VL 52

IS 11

BP 1815

EP 1823

DI 10.1007/DCR.0b013e3181b327a6

UT WOS:000273645400001

ER

46

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Kane, SV
Chao, JD
Mulani, PM

AF Kane, Sunanda V.
Chao, Jingdong
Mulani, Parvez M.

TI Adherence to infliximab maintenance therapy and health care utilization and costs by Crohn's disease patients

SO ADVANCES IN THERAPY

AB Studies suggest infliximab decreases hospitalization and surgery rates in Crohn'fs disease (CD). The aim of this analysis was to evaluate adherence to infliximab maintenance therapy and the impact of medication adherence on health care utilization and costs by patients with CD.
Patients with CD who had at least four infliximab infusions (with the time between consecutive infusions a parts per thousand currency sign12 weeks for the first four infusions) during the first year following infliximab initiation (index date) were identified from the Integrated Health Care Information Service claims database (2002-2006). Nonadherence was defined as fewer than seven infliximab infusions in the first year. One-year health care resource utilization and costs (excluding infliximab drug and administration costs) were compared between adherent and nonadherent patients, with adjustment for baseline characteristics.
A total of 571 patients with CD who were receiving infliximab maintenance therapy were identified. The infusion-based nonadherence rate was 34.3% during the first year of therapy. The multivariate analysis demonstrated that compared with adherent patients, nonadherent patients were more likely to have been hospitalized (odds ratio [OR]=2.7 [all-cause] and OR=2.5 [CD-related]; both P < 0.001). Compared with infliximab-adherent patients, adjusted medical costs by nonadherent patients were 73% ($6,692) and 90% ($4,961) greater for all-cause and CD-related medical costs, respectively (both P < 0.001), and adjusted hospitalization costs were 115% ($11,450) and 115% ($9,570) greater for all-cause and CD-related hospitalization costs, respectively (both P < 0.001).
More than one-third of patients on infliximab maintenance therapy were nonadherent to recommended maintenance. Further, nonadherence was associated with increased medical costs and a greater rate of hospitalization.

TC 9

Z9 9

SN 0741-238X

PD OCT

PY 2009

VL 26

IS 10

BP 936

EP 946

DI 10.1007/s12325-009-0069-7

UT WOS:000272459100004

ER

47

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Cannom, RR
Kaiser, AM
Ault, GT
Beart, RW
Etzioni, DA

AF Cannom, Rebecca R.
Kaiser, Andreas M.
Ault, Glenn T.
Beart, Robert W., Jr.
Etzioni, David A.

TI Inflammatory Bowel Disease in the United States from 1998 to 2005: Has Infliximab Affected Surgical Rates?

SO AMERICAN SURGEON

CT 20th Annual Scientific Meeting of the Southern California Chapter of the American-College-of-Surgeons

CY JAN 16-18, 2009

CL Santa Barbara, CA

SP Amer Coll Surg, So Calif Chapter

AB The treatment costs for patients in the United States with inflammatory bowel disease (IBD) exceed 1.7 billion dollars/year. Infliximab, an antibody to tumor necrosis factor-alpha, has been extensively used to treat IBD, with 390,000 IBD patients receiving the drug since its FDA approval in 1998. We sought to determine the impact of infliximab on population-based rates of hospitalizations and surgical care for patients with IBD in the United States. We used data from the Nationwide Inpatient Sample to analyze patterns of hospital-based treatment provided to patients with IBD between 1998 and 2005. Data from this analysis were combined with census data to calculate trends in population-based rates of treatment. Overall rates of hospitalization for patients with Crohn's disease and ulcerative colitis increased significantly between 1998 and 2005 (5.1%/year and 3.4%/year respectively, $P < 0.001$ for each). During the same time period there were no changes in the overall rates of surgical care. The expanding use of infliximab has not significantly impacted the use of surgical procedures for patients with either ulcerative colitis or Crohn's disease, and rates of nonsurgical hospitalizations have actually increased. Even in the era of infliximab, surgical care remains a mainstay in the treatment of IBD.

TC 14

Z9 16

SN 0003-1348

PD OCT

PY 2009

VL 75

IS 10

BP 976

EP 980

UT WOS:000270795300025

ER

48

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Sandborn, WJ
Rutgeerts, P
Feagan, BG
Reinisch, W
Olson, A
Johanns, J
Lu, JD
Horgan, K
Rachmilewitz, D
Hanauer, SB
Lichtenstein, GR
de Villiers, WJS
Present, D
Sands, BE
Colombel, JF

AF Sandborn, William J.
Rutgeerts, Paul
Feagan, Brian G.
Reinisch, Walter
Olson, Allan
Johanns, Jewel
Lu, Jiandong
Horgan, Kevin
Rachmilewitz, Daniel
Hanauer, Stephen B.
Lichtenstein, Gary R.
de Villiers, Willem J. S.
Present, Daniel
Sands, Bruce E.
Colombel, Jean Frederic

TI Colectomy Rate Comparison After Treatment of Ulcerative Colitis With Placebo or Infliximab

SO GASTROENTEROLOGY

AB BACKGROUND & AIMS: The efficacy of infliximab for treating patients with ulcerative colitis has been established. METHODS: The Active Ulcerative Colitis Trial (ACT)-1 and ACT-2 randomized, double-blind, placebo-controlled studies evaluated infliximab Induction and maintenance therapy in moderately to severely active ulcerative colitis. Overall, 728 patients received placebo or infliximab (S or 10 mg/kg) intravenously at weeks 0, 2, and 6, then every 8 weeks through week 46 (ACT-1) or 22 (ACT-2). Colectomy hospitalization, and surgery/procedure data through 54 weeks after the first infusion were obtained from ACT-1 ACT-2, and associated data sources. In the prespecified analysis, all data were combined to ascertain time to colectomy. Kaplan-Meier product-limit method was used to estimate the cumulative incidence of colectomy, and log-rank test was used to compare the combined infliximab group and placebo. RESULTS: Eighty-seven percent (630 of 728) of patients had complete colectomy follow-up; 13% (98 of 728) of patients had a median follow-up of 6.2 months. The cumulative incidence of colectomy through 54 weeks was 10% for infliximab and 17% for placebo (P = .02), yielding an absolute risk reduction of 7%. Compared with placebo, fewer ulcerative colitis-related hospitalizations and surgeries/procedures per 100 patient-years of treatment occurred with infliximab therapy: 40 vs 20 (P = .003) and 34 vs 21(P =.03), respectively. Serious adverse events occurring in infliximab-treated patients included serious infections, tuberculosis, histoplasmosis, listeriosis, and malignancy. CONCLUSIONS: Patients with moderately to severely active ulcerative colitis treated with infliximab were less likely to undergo colectomy through 54 weeks than those receiving placebo.

TC 77

Z9 84

SN 0016-5085

PD OCT

PY 2009

VL 137

IS 4

BP 1250

EP 1260

DI 10.1053/j.gastro.2009.06.061

UT WOS:000270255200018

ER

49

INCLUDED

PT J

AU Hyde, C
Bryan, S
Juarez-Garcia, A
Andronis, L
Fry-Smith, A

AF Hyde, C.
Bryan, S.
Juarez-Garcia, A.
Andronis, L.
Fry-Smith, A.

TI Infliximab for the treatment of ulcerative colitis

SO HEALTH TECHNOLOGY ASSESSMENT

AB This paper presents a summary of the evidence review group (ERG) report into the clinical effectiveness and cost-effectiveness of infliximab for moderately to severely active ulcerative colitis (UC) based upon a review of the manufacturer's submission to the National Institute for Health and Clinical Excellent (NICE) as part. of the single technology appraisal (STA) process. The submission indicated that the efficacy of infliximab (5 mg/kg) had been demonstrated in terms of higher response rates and a sustained response in health-related quality of life. For the cost-effectiveness analysis, the manufacturer built a Markov model to compare infliximab with standard care. It estimated the incremental cost per quality-adjusted life-year (QALY) gained was between 25,044 pound and 33,866 pound depending on the strategy used. The ERG report generally agreed with the evidence on effectiveness of infliximab for subacute exacerbations of UC. However, there were several areas Of uncertainty, of which the interpretation of the importance of the quality of life changes in the subacute situation and the assessment of the adequacy of the evidence of effectiveness of infliximab in the acute hospital-based situation were considered pre-eminent by the ERG. This challenged the estimates of cost-effectiveness offered and suggested that there should be a separate assessment of infliximab for acute exacerbations of moderately to severely active UC. The summary of the NICE guidance issued in April 2008 as a result of the STA states that: infliximab is not recommended for the treatment Of Subacute manifestations of moderately to severely active UC.

TC 0

Z9 1

SN 1366-5278

PD OCT

PY 2009

VL 13

BP 7

EP 11

DI 10.3310/hta13suppl3/02

UT WOS:000273002700003

ER

50

EXCLUDED / ABSTRACT

PT J

AU Shore, E

AF Shore, E.

TI THE COST EFFECTIVENESS OF INFLIXIMAB IN THE TREATMENT OF ACUTE ULCERATIVE COLITIS PATIENTS IN SCOTLAND

SO VALUE IN HEALTH

TC 0

Z9 0

SN 1098-3015

PD OCT

PY 2009

VL 12

IS 7

BP A347

EP A348

DI 10.1016/S1098-3015(10)74709-4

UT WOS:000269878100634

ER

51

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Cui, DJ

AF Cui, De-Jun

TI Early aggressive therapy for severe extensive ulcerative colitis

SO WORLD JOURNAL OF GASTROENTEROLOGY

AB The current ulcerative colitis (UC) treatment algorithm involves a step-up therapeutic strategy, mainly aiming at inducing and maintaining its clinical remission. Although this therapeutic strategy may seem to be cost-efficient and reduce the risk of side effects, recent trials and case reports have shown that top-down therapy using infliximab induces a rapid clinical response, enhances patient quality of life, promotes mucosal healing, reduces surgeries and indirect cost of treatment for patients with severe UC. Moreover, since long-term treatment with infliximab is safe and well tolerated, early aggressive top-down therapeutic strategy may be a more effective approach, at least in a subgroup of severe extensive UC patients.

TC 1

Z9 1

SN 1007-9327

PD SEP 7

PY 2009

VL 15

IS 33

BP 4218

EP 4219

DI 10.3748/wjg.15.4218

UT WOS:000269610100025

ER

52

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Angelberger, S
Vogelsang, H
Novacek, G
Miehsler, W
Dejaco, C
Gangl, A
Reinisch, W

AF Angelberger, Sieglinde
Vogelsang, Harald
Novacek, Gottfried
Miehsler, Wolfgang
Dejaco, Clemens
Gangl, Alfred
Reinisch, Walter

TI Public awareness of Crohn's disease and ulcerative colitis: A national survey

SO JOURNAL OF CROHNS & COLITIS

AB Background and aims: Crohn's disease (CD) and ulcerative colitis (UC) are lifelong inflammatory bowel, diseases (IBD) progressing over time. Lack of public awareness may contribute to tardy consultation of primary care physicians, late diagnosis and development of potentially preventable complications of disease. A public opinion poll has been performed to assess the awareness of CD and UC in the Austrian population. Methods: In March/April 2006, 122 interviewers of an international polling institute asked 1001 Austrians

aged 16 and over about their knowledge of CD and UC. People interviewed were selected using a quota sampling scheme representing the Austrian population.
Results: CD and UC were never heard/read in 68% and 79% (group 1), respectively, whereas 23% and 14% had already heard/read these terms (group 2). Only 9% and 7% of participants gained information on or were familiar with CD and UC (group3), respectively. Among provided choices of potentially afflicted organs interviewees of group 3 associated the terms "CD" and "UC" with an intestinal disease in 86% each. Among those of group 2 + 3 the corresponding figures were 53% and 60% for CD and UC, respectively. Overall, 7% and 4% of the participants stated to be aware and/or informed on CD and UC and correctly associated these terms with an intestinal disease.
Conclusions: This is the first study on public awareness of the terms "Crohn's disease" and "utcerative colitis". Poor knowledge in the public is reported which may vastly impact outcome and health economic consequences of IBD.

TC 0

Z9 0

SN 1873-9946

PD SEP

PY 2009

VL 3

IS 3

BP 157

EP 161

DI 10.1016/j.crohns.2009.01.003

UT WOS:000269271700003

ER

53 ---

INCLUDED

PT J

AU Connolly, MP
Nielsen, SK
Currie, CJ
Marteau, P
Probert, CSJ
Travis, SPL

AF Connolly, Mark P.
Nielsen, Sandy K.
Currie, Craig J.
Marteau, Philippe
Probert, Chris S. J.
Travis, Simon P. L.

TI An economic evaluation comparing concomitant oral and topical mesalazine versus oral mesalazine alone in mild-to-moderately active ulcerative colitis based on results from randomised controlled trial

SO JOURNAL OF CROHNS & COLITIS

AB Introduction: A previous randomised controlled trial has demonstrated that oral plus topical mesalazine enema is more effective than oral mesalazine alone for achieving clinical remission in mild-to-moderately active extensive ulcerative colitis (UC). To evaluate whether this strategy is cost-effective we conducted an economic evaluation comparing 1 g topical mesalazine in combination with 4 g oral mesalazine compared to 4 g mesalazine monotherapy in mild-to-moderately active UC.
Methods: The economic evaluation was based on the ability to achieve remission using changes from baseline in the ulcerative colitis disease activity instrument (UCDAI). A cost-utility analysis was used where the main outcome was quality-adjusted life years to reflect improved quality of life associated with achieving remission compared with active disease. A simulated Markov model with five health states was constructed to model cost and outcome changes over time: (1) active UC; (2) mesalazine-refractory active UC; (3) steroid-refractory active UC; (4) infliximab-responsive active UC; and (5) remission. To reflect parameter uncertainty in the cost-effectiveness analysis probabilistic sensitivity analysis (PSA) was

conducted by varying relevant clinical parameters. Results: Average treatment costs required to transition a patient from active UC to remission using oral and topical mesalazine compared with oral atone were 1812 pound and 2390 pound, respectively. Improved remission rates attributed to oral and topical mesalazine resulted in moderate improvements in quality-adjusted Life years (QALYs) compared to oral mesalazine atone. Disaggregation of medical costs indicated that medical consultations and diagnostic costs were similar for both treatment arms. An abbreviated analysis which considered costs up to steroid-refractory patients in subacute UC indicated that combination therapy offered a cost-savings of 285 pound over 16 weeks of therapy compared with monotherapy. Conclusions: The results indicate that the addition of 1 g topical mesalazine results in significant cost-savings and moderate quality of life improvements. We have also shown that irrespective of which treatment modality is used in steroid-refractory patients (eg, infliximab, azathioprine, ciclosporine) that topical mesalazine is cost-saving.

TC 4

Z9 4

SN 1873-9946

PD SEP

PY 2009

VL 3

IS 3

BP 168

EP 174

DI 10.1016/j.crohns.2009.02.005

UT WOS:000269271700005

ER

54

EXCLUDED / ABSTRACT

PT J

AU Pittet, V
Juillerat, P
Mottet, C
Felley, C
Ballabeni, P
Burnand, B
Michetti, P
Vader, JP

AF Pittet, Valerie
Juillerat, Pascal
Mottet, Christian
Felley, Christian
Ballabeni, Pierluigi
Burnand, Bernard
Michetti, Pierre
Vader, John-Paul

CA Swiss IBD Cohort Study Grp

TI Cohort Profile: The Swiss Inflammatory Bowel Disease Cohort Study (SIBDCS)

SO INTERNATIONAL JOURNAL OF EPIDEMIOLOGY

TC 16

Z9 18

SN 0300-5771

PD AUG

PY 2009

VL 38

IS 4

BP 922

EP 931

DI 10.1093/ije/dyn180

UT WOS:000268812300008

ER

55

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Bendtzen, K
Ainsworth, M
Steenholdt, C
Thomsen, OO
Brynskov, J

AF Bendtzen, Klaus
Ainsworth, Mark
Steenholdt, Casper
Thomsen, Ole Ostergaard
Brynskov, Jorn

TI Individual medicine in inflammatory bowel disease: Monitoring bioavailability, pharmacokinetics and immunogenicity of anti-tumour necrosis factor-alpha antibodies

SO SCANDINAVIAN JOURNAL OF GASTROENTEROLOGY

AB Antibody constructs targeting tumour necrosis factor-alpha (TNF) have become important in the management of several chronic immunoinflammatory diseases. Four recombinant anti-TNF drugs are currently approved for clinical use in patients with various chronic inflammatory diseases, three of which are effective in chronic inflammatory bowel disease. These proteins can dramatically lower disease activity and, in some patients, induce remission. Unfortunately, however, not all patients respond favourably to anti-TNF antibodies. For example, patients suffering from Crohn's disease do not benefit from etanercept, and some patients treated with the other anti-TNF constructs either do not respond at all (primary response failure), or they respond initially but have later relapses (secondary response failure) despite increased dosage and/or more frequent administration of the drugs. The reason(s) for these response failures are not clear but inter-individual and even intra-individual differences in bioavailability and pharmacokinetics may contribute. Furthermore, immunogenicity of the drugs, causing patients to develop anti-drug antibodies (ADAs), contributes to treatment failure. Monitoring patients for circulating levels of functional anti-TNF;F drugs and ADAs is therefore warranted so that treatment can be tailored to the individual patient (individual medicine or personal medicine) in order that effective and economical long-term therapy can be given with minimal risks to the patients.

TC 31

Z9 31

SN 0036-5521

PD JUL

PY 2009

VL 44

IS 7

BP 774

EP 781

DI 10.1080/00365520802699278

UT WOS:000268579400002

ER

56

EXCLUDED / ABSTRACT

PT J

AU Jones, J
Worobetz, L
Bedi, A
Manns, B

AF Jones, Jennifer
Worobetz, Lawrence
Bedi, Anil
Manns, Braden

TI A Cost-Utility Analysis of Infliximab Compared with Surgery for the Treatment of Ulcerative Colitis; A Public Payer Perspective

SO GASTROENTEROLOGY

CT Digestive Disease Week/110th Annual Meeting of the American-Gastroenterological-Association

CY MAY 30-JUN 04, 2009

CL Chicago, IL

SP Amer Gastroenterol Assoc

RI

Manns, Braden	I-8942-2012

TC 0

Z9 0

SN 0016-5085

PD MAY

PY 2009

VL 136

IS 5

SU 1

BP A172

EP A172

UT WOS:000275277200773

ER

57

PT J

AU Yen, EF
Kane, SV
Ladabaum, U

AF Yen, Eugene F.
Kane, Sunanda V.
Ladabaum, Uri

TI Cost-Effectiveness of 5-Aminosalicylic Acid Therapy for Maintenance of Remission in Ulcerative Colitis

SO AMERICAN JOURNAL OF GASTROENTEROLOGY

AB OBJECTIVES: Oral 5-aminosalicylic acid (5-ASA, mesalamine) is effective in inducing and maintaining remission in ulcerative colitis (UC). The relative benefits and costs of maintenance 5-ASA therapy are uncertain. Our aims were to evaluate this strategy's potential cost-effectiveness. METHODS: We constructed a Markov model to compare two strategies over 2 yr: (a) no maintenance 5-ASA, with 5-ASA 4.8 g/day given for flares, (b) maintenance 5-ASA 2.4 g/day, escalated and maintained at 4.8 g/day after the first flare. In both arms, the failure to induce remission led to other treatments, as needed: prednisone, parenteral corticosteroids, cyclosporine, 6-mercaptopurine, infliximab, and colectomy. RESULTS: Without maintenance 5-ASA, the mean flares per person were 1.92, and the mean cost per person was $3,402. With maintenance 5-ASA providing a relative risk of flare of 0.7 at 5-ASA cost of $198/month, flares per person decreased to 1.38 at a cost of $8,810/flare prevented. Maintenance 5-ASA increased discounted quality-adjusted life-years per person (QALYs per person) from 1.75 to 1.77 at a discounted cost of $224,000/QALY gained. The results were most sensitive to the flare risk reduction and cost of 5-ASA, the utilities of being in remission without or with 5-ASA, and the colectomy rates. At $15/month (the cost of sulfasalazine), maintenance 5-ASA cost $640/flare prevented and $16,300/QALY gained.

CONCLUSION: Maintenance 5-ASA therapy decreases UC flares, but its cost may be substantial, depending on society's willingness to pay. If sulfasalazine can be tolerated and yields comparable benefits, sulfasalazine maintenance therapy is likely to be cost-effective. The cost per QALY gained by 5-ASA maintenance is highly dependent on the quality of life while taking versus not taking maintenance 5-ASA, highlighting the importance of patients' preferences. (Am J Gastroenterol 2008;103:3094-3105).

TC 8

Z9 8

SN 0002-9270

PD DEC

PY 2008

VL 103

IS 12

BP 3094

EP 3105

DI 10.1111/j.1572-0241.2008.02130.x

UT WOS:000261361200022

ER

58

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Odes, S

AF Odes, Selwyn

TI How expensive is inflammatory bowel disease? A critical analysis

SO WORLD JOURNAL OF GASTROENTEROLOGY

AB Economic analysis of chronic diseases is required for proper allocation of resources and understanding cost-effectiveness studies of new therapies. Studies on health care cost of ulcerative colitis (UC) and Crohn's disease (CD) are reviewed here. These studies were carried out in various countries with disparate health care systems. In the United States, data were often modeled or retrieved from large insurance schemes. Surgery and in-patient hospitalization accounted for over half the outlay on UC and CD. Fistulous disease in CD and parenteral nutrition were very costly. In Canada, overall charges were lower than in the United States, but there too, surgical costs were relatively high. In European studies, economic data were abstracted directly from patients' files. One pan-European study examined the outlay on UC and CD in a community-based prospective inception cohort followed for 10 years. Overall costs in Europe were lower than in the United States. Surgery, hospitalization, year of follow-up, disease phenotype in CD and ASCA-positivity impacted significantly on costs. In all studies, the cost data were right skewed, aminosalicylates were expensive drugs, and biological agents the most expensive; moreover indirect costs were not calculated. Infliximab raised costs considerably in CD, but there were no long-term follow-up studies, so that the cost-benefit of biological agents remains unknown. In conclusion, costs of managing UC and CD vary by country, surgery, genotype and several other factors. The most important question for further research is whether the biological therapies are cost-effective in the long-term.

TC 15

Z9 16

SN 1007-9327

PD NOV 21

PY 2008

VL 14

IS 43

BP 6641

EP 6647

DI 10.3748/wjg.14.6641

UT WOS:000261380800007

ER

59

INCLUDED

PT J

AU Tsai, HH
Punekar, YS
Morris, J
Fortun, P

AF Tsai, H. H.
Punekar, Y. S.
Morris, J.
Fortun, P.

TI A model of the long-term cost effectiveness of scheduled maintenance treatment with infliximab for moderate-to-severe ulcerative colitis

SO ALIMENTARY PHARMACOLOGY & THERAPEUTICS

AB Background
Infliximab (IFX) has been shown to be efficacious in moderate-severe ulcerative colitis (UC).
Aim
To evaluate the cost-effectiveness of a scheduled maintenance treatment (SMT) with IFX in moderate-severe UC patients.
Methods
A Markov model was constructed to simulate the progression of a cohort of moderate-severe UC patients treated with IFX (5 mg/kg) SMT. Transitions were estimated from two phase III trials of IFX (ACT I and ACT II). Standard care, comprising immunomodulators and/or corticosteroids was used as a comparator. Two separate treatment strategies were evaluated - continued treatment in IFX responders and continued treatment in IFX patients achieving remission. The dose of IFX was estimated for a 73 kg typical UC patient in the UK. The results were calculated over 10 years using a discount rate of 3.5% for costs and outcomes. The outcome measure was quality-adjusted life years (QALYs) estimated using EQ-5D. Sensitivity analyses explored the uncertainty around the results.
Results
The incremental cost effectiveness ratio (ICER) for IFX was 27 pound 424 in the responder strategy and 19 pound 696 in the remission strategy at 10 years. In sensitivity analysis, the ICER for IFX in the responder strategy ranged from 21 pound 066 to 86 pound 322 and in the remission strategy ranged from 14 pound 728 to 46 pound 765. The model time horizon and patient body weight were important factors affecting results.
Conclusions
Eight-week SMT with IFX appears to be a cost-effective treatment option for adult patients suffering from moderate to severe UC.

TC 13

Z9 14

SN 0269-2813

PD NOV 15

PY 2008

VL 28

IS 10

BP 1230

EP 1239

DI 10.1111/j.1365-2036.2008.03839.x

UT WOS:000260131600007

ER

60

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Gibson, TB

Ng, E
Ozminkowski, RJ
Wang, SH
Burton, WN
Goetzel, RZ
Maclean, R

AF Gibson, Teresa B.
Ng, Eliza
Ozminkowski, Ronald J.
Wang, Shaohung
Burton, Wayne N.
Goetzel, Ron Z.
Maclean, Ross

TI The Direct and Indirect Cost Burden of Crohn's Disease and Ulcerative Colitis

SO JOURNAL OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

AB Objective: To estimate the direct medical and indirect (absenteeism and short-term disability) cost burden of Crohn's Disease (CD) rind Ulcerative Colitis (UC). Methods: Data were obtained from 1999 to 2005 MarketScan databases. Twelve-month expenditures for patients with CD and UC were compared to expenditures among an. equal number of propensity score matched comparison group patients. Regression analysis controlled for demographics and case-mix. Results: Annual medical expenditures were significantly higher for commercially insured CD and UC patients compared to matched comparison group patients ($18,963 vs $5300 for CD patients, $15,020 vs $4982 for UC patients, respectively, all P < 0.001). Indirect costs were also high for employed patients with these conditions. Conclusions: CD and UC are costly diseases with a signficant cost burden related to health care utilization and productivity loss. (J Occup Environ Med. 2008;50: 1261-1272)

RI

Goetzel, Ron	A-9670-2009

TC 28

Z9 28

SN 1076-2752

PD NOV

PY 2008

VL 50

IS 11

BP 1261

EP 1272

DI 10.1097/JOM.0b013e318181b8ca

UT WOS:000260880800007

ER

61

EXCLUDED / PEDIATRIC ULCERATIVE COLITIS

PT J

AU Guthery, SL
Dong, L
Dean, JM
Holubkov, R

AF Guthery, Stephen L.
Dong, Lydia
Dean, J. Michael
Holubkov, Richard

TI US estimates of hospitalized pediatric patients with ulcerative colitis: Implications for multicenter clinical studies

SO INFLAMMATORY BOWEL DISEASES

AB Background: The optimal clinical management of children hospitalized With ulcerative colitis (UC) is

evolving. There are limited data quantifying the number of pediatric patients with UC admitted to hospitals in the United States. We analyzed the Kids' Inpatient Database (KID, 2003), to estimate the distribution of hospitalized children with UC and estimate sample sizes available for clinical research. Methods: We limited Our analysis to Subjects age less than 19 years. We defined cases of UC as discharge records associated with all ICD-9 code of 556.0-556.9 in the first position. We defined colectomy as principal procedure code of 45.8. We generated weighted estimates for these analyses. To estimate the relationship between number of patients and number of hospitals necessary for clinical trials, we generated 1000 Simulated datasets. Results: A total of 2311 UC cases were identified. The mean age at admission was 13.1 (standard error [SEE.] 0.1) years, and 9% (SE 0.9%) underwent colectomy during their hospitalization. 1008 UC cases were treated at high-volume hospitals; the majority of these children were treated at children's hospitals. Simulation studies suggest that approximate to 5 high-volume hospitals would be necessary to generate sample sizes necessary for a pilot clinical trial of refractory UC. Conclusions: Approximately half of all yound patients hospitalized with UC in the US were treated at a limited number of high-volume hospitals, and approximate to 5 Such Centers would be adequate for pilot clinical trials of hospitalized patients with refractory UC.

TC 1

Z9 1

SN 1078-0998

PD SEP

PY 2008

VL 14

IS 9

BP 1253

EP 1258

DI 10.1002/ibd.20521

UT WOS:000259077300012

ER

62

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Maharshak, N
Arbel, Y
Gal-Oz, A
Rogowski, O
Shapira, I
Berliner, S
Vered, Y
Canaani, J
Dotan, I

AF Maharshak, Nitsan
Arbel, Yaron
Gal-Oz, Amir
Rogowski, Ori
Shapira, Itzhak
Berliner, Shlomo
Vered, Yaffa
Canaani, Jonathan
Dotan, Iris

TI Comparative analysis of Bayer wide-range C-reactive protein (wr-CRP) and the Dade-Behring high sensitivity C-reactive protein (hs-CRP) in patients with inflammatory bowel disease

SO JOURNAL OF DIGESTIVE DISEASES

AB OBJECTIVE: The recently introduced Bayer wide-range C-reactive protein (wr-CRP) assay might be relevant for the real-time low-cost and online determination of inflammatory bowel disease (IBD) activity. Our aim was to examine whether wr-CRP can substitute for the Dade Behring high sensitivity C-reactive

protein (hs-CRP) assay in IBD patients.
METHODS: A total of 71 patients with IBD, of whom 48 had Crohn's disease CD and 23 had ulcerative colitis (UC) with various intensities of disease activity participated in the study. The CRP of patients who were under treatment at the Department of Gastroenterology and Liver Diseases were measured using both wr-CRP and the hs-CRP.
RESULTS: A significant (r = 0.995; P < 0.001) correlation was noted between the hs-CRP and wr-CRP measurements for the whole sample as well as for the two diseases, CD (r = 0.994; P < 0.001) and UC (r = 0.997; P < 0.001), which were analyzed separately.
CONCLUSION: The Bayer wr-CRP assay might be a useful low-cost and real-time inflammation-sensitive biomarker in patients with IBD.

TC 2
Z9 2
SN 1751-2972
PD AUG
PY 2008
VL 9
IS 3
BP 140
EP 143
DI 10.1111/j.1751-2980.2008.00335.x
UT WOS:000258257600003
ER

63

EXCLUDED / ABSTRACT

PT J
AU Shen, B
AF Shen, Bo
TI Impact of preoperative infliximab use on postoperative infectious complications in ulcerative cokis: The price we have to pay?
SO INFLAMMATORY BOWEL DISEASES
TC 6
Z9 6
SN 1078-0998
PD JUL
PY 2008
VL 14
IS 7
BP 1019
EP 1021
DI 10.1002/ibd.20407
UT WOS:000257401800018
ER

64

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J
AU Wilhelm, SM
McKenney, K
Rivait, KN
Kale-Pradhan, PB
AF Wilhelm, Sheila M.
McKenney, Kathleen

Rivait, Kelly N.
Kale-Pradhan, Pramodini B.

TI A review of infliximab use in ulcerative colitis

SO CLINICAL THERAPEUTICS

AB Background: Infliximab is a chimeric immunoglobulin G1K monoclonal antibody that binds with high affinity and specificity to the soluble form of tumor necrosis factor (TNF)-alpha, preventing it from binding to cellular receptors. Infliximab also binds to membrane-bound TNF-alpha found on inflammatory cell surfaces, inducing apoptosis. Currently, infliximab is used for the induction and maintenance of remission in Crohn's disease (CD), with documented success. Infliximab's efficacy in the treatment of ulcerative colitis (UC) is now being investigated due to the similarities in the pathophysiology of CD and UC. Objective: The aim of this study was to review and evaluate the current literature of infliximab use in steroid-refractory UC to assess its role in treatment. Methods: A search of MEDLINE was conducted (1950-November 2007). Key terms included, but were not limited to, infliximab, inflammatory bowel disease, ulcerative colitis, cost, and quality of life. Studies included for review were limited to English-language, full-text, randomized, double-blind, placebo-controlled trials. Clinical trials were reviewed and summarized. Results: Four controlled clinical trials of infliximab in the treatment of steroid-refractory UC were found and assessed. In a double-blind, randomized, controlled trial in 43 patients with moderately severe, glucocorticoid-resistant UC, infliximab and placebo were not significantly different with respect to clinical and sigmoidoscopic remission or quality of life 2 and 6 weeks after infliximab treatment. In a multicenter, randomized, double-blind, placebo-controlled study in 45 patients with moderately severe to severe glucocorticoid-resistant UC, infliximab was associated with a significantly reduced need for colectomy compared with placebo (29% vs 67%; P = 0.017). The Active Ulcerative Colitis Trials (ACT) 1 and 2 together included 728 patients with moderate to severe glucocorticoid-resistant UC. The primary outcome, the rate of clinical response at 8 weeks, was significantly higher with Infliximab compared with placebo (5 mg/kg: ACT 1, 69.4%, ACT 2, 64.5%; 10 mg/kg: ACT 1, 61.5%, ACT 2, 69.2%; placebo: ACT 1, 37.2%, ACT 2, 29.3%; all, P < 0.001 vs placebo). Based on the data from ACT 1 and 2, infliximab was associated with improved health-related quality-of-life (HRQOL) scores based on the Inflammatory Bowel Disease Questionnaire and the 36-item Short Form Health Survey. Conclusions: Current data suggest that infliximab is an effective alternative treatment option for patients with moderate to severe UC with an inadequate response to conventional glucocorticoid treatment. Further trials are needed to assess infliximab's impact on the treatment and progression of UC, the HRQL of patients with UC, and the economic impact on the health care system.

TC 21

Z9 23

SN 0149-2918

PD FEB

PY 2008

VL 30

IS 2

BP 223

EP 230

DI 10.1016/j.clinthera.2008.02.014

UT WOS:000254466900001

ER

65

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Nguyen, GC
Tuskey, A
Dassopoulos, T
Harris, ML
Brant, SR

AF Nguyen, Geoffrey C.
Tuskey, Anne

Dassopoulos, Thernistocles
Harris, Mary L.
Brant, Steven R.

TI Rising hospitalization rates for inflammatory bowel disease in the United States between 1998 and 2004

SO INFLAMMATORY BOWEL DISEASES

AB Background: Recent epidemiological studies suggest that the prevalences of Crohn's disease (CD) and ulcerative colitis (UC) are increasing in the United States. We sought to determine whether nationwide rates of inflammatory bowel disease (IBD) hospitalizations have increased in response to temporal trends in prevalence.
Methods: We identified all admissions with a primary diagnosis of CD or UC, or 1 of their complications in the Nationwide Inpatient Sample between 1998 and 2004. National estimates of hospitalization rates and rates of surgery were determined using the U.S. Census population as the denominator.
Results: There were an estimated 359,124 and 214,498 admissions for CD and UC, respectively. The overall hospitalization rate for CD was 18.0 per 100,000 and that for UC was 10.8 per 100,000. There was a 4.3% annual relative increase in hospitalization rate for CD ($P < 0.0001$) and a 3.0% annual increase for UC ($P < 0.0001$). Surgery rates were 3.4 bowel resections per 100,000 for CD and 1.2 colectomies per 100,000 for UC and remained stable. There were no temporal patterns for average length of stay for CD (5.8 days) or for UC (6.8 days). The national estimate of total inpatient charges attributable to CD increased from $762 million to $1,330 million between 1998 and 2004, and that for UC increased from $592 million to $945 million.
Conclusions: Hospitalization rates for IBD, particularly CD, have increased within a 7-year period, incurring a substantial rise in inflation-adjusted economic burden. The findings reinforce the need for effective treatment strategies to reduce IBD complications.

TC 45

Z9 46

SN 1078-0998

PD DEC

PY 2007

VL 13

IS 12

BP 1529

EP 1535

DI 10.1002/ibd.20250

UT WOS:000251807500011

ER

66

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Ackermann, C
Kavanaugh, A

AF Ackermann, Christoph
Kavanaugh, Arthur

TI Tumor necrosis factor as a therapeutic target of rheumatologic disease

SO EXPERT OPINION ON THERAPEUTIC TARGETS

AB TNF-alpha is a crucial pro-inflammatory and immunregulatory cytokine that is central to the pathogenesis of various inflammatory and autoimmune conditions. A number of controlled trials have shown effectiveness for TNF-alpha inhibitiors in several diseases, in particular rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and Crohn's disease. These agents may also be useful in additional autoimmune conditions. The introduction of TNF-alpha inhibitors has revolutionized the therapeutic approach and treatment paradigms especially for patients with rheumatoid arthritis. Despite extensive investigation, the full profile of their mechanisms of action remain incompletely understood. Optimal use of these agents requires consideration of their possible adverse effects. in addition to the presently available TNF-alpha blockers, other agents targeting this key mediator are under study. Recent advances and future directions in anti-TNF-alpha therapy are discussed in this paper.

TC 33
Z9 35
SN 1472-8222
PD NOV
PY 2007
VL 11
IS 11
BP 1369
EP 1384
DI 10.1517/14728222.11.11.1369
UT WOS:000251116800001
ER

67

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Teml, A
Schaeffeler, E
Herrlinger, KR
Klotz, U
Schwab, M

AF Teml, Alexander
Schaeffeler, Elke
Herrlinger, Klaus R.
Klotz, Ulrich
Schwab, Matthias

TI Thiopurine treatment in inflammatory bowel disease - Clinical pharmacology and implication of pharmacogenetically guided dosing

SO CLINICAL PHARMACOKINETICS

AB This review summarises clinical pharmacological aspects of thiopurines in the treatment of chronic inflammatory bowel disease (IBD). Current knowledge of pharmacogenetically guided dosing is discussed for individualisation of thiopurine therapy, particularly to avoid severe adverse effects.
Both azathiciprine and mercaptopurine are pro-drugs that undergo extensive metabolism. The catabolic enzyme thiopurine S-methyltransferase (TPMT) is polymorphically expressed, and currently 23 genetic variants have been described. On the basis of an excellent phenotype-genotype correlation for TPMT, genotyping has become a safe and reliable tool for determination of a patient's individual phenotype. Thiopurine-related adverse drug reactions are frequent, ranging from 5% up to 40%, in both a dose-dependent and -independent manner. IBD patients with low TPMT activity are at high risk of developing severe haematotoxicity if pharmacogenetically guided dosing is not performed. Based on several cost-benefit analyses, assessment of TPMT activity is recommended prior to thiopurine therapy in patients with IBD. The underlying mechanisms of azathioprine/mercaptopurine-related hepatotoxicity, pancreatitis and azathioprine intolerance are still unknown.
Although the therapeutic response appears to be related to 6-thioguanine nucleotide (6-TGN) concentrations above a threshold of 230-260 pmol per 8 x 10(8) red blood cells, at present therapeutic drug monitoring of 6-TGN can be recommended only to estimate patients' compliance. Drug-drug interactions between azathioprine/mercaptopurine and aminosalicylates, diuretics, NSAIDs, warfarin and infliximab are discussed. The concomitant use of allopurinol without dosage adjustment of azathioprine/mercaptopurine leads to clinically relevant severe haematotoxicity due to elevated thiopurine levels.
Several studies indicate that thiopurine therapy in IBD during pregnancy is safe. Thus, azathioprine/mercaptopurine should not be withdrawn in strictly indicated cases of pregnant IBD patients. However, breastfeeding is contraindicated during azathioprine/mercaptopurine therapy.
Use of azathioprine/mercaptopurine for induction and maintenance of remission in corticosteroid-dependent or corticosteroid-refractory IBD, particularly Crohn's disease, is evidence based. To improve response rates in thiopurine therapy of IBD, comprehensive analyses including metabolic patterns and genome-wide profiling in patients with azathioprine/mercaptopurine treatment are required to identify novel candidate genes.

TC 65
Z9 71
SN 0312-5963
PY 2007
VL 46
IS 3
BP 187
EP 208
DI 10.2165/00003088-200746030-00001
UT WOS:000245351700001
ER

68

EXCLUDED / REVIEW

PT J
AU Cohen, RD
Thomas, T
AF Cohen, Russell D.
Thomas, Tojo
TI Economics of the use of biologics in the treatment of inflammatory bowel disease
SO GASTROENTEROLOGY CLINICS OF NORTH AMERICA
AB Studies of costs associated with inflammatory bowel diseases (IBD) have traditionally concentrated on direct costs of disease, with most accounted for by surgeries and hospitalizations. New research raising awareness of indirect costs, and the cost-implications of normalizing quality of life, has shown these components to represent an even larger percentage of overall disease costs. The introduction of potent but expensive biologic therapies has raised the question of whether society can or cannot afford to use these agents. Initial investigations suggest that use of these drugs leads to a substantial reduction of the use of medical resources and their associated costs. Future research combining these results with the favorable impact on indirect costs and quality of life will likely represent a new chapter in the economics of IBDs.
TC 13
Z9 17
SN 0889-8553
PD DEC
PY 2006
VL 35
IS 4
BP 867
EP +
DI 10.1016/j.gtc.2006.09.004
UT WOS:000243029500011
ER

69

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J
AU Domenech, E
AF Domenech, E
TI Inflammatory bowel disease: Current therapeutic options
SO DIGESTION
CT Workshop on Bacterial Flora in Digestive Disease - Focus on Rifaximin
CY JAN, 2005
CL Barcelona, SPAIN

AB Medical management of inflammatory bowel diseases (IBD) includes two treatment strategies: induction and maintenance of remission. 5-Aminosalycilates are mostly used for mild active IBD and for maintenance treatment in ulcerative colitis (UC). Glucocorticoids remain, despite their frequent (and occasionally severe) side effects, as the mainstay for induction of remission in moderate to severe active IBD, both UC and Crohn's disease (CID). Cyclosporine and infliximab have emerged as the main, rapid-acting, alternatives in steroid-refractory UC and CD, respectively. Thiopurines (azathioprine and 6-mercaptopurine) are the most efficient and used immunomodulators in IBD; steroid refractoriness, steroid dependency, and long-term maintenance of remission for both UC and CID are their main indications. Methotrexate and infliximab may be used in the same clinical settings as thiopurines in CID, but not in UC; however, these drugs are a second-line treatment because of safety profile and economic costs.

TC 32

Z9 37

SN 0012-2823

PY 2006

VL 73

SU 1

BP 67

EP 76

DI 10.1159/000089781

UT WOS:000235909700010

ER

70

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Smyth, CM
Picha, SB
Rathore, O
Deasy, J
Patchett, SE
Murray, FE

AF Smyth, CM
Picha, SB
Rathore, O
Deasy, J
Patchett, SE
Murray, FE

TI Increasing rates and changing patterns of hospital admissions for patients with inflammatory bowel disease in Ireland: 1996-2001

SO IRISH JOURNAL OF MEDICAL SCIENCE

AB Background The inflammatory bowel diseases require frequent hospital visits. The literature suggests that the incidence of IBD may be increasing.
Aim To investigate the pattern of admissions of patients with inflammatory bowel disease (IBD) to hospital over a five-year period (between 1996 and 2001).
Methods We obtained national data regarding admission rates for patients with IBD from the Economic and Social Research Institute (ESRI) during the years 1996 and 2001. Local data were gathered from the Hospital In-Patient Enquiry (HIPE) scheme for the same years.
Results Over this five-year period,there has been a substantial increase in the rate of admission with IBD (58% for Crohn's disease and 25% for ulcerative colitis), in particular in the number of day-case admissions for patients with Crohn's disease (125%). There has been little change in the number of patients undergoing surgery for their disease (Crohn's disease; 24% VS 20% and Ulcerative colitis; 17% Vs 16.6%) and in the length of hospital stay.
Conclusion Despite an increase in the rate of admission with IBD,there has been little change in the rates of surgical intervention and length of stay. The most dramatic increase was seen in the day-case admissions for patients with Crohn's disease and may reflect the use of anti-TNF alpha, (infliximab) in the treatment of this disease.

TC 4
Z9 4
SN 0021-1265
PD OCT-DEC
PY 2005
VL 174
IS 4
BP 28
EP 32
UT WOS:000235006500006
ER

71 **EXCLUDED / NOT COST-UTILITY ANALYSIS**

PT J

AU Shibolet, O
Regushevskaya, E
Brezis, M
Soares-Weiser, K

AF Shibolet, O
Regushevskaya, E
Brezis, M
Soares-Weiser, K

TI Cyclosporine A for induction of remission in severe ulcerative colitis

SO COCHRANE DATABASE OF SYSTEMATIC REVIEWS

AB Background Ulcerative colitis (UC) is characterized by a life-long chronic course with remissions and exacerbations. Approximately 15% of patients have a severe attack requiring hospitalization at some time during their illness. These patients are traditionally treated with intravenous corticosteroids, with a response rate of approximately 60%. The patients who do not respond to steroid treatment usually require surgical removal of the large bowel (proctocolectomy or colectomy with an anal pouch). This surgical procedure essentially cures the patient from the disease but is associated with complications such as pouchitis. Few alternative treatments exist for severe ulcerative colitis: immunosuppressive medications (such as azathioprine) have a slow onset of action and are therefore usually ineffective. Antibiotics are not proven to be effective and biological treatments such as in infliximab are still under investigation. The introduction of cyclosporine-A (CsA) for use in patients with severe ulcerative colitis (UC) has provided an alternative to patients previously facing only surgical options. Cyclosporine acts mainly by inhibiting T lymphocyte function, which is essential for the propagation of inflammation. Unlike most other immunosuppressive agents, CsA does not suppress the activity of other hematopoietic cells, does not cause bone marrow suppression and has a rapid onset of action. This reviews aims to systematically assess the effectiveness and safety of CsA for severe UC.
Objectives This review aimed to evaluate the effectiveness of cyclosporine A for patients with severe ulcerative colitis.
Search strategy Electronic searches of The Cochrane Library (Issue 1, 2004), EMBASE (1980- 2004), and MEDLINE(1966-2004); hand searching the references of all identified studies; contacting the first author of each included trial.
Selection criteria Randomised clinical trials comparing cyclosporine A with placebo or no intervention to obtain and maintain remission of idiopathic ulcerative colitis.
Data collection and analysis Two reviewers independently appraised the quality of each trial and extracted the data from the included trials. Relative risks (RR) with 95% confidence intervals (CI) were estimated. The reviewers assumed an intention to treat analysis for the outcome measures.
Main results Only two randomized controlled trials were identified that satisfied the inclusion criteria. These two trials could not be pooled for analysis because of major differences in design and patient populations. In the first trial, 11 patients received intravenous cyclosporine (4 mg/kg) and 9 received placebo. Two of 11 in the treatment group failed to respond to therapy compared with nine of nine in the placebo group (RR 0.18, 95% CI 0.05 - 0.64). However, 3/11 and 4/9 eventually underwent colectomy in the treatment and placebo groups respectively and follow-up was less than a month. In the second trial 15 patients were treated with intravenous cyclosporine and 15 with intravenous methylprednisolone. Five of 15 patients in the

cyclosporine group failed to respond to therapy as compared to 7/15 in the methylprednisolone group (RR 0.71, 95% CI 0.29 - 1.75). After 1 year 7/ 9 responders in the cyclosporine group were still in remission compared with 4/8 in the steroid group (p > 0.05) and the colectomy rate was similar in both groups. The mean time to response in the cyclosporine group in the 2 trials was short (7 days and 5.2 days). These results should be interpreted with caution given the small numbers of trials and patients evaluated for comparison, and limited follow-up (few weeks in one trial to a year in the other). The precise assessment of the occurrence of adverse events was difficult because the trials described different adverse reactions, which reversed after discontinuation of cyclosporine. There was no evidence in the trials reviewed that cyclosporine was more effective than standard treatment for preventing colectomy but this effect cannot be excluded due to the small sample size and rarity of this outcome. Additional limitations of current research include lack of data on quality of life, costs and long-term results of cyclosporine therapy. Authors' conclusions There is limited evidence that cyclosporine is more effective than standard treatment alone for severe ulcerative colitis. The relatively quick response makes the short-term use of cyclosporine potentially attractive, but the long- term benefit is unclear, when adverse events such as cyclosporine-induced nephrotoxicity may become more obvious. There is a need for additional research on quality of life, costs and long- term results from cyclosporine therapy in severe ulcerative colitis.

RI | Brezis, Mayer | A-1041-2010 |

TC 4

Z9 4

SN 1469-493X

PY 2005

IS 1

AR CD004277.pub2

DI 10.1002/14641858.CD004277.pub2

UT WOS:000232097000038

ER

72

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Gonzalez-Lama, Y
Abreu, L
Vera, MI
Pastrana, M
Tabernero, S
Revilla, J
Duran, JG
Escartin, P

AF Gonzalez-Lama, Y
Abreu, L
Vera, MI
Pastrana, M
Tabernero, S
Revilla, J
Duran, JG
Escartin, P

TI Long-term oral tacrolimus therapy in refractory to infliximab fistulizing Crohn's disease

SO INFLAMMATORY BOWEL DISEASES

AB Aims: To evaluate efficacy and safety of oral tacrolimus in cases of fistulizing Crohn's disease (FCD), which is refractory to conventional therapy including infliximab. Methods: Patients with fistulas, previously and unsuccessfully treated with all conventional therapy (i.e., antibiotics, azathioprine, or 6-mercaptopurine and infliximab), were enrolled in a prospective, uncontrolled, open-label study of long-term treatment with oral tacrolimus (0.05 mg/kg every 12 h). The evaluation of the clinical response was complemented by use of the perianal Crohn's disease activity index (PCDAI) and magnetic resonance imaging-based score (MRS) with determined periodicity. Results: Ten patients were included in the study (enterocutaneous fistula, 3 patients; perianal fistula, 4

patients; rectovaginal fistula, 3 patients) with 6 to 24 months of follow-up. Five patients were steroid-dependent, and 4 patients needed maintenance treatment with imnmnosuppressant agents. Four patients (40%) achieved complete clinical responses, which were verified by PCDAI and MRS. Five patients (50%) achieved partial responses (i.e., important decreases in fistula drainage, size, discomfort, and PCDAI/MRS values). Decreases in both the PCDAI and MRS were statistically significant ($P < 0.05$). All steroid-dependent patients stopped therapy with prednisone, and concomitant immunosuppressive therapy was tapered. The response was maintained, and no new flare-up of the disease was observed. Only mild adverse events were detected (I patient withdrew from treatment due to headache), and no case of nephrotoxicity or diabetes was detected. One patient had received no benefit from therapy after 6 months. Conclusions: Oral tacrolimus could be an effective and safe treatment for patients with FCD, even if there has been no response to infliximab treatment. Randomized studies are needed to compare oral tacrolimus with infliximab in terms of efficacy, safety, and costs.

RI | isabel, vera | G-5995-2012 |

TC 29

Z9 29

SN 1078-0998

PD JAN

PY 2005

VL 11

IS 1

BP 8

EP 15

DI 10.1097/00054725-200501000-00002

UT WOS:000226061600002

ER

73

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Martins, NB
Peppercorn, MA

AF Martins, NB
Peppercorn, MA

TI Inflammatory bowel disease

SO AMERICAN JOURNAL OF MANAGED CARE

AB inflammatory bowel disease is a complicated condition, including Crohn's disease, ulcerative colitis, microscopic colitis, and indeterminate colitis, that affects the intestine and several extraintestinal sites. There has been much debate regarding whether Crohn's disease and ulcerative colitis are distinct entities or if they exist along a continuum of the same disease process. In this article, the pathogenic mechanisms and clinical manifestations of inflammatory bowel disease are reviewed, as well as treatment options. Because Crohn's disease and ulcerative colitis are chronic diseases, they have an important economic effect on our healthcare system and the United States as a whole. Some newer and more expensive treatment options may provide overall cost savings in select patient populations because of decreased use of healthcare resources.

TC 13

Z9 13

SN 1088-0224

PD AUG

PY 2004

VL 10

IS 8

BP 544

EP 552

UT WOS:000223145600003

ER

74

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J

AU Geboes, K

AF Geboes, K

TI Is histology useful for the assessment of the efficacy of immunosuppressive agents in IBD and if so, how should it be applied?

SO ACTA GASTRO-ENTEROLOGICA BELGICA

CT Symposium on Advances in Gastroenterology

CY OCT 10-11, 2003

CL Brussels, BELGIUM

AB Crohn's disease and Ulcerative colitis are two chronic relapsing inflammatory bowel diseases of unknown etiology. Both conditions are characterized by a considerable morbidity and have an impact. upon the social and economic aspects of the patients life: At present, medical treatment is mainly aiming at the control of the inflammation. Drugs used for ulcerative colitis can induce microscopic healing of the mucosa. Similar results have been obtained recently with immunomodulatory drugs in Crohn's disease. The cost of these drugs is however high and the use of these drugs can be associated with side effects. Furthermore, many of the drugs need to be given for a long period. Therefore it is appropriate to assess the efficacy of the drugs before commercial use and even when used in routine practice. For both ulcerative colitis and Crohn's disease, clinical parameters combined in indices and endoscopy are commonly used together with some laboratory tests for the assessment of disease activity. In ulcerative colitis, histology has been used along with the other instruments for the measurement of disease activity because it was shown that the mucosal lesions could improve. More recently, histology has also been used for Crohn's disease. Routinely, disease activity when assessed with microscopy, should be divided into mild, moderate and severe. For drug trials and study purposes, more objective scoring systems should be used. Preferentially, a generally accepted score is used. This allows comparisons between different studies. Different scoring systems have been designed for ulcerative colitis and Crohn's disease. For the latter, multiple biopsies should be analysed. Most scoring systems still need validation.

TC 6

Z9 6

SN 0001-5644

PD JUL-SEP

PY 2004

VL 67

IS 3

BP 285

EP 289

UT WOS:000225345100009

ER

75

EXCLUDED / PEDIATRIC CROHN’S DISEASE

PT J

AU Kay, M
Wyllie, R

AF Kay, M
Wyllie, R

TI The real cost of pediatric Crohn's disease: the role of infliximab in the treatment of pediatric IBD

SO AMERICAN JOURNAL OF GASTROENTEROLOGY

TC 4

Z9 4

SN 0002-9270

PD APR
PY 2003
VL 98
IS 4
BP 717
EP 720
DI 10.1111/j.1572-0241.2003.07396.x
UT WOS:000182754400002
ER

76

EXCLUDED / NOT COST-UTILITY ANALYSIS

PT J
AU Rutgeerts, P
AF Rutgeerts, P
TI Current dilemmas in the management of inflammatory bowel disease
SO EUROPEAN JOURNAL OF SURGERY
AB Considerable advances have been made in the treatment of inflammatory bowel disease (IBD) mainly in that of Crohn's disease, but many questions still remain. We need to develop treatments that modify the disease. The use of inuunomodulation using cytokines and anti-cytokines is an important step to achieve this goal. The standard is now the chimeric monoclonal antibody against tumour necrosis factor (TNF) in Crohn's disease. These treatments, however, are associated with problems of immunogenicity and autoimmunity. Moreover a proportion of patients do not respond to treatment and we do not have measurements that predict response. The optimal use and the combined treatment with immunosuppression are under investigation. The safety of this treatment in the long-term is also not established. These costly drugs are not suitable for the management of mild to moderate Crohn's disease and ulcerative colitis (UC). If it turns out that the antigenic drive of the inappropriate immune reaction is in the lumen of the gut changing the gut flora by using probiotics may be the way to go.
TC 0
Z9 0
SN 1102-4151
PY 2002
VL 168
SU 587
BP 58
EP 61
UT WOS:000182391500009
ER

77

EXCLUDED / ABSTRACT

PT J
AU Garnett, WR
Yunker, N
AF Garnett, WR
Yunker, N
TI Treatment of Crohn's disease with infliximab
SO AMERICAN JOURNAL OF HEALTH-SYSTEM PHARMACY
TC 15
Z9 18
SN 1079-2082
PD FEB 15

PY 2001

VL 58

IS 4

BP 307

EP 316

UT WOS:000167013900007

ER

78

EXCLUDED / CROHN'S DISEASE

PT J

AU Hanauer, SB
Cohen, RD
Becker, RV
Larson, LR
Vreeland, MG

AF Hanauer, SB
Cohen, RD
Becker, RV
Larson, LR
Vreeland, MG

TI Advances in the management of Crohn's disease: Economic and clinical potential of infliximab

SO CLINICAL THERAPEUTICS

AB New therapies for Crohn's disease are being developed based on improvements in our understanding of the disease's immune and inflammatory properties. One of these new therapies is infliximab, a monoclonal antibody directed against the proinflammatory cytokine tumor necrosis factor-alpha. Recent studies indicate that treatment of moderately to severely ill Crohn's disease patients with infliximab produces a rapid and profound reduction in the signs, symptoms, and severity of this disease. Beyond its clinical impact, Crohn's disease also carries significant economic consequences. Earlier reports on the costs of managing this disease estimated the average annual medical costs per patient at $9197, with the total annual cost of illness estimated to exceed $1.7 billion. Hospitalizations and surgeries represented 80% of these costs. Additional analyses have been conducted for this review to reflect more current treatment patterns. Assuming that proven increases in response and remission rates lead to diminished disease severity, infliximab can be expected to reduce the number of hospitalizations and surgeries in moderately to severely ill patients, with substantial cost savings. Moreover, improvement in disease status and quality of life may allow Crohn's disease patients to lead more productive lives.

TC 35

Z9 36

SN 0149-2918

PD SEP-OCT

PY 1998

VL 20

IS 5

BP 1009

EP 1028

DI 10.1016/S0149-2918(98)80082-9

UT WOS:000076787300012

ER

79

80 EF

Center for Reviews and Dissemination (27 hits)

INCLUDED
Record #1
%%%%
TTL: Cost-utility analysis of infliximab and adalimumab for refractory ulcerative colitis
AUT: Xie F, Blackhouse G, Assasi N, Gaebel K, Robertson D, Goeree R
XSO: Cost Effectiveness and Resource Allocation
XYR: 2009
VOL: 7:20
XPT: Journal article
XST: This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.
XAC: 22010000513
XID: 02 Mar 2011
XLA: English
XPR: 20003364
DBN: NHS EED
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=22010000513

INCLUDED
Record #2
%%%%
TTL: Anti-TNF-alpha drugs for refractory inflammatory bowel disease: clinical- and cost-effectiveness analyses
AUT: Assasi N, Blackhouse G, Xie F, Gaebel K, Marshall J, Irvine EJ, Giacomini M, Robertson D, Campbell K, Hopkins R, Goeree R
XSO: Title to be Checked
PUB: Canadian Agency for Drugs and Technologies in Health
XYR: 2009
PAG: 1-72
XPT: Report
XST: This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.
XAC: 12011000556
XID: 25 Jul 2012
XLA: English
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12011000556

INCLUDED
Record #3
%%%%
TTL: Infliximab for the treatment of acute exacerbations of ulcerative colitis
AUT: Bryan S, Anddronis L, Hyde C, Connock M, Fry-Smith A, Wang D
XSO: Health Technology Assessment
PUB: NIHR Health Technology Assessment programme
XYR: 2010
VOL: 14(Suppl. 1)
PAG: 9-15
XPT: HTA Technology Assessment Report
XST: This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.
XAC: 32008100346
XID: 23 Dec 2008
XLA: English
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32008100346

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #4
%%%%
TTL: COmparison of iNfliximab and ciclosporin in STeroid Resistant Ulcerative Colitis: a Trial (CONSTRUCT)
XSO: Health Technology Assessment
PUB: NIHR Health Technology Assessment programme
XYR: 0
XPT: HTA Technology Assessment Report
XST: This is a bibliographic record of an on-going health technology assessment being undertaken by a member of INAHTA. Links to the published report and any other relevant documentation will be added when available.
XAC: 32010000361
XID: 21 Apr 2010
XLA: English
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32010000361

INCLUDED
Record #5
%%%%
TTL: A model of the long-term cost effectiveness of scheduled maintenance treatment with infliximab for moderate-to-severe ulcerative colitis
AUT: Tsai H H, Punekar Y S, Morris J, Fortun P
XSO: Alimentary Pharmacology and Therapeutics
XYR: 2008
VOL: 28(10)
PAG: 1230-1239
XPT: Journal article
XST: This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.
XAC: 22009100050
XID: 06 May 2009
XLA: English
XPR: 18729845
DBN: NHS EED
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=22009100050

EXCLUDED / PEDIATRIC ULCERATIVE COLITIS
Record #6
%%%%
TTL: Cost-effectiveness analysis of adjunct VSL#3 therapy versus standard medical therapy in pediatric ulcerative colitis
AUT: Park KT, Perez F, Tsai R, Honkanen A, Bass D, Garber A
XSO: Journal of Pediatric Gastroenterology and Nutrition
XYR: 2011
VOL: 53(5)
PAG: 489-496
XPT: Journal article
XST: This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.
XAC: 22012010035
XID: 26 Nov 2012
XLA: English
XPR: 21694634
DBN: NHS EED
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=22012010035

INCLUDED
Record #7
%%%%
TTL: Anti-TNF-a drugs for refractory inflammatory bowel disease: clinical- and cost-effectiveness analyses
AUT: Assasi N, Blackhouse G, Xie F, Gaebel K, Marshall J, Irvine EJ, Giacomini M, Robertson D, Campbell K, Hopkins R, Goeree R
XSO: Ottawa: Canadian Agency for Drugs and Technologies in Health (CADTH)
PUB: Canadian Agency for Drugs and Technologies in Health (CADTH)
XYR: 2009
XPT: Report
XST: This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.
XAC: 32008100445
XID: 02 Mar 2009
XLA: English
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32008100445

EXCLUDED / GUIDANCE
Record #8
%%%%
TTL: Infliximab for the treatment of acute exacerbations of ulcerative colitis
AUT: National Institute for Health and Clinical Excellence
XSO: London: National Institute for Health and Clinical Excellence (NICE)
PUB: National Institute for Health and Clinical Excellence (NICE)
XYR: 2008
XPT: Report
XST: This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.
XAC: 32011000376
XID: 16 Mar 2011
XLA: English
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32011000376

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #9
%%%%
TTL: Meta-analysis: the efficacy of azathioprine and mercaptopurine in ulcerative colitis
AUT: Gisbert JP, Linares PM, McNicholl AG, Mate J, Gomollon F
XSO: Alimentary Pharmacology and Therapeutics
XYR: 2009
VOL: 30(2)
PAG: 126-137
XPT: Journal article
XST: This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.
XAC: 12009107832
XID: 26 May 2010
XLA: English
XPR: 19392869
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12009107832

INCLUDED
Record #10
%%%%
TTL: An economic evaluation comparing concomitant oral and topical mesalazine versus oral mesalazine alone in mild-to-moderately active ulcerative colitis based on results from randomised controlled trial

AUT: Connolly MP, Nielsen SK, Currie CJ, Marteau P, Probert CS, Travis SP
XSO: Journal of Crohn's and Colitis
XYR: 2009
VOL: 3(3)
PAG: 168-174
XPT: Journal article
XST: This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.
XAC: 22009102794
XID: 10 Mar 2010
XLA: English
DBN: NHS EED
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=22009102794

INCLUDED
Record #11
%%%%
TTL: Cost-effectiveness of infliximab for the treatment of acute exacerbations of ulcerative colitis
AUT: Punekar YS, Hawkins N
XSO: European Journal of Health Economics
XYR: 2010
VOL: 11(1)
PAG: 67-76
XPT: Journal article
XST: This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.
XAC: 22010000722
XID: 27 Oct 2010
XLA: English
XPR: 19844750
DBN: NHS EED
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=22010000722

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #12
%%%%
TTL: Response to corticosteroids in severe ulcerative colitis: a systematic review of the literature and a meta-regression
AUT: Turner D, Walsh C M, Steinhart A H, Griffiths A M
XSO: Clinical Gastroenterology and Hepatology
XYR: 2007
VOL: 5(1)
PAG: 103-110
XPT: Journal article
XST: This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.
XAC: 12007000577
XID: 09 Aug 2008
XLA: English
XPR: 17142106
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12007000577

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #13
%%%%
TTL: Meta-analysis: pre-operative infliximab treatment and short-term post-operative complications in

patients with ulcerative colitis
AUT: Yang Z, Wu Q, Wu K, Fan D
XSO: Alimentary Pharmacology and Therapeutics
XYR: 2010
VOL: 31(4)
PAG: 486-492
XPT: Journal article
XST: This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.
XAC: 12010000962
XID: 04 Aug 2010
XLA: English
XPR: 19925496
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12010000962

Record #14
%%%%
TTL: Infliximab for ulcerative colitis, HTA ref 39417, Evidence Review Group Report for NICE
XSO: Health Technology Assessment
PUB: NIHR Health Technology Assessment programme
XYR: 0
XPT: HTA Technology Assessment Report
XST: This is a bibliographic record of an ongoing health technology assessment being undertaken by a member of INAHTA. Links to the published report and any other relevant documentation will be added when available.
XAC: 32007000909
XID: 15 Dec 2007
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32007000909

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #15
%%%%
TTL: Cyclosporine A for induction of remission in severe ulcerative colitis
AUT: Shibolet Oren, Regushevskaya Elena, Brezis Mayer, Soares-Weiser Karla
XSO: Cochrane Database of Systematic Reviews: Reviews
PUB: John Wiley & Sons, Ltd
XYR: 2005
VOL: Issue 1
XST: This is an abstract for a Cochrane review
XAC: 10000004277
XID: 13 Jul 2012
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=10000004277

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #16
%%%%
TTL: Meta-analysis: effect of preoperative infliximab use on early postoperative complications in patients with ulcerative colitis undergoing abdominal surgery
AUT: Yang Z, Wu Q, Wang F, Wu K, Fan D
XSO: Alimentary Pharmacology and Therapeutics
XYR: 2012
VOL: 36(10)
PAG: 922-928
XST: This is a systematic review that meets the criteria for inclusion on DARE. If you would like us to consider prioritising the writing of a critical abstract for this review please e-mail CRD-DARE@york.ac.uk quoting the Accession Number of this record. Please note that priority is given to fast track requests from the

UK National Health Service.
XAC: 12012050610
XID: 06 Feb 2013
XPR: 23002804
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12012050610

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #17
%%%%
TTL: Tumour necrosis factor alpha blocking agents for induction of remission in ulcerative colitis
AUT: Lawson Maureen M, Thomas Adrian G, Akobeng Anthony K
XSO: Cochrane Database of Systematic Reviews: Reviews
PUB: John Wiley & Sons, Ltd
XYR: 2006
VOL: Issue 3
XST: This is an abstract for a Cochrane review
XAC: 10000005112
XID: 13 Jul 2012
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=10000005112

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #18
%%%%
TTL: Meta-analysis technique confirms the effectiveness of anti-TNF-alpha in the management of active ulcerative colitis when administered in combination with corticosteroids
AUT: Rahimi R, Nikfar S, Abdollahi M
XSO: Medical Science Monitor
XYR: 2007
VOL: 13(7)
PAG: PI13-PI18
XPT: Journal article
XST: This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.
XAC: 12007002522
XID: 01 Sep 2008
XLA: English
XPR: 17599035
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12007002522

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #19
%%%%
TTL: Systematic review: steroid withdrawal in anti-TNF-treated patients with inflammatory bowel disease
AUT: Bultman E, Kuipers EJ, van der Woude CJ
XSO: Alimentary Pharmacology and Therapeutics
XYR: 2010
VOL: 32(3)
PAG: 313-323
XPT: Journal article
XST: This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.
XAC: 12010005318
XID: 06 Jul 2011
XLA: English
XPR: 20497138

DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12010005318

EXCLUDED / HORIZON SCANNING REVIEW
Record #20
%%%%
TTL: Infliximab (Remicade) for ulcerative colitis - horizon scanning review
AUT: NHSC
XSO: Birmingham: National Horizon Scanning Centre (NHSC)
PUB: National Horizon Scanning Centre (NHSC)
XYR: 2005
PAG: 7
XPT: Report
XST: This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.
TW: Available on request from NHSC.
XAC: 32005001217
XID: 09 Nov 2005
XLA: English
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32005001217

EXCLUDED / GUIDANCE
Record #21
%%%%
TTL: Infliximab for subacute manifestations of ulcerative colitis
AUT: National Institute for Health and Clinical Excellence
XSO: London: National Institute for Health and Clinical Excellence (NICE)
PUB: National Institute for Health and Clinical Excellence (NICE)
XYR: 2008
XPT: Report
XST: This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.
XAC: 32011000397
XID: 23 Mar 2011
XLA: English
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32011000397

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #22
%%%%
TTL: Systematic review: infliximab therapy in ulcerative colitis
AUT: Gisbert J P, Gonzalez-Lama Y, Mate J
XSO: Alimentary Pharmacology and Therapeutics
XYR: 2007
VOL: 25(1)
PAG: 19-37
XPT: Journal article
XST: This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.
XAC: 12007000126
XID: 29 Feb 2008
XLA: English
XPR: 17229218
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12007000126

Record #23
%%%%
TTL: Cost-effectiveness of 5-aminosalicylic acid therapy for maintenance of remission in ulcerative colitis
AUT: Yen EF, Kane SV, Ladabaum U
XSO: American Journal of Gastroenterology
XYR: 2008
VOL: 103(12)
PAG: 3094-3105
XPT: Journal article
XST: This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.
XAC: 22009100567
XID: 19 May 2010
XLA: English
XPR: 18775007
DBN: NHS EED
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=22009100567

EXCLUDED / HORIZON SCANNING REVIEW
Record #24
%%%%
TTL: Adalimumab (Humira) for ulcerative colitis
AUT: National Horizon Scanning Centre
XSO: Birmingham: National Horizon Scanning Centre (NHSC)
PUB: National Horizon Scanning Centre (NHSC)
XYR: 2009
XPT: Report
XST: This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.
XAC: 32010000518
XID: 12 May 2010
XLA: English
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32010000518

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #25
%%%%
TTL: Systematic review of postoperative complications in patients with inflammatory bowel disease treated with immunomodulators
AUT: Subramanian V, Pollok R C, Kang J Y, Kumar D
XSO: British Journal of Surgery
XYR: 2006
VOL: 93(7)
PAG: 793-799
XPT: Journal article
XST: This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.
XAC: 12006003593
XID: 30 Nov 2007
XLA: English
XPR: 16710880
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12006003593

EXCLUDED / NOT COST-UTILITY ANALYSIS
Record #26
%%%%

TTL: A systematic review and meta-analysis of the efficacy and adverse events of infliximab in comparison to corticosteroids and placebo in active ulcerative colitis
AUT: Nikfar S, Ehteshami-Afshar S, Abdollahi M
XSO: International Journal of Pharmacology
XYR: 2011
VOL: 7(3)
PAG: 325-332
XPT: Journal article
XST: This is a systematic review that meets the criteria for inclusion on DARE. If you would like us to consider prioritising the writing of a critical abstract for this review please e-mail CRD-DARE@york.ac.uk quoting the Accession Number of this record. Please note that priority is given to fast track requests from the UK National Health Service.
XAC: 12011003872
XID: 28 Sep 2011
XLA: English
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12011003872

EXCLUDED / PEDIATRIC ULCERATIVE COLITIS
Record #27
%%%%
TTL: Infliximab (Remicade) for paediatric ulcerative colitis
AUT: National Horizon Scanning Centre
XSO: Birmingham: National Horizon Scanning Centre (NHSC)
PUB: National Horizon Scanning Centre (NHSC)
XYR: 2011
XPT: Report
XST: This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.
XAC: 32011001635
XID: 21 Dec 2011
XLA: English
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32011001635