shortcut though impairs the analysis in many different ways, limiting our full understanding of the phenomenon being modelled and ultimately our ability to accurately assess 'value for money' beyond the simple 'average'. This paper explores the value of access to individual patient data for cost-effectiveness modelling, structuring the discussion of the topic around three interrelated questions. First, what benefits can access to IPD bring to cost-effectiveness modelling? Second, what are the challenges for the simultaneous statistically synthesis of AD plus IPD to derive input parameters for a cost-effectiveness model? Third, what is the value of access to IPD compared to AD for cost-effectiveness modelling? Using two different case studies, the above questions will be addressed and discussed in the context of the debate around CEA of individualised treatment decisions.

DISEASE-SPECIFIC STUDIES

GASTROINTESTINAL DISORDERS - Clinical Outcomes Studies

PGI1

THE EFFECTIVENESS AND TOLERABILITY OF COMBINED TREATMENT WITH PEGINTERFERON ALPHA-2A OR ALPHA-2B AND RIBAVIRIN IN THE TREATMENT OF PATIENTS WITH CHRONIC HEPATITIS C: RESULTS BASED ON THE NATIONWIDE HEPATITIS REGISTRY IN JAPAN

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OBJECTIVES: When comparing combined therapy with peginterferon alpha-2a or alpha-2b and ribavirin to treat chronic hepatitis C (CHC), the results of clinical trials, observational studies, and meta-analyses have been inconsistent. Their effectiveness and tolerability were investigated using the nationwide database of chronic hepatitis patients who received interferon therapy in Japan. **METHODS:** The proportion with a sustained virologic response (SVR) and the dropout rate due to adverse events (AEs) were compared between alpha-2a and alpha-2b. All patients also received ribavirin. Multivariate logistic regression was conducted with adjustment for age, sex, platelet counts, ALT, viral load, genotype, and whether the patient was treatment-naïve, which are associated with effectiveness and tolerability. **RESULTS:** By December 2011, the database included 7820 patients. CHC patients treated with either alpha-2a (n=1737) or alpha-2b (n=4495) were analyzed. The mean (SD) age was 58.1 (10.4) years, and 3131 (50.2%) were female. In total, 2503 (41.0%) patients had a platelet count <150x103, 2503 (40.5%) had ALT > 60 IU/L, and 5765 (93.2%) had a high viral load. The numbers with genotype 1, 2, and 3 were 4291 (69.2%), 1838 (29.6%), and 76 (1.2%), respectively. Overall, 4434 (71.2%) patients were treatment-naïve. SVR was achieved in 53.5% (95% CI: 51.1-55.9%) with alpha-2a and 61.6% (95% CI: 60.2-63.1%) with alpha-2b (p<0.001). The dropout rate due to any AEs was 10.3% (95%CI: 8.9-11.8%) and 9.3% (95%CI: 8.5-10.2%) for alpha-2a and alpha-2b, respectively (p=0.226). After adjustment for possible confounders, no differences in effectiveness or tolerability were observed between the therapies, and the odds ratio of alpha-2a for SVR was 0.97 (95% CI: 0.86-1.10), and its odds ratio for dropout due to any AEs was 0.96 (95% CI: 0.79-1.17). There was no significant interaction of genotype and therapy. **CONCLUSIONS:** Alpha-2a and alpha-2b in combination with ribavirin showed comparable effectiveness and tolerability in clinical settings.

PGI2

INFLIXIMAB REDUCES THE RISK OF SURGICAL INTERVENTIONS AND HOSPITALIZATION IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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OBJECTIVES: In addition to the pharmacological efficacy of infliximab therapy in inflammatory bowel disease (IBD), it is also important to evaluate its impact on other health outcomes, particularly in the rate of surgical interventions and hospitalizations, which have high economic burden and are believed to represent a marker of IBD severity. We aimed to estimate the impact of infliximab in these outcomes in patients with IBD. **METHODS:** Systematic review and meta-analysis of experimental (clinical trials) and observational studies comparing infliximab with any other control group in IBD. Studies were identified by searching Medline and Cochrane from inception to April 2012. Search results and studies characteristics were assessed independently. Subgroup analyses were done according to IBD type: Crohn disease (CD) and ulcerative colitis (UC). Pooled estimates were performed separately for clinical trials and observational studies. Odds ratios (OR) and 95% confidence intervals (CI) were derived by random-effects meta-analysis. Heterogeneity was assessed with I^2 test. **RESULTS:** Nine trials and 9 observational studies were included. Infliximab significantly decreased risk of gastrointestinal surgery in experimental studies (OR 0.36; 95%CI: 0.18-0.71), both in DC (OR 0.25; 95%CI: 0.10-0.63) and UC (OR 0:55; 95%CI: 0.40-0.76). In absolute terms, there was a 9% reduction in the rate of surgery (95%CI: 1-19%). Observational studies also showed a reduced risk of surgery, which was significant in the case of CD (OR 0.42; 95% CI: 0.22 to 0.78). Infliximab significantly reduced the risk of hospitalization, both in experimental (OR 0.48; 95%CI: 0.34-0.66) and observational (OR 0:38; 95%CI: 0.24-0.58) studies, with a decrease of 9% in hospitalization rate (95%CI: 5-14%). Mean duration of hospitalization was shorten by 4.2 days (95%CI: 1.9-6.5) in infliximab treated patients. **CONCLUSIONS:** Based on the best available evidence, infliximab therapy is associated with a reduced risk of gastrointestinal surgery and hospitalization rates in patients with IBD.

PGI3

TREATMENT OF CHRONIC HEPATITIS C GENOTYPE 1 IN POLAND – REAL-LIFE DATA

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OBJECTIVES: To describe health outcomes, the course of treatment and the demographic and clinical characteristics of HCV adult patients infected with genotype 1 receiving interferon-alfa+ribavirin therapy in Poland. **METHODS:** A retrospective analysis of anonymous data of patients treated in the HCV therapeutic programme of the National Health Fund was performed. Data was gathered from three medical centres and included demographic and clinical characteristics (sex, age, body weight, initial HCV RNA level, disease staging and grading) as well as treatment course (first line/retreatment, posology, treatment duration, outcomes and discontinuations). **RESULTS:** A total of 813 HCV genotype 1 adult patients' records [586 treatment-naïve (N) and 227 treatment-experienced (E)] were included in the analysis. 55% were male (N: 53%, E: 60%), mean age at the beginning of therapy was 48 (SD:13) years. Mean body weight was 68,0 (SD:11,8) kg in females and 82,4 (SD:12,3) kg in males. Mean initial HCV RNA was 5,9 (SD:0,8) $\log_{10}$IU/mL and 46% of patients had HCV RNA<800 000 IU/mL. A total of 85% records included data on disease staging (Sheuer 0-2: 67%; stage 3: 19%; stage 4: 14%). 96% of patients received pegylated interferons (pegylated interferon-alfa2a: 54%), 97% with ribavirin. A total of 15% of patients discontinued therapy prematurely (N: 14%, E: 18%) after a mean of 6 months, and mean treatment duration was 44 weeks for all patients. Overall SVR (sustained viral response) was achieved in 42% of patients (N: 45%, E: 33%). Among treatment-naïve patients not fully responding to therapy, 41% had relapse, 21% were partial responders and 38% were null-responders. **CONCLUSIONS:** The real-life results of HCV genotype 1 treatment, with SVR rates below 50% in treatment naïve patients, are unsatisfactory, especially when in Poland the prevalence of this difficult-to-treat genotype is one of the most highest in Europe. Forthcoming triple therapy with HCV protease inhibitors are promising and anticipated options for these patients.

PGI4

EVALUATION OF THE EFFICACY AND INCONTINENCE RATE OF BIOMATERIALS IN COMPARISON TO CONSERVATIVE AND OTHER INTERVENTIONAL THERAPIES IN TREATMENT OF PERIANAL FISTULA. A META-ANALYSIS

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OBJECTIVES: This meta-analysis of randomized controlled trials was conducted to evaluate the efficacy and incontinence rate of biomaterials (fibrin glue and fibrin plug) in comparison to conservative and other interventional therapy in the treatment of perianal fistula. **METHODS:** PubMed, Embase, Scopus, Google Scholar, and Web of Science were searched for clinical trial studies investigated the effects of biomaterials in the treatment of fistul in-ano. Clinical response and incontinence were the key outcomes of interest. Data were searched from the time period of 1966 through June 2012. **RESULTS:** Eight randomized placebo-controlled clinical trials that met our criteria (six comparing biomaterial with conservative treatment and two with other interventions) were included in the analysis. Pooling of data showed biomaterials effectiveness in comparison to other interventions was non significant with relative risk (RR) of 1.23 (95% CI of 0.31-4.84, P= 0.77). The RR for biomaterials comparing with conservative was non significant (RR= 0.73 with 95% CI = 0.31-0.89, P= 0.096). The incontinence rate RR in biomaterials and intervention was also non significant with RR of 0.35 (95% CI = 0.05-2.28, P = 0.27). **CONCLUSIONS:** This meta-analysis demonstrates that the effectiveness of biomaterials and conservative treatment was not different. The biomaterials in comparison to other interventional therapies did not show any difference in regard to effectiveness and also incontinence rate.

PGI5

EFFECTIVENESS AND SAFETY OF ANTACIDS IN PREGNANT WOMEN SUFFERING FROM GERD/HYPERACIDITY SYMPTOMS

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OBJECTIVES: Symptoms of gastro-oesophageal reflux disease are estimated to occur in 30-50% of pregnancies, with the incidence approaching 80% in some populations. Indian studies have shown prevalence ranging upto 50 % . As with many other conditions in pregnancy, medical therapy with pharmaceutical agents is a concern, as the potential teratogenicity of medications is not well known. Though prevalence numbers are high, many patients have mild and infrequent symptoms, which often respond to lifestyle and dietary modifications. However, some patients report very severe symptoms of hyperacidity affecting their Quality of Life which need treatment. The safety of H2 Receptor antagonists and PPIs in pregnancy is not well established. Antacids could be a good option as their systemic toxicity is low and safety profile is enhanced. **METHODS:** Data has been collected from practicing gynaecologists in a hospital located in Southern India . 50 female patients suffering from heartburn and/or dyspepsia as symptoms of hyperacidity and GERD were treated with antacids containing aluminium hydroxide, magnesium hydroxide and dimethicone. The patients were prescribed antacids for atleast 7 days and the effectiveness and safety profile of antacids was studied. The patients were followed up after one week and the response along with adverse effects were documented. **RESULTS:** The effectiveness was achieved in 85 % of women who took only antacids atleast for 1 week. In 10 % of patients, Proton Pump Inhibitor was also added to achieve the desired response. Apart from 2 cases of mild diarrhea, no other significant side effects were noted. **CONCLUSIONS:** Antacids containing aluminium hydroxide , magnesium hydroxide and dimethicone can be a good therapy option