THE IMPACT OF DIABETES TYPE 2 ON QUALITY OF LIFE

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OBJECTIVES: The Cost Of Diabetes type 2 in Poland (CODIP) study is the first attempt aimed at valuating clinical characteristics and Health Related Quality of Life (HRQoL) associated with type 2 diabetes in Poland.

METHODS: We assessed quality of life of 303 patients (mean age 61, mean time from diagnosis 10.86 year, males 49%). Detailed information on quality of life was collected with EuroQol-5D and Visual Analog Scale. The influence of complications and therapeutic strategies on quality of life was evaluated. The HRQoL score was analyzed as a function of number and type of complications or therapeutic strategies, controlled for age, BMI and sex.

RESULTS: The strong relationship between HRQoL and complications was observed. Patients without complications reported mean HRQoL of 0.63 (95% CI: 0.59–0.68). The presence of microvascular or macrovascular complications resulted in degresion of HRQoL to 0.55 (95% CI: 0.51–0.59) and 0.53 (95% CI: 0.49–0.58), respectively. Both types of complications were associated with the lowest HRQoL value: 0.44 (95% CI: 0.41–0.48).

Patients treated with diet and exercise only reported quality of life equalled 0.61 (95% CI: 0.47–0.72), while oral hypoglycemic drugs therapy decreased quality of life to 0.57 (95% CI: 0.53–0.62). Insulin based therapy was associated with the lowest quality of life scores: 0.46 (95% CI: 0.41–0.49) for monotherapy to 0.51 (95% CI: 0.47–0.54) for combined use of insulin and oral drugs. The complications, but not treatment type, were found to be independent predictor of HRQoL.

CONCLUSIONS: Patients diabetes type 2’s quality of life is affected by complications. Prevention of complications may result in significant improvement of diabetic patients’ quality of life.

GASTROINTESTINAL DISEASES/DISORDERS

GASTROINTESTINAL DISEASES—Clinical Outcomes Studies

AN EVIDENCE-BASED APPROACH PROVIDES A QUANTITATIVE ASSESSMENT OF THE EFFICACY OF ESOMEPRAZOLE FOR HEALING OFEROSE ESOEAGITIS BASED ON DISEASE SEVERITY

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OBJECTIVE: Number needed to treat (NNT) provides an estimate of the number of patients who need to be treated with a drug to avoid an adverse outcome on alternate therapy. This quantitative analysis focused on treatment responses to proton pump inhibitors according to disease severity. METHODS: Efficacy data from four clinical trials using once-daily esomeprazole 40mg compared with omeprazole 20mg (n = 3) and lansoprazole 30mg (n = 1) for treatment of erosive esophagitis (EE) were identified. EE was graded A–D using the Los Angeles (LA) classification. For each trial we calculated the therapeutic gain, the absolute risk reduction (ARR) and the number needed to treat (NNT) for healing EE at week 8, for all patients (LA Grades A–D) and separately for those with severe disease (LA Grades C & D). RESULTS: For all grades of esophagitis, the therapeutic gain achieved with esomeprazole was 9.5%, 7.2% and 2.4% versus omeprazole, and 3.8% versus lansoprazole. The NNT with esomeprazole for severe disease ranged between 5 and 10 relative to omeprazole. The NNT with esomeprazole for severe disease was 8 relative to lansoprazole, indicating that for every 8 patients treated with esomeprazole, 1 treatment failure with lansoprazole may be prevented.

CONCLUSIONS: Treatment with esomeprazole provided therapeutic gain regardless of the baseline severity of EE compared with lansoprazole and omeprazole. Because the severity of clinical symptoms is not predictive of disease severity, treatment with the most effective agent appears to be a rational therapeutic decision as supported in this evidence-based approach.

A RETROSPECTIVE AUDIT OF PATIENTS REDUCING PROTON PUMP INHIBITOR DOSE TO LANSOPRAZOLE 15MG

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OBJECTIVES: NICE recommends the use of proton pump inhibitors (PPIs) at the lowest effective dose in patients with gastroesophageal reflux disease. Changing patients from a standard or high dose PPI to esomeprazole 20mg has shown that only 5% (8/146) of patients returned to a higher dose PPI in the subsequent 6 months. The purpose of this study was to assess the frequency with which patients who had reduced PPI dose to lansoprazole 15mg returned to a higher dose PPI in the subsequent 6 months. The audit identified 175 patients previously on regular (≥2 PPI prescriptions in the previous 6 months) standard or high dose PPI who had been changed to lansoprazole 15mg. Within 6 months of the first lansoprazole 15mg prescription, 26% (46/175) of patients had changed back to a higher dose PPI. Similar switch rates were obtained if...
the analysis was restricted to patients who had received ≥4 prescriptions in the 6 months prior to their first lansoprazole 15 mg prescription (25%: 31/122). Amongst those patients with a specific diagnosis of GORD/RO, 37% (15/41) switched to a higher dose PPI within 6 months. Around half (52%; 16/31) of patients who returned to a higher dose had no specific reason recorded (16/31). However the most commonly recorded reason for failing on lansoprazole 15 mg was inadequate control of symptoms (35%; 11/31). CONCLUSION: The proportion of patients changed from standard or high dose PPI to lansoprazole 15 mg who required an increase in PPI therapy within 6 months was higher than that reported for patients treated with esomeprazole 20 mg.

**META-ANALYSIS OF PPI-BASED TRIPLE THERAPY FOR THE ERADICATION OF HELICOBACTER PYLORI**

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**OBJECTIVE:** The recommended treatment for Helicobacter pylori eradication in the UK is a proton pump inhibitor (PPI) in combination with amoxicillin 1g and clarithromycin 500 mg all twice daily for 7 days. The aim of this analysis was to compare the efficacies of the recommended PPI-based triple therapies for the eradication of *H. pylori* using omeprazole-based triple therapy as a common comparator. **METHODS:** The PPIs licensed in the UK for twice daily triple therapy are esomeprazole 20 mg (EAC), lansoprazole 30 mg (LAC), omeprazole 20 mg (OAC), pantoprazole 40 mg (PAC), and rabeprazole 20 mg (RAC). A meta-analysis of randomised controlled trials comparing a 7-day regimen of PPI-based triple therapies was conducted using omeprazole-based triple therapy as a common comparator. Data on eradication rates were extracted and re-analysed, where required, to provide “intention-to-treat” results. The primary method of calculating the summary effect estimates used a Fixed Effects model. A chi-squared test was used to assess heterogeneity for each comparison. A secondary analysis comparing 7-day regimens of PPI plus any dose of amoxycillin and clarithromycin was conducted to test the robustness of the results. **RESULTS:** The alternative strategies, compared with OAC, provided the following results—EAC (Relative Risk 1.01; 95% Confidence Interval: 0.95 to 1.08), LAC (RR 1.05; 95% CI: 0.94 to 1.17), PAC (RR 0.92; 95% CI: 0.80 to 1.06). No trials comparing rabeprazole with omeprazole using UK recommended triple therapy were found. Significant heterogeneity was detected in the LAC comparison with OAC and so these results should be treated with caution. The secondary analysis confirmed that there was no significant difference in the four alternative strategies compared to OAC. **CONCLUSIONS:** No PPI-based triple therapy was found to be significantly more efficacious than omeprazole-based triple therapy. However, esomeprazole 20 mg is the only PPI licensed in the UK for triple therapy that would be considered a low dose.

**ESOMEPRAZOLE AS MAINTENANCE THERAPY IN EROSIVE ESOPHAGITIS: A QUANTITATIVE ASSESSMENT OF EFFICACY USING AN EVIDENCE-BASED APPROACH**

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**OBJECTIVE:** Evidence-based techniques were applied to clinical trial data of esomeprazole for maintaining healed erosive esophagitis (EE) to provide a practical, quantitative analysis of its efficacy relative to lansoprazole. **METHODS:** Patients with a history of heartburn and EE, Los Angeles Grade A–D at baseline, received esomeprazole 40 mg once daily for up to 8 weeks for healing. Those with healed EE were randomized to receive once daily esomeprazole 20 mg (n = 615) or lansoprazole 15 mg (n = 609) for up to 6 months. For this retrospective analysis, the number needed to treat (NNT), the reciprocal of the absolute risk reduction (ARR), was calculated at 6 months for all patients and for subgroups with mild disease (LA Grade A or B) and severe disease (LA Grade C or D). **RESULTS:** In this evidence-based analysis, it was determined that 11 patients with EE would need to be treated with esomeprazole to prevent one treatment failure that otherwise may occur with lansoprazole regardless of the baseline grade of EE. As the severity of disease increased (LA Grade C or D), the NNT to prevent one relapse that may otherwise have occurred with lansoprazole decreased to 6. **CONCLUSIONS:** For patients with more severe disease, the NNT was lower, indicating a greater likelihood of therapeutic success with esomeprazole versus lansoprazole. This evidence supports esomeprazole as an effective treatment for maintenance of remission and prevention of treatment failure in gastroesophageal reflux disease patients with EE.

**GASTROINTESTINAL DISORDERS—Cost Studies**

**ECONOMIC BURDEN OF IRRITABLE BOWEL SYNDROME (IBS): ONE YEAR RESULTS. RITMO STUDY**


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