($p < 0.05$). GIQLI total score and symptoms subscale discriminated among most severity levels ($p < 0.05$). **CONCLUSIONS:** The GSRS and GIQLI demonstrated adequate reliability, and outperformed generic instruments on discriminant validity. Both instruments can be used to investigate effects on PRO's related to GI complications due to immunosuppressant therapies.

PGI12

HEALTH-RELATED QUALITY OF LIFE AND PATIENT SELF-PERCEIVED HEALTH STATUS IN IBS

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OBJECTIVES: Irritable bowel syndrome (IBS) is a chronic and episodic disorder characterized by abdominal pain and altered bowel habits. Its impact on generic and disease-specific quality of life and self-perceived health status is rarely assessed in The Netherlands. This study assessed the impact of IBS on health-related quality of life (HRQoL). **METHODS:** Patients using mebeverine, identified at community pharmacies, were administered a questionnaire regarding ROME-II-criteria to confirm the IBS diagnosis, abdominal complaints, use of medical resources, abdominal pain and discomfort (IGA-P VAS with 0 = no pain and 1 = very severe pain), patient self-perceived health status (VAS with 0 = worst imaginable health state i.e. death and 1 = best possible health state, and SF-6D), generic HRQoL (SF-36) and IBS-specific HRQol (IBSQoL). SF-36 outcomes were compared to a random sample of the Dutch population and other Dutch patients suffering from chronic diseases. The association between HRQol and severity of disease (IGA-P) was assessed. **RESULTS:** A total of 212 completed questionnaires were received. A total of 169 patients met the ROME-II-criteria for diagnosis of IBS. Of those, 18% suffered from IBS with diarrhea predominance, 19% from IBS with constipation predominance and 51% reported an alternating stool pattern. Severe abdominal pain (IGA-P >60 mm on a 100 mm VAS) was reported by 65%. Sufficient differences between the IBS-population and the Dutch population were measured for all dimensions of the SF-36. SF-36 and IBSQoL outcomes were associated with disease severity. Patients regarded their health state as low: 0.62 (0.2) on a VAS and 0.66 (0.1) using the SF-6D algorithm. **CONCLUSIONS:** IBS has a significant impact on all dimensions of HRQol. Our findings are consistent with other studies. There is an unmet medical need in patients suffering from IBS in The Netherlands.

PGI13

EFFECT OF TEGASEROD IN WOMEN WITH IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C) IN SOUTH AFRICA

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OBJECTIVES: Primary objective of the study was to determine the effect of tegaserod six mg b.i.d. on quality of life (QoL) of women with IBS-C (defined by Rome II criteria). The secondary objective was to determine the efficacy of tegaserod in this population. **METHODS:** This was a prospective open-label, multicenter study in South Africa with gastroenterologist, surgeon and gynaecologist enrollers. The study comprised a two-week treatment-free baseline period (rescue medication permitted) followed by a four-week treatment period (rescue medication permitted for patients not experiencing adequate relief with tegaserod). The IBS-QoL questionnaire, a validated instrument that assesses the impact of IBS and treatment of the condition, was completed at study entry, after the baseline period and at study end. It consists of seven domains: dysphoria, interference with activity, body image, health worry, food avoidance, social reaction and sexual relationship. Patients also kept a diary and recorded IBS symptoms daily and overall symptom relief weekly. **RESULTS:** In total, 242 patients from 36 centers were recruited; 210 completed and were included in the QoL and efficacy analyses. Most patients were Caucasian (78.1%) and the mean age was 38 (±11) years. Statistically significant improvements after four weeks of tegaserod treatment were observed for overall QoL (19.6% improvement from baseline) and for all IBS-QoL domains (both $p < 0.001$ vs baseline). Overall, symptom relief was reported by 68.7% of patients at Week four (95% CI: 62.0–75.4%). Statistically significant improvements were reported for the number of bowel movements, stool form, straining, sense of incomplete evacuation, abdominal pain and bloating (all $p \leq 0.001$). Symptom improvements were observed early (Week one of treatment) and sustained throughout the study. 58.1% of patients (95% CI 51.4–64.8%) responded to treatment and concurrently experienced overall QoL improvement. **CONCLUSIONS:** Tegaserod six mg b.i.d. significantly improves QoL and is efficacious in women with IBS-C.

GASTROINTESTINAL DISEASES DISORDERS

GASTROINTESTINAL DISEASES DISORDERS—Methods and Concepts

PGI14

COST-EFFECTIVENESS EVALUATION FOR A NEW DIAGNOSTIC TEST CONSIDERING ALSO COSTS FOR FALSE NEGATIVE AND FALSE POSITIVE DIAGNOSES AT VARIOUS PREVALENCE RATES

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OBJECTIVES: To evaluate the cost-effectiveness of a diagnostic technique when no gold standard is available. **METHODS:** Capsule endoscopy (CE) is a technique for intraluminal imaging of the entire small bowel. Sensitivity and specificity for CE, push enteroscopy (PE) and other procedures performed prior to diagnosis were evaluated from seven controlled clinical trials (n = 184). To evaluate the cost-effectiveness of CE in diagnosing obscure gastrointestinal bleeding (OGIB) a microsimulation model was developed. Procedure cost, costs of diagnostic failure and incremental cost-effectiveness ratios dependent on disease prevalence are given. Costs due to false negative diagnosis were examined in cycles with a prevalence range from 10% to 90%. One way as well as probabilistic sensitivity analysis was performed. Cost data reflect the Swiss healthcare payer perspective. **RESULTS:** Sensitivity for CE was 89–99% and 27–60% for PE. Specificity was 90–99% and 50–70% respectively. Mean future-costs reach from 7.664€ for cycle 1 to 3.129€ for cycle nine. With a prevalence >10% CE was the dominant strategy. For a prevalence of 50% cost savings are 2240€. **CONCLUSIONS:** The model proved to be helpful in the evaluation of CE where gold standard data were not available. From a health-economic perspective the use of CE can be recommended in the work-up of patients with OGIB. Based on the results of the described method Switzerland approved reimbursement for CE in patients with OGIB after negative upper and lower endoscopy.