

PGI7

CHARACTERISTICS OF CHILDREN AND ADOLESCENTS USING PROTON PUMP INHIBITORS OR HISTAMINE-2-RECEPTOR ANTAGONISTS: ANALYSIS OF THIN AND PHARMO DATABASES

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OBJECTIVES: To describe demographics and co-morbidities of children starting PPI or H2RA use. **METHODS:** Data were obtained from The Health Improvement Network (THIN, a UK primary care database) and the Dutch PHARMO Database Network (including outpatient pharmacy and hospital databases). Children (<19 years) starting a PPI or H2RA between 2009–2012 (THIN) and 2008–2010 (PHARMO) were selected. Demographics, medical history, co-morbidities and co-medication were assessed. **RESULTS:** The study included 15782 PPI starters (THIN, n=5957; PHARMO, n=9825) and 8980 H2RA starters (THIN, n=5696; PHARMO, n=3284). The proportion of males was similar between PPI and H2RA starters in each database (THIN, 41% vs 48%; PHARMO, 44% vs 48%). H2RA starters more often were <12 years of age (THIN, 73% vs 26%; PHARMO, 58% vs 36%) and PPI starters more often had received other prior acid-suppressing treatment (THIN, 9% vs 2%; PHARMO, 10% vs 7%). In THIN, a history of infectious or respiratory disease was more common in PPI starters: infectious disease, 89% vs 65% (odds ratio (OR) 1.20; 95% confidence interval (CI) 1.05–1.37); respiratory disease, 77% vs 49% (OR 1.20; 95%CI 1.08–1.34). In PHARMO, PPI starters were also more likely to suffer from asthma/chronic obstructive pulmonary disease (8% vs 6% (OR 1.35; 95%CI 1.14–1.60)) and more often used antibiotics (20% vs 13% (OR 1.53; 95%CI 1.37–1.72)) and non-steroidal anti-inflammatory drugs (25% vs 5% (OR 4.48; 95%CI 3.80–5.29)). PPI starters in PHARMO were also more likely to have a history of diabetes or epilepsy (diabetes, 1% vs <0.5% (OR 5.00; 95%CI 2.33–10.73); epilepsy, 2% vs 1% (OR 1.69; 95%CI 1.16–2.45)). **CONCLUSIONS:** Results from both databases indicated that H2RA starters were younger than PPI starters. PPI starters were more likely to have received other prior acid-suppressing treatment and had more co-morbidities than H2RA starters.

PGI8

HEPATOCELLULAR CARCINOMA: AN EPIDEMIOLOGICAL AND MANAGEMENT SURVEY-BASED ANALYSIS IN ITALY

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OBJECTIVES: To verify how Hepatocellular Carcinoma (HCC) management is carried out in Italy and to point out the organizational key variables useful for an economic assessment, considering that Italy is among the European States with the highest incidence of HCC according to recent published data and that HCC is the final and highest cost health state along the natural history of liver diseases. **METHODS:** A questionnaire was set up jointly by clinicians (hepatologists and infectivologists), pharmacoeconomists and HTA experts, and submitted to 9 centers in order to collect epidemiology and management data. The survey consisted of a series of questions regarding HCC patients: gender and age, HCC etiology, BCLC (Barcelona Clinic Liver Cancer) staging at diagnosis, current treatments, hospitalization regimens, number and description of diagnostic/outpatient procedures, other relevant concurrent pathologies. The survey was administered to patients in four Italian centers of excellence for liver diseases with well-established experience in treating HCC patients. **RESULTS:** A total of 596 questionnaires were collected, the majority of which regarding male patients (79%), with a mean age of 67. Etiology proved to be mainly HCV-related (56%) and most patients underwent full hospitalization (81%) with a mean duration of 16.5 days, with a wide variability among centers, concerning both diagnostic procedures (CT, MRI, ecography...) and treatments (surgery, liver transplantation, drugs...). **CONCLUSIONS:** The collected data show a major heterogeneity, linked to the different etiology and epidemiology of the disease along the peninsula, well characterized by a number of published studies, but prove to be very helpful in describing the current situation regarding HCC in Italy. This descriptive analysis will be useful to set up a prospective study with the aim to implement an economic model able to compare different treatments and diagnostic procedures, and including organizational aspects in accordance to a cluster-randomized logic.

PGI9

INCIDENCE OF ANASTOMOTIC LEAKS AFTER COLORECTAL SURGERIES USING HOSPITAL EPISODE STATISTICS IN THE UNITED KINGDOM

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OBJECTIVES: Reported incidence of gastrointestinal anastomotic leaks after colorectal surgeries varies across regions, mainly due to different definitions of anastomotic leaks. A recent study using Premier Perspective administrative database reported 6.18% incidence of post-operative anastomotic leaks in US. The objective of this study is to apply a similar definition of anastomotic leaks from the US study and estimate incidence of anastomotic leaks after colorectal surgeries in UK. **METHODS:** Hospital Episode Statistics database was used to identify patients receiving colorectal surgeries from January 2007 to December 2011. The index colorectal surgeries included colectomy, hemicolectomy, sigmoid colectomy, and low anterior resection identified by OPCS-4 codes. The anastomotic leak event was defined by re-intervention (OPCS-4 codes) or diagnosis (ICD-10 codes) within 30-day window following index colorectal surgeries. The re-intervention included re-operation, re-anastomosis, stent, colostomy, image guided drainage, abscess, and washout. The diagnosis was generalized acute peritonitis. Chi-square and t tests were used to compare demographic characteristics between patients who had leaks and those who did not. **RESULTS:** A total of 132,045 patients (mean age: 65 years, 50% male) received colorectal surgeries during 2007–2011. Of these, 8,434 (6.38%) had anastomotic leaks within 30 days of the colorectal surgeries. 2.63% leak cases were defined by reoperation, 1.82% by diagnosis of generalized acute peritonitis, 1.24%

by colostomy, 0.9% by image guided drainage, 0.7% by washout, 0.62% by abscess, 0.42% by re-anastomosis, and 0.01% by stent. Patients with leaks tended to be slightly younger and male, had higher Charlson Co-morbidity Index, and more likely admitted through emergency vs. elective surgery (p<0.05). **CONCLUSIONS:** Our study indicated an incidence rate of 6.38% for post-operative anastomotic leaks among patients undergoing colorectal surgeries in UK, compared to 6.18% leak rate seen in the US study. The results highlight the importance of future study in evaluating the impact of anastomotic leaks on patient's clinical and economic outcomes in UK.

PGI10

RESOURCE USE AND DISEASE PROGRESSION AMONG HCV-POSITIVE PATIENTS

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OBJECTIVES: Hepatitis C is an infectious disease affecting the liver; chronic infection can lead to cirrhosis. The actual standard of care in Italy is Peginterferon+ribavirin. Our aim was to describe treatment patterns, disease progression and resource use in HCV. **METHODS:** An observational retrospective cohort analysis based on 4 Local Health Units administrative and laboratory databases was conducted. HCV-positive patients between January 1, 2009- December 31, 2010 were included and followed-up for one year. To explore which covariates were associated to disease progression (cirrhosis, hepatocellular carcinoma -HCC-, death for any cause), Cox proportional hazards models were performed. **RESULTS:** A total of 9514 patients were analyzed, 55.6% male, age 58.1±16.1; 5.8% had HIV, 3.0% HBV, 1.6% HCV+HBV+HIV, 26.1% cirrhosis, 4.3% HCC. Genotypes frequencies were 1a (17%), 1b (34%), 2 (24%), 3 (19%), 4 (5%). Antiviral treatment was not administered to the majority of patients (79%); the main factors affecting this decision were: age >65 years (44%), females (46% VS 40% of treated), cirrhosis (30%), normal liver enzymes (28%), ongoing substance/alcohol abuse (7%), HCC (5%). Disease progression in the observed timeframe was less frequent among treated patients (incidence rate per 100 patients/year: cirrhosis 2.1±0.7 VS 13.0±1.0, HCC 0.5±0.3 VS 3.6±0.5, death for any cause 0.5±0.3 VS 6.4±0.7); at multi-variable Cox regression models, hazard ratios were, respectively, 0.30 (0.21–0.43), 0.41 (0.19–0.92) and 0.24 (0.12–0.48) (all p<0.05). For genotype1 subgroup, results were not statistically different between Peginterferon-ribavirin treated and untreated (cirrhosis: HR=0.82 (0.32–2.11), p=0.682). The annual expenditure for HCV management (drugs, hospitalizations, outpatient services) was €4,700 per patient. **CONCLUSIONS:** Actual standard of care was not widely used, especially for sensitive subgroups such as women and the elderly; in this context, there is an urgent need for treatment, but current therapies do not appear to be adequate for all patients, especially those with genotype1, which represents 60% of the Italian HCV population.

GASTROINTESTINAL DISORDERS – Cost Studies

PGI11

PERITONITIS FLUID TREATMENT IN RUSSIAN FEDERATION: EVALUATION OF ECONOMIC BURDEN IN REAL CLINICAL PRACTICE

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OBJECTIVES: Peritonitis is an inflammation of the parietal and visceral peritoneum which is accompanied by severe general condition of the body. Peritonitis as a complication of acute inflammatory diseases of the abdominal cavity is found in 15–20% of clinical observation and about 6% of all surgical procedures on the abdominal cavity. The research is conducted in regard to 4 technologies of fluid treatment, including: Reamberin, Ringer's solution, Plasma-Lyte and Sterofundin. **METHODS:** Retrospective researches analysis is considered as a source of data on real effectiveness. The decree of the RF Ministry of Health No 669 of October 15, 2007 is considered as a source of data on commonly used drugs and medical services. The price-list of the Clinical Center of the First MSMU charges for medical services is incorporated as the source of data on the price of medical services. **RESULTS:** The calculation is made for the hypothetical group of 100 patients with the peritonitis disease. During the cost of illness analysis of peritonitis the direct costs are estimated. They include: medical services and pharmacotherapy in the period of the residence in the in-patient department (euro per patient: 9 241 for Reamberin, 10 554,8 for Ringer's solution, 9 755,7 for Plasma-Lyte and 9 756,4 for Sterofundin). The cost-effectiveness analysis(CEA) results are the following: 10 241 euro for Reamberin, 12 639 euro for Ringer's solution, 12 302 for Plasma-Lyte and 11 683 euro for Sterofundin. The budget impact analysis(BIA) show that the 100% switching patients from Ringer's solution, Plasma-Lyte and Sterofundin to Reamberin saves respectively: 131 377 euro, 51 465 euro and 51 538 euro. **CONCLUSIONS:** Cost of illness analysis, CEA and BIA of peritonitis indicate that the scheme of therapy including Reamberin is the dominant one. Total costs are 9 241 euro per patient, CER is 10 241 euro per saved live.

PGI12

ORGANIZATIONAL AND ECONOMIC ISSUES RELATED TO THE INTRODUCTION OF BOCEPREVIR IN THE TREATMENT OF PATIENTS WITH GENOTYPE 1 CHRONIC HEPATITIS C IN ITALY

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OBJECTIVES: To present the critical points concerning organizational and economic issues of the introduction of boceprevir in the treatment of patients with genotype 1 chronic hepatitis C in Italy. **METHODS:** A budget impact analysis was conducted adapting the NICE (UK) scheme for this drug, using the Italian epidemiological context and the perspective of the National Health Service. The cost-utility analysis (CUA) was carried out using a Markov model comparing the triple therapy (TT) with peginterferon alfa, ribavirin and boceprevir to the double therapy (DT) with peginterferon alfa and ribavirin. Available Italian published scientific literature provided data source. The main outcome of the CUA was the incremental cost-effectiveness ratio (ICER). The organizational aspects

considered were: clinical management of patient with HCV chronic infection, access modalities, outpatient visit, planned and unplanned visits, hospital admission, role of the general practitioner (GP). **RESULTS:** The budget impact analysis shows that, considering both naïve and previously treated patients, the treatment with boceprevir has an impact on the National Health Service of almost €66 million for the first year. Compared to treatment with DT, the cost-utility analysis shows for the boceprevir-based treatment strategy an ICER of €8,622,00. The management of TT for its intrinsic complexity requires monthly outpatient visits, at least at the beginning of treatment, for monitoring the compliance to treatment, efficacy and side effects. A critical organizational point is potentially the request for boceprevir for each single patient by the medical prescriber, who needs to fill in detailed form from the Italian Agency of Drug (AIFA). **CONCLUSIONS:** The impact of the introduction of boceprevir on the budget is high, even if the ICER is favourable. Patients' management is particularly complex and there is the need for an alliance between the patients, their relatives, GPs and specialized centers.

PGI13

ENTERAL DIETS (ED): A COST-COMPARISON ANALYSIS FOR IN-HOSPITAL PREPARATIONS BASED ON REAL WORLD OBSERVATION

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OBJECTIVES: ED can be administered based on three different systems – powder based (Po), open, liquid (Op), and a completely closed (Cl). There are differences in the preparation, installation and delivery and in the diarrhea rates among them. Our aim was to measure the total costs for each system, considering the resources needed to prepare, delivery administer and discard of each system (hidden costs). **METHODS:** We measured the human (nurse, nutritionist, auxiliary personnel) resources involved in ED preparations in three hospitals of Brazil. Then, we calculated the costs of the process, based on the minimum official wage for each professional category. After, we added the costs of the diets and materials needed to the infusion. We used as base case a daily need of 1 000Kcal / patient. Additional analyses were performed to include the side effects of ED system. **RESULTS:** There were differences among the human resources needed for each system. Hidden costs were 63% of the total for Op, 58% for Po and 53% for Cl. Particularly, the nurse time varied from 18 minutes for Po and Op and 5 min for Cl for each infusion. Considering that and average patient would require daily 4 infusions of Po or Op, that represents a total of 72min of nurse time to these systems, against 5 min to Cl. Total daily costs, were Op US\$ 62.05; Po US\$ 50.75 and Cl US\$48.03. If we consider the costs of side effects, such as diarrhea, the costs are: Op US\$ 73.42; Po US\$ 62.15 and Cl 56.35. This increase in the difference among the costs is due to a lower incidence of diarrhea in Cl systems. **CONCLUSIONS:** There are many hidden costs on the ED systems. If we consider them Cl systems are less costly than Op and Po.

PGI14

COST ANALYSIS OF PROTON PUMP INHIBITORS IN THE TREATMENT OF ULCER DUODENUM IN UKRAINE

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OBJECTIVES: Proton pump inhibitors (PPIs) are essential components schemes of antyhelicobacter therapy (AT) of peptic ulcer disease. The aim of research - to determine the costs of the use of PPIs in the traditional triple schemes AT (first and second line) of the working age patients with a duodenal ulcer in Ukraine. The objects of research - preparations of omeprazole, pantoprazole, rabeprazole, lansoprazol, ezomeprazol, which are present in Ukraine. **METHODS:** Cost analysis on the use of PPIs in the schemes of AT was performed per one patient for 14 days with the daily doses of drugs: omeprazole - 40 mg, pantoprazole - 80 mg, rabeprazole - 40 mg, lansoprazol - 60 mg, ezomeprazol - 40 mg (according to the recommendations of the "Maastricht IV", 2010). For determining the costs only the costs of the PPIs were taken into account. The prices of drugs were taken from the information system "Drugs" of Company "Morion" (December, 2012). The currency ratio of UAH to dollar (USA) on 10.12.12 was 7.99:1. To determine the range of costs for use of PPIs determined their trade names with the minimum and maximum costs for the AT. **RESULTS:** The range of costs for use of PPIs in the traditional triple schemes AT in Ukraine is wide enough, respectively: omeprazole - 1.15 - 19.15 \$, pantoprazole - 5.11 - 49.28 \$, lansoprazol - 5.14 - 10.66 \$, rabeprazole - 4.27 - 63.40\$, ezomeprazol 1.81 - 36.42\$. **CONCLUSIONS:** Costs only for the use of PPIs in the schemes of AT of duodenal ulcer can be quite high in Ukraine. In this regard, the choice of PPIs for inclusion in the schemes of AT is advisable to use the results of pharmacoeconomic studies that will optimize the costs of the payer.

PGI15

ECONOMIC ANALYSIS OF USE OF HARMONIC DEVICES IN INPATIENT LAPAROSCOPIC CHOLECYSTECTOMY IN THE UNITED STATES

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OBJECTIVES: Harmonic® ultrasonic energy devices have been developed as a safer and more efficient alternative to traditional electrocautery (monopolar and bipolar) in laparoscopic cholecystectomy. However, the economic impact on hospital cost has not yet been assessed in the United States. The aim of the study is to evaluate the total cost of laparoscopic cholecystectomy performed with an ultrasonic device versus electrocautery from a hospital perspective. **METHODS:** A literature review was performed to identify publications via EMBASE and MEDLINE database. Nine randomized controlled studies were included in this analysis based on inclusion criteria. The clinical results were weighted based on No. of patients to calculate averages for both energy devices. The total departmental cost data for electrocautery group were obtained from a large US payor (PREMIER database) to apply the clinical findings to calculate the cost for the Harmonic group. The total cost in laparoscopic cholecystectomy with two energy devices was compared to determine which modality is more cost effective. **RESULTS:** The total case cost using an ultrasonic device in an inpatient laparoscopic cholecystectomy is \$7701 v.s. electrocautery is \$8637. The use of an ultrasonic device provides a hospital savings of \$936 per patient

treated. The savings mainly resulted from shorter operating time (13 Minutes) and decreased hospital stay (0.7 days). **CONCLUSIONS:** Although the instrument cost is higher for the ultrasonic device, the total procedural cost is lower compared to electrocautery. Utilization of the Harmonic® ultrasonic device in laparoscopic cholecystectomy can lead to substantial cost savings for US hospitals.

PGI16

MORTALITY AND MEDICAL COSTS ASSOCIATED WITH LIVER-RELATED DISEASES AMONG PATIENTS WITH HEPATITIS C VIRUS(HCV) INFECTION IN TAIWAN

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OBJECTIVES: To examine the mortality and medical costs during the first and the 2nd year following the onset of the five liver-related diseases, i.e. HCV infection, compensated cirrhosis (CC), decompensated cirrhosis (DCC), hepatocellular carcinoma (HCC), or liver transplantation. **METHODS:** Patients with HCV infection and patients who transitioned to the health state of liver-related disease were identified from the National Health Insurance Research Database (NHIRD) during 2008-2010 if any outpatient/inpatient service with primary diagnosis code of 070.54 for HCV infection or 571.5 for CC occurred, or if patients registered in the Registry of Catastrophic Illness with diagnosis code of 571.5 for DCC, 155 for HCC or V42.7 for post liver transplantation. Dual infection patients with diagnosis code of 070.30 for HBV or 042-044 for HIV were excluded. The date that the outpatient visit/admission with the diagnosis code associated with each health state of liver-related disease firstly occurred was defined as the index date. Regression-adjusted medical costs associated with each health state of liver-related disease within 1st year and 2nd year after the index date were estimated by generalized linear regression model. Excess risks of death for patients with DCC, HCC, or liver transplantation were assessed by Cox proportional hazard model. **RESULTS:** First year total medical costs associated with HCV infection, CC, DCC, HCC and liver transplantation were NT\$25,345, NT\$49,793, NT\$187,428, NT\$197,835, NT\$487,816, respectively. The 2nd year total medical costs associated with DCC, HCC and liver transplant were NT\$194,016, NT\$176,167 and NT\$270,009, respectively. Patients in the health states of DCC, HCC and liver transplantation posed higher risk of death with hazard ratio of 14.5 when compared with their matched control counterparts. **CONCLUSIONS:** Liver-related diseases followed by HCV infection impose substantial economic burdens to the National Health Insurance in Taiwan. Effective treatment for HCV infection may imply potential savings to the society.

PGI17

RESOURCE UTILIZATION AND COSTS FOR PATIENTS WITH INFLAMMATORY BOWEL DISEASES IN ITALY: A POPULATION-BASED ASSESSMENT

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OBJECTIVES: To describe health care resource utilization in treating patients affected by inflammatory bowel diseases (IBD) and to assess the related direct costs to the Italian health care system (HS) in its most populated region. **METHODS:** A retrospective observational study was conducted using data from DENALI, a data warehouse that organizes and integrates the health care administrative databases of the national HS in Lombardy (northern Italy) with a probabilistic approach. The Italian HS provides universal coverage and records the accesses to health care services at regional level. We enrolled adult patients with Ulcerative Colitis (UC) or Crohn's Disease (CD) diagnosed during the period 2003-2009. Patients were classified in two cohorts in relation to the type of IBD and were followed until December 31st, 2009 to assess the mean annual consumption of resources (hospitalizations, pharmaceutical prescriptions, outpatient services) and the related costs incurred by HS. **RESULTS:** We identified 5,523 patients with UC and 3,321 with CD and the mean annual cost per-capita was €2,386 (95%CI: 2,241-2,516) and €2,699 (95%CI: 2,538-2,914) respectively. The breakdown of expense was similar in the cohorts: pharmacological treatments accounted for 37% , hospitalizations for 47% and outpatient services for 16%. Use of mesalazine was high in patients with UC and CD: 94% and 88% of subjects was respectively prescribed at least one package during follow-up. High adherence (≥70%) to oral mesalazine was observed in 39% of patients with UC and in 24% of CD cohort. Less than 6% of patients used biologics, which were used only from 2008. **CONCLUSIONS:** This study confirms that patients with IBD represent a considerable economic burden for the Italian HS: prescribed drugs, especially mesalazine, account for a substantial proportion of health care costs. The results underline the importance of administrative databases and the need for further research, since the recent widespread use of biologics for treating IBD.

PGI18

UTILISATION AND COSTS OF INPATIENT AND OUTPATIENT SERVICES AMONG PATIENTS WITH IRRITABLE BOWEL SYNDROME- A STUDY USING THE CLINICAL PRACTICE RESEARCH DATALINK (CPRD)

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OBJECTIVES: Irritable bowel syndrome (IBS) is a common functional gastrointestinal disorder. We assessed utilisation of secondary care services and associated costs among patients with IBS. **METHODS:** IBS was identified by medical diagnosis and/or prescribing in the UK primary care setting. Patients had ≥12 months of medical history prior to diagnosis. Absolute resource use and expenditure were assessed post IBS and over four years (01/04/2008-31/03/2012) using Hospital Episode Statistic data. Inpatient admission, outpatient attendance and length of stay for any cause including IBS related conditions were assessed. Inpatient costs for the period were estimated using allocated Health Resource Group coded data. Outpatient costs