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OBJECTIVES: Advanced head and neck cancer (HNC) survivors may have permanent alteration in their ability to communicate with others. Health-related quality of life (HrQOL) outcomes have been emphasized as an important issue in cancer survivors. This study compared HrQOL of the HNC survivors (five years after primary treatments) who had speech problem (SP) to who did not (NSP). We also explored sensitivity of HrQOL instruments relative to this problem. **METHODS:** This study was observational, mailed survey study. Target samples were individuals who received HNC treatments before 2005. We identified subjects through the Central Arkansas Radiation Therapy Institute Registry or recurited by phiysicinas of the university Head and Neck Surgery Unit. Self-perceived speech problem and HNC-specific HrQOL outcomes were determined using the University of Washington Quality of Life Questionnaire (UW-QOL) version 4. HrQOL outcomes were also described using the EQ-5D and the SF-6D. A rank analysis of covariance was performed to test for differences between the two groups on HrQOL outcomes, adjusted for years after treatment, treatment received, and cancer site. We expected that a sensitive HrQOL instrument would produce significant lower HrQOL scores for the SP group when compared to the NSP group at p-value < 0.05. **RESULTS:** Forty-seven HNC survivors' HrQOL were analyzed (78% response rate). Survivors' age averaged 65 years (SD=13) and the average years after the primary treatment was 8 years (SD=2). 16 (34%) reported having speech problems (SP group). The UW-QOL-Composite and the SF-6D scores in the SP group were significant lower than the NSP group (62±16 vs. 78±15, p=0.007; 0.66±0.12 vs. 0.78±0.16, p= 0.023). While there was no difference on the EQ-5D scores between the two groups (0.78±0.16 (SP) versus 0.84±0.14 (NSP), p=0.252). **CONCLUSIONS:** HNC survivors with self-perceived speech problem reported significant lower HrQOL. The UW-QOL and the SF-6D are sensitive to detect HrQOL difference relative to speech problem.

PSU22

PERFORMANCE OF THE FUNCTIONAL ASSESSMENT OF VISUAL TASKS (VISTAS-18) AMONG CATARACT PATIENTS RECEIVING MONOFOCAL AND MULTIFOCAL INTRAOCULAR LENS IMPLANTS

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OBJECTIVES: This study was performed to examine the psychometric performance of the four VISTAS-18 scales (i.e., Near Function, Intermediate Function, Extended-Intermediate Function, Distant Function) to the known benefits of intraocular lens (IOL) surgery, and more subtle differences between monofocal and multifocal IOL types. **METHODS:** Subjects (Ss) were recruited from surgery clinics 2-8 weeks prior to receiving bilateral IOL implants. Visual assessments were conducted at the pre-surgical visit and then after recovery. Following both visits, Ss completed a self-report questionnaire and the VISTAS item pool. The four VISTAS-18 Function Scale scores were evaluated using change from baseline in visual acuity assessments, and as well the type of IOL implant. Responder analyses were conducted for each distance range. **RESULTS:** Ss (n=61) had a mean age of 69.0 years (SD= 9.5) were in good health prior to surgery, although with low satisfaction with their vision and very low satisfaction with their visual aids. Most Ss received monofocal (n=39) or multifocal (n=16) lenses. Uncorrected and corrected visual function improved significantly following surgery on all four VISTAS-18 scales. Greater improvements were observed on the Near (p=0.007) and Intermediate (p=0.017) Function Scales for recipients of multifocal versus monofocal lens. The responder analyses indicated that 10/15 (66%) individuals who received multifocal lenses reported a one or more point reduction in near range task difficulty, and 11/15 (73%) in the intermediate range, compared to only 10/35 (29%) and 16/30 (53%) of individuals receiving monofocal implants. **CONCLUSIONS:** The VISTAS-18 Function Scales performed well, both in terms of changes in visual acuity associated with IOL implantation, as well as in demonstration of responsiveness to more subtle differences in Near and Intermediate function associated with lens type. The clinical implications of reliable assessment of visual tasks in near, intermediate and distant ranges of vision are discussed.

PSU23

REHABILITATION NEEDS AND PREDICTIVE FACTORS OF HEALTH-RELATED QUALITY-OF-LIFE IN BREAST CANCER PATIENTS DURING TWO YEARS AFTER SURGERY - A MULTICENTER PROSPECTIVE STUDY

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OBJECTIVES: Provision of psychosocial support and rehabilitation for patients after cancer treatment is important for long-term health-related quality-of-life (HRQOL). Effective use of healthcare resources requires identification of patients requiring rehabilitation. The objectives of this study were to clarify the patterns of physical and psychosocial recovery over time and to identify the significant baseline and treatment-related factors predicting HRQOL at 6 months, 1 and 2 years after breast cancer surgery. **METHODS:** A multicenter longitudinal study was performed to evaluate physical conditions, anxiety, depression and HRQOL at one month, 6 months, and 1 and 2 years after surgery in 196 breast cancer patients. Physical conditions were evaluated using a patient-reported symptom checklist. HRQOL was rated using the Functional Assessment of Cancer Therapy scale-General (FACT-G) and the Breast Cancer subscale. Anxiety and depression were rated using the Hospital Anxiety and Depression Scale (HADS). **RESULTS:** More than 50% of patients had local problems of "tightness", "arm weakness" and "arm lymphedema", and systemic problems of "reduced energy, fatigue, and general weakness" postoperatively. The HRQOL score significantly improved one year after surgery, and scores for physical, emotional and functional well-being also increased with time, whereas the score for social well-being was highest at baseline and decreased with time. Depression and anxiety significantly improved with time. Concomitant disease, marital status and the presence of a partner, anxiety and depression at baseline, pathological lymph node involvement, and adjuvant intravenous chemotherapy were significant factors predicting FACT-G scores at 6 months and 1 and 2 years after surgery. Depression at baseline was a strong predictor of HRQOL up to 2 years after surgery. **CONCLUSIONS:** These results suggest that physical rehabilitation is required for tightness and lymphedema, and a further study of psychosocial interventions is required to improve depression and social well-being.

PSU24

COMPARISON OF THE RESPONSIVENESS OF THE SF-36 AND THE RAW AND RASCH-BASED SCORES OF THE OXFORD KNEE SCORE IN PATIENTS UNDERGOING TOTAL KNEE REPLACEMENT

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OBJECTIVES: To compare the responsiveness of the generic Short Form 36 (SF-36) and the raw and Rasch-based scores of the condition-specific Oxford Knee Score (OKS) in patients undergoing total knee replacement (TKR) **METHODS:** Adult patients undergoing TKR in a hospital of Singapore between 2001 and 2006 completed the SF-36 and OKS at baseline and at 6 and 24 months postoperatively. OKS data were fitted to the Rasch partial credit model using the Winsteps program. Responsiveness was assessed using effect size (ES), standardised response mean (SRM), and relative validity (RV). **RESULTS:** A total of 702 patients who had complete data at baseline and two follow-ups were included in the analysis. After removing items regarding limping and kneeling, the remaining OKS items fit the Rasch model. Bodily pain (BP) and Physical functioning (PF) were more responsive than the other SF-36 domains. In addition, the OKS raw scores (raw-OKS) and Rasch-based modified OKS (Rasch-OKS) were consistently more responsive than all eight SF-36 domains. At the 6-month follow-up, Rasch-OKS had the largest ES whereas raw-OKS had the largest SRM (2.7 and 1.9, respectively). When compared to raw-OKS, the RV of Rasch-OKS, BP, and PF were 1.5, 2.0, 2.8, respectively. Similar order was observed at the 24-month follow-up. **CONCLUSIONS:** The OKS is more responsive than the SF-36 in patients undergoing total knee replacement. The raw and Rasch-based scores of OKS have comparable responsiveness. Different responsiveness indices may give different results.

Surgery – Health Care Use & Policy Studies

PSU25

EFFECTIVENESS OF MINIMALLY INVASIVE SURGERY FOR TOTAL HIP ARTHROPLASTY

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OBJECTIVES: The main objective of this review is to determine the effectiveness of total hip arthroplasty with MIS compare to the traditional approach. Specifically, this appraisal aims to answer questions related to functionality, quality of life, and clinical results. **METHODS:** The bibliographic review was conducted in two phases: an initial phase of search for appropriate studies and a second phase of selection according to previously established criteria. The search for articles was carried out in major databases and subsequently in bibliographical references for the studies found. The databases reviewed were MEDLINE/PubMed/MeSH Database, EMBASE, Economic Evaluation Database/DARE/HTA, CSIC/EMI-Biomedicine, and ScienceDirect Collection. The search period was limited to the years 2003 to 2009. The selection of items was made at an early stage by screening article summaries followed by full texts. **RESULTS:** We initially selected more than 600 studies, 78 for detailed evaluation, and 32 final studies for inclusion in the review. The results of this review are presented in two sections. The first represents the main descriptive characteristics of the studies selected in favor of MIS (19), and the second presents the unfavorable studies (13). Among the main benefits we found a decrease of transfusion requirements, better mobilization and rehabilitation, low dislocation, reduced surgical time, shorter hospital stays, less soft tissue damage, and better short term results. The main drawbacks were increased risks of complications, malposition of prosthesis, healing problems, and irrelevant clinical incision size and functionality. **CONCLUSIONS:** The studies presented in this review show clear evidence of how MIS influences the effectiveness related to functional outcomes, hospital stays, and surgical aggressiveness of the intervention. In this regard, we found a greater number of comparable studies supporting minimally invasive surgery in terms of effectiveness than those that emphasize complications and disadvantages of this technique.

PSU26

TWO-YEAR CHANGES IN GENERIC AND OBESITY-SPECIFIC QUALITY OF LIFE AFTER GASTRIC BYPASS

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OBJECTIVES: The first objective was to assess the two-year changes in quality of life after gastric bypass in patients with severe obesity. Second, we analysed the effect of weight reduction on the different HRQL dimensions in the framework of the International Classification of Functioning, Disability and Health (ICF). **METHODS:** We carried out a prospective intervention study with consecutive patients referred to two bariatric surgical units in the Basque Country. We included generic (SF-36, EuroQuol 5D) and specific questionnaires (Moorehead-Ardelt, Obesity-related Problems scale). The SF-36 mental and physical dimensions and stigma theory, allowed us to apply an approach based on the ICF. We measured effect size (ES), standardized response mean (SRM) and ROC curves. **RESULTS:** Of 82 operated patients, 79 were tracked for 2 years. Average weight loss was 49 kg (28%) and BMI was reduced from 50.6 to 31.8. The initial problems and the final improvements were larger in the physical dimensions. The benefit of treatment was large for almost all HRQL domains as measured by EQ-5D, SF-36, OP and Moorehead-Ardelt. Only the improvements in some of the mental domains of the SF-36 were classified as small or moderate. ROC curves were not sensitive to change in BMI. **CONCLUSIONS:** We suggest that the negative impact of severe obesity on HRQL is mainly a cause of disability as described in the ICF. Two-year improvements in HRQL are related to recovery from disability after gastric bypass treatment. The primary focus on the physical dimension is not contradictory with evidence of the impact of weight-related stigmatization in obese individuals at the social level and its consequences in mental health. In the ICF framework,

Surgery – Research On Methods

PSU27

FRACTURE RELATED TREATMENTS AFTER PRIMARY SURGICAL INTERVENTIONS OF HIP FRACTURE EIGHT YEARS FOLLOW UP

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OBJECTIVES: The aim of our retrospective study was to analyze the further fracture related treatment/complication after primary treatment of femur neck fracture according to most frequently used types of operation. **METHODS:** The data derive from the financial database of the Hungarian National Health Insurance Fund Administration, based on the 10th revision of the International Classification of Diseases (ICD) with ICD code S7200. The following patients were included into the study: having social insurance identification number, being discharged from hospitals in 2000 after primary treatment of femur neck fracture, over the age 60. The patients with polytrauma or high energy trauma patient were excluded from the study. During the 8 year follow up period the further fracture related treatment and complications were analyzed according to the most frequently used types of operation. **RESULTS:** Altogether 3783 patients were included into the study. The distribution of primary surgical intervention was: arthroplasty 12.5%, screw fixation 73.6%, dynamic hip screw (DHS) 5.1%, femoral neck nailing 5.0%, Ender nailing 1.8%, Gamma nailing 1%, others 1 %. The fracture related treatment rate was 14,5%. The main types of further fracture related treatments are listed: 5.7% hip replacement, metalwork removal 3.6%, replacement of implants 2.48%, aseptic and septic look: 1.7%, 0.7% resection arthroplasties. The further fracture related treatment rate according to the most frequently used types of operation: arthroplasty 4.8 %, screw fixation: 16.1 %, DHS: 7.8%, femoral neck nailing: 21.5%, Ender nailing: 19.4 %, Gamma nailing: 2.4%. **CONCLUSIONS:** The methods, providing quickly full weight bearing (Gamma nailing, DHS, hip arthroplasty) had lower complication rate, while the methods (screw fixation, Ender nailing, femoral neck nailing) providing partial weight bearing had higher complication rate. The backgrounds of fracture related treatments should be investigated in the future.

PSU28

ECONOMIC IMPACT OF STEREOTACTIC RADIOSURGERY FOR MALIGNANT INTRACRANIAL BRAIN TUMORS

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OBJECTIVES: Brain metastases occur in a majority of patients with malignant disease and result in decreased quantity and quality of life. Treatment alternatives range from whole brain radiation therapy (WBRT), neurosurgery, and the newest modality, stereotactic radiosurgery (SRS). This article reviews economic evaluations of SRS in the metastatic setting and compares to other treatment options. **METHODS:** Studies were included if they were published in peer reviewed journals, primarily in patients with malignant brain metastasis, and at least included a cost analysis between interventions **RESULTS:** Uncertainty surrounding the cost-effectiveness of SRS exits due to lack of efficacy information between treatment alternatives, methodological limitations, and design differences between the available studies. However, when cost –effectiveness ratios are available, SRS appears to be a reasonable option in resource limited settings, with incremental cost-effectiveness ratios (ICERS) just below the $50,000 range. **CONCLUSIONS:** Better designed economic analysis in the setting of randomized clinical trials or observational studies need to be conducted to fully understand the economic value of SRS.

DISEASE-SPECIFIC STUDIES

Infection – Clinical Outcomes Studies

PIN1

PHARMACIST PARTICIPATION IN ANTIRETROVIRAL DRUG MONITORING FOR THE PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV AT WARINCHUMRAB HOSPITAL, UBONRATCHATHANI, THAILAND

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OBJECTIVES: Thailand has been one of the leading developing countries to implement a national program to prevent mother-to-child transmission (PMTCT) of HIV. The objective of this study was to determine the impact of pharmacist intervention to monitor HIV-infected pregnant women. Pharmacist provided medication and guideline information including phamacotherapeutic suggestion. **METHODS:** In this research, retrospective study was employed with descriptive statistics using average percentage frequency, making use of out-patients records of treatments in HIV-infected pregnant women who informed about the benefits of taking antiretroviral (ARV) drugs for PMTCT, side effects of ARV drugs, importance of adherence to drugs and the fact that HIV transmission to their infants can possibly occur despite ARV use by pharmacist. **RESULTS:** The HIV-infected pregnant women group of 24 cases, 4 were withdrawn due to unable to follow up, 20 cases have been followed-up and shown the effectiveness of medicine. There were 8 new patients (33.33%) firstly received ARV. The mean CD4 cell counts at baseline of all patients were 227+-69.28 cells/mm3. Most regimens for treatment was highly active antiretroviral therapy containing zidovudine (AZT)+lamivudine (3TC)+lopinavir/ritonavir (LPV/rtv) 41.67% where treated with AZT+3TC+nevirapine were secondly used (33.33%). It was found that 34.4% of patients had adverse drug reactions. The ADR incidence of ARV was 4.0 patients and 6.2 events per 1000 person-day. Gastrointestinal system such as nausea and vomiting were found at 12.50% and 8.33% were diarrhea were the most organ system affected. During the study period, 3 patients had to change ARV regimens because of ADRs. 16.67% were non-compliance but less than 7 days at early period. The rate of MTCT of HIV was 8.33% after monitoring for one year. **CONCLUSIONS:** The results indicated that a medication monitoring and evaluating process by pharmacist associated with improved rational used of drug in HIV-infected pregnant women. This project provides a foundation for future quality improvement.

PIN2

SAFETY AND EFFICACY OF TENOFOVIR AS COMPARED TO OTHER NUCLEOT(S)IDE ANALOGUES IN THE TREATMENT OF CHRONIC HEPATITIS B – A SYSTEMATIC REVIEW WITH MIXED TREATMENT COMPARISON

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OBJECTIVES: The aim of this study was to assess efficacy and safety of tenofovir (TDF) as compared to other nucleot(s)ide analogues (NAs), i.e. lamivudine (LAM), adefovir (ADV) and entecavir (ETV) in the treatment of chronic hepatitis B virus (HBV) infection. **METHODS:** Assessment was based on randomized controlled trials (RCTs) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines. Studies met the inclusion criteria if they directly compared at least two of following interventions: TDF, LAM, ADV, ETV or placebo. The electronic medical databases (EMBASE, MEDLINE, CENTRAL) were searched. Two reviewers independently selected trials, assessed their quality and extracted data. Mixed treatment comparison (MTC) was performed with WinBugs software. If feasible, subgroup analyses were performed according to hepatitis B antigen e (HBeAg) and or LAM resistance status. **RESULTS:** We identified 30 relevant studies (6674 patients) with 12-144 weeks of follow-up . MTC showed that TDF increased the chance of HBV DNA clearance at the end of treatment period as compared to ADV (OR = 13,16 [3,21; 54,20]), LAM (OR = 61,09 [11,10; 503,78]) and ETV (OR = 9,55 [1,53; 76,98]). Subgroup analysis in HBeAg-positive subjects revealed that TDV was more effective than ADV (OR = 21,60 [1,67; 285,40]) and LAM with respect to HBV DNA clearance but no difference were found between TDV and ETV (OR = 11,24 [0,53; 342,57). TDF showed similar efficacy to other NAs with respect to normalization of alanine aminotransferase activity (ALT) and histological improvement. TDF did not increase the risk of any and serious adverse events either in comparison with PLC or with other NAs. The rates of ALT flares were similar in all groups. **CONCLUSIONS:** TDF demonstrated the highest efficacy with respect to reduction of viral load in patients with chronic HBV and maintained a very good safety profile.

PIN3

COMPARING THE EFFICACY AND TOLERABILITY OF ANTI-RETROVIRAL THERAPY IN TREATMENT-NAÏVE HIV-1 INFECTED ADULTS: A SYSTEMATIC REVIEW OF RANDOMIZED CLINICAL TRIALS AND BAYESIAN MIXED TREATMENT COMPARISONS INCLUDING ATAZANAVIR/R, DARUNAVIR/R, LOPINAVIR/R, AND EFAVIRENZ

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OBJECTIVES: A framework for comparative research is useful for health technology assessment (HTA) and clinical decision making. The objective was to systematically assess efficacy and tolerability of 3rd agents, atazanavir/r (ATV/r) compared to darunavir/r (DRV/r), lopinavir/r (LPV/r) and efavirenz (EFV), in treatment-naïve HIV-1 infected adults. **METHODS:** A systematic literature search was conducted to identify published randomized clinical trials (1-1-2000 to present), in which the four anti-retroviral (ARV) treatments were used for these patients. Pooled esti-