PCN33
HEALTH RELATED QUALITY OF LIFE IN POST-OPERATIVE BREAST CANCER PATIENTS
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OBJECTIVES: This study was conducted to evaluate health related quality of life (HRQOL) in post-operative breast cancer patients of Korea. **METHODS:** A consecutive series of patients with breast cancer who visited to one university hospitals in Seoul after operation as a primary treatment from Feb to Mar 2012 were recruited. Their HRQOL was assessed using EQ-5D, SF36 and FACT-B. General and clinical information was obtained from the interviews and medical chart reviews. HRQOL was analyzed on general and clinical information of them. **RESULTS:** Among 487 patients with breast cancer, 487 patients complete the questionnaire. All study participants were female and their mean age was 52.5. In the aged, low education group, and divorced or bereaved people, their HRQOL were lower than those of the other groups, respectively. All correlation coefficients between EQ-5D index, 8 scales of SF-36 and FACT-B score were statistically significant ($p<0.001$, respectively). **CONCLUSIONS:** This study showed the HRQOL of post-operative breast cancer patients in South Korea.

DIABETES/ENDOCRINE DISORDERS - Clinical Outcomes Studies

PDB1
RISK FACTORS FOR HYPOGLYCEMIA AMONG VETERANS WITH TYPE 2 DIABETES MELLITUS
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OBJECTIVES: To identify risk factors among veterans with type 2 diabetes mellitus (T2DM) initiated on new anti-hyperglycemic treatments. **METHODS:** Electronic records were obtained for adults with at least 2 records of T2DM diagnosis (ICD-9-CM codes: 250.xx except for 250.x1 and 250.x3) from the VISN 16 data warehouse from January 1, 2004 to September 1, 2010. The first dispense date of a new antihyperglycemic agent (index drug) was defined as the index date. The hypoglycemia group and control group were identified by hypoglycemia (ICD-9-CM codes: 250.8, 251.0, 251.1 and 251.2) during index-treatment period and no hypoglycemia during one-year post-index period, respectively. Select patients had no records of hypoglycemia, cardiovascular disease, or microvascular complications during the one-year pre-index period. A logistic regression model was employed to identify the risk factors for post-index hypoglycemia. **RESULTS:** Among 44,261 patients (hypoglycemia: n=761, control: n=43,500), the incidence rate of hypoglycemia events was 3.57 per 100 patient-years. The hypoglycemia group was more likely to have renal disease, mental disorder, substance abuse, and tobacco use. More patients under poor glycemic control (HbA1c>7%) was found in the hypoglycemia group (91.4%) compared to those in the control group (87.8%) ($p=0.0043$). The hypoglycemia group used significantly more health care resources at baseline than the control group [hospitalization (14.6% vs. 7.2%, $p<0.0001$); emergency room (32.7% vs. 19.3%, $p<0.0001$); outpatient visits on average (13.33 vs. 7.34, $p<0.0001$)]. The hypoglycemia group was more likely to use insulin at baseline or initiated with insulin as the index drug. Insulin use (baseline or index) and renal disease were top risk factors (odds ratio>=2) in the logistical model. **CONCLUSIONS:** Among veterans with T2DM, the hypoglycemia group was in general sicker than the control group. Subpopulations who were insulin user or with comorbid renal disease were even at higher risk for hypoglycemia.

PDB2
EPIDEMIOLOGY, PATIENT BURDEN AND RELATED COSTS OF OBESITY IN INDIA
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OBJECTIVES: Recent changes in lifestyle has triggered an increased prevalence of obesity even in developing countries such as India. Obesity is known to be correlated with increased risk of Type 2 Diabetes and Cardiovascular diseases. The burden of obesity may be underestimated as Indians are at higher risk of comorbidities with comparatively lower BMI. The aim of our research was to assess the epidemiology and burden of obesity in India. **METHODS:** International and Indian medical databases (MEDLINE, EMBASE, dmri.in) as well as archives of Indian medical journals (nmji.in, japi.in) were searched to collect information regarding epidemiology and burden of obesity. **RESULTS:** Our search retrieved 27 relevant publications. The prevalence of obesity among Indian adults was setting-dependent. In rural areas, obesity was diagnosed in 5.1% - 8.5% and 5.2% - 12.7% of men and women, respectively. In urbanized regions 15.9% - 38.2% of men and 23.5% - 47.6% of women were obese. Evidence for burden of obesity was sparse and based on single trials reporting increased risk of diabetes (RR = 8.45 [1.09; 65,36]), hypertension (RR = 2.19 [1.16; 4,13]) and breast cancer (RR = 2.27 [1.28; 4,01]) in obese as compared to normal-weight patients. No correlation between overweight and excessive risk of death was found. Obesity and diabetes place a significant economic burden on society mainly due to indirect costs including productivity loss, decreased household earnings and higher dependence on welfare. Indeed, 15%-25% of household income is spent on treatment of diabetic patients in India, and with the rising incidence, this will only worsen over time. **CONCLUSIONS:** Obesity and diabetes burden the constrained health care system of India and the entire society, leading to lost productivity and decreased household incomes. With the rising prevalence, this burden will only worsen unless effective measures to address the same are put in place.

PDB3
EPIDEMIOLOGY, PATIENT BURDEN AND RELATED COSTS OF OBESITY IN CHINA
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OBJECTIVES: Obesity is a cause of more deaths than malnutrition in most high/middle income countries. Asians are especially likely to accumulate intra-abdominal fat increasing a risk of obesity-related comorbidities. The aim of our research was to assess the epidemiology and burden of obesity in China. **METHODS:** International and Chinese medical databases (MEDLINE, EMBASE, wanfangdata.com, cqvip.com, cnki.net, docin.com, wenku.baidu.com) were searched to collect information regarding epidemiology and burden of obesity. **RESULTS:** Our search retrieved 34 relevant publications. The prevalence of obesity among Chinese adults oscillated between 2.7% and 13.1% in rural and urban areas, respectively. Most often the overall prevalence in combined rural and urban populations was reported in the range between 4% and 11.6%. Epidemiological trends reveal an alarming increase in the prevalence of obesity among Chinese adults, which increased from 0.3%-2.9% in the late '80s and early '90s, to 3%-11.4 in the first decade of 21st century. This increase translates into a growing number of obesity-related diseases, such as hypertension reaching 18.8% in 2002 and type 2 diabetes (T2DM) affecting 2.6% population. In Beijing, hypertension and T2DM were 25% and 7.7%, respectively. In the Chinese population, severe obesity increases the risk of death by 29%. The growing costs of obesity is a burden on health care. The estimated direct costs of obesity in the year 2000 were nearly $6 billion, while the indirect costs associated with loss of productivity exceeded $43 billion, corresponding to 0.48% and 3.58% of gross national product (GNP), respectively. The estimates for productivity loss are rising dramatically to $106 billion in 2025, which represents an increase to 8.73% of China's GNP. **CONCLUSIONS:** The growing rates of obesity and obesity-related comorbidities is a rapidly growing economic burden on the Chinese health care system and calls for prevention and treatment strategies.

PDB4
DEVELOPMENT AND VALIDATION OF RP-HPLC-UV METHOD FOR DETERMINATION OF GLIPIZIDE IN HUMAN PLASMA
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OBJECTIVES: To develop and validate simple, sensitive and selective HPLC method for determination of glipizide in human plasma. **METHODS:** Liquid-liquid extraction method was used to extract glipizide from the human plasma samples. Chromatographic separation of glipizide was achieved using C18column (ZORBAX ODS 4.6 X 150mm). The mobile phase was comprised of 0.01 M potassium dihydrogen phosphate and acetronitrile (65:35, v/v) adjusted to pH 4.25 with glacial acetic acid. The analysis was run at a flow rate of 1.5 ml/min with an injection volume was 20 μL. The UV detector was operated at 275 nm. The proposed method was validated as with respect to selectivity, linearity, accuracy, precision, recovery, limit of quantification (LOQ) and stability. **RESULTS:** The calibration curve was linear over a concentration range of 50 – 1600 ng/mL. Intra-day and inter-day precision and accuracy values were below 15%. The limit of quantification was 50 ng/mL and the mean recovery was above 98%. Freeze-thaw, short-term, long-term and post-preparative stability studies showed that glipizide in plasma sample was stable. **CONCLUSIONS:** A rapid, simple, selective and sensitive HPLC method for determination of glipizide in human plasma was successfully developed. The method showed good recovery, accuracy and precision. The method can be successfully applied to in pharmacokinetics and bioequivalence studies to quantify glipizide in plasma samples.

PDB5
STATIN IS A REASONABLE TREATMENT OPTION FOR PATIENTS WITH POLYSYSTIC OVARY SYNDROME: A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS
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OBJECTIVES: To date no consensus has been reached on whether to administer statin to patients with Polycystic Ovary Syndrome (PCOS) routinely. Therefore, we conduct a meta-analysis to synthesize the existing literatures regarding therapeutic effects of statins on PCOS. **METHODS:** A comprehensive literature search was performed using terms such as polycystic ovary syndrome, ovary polycystic disease, PCOS, hyperandrogaenemia; exposures including statin, simvastatin, atorvastatin, rosuvastatin, lovastatin, mevastatin, pravastatin, lipidemic-modulating drugs, lipid lowering drugs, and testosterone; study types including randomized controlled trails or studies or randomized in the following bibliographic databases from inception to 30 Sep 2011: Medline, Embase, Cochrane Controlled Trials Register and Biological Abstracts. Identified reference lists were checked manually to retrieve related papers. **RESULTS:** In total, four RCTs were included. Three of four studies were double-blinded while none reported whether of the data was analyzed using Intention-to-Treat analysis. Serum total testosterone and lipid profiles were included as investigation outcomes in all four studies. Differences in reducing serum total testosterone were observed when comparing statin with placebo (Std MD= -3.03, 95%CI -5.85~-0.22, P=0.03) or statin+metformin with metformin (Std MD=-1.07, 95%CI: -2.06~-0.07, P=0.04). Heterogeneities were detected in both comparisons (I2=96% and 88% respectively). Meanwhile, statin was more effective than placebo in reducing LDL (WMD=-0.87, 95%CI -1.18~-0.55, P<0.0001), TC (WMD=-

1.23 95%CI -1.35~-1.11, P<0.00001), TG (WMD=-0.50, 95%CI -0.73~-0.27, P<0.00001); and statin+metformin was more effective than metformin in lowering LDL (WMD=-=-0.84, 95%CI: -1.33~-0.354, P=0.0009), TC (WMD=-1.28, 95%CI: -1.47~-1.10 P<0.00001), and TG (WMD=-0.27, 95%CI: -0.36~-0.19, P<0.00001). Heterogeneities were detected during the meta-analysis. **CONCLUSIONS:** Statins can positively reduce the concentration of total testosterone, TC, TG and LDL. It cannot be concluded, however, that statins have the long-term benefit. A large-scale, well-designed, randomized controlled study is needed to ascertain this uncertainty.

PDB6

PREDICTORS OF REACHING HBA1C GOAL IN T2DM PATIENTS USING DIPEPTIDYL PEPTIDASE-4 INHIBITORS (DPP4IS) COMBINATION THERAPY: A SUBGROUP ANALYSIS

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OBJECTIVES: To describe characteristics of T2DM patient subgroups who were more likely to achieve HbA1c goal < 7% with combination treatment of DPP4i with PIO or with MET using a predictive model. **METHODS:** Stepwise logistic regression was applied to MarketScan claims data to develop a predictive model that estimated the probabilities of HbA1c goal achievement in patients receiving DPP4i combinations. Sample selection criteria included: 1) T2DM diagnosis; 2) treatment of DPP4i with PIO or with MET; 3) baseline HbA1c ≥ 7%; and 4) with one-year continuous enrollment. Patients were ranked by the probabilityof achieving HbA1c<7% and grouped into cumulative percentiles; baseline characteristics of the optimal subgroups identified as the first 20th and 80th percentiles were reported. **RESULTS:** A total of 328 patients were included. The predictive model showed that patients who had neuropathy, cerebrovascular conditions, or higher total medication use at baseline were less likely to achieve goal on DPP4i combinations while patients with self monitoring blood glucose use at baseline were more likely to achieve goal (P< 0.05). The 80th percentile subgroup (n=270) had a goal reaching rate of 57.0%, mean age of 50.3 years old, 44.3% female, 38.5% on MET, 13.8% on thiazolidinedione (TZD), and HbA1c = 9.13% at baseline. The 20th percentile subgroup (n=83), achieved goal at the rate of 72.3%, mean age of 50.6 years old, 46.1% female, 53.9% on MET, 25.7% on TZD, and HbA1c = 8.96% at baseline. **CONCLUSIONS:** Predictive factors for reaching goal include: 1) use of self monitoring blood glucose, and 2) lack of neuropathy, cerebrovascular disease, or usage of medications. Subgroups that might benefit the most from DPP4i treatment were identified. These patients exhibited a higher likelihood of having prior use of MET or TZD, and baseline HbA1c less than 9.0%.

PDB7

NETWORK META-ANALYSIS OF FIXED DOSE COMBINATION THERAPIES FOR THE FIRST-LINE TREATMENT OF TYPE 2 DIABETES MELLITUS

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OBJECTIVES: To assess the relative efficacy and safety of fixed dose combinations (FDCs) of anti-diabetic drugs in treatment naïve patients with type 2 diabetes mellitus (T2DM) using network meta-analysis technique. **METHODS:** Randomized controlled trials, evaluating FDCs in treatment naïve patients with T2DM were searched via Embase® and MEDLINE®. The abstracts were reviewed and data extractions were conducted by two independent reviewers. The outcomes of interest included reduction in Hb1Ac levels, patients with HbA1c<7%, fasting plasma glucose (FPG) levels, and incidence of hypoglycemia. A network meta-analysis using WinBUGS® was performed to combine the reported direct and indirect evidence and a probability ranking for the included combinations was generated. **RESULTS:** Eleven trials (n=5781 patients) comparing the following FDCs: sulfonylureas/biguanides (SUL/BGU), thiazolidinediones/biguanides (TZD/BGU), dipeptidyl peptidase-4 inhibitors/biguanides (DPP-4/BGU), alpha-glucosidase inhibitors/biguanides (AGI/BGU), and thiazolidinediones/sulfonylureas (TZD/SUL) were included. Following network meta-analysis using BGU, TZDs, and SUL as common comparators, TZD/SUL was observed to be significantly better in terms of patients with HbA1c<7% than other FDCs [relative risk; 95% credible intervals vs. SUL/BGU (1.16; 1.03-1.3), vs. TZD/BGU (1.12; 1.01-1.24), and DPP-4/BGU (1.18; 1.07-1.29)]. Statistically, however, non-significant differences were observed among the FDCs other than TZD/SUL for this outcome. All FDCs achieved clinically meaningful reductions in HbA1c and FPG, though the differences between the FDCs were statistically non-significant. According to the probability ranking for reduction in HbA1c and FPG levels, the rank favored TZD/SUL followed by AGI/BGU, TZD/BGU, SUL/BGU, and DPP/BGU. The probability of occurrence of hypoglycemia was highest with SUL/BGU (78.3%) followed by TZD/SUL (20.2%), TZD/BGU (0.03%), and DPP-4/BGU (0.005%). Incidence of hypoglycemia was not reported for AGI/BGU. **CONCLUSIONS:** Clinically, all FDCs effectively achieved glycemic control in patients with T2DM, however, the risk ratios from network meta-analysis were inconclusive to determine the relative efficacy of these FDCs. The probability ranking suggested the potential use of TZD/SUL in treatment naïve T2DM patients.

PDB8

BARIATRIC AND METABOLIC SURGERY IN INDIA – EFFICACY AND SAFETY OF MINIMALLY INVASIVE PROCEDURES

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OBJECTIVES: Obesity and type 2 diabetes mellitus (T2DM) are major health issues in developing countries contributing to increased morbidity and mortality. Bariatric surgery is an effective procedure leading to durable weight loss in morbidly obese patients, while metabolic surgery aims at resolving T2DM. The objective of our study was to assess the efficacy and safety of those procedures in Indians. **METHODS:** A comprehensive search was performed in PUBMED and websites of Indian medical databases and journals (www.indmed.org, www.dmri.in, www.n-mji.in, www.japi.in). Studies met the inclusion criteria if they enrolled Indian obese patients with or without T2DM undergoing following laparoscopic procedures: sleeve gastrectomy, Roux-en-Y gastric bypass, adjustable gastric banding, single-incision sleeve gastrectomy. **RESULTS:** Our search retrieved nine studies (978 patients) of which three included T2DM patients (N = 91) exclusively. Postoperative excessive weight loss ranged from 59.1% to 76.1% after 12-months and from 65.2% to 71.1% after 24-months of follow-up. BMI was reduced by 5.9-20.5 kg/m^2, dyslipidemia was resolved in 34-100% patients and hypertension was improved in 67-95% individuals around one year after surgery. Moreover, at the same time joint pain was reduced in 57-97% patients and sleep apnea in 100% subjects. The incidence of asthma and depression were also reduced following bariatric/metabolic surgery. Metabolic procedures carried out in the subset of diabetics were associated with T2DM resolution in 61-100% of patients, reduction of HbA1c by 2.3-4.0 percentage points and improvement in fasting blood glucose by 60-144 mg/dl. Reduction of BMI among diabetics was in the range between 5.9–9.8 kg/m^2. Rates of postoperative complications were generally low and only one death was reported due to pulmonary embolism. **CONCLUSIONS:** Bariatric and metabolic procedures are effective in both weight reduction as well as improvement or resolution of T2DM. Those procedures are safe and beneficial in morbidly obese patients especially with T2DM.

PDB10

CLINICAL SURVEY TO ASSESS OUTCOMES IN DIABETES PATIENTS USING PEN NEEDLES OF DIFFERENT LENGTHS

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OBJECTIVES: Many studies have shown the distance from skin to muscle layer is shorter than imagined; it's important to ensure insulin injections are consistently made into subcutaneous layer, without leakage/backflow or subject-reported injection pain. The objective of this study was to assess clinical outcomes in T2DM patients switched from insulin injection with longer pen needles (PNs) to shorter PNs. **METHODS:** A retrospective study was conducted from July '09 to Jan '12 to compare lipohypertrophy, bleeding, bruising, insulin leakage, pain, and bulge on skin in a clinic in Yilan, Taiwan. Eighty-two patients with diabetes who were prescribed injectable insulin were included. Before Jul '09, all patients were prescribed 8 mm PNs. There was no limitation of insulin type, dosage, gender or education level. From July 2009 to August 2011, PN length was switched to 5mm, then (beginning Jul '11) to 4mm. Injection techniques and injection areas were inspected by certified diabetes educators every 3 months for all subjects. Standard injection technique were taught and followed-up in patients. All statistical analyses were conducted using SAS software (vs. 9.1). **RESULTS:** Demographic characteristics: age 60.5±14.3 years, 58.5% males, 92.7% T2DM, diabetes duration 16.0±7.0 years and insulin injection duration 6.8±4.2 years. A1C: 8.3±1.5%, 8.1±1.2% and 8.1±1.1% (p=0.3180); BMI: 25.3±3.4kg/m^2, 25.1±3.4kg/m^2 and 25.4±35.4kg/m^2 (p=0.8565). The bleeding/bruising decreased from 64.6% to 56.1% to 54.9% (p=0.0904), lipohypertrophy formation decreased from 26% to 20% to 15% (p= 0.1954). Reports of insulin leakage from tip or skin (p=0.8715, 0.5644), pain perception (p=0.1379) and bulge on skin (p=0.8039) were not statistically significant between 5mm and 4mm PNs. **CONCLUSIONS:** No significant changes in A1C and BMI associated with change in needle length from 8mm to 5mm and from 5mm to 4mm were observed. There was no apparent increase in leakage of insulin. A trend towards less bleeding and pain was observed when using shorter needles.

PDB11

EFFICACY OF EXENTAIDE IN TYPE 2 DIABETES MELLITUS IN A LOCAL HOSPITAL IN TAIWAN: A PILOT STUDY

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OBJECTIVES: Exenatide is a new antidiabetic agent which is an analog of incretin (glucagon-like peptide 1) with a adjunctive therapy with type 2 diabetes mellitus (T2DM),and has adverse events of nausea, vomiting and poor appetite. To assess the clinical efficacy of exenatide in T2DM. **METHODS:** Inclusion criteria were T2DM with inadequate glycemic control under oral antidiabetic agnets or insulin therapy. Exenatide were added on by the reatment course of exenatide is 5μg twice a day at first month and then adjusted to 10μg twice a day if tolerated. The primary outcomes are influence on HbA1C level and body weight. **RESULTS:** Eighteen patients, who were 7 male and 11 female with mean age of 43.46, were recruited. Of them had a mean body weight of 97.15kg and mean HbA1C of 9.1%. HbA1c improved significantly after 3 months and 6 months with mean reduction of 0.75%(p<0.002) and 0.97%(p<0.009). Mean body weight mild decreased at 3 months (4.33 kg) and reduced significantly at 4 months and 6 months with 5kg (p<0.005) and 9.74kg (p<0.0006). **CONCLUSIONS:** Exenatide improve HbA1c and body weight greatly within 6 months in a local hospital and may have great affect on the changing of life style, like diet control and frequency of Self-Monitoring of Blood Glucose. In future, a larger and long time study would need to demonstrate the validity of exenatide on the taiwanese.

PDB12

ROLE OF CHROMIUM IN TYPE-2 DIABETES THERAPY: A SYSTEMATIC REVIEW STUDY