equipment costs ($495 list price of Revolve per use) and depreciated cost of centrifugation ($100 per use) was also estimated. RESULTS: Base case assumed 100 AFGs per year (150ml of fat injected per case). Mean time to complete AFG was substantially faster using Revolve than centrifugation; 29.1 minutes versus 116.1 minutes (range: 25.1-32.0 versus 104-128.5 minutes, respectively). Mean time to complete AFG was greater for greater bleeding volumes. 210.0 ml versus 92.0 ml (ranges: 179-241.2 versus 82.4-102.0 ml, respectively). Consequently, rate of completing AFG was greater with Revolve than centrifugation: 5.2mL/min versus 1.1mL/min (range: 4.7-6.0 versus 1.2-1.4mL/min, respectively). Estimated cost savings for Revolve versus centrifugation was $2,075 per case and $207,476 per year. CONCLUSIONS: As popularity of AFG increases, evaluating economic impact of AFG systems becomes essential. Based on current findings, Revolve system results in substantial OR time and cost savings compared to centrifugation.

**PMD75**

**INTEGRATING BIG DATA TO ASSESS THE ECONOMIC IMPACT OF THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR THERAPY**

Madofo T., Consi S., Chiodini V., Mantovani L.G., Fornari C., Cesana G.

University of Milano - Bicocca, Monza, Italy

OBJECTIVES: The purpose of this study was to link clinical and administrative healthcare databases in order to assess the economic impact of implantable cardioverter defibrillator (ICD) with or without cardiac resynchronization pacing (CRT-D) in Lombardy, the most populated Italian region providing universal health-care coverage for about 10 million inhabitants. METHODS: Data were extracted from: i) data warehouse DENALI, that organizes healthcare administrative databases concerning all subjects covered by Lombardy Health System (HS), ii) national ICD database. After linking DENALI and clinical information extracted from the ICD database, we identified patients with ICD and followed them from the date of the initial implant to 12/31/2010, recording hospitalizations, drugs and outpatient claims. Direct healthcare costs were analysed from the perspective of the HS. We estimated the mean annual per-capita costs after the first ICD implant: overall and stratified by indication (primary and secondary prevention) or type of implanted device (single-chamber or CRT-D). RESULTS: During the Harmonic® device was introduced, 12,525 subjects underwent a first ICD implant. Mean annual per-capita cost during follow-up was €6,086 (95%CI: 5,970-6,211), 72.7% due to hospitalizations ($4,422, 15.7% to pharmacological therapies ($957) and 11.6% to outpatient services ($706). No differences were found between subjects in the mean annual expenditure for primary (€16,795, 95%CI: 6,001-6,653) and secondary (€5,996, 95%CI: 5,821-6,185) expenses. As for the type of implanted device, patients with CRT-D cost more than those with single-chamber or dual-chamber: respectively €6,595 (95%CI: 5,376-6,847), €7,285 (95%CI: 5,541-5,972) and €5,932 (95%CI: 5,717-1,473). The difference was attributable to hospitalization expenses. CONCLUSIONS: ICD use is growing and it is important to assess the efficacy and the burden of this therapy, given its economic implications. Further study in other settings with additional administrative and clinical information could overcome the limitation of both data sources, leading to an improvement in the monitoring of ICD therapy.

**PMD76**

**ECONOMIC AND PATIENT BURDEN OF LIPOHYPERTROPHY IN CHINESE PATIENTS WITH DIABETES**

Chen Y.1, DiMaggio C.1, Zhang L.1, Li Q.2, Sun Z.2, Jin G.2, Wei S.2, Liu J.2, Luan L.1, Chapman R.1, Incencio T.2

1Becton Dickinson, Franklin Lakes, NJ, USA, 2The First Affiliated Hospital of Chongqing Medical University, Chongqing, China, 3Southeast University Zhongda Hospital, Nanjing, China, 4Peking University, Beijing, China, 5The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China, 6, Liu J.

OBJECTIVES: DM is rapidly growing in China, affecting >114 million people. Lipohypertrophy (LH) is a known, preventable complication amongst insulin-injecting DM patients. This study demonstrates the economic and patient burden of LH in China. METHODS: An observational study was conducted among 401 insulin-injecting adult patients with DM from 4 cities, 2 with and 2 without needle reimbursement (FNR). Demographics, medical history, direct and indirect costs, insurance and FNR status were collected via patient survey, followed by HbA1c tests and physical exam to assess LH. RESULTS: LH was present in 52.9% of participants. Patients were an average of 59.6 (SD 18.4) years old and took insulin 5.6 (SD 3.6) times per day, averaging 33.0 (SD 18.4) U/day. HbA1c was 8.2% (1.8) and 7.7% (1.5), respectively, in those with and without LH (p = 0.003). LH was associated with higher dosing of insulin (38.1U vs 27.1U, p < 0.001), and longer duration of diabetes (5.8 years vs 4.7 years, p < 0.001). There were no differences in costs between LH and non-LH patients. With 84.8 million insulin injectors in China, the estimated excess annual direct cost of LH is RMB 2.2 billion ($360 million). Average pain scores (0-10) were higher if LH was present (7.2 vs. 5.0, p < 0.001), if 3 or more pads were used (3.8 vs. 5.3, p < 0.001), and if FNs were not reimbursed (2.8 vs. 1.7, p < 0.001). Patient satisfaction decreased as presence, number, and size of LH nodes increased (all p < 0.05). CONCLUSIONS: Adverse effects and implications of LH reach over half of insulin-injecting patients in China. Assessing the patient burden of LH including patient education on proper injection techniques including injection site rotation and reducing PN reuse, should be incorporated into routine DM management. Doing so may decrease this preventable complication, which may lessen LH-related economic and patient burden.

**PMD77**

**ECONOMIC ANALYSIS OF EVARESTTM COMPARED TO TACHOCEL® IN LIVER AND OTHER SURGICAL BLEEDING: AN INDIRECT COMPARISON**

Corral M.1, Jamous N.1, Ferko N.2, Bourque M.3

1Ethicon Biosurgery, Somerville, NJ, USA, 2Ethicon Biosurgery, Berkshire, UK, 3Cornerstone Research Group Inc., Burlington, ON, Canada

OBJECTIVES: Surgical bleeding remains prevalent and associated with substantial burden. Such bleeding can be more difficult to manage in certain surgeries (e.g., liver). Hemostats with a fibrinogen, thrombin and patch component may be especially beneficial for problematic bleeding types, however, direct comparative data are limited. This study indirectly compared the hemostats EVAREST and TachoCel. METHODS: A structured literature search identified studies of fibrin sealants combined with use of a pad, patch, fleece or sponge, for surgical bleeding. The search was restricted to RCTs, 2000 onward, studies including standard of care (SoC) and time to hemostasis (TTH). EVAREST (4 trials) and TachoCel (6 trials) were identified as the comparators. Pair-wise meta-analyses were completed using a random-effects model for hemostat vs. SoC. An adjusted indirect comparison was conducted using Bucher methodology and ITC software (Wells, 2009) for calculating the ratio of differences (RD) between EVAREST and TachoCel with 95% confidence intervals (CI). Mean TTH was analysed as it was a well-accepted, recommended measure. Typically, TTH measurements began at either 3 or 4 minutes. Studies were considered as the “anchor” if they used the same comparator in either conventional methods or topical hemostats. Indirect comparisons were completed for all surgery types and a liver surgery subgroup. RESULTS: A total of 894 patients were assessed. Across surgery types, the adjusted indirect comparison demonstrated that EVAREST reduced mean TTH by 1.15 minutes compared to TachoCel (MD = -1.15, 95%CI: -3.29, 0.99). However, this difference was not statistically significant. In the subgroup of liver surgical bleeding, EVAREST significantly reduced mean TTH by 2.73 minutes (MD = -2.73, 95%CI: -4.48, -0.98). CONCLUSIONS: This analysis suggests EVAREST may provide better hemostasis than TachoCel, particu-
larily in liver surgical bleeding. Caution must be taken in interpreting results given some patient differences. A head-to-head trial comparison may be necessary to confirm differences between products.

PMD60 EFFECT OF HYDROPHILIC COATING ISOTONIC TO URINE ON INFECTIONS AND COMPLICATIONS AMONG USERS OF INTERMITTENT URETHRAL CATHETERS
Neugroszyk K1, Svensson J1, Åberg-Hånansson M2, Lundqvist T2
1Research Laboratory, Stockholm, Sweden, 2”Wellpect HealthCare, Mölndal, Sweden
OBJECTIVES: Infections and urethral trauma are common complications among patients using intermittent urinary catheters. The objective of this study was to investigate the effect on complications of switching to a catheter with hydrophilic coating isotonic to urine. METHODS: A questionnaire was sent to 604 indwelling catheter patients, performing daily intermittent urinary catheterization in Europe and the USA. The participants were asked to report infections and complications, as well as current catheter type if applicable. Only patients reporting to currently be using a catheter type with hydrophilic coating isotonic to urine were included in the study. The patients who had previously switched catheters were asked to estimate their current infections, complications and problems as much less, same, more or much more compared to before the switch. Wilcoxon signed rank test was carried out to detect changes in level of consequences after switching. Analyses were performed separately for patients who switched but stayed on catheters with hydrophilic coating isotonic to urine and patients who switched from another catheter type. RESULTS: The initial response rate was 57% (n=391) of which 74% (n=288) were using catheters with hydrophilic coating isotonic to urine. 129 patients reported to have switched catheters, 41 (32%) stayed on the same catheter type. Patients who switched from another catheter type. Among those patients who switched from another catheter type to a catheter with hydrophilic coating isotonic to urine, an average of 15% reported more and 3% reported less problems compared to the baseline (p=0.043), UTIs (p=0.062), and general problems (p=0.001). The corresponding numbers for the patients who stayed on catheters with hydrophilic coating isotonic to urine were not statistically significant.

DISEASE-SPECIFIC STUDIES
DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1 URINARY TRACT INFECTION AMONG THE SGLT 2 INHIBITORS: A META-ANALYSIS OF 19 RANDOMIZED CONTROLLED TRIALS
Gangal NS, Kelch C, Heaton FC
University of Cincinnati, Cincinnati, ON, USA
OBJECTIVES: The goal of this meta-analysis was to determine if within the sodium- glucose cotransporter 2 (SGLT 2) inhibitors class, any individual drug increased the risk of urinary tract infection (UTI). METHODS: Data base search was conducted using Medline, PubMed, and Google Scholar. Study included trials of FDA approved SGLT 2 inhibitors canagliflozin, dapagliflozin and empagliflozin. For each trial, we abstracted the data on UTIs, related ADRs and safety. For randomized controlled trials which included patients with diabetes were included. Any trials with any special groups of patients, for example, patients with cardiovascular disease were excluded. RESULTS: This study includes 19 patients performing daily intermittent catheterization can benefit from switching to a catheter with hydrophilic coating isotonic to urine.

PDB2 STUDY OF PATIENT RELATED OUTCOMES OF TYPE 2 DIABETES AND COMPARATIVE ANALYSIS OF PIOGLILOZAN SALES PPE AND POST BAN IN MUMBAI,INDIA
Vadala S, Hegde P, Velankar K, Dhumal T, Majumdar A
GfK Custom Research, Wayland, MA, USA
OBJECTIVES: The aim of this study was to compare patients ADRs, post ban impact on its own to secure reimbursement. Analysis of claims and EMR data can be an excellent data source for supporting diagnostic utility modeling.

PDB3 COMPARATIVE OUTCOMES OF TESTOSTERONE THERAPY VERSUS NO THERAPY IN HYPOGONADISM
Hoopes J, Blanchette CM, Van Doren BA, Zacherle E
University of North Carolina at Charlotte, Charlotte, NC, USA
OBJECTIVES: Testosterone therapy for the treatment of hypogonadism in older men is controversial. Previous studies on benefits have been inconclusive and there is the belief that the known potential for negative cardiac outcomes outweighs any benefit. We used a sample of Medicare patients to test the time from diagnosis of hypogonadism to positive and negative events related to treating hypogonadism. METHODS: Using a 5% random sample of Medicare IDS claims spending using Dartmouth Atlas of Health Care online data. RESULTS: Among the 155,980 patients, 5.9% had a depression diagnosis within 30 days after AMI admission. DACC-based ADRs captured considerable variation in depression diagnosis (QkR: 0.74 – 1.21) and relatively low and high zip code-level ADRs were dispersed across the United States. ADRs for depression diagnosis were statistically significantly related to Medicare spending (p < 0.04, p < 0.01), but not local physician supply. CONCLUSIONS: Substantial geographic variation in depression diagnosis exists across the United States. Areas with higher depression diagnosis were more likely to have higher depression diagnosis rates. Further research is needed to explore if geographic variation in diagnosis affect health and economic outcomes to address whether depression was correctly, over- or under-diagnosed.