and 43.7%) and significantly less frequent elsewhere (China's being lowest: 5.7% and 22.4%). Dyslipidemia and obesity were significantly more frequent in the US (41.0% and 39.7%, respectively) than elsewhere (China's being lowest: 9.5% and 5.6%). Diagnosed depression was highest in UK (26.7%) and lowest in China (1.5%). UK had the highest absenteeism (11.5%) and activity impairment (33.8%). Presenteeism and overall work impairment were highest in Italy (27.5% and 30.3%, respectively) and UK (27.1% and 29.8%).

Conclusion(s): ED self-reported prevalence and burden, especially among men of sexually active age, can help inform populations in need of increased awareness and intervention.

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PHARMACOKINETIC COMPARISON OF TWO FIXED-DOSE REGIMENS OF AN ORAL TESTOSTERONE REPLACEMENT THERAPY

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Objectives: To evaluate the pharmacokinetics (PK) of a novel, oral testosterone replacement therapy (TRT), LPCN 1021 (testosterone undecanoate), using two fixed-dose regimens without titration.

Materials and Method(s): Two multi-center, open-label, single arm studies were conducted to assess different fixed-dose (no titration) regimens of LPCN 1021. Both studies were of similar design and included hypogonadal males with low testosterone (T) (< 300 ng/dL) who received 24 days of treatment with a 450-mg daily dose of LPCN 1021. The daily dose was divided into two equal doses (BID study) and three equal doses (TID study) taken with food. In total, 95 and 100 subjects were enrolled into BID and TID studies, with 94 and 97 subjects completing the BID and TID studies, respectively. On Day 24, intensive pharmacokinetic sampling was performed using blood samples obtained over a 24-hour period. The pharmacokinetics of testosterone and other relevant parameters were assessed. The PK analysis evaluated safety based on the proportion of patients with a maximum testosterone level (Cmax) above three predetermined thresholds.

Results: The average daily testosterone level (Cavg) was 476 ng/dL with 37% CV in the BID study and 386 ng/dL with 45% CV in the TID study. Mean Cmax was 1178 ng/dL with 47% CV for BID and 814 ng/dL with 44% CV for TID. Median time to maximum concentration (Tmax) was similar in both studies.

In the BID study Cmax per dose analysis, 85% of subjects had a Cmax < 1500 ng/dL and 7% of subjects between 1800 ng/dL and 2500 ng/dL. One subject exceeded the 2500 ng/dL limit. This subject was determined to have violated the exclusion criteria (history of gastric surgery/cholecystectomy). The TID study met all Cmax thresholds. Excursions above the thresholds were transient (BID study mean time > 1500 ng/dL = 1.7 hrs). No correlation between adverse event or other laboratory parameters and Cmax levels > 1500 ng/dL was found.

Conclusions: A twice daily fixed dose of LPCN 1021 resulted in higher testosterone levels (Cavg and Cmax) compared to three times daily dosing. The Cmax excursions observed in the BID study, had no apparent correlation to the overall safety profile. Cmax thresholds used in this study were derived from data for topical TRTs and, due to differing PK profiles, the relevance of these measures for an oral TRT is not known. PK data indicate that a fixed, twice daily dose of LPCN 1021 is an appropriate treatment regimen.

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IMPACT OF A PATIENT SUPPORT PROGRAM FOR ANDROGEL 1.62% TOPICAL TESTOSTERONE GEL ON ADHERENCE AMONG MALES WITH PRIMARY OR SECONDARY HYPOGONADISM

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Objective: To assess the impact of the Restoration Program (RP), a patient support program for AndroGel 1.62% topical testosterone therapy (TTh) gel, on adherence among patients with hypogonadism due to certain medical conditions (i.e. classical primary or secondary hypogonadism patients).

Materials and Methods: A retrospective cohort of male patients aged 18+ years, who were diagnosed with classical primary or secondary HG and initiated topical TTh between January 1, 2012, and December 31, 2015, was identified in the Symphony Health Systems database, which contains deidentified (HIPPA compliant) administrative claims from commercial U.S. health plans. All patients were required to have at least 12 months of activity within the database prior to (baseline) and following (follow-up) their initial topical TTh prescription fill (index date). Three groups were identified based on the type of TTh initiated and whether they were enrolled in RP: AndroGel 1.62% patients enrolled in RP (AGRP), AndroGel 1.62% patients not enrolled in RP (AGnonRP), and patients on other TTh therapies (OTTh). Adherence to the topical TTh was defined as PDC (Proportion of Days Covered) $\geq$80% based on refill history from the pharmacy claims data for each patient during the 12 months of follow-up. The proportions of patients adherent at the end of the follow-up were reported for each cohort. Adjusted logistic regression modeling was then used to compare likelihood of being adherent at 12 months between AGRP vs. AGnonRP and AGRP vs. OTTh controlling for age, region, insurance type, year of index date, retail vs mail order pharmacy, and patient income level.

Results: We identified 49,559 patients with classical primary and secondary hypogonadism who were treated with topical TTh, including 3,533 (7.1%) AGRP, 17,895 (36.1%) AGnonRP, and 28,131 (56.8%) OTTh. Mean age was 53, 55, and 55 for each group, respectively. Majority of patients had commercial insurance and filled prescription at retail pharmacies in all three groups. Adherence at 12 months was 21.9% for AGRP patients, 12.6% for AGnonRP patients, and 14.6% for OTTh patients. The adjusted likelihood of adherence at 12 months was shown to be similar between AGnonRP and OTTh patients (OR 0.999 95% CI 0.829 to 1.058). Comparing AGRP and AGnonRP showed an 84% higher likelihood of adherence at 12 months associated with AGRP (OR 1.839 95% CI 1.674 to 2.021).

Conclusions: In our study, being enrolled in the AndroGel 1.62% Restoration Program was associated with significantly better adherence at 12 months compared to patients not enrolled in this patient support program.

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TESTOSTERONE THERAPY LEADS TO SUSTAINED WEIGHT LOSS, IMPROVED ERECTILE FUNCTION AND REDUCTION OF MACE IN HYPOGONADAL MEN IN A 10-YEAR REAL-LIFE REGISTRY

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Objectives: We have previously reported reductions in weight and waist size during 8 years from uncontrolled registries (Saad et al. Int J Obes 2016;40:162). We investigated whether these effects could be sustained beyond this time and how they compared to an untreated control group.

Material and Methods: 400 men with testosterone ≤350 ng/dL and symptoms of hypogonadism received testosterone undecanoate 1000 mg every 3 months for up to 10 years. 376 hypogonadal men opted against testosterone therapy (TTh). Median follow-up: 8 years. Weight and waist circumference were measured at baseline and then every 3-6 months in treated and every 12 months in untreated patients. Erectile function and quality of life were assessed by questionnaires (IIEF-EF and AMS). Differences between groups were estimated and adjusted for age and metabolic syndrome parameters to account for baseline differences between groups.

Results: Mean age: 61±7 years (T-group: 58±7, CTRL: 64±5). Waist circumference decreased from 106±9 to 96±6 cm at 10 years in the T-group and from 110±11 to 109±9 cm in CTRL, estimated adjusted between-group difference: -12 cm (p<0.0001 for all). Weight decreased from 104±17 to 86±8 kg in the T-group (p<0.0001) and increased slightly from 94±12 to 94.3±10 in CTRL (p<0.0005), between-group difference: -20 kg (p<0.0001). The per cent weight change at 10 years was -18.7±7.3% in the T-group (p<0.0001) vs +2.7±4% in CTRL (p<0.01), between-group difference: -19.5% (p<0.0001). IIEF-EF increased from 18.7±5.4 to 26.9±1.8 in the T-group and decreased from 20.1±3.1 to 9.4±1.6 in CTRL, between-group difference: 18.3 (p<0.0001 for all). AMS improved from 51.2±9.8 to 17.1±0.2 in the T-group and worsened from 40.1±5.5 to 57.3±3 in CTRL, between-group difference: -40.4 (p<0.0001 for all). Major adverse cardiovascular events (MACE): in CTRL, there were 39 deaths (10.4%),45 myocardial infarctions (12%), and 42 strokes (11.2%). There were 6 deaths (1.5%) in the T-group. Medication adherence in the T-group was 100 per cent as all injections were performed in the office and documented.

Conclusions: Weight and waist circumference decreased sustainably in the T-group and remained largely stable in CTRL. These improvements may have contributed to reducing MACE in hypogonadal men receiving adequate TTh.

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SEX HORMONE BINDING GLOBULIN INDEPENDENTLY PREDICTS OLIGOSPERMIA IN MALE FERTILITY PATIENTS

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Introduction: We previously reported that due to the inherent variability of SHBG, clinical hypogonadism is over-diagnosed/under-diagnosed in 20% of patients. We further analyzed the data between classically hypogonadal men (G1 - total testosterone (TT) < 300) and those men who were "missed" but were hypogonadal using calculated bioavailable testosterone (cBT < 210) with the use of SHBG (G2). We analyzed the potential role of SHBG levels in the routine testing of male factor infertility by analyzing the relationship of TT and BT to common infertility parameters.

Methods: Retrospective review assimilated from 168 males seen in an infertility clinic for infertility from 2012-2014, to investigate the accuracy of TT in the biochemical diagnosis of hypogonadism using cBT as the reference value. The relationship between testosterone levels and other infertility parameters were calculated using nonparametric Spearman correlations. We compared semen parameters between G1 and G2 in men with and without azoospermia. We utilized a multivariable subanalysis with linear regression with backward elimination of nonsignificant variables. The possible predictors in the model included age, total testosterone, varicocele, FSH and SHBG.

Results: 168 men were seen in a fertility clinic for initial workup between 2012-2014. Using Spearman correlations SHBG