and precision over previously used models. DES is an essential approach to capturing these factors and using them to accurately portray the health and economic consequences of binder therapy.

A MULTICENTRE STUDY OF RENAL TRANSPLANT PATIENTS USING THE SF-36 AND THE END STAGE RENAL DISEASE SYMPTOM CHECK-LIST (ESRD-SCL)

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OBJECTIVES: The aim was to study the changes in the HRQOL during the first year following renal transplant. **METHODS:** A total of 508 patients from fifteen transplant centres in Spain were included in a kidney waiting list and 200 were prospectively studied. QoL over time (before, at three and six months after transplantation) was obtained using the SF-36 and the End-Stage Renal Disease Symptom Checklist (ESRD-scl). Clinical and socio-demographic records were searched. **RESULTS:** Some clinical variables (haemoglobin and serum creatinine) improved 3 months after transplantation. Comparison the SF-36 dimensions before and three months after transplantation, all domains, as well as physical (PCS) and mental component summaries (MCS) ($p < 0.01$), showed significant improvement except in Bodily Pain and Physical Functioning. Comparison of SF-36 between three and six months after transplantation, only role-physical showed significant improvement and the rest of physical dimensions showed similar scores, but mental functioning was a little worse than at three months post transplant. For ESRD-scl before and three months after transplantation, the symptoms were better (Limited Physical Capacity, Limited Cognitive Capacity, Cardiac and Renal Dysfunction and Transplantation-associated Psychological Distress, except for Increased Growth of Gum and Hair) ($p < 0.01$). Comparing three and six months post-tx, only Side Effects of Corticosteroids dimension showed significant improvement. Females significantly more often showed the worst HRQoL (MCS, Vitality, Mental Health and Role-emotional; $p < 0.001$). Age, educational level, dialysis modality before transplantation, time on dialysis and comorbidity index did not affect the HRQoL after transplantation. However, variables that were not significant in the overall score reached significance in some symptoms. **CONCLUSIONS:** The most important finding in this study is that all domains showed a significant improvement in HRQoL three months after transplantation, and at six months HRQoL was slightly improved, while mental domains remained the same with respect to measurements at three months.

OPEN MULTICENTER STUDY OF HEALTH RE LATED QUALITY OF LIFE BEFORE AND AFTER SOLID ORGAN TRANSPLANTATION (KIDNEY, LIVER, HEART AND LUNG)

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OBJECTIVES: The aim was to describe HRQoL before and after solid organ Tx and to compare those outcomes among different transplants. **METHODS:** A prospective study was carried out in 17 Spanish hospitals. The HRQoL (before, at 3 and 6 months after Tx) was obtained using the Short Form-36 (SF-36, with 6 dimensions and 2 summary scores: physical-PCS and mental-MCS). Sociodemographic and clinical data were also collected. Mean postoperative scores were compared with mean preoperative scores to determine the effect of Tx. **RESULTS:** Five hundred eight kidney (Kd), 389 liver (Lv), 79 heart (Ht) and 143 lung (Lg) pts and 173 Kd, 200 Lv, 57 Ht and 46 Lg pts who

received a transplant were studied. Mean age at Tx was 51 years; 70% were males. Different types of transplants start at different levels of HRQoL: Lg and Ht start out the worst, Lv in the middle, and Kd recipients the best. Comparison the SF-36 before and 3 months after Tx showed significant improvement, except Bodily Pain (BP) for Kd, Ht and Lg transplants. Six months of Tx, the HRQoL was considerably improved with respect to 3 months. The variations of SF36 were different between organs at 6 months post-Tx: for Kd transplant physical functioning (PF) showed similar scores but mental functioning (MF) was a little worse than at 3 months, for Lv all except General Health (GH) showed significant improvement, for Ht and Lg transplant social and MF showed a significant improvement and PF was a little better. Compared with the general population, all these pts were much worse before transplant. The Lg transplant express the best HRQoL on MCS. **CONCLUSIONS:** After Tx, improvement was clear with MF being the same as the general population, but there was still a significant physical deficit.

PATIENTS UNDER 65 YEARS OF AGE ON RENAL TRANSPLANT WAITING LISTS SHOW A WORSE PERCEIVED STATE OF HEALTH THAN OLDER ONES

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OBJECTIVES: The aim was to evaluate the perceived state of health (PSH) on kidney transplantation (n = 359). **METHODS:** The differences in PSH according to age (under or over 65 years) are presented here. The analysis corresponds to the base moment, when they are on the transplant waiting list. A generic PSH profile, the SF-36 Health Questionnaire and an index, EQ-5D are applied to each patient. To evaluate the differences with respect to sex in both measurements the Student-t test was used for independent samples and the chi-squared test for contingency tables. **RESULTS:** For the whole sample the PSH score was 42.09 8.6, MCS 46.6 11.5 and VAS 60.1 17.4. Patients aged 65 years or more (elderly) had similar PSH to those under 65 on 5 dimensions of SF-36 and in the two summary scores, and better ones in 3 dimensions: pain (p = 0.008), general health (p = 0.002), and vitality (p = 0-037). With regard to EQ-5D, the elderly patients showed a higher score for PSH (68.4 15.4 vs. 59 17.4; p = 0.001) and also on 4 of the 5 dimensions (except in personal care): mobility: (p = 0.035), daily tasks (p = 0.018), pain-discomfort (p = 0.026) and anxiety depression (p = 0.038). The PSH of patients of all ages on renal transplant waiting lists at the centres studied is worse than that to be expected in the general population as regards physical health (score under 45 points) but similar as regards mental health (score over 45 points). **CONCLUSIONS:** Among these patients, the elderly seem to show better PSH than the younger ones, the opposite of what is the case in the general population, probably due to positive selection of patients in better conditions in that age group. At the same time, the need for standardisation with respect to sex of scores on PSH questionnaires is demonstrated.

RESEARCH NETWORK ON TRANSPLANTATION: FEMALES ON THE WAITING LIST FOR RENAL TRANSPLANT SHOW A POORER PERCEIVED STATE OF HEALTH THAN DO MALES

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OBJECTIVES: To evaluate the perceived state of health (PSH)of renal transplant N = 359). METHODS: The differences in PSH according to sex are presented here for patients included to date at all centres in the study. The analysis corresponds to the base moment, when they are on the transplant waiting list. A generic PSH profile, the SF-36 Health Questionnaire and an index, EQ-5D are applied to each patient. To evaluate the differences with respect to sex in both measurements, the Student-t test was used for independent samples and the chi-squared test for contingency tables. RESULTS: For the whole sample, the PCS score was 42.09 8.6, MCS 46.6 11.5 and VAS 60.1 17.4. Females had worse PSH than males on 7 of 8 dimensions of SF-36 (the exception being Social Functioning) and in the two summary scores: PCS (40.2 9.1 in females, 43.3 8 in males) and MCS (44.9 11.7 vs. 47.7 11.2) (p < 0.05). With regard to EQ-5D, females showed a similar score to males in VAS (58.2 18.1 vs. 61.4 16.9), but poorer scores in 4 of the 5 dimensions (except in personal care): mobility (p = 0.047), everyday tasks (p = 0.0001) and anxiety-depression (p = 0.006). The PSH of patients of both sexes on renal transplant waiting lists at the centres studied is worse than that to be expected in the general population as regards physical health (score under 45 points), but similar as regards mental health (score over 45 points). VAS does not appear to be a good measurement of PSH as it oversimplifies, including as it does physical and mental aspects in a single index. CONCLUSIONS: Among these patients, the PSH of females is clearly worse than that of males, as is also the case in the general population, demonstrating the need for standardisation with respect to sex of scores on PSH questionnaires.

COMPARISON OF THE PRO ENDPOINTS FOUND IN LABELING CLAIMES OF URINARY INCONTINENCE DRUGS WITH THOSE RECOMMENDED BY THE CORRESPONDING EMEA NOTE FOR GUIDANCE

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OBJECTIVES: Compare the PRO endpoints used in the approval of medicinal products for urinary incontinence, which led to a PRO labeling claim, with those recommended by the EMEA note for guidance on the clinical investigation of medicinal products for the treatment of urinary incontinence (CPMP/EWP/18/01 final). METHODS: The PROLabels database is a unique on-line tool which collects information on the medicinal products for which the FDA and/or the EMEA have granted a PRO labeling claim. Using this database we searched the products with a urinary incontinence indication, and approved by the European Commission through the centralized procedure. For each drug, we analyzed the endpoints used in the clinical studies to assess treatment efficacy. These endpoints were then compared to those recommended by the CPMP guidance for the treatment of urinary incontinence. RESULTS: Three products have been retrieved, for which a marketing authorization in Europe to treat urinary incontinence was granted; all of which have been approved between June and October 2004. For the three products, the clinical outcomes measures used for evaluation included subjective outcome measures and quantification of symptoms (i.e. diaries and quality of life instruments), in accordance with the CPMP guidance. Only pad weighing tests were not used in these studies. In all 3 cases, quantification of symptoms resulted in a PRO claim. Quality of life assessment generated a labeling claim for two products, and subjective outcomes (global improvement) for one. CONCLUSIONS: In the

evaluation of medicinal products for urinary incontinence, there is a close adherence to the guidance concerning the choice of study endpoints, with different rates of success concerning the PRO claims obtained. The PROLabels database has proven its usefulness in retrieving the PRO endpoints used in clinical studies for products approval in a specific indication and in comparison to the guidance.

IMPACT OF OVERACTIVE BLADDER ON FREQUENCY OF SEXUAL ACTIVITY AND SEXUAL SATISFACTION IN WOMEN: RESULTS FROM THE EPIC STUDY

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OBJECTIVES: To evaluate the impact of overactive bladder (OAB) on the frequency of sexual activity and sexual enjoyment in women. METHODS: A population-based telephone survey was conducted in Sweden, Italy, Germany, the UK, and Canada to evaluate the prevalence and burden of OAB symptoms using current International Continence Society definitions. A nested case-control analysis was performed on data collected from women with OAB (cases, n = 995) and without OAB (controls, n = 1524). Survey respondents reported whether they experienced a decrease in sexual activity or enjoyment of sex owing to urinary symptoms and whether they had physician-diagnosed depression. Factors influencing sexual activity and sexual satisfaction were analyzed using logistic regression. RESULTS: Among participants aged ≤50 and >50 years the following reported being sexually active during the past 12 months, respectively: 78% and 41% of controls, 74% and 36% of cases without incontinence, and 74% and 35% of cases with incontinence. Cases were significantly more likely to report decreased sexual activity caused by urinary symptoms than were controls among respondents aged ≤50 (odds ratio [OR] = 4.3, 95% confidence interval [CI] = 2.4–7.7) and those aged >50 years (OR = 2.6, 95% CI = 1.2–5.2), after controlling for incontinence and depression. Among sexually active participants (n = 1420), OAB cases were significantly more likely to report decreased sexual enjoyment due to urinary symptoms than were controls (≤50 y: OR = 5.8, 95% CI = 3.0–11.4; >50 y: OR = 3.1, 95% CI = 1.1–8.9). CONCLUSIONS: This is the first multinational, population-based study to assess the impact of OAB on sexual activity and enjoyment in women. Women with OAB were significantly more likely than were controls to report decreased sexual activity and enjoyment due to urinary symptoms, even after adjusting for incontinence and depression. The impact of OAB on sexual activity and enjoyment appeared greatest in younger women (≤50 years of age).

LINGUISTIC VALIDATION OF THE OVERACTIVE BLADDER QUESTIONNAIRE (OAB-Q), OVERACTIVE BLADDER SHORT FORM QUESTIONNAIRE (OAB-Q SF), AND OAB ASSESSMENT TOOL (OAB-V8) IN 4 LANGUAGES

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