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Change in regulations for dispensing immunosppressants to patients who have undergone a kidney transplant

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Dear Editor,

Until a few months ago, renal transplantation patients received their immunosuppressant therapy from community pharmacies, after prescription validation by the pharmacist responsible for health certification, as these drugs are prescribed based on hospital diagnosis. Most patients were treated with immunosuppressive therapy regimens that, although not listed on the technical data sheet, were indeed recommended in clinical practice guidelines. In June 2009, the Servizo Galego de Saúde (SERGAS) sent an informational notice to pharmacists responsible for approval, reminding them that treatments with sirolimus, mycophenolate sodium, and mycophenolate mofetil, in conjunction with drugs other than cyclosporine, should not be validated. This measure assumed these prescriptions to be compassionate use of these medication combinations and that their dispensing should take place in hospital pharmacy services. These regulations remained in effect until September of that year (Instruction 8/09 of the Regional Ministry of health of the Government of Galicia), at which time the previous rule was reinstated, following the drafting of a new report on specific approval for these combinations.

This study aims to analyse the repercussion that this measure had on the quality of life of patients, to understand their economic implications, and to assess the burden of care on pharmacy and nephrology services. We use our experience in our hospital as an example, which is a level 2 hospital complex with a catchment area of 223,000 inhabitants, of whom more than 50% live in a rural area and about 30% are over 64 years of age.

Method

The influence on the quality of life of patients was quantified as disruption caused by the shift to the hospital setting and expressed as distance in kilometres (km). A travel distance of more than 5km was considered to be serious medication acquisition difficulty.

The economic implications were analysed from two standpoints. The first was to consider whether or not they were medication cost reduction measures. For this we calculated the difference in cost to SERGAS between the purchase of medications via the hospital or by reimbursement to community pharmacies. The second was to assess the magnitude of budgetary adjustment relating to dispensing outpatient pharmacy services as a percentage of increase in spending.

We analysed the increase (net or percentage) in the hospital workload at three levels: nephrology clinic, medical administration, and outpatient pharmacy service dispensing area.

Patient data were obtained from medical record software applications from SERGAS and from the pharmacy's SILICON® software. A data collection sheet was created in Excel for Windows and statistical analysis was performed with SPSS 15.0. We used measures of central trending (mean) and dispersion (standard deviation), and estimated means and proportions with 95% confidence intervals (95% CI).

Results

During the period from June to October 2009, 72 compassionate use or off-label medications were transmitted, corresponding to 63 patients (68% male, mean age 51.84 years, 95% CI 48.94 to 54.64). The most commonly prescribed medication was mycophenolate mofetil (74.6%). The increase of care in the outpatient setting was 3.15 patients per day. The direct cost savings for drug acquisition to SERGAS was €16,296. The increase in cost to the pharmacy service was €7,344/month. The average distance travelled by patients to acquire their treatment was 32.27km (range: 0-85). Sixty-eight point two percent of patients had serious difficulties in acquiring their treatments.

Discussion

Patients undergoing renal transplantation are those who have certainly seen their health become compromised over the course of their lives. Thus, it is the duty of the health system, the same way as with the general population but more emphatically in these patients, to provide

the highest possible quality of life. Travelling even 85km to pick up a portion of their treatment, during the morning from Monday to Friday carries a heavy penalty on the quality of life, especially when compared with picking up medications at a pharmacy that is likely located just a few metres from the home.

From an ethical point of view, this measure becomes a problem for the nephrologist. The doctor, as the person responsible for prescribing the drug, has had to ask the patient for an informed consent, communicating the potential risks to their health from being treated with a drug that is not legally recognised in Spain for that indication, except for the patient who has been taking the drug for several years.

In economic terms, this is an effective measure of cost containment. Such measures are essential to the sustainability of the health system, but must be accompanied by an increase in the pharmaceutical expenditure budget for hospitals.

We must not forget the burden of care, whose main disadvantage is the reduction of average time for patient care, since the measure was not accompanied by an increase in staff.

In recent times, in which the sustainability of the health system is continually being debated, we need to be aware that economic measures are necessary and essential to the welfare state, but only if they are not accompanied by a decrease in the patient's quality of life.

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Treatment with intravenous iron and ferritin level

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Dear Editor,
The 2006 K/DOQI guidelines on anaemia in patients on chronic haemodialysis (HD) indicate that treatment should be done with IV Fe in order to maintain a ferritin (FER) value of more than 200-500μg/l to achieve adequate erythropoiesis.[1] Other studies[2,3] state that FER should be kept in a higher range, but there are no controlled studies comparing the efficacy as measured by the Hb, EPO dose, and iatrogenic sequelae[4,5] in groups of patients with FER values above and below 500, with maximum values greater than 500 indicating high doses of IV Fe. Recent research shows that administration of low dose IV Fe on a continual basis causes increased protein oxidation, something that does not happen often with intermittent treatment.[6]

The purpose of this prospective observational case-control study is to evaluate, in 10 patients on HD, if the Hb and EPO dose changed with IV Fe administration in two different treatment protocols, lasting six months each. Patients were included after ruling out factors affecting erythropoiesis for six months before and during the study (transfusion, infection, inflammation, malnutrition, surgery, hospitalisation, severe hyperparathyroidism, etc.).

FER1 Protocol. Treated with 50mg Fe sucrose IV/1 HD session, 8 HD in a row (400mg) to achieve and maintain a maximum FER value greater than and close to 300μg/l; data collection six months before the start of the FER2 protocol.

FER2 Protocol. Treated with 25 mg Fe sucrose IV/1 weekly HD session for 16 weeks in a row (400mg) to achieve and maintain a maximum FER value greater than and close to 300μg/l; data collection from the fourth month of starting. FER was assessed, then 2 months to assess continued treatment in the two protocols, and we did not treat with IV Fe if there was an acute infection.

In each protocol we assessed: intact PTH/3 months, balanced KTV (Daugirdas)/month, albumin g/l/3 months, subjective global assessment of nutrition, PCR/3 months, Hb/month, EPO dose in units/kg/week, ferritin/2 months, total dose of IV Fe in mg/patient/6 months (Fe 6), total dose of IV Fe in mg/patient/1 month (Fe 1), range in mg/patient of Fe 6 (range Fe 6). Age (75 ± 12 years), female sex (40%), HD time in months and with vascular access, and high-flow membranes were similar. There was no statistically significant difference in PTH (268 ± 249, FER1 vs. 297 ± 198, FER2), eKTV (1.37 ± 0.1, FER1 vs. 1.34 ± 0.1, FER2), albumin (36.3 ± 3, FER1 versus 35.4 ± 3, FER2), mild malnutrition in both groups, CRP (11.4 ± 9, FER1 vs. 13 ± 11, FER2), or in the main variables: Hb (12.4 ± 0.4, FER1 versus 12.3 ± 0.3, FER2), EPO (99 ± 51, FER1 vs. 85 ± 46, FER2), Fe 6 (854 ± 204mg, FER1 vs. 598 ± 126, FER2), Fe 1 (142 ± 34mg, FER1 vs. 99 ± 21, FER2) and Fe 6 range (500-1100mg, FER1 vs. 400 to 800mg, FER2), but there was a difference with $p < 0.05$ in FER (332 ± 24, FER1 vs. 225 ± 37, FER2).

This prospective observational case-control study of patients on HD shows that Hb, EPO dose, and dose of IV Fe administered with the two protocols (FER maximum range greater than and close to 300μg/l vs FER maximum value of less than and close to 300) do not change. Prior scientific evidence[1,4] and data