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End-stage Renal Disease Costs for Patients New to Hemodialysis in Italy: The FARO-2 Study

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Authors' contributions

All the authors conceived and performed the present analysis and have written the manuscript. All the authors read and approved the final manuscript.

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ABSTRACT

Background: Increasing incidence and prevalence of end-stage renal disease (ESRD) together with the presence of several comorbidities in chronic kidney disease patients (CKD) could be associated with a relevant economic burden.
Aim: The aim of this analysis was to estimate the direct healthcare costs of ESRD and its major

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comorbidities in Italian patients who were naïve to hemodialysis (HD) recruited for the FARO-2 study.

Methods: The FARO-2 study was a retrospective observational study conducted in Italy that evaluated the patterns of treatment of secondary hyperparathyroidism (SHPT) and related costs in patients naïve to HD. The observational period was 2006–2008. Costs were measured in Euros (reference year: 2008). Resource use for the first 2 periods of 6 months of HD was monetized, with reimbursement calculated for SHPT drugs, phosphate binders, and erythropoietin-stimulating agents (ESAs); HD sessions; and hospitalizations due to ESRD and its major comorbidities. The analysis was performed by the Italian National Health Service (INHS) perspective.

Results: 567 patients were observed for at least 2 periods of 6 months. During the first 12 months after the initiation of HD, average direct healthcare costs were assessed using the percentage of patients treated and the average daily dosages (for drugs), the percentage of patients hospitalized and the types of hospitalizations (for inpatients), and the average weekly frequency of HD sessions. Total per-patient yearly costs totaled 34,789.9 €: HD accounted for 66.1% of expenditures, with hospitalizations and drugs accounting for 12.9% and 21.0% of expenditures, respectively (including 17.1% for ESAs).

Conclusions: Patients naïve to HD have a significant impact on Italian National Health Service expenditures, although only the costs related to treatment of ESRD and its comorbidities were calculated in the present study. The major cost drivers were HD and ESAs, while SHPT drugs and phosphate binders together accounted for only 3.9% of direct healthcare expenditures.

Keywords: Cost of illness; cost of drugs; secondary hyperparathyroidism; hospitalizations; clinical practice.

1. INTRODUCTION

The incidence and prevalence of end-stage renal disease (ESRD) are increasing worldwide [1-5] due to the aging of the population, an increasing prevalence of type 2 diabetes mellitus and hypertension, and a trend toward early initiation of renal replacement therapies [6,7].

Increasing comorbidities related to worsening chronic kidney disease (CKD) [8-12] may be associated with a rapid rise in healthcare costs after the initiation of dialysis. As healthcare expenditures continue to increase, health authorities need to develop new strategies to rationalize expenditures and maintain the best standards of care. Understanding the causes of increases in healthcare costs is the first step to developing strategies to keep expenditure growth under control. Economic studies are needed in healthcare, mainly because the economic resources available to healthcare systems are not enough to cover the costs associated with all healthcare treatments and programs [13,14].

Several studies have analyzed the costs associated with patients undergoing HD, both internationally and in Italy [15-19] these studies have highlighted the significant burden of HD in terms of morbidity and mortality, and from an economic perspective, direct and indirect costs [20-23]. A few studies investigated the differences in healthcare costs from pre-dialysis to dialysis [24-26] and confirmed the dramatic increase in healthcare expenditures associated with the initiation of dialysis treatment. Several studies also explored the costs of the first few months of dialysis treatment [25,27,28] none of these studies, however, were carried out from the Italian perspective. The present study, conducted by the Italian National Health Service (INHS) perspective, aimed to evaluate healthcare costs related to ESRD and its major comorbidities in the first 12 months after initiating hemodialysis (HD). The INHS is an universalistic system that grants to all Italian citizens and legal foreign residents a coverage in terms of healthcare services. The INHS provides essential drugs, hospital accommodation and treatments, specialistic and general practitioners' visits, laboratory tests and diagnostic procedures.

2. MATERIALS AND METHODS

As described elsewhere [29-32], the FARO study was a prospective multicenter survey that evaluated treatment practices in 28 dialysis centers in Italy from April 2006 to October 2007; during the study, data on secondary hyperparathyroidism (SHPT) management and alignment with Kidney Disease Outcomes Quality Initiative (KDOQI) target ranges from all patients receiving HD were recorded. The FARO-2 study [33-35] was designed to integrate the data of the

Table 1. Sources for hospitalizations causes, reimbursement tariffs, and number of hospitalizations in Italy (2008)

Causes of hospitalizations (as reported in the FARO-2 study)	DRGs (code and description)	DRG tariff (€)[36]	Number of admissions[37]
Cardiac complications	121: circulatory disorders with acute myocardial infarction, with major complications, discharged alive	4,289.18	21,178
	122: circulatory disorders with acute myocardial infarction, without major complications, discharged alive	3,416.01	33,397
	124: circulatory disorders except acute myocardial infarction with cardiac catheter, with complications	3,741.88	33,811
	125: circulatory disorders except acute myocardial infarction with cardiac catheter, without complications	1,795.17	64,938
	127: heart failure and shock	2,715.21	200,709
Vascular complications	130: peripheral or vascular disorders with complications and/or comorbidities	2,913.66	19,872
	131: peripheral or vascular disorders without complications and/or comorbidities	1,320.40	21,609
Cerebral complications	015: Transient ischemia	2,160.46	58,673
	016: nonspecific cerebrovascular disorders with complications and/or comorbidities	3,253.07	26,457
	017: nonspecific cerebrovascular disorders without complications and/or comorbidities	2,334.78	25,186
	014: specific cerebrovascular disorders except transient ischemic attack	3,448.67	113,042
Infections	320: kidney and urinary tract infections age >17 with complications and/or comorbidities	2,307.02	14,765
	321: kidney and urinary tract infections age >17 without complications and/or comorbidities	1,818.20	18,792
Bone diseases	244: bone diseases and specific arthropathies with complications and/ or comorbidities	2,455.17	4,029
	245: bone diseases and specific arthropathies without complications and/ or comorbidities	1,743.50	11,602
Diagnostic procedures in DH	Day hospital 316: renal failure	266.81	4,479
Anemia	395: red blood cell disorders age >17; 574: major hematologic/immunologic diagnosis except sickle cell crisis and coagulation disease	2,054.84	44,021
Hospitalization related to complications with arteriovenous fistula or Tesio catheter	316: renal failure	3,482.69	75,065
Hospitalizations related to kidney disease	316: renal failure	3,482.69	75,065

DRGs, Diagnosis-related group; DH, day-hospital

FARO study by collecting the same data from patients naïve to treatment with HD. The FARO-2 study included 26 dialysis centers operating within INHS that could be considered

representative of the Italian reality; patients selected for inclusion into the study had initiated dialysis during the FARO study and received dialysis treatment for ≤8 months. Data were collected retrospectively from 6 questionnaires, 4 of which were completed during the FARO study and 2 that were collected during the FARO-2 study (April–October 2008).

For the present analysis, per-patient healthcare costs related to the treatment of ESRD and major comorbidities were estimated for the first and second periods of six months of dialysis treatment. The following cost parameters were monetized: Drugs (for the treatment of SHPT, phosphate binders and erythropoietin-stimulating agents [ESAs]), hospitalizations (for ESRD and comorbidities), and HD sessions. For the monetization of drugs, the public prices reimbursed by the INHS were used for drugs distributed by territorial pharmacies, whereas prices charged to the INHS were considered for drugs distributed through INHS structures (reference year: 2008). Costs related to hospital admissions for ESRD complications and major comorbidities were estimated based on INHS tariffs for the supply of hospital care (reference year: 2008), [36] weighted by the number of admissions in Italy for 2008, [37] as reported in Table 1.

HD costs were estimated based on the Italian national tariffs that were in effect during the study. [38] The average cost per patient was defined as the sum of the costs of drugs, hospitalizations, and HD. In order to obtain the average daily per-patient cost of drugs, the daily drug cost was multiplied by the average daily dosages and percentages of patients treated; for inpatients, the average cost of each hospitalization was weighted by the percentage of patients hospitalized in order to estimate the average per-patient cost for hospitalization; for HD, the average weekly frequency of HD was multiplied by its unitary tariff.

3. RESULTS

A total of 568 patients were recruited in the FARO-2 study [mean age 65.5±15.2 (SD)]; of these patients 134 (23.6%) had diabetes. 567 patients were still in the study during the second period of six months of observation. In the first 2 period of six months after the initiation of dialysis, oral (PO) calcitriol, intravenous (IV) calcitriol, IV paricalcitol, and PO cinacalcet were used for the treatment of SHPT; calcium acetate, calcium carbonate, sevelamer, and lanthanum carbonate were used as phosphate binders. The vast majority (more than 93%) of patients were also treated with ESAs. The average dosages per drug and the percentages of patients treated in the 2 periods of six months following HD treatment initiation are reported in Table 2.

As was previously reported in the FARO study, the average weekly dose of paricalcitol decreased over time (from 13.10 mcg/week during the first period of six months to 10.66 mcg in the second period of six months). Aluminum hydroxide was used in 15.5% of patients during the first period of six months of observation; however, its use was not monetized because it was not charged to the INHS. The average per-patient costs of hospitalizations related to ESRD and its comorbidities are reported in Table 3.

During the first period of six months of HD, approximately 40% of patients were admitted to the hospital with a diagnosis related to kidney disease and 17% were admitted because of complications related to the arteriovenous fistula or Tesio catheter; the most frequent complications related to hospitalization were cardiac complications (more than 9% of patients during the first period of six months), followed by vascular complications (more than 4%). In the second period of six months, hospitalizations due to kidney disease decreased to approximately 6%, while admissions related to complications from the arteriovenous fistula or Tesio catheter increased to approximately 26%.

The frequency of dialysis sessions during the 2 periods of six months remained stable, with approximately 80% of patients undergoing 3 dialysis sessions/week; average per-patient costs linked to HD, weighted by the percentage of patients undergoing 3, 2, or 1 dialysis session/week was 433.7 €/week during the first period of six months and 449.8 €/week during the second period of six months.

Overall, the total cost per patient in the first period of six months, including SHPT drugs, phosphate binders, ESAs, hospitalizations related to ESRD, comorbidities, and HD sessions was 17,404.4 €, whereas in the second period of six months, the cost per patient was 17,358.5 €. On a yearly basis, ESRD-related direct healthcare costs were estimated to be 34,762.9 €.

Cost breakdowns per period of six months are reported in Table 4.

Table 2. Drugs usage during the first 2 period of six months of dialysis

	First six months period		Second six months period	
	Percentage of patients treated	**Average dosages (± SD)**	**Percentage of patients treated**	**Average dosages (± SD)**
SHPT drugs				
PO calcitriol	68.60%	1.72 mcg/week (1.11)	65.50%	1.59 mcg/week (0.81)
IV calcitriol	6.10%	2.18 mcg/week (0.87)	5.40%	2.54 mcg/week (0.66)
IV paricalcitol	20.30%	13.10 mcg/week (10.69)	27.90%	10.66 mcg/week (5.93)
Cinacalcet	0.90%	37.50 mg/die (15.00)	2.60%	38.33 mg/die (23.43)
Phosphate binders				
Calcium acetate	3.70%	1,690.50 mg/die (749.6)	4.80%	2,187.00 mg/die (1,101.71)
Calcium carbonate	49.50%	1,885.10 mg/die (933.79)	44.60%	2,114.40 mg/die (1,228.61)
Sevelamer	26.10%	3,257.30 mg/die (1,366.94)	29.30%	3,703.10 mg/die (1,694.80)
Lanthanum carbonate	0.00%		0.90%	1,250.00 mg/die (500.00)
ESAs	93.50%	11,132.00 UI/week (7,596.22)	93.60%	10,884.00 UI/week (8,312.76)

ESA, erythropoetin-stimulating agent; IV, intravenous; PO, by mouth; SD, standard deviation; SHPT, secondary hyperparathyroidism

Table 3. Hospitalizations related to ESRD and its associated comorbidities during the first 2 periods of six months of dialysis

Causes of hospitalization	First six months period		Second six months period	
	Percentage of patients hospitalized	**Average per-patient cost weighted by the % of use (€)**	**Percentage of patients hospitalized**	**Average per-patient cost weighted by the % of use (€)**
Cardiac complications	9.40	263.64	11.40	319.73
Vascular complications	4.40	91.68	6.90	143.77
Cerebral complications	2.80	82.92	5.70	168.81
Infections	1.10	22.37	5.10	103.70
Bone diseases	0.00	0.00	3.40	65.52
Diagnostic procedures in DH	0.60	1.60	2.30	6.14
Anemia	1.70	34.93	1.70	34.93
Hospitalizations related to arteriovenous fistula or Tesio catheter	17.10	595.54	26.30	915.95
Hospitalizations related to kidney disease	40.90	1,424.42	6.30	219.41
Average per-patient cost (€)		2,517.10		1,977.95

ESRD, end-stage renal disease; DH, day-hospital

Table 4. Breakdown of per-patient costs in first 2 periods of six months

	First period of six months (€)	**Second period of six months (€)**
SHPT drugs	324.02	381.40
Phosphate binders	282.99	363.75
ESAs	3,004.66	2,940.86
HD	11,275.60	11,694.56
Hospitalizations	2,517.10	1,977.95
Total	17,404.37	17,358.52

ESA, erythropoetin-stimulating agent; HD, hemodialysis; SHPT, secondary hyperparathyroidism

During the year studied in the present analysis, costs for HD sessions accounted for approximately 66% of the total costs and hospitalizations accounted for 13% of the total costs; among drugs, which as a whole accounted for 21% of the total costs, ESAs represented more than 80% of ESRD drug expenditures (17% of total expenditures).

4. DISCUSSION

For the first time, through the FARO-2 study, it was possible to collect data on the costs related to ESRD treatment and major comorbidities in Italy by analyzing real-world practice. As expected, even if patients with ESRD had relevant comorbidities, HD sessions represented the major cost drivers in patients beginning HD and undergoing 3 dialysis sessions/week on average. The relevance of dialysis sessions as a cost driver has been confirmed by other national and international studies, although these studies were not focused on patients who are new to HD treatment [39,24,18-20].

The results of the present analysis cannot be compared with the data previously published by Salonen et al. [27] as the present study is focused on patients undergoing HD and takes into account only direct healthcare costs related to ESRD and its comorbidities, not all healthcare costs (regardless of their relation to ESRD). In a study conducted by Coentrão et al. [28] in Portugal, the costs for HD sessions were not considered and patients undergoing HD were analyzed separately (patients with arteriovenous fistula or Tesio catheter); this makes any comparisons with the present study speculative at best. Because of the relevant differences in healthcare coverage, published US data [25] on patients undergoing dialysis are not comparable with the present study.

Major limitations of the FARO-2 are related to the design of the study, which was uncontrolled. However, the study reflects real-world practice in Italy in 2006–2008. Moreover, due to its study design, the FARO-2 study provided detailed information on resource consumption only for the week preceding each survey (specifically regarding drugs dosages); consequently, some data were extrapolated to the period covering 2 different surveys. The data on SHPT drugs and phosphate binders utilization included in the present study may have been influenced by the period of study itself (the use of lanthanum carbonate, for example, increased significantly in the following period of six months because of the recent commercialization); however, this reflects real-world practice during the study. Major strengths of the study are the sample size, the number of participating dialysis centers, and the non-interventional nature of the study, which provided insight into the real-world patterns of treatment during the study period.

5. CONCLUSIONS

Patients who are naïve to HD have a significant impact on INHS expenditures, even when only costs related to ESRD treatment and its comorbidities are taken into account. On a yearly basis, average per-patient costs were estimated to be 34,762.9 €; and HD sessions represented the major cost driver (approximately 66%). Drug costs represented about 21% of the total costs, with ESAs representing more than 80% of this expenditure; SHPT drugs and phosphate binders accounted for only approximately 4% of per-patient costs.

CONSENT

It is not applicable.

ETHICAL APPROVAL

The FARO-2 survey was approved by the ethical committees for each of the participant centers.

DISCLOSURES

An abstract reporting the preliminary results of this study has been published in the American Society of Nephrology Kidney Week 2014 Abstracts Supplement [40].

The design, study conduct, and financial support for the clinical trial were provided by AbbVie. AbbVie participated in the interpretation of data, review, writing and approval of the manuscript.

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COMPETING INTERESTS

Daniela Paola Roggeri and Alessandro Roggeri are consultants for AbbVie. Piergiorgio Messa is consultant for AbbVie, Amgen, Fresenius, and

Otsuka. Mario Cozzolino is consultant for AbbVie, Shire, Amgen, Sanofi/Genzyme, Vifor-Fresenius, and Roche. Diego Brancaccio has no conflict of interest to disclose. Sandro Mazzaferro is consultant for AbbVie and Amgen. Anna Maria Costanzo is AbbVie Italy Head Medical Affairs SH. Umberto di Luzio Paparatti is AbbVie Italy Affiliate Medical Director. Alessandro Possidoni is AbbVie Italy Affiliate Medical Manager. Ernesto Paoletti is consultant for Janssen-Cilag, AbbVie and Novartis.

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