Nephrology and renal replacement therapy in Romania

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Abstract

Background. In the context of the transformation of the Health Systems of Central and Eastern European countries, the role of professional associations is increasing, especially as regards data collection, analysis, and implementation of programmes for development of nephrology and renal replacement therapy (RRT).

Methods. The Romanian Renal Registry sent questionnaires to the heads of Haemodialysis and Nephrology Centres. The need for renal replacement therapy was deduced from the annual incidence (127 patients p.m.p.) of chronic renal failure.

Results. Although the rates of increase in the numbers of Nephrology Departments (+82%), HD Centres (+142%), and total number of patients alive on RRT (+196%) from 1991 to 1995 were higher than the European mean, only 27–30% of the incident patients (459 of 1000–1200 patients) could be provided with RRT. Sixty-two percent of the need for RRT in the age group 25–44 years was met, while only 20% of children (age <15 years) and people over 55 years requiring RRT received this treatment. Primary renal diseases in patients on RRT were glomerulonephritis (49%) or interstitial nephropathies (23%); diabetic nephropathies, nephroangiosclerosis and systemic diseases were rare (4, 2, and 1% respectively). Most of the CRF patients (88%) were treated by HD. Renal transplantation and peritoneal dialysis were seldom performed (8 and 4%). The cost of HD treatment in Romania (87 USD) is low, even though dialyser reuse is not common practice.

Conclusions. The increase in renal replacement therapy in Romania was mainly due to the expansion of the number of haemodialysis centres. Although a significant progress was realized, only one-third of the patients needing RRT could be treated in Romania in 1995.

Key words: renal replacement therapy; chronic renal failure epidemiology; chronic haemodialysis costs; renal transplantation; Romania

Introduction

The Health Systems of Central and Eastern European countries are undergoing a complex process of transformations which, ideally, should lead to a more flexible, efficient, and less expensive means of providing health care. This process is supposed to be based on a realistic view of the population’s need and the available resources.

In Romania, medicine is confronted with inconsistent legislation and deficient funding. The surging interest in nephrology and renal replacement therapy (RRT) obliged Romanian physicians to face many novel medical, technical, economic and ethical problems.

Expensive treatments impose judicious and sometimes subtle decisions at the national level. Virtually all nephrological activities in Romania are dependent on financial support by government. At the level of the Ministry of Health, a National Committee for Nephrology and Dialysis acts as an advisory body. The Romanian Society of Nephrology (RSN) was created in 1991 as a professional association. One of its main goals is to provide coordination of local initiatives and to constitute an effective lobby for national funding of end-stage renal disease (ESRD) treatment. After 1992 the two bodies cooperated to launch comprehensive programmes of treatment of ESRD. The need for accurate epidemiological data was approached by setting up the Romanian Renal Registry (1993).

The low health budget forced Romanian Nephrologists to use new political and financial instru-
ments characteristic of a free-market economy (for example, fund-raising). Probably, interventions of the recently created National Kidney Foundation (1996), of other non-profit health care organizations and of the industry will result in further influx of capital and know-how.

The major impetus for development of substitutive treatment for chronic renal failure (CRF) in Romania has been a change in medical policy after 1990 and elaboration, in 1992, of the Program of Development of Nephrology and Renal Replacement Therapy in Romania (1991–1995). This programme was designed by the Romanian Society of Nephrology and the Renal Romanian Registry. The programme was implemented after its approval by the Ministry of Health and the results of this programme will be analysed.

**Subjects and methods**

Questionnaires were sent to all the heads of the known Romanian Haemodialysis (HD) and Nephrology Centres every year from 1991 to 1995. Detailed information concerning the following items was requested: (i) the centres (date of establishment, number, type and functional status of HD units, type of water treatment station and number of beds), (ii) human resources (number of physicians, nurses and auxiliary personnel), (iii) RRT patients (primary renal disease, age at start of RRT and type of RRT) and (iv) cost of RRT. The rate of return of the questionnaires varied from 95 to 100%. The data were collected initially (1991–1992) by the Romanian Society of Nephrology and after 1993, by the Romanian Renal Registry.

**The need for renal services**

**Demographic data**

Romania has a population of $22.81 \times 10^6$ inhabitants, living in six historical provinces. The urban population makes up 54.4% of the total population [1].

**Chronic renal failure epidemiology**

In Romania the prevalence of renal diseases (in- and out-patients reported from the whole country to the Department for Statistics of the Ministry of Health) is 1233 per million population (p.m.p.). The annual CRF incidence is 127 patients p.m.p.; of these, 65–75 patients p.m.p. reach the uraemic phase each year. This means that each year a total of 1500–1700 new subjects require RRT. Unfortunately, in 1995 only 459 patients (27–30%) were provided with RRT. The other 1000–1200 patients (70–73%) were only provided with supportive therapy (Figure 1) [2].

If we assume that the age- and sex-specific rates reported by the Dialysis and Transplant Registry of New Zealand and Australia (ANZDATA) [3] apply to Romania; we estimate that the age group 25–44 years was acceptably covered by RRT (62% of the need), while only 20% of children (age <15 years) and 20% of people over 55 years of age were treated. The same uneven distribution could be observed for gender: women represent 46% of ESRD patients, but only 34% of them were actually treated, indicating that males are still preferentially receiving RRT.

The predominant cause of CRF in patients undergoing RRT in Romania was reported to be primary glomerulonephritis (49%, of which 9% were biopsy proven) and interstitial nephropathies (23%). Diabetic nephropathies, nephroangiosclerosis, and systemic disease with kidney involvement were infrequent causes (4, 2, and 1% respectively), in contrast to EDTA reports (Figure 2). It can be assumed that young, male patients with primary nephropathies are favourite candidates for RRT in our country.

**Resources**

**Nephrology Departments**

There are now 20 Nephrology Departments (eight with academic affiliation), about twice as many as in 1991 (Table 1). Not all of these departments have modern diagnostic facilities (e.g. well-equipped laboratories for biochemistry, immunology, and kidney histopathology) and their distribution is uneven (for instance, a quarter of the departments are in Bucharest).

**Physicians**

Initiatives of the Romanian Society of Nephrology led to the recognition of Nephrology by the Ministry of Health as a distinct medical specialty in 1992. As a result, the number of physicians working in Nephrology and Dialysis Centres continuously increased (Table 1). Currently, the main problems are: (i) the accreditation of physicians who have treated patients with kidney diseases and/or worked in HD centres for several years before the recognition of Nephrology as a distinct medical specialty, and (ii) the education of an increasing number of physicians according to the standards existing in developed countries.

**Haemodialysis centres**

Maintenance HD was introduced in Romania in 1974 when a HD centre was founded in ‘Carol Davila’ Teaching Hospital of Nephrology in Bucharest. Between 1989 and 1992, HD was available to ~ 460 patients per year (19.5 p.m.p.). Only 98 new patients (4.3 p.m.p.), which is less than 10% of those needing RRT, could enter the HD programme in 1991, leaving the rest of the patients to face death.

Between 1991 and 1995, 17 new HD centres were founded, and the existing centres were enlarged and their equipment modernized. At the end of 1995 there were 29 HD centres in Romania. It must be mentioned that two of these centres have children, and one diabetic patients, on their RRT programmes. Three-hundred and two HD machines were in operation (mean number of HD machines $= 150$, range 6–29), of 1500–1700 new subjects require RRT. Unfortunately, in 1995 only 459 patients (27–30%) were provided with RRT. The other 1000–1200 patients (70–73%) were only provided with supportive therapy (Figure 1) [2].

Bicarbonate dialysis is now possible in 5% of centres.

Cellulose type membranes were used in about the same proportion as were non-cellulose ones (polysulphones). Dialyser reuse is not a common policy, as only 12% of Romanian centres report reuse. The most popular HD regime in Romania is 131 h per week (4 hours per session, 3 sessions per week). Thirty-five percent of the patients undergo only two sessions per week due to the long distances from their homes to the HD centre. Currently, 16% of the centres in our country practice the urea kinetic modelling for HD prescription.
Because of financial limitations, non-fractionated heparin or ketoanalogues of amino acids are not currently in use. Epoietin is provided to a limited number of patients (18%), as is 2-calcidiol (11%). The number of HD patients continues to increase: in 1995 there were 3.75 more patients alive on RRT (1164 patients) and 4.0 more new patients starting RRT per year (397) than in 1991. The unequal geographical distribution is also reflected by the high proportion of patients (52%) not living in the town where their HD is located. The mean distance from these patients’ homes to their HD centres is 112 km. This adds a financial burden, which could better be used to found new HD centres. This fact decreases the quality of life of the patients and artificially inflates the HD cost: the cost of

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**Fig. 1.** CRF epidemiology and therapy in Romania (1995).

**Fig. 2.** Primary renal disease in patients (p.m.p.) starting RRT in Romania (1995) and in Europe (1993).
Table 1. Nephrology and CRF treatment by RRT in Romania (1991 vs 1995)

<table>
<thead>
<tr>
<th></th>
<th>1991</th>
<th>1995</th>
<th>Increase (%)</th>
</tr>
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<tbody>
<tr>
<td>Nephrology departments</td>
<td>11</td>
<td>20</td>
<td>+82</td>
</tr>
<tr>
<td>Number of physicians</td>
<td>49</td>
<td>68</td>
<td>+39</td>
</tr>
<tr>
<td>Haemodialysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HD centres</td>
<td>12</td>
<td>29</td>
<td>+142</td>
</tr>
<tr>
<td>HD machines</td>
<td>114</td>
<td>424</td>
<td>+272</td>
</tr>
<tr>
<td>Kidney transplantation</td>
<td>3</td>
<td>3</td>
<td>+0.0</td>
</tr>
<tr>
<td>Kidney transplantation centres</td>
<td>3</td>
<td>3</td>
<td>+0.0</td>
</tr>
<tr>
<td>New patients</td>
<td>98</td>
<td>459</td>
<td>+368</td>
</tr>
<tr>
<td>HD</td>
<td>96</td>
<td>397</td>
<td>+314</td>
</tr>
<tr>
<td>CAPD</td>
<td>0</td>
<td>20</td>
<td>+2000</td>
</tr>
<tr>
<td>Renal transplantation</td>
<td>2</td>
<td>42</td>
<td>+117</td>
</tr>
<tr>
<td>Patients treated (total)</td>
<td>439</td>
<td>1301</td>
<td>+196</td>
</tr>
<tr>
<td>HD</td>
<td>424</td>
<td>1164</td>
<td>+175</td>
</tr>
<tr>
<td>CAPD</td>
<td>0</td>
<td>20</td>
<td>+2000</td>
</tr>
<tr>
<td>Renal transplantation</td>
<td>175</td>
<td>117</td>
<td>+680</td>
</tr>
</tbody>
</table>

transportation for in-centre HD patients in Romania is $6.78 \times 10^8$ USD/year, reflecting an element of incoherence in health-care policy [2].

Other renal replacement therapy methods

Continuous ambulatory peritoneal dialysis (CAPD). In 1995, 20 patients were started on CAPD. In spite of logistic difficulties, the CAPD programme was successful, and for 1996 the Romanian Society of Nephrology proposed to start 175 new patients on CAPD.

Kidney transplantation. Kidney transplantation is performed in three centres and only from living donors. There is only one laboratory for histocompatibility testing and no National Transplant Registry. The facilities for life support of cadaveric donors are scarce. Transplanted patients were followed in a non-systematic fashion either by the transplantation team or the nephrologists. Most of the patients were treated with a combination of cyclosporin, azathioprine, and prednisone, but cyclosporin blood levels could only occasionally be measured. Although the cost of immunosuppressive therapy was supported by the Ministry of Health, the drugs were difficult to obtain. Forty-two grafts were performed in Cluj and Bucharest in 1995 under these conditions; this could be regarded as a success, but contributed only marginally to the global solution of CRF therapy (total number of patients living with a functional graft = 117), leaving the bulk of the uraemic patients to HD centres.

Relations between RRT methods. In Romania, most of the CRF patients (88%) are treated by HD, renal transplantation is seldom performed (8%), and peritoneal dialysis has been introduced only recently (4%). In other words HD is practically the only generally available modality of RRT [4,5].

The Budget

In 1996, 2.5% of the Ministry of Health budget was allocated to RRT (kidney transplantation excepted), i.e. to 0.007% of the potential health consumers. Such a figure is within the accepted European standards (2–4%) [5], even larger than in France (1.5%) [6], but this must be interpreted in the context that only about 3% of the Romanian budget goes to health care and that the absolute dimensions are much lower.

Renal replacement therapy costs

Cost-effectiveness analysis undertaken in other countries [7–13], show that in-hospital HD is the most expensive modality (more than 23000 USD per life-year gained). In comparison, Romanian renal services appear to be very inexpensive and of similar effectiveness; the cost per life-year gained is much lower than that reported elsewhere. The cost of HD treatment in Romania (87 USD) is the lowest, even though dialysers are not reused (Figure 4). Operating costs represent almost all of it (81 USD) and consist mainly of consumables and drugs (67 USD). A very tiny proportion (3%) is spent on salaries, since manpower is cheap.

Taking the above mentioned cost per session as represent-

Fig. 3. Total number of RRT patients in historical provinces of Romania (p.m.p.).
ative for an average ESRD patient treated three times a week and requiring no additional hospitalization, maintaining a patient alive costs about 13,338 USD per life-year gained. Consequently, a rough estimate of the total cost incurred by HD services in Romania in 1995 amounts to 16,000,000 USD.

Various factors, medical and auxiliary staff salaries being not the least, make haemodialysis cheaper (1,044 USD per month) than PD (1,246 USD per month) in Romania. The cost of renal transplantation is the lowest (646.5 USD per month in the first year, not including the cost of the surgical intervention).

Renal replacement therapy effectiveness

Given the above circumstances, it is remarkable that in terms of survival, the treatment by HD provided during the last decade in Romania proved to be almost as effective as that provided in developed countries [14]. During the last decade, 1- and 5-year survival rates were 90 and 55%, respectively; the crude mortality was under 10 per 100 HD patients treated per year.

It is questionable, however, whether the same still holds true when we consider patients’ quality of life. Patients who were refused inclusion in the HD programme in this period were children, people over 60 years old, and those having diabetes mellitus or any other systemic diseases known to alter significantly the chances of a successful treatment. This suggests that selection bias towards a population likely to have good survival might have brought the effectiveness of the HD treatment in Romania closer to that experienced by Western countries.

Results of the programme implementation

From 1991 the total number of patients alive on RRT increased by over 8 p.m.p. per year, reaching 57.3 p.m.p. in 1995. In absolute figures, the number of patients starting RRT in 1995 (459) was larger than the total number of patients treated in 1991 (439) (Table 1). However, judged by the total number of patients treated, RRT facilities are still insufficient in our country. Unfortunately, financial constraint placed Romania below the mean European value of the total number of patients alive on RRT and below other countries in the vicinity, which had the same sociopolitical structure (Figure 5).

In the past 3 years, the increase in the total number of patients alive on RRT, expressed as the percentage of 1995 vs 1991, was 300% in Romania, greater than the European mean (125%) and of the former communist countries (Figure 6). If this level of development is maintained and the incidence of ESRD remains the same, it can be extrapolated that the current Western European and US coverage rates will be attained in 45 and more than 90 (!) years respectively.

Nevertheless, the high rate of success in implementing the national maintenance dialysis programme encouraged Romanian renal support organizations to elaborate a new programme for the period 1996–1999.

Conclusions and the future

1. Implementing high-performance, high-cost medical technology and renal replacement therapy is feasible, even in adverse socioeconomic conditions. Comprehensive and scientifically sound programmes, based on proper epidemiological data and precise evaluation of resources can influence the decisions of health policy makers if sustained by credible professional associations. In this process, data collection by a national organ is crucial, as are periodic analyses of medical and economic performances.

2. Although significant progress was realized in the past 5 years, only one-third of the chronic failure patients needing renal replacement therapy could be treated in Romania in 1995. Consequently, selection had to be imposed, resulting in a peculiar distribution of primary renal disease of the patients treated and in high patient survival.

3. The increase of renal replacement therapy facilities in Romania was mainly due to expansion of the number of haemodialysis centres and only to a lesser degree due
to adoption of peritoneal dialysis and kidney transplantation. Further growth could follow two patterns:
(a) A continuous increase in the number of haemodialysis centres and HD machines, complemented by an active and efficient kidney transplantation programme, with peritoneal dialysis covering only selected groups of patients. This solution is medically sound, but it is costly and depends on high financial input over a short period of time. (b) A dynamic peritoneal dialysis programme coupled with an intensive kidney transplantation programme with haemodialysis as a support. In this case, the cost would be lower, but logistic difficulties would be higher. At any rate, it is imperative to develop an effective National Transplantation Programme.

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Received for publication: 29.7.96
Accepted in revised form: 15.1.97