Thrice-weekly nocturnal hemodialysis: the overlooked alternative to improve patient outcomes

Charles Chazot 1,
Ercan Ok 2,
Eduardo Lacson, Jr 3,
Peter G. Kerr 4,
Guillaume Jean 1
and Madhukar Misra 5

1Department of Nephrology, NephroCare Tassin-Charcot, Sainte Foy Les Lyon, Rhone Alpes, France,
2Department of Nephrology, Ege University, Izmir, Turkey,
3Medical Department, Fresenius Medical Care, North America, Waltham, MA, USA,
4Department of Nephrology, Monash Medical Centre, Clayton, Vic, Australia and
5Internal Medicine, Division of Nephrology, University of Missouri Health Care, Columbia, MO, USA

Correspondence and offprint requests to: Charles Chazot; E-mail: chchazot@gmail.com

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ABSTRACT

Hemodialysis (HD) therapy for patients suffering from end-stage renal disease (ESRD) has been a major breakthrough in medicine during the twentieth century. Empirically, the conventional treatment is prescribed as 3–4.5 h of dialysis, three times a week. However, this prescription is being questioned because of poor patient outcomes including a persistently high death rate. Over the past 30 years, Kt/V urea has been recognized as the predominant marker of dialysis adequacy. However, other important markers of ‘adequate’ dialysis are increasingly being recognized, including fluid and phosphate balance, and middle molecule removal. Conventional HD therapy, as it exists today, is limited in its scope to make a significant impact on these markers. Consequently, there is an active debate on novel HD strategies to improve patient outcomes. Recently, two randomized controlled trials (RCTs) have highlighted potential benefits for patients with two such strategies, short or long nocturnal daily dialysis. These two trials did, however, highlight the difficulty in recruiting patients for such studies. Consequently, there is an active debate on novel HD strategies to improve patient outcomes. Recently, two randomized controlled trials (RCTs) have highlighted potential benefits for patients with two such strategies, short or long nocturnal daily dialysis. These two trials did, however, highlight the difficulty in recruiting patients for such studies. A higher rate of blood access-related complications was also reported. Such novel strategies are also limited in their application by a higher economic burden and logistical difficulties. On the other hand, the thrice-weekly nocturnal HD prescription has been associated with excellent clinical results in observational reports published over recent years. Several non-randomized controlled studies support the clinical benefits of this approach. This prescription may overcome the limitations of daily dialysis and offer a potential for improving patient outcomes on HD.

INTRODUCTION

Chronic hemodialysis (HD) therapy for end-stage renal failure has been one of the major medical breakthroughs of the 20th century, providing a means to sustain life of patients afflicted with a previously lethal disease [1]. However, the best way of prescribing this therapy remains a matter of continued debate. The conventional HD prescription commonly in practice these days (three times 3–4.5 h per week) is much different from the prescription of 40 years ago (standard practice in the 1960s was to dialyze patients for 3 × 6–8 h per week [2]). The death rate remains tremendously high in dialysis patients and is mainly due to cardiovascular complications [3]. This has prompted a critical review of the way HD is currently prescribed, along with trials evaluating alternative strategies for prescribing HD. In 2010, the Frequent Hemodialysis Network (FHN) reported results of its first study, a randomized controlled trial (RCT), which highlighted the benefits of short-daily HD [4]. Following this, the second FHN trial comparing daily nocturnal long HD treatment with the conventional HD was also published [5]. The purpose of our article is to emphasize the benefits of prescribing a lesser publicized method, three times a week nocturnal HD [6–8] against the backdrop of the recently conducted trials mentioned above.
Phosphate removal is more important during the dialysis session, the higher the removal of phosphate, [24] with a lower post-dialysis phosphate rebound. Models of phosphate clearance have been proposed by Gotch et al., showing that time is a mandatory factor to remove enough phosphate when the protein intake meets the recommendations, even when short daily HD programs are applied [25].

**Middle molecule removal**

The independent influence of middle molecule blood levels on patient outcome was reported almost a decade and a half ago by Charra et al. [26]. In this report, the middle molecule index was independently and more significantly associated with the patient outcome than the Kt/V urea. More recently, the β2-microglobulin plasma level, a surrogate marker of middle molecules, has also been shown to be independently associated with decreased survival beyond the threshold levels of 27.5 mg/L [27] or 32.2 mg/L, respectively [28]. In the first study, the association between β2-microglobulin and mortality remained after adjustment for residual urea clearance. In the second study, it was also found in patients treated with HD for >5 years and without residual renal function. Furthermore, alternative dialysis techniques are far more efficient to improve the removal of β2-microglobulin, such as increased session duration of up to 8 h [24, 29] or the use of convective procedures [30].

**WHAT DO THE FHN TRIALS TELL US?**

The first published RCT (FHN In-Center Daily Trial, referred to as the Short Daily Trial) compared 120 patients under conventional treatment (three HD sessions per week, eKt/V urea of 1.1, 2.5–4 h of session duration) with 125 patients under in-center frequent dialysis (six sessions per week, eKt/V urea of 0.9, 1.5–2.75 h of session duration), on a 12-month follow-up basis (see Table 1). There were two composite co-primary outcomes combining death with either left ventricular mass assessed from magnetic resonance imaging or RAND 36-item health physical composite (PHC) and eight main secondary endpoints. The patients in the frequent group received a significantly higher total dialysis time per week (12.7 versus 10.4 h/week). Frequent dialysis was better than conventional treatment on these primary endpoints as well as for secondary outcomes such as left ventricular mass reduction (~16.4 versus ~2.6 grams after 12 months, P < 0.001), increase in PHC (+3.4 versus +0.2 after 12 months, P = 0.004) and decrease of predialysis systolic blood pressure (137 versus 147 mmHg, P < 0.001, despite lower antihypertensive agents) and phosphate level. This latter endpoint has been recently analyzed in detail, showing that in the frequent dialysis group a decrease of 0.46 mg/dL with a daily reduction of 1.35 g of phosphate binder dose when compared with the conventional dialysis group [31]. Moreover, there were less intradialytic hypotension episodes in the frequent dialysis group. In the latter group, the patients required significantly more interventions on the blood access questioning the safety of the daily use of the blood access. Also, serum albumin did not change and was not different
<table>
<thead>
<tr>
<th>Study category</th>
<th>Treatment location</th>
<th>Number of patients</th>
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<th>Improved outcomes at the end of follow-up</th>
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<tbody>
<tr>
<td>FHN Short Daily Trial [4]</td>
<td>RCT</td>
<td>In-center</td>
<td>245 (125 SDHD versus 120 controls)</td>
<td>12 months</td>
<td>Primary composite outcomes, LVM, PHC, predialysis phosphorus, predialysis systolic blood pressure (BP)</td>
<td>Beck Depression Inventory Score, predialysis serum albumin, erythropoietin-stimulating agent (ESA) dose, Trail Making Test part B, Death or hospitalization unrelated to vascular access, IDH</td>
</tr>
<tr>
<td>FHN Daily Nocturnal Trial [5]</td>
<td>RCT</td>
<td>Home for the daily nocturnal patients; home and in-center or home for the conventional group (mainly home)</td>
<td>87 (45 NHHD versus 42 controls)</td>
<td>12 months</td>
<td>Predialysis phosphorus, predialysis systolic blood pressure, intradialytic hypotension (IDH), KT/V urea</td>
<td>Primary composite outcomes, LVM; PHC, Beck depression inventory score, predialysis serum albumin, ESA dose, Trail Making Test part B, Death or hospitalization unrelated to vascular access,</td>
</tr>
<tr>
<td>Thrice-weekly nocturnal trial [8]</td>
<td>Prospective non-randomized case-control trial^2</td>
<td>In-center</td>
<td>594 (247 INHD versus 247 matched controls)</td>
<td>12 months</td>
<td>Mortality, hospitalization rate, LVM index, need for antihypertensive meds, KT/V urea, memory tests, body weight, serum albumin, predialysis phosphate, phosphate binders needs, ESA needs, hypotension episodes</td>
<td>Depression or anxiety scores, predialysis systolic BP^7</td>
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The second FHN trial (FHN Nocturnal Trial) addressed the clinical impact of the home daily long nocturnal HD (referred as ‘Daily Nocturnal Trial’) compared with home conventional HD, using the same composite primary and secondary endpoints as in the FHN daily trial, with the same follow-up (12 months) (see Table 1). From 118 enrolled patients (whereas the target was 250), 87 were randomized and assigned to either the conventional HD arm (n = 42) or the nocturnal HD arm \[ 32\]. Despite a lower adherence to the protocol, the patients in the nocturnal arm received a higher dialysis dose (1.82-fold higher weekly standard KT/V urea, 1.74-fold higher number of treatments per week, and a 2.45-fold higher weekly treatment time). The primary composite and main secondary endpoints were not significantly different between the two arms. Left ventricular mass reduction did not reach significance between arms and thus did not confirm the findings of the Alberta trial that had previously reported a significant left ventricular mass reduction in a smaller cohort (22 patients) studied for 6 months \[ 33\]. As analyzed by Stokes \[ 34\], compared with the Alberta cohort, the FHN Daily Nocturnal Trial included mainly incident patients with a large proportion of patients with a significantly preserved urine output. This might have blunted demonstration of benefit with daily nocturnal HD in comparison with conventional HD on several outcomes such as fluid excess and its results, hyperphosphatemia, erythropoiesis stimulating agent (ESA) index and λ2-microglobulin \[ 35\].

The patient enrollment and selection for randomization were not generalizable since the mortality in the conventional arm was \( \frac{1}{42} = 2.38\% \), which is at least 7 times lower than that in the general population of HD patients in the United States. Many patients in the control group performed more frequent dialysis sessions and those in the more frequent group performed more frequent dialysis sessions, with only 8% of the patients requiring additional phosphate in dialysate. Individual patients had a higher left ventricular mass reduction in the control group and with 42% of the patients enrolled in the nocturnal HD arm \( \text{mean BP} = 122/78\text{ mm Hg} \) compared with \( \text{mean BP} = 120/75\text{ mm Hg} \) at baseline, reflecting a more severe cardiovascular condition. The two other secondary endpoints that were improved in the nocturnal arm were the phosphate level and the prevalence of interdialytic hypotensive episodes. The average reduction of the phosphate level after 12 months was 1.24 mg/dL in the nocturnal arm, with 73% of the patients free of phosphate binders compared with only 8% in the control group. The prevalence of interdialytic hypotensive episodes was lower in the nocturnal arm (15.2% versus 45.3%). The intervention on blood access was increased in the nocturnal arm, but not statistically significant. As in the Short Daily Trial, no significant change was found in serum albumin levels between groups. However, many subjects were incident patients, a condition associated with improving nutritional parameters over time after the start of dialysis \[ 37, 38\]. This might have blurred the difference between groups and a longer follow-up might have been necessary to detect a difference between the two groups.

### Table 1: Continued

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<tr>
<td>Thrice-weekly cohort study [7]</td>
<td>Retrospective controlled cohort study [^4^]</td>
<td>In-center 2808 (746 INHD versus 2062 matched controls)</td>
<td>24 months</td>
<td>Mortality, KT/V urea, interdialytic weight gain, UF rate, phosphatemia, predialysis BP</td>
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Hence, the FHN Short Daily Trial shows evidence for clinical advantages of this alternative dialysis strategy based on the frequency. However, the improvement of the endpoints in the short daily group can also be attributed to the significantly longer cumulative weekly treatment time in these patients compared with the control group. The association between the total weekly time and survival was signified by Kjellstrand et al. [39] within cohorts treated by short daily dialysis. In 262 patients undergoing short daily dialysis, survival was related to the number of weekly dialysis hours and was optimal when >15 h/week. Regarding the FHN Daily Nocturnal Trial, even though the results do not confirm the Alberta results on the left ventricular mass because of the limited enrollment, phosphate balance and BP control were significantly improved. Neither trial showed an effect on hospitalization and survival but the follow-up was short and it will be interesting to revisit the outcomes after several years, particularly in the FHN daily trial, even on an intention-to-treat basis. The main concern raised by these trials was the complications of blood access, with a 76% increased risk for a first access event, even higher (90%) for an arterio-venous access in the FHN daily trial [40]. Whereas not reported in the last study, almost half of the patients in the nocturnal arm of the FHN Daily Nocturnal Trial used the button-hole technique that is associated with increased infection risk [41]. Also, cumulating the two trials, there were twice more catheter-related infectious events in daily patients than in the conventional groups [40]. It is therefore a limiting factor for the daily use of the blood access and it may negate the quoted benefits of these alternative HD schedules. Recently, Jun et al. [42] identified an increase of vascular access events with a dialysis frequency above 3.5 times per week in patients treated with extended time. Even if there was a trend to favor the rope-ladder method, they did not detect a significant difference between the rope-ladder and the button-hole cannulation technique. The other remaining question is the absence of nutritional improvement reported by observational studies utilizing short or nocturnal daily protocols [43, 44]. However, as shown by Lacson and Díaz-Buxo analyzing nine studies [45], serum albumin increased in all patients switched from standard to short and long daily dialysis treatment after 6 or 12 months. However, statistical significance was reached only in two studies consisting of 50 and 72 patients, respectively, that switched to short daily dialysis. The small number of patients in the other studies may explain the absence of significance. In the recent FHN trials, no significant changes were observed after 1 year in serum albumin, ePCR and post-dialysis body weight [32]. The significance of serum albumin is always questioned because it is influenced not only by nutrition but also by inflammation and fluid overload, these determinants being highly inter-related. What is not disputed is the prognostic value of serum albumin, both in prevalent and incident patients [46, 47]. Serum albumin increasing following a switch in dialysis strategy is a strong marker of the patient’s overall conditional improvement.

Moreover, intensive dialysis such as the daily long nocturnal type is especially efficient in removing phosphate leading to the need for phosphate supplementation to the dialysate in a large proportion of patients. This indirectly highlights the difficulty of removing phosphate with conventional HD treatment. Stated in a different way, it raises a theoretical concern for excessive removal of some nutrients including but not limited to phosphate, such as amino acids, vitamins or trace elements [48–50]. Notwithstanding the demonstrated safety from the long-lasting experience of the Toronto group on such issues [51], it is difficult to refute a concern for the theoretical construct of ‘overdialysis’.

Also, the long-term acceptability of daily treatment is seriously questioned. It has been recently reported that home HD treatment has a high dropout rate (around 25% during 1.0–1.8 years of follow-up in two recent studies [52, 53]), but the authors did not specify whether it is related to the daily or home nature of the treatment. In the recent report by Suri et al. [54], only 55% of the patients remained on the daily program on long-term. Moreover in this multinational cohort study, daily patients presented with a higher mortality rate than the propensity score-based matched patients, stressing that despite the favorable results of the FHN Daily Trial, it is premature to conclude that mortality will be improved by the daily dialysis programs. Last but not least, the economic burden of daily programs remains an unanswered question. It remains to be seen if more frequent dialysis would have economic benefits by decreasing hospitalizations. It should be noted that the need for ESAs was not changed in the recent daily trials [4, 5]. If the FHN Short Daily Trial seems to have been powered enough to detect such an effect, the Daily Nocturnal Trial was clearly under-powered in this regard. On the other hand, a nocturnal thrice-weekly program has reported in a controlled prospective cohort study that a clear decreased need for ESAs developed [8], making the case for questioning how the daily nature of dialysis therapy may be a contributory factor for extra blood losses. Promoting home programs may have a potential of cost savings [55]. However, the average age of incident dialysis patients, at least in Western countries and Japan, is progressively increasing and greatly limits training programs for home HD therapy, even though this barrier may be overcome by increasing programmatic experience in home dialysis therapy [56].

**The Thrice-Weekly Nocturnal Hemodialysis Alternative**

The Tassin experience that highlighted the achievement of prolonged patient survival uniformly utilized a treatment schedule of 3× 8 h per week on diurnal or nocturnal basis for over three decades [6]. The cornerstone of this result has been attributed, among others, to the blood pressure control, particularly the dramatic improvement of hypertension [57, 58]. According to the authors, the longer session duration in addition to the low salt diet is the key issue for easy correction of the patients’ extracellular volume excess, a recognized major pathogenetic factor for high blood pressure in HD patients [59]. However, these observations were based on the observational reports and not on RCTs (the holy grail of
scientific proof). The FHN Daily Nocturnal Trial has pointed out the important limitations to recruiting enough patients to conduct an RCT. It is easily understandable that patients are reluctant to enter a trial that proposes two treatments with important differences in the session length. For most patients, any extra time on HD is perceived as an additional burden to the existing burden of conventional dialysis therapy itself. Therefore, for these patients, a shorter treatment option often outweighs any potential benefits of the prolonged therapy. However, by promoting sleep during the dialysis session, as is the case for nocturnal dialysis, the quality-of-life burden of extended dialysis is obviated. Even when examining ‘conventional’ dialysis, longer hours were associated with better quality of life [60].

It is for this reason that we feel there is a need to think outside the box when looking at alternative dialysis strategies. In this regard, the study by Ok et al. [8] assumes significance. It compared 247 prevalent dialysis patients who voluntarily opted for nocturnal 3 × 8 h per week with 247 matched control patients (see Table 1). The matching was done out of a cohort of 1257 prevalent patients who had received information on the nocturnal dialysis program and was based on age, gender, presence of diabetes and dialysis vintage. The follow-up was 10.9 and 11.5 months, respectively, in the nocturnal and control groups. The mortality risk, the primary endpoint, was reduced by 68% in the nocturnal arm after multivariate adjustment, although the overall mortality rate in the study population was quite low. Among the secondary outcomes, the nocturnal group had significant improvement in the need for antihypertensive medications (from 22 to 8%, P < 0.02), left ventricular mass index (140 to 116 g/m², P < 0.001; unchanged in the control group), nutritional parameters (time-averaged serum albumin between groups: 4.02 versus 3.94, P = 0.01), phosphatemia (time-averaged between groups: 3.87 versus 4.96 mg/dL, P < 0.001) and the need for binders (22.4 versus 82.9% between groups, P < 0.001), ESA need (24.7 versus 53.7% of patients under ESA, with averaged weekly dose:1697 versus 2819 U, P < 0.001), hospitalization (5.43 versus 18.78 days per 100 patient-months, P = 0.002) and hypotensive episodes (reduction in the nocturnal group from 60.4 to 21.2 episodes per 1000 HD sessions, P < 0.001, whereas there was an increase from 67 to 84.3 episodes in the control group). The β2-microglobulin level did not change in the nocturnal arm, but increased in the control group. Some of the quality-of-life parameters deteriorated in the control group but remained stable in the nocturnal group. No particular concern was reported regarding the blood access. The limitations of the study were, beyond the absence of randomization, the young age of the patients (45 years) and a significant important dropout rate, especially in the control group (74 versus 29, P < 0.001). The authors explain that during the study some of the patients opted for being treated closer to their home once new facilities opened in their vicinity. However, a number of patients in the nocturnal program refused the transfer because such a program was not available in closer units.

More recently, a new study has reported the outcomes of 746 patients from Fresenius Medical Care North America units who were switched to in-center nocturnal HD (INHD) with a 2-year follow-up [7]. This study uses a propensity score-driven matching algorithm to define a suitable control group (on the basis of 1:3 match with 2062 selected patients from among 20 106 patients under convention HD therapy, see Table 1). It reports a survival advantage of 25% in the INHD group. Among the other endpoints, eKt/V_urea increased significantly, whereas the UF rate decreased dramatically (from 11 to 6 mL/h/kg, P < 0.0001) despite a significant increase in the interdialytic weight gain. Phosphatemia declined from 5.73 to 5.02 mg/dL (P < 0.001) in the INHD group, whereas it increased in the control group (5.75 to 5.85 mg/dL, P = 0.01). After 2 years, 59% of the patients remained on the nocturnal program. This report suffers from several limitations such as observational design, mix of incident and prevalent patients, absence of comorbidity matching, treatment-by-indication bias with preferred INHD orientation of patients with high UF requirements (often large patients). However, it confirms the clinical advantages of the thrice-weekly nocturnal HD reported by Ok et al. [8] regarding patient survival, eKt/V, UF rate and phosphate metabolism. The observational nature of these two studies is not questionable. It delineates association, not causation in the findings. Enrollment bias cannot be ruled out, patients agreeing for long treatment time being a priori more compliant with presupposed better outcomes. However, the large number of the patients in both cohorts, the extensive and thorough matching in the Ok study, and the careful and in-depth statistical analysis in the INHD study may have limited this bias. Moreover, these studies contrast with patient survival rates reported by Marshall et al. [61] from the ANZADATA registry. In this retrospective cohort analysis, the authors found no difference in survival between patients treated with in-center conventional HD and frequent/extended in-center HD. There was also no difference in survival in patients treated at home either conventionally or with frequent/extended strategy, having both the best survival underlying the superiority of home therapy and home-treated patients. The source data and practice patterns are markedly different from the Ok et al. and the INHD studies. The frequent/extended group was a mix of daily short and thrice-weekly extended time and the treatment time in the conventional groups, both in-center and at home, was much longer than in the control groups’ HD treatments (258 versus 226 min in the INHD study and 236 min in the Ok study). Such differences, particularly in the distribution of HD treatment time, might have attenuated the survival advantage of an extended time strategy.

Hence, with the possible exception of the Australian/New Zealand experience, the thrice-weekly nocturnal HD alternative is an efficient modality to improve intermediate outcomes in HD patients and can be a means to achieve higher patient survival. It has the advantage of sparing the blood access from frequent cannulation as well as limiting frequent travels to the dialysis unit, an important factor influencing the quality of life [62] and improving favorably economics due to lower costs than for daily strategies. Acceptability by the patients may be questioned. Ramkumar et al. [63] has
reported that among 100 HD patients, 68% of them were ready to accept daytime in-center short daily sessions, whereas only 20% of them would accept nocturnal long-hour sessions three times per week (and 7% for the long daily nocturnal treatment). However, a new evaluation in the lights of the recent trials and studies is needed. Besides the patient barriers in accepting extended duration, dialysis facility organization remains an important obstacle to implement extended nocturnal programs. It is the responsibility of the nephrology community and the patients’ associations to present the medical advantages of such dialysis prescription strategies to dialysis providers and make the case for viability in their respective treatment areas. Large healthcare companies have accepted this commitment, showing that the barriers can be overcome. Moreover, obtaining a specific coverage for both the nocturnal procedures and ‘pro rata temporis’ could be more realistic than the coverage for dialysis treatment. Of importance, promoting this technique at home will help to decrease the financial burden. The limitations that remain are the intermittence of the therapy and the concern over the ‘long week-end interval’ that is known to increase the risk of mortality in this three times/week setting [64, 65], with the increase of calls for cardiopulmonary resuscitation inside the dialysis unit on Mondays and Tuesdays [66]. This phenomenon is absent with short daily dialysis [39]. However, it can be speculated that the thrice-weekly nocturnal alternative technique may protect the patients from these complications, since there was no day of the week pattern of deaths observed in the INHD patient cohort reported by Lacson et al. [67]. Moreover, and especially for patients treated at home, applying alternate (every 2 days) long nocturnal dialysis treatment may further improve the outcomes and limit the toxicity of the long break at a reasonable price [68].

CONCLUSIONS

Conventional dialysis therapy may be suitable for an important proportion of patients, but a significant number of them may require alternative dialysis strategies because for instance of high UF needs, intradialytic side effects or phosphate imbalance. Currently, many dialysis opinion leaders push for implementation of daily programs. This is understandable given the various complications and high mortality rates experienced by the dialysis patients and the results of the FHN Short Daily Trial. However, both the dialysis community and the healthcare providers may come to realize that daily dialysis has its own share of issues. These are safety of blood access, patient reluctance, the risk of burn out, and organizational and financial issues. On the other hand, we feel convinced that thrice-weekly long HD, especially during the night, offers a reasonable compromise that embodies in some ways the best of all available alternative dialysis strategies. Even in the absence of RCT data with this dialysis strategy, controlled trials have brought forth strong evidence for significant improvements in patient outcomes, at a lower cost. Ideally, it would be necessary to run a RCT comparing short daily HD, daily nocturnal HD, 3-times weekly long nocturnal

HD and conventional HD. It is highly probable that this trial will never be organized, given the difficulties encountered in the FHN studies to recruit suitable patients. While the debate on the trial methodologies and designs continues, the dialysis community needs to direct its focus once again toward home and self-care therapy allowing alternative dialysis strategies at lower cost. This would also ‘decompress’ the dialysis units both in time and space to be able to offer longer or more frequent HD treatments for the patients who need and prefer such therapy, which are currently subjected to the ‘one-size-fits-all’ model. This strategy will be a small step toward achieving a real ‘dialysis adequacy’ accommodating all types of HD patients.

CONFLICT OF INTEREST STATEMENT

None declared.

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