



Renal Prognostic Benefit of High Cut Off Dialysis Membrane Treatment in the Management of Dialysis-Dependent Severe Acute Renal Failure Secondary to Myeloma Cast Nephropathy in a Local Cohort

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Abstract

Introduction: The objective of this observational study on a local cohort was to report the prognostic interest of using a High Cut-Off membrane dialysis protocol in the management of MM (myeloma tubulopathy) in patients with severe dialysis-dependent acute kidney injury (AKI). **Methodology:** This was a retrospective study conducted over a one-year period from September 1, 2023, to August 31, 2024. All hospitalized patients with dialysis-dependent AKI diagnosed with MM were treated according to the High Cut-Off protocol of usual chemotherapy. A free light chain proteinuria level above 1500 mg/L was required to confirm the diagnosis of MM. **Results:** In our cohort, we included 14 patients diagnosed with MM, 9 of whom were treated with the High Cut-Off protocol. Among these, 5 recovered renal function (RF), and 4 did not; 5 patients underwent conventional dialysis without RF recovery. The average age was 77 years, ranging from 45 to 92 years, with the highest age group being 65 to 85 years. Women were predominant, with a sex ratio of 1.4. The hematological diagnosis was similar in all groups (HCO+, HCO-, and conventional dialysis). Our results show a higher percentage of patients with subacute MM or pre-existing chronic kidney disease (CKD) in the HCO+ group, with mean creatinine levels of 133 $\mu\text{mol/L}$, 117 $\mu\text{mol/L}$, and 106.5 $\mu\text{mol/L}$, respectively. No patient with creatinine > 115 $\mu\text{mol/L}$ was found in the HCO+ group, while there were 3/5 (60%) in the HCO- group and 5 in the conventional dialysis group. A significant decrease in free light chain levels was observed at the end of the pro-

tol in 4 patients (25%) in the HCO+ group compared to none (0%) in the conventional dialysis group. In the group treated successfully with the HCO protocol, the time to RF recovery after initiating HCO treatment was 3 months for 3 patients and 6 months for 2 patients. **Conclusion:** In our study, the results suggest that the HCO protocol is beneficial, with 56% of patients weaned from dialysis, while no recovery was observed in the untreated group. Renal recovery was most notable around the third month after initiating the protocol. Further studies are needed to confirm these findings. This renal recovery, along with dialysis weaning, could have a significant positive impact on the quality of life of patients with MM and beneficial medico-economic repercussions.

Subject Areas

Nephrology-Hemodialysis

Keywords

End-Stage Renal Disease, Myeloma Tubulopathy, Multiple Myeloma, Hemodialysis, Nephrology, Perpignan

1. Introduction

Acute renal failure is a frequent complication of multiple myeloma and can lead to the development of end-stage renal disease, requiring haemodialysis or long-term renal transplantation in the event of prolonged complete remission. The causes of acute renal failure in multiple myeloma are varied and may include hypovolaemia, hypercalcaemia [1] or other newly classified monoclonal gammopathies of renal significance (MGRS), including amyloidosis, Randall's disease or Fanconi's syndrome.

However, the most common form of renal involvement in monoclonal gammopathies is myelomatous cast nephropathy or myelomatous tubulopathy (MT) [1].

Punir Y, *et al.* reported in their study that 90% of patients with AKI in multiple myeloma had TM, with a median survival of between 4 and 20 months, i.e. less than 20% of overall survival [2].

Tubular obstruction is secondary to the formation of cylinders in the urinary chamber by crystallisation of excess light chain (LC) with Uromodulin, a Tomm-Horsfall protein. In parallel, tubulorrhesis with infiltration of giant cells and massive reabsorption of light chains in the proximal tubules contribute to the rapid development of tubulointerstitial fibrosis.

The renal prognosis of myelomatous chain nephropathy is poor. Dialysis independence was reported in only 20% of patients in the era of conventional chemotherapy [3]-[7] and still occurs in a minority of patients treated with newer anti-myeloma agents, including bortezomib and the immunomodulatory drugs, thalidomide and lenalidomide [8]. Severe chronic renal failure has a major impact on

the survival of patients with multiple myeloma [3].

The cornerstone of management is the drastic and rapid reduction of free light chains.

Recent data suggest that the combination of new-generation chemotherapy regimens with efficient elimination of serum light chains by high-cut-off haemodialysis [8] or plasma exchange [9] could considerably increase the renal response rate [10], albeit without any impact on patient mortality (MYRE, EULITE).

High cut-off dialysis uses a high permeability membrane that is much higher than conventional membranes. It is designed to eliminate large molecules of 40 to 60 kDalton, which conventional membranes are unable to do.

There is some controversy as to the renal prognostic value of the High Cut-off protocol in the management of TM, which is why we have decided to report our experience in this field.

2. Material and Method

We conducted a retrospective descriptive study over a period of 1 year, from 1 September 2023 to 31 August 2024.

Our study included all patients hospitalised at the INS with dialysis-dependent ARF, diagnosed with TM treated with the High Cut-off (HCO) protocol in addition to the usual chemotherapy.

Tubular proteinuria and a blood free LC level >1500 mg/l were required for a diagnosis of ESRD.

Our variables were quantitative and qualitative, broken down into the following data:

A-Sociodemographic data: age, sex.

A-Clinical and Paraclinical Data

- Circumstances of discovery:
Bone pain, pathological fracture, ARF, hypercalcaemia, anaemia.
- Past history: Hypertension, diabetes, ischaemic heart disease, CKD= creatinine > 115 $\mu\text{mol/l}$ for 3 months prior to diagnosis of TM, organ transplant, MGUS, myeloma, COPD, immunosuppressive treatment, vasculitis.
- Favouring factors: NSAIDs; iodinated contrast agents, infectious syndrome, extracellular dehydration.
- Clinical signs: Anuria (diuresis less than 200 cc/24 h) oliguria (200 to 500 cc/24 h), abdominal pain, vomiting, headache, confusion, sensory-motor deficit, bone pain (bone and lumbar), hypertension, dyspnoea, cough, fever, AEG, epistaxis, polyuropolydipsia.
ECG: rhythm disturbances, giant J wave, short QT, ST + short convex dome.
- Biology: CBC; reticulocytes; blood ionogram; blood calcium; PTH; PTHrp, Vit D3; phosphorus, blood albumin, B2microglobulins, EPPS + IF + Ig quantification, BU, 24-hour PU or RAC, EPPU, Bence jones, calciuria, LDH, CRP, blood culture, ECBU.

Cytogenetic study

Medullogram: to look for plasmacytosis above 10%, dysmorphic.

-Imaging

CAT scan: to look for an infectious site, an obstructive cause of IR, and to detect bone fractures.

PET scan: extension assessment.

Spinal MRI: vertebral fracture, infiltrations, spinal cord compression.

Treatment

1) Chemotherapy:

- RD protocol (Dexa + Revlid).
- VTD protocol (velcade + thalidomide + dexamethasone).
- MTP protocol (melphalan + prednisone + thalidomide).
- MP protocol (melphalan + prednisone).
- CDT protocol (cyclophosphamide + Dexa + thalidomide).
- VAD protocol (vincristine + adriamycin + dexa).
- VCD protocol (velcade + cyclophosphamide + dexa).
- VD protocol (velcade + Dexa).
- Palliative care

Start date: this made it possible to determine whether treatment had started late or early and whether it would have a prognostic impact on the kidney.

2) Dialysis Using the High Cut Off Protocol

Technique:

High Cut Off

Dialysis membrane: PMMA (BK2 double membrane), hydrophilic membrane, symmetrical, high adsorptive properties very high pore size above 50 to 60 KDa sieving coefficient 60 to 100 KDa Kuf above 30 to 50 ml/h/mmHg, good compatibility.

Duration: 4 h with membrane change at the 2nd hour on a saturation phenomenon up to LC level below 500 mg/l.

Blood flow rate: 300 ml/min.

Dialysate flow rate: 500 ml/min.

Vascular access: temporary femoral catheter relayed by a tunnelled right jugular catheter.

Dialysis bath: individualised according to blood profile.

Anticoagulation: UFH (unfractionated heparin) Loading dose then maintenance at PSE.

Number of sessions: 10 sessions over 12 days.

Conventional

Type of dialysis, HD

Dialysis membrane: TS (Toray sulphone) according to body surface area. hydrophobic, asymmetric membrane excellent convective filtration capacity high pore size sieve coefficient 30 to 40 KDa, Kuf 20 to 30 ml/h/mmHg.

Duration: 4 hours, until recovery of renal function.

Blood flow rate: 300 ml/min.

Dialysate flow rate: 500 ml/min.

Vascular access: Temporary femoral catheter followed by a tunnelled right jugular catheter.

Individualised dialysis bath according to blood test.

Anticoagulation: HNF Loading dose then maintenance at PSE.

Cycle: 3 times a week.

B-Evolution: We assessed diuresis to evaluate the recovery of renal function and classify patients into two groups: Resumption of diuresis (over 300 cc/24 h), remaining anuric (under 300cc/24 h), resumption of renal function.

We measured Ig and light chains before and after each dialysis session to assess the effectiveness of the Hight cut off protocol in terms of lowering light chains.

Data analysis:

Our data was collected on pre-established survey forms; firstly and then The data was entered into an electronic form deployed using the KoboToolbox platform, we did not carry out any statistical analysis.

Ethical aspects:

To collect the data, we submitted the questionnaire and study protocol to the ethics committee for approval, and we respected the anonymity and confidentiality of the data.

3. Results

In our cohort, the mean age was 77 years, with extremes from 45 to 92 years, and the oldest age group was between 65 and 85 years (**Table 1**).

Females were predominantly represented, with a sex ratio of 1.4% in favour of males (**Table 1**).

We enrolled 14 patients with TM, 9 of whom received treatment using the Hight Cut Off protocol, 5 of whom recovered FR (HCO+) and 4 of whom did not (HCO-), and 5 of whom received conventional dialysis with 0 recovery (non-HCD) (**Table 2**).

Table 1. Distribution of patients according to socio-demographic parameters.

Socio-demographic	Parameters	Percentage (%)
Age		
45 - under 55 years	2	14
65 - under 75 years	5	36
75 - under 85 years	5	36
85 - under 95 years	2	14
Gender		
Male	5	36
Female	9	64

Mean age: 77; Range: 45 to 92; Sex ratio: 1.4%.

Table 2. Comparison between patients dialysed using the High Cut Off method and conventional dialysis.

	High Cut Off (HCO) protocol		Conventional Hemodialysis (CDH)	
	Recovered HCO+ (N = 5)	Not recovered HCO- (N = 4)	No recovery (N = 5)	
Age (mean)				
Sex: M/F	71		73	73
Comorbidities	2 (40%)	3 (60%)	3 (75%)/1 (25%)	2 (40%) 3 (60%)
	Ischemic heart disease (0)		Ischemic heart disease (1)	
	IC (2)		IC (1)	
Age (mean)	HTA (2)		HTA (5)	
	Diabetes (1)		Diabetes (1)	
	COPD (1)		COPD (1)	
Pre-existing CKD	chronic renal failure (0)	chronic renal failure (3)	chronic renal failure (1)	
(creatinine >115 µmol/l 3 months prior to inclusion)	106.5	133.8	117.4	
Mean creatinine in µmol/l Interval	80 to 90	140 to 289	121	
Creatinine at diagnosis in µmol/l	812.15	807.14	848	
Myeloma relapse		Rechute (1)	(0)	
	DEC (3)	DEC (4)	DEC (4)	
Contributing factors	AINS (3)	AINS (2)	AINS (3)	
	SI (0)	SI (1)	SI (2)	
	Renal symptoms			
Oliguria	0	1	0	
Anuria	2	2	2	
Type of CL	Kappa (2) Lambda (3)	Kappa (1) Lambda (3)	Kappa (2) Lambda (3)	
Type of Igmonoclonal	IgG (3) IgM (1) MM to CL (1)	IgA (2) IgG (2)	IgA(3) IgG(1) MM to CL(1)	
Mean CL at diagnosis in mg/l	10765	13277	12217	
Mean CL measured in the week after HCO treatment or between the 2nd and 3rd week for the conventional HD group in mg/l	2954 (99; 9000)	4614 (410; 8000)	7707 (3414; 12000)	
Interval in mg/l				
Type of chemotherapy	VD (4) VCD (1)	VD (2) VCD (1)	VD (100%)	

When comparing the two groups of patients, our results show a higher rate of patients with stigmata of subacute TM or pre-existing CKD (chronic renal failure)

in the HCO– and HDC (chronic haemodialysis) groups compared with the HCO+ group, with mean creatinine levels of 133 $\mu\text{mol/l}$, 117 $\mu\text{mol/l}$ and 106.5 $\mu\text{mol/l}$, respectively. No patient with creatinine > 115 μmol was found in the HCO+ group, compared with 3 patients/4 and 1 patient/5 in the HCO+ and HCD groups respectively (**Table 2**).

Table 3. Distribution of patients according to changes in CL rate and time to recovery.

Variables	Numbers	Percentages
Evolution of CL rate in the HCO+ patient group		
Before dialysis	10765	
3rd week	2920.23	
6th week	218	
Evolution of CL rate in the HCO+ patient group		
Before dialysis	13277	
3rd week	3614.2	
6th week	642	
Evolution of CL rate in the HDC group		
Before dialysis	12217.8	
3rd week	7707	
6th week	6389.5	
Recovery time (HCO+)		
3 months	3	37
6 months	2	25
No recovery	3	38
Recovery time (HCO)		
No recovery	5	100
3 months	0	0
6 months	0	0

Patients in the HCO+ group had a lower mean LC level on admission (10765 mg/l) than the HCO– and HDC group, with levels of 13277 mg/l and 12217 mg/l respectively.

The mean LC level measured one week after the end of the protocol in the HCO group or between the 2nd and 3rd week of treatment for the untreated group (HDC), was 2954 mg/L for the HCO+ group, 4614 mg/L for the HCO– group and 7707 mg/L for the HDC group.

A drastic fall in LC levels to <500 mg/L was noted in 3/5 (60%) patients in the HCO+ group at the end of the protocol, whereas this was the case for only ¼ (25%) patients in the HCO– group, and for no patient (0%) in the HCD group.

Our data show 2 patients who recovered but with CL levels >5000 mg/L, but

also one patient treated with HCO who remained dialysis-dependent with a CL level <500 mg/L (**Table 2**).

In the group of patients successfully treated with the HCO protocol, the time to recovery of renal function after initiation of HCO treatment was 3 months in 3 patients and 6 months in 2 patients (**Table 3**).

4. Discussion

We report our experience from a peripheral nephrology centre in the management of patients with acute renal failure requiring dialysis for myelomatous tuberculopathy, whether or not treated with the High Cut Off membrane.

Of the 14 patients suffering from myelomatous tuberculopathy, 5/9 patients (55.5%) in the group treated with the High Cut Off protocol recovered renal function enabling them to be weaned off dialysis, compared with no patients (0%) in the untreated group.

Although the number of patients in each group was too small to conclude that there was a significant statistical difference, these results seem to show a trend towards an improvement in renal prognosis in the medium term with the use of High Cut Off membranes in the acute phase of TM, without any impact on mortality.

We studied other criteria that could be linked to better renal recovery:

1) The presence of stigmata of subacute TM or pre-existing CKD as assessed on a work-up performed within 3 months prior to the episode of TM.

Our results show a higher rate of patients with stigmata of subacute TM or pre-existing CKD in the HCO- and HDC groups compared with the HCO+ group, with mean creatinine levels of 133 $\mu\text{mol/l}$, 117 $\mu\text{mol/l}$ and 106.5 $\mu\text{mol/l}$, respectively. No patient with creatinine >115 μmol was found in the HCO+ group, compared with 3 patients/4 and 1 patient/5 in the HCO+ and HDC groups respectively.

The presence of stigmata of TM with early renal damage or pre-existing CKD appears to be a prognostic factor for non-recovery of renal function despite treatment, as shown by the high percentage in the groups that did not recover, irrespective of whether or not they were treated with the HCO protocol. Rapid diagnosis in order to initiate prompt treatment would appear to be essential in this context.

In addition to its diagnostic value, a renal biopsy at the time of initial management could have a prognostic value by guiding the clinician in the choice of patients to treat or not according to histology.

2) Light chain levels on admission and at the end of treatment

The HCO+ patients had a lower mean LC level on admission (10765 mg/l) than the HCO- and HDC group, with respective levels of 13277 mg/l and 12217 mg/l.

These data do not rule out the hypothesis of a relationship between a high LC level on initial admission and renal prognosis.

The mean LC level measured one week after the end of the protocol in the HCO

group or between the 2nd and 3rd week of treatment for the untreated group (HDC), a LC level of 2954 mg/L for the HCO+ group, 4614 mg/L for the HCO– group and 7707 mg/L in the HDC group.

We confirmed a drastic drop in CL to a level of <500 mg/l in 3/5 (60%) patients in the HCO+ group at the end of the protocol, whereas this was the case for only ¼ (25%) patients in the HCO– group, and for no patient (0%) in the HDC group.

Although the number of patients was too small to conclude that there was a significant statistical difference, these results seem to indicate that the use of HCO membranes as an adjuvant to chemotherapy in the attack phase could have a positive impact on the renal prognosis of patients with TM complicated by dialysis-dependent AKI.

Studies suggest that a CL level <500 mg/l at the end of the protocol would be associated with a better renal prognosis [1].

However, our data show 2 patients who recovered but with CL levels >5000 mg/L, and also one patient treated with HCO who remained dialysis-dependent with a CL level <500 mg/L.

These findings are consistent with hypotheses already put forward in the literature: the precipitation concentration threshold of LC in the urinary chamber depends not only on its level, but also on its conformation and precipitation capacity in a given physiological medium, in this case in TM.

As we do not know the correlation between the onset of AKI (precipitation of LC in the light in the urinary chamber) and the level of LC in the blood for a given patient, with no previous history of TM in the case of a patient with *de novo* myeloma, it would probably be in the patient's interest, in order to optimise his renal prognosis, to prolong treatment by purification of LC by HCO (or plasma exchange) until a LC level of <500 mg/l is obtained.

In fact, we can rule out the possibility that if we had prolonged HCO treatment with closer monitoring of CL and stopped treatment only if the CL level fell below 500 mg/L, we would have had more patients weaned off dialysis in the medium term. A larger study population would also have been required to demonstrate this difference.

The aim of our study was not to prove the reduction of LC by HCO membranes. We had not found the interest in this in the sense that clearance of CL was proven in the EULYTE phase 2 study [11] which reported a median reduction in CL concentration was assessed for the first complete dialysis session (8 h in the HCO-HD group, 4 h in the HF-HD group), in order to determine the efficacy of a single treatment in eliminating the pathogenic isotype of CL. The clearance of CL - Kappa and CL Lambda through a HCO-HD dialyser was different, therefore all analyses of CL levels were performed by isotype. These data were analysed for 95% of patients in the HCO-HD group and 90% of patients in the HF-HD group with a κ isotype and 96% of patients in the HCO-HD group and 92% of patients in the HF-HD group with a λ isotype. These median reductions in CL concentrations were -77% (IQR -82 to -64) in the HCO-HD group and -20% (-41 to -8) in the

HF-HD group for kappa CL ($p < 0 - 0001$) [11]. These data demonstrate the effectiveness of the High Cut Off Protocol in eliminating light chains.

3) Recovery time

In the group of patients successfully treated with the HCO protocol, the time to recovery of renal function after initiation of HCO treatment was 3 months in 3 patients and 6 months in 2 patients. This prolonged recovery time proves that it is possible to wean patients off dialysis, even at a late stage, and that we must remain vigilant for signs of recovery of biological renal function in patients.

This delay is similar to that found in the MYRE study, the first randomised controlled trial to include patients with biopsy-confirmed cylinder nephropathy requiring haemodialysis. This trial found no difference between patients treated with high-flux haemodialysis (HF-HD) and HCO-HD in terms of renal recovery at 3 months [12].

Nevertheless, the authors found an improvement in renal prognosis in the HCO-HD group at 6 and 12 months, despite no difference in mortality at 12 months and no difference in patients alive and independent of haemodialysis at 12 months [7].

In comparison with data in the current literature on improvement in renal function in patients with TM treated with an HCO protocol, our population is similar or different in the following respects:

- In our study, the average age was 77, with the highest age range between 65 and 85. In the EULYTE phase 2 study, the mean age was 65, a younger population than ours [11].
- In our study, females were more represented, with a sex ratio of 1.4% in favor of females, but the literature reports a predominance of males. In the EULYTE phase 2 study, a male predominance of 57% was reported, and in the MYRE study the M/F ratio was 1:1 [12].

In our series, hypertension was the most frequent comorbidity, which is explained by its frequency in the general population as a cardiovascular DRF. This predominance was also found in the EULYTE phase 2 study [11].

- With regard to the circumstances of discovery, ARF was the main cause (28.8%), followed by anemia (25%). ARF is a frequent complication of myeloma, sometimes revealing the disease and weighing heavily on prognosis. Boufrioua E *et al.* similarly reported the discovery of multiple myeloma by AKI and anemia to be in the order of 28.4% and 25%, respectively [7].
- With regard to renal symptoms, anuria was the main symptomatology, with the same proportions in all patients in all groups (HCO+, HCO-, non-HCO).
- According to the type of Ig involved in myelomatous tubulopathy, IgG was more frequent in the HCO+ group (75%), and IgA in the HCO- and non-HCO group (55%).

Given the small size of the study population, we cannot draw any definitive conclusion on the involvement of IgA in renal functional prognosis. Nevertheless, there is no evidence in the literature to date of a detrimental impact on the renal

prognosis of IgA myeloma compared with IgG myeloma.

- In our study, we report a high frequency of use of the VD protocol (Bortezomib (VELCADE) and Dexamethasone) as a chemotherapy protocol, with a similar frequency of use in the 3 groups. This high rate of use of the VD protocol is due to the fact that virtually all patients had de novo myeloma discoveries, rather than relapses.

Bortezomib has demonstrated a rapid reduction in lymphocyte cell concentration. In addition, it inhibits NF- κ B pathways, reducing the release of local inflammatory cytokines and inducing anti-apoptotic pathways specific to tubular cells. One of the reasons for its choice as a first-line treatment, more specifically in patients with severe renal impairment, is that it does not require therapeutic adaptation to renal function, as elimination is hepatic, with no risk of accumulation. It is not known to induce nephrotoxic lesions. In the VISTA trial, the addition of Bortezomib (V) to Melphalan and prednisone (MP) significantly increased the overall response rate (ORR) from 46 to 68%, and the complete response rate (CR) from 5% to 31%, respectively in patients with eGFR <50 ml/min/1.73 m² [13].

- Taking into account the International Staging System classification, the majority of our patients were classified as stage 2 followed by stage 3, i.e. already with a poor prognosis.

4.1. What We Know about the Subject

TM is the most common kidney disease in multiple myeloma and is transplanted with a poor prognosis.

4.2. What's New in Our Study

Our results seem to show the beneficial effect of the HCO protocol, with 56% of patients able to be weaned off dialysis vs. no patients in the untreated group.

5. Conclusions

In our study, the results appear to show a beneficial effect of the HCO protocol, with 56% of patients weaned off dialysis compared with none in the untreated group. Average recovery was observed around the 3rd month following implementation of the protocol. Further studies on this subject are needed to confirm these results.

This renal recovery with weaning from dialysis appears to have a significant positive impact on the quality of life of multiple myeloma patients, as well as beneficial medico-economic repercussions.

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Authors' Contributions

All authors participated in data collection, analysis and drafting of the manuscript. The final manuscript was read and accepted by all authors.

Conflicts of Interest

The authors declare no conflict of interest.

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