REGIONE DEL VENETO







#### ASSESSMENT OF SAFETY AND EFFICACY OF EXPANDED HEMODIALYSIS USING MEDIUM CUT-OFF DIALYZER IN COMPARISON TO HEMODIAFILTRATION

Primi risultati clinici dal centro di Vicenza

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#### **UNMET CLINICAL NEEDS IN DIALYSIS**

Class		SOLUTE	MW (Da)	<b>Action/Effect</b>
Small	0 0 0	Urea Creatinine Vitamin B12	60 125 1250	General toxicity
Middle		β2Μ Leptin Myoglobin	12000 16000 17000	Amiloidosis CTS Malnutrition Organ damage
Large		κ-FLC Prolactin Interleukin-6 Hepcidin Bound P-Cresol Pentraxin-3 λ-FLC TNF-α (Trim)	23000 23000 25000 27000 33500 43000 45000 51000	Toxicity Infertility Inflammation Anemia CV Toxicity Acute Phase Prot. CV Toxicity Inflammation
Essential protein		Albumin	68000	Toxin binding capacity

Classification of Uremic Toxins and Their Role in Kidney Failure Mitchell H. Rosner et all.

#### **Removal of midlle molecules**

 $K_{c}$ 

#### **ON - LINE HEMODIAFILTRATION**



- Optimal vascular access (Qb)
- High-flux membrane
- Large convective volume (≥ 23 L)
- Ultrapure water

#### EXPANDED HEMODIALYSIS



- MCO-HRO
- Internal filtration/Backfiltration
- Water purity

#### **FILTRATION / BACKFILTRATION**



Alberta Alghisi<sup>3</sup>, Alessandra Brendolan<sup>4</sup>, Claudio Ronco<sup>1</sup> 2<sup>3</sup> 4

#### **Advanced Sieving Profile**



#### **Membrane Structure Functionalization with a-Tocopherol**



The aim of the study was to assess <u>safety</u> and <u>efficacy</u> of Expanded Hemodialysis with medium cut-off membrane in comparison to Hemodiafiltration with high-flux membrane.



This study was a subanalysis of a multi-center prospective study, focused on the subgroup of 18 patients afferent to the Dialysis centre at San Bortolo Hospital in Vicenza, Italy.



Patients were assigned into three group (6 patients each)



#### **EXPANDED HEMODIALYSIS**

**HEMODIAFILTRATION** 

#### TIMING



We analysed four early-week HD session, at the beginning of each month over a 3-months period:

T0  $\rightarrow$  First HD session analysed in our study

T1  $\rightarrow$  After one month from the first HD session

T2  $\rightarrow$  After two months from the first HD session

T3  $\rightarrow$  After three months from the first HD session



# **Descriptive analysis**

	HDF	HDX		p-value
Filter	FRESENIUS FX	THERANOVA	VIEX	
Urine Output (n/%)				ns
<100 ml	5 / 83.3	1/16.7	1/16.7	
< 500 ml	1 / 16.7	4 / 66.7	3 / 50	
>500 ml	0	1/16.7	2 / 33.3	
<b>Dialysis Vintage</b> (months) (median/IQR)	149.8 [37-100]	31.5 [18.5-113.2]	15 [2.5-42.5]	.042*
Session Length (min) (mean ± SD)	211.8 ± 11.1	202.6 ± 25	223.5 ± 17.2	0.001*
<b>Qb</b> (ml/min) (median/IQR)	300 [300-350]	300 [287-300]	290 [281-300]	< 0.001**
<b>Qf</b> (ml/min) (median/IQR)	99.1 [85.9-108.2]	11.8 [7.9-14.3]	13.15 [12.3-14]	< 0.001**

\* Comparison between groups

\*\* HDF vs HDx

# Albumin loss



#### Albumin loss

	Albumin loss (g) (mean/SD)
Vie-X	2.9/ 0.7
Theranova	3.7/ 0.9
FxFresenius	2.5/ 1.1

Covariates	p-value
Qb*	ns
Predialysis Serum Albumin	ns
Session Lenght	ns
Qf*	ns
Dialyzer	0.001



#### Serum albumin

	Serum Albumin (g/dL)	
	(Mean / SD)	
Vie-X		
то	4.06 / 0.15	
T1	3.96 / 0.12	
T2	4.16 / 0.13	
Т3	4.30 / 0.08	
Theranova		
то	3.91 / 0.25	
T1	3.91 / 0.21	
T2	3.98 / 0.20	
Т3	4.1 / 0.31	
Fx - Fresenius		
то	4.03 / 0.21	
T1	4.01 / 0.21	
T2	4.10 / 0.29	
Т3	3.95 / 0.27	



## Instantaneous Clearance



### **Clearance of Small Uraemic toxins**



#### **Clearance of Middle-molecules**



# **Removal Ratio**





## **Dialysis Adequacy**

	Vie-X	Theranova	Fresenius Fx	p-value
<b>RR Creatinine</b> (Mean±SD)	65.5 ± 6.3	66.3 ± 6.3	66.9 ± 5.1	ns
<b>RR Phosphate</b> (Mean±SD)	58.2 ± 11.2	56.1 ± 9.4	60.2 ± 7.3	ns
<b>RR Urea</b> (Mean±SD)	72.9 ± 5.1	72.1 ± 6.2	75.0 ± 4.4	ns
<b>Kt/V</b> (ID)* (Mean±SD)	$1.30 \pm 0.16$	$1.27 \pm 0.17$	$1.29 \pm 0.10$	ns

#### **Removal Ratio**

#### $\beta$ 2-microglobulin

	Vie-X	Theranova	FreseniusFx	p-value
I	13.7 ± 2.8	16.0 ± 2.9	16.5 ± 3.6	ns
F	6.9 + 1.1	7.2 ± 2.2	7.5 ± 1.8	ns
RR	48.2 ± 8.9	55.9 ± 9.3	55.7 ± 13.2	0.024



#### **Removal Ratio**

#### $\alpha$ 1-microglobulin

	Vie-X	Theranova	FreseniusFx	p-value
I	222.4 ± 54.1	212.7 ± 25.0	264.5 ± 22.0	< 0.001
F	232.4 ± 57.9	211.7 ± 33.1	25 <del>4.0 ±</del> 46.8	0.012
RR	- 4.5 ± 5.8	0.7 ± 13.2	4.5 ± 12.9	0.024



## **Removal Ratio**

#### Myoglobin

	Vie-X	Theranova	FreseniusFx	p-value
I	196.4 ± 86.2	266.6 ± 121.3	198.2 ± 73.8	0.005
F	118.9 ± 46.5	135.2 ± 47.1	123.2 ± 73.5	ns
RR	38.1 ± 8.6	47.1 ± 9	38.6 ± 23.1	0.07



# **Clinical outcomes**

#### Anaemia

#### **Erythropoietin resistance index (ERI)**

EPO dose (U)/ body weight (Kg)/ mean Haemoglobin (g/dl) over a 3-month period

- Basal-ERI
- ERI
- Δ-ERI



# **Clinical Outcomes**

#### **Disease Burden**

#### SF-36 questionnaire

Physical functioning (PF)	sum of points divided by 10
Role limitations due to physical health (RP)	sum of points divided by 4
Role limitations due to emotional health (RE)	sum of points divided by 3
Energy/ fatigue (E/F)	sum of point divided by 4
Emotional wellbeing (EW)	sum of point divided by 5
Social functioning (SF)	sum of point divided by 2
Bodily pain (BP)	sum of point divided by 2
General health (GH)	sum of point divided by 5

No differences between groups

# Discussion

#### The albumin paradox

- Mean albumin loss < 5 gram per HD session
- The higher albumin loss observed in Group 2 didn't influence serum albumin concentration
- In Group 1 after the introduction of MCO membrane, we observed an initial fall of serum albumin concentration, followed by a gradual increase.



# ViE-X performance



## HDx vs HDF





Larger sample size

## Future Perspectives



Long-term clinical outcomes



**Green Dialysis** 

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# Many thanks for your attention!