23rd Asian Pacific Congress of Nephology 2025 in Taipei

Analysis of the Novel LDL Apheresis Option, Rheocarna, for Chronic Limb-Threatening Ischemia (CLTI) in Hemodialysis Patients at Our Facility

Yoshihiro Arimura[1) 5)], Kanna Watanabe[1)], Aya Sato[1)], Tsunee Yamato[1)], Eiichiro Sakagawa[1)], Takashi Yasuda[1)], Yuhta Oyama[1)], Shinya Kaname[1) 5)], Yui Kato[2)], Keiko Inaba[3)], Kazue Saito[3)], Tatsunori Yanagimachi[4)], Taketo Motoyama[4)], Norihiko Ohura[6)],

1)Department of Internal Medicine, Kichijoji Asahi Hospital
2)Department of Rehabilitation, Kichijoji Asahi Hospital
3)Department of Nursing, Kichijoji Asahi Hospital
4)Department of Clinical Engineering, Kichijoji Asahi Hospital
5) Department of Nephrology and Rheumatology, Kyorin University School of Medicine
6) Department of Plastic, Reconstructive and Aesthetic Surgery, Kyorin University School of Medicine

Conflict of Interest Disclosure

In relation to this presentation, we disclose a conflict of interest with Kaneka Medix Corporation.

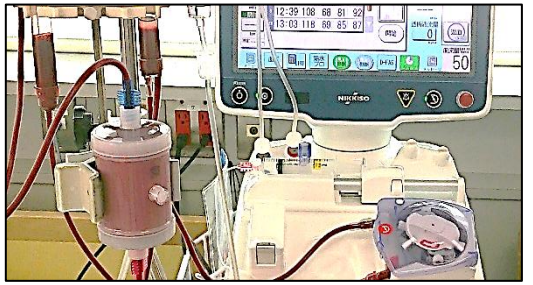
Kichijoji Asahi Hospital

The Renal Division of the Zenjinkai Group

2 hospitals, 86 dialysis clinics, serving ~9,000 chronic dialysis patients (May 2025)

Kichijoji Asahi Hospital

- **Our hospital:** central hospital for 39 dialysis clinics of our group in Tokyo
- **Outpatient dialysis**: cares for about 170 patients
- **In-patient beds**: 45; nearly all admissions are dialysis patients
- **Services:** dialysis care, rehabilitation, vascular access treatments, apheresis therapy




Background / Aims

Background:
Hemodialysis patients with CLTI often face lower-limb or toe amputations.

Rheocarna therapy: approved in Japan in 2021 as a novel LDL apheresis option for peripheral artery disease (PAD), including CLTI, due to atherosclerosis, who are unsuitable for revascularization.

Aim:
To assess the efficacy and safety of Rheocarna therapy in patients with CLTI on hemodialysis.

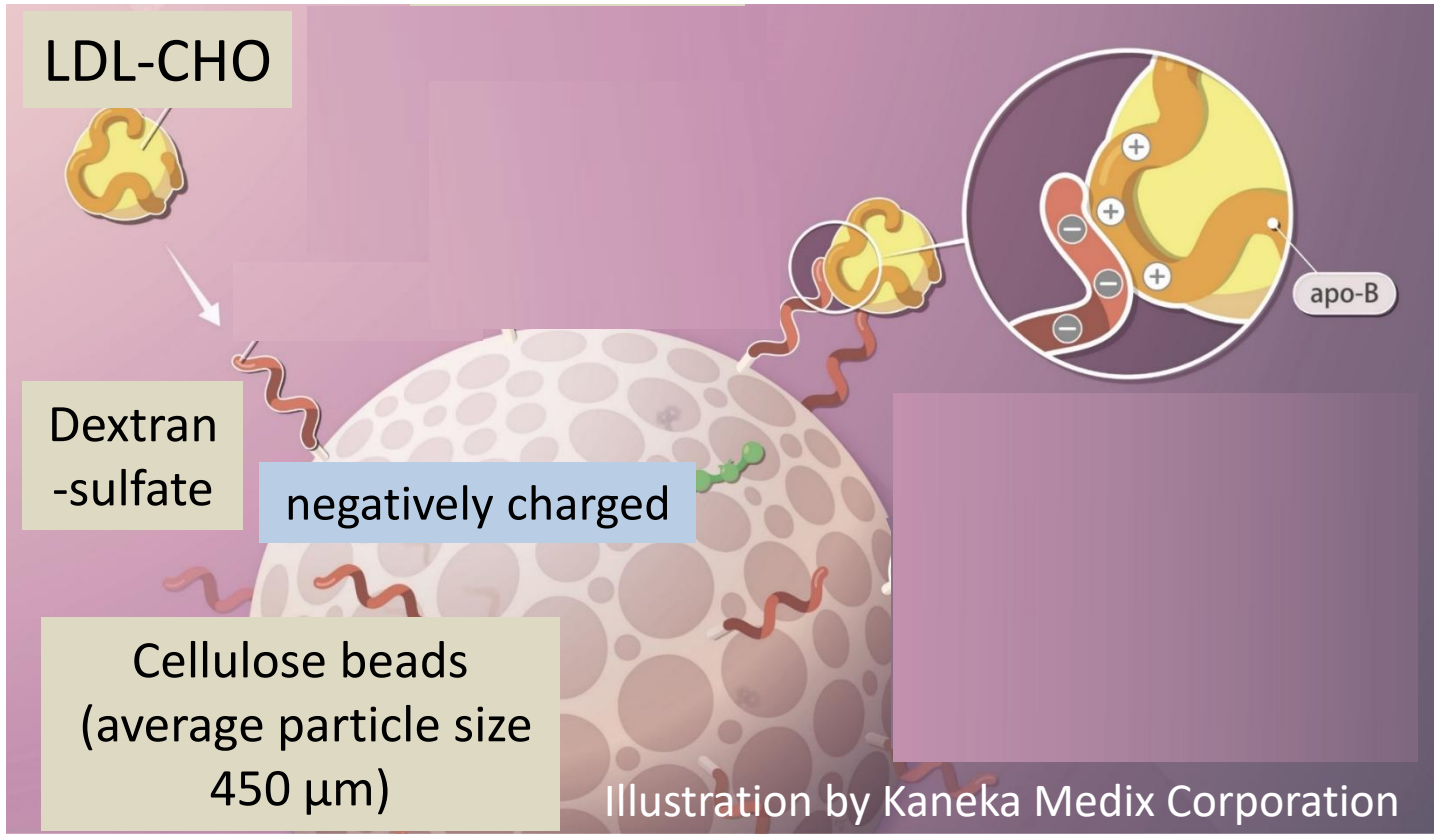
Rheocarna: Novel Adsorptive Blood Purifier

Cellulose beads in the column

Kaneka Medix Corp.

Removes substances that increase blood viscosity:

- LDL cholesterol
- Fibrinogen



LDL cholesterol: removed by binding to dextran sulfate on cellulose beads.

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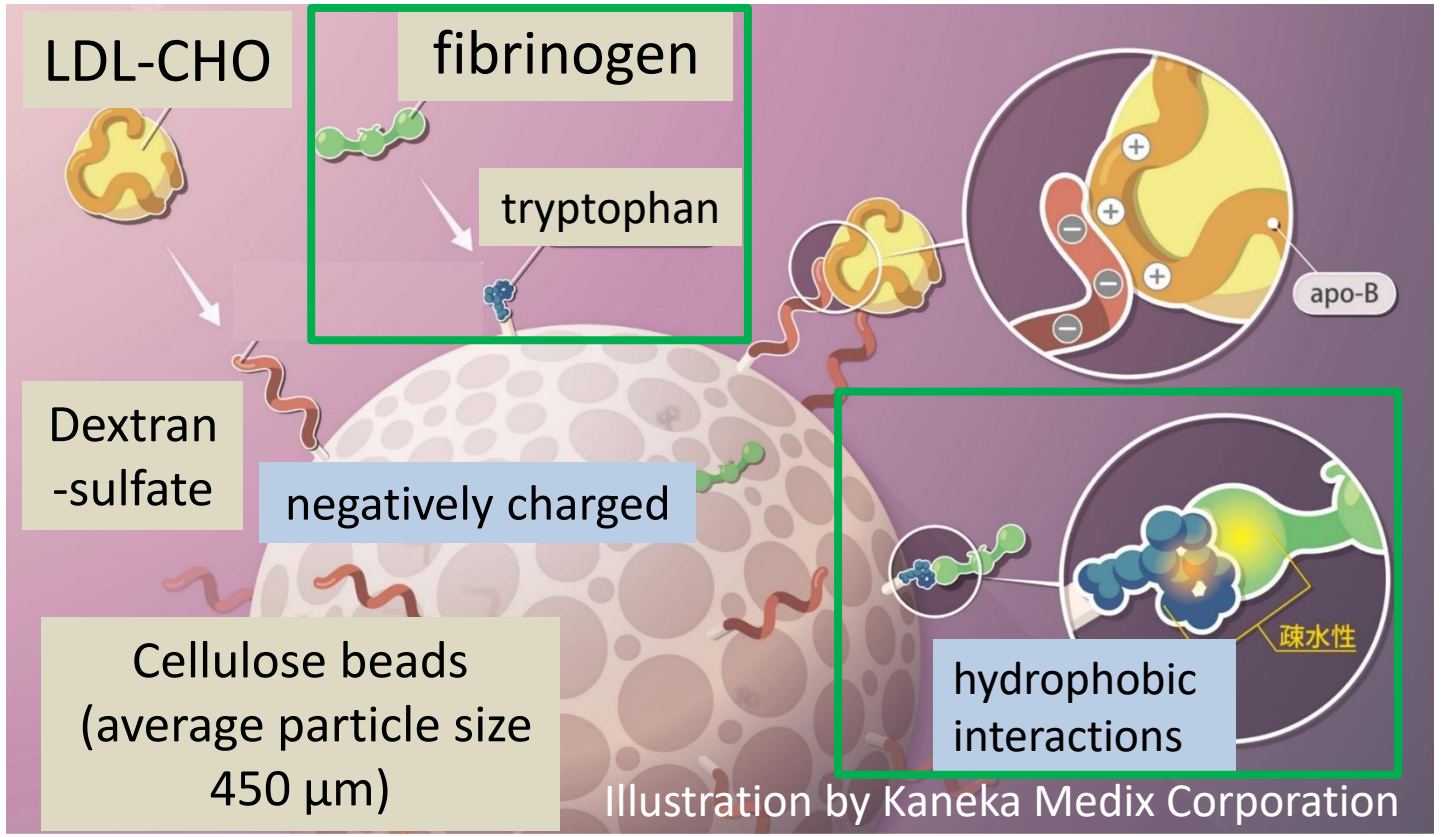
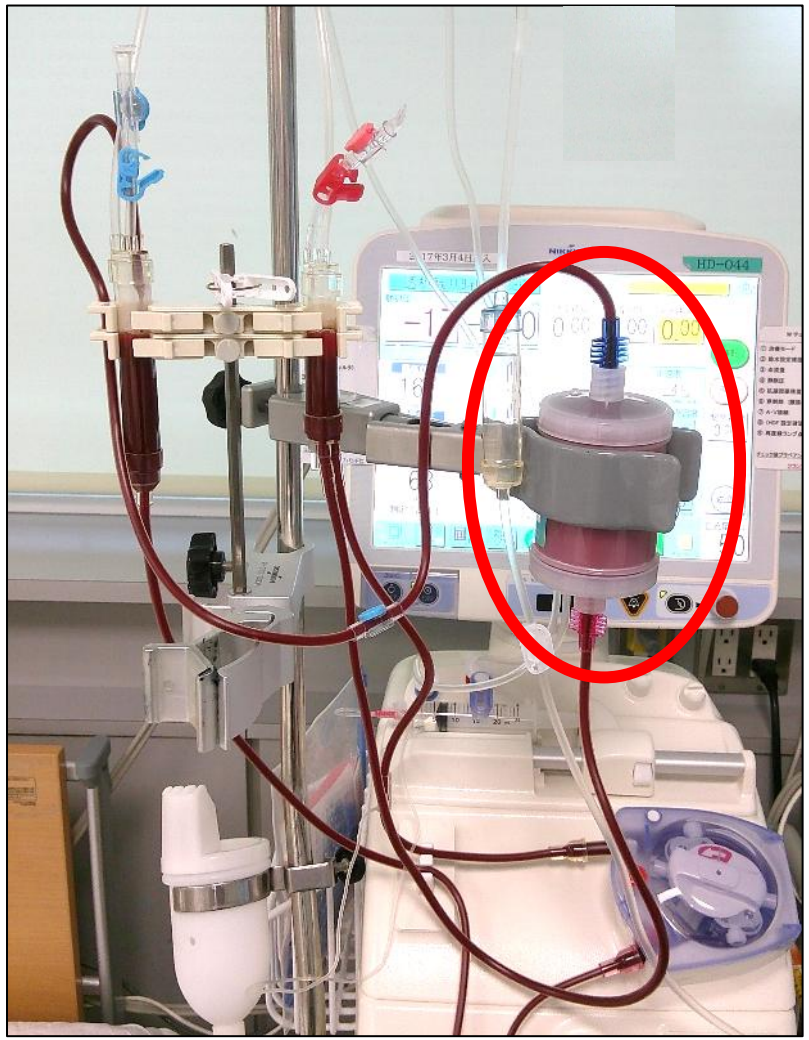


LDL cholesterol: removed by binding to dextran sulfate on cellulose beads.
Fibrinogen: removed by binding to tryptophan.

These processes help improve microcirculation.

How Rheocarna Therapy Is Performed



Rheocarna therapy:

- 2 h/session,
- 2 sessions/week,
  (performed before dialysis or on non-dialysis days)
- 24 sessions/cycle

Subjects

Cases: 191 Rheocarna treatments,17 patients

(at our facility from May 2022 to Oct 2024)

Mean age: 72 years

Sex ratio: Male–to–female: 2.4:1

Underlying diseases leading to dialysis:

Diabetes: 12, Nephrosclerosis: 2, Other: 3

Wound assessment (WIfI classification):

6 patients: Grade 3, 8 patients: Grade 2,

3 patients: Grade 1

WIfI cllasification

Wound (W)

0: No ulcer or gangrene

1: Small or superficial ulcer on leg or foot, without gangrene

2: Deep ulcer with exposed bone, joint, or tendon ± gangrene limited to digits (MAD or standard TMA ± SC)

3: Deep, extensive ulcer involving forefoot and/or midfoot ± calcaneal involvement ± extensive gangrene (CR of the foot or nontraditional TMA)

Journal of vascular surgery, 2014

Methods

Retrospective case series study

- **Therapeutic assessment:** wound evaluation (WIfI classification)
- **Laboratory data:** serum LDL-C, fibrinogen, and CRP levels before and after each Rheocarna session
- **Safety evaluation:** blood pressure, subjective symptoms and clotting in the dialysis circuit
- **Medical cooperation:** management system for Rheocarna therapy

Effectiveness of Rheocarna Therapy

Caset	Age	Sex	Severity Before Treatment (WIfI) (Wound grade)	Number of Rheocana Treatments Until Discharge	Severity at Discharge (WIfI) (Wound grade)	**Treatment Effect Assessment at Discharge**
1	87	M	2	6	2	**Stable**
2	75	F	1	24	1	**Stable**
3	75	F	1	24	1	**Stable**
4	69	M	3	24	2	**Healing**
5	72	M	2	24	1	**Healing**
6	82	M	1	24	3	**Worsened**
7	65	M	3	24	1	**Healing**
8	70	M	3	14	2	**Healing**
9	53	M	3	15	2	**Healing**
10	89	M	2	1	2	**Stable**
11	82	M	3	17	2	**Healing**
12	62	M	2	25	1	**Healing**
13	73	F	2	24	2	**Healing**
14	65	M	3	17	3	**Stable**
15	77	M	2	6	2	**Stable**
16	58	F	2	2	2	**Stable**
17	70	F	2	3	2	**Stable**

16±9 treatments

During hospitalization: No cases achieved complete healing; some were healing

Effectiveness of Rheocarna Therapy

Caset	Age	Sex	Severity Before Treatment (WIfI) (Wound grade)	Number of Rheocana Treatments Until Discharge	Severity at Discharge (WIfI) (Wound grade)	**Treatment Effect Assessment at Discharge**	Total Number of Rheocana Treatments (Including Post-Discharge)	Severity at End of Rheocana Therapy (WIfI) (Wound grade)	**Treatment Effect Assessment (Post-Discharge Follow-up: After Completion of Rheocana Therapy)**
1	87	M	2	6	2	**Stable**	6	2	**Stable**
2	75	F	1	24	1	**Stable**	24	0	**Healed**
3	75	F	1	24	1	**Stable**	24	1	**Healing**
4	69	M	3	24	2	**Healing**	24	2	**Healing**
5	72	M	2	24	1	**Healing**	24	0	**Healed**
6	82	M	1	24	3	**Worsened**	24	3	**Worsened**
7	65	M	3	24	1	**Healing**	48	0	**Healed**
8	70	M	3	14	2	**Healing**	14	2	**Healing**
9	53	M	3	15	2	**Healing**	39	0	**Healed**
10	89	M	2	1	2	**Stable**	1	2	**Stable**
11	82	M	3	17	2	**Healing**	22	2	**Healing**
12	62	M	2	25	1	**Healing**	25	0	**Healed**
13	73	F	2	24	2	**Healing**	24	0	**Healed**
14	65	M	3	17	3	**Stable**	17	3	**Worsened**
15	77	M	2	6	2	**Stable**	6	2	**Stable**
16	58	F	2	2	2	**Stable**	19	3	**Worsened**
17	70	F	2	3	2	**Stable**	24	0	**Healed**

16±9 treatments

21±11treatments

End of Rheocana Therapy: 41% (7 cases) Healed / 24% (4 cases) Healing

Effective Cases of Rheocarna Therapy

Case 5: 72 y/o Male
Primary Dis.: Diabetes, 5-M Dialysis

After 6 Rheocarna treatments:
WIfI: Wound Stage 2

Case 7: 65 y/o Male
Primary Dis.: Daibetes, 11-Y Dialysis

After 7 Rheocarna treatments:
WIfI: Wound Stage 3

Case17:70 y/o female
Primary Dis.:CGN, 27-Y Dialysis

Before Rheocana Therapy
WIfI: Wound Stage 2

Effective Cases of Rheocarna Therapy

Case 5: 72 y/o Male
Primary Dis.: Diabetes, 5-M Dialysis

After 6 Rheocarna treatments:
WIfI: Wound Stage 2

After 24 Rheocarna treatments:
WIfI: Wound Stage 0

Case 7: 65 y/o Male
Primary Dis.: Daibetes, 11-Y Dialysis

After 7 Rheocarna treatments:
WIfI: Wound Stage 3

After 24 Rheocarna treatments:
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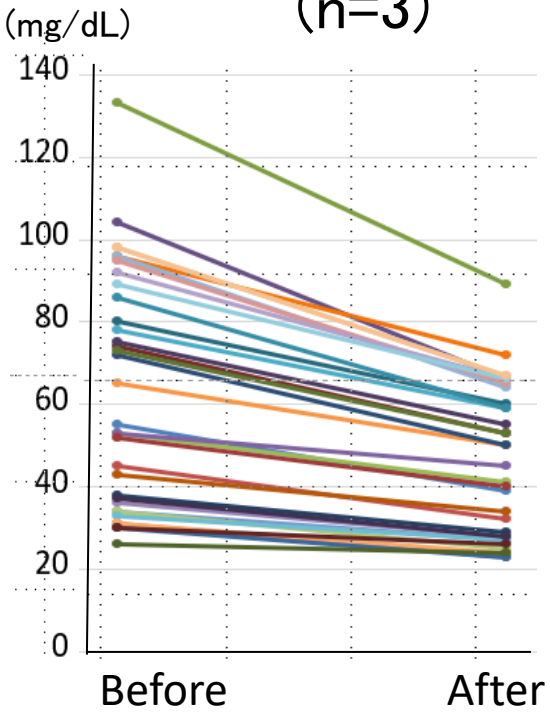
Case17:70 y/o female
Primary Dis.:CGN, 27-Y Dialysis

Before Rheocana Therapy
WIfI: Wound Stage 2

After 24 Rheocana Treatments:
WIfI: Wound Stage 0

Laboratory Data: Before and After 2-Hour Rheocarna Therapy

LDL-Cholesterol (n=3)



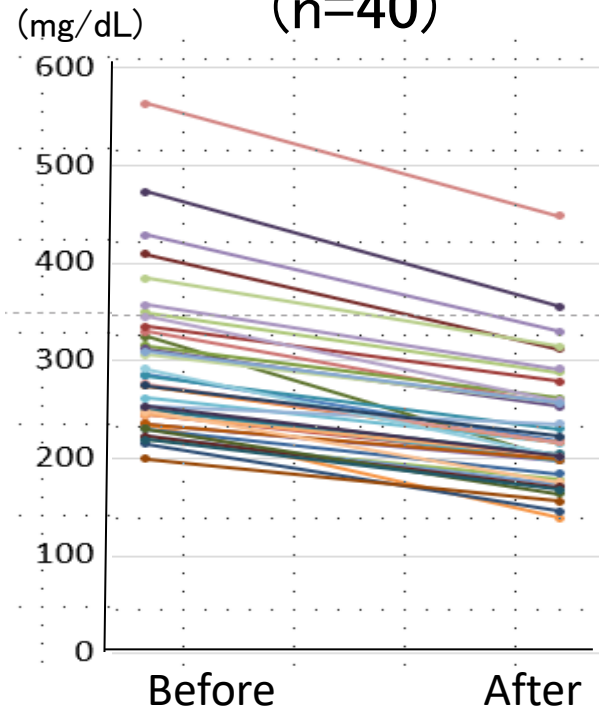
Mean 63.7 SD 27.94

Mean 46.4 SD 18.27

Removal Rate 26±7%

(p<0.001)

Fibrinogen (n=40)



Mean 292.7 SD 75.93

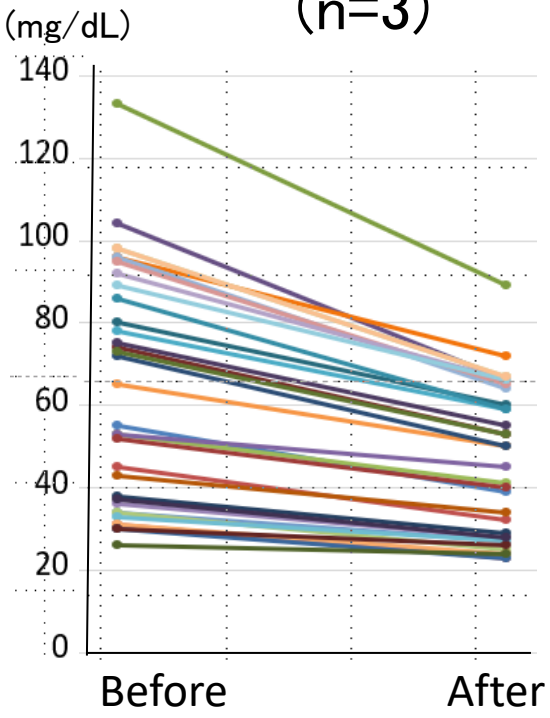
Mean 229.5 SD 62.05

Removal Rate 22±6%

(p<0.001)

Laboratory Data: Before and After 2-Hour Rheocarna Therapy

LDL-Cholesterol (n=3)



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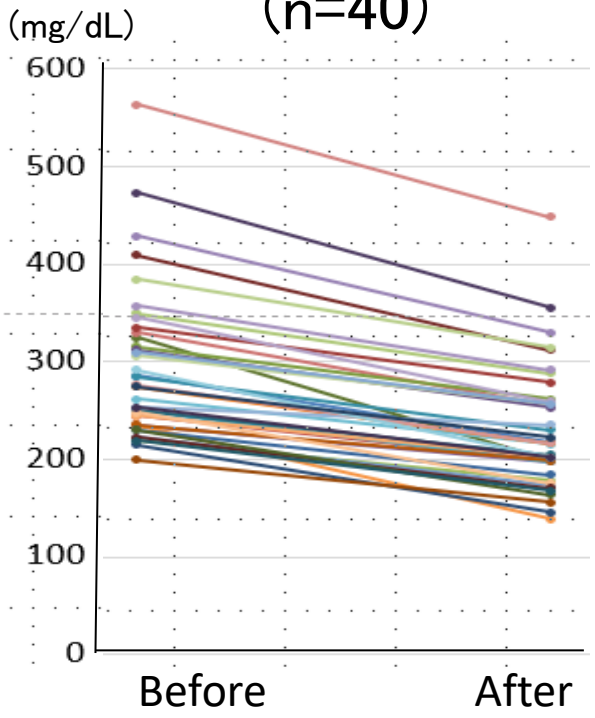


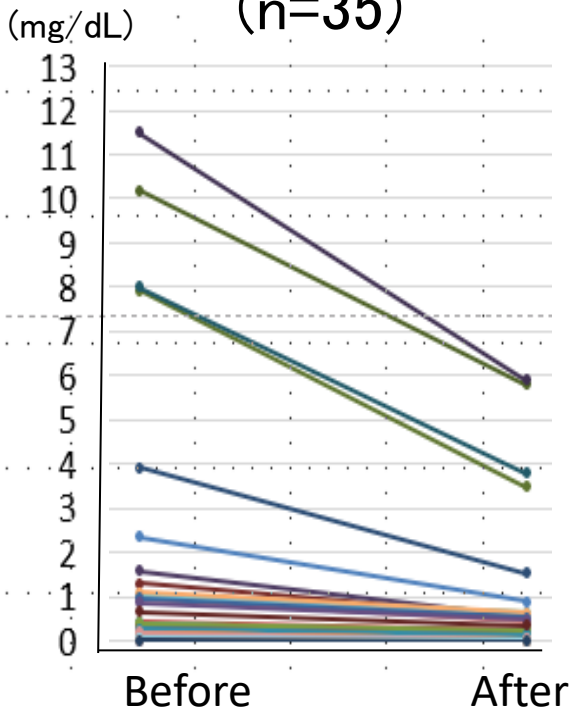
Mean 292.7 SD 75.93

Mean 229.5 SD 62.05

Removal Rate 22±6%

(p<0.001)

CRP (n=35)



Mean 1.6 SD 2.94

Mean 0.8 SD 1.50

Removal Rate 51±11%

(p<0.001)

CRP

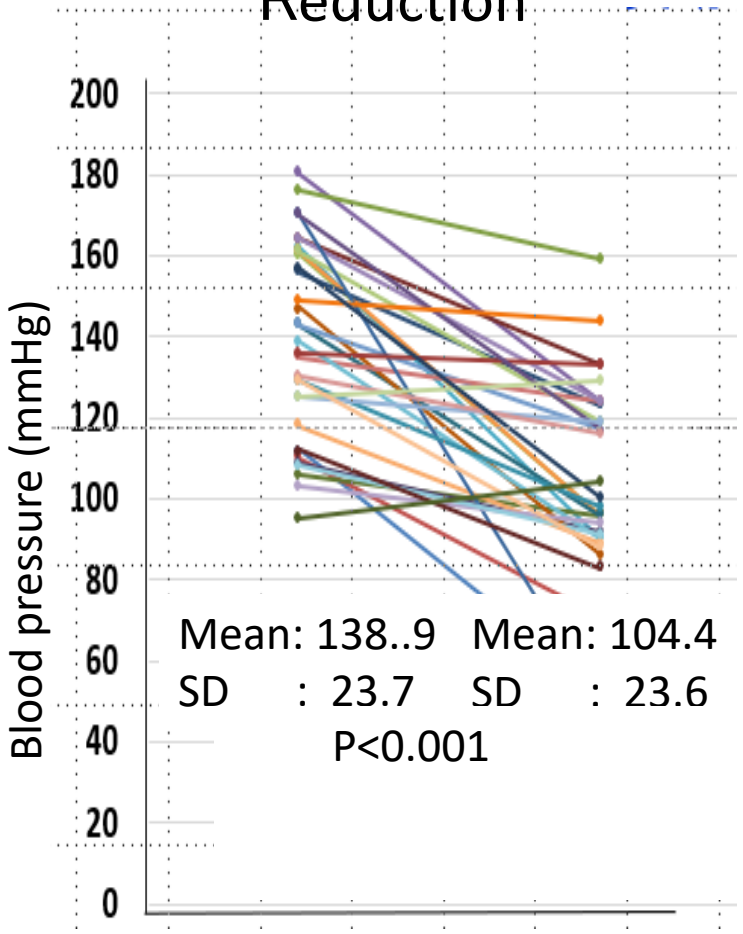
・・associated with Complement activation, inflammation

Rheocarna therapy may improve microcirculation and reduce inflammation

Safety

BP Reduction & Circuit Clotting during Reokana

Blood Pressure Reduction



BP reduction during Rheocarna:
≥30 mmHg drop: 57.6% (19/33);
89.5% of those occurred within 30 min and most recovered spontaneously

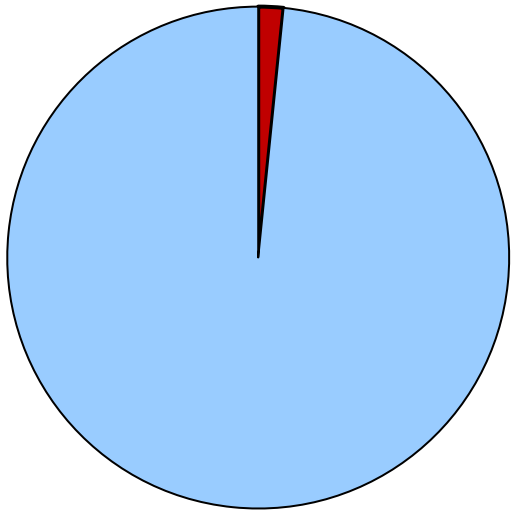
Symptoms: 94% had no symptoms
2 cases (malaise, nausea) managed with fluids and vasopressors

No sessions discontinued due to hypotension

Circuit Blood Clotting

(Heparin used in all cases)

3/191 : 1.6% of treatments



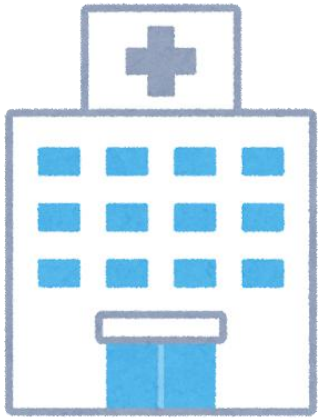
Controlled by increasing the heparin dose.

Medical Cooperation in Rheocarna Therapy (n=17)

Regional core hospitals

EVT (Endovascular treatment)
Bypass surgery
Amputation

9 cases (53%):
continued from regional core hospitals:



Kichijoji Asahi Hospital

8 cases (47%): initiated at our hospital

Dialysis Clinics

14 cases (82%):discharged to dialysis clinics to continue Rheocarna therapy

Conclusion

- Rheocarna therapy is effective in promoting wound healing in patients with CLTI on hemodialysis.
- Its effects may be related to reduced blood viscosity and suppression of inflammation.
- The therapy can be safely performed in patients with CLTI on hemodialysis.
- Strong medical cooperation is essential for delivering Rheocarna therapy.

Thank you for your attention