

This is a Fresenius Medical Care summary of:

## Safety aspects of lipidapheresis using DALI and MONET – Multicenter observational study

Kozik-Jaromin J et al. Germany, *Atheroscler Suppl* 2017;30:225–231

### Introduction

The relative lack of selectivity offered by plasma exchange and the necessity to replace plasma by other fluids has encouraged the development of selective lipidapheresis devices. In this study, direct adsorption of lipoproteins (DALI) and lipoprotein filtration (MONET) were investigated for their short and long-term safety, although the therapies are regarded as generally safe.

### Design

This was a German multicentre, open, prospective, observational trial. The lipidapheresis prescription adhered to the standard operating procedures of the participating centres. Data from 11 centres of 122 patients treated for at least 3 months was collected over 2 years. Routine lipid measurements from 2,154 DALI and 1,297 MONET sessions were evaluated. Adverse device effects (ADEs), technical complications, and treatment parameters, including heart rate and blood pressure, were reported.

### Results<sup>1</sup>

#### Treatments affected by ADEs and technical complications

	MONET n = 1,297	DALI n = 2,154
ADEs	0.4%	0.5%
Technical complications*	0.8%	2.1%

#### Reduction of thrombocytes and proteins\*

	MONET n = 1,297	DALI n = 2,154
Thrombocytes	8%	7%
Fibrinogen	58%	23%
Albumin	12%	7%
CRP	38%	24%

\* Technical complications adapted from Table 4 and Reduction of thrombocytes and proteins adapted from Table 5 of: Kozik-Jaromin J. et al.; *Atherosclerosis Supplements* 2017;30:225-231

#### ADEs per treatment

Symptoms	MONET n = 1,297 (Number of events)	DALI n = 2,154
Paleness	1	3
Hypotension	4	4
Headache	0	1
Vomitus	1	0
Edema	0	1
Nausea	1	2
Other*	2	7
<b>Total</b>	<b>9</b>	<b>18</b>

\* see publication for details

#### Technical complications per treatment

	MONET n = 1,297	DALI n = 2,154
Handling	2	0
Blood flow (technical problem)	1	7
Disposable problem	1	6
Machine problem	2	8
Puncture problem	2	25
MONET filtration problem	2	0
MONET plasma filtration problem	1	0
DALI adsorber problem	0	0

<sup>1</sup>Data and charts adapted from: Kozik-Jaromin J. et al.; *Atherosclerosis Supplements* 2017;30:225–231

### Conclusion

According to the authors: "...under routine use the frequency of side-effects is low with both systems. Changes of laboratory parameters typically did not lead to clinical manifestations and thus did not pose clinical concern. Still, monitoring of blood count and proteins in chronic apheresis patients is recommended."