Intradialytic hypotension (IDH): Effective reduction of hypotensive episodes (HE) by blood pressure–guided automated ultrafiltration control (bioLogic RR® Comfort)

B. Braun Avitum AG, Clinical Development

Background: Hypotensive episodes (HE) still belong to the most frequent and debilitating side effects of dialysis therapy. Intradialytic hypotension is a multifactorial event, preventive measures are of limited efficacy. Different technical methods have been applied in the past such as ultrafiltration (UF) profile or sodium profiling, temperature control or measurement of blood volume in order to prevent HE. All HE methods have their restraints. In contrast to surrogate parameters, blood pressure (BP) represents comprehensively the cardiovascular situation of the patient. The systolic BP (RR sys) itself, therefore, is used as an input parameter by bioLogic RR® Comfort. This automatic biofeedback-controlled BP-stabilising system regulates UF rates depending on the individual course of BP during therapy. In addition, bioLogic RR® Comfort uses a so called "guideline" technique based on analysis of up to 50 previous haemodialysis (HD) sessions in order to optimize the regulation of UF rate and BP thereby grossly reducing the frequency of required BP measurements. BP measurement intervals may, therefore, be extended up to 30 min. This BP-guided closed-loop system automatically regulates UF and hypertonic saline infusion rates depending on measured BP values. Objective of the study was to determine the effect of bioLogic RR® Comfort on the frequency and severity of HE in patients prone to intradialytic hypotension.

Methods: In this open, single-arm, retro- and prospective multicentre study 27 patients with a defined predisposition to intradialytic hypotension were observed in routine settings in German dialysis centres during a total observational period of 25 weeks. Data was evaluated retrospectively for 20 dialysis treatments (7 weeks) under conventional HD and prospectively for 54 dialysis treatments (18 weeks). Prospective treatments were performed using the Dialog Advanced dialysis machine (B. Braun Melsungen AG) where the bioLogic RR® Comfort was implemented. The device was used within product certification (CE). Eligible patients were identified by retrospective data collection and evaluation of data related to the patient's last 20 HD sessions. They must have had HE in 25% or more of their foregoing HD sessions. 1998 treatments were documented. The occurrence of HE, clinical symptoms, and therapeutic measures during HE were assessed. 3 specified periods of the observational period were chosen for documentation of dialysis parameters. Irrespective of the occurrence of an HE the total UF volume, the effective time of dialysis, and the trend data of each session were documented and filed.

Results: The proportion of dialysis treatments with HE decreased from 59.7% (n = 538) observed without bioLogic RR® Comfort to 34.2% (n = 1339) during the observational

phase with bioLogic RR® Comfort. The effectiveness of the system increased over time. In the first weeks with bioLogic RR® Comfort, the incidence of HE was reduced from 59.7% of the retrospective treatments to 39.3% of the prospective treatments (treatment No. 1 to 24). After 16 weeks, HE only occurred in 28.1% of treatments (treatment No. 49–54) (p = 0.001). bioLogic RR® Comfort was effective both in severe and mild HE. The incidence of severe HE was reduced by 44% from 52.8% (n = 540) without bioLogic RR® Comfort to 29.4% (n = 1458) with bioLogic RR® Comfort, the incidence of mild HE was reduced by 41% from 10.7% to 6.3%. Similarly, clinical symptoms related to HE (data not shown) as well as the need for therapeutic actions were significantly reduced. No changes in UF volume and total effective dialysis time were found in the selected observational period. The results of the study demonstrate, that the BP-stabilising system bioLogic RR® Comfort is effective in reducing HE in patients prone to intradialytic hypotension by 43%. bioLogic RR® Comfort achieves improvement in reduction of HE over time. The system is "learning" by continually updating and processing individual patient data thus stabilising the clinical course of patients. The reduction of hypotension-related symptoms benefits the patients, while the decreased need for therapeutic action supports a more stable and effective HD treatment in the long-term.

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