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A multicenter feasibility study on ultrafiltration via a single peripheral venous access in acute heart failure with overt fluid overload☆

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ABSTRACT

Objectives: The need for a central venous catheter has limited the widespread use of ultrafiltration in daily clinical practice for the treatment of acute heart failure (AHF) with overt fluid overload. We evaluated the feasibility of a new ultrafiltration device, the CHIARA (Congestive Heart Impairment Advanced Removal Approach) system, that utilizes a single-lumen cannula (17G, multi-hole) inserted in a peripheral vein of the arm.
Methods: In this multicenter, prospective, feasibility study, consecutive ultrafiltration treatments (lasting ≥6 hours and with an ultrafiltration rate ≥100 ml/h) with the CHIARA device and a single peripheral venous approach were performed at 6 Italian hospitals. For each session, we evaluated the performance of the venous access, the ultrafiltrate volume removed, and the cause of its interruption.
Results: One-hundred-three ultrafiltration sessions were performed in 55 patients with AHF (average 1.9 ± 1.7 treatment/patient). The overall median length of ultrafiltration treatment was 14 h (interquartile range 7–21) with removal of 3266 ± 3088 ml of fluid (183 ± 30 ml/hour). The treatment was successfully completed in 92 (89%) sessions and in 80% of patients. The mean suction flow rate from the vein was 70 ± 20 ml/min, while the mean re-injection flow rate was 98 ± 26 ml/min. There were no clinically relevant complications related to the venous access and/or to the anticoagulant therapy with heparin.
Conclusions: The study demonstrated that the CHIARA system satisfies clinical applicability and efficacy criteria in the treatment of AHF, in terms of adequate fluid removal through a single peripheral venous access.

1. Introduction

Extracorporeal ultrafiltration has been proposed for the treatment of patients with acute heart failure (AHF) and overt fluid overload not fully responsive to diuretics and as an alternative to high-dose diuretic therapy, with the aim to obtain more decongestion and less neurohormonal activation [1–5]. Although it represents a rapid and physiologic method of fluid removal, the need for a double-lumen central venous catheter (CVC) and for admission to the Intensive Care Unit (ICU) has limited its widespread use in daily clinical practice. These limitations can possibly be overcome by the recent development of a new dedicated device for ultrafiltration, the CHIARA (Congestive Heart Impairment Advanced Removal Approach) system that uses a single-lumen cannula inserted in a peripheral vein of the arm. This system is based on a push-pull syringe pump, a ball with an inner silicone membrane for blood and saline separation, and two check valves that drive the blood from and to the same peripheral vein through alternate flows, which can be adjusted separately (Fig. 1).

The CHIARA system has never been used in the clinical setting thus far, and we have no information about its operative performance. Therefore, we designed a multicenter study to evaluate the feasibility of this innovative "minimal invasive" ultrafiltration approach for the treatment of AHF.

2. Methods

2.1. Study population

Patients with AHF and overt fluid overload were consecutively enrolled from January 31st, 2013 to December 31st, 2015, at 6 Italian hospitals.

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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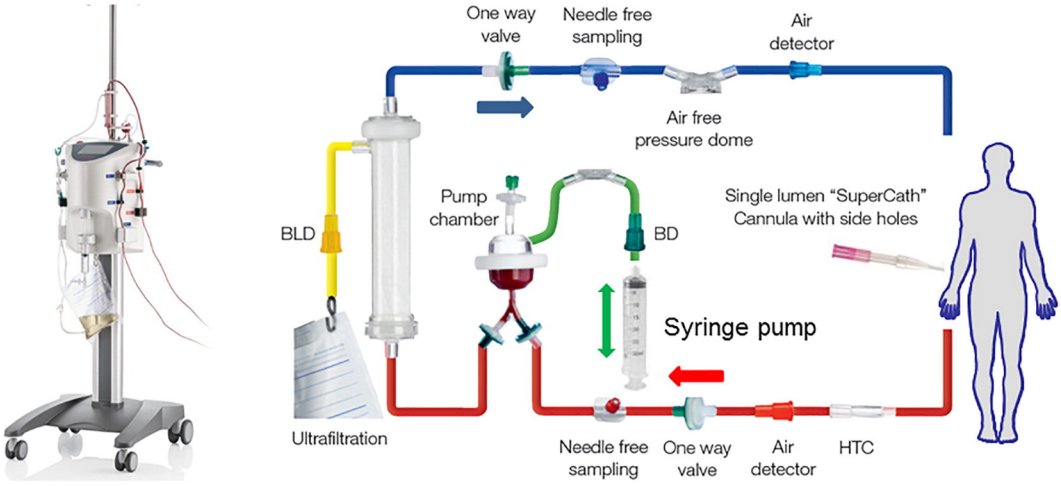

Fig. 1. Left = the CHIARA system; right = scheme of ultrafiltration using the CHIARA system, based on an alternating axial piston pump, constituted by a syringe, a blood/saline separation ball (pump chamber) and two unidirectional valves, that draws and re-injects the blood from and to the same peripheral vein of the arm. BD = blood detector; BLD = blood leakage detector in the ultrafiltrate line; HTC = hematocrit sensor.

Inclusion criteria were: AHF with age > 18 years, New York Heart Association (NYHA) functional class III or IV, systolic and/or diastolic dysfunction, estimated weight gain due to peripheral fluid overload ≥4 kg in the preceding 2 months (estimation of reference body weight was based on body weight referred by the patient as their normal weight), poor response to intravenous diuretics at discretion of the treating physician, and an adequate peripheral venous access allowing a withdrawal flow rate ≥ 60 ml/min (suitable peripheral access). Exclusion criteria were: contraindications to anticoagulation, severe renal insufficiency (serum creatinine ≥ 3.0 mg/dl), acute pulmonary edema, cardiogenic shock, and presence of acute or chronic clinical conditions considered by the clinicians as potential contraindications to ultrafiltration.

The investigation conforms with the principles outlined in the Declaration of Helsinki. The Ethical Committees of all the institutions approved the research protocol, and all subjects gave written informed consent to participate in the study.

2.2. Study protocol

This study was designed as a prospective, open-label, observational, multicenter study. A complete clinical and laboratory evaluation was made, with particular attention to body weight and fluid balance, renal function (serum creatinine concentration, estimated glomerular filtration rate [eGFR]), and plasma electrolytes, all of which were evaluated before and 24 h after ultrafiltration. All eligible patients were then treated with a single or multiple session(s) of ultrafiltration. Ultrafiltration sessions were performed only during the hours of the day (maximal length allowed for each single session 12 h); this was planned in order to avoid nurse work overload during the night shift. If required, a new session was performed the following morning after a temporary treatment withdrawal during the nighttime. The same peripheral venous cannula was maintained during the overall ultrafiltration treatment.

All ultrafiltration treatments were performed with the CHIARA system (MediCon Ingegneria S.r.l., Budrio [Bologna], Italy) and a dedicated circuit (CHIARAKIT, Haemotronic®, S.p.A., Mirandola [Modena], Italy). The initial ultrafiltration rate, as well as its possible adjustment during the procedure, was left to the discretion of the physician in charge of the patients. Cumulative fluid removal (ultrafiltration plus urine output) was recommended not to exceed 75% of the estimated initial body weight increase to reduce the risk of hypovolemia-induced acute kidney injury associated with excessive dehydration [6]. Achievement of this target was defined as end of treatment. Moreover, hematocrit changes (%) were automatically and continuously monitored inside the extracorporeal circuit by a dedicated integrated sensor in order to guide physicians for ultrafiltration rate adjustments (reduction of ultrafiltration rate in case of hematocrit increase), and thus prevent hypovolemia during ultrafiltration [3]. Additional pharmacologic therapy was left to the discretion of the cardiologist in charge of the patient. Specifically, diuretic therapy withdrawal was not required and continuation of diuretic therapy at unchanged doses recommended during ultrafiltration sessions.

2.3. Peripheral venous access

In order to increase the success rate and avoid premature circuit failure and/or filter clotting, accurate preliminary selection and evaluation of the peripheral vein access were performed. The choice of venous access followed this sequence: antecubital veins, cephalic veins, and basilic veins. A single-lumen cannula (17 gauge, single-lumen, multihole, 25–32 mm long catheter) was inserted in the best approachable vessel; the withdrawal flow rate was manually estimated by a syringe and a dedicated device (Haemocatch®, Haemotronic®, S.p.A., Mirandola [Modena], Italy). In patients in whom a withdrawal flow rate ≥ 10 ml/10 s was confirmed, ultrafiltration treatment was started. Patients without adequate withdrawal flow rate through the peripheral cannula were excluded from the study; in these patients, the decision to use a CVC, as an alternative approach for ultrafiltration, was left to the discretion of the physician.

2.4. Anticoagulation protocol

The following anticoagulation protocol was recommended during ultrafiltration: a loading bolus of 3000–5000 IU heparin (2000 IU for patients with an international normalized ratio value ≥ 2) was directly administered into the circuit, upstream the filter; then, a continuous heparin infusion rate of 500–800 UI/h was maintained during the entire ultrafiltration session. Lower heparin bolus and infusion rates were allowed if clinically indicated. Due to the short duration of each ultrafiltration session, no measurement of anticoagulation parameters for adjustment of heparin dose was required.

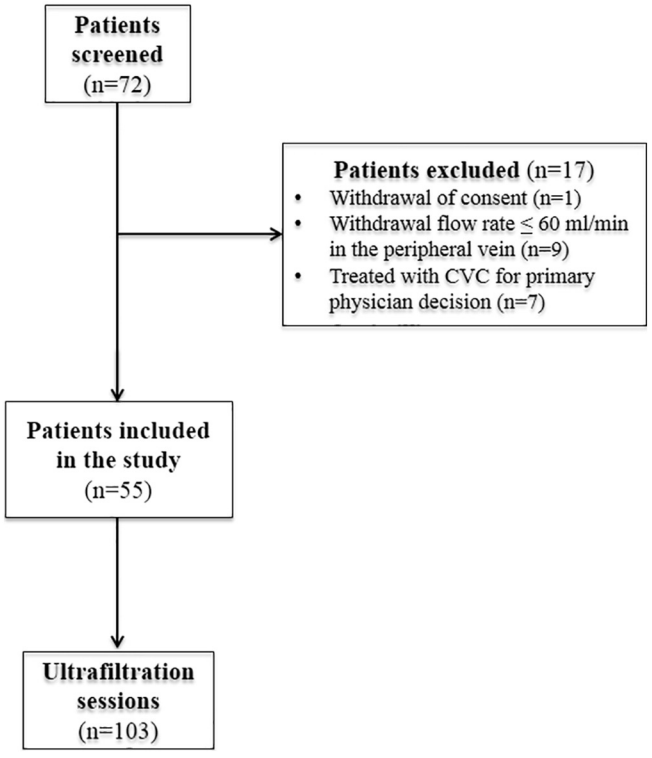

Fig. 2. Diagram showing the flow of participants through each stage of the study. CVC = central venous catheter.

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