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MECHANIZED LYMPHATIC DRAINAGE IN ACUTE DECOMPENSATED HEART FAILURE. A STUDY ON A HYDRODYNAMIC TEST BENCH

A.S. Buchnev[1], *G.P. Itkin*[1, 2], *A.A. Drobyshev*[1], *A.P. Kuleshov*[1], *O.Yu. Esipova*[1], *A.I. Syrbu*[1]

[1] Shumakov National Medical Research Center of Transplantology and Artificial Organs, Moscow, Russian Federation

[2] Moscow Institute of Physics and Technology, Moscow, Russian Federation

Objective: to investigate the effectiveness of a new mechanized lymphatic drainage method in acute decompensated heart failure (ADHF) modeling through local reduction in venous pressure in the site of lymphatic drainage from the thoracic duct. **Materials and methods.** Main components of the device are a catheter with built-in inlet and outlet mechanical valves designed for insertion into the left brachiocephalic vein through the left internal jugular vein. It comes with an extracorporeal drive system made as a valveless pulsator pump with a 10 ml shock discharge and a controller ensuring preset frequency and pressure/rarefaction duty cycle. The operating principle of the device is based on local reduction of venous pressure in the site of lymphatic drainage from the thoracic duct (in the junction of the left internal jugular and subclavian veins). **Results.** When modeling hydrodynamics under ADHF conditions on a hydrodynamic test bench, the upper venous flow through the left brachiocephalic vein was 0.4 l/min, the pressure in the site of lymphatic drainage from the thoracic duct, was decreased from 20–25 mmHg to 0–5 mmHg due to operation of the mechanized drainage device with suction/injection phase duration ratio 0.2/0.8 and pulsator pump operating frequency from 30 to 60 beats/min.

Keywords: lymphatic system, thoracic duct, heart failure, local decrease in venous pressure, catheter, pulsator pump.

INTRODUCTION

As we know, ADHF remains the most common cause of emergency hospitalization requiring intensive care and is accompanied by high patient mortality. Approximately half of patients with ADHF are discharged from the hospital not fully recovered and about 25% of patients require rehospitalization within one month, and over 50% are rehospitalized after 6 months and almost 66% of the total number die [1–4].

One of the main symptoms of ADHF disease is the phenomena of organ and tissue edema associated with difficulties in the lymph discharges into the venous system due to increased central venous pressure (CVP) [5–10]. At the same time, pharmacotherapeutic agents based on loop diuretics have limited progress in improving the condition of these patients, many of whom become resistant to such therapy [11–14].

It is known that under physiological normal conditions, $^3/_4$ of the lymph drains into the left subclavian vein through the left thoracic duct (TD) and $^1/_4$ of the lymph flows through the right lymphatic duct into the right subclavian vein. In ADHF, increased CVP makes it difficult for lymph to drain into the venous system. Lack of progress in pharmacotherapy of patients with ADHF, based on the use of loop diuretics, have limited progress in improving the condition of these patients, with resistance to their administration in many cases [15, 16]. This has stimulated the development of a number of new methods aimed at normalizing lymph circulation in these patients. In separate early works, it was shown that in patients with ADHF, external TD decompression can improve such symptoms of the disease as dyspnea, orthopnea, and anorexia [17]. External TD drainage can lead to significant metabolic, immunological and fluid imbalance. TD shunting into the pulmonary vein has also been described, but it requires complex surgical procedures [18, 19]. Therefore, the problem of creating conditions for local reduction in venous pressure in the site of lymphatic drainage from the TD, remains rather acute.

One of the first developments of such system proposed by WhiteSwell is based on the use of an axial pump built into an intravenous venous catheter inserted into the left internal jugular vein with blood intake from the site of lymphatic drainage from the TD, and blood discharge into the left brachiocephalic vein (Fig. 1) [20, 21].

The device for local reduction of venous pressure in the site of lymphatic drainage from the thoracic duct is

Corresponding author: Alexander Buchnev. Address: 1, Shchukinskaya str., Moscow, 123182, Russian Federation. Phone: (926) 470-09-88. E-mail: labbts@mail.ru

based on the use of an intravenous catheter (1) with a mechanically driven axial pump (2) installed in it using a shaft from an external drive (3). The catheter (1) is inserted into the left internal jugular vein (5) before entering the left brachiocephalic vein (6), with heparin continuously injected between the pump drive cable and the catheter to reduce the possibility of thrombosis [22], potentially causing bleeding during this procedure.

Local reduction of venous pressure in the site of lymphatic drainage from the thoracic duct (7), is performed by drawing blood through the drainage orifice (8) located in the area of confluence of the left internal jugular (5) and subclavian (9) veins, and releasing blood into the brachiocephalic vein (6) at the axial pump outlet (2). To increase the efficiency of the system, there is an inflatable balloon (4) at the exit of the catheter (1) partially or completely blocking blood flow through the left brachiocephalic vein.

More than 20 patents were obtained for this system from 2016 to 2021. However, to date, there have been no publications on the implementation of these projects in experiment and clinical practice. Preliminary calculations show that for effective local reduction of venous pressure in the site of lymphatic drainage from the TD, in such a system, it is necessary to create a 0.8–1 l/min flow. As simple calculations show, in ADHF conditions with 50% reduction in cardiac output, the total venous flow in the upper parts of the circulatory system also decreases by 50% and is 0.8 l/min (0.4 l/min each for the left and right parts). Therefore, the flow of 0.8–1 l/min required to reduce local pressure in the site of lymphatic drainage from the TD, may result in venous stasis in the right upper veins. To solve this problem, we proposed a method and device based on pulse blood flow formation in the site of lymphatic drainage from the TD (Fig. 2) [23].

The device contains a catheter (1) introduced through the left internal jugular vein (5), connected to a valveless pump (2) with a pneumatic drive (3). Thus, reduction of local pressure in the lymphatic drainage site (7) is realized by displacement of blood volume from a given space through inlet valve (8) in the venous catheter into the chamber of the valveless pump (2). Thus, conditions of local pressure reduction in the site of lymphatic drainage from the TD (by analogy with WhiteSwell system operation mode) are created during the suction phase. During the injection phase of the valveless pump (2), blood volume returns to the venous circulation system through the exit valve (9) of the catheter. Thus, the average flow through the left brachiocephalic vein is maintained at the initial flow level (0.4 l/min).

MATERIALS AND METHODS

A hydrodynamic test bench (HTB) simulating upper left brachial venous system (Fig. 3) was developed to assess the effective performance of the mechanized lymphatic drainage system. The HTB includes: Rotaflow pump (Maquet Inc., Germany) (1) providing venous circulation under ADHF conditions at 0.4 l/min, venous reservoir (2) simulating right atrium entrance at 20–25 mmHg CVP, left superior venous system including left internal jugular vein simulator (3), left subclavian vein (4), and left brachiocephalic vein (7) with a thoracic duct simulator (5).

A catheter (6) with 5 mm internal diameter was inserted into the internal jugular vein simulator (3) up to the entrance to the left brachiocephalic vein (7) with an inlet valve (8) located at the level of the confluence of the left internal jugular vein (3) and left subclavian vein (4) (i.e., in the site of lymphatic drainage from the TD (5)) and an outlet mechanical valve (9) at the distal end of the catheter. The catheter is hermetically connected to

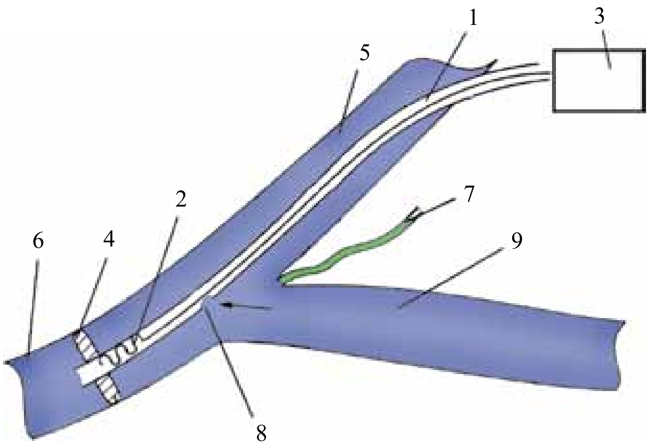

Fig. 1. Schematic diagram of the device for local reduction of venous pressure in the site of lymphatic drainage from the thoracic duct. WhiteSwell. 1, intravenous catheter; 2, axial pump; 3, external pump drive; 4, inflatable balloon catheter; 5, internal jugular vein; 6, brachiocephalic vein; 7, thoracic duct; 8, distal suction branch pipe; 9, left subclavian vein

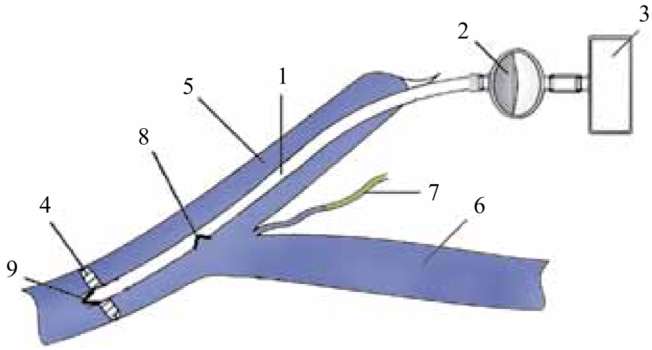

Fig. 2. A new method and device for local reduction of venous pressure in the site of lymphatic drainage from the TD. 1, intravenous catheter; 2, valveless pump; 3, external drive of the valveless pump; 4, inflatable balloon catheter; 5, left internal jugular vein; 6, left brachiocephalic vein; 7, thoracic duct; 8, inlet valve; 9, outlet valve

external valveless pump (10) with a flexible 20 ml diaphragm, driven by a pneumatic drive Sinus IS (MZEMA, Russia) (11) with a given frequency and pressure/rarefaction duty cycle. To increase the efficiency of the device, there is an inflatable balloon (12) behind the inlet valve (8) on the outer wall of the catheter, connected through a port to a separate channel (13) of the catheter to fill the balloon (12) with gas or liquid, providing partial/full blockage of the lumen between the left brachiocephalic vein (7) and the outer diameter of the balloon.

Fluid flow rate was recorded using a TS420 ultrasonic sensor (Transonic Systems, Inc, USA) (14, 15).

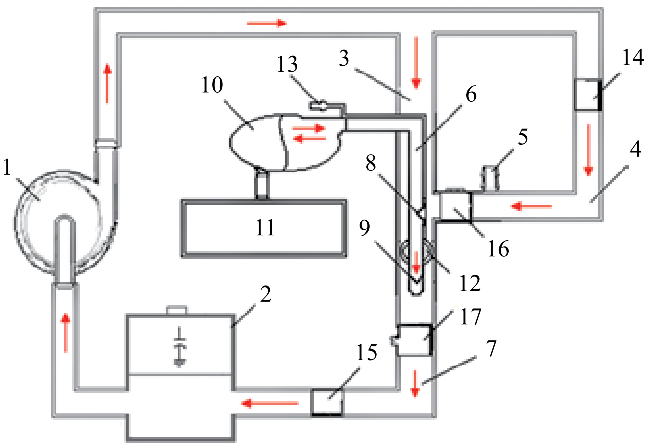

Fig. 3. Schematic diagram of hydrodynamic test bench. 1, Rotaflow centrifugal pump; 2, venous reservoir; 3, left internal jugular vein; 4, left subclavian vein; 5, thoracic duct; 6, intravenous catheter; 7, brachiocephalic vein; 8, inlet catheter valve; 9, outlet catheter valve; 10, valveless pump; 11, valveless pump drive; 12, inflatable balloon catheter; 13, balloon filling catheter; 14, fluid flow sensors in the left subclavian vein; 15, fluid flow sensors in the circuit; 16, pressure sensor located in the thoracic duct site; 17, pressure sensor in right atrium site

The pressure in the system was set at 20 ± 5 mmHg and recorded using pressure transducers (Edwards, USA) (16, 17) with the Angioton (Biosoft-M, Russia) multichannel hydrodynamic measurement module with data output to a personal computer for data recording and processing.

The system operation is determined by frequency of valveless pump and ratio of suction/injection phase durations. In the mode of fluid suctioning by the valveless pump (10) through catheter inlet valve (8), the pressure in the area of the junction of the left internal jugular and left subclavian veins will decrease, creating conditions for lymph drainage from TD into the venous system. In the injection mode, the valveless pump (10) ejects the withdrawn blood through the exit valve (9) of the catheter (6) into the left brachiocephalic vein (7). To maintain a given average blood flow through the left brachiocephalic vein at 0.4 L/min (in accordance with the conditions of venous circulation in ADHF), in this work, we chose 50 beats/min as the frequency of the valveless pump at a suction/injection phase duration ratio of 0.2/0.8.

RESULTS

A mechanized lymphatic drainage device with its valveless pump having changing frequency parameters, was tested on a hydrodynamic test bench. Based on the obtained data, a specialist can set the appropriate operating mode for the device for the greatest unloading (reduction of venous pressure in the site of lymphatic drainage from the thoracic duct). The data obtained are summarized in Table.

The effect of the mechanized lymphatic drainage device is shown in Fig. 4, which shows the dynamics of venous pressure obtained on the hydrodynamic test bench in ADHF (a) and in the operation of the device (b) in the site of lymphatic drainage from the thoracic duct.

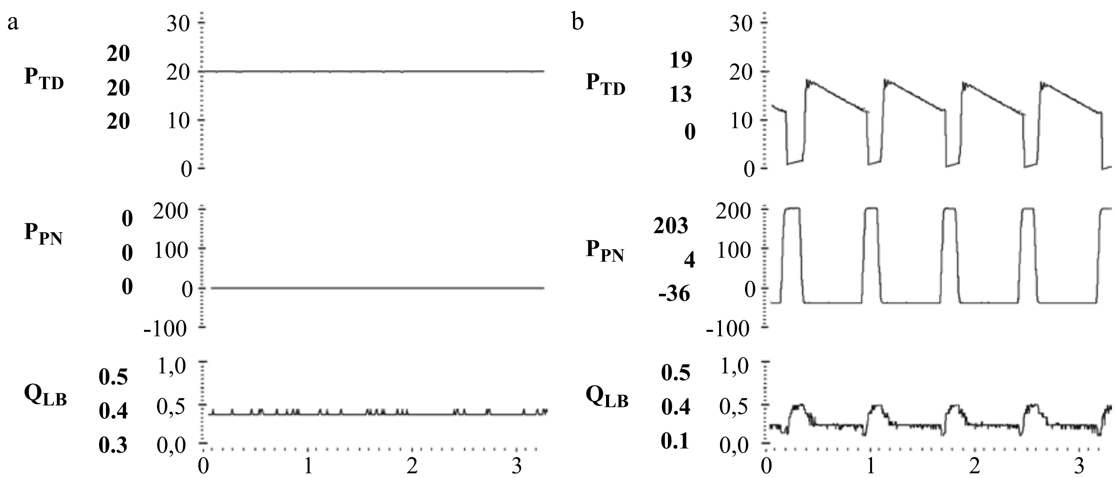

Fig. 4. Circulatory hemodynamics obtained in ADHF simulation conditions (a) and during operation of the mechanized lymphatic drainage device (b) (P_{TD}, pressure in the site of lymphatic drainage from the thoracic duct; P_{PN}, pneumatic pressure of the valveless pump drive; Q_{LB}, flow in the left brachiocephalic vein simulator)

Table

Hemodynamic variables in ADHF simulation condition when a valveless pump is operated at different frequencies

F (bpm)	P_{TD} (mmHg)	P_{CVP} (mmHg)	tc/td
20	–2 ± 1	20 ± 2	1/4
30	0 ± 1	20 ± 2	1/4
40	2 ± 1	20 ± 2	1/4
50	4 ± 1	20 ± 2	1/4
60	5 ± 1	20 ± 2	1/4

Note. F, valveless pump frequency; P_{TD}, venous pressure in the site of lymphatic drainage from the thoracic duct; P_{CVD}, central venous pressure; tc/td, systole/diastole duration ratio of the valveless pump.

As a result of the valveless pump operation at a 10 ml shock discharge in the suction phase, the venous pressure decreased from 20 ± 5 mmHg to 0 ± 3 mmHg with 30 beats/min pump frequency and a suction/injection duty cycle of 0.2/0.8. Thus, conditions are created during the longer period of the work cycle of the mechanized lymphatic drainage device to ensure normalization of lymph drainage from the thoracic duct. Average blood flow through the left brachiocephalic vein is maintained – 0.4 ± 0.1 L/min.

CONCLUSION

This study presents the design and preliminary characteristics of a proposed mechanized lymphatic drainage device designed to alleviate the symptoms of lymphedema in patients with ADHF. Tests on a hydrodynamic bench confirm the possibility of using this device to normalize lymphatic circulation from the thoracic duct to the venous bed by locally reducing the venous pressure to 0 mmHg in ADHF conditions within the general target criteria. This device can be considered as one of the options to restore lymph circulation in patients with ADHF to effectively treat a sufficiently large group of patients with ADHF with minimal drug therapy using diuretics or hemodialysis and relieve symptoms of organ and tissue edema to normal levels with minimal antithrombotic therapy. In addition, this device can be further used to normalize lymphatic circulation in the pulmonary circuit to relieve pulmonary edema symptoms [24].

The authors declare no conflict of interest.

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