AN AUTOMATIC LOW-VOLUME PERITONEAL DIALYSIS FOR INFANT AND CHILD PATIENTS

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Abstract
In the recent years, continuous peritoneal dialysis (CPD) had a widespread development in Pediatrics due to the fact it is a simple and safe system for fluid management, however, CPD can cause relevant side effects, such as for example symptomatic fluid retention in patients. Thus, the main criteria capable of minimizing the expected morbility and mortality rate remains, de facto, an open question. In the paucity of clinical data concerning the definition and measures the adequacy of dialysis in children treated by means of CPD, the low-volume technique appears an effective modality of the treatment. Due to: (a) the lack, in the authors’ knowledge, of commercially available systems for neonatal and pediatric use and (b) the cumbersome and time-consuming surveillance in the manually supervised low-volume CPD, the development of an automatic delivering system appears of interest. In the present paper we describe: (a) the design criteria of a simple and entirely automatic system that is directly settable by pediatric nephrologists and (b) the outcomes of the metrological tests obtained in the in-vitro trials.

Key Words
Medical devices, measurement and instrumentation, peritoneal dialysis, neonatal device

1. Introduction
Due to the extensive use of continuous peritoneal dialysis (CPD), considerable attention has been focused on the adequacy in fluid management and the connected morbidity and mortality in hemodialysed patients. CPD shows significant clinical challenges [1, 2] mainly because it is characterized by an intrinsic simplicity; in addition its efficacy mainly depends on: osmolarity, amount of delivered volume and dwelling time of the fluid utilized in the dialysis. However, clinical observations document suboptimal fluid management across the population of the peritoneal dialysis. In fact, Tzamaulukas et al [3] observed a 25 % incidence of symptomatic fluid retention in patients treated with CPD. Moreover, it must be taken into account that when infants and children are treated with CPD they differ from adults with respect to the low volume of the management of dialysis; the cited condition implies a more restrictive constraint in the management of the CPD. In fact, in Pediatrics pathological complications due to inadequacy of CPD determine high mortality in pediatric intensive care patients [4 - 6]. Recent research [7] suggests the delivering of low volume peritoneal dialysis (≤ 10 ml) for infants and newborns in order to avoid the increase of pulmonary artery pressure and other pathologies which may compromise myocardial functions in critical illnesses [8]. Moreover, Golej et al. [7] demonstrate that a mean ultrafiltration of 2.8 ml/kg body weight per hour offers a safe and adequate ultrafiltration procedure for pediatric critical care patients suffering from minor oliguria and fluid overload; this observation determines that a CPD system has to assure a capability to measure up to 0.1 ml. In the authors’ knowledge, the automatic devices for CPD both commercially available or described in the scientific literature previously cited, do not currently allow to set volumes lower than 30-50 ml, i.e. a range that is of interest for Pediatric use. Thus, the aim of the present work is to describe and metrologically characterize a novel and simple automatic device for low volume peritoneal dialysis mainly intended for newborn and infant use. It’s main design characteristic is the capability of delivering and draining the volumes of dialysis down to 1 ml with an accuracy of 0.1 ml.

2. Experimental set-up and methodology
The experimental set-up (see Fig.1) is based on a gravimetric method and consists of: (a) two load cells which measure the weights of the sacks containing the fluid which must be delivered to the patient and the fluid which has been drained; (b) two interception valves which allow or exclude the path between the sacks and the patient; and (c) a control unit composed by a PC and a 16 bit A/D acquisition board which controls the dwelling time and the delivered volume by means of an on-line processing of the weight measured by means of the load cells and by driving the valves via the A/D channels. It
was decided not to use pumps controlled by the outputs of the load cells to improve the robustness of the system.

The two identical load cells are characterized by a full scale of 5 kg (49.5 N), a minimum load cell verification interval (Vmin) equal to 0.0360 % of Cn, where Cn is the sensitivity that is equal to 2 mV/V. The accuracy class main of the two identical strain gage amplifiers is equal to 0.1; moreover, the measuring frequency range of the amplifiers is set to 0-10 Hz to minimize the effects induced by the accidental movement of the sacks, an occurrence that has to be taken into account in current use of the proposed set-up (see Fig. 2). A graphical user interface has been implemented in order to allow the clinician to set the main parameters of the dialysis both directly and easily, i.e. the duration of the treatment and the value of ultrafiltrate volume. Finally, a heater is placed along the delivery path in order to warm the fluid to body temperature prior the delivery to the patient. Distilled water is used in the present in-vitro measurement, while the patient is simply simulated by a sack.

Experimental trials have been carried out by delivering volume with values equal to 1, 3, 5, 8, 10, 12, 14, 18, 25, 40 and 50 ml and by draining identical quantities from the patient’s simulator. In order to assess the accuracy of the device in terms of delivered and drained volume, the amount of volume which reaches the patient has been measured by graduated burettes of different volumes, see Tab.1. Ten runs for each volume value were performed and the results are reported in the following paragraph.

<table>
<thead>
<tr>
<th>Range of variations of the set delivered volume (ml)</th>
<th>Volume of the burette (ml)</th>
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<tbody>
<tr>
<td>1-10</td>
<td>1.00 ± 0.01</td>
</tr>
<tr>
<td>12-18</td>
<td>20.0 ± 0.1</td>
</tr>
<tr>
<td>25-50</td>
<td>100 ± 1</td>
</tr>
</tbody>
</table>

3. Results and discussion

The results of the tests are reported in Fig.3 and performed by setting a desired amount of volume through the graphical user interface and by measuring the actual volume which reached the patient, i.e. the volume measured by means of the burette. It must be noted that the relationship is linear with an angular coefficient equal to 1. Absolute errors which are less than 0.4 ml (p<0.01) on volume delivered up to 18 ml have been measured. In particular it must be noted that the absolute error on a volume delivered of 1 ml is 0.1 ml (p<0.01), and consequently the system has perfectly accomplished the design constraints of the selected application as indicated in the introductory paragraph. The highest absolute error was reported in correspondence of a volume delivered equal to 50 ml and it resulted equal to 1.0 ml (p<0.01).
As was to be expected, the percentage error, calculated as the percentage ratio between the absolute error and the value expected, is higher for low volumes (9.5% at 1 ml) but tends to decrease up to < 2% for volumes higher than 5 ml (p<0.01) with the exception of set volumes of 12 and 25 ml. For the volumes previously indicated the error unexpectedly reaches a value of about 4%.

In Fig. 4, instead, are reported the results of the tests performed by measuring the actual volume which was drained from the patient. Also on that occurrence the relationship is linear with an angular coefficient equal to 1. Absolute errors constantly less than 0.4 ml on volume delivered up to 10 ml were measured. It must be noted that the absolute error on a volume drained of 1 ml is 0.1 ml. The highest absolute error was reported in correspondence of a volume delivered equal to 40 ml and it resulted equal to 1.0 ml.

The percentage error is higher for low volumes (8.9% at 1 ml) but tends towards a value less than 4% for volumes higher than 10 ml (p<0.01). It must be noted that the errors on the volume drained are slightly higher than those on the volume delivered, this effect could be ascribed to the non perfect constraint of the draining tube which introduces errors on the weight measured by load cell no. 2, see Fig. 1.

4. Conclusions

From the analysis of the results obtained by means of the simple and economical system proposed here, it emerges that the system verifies the design constraints regarding the metrological quality in the imposed volumes in the CPD management in pediatric use. Thus, the validation tests of the in-vitro carried out trials allows the conduction of the successive research phase. In fact, in order to assess the viability of the proposed automatic system in the ambulatory current use, it is necessary to carry out a series of measurements in infants and children affected by renal impairments and this will be the target in the on-going research phase that will be conducted at the “Nephrology Department” of the Children’s Hospital “Bambino Gesù” of Rome – ITALY.

References