External negative pressure device for reducing intra-abdominal pressure

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Abstract— **Acute intra-abdominal hypertension is frequent in critical patients. In these cases Intra-abdominal pressure (IAP) can reach upto 20 mmHg. In those cases, abdominal punction and surgery are indicated for its reduction. Several types of reserch report adverse situations in the cardiovascular and respiratory systems when IAP is abruptly reduced. Also, minimally invasive methods are of great clinical interest. Papers, in which efficacy of IAP reduction by means of external negative pressure is proven, do exist. But no actual implementation of controlled reduction systems for clinical use has been published until now. A mathematical model that shows the relation between IAP and external pressure is developed. Negative external pressure is applied using a vaccum chamber over the abdomen. A control system for controlled reduction of IAP is implemented. An integrated, computer based system (ABDOPRE) was developed. The system is being tested on critical patients, registering a satisfactory IAP reduction in some.**

Keywords— **IAP, Negative pressure**

I. Introduction

Since 2000, interest in critical patients' IAP (intra-abdominal pressure) has risen due to the fact that early treatment of high IAP has proven to improve said patients' evolution [1]. However, this interest can be traced back to 1858 and to 1882 when Mosso and Pelacani [4] used a vesical catheter for the first time. Numerous publications on the subject appeared during the 1980s and its importance is backed by an exponential growth during the 1990s. Although the etiology of IAP and its relation to the Acute Compartment Syndrome (ACS) are gradually being studied, definitions on IAP degrees have been discussed in international consensuses since 2004 [2]. IAP above 10 mmHg causes alterations in veins' and arteries' flow but without clinical manifestations. If IAP is kept above 20 mmHg, it affects abdominal organs with diverse complications which can be avoided by means of abdominal decompression, surgery being a possible treatment.

We have set for ourselves the goal of achieving similar results in a less traumatic way for the patient by means of controlled application of negative pressure on the patient's abdomen. In order to measure and control IAP, we used Kron's intravesical catheter (1983) published by Iberti [5] and recently modified by Cheatham in 1998 [6]. The volume of infusion in the catheter (Foley) varies from 50 to 100 ml of saline serum, although recent norms mention only 25 ml [2]. Despite the concept being familiar among clinicians, at the time this paper was written, documentation on attempts of reducing IAP by means of negative external pressure was still scarce. In the last three years, some papers about negative external pressure application have been published [8]; but none of them deals with controlled IAP reduction avoiding the negative effects of fast IAP reduction. Therefore, ABDOPRE constitutes an original contribution as a new clinical instrument for controlled reduction of high IAP, which also helps researchers deepening the study of IAP's and ACS's physiopathology.

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II. State of the Art

Intra-abdominal hypertension relief by means of external negative pressure is a technique that has existed for several years [12] [15] [8] [11] with possitive clinical results in patients without hemodynamic compromise [12].

In USA, a patent of a mechanical design of a device for application of negative pressure over abdomen has been registered [11].

Even though experiments of negative pressure application have been published, no result of clinical use of this method has been published.

In 2003, Franco Valenza et al show in [12] that intra-abdominal hypertension may be reduced by means of negative external pressure over abdomine. The research was realised over patients which were between 17 and 57 years old with no hemodynamic inestability, and were in an intensive care unit. They showed that by generating a negative pressure of absolute value equal to that of IAP and decreasing it other 10 cmH_2O, the IAP decreased about $8.7 \pm 4.3 mmHg$ in some patients. No cardiac output variations were detected. In 2004, Franco Valenza et al presented in [8] that continuos application of negative pressure over the abdomen causes an increase in the lungs' volume and provokes changes in intratoracic bloodstream.

In 2006, a group of definitions regarding abdominal hypertension, its expression and treatment, is presented [2]:

- IAP is the stable pressure within the abdominal cavity.
- IAP must be expressed in $mmHg$ and be messured after making sure there are no muscle contractions that may alter it.
- IAP reference for measure is the intravesical pressure.
- Normal IAP for adult critical patients is between $5 mmHg$ and $7 mmHg$.
- Abdominal hypertension is the manteinance of IAP above $12 mmHg$.
- Abdominal hypertension is graded as follows: Grade 1- $12 - 15 mmHg$, Grade 2- $16 - 20 mmHg$, Grade 3- $21 - 25 mmHg$, Grade 4- $> 25 mmHg$.

III. Specifications and design

The system has four main functional blocks: an abdominal vacuum chamber, a signal acquisition part, a control part, and a user interface which includes GUI and clinical record.

The vacuum chamber is rigid and fits the patient's abdomen. Inside the chamber, negative pressure (with respect to athmosphere) is generated by means of a vacuum pump [11]. As explained below, augments abdomen height and reduces IAP. IAP is measured by means of an intravesical catheter which is connected to a transducer [2]. This signal is received by the control block which commands the vacuum pump. All signals and data is displayed into the GUI and recorded in the clinical log. Figure 1 shows a typical connection set up for the system.

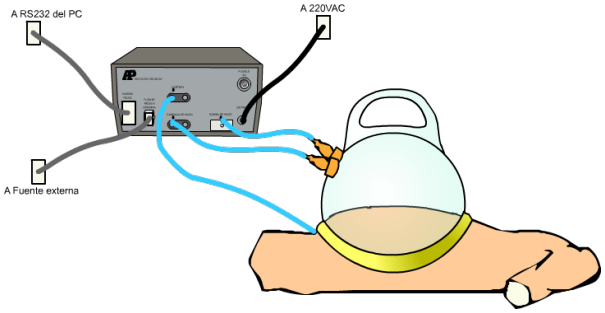

Fig. 1. Typical connection set up

The system offers the possibility of setting the treatment's protocol to be applied over the patient. This protocol is defined by the physician, using the GUI, specifying the following parameters:

1. Desired final value for the IAP
2. IAP tolerance (e.g. 0.4 mmHg)
3. Timing for the treatment (in minutes)
4. Instructions at the ending (restart the protocol or stop)

The system records the evolution of the patients IAP in a graph, together with the therapeutic objective, in order to verify, at every moment, the correct behavior of the system. The evolution is represented in a detailed scale and in a tendency graph, the reading of which allows ensuring the quality of the treatment. At the end of each protocol, the system generates a document for the patients clinical record. Patients data are followed by the name of the protocol, its starting and ending times, and a graph of the real IAP together with the desired IAP.

IV. Problem modelling

The abdomen is considered as a compartment filled mostly with incompressible liquids and gases. According to Pascal's law it is deduced that the pressure is homogeneous in the whole compartment. We understand the abdomen as a cuboid body whose only non rigid wall is the upper. This allows us to understand the abdomen as vertically compressible. The negative external pressure is applied over this wall, by means of fitting the vacuum chamber onto the abdomen. The abdominal external pressure is, therefore, the inner chamber pressure.

Considering that temperature inside the abdomen is almost constant in time with respect of its changes in size and pressure, we consider the abdomen as a compressible body which fulfills the isothermic compression equations: $\beta_T = -\frac{1}{V}\left(\frac{\partial V}{\partial P}\right)_T$; being β_T the adiabatic compressibility constant of the body.

Firstly, we will proof that the change in volume within the chamber is directly proportional to the pressure variation in it, this means that the volume change of the abdomen is directly proportional to the variation of the abdominal external pressure.

Let β_T be:

$$\beta_T = -\frac{1}{Va}\left(\frac{\partial Va}{\partial P}\right)_T \tag{1}$$

where Va is the abdominal volume, P is external pressure over the abdomen and T the temperature in it. Being T constant, we get that:

$$\beta_T.dP = -\frac{dVa}{Va} \tag{2}$$

Therefore,

$$\beta_T.\Delta P = -log\left(\frac{Va_0 + \Delta Va}{Va_0}\right) \tag{3}$$

It is supposed that $\Delta Va << Va_0$. Therefore,

$$\beta_T.\Delta P = -\left(\frac{Va_0 + \Delta Va}{Va_0} - 1\right) = -\left(\frac{\Delta Va}{Va_0}\right) \tag{4}$$

Since the total volume of abdomen plus chamber is constant, we get that $dVa = -dVc$. Therefore,

$$\beta_T.\Delta P = \left(\frac{\Delta Vc}{Va_0}\right) \tag{5}$$

Let $K = \frac{1}{\beta_T Va_0}$, we get to:

$$K.\Delta Vc = \Delta P \tag{6}$$

We consider the abdomen as a mixture of liquids and gas. By varying P (intra-chamber pressure), we see that also varies the abdominal volume. When P is reduced, Va augments and this generates that intra-abdominal gas' pressure reduces following the Ideal Gas Law. Being P_{IA} the intra-abdominal pressure we have that $P_{IA}.V = m.R.T$ where $T = 300K$, m is the gas mass and R the universal constant of gases. Therefore,

$$dP_{IA} = -\frac{m.R.T}{V^2}.dV \tag{7}$$

Being V, the gas volume, since we consider the liquids to be uncompressible, dV is also the variation of the abdominal volume, so $dV = dVa$. Therefore, from equation 6, we get:

$$dP_{IA} = -\frac{m.R.T}{V^2}.\frac{-dP}{K} \tag{8}$$

If we keep the assumption that $V >> dV$,

$$dP_{IA} = C.dP \tag{9}$$

Where $C > 0$. Therefore, when reducing the pressure in the vacuum chamber, IAP proportionally reduces.

V. Vacuum chamber

The vacuum chamber is a device to be placed upon the abdomen of the patient, covering it in all its surface, in order to generate a negative pressure in comparison to the atmospheric pressure, to diminish IAP.

It must be made of a sufficiently rigid material so that it can support the differential pressure without any deformation. The chamber must have a light weight so as to not bother the patient. It must also have a right height so that it does not interfere with other existing instruments in the ICU facilities, and also to improve its storage and its and positioning.

In order to be able to observe the evolution of the abdomen, the chamber must be transparent. The contact with the patient must be hypoallergenic and must not do any hurt. A curved contact in a shape similar to an eyelash or a snail or a rubber contact with curvature were considered . Due to the difficulty to make the curved contact, the option of a rubber with curvature was the chosen one. The hose connector for the vacuum pump and the pressure gauge or transducer, must be placed in a comfortable place for its use. So it was decided to place it in the zone of the chamber compartment near the lower part of the abdomen. For a better manipulation of the chamber, a handle was placed at the top.

A. Bell fitting onto patient's abdomen

The vacuum chamber needs to be supported by an osseous structure of the abdomen, which is: sternum, costal arches, anterior superior iliac spines and pubis. Measurements were made on 12 male ICU patients and 7 female patients. The results are shown in Table **??**. Figure **??** shows the schematic mechanical design of the chamber.

VI. Control system

A first approach to the solution of the problem aims to determine the parameters of the theoretical model, so as to control the system on the basis of a prediction of the evolution of the IAP in time. Nevertheless, the perturbations in the signal due to electronic noise make the parameters to change their values significantly, preventing a good control of the system.

A simpler option consists on approximating the evolution of the IAP by a straight line and adjust the duty cycle of the vacuum pump. Although this approximation is correct for short periods of time, the variation of the slopes for different duty cycles of the vacuum bomb let see an instability of the system, tending to turn on the pump for a longer period of time at the beginning of the treatment than at the end of it. This entails the need to diminish the pressure in the bell's compartment in a single duty cycle 3 to 4 mmHg.

Finally it was decided to use as definitive routine of control the follow up of a reduction pattern, which is simpler and stable. This means that the value of the IAP is controlled in time and space, by applying an external negative pressure. For every moment t in time, the maximum value and minimum "acceptable" value for IAP are defined as "IAP tolerance". The control is done turning the pump on and off in correspondence with the measured value of real IAP in a certain time t. This method is independent of the possible leaks (inevitable) that may occur. It also allows to choose the prefered evolution for the IAP in time. In every case, after reaching the reduced value of IAP, the objective is to maintain it during a long period of time.

That IAP evolution in time is called *treatment protocol*, and is defined by the physician using the GUI, as explained in section III.

VII. Electrical safety considerations

According to IEC-60601 specifications, this system can be classified as *Class I, Type BF*. Several considerations were bared in mind for its design. Since the first prototype was conceived to work using a Notebook, which may need to be plugged to the power network, isolation amplifiers were used for interfacing.

DALE600 was used to verify leakage currents. All leakage currents (earth leakage, and catheter-earth leakage) were below $3\mu A$. This is in accordance to all safety regulations required in IEC-60601.

VIII. Discussion

A prototype for reducing IAP, based on an automatic control system which measures it through a catheter was developed. The specifications were agreed directly with the medical team, who conceived the apparatus and will use it in order to satisfy its need for treatment. Since no technical specifications from similar equipment were found, the project set the challenge of getting into an unknown territory.

The project of ABDOPRE was developed within the university environment, in close collaboration with the medical team, which gives it the practicality that otherwise would not have had. In case that the clinical application of ABDOPRE turns successful, it will make available to Health Institutions a reliable equipment for reducing IAP and for the treatment of ACS syndrome. Once the equipment gets the approval from sanitary authorities, it aims to get a technological transfer to the industry.

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