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Negative pressure device for intra-abdominal pressure reduction

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Abstract. A device that generates negative extra-abdominal pressure (ABDOPRE) for treatment of patients with high intra-abdominal pressure was developed. It includes pressure sensors for transducing intra-abdominal pressure through an intra-vesical catheter and negative pressure in the vacuum bell which is placed over the abdomen. By means of a control system, a pattern for reducing IAP is set, according to a clinical protocol. The external negative pressure is generated using a vacuum pump connected to the bell. The system registers the values of interest for the medical history. The system is being tested over ICU patients, registering a satisfactory IAP reduction.

1. Introduction

Since 2000, interest in ICU 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.

2. Methods and materials

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. Therefore, and following current clinical practice, IAP will be measured by means of an intravesical catheter connected to a three-route key, for urine evacuation [2].

The main component of the control system is a PIC microcontroller, which is optimized for control operations. The pressures of interest are measured by a transducer which output is amplified using an instrumentation amplifier. This signal is digitalized by the PIC's A/D converter. The PIC send this digital signal to a PC in real-time, where a control logic is implemented. Then the PC commands the PIC to handle the peripherals (pump, alarm).

Since medical grade power sources have mostly DC output voltages, for simplicity the used transducers are piezoelectric. As IAP and bell pressures should be measured relatively with atmospheric pressure, differential transducers are preferred; bell's transducer should work in a range of 0 to -100 mmHg, while IAP's transducer in a range of 0 to +40 mmHg [1] and should be compatible with physiologic serum. After studying various possibilities and market availability, the chosen transducers were Honeywell 143PC03D for both bell's and IAP's pressure.

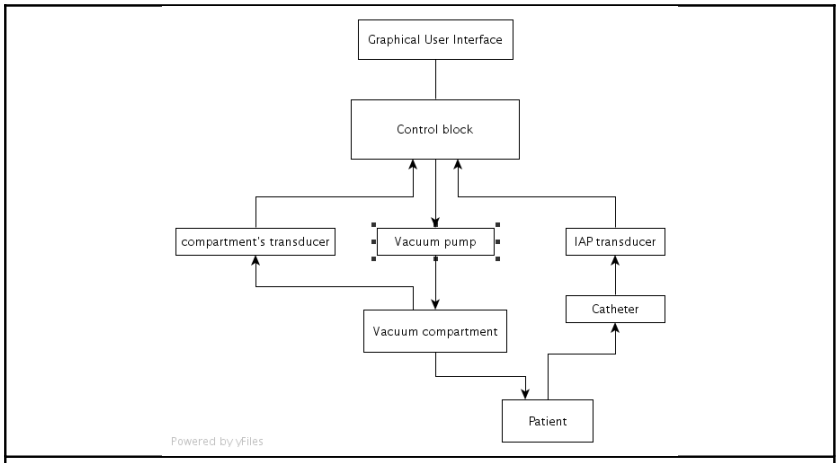

Figure 1. ABDOPRE's block diagram.

The PIC is required to have at least two A/D converters, digital outputs and inputs for handling the pump and alarms and an integrated serial communication block, for connecting to the PC. A PIC with internal oscillator was preferred for simplicity. Both programme and data memory are small enough to fit any PIC in the market. PIC 16F690 was selected due to availability in Uruguay's market.

In figure 1 the system's block diagram is shown.

2.1. 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 adjusting 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 choosing the wanted 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.

2.2. Project of the vacuum bell

The vacuum bell 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 manage to diminish the IAP.

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

Figure 2 . Vacuum's bell photo.

In order to be able to observe the evolution of the abdomen, which is being intervened, there were considered as possible materials to make the bell those which had certain transparency. 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 connectors 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 them in the zone of the bell compartment near the lower part of the abdomen. For a better manipulation of the bell compartment, a handle was placed at the top as shown in figure 2.

2.3. Bell fitting onto patient's abdomen

In order to fit ABDOPRE onto patient's abdomen it is necessary to have an element for visual feedback, which indicates the nurse whether the vacuum is being generated or if the bell's position needs to be improved. In the GUI a positioning protocol is defined. It consists in evacuating air from inside the bell and measuring the resulting pressure. If such pressure is lower than certain threshold, a green image is shown, whereas the non-air tightness of the contact is indicated by a red image.

2.4. Documentation and clinical protocol

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

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

ABDOPRE records the evolution of the patient's 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 (30 cm/min) and in a tendency graph (1 cm/h), the reading of which allows ensuring the quality of the treatment. At the end of each protocol, ABDOPRE generates a document for the patient's clinical record. Patient's 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.

3. Results

In order to realize the testing for the whole system (control system and bell), a phantom with some abdomen characteristics was constructed. The phantom's shape is so that it fits the vacuum bell. This design permits compressible object behaviour similar to the developed abdomen model. In the first months of year 2007, ABDOPRE was tested with this phantom reaching a maximum intra-phantom pressure reduction of 12 mmHg. A reduction pattern and instant intra-phantom pressure graph is shown in figure 3.

The clinical performance will be evaluated by applying ABDOPRE to about twenty ICU patients. The protocol used follows the following parameters: i) IAP will be reduced down to normal IAP for ICU ventilated patients; ii) the reduction time will be around 20 minutes; iii) IAP will be maintained reduced for several hours. Clinical test of ABDOPRE started to take place in August and the team is aiming to keep testing it to evaluate its performance.

System's safety for medical application involves several aspects. It is mandatory to follow the normative for leakage currents. It is also needed to demonstrate that ABDOPRE is stable and its control system will not produce any harmful behaviour for the patient.

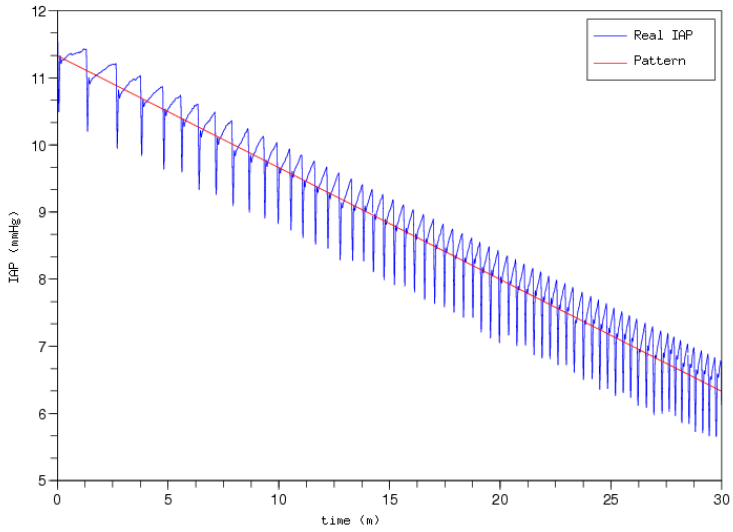

Figure 3 . Intra-phantom pressure time evolution applying a reduction pattern.

Measured leakage currents must be lower than the maximum allowed by IEC-60601-1 specifications for microshock currents (10 uA). In order to ensure this ABDOPRE is design to be connected to a medical grade DC power supply. Maximum measured leakage currents are about 1 uA.

4. Conclusions

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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