Non-invasive Negative Pressure System to Treat Abdominal Hypertension

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Abstract— **Abdominal hypertension can complicate critical care conditions. If untreated and sustained, abdominal hypertension can lead to the abdominal compartment syndrome with its high morbidity and mortality. Treatment of severe abdominal hypertension is often surgical. We designed ABDOPRE, a system to non-invasively lower abdominal pressure. A bell-shaped chamber is applied on the patient's abdomen and by means of a vacuum pump a negative pressure is generated in the chamber outside the abdomen. ABDOPRE senses intra-abdominal pressure from an indwelling urinary bladder catheter. The desired value of abdominal pressure and the time allowed to reach this value are entered into the system which servo-controls the vacuum pump, according to treatment protocols. Pressure data of the monitoring/treatment sessions are recorded to allow review of patient response and a daily report is available for the Electronic Medical Record. Preliminary observations were made on intensive care patients.**

Keywords—**Abdominal Hypertension, Intra Abdominal Pressure, Bladder Catheter, Clinical Instrument**

I. Introduction

Interest in intra-abdominal pressure (IAP) and its non-invasive measurement by means of a urinary bladder catheter can be traced as far back as 1858 (Mosso) and 1882 (Pelacani), (both quoted in [1]).

It is recognized that intra-abdominal hypertension (IAH) occurs in a variety of critical medical and surgical conditions. If sustained, high IAP can lead to the abdominal compartment syndrome (ACS) [2, 3], i.e. intra-abdominal organ dysfunction resulting from IAH-induced organ hypo-perfusion, a condition with high morbidity and mortality. This occurs when IAP exceeds perfusion pressure.

The aetiology, definition and grading of IAP and its relation to the ACS have been the object of an International Consensus Conference [4, 5]. IAP 10-20 mmHg alters abdominal blood flow without clinical effects. Above 20 mmHg, abdominal organ perfusion is jeopardized with complications that may be avoided by abdominal decompression.

Monitoring IAP is indicated in patients at risk of developing IAH and the ACS. Treatment of IAH reduces the incidence of the ACS and improves prognosis. Surgical decompression is at present the gold standard in the treatment of the ACS [3]. Abdominal perimeter and skin tension have been discarded as indicators of IAH [4].

We developed a non-invasive device called **ABDOPRE** (short for ABDOminal PREssure) to reduce IAP [7, 8]. The device consists of a Plexiglas bell placed air-tightly on the patient's abdomen, resting on the bones framing the abdomen. The bell is connected to a vacuum pump. Negative pressure in the bell lifts the abdominal wall, i.e. it increases intra-abdominal volume thereby reducing IAP.

II. State of the art

The concept of IAP and the risks of IAH are familiar among intensivists. Some papers have addressed relief of IAH by means of externally applied negative pressure in haemodynamically stable patients [9, 10, 11, 12]. However, no dedicated system exists to servo-control IAP. No clinical outcome results appear to have been published. There exist no clinical trials evaluating the safety and efficacy of reducing IAP by non-invasive means.

A patent has been filed which concerns the mechanical design of a device applying negative pressure over the abdomen [12]. In 2003 IAP was shown to be reduced in adult Intensive Care Unit (ICU) haemodynamic stable patients by means of negative external pressure [9], a negative pressure whose absolute value was equal to IAP + 10 cmH_2O caused IAP to decrease by 8.7±4.3 mmHg. No cardiac output variations were detected. Continuous application of negative pressure over the abdomen increases lung volume and causes changes in intra-thoracic blood flow [11].

A Consensus Conference defined IAH and published recommendations for its treatment [4, 5]. IAP is defined as the pressure in the abdominal cavity, it is expressed in mmHg and should be measured in the absence of muscular contraction of the abdominal wall. It is measured by means of a urinary bladder catheter, i.e. it is considered equal to

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the pressure in the fluid-containing bladder. Normal IAP in adult patients is 5-7 mmHg.

Abdominal hypertension is defined as IAP constantly above 12 mmHg. It is graded as follows:
Grade 1: 12-15 mmHg,
Grade 2: 16-20 mmHg,
Grade 3: 21-25 mmHg,
Grade 4: above 25 mmHg.

III. Specifications and Design

The system has four functional blocks: a vacuum chamber, a signal acquisition part, a control part, and a user interface, including a graphic user interface (GUI) and a clinical record (Figure 1).

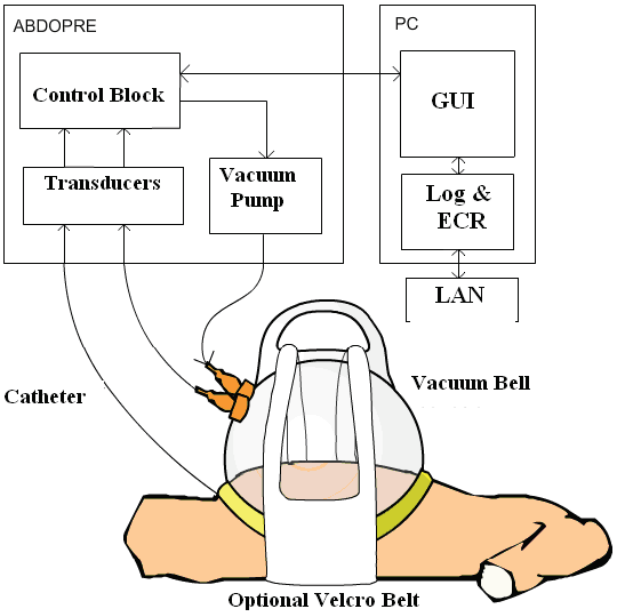

Fig. 1 Blocks of **ABDOPRE.** The Optional "Velcro" belt is used to keep the bell in place when no negative pressure is applied. (GUI: Graphic User Interface. ECR: Electronic Clinical Record. LAN: Local Area Network).

The chamber is rigid, transparent, and fits the abdomen air-tightly. Inside the chamber a negative pressure with respect to atmospheric pressure is generated by a vacuum pump. During operation it lifts the abdominal wall and reduces IAP. We measured IAP by means of Kron's urethral catheter (1984) [13], used by Iberti (1989) [14], and modified by Cheatham (1998) [15]. The volume of saline solution we placed in the bladder to measure IAP was 50-100 ml. Measuring IAP in ICU patients is recommended [16].

We connected the catheter to the transducer sending signals to the control block operating the vacuum pump. All signals are displayed on the GUI and recorded in the log.

ABDOPRE allows adopting different treatment protocols for different patients, by setting the following parameters:

1. Desired value for IAP,
2. IAP tolerance (e.g. 0.4 mmHg),
3. Duration of treatment (in minutes),
4. End of treatment instructions (restart, change protocol or stop).

ABDOPRE displays and graphs IAP and its set value. At the end of each treatment a document is created for the records.

IV. Problem Modelling

The abdomen is considered a compartment filled with gases and liquids. According to Pascal's law, pressure is homogeneous in it. We modelled the abdomen as a cuboid body whose only non-rigid wall is its anterior wall, i.e. the anterior wall is considered compressible.

Admitting abdominal temperature is constant, regardless of changes in volume and pressure, we consider the abdomen as a compressible body which obeys the isothermal compression equation:

$$\beta_T = - 1/V \, (\delta V/\delta P)_T \qquad (1)$$

where β_T is the adiabatic compressibility constant.

We showed that volume changes within the chamber are directly proportional to pressure variations in it, i.e. that abdominal volume changes are directly proportional to variations of external abdominal pressure.

Let $$\beta_T = - 1/V_a \, (\partial V_a/\partial P)_T \qquad (2)$$

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

$$\beta_T \, .dP = -(dV_a / V_a) \qquad (3)$$

Therefore, $$\beta_T \, . \, \Delta P = - \log [(V_{a0} + \Delta V_a) / V_{a0}] \qquad (4)$$

But: $$V_a << V_{a0}$$

therefore: $$\beta_T \, . \, \Delta P = - \{ [(V_{a0} + \Delta V_a) / V_{a0}] - 1 \} \qquad (5)$$

Since total volume (abdomen & chamber) is constant:

$$dV_a = - dV_c$$

where V_c is the chamber volume,

$$\beta_T \, . \, \Delta P = - (\Delta V_c / V_{a0}) \qquad (6)$$

Letting $K = (1 / \beta_T V_{a0})$ we get:

$$K . \Delta V_c = - \Delta P \qquad (7)$$

By varying P (pressure inside the chamber, i.e. outside the abdomen) abdominal volume varies proportionally. When P is reduced V_a increases.

Assuming abdominal gases obey the Ideal Gas Law, reducing P reduces intra-abdominal pressure. Let P_{IA} be IAP:

$$P_{IA} \cdot V = n.R.T$$

where T = 300 K, n is the number of gas moles and R the universal gas constant. Therefore,

$$dP_{IA} = - (n.R.T / V^2) \cdot dV \quad (8)$$

where V is the volume of gas, since we consider liquids to be uncompressible; dV is the change in abdominal volume, so $dV = dV_a$. Therefore, from equation (7) we get:

$$dP_{IA} = - (n.R.T / V^2) \cdot (-dP / K) \quad (9)$$

Keeping the assumption $V >> dV$,

$$dP_{IA} = C.dP \quad (10)$$

where $C > 0$. In other words when reducing the pressure in the chamber, IAP is proportionally reduced.

V. Vacuum chamber

The vacuum chamber of **ABDOPRE** rests on the rigid structures framing the abdomen: distal sternum, costal arches, anterior superior iliac spines and pubic symphysis. In order to generate a negative pressure (compared to atmospheric pressure) outside the abdomen and therefore to reduce IAP the bell must be stiff to support the differential pressure without deforming. It must be light to minimise discomfort to the patient. It must be high enough to accommodate the patient's abdomen when it is lifted by negative pressure (Figure 2.), but not too tall in order not to interfere with bed-side activities.

The chamber must be transparent in order to allow continuous observation of the abdomen (e.g. immediately detect the development of an abdominal hernia - umbilical or other - caused by negative pressure). Bell-patient contact must be hypoallergenic and non-traumatic. An appropriate, curved, rubber-covered contour proved to be air-tight.

Tubes connecting the chamber with the vacuum pump and pressure transducers are placed in comfortable positions for operation, at the distal part of the abdomen. A handle is placed at the top of the chamber.

VI. Control system

We designed a control system by means of a stable routine. Maximum and minimum acceptable IAP values are set. We called the difference between these two values "IAP tolerance". The pump is turned on and off according to whether measured IAP lies within this tolerance or not. This method does not depend upon any (inevitable) air leak into the chamber. After reaching a set IAP value the system operates to keep it within the tolerance interval.

VII. Electrical safety considerations

According to international standard IEC-60601, **ABDOPRE** can be classified as Class I, Type BF [17]. Since the first prototype worked using a computer, which may be plugged to the power network, insulation amplifiers were used for interfacing patient signals to the A/D circuits. Instrument DALE600 was used to measure leakage currents. Earth leakage and catheter-earth leakage currents were below 3μA, i.e. within IEC-60601 safety limits.

VIII. First applications

After obtaining Ethics Committee approval, ICU patients were selected according to a protocol to have IAP measured and lowered by **ABDOPRE**. Results are reported in a companion paper [18], a patient treated with **ABDOPRE** is shown (Figure 2, IAP down from 14 to 9 mmHg).

IX. Discussion

We developed a prototype device to reduce IAP by means of an automatic control system which measures IAP from a urinary catheter and activates a vacuum pump connected to a bell shaped chamber placed on the patient's abdomen. It was an interdisciplinary conception [7, 18] with the medical team using **ABDOPRE** for treatment.

If the abdomen is stretched as a result of high IAP, the application of negative pressure may be contra-indicated. However high IAP may jeopardize abdominal perfusion, without stretching the abdominal wall. So while being a relative contra-indication, the presence of a stretched abdominal wall is unlikely to be a frequent cause for not using ABDOPRE.

Further studies will establish long-term effects of negative pressure on the abdomen for high IAP. IAP reduction may prove sustained or not. Negative pressure may have to be switched off (due to loss of efficacy) only to be re-applied after a pause to reduce IAP again (i.e. efficacy may be intermittent). ABDOPRE would thus intermittently restore abdominal perfusion.

ABDOPRE may be contra-indicated in haemodynamic instability, hypotension or hypovolaemia. Use of ABDOPRE is prescribed and supervised by intensivists. Hypovolaemia or hypotension should be treated as usual according to haemodynamic parameters and clinical judgement before applying negative pressure. Treatment-resistant haemodynamic instability may be an absolute contra-indication of ABDOPRE if it proves haemo-dynamically detrimental after negative pressure is applied.

First clinical results suggest that the design goal may have been reached [18]. If clinical trials confirm them, intensivists will have in their armamentarium a reliable equipment for reducing IAP and for prevention and treatment of IAH and the ACS.

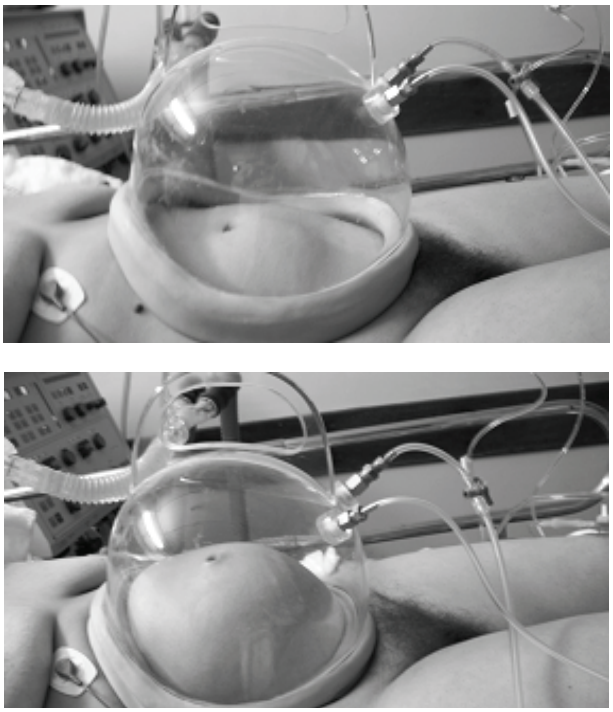

Figure 2. **ABDOPRE** applied to a patient. The abdomen is lifted when negative pressure is applied in the bell. **IAP** (Intra-Abdominal Pressure) of 14 and 9 mmHg were recorded in the upper and lower photos respectively.

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