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ABDOPRE: An external device for the reduction of intra-abdominal pressure. Preliminary clinical experience

ABDOPRE: Dispositivo de aplicación externa para reducción de presión intraabdominal. Experiencia clínica preliminar

ABDOPRE: dispositivo de aplicação externa para redução da pressão intra-abdominal. Experiência clínica preliminar

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ABSTRACT

This article describes a device for the reduction of intra-abdominal pressure. The device (ABDOPRE) includes a unique external servo-control mechanism, based on urinary bladder pressure measurement. The results of ABDOPRE use in the first four intra-abdominal hypertension patients are reported; the device resulted in a reduction of intra-abdominal pressure between 16% and 35% in

3 cases and in a paradoxical increase of the intra-abdominal pressure in an obese woman, likely due to inappropriate chamber size for the patient's anatomy. These results are promising and ABDOPRE may be useful in clinical practice.

Keywords: Abdominal cavity/physiopathology; Compartment syndromes; Monitoring, physiologic/instrumentation; Monitoring, physiologic/methods; Case reports

INTRODUCTION

Intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS) are frequent in critically ill patients and are independently associated with increased morbidity and mortality.⁽¹⁾ Intra-abdominal pressures (IAP) above 20 mmHg have a negative impact on both intra- and extra-abdominal organ perfusion.⁽²⁾ This manuscript reports on a prototype device (ABDOPRE) able to generate a negative pressure over the patient's abdomen, aimed to reduce the IAP; it additionally reports on the preliminary medical experiences with this device. This device is proposed to provide controlled reduction of the IAP.

Since 2006, the Department of Intensive Care Medicine and the Biomedical Engineering group have been cooperating to build a device – called ABDOPRE – able to accomplish the proposed objectives (Figures 1, 2 and 3).⁽³⁾ ABDOPRE is comprised of the following: 1) a vacuum pump (150 mmHg pressure, maximal flow 0.4 L/min, fed by a 6-Volt source and with 65 dB noise) plus connections; 2) a rigid and transparent chamber, adjustable to the skin; and 3) a pressure data acquisition and automated control system (servo-controlled) and a user's interface screen.⁽³⁾ The IAP was continuously measured according to Balogh's⁽⁴⁾ technique, using a 3-way intravesical catheter, keeping the urine output independent. The ABDOPRE software allows maintenance of the hypotensive therapy schedule. The ABDOPRE scan concomitantly displays the IAP and therapeutic target, allowing physicians to monitor

This study was conducted at Universidad de la República Oriental – UDELAR – Montevideo – Uruguay.

Conflicts of interest: This device, called ABDOPRE, was projected by the institution's Departamento de Medicina Intensiva y el Núcleo de Ingeniería Biomédica.

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both the device performance and patients' IAP. In contrast to the model described by Valenza et al.,⁽⁵⁾ ABDOPRE has a servo-controlled pressure system, which uses the intravesical pressure as a control variable.

Informed consent was obtained from a patient's relative. The investigators played the role of healthy volunteers. The institution's Ethics Committee approved this study protocol.

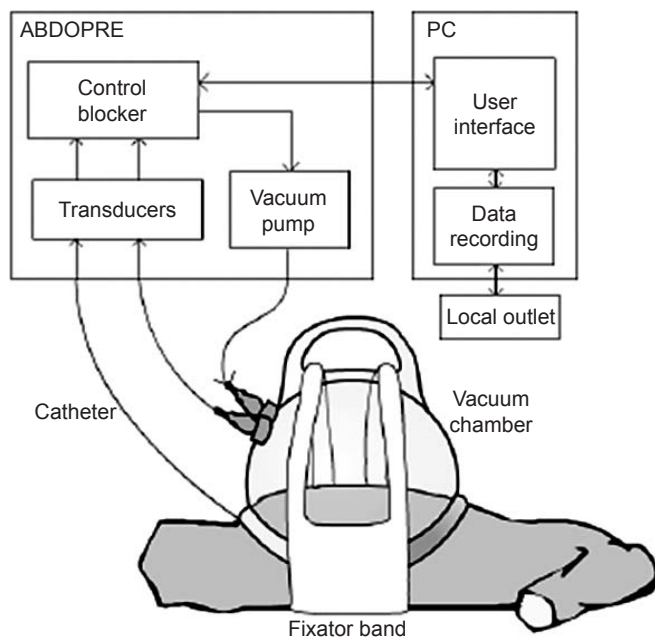


Figure 1 - Schematic of the ABDOPRE and its adaptation over a patient's abdomen. The fixator band is optional, as it is pressure adjusted.



Figure 2 – ABDOPRE: initial use in a patient resulting in decreased intra-abdominal pressure (IAP).



Figure 3 – Different views of ABDOPRE.

CASES

The initial assay was conducted on a healthy volunteer achieving a -90-mmHg chamber pressure. During progressive negative pressures, the subject experienced considerable abdominal expansion. From -30 mmHg on, the subject reported some abdominal wall discomfort due to stretching; therefore, the test was discontinued. The test duration was 3 minutes. Upon completion of the test, the subject had an erythema on the chamber contact area.

ABDOPRE was tested in 4 patients: 2 female and 2 male. The mean age was 48.5 years (ranging from 18 to 78 years) (Table 1). Mean body weight was 74 Kg, and the mean APACHE II score was 22. The IAP was measured as millimeters of mercury (mmHg). All 4 patients had Grade I IAH. In 2 patients, the IAP dropped to 9 mmHg, with a delta intra-abdominal pressure ($\Delta IAP = IAP_{initial} - IAP_{final}$) of -5 mmHg and -3 mmHg, respectively. Another patient displayed a drop from 12 mmHg to 10 mmHg, $\Delta IAP = -2$ mmHg. The mean percent change was -25.3% (range 16-35%). In one patient, the IAP was increased by 38% over the baseline. This finding was an obese female patient (95 Kg) with a 34.9 body mass index (BMI) for whom the chamber was too small. This increased IAP was likely explainable by a 'ventosa effect', developed due to the inadequate proportion between the glass chamber and the abdominal wall. Therefore, the intra-abdominal volume was reduced due to intromission of part of the abdominal wall into the chamber; additionally, perhaps the chamber plus part of the abdominal wall

Table 1- Measurements of intra-abdominal pressure using ABDOPRE and patients' characteristics

Patients	Gender	Age	Diagnosis	IAPi	IAPf	Δ IAP	% change	MBPi	MBPf	HRi	HRf	APPi	APPf
1	F	44	Acute brain injury	14	9	-5	-35	104	96	111	103	90	87
2	M	18	Acute brain injury	12	10	-2	-16	98	93	80	86	86	83
3	M	54	Hemorrhagic stroke	12	9	-3	-25	79	77	118	104	67	68
4	F	78	Respiratory sepsis	13	18	5	38	109	100	90	68	96	82

F – female; M – male; IAPi – initial abdominal pressure; IAPf – final abdominal pressure; Δ IAP – intra-abdominal pressure difference; % percent of change; MBPi – initial mean blood pressure; MBPf – final mean blood pressure; HRi – initial heart rate; HRf – final heart rate; APPi – initial abdominal perfusion pressure; APPf – final abdominal perfusion pressure.

represented an increased weight over the abdomen, resulting in this paradoxical effect on the IAP.

IAP reductions were obtained for all patients with -35 mmHg pressures, with the target achieved within the proposed time (10 minutes) and maintained for about 1 hour. No changes in mean blood pressure or heart rate were observed, and no arrhythmia was identified. The procedure was well tolerated, with no discomfort observed and no ventilator issue ascribable to pain. All patients were sedated (midazolam 0.083 mg/Kg/hour) and under analgesia (fentanyl 3 mcg/Kg/hour) as continuous infusion.

COMMENTS

This article reports on a preliminary trial with a small number of cases. The performance of the device was acceptable and safe. In 3 of the 4 patients, IAP was reduced by about 25%. The fourth case had a paradoxical increase; the likely explanation was addressed earlier in this paper. This failure led to a chamber review; consequently, its diameter was increased to prevent this paradoxical effect. The initial prototype (Figure 2) would be inconvenient for obese patients. However, this should be considered as a developing device that remains to be improved. Its use according to appropriate research protocols will allow optimization of its performance and the user's interface and may potentially provide a clinical tool for the management of IAH.

RESUMEN

Se describen los objetivos de reducción de la presión intraabdominal y el proyecto de un dispositivo que los

cumpla. ABDOPRE comprende por primera vez un mecanismo servocontrolado de aplicación externa que toma la presión intravesical como variable de control. Se presenta el resultado de la aplicación en 4 pacientes afectados por hipertensión intraabdominal, con el resultado de una reducción de entre 16% y 35% en tres casos y de un aumento paradójico de presión en un caso debido a desajuste de la geometría de la campana de vacío a la anatomía obesa del paciente. Estos resultados prometen el posible uso de ABDOPRE para la reducción de la hipertensión intraabdominal en la práctica clínica.

Descriptor: Cavidad abdominal/fisiopatología; Presión; Síndromes compartimentales; Monitoreo fisiológico/instrumentación; Monitoreo fisiológico/métodos; Informes de casos

RESUMO

São descritos os objetivos de redução da pressão intra-abdominal e o projeto de um dispositivo que os atenda. O ABDOPRE compreende, pela primeira vez, um mecanismo de servo-controle de aplicação externa que mede a pressão intravesical como variável de controle. São apresentados os resultados da aplicação em 4 pacientes com hipertensão intra-abdominal, produzindo uma redução de 16% a 35% em três casos e um aumento paradoxal da pressão em um dos casos, devido a um desajuste entre a geometria da câmara de vácuo e a alteração anatômica acarretada pela obesidade da paciente. Estes resultados são promissores em relação ao possível uso do ABDOPRE na prática clínica para redução da hipertensão intra-abdominal.

Descritores: Cavidade abdominal/fisiopatologia; Pressão; Síndromes de compartimento; Monitorização fisiológica/instrumentação; Monitorização fisiológica/métodos; Relatos de casos

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