Abdominal decompression protocol defined by therapeutic elements of ABDOPRE: 1st version

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Abstract. The intra-abdominal hypertension and the abdominal compartment syndrome are severe complications which affect patients in intensive care units (ICUs), increasing length of stay and mortality. The therapeutic use protocol of the ABDOPRE device, is designed to reduce intra-abdominal pressure noninvasively through the application of external negative pressure. The pathophysiology of intra-abdominal hypertension and abdominal compartment syndrome is discussed, along with the limitations of current treatments, and the evolution of the ABDOPRE device is presented. Preliminary clinical results in critical patients suggest that ABDOPRE is effective in reducing intra-abdominal pressure and is well tolerated. The flow chart resulted in this work illustrates the translation of the medical concept to a detailed specification, ready to be included in the software programming of the ABDOPRE microcontroller. ABDOPRE is thus a promising biomedical device for reducing intra-abdominal pressure, aiming to prevent abdominal compartment syndrome without resorting to surgical decompression. Implementing this in daily practice is a goal that aspires to be achieved after introducing improvements suggested by future clinical studies and technological developments.

Keywords: Intra-abdominal Pressure, Intra-abdominal Hypertension, Abdominal Compartment Syndrome, Treatment, ABDOPRE, Biomedical Equipment.

1 Introduction

During the second half of the 19th century, intra-abdominal pressure (IAP) began to be measured to correlate its increase with physiological alterations affecting organ function in critically ill patients. In 1984, the concept of abdominal compartment syndrome (ACS) was introduced, and indications for abdominal decompression were established [3],[4]. The 2004 International Consensus Conference in Noosa, Australia,

unified the diagnostic and treatment criteria for intra-abdominal hypertension (IAH) and ACS, thus facilitating the comparison of results between studies [3],[4].

IAH is defined as a sustained or repeated increase in IAP above 12 mmHg, while ACS is characterized by an IAP exceeding 20 mmHg associated by multiple organ dysfunction or failure [3],[4]. Both conditions are common in critically ill patients, particularly those with sepsis, abdominal trauma, acute pancreatitis, major burns, complicated post-surgery, among others [4]. The elevation of IAP can have devastating effects on multiple organ systems, including the cardiovascular, respiratory, renal, and gastrointestinal systems, significantly increasing mortality [4].

Currently, the management of IAH and ACS includes medical and surgical interventions depending on the degree of intra-abdominal pressure the patient presents. Medical strategies focus on the evacuation of intraluminal contents and the administration of diuretics, while surgical interventions, such as laparotomic decompression, are reserved for severe cases [3]. However, these maneuvers can be invasive and risky [3],[4]. The ABDOPRE device was developed as a non-invasive solution for reducing IAP [1],[2],[5],[6].

This research aims to specify the behavior of ABDOPRE Vaccum Bell (Fig.1) during intra-abdominal pressure (IAP) reduction therapy [1],[2],[5],[6]. The therapeutic elements of ABDOPRE are defined as i) the reduction of IAP by a given amount of pressure within a specified time, and ii) the maintenance of IAP for a specified duration. The specification is written in formal language using these therapeutic elements of ABDOPRE, represented through a flowchart. Preliminary clinical results from its use in ICU patients at the Dr. Manuel Quintela Hospital de Clínicas in Uruguay will be described.

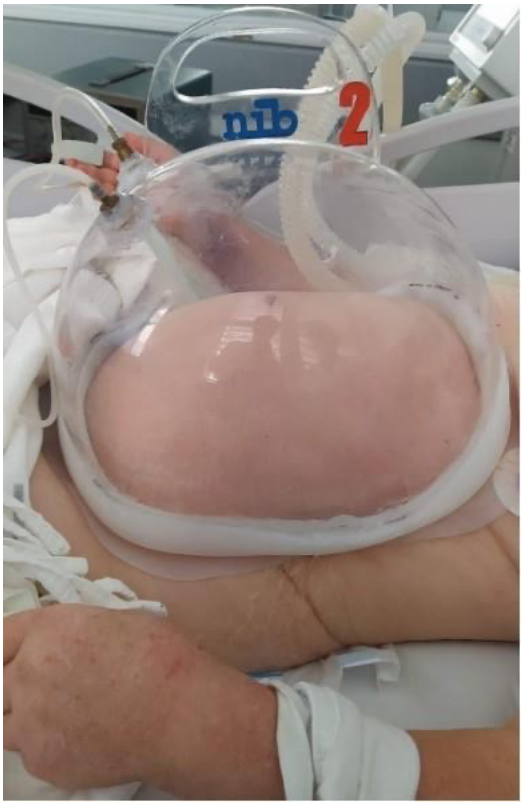

Fig. 1. ABDOPRE Vacuum bell

2 Materials and Methods

Inclusion of ABDOPRE in the Intra-abdominal Hypertension Treatment Protocol

A literature search was conducted on the published background regarding ABDOPRE [1],[2], as well as on the guidelines and complementary information for the treatment of intra-abdominal hypertension and abdominal compartment syndrome [3],[4]. The literature search was performed on portals such as Timbó Foco, PubMed, and IEEE Xplore Digital Library, among others.

Once the relevant literature provided by the bibliographic sources was reviewed, steps were established for the therapeutic protocol of IAH. The indication for the use of ABDOPRE consists of conditions of IAH with intra-abdominal pressures between 12 mmHg and 20 mmHg (IAH grade 1 and 2).
The application protocol includes the following steps:

1. Place ABDOPRE on the patient's abdomen for one hour at a negative pressure of 35 mmHg [1], while monitoring vital signs.
2. After one hour, measure the IAP, intracranial pressure, respiratory, hemodynamic, and renal parameters.
3. Evaluate if the IAP decreased to values below 12 mmHg: i) If IAP <12 mmHg, remove the device. ii) If IAP >=12 mmHg, activate ABDOPRE for one more hour with a negative pressure of -35 mmHg.
4. At the end of the next hour, for patients without an initial therapeutic response, thoroughly evaluate the patient for other causes of IAP decompensation.
5. Evaluate if the IAP decreased to values below 12 mmHg: i) If IAP <12 mmHg, remove the device. ii) If IAP >=12 mmHg, the treating physician will decide whether to activate ABDOPRE again for one more hour with a negative pressure of -35 mmHg.

Subsequently, a flowchart specifying this protocol is developed. This diagram facilitates the understanding and monitoring of the activities to be followed, allowing the identification of key points and possible areas for improvement. Using standardized symbols, a coherent and precise representation of the therapy is ensured, ensuring that all involved parties have a shared vision of the procedure.

3 Results

The result of our work is the flow chart of Fig. 2 as a detailed specification of a new treatment, as per its verbal specifications of the interdisciplinary team. ABDOPRE therefore represents an innovation in the field of intensive care medicine and biomedical engineering. The flow chart of Fig. 2 illustrates the translation of the medical concept to a detailed specification, ready to be included in the software programming of the ABDOPRE microcontroller. This software embodies a new clinical treatment, which was suggested empirically for the first time when ABDOPRE was developed [1]. It should be considered that IAP was previously always treated with a surgical procedure, hopefully turned unnecessary in some cases by ABDOPRE. By operating a pump and a bell affixed on the abdomen, for the first time the IAP is reduced to levels below 12 mmHg as a consequence of applying a pressure reduction protocol by ABDOPRE. The detailed specification in the diagram ensures a successful implementation based on the understanding of the underlying processes.

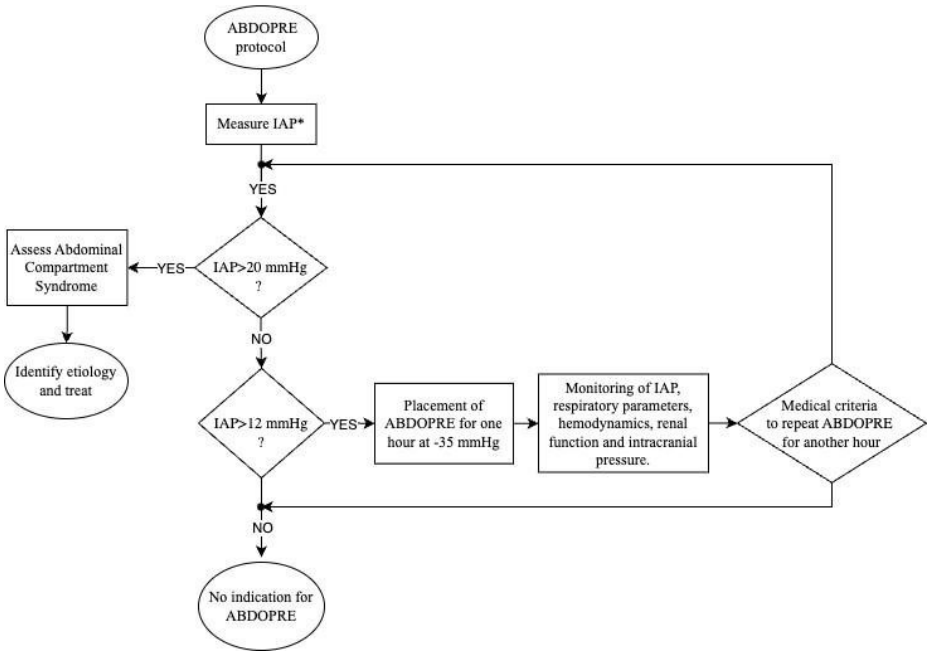

Fig. 2. Flowchart of the ABDOPRE therapeutic protocol. *IAP: Intraabdominal pressure.

4 Discussion

First use of ABDOPRE was conducted on four IAH Grade 1 and Grade 2 patients in the ICU of the Hospital de Clínicas, Uruguay. The selected patients had IAP between 12 and 15 mmHg. The ABDOPRE Fig 2 protocol was applied [1]. In three out of four patients, a reduction in IAP was observed: 5 mmHg, 2 mmHg, and 3 mmHg, respectively from 14, 12 and 12 mmHg, well into the safe pressure zone. In the fourth patient, who had severe obesity, IAP increased due to a misalignment in the vacuum bell geometry, highlighting the need to adapt the device design for different body morphologies [1], geometric modification performed shortly after [7].

These preliminary results indicate that ABDOPRE is effective in reducing IAP, with good patient tolerance and no adverse effects. However, several areas for improvement are identified:

- Device Adaptability: The efficacy of the device may be compromised in case of severe obesity. This suggests the need to develop vacuum bells of different shapes and sizes to better adapt to the patient's anatomy [5].
- Durability and Maintenance: The continuous use of the device in a clinical setting requires it to be robust and easy to maintain. The use of better materials and a modular design could improve the device's durability [5].
- Software Optimization: Although the software allows for precise IAP control, additional improvements can be made to the user interface to ease its use by medical personnel [6].
- Long-Term Studies: Preliminary results are promising, but long-term studies with a large number of patients are required to confirm the efficacy and safety of ABDOPRE. These studies should include diverse clinical scenarios to fully evaluate the device's potential, in addition to the first protocol presented here in Fig. 2.

5 Conclusion

The ABDOPRE biomedical equipment represents an innovative and less invasive alternative for managing IAH in critically ill patients. Preliminary results suggest that it is effective and well tolerated, although improvements in its design and therapeutic algorithm functionality are needed to optimize its use in a variety of clinical settings. Future larger and long-term clinical studies will be essential to validate these findings and determine the impact of ABDOPRE on clinical practice.

Knowledge and monitoring of IAH are crucial for early diagnosis and appropriate treatment, as untreated ACS can result in multiorgan dysfunction and high mortality. It is essential to monitor parameters such as lung mechanics, hemodynamic parameters, diuresis, IAP, and pH in critically ill patients susceptible to developing ACS.

6 Future work

Given that ABDOPRE is still an experimental treatment, a thorough evaluation of potential short-, medium-, and long-term side effects is recommended. Among these, consideration should be given to dermatological effects, as well as any other repercussions that could affect the patient's overall health. This involves establishing specific protocols that consider individual variations in treatment response, ensuring that effectiveness is maximized while potential risks are minimized. Personalizing these durations of use is vital to tailor the treatment to each patient's particular needs, thus ensuring more effective and safer management of abdominal hypertension.

Considerable effort is being made to determine the protocols to be applied in other clinical conditions. This work is particularly relevant in the context of the ABDOPRE third bell, designed for use in obese patients. This approach also aims to optimize therapeutic outcomes and improve the quality of life for individuals affected by obesity.

Future work on ABDOPRE will consist of refinements of Fig 2 -and the protocol it specifies- which will be applied to patients, laying the groundwork for future technological improvements and adaptations. The first ABDOPRE protocol implemented as in Fig 2 was limited to adult patients (age > 18) with IAP between 12 and 20 mmHg (IAH stage 1 & 2) and under critical care [1].

References

1. Schandy A, Pracca F, Simini F. Dispositivo de aplicación externa para reducción de presión intraabdominal: experiencia clínica preliminar. Revista Uruguaya de Medicina Intensiva. 2020;35(2):123-129.
2. González Díaz CA, Chapa González C, Laciar Leber E, Vélez HA, Puente NP, Flores DL, Andrade AO, Galván HA, Martínez F, García R, Trujillo CJ, Mejía AR, eds. Treatment of Abdominal Hypertension: Development of an Original Non-invasive Device ABDOPRE. VIII Latin American Conference on Biomedical Engineering and XLII National Conference on Biomedical Engineering Proceedings of CLAIB-CNIB 2019, October 2-5, 2019, Cancún, México. IFMBE Proceedings. 2020; 75:567-574.
3. The Pediatric Guidelines Sub-Committee for the World Society of the Abdominal Compartment Syndrome, Kirkpatrick AW, Roberts DJ, De Waele J, Jaeschke R, Malbrain MLNG, et al. Intra-abdominal hypertension and the abdominal compartment syndrome: updated consensus definitions and clinical practice guidelines from the World Society of the Abdominal Compartment Syndrome. Intensive Care Med. July 2013;39(7):1190-206.
4. Vidal-Cortés P, Díaz-Carrasco MS, Aguilar Alonso E. La hipertensión intraabdominal y el síndrome compartimental abdominal: ¿qué debe saber y cómo debe tratarlos el cirujano? Cirugía Española 2008;83(5):247-257.
5. Maassardjian G, González M, Sánchez P, Pracca F, Simini F. Airtight Hypoallergenic Gasket Design for ABDOPRE Vacuum Bell. XXIV Congreso Argentino de Bioingeniería y XIII

Jornadas de Ingeniería Clínica SABI 2023, Buenos Aires, Argentina. 2023; http://www.nib.fmed.edu.uy/sitio_nib/BibliotecaNIB/PublNIB388.pdf

6. González M, Sánchez P, Pracca F, Simini F. Optimización de un circuito de adquisición de sensores de presión del sistema de reducción de la hipertensión abdominal basado en campana de vacío ABDOPRE. XXIV Congreso Argentino de Bioingeniería y XIII Jornadas de Ingeniería Clínica SABI 2023, Buenos Aires, Argentina. 2023; http://www.nib.fmed.edu.uy/sitio_nib/BibliotecaNIB/PublNIB397.pdf
7. Urruty. L, Simini. F, Pereyra. M, David. M y Pracca. F, "Non-invasive Treatment of Abdominal Hypertension: a new vacuum chamber," en 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Chicago, IL, USA: IEEE, 2014; doi: 10.1088/1742-6596/90/1/012035.