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A better understanding of daily life abdominal wall mechanical solicitation: Investigation of intra-abdominal pressure variations by intragastric wireless sensor in humans

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ABSTRACT

Intra-abdominal pressure (IAP), as the main mechanical load applied to the abdominal wall, is decisive in the occurrence of ventral hernia. The objective of the study was to propose a comprehensive evaluation of IAP based on a limited risk and discomfort method. A prospective study was carried out in 20 healthy volunteers. The intragastric pressure, validated for estimating IAP, was assessed by an ingestible pressure sensor. Volunteers realized a set of supervised exercises, then resumed their daily activities with the pressure continuously recorded until gastric emptying. Coughing and jumping exercises resulted in the highest IAP levels with maximum peaks of 65 \pm 35 and 67 \pm 31 mmHg and pressure rates of 121 and 114 mmHg.s⁻¹ respectively. The position did not affect the IAP variation. Men had significantly higher pressure values for pushing against a wall (*P < 0.01*), Valsalva maneuver and legs raising (*P<0.05*) exercises. During daily life, IAP greater than 50, 100, and 150 mmHg occurred on average five times, twice, and once per hour, respectively. This study provides a real-life characterization of the IAP allowing the quantification of mechanical solicitation applied to the abdominal wall and the identification of risk situations for the occurrence of ventral hernias.

1. Introduction

The biomechanical conflict between intra-abdominal pressure and the resistance of the abdominal wall plays a central role in the pathology of ventral hernias. The natural overpressure of the abdominal cavity during mechanical solicitation in everyday life (breathing, coughing, walking, jumping, etc.) compresses the viscera against the anterolateral musculo-aponeurotic wall. In response, an healthy abdominal wall deforms while holding the viscera in the peritoneal cavity [1]. However, if the stress generated by this compression locally exceeds the failure stress of the musculo-aponeurotic tissues, a rupture occurs, causing the passage of tissues or organs through an opening or hernia defect in the abdominal wall. Defects occur in areas of constitutional (hernia) or acquired (postoperative) weakness. Patients often report that the hernia occurred during unusually heavy exertion.

Respectively 45,000 and 500,000 ventral hernia repairs are performed every year in France and in the United States. They represent an important medico-economic issue estimated about US\$ 3.2 billion in the United States [2, 3]. Treatment of symptomatic hernias requires surgical repair, combining closure of the orifice and strengthening of the suture with a prosthetic implant. Many different implants and surgical techniques can be employed [4–6]; however, the results are largely perfectible, considering that the 2-years recurrence rate can be as high as 28% [7].

Surprisingly, the patient's intra-abdominal pressure profile is never considered in the preoperative evaluation, choice of surgery, or provision of postoperative advice. Data on variations in intra-abdominal pressure in everyday life and their consequences for the abdominal wall are limited. The tools for measuring intra-abdominal pressure were developed for the exploration of intra-abdominal hypertension associated with abdominal compartment syndrome, a critical medical situation in some patients in intensive care units $[8-10]$. The reference measurement method is intravesical pressure by a urinary catheter [11–14]. Other methods, such as stomach measurement via gastric tube

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[15, 16] or vena cava measurement using a central catheter $[17]$ have been validated. These invasive methods, which are painful and associated with infectious risks, have also been used to investigate the pressure in physiological situations. However, the discomfort brought about by these catheters, which restrict patient movements, probably biased the quality of the measurements for healthy people or those with a ventral hernia [18].

There is a commercially available device that allows intragastric pressure measurement without a wire or invasive catheter, the Smart-Pill™ (Medtronic, Minneapolis, MN, U.S.A), an ingestible capsule developed for monitoring patients with functional gastrointestinal disorders. This capsule includes pH, temperature and pressure sensors. The technology does not cause any discomfort and allows continuous measurement of intragastric pressure without requiring complex experimental means or medical procedures.

The objective of this study is to quantify the impact of daily activities on abdominal pressure in order to estimate the resulting mechanical stresses. The protocol explores the stereotypical exercises used in the literature and proposes a more complete evaluation by analyzing the kinetics of pressure variations, the effect of posture and the influence of sex. The monitoring of pressure levels outside the experimental laboratory complements this protocol and allows a better understanding of real-life conditions.

2. Methods

2.1. Cohort

This monocentric prospective study was authorized by the responsible ethics committee (authorization n◦CPP2019–05–039a/2019- A00806–51/19.04.03.57841) of the National Medicines Safety Agency and the French Institute of Sciences and Technologies of Transport and Networking. Written consent was obtained for each participant after the information meeting held one week before the examination.

A cohort of 20 healthy adults was formed. The criteria for inclusion of the volunteers were as follows: age over 18, benefitting from a health insurance scheme, and no pathology of the abdominal wall. The exclusion criteria included contraindications to the ingestion of the SmartPill (pathologies and disorders of the digestive system, swallowing disorders, gastrointestinal surgery dating back less than three months, etc.), history of hernia repair, history of cesarean, and being pregnant at the time of the study. For each volunteer, data on the age, weight, height, abdominal perimeter, physical activity index, and smoking status were collected. The physical activity index corresponded to the frequency of participation in a sporting activity, from low (less than once a week) to medium (about once a week) and high (several times a week). All the volunteers had to complete a medical questionnaire prior to ingestion of the capsule.

2.2. Protocol

2.2.1. Intragastric pressure sensor

The measurement of intra-abdominal pressure was conducted using a commercial medical device, the SmartPill. The SmartPill is an ingestible capsule of 26 mm in length and 13 mm in diameter; it has been approved by the Food and Drug Administration and meets the European Community standards for the evaluation of intestinal transit and functional intestinal disorders. It contains pH, temperature, and pressure sensors. Its accuracy is ± 0.28 for pH measurement, ± 0.5 °C for temperature measurement, and ± 3.6 mmHg for pressure measurement. The battery life of the device is more than 5 days. The recorded data are transmitted to an external receiver box by radiofrequency with a sampling frequency of 2 Hz [19–21].

With the aim of standardizing the pressure measurement between the different volunteers, the manufacturer's recommendations were followed: All the volunteers were instructed to fast for at least 8 h before

ingestion of the capsule and to refrain from smoking during the 6 h preceding ingestion. Compliance with these instructions was verified by a medical doctor during the visit for inclusion in the study. The ingestion of the SmartPill was preceded by a standardized snack (SmartBar, Medtronic, Minneapolis, MN).

2.2.2. Protocol

The SmartPill was calibrated in pH, ambient temperature and ambient pressure. It was paired with its receiver before ingestion. After ingestion of the SmartPill, the protocol consisted of two phases. In the first phase volunteers completed a series of supervised exercises inside the hospital. In the second phase, the volunteers left the hospital and returned to their daily-life activities.

During the first phase, the exercise session was supervised by an examiner, who repeated the instructions before the beginning of the exercise, checked the volunteer's posture, and indicated the start and duration of each exercise. The exercises were grouped into the following categories: breathing (natural and guided), an apnea after calm exhalation, and muscle activation exercises (coughing, Valsalva maneuver, legs raising, stomach vacuum, jumping, lifting a weight, and pushing against a wall). Details of exercises, number of repetitions, position of the volunteers and instructions are visible in Table 1.

During the second phase, the participants left the examination center, keeping the receiver box close to their abdomen (hung on their belt or shoulder strap) to ensure the best possible transmission of data between the SmartPill and the receiver. The data were saved until the capsule was evacuated. An appointment was made to collect the receiver a few days later.

2.3. Data analysis

2.3.1. Export and selection of data ranges to analyze

Data stored in the receiver box (SmartPill™ Motility Recorder, Medtronic, Minneapolis, MN, U.S.A) was exported to a PC via MotiliGI™ Software (Medtronic, Minneapolis, MN, U.S.A). The moments of ingestion and gastric emptying were automatically located by the software thanks to variations in pH, temperature, and pressure.

Data could be exported in several modes, which were as follows: raw data (in mV), converted data (in mmHg), calibration data (in mmHg), data with temperature compensation (in mmHg), and baseline compensated data (in mmHg). The analysis was carried out from data with temperature compensation, which are the raw data (in mV) multiplied by the scale factor of the sensor, adjusted according to the calibration point (pH 6, atmospheric pressure, ambient temperature) and the deviation of the sensor due to the rise in temperature.

2.3.2. Data processing

The pressure data recorded during the exercises were processed with MATLAB® calculation software and Excel® software (Microsoft). Data were expressed relative to the baseline intra-abdominal pressure. The baseline value was defined according to the criteria used in the literature, corresponding to the pressure measured at the end of natural or mechanical exhalation for the patient in supine position [9]. In this study, the baseline pressure corresponded to the average of the lower peaks noted during the natural breathing exercise. Fig. 1 shows the pressure-time curves of two volunteers for breathing and muscle activation exercises.

For the natural and guided breathing, the mean amplitudes between exhalation and inhalation peaks (in mmHg) were calculated. For apnea after calm exhalation, the average value of the pressure plateau (mmHg) occurring during the 10 s apnea was calculated for the three repetitions. For coughing and jumping, the maximum peak (in mmHg) was identified for each position. For the other muscle activation exercises, the mean peak value (mmHg) during the three repetitions of the exercise was computed. The pressure rate was calculated as the slope of the curve preceding the maximum or minimum peak related to each exercise*.*

Table 1

Description of supervised exercises.

Fig. 1. Pressure-time curves extracts from two volunteers. This figure shows extracts of pressure-time curves from two volunteers during supervised exercises. Each exercise shown can be identified by its specific pressure-time curve.

Concerning the analysis of daily life, the frequencies of pressure peaks above the threshold values of 50, 100, 150, and 200 mmHg were calculated. To do so, every peak exceeding the threshold value was taken into account. The data were analyzed until gastric emptying as the correlations between intra-abdominal pressure and pressures in the rest of the digestive tract has not yet been demonstrated.

2.3.3. Statistical analysis

The intra-individual variability for the repetitions of the same exercise (i.e. standard-error) was calculated using the following formula: *Standard Error* = Sd / \sqrt{n} where Sd is the standard deviation associated with the series of measurements and n is the number of measurements.

Descriptive statistics were used to describe data for the whole cohort. Thus, the average pressure variations (associated with their standard deviation), average pressure rates (associated with their standard deviation), and average standard errors were calculated for each exercise. Bar charts (Fig. 3) were used to visualize the differences between sex groups during supervised exercises. Significance levels corresponding to differences between groups were calculated using the Mann-Whitney statistical test. The same statistical test was used to calculate differences between smokers and nonsmokers groups.

To establish the presence of possible correlations between the different exercises, a principal component analysis (Fig. 4) was carried out using the values obtained for the pressure peaks, expressed as a variation compared with the baseline pressure during the different supervised exercises. The arrow vectors represent the exercises. The angles between the different vectors symbolize the correlations between the exercises. The obtuse angles represent negative correlations, while acute angles represent positive correlations. The more obtuse or acute the angle, the stronger the negative or positive correlation between the two exercises. Finally, a right angle between two vectors marks a lack of correlation between the two exercises involved.

Regarding the analysis of data for daily life, the frequencies of pressure peaks occurring at the different thresholds are presented as box plots (Fig. 5).

3. Results

3.1. Demographic data

The cohort was composed with 8 women and 12 men. The average age was 31 years old (range 22–54). Body mass index and waist circumference were respectively 23 ± 2 kg/m² and 804 ± 77 mm. Physical activity criteria was high for 8 volunteers, moderate for 10 volunteers, and mild for 1 volunteer. There were 6 active smokers.

3.2. Supervised exercises

Table 2 shows the pressure variations (in mmHg) compared with the individual baseline pressure during supervised exercises. The pressure amplitude during guided breathing $(12 \pm 12 \text{ mmHg})$ was four times higher than that during natural breathing $(3 \pm 1 \text{ mmHg})$. The smallest pressure variation compared with the baseline pressure was observed during the apnea after calm exhalation $(1 \pm 6 \text{ mmHg}$ in the supine position).

The muscle activation exercises caused the most significant pressure variations. Four exercises were responsible for the highest intraabdominal pressure increases; these were as follows: coughing (67 ± 12) 31 mmHg while standing), jumping $(65 \pm 35 \text{ mmHg})$, lifting a weight $(63 \pm 21 \text{ mmHg})$, and pushing against a wall $(67 \pm 29 \text{ mmHg})$. The Valsalva maneuver resulted in a lower pressure increase (52 ± 28 mmHg for the supine position) for all volunteers. However, during the supervised exercises session and for the entire cohort, the highest pressure peak was recorded during a Valsalva maneuver (157 mmHg).

The position of the volunteer during the exercises (apnea after calm exhalation, coughing and Valsalva maneuver) did not seem to affect the pressure variation. The baseline wander at rest showed oscillations *<* 0.5 mmHg for all participants.

Intra-individual variability for the repetitions of the same exercise, called "standard error", is presented in Table 2. The lower values were observed for the apnea (0.5 – 0.7 mmHg depending on the position) and for the legs raising exercise (0.9 mmHg). The higher value was observed for the exercise of pushing against a wall (5.7 mmHg).

The pressure rates are presented in Fig. 2. The lowest absolute values were found for natural inhaling and exhaling (with values around 2

mmHg.s⁻¹). Three exercises led to a pressure decrease: natural exhaling, guided exhaling, and stomach vacuum. The higher pressure rates were obtained for muscle activation exercises: especially for coughing (121 mmHg.s⁻¹) and jumping (114 mmHg.s⁻¹).

3.3. Influence of sex and smoking habits on intra-abdominal pressure levels

The bar charts (Fig. 3) represents the pressure levels according to sex for muscle activation exercises. Men had significantly higher pressure values than women for the pushing against a wall exercise, Valsalva maneuver, and leg raising (respectively 83, 66, and 44 mmHg on average for men and 48, 39, 32 mmHg for women, with P respectively *P < 0.01, P < 0.01, P < 0.05.)*

There was no significant difference (*P>0.05*) between smokers and nonsmokers for all the exercises.

3.4. Principal component analysis

The principal component analysis presented in Fig. 4 makes it possible to estimate the correlations (positives or negatives) that may exist between the different imposed exercises. The strongest positive correlation was found between the jumping and lifting a weight exercises. There was a negative correlation between legs raising and coughing exercises. No correlation was found between the legs raising exercise and the Valsalva maneuver.

3.5. Analysis of daily life pressures

In total, 199 recorded hours until gastric emptying were analyzed in 19 participants. The average gastric emptying time was 11 ± 8 h (range 1 – 24 h). The average pressure was -1.1 ± 8.7 mmHg. The mean maximum pressure peak recorded per volunteer was 223 ± 72 mmHg, ranging from 123 mmHg to 380 mmHg.

Fig. 5 presents the frequency of pressure peaks per hour. On average, peaks greater than 50 mmHg appeared five times an hour, peaks greater than 100 mmHg appeared twice an hour, peaks greater than 150 appeared once an hour. Peaks above 200 mmHg were rare and appear on average less than once an hour. There was a wide dispersion in the number of peaks between individuals, varying from once an hour to more than 15 times an hour for peaks greater than 50 mmHg.

4. Discussion

This study assessed intragastric pressure using an ingestible wireless

Table 2

Variations of pressure according to exercise and subject position.

Values are presented as variations from individual baseline pressure (in mmHg).

SE is average Standard-Error and represents intra-individual variability for an exercise.

Standard deviations are also represented.

Fig. 4. Principal component analysis of muscle activation exercises. The analysis was carried out from the average of maximum pressure peaks for each volunteer and each exercise. Each triangle represents a participant. F1 and F2 are the dimensions on which the most observations are represented.

sensor, allowing intra-abdominal pressure to be estimated. This is the first time that the variations in physiological intra-abdominal pressure were recorded during exercises in healthy adults without uncomfortable

Fig. 3. Pressure peaks for men and women. Values are pressure peaks' average for all volunteers of each sex group (in mmHg). Standard

deviations are also represented. *Significant difference *P < 0.05.* **Significant difference *P < 0.01*.

Fig. 5. Occurrence of pressure peaks in daily life. The figure shows the frequency of pressure peaks per hour exceeding a given threshold. The data refer to the entire population and only to the period when the pressure sensor is in the stomach excluding the period of the supervised exercises.

and high-risk catheters. These exercises replicated daily activities involving the abdominal wall. In addition, it is the first time such assessment has been performed outside the controlled conditions of a laboratory, reflecting real-life conditions.

This study, carried out in a relatively young cohort (average age: 31 \pm 9 years), showed that the coughing and jumping exercises caused the greatest stress on the abdominal wall. The quality of our methodology can be appreciated by the intra-individual repeatability of the measurements. Indeed, the low values of the individual standard errors when repeating the same exercise showed that the measurement was reliable and that the exercises have been well understood. In addition, the similar order of magnitude between the values of the pressure peaks recorded during daily life and during the imposed exercises showed that the chosen exercises correctly reflected the main stresses of real life.

The results in terms of pressure peaks of the present study can be compared with the previous studies in healthy adults of Cobb et al. [18], Grillner et al. [22] and Iqbal et al. [23] (Table 3). In these studies, the pressure measurement was performed intravesically [18, 23] or intragastrically [22], in supine [18, 23], sitting [18], and standing [18, 22] positions. For coughing and Valsalva maneuver, similar values were obtained. For jumping, the pressure variations measured in our study are similar to those of Grillner (intragastric) but much lower than those measured by Cobb (intravesical). For calm exhalation, the present study proposed values similar to those obtained by Cobb for the supine position, however he showed an influence of the position that we didn't witness. The difference in measurement location could explain all of the stated differences between the studies. Indeed, the effect of the volunteer's position on the IAP seems to depend on the location of the sensor. In the supine position, the pressure seems to be the same, regardless of the position of the sensor in the abdomen. An animal study showed identical pressures in the bladder, in the femoral vein and the inferior and superior cava veins [24] during an induced increase in intra-abdominal pressure in supine position. The transition from the supine position to the sitting position or from the sitting position to the standing position shows different effects depending on the pressure sensor location.

Those body position changes lead to an increase in the intravesical pressure, as shown in the studies by Cobb et al. [18] and by De Keulenaer [25], but not in the intragastric pressure, as reported in the present study.

These overpressure can be explained by the weight of the viscera applied to the bladder by gravity in sitting and standing positions [10]. Due to its anatomical location, the stomach is not affected by this overpressure.

The present study allows a better comprehension of the exercises involving the abdominal wall. In the literature, only pressure peaks are reported [18, 22, 23].

We think the pressure rate and the frequency of peaks should also be taken into account. From a biomechanical point of view, variations in intra-abdominal pressure are directly correlated to the efforts applied to the abdominal wall. An experimental study has shown a linear relationship between intra-abdominal pressure and forces applied on the linea alba [26]. The pressure rate also has an impact on the mechanical loading of tissues. The soft tissues of the abdominal wall are viscoelastic and therefore their mechanical properties depend on the pressure rate.

Thus, the IAP profile can estimate the stress imposed on the muscles and aponeurosis of the abdominal wall caused by physical activities. Coughing and jumping can be considered the exercises that put the most stress on the abdominal wall, since they combine both high maximum peaks (65 and 67 mmHg, respectively) and high pressure rates (121 and 114 mmHg. s^{-1} respectively). The study also reveals that the frequency of pressure peaks varies widely between volunteers. This frequency is probably also a highly important factor for the evaluation of the abdominal wall injury risk: individuals with a high frequency profile are certainly the most at risk for abdominal wall pathology.

During muscle activation exercises, the pressure values were significantly higher in men than in women for pushing against a wall (*P < 0.01*), as well as for legs raising exercises and the Valsalva maneuver (*P < 0.05*). This is probably due to the larger muscle mass of men compared with women. A study based on CT scan measurements showed that men had greater muscular areas and thicknesses for all the muscles of the abdominal wall except the transversus abdominis muscle [27]. Therefore, greater muscle mass could lead to higher intra-abdominal pressure values during exercises involving muscle contraction. Logically, coughing, preferably involving the transversus abdominis muscle [28], does not present a difference between men and women. Understanding the muscles involved in the exercises also requires a principal component analysis, which highlights the correlations between the exercises. Thus, the close correlations between lifting a weight, pushing against a wall, and jumping are probably explained by a contribution of the same abdominal muscles in the performance of these exercises. Finally, differences on muscle activation between smokers and nonsmokers reported in a previous study [29] didn't result in statistically significant differences in intra-abdominal pressure levels in this study.

This study has limitations related to the capsule technology and to our protocol. The SmartPill capsule sampling frequency is 2 Hz, as a result some pressure peaks may not have been recorded. To limit this bias, we increased the number of acquisitions for dynamic exercises (coughing and jumping), and we also chose to retain the maximum value instead of the average value. On the other hand, the selection of the cohort might be considered as a limitation. The cohort was younger and more athletic than the general population. Further studies may be conducted in other populations in terms of age and BMI. Finally, data loss was observed. These represented only 5% of the total time on average during the imposed exercises. In contrast, these represented 22% of the total time on average during the analysis of daily life data. However, this high percentage found for the analysis of daily life data is not necessarily related to the technological characteristics of the Smartpill. In fact, during this phase, some volunteers moved the boxreceiver away from the device, for example by leaving it in the locker room during a sports session or outside the bathroom during shower time.

5. Conclusions

Surgeons consider chronic coughing and severe abdominal strain to be risk factors for abdominal hernias [30]. Quantitative data about intra-abdominal pressure variations, pressure rates and the frequency of high-pressure peaks presented in this study reinforces this observation. These considerations may lead to a personalization of clinical practices.

Table 3

Literature review on physiological intra-abdominal pressure depending on exercise and subject position.

Values presented as mean $(\pm$ Standard Deviation), in mmHg.

They could be used to assess the individual risk of incisional hernia after abdominal surgery. Individual risk assessment could also be considered in surgical planning, for the choice of surgical implants, and postoperative recommendations. In addition, the data obtained can be used as validation data for the abdominal wall numerical models that have been developed in recent years to optimize the development of new implants or surgical procedures.

Authors' contributions

Andréa Soucasse: Data curation, Formal analysis, Investigation, Validation, Visualization, Writing – Original draft

Arthur Jourdan: Conceptualization, Formal analysis, Investigation, Methodology, Visualization, Writing – Review and editing

Lauriane Edin: Investigation

Jean-François Gillion: Writing – Review and editing

Catherine Masson: Conceptualization, Methodology, Supervision, Validation, Visualization, Writing – Review and editing

Thierry Bege: Conceptualization, Methodology, Supervision, Validation, Visualization, Writing – Review and editing

All authors have made substantial contributions to:

- The conception and the design of the study, or acquisition of data or analysis and interpretation of data
- Drafting the article or revising it critically for important intellectual content
- Final approval of the version to be submitted

Declarations / Statements

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Declaration of Competing Interest

None

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