Influence of body position on the defecation model measured during high resolution anorectal manometry in children: a controlled study.

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ABSTRACT

Background

Functional disorders of the lower gastrointestinal tract, including constipation, are one of the most frequent reasons for consultations with a paediatric gastroenterologist. Three-dimensional high-resolution anorectal manometry (3D HR-ARM) is a non-invasive test, performed by placing a catheter with numerous pressure sensors to the rectum. It allows to assess the function of the lower gastrointestinal tract. 3D HR-ARM may disclose impaired relaxation or paradoxical contraction of the pelvic floor muscles and/or inadequate propulsive forces during bear down manoeuvre - this is called dyssynergic defecation. It is suspected that dyssynergic defecation may be a cause of constipation in a significant percentage of patients.

Nowadays 3D HR-ARM is provided in a supine position, although the study in healthy adults using an anorectal catheter showed that the percentage of abnormal results during bear down manoeuvre in the supine position can reach as much as 67-87%. Such a high percentage of false positive results may result from a non-physiological position during the examination. Assessment of 3D HR-ARM results in the paediatric population requires validation in a sitting position.

The aim of the study is to assess the influence of body position on parameters of bear down manoeuvre during 3D HR-ARM in children with constipation in comparison with healthy volunteers.

Methods

This is an open, prospective study. Study participant aged 5-18 years, will be divided into two groups: I. patients with constipation diagnosed according to the Rome IV criteria and II. healthy controls. The study population will have no history of surgery due to congenital anomalies in lower gastrointestinal tract, inflammatory bowel diseases or inflammation of the large intestine with a different aetiology, anal fissure, inflammation of the anal area or other conditions which, in the opinion of the researcher, could affect the functioning of the distal gastrointestinal tract.

The test will be performed both in supine and sitting position successively, using 3D HR-ARM. Resting, squeeze pressures, and bear down manoeuvre variables will be obtained. Diagnosis of dyssynergic defecation requires ≤ 20% relaxation of anal sphincter and/or intrarectal pressure ≥40 mmHg during bear down manoeuvre.

There should be 30 people in the constipation group and healthy controls. Due to possible differences depending on age, it was decided to conduct the study in two separate age groups: I. 5-10 years old, and II. 11-18 years old. The total number of patients in the study will therefore be 120 people.
The primary end point of the study will be the assessment of difference in number of patients with dyssynergic defecation in sitting and lying position.
The study was approved by the Ethics Committee of the Medical University of Warsaw, Poland (KB/178/2019).

BACKGROUND

Functional disorders of the lower gastrointestinal tract, including **constipation**, are frequent reasons for consultations with paediatric gastroenterologist [1]. Anorectal manometry is a non-invasive, standardized test performed by placing a catheter with numerous pressure sensors to the rectum. It allows to assess the function of the lower gastrointestinal (GI) tract by measurement of pressure activity in this area [2]. It can be used to diagnose functional disorders of lower GI (such as constipation, faecal incontinence), congenital anomalies (i.e. Hirschsprung's disease). Anorectal manometry is also useful in postoperative evaluation of sphincter function in patients with congenital defects such as Hirschsprung disease or anorectal atresia.

Three-dimensional high-resolution anorectal manometry (3D HR-ARM) is the most advanced system of anorectal manometry used in clinical practice. In this project, will be used catheter (Manoscan 360 3D, Medtronic, Duluth, USA) that provide a continuous and dynamic spatiotemporal mapping of anorectal pressures [3]. This system operates with rigid probe of a greater diameter. The catheter consists of 256 sensors that asses longitudinally and circumferentially pressure in the rectum and is able to produce detailed three-dimensional maps of obtained results. This allows for more detailed data acquisition and easier interpretation of results. There is a lumen inside the probe through which air can be administered into the balloon (3.3 cm in length), allowing for the measurement of the rectoanal inhibitory reflex (RAIR) and intrarectal pressure. Resting pressure, maximum squeeze pressure, canal length, bear down manoeuvre variables (such as percentage of anal relaxation rate, residual anal pressure, rectoanal pressure gradient, intrarectal pressure), RAIR is measured during each test. The catheter is connected to a recorder and amplifier system (ManoScan A120; Medtronic, Duluth,USA).

So far, 3D HR-ARM is provided in lying (supine or left lateral) position. Experience of our Department show that supine position with maintained eye to eye contact between patient and doctor providing the test, allows to easier cooperation during examination. It is crucial (specially with younger

patients) to alleviate stress during the procedure. Every subsequent part of the protocol is explained before the start and verbal instructions during manoeuvres are served. It has been proved to influence results in adults [4]. Another very important aspect of this examination is ensuring intimate examination conditions (one patient in examination room, close parent presence during whole time).

Despite the simplicity of the manometric test and easiness of data interpretation, most of the research on standards or influence of age and sex on anorectal manometry parameters were performed on the adult population. Moreover, the manometry catheters used to collect data were less advanced than 3D HR-ARM [5]. Recently the number of conducted researches on this topic in the paediatric population is increasing. Our department is playing a significant role in the field of research on 3D HR-ARM. In the last few years, our team published several papers on 3D HR-ARM including results of study on cut-off values for diagnosis of dyssynergic defecation (DD) in children [6].

The abnormal defecation dynamics model may be revealed in detail using 3D HR-ARM, which may disclose impaired relaxation or paradoxical contraction of the pelvic floor muscles and/or inadequate propulsive forces during bearing down manoeuvre – this is diagnosed as DD[7]. It is suspected that dyssynergia of the pelvic floor during defecation may be a cause of constipation in a significant percentage of patients [8][9].

So far only a few studies have been performed comparing the pressure values during bear down manoeuvre in both sitting and lying positions. Those studies were carried out in adults. In the study by Rao et al. healthy volunteers presented DD in the supine position significantly more frequently than in the sitting position (36% vs 20%) [10]. The study by Su et al. showed that a propulsive force that was too low was the cause of false-positive results [11]. In the study by Wu et al.[12] the sitting position not only significantly affected the propulsive force, but also had a significant impact on the percentage of anal canal relaxation and rectoanal pressure gradient during bear down manoeuvre. Patients with constipation significantly more often presented the inadequate relaxation of the anal canal, which was more visible in the sitting position. It has been shown that the rectoanal pressure gradient evaluated in the sitting (but not lying) position and significantly correlates with the effective defecation assessed on the balloon expulsion test.

The study in healthy adults using 3D HR-ARM showed that the percentage of abnormal results during bear down manoeuvre in the supine position can reach as much as 67-87% [13][14]. Such a high percentage of false positive results may result from a non-physiological position during the examination. Assessment of 3D HR-ARM results obtained in the paediatric population requires validation in a sitting position.

The aforementioned studies are first milestones in the field that suggest revision of the position in which 3D HR-ARM is performed per protocol. Thus far no similar scientific research has been performed in children. Moreover, the reference values of registered pressures during 3D HR-ARM in people without constipation were not specified, which would allow for a more precise diagnosis of patients with an incorrect defecation model and a precise selection of patients who could benefit from a certain type of treatment, for example biofeedback therapy.

RESEARCH OBJECTIVE

The assessment of the influence of body position on manometric parameters of bear down manoeuvre during 3D HR-ARM in paediatric patients with functional constipation compared to healthy volunteers.

METHODS

The study will be prospective with a defined study group and control group.

Inclusion criteria – the study group:

- age from 5 to 18 years old
- functional constipation diagnosed on the basis of Rome IV criteria
- parental or guardian written consent to the participation of the child in the study; in the case of a child ≥16 years old also the child's written consent

Inclusion criteria – the control group:

- age from 5 to 18 years old
- no lower gastrointestinal symptoms
- parental or guardian written consent to the participation of the child in the study; in the case of a child ≥16 years old also the child's written consent

Exclusion criteria – the study group and the control group:

- undergone surgeries due to congenital anomalies in the lower gastrointestinal tract
- inflammatory bowel diseases or inflammation of the large intestine with a different aetiology
- anal fissure, inflammation of the anal area or other conditions which, in the opinion of the researcher, could affect the functioning of the distal gastrointestinal tract

SAMPLE SIZE

The sample size was calculated to detect a 45% difference in the percentage of patients with a negative rectoanal gradient, assuming equal groups, alpha = 0.05, beta = 0.1, and a 30% drop out percentage. There should be 30 people in the constipation group and 30 healthy volunteers.

Due to possible differences depending on age, it was decided to conduct the study in two separate age groups (I. younger, i.e. 5-10 years old and II. older, 11-18 years old). The total number of patients in the study will therefore be 120 people.

END POINTS

Primary end point:

The difference in the number of patients with DD (defined as ≤ 20% relaxation of anal sphincter and/or intrarectal pressure ≥40 mmHg during bear down manoeuvre) in sitting and lying position.

Secondary end point:

Values of manometric parameters obtained in the lying and sitting position, i.e.:

- mean resting pressure of the anal sphincter (mmHg)
- maximum squeeze pressure (mmHg)
- mean anal canal length (cm)
- the assessment of parameters of defecation dynamics during HR-ARM: percentage of anal relaxation rate, residual anal pressure, rectoanal pressure gradient.

All secondary end points will be assessed in sitting and lying position in the two groups.

LOCATION

The Department of Paediatric Gastroenterology and Nutrition, Medical University of Warsaw.

INTERVENTION

The parents of children who are patients of the Department of Paediatric Gastroenterology and Nutrition, who meet the inclusion criteria will be offered the option to participate in the study. After the physical examination and the anthropometric measurements, the 3D HR-ARM will be performed in the lying and then in the sitting position.

In all cases, the condition for enrolment will be obtaining the written consent of the child's parents or guardians, or in the case of a child ≥ 16 years old also the child's consent.

ETHICAL CONSIDERATION

Before starting, it will be explained to parents and children how the manometry will be performed. Full privacy will be maintained during the manometric procedure.

The study was approved by the Ethics Committee of the Medical University of Warsaw, Poland (KB/178/2019).

EXPECTED BENEFITS

The test will determine the reference pressure values recorded during bear down manoeuvre in the lying and sitting position. This will improve adequacy of diagnosis of DD in patients with functional constipation as well as the choice of the appropriate treatment method, for example biofeedback therapy.

RISK AND INCOVENIENCES FOR PATIENTS:

The participation in the study will be similar to a routine hospitalization of patients with constipation in our Department. In addition to routine examinations performed as a part of the hospitalization, the HR-ARM in the lying and then the sitting position will be performed. During the test the patient may experience anal discomfort. After examination, lower gastrointestinal bleeding may occur, but it's extremely rare.

THE FIELD AND DISCIPLINE OF KNOWLEDGE:

Field: medical sciences and health sciences

Discipline: medical sciences

Speciality: paediatric gastroenterology

FUNDING SOURCE:

12 000 PLN - manometric disposable sheaths

300 PLN - stationery

10 000 PLN - publications cost

Source: Statutory money of Department of Paediatric Gastroenterology and Nutrition.

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