

Digital rectal examination and transabdominal ultrasound as diagnostic tools for constipation. Examination of the rectum in children with urology symptoms

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Primary: To investigate if there is a correlation between findings of transabdominal ultrasound measurement of the rectum and rectal digital examination. Secondary: To investigate if there is a correlation between an enlarged rectum (diameter >...

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|------------------------------|--|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Gastrointestinal motility and defaecation conditions |
| Study type | Observational non invasive |

Summary

ID

NL-OMON35605

Source

ToetsingOnline

Brief title

Rectal examination versus ultrasound.

Condition

- Gastrointestinal motility and defaecation conditions
- Urinary tract signs and symptoms

Synonym

constipation, irregularity

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Stichting Poeppoli

Intervention

Keyword: children, constipation, diagnostics, urology

Outcome measures

Primary outcome

The mean rectal diameter size measured by the US will be categorized in < 30 mm

(= normal) and 30 mm or more (= abnormal). The digital rectal examination will

give categorical data; an empty, half-filled or filled ampula. A half filled

rectum with soft stool is considered as a fecal mass with digital examination.

We will perform a Kappa test to know if the proportions with a characteristic

(large and filled, normal and empty) are the same with the two tests.

Secondary outcome

For all patients the rectal size category (normal or enlarged) will be compared

to the category based on the pediatric Rome III criteria (constipation yes or

no). A Kappa test will be done to investigate if both methods correlate.

Study description

Background summary

Functional constipation in children comprises a variable combination of gastrointestinal symptoms without signs of an underlying organic etiology. The pediatric Rome III criteria are useful for clinicians dealing with this disorder. This symptom-based classification can be used as a diagnostic tool, but is also used by physicians to explain patients and parents what a functional diagnosis is. When a patient has at least two out of six Rome III criteria the diagnosis of functional childhood constipation can be made (see

Tab 1). Additional diagnostic testing is generally not required to establish a diagnosis (1, 2).

One of the Rome III criteria is the presence of a large fecal mass in the rectum (1). This can be assessed by performing a digital rectal examination. It is recommended to do an anorectal examination at least once for a complete work-up of chronic constipation(1, 2). The examination includes inspection of the perianal region for perianal feces, fissures, hemorrhoids or malformations. With digital rectal examination the anal tone, rectum size and possible abnormalities can be evaluated as well as the amount, consistency and location of stool within the rectum.(2).

Often children with constipation are referred to pediatric gastroenterologists without prior perianal inspection or digital rectal examination(3). The lack of a rectal exam as part of the workup in this setting can be explained by multiple reasons. For one, physicians can be uncomfortable with the procedure because of inexperience. Concerns regarding trauma to the child or damaging the physician-child relationship can be the reason as well. Another consideration is that the physician assumes that rectal examination is not indicated (3). Obesity or refusal of the patient can be other child specific reasons to not perform a rectal exam(1).

Alternative methods are described and applied to assess the degree and location of stool in the rectum. An abdominal radiograph can be used(1) although several studies report poor diagnostic accuracy of fecal loading assessment with this test.(4, 5)

Measurement of the transverse diameter of the rectum with bladder ultrasonography(US) is used in a few centers, mainly by pediatric surgeons and urologists, as a parameter for constipation. In 2004 Klijn et.al evaluated this clinical practice and found a significant larger diameter of the rectum in patients with dysfunctional voiding and constipation compared to those with a normal defecation pattern(6). This difference between children with normal and abnormal bowel habits has been confirmed by others(7-9). Singh et. al found a significant difference in the median rectal size in children with only constipation (3.4 cm, range,2.10-7.0) compared to healthy children without constipation or urology problems (2.4 cm range, 1.3-4.2)(7). The presence of feces in the rectum and the effect of the fecal mass on the bladder were evaluated by Lakshminarayanan et al. They also consider this test to be a simple and reliable technique to demonstrate fecal loading in children with constipation (10). So far there is no consensus regarding the possible correlation between age and the transverse diameter of the rectum(8, 9). Although multiple studies demonstrated a significant larger rectum diameter among children with constipation(6-8), only one studied the possible correlation between a dilated rectum measured by ultrasound and a fecal mass detected by digital rectal examination(9). An excellent agreement was found between the findings obtained by digital rectal examination and ultrasound;

i.e. children with a palpable fecal mass exhibited markedly larger rectal diameters than those without rectal impaction. In this small study (constipation n=27, healthy controls n=24) all investigations were performed by the same observer(9).

This study will compare the findings of transverse rectal diameter measured by transabdominal US to digital rectal examination performed by different observers. This is relevant because up till now, the performance of a rectal digital examination is recommended to evaluate the Rome III criteria in children suspicious for functional constipation. All rectal examinations for this study will be performed by the research fellow.

Reference List

- (1) Rasquin A, Di Lorenzo C, Forbes D, Guiraldes E, Hyams JS, Staiano A, et al. Childhood functional gastrointestinal disorders: child/adolescent. *Gastroenterology* 2006 May;130(5):1527-37.
- (2) Constipation Guideline Committee of the North American Society for Pediatric Gastroenterology HaN. Evaluation and treatment of constipation in infants and children: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. *Journal of Pediatric Gastroenterology & Nutrition* 2006 Sep;43(3):e1-13.
- (3) Gold DM, Levine J, Weinstein TA, Kessler BH, Pettei MJ. Frequency of digital rectal examination in children with chronic constipation. *Archives of Pediatrics & Adolescent Medicine* 1999 Apr;153(4):377-9.
- (4) Bongers ME, Voskuil WP, van Rijn RR, Benninga MA. The value of the abdominal radiograph in children with functional gastrointestinal disorders. *Eur J Radiol* 2006 Jul;59(1):8-13.
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- (6) Klijn AJ, Asselman M, Vijverberg MA, Dik P, de Jong TP. The diameter of the rectum on ultrasonography as a diagnostic tool for constipation in children with dysfunctional voiding. *J Urol* 2004 Nov;172(5 Pt 1):1986-8.
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- (10) Lakshminarayanan B, Kufeji D, Clayden G. A new ultrasound scoring system for assessing the severity of constipation in children. *Pediatr Surg Int* 2008 Dec;24(12):1379-84.

Study objective

Primary: To investigate if there is a correlation between findings of transabdominal ultrasound measurement of the rectum and rectal digital examination.

Secondary: To investigate if there is a correlation between an enlarged rectum (diameter > 30 mm) and fulfillment of the pediatric Rome III criteria for functional constipation.

Study design

This is a prospective open study. Participants will be patients already scheduled for a urology procedure in the operation room (OR). Transabdominal ultrasound (US) is routinely performed in all patients in the OR. Transabdominal US is performed to evaluate bladder filling and the diameter of the rectum before starting the procedure. A Paracetamol suppository is given to all patients for pain relief; rectal digital examination is done during placement. In the recovery area parents will be asked about the bowel habits of their child.

Ultrasound

Transabdominal measurement of the rectal diameter is performed with the patient in supine position as described by Klijn et al. A 7.5 MHz sector probe is applied to the abdomen approximately 2 cm above the symphysis at a 10 to 15-degree downward angle. The diameter of the rectum is measured in the transverse plane. At each session the diameter is measured two times and a mean value will be calculated. Measurement can be performed with a moderately (30% to 70% of capacity for age) filled bladder (Klijn 2004).

Anorectal examination

Anorectal examination of the anorectal region encloses inspection and digital rectal examination. During inspection of the perianal region the presence or absence of perianal feces, anal fissures or hemorrhoids will be assessed. During digital examination the amount and consistency of stool will be assessed and presence or absence a rectal scybalus evaluated. This exam will be done by another person blinded for the findings of the Ultrasound. All anorectal examinations for this study will be performed by the research fellow.

Test results will be reported on a form which is designed for this study. These forms will be placed in the patient chart before they go to the OR.

Screening:

In the recovery room questions will be asked to the parents regarding the bowel habits of their child (defecation frequency, painful and/or hard stools, fecal incontinence, stool withholding behavior, large amounts of stools). Also questions about the patients medical history (abnormalities/malformations or previous surgery in the anorectal/pelvic region) will be asked.

Study burden and risks

There is no additional risk for participating subjects in this study since the digital rectal examination is a safe and non-invasive test. There is no additional cost to participate in this study. Participation in this study has no direct benefits for the study subjects. Study subjects will not be paid to be in this study.

Contacts

Public

Universitair Medisch Centrum Utrecht

P.O.Box 85090
3508AB Utrecht
Nederland

Scientific

Universitair Medisch Centrum Utrecht

P.O.Box 85090
3508AB Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Patients scheduled for a Urology procedure in the Operation Room of Wilhelmina Children's Hospital/ University Medical Center Utrecht or in the Emma Children's Hospital/AMC Amsterdam
- Boys and girls

- Children age 4 -17 years

Exclusion criteria

- Empty bladder or maximal bladder filling
- Children with known organic abnormalities/malformations or previous surgery in the anorectal/pelvic region

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-03-2010

Enrollment: 85

Type: Actual

Ethics review

Approved WMO

Date: 21-01-2010

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 20-12-2010

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL29023.041.09 |