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ORIGINAL ARTICLE

Intrastomal 3D ultrasound; an inter- and intra-observer evaluation

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Abstract
Background The aim of this study was to determine intra- and interobserver reliability in 3D intrastomal ultrasound imaging of parastomal hernia and protrusion.
Method A total of 40 patients were investigated. Two or three physicians evaluated the images twice, 1 month apart.
Results Inter-observer agreement was 72 % with a kappa value 0.59. For the last 10 patients there was an agreement of 80 % with a kappa value of 0.70. Intraobserver agreement was 80 % for one observer and 95 % for the other. The learning curve levelled out at around 30 patients.
Conclusion Considering the learning curve of 30 patients, 3D intrastomal ultrasound is a reliable investigation method. 3D intrastomal ultrasonography has the potential to be the investigation of choice to differentiate between a bulge, a hernia, or a protrusion.

Keywords Intrastomal · Intraobserver · Interobserver · 3D ultrasound · Evaluation

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Introduction

Parastomal hernia or a bulge surrounding the stoma is a common complication among patients with a temporary or permanent stoma. The frequency of parastomal hernia in the literature has been reported to be up to 50 % depending on diagnostic criteria and the interval between surgery and evaluation [1]. The majority of all parastomal hernias develop within a few years, but can appear as late as 20 years after surgery [2]. The definition of parastomal hernia is not uniform, and the distinction between a bulge in the abdominal wall and a parastomal hernia is vague. There are few comparisons between clinical examination and radiology. One of these [1] showed an increase in incidence from 52 % to 78 % when CT scanning was added to the physical examination. CT scanning, however, is not the optimal radiological examination, partly due to the obvious disadvantage that a routine CT scan is performed in the supine position, and during provocation one may still miss a parastomal hernia [3]. In a previous study by us, a most striking result was a low interobserver reliability between the investigating surgeons despite the fact that four of the five examiners were experienced colorectal surgeons with a special interest in parastomal hernia [4].

This led us to explore the possibility to detect parastomal hernia using 3D intrastomal ultrasound. In our preliminary report, we concluded that it is possible to distinguish between a hernia, a bulge, or a protrusion of the intestine [5]. When using render mode, the pictures have a clear boundary between anatomical structures such as rectal muscle, fascia, and the bowel. These three structures are most important to identify when evaluating the shape and the size of a possible parastomal hernia or protrusion. The examination is

Table 1 Protocol used for clinical and ultrasonography evaluation

Assessment of 3 D intrastomal ultrasonography,
investigator patient name

Clinical investigation

Inspection;	Erect	bulge	☐	no bulge	☐				
	Position	9-12	☐	12-3	☐	3-6	☐	6-9	☐
	Supine	bulge	☐	no bulge	☐				
	Position	9-12	☐	12-3	☐	3-6	☐	6-9	☐
Palpation	Normal	☐							
	Weakness	☐							
	Position	9-12	☐	12-3	☐	3-6	☐	6-9	☐
	Protrusion	☐							
	Hernia	☐							
	Position	9-12	☐	12-3	☐	3-6	☐	6-9	☐
Ultrasound	Normal	☐							
	Protrusion	☐							
	Hernia	☐							
	Position	9-12	☐	12-3	☐	3-6	☐	6-9	☐
	Intestine	yes	☐	no	☐				
	Fascia	circ.	☐	partial	☐	no ass.	☐		
	Rectus	circ.	☐	partial	☐	no ass.	☐		
	Mesh	no	☐	onlay	☐	sublay	☐		

Comments ☐ ....

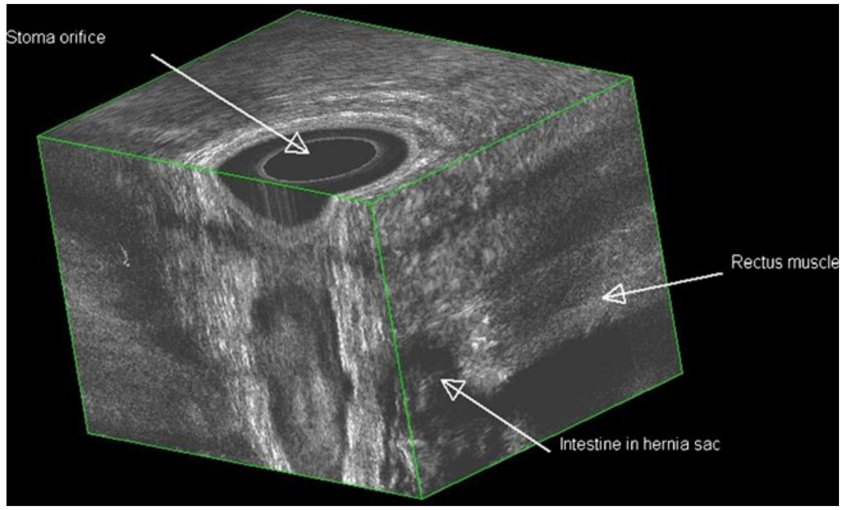

Fig. 1 Parastomal hernia

dynamic and is possible to perform in both the supine and erect positions. Before it can be used in routine clinical practice, intrastomal 3D ultrasonography must be evaluated for reliability. This evaluation must include validity of the examination, and inter- as well as intra-observer reliability when assessing images. The aim of this study was to determine the intra- and interobserver reliability of 3D intrastomal ultrasound and to assess the learning curve.

Methods

Investigators In this study, there are three physicians from two different hospitals, one experienced in endoanal and endorectal ultrasound and two with short training.

Ultrasound machine Profocus 2202 (BK Medical, Herlev, Denmark) was used with the 2050 transducer (BK Medical). This is a transducer fit for 3D ultrasound uptake in anal and rectal investigations. The probe was covered with a water-filled balloon and taped individually according to the degree of subcutaneous fatty tissue. After introduction into the stoma the balloon was filled and usually 30–40 ml of water was required. The rectal setting with 9 MHz was used. Both ordinary images and render mode images were evaluated.

Patients Forty patients from Karolinska University Hospital, Sunderby Hospital, and Norrlands University Hospital were recruited. The patients had the following stomal complaints: bulging, suspected hernia, leakage, pain, or change in complexion of the stoma. The majority of the patients had colostomies whereas a few had an ileostoma. None of the patients had urostoma. The BMI of all patients were below 35. All patients were informed about the experimental nature of the investigation and could, at any moment, terminate their participation because of pain or any other reason.

Study design All patients were clinically examined by two or three physicians and the results were recorded in a separate protocol. To standardise evaluation of the 3D ultrasonography examination, a strict protocol was followed (Table 1). One physician performed the 3D ultrasound investigation in both

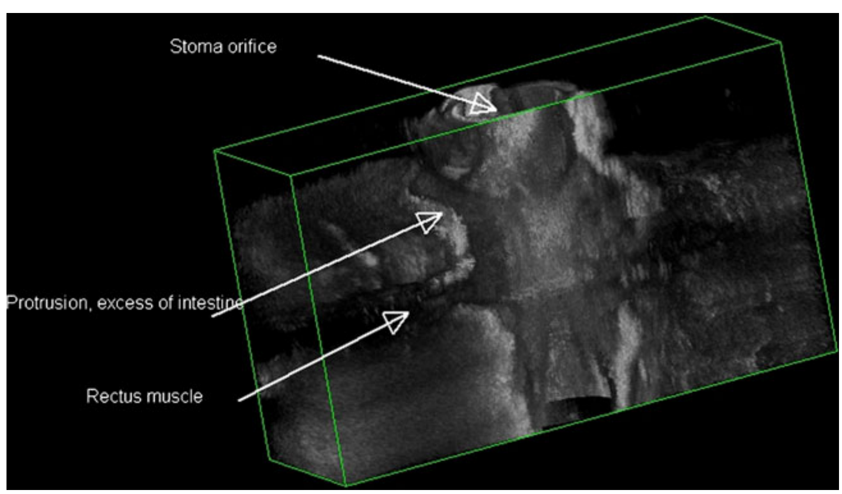

Fig 2 Stoma protrusion

supine and erect positions, both with and without a valsalva manoeuvre. Results were categorised in the protocol as normal, a protrusion, or a parastomal hernia. Protrusion was defined as subcutaneous excess of the stoma intestine but with an intact aperture (Fig. 1) whereas a hernia was defined as defect of the fascia with a protruding hernia sac at the passage of the stoma intestine through the abdominal wall (Fig. 2). Identification of anatomical landmarks was indicated and probable content in the hernia sac registered. Images from the examinations were transferred to USB memory sticks, allowing all three physicians to make their own assessment according to the protocol. Assessments were performed after each sequence of examinations and 1 month later. The study protocol included 20 patients in the base sample. To reach the top of the learning curve, groups of 10 patients were added. Following the base sample and the subsequent additional groups, the images were discussed between the physicians after individual assessments had been made. In total, 40 patients were included before the learning curve levelled out. The study design thus ended up in a three-step learning curve for evaluation of intra- and inter-observer reliability.

Statistics

Statistics were evaluated with Fleiss' kappa [6] for calculation of inter-rater reliability with more than two observers. The interpretation of kappa values is shown in Table 4. Calculation of congruence between investigators was calculated as the proportion of unanimous assessments.

The study was approved by the local Ethics Committee (2009/1308-31/2).

Results

Seventeen patients were investigated by all three investigators and the succeeding 23 by two of the investigators. The results reveal a stepwise improvement (Tables 2 and 3). Inter-observer Fleiss' kappa was 0.59 for the entire cohort. The overall agreement between two investigators was 80 % and by three investigators 58.8 % (17/40 examinations).

Although two of the investigators had a short training period, 3D intrastomal ultrasound interobserver reliability increased from moderate agreement to substantial agreement [6] (Table 4). Concurrently, intraobserver agreement, between each group of patients added, improved. The initial 20 patients showed good agreement in one case and acceptable in the other two. After 30 patients, this had improved to good and excellent (Table 2), respectively. By the last 10 patients, the learning curve had reached its top.

Table 2 Inter-observer reliability

Patient number	1–20	21–30	31–40	Total
Kappa value	0.41	0.55	0.7	0.59
Agreement	70 %	70 %	80 %	72.5 %

Table 3 Intra-observer agreement and Kappa values

Patient number	1–20	21–30	31–40	Total
Kappa, observer 1	0.66	1.0	0.76	0.79
Agreement, 1	80 %	100 %	90 %	93 %
Kappa, observer 2	0.19	0.53	1.0	0.39
Agreement, 2	70 %	70 %	100 %	80 %

Discussion

It is possible to reach a high degree of agreement between investigators, with high intraobserver reliability, and with a rather short learning curve. Kappa values for intraobserver reproducibility differed considerably between observers at the beginning of their learning curve. The 3D ultrasound sampling is quiet easy to perform but it is obvious that evaluation of images has a longer learning curve. Evaluation of data emphasises differentiation between hernia and a protrusion as being the most critical step, whereas differentiation between normal and abnormal seems easier. One reason why the learning curve is shorter for those with experience of rectal ultrasound may be the use of render mode. The difference seen between the experienced physician and those with less practice indicates this. These computer-modified images enhance certain structures, but the 3D image may also become more complex to evaluate [7]. Assessment of intrastomal ultrasound images is quiet similar to that in rectal ultrasound [8]. It differs from anal images where there are strict anatomical landmarks. Despite this reproducibility in the anal field is also insufficient [9]. Studies concerning 3D endoanal ultrasound assessment of the anal sphincter showed somewhat divergent results for both inter- and intra-observer measurements [9, 10]. 3D ultrasound and volumetric analysis of the placenta as well as assessment of the pelvic floor anatomy showed good intra- and inter-observer

Table 4 Statistical level of agreement with Fleiss Kappa Values

Kappa value	Statistical level of agreement
<0	Poor
0.01–0.20	Slight agreement
0.21–0.40	Fair agreement
0.41–0.60	Moderate agreement
0.61–0.80	Substantial agreement
0.81–1.00	Almost perfect agreement

agreement [7, 11]. These improved results may partly be an effect of modern 3D techniques. Anal and rectal ultrasound assessments are often compared with other modalities and not evaluated for intra- and inter-observer agreement [12].

In rectal ultrasound, tissue attenuation is affected, for example, by cancer infiltration and inflammation. Similar variations are seen in intrastomal ultrasound, where the thickness of rectus abdominis muscle is affected by age, gender, and previous surgery. The externus fascia and surrounding tissues may differ, especially after surgery. Thus, experience of rectal 3D ultrasound may enhance the understanding of intrastomal images. There are no studies on inter- or intra-observer validity in rectal 3D ultrasound. Studies on 2D ultrasound from the 1990s, however, showed good agreement, but with nonsignificant kappa values [13, 14].

As regards the learning curve, 3D intrastomal ultrasound is safe and easy to perform. When difficulties arise during the evaluation process, images may be sent to a more experienced interpreter. To ensure accurate interpretation of images, a formal education with accreditation may be justified.

Intrastomal 3D ultrasound has the potential to be the investigation of choice to differentiate between a bulge representing a weakness of the abdominal wall, a hernia or a protrusion, in cases of stoma-related complaints. In this aspect, possible surgical intervention can be chosen on a more individualised basis. If there is a protrusion a small operation at the stoma orifice is sufficient while a parastomal hernia necessitate a more complex intervention. In case of a bulge of the abdominal wall, the cause of complaints may not be solved with surgery. Furthermore, it is important to diagnose smaller hernias with a potential risk for incarceration of the small bowel.

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