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Evacuation Proctography: A Prospective Study of Diagnostic and Therapeutic Effects¹

PURPOSE: To determine the diagnostic and therapeutic effects of evacuation proctography.

MATERIALS AND METHODS: Forty-seven referring clinicians completed preevacuation proctography questionnaires for 50 patients, detailing diagnoses, confidence in these, intended management, and what they hoped to learn. After evacuation proctography, the radiology report was returned with a second questionnaire asking the diagnosis in the light of evacuation proctographic findings, their confidence, and what they had learned. Clinicians quantified management contribution and indicated how useful they found evacuation proctography in general. Results from pre– and post–evacuation proctography questionnaires were compared to determine the diagnostic and therapeutic effects.

RESULTS: Diagnostic confidence rose significantly after evacuation proctography (mean, 7.0 before evacuation proctography vs 8.4 after evacuation proctography; P < .001). Lead diagnosis changed in nine (18%) patients. Intended surgical management became nonsurgical after evacuation proctography in seven (14%) patients, and intended nonsurgical therapy became surgical in two (4%). Surgery remained likely in 15 patients, but its nature changed in five (10%). Five (10%) clinicians stated that evacuation proctographic findings resolved diagnostic conflict, and nine (18%) found that evacuation proctographic findings revealed unsuspected diagnoses. Clinicians found evacuation proctography of major benefit in 20 (40%) cases studied and of moderate benefit in 20 (40%). In general, 20 (43%) clinicians found evacuation proctography very useful and 24 (51%) found it moderately useful.

CONCLUSION: Evacuation proctography has a substantial diagnostic and therapeutic effect and is of considerable benefit to referring clinicians.

Evacuation proctography (defecography) documents the act of voluntary rectal evacuation, which provides information on anorectal structure and function. There is a current explosion of interest in functional pelvic floor disorders, which has been stimulated by developments in imaging and anorectal physiologic testing (1). This has created considerable clinical demand for evacuation proctography, which has gained general acceptance over the past decade, in both the United States and Europe.

Despite its popularity, surprisingly little work has been done to determine the therapeutic effect of evacuation proctography, although its technical and diagnostic performances have been assessed extensively. However, the presence of supposedly abnormal findings in asymptomatic volunteers (2,3), wide interobserver variation (4), and the difficulties encountered by investigators in evaluating radiologic findings with respect to clinical outcome have led some authors to question its value (5). There are particular difficulties facing investigators who wish to determine the benefits, or otherwise, of evacuation proctography, and studies attempting to do so (6,7) have attracted fierce criticism from advocates of the technique (8,9). Because the etiology of functional pelvic floor disorders remains largely unknown and there is no consensus on treatment, attempts to determine

Diagnosis before Evacuation Proctography	Intended Treatment before Evacuation Proctography	Evacuation Proctographic Finding	Diagnosis after Evacuation Proctography	Intended Treatment after Evacuation Proctography	Contribution of Evacuation Proctograph
Anismus	Biofeedback	Anismus	Anismus	Biofeedback	Moderate
Rectal intussusception	Surgery	Low-grade intussusception	Rectal intussusception	Reassurance	Moderate
Obstructed defecation	Biofeedback	Incontinent	Obstructed defecation	Reassurance	Moderate
Descending perineum	Medical	High-grade intussusception	Descending perineum	Medical	Minor
Anismus .	Biofeedback	Rectocele	Rectocele	Biofeedback	Moderate
Rectocele	Surgery	Rectocele	Rectocele	Surgery	Major
Rectal intussusception	Surgery	Enterocele	Enterocele	Surgery*	Major
Anismus	Reassurance	Sigmoidocele	Sigmoidocele	Surgery	Major
Rectal intussusception	Surgery	Sigmoidocele	Sigmoidocele	Surgery*	Major
Anismus	Medical	Anismus	Anismus	Biofeedback	Moderate
Complete rectal prolapse	Surgery	Complete rectal prolapse	Complete rectal prolapse	Surgery	Major
Anismus	Biofeedback	Anismus	Anismus	Biofeedback	Minor
Rectal intussusception	Medical	Normal	Normal	Medical	Moderate
Anismus	Biofeedback	Anismus	Anismus	Biofeedback	Major
Solitary ulcer syndrome	Surgery	High-grade intussusception	Solitary ulcer syndrome	Surgery	Moderate
Anismus	Biofeedback	Anismus	Anismus	Biofeedback	Major
Rectocele	Biofeedback	Rectocele	Rectocele	Biofeedback	Moderate
Anismus	Biofeedback	Normal	Anismus	Reassurance	Major
Rectal intussusception	Surgery	Low-grade intussusception	Rectal intussusception	Reassurance	Major
Anismus	Biofeedback	Anismus	Anismus	Biofeedback	Major
Anismus	More tests	Normal	Anismus	More tests	No benefit
Rectal intussusception	Surgery	Enterocele	Enterocele	Surgery*	Major
Anismus	Biofeedback	Rectocele	Anismus	Medical	Minor
Rectal intussusception	Surgery	Enterocele	Enterocele	Surgery*	Major
Anismus	Biofeedback	Anismus	Anismus	Biofeedback	Major
Rectocele		Rectocele	Rectocele		,
Complete rectal prolapse	Surgery	Complete rectal prolapse		Surgery Surgery	Major Major
	Surgery		Complete rectal prolapse		
Rectal intussusception	Biofeedback	Rectal intussusception	Rectal intussusception	Biofeedback	Moderate
Incontinence	Surgery	Normal	Incontinence	Medical	Moderate
Rectal intussusception	Medical	Low-grade intussusception	Rectal intussusception	Medical	Moderate
Incontinence	Surgery	Normal	Incontinence	Medical	Major
Rectal intussusception	Surgery	Low-grade intussusception	Rectal intussusception	Surgery	Moderate
Rectal intussusception	Surgery	Normal	Rectal intussusception	Medical	Minor
Slow colonic transit	Biofeedback	Normal	Slow colonic transit	Biofeedback	Moderate
Rectal intussusception	Surgery	Low-grade intussusception	Rectal intussusception	Biofeedback	Moderate
Rectocele	Surgery	High-grade intussusception	Rectal intussusception	Surgery*	Major
Solitary ulcer syndrome	Surgery	High-grade intussusception	Solitary ulcer syndrome	Surgery	Moderate
Rectocele	Surgery	Rectocele	Rectocele	Surgery	Major
Obstructed defecation	Medical	Normal	Obstructed defecation	Biofeedback	Minor
Anismus	Biofeedback	Rectal stricture	Rectal stricture	Surgery	Major
Anal pain	Medical	Normal	Anal pain	Medical	No benefit
Rectal intussusception	Medical	Low-grade intussusception	Rectal intussusception	Medical	Minor
Incontinence	Surgery	Incontinent	Incontinence	Surgery	Moderate
Solitary ulcer syndrome	More tests	High-grade intussusception	Solitary ulcer syndrome	Biofeedback	Minor
Rectal intussusception	Surgery	Normal	Rectal intussusception	Medical	Major
Descending perineum	Medical	Incontinence	Descending perineum	Medical	Moderate
Rectocele	Surgery	Rectocele	Rectocele	Surgery	Moderate
Anal pain	Reassurance	Normal	Anal pain	Reassurance	Minor
Rectocele	Medical	Rectocele	Rectocele	Medical	Moderate
Obstructed defecation	Reassurance	Anismus	Obstructed defecation	Reassurance	Moderate

Note.—"Reassurance" means reassurance that no serious condition is present and no treatment is needed.

*Altered surgical approach.

benefit on the basis of clinical outcome inevitably include assessment of any treatment. Also, patients present with subjective symptoms rather than signs, so that groups are clinically heterogeneous. Given this, it may be more appropriate to determine whether evacuation proctography improves diagnostic confidence and to assess its contribution to management. We aimed to determine the diagnostic and therapeutic effects of evacuation proctography with a prospective study in

which established indexes (10,11) were used to measure the effects of imaging.

MATERIALS AND METHODS

To determine the diagnostic and therapeutic effects, a pre- and postintervention observational study design was used (12). Fifty consecutive adult patients were examined. There were seven men (mean age, 60 years; age range, 33–80 years) and 43

women (mean age, 49 years; range, 20–82 years). Over the study period, all physicians referring adult patients for evacuation proctography were asked to complete a preexamination questionnaire at the time of requesting the examination. This questionnaire asked physicians to detail their leading clinical diagnosis and their confidence in this by using a 10-point scale ("1" indicating least confident and "10" indicating most confident). They were asked what they hoped

224 • Radiology • April 1999 Harvey et al

to learn from evacuation proctography by answering "yes" or "no" to the following possibilities: confirmation of clinical diagnosis, resolution of conflict between history and clinical findings, diagnosis of unsuspected anorectal disorder, not expected to be helpful. They were asked to detail diagnostic tests that had been performed or that were to be requested from the following possibilities: barium enema examination, anal endosonography, colonic transit studies, anorectal physiology, sigmoidoscopy, colonoscopy, or a combination of these. Finally, they were asked to anticipate the patient's likely treatment after evacuation proctography by selecting from the following possibilities: surgical, medical, biofeedback, reassurance only, further tests. There were 47 referring clinicians, including those based within our own hospital and others from a large number of teaching and district general hospitals. Clinicians were of all qualified hospital grades from both medical and surgical specialities.

Evacuation proctography was performed by using a standard technique. One hour before the examination, 300 mL of dilute barium suspension (Baritop; Bioglan Laboratories, Hitchin, England) were given orally to opacify the small bowel (13). Two glycerine suppositories were then administered rectally and retained for 20 minutes; patients then were invited to empty the rectum in the toilet. With the patient in the left lateral position, 120 mL of barium paste (E-Z-paste; E-Z-Em. Westbury, NY) was instilled into the rectum via a bladder syringe. The patient was then seated upright on a specially designed commode and asked to empty the rectum as rapidly and completely as possible during lateral digital fluoroscopy at a rate of one frame per second. Filming was intermittent if evacuation was delayed, prolonged, or both so that the maximum total screening time was kept to less than 60 seconds. All examinations were reported by one of two consultant radiologists (S.H., C.I.B.) experienced in evacuation proctography.

The radiologic report was divided into two categories, as per our usual practice. The first described any structural abnormality present; structural abnormalities were broadly categorized into prolapse (including high-grade intrarectal intussusception, intraanal intussusception, anterior mucosal prolapse, and complete rectal prolapse), rectocele, enterocele, sigmoidocele, perineal ballooning, and excessive pelvic floor descent. No structural measurements were made owing to considerable overlap with normal findings

(2,3). In addition to structural findings, if present, evacuatory function was also assessed and reported as normal, incontinent, or impaired evacuation. Impaired evacuation was defined as the inability to evacuate most of the enema within 30 seconds (1.9).

The radiologic report was returned to the referring clinician along with a postexamination questionnaire. Referring clinicians did not have access to their preexamination responses when completing this second questionnaire. Clinicians were asked to state their leading diagnosis in light of the evacuation proctographic findings and their certainty by using the same 10-point scale used previously. They were asked what they had learned from the results of evacuation proctography; answers were grouped into approximately the same four categories as previously: It confirmed clinical diagnosis, it resolved conflict between history and clinical findings, it revealed an unsuspected anorectal disorder, or it was not helpful. Clinicians were asked the patient's likely treatment in the light of evacuation proctographic findings: surgical, medical, biofeedback, reassurance only, or further tests. If further tests were planned, clinicians were asked to indicate what these were. Clinicians were asked to assess the contribution of findings of evacuation proctography to the patient's treatment in this particular case: major, moderate, minor, or nil. Finally, clinicians were asked to indicate how useful they found evacuation proctography generally: very useful, moderately useful, of minor use, or not useful.

Pre- and postexamination questionnaires were compared, and confirmation of, or any change in, diagnosis was determined. Changes in clinicians' certainty in these diagnoses were calculated, and significance was determined by using the paired Student t test, parametric distribution having been confirmed by using the Kolmogorov-Smirnov test. Preexamination expectations were compared with postexamination findings, and the number of follow-up investigations was calculated. Changes in intended management were determined, and the value of evacuation proctography in each individual case, and generally, was assessed.

RESULTS

Diagnostic Confidence

The leading preevacuation proctographic diagnosis was rectal prolapse (including all grades of internal rectal intussusception and complete rectal prolapse); it was diagnosed in 16 patients. The diagnosis was anismus (puborectalis paradox) in 13 patients, rectocele in seven, obstructed defecation in three, solitary rectal ulcer syndrome in three, incontinence in three, descending perineum syndrome in two, anal pain in two, and idiopathic slow transit constipation in one (Table). Clinicians' preexamination mean confidence level ± SD in these leading diagnoses was 7.0 ± 2.2 (range, 1-10) compared with a post-evacuation proctography mean of 8.4 \pm 2.3 (range, 0-10; P <.001) (Fig 1). The leading clinical diagnosis remained unchanged after evacuation proctography in 41 (82%) patients but was changed in nine (18%) patients: In five patients with a pre-evacuation proctographic diagnosis of rectal intussusception, the diagnosis was changed to enterocele in three, sigmoidocele in one, and normal in one. A leading diagnosis of anismus was reclassified as rectocele in one patient and as sigmoidocele in one patient (Fig 2). In a third patient, suspected anismus was actually a rectal ampullar stricture (Fig 3). In a patient with a diagnosis of rectocele, the diagnosis was reclassified as rectal intussusception after evacuation proctography (Fig 4).

Expectations and Management Plans

Before examination, 28 (56%) clinicians hoped evacuation proctography would confirm their clinical diagnosis. five (10%) hoped it would resolve conflict between historic and clinical findings, 15 (30%) thought it might reveal unexpected findings, and two (4%) did not expect imaging to be helpful. After evacuation proctography, 31 (62%) stated that evacuation proctographic findings had confirmed their clinical diagnosis, five (10%) stated that these findings had resolved a conflict between historic and clinical findings, nine (18%) found that evacuation proctography had revealed unsuspected diagnoses, and five (10%) stated they did not learn anything important.

Intended management before and after evacuation proctography is shown in the Table. Intended management before evacuation proctography was surgical in 22 patients; however, this decision was changed after evacuation proctography in seven of these 22 patients: Five patients with suspected high-grade intussusception had either low-grade intussusception or were normal, one patient with incontinence showed no contrast material leakage during evacuation proctogra-

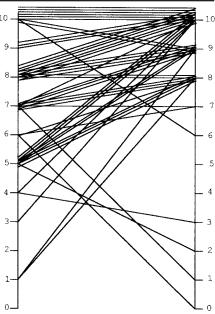


Figure 1. Graph shows clinicians' confidence in their clinical diagnoses before (left vertical axis) and after (right vertical axis) evacuation proctography (I = least confident, I0 = most confident). Mean preexamination value, 7.0; mean postexamination value, 8.4 (P < .001).

phy, and another patient with incontinence whose postanal repair was thought to have failed had a satisfactory anorectal angle revealed at evacuation proctography. Conversely, for two patients, initially intended conservative treatment was changed to surgery after evacuation proctography: An unsuspected sigmoidocele was visualized in one patient thought to have anismus (Fig 2) and a rectal stricture was visualized in the other thought to have anismus (Fig 3). Surgery remained the likely management in 15 patients both before and after evacuation proctography; however, the nature of this surgery changed in five patients: Three of four patients thought to have high-grade rectal intussusception had enterocele; the fourth had a sigmoidocele. In one woman, a large rectocele was reclassified as highgrade intussusception (Fig 4).

Examinations prior to evacuation proctography included barium enema (n = 12), anal endosonography (n = 19), colonic transit studies (n = 5), anorectal physiology (n = 22), and sigmoidoscopy or colonoscopy (n = 25). Further investigations were planned in only four (8%) patients after evacuation proctography; all were to undergo anorectal physiology combined with either anal endosonography (two patients) or colonic transit studies (one patient; one patient underwent only anorectal physiology).



Figure 2. Evacuation proctogram in a 50-yearold woman reveals a large anterior sigmoidocele (arrows). Anismus had been clinically diagnosed before evacuation proctography, and the intended management was nonsurgical. After evacuation proctography, the patient was to be treated surgically.

How Useful Is Evacuation Proctography?

Clinicians found evacuation proctography to be of major benefit in 20 (40%) of the 50 cases studied, of moderate benefit in 20 (40%), of minor benefit in eight (16%) and of no benefit in two (4%). Overall, 47 clinicians participated in the study. Twenty (43%) of these generally found evacuation proctography very useful; 24 (51%), moderately useful; three (6%), of minor use; and none, of no use.

DISCUSSION

Although evacuation proctography has become the examination of choice for the investigation of anorectal dysfunction in many centers, its clinical relevance continues to be debated. There have been previous attempts to determine the benefits or otherwise of evacuation proctography. Ott and co-workers (6) tried to assess the clinical effect of evacuation proctography in 55 patients in a retrospective case-note review in which cases were sorted into normal and abnormal groups on the basis of the radiologic report. Because comparisons of proctographic measurements were not significantly different between groups, the authors assumed that these measurements were valueless, a conclusion that is hardly sur-

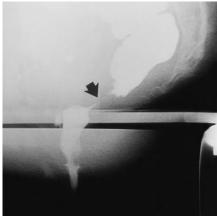


Figure 3. Evacuation proctogram in a 36-year-old woman with a clinical diagnosis of anismus reveals a midampullary stricture (arrow). The intended biofeedback therapy was changed to surgery after evacuation proctography.

prising on further analysis, since all the patients had a defecatory disorder and were compared with each other and not with control subjects. The authors also assumed that effective imaging is reflected in better patient outcome, an approach that may be misplaced because it necessarily integrates treatment assessment (10-12). Hiltunen and co-workers (7) studied the cases in 73 patients retrospectively, concluding that evacuation proctography was of limited clinical benefit, again because they were unable to differentiate between subgroups by using standard measurements. Once more, there was no comparison with control subjects.

These studies generated considerable debate (8,9), but they rightly addressed a lack of consensus with regard to the value of functional pelvic floor imaging in clinical management. The technical and diagnostic performances of an imaging test are relatively easy to measure (10,11), and both have been extensively assessed for evacuation proctography. However, diagnostic effect (does the test alter diagnostic confidence?) and therapeutic effect (does the test contribute to, or alter, management?) are more difficult to establish. Although evacuation proctography can image a wide spectrum of pelvic floor disorders, its precise therapeutic effect is difficult to determine and has not been previously established. This is in part due to confusion over indications for evacuation proctography (8), the observation that some apparently abnormal findings may be present in asymptomatic individuals (2,3), wide interobserver variation (4), differing examination techniques, and problems in interpretation. Indeed, some authors suggest that functional parameters of evacuation are most relevant (14,15),

Harvey et al



Figure 4. Evacuation proctogram in a 54-yearold woman reveals rectal intussusception (arrows). Rectocele had been clinically diagnosed before evacuation proctography, and surgery was intended. After evacuation proctography, the surgical approach was changed.

while others rely on structural measurements (16). Furthermore, the majority of patients complain of constipation; a symptom rather than a clinical sign. Subjective interpretation of disturbed bowel function and numerous possible causes ensures that any group of consecutive examinations will be heterogeneous, making meaningful analysis difficult. Confounding this, treatment for chronic, severe constipation is frequently ineffective, which biases studies on the basis of clinical outcome. The best method to assess therapeutic effect is the randomized trial, but clinicians are reluctant to deny patients access to seemingly beneficial imaging. For this reason, prospective, observational, "intention-to-treat" studies are acceptable alternatives (12).

Using this approach, we found that evacuation proctography has considerable diagnostic and therapeutic effects. Proctographic findings confirmed the clinical diagnosis in 62% of cases, resolving diagnostic conflict in 10%. Diagnostic performance was confirmed with a statistically significant increase in diagnostic confidence after evacuation proctography, with leading diagnoses changed in 18% of cases. This translated into considerable therapeutic effect, with prevention of surgery in 14% of patients and introduction of surgery as intended management in 4% in whom it had not been considered previously. Furthermore, of those 15 patients in whom surgery remained the likely therapy, surgical technique was altered in a third as a consequence of unexpected findings revealed at evacuation proctography. It is well recognized that evacuation proctography often discloses findings that are clinically unsuspected; Kelvin and co-workers (13) discovered additional findings in 48 (65%) of 74 consecutive patients by using the technique. The present study findings confirm that this diagnostic performance translates into tangible therapeutic effect after it has been related back to the referring clinician. It should also be remembered that intended therapy may change, even when the leading diagnosis remains the same: for example. intended surgery for suspected high-grade intussusception may be withheld if evacuation proctography demonstrates low-grade intussusception considered to be within normal limits by many clinicians.

We attempted to remove any confounding variables introduced by ordering a battery of tests simultaneously, by asking clinicians directly what they felt had been the contribution of evacuation proctography in each individual case; clinicians stated it was of major benefit in 40% of the patients examined and of moderate benefit in a further 40%. Indeed, it was thought to have been of no benefit in only 4%. Of the 47 clinicians who participated, 44 (94%) generally thought evacuation proctography to be of major or moderate use, the majority using it to confirm their leading diagnosis. After evacuation proctography, only four patients were to undergo further investigations, but this may be partly due to the ordering of other tests simultaneously with evacuation proctography.

There is often no clinical consensus with regard to the treatment of certain anorectal disorders, which explains apparent inconsistencies in clinicians' intended management plans before and after evacuation proctography. For example, some clinicians will treat high-grade rectal intussusception surgically while others, believing it to be secondary to an unsuspected functional disorder of evacuation, will favor conservative management (14). Similarly, the clinician may still believe a patient has a particular anorectal disorder, despite apparently normal or inconclusive evacuation proctographic findings and direct management appropriately. This study has attempted to eliminate confounding variables of differing opinions, treatments, and efficacy by directly asking referring clinicians their opinion of evacuation proctography in the specific case being investigated and in their experience generally. In contrast to previous studies, where these variables remained unaccounted for, this study found evacuation proctography to be of major benefit to the referring clinician, as evidenced by therapeutic effect and their own admission. It has been suggested that as far as imaging tests are concerned the ultimate consumer is the referring clinician, rather than the patient (17). Whether a particular imaging technique assists clinical understanding and management is perhaps the most relevant question in its assessment.

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