CIRUGÍA ESPAÑOLA

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Original article

Evaluation of three-dimensional endoanal endosonography of perianal fistulas and correlation with surgical findings

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ARTICLE INFORMATION

Article history:
Received December 18, 2009
Accepted February 15, 2010
Online April 13, 2010

Keywords:
Perianal fistula
Three-dimensional endoanal endosonography
Two-dimensional ultrasound

ABSTRACT

Objective: This study aims to assess the accuracy of three-dimensional endoanal ultrasound (3D-US), two-dimensional ultrasound (2D-US) and physical examination (PE) for the diagnosis of perianal fistulas and correlate the results with intraoperative findings.

Materials and methods: A prospective, observational study with consecutive inclusion of patients was performed between December 2008 and August 2009. Twenty-nine patients diagnosed with a perianal fistula due to undergo surgery were included. All patients underwent PE, 2D-US and 3D-US, and the results were compared to intraoperative findings. The examinations were repeated with hydrogen peroxide instilled through the external opening.

Results: Internal opening (IO): no significant differences with regards to the number of IO diagnosed by PE and 2D-US or 3D-US ($P>.05$). Primary tract: good concordance between 3D US and surgery (k=0.61), and this was higher than any of the other techniques used (PE: k=0.41; 2D-US: k=0.56). Secondary tracts: both 2D and 3D-US show good concordance with surgery (86%, k=0.66; 90%, k=0.73, respectively). Abscesses/cavities: The ultrasound examinations showed a moderate concordance with surgery (k=0.438, k=0.540, respectively).

Conclusions: 3D-US shows a higher diagnostic accuracy than 2D-US when compared with surgery to estimate primary fistula height in transphincteric fistulas. 3D-US shows good concordance with surgery for diagnosing primary and secondary tracts and a high sensitivity and specificity for diagnosis of the IO. There was a tendency to overestimate fistula height with 2D-US as shown by the lower specificity of 2D-US for the diagnosis of high transphincteric fistulas and lower sensitivity of 2D-US for low transphincteric fistulas.

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Evaluación de las fístulas perianales mediante ecografía endoanal tridimensional y correlación con los hallazgos intraoperatorios

Palabras clave:
Fístula perianal
Ecografía tridimensional endoanal
Ecografía bidimensional endoanal

RESUMEN

Objetivo: Evaluar la fiabilidad diagnóstica de la ecografía tridimensional (ECO 3D) vs. la bidimensional (ECO 2D) y la exploración física en el diagnóstico de las fístulas perianales correlacionándolo con los hallazgos intraoperatorios.
Material y método: Estudio prospectivo, observacional con pacientes incluidos de forma consecutiva entre diciembre 2008 y agosto 2009. Se incluyen 29 pacientes diagnosticados de fístula perianal subsidiarios de tratamiento quirúrgico. Se realizó una exploración física, ECO 2D, ECO 3D comparándolos con los hallazgos intraoperatorios. Cuando el orificio fistuloso externo se encuentra abierto, se repiten ambas exploraciones instilando agua oxigenada.
Resultados: Orificio fistuloso interno: sin diferencias significativas entre la exploración física y las ecografías ($p > 0,05$). Trayecto fistuloso primario: el grado de concordancia entre la ECO 3D y los hallazgos intraoperatorios es bueno ($k = 0,61$), y superior al resto de las exploraciones físicas ($k = 0,41$; ECO 2D: $k = 0,56$). Trayecto fistuloso secundario: ECO 2D y ECO 3D muestran buena concordancia con la cirugía (86%, $k = 0,66$; 90%, $k = 0,73$, respectivamente). Abscesos/cavidades adyacentes: las ecografías muestran una concordancia moderada con los hallazgos intraoperatorios ($k = 0,438$, $k = 0,540$, respectivamente).
Conclusiones: La ECO 3D tiene una fiabilidad diagnóstica mayor a la ECO 2D comparando con los hallazgos intraoperatorios para estimar la altura de las fístulas transesfintéricas. ECO 3D muestra buena concordancia con la cirugía en el diagnóstico de trayectos primarios y secundarios y una alta fiabilidad para el orificio fistuloso interno. Existe una tendencia a sobreestimar la altura de la fístula con ECO 2D, esto se deduce de la menor especificidad de la ECO 2D para el diagnóstico de fístulas transesfintéricas altas y la menor sensibilidad en las fístulas transesfintéricas bajas.

Introduction

The main goal of treatment of perianal fistulas is to cure with a low rate of recurrence and to preserve anal continence.[1] The preoperative identification of the primary fistulous tract, secondary extensions, and internal fistulous orifice (IFO) plays an important role in proper planning and selection of the surgical technique thus avoiding incomplete drainage of abscesses, early recurrence and minimising iatrogenic sphincter injury.[2]

The surgical treatment may vary depending on the preoperative classification of the fistula and its relationship to the sphincters. With two-dimensional endoanal ultrasound (2D-US), the actual spatial relationships between some elements are harder to perceive, thus losing information.[3,4] This is a supportive exploratory test that offers qualitative information on the height and tract of the fistulas. However, three-dimensional endoanal ultrasound (3D-US) provides a view in all spatial directions and allows for the exact measurement of various angles, distances, areas and volumes thereby providing quantitative information. As a result, 3D-US is a valuable technique for detecting anorectal disorders, facilitating the interpretation of results from the images obtained, and providing additional information that can change the approach to surgery.[5]

The main objective of this study is to evaluate the diagnostic reliability of 3D-US vs 2D-US and physical examination (PE) in the diagnosis of perianal fistulas, correlating it with intraoperative findings, as well as to quantitatively define the height of the primary fistulous tract in a useful manner for the study and treatment of fistulas.

Material and methods

A prospective, observational study was carried out with patients added consecutively between December 2008 and August 2009. Patients were recruited from the University Clinical Hospital of Valencia and were studied and operated on by the same team of surgeons from the Coloproctology Unit of the Department of General Surgery. The study protocol was approved in advance by the hospital's Ethics Committee.

- **Inclusion criteria.**
  - Patients diagnosed with perianal fistula of cryptoglandular origin.
  - Older than 18 years.
  - Signed informed consent.
- **Exclusion criteria.**
  - Patients operated on in other centres.
  - Patients with chronic inflammatory bowel disease.
  - Patients treated with other non-surgical techniques or drugs that could influence the outcome, such as the use of plugs, biological glues, stem cell therapy, etc.

Study protocol

Physical examination

The PE was performed in outpatient clinics by surgeons of the Coloproctology Unit. Through palpation of the perianal area and rectal touch, the fistula anatomy is defined, classifying it into intersphincteric, high or low transsphincteric, suprasphincteric and extrasphincteric fistula. Special attention is paid to the existence of a secondary tract, the localisation of the external fistulous orifice (EFO), and the height of the IFO.

Ultrasound

All ultrasounds were performed by the same surgeon with the B & K Medical Systems Pro Focus 2202® ultrasound with B-K 2050 probe (B-K Medical, Herlev, Denmark).

The patient is examined in a jack-knife position with the probe inserted through the anus. The ultrasound is performed systematically from the upper third to the lower third of the anal canal. First, a 2D-US examination is performed followed by a 3D-US at a frequency of 10 MHz, which allows for a focal range of 5-45 mm, an axial resolution of 0.5 mm and a lateral resolution of 0.5-1 mm.

In cases where the EFO is found open, both examinations are repeated and peroxide (10%) is inserted with a cannula.

- **2D-US:** we evaluate the visualisation of the IFO empty or with peroxide inserted, the height inside the anal canal and the localisation using the hourly classification and the classification published by Cho.[6]

The primary fistulous tract is classified following a modified Parks classification for:

- Not visualised.
- Intersphincteric: the tract crosses the intersphincteric space without crossing fibres of the external anal sphincter (EAS).
- Low transsphincteric: the tract crosses the EAS or both in the most distal two thirds of the anal canal.
- High transsphincteric: the tract crosses both sphincters in the high third of the anal canal.
- Suprasphincteric: the tract crosses the intersphincteric space surrounding the upper edge of the puborectalis.
- Extrasphincteric: the tract is found to be outside the EAS.

Other data obtained with this technique are the presence of secondary tracts (hipogenic tracts that meet the primary tract at some point) and the existence or not of perianal cavities and abscesses.

- **3D-US:** a three-dimensional ultrasound is then performed without removing the probe, which allows us to obtain sagittal and coronal images of the anal canal.

We reassess the location and height of the IFO, the primary tract of the fistula and the possible secondary tracts and abscesses corroborating and improving the information obtained from the 2D-US. A quantitative measure in millimetres and as percentages is performed to determine the size of the affected area of the internal anal sphincter (IAS) and EAE.

We classify the fistulas using the 3D-US according to their primary tract, as (Figure 1):

- Not visualised.
- Intersphincteric: the tract crosses the intersphincteric space without crossing EAS fibres.
- Low transsphincteric: affects less than 66% of the EAS.
- High transsphincteric: affects 66% or more of the EAS.
- Suprasphincteric: the tract crosses the intersphincteric space surrounding the upper edge of the puborectalis.
- Extrasphincteric: the tract is found to be outside the EAS.

Surgery

All operated patients were given loco-regional anaesthesia by two surgeons from the Coloproctology Unit.

First, a PE is performed under anaesthesia by placing a Hill-Ferguson valve and cannulate the fistulous tract with a stylus. Data is recorded on the location and height of the IFO, type of fistula, the surgical technique performed and the section of the EAS and EAI, in the case of performing fistulotomy.

Statistical analysis

The data obtained with the PE, the 2D-US and the 3D-US are compared with the surgical data that are considered the *gold standard*. The concordance rate the Kappa coefficient (degree of non-random correlation between different qualitative medicines of the same variable) are calculated. Additionally, the sensitivity, specificity and predictive values of each test are calculated. The chi-squared test was used to compare differences

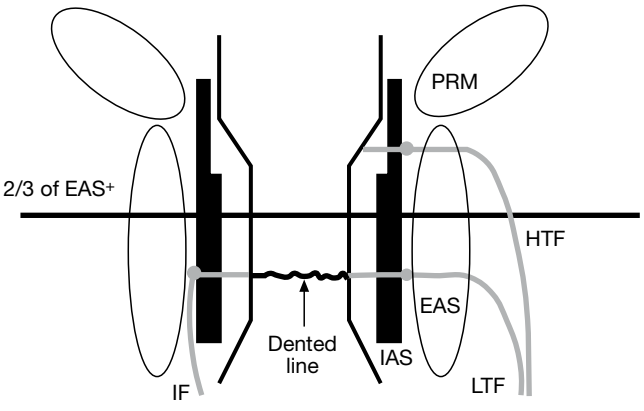

Figure 1 – Diagram of the anal canal.
EAS indicates external anal sphincter; HTF, high transsphincteric fistula; IAS, internal anal sphincter; IF, intersphincteric fistula; LTF, low transsphincteric fistula; PRM, puborectalis muscle.
+Dividing line between high and low anal canal.

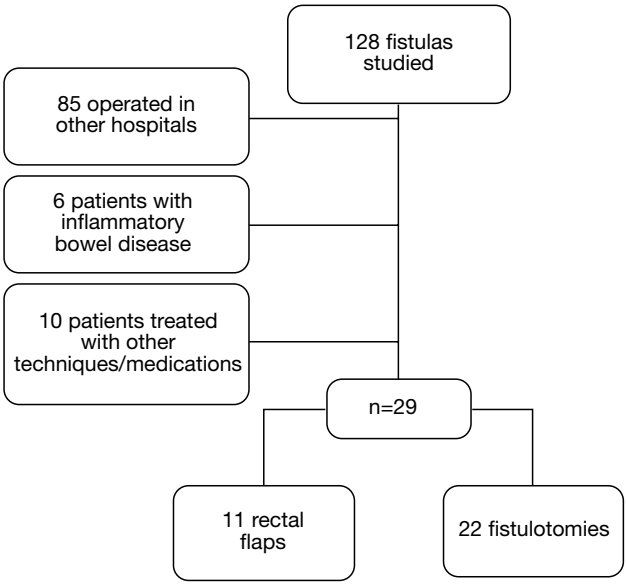

Figure 2 – Patient distribution.

between percentages considered statistically significant when $P<.05$. Statistical analysis was performed using SPSS® software, version 15.0, for Windows (SPSS Inc, Chicago, IL, USA).

Results

A total of 128 consecutive patients were included between December 2008 and August 2009. Eighty-five patients were excluded for being operated in other centres and 14 for not meeting the previously described inclusion criteria (Figure 2).

Twenty-nine patients were studied with a mean age of 47.72 (21-76), 15 of whom were men. The gynaecological history for the women and the surgical history for perianal pathology are listed in Table 1.

The results of the evaluation of fistulas with the PE, the 2D-US, the 3D-US and the surgery are shown in Table 2.

Internal fistulous orifice

During surgery, 28 IFO were found in 29 patients. The majority of the IFO (n=21; 72%) were found in during PE by performing a rectal exam. All of the IFO were found with 2D-US and 3D-US except for one patient (n=28; 97%), in whom the IFO was not visualised with either of the two examinations despite the insertion of peroxide. The patient who was not diagnosed with the ultrasound was not the same patient whose IFO was not found during surgery. There were no significant differences between the number of IFO diagnosed with examinations ($P>.05$) and the number diagnosed with surgery (Table 3).

Primary fistulous tract

During surgery, 7 intersphincteric tracts, 11 low transsphincteric and 11 high transsphincteric were diagnosed. During the PE, 4 of the 29 patients could not be classified due to pain or lack of palpation of the tract during the exam. Some 15 patients (51%) were diagnosed properly. Using 2D-US and 3D-US, 20 (71%) and 22 (79%) patients, respectively, were classified correctly, as shown in Table 3. One patient could not be classified either with 2D-US or 3D-US due to the impossibility

Table 1 – Gynaecological history and surgical history of perianal disease

	n=29
No. of women vaginal birth (n=14)	5 (36%)
Episiotomy (n=14)	3 (21%)
Hysterectomy (n=14)	1 (7%)
Perianal abscess drainage	19 (66%)
String delivery	8 (28%)
Fistulotomy	3 (10%)
Fistulectomy	1 (3%)
ILS	1 (3%)
Haemorrhoidectomy	0 (0%)
Rectal mucosal advancement	0 (0%)

ILS indicates internal lateral sphincterotomy.

Table 2 – Results of the evaluation of fistulas in 29 patients

	Physical examination	2D-US	3D-US	Surgery
IFO visualisation n, %	21 (72)	28 (97)	28 (97)	28 (97)
Primary tract n, %				
Intersphincteric	10 (34)	6 (21)	5 (17)	7 (24)
Transsphincteric:				
Low	8 (28)	7 (24)	12 (41)	11 (38)
High	7 (24)	15 (52)	11 (38)	11 (38)
Not classified	4 (14)	1 (3)	1 (3)	0 (0)
Secondary tract n, %	2 (7)	8 (28)	9 (31)	7 (24)
Adjacent abscesses n, %	4 (14)	11 (38)	12 (41)	6 (21)

2D-US indicates two-dimensional endoanal ultrasound; 3D-US, three-dimensional endoanal ultrasound; IFO, internal fistulous orifice.

Table 3 – a. Degree of concordance and K coefficient (K) between intraoperative findings and the various diagnostic techniques employed

	Examination	Physical	2D-US		3D-US	
	Concordance	k	Concordance	k	Concordance	k
IFO visualised	20/29	[a]	27/29	[a]	27/29	[a]
	69%		93%		93%	
Primary tract	15/25	0.41	20/28	0.56	22/28	0.61
	52%		71%		79%	
Secondary tract	22/29	0.13	25/29	0.66	26/29	0.73
	76%		86%		90%	
Adjacent abscesses	21/29	0.04	22/29	0.44	23/29	0.54
	72%		76%		79%	

2D-US indicates two-dimensional endoanal ultrasound; 3D-US, three-dimensional endoanal ultrasound; IFO, internal fistulous orifice; k<0, without concordance; k=0, random concordance; k=0-0.19, insignificant; k=0.2-0.39, low; k=0.4-0.59, moderate; k=0.6-0.79, good; k=0.8-1, very good.
[a]P>.05.

Table 4 – Efficiency paramaters of diagnostic tests used in connection with surgery: sensitivity (S), specificity (Sp), positive predictive value (PPV) and negative predictive value (NPV)

		S	Sp	PPV	NPV
IFO visualised, %	PE	75	100	100	13
	2D-US	96	100	96	100
	3D-US	96	100	96	100
Primary tract, %					
Intersphincteric:					
	PE	100	86	70	100
	2D-US	86	100	100	96
	3D-US	71	100	100	92
Transsphincteric:					
	PE	73	100	100	86
Low	2D-US	64	100	100	82
	3D-US	100	94	92	100
	PE	64	100	100	82
High	2D-US	100	78	73	100
	3D-US	100	100	100	100
	PE	30	100	100	82
Secondary tract, %	2D-US	100	95	87	100
	3D-US	100	91	78	100
	PE	67	100	100	92
Adjacent abscesses, %	2D-US	100	78	55	100
	3D-US	100	74	50	100

2D-US indicates two-dimensional endoanal ultrasound; 3D-US, three-dimensional endoanal ultrasound; IFO, internal fistulous orifice; PE, physical examination.

of distinguishing the active fistulous tract from the fibrosis of previous perianal surgeries.

Secondary tracts

One or more secondary tracts were diagnosed with 2D-US and 3D-US in 8 and 9 patients, respectively, with good concordance with the surgery (86%, k=0.66; 90%, k=0.73) (Table 3).

Adjacent cavities and abscesses

Abscesses and perianal cavities were visualised under 2D-US in 11 patients (38%) and in 12 patients (41%) under 3D-US during diagnosis of the fistula. In only 4 cases (14%) was the cavity or abscess diagnosed through PE using rectal exam. Only 6 patients (21%) had an abscess at the time of surgery. The ultrasound examinations show moderate concordance with the surgery (k=0.44, k=0.54, respectively) while the PE shows insignificant concordance (k=0.04) (Table 3).

The sensitivity, specificity and predictive values (effectiveness indexes) of the various examinations are shown in Table 4.

Discussion

The endoanal 3D-US is a new test in the diagnostic arsenal for perianal fistulas and many studies like ours show its

superiority over the 2D-US. Ratto et al published a rate of accurate diagnoses for primary tracts of 98.5%, 98.5% for secondary tracts, and 96.4% for IFO when using 3D-US as compared to 89.9%, 83.3%, and 87.9%, respectively, when using 2D-US.[7] Santoro and Fortling confirmed through a study of 57 patients with perianal fistulas that the 3D-US improves the accuracy of identifying IFO vs the conventional 2D-US (2D-US: 66.7 vs 3D-US: 89.5%; *P*=.0033).[2,8] However, when comparing the 3D-US to the MRI with endoanal coil, the results are similar.[9] While this may be true, there are still very few studies on this subject. In our case, we prefer the use of ultrasound given its advantages (inexpensive, easy to handle, quick, safe and mobile) and we only use the MRI when there is diagnostic uncertainty.

There are several ways of classifying fistulas in a practical manner. Some authors have modified the Parks classification dividing fistulas into: intersphincteric; low, medium and high transsphincteric, suprasphincteric; and extrasphincteric.[10] In this study we propose a new division of low and high transsphincteric fistulas according to whether they affect less than 66% of the EAS or if the injury affects more than 66%, respectively. Like other authors, we believe that fistulotomy is a treatment for low transsphincteric fistulas but that those that affect half or more of the EAS remain a surgical challenge.[11] This way, the classification is simplified and leads us toward electing the surgical technique.

This study shows good correlation between the diagnosis performed using 3D-US and surgery, out-performing the PE and the 2D-US, above all, in transsphincteric fistulas that are the ones that really cause uncertainty in the diagnosis and proper treatment. According to our results, the 2D-US tends to overestimated transsphincteric fistulas classifying them higher than they really are. This is shown by the lower specificity of the 2D-US for the diagnosis of high transsphincteric fistulas and a lower sensitivity to low transsphincteric fistulas. With the 3D-US, however, these errors are minimised as shown in [Table 2] and [Table 4] with a notable improvement in sensitivity and specificity.

It was not possible to calculate the Kappa coefficient in the IFO diagnosis due to the low or high incidence of these characteristics. Regardless, we have not found significant differences between the examinations and the surgery when visualising the IFO, in accordance with the study published by Poen using 21 patients.[12] The three examinations show high sensitivity and specificity when diagnosing the height and location of the IFO.

When diagnosing the primary fistulous tract, the 3D-US has shown greater concordance and efficacy with the surgery than the 2D-US (k=0.609 vs k=0.557). Several studies have compared the agreement between surgery and the 2D-US and 3D-US inserting peroxide and the degree of concordance has been good.[9,12] The justification for this is that peroxide was not used in all patients since patients with closed EFO, in whom diagnosis is more difficult, were not excluded from the study.

With 3D-US we get good concordance (k=0.731) for diagnosing secondary tracts, better concordance than that obtained with 2D-US, with no differences from that published by Poen et al[12] (k=0.61). With a 3D-US, however, more secondary fistulous tracts are diagnosed (n=9; 31.03%) than with surgery (n=7; 24.13%). This can be explained by the fact that complex or very high fistulous tracts can go unnoticed during surgery. In light of these findings, we should consider, as have other authors, whether surgery really is the *gold standard* for the diagnosis of fistulas or whether we should use MRI with endoanal coil, or as we believe, the 3D-US as reference tests for the diagnosis of fistulas.[12,13]

The diagnosis of adjacent perianal abscesses and cavities through ultrasound shows moderate concordance with surgery (2D-US, k=0.438; 3D-US, k=0.540) and insignificant concordance with the PE. However, the three examinations are shown to be effective in diagnosis. This is because the ultrasounds diagnose abscesses and cavities that are not visible through examination, especially the latter, but due to the time interval, changes occur during surgery, as happens with secondary tracts.

Despite the results obtained in this study, there are some limitations, such as the limited number of patients, although this number is greater than or similar to those studies already published. Another limitation may be the exclusion of suprasphincteric and extrasphincteric fistulas, whose prevalence is very low and where the role of the MRI vs the 3D-US is more debatable.[4,9] All ultrasounds were evaluated by the same surgeon belonging to the colorectal surgery unit. This fact lowers the variability of the results but at the same time produces a bias as we believe it more appropriate to carry out the measurements using two independent observers and later examine whether there are significant differences between the two. We worked to achieve a study performing ultrasounds after surgery to evaluate whether examination under anaesthesia is the *gold standard* for the diagnosis of perianal fistulas or whether it has been superseded by 3D-US when dealing with intersphinteric and transsphincteric fistulas especially the latter where 2D-US shows limitations.

We can conclude that 3D-US has greater diagnostic reliability than 2D-US for estimating the height of the primary tract in transsphincteric fistulas. The 3D-US shows good concordance with the surgery in the diagnosis of primary and secondary tracts.

Conflicts of interest

The authors affirm that they have no conflicts of interest.

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