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Original Article

International consensus on the use of intestinal ultrasound in inflammatory bowel disease trials

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Abstract

Background and Aims: Intestinal ultrasound (IUS) is increasingly used to monitor treatment efficacy in inflammatory bowel disease (IBD) trials. However, standardized definitions for response, remission, and optimal assessment timing remain undefined. An international expert consensus meeting was held to establish IUS endpoints for clinical trials.

Methods: A panel of 35 international gastroenterologists and radiologists participated in a modified Delphi process, reviewing the literature and developing consensus statements. Agreement was defined as at least 75% consensus.

Results: Consensus was reached on 150 statements across four domains: general IBD (30 statements), luminal Crohn's disease (CD) (43), perianal CD (51), and ulcerative colitis (UC) (26). For luminal CD and UC, ultrasound response was defined by: (1) a ≥25% reduction in bowel wall thickness (BWT) from baseline, or (2) multifactorial improvement, combining BWT reduction with ≥1 grade decrease in color Doppler signal (CDS) or another IUS parameter. Assessments were set at weeks 4-8 for the colon and week 12 for the terminal ileum. Ultrasound remission in luminal CD was defined as: (1) BWT normalization (≤3 mm) or (2) normalization of multiple parameters, including BWT, CDS, and all other IUS parameters. Similar remission criteria were proposed for UC, but the sigmoid BWT normal range (3-4 mm) remained uncertain. The bowel ultrasound score (BUSS) for CD and the Milan ultrasound criteria (MUC) for UC were supported as standardized scoring systems for trials.

Conclusion: This consensus provides standardized IUS definitions to enhance consistency in IBD trials, supporting the integration of IUS in future research.

Key words: inflammatory bowel disease; intestinal ultrasound; endpoints.

1. Introduction

In recent decades, there has been a significant increase in the use of intestinal ultrasound (IUS) for the clinical management of patients with inflammatory bowel disease (IBD). With diagnostic accuracy similar to magnetic resonance enterography (MRE), IUS serves as a complementary tool to colonoscopy, enabling effective assessment of the small bowel and the detection of penetrating and stricturing complications in Crohn's disease (CD).[1,2] Additionally, its ability to accurately identify colonic inflammation makes it a valuable tool for evaluating CD localized to the colon and for managing patients with ulcerative colitis (UC).[3] Several ultrasonographic scoring systems have been developed and validated against colonoscopy as the reference standard for both CD and UC.[2,4,5] This widespread adoption has been facilitated by the efforts of the International Bowel Ultrasound Group (IBUS), which has established a standardized training program for IUS. These initiatives pave the way for broader dissemination and implementation of IUS in the USA and Asia.[6]

IUS is a non-invasive and patient-friendly imaging modality. It enables precise, reliable, real-time monitoring of treatment response and the achievement of therapeutic targets.[7–9] These characteristics make it an appealing tool for use in clinical trials. While colonoscopy remains the gold standard for efficacy assessment in clinical trials, it has recognized limitations. The European Medicines Agency (EMA) guidelines state that cross-sectional imaging modalities, such as MRE and, by extension, IUS, may be utilized to assess efficacy in clinical trials if fully validated.[10]

A 2021 international consensus established initial definitions for IUS response and remission; however, variability remained in the assessment criteria, scoring systems, and optimal evaluation timing.[11] Recent systematic reviews have highlighted substantial heterogeneity in defining response and remission based on ultrasonographic findings, as well as in the scoring systems used to evaluate treatment efficacy.[12–17] These discrepancies underscore the need for further validation and harmonization of IUS outcome criteria to improve its utility in clinical practice and support its inclusion in clinical trials. To address this gap, we organized an international expert consensus meeting aimed at standardizing and defining endpoints for the use of IUS in IBD trials. In addition to identifying treatment response and remission criteria, the consensus also addressed essential technical and procedural aspects, such as equipment requirements, operator expertise, and centralized image reading, to ensure standardization, reproducibility, and feasibility across multicenter clinical trials. This comprehensive approach is intended to support the robust integration of IUS into future trial design.

2. Methods

A comprehensive literature review conducted by two of the authors (MA and SD) resulted in 375 proposed statements on the use of IUS in IBD clinical trials. This systematic review, focused on definitions of IUS treatment response and remission in IBD, was recently published.[16] It included studies involving adult patients with CD or UC undergoing treatment, in which IUS was used to assess treatment response or remission. Eligible studies were required to include a minimum of two IUS assessments for luminal disease, with disease activity evaluated through clinical scores, biomarkers, endoscopy, other cross-sectional imaging modalities, or a combination of these. Editorials, comments, letters, abstracts, and review articles were excluded. Only peer-reviewed studies published in English were considered. In addition, other recently published systematic reviews were consulted to address the use of IUS in evaluating stricturing and penetrating complications in CD.[12–15,17] Together, this body of literature formed the basis for the development of 375 initial statements, which were subsequently refined through a Delphi process. These statements were classified into four domains: 61 related to IBD in general, 137 focusing on luminal CD, 78 on perianal CD, and 99 on UC. Rather than starting with open-ended input from participants, this pre-structured list of statements, based on current evidence, served as the foundation for the consensus process. These initial statements were reviewed, discussed and consolidated by an Executive Committee of 12 panelists (MA, BC, VJ, VL, KN, RP, JR, DR, BES, JS, LPB, and SD), selected for their recognized expertise in IBD and IUS, geographic representation, and clinical research experience. The Executive Committee was responsible for refining the statements by assessing their clarity, relevance, and redundancy, which resulted in 369 definitive statements: 60 on IBD in general, 134 on luminal CD, 78 on perianal CD, and 97 on UC. These final statements, along with the results of the literature review, were presented to a broader consensus group of 35 international participants, including

leading gastroenterologists ($n = 29$) and radiologists ($n = 6$), who were invited based on their specific expertise in IBD, IUS, and clinical trial design. To facilitate the consensus process and enable expert interaction, a structured virtual meeting was held on June 17, 2024, with all participants in attendance, to establish international expert agreement on definitions and endpoints for the use of IUS in IBD clinical trials. During this meeting, the results of the comprehensive literature review were presented, and the proposed statements were discussed in depth by the broader consensus group. While the Delphi method typically limits direct interaction between participants, the modified Delphi approach[18] used in this consensus process intentionally incorporated a moderated discussion step to enhance clarity and mutual understanding before voting. Each statement was then subjected to a rigorous anonymous voting process using an electronic platform to ensure impartiality. Participants were allowed to abstain from voting on statements outside their area of expertise. A consensus threshold was defined a priori: statements were considered approved if ≥75% of participants endorsed them. Statements not reaching this threshold were excluded from the final recommendations.

All participants were actively involved in drafting of the manuscript, incorporating the consensus results and ensuring the completeness and accuracy of the document. The final version of the manuscript was reviewed and approved by all participants, marking a significant milestone in the creation of standardized guidelines for the use of IUS in IBD clinical trials.

2.1. Ethics statement

No ethical approval or informed consent was required, as this is a consent-based article that does not involve human or animal subjects.

3. Results

The consensus included 35 voting participants. The following recommendations are based on expert opinion and a systematic literature review. Statements for which there was agreement are summarized in Tables 1-4. Statements that were excluded (consensus of ≥75% not achieved) are shown in Tables S1-S4. For the use of IUS in IBD trials in general, 30 statements were approved (Table 1) and 30 were not approved (Table S1). For luminal CD, 43 statements were approved (Table 2) and 91 were not (Table S2). For peri-anal CD, 51 were approved (Table 3) and 27 were not (Table S2). For UC, 26 were approved (Table 4) and 71 were not (Table S4).

3.1. Approved statements for IUS in IBD clinical trials (Table 1)

The panelists agreed that a site qualified to participate in clinical trials involving the use of IUS in IBD should have an approved IUS machine, and ≥1 approved sonographer and approved test case (94.4%).

The minimum requirements for ultrasound equipment should include both low-frequency (1-6 MHz) and high-frequency (2-12 MHz, 4-8 MHz) transducers, the ability to set and display color Doppler flow speed to 5-7 cm/s, the annotation of scan location, the recording of cine loops up to 60 s, and the ability to export files in DICOM format (all 100%).

An approved sonographer is considered a gastroenterologist, internist, pediatrician, or radiologist, who is trained in IUS and has independently performed more than 200 IUS scans (78.9%).

IUS should be evaluated in an independent central review blinded to patient information (89.4%). Central readers should have at least 5 years of experience in IUS scans (78.9%) or independently performed at least 200 IUS scans (83.3%).

IUS should be performed with a transabdominal approach (100%) and should begin with a low-frequency transducer and then be completed with a high-frequency transducer for detailed interrogation of the intestinal wall (100%). A systematic and standardized approach should be used to examine the entire intestine (100%). Color Doppler ultrasound optimized to detect blood flow within the intestinal wall should always be performed in IBD patients (89.4%).

The panelists agreed that IUS should be performed with a transabdominal approach and complemented with a transperineal approach only in cases where evaluation of the rectum is necessary (84.2%).

The panelists agreed that transperineal ultrasound (TPUS) should be utilized for detecting and classifying perianal fistulizing disease, as well as detecting perianal abscesses (88%).

The ultrasound follow-up should be performed with the same model of ultrasound equipment used at baseline (89.4%) and the same preparation as the baseline scan (89.4%). Ultrasound response should be reported for the whole bowel, segment by segment (94.7%).

Panelists agreed that the response rate varies between CD and UC (83.3%), varies between colonic and small intestine segments (88.8%), depends on the drug class (78.9%), depends on the time of assessment (100%), and depends on disease activity at baseline (89.4%).

3.2. Approved statements for IUS in luminal CD clinical trials (Table 2)

3.2.1. IUS response assessment

The panelists reached a consensus on the ultrasonographic parameters that should be evaluated to assess the response. These included bowel wall thickness (BWT, 100%), color Doppler signals (CDS, 100%), bowel wall stratification (BWS, 83.3%), thickening of the submucosal layer (77.7%), inflammatory mesenteric fat (IFAT, 77.7%), and length of disease (94.4%).

The panelists reached a consensus on the specific changes in IUS parameters from baseline that define an ultrasound response, depending on the parameters considered. When evaluating a single parameter, ultrasound response was defined as a reduction of at least 25% in BWT compared to baseline, with 94.1% agreement. For multiple parameters, they agreed that ultrasound response should be defined as a reduction of at least 25% in BWT, accompanied by a decrease of at least one grade in CDS (93.7%). Alternatively, response could also be defined as a reduction in BWT along with either a decrease of one grade in CDS, a reduction of one category, or the normalization of at least one other additional ultrasound parameter (87.5% agreement). Lastly, the panelists agreed that a reduction of at least 2.0 mm in BWT combined with a decrease of one grade in CDS could also define an ultrasound response, with 75% agreement.

The panelists agreed that ultrasound response should be determined by a decrease in bowel ultrasound score (BUSS) ≥1.2 points (83.3%).[8,19]

In the context of complications, the panelists reached a consensus on the changes in IUS parameters that indicate an

Table 1. Approved statements for intestinal ultrasound in inflammatory bowel disease clinical trials.

No.	Proposed statements	Agreement, % (*n*/*N*)
	Statements for intestinal ultrasound (IUS) machine	
1	The minimum requirements for ultrasound equipment should include both low-frequency (1-6 MHz) and high-frequency (2-12 MHz, 4-8 MHz) transducers	100 (12/12)
2	The minimum requirements for ultrasound equipment should include the ability to set and display color Doppler flow speed to 5-7 cm/s	100 (12/12)
3	The minimum requirements for ultrasound equipment should include the annotation of scan location	100 (13/13)
4	The minimum requirements for ultrasound equipment should include the recording of cine loops up to 60 s	100 (13/13)
5	The minimum requirements for ultrasound equipment should include exporting files in DICOM format	100 (14/14)
	Statements for basic IUS technique	
1	IUS should be performed with a transabdominal approach	100 (20/20)
2	IUS should be performed with a transabdominal approach and completed with a transperineal approach only in cases where evaluation of the rectum is necessary	84.2 (16/19)
3	In the setting of IUS, transperineal ultrasound should be utilized for detecting and classifying perianal fistulizing disease, as well as detecting perianal abscesses	88 (16/18)
4	IUS scan should begin with a low-frequency transducer and then be completed with a high-frequency transducer for detailed interrogation of the intestinal wall	100 (12/12)
5	IUS scan should be performed with a high-frequency transducer for detailed interrogation of the intestinal wall	85.7 (12/14)
6	A systematic and standardized approach should be used to examine the entire intestine	100 (20/20)
7	Color Doppler ultrasound optimized to detect blood flow within the intestinal wall should always be performed in IBD patients	89.4 (17/19)
	Statements for advanced IUS technique	
1	Small intestine contrast ultrasonography (SICUS), following ingestion of a neutral contrast agent (typically 200–500 mL of a polyethylene glycol solution) should NOT always be performed for assessing small bowel	75 (9/12)
2	SICUS, following ingestion of a neutral contrast agent (typically 200–500 mL of a polyethylene glycol solution) should be performed for assessing small bowel, only in selected cases	75 (9/12)
	Statements for IUS interpretation	
1	IUS should be evaluated in a blinded independent central review to patient information	89.4 (17/19)
2	Central readers should have at least 5 years of experience in intestinal ultrasound scans	78.9 (15/19)
3	Central readers should have independently performed at least 200 intestinal ultrasound scans	83.3 (15/18)
	Statements for minimum training to perform IUS	
1	An approved sonographer is a gastroenterologist, internist, pediatrician, or radiologist, who is trained in IUS and has independently performed more than 200 intestinal ultrasound scans	78.9 (15/19)
	Statements for minimal requirements to be a qualified site	
1	A qualified site should have an approved IUS machine and ≥1 approved sonographer and approved test case	94.4 (17/18)
	Statements for IUS follow-up	
1	The ultrasound follow-up should be performed with the same model of ultrasound equipment used at baseline	89.4 (17/19)
2	The ultrasound follow-up should be performed with consistent machine settings	94.4 (17/18)
3	The ultrasound follow-up should be performed following the same preparation as the baseline scan	89.4 (17/19)
4	Ultrasound response should be reported for the whole bowel, segment by segment	94.7 (18/19)
5	The ultrasound response should be reported for the entire intestine, separately for the colon and the terminal ileum	94.4 (17/18)
6	The ultrasound response should be reported for the whole bowel overall	94.4 (17/18)
7	Response rate differs between Crohn's disease (CD) and ulcerative colitis (UC)	83.3 (15/18)
8	Response rate varies between colonic segments and small bowel segments	88.8 (16/18)
9	Response rate depends on the class of drug	78.9 (15/19)
10	Response rate depends on the time of assessment	100 (19/19)
11	Response rate depends on the baseline activity of the disease	89.4 (17/19)

ultrasound response. In the presence of stricturing complications, these criteria include the disappearance of the stricture (94.1%), prestenotic dilation <2.5 cm (76.4%), prestenotic dilation <3 cm (82.3%), ≥50% reduction in luminal narrowing compared to baseline (82.3%), or a combination of a ≥25% reduction in BWT, a Limberg score ≤1, and prestenotic dilation <2.5 cm, as defined by the STRIDENT criteria (76.4%).[20] In addition, for penetrating complications, ultrasound response was defined by the disappearance of the fistula (94.1%) or the disappearance of the inflammatory mass (94.1%).

Panelists reached a consensus on the timing of response assessments, with slight differences between terminal ileum and colon. For the terminal ileum, ultrasound response should be assessed after the start of treatment at 12 weeks (88.2%), at 16 weeks (75%), at 24 weeks (93.7), and at 48-52 weeks (82.3%). Ultrasound response in the colon should be assessed after the start of treatment at 4 weeks (75%), at 8 weeks (81.2%), at 12 weeks (94.1%), at 24 weeks (93.7%), and at 48-52 weeks (82.3%).

The panelists agreed that the response rate depends on the time of assessment. Reduction in BWT of at least 25% or at least 1 mm should be assessed at weeks 12-16 (86.6%).

The panelists agreed that the timing to assess ultrasound response should be determined by the type of treatment (88.2%).

3.2.2. IUS remission assessment

Panelists reached a consensus on the definition of ultrasound remission (also defined as transmural remission), with all

Table 2. Approved statements for intestinal ultrasound in luminal Crohn's disease clinical trials.

No.	Proposed statements	Agreement, % (*n*/*N*)
	Statements for intestinal ultrasound (IUS) response assessments	
	Parameters of IUS that should be assessed to evaluate response	
1	Bowel wall thickness (BWT)	100 (19/19)
2	Color Doppler imaging signals (CDS)	100 (19/19)
3	Bowel wall stratification (BWS)	83.3 (15/18)
4	Thickening of submucosal layer	77.7 (14/18)
5	Inflammatory mesenteric fat (IFAT)	77.7 (14/18)
6	Length of disease	94.4 (17/18)
	Improvement in IUS parameters compared to baseline, indicating ultrasound response	
7	Disappearance of the stricture	94.1 (16/17)
8	Prestenotic dilatation <2.5 cm	76.4 (13/17)
9	Prestenotic dilatation <3 cm	82.3 (14/17)
10	Luminal narrowing decrease by 50% compared to baseline	82.3 (14/17)
11	Reduction in BWT ≥25%, Limberg score ≤1, prestenotic dilation <2.5 cm (STRIDENT study[19])	76.4 (13/17)
12	Disappearance of the fistula	94.1 (16/17)
13	Disappearance of the inflammatory mass	94.1 (16/17)
14	Percentage reduction in BWT ≥25% compared to baseline	82.3 (14/17)
15	Ultrasound response should be defined as a ≥25% reduction in BWT from baseline if improvement is limited to a single parameter	94.1 (16/17)
16	Ultrasound response should be defined by the reduction in BWT ≥25% and reduction of 1 grade in CDS	93.7 (15/16)
17	Ultrasound response should be defined by the reduction in BWT ≥2.0 mm and reduction of 1 grade in CDS	75 (12/16)
18	Ultrasound response should be defined by the reduction in BWT and reduction of 1 grade or category/normalization of at least one other IUS parameter	87.5 (14/16)
	Statements for response evaluation time points	
1	Response rate depends on the time of assessment: BWT ≥25% or ≥1 mm at weeks 12-16	86.6 (13/15)
2	The timing to assess ultrasound response should be determined by the type of treatment	88.2 (15/17)
3	Ultrasound response should be measured in both the terminal ileum (TI) and colon after the start of treatment at 8 weeks	87.5 (14/16)
4	Ultrasound response should be measured in both the TI and colon after the start of treatment at 12 weeks	100 (17/17)
5	Ultrasound response should be measured in both the TI and colon after the start of treatment at 24 weeks	93.7 (15/16)
6	Ultrasound response should be measured in both the TI and colon after the start of treatment at 48-52 weeks	88.2 (15/17)
7	Ultrasound response should be measured in the TI after the start of treatment at 12 weeks	88.2 (15/17)
8	Ultrasound response should be measured in the TI after the start of treatment at 16 weeks	75 (12/16)
9	Ultrasound response should be measured in the TI after the start of treatment at 24 weeks	93.7 (15/16)
10	Ultrasound response should be measured in the TI after the start of treatment at 48-52 weeks	82.3 (14/17)
11	Ultrasound response should be measured in the colon after the start of treatment at 4 weeks	75 (12/16)
12	Ultrasound response should be measured in the colon after the start of treatment at 8 weeks	81.2 (13/16)
13	Ultrasound response should be measured in the colon after the start of treatment at 12 weeks	94.1 (16/17)
14	Ultrasound response should be measured in the colon after the start of treatment at 24 weeks	93.7 (15/16)
15	Ultrasound response should be measured in the colon after the start of treatment at 48-52 weeks	82.3 (14/17)
	Statements for IUS response assessments by advanced IUS techniques	
1	Ultrasound response should NOT be measured using ultrasound elastography (UE)	100 (19/19)
	Statements for IUS response assessments by ultrasound scores	
1	Ultrasound response should be determined by a decrease in bowel ultrasound score (BUSS) ≥1.2 points[8,18]	83.3 (10/12)
	Statements for IUS remission assessments	
1	Ultrasound remission should be defined by BWT ≤3 mm	88.2 (15/17)
2	Ultrasound remission should be defined by BWT ≤3 mm AND normalization of CDS	76.4 (13/17)
3	Ultrasound remission should be defined by normalization of all IUS parameters	88.2 (15/17)
4	Ultrasound remission should be defined by BWT ≤3 mm and normalization of all IUS parameters	94.1 (16/17)
	Statements for remission evaluation time points	
1	Ultrasound remission should be measured after the start of treatment at 12 weeks	82.3 (14/17)
2	Ultrasound remission should be measured after the start of treatment at 24 weeks	93.7 (15/16)
3	Ultrasound remission should be measured after the start of treatment at 48-52 weeks	94.1 (16/17)
	Statements for IUS remission assessments by ultrasound scores	
1	Ultrasound remission should be determined by the BUSS ≤3.52[8,20]	76.9 (10/13)

accepted criteria consistently including a BWT of ≤3 mm. These criteria included BWT ≤3 mm as the sole indicator of remission, which was supported by 88.2% of the panelists. In addition, remission was defined as BWT ≤3 mm combined with normalization of the CDS, which was agreed by 76.4% of the panelists. Another accepted definition included normalization of all parameters of the IUS, which received a consensus of 88.2%. Finally, a definition combining BWT ≤3 mm and normalization of all IUS parameters was accepted by 94.1% of the panelists.

Table 3. Approved statements for intestinal ultrasound in perianal Crohn's disease clinical trials.

No.	Proposed statements	Agreement, % (*n*/*N*)
	Statements for preparation for transperineal ultrasound (TPUS)	
1	Preparation is not required	92.8 (13/14)
	Statements for TPUS machine	
1	The minimum requirements for ultrasound equipment should include both low-frequency (1-6 MHz) and high-frequency (2-12 MHz) transducers	90.9 (10/11)
2	The minimum requirements for ultrasound equipment should include the ability to set and display color Doppler flow speed to 5-7 cm/s	100 (11/11)
3	The minimum requirements for ultrasound equipment should include the annotation of scan location	100 (14/14)
4	The minimum requirements for ultrasound equipment should include the recording of cine loops up to 60 s	100 (12/12)
5	The minimum requirements for ultrasound equipment should include exporting files in DICOM format	100 (12/12)
6	A high-resolution micro-convex transducer should be used (4–8 MHz)	100 (12/12)
	Statements for basic TPUS technique	
1	A transabdominal approach should be used to assess any high pelvic collection beyond the range of the transperineal transducer	100 (12/12)
2	Patient should be in the dorsal lithotomy position	80 (8/10)
3	Patient should be in the left lateral position	90 (9/10)
4	Patient may be in the dorsal lithotomy position or in the left lateral position	80 (8/10)
5	The transducer should be positioned over the anus	81.8 (9/11)
6	The transducer should be positioned on external orifice of the fistula	90.9 (10/11)
7	The transducer should be placed on the perineum, between the scrotum and the anal canal in men and the introitus and anal canal in women	100 (11/11)
8	Axial and longitudinal images should be acquired	100 (11/11)
9	The main anatomical perianal landmarks, including the anal canal, internal and external anal sphincters, pubic symphysis, urinary bladder, prostate or vagina, should be identified	100 (12/12)
10	Color Doppler ultrasound should be performed	91.6 (11/12)
	Statements for TPUS interpretation	
1	TPUS should be evaluated in a in a blinded independent central review to patient information	87.5 (14/16)
2	TPUS should be read centrally with a single read	75 (12/16)
3	TPUS should be read centrally with two reads	87.5 (14/16)
	Statements for TPUS follow-up	
1	The ultrasound follow-up should be performed with the same model of ultrasound equipment used at baseline	87.5 (14/16)
2	The ultrasound follow-up should be performed with consistent machine settings	100 (15/15)
3	The ultrasound follow-up should be ideally performed by the same operator	81.2 (13/16)
4	Response rate depends on the class of drug	81.2 (13/16)
5	Response rate depends on the time of assessment	87.5 (14/16)
6	Response rate depends on the disease duration	87.5 (14/16)
7	Response rate depends on the baseline activity of the disease	87.5 (14/16)
	Statements for TPUS response assessments	
	Parameters of TPUS that should be assessed to evaluate response	
1	Anal sphincter integrity should be assessed	94.1 (16/17)
2	Number of fistulae/sinuses/collections should be reported	100 (17/17)
3	Internal opening of any fistulous tract should be described using a clock-face position relative to the anal canal (ant/post, right/left, upper/mid/lower third)	100 (15/15)
4	External opening of any fistulous tract should be described using a clock-face position relative to the anal verge	100 (15/15)
5	Fistulae should be classified according to Park's criteria (intersphincteric, transphincteric, extrasphincteric, suprasphincteric, superficial)	88.2 (15/17)
6	Fistulae should be classified as simple (low trans- and intersphincteric fistulae) or complex (multiple >1, high trans-, supra-, extrasphincteric fistulae, horseshoe, or rectovaginal fistulae, if presence of abscesses or anal stricture)	94.1 (16/17)
7	Each fistula should be described with reference to its distance to the skin, its length (cm), extension with its branches, and maximum diameter (mm)	100 (17/17)
8	Size and site of collections >10 mm should be described (superficial, perianal, ischioanal, intersphincteric, intralevator, suprasphincteric, horseshoe)	94.1 (16/17)
9	Bowel wall thickness (BWT) of the rectum should be measured	93.3 (14/15)
10	Color Doppler signals (CDS) of the rectum should be detected	86.6 (13/15)
	Improvement in TPUS parameters compared to baseline, indicating ultrasound response	
11	Reduced number of separate fistulae	93.3 (14/15)
12	Reduced length/size of fistula ≥50% compared to baseline	76.9 (10/13)
13	Reduced number of collections	100 (14/14)
14	Reduced size of collection ≥50% compared to baseline	76.9 (10/13)
15	Reduced vascularity (CDS)	84.6 (11/13)
	Statements for TPUS remission assessment	
1	Disappearance of all the fistulae	93.3 (14/15)
2	Disappearance of all the collections	100 (15/15)
	Statements for TPUS response evaluation time points	
1	Weeks 12-16	100 (15/15)
2	Week 24	78.5 (11/14)
3	Weeks 48-52	78.5 (11/14)
	Statements for TPUS remission evaluation time points	
1	Weeks 12-16	93.3 (14/15)
2	Week 24	78.5 (11/14)
3	Week 36	78.5 (11/14)
4	Weeks 48-52	92.8 (13/14)

Table 4. Approved statements for intestinal ultrasound in ulcerative colitis clinical trials.

No.	Proposed statements	Agreement, % (*n*/*N*)
	Statements for intestinal ultrasound (IUS) response assessments	
	Parameters of IUS that should be assessed to evaluate response	
1	Bowel wall thickness (BWT)	100 (17/17)
2	Color Doppler imaging signals (CDS)	100 (17/17)
3	Bowel wall stratification (BWS)	87.5 (14/16)
4	Thickening of submucosal layer	81.25 (13/16)
5	Inflammatory mesenteric fat (IFAT)	75 (12/16)
6	Extent of disease	88.2 (15/17)
	Improvement in IUS parameters compared to baseline, indicating ultrasound response	
7	Percentage reduction in BWT ≥25 % compared to baseline	87.5 (14/16)
8	Reduction of 1 grade in CDS compared to baseline	75 (12/16)
9	Decrease in CDS from grade 3 to grade 2 or from grade 2 to grade 0 or 1	81.2 (13/16)
10	Reduction of 1 category (from extensive disruption to focal disruption) in BWS compared to baseline	81.2 (13/16)
11	Ultrasound response should be defined as a ≥25% reduction in BWT from baseline if improvement is limited to a single parameter	93.7 (15/16)
12	Ultrasound response should be defined by the reduction in BWT ≥25% and reduction of 1 grade in CDS	81.2 (13/16)
	Statements for response evaluation time points	
1	Ultrasound response should be measured after the start of treatment at 8 weeks	80 (12/15)
2	Ultrasound response should be measured after the start of treatment at 12-16 weeks	93.7 (15/16)
3	The timing to assess ultrasound response should be determined by the type of treatment	75 (12/16)
	Statements for IUS response assessments by advanced IUS techniques	
1	Ultrasound response should NOT be measured using CEUS (contrast-enhanced ultrasound)	78.9 (15/19)
2	Ultrasound response should NOT be measured using small-intestine contrast ultrasonography (SICUS)	89.4 (17/19)
3	Ultrasound response should NOT be measured using ultrasound elastography (UE)	100 (19/19)
	Statements for IUS response assessments by ultrasound scores	
1	Ultrasound response should be determined by a decrease in Milan Ultrasound Criteria (MUC) ≥2 points from baseline[9]	91.6 (11/12)
	Statements for IUS remission assessments	
1	Ultrasound remission is defined by normalization of BWT and of all other IUS parameters	86.6 (13/15)
2	Ultrasound remission is defined by normalization of BWT and CDS = 0/1	86.6 (13/15)
	Statements for remission evaluation time points	
1	Ultrasound remission should be measured after the start of treatment at 12-16 weeks	87.5 (14/16)
2	Ultrasound remission should be measured after the start of treatment at 24-36 weeks	81.2 (13/16)
3	Ultrasound remission should be measured after the start of treatment at 48-52 weeks	94.1 (16/17)
	Statements for IUS remission assessments by ultrasound scores	
1	Ultrasound remission should be determined by the MUC ≤6.2 points for MES ≤1[9]	76.9 (10/13)
2	Ultrasound remission should be determined by the MUC < 4.3 points for MES = 0[9]	76.9 (10/13)

The panelists agreed that ultrasound remission should be determined by the BUSS ≤3.52 (76.9%).[8,21]

Panelists reached a consensus on the timing of remission assessment both for the ileum and colon. Ultrasound remission should be measured after the start of treatment at 12 weeks (82.3%), at 24 weeks (93.7%), and at 48-52 weeks (94.1%).

3.3. Approved statements for IUS in perianal CD clinical trials (Table 3)

The panelists agreed that no preparation is required (92.8%).

The panelists reached a consensus on the minimum requirements for ultrasound equipment, which should include both low-frequency (1-6 MHz) and high-frequency (2-12 MHz) transducers (90.9%), the ability to set and display color Doppler flow speed to 5-7 cm/s (100%), annotation of the scan location (100%), recording of cine loops up to 60 s (100%), and the ability to export files in DICOM format (100%).

The panelists agreed that a high-resolution micro-convex transducer should be used (4-8 MHz) (100%).

TPUS should be evaluated in a blinded independent central review to patient information (87.5%) and should be read centrally with a single read (75%) or with two reads (87.5%).

The panelists agreed that a transabdominal approach should be used to assess any high pelvic collection beyond the range of the transperineal transducer (100%). For the transperineal approach, the patient should be positioned in the dorsal lithotomy position (80%) or the left lateral position (90%). The transducer should be placed over the anus (81.8%), on the external orifice of the fistula (90.9%), or on the perineum (between the scrotum and the anal canal in men and the introitus and anal canal in women) (100%). Axial and longitudinal images should be acquired (100%). The main anatomical perianal landmarks, including the anal canal, internal and external anal sphincters, pubic symphysis, urinary bladder, and prostate (or vagina), should be identified (100%). Color Doppler ultrasound should be performed (91.6%).

The panelists agreed that the ultrasound follow-up should be performed with the same model of ultrasound equipment used at baseline (87.5%), and ideally by the same operator (81.2%).

Panelists agreed that the response rate is influenced by the class of drug (81.2%), on the time of assessment (87.5%), on the disease duration (87.5%), and on the baseline activity of the disease (87.5%).

3.3.1. TPUS response assessments

The panelists reached a consensus on the ultrasonographic parameters that should be evaluated to assess treatment response. They agreed that anal sphincter integrity should be evaluated (94.1%), along with the number of fistulae, sinuses, and/or collections (100%). The internal opening of any fistulous tract should be described using a clock-face position relative to the anal canal (ant/post, right/left, upper/mid/lower third) (100%), while the external opening of any fistulous tract should be described using a clock-face position relative to the anal verge (100%). Fistulae should be classified according to Park's criteria (intersphincteric, transphincteric, extrasphincteric, suprasphincteric, superficial) (88.2%), or as simple (low trans- and intersphincteric fistulae) or complex (multiple >1, high trans-, supra-, extrasphincteric fistulae, horseshoe, or rectovaginal fistulae, presence of abscesses or anal stricture) (94.1%). The fistulae should also be described in terms of their distance to the skin, length (cm), extension with branches, and maximum diameter (mm) (100%). Any collections larger than 10 mm should be detailed, specifying their size and location as superficial, perianal, ischioanal, intersphincteric, intralevator, suprasphincteric or horseshoe (94.1%). BWT of the rectum should be measured (93.3%), and the presence of CDS in the rectum should be detected (86.6%).

The panelists reached a consensus on the specific changes in TPUS parameters from baseline that define an ultrasound response. This was characterized by a reduction in the number of separate fistulae (93.3%), a decrease in fistula length/size of at least 50% compared to baseline (76.9%), a reduced number of collections (100%), a reduction in collection size of at least 50% compared to baseline (76.9%), and diminished vascularity as assessed by CDS (84.6%).

Panelists reached a consensus on the timing of response assessment. The ultrasound response should be measured at weeks 12-16 (100%), week 24 (78.5%), and weeks 48-52 (78.5%).

3.3.2. TPUS remission assessments

The panelists reached a consensus on the definition of ultrasound remission, which was characterized by the complete disappearance of all fistulae (93.3%) and the resolution of all collections (100%).

The panelists reached a consensus on the optimal timing for assessing ultrasound remission. They agreed that remission should be evaluated at weeks 12-16 (93.3%), week 24 (78.5%), week 36 (78.5%), and weeks 48-52 (92.8%).

3.4. Approved statements for IUS in UC clinical trials (Table 4)

3.4.1. IUS response assessment

The panelists reached a consensus on the ultrasonographic parameters to be evaluated when assessing treatment response. These include BWT (100%), CDS (100%), BWS (87.5%), thickening of the submucosal layer (81.2%), IFAT (75%), and the extent of disease (88.2%).

The panelists also agreed on the specific changes in IUS parameters from baseline that define an ultrasound response, depending on whether a single parameter or multiple parameters are evaluated. For a single parameter, an ultrasound response was defined as a reduction of at least 25% in BWT compared to baseline, with 93.7% agreement. When considering multiple parameters, the response was defined as a reduction of at least 25% in BWT accompanied by a decrease of at least one grade in CDS, with 81.2% agreement.

The panelists agreed that ultrasound response should be determined by a decrease in Milan Ultrasound Criteria (MUC) ≥2 points from baseline.[9]

Panelists reached a consensus on the timing of the response assessment. Ultrasound response should be measured after the start of treatment at 8 weeks (80%), and at 12-16 weeks (93.7%%).

The panelists agreed that the timing to assess ultrasound response should be determined by the type of treatment (75%).

3.4.2. IUS remission assessment

The panelists reached a consensus on the definition of ultrasound remission (also defined as transmural remission). They agreed that remission should be defined either by the normalization of BWT and all other IUS parameters (86.6%) or by the normalization of BWT with a CDS grade of 0 or 1 (86.6%).

The panelists agreed that ultrasound remission should be defined according to the MUC. Specifically, an MUC score ≤6.2 points corresponds to a Mayo Endoscopic Score (MES) ≤1 (76.9%), whereas an MUC score of <4.3 points aligns with an MES of 0 (76.9%).[9]

Panelists reached a consensus on the timing of remission assessment. Ultrasound remission should be measured after the start of treatment at 12-16 weeks (87.5%), at 24-36 weeks (81.2%), and at 48-52 weeks (94.1%).

4. Discussion

There is a growing body of evidence to support the use of IUS for monitoring and evaluating treatment responses in patients with IBD, including CD and UC. According to EMA guidelines, it is essential to define and validate efficacy endpoints for cross-sectional imaging modalities, such as MRE and, by extension, IUS, before their adoption in clinical trials.[10] This international expert consensus was therefore conducted to define ultrasound response and remission criteria for clinical trials, along with the optimal timing for assessment, both in patients with CD and UC.

For the use of IUS in IBD trials, 150 recommendations were developed through a rigorous Delphi process. Of these, 30 address the general use of IUS in IBD trials (Table 1), 43 pertain to luminal CD (Table 2), 51 focus on perianal CD (Table 3), and 26 apply to UC (Table 4).

Notably, 219 additional statements did not reach consensus (Tables S1-S4), reflecting the complexity of the topic and current limitations in the available evidence. This outcome underscores the rigor of the process and outlines a clear research agenda by identifying unresolved areas that warrant further investigation and methodological standardization.

These recommendations, based on a combination of published evidence and expert consensus, aim to standardize IUS endpoints for IBD clinical trials. The panelists included gastroenterologists and abdominal radiologists from diverse countries, ensuring that the guidelines incorporate international perspectives and reflect varied clinical practices.

Panelists were allowed to abstain from voting on statements outside their specific field of expertise, ensuring that responses were limited to those with adequate experience and confidence in the topic.

Agreement was reached on the minimum requirements for a site to be considered qualified. In particular, the site must have an approved IUS machine, at least one approved

sonographer, and one approved test case. An approved sonographer is defined as a gastroenterologist, internist, pediatrician, or radiologist who is trained in IUS and has independently performed more than 200 IUS scans. This underlines the crucial importance of specific training in IUS to standardize the approach and ensure consistency in the assessment and collection of parameters. Furthermore, the key role of central reading in clinical trials was confirmed to ensure consistency, minimize variability, and improve the reliability of data interpretation across study sites.[22] Recent studies on the learning curve in IUS support this threshold, showing that basic competence in detecting BWT via IUS is typically achieved after approximately 80 scans, with advanced skills requiring up to 97-100 scans.[23] Therefore, our requirement of ≥200 self-performed IUS exams for both study sonographers and central readers aligns with current evidence and provides a sufficient margin to ensure both basic and advanced skill acquisition.

We emphasize that these thresholds represent a pragmatic consensus-based standard rather than a formal competency certification. Future efforts should focus on developing structured, competency-based training programs to further improve the quality and reproducibility of IUS assessments in clinical trials.

Panelists reached a consensus on the ultrasound parameters to be evaluated, which are the same for both luminal CD and UC. These parameters include BWT, CDS, BWS, IFAT, thickening of the submucosal layer, and extent of disease. The agreement on the thickening of the submucosal layer emphasizes that UC, like CD, should be considered a transmural disease.[24,25]

Two distinct definitions of ultrasound response have been approved for both luminal CD and UC. The first definition requires that the ultrasound response is defined as a reduction in BWT of at least 25% from baseline. The second definition involves the improvement of more than one parameter and is defined as a reduction in BWT accompanied by a reduction of at least one grade/category or normalization of at least one other IUS parameter, preferably a one-grade reduction in the CDS. The first definition may be particularly suitable for clinical trials focusing on the primary efficacy evaluation of a treatment with a simple and measurable endpoint of BWT change. Conversely, the second definition may be more appropriate for studies that aim to evaluate a broader spectrum of treatment effects, incorporating multiple aspects of bowel disease activity to provide a more comprehensive assessment of therapeutic response. In the presence of a stricturing disease, panelists agreed that response should be defined by a reduction of prestenotic dilatation to <2.5 cm or <3 cm, a reduction of luminal narrowing by at least 50% compared to baseline, or disappearance of the stricture. In addition, the definition of the STRIDENT study,[20] which includes a reduction in BWT ≥25%, a Limberg score ≤1, and a prestenotic dilatation <2.5 cm, was also approved. Panelists reached consensus on the timing for the evaluation of the ultrasound response, which differs between the colon and the terminal ileum. Assessments should begin at weeks 4-8 for the colon and week 12 for the terminal ileum. This recommendation is justified by the recognized differences in healing dynamics between the small and large intestine.[26,27]

Regarding ultrasound remission in luminal CD, two definitions have been approved, following a similar approach to that used for ultrasound response, where two definitions were also established. The first focuses exclusively on normalizing BWT to ≤3 mm. The second includes not only normalizing BWT but also the normalization of other ultrasonographic parameters. This approach highlights the possibility of choosing different endpoints, reflecting varying degrees of remission depth. A similar agreement was reached for UC; however, the optimal cutoff for BWT in UC remains a matter of debate, particularly for the sigmoid colon. Uncertainty persists regarding whether a BWT of between 3 and 4 mm should be considered within the normal range. The BWT of the sigmoid colon can occasionally exceed 3 mm in certain non-inflammatory conditions, such as symptomatic uncomplicated diverticular disease. Unlike IBD, however, the thickening in these cases arises from hypertrophy of the muscularis propria rather than thickening of the mucosal and submucosal layers associated with IBD.[28,29]

Only the BUSS for CD[8,19] and the MUC[9] for UC were approved as activity scores to be used in clinical trials. Notably, the panelists did not reach agreement on the use of the IBUS-SAS, which is a valuable scoring system developed through an international collaborative effort.[30] However, it is important to note that in the original development study in CD, endoscopic activity was not used as the reference standard, and no specific cut-off values for disease activity were proposed. More recently, several research groups have attempted to correlate IBUS-SAS with endoscopic activity and have proposed cut-off values. Nevertheless, these results have been inconsistent, with significant discrepancies in the thresholds reported across studies.[8,31–34] The lack of consensus on IBUS-SAS probably reflects the current heterogeneity in cut-off values and validation methods across studies. This reinforces the need for further standardization before such score can be reliably used in multicenter clinical trials. Regarding its application in UC, no studies to date have assessed treatment response using IBUS-SAS in UC populations. It is important to emphasize that the IBUS-SAS was originally developed and validated in patients with CD, and has only recently been applied to UC. To our knowledge, only two studies have evaluated its performance in UC, each employing different cut-offs for defining endoscopic activity.[35,36] This further underscores the need for robust validation and harmonization of cut-off definitions before the IBUS-SAS can be recommended as an outcome measure in UC clinical trials. Furthermore, it is important to emphasize that recommendations relating to specific ultrasound scores should be interpreted within a broader context, recognizing the current lack of a universally adopted approach, the ongoing development of the field, and the need for flexibility as new evidence emerges.

Finally, this represents the first international expert consensus addressing the use of TPUS in perianal disease. Although the current evidence is limited, TPUS is increasingly used in expert centers as a non-invasive tool for diagnosis and longitudinal monitoring. The panel reached consensus based on the best available evidence, including the recent ECCO-ESGAR topical review by Kucharzik et al.,[14,17] as well as expert experience. Agreement was achieved on the minimal requirements for ultrasound equipment, the technique, and the parameters to assess. Specifically, the response was defined as a reduction in the number of separate fistulae, a decrease in the length/size of the fistula by at least 50% compared to baseline, a reduced number of collections, a decrease in the size of collections by at least 50% compared to baseline, or reduced vascularity (CDS). Remission was defined as the complete disappearance of all fistulae and collections. Additionally, agreement was reached on the evaluation time points: weeks 12-16, 24, and 48-52.

In conclusion, this consensus represents a rigorous and transparent effort involving a diverse international panel of experts in IBD and IUS. It addresses all aspects of IUS and TPUS in IBD, establishing clear definitions for treatment response and remission and providing standardized endpoints for the assessment of treatment efficacy in clinical trials.

By setting consistent criteria, this international expert consensus is poised to enhance the quality and reliability of clinical trials in IBD, enabling better comparison of treatment outcomes and guiding more effective therapeutic strategies.

Author contributions

M.A., S.D., and L.P.B. conceived the study. M.A. wrote the article and created tables. M.A., V.J., B.S., D.R., B.C., V.L., K.N., R.P., P.B., D.B., A.D., I.R., J.F., M.F., F.F., J.H., A.H., T.K., N.K., T.K., A.L., P.L., R.L., E.L., E.L., F.M., P.A.O., S.S., B.E.S., S.V., S.W., J.S., J.R., L.P.B., and S.D. critically reviewed the content of the paper and supervised the project. All authors discussed the statements and approved the final manuscript.

Supplementary material

Supplementary material is available at *ECCO-JCC* online.

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A.H. has served as consultant, advisory board member or speaker for AbbVie, Arena, Atlantic, Bristol-Myers Squibb, Celgene, Celltrion, Falk, Galapogos, Lilly, Janssen, MSD, Napp Pharmaceuticals, Pfizer, Pharmacosmos, Shire, and Takeda; and serves on the Global Steering Committee for Genentech.

T.K. served as an advisory board member, consultant, or speaker for AbbVie, Alfresa Pharma, Alimentiv, Bristol Myers Squibb, Celltrion, Covidien, EA Pharma, Eli Lilly, Ferring Pharmaceuticals, Galapagos, Gilead Sciences, Janssen Pharmaceuticals, JIMRO, Kissei Pharmaceutical, Kyorin Pharmaceutical, Mitsubishi Tanabe Pharma, Mochida Pharmaceutical, MSD, Nippon Kayaku, Pfizer, Takeda, and Zeria Pharmaceutical, and has received research funding from AbbVie, Alfresa Pharma, Bristol Myers Squibb, EA Pharma, Gilead Sciences, Kyorin Pharmaceutical, Mochida Pharmaceutical, Nippon Kayaku, Otsuka Holdings, Pfizer, Sekisui Medical, Samsung, Takeda, and Zeria Pharmaceutical.

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Data availability

The data underlying this article are available in the article and in its online supplementary material.

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