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Shiha, M.G., Bowker-Howell, F.J., Harper, A.M. et al. (2025) Exploring the views of primary and secondary care physicians on the no-biopsy diagnosis of coeliac disease in adults: a qualitative interview study. Frontline Gastroenterology, 16 (2). pp. 101-107. ISSN: 2041-4137

https://doi.org/10.1136/flgastro-2024-102837

OPEN ACCESS

Original research

Exploring the views of primary and secondary care physicians on the no-biopsy diagnosis of coeliac disease in adults: a qualitative interview study

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► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/flgastro-2024-102837).

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Received 15 August 2024
Accepted 19 September 2024

Check for updates

To cite: Shiha MG, Bowker-Howell FJ, Harper AM, *et al*. *Frontline Gastroenterology* Epub ahead of print: [please include Day Month Year]. doi:10.1136/flgastro-2024-102837

ABSTRACT

Objective Despite mounting evidence supporting a no-biopsy approach for the diagnosis of coeliac disease in adults, established clinical pathways in primary and secondary care could hinder implementation in clinical practice. We aimed to identify the barriers and facilitators to a no-biopsy diagnostic pathway of coeliac disease in primary and secondary care.

Methods We conducted a qualitative study using semistructured interviews with gastroenterologists and general practitioners (GPs). We used a predefined interview topic guide consisting of open-ended questions and prompts to facilitate discussion about the views of primary and secondary care physicians on the no-biopsy diagnosis of coeliac disease in adults.

Results We interviewed 24 physicians (12 gastroenterologists and 12 GPs) across England between February and March 2024. Participants had different levels of experience ranging between 2 years and 30 years. Gastroenterologists were more familiar with the no-biopsy approach and the evidence supporting it compared with GPs. Both groups were supportive of the no-biopsy approach but acknowledged the lack of clear guidelines as a major barrier to implementation in clinical practice. Increased patient satisfaction, shorter waiting times to start treatment and reduced endoscopy service pressures and costs were perceived as the main advantages of the no-biopsy approach. However, participants had concerns regarding false-positive results, missing concurrent pathology, dealing with persistent symptoms after treatment without biopsy confirmation and the increased workload in primary care.

Conclusion The safe and effective implementation of this no-biopsy approach depends on developing clear evidence-based clinical guidelines and referral pathways, along with comprehensive education for all healthcare providers involved.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Traditionally, the diagnosis of coeliac disease in adults requires endoscopy with duodenal biopsy.
⇒ There is a growing debate about the accuracy and feasibility of serology-based diagnosis of coeliac disease in adults.

WHAT THIS STUDY ADDS

⇒ The study reveals key factors that could either support or hinder the acceptance of the no-biopsy approach, such as confidence in serological tests and concerns about missed diagnoses.
⇒ Primary and secondary care physicians have varying opinions on the no-biopsy approach, influenced by their clinical experiences.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Physicians' insights could inform the development of less invasive and more patient-friendly diagnostic pathways for coeliac disease.
⇒ The correct and safe implementation of this no-biopsy approach relies on having clear evidence-based guidelines and collaboration between primary and secondary care providers.

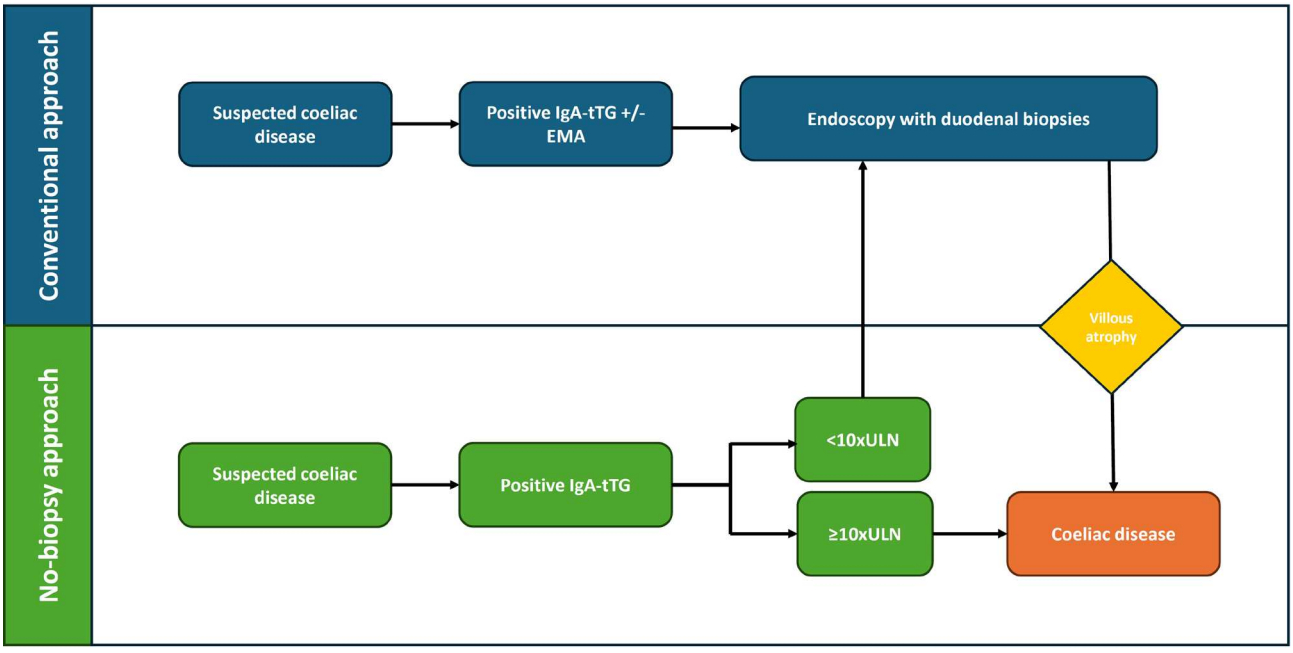

Figure 1 Comparison between the conventional serology-biopsy approach to diagnose coeliac disease and the proposed no-biopsy approach. EMA, endomysial antibodies; tTG, tissue transglutaminase; ULN, upper limit of normal.

INTRODUCTION

Coeliac disease (CD) is the most common autoimmune enteropathy, with an estimated global prevalence of approximately 1%.[1] It is triggered by gluten ingestion in genetically predisposed individuals, leading to an immune response that results in inflammation and damage to the intestinal mucosa.[2] People with CD present with various symptoms ranging from gastrointestinal symptoms such as abdominal pain, bloating and diarrhoea to systemic symptoms like fatigue and neuropathy.[3] Owing to this broad range of presentations and lack of awareness among clinicians, many patients with CD remain undiagnosed, misdiagnosed or experience significant delays in diagnosis.[4]

The diagnosis of CD in adults requires a combination of serological tests for specific antibodies, such as antitissue transglutaminase (tTG) and endomysial antibodies, and confirmatory histological findings on duodenal biopsies.[5] While biopsy has been the gold standard diagnostic test for CD for almost 70 years, recent evidence suggests that adults with IgA-TTG ≥10 × upper limit of normal (ULN) and a medium-to-high pretest probability of CD could be diagnosed based on serology alone (figure 1).[6] This no-biopsy approach to diagnosis in adults has been a matter of ongoing debate over the past decade.[7–9] Although the no-biopsy approach may streamline diagnosis and reduce endoscopy-related risks and costs,[10] many experts raised concerns that patients may inappropriately implement a lifelong gluten-free diet without having confirmatory biopsies, and that serology-based diagnosis could result in misdiagnosing CD in patients with borderline serology or missing concurrent pathology without endoscopy.[11] This is a relevant concern as coeliac serology is widely available in both primary and secondary care. Yet, the evidence supporting the no-biopsy approach is currently based on data from secondary and tertiary care settings.

Understanding the views of general practitioners (GPs) and gastroenterologists on the no-biopsy approach is critical to its feasibility and safe implementation. This study aimed to provide insights into the potential barriers and facilitators to a no-biopsy diagnostic pathway of CD in primary and secondary care.

METHODS

Study design and participants

We conducted semistructured one-on-one interviews with gastroenterologists and GPs to explore their views on the no-biopsy approach to diagnosing CD in adults. Purposive sampling ensured a diverse sample based on age, sex, experience, practice settings and geographical locations. All participants were fully qualified gastroenterologists and GPs. Potential participants were identified via the authors' professional networks and approached via email. No potential participants refused to participate in the study. All participants provided informed consent.

Data collection

One researcher (MGS) conducted all interviews via video-conferencing software (Google Meet) or in person, according to participant preference. An interview topic guide (online supplemental material) was developed by the research team to cover topics such as knowledge about the no-biopsy approach, perceived advantages and disadvantages, barriers

to implementation and patient communication. All interviews were recorded, transcribed verbatim and anonymised.

Data analysis

Transcripts were analysed using reflexive thematic analysis[12] in qualitative data analysis software (NVivo, V.14, QSR International, Australia). Transcripts were reviewed by two authors (MGS and FJBH) for accuracy and data familiarisation, then coded independently to identify themes. Following initial coding, any discrepancies were resolved through consensus to ensure the validity of thematic development. Data analyses were performed concurrently with data collection to establish the sample size based on data saturation in real time. Themes and subthemes were refined through an iterative process, capturing participants' nuanced perspectives. The final thematic framework structured the data into common themes reflective of the range of views and experiences of gastroenterologists and GPs.

RESULTS

Participants' characteristics

In total, 24 physicians (12 gastroenterologists and 12 GPs) across England were interviewed virtually or in person from February to March 2024. Participants (62.5% male, 58.3% from North of England and 50% non-white) had different levels of experience ranging between 2 years and 30 years as independent physicians. Out of the 24 participants, 10 were from South Yorkshire. The remaining participants were from various regions across England, including five from the Midlands, three from the South West and one each from West Midlands, West Yorkshire, North East, East of England, South East and North West.

Knowledge and awareness

All gastroenterologists were familiar with the no-biopsy approach, and some had already implemented it in their practice. Conversely, half the GPs were not aware of the no-biopsy approach or had limited knowledge of it.

Main themes

The themes that emerged from the reflexive thematic analysis constituted three overarching groups: the benefits of the no-biopsy approach, concerns regarding accuracy and safety and implementation in clinical practice. Online supplemental table 1 presents an overview of the main themes with representative quotes.

Benefits

Primary and secondary care physicians highlighted multiple benefits to the no-biopsy approach for patients and the healthcare system.

Benefits to patients centred on avoiding an invasive and uncomfortable procedure. All 12 gastroenterologists cited this as a benefit of the no-biopsy approach, compared with seven GPs.

> We create a lot of harm psychologically by doing gastroscopy […] so anything that we can do by reducing that is really important. (G)

Many interviewees also described the specific benefit of enabling patients to avoid the pre-endoscopy gluten challenge.

> Why would you put them back again on four weeks of gluten-rich diet, majority of them are really resisting it because of horrible symptoms they've experienced in the first place. (G)

It was also felt that the no-biopsy approach would benefit patients by reducing delays to diagnosis and enabling earlier initiation of a gluten free diet (GFD).

> I don't want to send a patient in a pipeline where they're waiting six months a year to get told something which otherwise have a blood test done today, and tomorrow you can have the answer. (GP)

The most frequently cited healthcare system benefit was the potential for no-biopsy diagnosis to reduce endoscopy waiting lists and lessen the burden on secondary care, as well as making financial savings.

> I think pragmatism is what we need in a failing NHS at the moment, and this is a very pragmatic approach. (G)

Multiple participants specifically referred to the positive environmental impact.

> You're reducing the number of endoscopies and histology, which in the environment of looking towards greener and more sustainable endoscopy has some merit. (G)

Concerns

Accuracy, safety and impact on GP workload arose as potential concerns about the no-biopsy approach.

Participants from both groups expressed concern that the approach could lead to false-positive results.

Some gastroenterologists were concerned about misinterpretation of the no-biopsy approach leading to inappropriate over-diagnosis of CD in primary care based on positive serology results regardless of the levels.

> The risk is the sort of complacency[…]. I suspect there's a perception amongst some GPs that positive coeliac serology always equals coeliac disease. (G)

Several interviewees also commented that no-biopsy diagnosis may impact the management of non-responsive CD and that management may be more complicated without a baseline biopsy to provide diagnostic certainty.

> For those patients who don't respond to a gluten-free diet and have persistent symptoms, you haven't

> got that initial biopsy definitively saying they've got coeliac disease. (G)

The most common concern expressed regarding safety was missing concurrent pathology that endoscopy could pick up. While this was voiced by nearly half of the participants, the majority felt that there would be limited risk if clear red flag guidance were in place, although one gastroenterologist remained worried that doctors might fail to recognise red flags.

The worry about overburdening primary care was shared by gastroenterologists and GPs.

> More and more stuff does get pushed back onto Primary Care without the resources to do it. (GP)

Several GPs acknowledged that it may be a challenge but that this should not prevent implementation.

> GPs do take a pride in their work and would be able to do this. (GP)

IMPLEMENTATION

All interviewees were willing to adopt the no-biopsy approach.

> I think GPs would be very happy with a no-biopsy policy, and I think patients would be very happy. (GP)

For many, this depended on the implementation of clear pathways and evidence-backed guidelines supported by official bodies.

> It's about having a robust pathway in place so if a GP diagnoses it, it's not all on them. (GP)

Successful dissemination of these recommendations was identified as a potential challenge.

Interviewees highlighted the need for clarity and publicity, stating that recommendations must not be '*buried away in a BSG guideline*'. Education was identified as crucial to ensuring appropriate implementation.

Sentiment towards primary care management of CD was complex. The question of whether a serology-based diagnosis of CD could be solely made in primary care elicited contradictory views from gastroenterologists and GPs. GP participants were largely positive, while emphasising the need for robust guidelines, secondary care support and more education:

> I would feel perfectly happy - if somebody came in with a ten-times normal threshold tissue transglutaminase - to say you are celiac […] but I wouldn't want them to miss the opportunity of being linked in with the hospital dietitian and the kind of the follow-up there. (GP)

Gastroenterologists expressed mixed views. Some felt that '*GPs are well placed to do that' G*, while others thought that patients '*needed to be still referred to a gastroenterologist*' (G).

Interviewees believed that streamlining communication between primary care, dietitians and gastroenterologists would enhance patient care and strengthen confidence in the no-biopsy pathway. Dietitians were specifically described as 'an essential part of the management' (GP).

Broadly, both groups of interviewees recognised several potential areas of difficulty but felt that these barriers would be surmountable with careful planning and concerted action. This was captured by one GP:

> I think actually a lot of the barriers would just come tumbling down. I think all that's needed is some evidence to back up some statements about what the safety is, maybe with some caveats about groups of patients that wouldn't be ideal for it, and in agreement with the BSG committee. (GP)

DISCUSSION

In this qualitative interview study, we explored the views of primary and secondary care physicians on the no-biopsy approach to diagnosing adults with CD. All interviewees were willing to adopt the no-biopsy approach in their practice if it was supported by evidence, backed by clear national guidelines, and accompanied by robust pathways to ensure patients receive appropriate follow-up. Increased patient satisfaction by avoiding endoscopy, shorter time to start treatment and the cost and environmental benefits for the National Health Service (NHS) were perceived as the main. Concerns were expressed about the risk of false-positive results, inappropriate over-diagnosis of CD and missing concurrent pathology (figure 2).

The invasive nature of endoscopy can be a significant source of stress and anxiety for patients with suspected CD. Endoscopy-related anxiety extends across all the procedural stages, from waiting for an appointment to waiting for the results.[13] Endoscopies in the UK are performed under minimal conscious sedation or without sedation,[14] which could further exacerbate distress and anxiety. Moreover, patients with CD encounter long waits for endoscopy and experience uncertainty in managing their diet around the procedure.[15] Consequently, more than a third of patients with positive coeliac serology in primary care are not referred for endoscopy and biopsy to confirm the diagnosis of CD.[16] Implementing novel systems such as automated alerts and direct patient notification for positive coeliac serology results in primary care could reduce the number of patients with suspected CD who are not appropriately referred to gastroenterology.

From a physician's perspective, a no-biopsy approach offers quicker diagnosis and treatment without requiring endoscopy, thereby reducing procedural anxiety and avoiding unnecessary delays. Endoscopy is also costly and ranks among the highest waste-generating procedures in healthcare.[17] Physicians recognised the potential benefits of the no-biopsy approach in cutting costs, reducing waiting lists and decreasing the environmental impact of endoscopy.

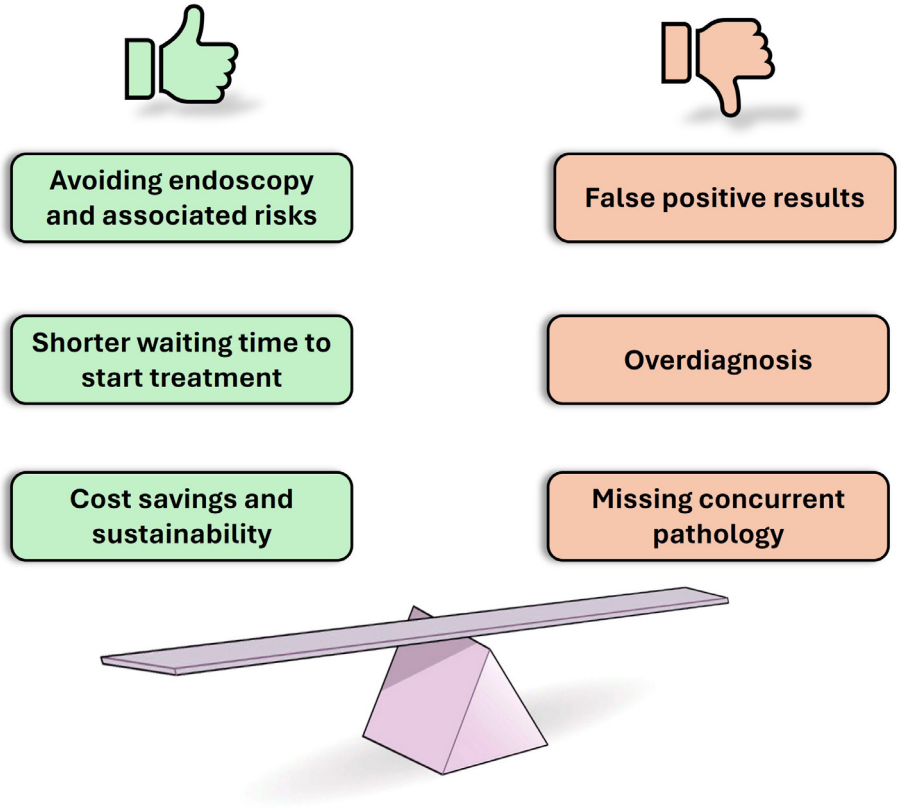

Figure 2 Potential advantages and disadvantages of the no-biopsy approach to diagnose adult coeliac disease.

Studies examining the accuracy of the no-biopsy approach have consistently shown that the positive predictive value (PPV) of IgA-TTG≥10× ULN to identify patients with CD was >95%.[6] All these studies were conducted in secondary and tertiary care settings with a high pretest probability of CD. Therefore, implementing the no-biopsy approach in a low prevalence setting, such as primary care, could potentially increase the risk of false positives and jeopardise diagnostic accuracy. There is a pressing need for more data from primary care to better understand the accuracy and implications of the no-biopsy approach in settings with lower pretest probabilities of CD. This should be paralleled with increasing education about CD in primary care to ensure patients get accurate diagnoses. Such efforts will help minimise the risk of false positives and ensure that only those truly affected by the condition commence a lifelong GFD.

To mitigate the risk of missing concurrent pathology if endoscopy is avoided, the British Society of Gastroenterology (BSG) COVID-19-specific interim guidance recommended that the no-biopsy approach be limited to those below 55 years.[18] Subsequent studies showed that the risk of significant co-pathology in patients with CD is negligible.[19 20] More recently, a nationwide analysis of the UK National Endoscopy Database reported an adjusted PPV of upper gastrointestinal cancer in individuals below 50 years of <1% regardless of presenting symptoms.[21] While these findings are reassuring, our results indicate that some primary and secondary care physicians remain concerned about adopting the no-biopsy approach, particularly in older patients and those presenting with red flag symptoms. Therefore, future guidelines and referral pathways should clearly define criteria for the no-biopsy approach to support physicians in making informed decisions while maintaining patient safety.

The shift to serology-based diagnosis challenges decades of established clinical practice. Many physicians and patients view the traditional endoscopy and biopsy approach as the gold standard for accurate diagnosis.[15] Therefore, adopting the no-biopsy approach requires a mindset change among healthcare providers and patients alike. It is crucial that patients are provided with comprehensive information about the benefits and risks of each diagnostic approach to make well-informed decisions that align with their preferences.[22] This shared decision-making ensures greater patient satisfaction and adherence to treatment.

GPs expressed concern that implementing the no-biopsy approach may shift the burden of CD diagnosis onto primary care without the appropriate support and resources. To address this, it is important to prioritise the role of dietitians in the frontline care for CD, supported by interested gastroenterologists and a robust evidence-based standard operating procedure. This model may provide a high-quality, safety-netted service while alleviating the pressure on GPs.

Our study has several strengths. To the best of our knowledge, this is the first qualitative study to explore the physician's views on the no-biopsy approach to diagnosing CD in adults. This provides valuable insight into the perspectives of healthcare professionals, which may inform future practice guidelines. Another strength was the diverse clinical experience of the physicians included in the study, eliciting a range of opinions and perspectives. Finally, data saturation was achieved with an appropriate sample size due to real-time analysis, and two authors coded the transcripts independently to reduce bias and to ensure the validity of the thematic analysis.

The study also had some limitations. First, all participants were from England, with over half based in the north, so their views may not be generalisable to other healthcare settings with different practices. Second, participants were identified through the authors' professional networks, which may have introduced selection bias. To mitigate this, we made efforts to ensure that participants represented a diverse range of views, regions and professional backgrounds. Third, some participants were unfamiliar with the no-biopsy approach before the interview, which may have limited their ability to provide fully informed opinions. Fourth, interviews were conducted by a single researcher, which may have introduced interviewer bias. However, this also ensured consistency in the questioning approach and was mediated by using an interview topic guide that had been developed collectively.

Following the implementation of the no-biopsy approach, larger qualitative studies will be essential to explore the views and experiences of physicians, patients and dietitians. These studies can provide further insights into the practical challenges, benefits and concerns associated with this novel diagnostic strategy. In conclusion, gastroenterologists and GPs are willing to adopt a no-biopsy approach to diagnosing CD in adults. The correct and safe implementation of this approach relies on having clear evidence-based guidelines and collaboration between primary and secondary care providers. Involving patients in shared decision-making will ensure that their preferences and concerns are considered, eventually leading to more patient-centred care.

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Acknowledgements We are grateful to the patients and physicians who shared their time and experiences to make this study possible. We also thank Keira Shepherd and Heidi Urwin from the Coeliac UK for their support and help throughout the project.

Contributors MGS, MMCE, JB and DSS contributed to the conception and design of the study. MGS and FJBH reviewed and coded the transcripts. MGS wrote the initial manuscript draft. All authors helped with data interpretation, critically revised the manuscript and approved its final version. MGS is the guarantor of the article.

Funding Funding was received from the Coeliac UK (Sponsored Dissertation Award). Coeliac UK had no role in study design, data collection, data analysis, data interpretation or in the writing of the report.Funding was received from the Coeliac UK (Sponsored Dissertation Award). Coeliac UK had no role in study design, data collection, data analysis, data interpretation or in the writing of the report.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the University of Sheffield's Ethics Committee in January 2024 (reference number 058425). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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Topic guide

	Interview Questions/prompts
Introduction	- Introduction and confirming consent. - What is the interview about, and what are the main objectives of the study. - Please tell us about your background and experience in managing patients with coeliac disease. - How often do you diagnose and manage patients with coeliac disease in your clinical practice?
Knowledge and awareness	- Do you follow specific clinical guidelines when investigating and diagnosing adult patients with coeliac disease? And what is your usual practice when investigating and diagnosing patients with coeliac disease? - What do you know about the concept of the no-biopsy approach to diagnose coeliac disease in adults? - Are you aware of the evidence supporting the no-biopsy approach? - Have you used the no-biopsy approach to diagnose patients with coeliac disease in your practice?
Perceived advantages	- From your perspective, what are the potential advantages of the no-biopsy approach? - What is the positive impact of implementing the no-biopsy approach on patient care and healthcare utilisation?
Perceived disadvantages	- Do you have any concerns about implementing the no-biopsy approach in adults? - What are the potential risks of diagnosing patients with coeliac disease without biopsy?
Implementation of the no-biopsy approach in practice	- What challenges or barriers might be encountered if the no-biopsy approach was implemented in clinical practice? - What is the best way to integrate the no-biopsy approach in the existing referral pathways for patients with suspected coeliac disease? - Do you think patients with coeliac disease should be diagnosed and managed in primary care without referral to Gastroenterology? - What changes to the current guidelines are necessary?
Shared decision making	- How would you explain the no-biopsy approach to patients? - What information do you think patients should be provided with regarding the no-biopsy diagnosis? - Are there any specific patient concerns that you may have encountered when discussing the no-biopsy approach? And how do you address such concerns?
Ending the interview	- Do you have any additional comments or thoughts about the no-biopsy approach? - Thank the participant for their time and end interview.

Supplementary Table 1 - Overview of the main themes with representative quotes

Theme	Subtheme	Area	Representative quotes
Benefits	Patient benefits	Avoiding endoscopy (G12, GP7), and associated risks (G2, GP2)	• *"I think we create a lot of harm psychologically by doing gastroscopy. And so, anything that we can do by reducing that is really important."* G • *"If you give them an option that you don't have to stick a camera down their throat, I think they would be much more receptive to it."* GP
		Avoiding pre-endoscopy gluten challenge (G3, GP4)	• "*If you have got the initial TTG of over 100 from GP, then that's the diagnosis already. Why would you put them back again on four weeks of gluten-rich diet? The majority of them are really resisting it because of horrible symptoms they've experienced in the first place"* G • *"Once you've sort of dangled this carrot of if you go gluten-free, a lot of these symptoms will go, and you'll improve, and then you say actually you've got to have this biopsy first, and what's worse than that. You've got to load the gluten in order to get a clearly positive test. So, if there was any alternative to this route, we would welcome it in Primary Care"* GP
		Reduces delays in diagnosis and treatment (G5, GP9)	• *"If you've got a patient who meets the criteria you can effectively give them that diagnosis and get them started on treatment and avoid the need for an unnecessary wait for an outpatient review."* G • "*I don't want to send a patient in a pipeline where they're waiting six months a year to get told something which otherwise have a blood test done today, and tomorrow you can have the answer*" GP
	NHS benefits	Reducing waiting lists (G5, GP6), and burden on secondary care (G2, GP5)	• *"I think with the way things are, the waiting list to have an endoscopy Is really really long*" GP • "*That'll be amazing because that will really save a lot of waiting.*" GP
		Cost savings (G6, GP3)	• "*There is an argument that you can make economically in terms of costs*" G
		Sustainability (G4)	• *"Reducing the number of endoscopies and histology, which in the environment of looking towards greener and more sustainable endoscopy, has some merit"* G • *"So I think it's much more greener, it's a more patient-friendly pathway, certainly more patient preferable." G*

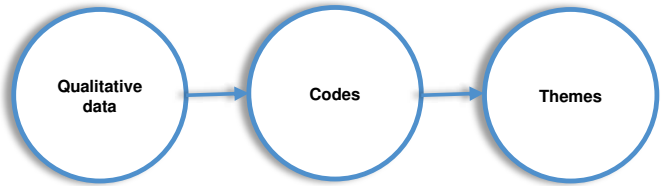
Concerns	Accuracy	False positive/overdiagnosis (G3, GP1)	• *"there's always risks in anything that is anything other than the gold standard whether you've got some sort of mimic or some other condition, but you're probably talking about very rare cases."* G • *"Everybody wants to know for sure and if the endoscopy is the gold standard at the moment and the results from the blood tests are not as accurate or if there's a discrepancy then I personally get the patient would probably like to know for sure."* GP
		Lack of baseline histology/managing refractory patients (G6, GP2)	• *"And for those that aren't better, it's a bit of information missing as to where you started from. You're making the assumption that they definitely had celiac disease. And that's still an assumption you'll never be able to shave"* G • *"the concern is if you have a complicated course by which you don't get better quickly, do you have a baseline from which to compare? and you don't really know which direction things are going to go down."* G
	Safety	Missing concurrent pathology (G8, GP3)	• *"I guess there's a risk of missing other diagnoses. So, of course, there are lots of patients who've got other pathology who also happen to have it"* G
	Workload	Overburdening primary care (G1, GP4)	• *"This is another condition that's being passed from secondary care into primary care."* GP • *"The primary care system might not be able to cope with these additional demands, but you know, this is not what patients want or need. And you know, GPs being overstretched should not be a barrier to giving the most appropriate patient-centred care."* G
Implementation	Acceptability	Willingness to adopt a serology-based diagnosis (G12, GP12)	• *"I can only see it as a win for everyone, Primary Care, secondary care, and most importantly, the patients because for me. It becomes a no-brainer if it is a reliable test"* GP • *"I'll tell you now. I think the no-biopsy approach is brilliant. And I think it's the way we should be going."* GP • *"It (*endoscopy*) becomes an unnecessary procedure unless there is data showing that there is something to add." G*
		Challenging standard practice (G2, GP2)	• *"I think the major thing is people don't like changing what they already do."* G • *"I think actually a lot of the barriers would just come tumbling down. I think all that's needed is some evidence to back up some statements about safety and maybe with some caveats about groups of patients that wouldn't be ideal for"* G

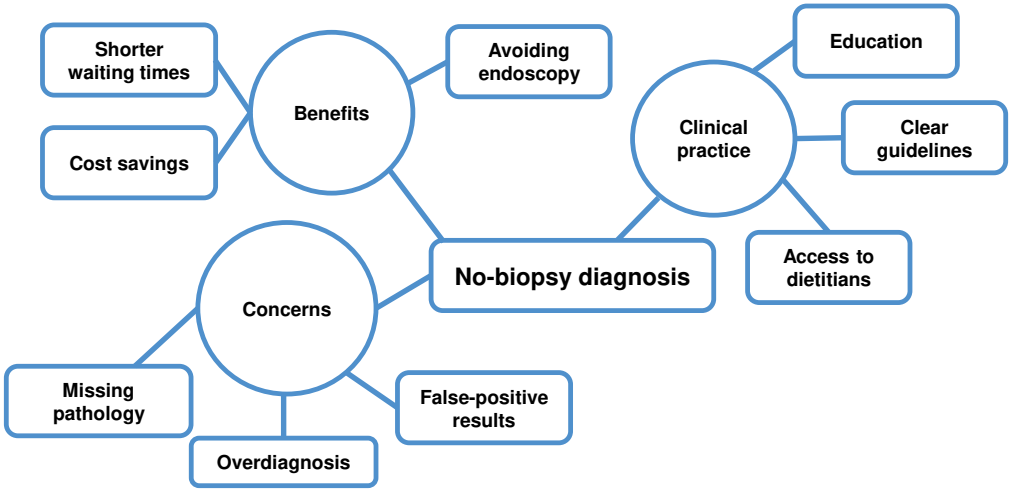
	Practicality	Need for clear guidelines (G10, GP9)	• *"Guidelines must be changed to incorporate the no-biopsy but to put it in black and white" G* • *"The guidance would have to be very clear; I wouldn't say that everything's black and white, but you'd have to have very clear guidance for GPs to be able to follow."* GP
		Need for education (G4, GP5)	• *"Yeah, so it's education all the way"* GP • *"I think it's education, isn't it? I mean, I think celiac disease is quite complex."* GP
		Available resources and access to guidance/services (G1, GP5)	• *"Would feel perfectly happy to diagnose coeliac non-biopsy, but wouldn't want them to miss the opportunity of being linked in with the hospital dietitian and the kind of follow-up there"* GP • *"There's a lot of things ensuring that there's a very clear protocol to follow and, as I say, straightforward access to dietitian support diagnosis and a clear idea of who, if any, to ask in terms of follow-up"* GP

G: Gastroenterologist; GP: General practitioner

Exploring the views of primary and secondary care physicians on the no-biopsy diagnosis of coeliac disease in adults: A qualitative interview study

24 semi-structured interviews with Gastroenterologists and GPs





Primary and secondary care physicians are willing to adopt a serology-based diagnosis of coeliac disease in adults. The safe and effective implementation of this no-biopsy approach depends on developing clear evidence-based clinical guidelines and referral pathways, along with comprehensive education for all healthcare providers involved.

Shiha MG, et al. *Frontline Gastroenterology* 2024. DOI: 10.1136/flgastro-2024-102837

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