Title: Clinical Utility of small bowel ultrasound assessment of Crohn's Disease in Adults: A systematic scoping review

Running Title: Clinical utility of SBUS in CD

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Keywords: Crohn's Disease, Ultrasound, Clinical Utility.

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Abstract:

Background: Ultrasound is an alternative to Magnetic Resonance Enterography, and has the potential to significantly reduce waiting times, expedite clinical decision making and improve patient experience. Point of care ultrasound is an advantage of the US imaging modality, where same day scanning, interpretation and treatment decisions can be made.

Aim: To systematically scope the literature on point of care ultrasound use in small bowel Crohn's disease, generating a comprehensive list of factors relating to the current understanding of clinical utility of this imaging modality.

Methods: Searches included: MEDLINE, EMBASE, Cochrane Library, CINAHL, PsycINFO, clinicaltrial.gov,'TRIP' and Epistemonikos. Reference lists of included studies were hand searched. Search terms were searched for as both keywords and subject headings (MeSH) as appropriate. Searches were performed with the 'suggested search terms' and 'explode' selection, and restricted to 'human', 'adult' and 'English language' publications. No date limits were applied to be as inclusive as possible. Two investigators conducted abstract and full text review. No formal quality appraisal process was undertaken; however, quality of sources was considered when reporting findings. A narrative synthesis was conducted.

Results: The review included 42 sources from the UK, Europe, Japan, Canada and the USA. SBUS has been shown to be as accurate in detecting presence of SBCD, is quicker, safer and more acceptable to patients,compared to magnetic resonance enterography. small bowel ultrasound is used widely in central Europe and Canada but has not been embraced in the UK. Further research considering economic evaluation, clinical decision making and exploration of perceived barriers to future implementation of small bowel ultrasounds is required.

Keywords: Crohn's Disease, Ultrasound, Clinical Utility.

Key points:

1. **What is known:** SBUS has been shown have a relatively comparable accuracy to MRE in detecting presence of SBCD. SBUS, and POCUS, are used widely in central Europe, Canada and some parts of the USA, but has not been embraced in the UK and other parts of the world.

2. **What this study adds:** This study consolidates and comprehensively presents what is known regarding the clinical utility of small bowel ultrasounds and point of care ultrasound for use in Crohn's Disease. This study gives insight into the future directions of research in this field.
3. **Future implications of this work:** this study is the first step in a programme of work to investigate barriers and enablers to implementation of a small bowel ultrasound, point of care, service for Crohn's Disease in the NHS. Through this work we have been able to better direct our research to investigate stakeholder perceptions of barriers to implementation, clinical decision-making behaviours and cost effectiveness studies.

Author contributions:

Shellie J Radford is acting as the submission's guarantor. all co-authors have approved this final version of the manuscript for submission.

Shellie J Radford undertook the literature searches, read and analysed the data, conducted a narrative review, wrote the manuscript and collated reviews from co-authors.

Dr Gordon Moran was second author, reading and analysing the data, contributed to the narrative review of the data, whole manuscript review and final editing.

Dr Christopher Clarke was appointed as third reviewer, however no discrepancies occurred.

Dr Paul Leighton, Dr Bethany Shinkins and Professor Stuart Taylor offer expert overview and whole manuscript review.

Introduction

The UK prevalence of Crohn's Disease (CD) is one of the highest world-wide.[1] The mean cost per patient-year during follow-up has been reported as €3542 (median €717 [214–3512]) for patients with CD, with an overall annual cost to the National Health Service (NHS) of up to £470 million.[2]

Assessing treatment response with more objective measures and a wider array of biological therapies has significantly increased the projected IBD healthcare burden for the next decade. [3,4] To ensure cost-effective IBD practice, complex and expensive pharmacological interventions should be targeted at patients most likely to benefit.[5]

Cross sectional imaging is used to diagnose and monitor disease activity in small bowel CD (SBCD).[6] Magnetic Resonance Enterography (MRE),with oral preparation and intravenous contrast is a standard of care modality in the UK for assessment and monitoring of SBCD.[6] However, waiting times for an NHS MRE may be up to 4 weeks or in some instances longer, with reporting is then undertaken at a later date. Additionally, the use of gadolinium as contrast agent has a risk of allergy, is expensive and has been implicated with long-term brain deposition in exposed patients.[7] The European Crohn's and Colitis Organisation [ECCO] and the European Society of Gastrointestinal and Abdominal Radiology [ECCO-ESGAR] guidelines have already negated some of the risks posed by the use of gadolinium, by stating that gadolinium should be used on a case by case basis.[8] Some centres are moving away from its use and have shown no significant decrease in accuracy.[9] However, there is still a clinical need to find quicker, more tolerable and cheaper alternatives for monitoring patients with IBD.

Abdominal ultrasound (US) is an alternative to MRE, with the potential to reduce waiting times, speed up clinical decision-making and improve patient experiences and outcomes.[10]

Point of Care (Abdominal) US (POCUS) is an advantage of the US imaging modality, where same day scanning and interpretation can be undertaken.

This review is undertaken as the first step in investigating the use of POCUS for assessment of disease activity in SBCD. Due to the vastness of the existing evidence and the objective of this review, it was decided that a scoping review, rather than a systematic literature review, was more appropriate.[11] The objective was to systematically scope the literature on POCUS use in SBCD, identify specific characteristics and expand the current understanding of the clinical utility of POCUS for patients with SBCD.

Multidimensional model of clinical utility

Clinical utility can be described as a multi-dimensional judgement about the usefulness, benefits, and drawbacks of an intervention. The model of dimensions of clinical utility presented by Smart[12] (Figure 1) provides a frame work for assessing the clinical utility of a new technology or technique, asking whether the innovation is appropriate, accessible, practicable, and acceptable for the purposes of the task intended. In this scoping review, factors were identified and grouped into themes in relation to the factors of clinical utility.

Methods

Preliminary searches of MEDLINE, Cochrane Database of Systematic Reviews and JBI Evidence Synthesis were conducted, no current systematic reviews or scoping reviews on the same topic were identified. Methods for this study were developed based on established scoping review methodology. [13,14] The research question was: “What evidence is currently available on the clinical utility of POCUS for the diagnosis and management of SBCD?”.

Inclusion criteria:

Searches of electronic databases of published literature included: MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and

PsycINFO. Searches were also conducted of clinicaltrial.gov for current clinical trials, 'TRIP' and Epistemonikos. Reference lists of included studies, grey literature and non-indexed sources were hand searched to identify additional sources of relevance.

Search terms were searched as keywords in title and/or abstract and subject headings (MeSH) as appropriate. Search terms (Table 1) were determined through consideration of previously reviewed literature and preliminary searches of Google Scholar. The Boolean operator 'OR' was used within each facet to maximise searches, with the operator 'AND' used between facets to combine terms, truncation of terms was used to be as inclusive as possible. Searches were performed with 'suggested search terms' and 'explode' selection, included any type of study design, and restricted to 'human', 'adult' and 'English language' publications. No date limits were applied to be as inclusive as possible.

Table 1: Key search terms

Crohn's Disease (MeSH)	Small Bowel	Ultrasound (MeSH)
Crohn's Disease	ileal	Ultrasound
Crohn's	Ileum	US
CD	Ileitis	Sonography
Crohn*		Echography
Inflammatory bowel disease		Point of care ultrasound
IBD		POCUS
		ultrasonography

Two investigators (SJR and GWM) independently screened the title and abstract of all retrieved citations for inclusion against inclusion criteria. Each author reviewed each title and abstract, if both agreed to include the full text for review it was included, if both chose to exclude it was excluded. There were no disagreements which led to the need for a third author deliberation. No formal quality appraisal process was undertaken; however, quality of sources was considered when reporting findings.

The two investigators (SJR and GWM) then each independently assessed all full-text articles to determine if they met inclusion criteria. There were no disagreements about study eligibility at the full-text review stage that required discussion with a third investigator. Reasons for exclusion of full text sources were recorded and reported in the PRISMA[15] flow diagram (Figure 2). A narrative synthesis was conducted to explore relationships within and across the included sources.

Results

The review included 42 sources (table 2). A common view across 24 of the included sources was that US is non-invasive test that is acceptable to and well tolerated by patients, is safe and is inexpensive.[8,10,16–37]

Only four sources directly mention the use of POCUS.[10,30,36,38] the remainder discuss the use of small bowel ultrasound (SBUS). For the purposes of this review, we consider the use of SBUS without contrast agents, minimal or no bowel preparation and not the use of specialised tests such as doppler or elastography scanning.

In central Europe and Canada SBUS is widely used, often performed by gastroenterologists. This allows gastroenterologists to have a whole view of patient management, reducing waiting times for clinical decision making.[34,36]

The METRIC study showed that both SBUS and MRE had a diagnostic accuracy above 90% for detecting SBCD. Sensitivity of SBUS for small bowel disease presence and extent were 92% and 70% respectively.[39] Sensitivity and specificity were significantly greater for MRE, with a 10% and 14% difference for extent and a 5% and 12% difference for presence.[39] It was also found that there was substantial sonographic agreement for the presence of SBCD, both in newly diagnosed and relapsed disease. [40] Agreement for SBCD extent was inferior to that of presence alone; this is in contrast to previous work by Parente et al[41], who reported near perfect agreement for segmental localisation.

The most prominent parameter for detection of inflammation throughout the reviewed sources was bowel wall thickness (BWT), which correlates well with clinical disease activity markers.[8,10,17–22,24,25,27–29,32,34,35,37,38,42–46] The most common cut off value was BWT exceeding 3mm being considered pathological and a BWT of 2mm or less considered normal.[31,32,42]

A number of SBUS scores have been developed, most lack validation, were developed from small sample sizes or are limited to quantification of 'damage' or the risk of surgery.[25,47] Novak et al[25] have developed a promising, simple US score for identifying CD activity comparing BWT to endoscopic activity, however the results reported have not yet been externally validated.[25]

Fraquelli et al[34] notes that the use of SBUS in different clinical settings may impact on the utility of SBUS. In specialist centres where the pre-test probability of IBD is elevated, US would be used to 'rule in' the disease. Alternatively, in primary care SBUS would be a useful tool to 'rule out' the disease.[48]

Paredes et al[49] used SBUS for assessing changes induced with an anti-tumour necrosing factor (TNF) therapy in CD. The study reported a significant reduction in BWT in patients receiving anti-TNF therapy, however, 'resolution' of inflammation visible on SBUS was only achieved in 29% of subjects.[34] Results from Ripolles et al [45]showed that SBUS may be able to predict the 1 year response to anti-TNF therapy after 12 weeks of treatment with 85% (22/26) of patients showing a sonographic response at 12 and 52 weeks. Moreover, in the majority of patients (96%), clinical and biological response corresponded to sonographic response. Multiple authors suggest that SBUS may have a role in supporting MRE as a useful examination for monitoring the response to treatment in CD patients.[23,29,34,38,50]

The METRIC[39] study found no major difference between MRE and SBUS on therapeutic decision-making. Both tests agreed with a final therapeutic decision based on all tests in >

75% of cases. Very little further investigation into the impact of the use of SBUS on the clinical decision-making behaviours of clinicians has been undertaken, nor exploration of the confidence of clinical decisions made using each imaging modality.

Multiple sources refer to SBUS being inexpensive, however there is little empirical evidence within the included sources to support this claim.[20–23,26,39,51] The METRIC[39] study presents data on a cost-utility analysis of MRE vs SBUS indicating a trend towards SBUS over MRE. However, given the small non-significant differences in costs and QALYs between the two options, it was not possible to endorse US or MRE on cost-effectiveness grounds.

The benefits of POCUS being performed by a member of the clinical IBD team include increased capacity for real time interpretation of findings, expediting decisions concerning disease management and strengthening the rapport between Health care professionals (HCPs) and patients.[35,36,38] Many centres have standalone IBD US lists. These lists may be advantageous in expanding capacity to perform SBUS, particularly in centres where gastroenterologists are not trained in SBUS. This may also maximise healthcare resource allocation via predictable patient bookings.[36]

Over the last few years, outside of the UK, the widespread availability of US technology and the increasing expertise of practitioners has boosted the uptake and role of US in assessing patients with IBD.[31,34,39,43] Throughout the included sources results reported were from SBUS being performed by individuals with extensive experiences of SBUS. [16,17,19–21,26,28–30,37,44,45,48] For example, Taylor et al [39] reports that the team involved in the METRIC study had an average of 8 years (4-11) experience of interpreting US. Despite SBUS typically being performed using standard devices and techniques, the uptake is not widespread or universal. Multiple authors have speculated this is due to lack of training availability and the substantial training and experience requirements of those preforming the test.[34,52] However, interobserver agreement between sonographers with variable experience in SBUS has been reported in preliminary studies showing satisfactory results.[10,16,17,34,36,37,40,42,48] With appropriate training, transabdominal US can be performed by specialist gastroenterologists in clinic as part of routine care.[30] Gastroenterologist-performed SBUS is yet to establish universal acceptance.[53] The benefit of SBUS being performed within a radiology department by a dedicated sonographer or radiologist is the potential for increased diagnostic accuracy in detecting pathology.[36]

SBUS and MRE are the most preferred imaging modalities by patients with CD.[39] SBUS is well tolerated by patients with IBD.[8,26] MRE recovery time has been shown to be significantly longer than US, with 15 participants out of 149 (10%) reporting immediate recovery following MRE compared with 102/147 (69%) for US.[54] The proportion of participants willing to repeat MRE was 127/147 (91%). This was lower than for US where 133/135 (99%) were happy to repeat the test.[54] Overall 128/145 patients rated MRE as very or fairly acceptable, while 144/146 (99%) participants rated US as very or fairly acceptable. Issues reported by patients concerning MRE mainly reflected ingesting contrast, repeated breath holds and the after-effects of contrast such as diarrhoea and bloating. Perceived scan burden was significantly higher for MRE than SBUS. One important finding is that patients rated diagnostic accuracy as the most important attribute and more important than the challenges related to discomfort of undergoing scans.[55] None of the included sources presented findings related to preferences of HCPs or patients as to where and when SBUS should be delivered.

Discussion

Mucosal healing, defined by the absence of ulcerations, is recommended as the therapeutic goal in clinical practice. MRE is the current standard for assessing SBCD, however It is expensive, time consuming and poorly tolerated by patients.[7,30]

Meta-analyses suggest MRE and SBUS have similar accuracy for diagnosing and staging SBCD.[56] SBUS could be a good alternative to more invasive and expensive imaging techniques. Besides being quick, well tolerated and readily available, SBUS is reported and interpreted at the time of scanning and allows for expedited clinical decision-making.[10] POCUS is reported as having impact on clinical decision making in routine IBD care by expediting clinical decision makng.[10,30,36] However there is no current evidence on the impact that SBUS has on the nature of clinical decision making behaviours, or confidence of HCPs making those clinical decisions.

Multiple sources referred to SBUS as inexpensive. However, none of the included sources presented clear data relating to cost or cost effectiveness of SBUS or POCUS. More data on the cost effectiveness of SBUS are needed to encourage the implementation of SBUS in IBD services.[10] SBUS involves the use of standard ultrasound equipment that is readily available in most hospitals, however increasing scanning capacity also involves increased resources such as staffing and training. SBUS is often seen as having limited clinical utility due to operator dependence.[36] However, this criticism is perhaps more reflective of a previous lack of identifiable international performance and training standards.[36] NHS radiology workforce is short staffed by 33%, and is already at a deficit before considering the backlog following COVID-19.[57] ECCO-ESGAR Guidelines describe the dedicated training in bowel US process, and that SBUS should be performed following training in general abdominal US.[8]

Although various SBUS activity scores are available, the methodology for development was insufficient in most studies. There are several scoring systems for disease activity assessment using SBUS in CD, however until recently none had been completely validated.

There is no current work to investigate patient or HCPs preferences or service delivery. There are also questions relating to HCP perceptions of acceptability related to the diagnostic accuracy and confidence in basing clinical decisions on SBUS. It would seem prudent to investigate broader stakeholder perceptions of the use of POCUS in order to better understand perceived barriers and enablers to POCUS implementation in world-wide healthcare systems and recognise and manage preferences for future service delivery.

Limitations

Scoping reviews do not formally evaluate the quality of evidence gathering information from a wide range of study designs and methods, providing a descriptive account of available information leading to broad overview of the available literature. The outcomes represent an accurate response to the research question. Continuous conversations between authors occurred throughout to ensure a unanimous decision regarding article searches, thus limiting any potential bias. The scope of background information collected, disease activity levels, depth of data relating to the use of SBUS/POCUS vary vastly between sources.

Conclusions

SBUS has been shown have a relatively comparable accuracy to MRE in detecting presence of SBCD. SBUS, and POCUS, are used widely in central Europe, Canada and some parts of the USA, but has not been embraced in the UK and other parts of the world. The resources required in terms of equipment, are readily available in most hospitals. Resource implications for future implementation include training of gastroenterologists and staffing of supporting radiology departments

Multiple sources reported SBUS as an inexpensive test, however there is scant literature to support this. Further research in this area would better inform decision makers regarding future intervention implementation.

SBUS is reported as being a useful tool to expedite clinical decision making, but there is no evidence relating to the impact on the nature of clinical decision making by HCPs. Further research in this area would help us to better understand the impact of POCUS on clinical practice, leading to better understanding of practicable and acceptable aspects of clinical utility.

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Figures:

Figure 1: Factors of Clinical utility

The model of dimensions of clinical utility presented by Smart[12] encompasses elements of work practice alongside other factors such as economic considerations, stakeholder acceptability and future planning for interventions and services. Assessing the clinical utility of a new technology or technique involves asking whether the innovation is appropriate, accessible, practicable, and acceptable for the purposes of the task intended.[12,58,59]

Figure 2: PRISMA flow diagram – Supplimental material

The flow diagram depicts the flow of sources through the different phases of screening for inclusion and exclusion. we included 42 sources in our scoping review. Reasons for full test exclusion are detailed in the PRISMA flow diagram.

Table 2: Table of included sources – supplemental material