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Acceptability of chronic liver disease screening in a UK primary care setting: a qualitative evaluation

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ABSTRACT

Objectives The increasing incidence of chronic liver disease (CLD) in the UK may be attributed to a rise in preventable risk factors, including hazardous alcohol use and type 2 diabetes. Transient elastography (TE) can rapidly stratify risk of CLD in primary care populations and provide an opportunity to raise patient awareness of risk factors.

This study explores patients' experiences of TE screening in a primary care setting. In addition, patient awareness of CLD risk is explored.

Study design and setting This study used a qualitative process evaluation of a community screening pathway for CLD (Nottingham, UK). Participants completed semistructured interviews, which were audio-recorded, transcribed verbatim and analysed thematically.

Participants Twenty adults were purposively recruited 6 months to 2 years after TE screening. Inclusion criteria included (1) hazardous alcohol use, (2) type 2 diabetes and/or (3) persistently elevated liver enzymes without known cause.

Results Undergoing TE in primary care was seen as acceptable to most participants. Hazardous alcohol use was identified as the primary cause of CLD; no participants were aware of metabolic risk factors. TE improved understanding of personal risk factors and prompted contemplation of lifestyle changes across all TE stratifications. However, participants' perceptions of risk were altered by the healthcare providers' communication of TE scores.

Conclusions High acceptability of TE, regardless of the risk factor, provides strong support for inclusion of TE stratification in primary care. Findings highlight the positive impact of receiving TE on risk awareness. Future clinical iterations should improve the structure and communication of TE results to patients.

Strengths and limitations of this study

- This study presents the first qualitative evaluation of experiences of patients undergoing transient elastography screening in primary care for non-viral liver disease.
- Purposive sampling allowed for representation of varied general practitioner locations and chronic liver disease risk factors/diagnoses.
- Limited ethnic diversity in the sample potentially limits its generalisability to non-white British populations.
- The interviewer was involved in a larger community study of the screening pathway, which may have inadvertently impacted the findings.

INTRODUCTION

Chronic liver disease (CLD) is the third most common cause of premature death in the UK, with mortality rates increasing by 400% since 1970.[1] The rising incidence of CLD and the associated increase in mortality are driven by a rise in risk factors, such as hazardous alcohol use and type 2 diabetes, and are therefore considered preventable.[2 3] However, the largely asymptomatic nature of CLD means initial detection of the disease predominantly occurs following hospitalisation with decompensation, resulting in significantly impaired prognosis.[4]

Traditional approaches to the identification of CLD in primary care settings demonstrate poor sensitivity.[5] In a community population, abnormal liver enzymes were observed in approximately one-fifth of patients tested over a 5-year period.[5] Despite this, detection of significant liver disease was remarkably low, occurring in only 1.14% of the sample.[5] Conversely, normal liver enzyme results do not accurately exclude underlying CLD; approximately 88% of patients with non-alcoholic fatty liver disease (NAFLD) above the age of 65 years present with normal liver enzymes.[6] To improve the accuracy of early liver disease detection, recent guidelines recommend the use of additional risk stratification tools, particularly in patients with a known history of harmful alcohol use or NAFLD.[7]

Novel risk stratification approaches, such as transient elastography (TE), enable rapid identification of CLD in those who may be unaware of their illness.[8] TE provides an immediate numerical value for liver stiffness, allowing feedback to patients regarding their risk of liver disease within the same

appointment. Furthermore, the non-invasive nature of TE allows for rapid risk stratification that is readily deliverable in community settings.[9] The Nottingham Community Liver Study was a large feasibility study that embedded portable TE devices (Fibroscan; EchoSens, Paris, France) into two general practitioner (GP) practices in the Rushcliffe borough of Nottingham, UK. The primary objective was to assess whether inclusion of TE as a risk stratification tool could improve early identification of CLD. The combined patient population of both practices was 12 368, of whom 10% had type 2 diabetes or harmful alcohol use as a risk factor for CLD. TE screening of patients with these risk factors led to a 140% increase in diagnosis of cirrhosis, despite 90.9% of the patients with cirrhosis having normal liver enzymes.[9]

Integration of TE into primary care settings has allowed for successful identification of previously undetected CLD. However, before further implementation, it is important to assess the acceptability of this intervention to patients, including any barriers or enablers to uptake. This study presents a qualitative process evaluation of the Nottingham Community Liver Study, exploring the impact of undergoing TE in a primary care setting. We sought to understand patients' experiences of the delivery and process of TE screening for CLD and the broader impact of TE screening on patient risk awareness.

METHODS

Study design and setting

This study was a qualitative process evaluation that used semistructured interviews to explore participants' experiences of CLD screening in primary care. Participants were purposively sampled from a large cohort of patients who underwent stratification of CLD in the community using a portable TE device (Fibroscan; EchoSens) as part of the Nottingham Community Liver Study (Nottingham, UK). A detailed description of this study and the recruitment processes has been published previously.[9] Briefly, patients with defined risk factors for development of CLD were identified through electronic medical records and invited by their GPs to attend a liver assessment at their GP practice. Risk factors included any of (1) hazardous alcohol intake (defined as (i) >14 units per week for women and >21 units per week for men, (ii) and/or presence of alcohol misuse READ code, (iii) and/or Alcohol Use Disorders Identification Test score >8), or (2) type 2 diabetes, or (3) persistently raised liver enzymes without known cause. Patients were excluded if they showed evidence of hepatic fibrosis, cirrhosis or metastatic malignancy from previous investigation; contraindications existed for performing TE (eg, pregnancy, pacemakers); or severe cognitive impairment prevented consent.[9 10] Before undergoing TE, patients were provided with information about the TE procedure. Following TE, all patients received lifestyle advice from the nursing staff and a British Liver Trust 'Looking After Your Liver' leaflet, regardless of the TE result or risk factor.

To adequately represent those undergoing TE, the sampling strata for invitation for interview were (1) GP surgery location (suburban vs inner city), (2) CLD risk factor (hazardous alcohol use or type 2 diabetes) and (3) diagnosis assigned after community liver disease stratification (normal liver stiffness vs liver fibrosis vs liver cirrhosis). Patients were excluded from interview selection if they were unable to communicate in English. Written consent was obtained following discussion with a trained research nurse.

Data collection and interview procedure

Interview questions were predominantly open-ended, with probes used where necessary to expand on participant responses. Both positive and negative views of the intervention were explored. The interview guide (online supplemental appendix 1) was reviewed by an independent qualitative researcher (MB). The guide was piloted with a trained research nurse and the initial three participants for testing and refinement. Only minor amendments were made following the pilot, meaning the initial three participants were included in the analysis.

Face-to-face interviews were conducted over a 6-month period (by DH) with patients who had attended a TE assessment 6 months to 2 years before data collection. Interviews took place either in the participant's home (n=14) or in an interview room at a tertiary care centre (n=6) (participant choice). Participants were notified that their interview responses would be anonymised. Interviews continued until data saturation was reached. Interviews were digitally audio-recorded and transcribed verbatim by a specialist transcription company.

Data analysis

Data were analysed thematically using an inductive approach.[11] During the first phase of analysis, DH conducted a preliminary scan of the data, allowing generation of initial codes for data extracts. The analysis was then refocussed to sort and group the codes into analytical categories or 'themes'. A 'constant comparative' method was used to compare individual data items with the rest of the data, ensuring that the preliminary themes retained importance with additional interviews.[12] To ensure reliability of the coding system, MB independently coded and compared five interview transcripts.

During the second phase, themes were refined to ensure data cohered together meaningfully, with themes being clear and distinct. Themes were reorganised and collapsed as required. Finally, a detailed analysis was conducted for each theme, and data excerpts were identified to illustrate the final themes. All coding was checked by an independent researcher (MB) to ensure validity. NVivo V.11 (QSR International, Melbourne, Australia) was used as a data management tool throughout the analysis process.

Table 1 Demographic and clinical characteristics of the interviewed patients (n=20)

Characteristics	n (%)
Gender	
Male	12 (60)
Female	8 (40)
GP location	
Inner city	12 (60)
Suburban	8 (40)
CLD risk factor	
Alcohol	8 (40)
Type 2 diabetes	12 (60)
TE result*	
Abnormal—cirrhosis	6 (30)
Abnormal—fibrosis	7 (35)
Normal	7 (35)

*TE result refers to diagnosis assigned on the basis of TE (FibroScan) reading of liver stiffness and subsequent confirmatory tests for abnormal scan to determine whether cirrhosis was present. Normal TE result, <8 kPa; Abnormal—fibrosis result, 8–15 kPa; Abnormal—cirrhosis result, >15 kPa.
CLD, chronic liver disease; GP, general practitioner; TE, transient elastography.

Patient and public involvement

Patients and members of the public were not involved in the study design, interpretation of results or writing of the manuscript.

RESULTS

Participants

In total, 28 participants were invited for the interview. Eight declined participation, of whom seven declined due to time limitations and one could not remember undergoing TE. The remaining 20 participants completed the interview (mean length of the interview was 27.6 min; SD=7.6; range, 16–46 min). The mean age of the participants was 57.9 years (SD=9.3; range, 40–71 years), and 12 participants (60%) were men. Participants were adequately distributed across the sampling strata (see table 1).

Thematic analysis

Analysis of the interviews revealed three main themes and two corresponding subthemes. Subthemes detail general acceptability, comprehension and impact of receiving TE results. Participant awareness of their risk of CLD before and after TE was also explored. The presenting risk factor and TE stratification are provided for each quoted participant.

Liver disease risk awareness

Participants discussed the impact that the risk stratification pathway had on their own risk awareness. Before undergoing TE in primary care, participant knowledge of CLD risk factors was relatively limited. Hazardous alcohol use was recognised to be an important cause of CLD by all bar one of the participants. This knowledge was acquired from a number of sources, including media reports on the risks of alcohol and personal experiences of hepatic cirrhosis in close family or friends. Participants endorsed strong knowledge of the symptoms occurring in decompensated liver disease and attributed these symptoms to excessive alcohol consumption. The term 'alcoholic' was commonly used to describe the origins of these symptoms:

> I used to work with a bloke, he was an alcoholic, plain and simple. He was taken into hospital numerous times because of his liver packing up, he was down to 10ml of liquid in a day at one point, that's how ill he was, where he had to pack up drinking totally or die. (Participant 16, type 2 diabetes, liver fibrosis)

Despite consistent knowledge of alcohol use as a risk factor for CLD, awareness of personal risk of CLD in patients with hazardous alcohol use was variable. Opportunistic intervention by GPs generated awareness of multiple participants' hazardous levels of alcohol use and led to a subsequent liver scan referral. However, several participants described that their alcohol intake was in keeping with their social group and endorsed feeling surprised when notified that their alcohol consumption level was considered to be hazardous and a risk factor for CLD.

Before TE, only one participant was aware that obesity could lead to CLD, and none of the participants were aware that type 2 diabetes was a risk factor. Subsequent to risk stratification, most participants reported an increased awareness of their personal risk factor for CLD, regardless of the TE result. In participants with hazardous alcohol use, this was acknowledgement that their personal alcohol consumption was hazardous, whereas for participants with type 2 diabetes it was learning that type 2 diabetes and obesity are risk factors for progressive CLD:

> It was not something that ever crossed my mind, that diabetes could give you any serious problems with your liver or kidneys or anything. That was all very new to me, when they asked me to do the study, to go for the scan. (Participant 6, type 2 diabetes, liver cirrhosis)

Experience of stratification pathway

Acceptability and understanding of screening

Motivation to attend the TE appointment was driven by both medical and emotional factors. Participants with hazardous alcohol use were not routinely part of a medical programme (ie, diabetes management) prior to this study. Therefore, the invitation to undergo TE was unexpected and generated both surprise and anxiety in some individuals. However, in interviewed participants, this did not appear to preclude attendance for the TE appointment. Several participants discussed being accustomed

to screening procedures as part of their routine diabetes care and were happy to attend on the recommendation of the GP team alone. Other participants endorsed a desire to attend the TE scan to enable the early detection of a liver problem before it resulted in any significant symptoms:

> I was okay because I wanted things finding out, if there was anything, you know, wrong with me. (Participant 2, type 2 diabetes, liver cirrhosis)

The majority of participants recalled a basic understanding of the TE device derived from either a leaflet provided prior to the appointment or the explanation provided by the nurses during the appointment. Several participants accurately described the use of TE to explore scarring in the liver and used terminologies such as 'rigidity', 'hardness' or 'stiffness':

> The two nurses, they were very good and they explained how it worked and what happens to the test, so they explained it well, what it was measuring; it was the density of the liver, like an ultrasound, so they explained all that and they were very good. (Participant 20, hazardous alcohol use, normal liver scan)

The process of being screened for CLD in a primary care setting was regarded as a positive experience by most. Many participants reported that being reviewed at their GP practice, rather than in a hospital setting, was convenient and allowed attendance outside of working hours. One participant also felt that attendance rates for liver scans in the community would be improved due to this convenience. For most participants, the rapidity of the screening was seen as surprising, while the TE scan itself was described as painless:

> It was all done in 20 minutes over and done with and it was not a problem at all, it was probably the easiest scan I've ever had, for anything! When they say 'it's done', you think 'already?'. 'It takes a bit longer than this to have an appointment with the GP'. (Participant 16, type 2 diabetes, liver fibrosis)

One participant described the scan as an uncomfortable procedure, although later described the process of having a liver biopsy as comparatively more painful. Negative feedback was also expressed by one participant for whom it was not possible to obtain a valid liver assessment in the community. Although the participant felt that the concept of community liver scanning was a good idea, he did not feel that the process itself was well executed. This participant was subsequently referred to secondary care for TE screening.

Comprehension of results

Participants' recall of their numerical liver stiffness value was inconsistent. Several participants did not remember receiving a numerical result, whereas approximately half of the participants interviewed were still able to recall their exact liver stiffness measurement. Participants' preference for the format of their liver stiffness result also varied. Some participants felt that simple categorisation of their scan result as normal or abnormal was informative enough. Other participants preferred a numerical value as the result felt more personalised and provided a baseline for comparison in case further scans were required:

> The terms 'satisfactory', 'normal', 'good', 'very good', 'excellent', they're all subjective, they mean different things to different people but a score is a score, if you have a score of 6.1, it's not 6.2 and neither is it 5.9, it's a definite starting point. (Participant 5, type 2 diabetes, normal liver scan)

Several participants felt able to use the numerical liver stiffness result to assess the severity of their liver disease. However, multiple participants described feeling uncertain about how to interpret the severity of abnormal results as the possible ranges and severities of liver stiffness results did not appear to be consistently discussed during the screening.

Impact of screening result

Most participants reported the expectation that liver abnormality would not be detected. This was derived from a number of factors, including a prior lack of knowledge regarding their own risk factor for developing CLD, the absence of previous symptoms and in several participants previously normal liver function blood tests. Following delivery of the scan results, participants with normal liver stiffness described a sense of relief that a significant problem or additional comorbidity was not detected. Conversely, participants with elevated liver stiffness results commonly reported feeling surprised, shocked or anxious. For those diagnosed with cirrhosis, most expressed concern that their disease would progress quickly or result in their premature death. However, several participants expressed relief following diagnosis with cirrhosis rather than an underlying malignancy:

> Everybody thinks there might be cancer there sometimes and it was just 'oh it's not a cancer, it's that … in another five years or so!' (Participant 19, type 2 diabetes, liver cirrhosis)

Provider delivery of the scan result appeared to contribute to the impact of the result. Specifically, several participants with fibrosis felt that the abnormality of their TE results did not represent a significant health issue because of the message conveyed by the healthcare provider conducting the scan. This resulted from the perception that mild elevations did not warrant concern:

> They told me that mine was above but not serious. That's what they said it was. Nothing to worry about, it was above normal but 'don't worry about it'. (Participant 9, type 2 diabetes, liver fibrosis)

The CLD screening process provided multiple opportunities to raise participant awareness of their liver health and fostered contemplation of potential lifestyle changes.

Both hazardous alcohol users and participants with type 2 diabetes receiving normal liver stiffness results reported immediate contemplation of lifestyle changes. Participants with elevated liver stiffness discussed the abnormal result, and subsequent advice from the nursing team and liver specialist, as the initiator of contemplation of lifestyle changes. Several participants discussed that being told they had an abnormal liver scan was a 'wake-up call' and subsequently prompted them to consider changes that could be made to their lifestyle.

> *What was the trigger that got you thinking that you needed to do something?*
>
> Having an abnormal test, no doubt about that. I think we all like to think we're perfect …! If there's something wrong and you can do something about it, you're daft if you don't, that's the way I look at it. (Participant 9, type 2 diabetes, liver fibrosis)

As a marker of acceptability, all participants were willing to undergo further CLD screening in primary care, with most reporting that an interval of 3–5 years for repeated TE scans would be reasonable. Participants with normal liver stiffness felt it would be important to repeat the liver scan to ensure that no new abnormality had developed. For participants with abnormal liver stiffness, the most important reasons for repeating the TE scan were to monitor for worsening of their CLD and to detect whether improvements in lifestyle had resulted in subsequent improvements in liver stiffness.

DISCUSSION

Summary

This study provides a qualitative evaluation of patients' experiences with a primary care liver disease stratification pathway. Specifically, the study provides insight into patients' perceptions of TE screening and diagnosis in the community while exploring patient risk awareness. The resulting themes suggest that screening for risk of CLD in the community is acceptable to 'at-risk' patients. Most participants reported positive experiences of the screening process, highlighting the convenience of undergoing TE in a primary care setting, the speed of the appointment and the painless nature of the TE scan. Participants were willing to undergo a repeat TE scan in the future. For any screening programme, participant's acceptance of the investigation is crucial; therefore, these findings add to the evidence that TE is a suitable method for risk stratification of CLD in primary care populations. While most participants reported knowledge of excessive alcohol use as a risk factor, there was very limited awareness of the connection between diabetes and CLD. Importantly, undergoing TE improved risk awareness in all participants and prompted contemplation of lifestyle changes in most.

Comparison with existing literature

The utility and acceptability of TE as a risk stratification tool have been well documented, including populations with hepatitis C.[10 13 14] This study builds on these findings by demonstrating the acceptability of TE to patients with non-viral risk factors, allowing effective risk stratification in patients with both hazardous alcohol use and metabolic conditions.

Within this study, many hazardous alcohol users were unaware that their alcohol use reached hazardous levels before referral for TE. This corroborates previous qualitative work demonstrating that midlife drinking is heavily governed by social norms and an association between problem drinking and the inability to fulfil basic family and work responsibilities.[15 16] A lack of patient knowledge may also result from healthcare providers' limited understanding about problematic drinking behaviours. In their qualitative interview study of healthcare professionals who deliver brief intervention advice for alcohol, Rapley and colleagues demonstrated that providers were uncertain of what constituted 'at-risk' alcohol intake, resulting in reduced confidence to provide alcohol consumption advice.[17] A lack of risk awareness did not, however, seem to preclude uptake of the TE scan in those with hazardous alcohol use.

Strikingly, knowledge that obesity and type 2 diabetes are risk factors for CLD was uncommon even in patients with these risk factors. Participants with type 2 diabetes frequently reported surprise at receiving an invitation to undergo TE screening. Wieland and colleagues explored awareness of NAFLD risk in individuals presenting to an endocrinology clinic. Of those with significant risk factors (ie, overweight/obese and insulin-resistant), only 24% were aware of their risk of developing NAFLD.[18] Previous studies have also described a lack of NALFD-specific knowledge among primary care providers, leading to the absence of CLD education during routine diabetes consultations and support courses.[19 20] In this study, TE screening provided an opportunity to raise awareness of patients' risk of developing CLD. However, education courses and public health interventions enhancing knowledge of CLD risk factors in both patients and healthcare professionals are warranted.

Implications for practice

The results highlighted several areas within the pathway that may require modification prior to further implementation. Negative feedback about the stratification pathway related to failed liver stiffness acquisition. Although body mass index (BMI) was not formally assessed as part of the qualitative process evaluation, it is worth considering the impact of BMI on stiffness acquisition. In the Community Liver Study, 97% of patients were successfully stratified using a medium-sized probe in primary care.[9] However, patients with a BMI ≥35 kg/m^2 were referred to secondary care to undergo TE with an extra-large (XL) probe. Recent data suggest that use of an XL-sized probe on a portable TE device significantly increases the number of valid and reliable readings in patients with a raised BMI.[21] Given the increasing rates of overweight and obesity in primary care settings, a community stratification pathway

should have both medium and XL probe sizes available for use to improve successful liver stiffness acquisition rates. Given that patients' experiences of undergoing TE in the community will likely be impacted by BMI, future studies should address the subjective experience of patients with a range of BMIs.

Previous behaviour change studies have also demonstrated that numerical biomarker feedback increases lifestyle advice uptake by demonstrating physical damage that patients have caused to themselves.[22 23] Within this study, the utility of the numerical liver stiffness value was variable. Some patients struggled to comprehend the context or scaling of their result, whereas others found the specific liver stiffness unit useful as a baseline or comparison point. Feedback to patients could be improved by ensuring a clear and structured explanation of how the result relates to the degree of liver scarring, with the provision of a more comprehensive scale to anchor the feedback. It also seemed that the perception of risk of developing CLD varied as a result of the way in which these liver stiffness values were explained. Specifically, while significantly abnormal results generated short-term shock and anxiety, less severe or normal results were perceived as 'nothing to worry about'. Given that all patients were referred for liver assessment based on a compilation of risk factors, the prospective risk of developing CLD should be clearly conveyed to patients. Providers may therefore benefit from additional training and guidance in the delivery of TE results to patients.

Strengths and limitations

This study has several strengths. First, participants were invited to be interviewed 6 months to 2 years following their TE appointment, allowing assessment of long-term perceptions about the process while minimising the likelihood that details of the pathway were forgotten. In addition, participants were purposively sampled from inner city and suburban locations, with different CLD risk factors and CLD diagnoses. It is believed that the use of this sampling technique may allow transferability to similar primary care settings within the UK.

Several limitations to the study have also been noted. It is possible that engagement with other liver disease services during the period between TE and interview may have impacted participant recall. Those diagnosed with cirrhosis will have been referred to secondary care hepatology services, with the remainder returned to primary care. However, we noted no differences in the identified main themes between risk groups, just in the subtheme relating to immediate response to the result. In addition, the characteristics of the individuals who declined to participate were not stored following their decline. As a result, it is possible that those who chose not to participate were inherently different from those who participated. As with most qualitative data collection, the interviewer's presence may have impacted participant responses. Importantly, the interviewer (DH) was involved in the larger community study and had previously met those participants with elevated liver stiffness (n=13). To minimise response bias, participants were notified that all interview transcripts would be anonymised. The reliability and validity of data collection and analysis were also optimised by including an independent researcher (MB) in the development of the interview guide and through investigator triangulation during transcript coding. While attempts were made to represent broader community populations, two sampling limitations are noted. First, non-English-speaking patients were excluded from the interviews. Liver disease prevalence varies widely among different ethnic groups, particularly regarding aetiology and risk of hospitalisation and mortality.[24 25] Our findings may therefore not generalise to ethnically diverse populations. Furthermore, the age range of interviewees was relatively narrow (40–71 years). However, this reflects the decades where people are most at risk of developing CLD, with the average age of death from CLD being 59 years in the UK.[26]

CONCLUSION

In summary, undergoing TE to screen for CLD in the community was acceptable to most participants and resulted in greater awareness of liver disease risk, regardless of the risk factor. The findings suggest benefits of population-based liver disease screening in addition to merely earlier diagnoses. Future interventions should target improved awareness of liver disease risk factors in both patients and providers.

Contributors DH, GA, TC, ING and MB contributed to the study design. Data collection was completed by DH and MB. Data analysis was completed by HK, DH, JRM and MB. HK and DH wrote and revised the current manuscript. Critical revisions to the manuscript were made by HK, DH, JRM, GA, TC, ING and MB. All authors have approved the final version.

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Patient consent for publication Not required.

Ethics approval Ethical approval was received from the East Midlands—Leicester Research Ethics Committee (13/EM/0123).

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