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Acceptability of chronic liver disease screening in primary care: A qualitative evaluation

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ACCEPTABILITY OF CHRONIC LIVER DISEASE SCREENING IN PRIMARY CARE: A QUALITATIVE EVALUATION

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ACCEPTABILITY OF CHRONIC LIVER DISEASE SCREENING IN PRIMARY CARE: A QUALITATIVE EVALUATION

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 patient experiences of TE screening in a primary care setting. Additionally, patient awareness of CLD risk is explored.

Study design and setting

A qualitative process evaluation of a community-screening pathway for CLD (Nottingham, UK). Participants completed semi-structured interviews, which were audio-recorded, transcribed verbatim, and analysed thematically.

Participants

Twenty adults were purposively recruited six months to two years post-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 change across all TE stratifications.

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However, participants' perceptions of risk were altered by the healthcare providers' communication of TE scores.

Conclusions

High acceptability of TE, regardless of 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 patient experiences undergoing transient elastography screening in primary care for non-viral liver disease.
- Use of inductive analysis provides support for wider implementation of the screening pathway whilst identifying areas for improvement.
- Although participants were purposively sampled across urban and suburban primary care locations, there was limited ethnic diversity in the sample interviewed potentially limiting 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.

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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 associated increase in mortality is driven by a rise in risk factors, such as hazardous alcohol use and type 2 diabetes, and is 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 five-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) over 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,

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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 risk factors for CLD. TE screening of patients with these risk factors led to a 140% increase in diagnoses of cirrhosis, despite 90.9% of the cirrhotic patients having normal liver enzymes(9).

Integration of TE into primary care settings has allowed for successful identification of previously undetected CLD. However, prior to 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 patient 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 was a qualitative process evaluation that used semi-structured 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, Paris), 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

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attend a liver assessment at their GP practice. Risk factors included hazardous alcohol intake (defined as i) >14 units per week for women, > 21 units per week for men, ii) and/or presence of alcohol misuse READ code, iii) and/or AUDIT score > 8), type 2 diabetes, and/or 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 (e.g. pregnancy, pacemakers), or severe cognitive impairment prevented consent(9,10). Sampling strata for invitation for interview were i) GP surgery location (suburban versus inner city), ii) CLD risk factor (hazardous alcohol use vs. type 2 diabetes), and iii) 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. Ethical approval was received from the East Midlands – Leicester Research Ethics Committee (13/EM/0123).

Data collection and interview procedure

Interview questions were predominantly open-ended, allowing both the researcher and participant to pursue avenues of interest when these arose. Probes were used where necessary to expand upon participant responses. Both positive and negative views of the intervention were explored. The interview guide was reviewed by an independent researcher (MB) who has significant expertise in qualitative methodologies. The guide was piloted with a trained research nurse and the initial three participants for testing and refinement. Only minor amendments were

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made following the pilot, meaning the initial three participants were included in the analysis.

Face-to-face interviews were conducted over a six month period by the primary researcher (DH) with patients who had attended a TE assessment six months to two years prior to data collection. Interviews took place either in the participant's home (n=14) or 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 was 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 re-focussed 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, whilst themes were clear and distinct. Themes were reorganised and collapsed as required. Finally, a detailed analysis was conducted for each theme and data excerpts were identified and assigned to illustrate the final themes. All coding was checked by an independent researcher (MB) to ensure

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validity. NVivo 11 (QSR International Ltd, Melbourne, Australia) was used as a data management tool throughout the analysis process.

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 interview; 8 declined participation whilst the remaining 20 participants completed the interview (mean length of interview was 27.6 minutes; standard deviation 7.6; range 16-46 minutes). Mean participant age was 57.9 years (standard deviation = 9.3; range 40-71 years), and 12 participants (60%) were male. Participants were adequately distributed across the sampling strata (see Table 1).

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

*TE result refers to diagnosis assigned on the basis of Transient Elastography (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

Thematic analysis

Analysis of the interviews revealed three main themes and two corresponding sub-themes. The themes herein follow the chronological order of patients' experiences after referral for TE screening. Subthemes detail general acceptability, comprehension, and impact of receiving TE results. Participant awareness of their

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risk for CLD prior to and following TE was also explored. The presenting risk factor, geographic location, and TE stratification are provided for each quoted participant.

1. Experience of stratification pathway

Acceptability and understanding of TE 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 (i.e. diabetes management) prior to the current 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, Inner City GP, 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 terminology such as ‘rigidity’, ‘hardness’ or ‘stiffness’.

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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, Inner City GP, 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, whilst 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, Inner City GP, 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

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to secondary care for TE screening.

Comprehension of results

Participant recall of their numerical liver stiffness value was inconsistent. Several participants did not remember receiving a numeric result, whilst approximately half of participants interviewed were still able to recall their exact liver stiffness measurement. Participant preference for the format of their liver stiffness result was 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, Suburban GP, 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.

2. **Impact of screening result**

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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, Suburban GP, 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 health care 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, Inner City GP, Liver Fibrosis

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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 change. 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 exactly 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, Inner City GP, 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 three to five years for repeated TE scans would be reasonable. Participants with normal liver stiffness felt it would be important to repeat the liver scan at a future interval, 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 the liver in order to ensure that their CLD had not worsened, and to detect if improvements in lifestyle had resulted in subsequent improvements in liver stiffness.

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3. Liver disease risk awareness

Participants discussed the impact that the risk stratification pathway had on their own risk awareness. Prior to 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. So he did.

Participant 16, Type 2 diabetes, Inner City GP, 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.

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Prior to 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 TE result. In participants with hazardous alcohol use this was acknowledgement that their personal alcohol consumption was hazardous, whilst 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, Suburban GP, Liver Cirrhosis

Discussion

Summary

The current study provides a qualitative evaluation of patient experiences with a primary care liver disease stratification pathway. Specifically, the study provides insight into patient perceptions of TE screening and diagnosis in the community, whilst 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 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. Whilst most

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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 change in most.

Comparison with existing literature

The utility of TE as a risk stratification tool has been well documented, with early work demonstrating the acceptability of liver disease screening in populations with hepatitis C (10,16,17). The current study builds upon 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 the current study, many hazardous alcohol users were unaware that their alcohol use reached hazardous levels prior to 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(18,19). A lack of patient knowledge may also result from health care 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(20). A lack of risk awareness did not however seem to preclude uptake of the TE scan in those with hazardous alcohol use.

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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 (i.e. overweight/obese and insulin resistant), only 24% were aware of their risk for developing NAFLD(21). Previous studies have also described a lack of NALFD specific knowledge amongst primary care providers, leading to the absence of CLD education during routine diabetes consultations and support courses(22,23). In the current study, TE screening provided an opportunity to raise awareness of patients' risk for 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

Despite showing the risk stratification pathway to be acceptable to patients, 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. In the Community Liver Study, 97% of patients were successfully stratified using a medium-sized probe in primary care(9). However, patients with a body mass index (BMI) ≥ 35 kg/m^2 were referred to secondary care to undergo TE with an extra-large (XL) probe. Recent data suggests that use of an XL sized probe on a portable TE device significantly increases the number of valid and reliable readings, particularly in patients with a raised BMI(24). Given the increasing rates of overweight and obesity in primary care

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settings, a community stratification pathway should have both Medium and XL probe sizes available for use, particularly in patients with an elevated BMI. This will likely improve successful liver stiffness acquisition rates, prevent patient disappointment, and reduce referrals to secondary care.

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(25,26). This suggests that patients readily comprehended the feedback. Within the current study, the utility of the numerical liver stiffness value was variable. Some patients struggled to comprehend the context or scaling of their result whilst 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 perception of risk for developing CLD varied as a result of the way in which these liver stiffness values were explained. Specifically, whilst 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, prospective risk for 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 interview six months to two years following their TE appointment, allowing assessment of

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longer-term perceptions about the process whilst minimizing the likelihood that details of the pathway were forgotten. Additionally, participants were purposively sampled from inner city and suburban locations, with different CLD risk factors and CLD diagnoses. It is believed that use of this sampling technique may allow transferability to similar primary care settings within the United Kingdom.

Several limitations to the study have also to been noted. As with most qualitative data collection, the interviewer's presence may have impacted participant response. 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. Whilst 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 in regards to aetiology and risk of hospitalisation and mortality (13,14). Our findings may therefore not generalise to ethnically diverse populations. Further, 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(15).

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

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of 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.

Author Contributions

DH, GPA, TC, ING, and MB all 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, GPA, TC, ING, and MB. All authors have approved the final version.

Data sharing statement

Redacted data are available upon reasonable request.

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Standards for Reporting Qualitative Research (SRQR)*

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	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	**1**
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	**3-4**
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	**5**
Purpose or research question - Purpose of the study and specific objectives or questions	**6**
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	**6 & 8 (design section & data analysis section)**
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	**7, 8 & 20 (data collection section, data analysis section & strengths and limitations section)**
Context - Setting/site and salient contextual factors; rationale**	**6 to 8**
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	**6 to 8**
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	**7 & 8 (design section and data collection section)**
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	**7 & 8 (design section and data collection section)**

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Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	**7 & 8 (data collection and interview procedure section)**
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	**9 (participants section) and Table 1**
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	**8 (data collection and data analysis section)**
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	**8 (data analysis section)**
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	**8 (analysis section)**

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	**9-16**
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	**9-16**

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	**16-20**
Limitations - Trustworthiness and limitations of findings	**20 & 21 (strengths and limitations section)**

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	**2**
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	**2**

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*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014
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Acceptability of chronic liver disease screening in a UK primary care setting: A qualitative evaluation

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ACCEPTABILITY OF CHRONIC LIVER DISEASE SCREENING IN A UK PRIMARY CARE SETTING: A QUALITATIVE EVALUATION

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ACCEPTABILITY OF CHRONIC LIVER DISEASE SCREENING IN A UK PRIMARY CARE SETTING: A QUALITATIVE EVALUATION

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 patient experiences of TE screening in a primary care setting. Additionally, patient awareness of CLD risk is explored.

Study design and setting

A qualitative process evaluation of a community-screening pathway for CLD (Nottingham, UK). Participants completed semi-structured interviews, which were audio-recorded, transcribed verbatim, and analysed thematically.

Participants

Twenty adults were purposively recruited six months to two years post-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 change across all TE stratifications.

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However, participants' perceptions of risk were altered by the healthcare providers' communication of TE scores.

Conclusions

High acceptability of TE, regardless of 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 patient experiences undergoing transient elastography screening in primary care for non-viral liver disease.
- Purposive sampling allowed for representation of varied GP locations and chronic liver disease risk factors/diagnoses.
- Limited ethnic diversity in the sample potentially limits 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.

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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 associated increase in mortality is driven by a rise in risk factors, such as hazardous alcohol use and type 2 diabetes, and is 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 five-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) over 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,

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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 risk factors for CLD. TE screening of patients with these risk factors led to a 140% increase in diagnoses of cirrhosis, despite 90.9% of the cirrhotic patients having normal liver enzymes(9).

Integration of TE into primary care settings has allowed for successful identification of previously undetected CLD. However, prior to 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 patient 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 was a qualitative process evaluation that used semi-structured 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, Paris), 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

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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, > 21 units per week for men, ii) and/or presence of alcohol misuse READ code, iii) and/or AUDIT 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 (e.g. pregnancy, pacemakers), or severe cognitive impairment prevented consent(9,10). Prior to 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 TE result or risk factor.

To adequately represent those undergoing TE, the sampling strata for invitation for interview were i) GP surgery location (suburban versus inner city), ii) CLD risk factor (hazardous alcohol use or type 2 diabetes), and iii) 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. Ethical approval was received from the East Midlands – Leicester Research Ethics Committee (13/EM/0123).

Data collection and interview procedure

Interview questions were predominantly open-ended, with probes used where necessary to expand upon participant responses. Both positive and negative views of the intervention were explored. The interview guide (appendix 1) was reviewed by an independent qualitative researcher (MB). The guide was piloted with a trained

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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 six month period (by DH) with patients who had attended a TE assessment six months to two years prior to data collection. Interviews took place either in the participant's home (n=14) or 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 was 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 re-focussed 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, whilst themes were 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 11

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(QSR International Ltd, Melbourne, Australia) was used as a data management tool throughout the analysis process.

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 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 interview was 27.6 minutes; standard deviation 7.6; range 16-46 minutes). Mean participant age was 57.9 years (standard deviation = 9.3; range 40-71 years), and 12 participants (60%) were male. Participants were adequately distributed across the sampling strata (see Table 1).

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

Characteristic	n (%)
Gender	
Male	n=12 (60%)
Female	n= 8 (40%)
GP location	
Inner city	n=12 (60%)
Suburban	n=8 (40%)
CLD Risk factor	
Alcohol	n=8 (40%)
Type 2 diabetes	n=12 (60%)

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*TE result**	
Abnormal – Cirrhosis	n=6 (30%)
Abnormal – Fibrosis	n=7 (35%)
Normal	n=7 (35%)

*TE result refers to diagnosis assigned on the basis of Transient Elastography (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

Thematic analysis

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

1. Liver disease risk awareness

Participants discussed the impact that the risk stratification pathway had on their own risk awareness. Prior to 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:

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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.

Prior to 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 TE result. In participants with hazardous alcohol use this was acknowledgement that their personal alcohol consumption was hazardous, whilst 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.

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Participant 6, Type 2 Diabetes, Liver Cirrhosis

2. Experience of stratification pathway

Acceptability and understanding of TE 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 (i.e. diabetes management) prior to the current 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 terminology such as ‘rigidity’, ‘hardness’ or ‘stiffness’.

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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, whilst 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

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to secondary care for TE screening.

Comprehension of results

Participant recall of their numerical liver stiffness value was inconsistent. Several participants did not remember receiving a numeric result, whilst approximately half of participants interviewed were still able to recall their exact liver stiffness measurement. Participant preference for the format of their liver stiffness result was 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.

3. Impact of screening result

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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 health care 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

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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 change. 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 exactly 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 three to five 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 if improvements in lifestyle had resulted in subsequent improvements in liver stiffness.

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Discussion

Summary

The current study provides a qualitative evaluation of patient experiences with a primary care liver disease stratification pathway. Specifically, the study provides insight into patient perceptions of TE screening and diagnosis in the community, whilst 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 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. Whilst 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 change in most.

Comparison with existing literature

The utility and acceptability of TE as a risk stratification tool has been well documented, including populations with hepatitis C(10,13,14). The current study builds upon 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.

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Within the current study, many hazardous alcohol users were unaware that their alcohol use reached hazardous levels prior to 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 health care 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 (i.e. overweight/obese and insulin resistant), only 24% were aware of their risk for developing NAFLD(18). Previous studies have also described a lack of NALFD specific knowledge amongst primary care providers, leading to the absence of CLD education during routine diabetes consultations and support courses(19,20). In the current study, TE screening provided an opportunity to raise awareness of patients' risk for developing CLD. However, education courses and public health interventions enhancing knowledge of CLD risk factors in both patients and healthcare professionals are warranted.

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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 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 body mass index (BMI) ≥ 35 kg/m^2 were referred to secondary care to undergo TE with an extra-large (XL) probe. Recent data suggests 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 patient 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 the current study, the utility of the numerical liver stiffness value was variable. Some patients struggled to comprehend the context or scaling of their result whilst 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

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scale to anchor the feedback. It also seemed that perception of risk for developing CLD varied as a result of the way in which these liver stiffness values were explained. Specifically, whilst 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, prospective risk for 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 interview six months to two years following their TE appointment, allowing assessment of longer-term perceptions about the process whilst minimizing the likelihood that details of the pathway were forgotten. Additionally, participants were purposively sampled from inner city and suburban locations, with different CLD risk factors and CLD diagnoses. It is believed that use of this sampling technique may allow transferability to similar primary care settings within the United Kingdom.

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. Additionally, the characteristics of the individuals who declined to participate were not stored following their decline. As a result, it is possible that those

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who chose not to participate were inherently different to those who participated. As with most qualitative data collection, the interviewer's presence may have impacted participant response. 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. Whilst 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 in regards to aetiology and risk of hospitalisation and mortality(24, 25). Our findings may therefore not generalise to ethnically diverse populations. Further, 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 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.

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Author Contributions

DH, GPA, TC, ING, and MB all 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, GPA, TC, ING, and MB. All authors have approved the final version.

Data sharing statement

Redacted data are available upon reasonable request.

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APPENDIX 1: Interview Guide

Prior knowledge of liver disease/views of health:

- Before being contacted about the liver tests, how would you describe your health?
- Can you tell me what you knew about the risks of excessive alcohol consumption/diabetes? (probe to ask about liver disease if not mentioned by participant)
- Ask about patient's own risk – alcohol consumption/diabetes control pre-scan?
- Had you intended to make any attempts to improve your lifestyle/health prior to the liver tests? (probe to ask why/why no prior attempts). If so, what did you do? What triggered the previous lifestyle changes?
- Who contacted you about having tests to check your liver function?
- What information did you receive about the scan before having it?
- Did you understand why you were contacted to have the scan done?
- How did you feel about being contacted?

Scan experience and results:

- When did you have the liver scan done?
- Please take me through what you remember about having the liver scan done?
- How would you describe your feelings about having this test done?
- Did you understand what the scan was looking for?
- Can you tell me about your results from the liver scan? Probe around who discussed the results and were they explained clearly?
- Have you remembered the number result (liver stiffness) that the scan produced? If so, did this result mean anything to you?
- How did the scan results make you feel at the time?

Current Health Beliefs:

- Did having the liver tests have an impact on how you view your health?
- Since having the tests, is there anything you have learned about liver disease?
- To what extent have your health beliefs changed since having the liver scan?
- To what extent has information from the doctors or nurses had a role in changing how you view your health?
- Has the scan prompted you to make lifestyle changes?

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Standards for Reporting Qualitative Research (SRQR)*

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	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	**1**
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	**3-4**
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	**5**
Purpose or research question - Purpose of the study and specific objectives or questions	**6**
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	**6 & 8 (design section & data analysis section)**
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	**7, 8 & 20 (data collection section, data analysis section & strengths and limitations section)**
Context - Setting/site and salient contextual factors; rationale**	**6 to 8**
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	**6 to 8**
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	**7 & 8 (design section and data collection section)**
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	**7 & 8 (design section and data collection section)**

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Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	**7 & 8 (data collection and interview procedure section)**
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	**9 (participants section) and Table 1**
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	**8 (data collection and data analysis section)**
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	**8 (data analysis section)**
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	**8 (analysis section)**

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	**9-16**
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	**9-16**

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	**16-20**
Limitations - Trustworthiness and limitations of findings	**20 & 21 (strengths and limitations section)**

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	**2**
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	**2**

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*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:
O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014
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