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Diagnostic reasoning while determining slow-onset heart failure in general practice. A think-aloud study

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Abstract

Objectives Diagnosing heart failure (HF) in general practice is challenging. Our aim was to investigate how general practitioners (GPs) diagnose slow-onset HF in real-world patients. **Design** Think-aloud study.

Methods Fourteen GPs were asked to reason about four real-world HF cases from their own practices. The cases were selected through a clinical audit. This was followed by an interview to clarify some thoughts. The QUAGOL was used as a guide in data analysis. **Results** We developed a conceptual diagnostic model, based on three important reasoning steps. First, GPs assessed the likelihood of HF based on the presence or absence of HF signs and symptoms. However, many barriers were noted in this assessment. Second, if HF was considered based on step one, further diagnostic steps were influenced by patient and social factors and by the GPs' attitude towards the HF diagnosis. Third, the choice and implications of these further diagnostic steps (NT-proBNP, electrocardiography and/or cardiac ultrasound) were again influenced by many factors, such as the GPs' knowledge about these tests and the quality of the cardiologists' reports.

Conclusion This think-aloud study identified the factors that influenced the diagnostic reasoning about HF in general practice. As a consequence, targets to improve this diagnostic reasoning were identified: a paradigm shift towards a comprehensive risk assessment, rethinking the HF definition in the very old, promoting access to NT-proBNP and convincing GPs of the added value of a validated HF diagnosis.

Key words

Chronic heart failure; general practitioners; diagnosis; qualitative research

Strengths and limitations of this study

- This is the first study about the diagnostic reasoning of GPs concerning their own real-world heart failure patients. Given the complexity of a heart failure diagnosis in general practice, further insight about this subject is important.
- The think-aloud design is ideal to capture a sequence of thoughts involved in decision-making. It was followed by an interview to clarify some thoughts and strengthen data-collection.
- The participating GPs were diverse in background, consistent with the general GP population; however, we did not include GPs operating in solo practice.
- The QUAGOL was used as a guide for data-analysis enhancement thorough (re)reading, thinking, and discussion about the research results before starting the actual coding process.
- We designed a conceptual diagnostic model and identified targets to improve the diagnostic reasoning of GPs.

Introduction

Heart failure (HF) is a prevalent disease that affects older patients in particular.^{1 2} The first clinical presentation usually takes place in the general practice setting.¹ A distinction is made between acute and slow-onset HF. Early diagnosis of HF is important to initiate treatment in a timely manner and to delay progression to overt HF.¹ However, a diagnosis of slow-onset HF in general practice is challenging, leading to both under-and-over diagnosis.¹

Barriers affecting the diagnostic process for general practitioners (GPs) were mapped by qualitative studies and showed that GPs were unfamiliar with the natural history of HF, lacked the tools (e.g., cardiac ultrasound (US) and NT-proBNP) to diagnose and manage HF and were not fully aware of relevant research evidence and guidelines, despite their availability.⁷⁸ Also, the GPs' need for education was expressed, as well as the importance of a holistic and chronic care approach to heart failure.⁷ Additionally, GPs' reasoning when considering a diagnosis of HF was previously investigated with case-vignette studies. The objective of the latter was to compare GPs' reasoning with evidence-based guidelines.⁹ However, little is known about GPs' reasoning on real patients in daily practice. Gaining insight into how GPs reach a diagnosis of HF in daily practice is important, as this can provide points of action to improve the diagnostic process.

Therefore, our aim was to investigate how GPs diagnose HF in real-world patients and which clinical reasoning processes are involved. Furthermore, a diagnostic model was built to capture all these concepts together.

Method

Think-aloud method

A method that is often used to describe the sequence of thoughts involved in decisionmaking is the think-aloud technique.¹⁰ Subjects are instructed to say their thoughts aloud while performing a task, and the verbal reports are usually audio-taped, transcribed to written form, and then analysed. The main objective in using the think-aloud technique is not to judge the outcomes of a participant's cognitive process as either successful or unsuccessful decisions but, rather, to explore the process of performance.^{10 11} As our goal was to unravel which arguments, barriers and facilitators play a role in the diagnosis of realworld GP patients with slow-onset HF, the think-aloud method seemed well suited to achieve this. For the methodological orientation to underpin the study, we used the constructivist grounded theory methodology as described by Glaser and Straus (1965).^{12 13} Constructivist grounded theory is an approach in which researchers generate a theory of a process, action, or interaction. This theory development is shaped by or "grounded" in the viewpoints of various participants as well as in the viewpoints of the researchers, as the latter interpret the data.¹³ The consolidated criteria for reporting qualitative studies (COREQ) was used as guidance to report our study.¹⁴

Ethical considerations

The research ethics committee of the KU Leuven approved the study (mp19078). Before the think-aloud sessions, the GPs received written information about the aim of the study and about the method. There was no remuneration provided for participation in the study. Written standard consent procedures were deployed by all participant GPs.

Participants

According to the theoretical sampling method, participating GPs and practices were selected as the analysis progressed for their ability to provide data that would confirm, challenge, or

expand the emerging theory.¹⁵ We aimed to include a representative sample of gender, years of practice experience, practice type and location that were consistent with the reality standards. Initially, three family practices were selected, 2 urban and 1 more rural. After 11 think-aloud sessions in these three practices, we decided to select one more rural practice with GPs not involved in academic teaching or research to guarantee a wide range of GP profiles (Table 1). GPs were all approached by e-mail. All approached GPs consented to participate.

Data collection

First, we performed a clinical audit in each electronic health record (EHR) to identify possible HF patients (Supplemental files 1 and 2). The participants were asked to assign an HF diagnosis 0/1 and grade how certain they were about the diagnosis (Likert scale ranging from 0-10-25-50-75-90-98%) (Supplemental file 3). Afterwards, four patients were chosen at random for the think-aloud session: two of each binary code and, in each category, one with a high grade of certainty (i.e., >75%) and one with a low grade of certainty (i.e., <75%). The order of the cases was chosen at random for all participants. The think-aloud session took place in the GPs' own offices. All sessions were audio-recorded. The only intervention of the researcher during the think-aloud session was that a participant who was silent for more than approximately 15 seconds was reminded to say his or her thoughts aloud about the information presented.¹⁰ The interviewer made field notes during the think-aloud session. After each think aloud session, the participant was asked to clarify some thoughts in a follow-up interview. This whole process and the verbatim transcriptions made afterwards were led by one of the authors (PDW), a GP trainee at the time of the study. The interviewer was familiar with two of the (urban) participating practices since he was trained there. He was unfamiliar with the other two practices. As a GP trainee he had a medical background and experience as a GP, hence understanding the medical terminology and barriers

associated with HF in general practice. If requested, the GPs first got a test case (not recorded), also selected at random from the audit, in order to get acquainted with the thinkaloud method. Then, they continued with their four personal study cases. Likewise, the interviewer did two practice pilot moments to become familiar with the think-aloud method and follow-up interview techniques. An educational specialist (SP) acquainted with qualitative research was involved in these test performances and helped to adjust and finetune the data collection techniques. The data of the test performances were not included in the study. Data collection was continued until data saturation was reached.¹¹

Data Analysis

The QUAGOL was held as a guide for the data analysis.¹⁶ All transcripts were entered into NvivoV.11 software (QSR International, Melbourne, Australia, a data management platform, for qualitative data analysis. After two of the authors (PDW and MS – a GP specialized in HF) familiarised themselves with the data by making one-sheet summaries to aid categorization and conceptualization, they independently coded each line of text according to its meaning and content. Codes were created inductively. After reading and coding the findings of a sample of transcripts, the two researchers discussed and compared the codes for similarities and differences until a primary coding framework was constructed. Subsequently, the findings of the other transcripts were independently read and coded. The two authors discussed their respective coding frameworks frequently to reach consensus. Codes were added, modified or merged when necessary. This process resulted in a tree structure with several layers for organizing the descriptive themes. From these a set of analytical themes emerged that were discussed by the research team. Our collaborative approach and the iterative constant comparison limited the extent to which individual perspectives or background could dominate our interpretation.¹³

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Results

The 14 participants had been specialists in family medicine for an average of 13 years (range 0-38). Their average age was 40 years old (range 27-63), and 9 of them were women (64%) (Table 1). The length of the think-aloud session and follow-up interview was, on average, 27 minutes (range 22-42). We summarized our findings in a conceptual diagnostic model (Figure 1).

Step 1: Assessing the likelihood of HF

Implicitly, every GP assessed how likely HF was in their patient. To estimate the likelihood, many factors were considered, such as cardiovascular (CV) risk factors, CV antecedents and medication, comorbidities, past HF hospitalizations, and HF signs and symptoms. In patients without any or little risk factors, GPs considered HF unlikely (Figure 1).

"He is 43 and is still a young man. As far as I know, something cardiac never occurred to him. I can also see this in his antecedents list. He never had any complaint that I can link with HF like dyspnoea, oedema, etc. So, actually, I am not 98%, but 100% sure he doesn't have HF!" (GP 3)

In patients with a CV history, the presence of HF signs and symptoms was cited as the most important discriminator to distinguish between being at risk for HF or having HF (Figure 1). Consequently, for almost all GPs, the clinical assessment determined the further diagnostics process and their risk assessment.

"If a patient has symptoms we look further but without symptoms we don't. (...) In my opinion, the clinical aspect is the most important. For instance, the oedema, the gain of weight and the minimized exercise capacity." (GP 14)

However, many GPs recognized barriers in this clinical approach. (Table 2). It was apparent that almost every GP experienced difficulties caused by overlap in signs and symptoms with comorbidities in these real-world cases.

"Yes, of course, there are many overlapping symptoms. She suffers from chronic hypoxia, and this is causing her fatigue. Her limited exercise tolerability, dyspnoea, cough and abnormal lung auscultation can also be caused by this. The core symptoms are overlapping, which makes it very difficult to appoint a clear (HF) diagnosis to someone with chronic obstructive lung disease on clinical grounds." (GP 4)

Even without concurrent comorbidities, it remained difficult to assess patients clinically due to the non-specificity of HF signs and symptoms.

"She had a little peripheral oedema in summer. Is this linked with HF? I really don't know." (GP 2)

Additionally, many patients already received CV medication, possibly masking HF symptoms and signs.

"It could always be possible that he has a slight aspect of HF and because of the ACEinhibitor he takes it is just masked. That it suffices to control his symptoms." (GP 7)

Other barriers mentioned were difficulties to assess the HF risk in immobile patients, which was often the case in this population of elderly; the relapsing remitting course of HF was also a challenge (Table 2).

Step 2: Considering further diagnostic steps

The decision about further diagnostic steps was influenced by patient and social factors and by the GPs' attitudes towards HF diagnosis (Table 3).

2.1. Patient and social factors

GPs tended to choose a merely clinical approach without technical investigations in palliative care situations and in patients living in long term care facilities. Old age and frailty were also patient factors GPs considered to choose such an approach.

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"Well, mostly, there is a good reason why someone arrives at a long-term care facility. Because living alone at home is arduous, excursions are getting difficult or dementia is progressing. The need for care increases, and the drive to do technical investigations decreases. The benefits for the patient are limited compared to the efforts that these investigations require. And, besides, if you visit a cardiologist, it is rarely one investigation, and I think it would be too big of a burden for him." (GP 12)

Thereby, the patients' own attitude towards diagnosis, follow-up and treatment was seen as an influencing factor for GPs to reject or favour further diagnostic steps. Additionally, patients' lifestyle, self-care and compliance were seen as fundamental elements to sustain this attitude.

"I think this patient will ask for further investigations herself because she is a worried person and wants rather too many than too few technical investigations." (GP 11) "I have the impression that this lady is fed up with all medical follow-up. She sighs very deeply when I want to refer her. Therefore, it is important for me to have an eye on her." (GP 2)

Some GPs were frustrated by non-compliant patients, others empathically linked this to the relapsing remitting nature of HF.

"I think compliance is more difficult for someone who has relapsing periods where he feels better so he doesn't understand why he needs to take his medication. It is a trait of HF, more than in other chronic illnesses, that the good days switch into bad days and the other way around." (GP 6)

A language barrier, a short length of the GP-patient relationship and masking comorbidities lowered the threshold for further diagnostic steps. GPs had less trust in their clinical assessment in these cases.

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"Because of the language barrier, it is very hard to do a proper history. Consequently, he only comes with his complaints, and he is unable to answer my questions. Combined with his cardiovascular risk profile, I consider him even more at risk because I feel I don't have any control on his situation." (GP 8)

2.2 GPs' attitudes towards further diagnostic steps

Clearly, GPs' attitudes towards further investigations also influenced clinical decision making. An important consideration was the potential prognostic benefit of an objectified HF diagnosis.

"In this case, a cardiologist's referral could be definitely interesting. She is only 70 years old, and making the correct diagnosis could be very important for her prognostically." (GP 1)

Reversely this was also mentioned as a barrier for referral.

"It has been a while since this patient visited a cardiologist. I might consider referring him again, but, on the other hand, I am wondering: 'if we can label him with an HF diagnosis, would this change anything for his current medical treatment and life expectancy?" (GP 7)

GPs tended to set out personal priorities for each patient with multi-morbidity, emphasizing the patient's needs for well-being.

"The question is if it is a priority to diagnose HF. For this man, 76 years old but biologically older, I am wondering if you shouldn't aim for what is really important to him. He has a lot of pain and doesn't see the connection with lack of exercise because of his dementia. (...) What is the priority for this patient? In my opinion, it is not the diagnosis but being more active." (GP 6)

In addition, differences were noted in the way GPs dealt with diagnostic uncertainty. Some GPs always strived for objectified diagnoses and only accepted uncertainty in exceptional circumstances, while other GPs obviously felt more comfortable with a certain degree of

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uncertainty and were more reluctant to refer. This attitude was not linked to age or practice type but was rather linked to the GP's personality.

The difference between HF with reduced ejection fraction (HFrEF) or preserved ejection fraction (HFpEF) or systolic versus diastolic HF and their therapeutic implications were not always known by the participating GPs. Although, for those who were aware of the difference, it did influence their decision making.

"This is an example where the clinical diagnosis was very obvious and, at this moment, you start making considerations. She is a single, 87 years old, less mobile elderly women; what is the added value of objectifying your diagnosis? And, in particular, does this make any prognostic difference for her? In my opinion, this is the prototype of diastolic HF: the obese, elderly women where, from a prognostic view, not so much could be gained. An ACE-inhibitor and a beta-blocker – by the way, she already takes one – don't have any prognostic importance. It is just controlling the symptoms with diuretics. So, at this point of view, I am not going to bother her with cardiologist referrals for my own wish for certainty." (GP 1)

Step 3: Choice and implications of further diagnostic steps

When GPs chose to refer, they almost immediately opted for a cardiologist and/or cardiac ultrasound (US) referral (Figure 1). GPs rarely mentioned ECG or NT-proBNP spontaneously. Influencing factors on how they decided and dealt with these investigations and their results were described in Table 4.

3.1 NT-proBNP and/or ECG as diagnostic tests in HF

NT-proBNP:

NT-proBNP as a diagnostic test was rarely mentioned during the think-aloud. The views of the GPs were further explored in the interviews afterwards. First, almost every GP considered the fact that the test is not reimbursed as an important barrier.

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"I like using the test, or, better, I would like using it. The problem is that in ambulatory
practice the test is not reimbursed. For me this is a big obstacle to use it systematically in my
daily routine." (GP 12)
Most GPs knew NT-ProBNP is a good marker to exclude HF but possible other indications
were not very clear.
"The cardiologist once asked me to measure it (NT-ProBNP) again. The rationale behind
this, to control the value in follow-up, is not clear to me. It is an excellent parameter to
exclude rather than prove HF. I can imagine when someone is less decompensated, there
will be less stretch on the heart, and the parameter will fall, but I don't know if it is a good
parameter to follow the severity of heart failure. I rather think it isn't." (GP 4)
Although there were GPs who did not see the benefit of the test at all, almost all GPs
admitted the test simply was not integrated in their work flow.
"(NT-pro)BNP? No, however, I was involved in academic research of the subject; I must
admit it is not accustomed in my flow yet." (GP 9)
Some GPs acknowledged they were not always sure how to interpret the results.
"I am not so sure about its cut-off values. In my opinion, it is something vague. You might
say it is elevated or not, but it remains difficult to interpret." (GP 14)
ECG:
If GPs mentioned an ECG, it was mostly done by the cardiologist rather than being one they
performed themselves. Whether it could be helpful in the assessment of HF differed between
all participating GPs.
"An ECG, if I am right, is a test which is very sensible for HF, but not specific. So, ideal to
exclude but hard to prove. According to me, a perfectly normal ECG excludes HF. But, in
this case, she has an AF, so I already know what to expect." (GP 4)

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3.2. Cardiologist and cardiac ultrasound (US)

Different attitudes towards the positive and negative predicted value of cardiac US were noted. The negative predictive value of a normal cardiac US was widely accepted. However, the perception of the need and positive predictive value differed between the participating GPs.

"I always make decisions based on clinical grounds and never according to an aberrant cardiac ultrasound." (GP 14)

"But, here I notice I really need the cardiac ultrasound to exclude HF, while for demonstrating HF I don't need that anymore." (GP 8)

"I just like having a cardiac ultrasound because it is very clear to me." (GP 5)

Attitudes towards the value of a cardiologist referral and the interpretation of the cardiac US results depended on the quality of the cardiologist's report and the GPs' knowledge about cardiac US. GPs reported frustrations about the lack of an ejection fraction (EF) or a confirmed HF diagnosis in the reports from the cardiologists and suggested that explicitly asking for it could help.

"The cardiologists' reports are often not that great. It happens that they don't mention the EF and are not giving any information about it at all. I must admit it is better now than last year's, and it is a bit cardiologist-dependent. But, it could be vexing because you would like to advise your patients what they should do." (GP 12)

"You should ask it (HF) particularly because sometimes they (cardiologists) remain silent about it. Often HF isn't mentioned in the cardiologists' conclusion, while it is a very important risk factor for hospitalization and mortality." (GP 4)

Some GPs reported a lack of mutual trust in the collaboration with cardiologists.

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"Hardly one listens to the patient or the GP. A flare that doesn't take place in the hospital is considered to be a non-existing flare." (GP 8)

Those GPs who were aware of the difference between HFrEF and HFpEF acknowledged that an HFrEF diagnosis was easier to assign than an HFpEF diagnosis. If a cardiologist did not confirm the HFpEF diagnosis in symptomatic patients, diagnostic doubt remained for most GPs. Some GPs who very experienced in HF drew their own conclusions based on the clinical image and cardiac US report.

"What you see by these type of patients is that cardiologists aren't either always able to recognize this clinical image as HF with preserved EF, while, in this case, you have several clinical and even some echocardiographic arguments." (GP 6)

Remaining diagnostic doubts after referral had a negative influence on the GPs' attitudes towards referral. A cardiorenal consultation was seen as a big advantage because of the multifactorial approach needed for HF (Table 4).

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Discussion

This think-aloud study highlights the influencing factors in the diagnostic reasoning process of slow-onset HF in general practice. A conceptual diagnostic model was built to capture the three main diagnostic reasoning steps. First, GPs assessed the likelihood of HF using the presence or absence of HF signs and symptoms as the main discriminating factor. However, many barriers were noted in this assessment. Second, if HF was considered, further diagnostic steps were influenced by patient and social factors and by the GPs' attitudes towards HF diagnosis. Third, the choice and implications of these further diagnostic steps (NT-proBNP, electrocardiography and/or cardiac ultrasound) were again influenced by the GPs' knowledge of these tests and the quality of cardiologists' reports.

Step 1: Assessing the likelihood of HF

Our study showed that every GP implicitly assessed the likelihood of HF according to the concept of the cardiovascular continuum or the HF stages of the American Heart Association (AHA) guideline. This is a valuable approach, since HF is a syndrome that progresses from asymptomatic structural heart disease in patients with CV risk factors to symptomatic HF.^{17 18} Additionally, in line with former studies, the assessment of HF signs and symptoms by the GP was seen as the main discriminating factor to withhold a diagnosis of HF and/or to consider further diagnostic steps.^{7 9} However, at the same time, GPs reported many barriers in this clinical approach, especially in real-world older patients with comorbidities, as confirmed in other studies.^{5 6} Furthermore, it was shown that 77% of Belgian GP patients are already in NYHA stage III-IV at the time of HF diagnosis.¹⁹ Consequently, one might suspect that GPs tend to overestimate the value of their clinical assessment, especially in older HF patients, leading to delayed or missed diagnoses.^{4-6 20} This provides important points of action to improve the diagnostic process in HF. First, a paradigm shift is needed towards early identification of HF patients and prevention of

disease progression. Early intervention in HF Stage A (CV risk factors) and B (asymptomatic structural heart disease) patients have been shown to lead to a long-term reduction in morbidity and mortality.²¹ Therefore, we would like to emphasize the importance, not only to consider further diagnostic steps when signs and symptoms are present, but also when substantial risk factors or comorbidities are known (Figure 1, curled arrow).^{22 23} Second, the question arises whether the current definition of HF is applicable in the very old. Signs and symptoms lose their value in this age group, while the prevalence of functional and structural cardiac abnormalities rises.⁶

Step 2: Considering further diagnostic steps

Our study revealed patient-related, social and GP-related factors that were not reproducible by case-vignette studies ⁹ or discussed in HF guidelines.^{1 18} Patient-related and social factors are generally not modifiable; however, GP-related factors are. The importance GPs attach to person-centred care was highlighted. As many GPs mentioned in our study, what matters to them and to the patients is the prognostic and therapeutic implications of cardiac abnormalities. This is an issue that HF guideline developers should consider.^{1 18} NT-proBNP could support GPs in this risk stratification, as it provides prognostic information in cardiac outpatients. ^{1 3 20 24 25} Additionally, in our study, the concepts of HFrEF and HFpEF were cited by very few GPs. Interestingly, some GPs reckoned that they could distinguish HFrEF from HFpEF based on the patients clinical profile, while cardiac US remains the gold standard.^{1 18} Therefore, we plead for a better understanding of cardiac ultrasound reports and propose targeted education as an area of improvement.^{7 26}

Step 3: Choice and implications of further diagnostic steps

NT-proBNP and ECG are recommended by all HF guidelines.^{1 18} Conversely, they were rarely mentioned by GPs in this think-aloud study. In the follow-up interview, the lack of reimbursement for NT-proBNP tests was cited as a significant barrier. This accounted for

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the GPs' unfamiliarity with the test and the uncertainty regarding how to integrate it in their practice. However, one GP correctly quoted the value of NT-proBNP in the early stages of HF but voiced scepticism towards extended use in follow-up.²⁷ Furthermore, the cost of the test could account, in part, for the fact that 77% of Belgian GP patients are already in NYHA stage III-IV at the time of HF diagnosis.¹⁹ To withhold ECG as a valuable diagnostic tool, repeated training of GPs to fine-tune their interpretation skills remains important.²⁸ However, as quoted pertinently in our study, a negative ECG excludes HF, but the elderly rarely have a completely normal ECG.¹⁶ Our study also showed that GPs sought more information on the correct interpretation of cardiac US reports when diagnosing slow-onset HF. In contrast with the predominantly Anglo-Saxon literature, there were few practical barriers for cardiologist referrals and cardiac US.^{78,29} Thus, better access alone to cardiac US is not sufficient because a better understanding of and education in interpreting cardiologists' reports is needed.^{8,9} Additionally, GPs noted that cardiologists are responsible to describe HF diagnoses clearly in their reports, which, in the case of HFpEF, remains a difficult task.¹³⁰

Implications for practice

The diagnostic flowchart of the ESC HF guideline already promotes using NT-proBNP or BNP as a diagnostic test when patients have a prior history of ischaemic heart disease, hypertension, cardiotoxic medication or chronic diuretic use.¹ However, this should be more widely disseminated in practice. Access to natriuretic peptides is indispensable to achieve this.^{1 22 24 25} The main modifiable barrier for further investigations in this study is not, as formerly described, a lack of access or a pure lack of knowledge. It is a lack of belief in the added value of further investigations. A remaining uncertainty after cardiologist referral contributes to this. Uncertainty remains because cardiologists do not assign HFpEF diagnoses easily themselves, and GPs are not able to correctly interpret echocardiography

reports. Additionally, GPs are confronted with a high percentage of HFpEF patients, whose prognosis does not change much with available treatment. Therefore, assigning a diagnosis in this patient group seems less important. Education and guidelines for GPs should target these beliefs because a distinction between HFrEF and HFpEF cannot always be made clinically and a correct HFpEF diagnosis does have important prognostic implications.³¹

Methodological strengths and limitations of this study

The variability in the years of experience, the nature of the practice and the gender of the fourteen participating GPs reflected the general GP population. Therefore, differences in working conditions, access to cardiac US and cooperation with specialists was well covered. However, there were no solo-operating GPs included in the study. This form of practice is declining but is currently still represented in the Belgian health care system. In this survey, there was also a higher fraction of participant GPs involved in academic teaching and/or research. To correct for this imbalance, one extra rural practice with three GPs who were not involved in academic teaching or research was added in the study. As far as we know, this is the first study where a think-aloud approach on real-world patients was performed. This enabled us to highlight the importance GPs attach to person-centred care and to analyse GPs' diagnostic reasoning with respect to slow-onset HF and the differences with the existing guidelines.

Page 200 of 37

Conclusion

This think-aloud study identified the influencing factors in the diagnostic reasoning process of HF in general practice. As a consequence, targets to improve this diagnostic reasoning were identified: a paradigm shift towards earlier risk assessment, rethinking the HF definition in the very old, promoting access to NT-proBNP and convincing GPs of the added value of an objectified HF diagnosis. tor peer terrier only

Word Count 4651

Competing interests None to declare.

Author contributions MS, PDW, SP and BV are responsible for the design of the study. PDW performed the audit and think-aloud interviews in each practice. MS and PDW analysed the data and wrote the manuscript. All authors revised the manuscript.

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Ethics approval and consent to participate The research ethics committee of the KU Leuven approved the study (mp19078) on 30th of March 2017. All participating GPs gave informed consent.

Data sharing statement All authors had full access to all data in the study and assume responsibility for the integrity of the data and the accuracy of the data analyses.

Availability of data and materials The dataset supporting the conclusions of this article is held at the University of Leuven, Belgium and can be shared upon contacting the corresponding author.

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Figure legend

Figure 1: Diagnostic reasoning model

HF, heart failure; CV, cardiovascular; GP, general practitioner; US, ultrasound; ECG, electrocardiography

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Table 1: Characteristics of the participating GPs

GP	Gender	Years of	Age	Practice type	Location of	Clinical roles besides GP	
number)	(M/F)	experience*		(number of GPs)	GP practice		
1	М	28	53	Group (5 + trainee)	Rural	University teacher; Training supervisor	
2	F	in training	27	Group (5 + trainee)	Rural	/	
3	F	15	42	Group (5 + trainee)	Rural	/	
4	М	3	30	Group (5 + trainee)	Rural	/	
5	F	5	42	Group (5+ trainee)	Rural	/	
6	М	34	59	Duo (+ trainee)	Urban	Local coordinator CHF care; Training supervisor	
7	F	38	63	Duo (+ trainee)	Urban	GP training coordinator; Training supervisor	
8	М	16	43	District health centre (3 + trainee)	Urban	GP training coordinator; Training supervisor	
9	F	18	45	District health centre (3 + trainee)	Urban	University professor	
10**	F	1	27	District health centre (3 + trainee)	Urban	/	
11	F	2	30	District health centre (3 + trainee)	Urban	University teacher	
12	М	20	47	Group (4 + trainee)	Rural	/	
13	F	1	27	Group (4 + trainee)	Rural	/	
						2	

Page	e 27 of 37				ВМЈ Ор	en				
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2 3										
4 5 6	14	F	4	31	Group (4+ trainee)	Rural		/		
7	* Years i	n training are	excluded							
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Table 2: Assessing the likelihood of HF – Influencing factors				
Barriers in the	- Overlap with comorbidities			
assessment of HF	- Non-specificity of some symptoms and signs			
symptoms and signs	- Masked by medication			
	- Difficult in immobile patients			
	- Relapsing remitting course			

Table 3: Considering f	Table 3: Considering further diagnostic steps – Influencing factors			
Patient and social	- Attitude towards diagnosis, follow-up and treatment			
factors	- Lifestyle, self-care and compliance			
	- Choice for a palliative care approach			
	- Age, frailty and impact of stay in a long-term care facility			
	- Length GP-patient relationship			
	- Language barrier			
	- Comorbidities that influence clinical assessment			
GP factors	- Perceived value of cardiologist referral and an objectified			
	HF diagnosis regarding:			
	° Implications for further treatment			
	° GPs' priorities			
	- Dealing with diagnostic uncertainty			
	- Diastolic vs systolic HF			

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rable 4: Choice and in	iplications of further diagnostic steps – influencing factors
NT-ProBNP	- Price as a barrier, demand for reimbursement
	- Utility (not) known
	- Interpretation problems
NT-ProBNP and ECG	- Perception of positive and negative predictive value
	- Integrated in work flow
~	- Uncertainty about indication
Cardiologist and	- Perception of positive and negative predictive value
cardiac US	- GPs' knowledge about cardiac US
	- Quality of cardiologist report
	° Confirmation of HF diagnosis by cardiologist
	- ° Remaining diagnostic uncertainty after cardiologist
	appointment
	- Clinical assessment of HF by cardiologist and mutual tru
	- Importance of cardiorenal consultation
	- HFpEF as a new difficult entity





Supplemental file 1: Queries used to search for HF patients in the EHR

Registered HF patients: used queries^	
Heart failure coded	ICPC-2-code: K77
Heart failure free text	"hartfalen" OR "corfalen" OR "hartsdecompensatie"
	OR "hartdecompensatie" OR "cordecompensatie" OR
	"NYHA" OR "LVfalen" OR "linkerventrikelfalen"
	OR "LVdysfunctie" OR "linkerventrikeldysfunctie"
	OR "LVdecompensatie" OR
	"linkerventrikeldecompensatie" OR "gedaalde EF"
	OR "gedaalde ejectiefractie" OR "gedaalde LVEF"
	OR "verminderde EF" OR "verminderde
	ejectiefractie" OR "verminderde LVEF"
	"decompensatie" NOT "psychische decompensatie"
Non-registered HF patients: used queries*	
HF risk factors	CL I
HF risk factors Atrial fibrillation coded	ICPC-2 code K78
HF risk factors Atrial fibrillation coded Atrial fibrillation free text	ICPC-2 code K78 "voorkamerfibrillatie" OR "VKF"
HF risk factors Atrial fibrillation coded Atrial fibrillation free text Ischaemic heart disease coded	ICPC-2 code K78 "voorkamerfibrillatie" OR "VKF" ICPC-2 code K74 OR K75 OR K76
HF risk factors Atrial fibrillation coded Atrial fibrillation free text Ischaemic heart disease coded Ischaemic heart disease free text	ICPC-2 code K78 "voorkamerfibrillatie" OR "VKF" ICPC-2 code K74 OR K75 OR K76 "angor" OR "ischemie" OR "infarct" OR
HF risk factors Atrial fibrillation coded Atrial fibrillation free text Ischaemic heart disease coded Ischaemic heart disease free text	ICPC-2 code K78 "voorkamerfibrillatie" OR "VKF" ICPC-2 code K74 OR K75 OR K76 "angor" OR "ischemie" OR "infarct" OR "myocardinfarct" OR "hartinfarct"
HF risk factors Atrial fibrillation coded Atrial fibrillation free text Ischaemic heart disease coded Ischaemic heart disease free text	ICPC-2 code K78 "voorkamerfibrillatie" OR "VKF" ICPC-2 code K74 OR K75 OR K76 "angor" OR "ischemie" OR "infarct" OR "myocardinfarct" OR "hartinfarct" NOT: "cerebrale ischemie", "cerebrovaculaire
HF risk factors Atrial fibrillation coded Atrial fibrillation free text Ischaemic heart disease coded Ischaemic heart disease free text	ICPC-2 code K78 "voorkamerfibrillatie" OR "VKF" ICPC-2 code K74 OR K75 OR K76 "angor" OR "ischemie" OR "infarct" OR "myocardinfarct" OR "hartinfarct" NOT: "cerebrale ischemie", "cerebrovaculaire ischemie", "retina ischemie", "N. opticus ischemie",

ledematen", "nierinfarct", "cerebellair infarct",

"cerebraal infarct", "herseninfarct

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Valvular heart disease coded	ICPC-2 code K83
Valvular heart disease free text	"stenose" OR "insufficiëntie" OR "klep" OR
	"kleplijden"
	NOT: "spinaalkanaalstenose", "dacryostenose",
	"urethrastenose", "anale stenose","
	nierarteriestenose", "A. Renalisstenose",
	"cervixstenose", "oesophagusstenose",
	"nierinsufficiëntie", "veneuze insufficiëntie",
	"arteriële insufficiëntie", "respiratoire insufficiëntie",
	"acute bijnierinsufficiëntie", "ovariuminsufficiëntie",
	"kleptomanie"
Hypertension complicated coded	ICPC-2 code K87
Cardiomyopathy free text	"cardiomyopathie" OR "CMP"
Congenital anomaly cardiovascular coded	ICPC-2 code K73
Congenital anomaly cardiovascular free text	"ASD" OR "VSD" OR "septumdefect" OR "fallot"
HF symptoms and signs	4
Edema lung free text	"longoedeem"
Edema free text	"oedeem"
	NOT: "angioneurotisch oedeem", "angiooedeem",
	"Quincke's oedeem", "lymfoedeem", "scrotaal
	oedeem", "allergisch oedeem", "oedeem van Reinke"
Orthopnoea free text	"orthopnee"
Dyspnoea free text	"inspanningsdyspnee" OR "dyspnee d'effort"
HF medication (all searched without time limit ANI	D prescribed last 6 months AND last 12 months)
ACE-I AND diuretics	Medication group/ATC code: "ACE-I" OR "ACE-
	remmers" AND "diuretics"
ACE-I AND β-blockers	Medication group/ATC code: "ACE-I" OR "ACE-
	remmers" AND "β-blockers"
P blockers AND division	
B-blockers AND dimencs	Medication group/ATC code: "β-blockers" AND

	"diuretics"
ARB AND diuretics	Medication group/ATC code: "sartaan" OR
	"angiotensin-II-antagonisten" AND "diuretics"
ARB AND β-blockers	Medication group/ATC code: "sartaan" OR
	"angiotensin-II-antagonisten" AND "β-blockers"
Digoxine and derivates	Medication group/ATC code: "digoxine en
	derivaten" OR "hartglycosiden"
MRAs	Medication group/ATC code: "Potassium-sparing
	diuretics"

HF, heart failure; EHR, electronic health record; ICPC-2, International Classification Primary Care, Second Edition; ACI-I, angiotensin-converting enzyme inhibitor; ARB, angiotensin II- receptor blockers; MRA, mineralocorticoid receptor antagonist

* Only patients older than 40 years of age were included in the audit

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Supplemental file 2: Sample sheet sent to participants

Name	Surname	Gender	Date of birth	CHF? 1/0	Likert scale %?	Audit findings	Name Doct
A	F	F	22-4-1947			Vrije tekst kleplijden, vrije tekst oedeem, vrije tekst VKF	Doctor A
A	F)	M	24-5-1958			Vrije tekst kleplijden, vrije tekst VKF	Doctor A
A	MM	F	12-7-1950			Vrije tekst kleplijden	Doctor A
A	AJ	M	21-3-1933			Vrije tekst kleplijden, Vrije tekst longoedeem, vrije tekst o	Doctor A
A	MC	M	11-4-1957			Vrije tekst kleplijden	Doctor A
A	FL	M	23-5-1943			Vrije tekst kleplijden, vrije tekst decompensatie, vrije tekst	Doctor A
A	RA	M	14-10-1950			vrije tekst oedeem	Doctor A
A	A	M	20-1-1952			Vrije tekst kleplijden	Doctor A
A	IA	F	13-2-1964			vrije tekst congenitaal, vrije tekst kleplijden	Doctor A
A	CM	F	12-3-1954			Vrije tekst kleplijden	Doctor A
A	R	M	9-2-1938			vrije tekst ischemisch hartlijden, vrije tekst kleplijden, vrij	Doctor A
в	F	M	25-9-1960			vrije tekst ischemisch hartlijden, vrije tekst kleplijden, vrij	Doctor A
8	IM	F	13-9-1962			Vrije tekst kleplijden, vrije tekst oedeem	Doctor A
8	DH	F	26-1-1963			vrije tekst congenitaal	Doctor A
8	RA	M	21-3-1950			vrije tekst ischemisch hartlijden, vrije tekst kleplijden	Doctor A
в	B	F	13-3-1971			Vrije tekst kleplijden, vrije tekst HF	Doctor A
8	CT	F	10-1-1942			Vrije tekst kleplijden, vrije tekst oedeem	Doctor A
8	M	M	10-7-1956			vrije tekst ischemisch hartlijden, vrije tekst kleplijden	Doctor A
8	DC	F	14-11-1935			Combi Diuretica B-Blok, K sparend D, gecodeerd ischemisc	Doctor A
8	JF	M	21-1-1974			vrije tekst decompensatie	Doctor A
8	G	F	15-12-1929			Combi ACE B-BLOK, combi diuretica ACE, combi diuretica I	Doctor A
8	CM	F	21-10-1962			Vrije tekst kleplijden	Doctor A
8	EJ	M	23-12-1932			Combi Diuretica B-Blok, vrije tekst ischemisch lijden, vrije	Doctor A
B	MA	F	10-12-1933			vrije tekst congenitaal, vrije tekst decompensatie, vrije te	Doctor A
8	A	M	6-5-1936			Combi Diuretica B-mok	Doctor A
8	IC	M	20-7-1965			vrije tekst oedeem	Doctor A
B	AR	M	16-10-1969			vrije tekst ischemisch hartlijden	Doctor A
8	JM	M	12-3-1943			vrije tekst ischemisch hartlijden, vrije tekst kleplijden	Doctor A
8	PJ	F	15-10-1939			Combi ACE B-BLOK, combi diuretica ACE, combi diuretica I	Doctor A
8	CG	F	11-5-1963			Gecodeerd Ischemisch hartlijden, vrije tekst ischemisch h	Doctor A
B	MM	F	7-2-1951			Vrije tekst kleplijden, vrije tekst oedeem	Doctor A
8	PW	M	27-8-1957			Vrije tekst kleplijden	Doctor A
8	RA	M	22-7-1938			Gecodeerde HE, Combi ACE B-BLOK, digitalis, vrije tekst d	Doctor A

Supplemental file 3: Sample filled-in sheet

4	Name	Surname	Gender	Date of birth	CHF? 1/0	Likert scale %?	Audit findings	Name Doctor
5 /	A	F	F	22-4-1947	0	50	Vrije tekst kleplijden, vrije tekst oedeem, vrije tekst VKF	Doctor A
6	A	FJ	M	24-5-1958	0	90	Vrije tekst kleplijden, vrije tekst VKF	Doctor A
7	A	MM	F	12-7-1950	0	90	Vrije tekst kleplijden	Doctor A
8 /	A	AJ	M	21-3-1933	1	50	Vrije tekst kleplijden, Vrije tekst longoedeem, vrije tekst o	Doctor A
9 /	A	MC	M	11-4-1957	0	98	Vrije tekst kleplijden	Doctor A
10	A	FL	M	23-5-1943	deceased		Vrije tekst kleplijden, vrije tekst decompensatie, vrije tekst	Doctor A
11 /	A	RA	M	14-10-1950	0	90	vrije tekst oedeem	Doctor A
12	A	A	M	20-1-1952	0	90	Vrije tekst kleplijden	Doctor A
13	A	IA	F	13-2-1964	0	98	vrije tekst congenitaal, vrije tekst kleplijden	Doctor A
14	A	CM	F	12-3-1954	0	98	Vrije tekst kleplijden	Doctor A
15	A	R	M	9-2-1938	1	. 50	vrije tekst ischemisch hartlijden, vrije tekst kleplijden, vrij	Doctor A
16	В	F	M	25-9-1960	0	90	vrije tekst ischemisch hartlijden, vrije tekst kleplijden, vrij	Doctor A
17 8	В	IM	F	13-9-1962	0	98	Vrije tekst kleplijden, vrije tekst oedeem	Doctor A
18	В	IH	F	26-1-1963	unknown		vrije tekst congenitaal	Doctor A
19	В	RA	M	21-3-1950	1	25	vrije tekst ischemisch hartlijden, vrije tekst kleplijden	Doctor A
20	В	В	F	13-3-1971	0	98	Vrije tekst kleplijden, vrije tekst HF	Doctor A
21 8	В	СТ	F	10-1-1942	0	25	Vrije tekst kleplijden, vrije tekst oedeem	Doctor A
22 8	В	M	M	10-7-1956	0	90	vrije tekst ischemisch hartlijden, vrije tekst kleplijden	Doctor A
23 8	В	DC	F	14-11-1935	0	50	Combi Diuretica B-Blok, K sparend D, gecodeerd ischemisc	Doctor A
24 8	в	JF	M	21-1-1974	0	98	vrije tekst decompensatie	Doctor A
25 8	в	G	F	15-12-1929	0	25	Combi ACE B-BLOK, combi diuretica ACE, combi diuretica l	Doctor A
26	В	CM	F	21-10-1962	0	90	Vrije tekst kleplijden	Doctor A
27 8	В	EJ	M	23-12-1932	1	50	Combi Diuretica B-Blok, vrije tekst ischemisch lijden, vrije	Doctor A
28	в	MA	F	10-12-1933	0	50	vrije tekst congenitaal, vrije tekst decompensatie, vrije te	Doctor A
29	в	A	M	6-5-1936	unknown		Combi Diuretica B-Blok	Doctor A
30 8	В	IC	M	20-7-1965	0	98	vrije tekst oedeem	Doctor A
31 8	В	AR	M	16-10-1969	0	98	vrije tekst ischemisch hartlijden	Doctor A
32 8	В	JM	M	12-3-1943	0	50	vrije tekst ischemisch hartlijden, vrije tekst kleplijden	Doctor A
33 8	В	PJ	F	15-10-1939	0	50	Combi ACE B-BLOK, combi diuretica ACE, combi diuretica I	Doctor A
34 8	В	CG	F	11-5-1963	0	98	Gecodeerd Ischemisch hartlijden, vrije tekst ischemisch h	Doctor A
35 8	В	MM	F	7-2-1951	0	90	Vrije tekst kleplijden, vrije tekst oedeem	Doctor A
36	В	PW	M	27-8-1957	0	90	Vrije tekst kleplijden	Doctor A
37 8	В	RA	M	22-7-1938	1	50	Gecodeerde HF, Combi ACE B-BLOK, digitalis, vrije tekst d	Doctor A

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Manuscript: Diagnostic reasoning while determining slow-onset heart failure in general practice: a Think aloud study.

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

32-item checklist		
Developed from: Tong A, Sainsbury P, Craig J. C 32-item checklist for interviews a 2007. Volume 19, Number 6: pp	consolidated criteria for reporting qualitative resea and focus groups. <i>International Journal for Qualit</i> y 9. 349 – 357	rch (COREQ): a
		(C
No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		9
1. Inter viewer/facilitator	Which author/s conducted the inter view or focus group?	Page 6
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Page 1
3. Occupation	What was their occupation at the time of the study?	Page 1 and 6-7
4. Gender	Was the researcher male or female?	Page 1 and 6-7
5. Experience and training	What experience or training did the researcher have?	Page 6-7
Relationship with participants	Č,	
6. Relationship established	Was a relationship established prior to study commencement?	Page 6
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Page 6
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Page 6

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	BMJ Open	Pag
)omain 2: study design		
Somain 2. Study design		
Theoretical framework		
Description and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Page 5
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 5 and 6
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Page 5 and 6
12. Sample size	How many participants were in the study?	Page 6 and 8
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Page 6
Setting		
14. Setting of data	Where was the data collected? e.g. home, clinic, workplace	Page 6
15. Presence of non-	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Page 6 – 8 and Table 1
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 6-7
18. Repeat interviews	Were repeat inter views carried out? If ves, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 6
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Page 6
21. Duration	What was the duration of the inter views	Page 8

22. Data saturation 23. Transcripts returned	Was data saturation discussed?		
23. Transcripts returned		Page 7	
	Were transcripts returned to participants	No	Pro
Domain 3: analysis and findings			otected
Data analysis			d by c
24. Number of data coders	How many data coders coded the data?	Page 7	opyrig
25. Description of the coding tree	Did authors provide a description of the coding tree?	No	ht, incl
26. Derivation of themes	Were themes identified in advance or derived from the data?	Page 7	uding fo
27. Software	What software, if applicable, was used to manage the data?	Page 7	r uses
28. Participant checking	Did participants provide feedback on the findings?	No	related
Reporting			to te
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Page 8 to 15	ext and data mi
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes, there was. Page 8 to 19	hing, Al t
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes. they were. From page 8 to 15	raining, a
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Discussion of major and minor themes From page 16 to 19	uhd similai

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A think-aloud study about the diagnosis of chronic heart failure in Belgian general practice

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A think-aloud study about the diagnosis of chronic heart failure in Belgian general practice

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Abstract

 Objectives Diagnosing chronic heart failure (CHF) in general practice is challenging. Our aim was to investigate how general practitioners (GPs) diagnose CHF in real-world patients. **Design** Think-aloud study.

Methods Fourteen GPs were asked to reason about four real-world CHF cases from their own practices. The cases were selected through a clinical audit. This was followed by an interview to get a deeper insight in their reasoning. The qualitative analysis guide of Leuven (QUAGOL) was used as a guide in data analysis.

Results We developed a conceptual diagnostic model, based on three important reasoning steps. First, GPs assessed the likelihood of CHF based on the presence or absence of HF signs and symptoms. However, this approach had serious limitations since GPs experienced many barriers in their clinical assessment, especially in comorbid elderly. Second, if CHF was considered based on step one, the main influencing factor to take further diagnostic steps was the GPs' perception of the added value of a validated CHF diagnosis in that specific case. Third, the choice and implications of these further diagnostic steps (NT-proBNP, electrocardiography and/or cardiac ultrasound) were influenced by the GPs' knowledge about these tests and the quality of the cardiologists' reports.

Conclusion This think-aloud study identified the factors that influenced the diagnostic reasoning about CHF in general practice. As a consequence, targets to improve this diagnostic reasoning were withheld: a paradigm shift towards an earlier and more comprehensive risk assessment with among others access to natriuretic peptide testing and convincing GPs of the added value of a validated HF diagnosis.

Key words

Chronic heart failure; general practitioners; diagnosis; qualitative research

Article summary

Strengths and limitations of this study

- This is the first study about the diagnostic reasoning of GPs concerning their own real-world heart failure patients.
- The think-aloud design is ideal to capture a sequence of thoughts involved in decision-making.
- The participating GPs were diverse in background, consistent with the general GP population; however, we did not include GPs operating in solo practice.
- The QUAGOL was used as a guide to enhance the data-analysis since it promotes thorough (re)reading, thinking, and discussion about the research data before starting the actual coding process.
- We designed a conceptual diagnostic model and identified targets to improve the diagnostic reasoning of GPs.

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Introduction

Heart failure (HF) is a prevalent disease that affects older patients in particular.¹² The first clinical presentation usually takes place in the general practice setting.¹ A distinction is made between acute and chronic HF (CHF). Early diagnosis of HF is important to initiate treatment in a timely manner and to delay progression to overt HF.¹ However, a diagnosis of CHF in general practice is challenging, leading to both under-and-over diagnosis.¹³⁻⁶

Barriers affecting the diagnostic process for general practitioners (GPs) were mapped by qualitative studies and showed that GPs were unfamiliar with the natural history of HF, lacked the tools (e.g., cardiac ultrasound (US) and NT-proBNP) to diagnose and manage HF and were not fully aware of relevant research evidence and guidelines, despite their availability.⁷⁸ Also, the GPs' need for education was expressed, as well as the importance of a holistic and chronic care approach to HF.⁷ Additionally, GPs' reasoning when considering a diagnosis of HF was previously investigated with case-vignette studies. The objective of the latter was to compare GPs' reasoning with evidence-based guidelines.⁹ However, little is known about GPs' reasoning on real patients in daily practice. Gaining insight into how GPs reach a diagnosis of HF in daily practice is important, as this can provide points of action to improve the diagnostic process.

Therefore, our aim was to investigate how GPs diagnose CHF in real-world patients and which clinical reasoning processes are involved. Furthermore, a diagnostic model was built to capture all these concepts together.

Method

Think-aloud method

A method that is often used to describe the sequence of thoughts involved in decisionmaking is the think-aloud technique.¹⁰ Subjects are instructed to say their thoughts aloud while performing a task, and the verbal reports are usually audio-taped, transcribed to written form, and then analysed. The main objective in using the think-aloud technique is not to judge the outcomes of a participant's cognitive process as either successful or unsuccessful decisions but, rather, to explore the process of performance.^{10 11} As our goal was to unravel which arguments, barriers and facilitators play a role in the diagnosis of realworld GP patients with CHF, the think-aloud method seemed well suited to achieve this. For the methodological orientation to underpin the study, we used the constructivist grounded theory methodology as described by Glaser and Straus (1965).^{12 13} Constructivist grounded theory is an approach in which researchers generate a theory of a process, action, or interaction. This theory development is shaped by or "grounded" in the viewpoints of various participants as well as in the viewpoints of the researchers, as the latter interpret the data.¹³ The consolidated criteria for reporting qualitative studies (COREQ) was used as guidance to report our study.¹⁴

Ethical considerations

The research ethics committee of the KU Leuven approved the study (mp19078). Before the think-aloud sessions, all participant GPs were asked informed consent based on written information about the aim and methods of the study. There was no remuneration provided for participation in the study.

Patient and public involvement

No patients and/or public were involved in the development of the research question, study design or interpretation of the data.

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Participants

The setting of this think-aloud study was general practice in Belgium. All general pratices in Belgium form of the public health care system. According to the theoretical sampling method, participating GPs and practices were selected as the analysis progressed for their ability to provide data that would confirm, challenge, or expand the emerging theory.¹⁵ We aimed to include a representative sample of gender, years of practice experience, practice type and location that were consistent with the reality standards. Initially, three family practices were selected, 2 urban and 1 more rural. One of the urban practices was a district health centre that was financed at practice-level and receives a fee for each registered patient. The other practices work in a pay-for-performance system where GPs get paid for each patient that consults them. The latter is the most common system in Belgium. After 11 think-aloud sessions in these three practices, we decided to select one more rural practice with GPs not involved in academic teaching or research to guarantee a wide range of GP profiles (Table 1). GPs were all approached personally or by e-mail. All approached GPs consented to participate.

Data collection

Since HF patients are often not registered as such in the GPs' electronic health record (EHR), we first performed a clinical audit in each EHR to identify possible HF patients. This clinical audit consisted of the search on a registered (coded or free text) diagnosis of HF, combined with the search on coded or free text diagnoses of risk factors for HF, HF symptoms and signs and combinations of HF medication (Supplemental file 1). The list of all possible HF patients was then presented to each treating physician and they were asked to judge which patients had HF or not (0/1) and grade how certain they were about the diagnosis (Likert scale ranging from 0-10-25-50-75-90-98%), based on their knowledge of the patient file. Afterwards, four patients of each GP were chosen at random for the think-

Page 7 of 39

BMJ Open

aloud session: two of each binary code (HF 0/1) and, in each category, one with a high grade of certainty (i.e., >75%) and one with a low grade of certainty (i.e., <75%). The order of the cases was chosen at random for all participants. The GPs were asked to think-aloud about why they did or did not appoint the HF diagnosis in their own real-world patients based on the patient file in the EHR. The think-aloud session took place in the GPs' own offices. All sessions were audio-recorded. The only intervention of the researcher during the think-aloud session was that a participant who was silent for more than approximately 15 seconds was reminded to say his or her thoughts aloud about the information presented.¹⁰ The interviewer made field notes during the think-aloud session. After each think aloud session, the participant was asked to clarify some thoughts in a follow-up interview. This whole process and the verbatim transcriptions made afterwards were led by one of the authors (PDW), a GP trainee at the time of the study. The interviewer was familiar with two of the (urban) participating practices since he was trained there. He was unfamiliar with the other two practices. As a GP trainee he had a medical background and experience as a GP, hence understanding the medical terminology and barriers associated with HF in general practice. If requested, the GPs first got a test case (not recorded), also selected at random from the audit, in order to get acquainted with the think-aloud method. Then, they continued with their four personal study cases. Data-collection techniques were piloted under the supervision of a qualitative research expert (SP). The data of the test performances were not included in the study. Data collection was continued until data saturation was reached. Data saturation was defined as the moment when the last two interviews no longer contributed any new elements and when a certain category had been exhaustively described in all its dimensions and variations. This means that conducting additional interviews would no longer provide new insights.¹¹

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Data Analysis

The Qualitative analysis guide of Leuven (QUAGOL) was held as a guide for the data analysis.¹⁶ The QUAGOL is a theory and practice-based guide that offers a comprehensive method to guide the process of qualitative data analysis within the grounded theory approach. It promotes thorough (re)reading, thinking, and discussion about the research data before starting the actual coding process.¹⁶ All transcripts were entered into NvivoV.11 software (QSR International, Melbourne, Australia, a data management platform, for qualitative data analysis. After two of the authors (PDW and MS – a GP specialized in HF) familiarised themselves with the data by making one-sheet summaries to aid categorization and conceptualization, they independently coded each line of text according to its meaning and content. Codes were created inductively. After reading and coding the findings of a sample of transcripts, the two researchers discussed and compared the codes for similarities and differences until a primary coding framework was constructed. Subsequently, the findings of the other transcripts were independently read and coded. The two authors discussed their respective coding frameworks frequently to reach consensus. Codes were added, modified or merged when necessary. This process resulted in a tree structure with several layers for organizing the descriptive themes (Supplemental file 2). From these a set of analytical themes emerged that were discussed by the research team. Our collaborative approach and the iterative constant comparison limited the extent to which individual perspectives or background could dominate our interpretation.¹³

Results

The 14 participants had been specialists in family medicine for a median of 10 years (interquartile range 1.8-22). Their mean age was 40 ± 13 years old, and 9 of them were women (64%) (Table 1). The length of the think-aloud session and follow-up interview was, on average, 27 minutes (range 22-42). We summarized our findings in a conceptual diagnostic model

(Figure 1).

Step 1: Assessing the likelihood of HF

Implicitly, every GP assessed how likely HF was in their patient. To estimate the likelihood, many factors were considered, such as cardiovascular (CV) risk factors, CV diseases and medication, comorbidities, past HF hospitalizations, and HF signs and symptoms. In patients without any or few risk factors, GPs considered HF unlikely (Figure 1).

"He is 43 and is still a young man. As far as I know, something cardiac never occurred to him. I can also see this in his antecedents list. He never had any complaint that I can link with HF like dyspnoea, oedema, etc. So, actually, I am not 98%, but 100% sure he doesn't have HF!" (GP 3, Think aloud session)

In patients with a CV history, the presence of HF signs and symptoms was cited as the most important discriminator to distinguish between being at risk for HF or having HF (Figure 1). Consequently, for almost all GPs, the clinical assessment determined the further diagnostics process and their risk assessment.

"If a patient has symptoms we look further but without symptoms we don't. (...) In my opinion, the clinical aspect is the most important. For instance, the oedema, the gain of weight and the minimized exercise capacity." (GP 14, Follow-up interview)

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However, many GPs recognized barriers in this clinical approach. (Table 2). It was apparent that almost every GP experienced difficulties caused by overlap in signs and symptoms with comorbidities in these real-world cases.

"Yes, of course, there are many overlapping symptoms. She suffers from chronic hypoxia, and this is causing her fatigue. Her limited exercise tolerability, dyspnoea, cough and abnormal lung auscultation can also be caused by this. The core symptoms are overlapping, which makes it very difficult to appoint a clear (HF) diagnosis to someone with chronic obstructive lung disease on clinical grounds." (GP 4, Follow-up interview)

Even without concurrent comorbidities, it remained difficult to assess patients clinically due to the non-specificity of HF signs and symptoms.

"She had a little peripheral oedema in summer. Is this linked with HF? I really don't know." (GP 2, Follow-up interview)

Additionally, many patients already received CV medication, possibly masking HF symptoms and signs.

"It could always be possible that he has a slight aspect of HF and because of the ACEinhibitor he takes it is just masked. That it suffices to control his symptoms." (GP 7, Thinkaloud session)

Other barriers mentioned were difficulties to assess the HF risk in immobile patients, which was often the case in this population of elderly; the relapsing remitting course of HF was also a challenge (Table 2).

Step 2: Considering further diagnostic steps

The decision about further diagnostic steps was influenced by patient and social factors and by the GPs' attitudes towards HF diagnosis (Table 3).

GPs tended to choose a merely clinical approach without technical investigations in palliative care situations and in patients living in long term care facilities. Old age and frailty were also patient factors GPs considered to choose such an approach.

"Well, mostly, there is a good reason why someone arrives at a long-term care facility. Because living alone at home is arduous, excursions are getting difficult or dementia is progressing. The need for care increases, and the drive to do technical investigations decreases. The benefits for the patient are limited compared to the efforts that these investigations require. And, besides, if you visit a cardiologist, it is rarely one investigation, and I think it would be too big of a burden for him." (GP 12, Follow-up interview)

Thereby, the patients' own attitude towards diagnosis, follow-up and treatment was seen as an influencing factor for GPs to reject or favour further diagnostic steps. Additionally, patients' lifestyle, self-care and compliance were seen as fundamental elements to sustain this attitude.

"I think this patient will ask for further investigations herself because she is a worried person and wants rather too many than too few technical investigations." (GP 11, Follow-up interview)

"I have the impression that this lady is fed up with all medical follow-up. She sighs very deeply when I want to refer her. Therefore, it is important for me to have an eye on her." (GP 2, Follow-up interview)

A language barrier, a short length of the GP-patient relationship and masking comorbidities lowered the threshold for further diagnostic steps. GPs had less trust in their clinical assessment in these cases.

"Because of the language barrier, it is very hard to do a proper history. Consequently, he only comes with his complaints, and he is unable to answer my questions. Combined with his Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

cardiovascular risk profile, I consider him even more at risk because I feel I don't have any control on his situation." (GP 8, Think-aloud session)

2.2 GPs' attitudes towards further diagnostic steps

 Clearly, GPs' attitudes towards further investigations also influenced clinical decision making. An important consideration was the potential prognostic benefit of an objectified HF diagnosis.

"In this case, a cardiologist's referral could be definitely interesting. She is only 70 years old, and making the correct diagnosis could be very important for her prognostically." (GP 1, Follow-up interview)

Conversely this was also mentioned as a barrier for referral.

"It has been a while since this patient visited a cardiologist. I might consider referring him again, but, on the other hand, I am wondering: 'if we can label him with an HF diagnosis, would this change anything for his current medical treatment and life expectancy?" (GP 7, Think-aloud session)

GPs tended to set out personal priorities for each patient with multi-morbidity, emphasizing the patient's needs for well-being.

"The question is if it is a priority to diagnose HF. For this man, 76 years old but biologically older, I am wondering if you shouldn't aim for what is really important to him. He has a lot of pain and doesn't see the connection with lack of exercise because of his dementia. (...) What is the priority for this patient? In my opinion, it is not the diagnosis but being more active." (GP 6, Follow-up interview)

In addition, differences were noted in the way GPs dealt with diagnostic uncertainty. Some GPs always strived for objectified diagnoses and only accepted uncertainty in exceptional circumstances, while other GPs obviously felt more comfortable with a certain degree of

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uncertainty and were more reluctant to refer. This attitude was not linked to age or practice type but was rather linked to the GP's personality.

The concept of categorisation based on ejection fraction (EF) in HF and the therapeutic implications of a HF with reduced ejection fraction (HFrEF) diagnosis versus a HF with preserved ejection fraction (HFpEF) diagnosis, were not always known by the participating GPs. Although, for those who were aware of the difference, it did influence their decision making.

"This is an example where the clinical diagnosis was very obvious and, at this moment, you start making considerations. She is a single, 87 years old, less mobile elderly women; what is the added value of objectifying your diagnosis? And, in particular, does this make any prognostic difference for her? In my opinion, this is the prototype of diastolic HF: the obese, elderly women where, from a prognostic view, not so much could be gained. An ACE-inhibitor and a beta-blocker – by the way, she already takes one – don't have any prognostic importance. It is just controlling the symptoms with diuretics. So, at this point of view, I am not going to bother her with cardiologist referrals for my own wish for certainty." (GP 1, Follow-up interview)

Step 3: Choice and implications of further diagnostic steps

When GPs chose to refer, they almost immediately opted for a cardiologist and/or cardiac ultrasound (US) referral (Figure 1). GPs rarely mentioned ECG or NT-proBNP spontaneously. Influencing factors on how they decided and dealt with these investigations and their results were described in Table 4.

3.1 NT-proBNP and/or ECG as diagnostic tests in HF

NT-proBNP:

NT-proBNP as a diagnostic test was rarely mentioned during the think-aloud. The views of

the GPs were further explored in the interviews afterwards. First, almost every GP considered the fact that the test is not reimbursed as an important barrier.

"I like using the test, or, better, I would like using it. The problem is that in ambulatory practice the test is not reimbursed. For me this is a big obstacle to use it systematically in my daily routine." (GP 12, Follow-up interview)

Most GPs knew NT-ProBNP is a good marker to exclude HF but possible other indications were not very clear.

"The cardiologist once asked me to measure it (NT-ProBNP) again. The rationale behind this, to control the value in follow-up, is not clear to me. It is an excellent parameter to exclude rather than prove HF. I can imagine when someone is less decompensated, there will be less stretch on the heart, and the parameter will fall, but I don't know if it is a good parameter to follow the severity of heart failure. I rather think it isn't." (GP 4, Follow-up interview)

Although there were GPs who did not see the benefit of the test at all, almost all GPs admitted the test simply was not integrated in their work flow.

"(NT-pro)BNP? No, however, I was involved in academic research of the subject; I must admit it is not accustomed in my flow yet." (GP 9, Follow-up interview)

Some GPs acknowledged they were not always sure how to interpret the results.

"I am not so sure about its cut-off values. In my opinion, it is something vague. You might say it is elevated or not, but it remains difficult to interpret." (GP 14, Follow-up interview)

<u>ECG</u>:

 If GPs mentioned an ECG, it was mostly done by the cardiologist rather than being one they performed themselves. Whether it could be helpful in the assessment of HF differed between all participating GPs.

"An ECG, if I am right, is a test which is very sensible for HF, but not specific. So, ideal to exclude but hard to prove. According to me, a perfectly normal ECG excludes HF. But, in this case, she has an AF, so I already know what to expect." (GP 4, Follow-up interview)

3.2. Cardiologist and cardiac ultrasound (US)

Different attitudes towards the positive and negative predicted value of cardiac US were noted. The negative predictive value of a normal cardiac US was widely accepted. However, the perception of the need and positive predictive value differed between the participating GPs.

"I always make decisions based on clinical grounds and never according to an aberrant cardiac ultrasound." (GP 14, Follow-up interview)

"But, here I notice I really need the cardiac ultrasound to exclude HF, while for demonstrating HF I don't need that anymore." (GP 8, Follow-up interview)

"I just like having a cardiac ultrasound because it is very clear to me." (GP 5, Think-aloud session)

Attitudes towards the value of a cardiologist referral and the interpretation of the cardiac US results depended on the quality of the cardiologist's report and the GPs' knowledge about cardiac US. GPs reported frustrations about the lack of an ejection fraction (EF) or a confirmed HF diagnosis in the reports from the cardiologists and suggested that explicitly asking for it could help.

"The cardiologists' reports are often not that great. It happens that they don't mention the *EF* and are not giving any information about it at all. I must admit it is better now than last year's, and it is a bit cardiologist-dependent. But, it could be vexing because you would like to advise your patients what they should do." (GP 12, Follow-up interview)

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"You should ask it (HF) particularly because sometimes they (cardiologists) remain silent about it. Often HF isn't mentioned in the cardiologists' conclusion, while it is a very important risk factor for hospitalization and mortality." (GP 4, Follow-up interview)

Some GPs reported a lack of mutual trust in the collaboration with cardiologists.

"Hardly one listens to the patient or the GP. A flare that doesn't take place in the hospital is considered to be a non-existing flare." (GP 8, Follow-up interview)

Those GPs who were aware of the difference between HFrEF and HFpEF acknowledged that an HFrEF diagnosis was easier to assign than an HFpEF diagnosis. If a cardiologist did not confirm the HFpEF diagnosis in symptomatic patients, diagnostic doubt remained for most GPs. Some GPs who very experienced in HF drew their own conclusions based on the clinical image and cardiac US report.

"What you see by these type of patients is that cardiologists aren't either always able to recognize this clinical image as HF with preserved EF, while, in this case, you have several clinical and even some echocardiographic arguments." (GP 6, Follow-up interview)

Remaining diagnostic doubts after referral had a negative influence on the GPs' attitudes towards referral. A cardiorenal consultation was seen as a big advantage because of the multifactorial approach needed for HF (Table 4).

Discussion

This think-aloud study highlights the influencing factors in the diagnostic reasoning process of CHF in general practice. A conceptual diagnostic model was built to capture the three main diagnostic reasoning steps. First, GPs assessed the likelihood of HF using the presence or absence of HF signs and symptoms as the main discriminating factor. However, this approach had serious limitations since GPs experienced many barriers in their clinical assessment, especially in comorbid elderly. Second, if CHF was considered based on step one, the main influencing factor to take further diagnostic steps was the GPs' perception of the added value of a validated CHF diagnosis in that specific case. Third, the choice and implications of these further diagnostic steps (NT-proBNP, electrocardiography and/or cardiac ultrasound) were influenced by the GPs' knowledge about these tests and the quality of the cardiologists' reports.

Step 1: Assessing the likelihood of HF

Every GP assessed the likelihood of HF as a first step. The arguments GPs used in their assessment coincided with the concept of the cardiovascular continuum or the HF stages of the American Heart Association (AHA) guideline. These concepts describe HF as a syndrome that progresses from asymptomatic structural heart disease in patients with CV risk factors to symptomatic HF, making this likelihood assessment a valuable approach.^{17 18} Additionally, in line with former studies, the assessment of HF signs and symptoms by the GP was seen as the main discriminating factor to withhold a diagnosis of HF and/or to consider further diagnostic steps.⁷⁹ However, at the same time, GPs reported many barriers in this clinical approach, especially in real-world older patients with comorbidities, as confirmed in other studies.⁵⁶ Furthermore, it was shown that 77% of the HF patients diagnosed in primary care in Belgium are already in New York Heart Association (NYHA) stage III-IV and thus unmistakably symptomatic at the time of diagnosis.¹⁹ Consequently,

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one might suspect that GPs tend to overestimate the value of their clinical assessment, especially in older HF patients, leading to delayed or missed diagnoses.^{4-6 20} This provides important points of action to improve the diagnostic process in HF. First, a paradigm shift is needed towards early identification of HF patients and prevention of disease progression. Early intervention in HF Stage B (asymptomatic structural heart disease) patients led to a reduction in morbidity and mortality.²¹ Therefore, we would like to emphasize the importance, not only to consider further diagnostic steps when signs and symptoms are present, but also when substantial risk factors or comorbidities are known (Figure 1, curled arrow).^{22 23} Second, the question arises whether the current definition of HF is applicable in the very old. The definition of HF restricts itself to stages at which clinical symptoms are apparent. As shown by our study, this is particularly difficult in elderly as signs and symptoms lose their value in this age group. Demonstrating an underlying cardiac cause is another essential part of the HF definition. This is especially challenging in HFpEF patients. A high proportion of HFpEF patients have concurrent atrial fibrillation while diastolic dysfunction is very difficult to assess in this patient group.^{24 25} Additionally, some patients only exhibit symptoms (and echocardiographic abnormalities) on exertion.^{24 25} Conversely, the prevalence of mild to moderate diastolic dysfunction is very high in elderly but it is difficult to decide upon the clinical significance of these cardiac phenotypes.^{6 25 26} In response to these diagnostic problems, the Heart Failure Association (HFA) introduced a new consensus on the HFpEF diagnosis on the latest ESC congress.²⁷ Time will tell whether this new HFpEF definition will resolve all diagnostic doubts.

Step 2: Considering further diagnostic steps

Our study revealed patient-related, social and GP-related factors that were not reproducible by case-vignette studies ⁹ or discussed in HF guidelines.^{1 18} Patient-related and social factors are generally not modifiable; however, GP-related factors are. The importance GPs attach to Page 19 of 39

BMJ Open

person-centred care was highlighted. As many GPs mentioned in our study, what matters to them and to the patients is the prognostic and therapeutic implications of cardiac abnormalities. This is an issue that HF guideline developers should consider.^{1 18} NT-proBNP could support GPs in this risk stratification, as it provides prognostic information in cardiac outpatients. ^{1 3 20 28 29} Additionally, in our study, the concepts of HFrEF and HFpEF were cited by very few GPs. Interestingly, some GPs thought that they could distinguish HFrEF from HFpEF based on the patients clinical profile, while cardiac US remains the gold standard.^{1 18} Therefore, we recommend that GPs have a better understanding of cardiac ultrasound reports and propose targeted education as an area of improvement.^{7 30}

Step 3: Choice and implications of further diagnostic steps

NT-proBNP and ECG are recommended by all HF guidelines.¹¹⁸ Conversely, they were rarely mentioned by GPs in this think-aloud study. In the follow-up interview, the lack of reimbursement for NT-proBNP tests was cited as a significant barrier. In Belgium, the cost of natriuretic peptide testing is relayed on the patient (+/- 25 euro per test) due to an impasse in the negotiations with clinical biologists. This accounted for the GPs' unfamiliarity with the test and the uncertainty regarding how to integrate it in their practice. However, one GP correctly quoted the value of NT-proBNP in the early stages of HF but voiced scepticism towards extended use in follow-up.³¹ Furthermore, the cost of the test could account, in part, for the fact that 77% of Belgian HF patients in primary care are already in NYHA stage III-IV at the time of HF diagnosis.¹⁹ To withhold ECG as a valuable diagnostic tool, repeated training of GPs to fine-tune their interpretation skills remains important.³² However, as quoted pertinently in our study, a negative ECG excludes HF, but the elderly rarely have a completely normal ECG.¹⁶ Our study also showed that GPs sought more information on the correct interpretation of cardiac US reports when diagnosing CHF. In contrast with UK

better access alone to cardiac US is not sufficient because a better understanding of and education in interpreting cardiologists' reports is needed.^{8 9} Additionally, GPs noted that cardiologists are responsible to describe HF diagnoses clearly in their reports, which, in the case of HFpEF, remains a difficult task.^{1 24}

Implications for practice

 The diagnostic flowchart of the ESC HF guideline already promotes using NT-proBNP or BNP as a diagnostic test when patients have a prior history of ischaemic heart disease, hypertension, cardiotoxic medication or chronic diuretic use.¹ Belgian GPs rather use the national GP guideline about CHF published in 2011. Recommendations are generally in line with the ESC HF guideline but the use of natriuretic peptides is not actively promoted in this guideline since the test is not reimbursed in Belgium.³⁴ The paradigm shift to an earlier risk assessment should be more widely disseminated in practice. However, access to natriuretic peptides is indispensable to achieve this.^{1 22 28 29} The main modifiable barrier for further investigations in this study is not, as formerly described, a lack of access or a pure lack of knowledge. It is a lack of belief in the added value of further investigations. A remaining uncertainty after cardiologist referral contributes to this. Uncertainty remains because cardiologists do not assign HFpEF diagnoses easily themselves, and GPs are not able to correctly interpret echocardiography reports.³⁵ Additionally, GPs are confronted with a high percentage of HFpEF patients, whose prognosis does not change much with available treatment. Therefore, assigning a diagnosis in this patient group seemed less important in their opinion. Education and guidelines for GPs should target these beliefs because a distinction between HFrEF and HFpEF cannot always be made clinically and a correct HFpEF diagnosis does have important prognostic implications.³⁶

Methodological strengths and limitations of this study

The variability in the years of experience, the nature of the practice and the gender of the

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fourteen participating GPs reflected the general GP population. Therefore, differences in working conditions, access to cardiac US and cooperation with specialists was well covered. However, there were no solo-operating GPs included in the study. This form of practice is declining but is currently still represented in the Belgian health care system. In this survey, there was also a higher fraction of participant GPs involved in academic teaching and/or research, explaining our recruitment success rate of 100%. To correct for this imbalance, one extra rural practice with three GPs who were not involved in academic teaching or research was added in the study. As far as we know, this is the first study where a think-aloud approach on real-world patients was performed. This enabled us to highlight the importance GPs attach to person-centred care and to analyse GPs' diagnostic reasoning with respect to CHF and the differences with the existing guidelines.

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Conclusion

This think-aloud study identified the influencing factors in the diagnostic reasoning process of HF in general practice. As a consequence, targets to improve this diagnostic reasoning were identified: a paradigm shift towards earlier risk assessment, rethinking the HF definition in the very old, promoting access to NT-proBNP and convincing GPs of the added value of an objectified HF diagnosis through a better cooperation with cardiologists.

Competing interests None to declare.

Author contributions MS, PDW, SP and BV are responsible for the design of the study. PDW performed the audit and think-aloud interviews in each practice. MS and PDW analysed the data and wrote the manuscript. All authors (MS, PDW, SP, BV, BA and SJ) revised the manuscript.

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Data sharing statement All authors had full access to all data in the study and assume responsibility for the integrity of the data and the accuracy of the data analyses.

Availability of data and materials The dataset supporting the conclusions of this article is held at the University of Leuven, Belgium and can be shared upon contacting the corresponding author.

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Figure legend

Figure 1: Diagnostic reasoning model

HF, heart failure; CV, cardiovascular; GP, general practitioner; US, ultrasound; ECG, electrocardiography

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Table 1	l: Character	ristics of the pa	articip	ating GPs		20 March cluding fc
GP	Gender	Years of	Age	Practice type	Location of	Sclinical roles besides GP
(number	?) (M/F)	experience*		(number of GPs)	GP practice	Downlo Su s relate
1	М	28	53	Group (5 + trainee)	Rural	Uting sity teacher; Training supervisor
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3	F	15	42	Group (5 + trainee)	Rural	/ S) · / data n
4	М	3	30	Group (5 + trainee)	Rural	njope /
5	F	5	42	Group (5+ trainee)	Rural	/ / Al trai
6	М	34	59	Duo (+ trainee)	Urban	Local coordinator CHF care; Training super
7	F	38	63	Duo (+ trainee)	Urban	GP training supervis
8	М	16	43	District health centre (3 + trainee)	Urban	GP training coordinator; Training supervis
9	F	18	45	District health centre (3 + trainee)	Urban	ମୁନ୍ଦୁ ଅନୁସୁ ଅନୁମୁନ୍ଦୁ ଅନୁ ଅନୁସୁ ଅନୁ ଅନୁ ଅନୁ ଅନୁ ଅନୁ ଅନୁ ଅନୁ ଅନ୍ତ୍ର ଅନୁ ଅନୁ ଅନୁ ଅନୁ ଅନୁ ଅନୁ ଅନୁ ଅନୁ ଅନୁ ଅନୁ
10**	F	1	27	District health centre (3 + trainee)	Urban	gies. /
11	F	2	30	District health centre (3 + trainee)	Urban	University teacher
12	М	20	47	Group (4 + trainee)	Rural	gr app /
13	F	1	27	Group (4 + trainee)	Rural	que /
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1 2 3 4	14	F	4	31	Group (4+ trainee)	Rural	n 20 March including fo	/	
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Table 2: Assessing the likelihood of HF – Influencing factors					
Barriers in the	- Overlap with comorbidities				
assessment of HF	- Non-specificity of some symptoms and signs				
symptoms and signs	- Masked by medication				
Symptome and Signe					
	Difficult in immediate notionts				
	- Difficult in immobile patients				
	- Relapsing remitting course				

Table 3: Considering further diagnostic steps – Influencing factors				
Patient and social	- Attitude towards diagnosis, follow-up and treatment			
factors	- Lifestyle, self-care and compliance			
	- Choice for a palliative care approach			
	- Age, frailty and impact of stay in a long-term care facility			
	- Length GP-patient relationship			
	- Language barrier			
	- Comorbidities that influence clinical assessment			
GP factors	- Perceived value of cardiologist referral and an objectified			
	HF diagnosis regarding:			
	° Implications for further treatment			
	° GPs' priorities			
	- Dealing with diagnostic uncertainty			
	- Diastolic vs systolic HF			

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Table 4: Choice and implications of further diagnostic steps – Influencing factors				
NT-ProBNP	-	Price as a barrier, demand for reimbursement		
	-	Utility (not) known		
	-	Interpretation problems		
NT-ProBNP and ECG	-	Perception of positive and negative predictive value		
	-	Integrated in work flow		
	-	Uncertainty about indication		
Cardiologist and		Perception of positive and negative predictive value		
cardiac US	-	GPs' knowledge about cardiac US		
		Quality of cardiologist report		
		° Confirmation of HF diagnosis by cardiologist		
	-	° Remaining diagnostic uncertainty after cardiologist		
		appointment		
	-	Clinical assessment of HF by cardiologist and mutual trust		
	-	Importance of cardiorenal consultation		
	-	HFpEF as a new difficult entity		
	-	0		







neart fanure, CV, cardiovascular, GP, general practitioner, OS, uttrasound, ECG, electrocardiography

Figure 1: Diagnostic reasoning model

Supplemental file 1: Queries used to search for HF patients in the EHR

Heart failure coded	ICPC-2-code: K77
Heart failure free text	"hartfalen" OR "corfalen" OR "hartsdecompensatie"
	OR "hartdecompensatie" OR "cordecompensatie" OR
	"NYHA" OR "LVfalen" OR "linkerventrikelfalen"
	OR "LVdysfunctie" OR "linkerventrikeldysfunctie"
	OR "LVdecompensatie" OR
	"linkerventrikeldecompensatie" OR "gedaalde EF"
	OR "gedaalde ejectiefractie" OR "gedaalde LVEF"
	OR "verminderde EF" OR "verminderde
	ejectiefractie" OR "verminderde LVEF"
	"decompensatie" NOT "psychische decompensatie"

Non-registered HF patients: used queries*

HF risk factors

Atrial fibrillation coded	ICPC-2 code K78
Atrial fibrillation free text	"voorkamerfibrillatie" OR "VKF"
Ischaemic heart disease coded	ICPC-2 code K74 OR K75 OR K76
Ischaemic heart disease free text	"angor" OR "ischemie" OR "infarct" OR
	"myocardinfarct" OR "hartinfarct"
	NOT: "cerebrale ischemie", "cerebrovaculaire
	ischemie", "retina ischemie", "N. opticus ischemie",
	"ruggenmergischemie", "ischemie van de
	ledematen", "nierinfarct", "cerebellair infarct",
	"cerebraal infarct", "herseninfarct
Valvular heart disease coded	ICPC-2 code K83
--	---
Valvular heart disease free text	"stenose" OR "insufficiëntie" OR "klep" OR
	NOT: "spinaalkanaalstenose", "dacryostenose",
	"urethrastenose", "anale stenose","
	nierarteriestenose", "A. Renalisstenose",
	"cervixstenose", "oesophagusstenose",
	"nierinsufficiëntie", "veneuze insufficiëntie",
	"arteriële insufficiëntie", "respiratoire insufficiëntie"
	"acute bijnierinsufficiëntie", "ovariuminsufficiëntie"
	"kleptomanie"
Hypertension complicated coded	ICPC-2 code K87
Condiamyonathy free text	"condiantyanathia" OP "CMP"
Cardiomyopathy nee text	cardioniyopathe OK CMF
Congenital anomaly cardiovascular coded	ICPC-2 code K73
Congenital anomaly cardiovascular coded Congenital anomaly cardiovascular free tex	ICPC-2 code K73 t "ASD" OR "VSD" OR "septumdefect" OR "fallot"
Congenital anomaly cardiovascular coded Congenital anomaly cardiovascular free tex	ICPC-2 code K73 t "ASD" OR "VSD" OR "septumdefect" OR "fallot"
Congenital anomaly cardiovascular coded Congenital anomaly cardiovascular free tex HF symptoms and signs Edema lung free text	ICPC-2 code K73 t "ASD" OR "VSD" OR "septumdefect" OR "fallot" "longoedeem"
Congenital anomaly cardiovascular coded Congenital anomaly cardiovascular free tex HF symptoms and signs Edema lung free text Edema free text	ICPC-2 code K73 t "ASD" OR "VSD" OR "septumdefect" OR "fallot" "longoedeem" "oedeem"
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B-blockers AND diuretics	Medication group/ATC code: "β-blockers" AND
	"diuretics"
ARB AND diuretics	Medication group/ATC code: "sartaan" OR
	"angiotensin-II-antagonisten" AND "diuretics"
ARB AND β-blockers	Medication group/ATC code: "sartaan" OR
	"angiotensin-II-antagonisten" AND "β-blockers"
Digoxine and derivates	Medication group/ATC code: "digoxine en
	derivaten" OR "hartglycosiden"
MRAs	Medication group/ATC code: "Potassium-sparing
	diuretics"

HF, heart failure; EHR, electronic health record; ICPC-2, International Classification Primary Care, Second Edition; ACI-I, angiotensin-converting enzyme inhibitor; ARB, angiotensin II- receptor blockers; MRA,

mineralocorticoid receptor antagonist

* Only patients older than 40 years of age were included in the audit

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3 A	Supplemental file 2: Coding tree of descriptive themes
5	Assessing the likelihood of HF
6	HE symptoms and signs
7	In symptoms and signs
8	Influencing factors
9 10	Presence of HF symptoms and signs as most decisive discriminator
11	Non-specific symptoms/signs
12	Masking factors
13	Reaction on medication start/stop
14	Relapsing-remitting course of HF
15 16	Difficult in immobile patients
17	Overlap with comorbidities
18	Reasoning according to the cardiovascular continuum
19	Considering further diagnostic tests
20	Detions fostore
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23	Patient attitude towards diagnosis, follow-up and treatment
24	Comorbidities
25	Family history of HF
26	Stay in a long-term care facility
27 28	Choice for a palliative care approach
29	Age
30	Lifestyle
31	Length GP-natient relationship
32	Language barrier
34	Compliance
35	
36	Sell-care
37	GP factors
38 30	Attitude towards clinical assessment
40	Perceived value of referral to cardiologist
41	HF in a chronic vs acute care approach
42	Diastolic vs systolic HF
43	Need for objectification of the diagnosis
44 45	Impact of the HF diagnosis on further management
46	Dealing with uncertainty
47	Implications of further diagnostic steps
48	Natriuratic pantides and ECG
49 50	Attitude terrende ECC
50 51	Attitude towards ECG
52	Perceived value of ECG in the diagnosis of HF
53	Attitude towards natriuretic peptides
54	Perceived value of natriuretic peptides in the diagnosis of HF
55 56	Lack of reimbursement as an influencing factor
57	Indication of natriuretic peptides: when use it?
58	Interpretation of natriuretic peptides
59	Cardiologist FU and echocardiography
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Attitude towards echocardiography Perception of positive predictive value FU in patients at risk HFpEF as a new entity Negative predictive value of a normal echocardiography Incomplete echocardiography reports HFrEF diagnosis versus HFpEF diagnosis Own interpretation of echocardiography reports Attitude towards cardiologist/specialist FU Added value of a cardiorenal consultation Role GP and patient vs role specialist Assigning the HF diagnosis (or not) The value of the clinical assessment by the cardiologist Dealing with the cardiologist report Dealing with ongoing uncertainty after referral Asymptomatic patient at the cardiologist consultation

Manuscript: Diagnostic reasoning while determining slow-onset heart failure in general practice: a Think aloud study.

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

32-item checklist		
Developed from: Tong A, Sainsbury P, Craig J. C 32-item checklist for interviews a 2007. Volume 19, Number 6: pp	consolidated criteria for reporting qualitative resea and focus groups. <i>International Journal for Qualit</i> 9. 349 – 357	rrch (COREQ): a y in Health Care.
No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics 1. Inter viewer/facilitator	Which author/s conducted the inter view or focus group?	Page 6
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Page 1
3. Occupation	What was their occupation at the time of the study?	Page 1 and 6-7
4. Gender	Was the researcher male or female?	Page 1 and 6-7
5. Experience and training	What experience or training did the researcher have?	Page 6-7
Relationship with participants	0	
6. Relationship established	Was a relationship established prior to study commencement?	Page 6
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Page 6
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Page 6

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	BMJ Open	Pag
Domain 2: study design		
Theoretical framework		3
9. Methodological prientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Page 5
Participant selection		rignt,
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 5 and 6
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Page 5 and 6
12. Sample size	How many participants were in the study?	Page 6 and 8
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Page 6
Setting		
14. Setting of data	Where was the data collected? e.g. home, clinic, workplace	Page 6
15. Presence of non-	Was anyone else present besides the participants and researchers?	No
 Description of sample 	What are the important characteristics of the sample? e.g. demographic data, date	Page 6 – 8 and Table
Data collection	1	
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 6-7
18. Repeat interviews	Were repeat inter views carried out? If ves, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 6
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Page 6
21. Duration	What was the duration of the inter views	Page 8

		1
	or focus group?	
22. Data saturation	Was data saturation discussed?	Page 7
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Page 7
25. Description of the coding tree	Did authors provide a description of the coding tree?	No
26. Derivation of themes	Were themes identified in advance or derived from the data?	Page 7
27. Software	What software, if applicable, was used to manage the data?	Page 7
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Page 8 to 15
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes, there was. Page 8 to 19
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes. they were. From page 8 to 15
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Discussion of major and minor themes From page 16 to 19