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Validity of heart failure diagnosis in patients with obesity

Degree Project in Medicine

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1. Abstract

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1.1 Background

Heart failure (HF) is a syndrome affecting the function of the heart where the main symptoms are dyspnea, fatigue and peripheral edema. Patients with obesity often present similar symptoms to those seen in HF, and diagnosing HF in this patient group is known to provide some difficulty. The validity of HF diagnosis in the Swedish discharge register has previously been shown to be high, but the validity in patients with concurrent obesity has not been investigated.

1.2 Methods and results

The study population consisted of all patients registered with a diagnostic code of obesity at the Obesity Care Unit (2000-2006) or at the Regional Obesity Centre (2007-2017) and who had a concurrent HF code either at Sahlgrenska university hospital or at the nearby Kungälv hospital, both in western Sweden. Relevant information from patient records was filled in using a form designed for the purpose of this study. The HF diagnosis was then classified as definite, probable or miscoded by a team consisting of a medical student and an experienced cardiologist. Out of 8,202 obese patients, 77 had a HF diagnosis. After exclusions, HF could be validated in 45 patients. Of these, 64.4 % were classified as definite, 33.3 % as probable and 2.2 % as miscoded, which is comparable to a prior study in unselected HF patients.

1.3 Conclusion

The validity of HF diagnosis in obese patients is comparable to the validity in patients without obesity. Because of the limited size of this study population, further and larger studies are needed to verify these results.

1.4 Key words

Heart failure, validation, obesity, diagnosis

2. Background

Heart failure (HF) is a serious and common condition. The prevalence of HF in Sweden is estimated to 2 % which is comparable to the prevalence in the rest of the western world (1, 2). Incidence of HF has been decreasing in the general population since the mid-1990's, except in the young ≤ 45 years where incidence and prevalence are increasing (1, 3). In established HF, 5-year mortality of is estimated at about 50 % and the lifetime risk of HF is one in five in both men and women (4). Risk factors for HF are coronary heart disease, diabetes, valvular heart disease, hypertension, smoking and obesity (5).

The prevalence of obesity is increasing worldwide. According to the recent WHO report on non-communicable diseases, 39 % of all adults over the age of 18 are currently overweight, defined as having a body mass index (BMI) ≥ 25 kg/m^2, and the prevalence of obesity (defined as having a BMI ≥ 30 kg/m^2) was 15 % in women and 11 % in men. This is almost twice as high as the prevalence in 1980 (6). Obesity is a major risk factor for cardiovascular disease and type II diabetes, as well as a risk factor in some cancers (7, 8).

The effect of obesity on the cardiovascular system can partly be explained through dyslipidemia, hypertension and hyperglycemia, including diabetes (9). Previous studies have shown that obesity also plays a role independently of these factors, with a stepwise increase in the risk of a future HF diagnosis for each BMI unit, starting already at levels that are considered normal (10). In contrast, mortality in HF may be lower in patients who are overweight or obese (11). Further studies regarding the effect of weight loss on HF mortality are needed to further clarify this seemingly paradoxical relationship.

There is no unequivocal definition of HF, which can make diagnosis difficult. To aid clinicians there are several available guidelines. Since 1995, the European Society of Cardiology (ESC) regularly publishes updated guidelines on the diagnosis and management of HF. According to the ESC, a diagnosis of HF requires the presence of symptoms, clinical signs (from 2008) and objective evidence. Classical symptoms of HF are dyspnea, fatigue and limited physical activity and typical signs are rales, peripheral edema and a third heart sound, S_3 (12-18). Clinicians in Europe generally have a high awareness of the ESC guidelines. This also applies specifically to Swedish clinicians where 71 % of Swedish cardiologists have reported that they adhere closely to the ESC guidelines in clinical practice (19).

There have been previous studies evaluating how well the ESC guidelines for diagnosing HF are followed in clinical praxis in Sweden. One study investigating 317 men with a diagnosis of HF in the Swedish hospital discharge registry found that 82 % of the diagnoses of could be classified as “definite” cases and 16 % as “questionable” in concordance with the ESC guidelines (20). An as yet not published study in Gothenburg looking at the validity of HF diagnosis in the discharge register of Sahlgrenska university hospital in western Sweden found that 62.3 % of HF diagnoses could be classified as “definite”, 32.1 % as “probable” and 5.6 % as “miscoded” (Schaufelberger M et al, Validity of the heart failure diagnosis in Western Sweden 2000 – 2012, manuscript). These studies investigated unselected patients with a discharge diagnosis of HF but it is still unknown how the validity of the diagnosis may be affected by concurrent obesity, which may present with similar symptoms.

Diagnosing HF in patients with obesity provides several challenges. Common symptoms of HF include dyspnea, swelling of the lower legs and reduced exercise tolerance (18), symptoms which are also commonly present in obese patients. As the diagnosis of HF relies

heavily on the presence of symptoms this can be problematic. Symptoms of HF have been shown to be present to a greater extent in obese patients with HF compared to patients with normal BMI (11). Signs of HF are generally present to a lower extent in patients with concurrent obesity, with the exception of edema which is seen more often (11). Obesity may also provide difficulties in the interpretation of echocardiographic images as these are more often of poor quality in obese patients (21).

Another potential difficulty in diagnosing HF in patients with obesity is interpretation of natriuretic peptide concentration. Testing levels of the natriuretic peptides Brain Natriuretic peptide (BNP) and N-terminal prohormone of BNP (NT-proBNP) are now well-established tools in diagnosing HF, where raised levels of natriuretic peptides correlate with a higher probability of HF in patients with dyspnea (22, 23). However, studies have shown that there is an inverse relationship between BNP / NT-proBNP levels and body weight making test results more complex to assess in the obese patient (24, 25). A review article published in 2014 (25) recommends adjusting cut-off points for BNP-levels according to body weight but that with respect to NT-proBNP it should be enough to adjust cut-off points for age as recommended in the general population. Here, body weight does not critically affect the specificity or sensitivity of the test.

As the prevalence of obesity continues to rise and the incidence of HF increases in younger individuals, the patient group consisting of young, obese patients with HF is of interest for further studies. Data from the Swedish National Patient Registry (NPR) regarding diagnoses is often used in population-based studies, and accordingly it is of interest to know to what extent these diagnoses conform to standard diagnostic guidelines.

3. Aim / Research question

3.1. Aim

The aim of this study was to investigate the validity of HF diagnoses in the Swedish national patient registry (NPR) in patients with a concurrent obesity diagnosis using information from medical records.

3.2. Research question

What is the validity of HF diagnoses in the Swedish national patient registry in patients with concurrent obesity?

4. Material and methods

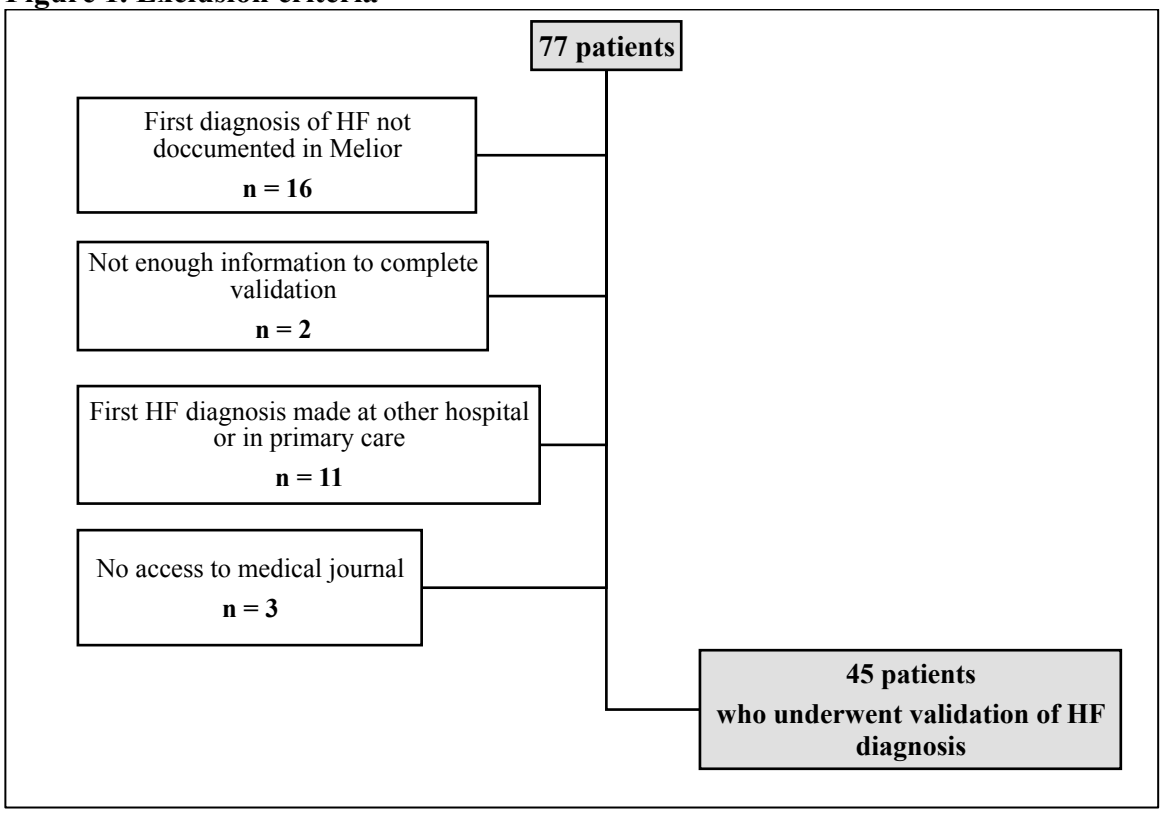
4.1. Participants

In this study, the study population was derived from consecutive patients with an obesity diagnosis (ICD10 E65 – E66) recorded at the Obesity care unit (2000 – 2006) or at the Regional Obesity Center at Sahlgrenska University hospital (2007 – 2017) identified from the register of medical records of the Västra Götaland Region (VGR) in Sweden (n=8,202). From these 8,202 patients, all patients with an additional diagnosis of HF were selected using International Classification of Disease codes for HF (ICD10 I50.0 – I50.9). The study population thus identified consisted of 77 patients, all with a diagnosis of obesity and a concurrent diagnosis of HF.

From these 77 patients the medical records in the digital record system of the VGR (Melior) were reviewed. 45 of the patients went through a validation of the HF diagnosis (Figure 1). Patients were excluded in cases where a validation could not be made. This could be due to the first diagnosis of HF not being recorded at Sahlgrenska university hospital or Kungälv

hospital, but at another hospital or in primary care, or because the patient was diagnosed before the era of digital patient records, with subsequent loss of information. Patients were also excluded if the record was blocked by the patient and therefore could not be scrutinized. 2 patients were excluded because the patient records did not contain enough information for the diagnosis to be validated.

Figure 1. Exclusion criteria



Flowchart showing exclusion of patients where a validation of the HF diagnosis could not be made.

4.2. Data collection

Information from patient visits at inpatient- or outpatient clinics in western Sweden are recorded in the digital record system (Melior). All principal and contributory diagnoses are then sent to and registered in the Swedish National Patient registry (NPR), which includes records of all hospitalizations (inpatient registry) and specialist outpatient visits (outpatient registry, since 2001). The registry has 100 % coverage of discharges from Swedish hospitals

since 1987 and onwards. Data regarding diagnoses in the NPR are frequently used for administrative or research purposes. A validation of the Swedish national inpatient register (IPR) has shown that the positive predictive value (PPV) of diagnoses is 85-95 % for most diagnoses (26).

Information on each patient was obtained using medical records in the digital system Melior. A form designed for the purpose of this study was used to document information regarding the obesity and the HF diagnosis (Appendix). The first diagnosis of HF according to ICD-10 codes in each patient journal was validated.

Patient history and signs of heart failure

In cases where the patient received their HF diagnosis during a hospitalization, information regarding signs and symptoms was taken from the entire hospitalization period. In cases where the patient received their diagnosis at an outpatient clinic, information from the visit to the clinic was primarily used. If no physical examination was performed and / or if the patient history was incomplete, this information was taken from the clinical unit that referred the patient to the clinic via the referral note.

Echocardiography

The most recent echocardiography report was analysed. If an echocardiography was not performed at the time of HF diagnosis, echocardiographic examinations from the time with the most obvious signs of HF previous to the diagnosis were used. An echocardiography report with a left ventricular ejection fraction (LVEF) < 50 % was considered pathological and as objective evidence of HF. In all cases with LVEF > 50 %, the test results were interpreted by an experienced cardiologist.

A pathological echocardiography report fulfilling HF criteria, magnetic resonance imaging (MRI) of the heart, left ventricular (LV) angiography and scintigraphy of the heart were all considered as objective evidence of HF. As in the case of echocardiography results, MRI, LV angiography and scintigraphy results were considered as showing objective evidence of HF if LVEF was < 50 %. If LVEF was > 50 %, the results were interpreted by an experienced cardiologist.

Electrocardiography (ECG)

In the case of hospitalizations, the first ECG, most often from the emergency care department was used. If the diagnosis was recorded from an outpatient visit, the most recent ECG report was used. An ECG was considered pathological if at least one of the following was present; rhythm other than sinus or AV-block I, QRS-duration > 100 ms or pathological Q waves.

Chest X-ray

If multiple chest X-rays were performed before the diagnosis of HF, the most recent examination was used. Finds considered signs of HF were: pulmonary congestion, widening of the pulmonary vessels, edema, redistribution and cardiomegaly.

Natriuretic peptides

Both the latest value of NT- proBNP obtained and the highest value was recorded. Reference values from the review article by C.Madamanchi et al. (25) were used.

4.3. European Society of Cardiology guidelines

New guidelines for the diagnosis and treatment of HF were published by ESC during the time when the patients were diagnosed with HF: in 1995, 2001, 2005, 2008, 2012 and 2016. In this study it was assumed that new guidelines would be implemented in clinical work the year after they were published. This means that the 2001 guidelines would be in clinical use from 2002, hence the validation of the diagnoses made in 2002 was made according to the guidelines published in 2001, etc.

Table 1. Diagnostic assessments supporting or opposing the heart failure diagnosis from the different ESC guidelines between years 1995 – 2008.

	1995	2001	2005	2008
	Supports if present/ Opposes if normal or absent	Supports if present/ Opposes if normal or absent	Supports if present/ Opposes if normal or absent	Supports if present/ Opposes if normal or absent
Appropriate symptoms	+++*/---	+++*/--	+++*/---	++*/--
Appropriate signs	+++/-	+++/-	+++/-	++*/-
Response to treatment	+++/---	+++/---	+++/---	+++/--
Pathological ECG	/---	/---	/---	++/--
Cardiac dysfunction on imaging	+++*/---	+++*/---	+++*/---	+++**/--
Chest X- ray	+/-	+/-	+/-	+++/-
Natriuretic peptides	n/a	+ (if elevated) /---	+ (if elevated) /---	+++ (if elevated) /---

Abbreviations: +/- of some importance, ++/-- of particular/ considerable importance, +++/--- of major importance, ECG; electrocardiogram, ESC; European society of cardiology. * Necessary for definite diagnosis. ** Considered an objective evidence of cardiac dysfunction. n/a; Not applicable. *This assessment is adapted from the heart failure diagnostic guidelines edited by the ESC in 1995, 2001, 2005 and 2008. This adaptation was made by Schaufelberger M et al. (unpublished).*

The importance of different diagnostic tools for the diagnosis of HF between years 1995 – 2008 is described in Table 1. The changes in diagnostic recommendations included the

addition of a mandatory criterion of clinical signs of HF in the guidelines published 2008. The guidelines of 2012 state the signs-criterion as necessary for HF diagnosis as in the guidelines of 2008, however with the footnote that signs may be missing in patients with early HF or when treated with diuretics (Table 2). From 2012 the definition of HF was extended to defining HF with preserved ejection fraction (HF-PEF) and HF with reduced ejection fraction (HF-REF) as two different entities based on echocardiography results, hence making echocardiography an obligatory examination for the diagnosis to be made. This is also the case in the guidelines of 2016, where the definition of HF is further extended to HF with mid-range EF (HFmrEF) for patients with an EF between 40 - 49 % (Figure 2).

Table 2. The definition of HF according to the ESC guidelines of 2012 (16).

The diagnosis of HF-REF requires three conditions to be satisfied:
1. Symptoms typical of HF
2. Signs typical of HF*
3. Reduced LVEF
The diagnosis of HF-PEF requires four conditions to be satisfied:
1. Symptoms typical of HF
2. Signs typical of HF*
3. Normal or only mildly reduced LVEF and LV not dilated
4. Relevant structural heart disease (LV hypertrophy / LA enlargement) and / or diastolic dysfunction.

Abbreviations: LA = left atrial; LV = left ventricular; LVEF = left ventricular ejection fraction.
*Signs may not be present in the early stages of HF (especially in HF-PEF) and in patients treated with diuretics.

Figure 2. The definition of HF according to the ESC guidelines of 2016 (17).

Type of HF		HFrEF	HFmrEF	HFpEF
CRITERIA	1	Symptoms ± Signs[a]	Symptoms ± Signs[a]	Symptoms ± Signs[a]
	2	LVEF <40%	LVEF 40–49%	LVEF ≥50%
	3	–	1. Elevated levels of natriuretic peptides[b]; 2. At least one additional criterion: a. relevant structural heart disease (LVH and/or LAE), b. diastolic dysfunction (for details see Section 4.3.2).	1. Elevated levels of natriuretic peptides[b]; 2. At least one additional criterion: a. relevant structural heart disease (LVH and/or LAE), b. diastolic dysfunction (for details see Section 4.3.2).

BNP = B-type natriuretic peptide; HF = heart failure; HFmrEF = heart failure with mid-range ejection fraction; HFpEF = heart failure with preserved ejection fraction; HFrEF = heart failure with reduced ejection fraction; LAE = left atrial enlargement; LVEF = left ventricular ejection fraction; LVH = left ventricular hypertrophy; NT-proBNP = N-terminal pro-B type natriuretic peptide.
[a]Signs may not be present in the early stages of HF (especially in HFpEF) and in patients treated with diuretics.
[b]BNP>35 pg/ml and/or NT-proBNP>125 pg/mL.

4.4. Validation of the diagnosis

The HF diagnosis of all patients underwent primary validation by a medical student (KA) and was classified as definite, probable or miscoded according to the relevant ESC guidelines. In cases with uncertainty as to the validity of the diagnosis, the validation was made by an experienced cardiologist. In all cases where the patient presented with symptoms and / or signs of HF accompanied by an echocardiographic examination with LVEF > 50 %, the validation was also made by an experienced cardiologist. 5 randomly selected patients went through a second validation by an internist at the department of medicine to evaluate inter-observer accuracy.

Typically, a diagnosis validated as definite would have to fulfil the symptoms and (according to the ESC guidelines of 2008 and later) signs criterion of HF accompanied by an echocardiography report showing objective evidence of HF. The diagnosis would be further supported by a chest X-ray showing signs of HF and a pathological ECG even if these were not necessary for the diagnosis to be classified as definite. A probable diagnosis would typically fulfil the symptoms- and (2008) signs criterion but lack echocardiography results or other objective evidence of HF. A miscoded diagnosis would show symptoms or signs of HF without objective evidence, with an echocardiography report lacking signs of HF. The diagnosis would be further contradicted by a normal ECG and / or chest X-ray without signs of HF. A diagnosis would also be classified as miscoded if neither symptoms nor clinical signs (2008) were present.

5. Ethics

This study was performed without contact with or informed consent from the patients involved, with the data presented in such a way that it was not possible to identify individual

patients. No biological material was collected from participants. The medical records were handled using the hospitals digital system, Melior and no physical copies of the patient journals were saved. The study was approved by the Regional Ethics Review board in Gothenburg 2017-03-22, registration number: 171-17.

6. Data collection procedures

Personal identification numbers were acquired for all patients who received an obesity diagnosis made at the obesity care unit (2000-2006) or at the Regional Obesity Centre (2007-2017). From these patients, all patients with a concurrent HF diagnosis were selected using international classification of disease codes (ICD10) E66 and E65 for obesity and I50 for HF. The personal identification numbers of these patients were transferred to an Excel file and were assigned an ID number used throughout the study. The key document containing personal identification numbers and corresponding ID numbers of the participants was stored in one copy on a hard drive at Sahlgrenska university hospital.

Information regarding the HF diagnosis was extracted from the medical records of each patient using a form especially designed for this study (Appendix 1) and was then transferred into an Excel document. After excluding patients where the HF diagnosis could not be validated (Figure 1), the data was transformed into an SPSS file. All statistical analyses were made using SPSS. Descriptive statistics were used to describe baseline characteristics, percentages and to calculate mean and median values and standard deviations (SD).

To check for inter observer-accuracy; five patient records were accessed in order to go through a second validation of the HF diagnosis performed by an internist. These patients were randomly selected using the RANDBETWEEN function in Excel.

7. Results

7.1. Study population

8202 patients received an obesity diagnosis code at the regional obesity center of Sahlgrenska university hospital during the period 2000 to 2017. Of these patients 77 were diagnosed with HF (before or after the obesity diagnosis) before 2017. After exclusions, the HF diagnoses of 45 patients were validated (Figure 1). Baseline characteristics of patients are shown in Table 3.

Table 3. Baseline characteristics

Characteristic	**Median**	**Number of patients n (%)**
Age at HF diagnosis (years)		
- Median (min - max)	58 (35 – 77)	
Women		15 (33.3)
Men		30 (66.7)
BMI at obesity diagnosis (kg/m^2)*		
- Median (min - max)	41.6 (29.5 – 61.0)	
- Missing values		10 (22.2)
Hospital		
- Sahlgrenska hospital		28 (62.2)
- Östra hospital		10 (22.2)
- Mölndal hospital		3 (6.67)
- Kungälv hospital		4 (8.89)
Diagnosis validated from		
- inpatient clinic		35 (77.8)
- outpatient clinic		10 (22.2)
Validated according to		
- ESC guidelines of 1995		5 (11.1)
- ESC guidelines of 2001		12 (26.7)
- ESC guidelines of 2005		11 (24.4)
- ESC guidelines of 2008		10 (22.2)
- ESC guidelines of 2012		7 (15.6)
- ESC guidelines of 2016		0 (0)

** Value taken from time of first visit to obesity center. This could be before or after HF diagnosis.*

7.2. Validity

A total of 29 cases (64.4 %) of the HF diagnoses were classified as definite, 15 (33.3 %) as probable and 1 (2.2 %) as miscoded (Table 4). The proportion of definite cases increased over time with 20.0 % in 1995, 58.3 % in 2001, 63.6 % in 2005, 70.0 % in 2008 and 100 % in 2012. There were no diagnoses of HF made during 2017 validated in this study and accordingly no diagnoses were validated according to the guidelines of 2016.

Table 4. Validity of HF diagnosis and year of ESC guidelines.

ESC guidelines	Total n	Definite n (%)	Probable n (%)	Miscoded n (%)
1995	5	1 (20.0)	4 (80.0)	0
2001	12	7 (58.3)	5 (41.6)	0
2005	11	7 (63.6)	4 (36.4)	0
2008	10	7 (70.0)	2 (20.0)	1 (10.0)
2012	7	7 (100)	0	0
2016	0			
Total validity	45	29 (64.4)	15 (33.3)	1 (2.2)

There were 35 diagnoses made at inpatient clinics and 10 diagnoses at outpatient clinics (Table 5). The proportion of definite diagnoses was 60 % and 80 % respectively.

Table 5. Validity of HF diagnosis in the inpatient- and outpatient clinic.

	Total n (%)	Definite n (%)	Probable n (%)	Miscoded n (%)
Inpatient clinic	35 (100)	21 (60.0)	13 (37.1)	1 (2.9)
Outpatient clinic	10 (100)	8 (80.0)	2 (20.0)	0 (0)

7.3. Inter-observer accuracy

5 randomly selected patients went through a secondary validation by an internist at a medicine clinic to check for inter-observer accuracy. Four of these were validated in the same way as in the primary validation, three as definite and one as probable HF. One was given to an

experienced cardiologist for further evaluation, a decision made by both the medical student in the primary validation and by the internist performing the secondary validation. This diagnosis was then classified as definite.

8. Discussion with Conclusions and Implications

8.1. Results in relation to existing literature

In this study, 64.4 % of cases were classified as definite cases of HF, 33.3 % as probable and 2.2 % as miscoded.

In the study by Ingelsson et al (20) which was performed in a much earlier setting 82 % of 317 HF diagnoses in the IPR were classified as definite, 16 % as questionable and 2 % as miscoded. For the diagnosis to be classified as definite, the presence of symptoms, signs and objective evidence of HF was required. Objective evidence was preferably from an echocardiography but could also be from an electrocardiography or from a chest X-ray in cases where an echocardiography was not performed. In our study, an X-ray showing signs of HF and a pathological electrocardiography supported the HF diagnosis but were not considered objective evidence. Hence it is likely that some cases classified as probable in our study would be classified as definite in the study by Ingelsson et al.

In a recent study published in 2017, the medical records of 712 patients diagnosed with HF after hospitalization at one of 14 different hospitals in Texas, USA, were examined (27). 19 % of these diagnoses were classified as having low probability, 33 % as medium probability and 48 % as high probability. The validation was made according to a protocol based on recent American and European guidelines for the diagnosis of HF. According to the protocol of the study, raised natriuretic peptides, echocardiography, chest x-ray, symptoms and signs were all

needed for the diagnosis to be classified as having high probability. These demands are stricter than those of our study and it is therefore likely that part of the diagnoses classified as definite in our study would be classified as having medium probability in the study by Carey SA et al. This may partly explain why our results indicate a higher validity of the HF diagnosis.

In a study by Schaufelberger et al (manuscript), 62.3 % of 965 patients hospitalized at Sahlgrenska university with a diagnosis of HF were classified as definite, 32.1 % as probable and 5.6 % as miscoded. In this study the validation was made according to the ESC guidelines using a similar protocol as the one used in our study. The results of the two studies are similar, which would indicate that the validity of HF diagnosis is not lower in obese patients compared to in the general population.

8.2. Group characteristics

Table 2 shows baseline characteristics of the patient group. The median age for HF diagnosis was 58 years. This can be compared to the median age of HF in the general population, which is between 70 – 76 years (28, 29). That the age of the study population was generally low at the time of diagnosis may affect the results of the validation. It is possible that younger patients are more extensively examined, and that the validity of the diagnosis is therefore higher in younger age groups. The design and size of this study is not appropriate to answer this question. In our study, only 33.3 % of patients were women. Due to the small size of this study, it is possible that this is only due to chance but a similar distribution between sexes is found in other studies looking at HF patients in younger age groups (3). An explanation to this may be that women have a lower prevalence of HF (1) and are diagnosed with HF later than men (28).

8.3. Comments on specific cases

It was noted during the acquisition of data from the patient journals that the level of detail in documentation was generally lower in journal notes from outpatient clinics than in those from inpatient clinics. In six cases, no record of a physical examination was found in the patient journal. Four of these patients were diagnosed with HF at an outpatient clinic. Since only 10 diagnoses made at outpatient clinics were validated, these 4 constitute a substantial portion. However, 3 of these cases could be classified as definite even without recorded signs of HF. Two diagnoses were from the period before 2008 when the signs criterion was added to the ESC guidelines and in one case, diagnosed in 2014 the patient was taking medications (candesartan) which could potentially mask the signs of HF and was therefore classified as definite in a second validation by an experienced cardiologist. Even if it is unlikely that the fact that the records from outpatient clinics were shorter and less detailed would have affected the results of this study, it is important to note this in the planning of future validation studies.

It is also worth commenting the one case of HF validated as miscoded in this study. This patient showed no symptoms of HF and an examination showed no signs of HF. There was an echocardiography performed a few months previous to the diagnosis showing reduced LVEF, which, in the absence of symptoms, was not considered sufficient to validate the diagnosis as probable. This decision was taken both in the primary validation by the medical student and in a secondary validation by an experienced cardiologist.

8.4. ESC guidelines of 2008

When validating in accordance to the ESC guidelines, the guidelines published in 2008 stand out in several ways. As previously mentioned, in 2008 clinical signs of HF were added as a mandatory criterion for the diagnosis. Regarding the criterion of objective evidence of HF this

was broadened to include cardiomegaly, third heart sound, cardiac murmurs, raised natriuretic peptide concentration or abnormality on the echocardiogram. This means that in contrast to previous and later years, it was enough for a patient to experience symptoms of HF, show signs of HF and for example show cardiomegaly on chest X-ray for the diagnosis to be classified as definite, where in previous and subsequent years cardiac dysfunction on imaging is needed for a definite diagnosis. A total of 10 cases in this study (22.2 %) were validated according to the ESC guidelines of 2008.

8.5. Limitations of the study

The major limitation of this study is the limited number of patients. With only 45 validated diagnoses we cannot draw definitive conclusions from the data. However, the results can give an indication as to whether it would be relevant to do further studies in this area.

As this study was a retrospective review of medical records, we only had access to information documented in these. The evaluation of the diagnosis depended heavily on accurate and descriptive medical notes and we could never presume to have access to the same information as the diagnosing clinician. Although the validation was made according to the ESC guidelines, a clinical judgement was needed by a medical student or by a cardiologist and the classification of the diagnoses cannot be considered completely objective. However, when checking for inter-observer accuracy the five diagnoses that went through a secondary validation were validated in the same way as in the primary validation. This indicates that inter observer accuracy was high.

8.6. Conclusion

In conclusion, this study indicates that the validity of HF diagnosis in the NPR among patients with obesity is comparable to the validity in patients without obesity. However, due to the size of the study population, further and larger studies are needed to verify these results.

9. Populärvetenskaplig sammanfattning på svenska

Hjärtsvikt är en allvarlig sjukdom med dålig prognos. Ungefär 2 % av den svenska befolkningen lider av hjärtsvikt och man har sedan 1990-talet sett en minskning av antalet nya hjärtsviktsfall, men att hjärtsvikt hos unga ökar. Hjärtsvikt har flera riskfaktorer såsom hjärtinfarkt, högt blodtryck och vissa hjärtfel, och man har i tidigare studier visat att fetma är en stark riskfaktor. Fetma, definierat som ett Body Mass Index (BMI) över 30 kg/m^2, är ett ökande hälsoproblem i befolkningen och nästan dubbelt så många individer världen över har fetma idag jämfört med på 1980-talet.

Det finns inget enskilt test som kan utföras för att ställa en hjärtsviktsdiagnos, utan diagnosen är beroende av att patienten uppvisar symptom och fynd vid en kroppsundersökning. Typiska symptom är underbenssvullnad, andfåddhet och minskad kondition. Dessa symptom finns även hos patienter med fetma vilket kan göra det svårare att ställa en hjärtsviktsdiagnos. European Society of Cardiology (ESC) publicerar regelbundet riktlinjer för behandling och diagnossättning av hjärtsvikt och tidigare studier har visat att hjärtsviktsdiagnoser i svenska patientregister stämmer väl överens med dessa riktlinjer.

Syftet med denna studie var att undersöka om patienter med fetma som även har en hjärtsviktsdiagnos verkligen har hjärtsvikt enligt ESC:s riktlinjer. Detta gjordes genom att granska patientjournaler från alla patienter som fått en fetmadiagnos på Västra Götalandsregionens regionala obesitascentrum mellan år 2000 – 2017 som även fått en hjärtsviktsdiagnos innan år 2017. Ett speciellt framtaget formulär användes för att samla information från det första tillfället med en hjärtsviktsdiagnos i patientjournalen och varje diagnos bedömdes sedan som säker, trolig eller felaktig enligt ESC:s riktlinjer. Sammanlagt undersöktes hjärtsviktsdiagnoser hos 45 patienter.

Av de 45 hjärtsviktsdiagnoser som undersöktes bedömdes 64 % som säker hjärtsvikt, 33 % som trolig hjärtsvikt och 2 % som felaktiga. Detta resultat är jämförbart med resultaten från tidigare studier som undersökt hjärtsviktsdiagnoser hos befolkningen i stort. Resultaten från denna studie tyder på att hjärtsviktsdiagnoser hos patienter med fetma är ungefär lika välställda som hos resten av befolkningen men studiens storlek gör att fler, större studier behövs för att säkerställa resultaten.

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12. Appendix

12.1. Form for extracting data from patient records

PATIENTFORMULÄR obesitas

1. Id: ..... **Granskare:** .....

2. Valideringsdatum:
(ÅÅ-MM-DD) | | | | | | |

FETMADIAGNOS

3. Fetmadiagnosdatum:
(inskrivning på obesitasmottagning)
(ÅÅ-MM-DD) | | | | | | |

4. Diagnoskod obesitasmottagning (ICD10)
E65 Lokaliserad fetma
E66.0 Extrem fetma orsakad av kaloriöverskott
E66.01 Annan fetma orsakad av kaloriöverskott
E66.1 Läkemedelsutlöst fetma
E66.2 Extrem fetma m. alevolär hypoventliation
E66.8 Annan specificerad fetma/ sjuklig fetma
E66.9 Fetma, ospecificerad | | | | | |

5.a Diagnossättning
Huvuddiagnos (1)
Bidragande diagnos (2) |

5.b Om bidragande diagnos, huvuddiagnos: | | | | | |

6.a Ev. känd obesitas sedan:
(Journalanteckning/ diagnoskod)
(ÅÅ-MM-DD) | | | | | | |

6.b Sjukhus:
(Om tidigare fetmadiagnos)
SU (öppenvård) (1) SU (slutenvård) (2)
Slutenvård inom VGR (ej SU) (3) Öppenvård inom VGR (ej SU) (4) |

6.c Mottagning:
(Fritext)
.....

7. Vikt, kg:
(en decimal) ..... kg

8. Längd, cm:
..... cm

9. Vikt inom 1 år innan diagnos:
(en decimal) ..... kg

10. Vikt inom 1 år efter diagnos:
(en decimal) ..... kg

11.a Uppgifter om bukfetma
(Kvinnor >88, män >102cm)
Ja (1)
Nej (0)
Okänt (2)
☐

11.b Om ja, hur?
Mätning (1)
Journalanteckning (2)
☐

12. Önskemål om fetmakirurgi
Ja (1)
Nej (0)
Ej lämpligt enl. läkare (2)
Okänt (3)
☐

13. Genomgått fetmakirurgi
Ja (1)
Nej (0)
Okänt (2)
☐

14.a Tidigare seriöst försök att gå ner i vikt (ex. kostförändring/ motion)
Ja (1)
Nej (0)
Okänt (2)
☐

14.b Om ja, hur?
(Fritext)
.....
.....

BAKGRUNDSINFORMATION vid index*

15. Kön
Man (0)
Kvinna (1)
☐

16. Födelseår och månad:
(ÅÅ-MM)
☐☐☐☐

17.a Civilstånd
Singel (1)
Gift/ sambo (2)
Särbo (3)
Skild (4)
Änka/änkling (5)
Annat (6)
☐

17.b Om annat, vad:
(Fritext) .....

18. Härkomst/ etnicitet
Svensk (1) Nordisk, ej Sverige (2)
Europeisk (3) Utom Europa (4)
Okänt (5)
☐

19. Antal personer i hushåll
☐

20.a Avliden (idag)
Ja (1)
Nej (0)
Okänt (2)
☐

20.b Om ja, datum:
(ÅÅ-MM-DD)
☐☐☐☐☐☐

MÄTVÄRDEN vid index*

21. Systoliskt blodtryck: ..... mmHg

22. Diastoliskt blodtryck: ..... mmHg

23. LDL: ..... mmol/L

24. HDL: ..... mmol/L

25. TG: ..... mmol/L

26. S-kolesterol/ plasmakolesterol: ..... mmol/L

27. HbA1c:
(ange enhet)
mmol/mol
eller % .....

* Index: fetmadiagnos. Använde värden närmst i tiden till inskrivning på obesitasmottagning

FETMAKIRURGI

28. Operationskod:
(Åtgärdskod, efter 1997)
JDF00 Gastroplastik
JDF01 Laparoskopisk gastroplastik
JDF10 Gastric bypass
JDF11 Laparoskopisk gastric bypass
JDF20 Magsäcksbandning
JDF21Laparoskopisk magsäcksbandning
JFD03 Duodenal bypass
JFD04 Laparoskopisk duodenal bypass
Okänt (0)

29. Ålder (i år) vid fetmakirurgi:

30. Datum för fetmakirurgi:
(ÅÅ-MM-DD)

31. Sjukhus:
(Fritext) .....

32. Klinik:
(Fritext) .....

33. Vikt, kg:
(en decimal) ..... kg

34. Vikt 1 år efter operation
(en decimal) ..... kg

Läkemedel

35.a A10 Diabetesmed
Ja (1)
Nej (0)

35.b Om ja, kod(er):

36.a C kapitlet Hjärta och kretslopp
Ja (1)
Nej (0) ☐

36.b Om ja, kod(er):

37.a N05 Neuroleptika, lugnande medel och sömnmedel
Ja (1)
Nej (0) ☐

37.b Om ja, kod(er):

38.a N06 Psykoanaleptika
Ja (1)
Nej (0) ☐

38.b Om ja, kod(er):

ÖVRIGA SJUKDOMAR

39.a Diabetes
(Diagnos i journaltext)
Ja (1)
Nej (0)
Okänt (2) ☐

39.b Om ja, år: (ÅÅ) ☐☐

39.c Om ja, typ:
Typ I (1)
Typ II (2)
Graviditetsdiabetes (3)
Okänt (4) ☐

40.a Diabetesbehandling
(Diagnos i journaltext)
Ingen behandling (1)
Kost (2)
Kost + insulin (3)
Kost + tablett (4)
Kost + tablett + insulin (5) ☐

40.b Annan injektionsbehandling
Ja (1)
Nej (0) ☐

41.a Hypertoni
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

41.b Om ja, år: (ÅÅ) ☐☐

41.c Behandling för hypertoni
Ja (1)
Nej (0) ☐

41.d om ja, hur?
(Fritext)
.....

42.a Ischemisk hjärtsjukdom
(Diagnos i journaltext)
Ja (1)
Nej (0)

42.b Om ja, år: (ÅÅ)

43.a Kardimyopatier
(Diagnos i journaltext)
Ja (1)
Nej (0)

43.b Om ja, år: (ÅÅ)

44.a Förmaksflimmer
(Diagnos i journaltext)
Ja (1)
Nej (0)

44.b Om ja, år: (ÅÅ)

45.a Hjärtsvikt
(Diagnos i journaltext)
Ja (1)
Nej (0)

45.b Om ja, år: (ÅÅ)

46.a KOL eller astma
(Diagnos i journaltext)
Ja (1)
Nej (0)

46.b Om ja, år: (ÅÅ)

47.a Stroke
(Diagnos i journaltext)
Ja (1)
Nej (0)

47.b Om ja, år:(ÅÅ)

48.a Obstruktiv sömnapné, ev. CPAP-behandling
(Diagnos i journaltext)
Ja (1)
Nej (0)

48.b Om ja, år: (ÅÅ)

49.a Lungemboli eller DVT
(Diagnos i journaltext)
Ja (1)
Nej (0)

49.b Om ja, år: (ÅÅ)

50.a Kronisk psykisk sjukdom
(Diagnos i journaltext)
Ja (1)
Nej (2)

50.b Om ja, år: (ÅÅ)

51.a Allvarlig ätstörning
(Uppgift om anorexi/ bulimi)
Anorexi(1)
Bulimi (2)
Ingen (3)

51.b Om ja, år: (ÅÅ)

52.a Hyperthyreos
(Diagnos i journaltext)
Ja (1)
Nej (0)

52.b Om ja, år: (ÅÅ)

53.a Hypothyreos
(Diagnos i journaltext)
Ja (1)
Nej (0)

53.b Om ja, år: (ÅÅ)

54.a Inflammatorisk systemsjukdom
(Diagnos i journaltext)
Ja (1)
Nej (0)

54.b Om ja, år: (ÅÅ)

55.a Njurinsufficiens
(Diagnos i journaltext)
Ja (1)
Nej (0)

55.b Om ja, år: (ÅÅ)

55.c Serum kreatinin
(om relevant)

..... µmol/L

56.a Cancersjukdom de senaste 5 åren
Ja (1)
Nej (0)

56.b Om ja, år: (ÅÅ)

56.c Om ja, vilken:
(Fritext)

.....

57. Rökare
Aldrig (1)
Aktiv (2)
Ex-rökare (Slutat minst tre månader) (3)
Okänt (4)

58.a Missbruk (Ex. alkohol, droger)
Ja (1)
Nej (0)

58.b Om ja, vilket?
(Fritext)
.....

59. Annan sjukdom eller kommentar: .....
(Fritext)
.....
.....
.....

PATIENTFORMULÄR Hjärtsvikt

Extra granskare:
(Vid svårtolkade värden) .....

60. Valideringsdatum: (ÅÅ-MM-DD) ☐☐☐☐☐☐

61. Diagnosdatum, hjärtsvikt: (ÅÅ-MM-DD) ☐☐☐☐☐☐

62. Sjukhus och klinik för epikris:
(Fritext) .....

63. Diagnossättning
Huvuddiagnos (1)
Bidiagnos (2) ☐

64. Ålder (i år) vid hjärtsvikt:
(vid epikris) ☐☐

65.a Avliden:
(Idag)
Ja (1)
Nej (0) ☐

65.b Om ja, datum:
(ÅÅ-MM-DD) ☐☐☐☐☐☐

Anamnestiska uppgifter*

66. Trötthet:
Ja (1)
Nej (0)
Okänt (2) ☐

67. Viktuppgång:
Ja (1)
Nej (0)
Okänt (2) ☐

68. Bensvullnad:
Ja (1)
Nej (0)
Okänt (2) ☐

69. Dysapné:
Ja (1)
Nej (0)
Okänt (2) ☐

70. Hosta:
Ja (1)
Nej (0)
Okänt (2) ☐

71. Ortopné:
Ja (1)
Nej (0)
Okänt (2) ☐

72. Övrigt/ kommentar:
(Fritext)

Statusfynd

73. Halsvenstas:
Ja (1)
Nej (0) ☐

74. Perifera ödem:
Ja (1)
Nej () ☐

75. Leverförstoring:
Ja (1)
Nej (0) ☐

76. Ascites:
Ja (1)
Nej (0) ☐

77. Perkussionsdämpning:
Ja (1)
Nej (0) ☐

78. Lungrassel/ krepitationer:
Ja (1)
Nej (0) ☐

79. Takypné > 20:
Ja (1)
Nej (0) ☐

80. Cyanos:
Ja (1)
Nej (0) ☐

81. Blåsljud:
Ja (1)
Nej (0) ☐

82. Tarkyardi > 90:
Ja (1)
Nej (0) ☐

83. Tredje ton:
Ja (1)
Nej (0) ☐

84. Övriga statusfynd eller kommentar:

(Fritext) .....

Genomförda undersökningar och svar

85.a UCG utfört:
Ja, transthorakalt (1)
Ja, transesofagalt (2)
Nej (0) ☐

86. Rytm: .....

87. EF: (%) .....

85.b Om ja, datum:
(ÅÅ-MM-DD ☐☐☐☐☐☐

88.VK-dialation:
(med ord)
Ja (1)
Nej (0) ☐

89.
Diameter: ..... mm

90. VK-hypertrofi:
(med ord)
Ja (1)
Nej (0) ☐

91. Klaffel:
Ja (1)
Nej (0) ☐

92. Lungvensreversering:
(med ord)
Ja (1)
Nej (0) ☐

93. Decelerationstid < 150 ms:
Ja (1)
Nej (0) ☐

94. S/D kvot < 1:
Ja (1)
Nej (0) ☐

95. E/É:
<8 (1)
8-15 (2)
> 15 (3) ☐

96. Patologisk E/A-kvot:
(med ord)
Ja (1)
Nej (0) ☐

97. Pseudonormaliserad E/A-kvot:
(med ord)
Ja (1)
Nej (0) ☐

98. E/A-kvot:
.....

99. Relaxationsstörning i vänster kammare
(med ord)
Ja (1)
Nej (0) ☐

100. Diastolisk dysfunktion:
(med ord)
Ja (1)
Nej (0) ☐

101. Vänster förmak > 40 ml/m^2
Ja (1)
Nej (0) ☐

102. Måttligt eller kraftigt förstorat
(med ord)
Ja (1)
Nej (0) ☐

103. Vänster förmak yta:
..... cm^2

104. Höger förmak dilatation
Ja (1)
Nej (0) ☐

105. Höger kammar dilatation
Ja (1)
Nej (0) ☐

106. Höger förmak yta:
..... cm^2

107. BNP/NT-proBNP (ng/l)
>2000 (1)
>1800 (2)
>900 (3)

108. BNP/NT-proBNP:
(Högsta värdet som antecknats)
..... ng/l

109. Serum kreatinin
(vid hjärtsvikt)
..... µmol/L

450–900 (4)
400–450 (5)
<400 (6)
Ej taget (7) ☐

110. Sviktbild vid lungröntgen/ CT thorax

Ja (1)
Nej (0)
Ej utfört (2) ☐

111. EKG

Ja (1)
Nej (0) ☐

112. Rytm

SR (1)
FF (2)
PM-ryt (3)
Övrigt (4) ☐

113. QRS-bredd:

..... ms

114. Patologiskt EKG

Ja (1)
Nej (0) ☐

115. LBBB:

Ja (1)
Nej (0) ☐

116. RBBB:

Ja (1)
Nej (0) ☐

117. Patologisk Q-våg:

Ja (1)
Nej (0) ☐

118. VK-hypertrofi:

Ja (1)
Nej (0) ☐

119. Pat. R-vågsprogression:

Ja (1)
Nej (0) ☐

120. Förlängd QTC-tid:

Ja (1)
Nej (0) ☐

121. ST-förändringar:

Ja (1)
Nej (0) ☐

122. T-förändringar:

Ja (1)
Nej (0) ☐

123. Positivt svar på behandling:

Ja (1)
Nej (0)
Okänt (2) ☐

124.a Hjärtscintigrafi

Ja (1)
Nej (0) ☐

125.a MR-hjärta:

Ja (1)
Nej (0) ☐

124.b Om ja:
(Kommentar) .....

125.b Om ja:
(Kommentar) .....

126.a Anemi
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

127. Koronarangiografi

Ja (1)
Nej (0) ☐

126.b Om ja, HB:
.....
g/l

127.b Om ja:
(Kommentar) .....

128. Övriga kommentarer:
(fritext)
.....

.....

.....

.....

.....

.....

.....

ÖVRIGA SJUKDOMAR, hjärtsvikt

129. Diabetes
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

130. Hypertoni
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

131. Ischemisk hjärtsjukdom
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

132. Kardimyopatier
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

133. Förmaksflimmer/ fladder
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

134. Obstruktiv sömnapné, ev. CPAP-behandling
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

135. KOL eller astma
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

136. Hyperthyreos
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

137. Inflammatorisk systemsjukdom
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

138. Hypothyreos
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

139. Njurinsufficiens
(Diagnos i journaltext)
Ja (1)
Nej (0) ☐

140. Serum kreatinin
(om relevant)

..... µmol/L

141. Missbruk (Ex. alkohol, droger)
Ja (1)
Nej (0) ☐

142. Annan sjukdom eller kommentar:
(Fritext)

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