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Management of patients with chronic obstructive lung disease, Type 2 diabetes and both diseases in primary care in Denmark

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ABSTRACT

INTRODUCTION: We studied the implementation of recommended yearly control visits, quality of care and characteristics and co-morbidities of patients with chronic obstructive lung disease (COPD), Type 2 diabetes mellitus (T2DM) and those with both conditions in a sample of Danish general practices.

METHODS: This was a retrospective audit of patient records from 2017 in 164 general practices in Denmark. Up to 15 patients were randomly selected in each practice for assessment of relevant parameters and quality of care, producing a total of 820 patients with COPD, 823 patients with T2DM and 709 patients with both COPD and T2DM.

RESULTS: Formalised annual control visits were completed in 72% of the patients with T2DM and 48% of the patients with COPD. Approximately 13% of the patients were followed by a specialist. Patients with both diseases had the highest number of healthcare contacts but the lowest fulfilment of annual control visits. The standard of care was fair, although assessment of the disease characteristics of COPD was less complete in patients with both conditions. Cardiovascular diseases including heart failure were significantly more common in patients with both conditions (42%) than in those with COPD only (29%) or T2DM only (27%).

CONCLUSIONS: In 2017, the implementation of annual control visits for COPD was less complete than for T2DM. Patients with both diseases had the highest prevalence of cardiovascular disease and use of health resources, suggesting that this group needs additional attention.

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TRIAL REGISTRATION: not relevant.

The prevalence of both chronic obstructive lung disease (COPD) and Type 2 diabetes mellitus (T2DM) in Denmark has been increasing for some decades [1-6]. GPs play an important role in the management of these diseases; and for more than five years, formalised annual control visits have been recommended in order to review treatment and promote self-management [7]. In the most recent collective agreement between the GPs and the public healthcare system (OK18), both COPD and T2DM were given a special status as the compensation to doctors was standardised and constitutes a fixed annual payment regardless of the number of consultations [7, 8]. It is planned that in the future, a higher proportion of patients should be followed by their GP rather than in hospital-based outpatient clinics.

The purpose of this study was to assess the quality of care including the implementation of formalised annual control visits for patients with COPD, T2DM and both conditions in 2017, before the implementation of OK18, in a representative sample of Danish general practices.

METHODS

We aimed to recruit approximately 165 GPs. To ensure a representative sample, we included GPs from all of Denmark, including both city and countryside practices and a mix of various types of GP clinics: solo practices, companionships and occupational clinics. In total, 477 GPs were invited among whom 173 initially accepted to participate with 164 individual GPs eventually completing data collection. Invitation to participate was distributed by the sponsor's local representatives from August 2018 to March 2019. GPs reported their cooperation with the sponsor, Boehringer Ingelheim, to the Danish Medicines Agency. They had to use of one of the most frequently used electronic patient journal (EPJ) systems and have used the International Classification of Primary Care, Second Edition (ICPC-2) since 2016 [9]. Compared with all Danish GPs, the participating doctors were of similar age (52 years), were based in clinics with a comparable number of doctors per clinic (1.7 doctor/clinic in the present study versus 1.9 doctor/clinic in all of Denmark) and were more often men than women (57% versus 47%).

Patients and variables

The participating GPs produced three lists of patients: COPD (R-95), T2D (T90) and concomitant COPD and T2D (R95 + T90). When possible, the search comprised only patients assigned to the participating GP. In few cases, the search comprised all patients in the companionship clinic. The search lists were manually confirmed by the participating GPs to ensure that they contained patients who were actively assigned to the clinic. Nursing home residents were excluded as the treatment goals, including the possibility of conducting the annual formalised control visit for these patients, may differ from those of the rest of the population.

In order to be included, patients should have been diagnosed with COPD and/or T2DM prior to 1 January 2017. Among the patients meeting the inclusion criteria, five patients were selected at random per group per clinic. If fewer than five patients were identified, data were registered for

all patients in the group. The selection was based on random computerised selection prior to any data capture. The GPs manually revised all contacts in 2017 and registered if the contact was focused on COPD, T2DM or "other". When the GP identified the contact as a formalised annual control visit made within the 12 months from the day of registration, the contact was registered as an annual control visit. Such a visit is usually planned months ahead and focuses on long-term treatment goals, life-style factors and adherence to medications, including correct inhalation or injection technique. This contrasts acute and subacute visits which address acute problems like exacerbations or infections. In the present study, the GPs themselves decided if an annual formalised control visit had been performed.

Information on demographics, clinical characteristics, co-morbidities and prescribed medication was retrieved from the record, regardless of whether it was collected at a formalised control visit or in connection with another visit. The information was anonymised and entered into a secured database from 5 November 2018 to 12 April 2019.

Statistical analysis

Descriptive analyses were performed using percentage of population for categorical variables and mean (± standard deviation) for continuous variables. For statistical tests, the Kruskal-Wallis test was used for continuous variables and Pearson's chi-squared test for categorical variables. All statistical tests were assessed using a nominal two-sided significance level of 5%. No adjustment for multiplicity was performed.

Funding source

The present study was sponsored by Boehringer Ingelheim Denmark. It was a non-drug, non-interventional study, and approval from the scientific ethical committee and the Danish Medicines Agency were not mandatory. The protocol for the study was reviewed by the Danish College of General Practitioners' (DSAM) Multi-Practice Committee (MPU 13-2018).

Trial registration: not relevant.

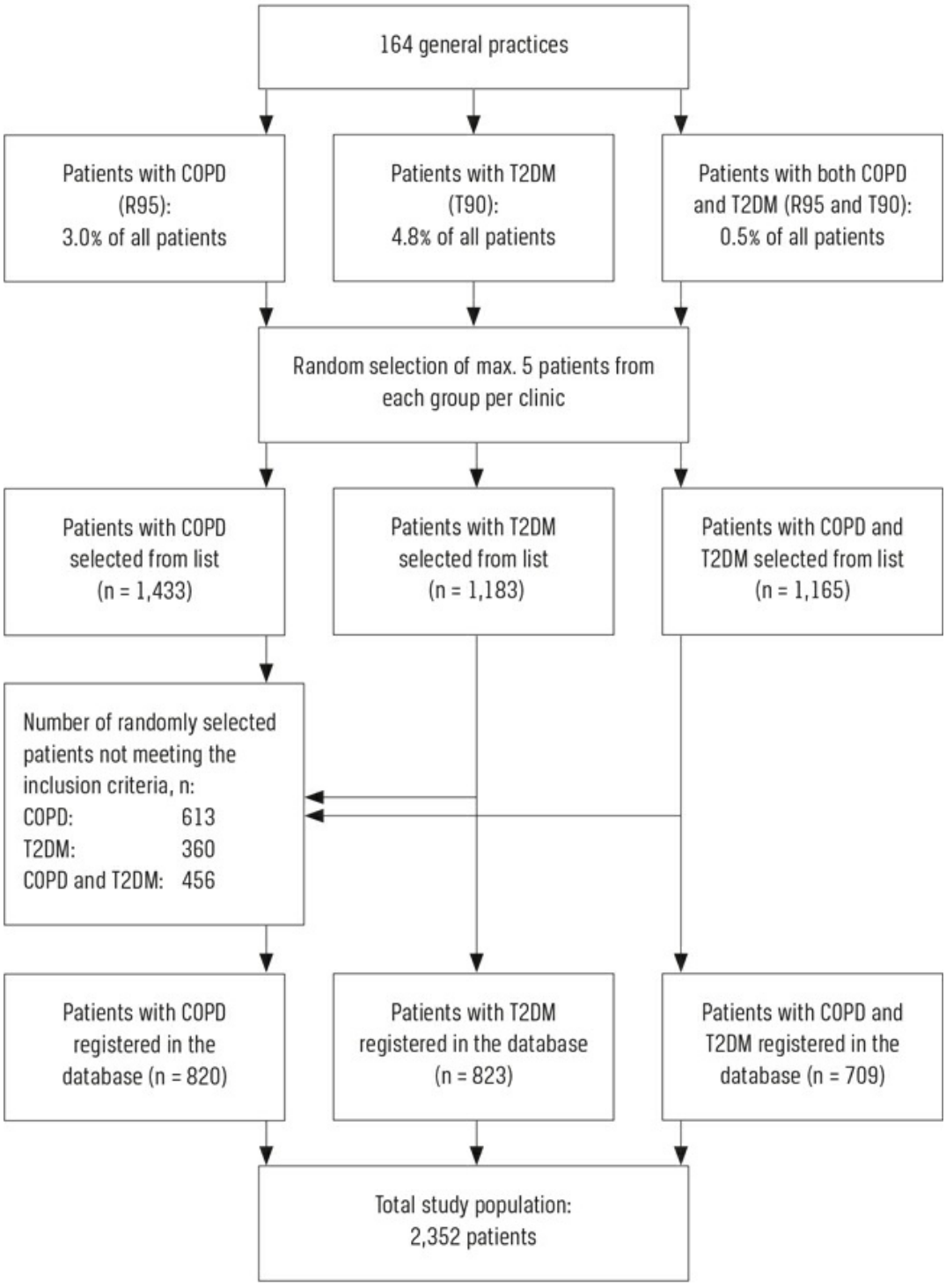
RESULTS

In total, 164 GPs completed data registration, producing 820 patients with COPD, 823 patients with T2DM and 709 patients with both diseases. These 2,352 patients constituted the study population. The flow chart describing recruitment of the records for the study is shown in **Figure 1**.

On average, patients with T2DM were younger, had a higher BMI and were less often smokers and alcohol abusers than those with COPD (**Table 1**). Patients with COPD had a higher cholesterol blood level than those with T2DM. In general, those with both COPD and T2DM showed characteristics that were in between the characteristics in patients with only one disease. In those with both COPD and T2DM, information on dyspnoea and consequently on the Global Initiative for COPD A-D classification was more often missing [10]. Patients with concomitant T2DM and COPD

and patients with T2DM only were similarly well controlled with respect to glycaemic control and prevalence of retinopathy, whereas elevated urinary albumin and peripheral neuropathy were significantly more common in patients with both conditions than in those with T2DM only.

FIGURE 1 / Flow chart describing the selection of the electronic patient records.



COPD = chronic obstructive pulmonary disease; T2DM = Type 2 diabetes mellitus.

Co-morbidities, formalised annual control visits and other healthcare utilisation are shown in **Table 2.** Musculoskeletal disease and ischaemic heart disease, heart failure and peripheral atherosclerosis were significantly more prevalent in patients with both diseases, whereas osteoporosis was significantly less common in those with T2DM only and highest in those with COPD only. COPD was associated with concomitant asthma, whereas the prevalence of dementia and psychiatric disease did not differ between the three groups. Prevalence of at least one cardiovascular co-morbidity was slightly higher in patients with COPD than in those with T2DM (29% versus 27%) (Table 2).

Approximately 72% of the patients with T2DM had attended the formalised annual control visit for their diabetes, whereas only 48% of COPD patients received a similar control visit for their COPD (Table 2). Patients with both conditions had the highest number of contacts to their GP and admissions to hospital. Yet, the formalised annual control visits showed a non-significantly lower fulfilment for T2DM (69% versus 72%) and a significantly lower fulfilment for COPD (42% versus 48%). Approximately 12-13% of the patients were followed by specialists without differences between the three groups (Table 2).

The duration of COPD and T2DM and the treatment of the patients are depicted in **Table 3.** Vaccination against influenza was more common in patients with both diseases than in those with COPD only, whereas no difference was seen with regards to pneumococcal vaccine.

TABLE 1 / General characteristics of participants by presence of chronic obstructive pulmonary disease and Type 2 diabetes and both conditions.

	COPD (N = 820)	T2DM (N = 823)	T2DM and COPD (N = 709)	p-value[a]
General characteristics				
Male sex, n (%)	414 (50.5)	458 (55.7)	424 (59.8)	0.0012
Age, yrs, mean (± SD)	70.6 (± 10.3)	67.5 (± 11.8)	71.7 (± 9.2)	< 0.0001
BMI, kg/m², mean (± SD)	25.9 (± 5.1)	30.4 (± 7.1)	30.0 (± 6.4)	< 0.0001
Smoking, %:				< 0.0001
Never	6.0	41.6	8.6	
Former	49.5	27.9	48.1	
Current	38.8	13.9	35.5	
Unknown	5.7	16.6	7.8	
Alcohol abuse according to assessment of the GP, n (%)	83 (10.1)	35 (4.3)	48 (6.8)	< 0.0001
Cardiovascular risk				
Blood pressure, mmHg, mean (± SD):				
Systolic	133 (± 16)	132 (± 13)	131 (± 15)	0.0133
Diastolic	79 (± 10)	78 (± 10)	76 (± 10)	< 0.0001
eGFR, n (%):				0.0004
> 90 ml/min./1.73 m²	216 (26.3)	238 (28.9)	154 (21.7)	
60-90 ml/min./1.73 m²	425 (51.8)	403 (49.0)	351 (49.5)	
30-59 ml/min./1.73 m²	131 (16.0)	148 (18.0)	170 (24.0)	
< 30 ml/min./1.73 m²	48 (5.9)	34 (4.1)	34 (4.8)	
Cholesterol, mmol/l, mean (± SD):				
Total	4.9 (± 1.1)	4.2 (± 1.1)	4.1 (± 1.0)	< 0.0001
LDL	2.7 (± 0.9)	2.0 (± 0.9)	1.9 (± 0.8)	< 0.0001
HDL	1.6 (± 0.5)	1.3 (± 0.4)	1.3 (± 0.4)	< 0.0001
COPD assessment				
FEV1, % of predicted value, mean (± SD)	64.4 (± 21.7)	-	65.4 (± 20.7)	0.4961
FEV1/FVC, %, mean (± SD)	58.1 (± 12.8)	-	62.8 (± 12.3)	< 0.0001
COPD exacerbations, n (%):				
Patients with ≥ 1 examination	106 (13.1)	-	93 (13.2)	0.9188
Patients hospitalised for examination	67 (8.3)	-	76 (10.8)	0.0893
MRC dyspnoea score, %:				0.0053
1-2	41.5	-	34.3	
3-5	25.9	-	26.0	
Unknown	32.7	-	39.8	
GOLD classification, %				0.0244
A	39.8	-	32.4	
B	18.8	-	20.7	
C	2.9	-	3.2	
D	8.9	-	7.9	
Unknown	29.6	-	35.7	
Diabetes assessment				
HbA_{1c}, mmol/mol, mean (± SD)	-	53 (± 13)	52 (± 13)	0.0807
Albuminuria class, n (%):				0.0232
Normoalbuminuria	-	500 (73.4)	385 (65.5)	
Microalbuminuria	-	149 (21.9)	169 (28.7)	
Macroalbuminuria	-	32 (4.7)	34 (5.8)	
Unknown	-	142 (17.3)	121 (17.1)	
Diabetic retinal changes, n (%)	-	66 (8.9)	47 (7.6)	0.3599
Peripheral neuropathy, n (%)	-	128 (16.8)	149 (23.2)	0.0023

COPD = chronic obstructive pulmonary disease; eGFR = estimated glomerular filtration rate; FEV1 = forced expiratory volume in 1st sec.; FVC = forced vital capacity; GOLD = Global Initiative for Chronic Obstructive Lung Disease; HbA_{1c} = glycated haemoglobin; HDL = high-density lipoprotein; LDL = low-density lipoprotein; MRC = Medical Research Council; SD = standard deviation; T2DM = Type 2 diabetes mellitus.
a) Kruskal-Wallis test for continuous variables and Pearson's χ^2-test for categorical variables.

TABLE 2 / Co-morbidities and utilisation of health resources in 2017.

	COPD (N = 820)	T2DM (N = 823)	T2DM and COPD (N = 709)	p-value[a]
Co-morbidities, n (%)				
Ischaemic heart disease:				
With angina	50 (6.1)	57 (6.9)	69 (9.7)	0.0205
Without angina	56 (6.9)	63 (7.7)	113 (16.0)	< 0.0001
Previous MI	34 (4.2)	56 (6.8)	98 (13.8)	< 0.0001
Heart failure	62 (7.6)	55 (6.7)	96 (13.6)	< 0.0001
Peripheral atherosclerosis	99 (12.1)	71 (8.6)	119 (16.8)	< 0.0001
Previous TCI or stroke	63 (7.7)	70 (8.5)	70 (9.9)	0.3182
≥ 1 cardiovascular morbidity	236 (28.8)	218 (26.5)	296 (41.7)	< 0.0001
Osteoporosis	137 (16.9)	28 (3.4)	75 (10.7)	< 0.0001
Musculoskeletal disease	174 (21.3)	170 (20.7)	193 (27.4)	0.0032
Psychiatric disease	100 (12.2)	92 (11.2)	92 (13.0)	0.5603
Dementia	20 (2.4)	21 (2.6)	19 (2.7)	0.9577
Asthma	104 (12.7)	31 (3.8)	77 (10.9)	< 0.0001
Healthcare utilisation in 2017				
General practice, n, mean (± SD):				
Contacts due to diabetes	-	4.3 (± 3.6)	4.6 (± 4.1)	0.3364
Contacts due to COPD	3.1 (± 4.7)	-	2.7 (± 3.3)	0.0011
Contacts for other problems	8.7 (± 9.5)	7.8 (± 8.5)	9.5 (± 9.1)	< 0.0001
Total contacts in general practice	11.7 (± 11.3)	12.1 (± 9.6)	16.8 (± 11.1)	< 0.0001
Hospital admissions in 2017, n (± SD)	0.3 (± 0.9)	0.3 (± 1.1)	0.5 (± 1.0)	< 0.0001
Patients with yearly control in 2017, n (%):				
Control of diabetes	-	591 (71.8)	490 (69.1)	0.1582
Control of COPD	397 (48.4)	-	294 (41.5)	0.0058
Patients followed by specialists, n (%):				
Endocrinologist	-	108 (13.1)	87 (12.3)	0.6052
Pulmonologist	101 (12.3)	-	91 (12.8)	0.7526

COPD = chronic obstructive pulmonary disease; MI = myocardial infarction; SD = standard deviation; T2DM = Type 2 diabetes mellitus; TCI = transitory cerebral ischaemia.

a) Kruskal-Wallis test for continuous variables and Pearson's $\chi 2$-test for categorical variables.

TABLE 3 / Duration of disease and treatment.

	COPD (N = 820)	T2DM (N = 823)	T2DM and COPD (N = 709)	p-value[a]
Duration of COPD, %				0.2594
⟨ 2 yrs	1.1	-	2.1	
2-5 yrs	32.8	-	32.7	
5-10 yrs	46.9	-	44.0	
⟩ 10 yrs	19.1	-	21.2	
Treatment of COPD, n (%)				
Vaccinations:				
Influenza	527 (64.5)	-	512 (72.3)	0.0011
Pneumococcae	247 (30.4)	-	209 (29.6)	0.7296
Inhaled medications:				
SABA	367 (44.8)	-	336 (47.4)	0.3026
LABA	95 (11.6)	-	84 (11.8)	0.8736
LAMA	214 (26.1)	-	174 (24.5)	0.4857
LABA/LAMA	254 (31.0)	-	188 (26.5)	0.0551
ICS	72 (8.8)	-	73 (10.3)	0.3131
ICS/LABA	182 (22.2)	-	173 (24.4)	0.3084
ICS/LABA/LAMA	33 (4.0)	-	31 (4.4)	0.7348
Duration of T2DM, %				0.6468
⟨ 2 yrs	-	1.2	1.7	
2-5 yrs	-	23.3	23.2	
5-10 yrs	-	41.6	39.1	
⟩ 10 yrs	-	33.9	36.0	
Glucose-lowering treatment, n (%)				
Nonpharmacological treatment alone	-	86 (10.4)	103 (14.5)	0.0155
Metformin	-	607 (73.8)	487 (68.7)	0.0287
Sulfonylurea	-	61 (7.4)	30 (4.2)	0.0086
DPP-4 inhibitor	-	164 (19.9)	104 (14.7)	0.0069
SGLT2-inhibitor	-	143 (17.4)	90 (12.7)	0.0110
GLP-1 inhibitor	-	82 (10.0)	72 (10.2)	0.9010
Insulin	-	151 (18.3)	166 (23.4)	0.0147
Treatment of cardiovascular disease, n (%)				
ACEI/ARB inhibitor	-	502 (61.0)	440 (62.1)	0.6699
Calcium antagonist	-	267 (32.4)	237 (33.4)	0.6824
Beta blocker	-	210 (25.5)	200 (28.2)	0.2410
Tiazide diuretics	-	238 (28.9)	200 (28.2)	0.7591
Loop diuretics	-	112 (13.6)	220 (31.0)	⟨ 0.0001
Aldosteron antagonist	-	46 (5.6)	50 (7.1)	0.2388
Statins	-	591 (71.8)	530 (74.8)	0.1949
Anticoagulant/antiplatelet treatment	-	343 (41.7)	399 (56.3)	⟨ 0.0001

ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; = COPD = chronic obstructive pulmonary disease; DPP = dipeptidyl peptidase; GLP = glucagon-like peptide; ICS = inhaled corticosteroid; LABA = long-acting beta-agonist; LAMA = long-acting antimuscarinic agent; SABA = short-acting beta-agonist; SGLT = sodium-glucose transport protein; T2DM = Type 2 diabetes mellitus.
a) Kruskal-Wallis test for continuous variables and Pearson's χ^2-test for categorical variables.

There were no differences regarding treatment with inhaled medications between those with COPD only and those with both COPD and T2DM. More than 90% received treatment including a long-acting bronchodilator, whereas 35% among patients with COPD only and 39% among those

with both diseases were treated with an inhaled corticosteroid (ICS) (Table 3). Use of ICS in patients without asthma or exacerbations reached 19% in those with COPD and 23% in those with both COPD and T2DM. Approximately 10% received ICS without a long-acting antimuscarinic receptor antagonist with no differences between those with COPD/T2DM and COPD alone. Approximately 21% were treated with three maintenance inhaled medications.

Approximately 70% of patients with T2DM were treated with metformin in combination with other drugs with no difference between those with T2DM only and those with both T2DM and COPD (Table 3). However, more patients with both T2DM and COPD received non-pharmacological treatment only, and fewer patients in this group were treated with sodium-glucose transport protein 2 inhibitors, despite a high proportion with cardiovascular co-morbidities in this group (Table 2 and Table 3). Most patients with T2DM received lipid-lowering treatment (> 72%) and antihypertensive medication.

DISCUSSION

This nationwide survey of electronic patient records in primary care in Denmark showed that although the standards of care for COPD and T2DM in 2017 were mostly in accordance with national guidelines, the formalised annual control visits were significantly more often fulfilled for T2DM (in approximately 70% of the patients) than for COPD (in approximately 45% of the patients). Thus, although the care of COPD in general practice has moved from episodic assessments during an exacerbation to a more continual care and although care had improved since 2013 [11], our study shows that COPD management still lacks behind the care for T2DM. This may have several explanations. Firstly, the management programmes describing the standard care for diabetes in primary practice were introduced earlier than the similar programmes for COPD. Secondly, it may also reflect previous findings that the GPs find it more difficult to provide care for COPD than for T2DM [12]. The distinction between patients with COPD and those with asthma or asthma-COPD overlap is imprecise, and the presence of reversibility in COPD can be confusing. In addition, the treatment goals are more vaguely defined in COPD, where a biomarker reflecting the overall standard of care like glycated haemoglobin (HbA_{1C}) is not available and therefore the treatment goals are processes like smoking cessation support, correct use of inhalers and participation in pulmonary rehabilitation. It will be interesting to follow the progress of management of both COPD and T2DM, including the implementation of the annual control visits in the future, after establishment of the cooperating GP clusters following the OK18.

Both T2DM and COPD are conditions associated with a high risk of developing cardiovascular complications [13, 14]. In our study, the percentage of patients with at least one cardiovascular co-morbidity was 29%, 27% and 42% in COPD, T2DM and in those with both diseases, respectively. Despite this, there seems to be less focus on cardiovascular co-morbidity among patients with COPD, even though we observed not only a higher prevalence of smoking but also higher cholesterol values.

Our results show that the assessment of disease characteristics of COPD was more often missing in individuals with concomitant COPD and T2DM than in patients with COPD only. Patients with both COPD and T2DM also had the highest use of health resources and the highest prevalence of cardiovascular disease, albuminuria and peripheral neuropathy, the latter finding being in keeping with earlier observations [15, 16]. Even though a Dutch study conducted in a primary care setting failed to find any negative influence of COPD on the longitudinal progression of HbA_{1C} in patients with diabetes, a recent Danish study suggested that use of inhaled steroids may be associated with an increased risk of developing diabetes [17-20]. Overall, our observations suggest that patients with both COPD and T2DM should be given additional focus.

For both COPD and T2DM, lifestyle interventions, particularly smoking cessation, play a very important role. It is therefore disappointing that so many patients included in the present study were still smokers. We do not have information on smoking cessation interventions in the present dataset, but previous Danish studies indicate that prescription of antismoking medications for COPD patients is underused and that the incidence of both COPD and T2DM in previously healthy smokers is unfortunately not associated with an increased chance of stopping smoking [18, 19]. Our findings confirm that there is still a need to focus on smoking cessation in these patients.

The cornerstone of medical treatment of COPD is long-acting bronchodilatation, which was provided to more than 90% of the patients in the present study. Treatment with ICS is recommended only in patients with frequent exacerbations or in those with concomitant asthma [10]. Thus, in the present study, approximately 20% of the patients could probably have done without ICS.

In T2DM, standard care is multifactorial based on lifestyle modification in combination with medical treatment. With respect to glycaemia, metformin is the first choice in all patients who tolerate it, often in combination with a broad choice of second-line drugs. In the present study, approximately 70% of the patients were treated with such a combination.

A major limitation of the present study is the fact that although we know the proportion of the patients who are followed by endocrinologists or pulmonologist, we do not know if these specialists performed annual control visits, but this is likely and improves the fulfilment of the annual control visits for both conditions by the participating GPs. Yet, as the percentage of the patients followed by the specialists was similar for COPD and T2DM, this lack of information is very unlikely to change our main observation of fewer annual control visits in patients with COPD than in patients with T2DM. Another limitation is that the GPs were not included at random. Although we aimed to prevent selection bias by contacting a broad geographical organisational range of the GPS, those who agreed to participate had a special interest in the two diseases, and this will most likely produce a better standard of care than in Denmark as whole. In addition, GPs who did not wish to participate in studies sponsored by medical companies were not included, and this bias may also result in a non-representative sampling. Finally, we did not include patients treated for either COPD or T2DM, but not diagnosed with these diseases by the participating GP.

We assume that inclusion of such patients will reduce the fulfilment of the formalised annual control visits.

CONCLUSIONS

In 2017, the implementation of formalised annual control visits in Danish general practice was much higher for T2DM than for COPD. Although patients with both T2DM and COPD had the highest prevalence of cardiovascular disease and the highest number of contacts with their GPs, important aspects of COPD were less often registered in this group, suggesting that in multimorbid patients, some disease characteristics of the individual diseases may be overlooked. As the organisation of the GPs into cooperating clusters has been implemented from 2018 as part of OK18, it will be interesting to monitor the quality of care for T2DM and COPD in the coming years.

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