ISSN: 2754-4745

Journal of Physical Medicine Rehabilitation Studies & Reports

SCIENTIFIC Research and Community

Research Article

Open Access

Smoking Cessation Intervention (SCI) in Patients with Type 2 Diabetes Mellitus - a Cohort Study

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ABSTRACT

Rehabilitation programs for patients diagnosed with Type 2 diabetes mellitus (T2DM) include smoking cessation to reduce development of complications and pre-mortality. This study aimed to compare successful smoking cessation after the intensive 6-week Gold Standard Program (GSP) among smokers with and without T2DM in Denmark. Additionally, we evaluated predictors of successful quitting.

This register-based cohort study evaluated data from a total of 38,776 patients collected over a decade via the Danish STOPbase for Tobacco & Nicotine from 252 Stop-Units across Denmark. A further 1,373 (4%) did not consent to the 6-month follow-up or had died/immigrated and were not part of this study. In the Danish National Patient Registry, 1,400 patients were diagnosed with T2DM prior to participating in the GSP and the control group of 36,888 patients had no diagnosis of diabetes. In addition, 488 patients had other types of diabetes and were excluded. The follow-up rates were about two thirds in the T2DM and the control groups; 67.3 % (942/1,400) and 68.6% (25,312/36,888), respectively.

After 6 months, the continuous abstinence rate was 25.3% and 24.9% (adjusted OR 1.09; 95% CI 0.94-1.26) for the T2DM and control groups, and the 14-day point prevalence was 29.4% and 29.2% (adjusted OR 1.08; 95% CI 0.93-1.25). Compliance, measured as meeting adherence, was the strongest predictor of successful quitting (adjusted OR 3.27; 95% CI: 3.07-3.49).

In conclusion, after participation in the GSP for 6 months, there was no statistical difference in successful quitting between patients with and without T2DM; therefore, we rejected the hypothesis. Compliance was the utmost important predictor of successful smoking cessation.

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Received: October 12, 2024; **Accepted:** October 17, 2024; **Published:** November 07, 2024

Keywords: Tobacco, Type 2 Diabetes Mellitus, Smoking Cessation Intervention, Successful Quitting

Introduction

Worldwide, smoking is still one of the most important risk factors for burden of diseases and adds significantly to the risk of complications as well as to the overall mortality among patients with type 2 diabetes mellitus (T2DM) [1, 2]. Smoking even seems to be an independent risk factor for this patient group, as the overall mortality is still significantly increased after addressing other risk factors, including cardiovascular diseases. In addition, smoking cessation reduces the mortality by about 30% in this patient group, for both men and women [3].

Several studies have evaluated the effect of a comprehensive rehabilitation program including smoking cessation intervention (SCI) for patients with T2DM and found significant effect on developing minor and major complications as well as mortality, short and long term. Amongst these was the early Danish Steno-II RCT [4, 5]. Today, smoking cessation is an important part of managing T2DM and has increasingly been recommended in national and international guidelines [6, 7].

To obtain the best outcome, SCIs with the highest successful quit rates would be preferable for patients with T2DM. Overall, intensive SCIs combining motivational and pharmaceutical support with patient education delivered over at least four sessions and subsequent follow-up are superior to briefer interventions [8]. Among patients with T2DM, this brief intervention did not change the quit rates or glycemic control at 12 months follow-up compared to the control group, neither as a stand-alone treatment or as part of a multiple intervention [9, 10].

In Denmark, the intensive 6-week Gold Standard Program (GSP), with follow-up after six months, is the standard intervention delivered free of charge by trained therapists at Stop-Units spanning the entire country and mainly in primary health care settings [11]. These Stop-Units report data collected on smoking

history and socio-demographic profile, compliance, use of pharmaceutical support and follow-up for all individual participants, after informed consent, to the national STOP-base for Tobacco & Nicotine (previously named the Smoking Cessation Database [12].

The aim of this study was to compare 6-month successful smoking cessation in a cohort of smokers with and without T2DM following completion of the intensive 6-week Gold Standard Program (GSP). Additionally, we evaluated predictors of successful quitting. The hypothesis was that given the additional disease burden of smokers diagnosed with T2DM compared to smokers without, the T2DM group would be more likely to quit than other smokers.

Materials and Methods

Inclusion criteria were daily smokers over 18 years of age, registered in the STOPbase, and participated in the GSP from 2006 to 2016. A total of 1,373 (4%) did not consent to the 6-month follow-up or had died/immigrated and were not part of this study, thereby leaving a total of 38,776 patients to be looked up for a diabetes diagnosis in the Danish National Patient Register. After excluding 488 with diabetes type 1 (ICD-DE10) and other diabetes diagnosis (DE12-14 and DO24), the cohort included 1,400 persons with T2DM (DE11) and 36,888 without this diagnosis (figure 1). The characteristics showed that the T2DM group included more males, heavy and disadvantaged smokers, retirees, those who had no or short education, lived alone, and were unemployed (table 1).

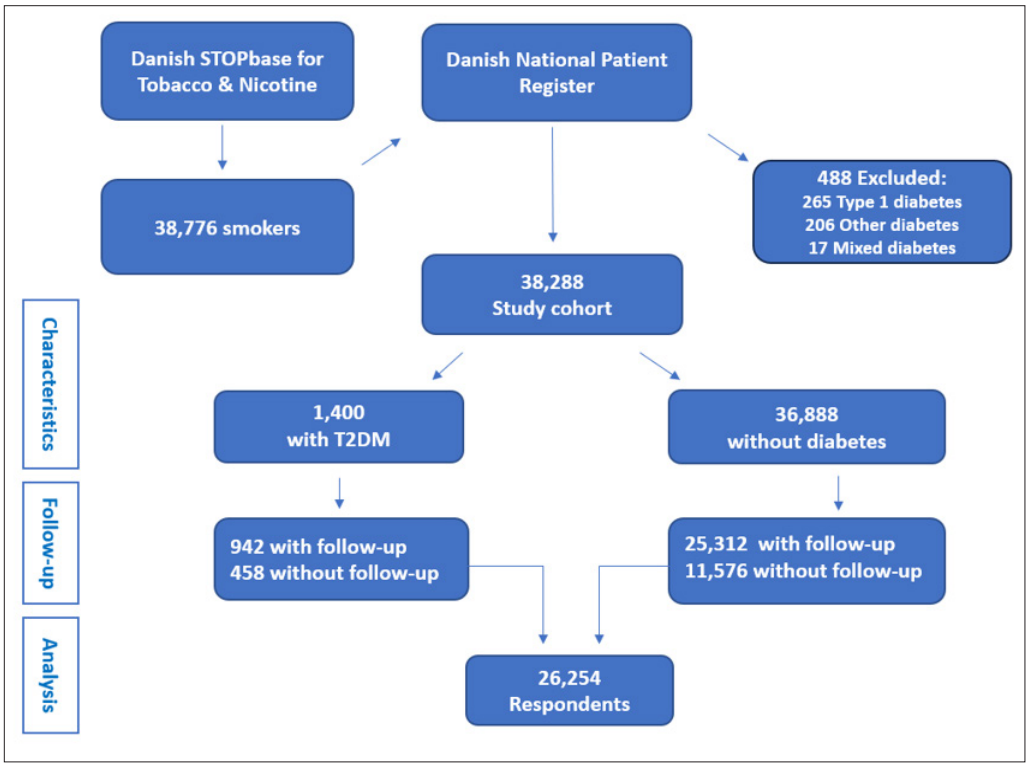

Figure 1: Flowchart detailing the Study Population Inclusion

Table 1: Baseline Characteristics in n and %; T2: Type 2; FNDS: Fagerström Nicotine Dependency Score

	T2 Diabetes (n =1,400)	Control (n = 36,888)	Total (n = 38,288)
Age			
18 - 35 years	39 (2.8%)	7,145 (19.4%)	7,184 (18.8%)
36 - 64 years	894 (63.9%)	24,549 (66.6%)	25,443 (66.5%)
65 years or above	467 (33.4%)	5,194 (14.1%)	5,661 (14.8%)
Missing	0 (0%)	0 (0%)	0 (0%)
Sex			
Men	783 (55.9%)	14,926 (40.5%)	15,709 (41.0%)
Women	617 (44.1%)	21,962 (59.5%)	22,579 (59.0%)
Employment			
Employed	358 (25.6%)	20,721 (56.2%)	21,079 (55.1%)
Unemployed	475 (33.9%)	6,994 (19.0%)	7,469 (19.5%)
Studying	10 (0.7%)	1,728 (4.7%)	1,738 (4.5%)
Retired	519 (37.1%)	6,375 (17.3%)	6,894 (18.0%)
Missing	38 (2.7%)	1,070 (2.9%)	1,108 (2.9%)

Education			
No or short education	511 (36.5%)	10,361 (28.1%)	10,872 (28.4%)
Medium	258 (18.4%)	7,711 (20.9%)	7,969 (20.8%)
High	555 (39.6%)	17,479 (47.4%)	18,034 (47.1%)
Missing	76 (5.4%)	1,337 (3.6%)	1,413 (3.7%)
Heavy Smokers (> 20 cigarettes daily and/or > 20 packyears and/or FNDS > 7)			
No	127 (9.1%)	8,488 (23.0%)	8,615 (22.5%)
Yes	1,237 (88.4%)	27,535 (74.6%)	28,772 (75.1%)
Missing	36 (2.6%)	865 (2.3%)	901 (2.4%)
Disadvantaged Smokers (unemployed and/or no and short education)			
No	590 (42.1%)	21,169 (57.4%)	21,759 (56.8%)
Yes	757 (54.1%)	14,254 (38.6%)	15,011 (39.2%)
Missing	53 (3.8%)	1,465 (4.0%)	1,518 (4.0%)
Living with Smoker			
No	976 (69.7%)	24,521 (66.5%)	25,497 (66.6%)
Yes	409 (29.2%)	12,028 (32.6%)	12,437 (32.5%)
Missing	15 (1.1%)	339 (0.9%)	354 (0.9%)
Quit Attempts			
None	542 (38.7%)	14,193 (38.5%)	14,735 (38.5%)
1-3 Attempts	700 (50.0%)	18,263 (49.5%)	18,963 (49.5%)
More than 3 Attempts	118 (8.4%)	3,657 (9.9%)	3,775 (9.9%)
Missing	40 (2.9%)	775 (2.1%)	815 (2.1%)
Compliance (> 75% of the scheduled sessions)			
No	535 (38.2%)	14,163 (38.4%)	14,698 (38.4%)
Yes	848 (60.6%)	22,267 (60.4%)	23,115 (60.4%)
Missing	17 (1.2%)	458 (1.2%)	475 (1.2%)
Gold Standard Program Course Format			
Individual	357 (25.5%)	6,616 (17.9%)	6,973 (18.2%)
Group	1,043 (74.5%)	30,272 (82.1%)	31,315 (81.8%)
Missing	0 (0%)	0 (0%)	0 (0%)
Healthcare Recommendation			
No	207 (14.8%)	13,783 (37.4%)	13,990 (36.5%)
Yes	1,142 (81.6%)	21,397 (58.0%)	22,539 (58.9%)
Missing	51 (3.6%)	1,708 (4.6%)	1,759 (4.6%)

Outcome Measurements

The primary outcome was 6-month continuous abstinence, measured as continuous abstinence rate, which was defined as no smoking at all after participating in the GSP. The smoking status was collected via a structured telephone interview by experienced therapists after 6 months (5-7 months). This manual-based follow-up procedure included four telephone attempts of which one would have to take place outside working hours. The secondary outcome measure was 14-day point prevalence of smoking abstinence collected at the same follow-up interview.

Data Collection

Baseline data from the STOPbase included demographic and socio-economic information as well as the smoking history and details of the intervention such as meeting adherence, group or individual format, use of pharmaceutical support (table 1) [13]. Heavy smoking was defined by smoking at least 20 cigarettes per day and/or at least 20 packyears and/or a Fagerström nicotine dependency score of at least 7 on a 10-step Likert scale. In addition, disadvantaged smokers were defined by having no job and/or no and short education, while compliance was measured as meeting adherence, considering at least 75% as complete compliance (table 1) [13].

Similarly, the outcome data were also extracted from the STOPbase. The online registration process with the STOPbase provided automatic data validation and ensured that only requisite information was entered [14].

Data on the T2DM diagnosis were collected from the Danish National Patient Register (NPR) characterized by robust data quality, including examinations and treatment of diabetes [15].

The continuous abstinence rate and 14-day point prevalence were presented as crude rates. The Chi2 analysis was utilized to test for significant relationship of all variables against continuous quitting and followed by a multiple logistic regression model to adjust for confounders and test for significant predictors.

A power estimate indicated that 329-1377 in each group would be relevant to identify a difference based on 5% significance level and a power of 80% [11].

The results were presented as odds ratios (OR) with 95% confidence interval (CI). A CI not including "1" was considered

statistically significant. The statistical analyses were conducted utilizing R® version 4.3.0.

Ethical Considerations

We worked with data collected from the STOPbase for Tobacco & Nicotine, Central Person Register and the National Patient Register. At birth or upon immigration, all Danish residents are assigned a unique 10-digit personal identification number known as a central person register (CPR) number with information on the sex and date of birth of the individual. The STOPbase was established in 2001 and CPR numbers have been included since 2006. All persons in the STOPbase participated after giving informed consent.

This project was approved by the Danish Data Protection Agency (P-2021-900)/2014-41-3370/2010-41-5463/2000-54-0013) and considered by the Scientific Ethical Committee of the Capital Region (2021-685 27/ HC-FSP-2010-049), and they had no comments.

Results

A total of 26,254 persons were followed up. The quit rates for continuous abstinence were 25.3% and 24.9% for the T2DM and control groups, respectively with an adjusted OR of 1.09 (95% CI: 0.94-1.26). Secondly, the point prevalence abstinence rate was 29.4% and 29.2%, respectively with an adjusted OR 1.08 (95% CI: 0.93-1.25) (Figure 2).

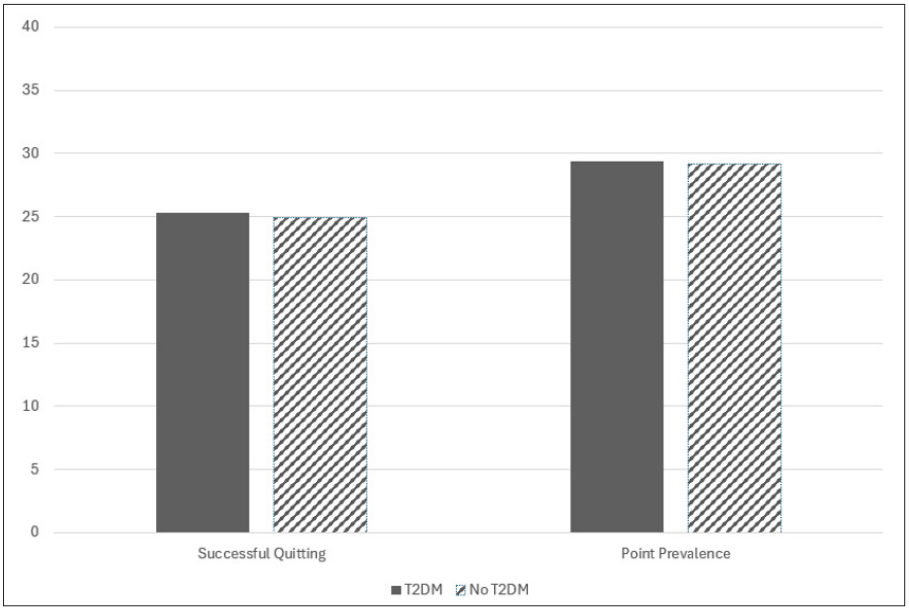

Figure 2: Successful Quitting and Point Prevalence Data for Study Population

Among the predictors for successful continuous quitting, compliance, defined as participating in at least 75% of the GSP sessions, was the strongest positive predictor; adjusted OR 3.27 (CI 3.07 – 3.49). Other significant positive predictors were belonging to the 36-64 age group, making > 3 attempts to quit prior to the GSP, following the individual course format, participation in GSP at a pharmacy setting, and the intervention period of 2011-2016. In contrast, the negative predictors were being a woman, a heavy or disadvantaged smoker, living with a smoker, and being recommended to smoking cessation intervention by the health care staff (table 2).

Table 2: Predictors for 6-Month Continuous Abstinence Post-Participation in the GSP

	Adjust. Odds Ratio	p-value	95%, Confidence Interval
Type 2 Diabetes	1.09	0.266	0.94 - 1.26
Age			
18 - 35 years	1		
36 - 64 years	1.20	<0.001	1.11 - 1.30
65 or older	1.08	0.154	0.97 - 1.20
Sex			
Men	1		
Women	0.86	<0.001	0.81-0.91
Smoking Status			
Not a Heavy Smoker	1		
Heavy Smoker	0.76	<0.001	0.71-0.82
Disadvantaged Smoker	0.82	<0.001	0.77-0.86
Living with Smoker	0.91	0.001	0.85-0.96

Quit Attempts			
No quit attempts	1		
1-3 quit attempts	1.01	0.713	0.95-1.07
3+ quit attempts	1.17	0.002	1.06-1.29
Setting for GSP			
Municipality	1		
Pharmacy	1.10	0.027	1.01-1.19
Hospital	1.05	0.365	0.94-1.18
General Practice clinic	1.57	0.110	0.90-2.72
Private	1.06	0.735	0.76-1.48
Individual	1.23	<0.001	1.14-1.33
Being compliant			
No	1		
Yes	3.27	<0.001	3.07-3.49
Healthcare staff recommendation			
No	1		
Yes	0.88	<0.001	0.83-0.94
Intervention period			
2006 - 2010	1		
2011 - 2016	1.09	<0.001	1.02 - 1.16

Discussion

Although we hypothesized that T2DM patients would be more successful in quitting, which they were by the smallest of margins, there was no significant difference of the continuous abstinence rate for patients with and without T2DM at follow-up after participating in the intensive GSP, delivered free of charge in Stop-units dispersed across entire Denmark. The main predictor for successful smoking quitting was meeting adherence above 75%.

In Europe, T2DM has become one of the most significant public health challenges where 6.8% of the adult population has T2DM and is responsible for one in ten deaths. Moreover, chronic NCDs, specifically type 2 diabetes mellitus, are on the front-line and have placed an inordinate burden on national health systems due to the large number of T2DM cases, chronic treatment measures, and the high cost of diabetes related complications [16]. Quitting smoking can reduce the risk of these complications and prevent proliferation of smoking related diseases among this patient group already burdened by T2DM.

The level of successful quitting varies among the different types of smoking cessation interventions. Overall, the more intensive the intervention, the higher the effect. This is also the case among patients with diabetes [8, 17-19].

The GSP has been shown similar high successful smoking cessation rates when previously evaluated in randomized controlled trials compared to control groups receiving no or minor interventions [20-24].

After implementation nationwide, the cohort studies on the intensive GSP have shown only minor differences for patients with and without having a specific diagnosis, such as cancer, arthritis, severe mental disease, being pregnant, disadvantaged, and heavy smokers [14, 25-29]. These robust results might indicate that the intensive GSP itself might impact the outcome more than specific diseases and conditions of smokers in practice.

A recent scoping review reported conflicting results after behavioral intervention [30].

Overall, three of eight randomized trials showed significant differences of briefer interventions, like 5As, and motivational interviewing compared to the control groups while five other trials did not [9, 31-37].

The three studies with significant effects had the longest intervention, most sessions and additional nicotine replacement therapy. However, the successful quit rates were lower than the rates of the present study evaluating the intensive GSP.

The majority of the predictors in this GSP study would not be modifiable. However, it seems both possible and beneficial to increase compliance, measured as meeting adherence during the intensive GSP. Moreover, when implementing SCIs, it is important to develop and evaluate new ways of keeping those who have already started such intensive programs on board in order for them to reap the long-term, positive health implications of smoking cessation.

Despite being of statistical significance, the other predictors seem to have lesser clinical significance. For instance, more than four out of five participants were recommended to quit smoking by clinical staff, and these patients had a slightly lower quit rate compared to those not recommended to stop smoking by healthcare staff. However, a minor benefit in quit rates by advising clinical staff to not recommend smoking cessation to patients would be followed by more deleterious consequences due to a reduced number of patients undergoing smoking cessation intervention. Similarly, delivering "individual" instead of "group" interventions would amount to 3-4-fold higher costs per patient. In practice, the extra resource consumption would probably result in a reduction of the total number of patients undertaking smoking cessation intervention.

Bias and Limitations

The premise that SCIs in Denmark are offered at no charge and without requiring a referral from a healthcare provider can reduce selection bias. However, gaining access to SCIs may be easier for smokers belonging to a higher socio-economic status than those from lower socio-economic strata. Moreover, the study population was obtained from a national database to which both public and private facilities reported, which again limits selection bias.

The smoking status was not validated by carbon monoxide or cotinine analyses, and some over-estimation may have been a reality, probably impacting both groups similarly. However, the collection by trained therapists via structured interviews was considered a strength compared to having the patients filling in a questionnaire [38].

The completeness of data was high, ranging from 95-100% in the STOPbase. To limit potential misclassification of participants, we utilized ICD-10 codes to classify patients and included only those with a T2DM diagnosis in our diabetic group [11]. However, the likelihood that our control group may have included persons with undiagnosed T2DM could not be ruled out completely.

Another bias could be attributed to one-third of the patients dropping out, mostly due to non-respondents and others not wishing to be contacted. This could have an impact on actual quit rates based on the initial study population since we have no means of determining the outcome among the dropouts. On the other hand, we still had a large study cohort. More importantly, completeness of data was high, ranging from 95-100%. Also, smoking cessation clinics/settings from municipalities across all of Denmark reported into the STOPbase, and this data was collected systematically, both key factors in terms of minimizing selection bias.

It would have strengthened the level of evidence to use a randomized design. The feasibility of conducting an RCT in this setting in Denmark could raise ethical issues regarding having a control group of smokers not receiving or benefitting from an already implemented standard smoking cessation program. Still, the different settings could have been randomized, which we are evaluating in an ongoing randomized sub-study for another patient group [39].

Extrapolating the results to other parts of the world should be done only when considering different cultural traditions, lifestyle, education levels, employment status, smoking habits, social norms, economic conditions, access to health care and similar smoking cessation programs, and the cost of accessing health care in many parts of the globe.

Perspectives

The GSP enabled one in four of the study population to stop smoking, and hence derive long-term benefits of remaining smoke-free, as seen in patients with and without T2DM in this study. These patients stand to gain from improved health overall, both physical and emotional [40, 41]. In addition, their families and other persons in their network would benefit by abstaining from second-hand smoking.

The clinical implications are clear; physicians and health care providers have an obligation to caution their patients with diabetes about the added risk posed by smoking and the major benefit of quitting [42]. Clinicians should recommend and support all diabetic smokers to enter the most effective SCI.

In terms of the impact on health care systems, successful smoking cessation may result in these patients with diabetes requiring fewer clinic visits, avoiding hospital readmissions, and reducing healthcare needs overall for this vulnerable group. This is turn diminishes the burden on health care systems and costs incurred resulting from having to care for patients who suffer from complications related to the combination of T2DM and smoking. It allows health care resources to be reallocated to areas of need such as treating patients with other debilitating medical conditions and acute or more chronic health issues. Also, health care staff can be trained and/or redirected to serve other health care needs.

For society at large, the implications of improved health outcomes for diabetic smokers who have quit smoking, and the resulting reduced disease burden, is a boon to their overall well-being, these working adults taking less sick time or premature retirement, and thereby increasing productivity. The possibility to utilize medical resources, freed up due to better health of these former smokers, to serve other unmet medical needs of the community is a significant serendipity culminating from them successfully participating in an intensive smoking cessation intervention such as the Gold Standard Program.

Future research should evaluate if an intensive SCI designed specifically for smokers with T2DM would have an even better effect than the standardized GSP. The cost-effectiveness of such intensive programs has mainly been established in high-income countries, and it would be very relevant to evaluate this in middle and low-income countries.

In conclusion, we did not find any differences in successful quitting at six months, after participating in the intensive 6-week Gold Standard Program, for patients with and without T2DM. About one in four stayed continuously abstinent over the 6-month period. Compliance was the most important predictor of successful smoking cessation.

Declarations

Ethics Approval and Consent to Participate

This project was approved by the Danish Data Protection Agency (P-2021-900)/2014-41-3370/2010-41-5463/2000-54-0013) and considered by the Scientific Ethical Committee of the Capital Region (2021-685 27/ HC-FSP-2010-049), and they had no comments. All patients provided informed consent for follow-up after treatment.

Consent for Publication

Not applicable

Availability of Data and Materials

The datasets generated and analyzed during the current study are not publicly available since these are from the Danish STOPbase for Tobacco & Nicotine and Danish National Patient Register. However, upon reasonable request, the corresponding author and co-authors will assist requests in keeping with patient privacy guidelines and Danish STOPbase & Danish National Patient Register regulations.

Competing Interests

There are no conflicts of interest in this study. The funders had no influence on the study design, analyses, interpretation of results, writing of the manuscript or publication of this article.

Funding
Study research was funded by the Parker Institute at Bispebjerg and Frederiksberg Hospital is supported by a core grant from the Oak Foundation (#OFIL 24-074). The funders did not participate in any shape or form in this study.

Authors' Contributions
RSQ came up with the study concept of evaluating smoking cessation in Danish smokers with and without type 2 diabetes, following which, HT contributed to the study design while MR extracted relevant data from the Danish STOPbase & National Patient Register and provided data sets to RSQ. Both MR and RSQ analyzed the patient data; RSQ wrote the initial study manuscript for his Master of Medical Science thesis at Lund University, Sweden after which HT, MR & RSQ contributed to adapting the original manuscript for publication in its current form. All authors have read/agreed to the final version of the manuscript and meet the criteria for authorship. This work has not been previously presented at a conference or published as a conference abstract, and neither is it under consideration for publication elsewhere.

Acknowledgements
The authors extend their sincere appreciation to patients who participated in the Gold Standard Program without which this study could not have been conceptualized, implemented and completed. Also, we wish to thank the Secretariat of the Danish STOPbase for Tobacco & Nicotine for their support.

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