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Lavikainen, Piia

2020-12

Lavikainen , P , Aarnio , E , Niskanen , L , Mäntyselkä , P & Martikainen , J 2020 , ' Short-term impact of co-payment level increase on the use of medication and patient-reported outcomes in Finnish patients with type 2 diabetes ' , Health Policy , vol. 124 , no. 12 , pp. 1310-1316 . https://doi.org/10.1016/j.healthpol.2020.08.001

http://hdl.handle.net/10138/325227
https://doi.org/10.1016/j.healthpol.2020.08.001

Health Policy 124 (2020) 1310–1316

Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Short-term impact of co-payment level increase on the use of medication and patient-reported outcomes in Finnish patients with type 2 diabetes

Piia Lavikainen[a,*], Emma Aarnio[a], Leo Niskanen[b], Pekka Mäntyselkä[c,d], Janne Martikainen[a]

[a] School of Pharmacy, University of Eastern Finland, P.O. Box 1627, FI-70211, Kuopio, Finland
[b] Internal Medicine, Päijät-Häme Central Hospital, P.O. BOX, FI-15850 Lahti, Finland
[c] Institute of Public Health and Clinical Nutrition, General Practice, University of Eastern Finland, P.O. Box 1627, FI-70211, Kuopio, Finland
[d] Primary Health Care Unit, Kuopio University Hospital, P.O. Box 100, FI-70029, Kuopio, Finland

ARTICLE INFO

Article history:
Received 4 March 2019
Received in revised form 8 May 2020
Accepted 3 August 2020

Keywords:
Type 2 diabetes
Co-payment increase
Patient-reported outcomes

ABSTRACT

A new reimbursement scheme for non-insulin medications used for treatment of hyperglycemia in type 2 diabetes (T2D) was implemented in Finland on January 1, 2017. The aim of the study was to evaluate the impact of this co-payment increase (i.e. + 35 percentage points) on patient-reported satisfaction for diabetes care, diabetes medication use, and financial difficulties. Baseline data were collected in 114 pharmacies, where patients with T2D were asked to fill in a questionnaire in November 2016. Follow-ups were conducted at 6 and 12 months. In total, 955 participants with T2D attended the baseline examination. During the follow-up, satisfaction with diabetes care decreased significantly ($p < 0.001$). Use of insulin increased (OR 1.16, 95 % CI 1.06–1.27) whereas use of metformin and DPP-4 inhibitors decreased (metformin: OR 0.80, 95 % CI 0.70–0.90; DPP-4 inhibitors: OR 0.82, 95 % CI 0.73–0.93). Financial difficulties with the purchase of diabetes medications were reported more often both at 6 (OR 2.44, 95 % CI 1.96–3.03) and at 12 months (OR 2.70, 95 % CI 2.18–3.35) than at baseline. These negative short-term effects require future studies. If persistent, the long-term effects of lower treatment satisfaction and increased financial difficulties may imply impaired metabolic control and increased diabetes complication risk and health care costs. Patient perspective should be taken into account in future policy making.

1. Introduction

Diabetes is one of the most significant diseases worldwide with an estimated 425 million adults suffering from it in 2017 [1]. It is a lifelong disease that affects quality of life, introduces comorbidities and increases mortality risk [2]. In 2016, 364 000 persons out of 5.5 million Finnish inhabitants (6.6 %) received reimbursement for diabetes medications and the large majority of them (257 000) had type 2 diabetes (T2D). For diabetes medications other than insulin, the corresponding figure was 308 000. In Finland, the number of persons with T2D has increased linearly during the 20th century and at this growth rate half a million persons with T2D diagnosis will be sinister reality by the year 2030.

When compared with other Nordic countries, consumption of diabetes medications is high in Finland [3] leading to high pharmaceutical expenditure. Currently, diabetes care accounts for around 15 % of the total expenditure of Finnish health care system [2]. According to the Finnish Diabetes Association, the pharmaceutical costs were about 32 % of the direct health care costs of the diabetes care or around 9 % of the total costs (i.e. including both direct and productivity costs) of diabetes in 2011 [4]. Due to cost containment pressures, the Finnish Government set an aim of EUR 150 million savings in medicine reimbursement expenditure [5–7]. One of the actions was an implementation of a new special reimbursement scheme (SRS) increasing the co-payment level of T2D patients by 35 percentage points in Finland on January 1, 2017 aiming to EUR 20 million savings [5–7]. Reimbursement of non-insulin diabetes medications was lowered to be on the same level as of cardiovascular medications. The new SRS resulted in EUR 26 million (24 %) short-term savings in total medication reimbursement costs for the Finnish health care system, but the co-payments of T2D patients more than tripled (from EUR 11.9 million to EUR 39.7

* Corresponding author at: Faculty of Health Sciences, School of Pharmacy, University of Eastern Finland, P.O. Box 1627, FI-70211, Kuopio, Finland.
E-mail addresses: piia.lavikainen@uef.fi (P. Lavikainen), emma.aarnio@uef.fi (E. Aarnio), leo.niskanen@fimnet.fi (L. Niskanen), pekka.mantyselka@uef.fi (P. Mäntyselkä), janne.martikainen@uef.fi (J. Martikainen).

https://doi.org/10.1016/j.healthpol.2020.08.001

million, +334 %) after the first year of new legislation coming into effect [8].

In previous international studies, co-payment increases related to diabetes medications has been associated with decreased use of [9,10] and lowered adherence to diabetes medications [11–13], and therefore, with impaired glycemic control [11,13].

Currently little is known about the effects of significantly increasing co-payments on patient-reported outcomes, such as, treatment satisfaction or financial difficulties with the purchase of medications prescribed by physicians. However, this kind of patient perspective data could have policy relevant implications for future co-payment policies. Therefore, the aim of the present study is to evaluate the effect of the above policy change on the patient-reported outcomes of satisfaction with diabetes care, utilization of diabetes medications, as well as financial difficulties with the purchase of diabetes medications.

2. Materials and methods

2.1. Setting

In Finland, all residents are eligible for reimbursement for prescription medications purchased from community pharmacies under the Health Insurance Act [14]. There are three reimbursement categories based on medical grounds [15]. Since 2016, 40 % of the medication cost in the Basic Refund Category, 65 % of the cost in the Lower and 100 % of the cost in the Higher Special Refund Categories are reimbursed by the National Health Insurance Scheme [14,15]. Reimbursements are available after an initial deductible EUR 50 per calendar year. In the Higher Special Refund Category the patient pays a EUR 4.50 co-payment for each purchased medication. However, if patient's co-payments exceed a certain limit during a calendar year (EUR 610.37 in 2016 and EUR 605.13 in 2017), the patient becomes eligible for an Additional Refund. After reaching the Additional Refund limit, the patient pays EUR 2.50 co-payment for each purchased medication until the end of the calendar year, the Social Insurance Institution (SII) covers the remaining costs.

The Pharmaceuticals Pricing Board grants the approvals for reimbursement for medicinal products [15]. To be entitled to a special reimbursement for medication costs, the patient must have a certain severe and chronic disease, such as diabetes fulfilling the medical criteria defined by the SII. A medical certificate must be submitted to the SII by a physician to confirm the need for the medication. To be entitled to special reimbursement for antidiabetic medications other than insulin, the SII requires the patient to have confirmed diabetes based on at least one of the following criteria: fasting plasma glucose ≥7.0 mmol/l (whole blood ≥6.1 mmol/l), a random venous plasma glucose concentration ≥11.1 mmol/l (whole blood ≥10.0 mmol/l), 2 -h plasma glucose ≥11.1 mmol/l (whole blood ≥10.0 mmol/l) in an oral glucose tolerance test, or HbA1c ≥48 mmol/mol. In addition, to receive special reimbursement for GLP-1 analogues, other antidiabetic medications need to be first tried and the patient has to have a BMI ≥ 30 kg/m^2.

On January 1, 2017 the reimbursement level of antidiabetic medications other than insulin was changed from Higher (100 %) to Lower Special Refund Category (65 %) due to the Government Programme to achieve savings in medication costs [5–8]. Thus, the new SRS introduced a co-payment of 35 % of the cost of each purchased non-insulin medication for T2D patients instead of a fixed EUR 4.50 co-payment for each purchased medication in 2016.

2.2. Study design

In the present study, data were collected from 114 community pharmacies covering all geographical areas in Finland. Potential study participants were identified in pharmacies through examinations of purchased medications and checking available reimbursement codes in their personal health insurance card during their pharmacy visit. Data consisted of a baseline examination conducted in November 2016 prior to the implementation of the new SRS (January 1, 2017) and 6- and 12-month follow-up examinations conducted in May and November in 2017. Electronic structured questionnaires (filled with a mobile tablet) were used at the baseline and, at that time, participants were asked to choose between electronic questionnaire and phone interviews for 6- and 12-month follow-up examinations.

According to the local and national ethical instructions for research (Finnish Advisory Board on Research Integrity: http://www.tenk.fi/en/request-for-ethical-review-in-human-sciences), this study did not require ethical approval. The autonomy of research subjects was respected, there was informed consent, no harm was possible for the subjects and confidentiality of the subjects, and research data was protected.

2.3. Patient-reported outcomes

Use of diabetes medications was measured as a self-reported use of insulin (Anatomical Therapeutic Chemical (ATC) classification code [16] A10A), metformin (A10BA02), sulfonylureas (A10BB), combinations of oral blood glucose (BG) lowering drugs (A10BD), glitazones (A10BG), DPP-4 inhibitors (A10BH, gliptins), glinides (A10BX02), GLP-1 analogues (A10BJ), and SGLT2 inhibitors (A10BK) at the time of the data collection. Patient-reported reasons for changes in diabetes medication use were measured with insulin and non-insulin related structured questions providing alternative classes for reasons, such as effectiveness of the medication, suitability of the treatment, changes in need for the treatment, financial issues, or other reasons.

Patient-reported satisfaction with diabetes care during the past 6 months was measured with a 1–10 scale, where the lowest value (1) indicated full dissatisfaction and the highest (10) perfect satisfaction with diabetes care. Financial difficulties with the purchase of diabetes medication prescribed by physician during the last 6 months was measured with a binary variable indicating at least some problems or no problems at all.

2.4. Covariates

Background factors considered were age, gender, education (basic education/vocational upper secondary education and training/post-secondary non-higher vocational education/matriculation examination/university or polytechnic degree), and household monthly net income (EUR < 1000, EUR 1000–1999, EUR 2000–2999, EUR 3000–3999, EUR ≥ 4000). Diabetes complications at baseline were defined as an indicator (yes/no) of existence of at least one of the following patient-reported complications: diabetic retinopathy, neuropathy, nephropathy, symptoms of peripheral vascular disease (intermittent claudication), history of foot ulcer(s), myocardial infarction, or stroke. Baseline use of diabetes medications were also considered as covariates.

2.5. Statistical methods

Independent samples *t*-test was applied to test differences in satisfaction to diabetes care between those who experienced at least some financial difficulties in purchasing diabetes medications and those who did not experience difficulties at all.

Linear mixed models were applied to examine changes in diabetes care satisfaction during the follow-up. Linear mixed models allowed for person-specific random intercepts (variance components model) meaning that a participant was allowed to have

Table 1
Characteristics of T2D persons who attended baseline examination (n = 955) as frequencies and proportions unless otherwise stated.

	Baseline participants (n = 955)
Age, mean (SD)	65.2 (10.2)
Female	460 (48.2)
Duration of diabetes	
<1 year	42 (4.4)
1 year	26 (2.7)
2–5 years	232 (24.3)
6–10 years	312 (32.7)
11–20 years	253 (26.5)
>20 years	90 (9.4)
BMI, mean (SD)	31.3 (6.1)
<24.99	127 (13.4)
25.00–29.99	296 (31.1)
30.00–34.99	292 (30.7)
35.00–39.99	155 (16.3)
40 or over	81 (8.5)
Missing	4
Smoking status	
Current smoker	148 (15.5)
Former smoker	374 (39.2)
Never smoked	433 (45.3)
Education	
Basic education or other	379 (39.7)
Vocational upper secondary education and training	185 (19.4)
Post-secondary non-higher vocational education	222 (23.3)
Matriculation examination	59 (6.2)
University or polytechnic degree	110 (11.5)
Household monthly net income, EUR	
<1000	107 (11.2)
1000–1999	362 (37.9)
2000–2999	254 (26.6)
3000–3999	108 (11.3)
≥4000	124 (13.0)
Diabetes complications	300 (31.4)
Diabetic retinopathy	119 (12.5)
Neuropathy	102 (10.7)
Myocardial infarction	67 (7.0)
Symptoms of peripheral vascular disease (intermittent claudication)	50 (5.2)
History of foot ulcer(s)	45 (4.7)
Nephropathy	27 (2.8)
Stroke	27 (2.8)
Comorbidities	
Amblyopia, cataract or glaucoma	155 (16.2)
Coronary heart disease	157 (16.4)
Antihypertensive medication	764 (80.0)
Cholesterol medication	643 (67.3)
No comorbidities	328 (34.3)

his/her own level of satisfaction at the baseline. Changes in diabetes medication use and financial problems experienced were estimated with generalized estimation equations (GEE) for repeated measures logistic regression models. Unstructured covariance matrix and robust covariance matrix estimator were applied in all GEE-based analyses. Interaction effects between age and income were tested in all models but term was omitted from the final models because it failed to reach statistical significance.

Statistical analyses were performed with IBM SPSS Statistics version 24.0 (SPSS, Inc., Chicago, IL, USA) and SAS version 9.4 (SAS Institute Inc., Cary, North-Carolina, USA).

3. Results

In total, 955 participants with T2D attended the baseline examination in November 2016. Of those, 855 (85.5 %) agreed to attend to the follow-up examinations (Supplementary Fig. 1). Among the baseline examination participants (n = 955), mean (SD) age was 65.2 years (10.2) and 51.8 % were male (Table 1). Roughly a third (35.9 %) had had T2D for over 10 years and roughly half (49.1 %) had a household monthly net income less than EUR 2000. Three out of ten (31.4 %) of the participants had experienced diabetes complications at the baseline of which diabetic retinopathy and neuropathy were the most common ones (experienced by 12.5 % and 10.7 % of the baseline participants, respectively). Around a third (34.3 %) had no other comorbidities at baseline, 16.4 % had coronary heart disease, and 16.2 % had amblyopia, cataract or glaucoma. Eight out of ten participants used hypertension medication and 67.3 % cholesterol medication at baseline.

Mean (SD) satisfaction to diabetes care was 8.20 (1.63) before, 7.89 (1.77) at 6 months after and 7.95 (1.75) at 12 months after the co-payment increase (Table 2). Mean satisfaction decreased significantly at 6 months (−0.34 units; SE 0.07) and 12 months after the co-payment increase (−0.28; SE 0.07) (Fig. 1A). Baseline metformin use was associated with higher satisfaction to diabetes care than non-use (Supplementary Table 1). Matriculation examination and university or polytechnic degree educations were associated with lower satisfaction than basic education.

Metformin was used by 76.1 % of the participants at baseline, 72.4 % at 6 months after and 71.6 % at 12 months after the co-payment level increase (Table 2). The corresponding figures for DPP-4 inhibitors (gliptins) were 36.1 %, 30.3 %, and 32.2 %, respectively. At 12 months, the probability of using metformin was 0.80-times (95 % confidence interval, CI, 0.70–0.90) of that at baseline, and the probability of using DPP-4 inhibitors 0.82-times (95 % CI 0.73–0.93) of that at baseline (Fig. 2). The use of GLP-1 analogues first decreased from 9.2 % to 6.6 % (odds ratio, OR, 0.73, 95 % CI, 0.58–0.93) between the baseline and the 6-month follow-up examination, but then returned to its baseline level (8.8 %, OR 0.95, 95 % CI 0.76–1.19 when compared with baseline use). Similarly, the use of SGLT2 inhibitors decreased initially, but stabilised thereafter. Use of insulin increased from baseline (29.6 %) to 34.4 % at 6-month and 33.8 % at 12-month examinations. Use of insulin at the 12-month examination was 1.16-times (95 % CI 1.06–1.27) more likely than at the baseline (Fig. 2). Women used less insulin than men (OR 0.64, 95 % CI 0.49–0.85) (Supplementary Table 2). Adjusting the analyses also for use of other diabetes medications at baseline as well as existence of diabetes complications at baseline did not alter the results (Supplementary table 3). However, those who had experienced diabetes complications at baseline were less likely to use metformin over time, but there was no interaction with time. On the contrary, insulin use was more likely among those who had complications at baseline. Seven and half per cent (4/53) of new-users of insulin reported that insulin treatment was started because it was more affordable. More than a fourth (27.7 % or 36/130) of patients who had discontinued non-insulin medication use reported they had done it due to financial reasons. Due to low proportions of users of sulfonylureas, glitazones, and glinides (Table 2), effects of the co-payment increase to the utilization of these drugs was not analyzed.

At least some financial difficulties with the purchase of diabetes medications was experienced by 16.5 % of the participants at baseline, increasing to 30.0 % at 6 months and 33.0 % at 12 months after the co-payment level increase (Table 2). Probability of experiencing at least some financial difficulties with the purchase of diabetes medication was 2.44-fold (95 % CI 1.96–3.03) 6 months after the co-payment increase when compared with the baseline probability (Fig. 1B). The change remained on its level at 12 months. Older age decreased the probability of experiencing at least some financial difficulties (OR 0.95, 95 % CI 0.94–0.96) (Supplementary Table 4). Patients in the lowest net income categories were more likely to experience at least some financial difficulties when compared with persons in the highest net income category (EUR ≥ 4000). Use of GLP-1 analogues (OR 2.37, 95 % CI 1.47–3.84), combinations of oral BG lowering drugs (OR 2.22, 95 % CI 1.38–3.58), DPP-4 inhibitors (OR 2.09, 95 % CI 1.51–2.88), and SGLT2 inhibitors (OR

Table 2
Satisfaction with current diabetes care, use of diabetes medications, and financial difficulties experienced at study waves as frequencies and proportions unless otherwise stated.

	Baseline (n = 955)	6 months (n = 633)	12 months (n = 603)
Mean satisfaction with current diabetes care (SD)	8.20 (1.6)	7.89 (1.8)	7.95 (1.8)
Missing	0 (0)	10 (1.6)	2 (0.0)
Use of insulin	283 (29.6)	218 (34.4)	204 (33.8)
Use of non-insulin diabetes medication	929 (97.3)	603 (95.3)	574 (95.2)
Metformin	727 (76.1)	458 (72.4)	432 (71.6)
DPP-4 inhibitors	345 (36.1)	192 (30.3)	194 (32.2)
SGLT2 inhibitors	130 (13.6)	85 (8.9)	90 (14.9)
Combinations of oral BG lowering drugs	114 (11.9)	72 (11.4)	81 (8.5)
GLP-1 analogues	88 (9.2)	42 (6.6)	53 (8.8)
Sulfonylureas	33 (3.5)	17 (1.8)	19 (3.2)
Glitazones	27 (2.8)	10 (1.6)	11 (1.8)
Glinides	8 (0.8)	2 (0.2)	4 (0.7)
Financial difficulties with diabetes medication			
Not at all	797 (83.5)	427 (67.5)	399 (66.2)
At least some difficulties	158 (16.5)	190 (30.0)	199 (33.0)
Missing	0 (0)	16 (2.5)	5 (0.8)

Abbreviations: BG, blood glucose.

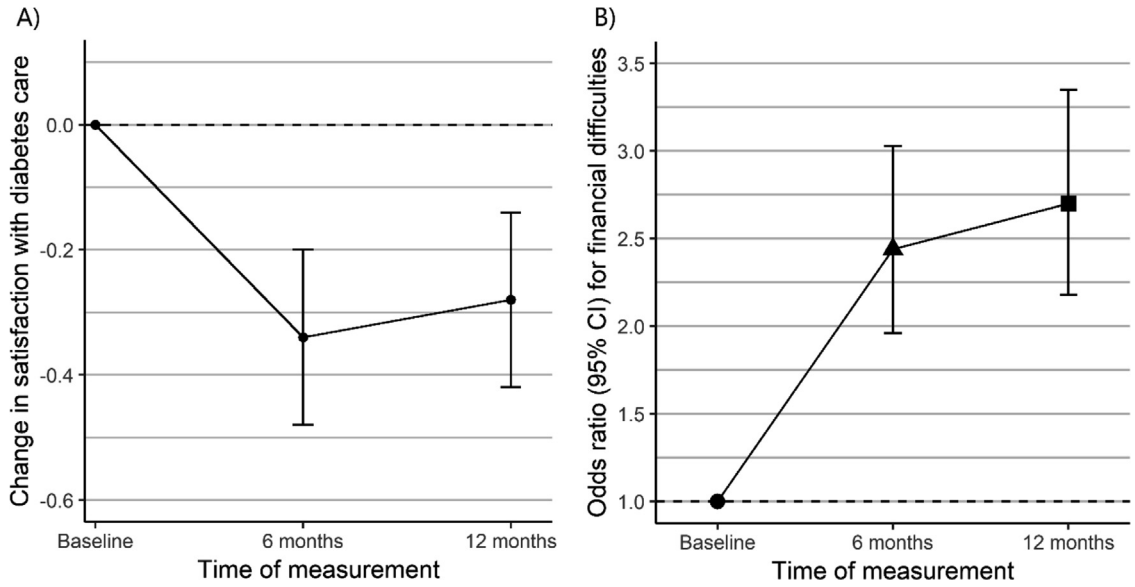

Fig. 1. A) Adjusted change from baseline in satisfaction with diabetes care (negative values indicate decreasing satisfaction). B) Adjusted odds ratios for experiencing at least some financial difficulties to purchase diabetes medications. Error bars represent 95 % confidence intervals for change from baseline (A) or odds ratio (B).

1.62, 95 % CI 1.11–2.36) at baseline were associated with a higher risk of experiencing financial difficulties. Those who experienced at least some financial difficulties 6 months after the co-payment level increase were more dissatisfied with diabetes care at that time than those who did not experience financial difficulties (means: 7.35 (SD 2.08) and 8.15 (SD 1.53), $p < 0.001$, respectively). The association remained at the 12-month follow-up.

4. Discussion

Our study results show decreased treatment satisfaction after the first year of the new SRS implementation; especially among those who experienced at least some financial difficulties with the purchase of diabetes medications. Based on our study, the use of insulin increased, whereas use of metformin and DPP-4 inhibitors decreased among study participants. In addition, the use of GLP-1 analogues decreased during the first 6-month follow-up. Furthermore, the risk of experiencing financial difficulties with the purchase of diabetes medications doubled compared to baseline. Logically financial difficulties were more often experienced among persons with low household net income than persons with higher household net incomes. Use of newer and more expensive diabetes medications (i.e. DPP-4 inhibitors, SGLT2 inhibitors, and GLP-1 analogues) as well as combinations of oral BG lowering drugs prior to the co-payment level increase increased the risk to experience financial difficulties after the policy change.

Although direct comparison of our study with previous ones is hampered by the different methods used to assess the effects of co-payment increase, our findings are nevertheless in line with previous studies suggesting that diabetes medication co-payment increases are associated with the use of less expensive medications [17] and reductions in the use of diabetes medication [9]. According to a report of the SII, the new SRS has markedly increased the co-payments especially among those T2D patients who used newer medications, such as DPP-4 inhibitors and GLP-1 analogues [18]. The observed decline in the use of metformin in our study may result from the natural progression of T2D and subsequent treatment intensification with insulins. This is, however, unlikely due to a relative short follow-up time and the fact that guidelines endorse continuation of metformin use when starting basal insulin [19–21]. During the study period the emergence of cardiac and renal protection of SGLT2 inhibitors as well as some GLP-1 analogues became

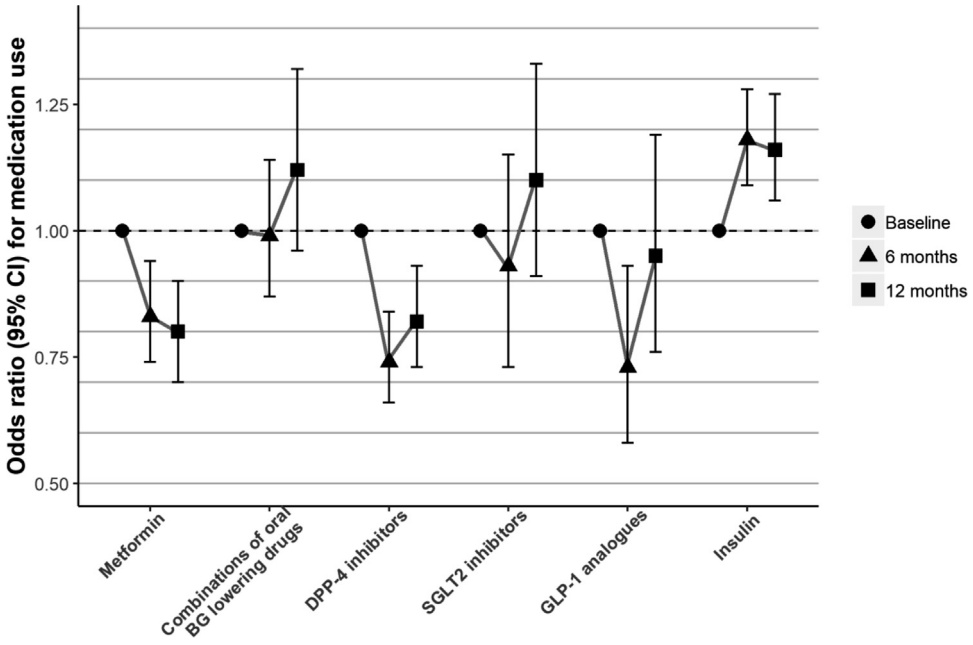

Fig. 2. Adjusted odds ratios for use of diabetes medications. Error bars represent 95 % confidence intervals. Abbreviations: BG, blood glucose.

realised and also heavily marketed among physicians [22], but these aspects were not reflected in the observed drug use pattern. In the current study, 28 % of the patients reported they discontinued non-insulin diabetes medication use due to financial reasons and 8% had initiated insulin use due to the same reasons. Typically, insulin initiation is based on a clinical need of the treatment of hyperglycemia, but there are commonly known challenges regarding insulin use, such as weight gain and hypoglycemia. Therefore, it is likely that a 100 % reimbursable insulin is initiated instead of a 65 % reimbursable GLP-1 analogue due to economic situation of a patient. This may occur despite the fact that the current guidelines prefer GLP-1 analogues as a first injectable drug [22]. In our previous study conducted in the same population, it was observed that almost half (47 %) of the participants reported an effect of the co-payment level increase in an open-ended question at the 12-month follow-up examination [23]. Most commonly reported effects were economic effects (33 %), such as increased expenditure (17 %) or difficulty in purchasing medicines (9 %), after the co-payment level increase. However, only 2 % reported in the open-ended question that they had discontinued diabetes medication use. It remains unknown whether the new SRS will lead to reduced non-insulin diabetes medication prices in the near future. In this regard expiring patents of DPP-4 inhibitors and introduction of biosimilars may be more decisive.

Financial difficulties were associated with household incomes. Roughly half of the T2D patients had a household monthly net income less than EUR 2000, while median household net income was EUR 3094 (mean EUR 3692) in the general Finnish population in 2016 [24] indicating that the majority of T2D patients were retired due to age (59 %) or disability (14 %). However, in line with a previous study, financial difficulties were more common among younger patients than older ones [25]. In that study, higher monthly co-payments were also associated with financial difficulties [25]. In Finland, the reimbursement scheme takes multimorbidity into account via the Additional Refund limit (EUR 605.13 in 2017) and it is likely, that patients with multiple comorbidities are eligible for the Refund. However, other drugs most commonly used in T2D patients are blood pressure lowering drugs and statins, which do not add much to total burden due to their relatively low price. Finnish residents whose income and assets do not cover their essential daily expense may be eligible for basic social assistance granted by the SII. The Finnish Government was demanded to monitor the effects of the co-payment increase on diabetes medication use as well as on use of basic social assistance. Thus, identification of patients or groups of patients with financial difficulties is needed. They should be provided with more information about the reasons for T2D medication use and possible options for medications, as well as assistance in modifying their medication regimens [25].

In previous studies, treatment satisfaction has been observed to be lower among patients who have a lower educational level and who are insulin treated or have a diabetic complication [26,27]. On the contrary, in our study, satisfaction with diabetes care was lower among patients with higher education. Metformin use was associated with higher satisfaction with diabetes care, which may be due to an easier phase of the disease. Lower treatment satisfaction with T2D care is also reported to be related to difficulties in adherence to taking medications [29–32], attending follow-up clinic visits [29], and, further, higher BG levels [33]. Generally, measurement of treatment satisfaction in diabetes is important as it has been shown to be associated with positive outcomes, reduced disease costs and better health [28].

According to previous studies, co-payment level increases decrease adherence to taking diabetes medications [11–13] and affect BG levels [11,13]. Moreover, poor glucose control increases the risk of micro- and macrovascular complications [34–36]. Therefore, co-payment level increases may raise hospitalization costs and, despite of lowering T2D medication costs for society, the savings may be diluted [13]. In our study, we were able to examine short-term effects of co-payment level increases. Medication costs are only a minor part of diabetes care [4], and the performed actions may postpone diabetes costs to the future due to increases in diabetes-related comorbidities. Future studies are needed on the long-term effects of reduced treatment satisfaction and increased financial difficulties on metabolic control and, furthermore, on diabetes complication risk and health care costs. Increasing co-payment is a double-edged sword. For the majority it may increase the cost awareness of the current usage of drugs and perhaps decrease the futile use with little economic conse-

quences. However, there remains a vulnerable population in this regard not readily identified by official sale statistics and increasing co-payments can jeopardise their possibilities to acceptable level of glycemic control and increase their risk of end-organ complications. Patient perspective should be thus taken into account in policy making which supports the patient-centric approach in health care [37,38], as reflected in recent diabetes treatment guidelines, where economic constraints are one of the major patient characteristics guiding treatment choices [22].

The major strength of the study is that we were able to analyse the effects of rather drastic co-payment increase from the patient-perspective, which cannot be examined from the national registers in Finland. As a limitation, there is always a selection bias - those who respond can have other characteristics that deviate the results. However, the sociodemographic structure and medication distribution patterns were very similar to that in general in Finnish T2D subjects [39,40]. Further, we did not control for any changes in HbA1c levels and cannot therefore assess the effects of the co-payment level increase to changes in metabolic control. Furthermore, assessment of adherence was not possible in a stringent way, since the responses reflect patients' views, which may be subject to under- or over-reporting. Thus, we used patient-reported outcomes that rely on patient's insight and, for example, self-reported measures of diabetes medication use may suffer from recall bias. In the current study, a novel measure for treatment satisfaction was utilized when compared with previous studies [26–28] utilizing the Diabetes Treatment Satisfaction Questionnaire (DTSQ). It is also possible that patients tended to report financial difficulties in purchasing medications frequently after the policy change because they used to pay less before the co-payment level increase.

5. Conclusions

The co-payment level increase decreased treatment satisfaction and increased financial difficulties with the purchase of medications prescribed by physicians. Changes in medication use were observed during the follow-up. Future studies are needed on the long-term effects of reduced treatment satisfaction and increased financial difficulties on metabolic control and, furthermore, on diabetes complication risk and health care costs. Patient perspective should be taken into account in future policy making.

Declaration of Competing Interest

Janne Martikainen is a founding partner of ESiOR Oy, which provides health economic, outcome research, and market access services for pharmaceutical and medical companies, as well as hospitals and other health and social care providers. Leo Niskanen has received grant support for the institution from Novo Nordisk and lecture fees from Boehringer Ingelheim, Sanofi-Aventis, AstraZeneca, Eli Lilly and MSD. Piia Lavikainen, Emma Aarnio, and Pekka Mäntyselkä declare no conflicts of interest.

Acknowledgements

We thank the Social Insurance Institution Finland for financial support (32/26/2017) and Farenta Oy for sharing data applied in the present study.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.healthpol.2020.08.001.

References

[1] International diabetes atlas, Eight edition International Diabetes Federation; 2017. Available at: http://www.diabetesatlas.org/ [Accessed 26 October 2018].
[2] Type 2 diabetes. Current care guidelines. Working group set up by the Finnish Medical Society Duodecim, the Finnish Society of Internal Medicine and the Medical Advisory Board of the Finnish Diabetes Society. Helsinki: The Finnish Medical Society Duodecim; 2018. Available at: www.kaypahoito.fi [Accessed 26 October 2018].
[3] Health statistics for the nordic countries 2017. Nordic Medico-Statistical Committee; 2017.
[4] Koski S, Kurkela O, Ilanne-Parikka P, Rissanen P, Available at: Costs of diabetes in Finland in 2002-2011 [in Finnish]. Diabetes in numbers. Finnish Diabetes Association; 2017. p. 1 https://www.diabetes.fi/files/9237/Diabetes_lukuina_2017_flyer.pdf.
[5] Finland, a land of solutions. Strategic programme of prime minister Juha Sipilä's government 29 may 2015. Government Publications 12/2015; 2015. Available at: https://vnk.fi/documents/10616/1095776/Ratkaisujen+Suomi_EN.pdf/c2f3123a-d891-4451-884a-a8cb6c747ddd/Ratkaisujen+Suomi_EN.pdf.pdf?version=1.0.
[6] Government proposal 184/2016 [in Finnish]; 2016. Available at: https://www.eduskunta.fi/FI/vaski/HallituksenEsitys/Documents/HE_184+2016.pdf.
[7] Ruskoaho H, Available at: http://urn.fi/URN: ISBN:978-952-00-3815-1 Inspection of the medicine reimbursement scheme regarding the savings in medicines in 2017 [in Finnish]. Reports and memos of the Ministry of Social Affairs and Health 31/2016; 2016.
[8] National Agency for Medicines and Social Insurance Institution, Helsinki, Finland Finnish statistics on medicines 2017; 2018.
[9] Goldman DP, Joyce GF, Escarce JJ, Pace JE, Solomon MD, Laouri M, et al. Pharmacy benefits and the use of drugs by the chronically ill. JAMA 2004;291(19), 2344–50.
[10] Roblin DW, Platt R, Goodman MJ, Hsu J, Nelson WW, Smith DH, et al. Effect of increased cost-sharing on oral hypoglycemic use in five managed care organizations: how much is too much? Medical Care 2005;43(10):951–9.
[11] Hunt J, Rozenfeld Y, Shenolikar R. Effect of patient medication cost share on adherence and glycemic control. Managed Care 2009;18(7):47–53.
[12] Eaddy MT, Cook CL, O'Day K, Burch SP, Cantrell CR. How patient cost-sharing trends affect adherence and outcomes: a literature review. P T 2012;37(1):45–55.
[13] Snider JT, Seabury S, Lopez J, McKenzie S, Wu Y, Goldman DP. Impact of type 2 diabetes medication cost sharing on patient outcomes and health plan costs. The American Journal of Managed Care 2016;22(6):433–40.
[14] Ministry of Social Affairs and Health, Available at: https://www.finlex.fi/fi/laki/ajantasa/2004/20041224 [Accessed 8 January 2019] Health insurance act 2004/1224 (in Finnish); 2019.
[15] National Agency for Medicines and Social Insurance Institution, Helsinki, Finland Finnish statistics on medicines 2016; 2017.
[16] WHO, Available at: http://www.whocc.no/atcddd/ [Accessed 4 June 2018] About the ATC/DDD system; 2018.
[17] Saito EP, Davis JW, Harrigan RC, Juarez D, Mau MK. Copayment level and drug switching: findings for type 2 diabetes. The American Journal of Pharmacy Benefits 2010;2(6):412–20.
[18] Kurko T, Heino P, Martikainen JE, Aaltonen K. Diabeteksen lääkehoidot ja korvaustason laskun vaikutus omavastuisiin (in Finnish with English summary). Finnish Medical Journal 2018;73:1584–90.
[19] Diabetes Canada Clinical Practice Guidelines Expert Committee, Lipscombe L, Booth G, Butalia S, Dasgupta K, Eurich DT, et al. Pharmacologic glycemic management of type 2 diabetes in adults. Canadian Journal of Diabetes 2018;42(Suppl 1):S88–103.
[20] American Diabetes Association. 8. Pharmacologic approaches to glycemic treatment. Diabetes Care 2017;40(Suppl. 1):S64–74, http://dx.doi.org/10.2337/dc17-S011.
[21] Silver B, Ramaiya K, Andrew SB, Fredrick O, Bajaj S, Kalra S, et al. EADSG guidelines: insulin therapy in diabetes. Diabetes Therapy 2018;9(2):449–92.
[22] Davies MJ, D'Alessio DA, Fradkin J, Kernan WN, Mathieu C, Mingrone G, et al. Management of hyperglycemia in Type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2018;41(12):2669–701, http://dx.doi.org/10.2337/dci18-0033.
[23] Suviranta T, Timonen J, Martikainen J, Aarnio E. The effects of reimbursement reform of antidiabetic medicines from the patients' perspective – a survey among patients with type 2 diabetes in Finland. BMC Health Services Research 2019;19:769.
[24] Official Statistics of Finland: Income distribution statistics [e-publication]. ISSN=1795-8121. Income differentials between population subgroups 2016, 2 Households' disposable income on average EUR 38,300 [in Finnish]. Helsinki: Advisory Board of Official Statistics of Finland; 2019 [referred December 27, 2019]. Access method http://www.stat.fi/til/tjt/2016/02/tjt_2016_02_2018-03-23_kat_002_fi.html.
[25] Piette JD, Heisler M, Wagner TH. Problems paying out-of-pocket medication costs among older adults with diabetes. Diabetes Care 2004;27(2):384–91.
[26] Biderman A, Noff E, Harris SB, Friedman N, Levy A. Treatment satisfaction of diabetic patients: what are the contributing factors? Family Practice 2009;26(2):102–8.
[27] Nicolucci A, Cucinotta D, Squatrito S, Lapolla A, Musacchio N, Leotta S, et al. Clinical and Socio-economic correlates of quality of life and treatment satisfac-

tion in patients with type 2 diabetes. Nutrition, Metabolism & Cardiovascular Diseases 2009;19:45–53.
[28] Bener A, Al-Hamaq AO, Yousafzai MT, Abdul-Ghani M. Relationship between patient satisfactions with diabetes care and treatment. Nigerian Journal of Clinical Practice 2014;17:218–25.
[29] Briesacher BA, Gurwitz JH, Soumerai SB. Patients at-risk for cost-related medication nonadherence: a review of the literature. Journal of General Internal Medicine 2007;22(6):864–71.
[30] Blone L, Dey J, Tesa MA, Guthrie RD. Defining and measuring quality of diabetes care. Primary Care 1999;26:841–55.
[31] Finkel MI. The importance of measuring patient satisfaction. Employment Benefits Journal 1997;22:12–5.
[32] The QuED Study Group-Quality of Care and Outcomes in Type 2 Diabetes. Correlates of satisfaction for the relationship with their physician in type 2 diabetic patients. Diabetes Research and Clinical Practice 2004;66:277–86.
[33] Bradley C, Lewis KS. Measures of psychological well-being and treatment satisfaction developed from the responses of people with tablet-treated diabetes. Diabetic Medicine 1990;7:445–51.
[34] Selvin E, Marinopoulos S, Berkenblit G, Rami T, Brancati FL, Powe NR, et al. Meta-analysis: glycosylated hemoglobin and cardiovascular disease in diabetes mellitus. Annals of Internal Medicine 2004;141(6):421–31.
[35] Stratton IM, Adler AI, Neil HAW, Matthews DR, Manley SE, Cull CA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ 2000;321(7258):405–12.
[36] UKPDS Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998;352(9131):837–53.
[37] Skovlund SE, Lichtenberg TH, Hessler D, Ejskjaer N. Can the routine use of patient-reported outcome measures improve the delivery of person-centered diabetes care? A review of recent developments and a case study. Current Diabetes Reports 2019;19(9):84, http://dx.doi.org/10.1007/s11892-019-1190-x.
[38] Wang MJ, Hung LC, Lo YT. Glycemic control in type 2 diabetes: role of health literacy and shared decision-making. Patient Preference and Adherence 2019;13:871–9, http://dx.doi.org/10.2147/PPA.S202110, eCollection 2019.
[39] Pajunen P, Laatikainen T, Sundvall J, Vartiainen E, Peltonen M. Diabetespotilaiden hoitotasapaino FINRISKI 2012 -väestötutkimuksessa [how well type 2 diabetic individuals reach their treatment goals: FINRISK 2012 study] (in Finnish with English summary). Finnish Medical Journal 2014;23(69):1705–9.
[40] Saaristo T, Peltonen M, Keinänen-Kiukaanniemi S, Vanhala M, Saltevo J, Niskanen L, et al. National type 2 diabetes prevention programme in Finland: FIN-D2D. International Journal of Circumpolar Health 2007;66(2):101–12.