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Rates and Factors Associated With Laxative Prescription Among Type 2 Diabetes Patients in Primary Care

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Background: Diabetes mellitus (DM) is a common noncommunicable disease. Several gastrointestinal symptoms such as diarrhea, chronic constipation, and fecal incontinence are often observed in DM patients; among these, chronic constipation is the most commonly reported. Given the growing prevalence of diabetes-associated chronic constipation, the problem of laxative prescribed without diagnosis of constipation among type 2 diabetes patients has been found in the primary care unit. Therefore, it should attend to investigate the rate and factors associated with laxative prescription in type 2 diabetes.

Objective: To evaluate the rate and factors associated with laxative prescription in type 2 diabetic patients at the primary care unit and general practitioner outpatient clinic at Songklanagarind Hospital.

Results: Overall, 386 patients diagnosed with type 2 diabetes were enrolled (55.7% female; mean age, 63.3 years; median duration of type 2 diabetes, 7 years; median visit in 5 years of each patient, 44 visits). Prevalence of laxative prescriptions was 16.6%. Rate of laxative prescriptions was 1.7% within 5 years. Patients with no diagnosis constipation according to ICD-10 about 81.2%. The statistically significant factors associated with laxative prescriptions in diabetic patients were age, number of hospital visit in 5 years, duration of type 2 DM disease, height, diastolic blood pressure, hemoglobin, hematocrit, serum uric acid, and glomerular filtration rate.

Conclusions: Most laxative prescribed diabetic patients were without written diagnosis of constipation. Factors associated with laxative prescriptions were age, number of hospital visit, duration of type 2 DM disease, height, diastolic blood pressure, hemoglobin, hematocrit, serum uric acid, and glomerular filtration rate.

Keywords: Rate, Laxatives prescriptions, Type 2 diabetes

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Introduction

Diabetes mellitus (DM) is a common noncommunicable disease. Several gastrointestinal symptoms such as diarrhea, chronic constipation, and fecal incontinence are often observed in DM patients;[1-3] among these, chronic constipation is the most commonly reported.[4] The prevalence of chronic constipation in the general population is reported as around 14%.[5] A previous descriptive cross-sectional study with 372 diabetic patients treated at an outpatient clinic in Brazil reported that about 31% of patients had chronic constipation. Prevalence studies conducted in the US, Europe, and Hong Kong reported the rate of chronic constipation in diabetic patients to be 10%, 13% to 22%, and 27.5%, respectively, indicating that chronic constipation is a very common gastrointestinal symptom in diabetics.[6-9] Although the pathogenesis that causes constipation is uncertain. There is a theory that DM can causes abnormal autonomic nervous system, affects the lower rate of gastrointestinal motility and then causes constipation. The occurrence of chronic constipation is significantly higher in diabetic patients with autonomic neuropathy compared to those without neuropathy (22% vs 9.2%, $P < .04$).[10] However, there has been no previous study about the prevalence of constipation in DM patients in Thailand. Meanwhile, the problem of underdiagnosed constipation represented with different between number of diagnosed patients and time of laxative prescription has been found in the primary care unit, affecting inconsistency of constipation diagnosis data.

Underdiagnosed of diseases has been found to be related with underreporting of symptoms by patients or undetected in routine assessment,[11-12] in case of diagnosis record inconsistency by the physician may affect to less number of diagnosed patients as it could be, which affects the patient's safety and hospital care cost with reimbursement on diagnostic related group (DRG) payment system. According to this problem, this study aimed to evaluate the rate and factors associated with laxative prescriptions and underdiagnosed constipation in diabetes patients.

Methods

Participants

This was a retrospective cross-sectional descriptive study. Study population was identified by hospital information system (HIS), approximately 1,352 patients were diagnosed with type 2 diabetes in 2018. According to previous studies, the prevalence studies conducted in the US, Europe, and Hong Kong reported the rate of chronic constipation in diabetic patients to be 10%, 13% to 22% and 27.5%, respectively.[6-9] There is no data of the prevalence of constipation in type 2 diabetic patients in Thailand before. This study assumed that prevalence is 0.5 for the largest populations purpose.

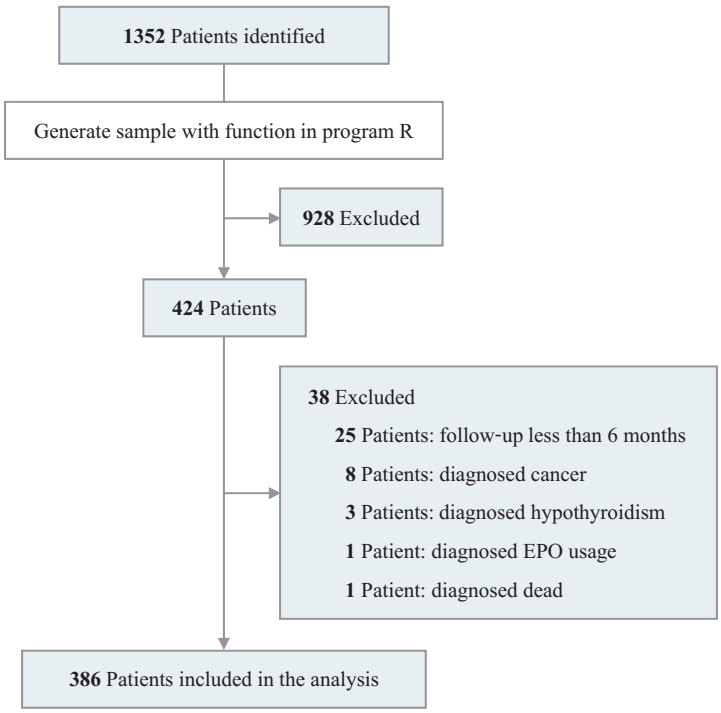
The sample size was calculated with n4 studies program (formula: $n = Z^2pq/d^2$; where n, desired sample size; Z, the reliability coefficient at the 95% confidence interval [CI] = 1.96; p, prevalence rate = 0.5; q, 1-p = 50%; and d, degree of error = 0.05). After calculated, the sample size was 385 patients. For preventing data error, this study increased the number of samples about 10%. So the sample size was 424 patients.

Patients diagnosed with type 2 DM according to ICD-10 code E11.0-E11.9, or took antiglycemic drugs at primary care unit and general practitioner outpatient clinic at Songklanagarind Hospital, Thailand from January 1, 2018, to December 31, 2018, were enrolled. Type 2 DM patients followed up less than 6 months, and also underlying disease such as hypothyroid or chronic kidney disease which received erythropoietin, received morphine, previous gastric surgery, pregnant, diagnosed cancer 10 years, were excluded from this study. After sampling with computer generated list, 424 patients were included in this study, and 38 patients were excluded by exclusion criteria. Finally, there were 386 patients that were analyzed in the study (Figure 1).

Ethics

Ethical approval was gained from the Faculty of Medicine, Prince of Songkla University (certificate of approval No. REC.62-410-9-4)

Figure 1. Summary of Strategy Results



Abbreviation: EPO, erythropoietin.

Outcomes

The primary outcome of this study was to estimate the rate of laxatives prescriptions in type 2 DM. The secondary outcome was to describe factors associated with laxatives prescriptions in type 2 DM.

Data Collection

The case record form was face validated by 3 experts, 2 professors of family medicine department, and 1 statistician. After permitted from the hospital director and ethic committee, data collection was performed by researchers. All independent variables were collected from latest lab results. According to laxatives mechanism from literature review, the duration of action is too short to find the relationship of laxatives and to go through lab investigations. In addition, blood samples for constipation is not be done for general routine. One blood sample would be appropriate. A number of laxative prescriptions was collected every visits. Duration of type 2 DM disease was collected from previous medical history.

Statistical Analysis

All data were input in a case record form. Double data entry was done by researchers using Microsoft Excel 2001 (Microsoft Corporation). Statistical analysis was performed using program R version 3.6.0 (R Project for Statistical Computing). Descriptive statistics such as percentage, mean, median, and interquartile range (IQR) were analyzed in this study.

Categorical data were presented using percentages and continuous data were presented using the mean and standard deviation (SD) or median and IQR depending on the distribution of data.

Rate and prevalence of laxative prescriptions were calculated by frequency distribution and percentage. Factors associated with laxative prescriptions were performed using the chi-square test or Fisher exact test for categorical variables and using sample *t* test, Wilcoxon rank sum test for continuous variables with symmetrical and asymmetrical distribution of data respectively. A *P* value less than .05 was considered statistically significant.

Results

Most of participants were female (55.7%). The majority of the population has the rights to maintain the Government scheme 197 patients (51%), followed by Universal coverage scheme 114 patients (29.6%) and cash 42 patients (10.9%), respectively. The mean (SD) age of patients was 63.3 (10.6) years. Patients who were prescribed laxative has mean age more than patients who were not prescribed laxative with statistically significant ($P < .05$). The median weight of the population was 65 kg. The median height of the population was 159 cm. Patients who were prescribed laxative has median height less than patients who were not prescribed laxative with statistically significant ($P < .05$). The median systolic blood pressure of the population was 134 mmHg. The median diastolic blood pressure of the population was 74.2 mmHg. Patients who were prescribed laxative has median diastolic blood pressure less than patients who were not prescribed laxative with statistically significant ($P < .05$). The median number of hospital visit was 44 times. Patients who were prescribed laxative has median number of hospital visits more than patients who were not prescribed laxative with statistically significant ($P < .05$). The median duration of type 2 DM disease was 7 years. Patients who were prescribed laxative has median duration of type 2 DM disease more than patients who were not prescribed laxative with statistically significant ($P < .05$). The prevalence of laxative prescriptions was 16.6%. The rate of laxative prescriptions was 0.017. The rate of laxative prescriptions in 5 years was 1.7%. According to ICD-10 diagnosis, prevalence of no diagnosis constipation in this population was 81.2%. Factors associated with laxative prescriptions in diabetic patients were age, number of hospital visit, duration of type 2 DM disease, height, diastolic blood pressure, hemoglobin, hematocrit, serum uric acid, and glomerular filtration rate (GFR) (Table 1).

Subgroup analysis was performed in prescribed laxative patients. According to number of laxative prescriptions, prescribed patients were divided into 3 groups (1-5 times, 6-10 times, and more than 10 times of laxative prescription) to find the differences. The majority of the population (76.5%) were prescribed 1-5 times of laxative. There were no statistically significant differences between 3 groups except the low-density lipoprotein cholesterol (LDL-C) (Table 2).

Table 1. Descriptive Data of Non-Prescribed Laxative Group and Prescribed Laxative Group

Demographic	No. (%)			
	Total (N = 386)	Non-Prescribed Laxative Group (n = 322)	Prescribed Laxative Group (n = 64)	*P* Value*
ICD-10 diagnosed constipation				
No diagnosis constipation	370 (95.9)	318 (98.8)	52 (81.2)	< .001
Diagnosed	16 (4.1)	4 (1.2)	12 (18.8)	
Age, mean (SD), y	63.3 (10.6)	62.7 (10.7)	66.4 (9.5)	.012
Gender				
Male	171 (44.3)	150 (46.6)	21 (32.8)	.059
Female	215 (55.7)	172 (53.4)	43 (67.2)	
Medical payment				
Personal payment	42 (10.9)	39 (12.1)	3 (4.7)	.55
Government scheme	197 (51)	162 (50.3)	35 (54.7)	
Universal coverage scheme	114 (29.5)	94 (29.2)	20 (31.2)	

Table 1. Descriptive Data of Non-Prescribed Laxative Group and Prescribed Laxative Group (Continued)

Demographic	No. (%)			
	Total (N = 386)	Non-Prescribed Laxative Group (n = 322)	Prescribed Laxative Group (n = 64)	*P* Value*
Social security scheme	16 (4.1)	13 (4)	3 (4.7)	
Local government officer scheme	17 (4.4)	14 (4.3)	3 (4.7)	
Number of visit, median (IQR), time	44 (25, 65.8)	41.5 (22, 59.8)	60.5 (39, 88.5)	< .001
Duration of type 2 DM disease, median (IQR), year	7 (4, 12)	6 (3.5, 12)	10 (6.5, 14)	< .001
Weight, median (IQR), kg	65 (58, 75)	65 (58, 75.2)	64.3 (58.5, 73.2)	.68
Height, median (IQR), cm	159 (154, 165)	160 (155, 165.5)	155 (153.8, 161.5)	.023
SBP, median (IQR), mmHg	134 (124, 144)	135 (124, 145)	131 (122, 138)	.098
DBP, mean (SD), mmHg	74.2 (10.6)	75 (10.3)	70 (11.3)	.001
Laboratory test				
Hb, mean (SD), g/dL	13.1 (1.6)	13.2 (1.5)	12.7 (1.8)	.007
Hct, mean (SD), %	39.9 (4.4)	40.2 (4.2)	38.7 (5)	.010
Uric acid, mean (SD), mg/dL	5.8 (1.4)	5.7 (1.4)	6.2 (1.5)	.041
GFR, median (IQR), mL/min/1.73 m^2	86 (68, 98)	88 (69.2, 99)	79.5 (63.5, 96.2)	.042
Pharmacological treatment**				
Metformin	334 (86.5)	281 (87.3)	53 (82.8)	.45
Glipizide	150 (38.9)	122 (37.9)	28 (43.8)	.46
Pioglitazone	57 (14.8)	45 (14)	12 (18.8)	.43
Acarbose	2 (0.5)	2 (0.6)	0 (0)	.99
Gliptin	6 (1.6)	5 (1.6)	1 (1.6)	.99
Gliflozin	5 (1.3)	4 (1.2)	1 (1.6)	.99
Insulin	43 (11.1)	38 (11.8)	5 (7.8)	.48
Statin	330 (85.5)	275 (85.4)	55 (85.9)	.99
Fibrate	6 (1.6)	5 (1.6)	1 (1.6)	.99

Abbreviations: DBP, diastolic blood pressure; GFR, glomerular filtration rate; Hb, hemoglobin; Hct, hematocrit; IQR, interquartile range; SBP, systolic blood pressure; SD, standard deviation;

* *P* value < .05 was considered statistically significant.

** One patient may takes more than one medication.

Table 2. Descriptive Data of Prescribed Laxative Patients

Laboratory Test	Number of Prescribed Laxatives				*P* Value*
	Total (N = 64)	1 - 5 times (n = 49)	6 - 10 times (n = 6)	> 10 times (n = 9)	
LDL-C, median (IQR), mmol/L	98.2 (83.9, 118.6)	103.9 (86.3, 126.9)	99.3 (79.4, 110.9)	89.3 (70.4, 94)	.033

Abbreviations: IQR, interquartile range; LDL-C, low-density lipoprotein cholesterol.

* *P* value < .05 was considered statistically significant.

Discussion

A retrospective cross-sectional descriptive study was conducted in primary care unit and general practitioner outpatient clinic. According to the study, the rate of laxative prescriptions within 5 years was 1.7% with significant associated factors of laxative prescriptions in diabetic patients, including age, number of hospital visits in 5 years, duration of type 2 DM disease, height, diastolic blood pressure, hemoglobin, hematocrit, and serum uric acid.

In this study, most of laxative prescribed diabetic patients were female (55.7%). This result related with previous study[13] which reported higher prevalence of constipation in type 2 diabetes patients in female more than male. Age of patients and duration of DM type 2 disease were associated with laxative prescriptions with statistically significant. Related with previous study which found that constipation is associated with age and duration of disease.[13-14]

Regarding to previous study, hemoglobin A_{1c} (HbA_{1c}) exceed 7% is associated with constipation in type 2 DM patients.[15] This study showed that the median HbA_{1c} of the population was 6.9 mg%. There were no statistically significant differences in fasting plasma glucose and HbA_{1c} between patients who were prescribed laxative and patients who were not prescribed laxative. This results may be due to the difference of clinical settings. In endocrine outpatient department may have more complicated type 2 diabetes patients.

According to previous study in Brazil,[11] prevalence of constipation in type 2 DM patients was 31.2% which was different from the present study (16.6%). This result revealed to the difference of clinical settings. In endocrine outpatient department may have more complicated type 2 diabetes patients, especially diabetic neuropathy[13] which may cause the higher prevalence of constipation.

This study found patients who take laxative prescribed without constipation diagnosis about 81.2% as same as previous study in Belgium.[14] Since the ROME IV criteria are used principally for research purpose and are not widely applied in real-world clinical settings, constipation tends to be subjective and easily misdiagnosed, which leads to underestimate the true prevalence of constipation in type 2 DM patients.

According to number of laxative prescriptions, the present study divided prescribed patients into 3 groups (1-5 times, 6-10 times, and more than 10 times of laxative prescription) to find the differences. The majority of the population in this study (76.5%) were prescribed 1-5 times of laxative. There were not statistically significant in gender, medical insurance, age, weight, height, systolic and diastolic blood pressures, number of hospital visit, duration of type 2 DM disease, and type of antidiabetic or antilipidemic drugs. There were no statistically significant in laboratory investigations between 3 groups except the LDL-C. In this study, higher LDL-C associated with lowering laxative usage, which no theory support this finding. From previous studies, few studies have examined the relationship between laxatives use and laboratory results. Thus, further study to identify the relationship between LDL-C level and laxatives usage in type 2 diabetes patients is recommended.

As a retrospective study design, it is difficult to determine whether constipation is caused by DM. There are many confounders that could not collect the data, such as dietary record, physical activity, functional status, all medication intake, water intake, and types of food and comorbid disease. This study was collected data from primary care unit and general practitioner outpatient clinic setting only. This might be aware if using this results in other specialty clinic. There are many incompletion of important data, especially ICD-10 diagnosis of constipation. According to the purpose of investigate underdiagnoses, this study investigated patients who take laxative prescribed without constipation diagnosis or other purposes of laxative usage. From Thai diagnosis related group (TDRG), underdiagnosis is not only increase the economic burden, but also leads to delay in the establishment of proper treatment.

Because of the limited evidence in relationship between constipation and laboratory investigation, consequently prospective cohort study with selected criterion is recommended. This study assume the underdiagnosed data and

found that most of laxative prescribed patients were no diagnosis of constipation. It interestingly tendency for further study to investigate the prevalence of underdiagnosed of constipation among type 2 diabetes with a direct protocol.

This study found higher LDL associated with lowering laxative usage, but no theory support this finding. Study of the relationship between LDL level and laxatives usage in type 2 diabetes patients is recommended. Finally, the prospective study use the ROME IV criteria as an instrumental for constipation diagnosis is required.

Conclusions

The statistically significant factors associated with laxative prescriptions were age, number of hospital visit, duration of type 2 DM disease, height, diastolic blood pressure, hemoglobin, hematocrit, serum uric acid, and glomerular filtration rate. Most laxative prescribed diabetic patients were no diagnosis of constipation. This problem may lead to underdiagnosis of constipation, which affects the patient's safety and hospital care cost.

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อัตราการสั่งจ่ายยาและปัจจัยที่เกี่ยวข้องต่อการสั่งจ่ายยาระบายในผู้ป่วยโรคเบาหวานชนิดที่ 2 ในบริการปฐมภูมิ

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บทนำ: โรคเบาหวานเป็นโรคไม่ติดต่อที่พบบ่อย อาการด้านทางเดินอาหารที่พบได้บ่อยในผู้ป่วยโรคเบาหวานคือ ท้องเสีย ท้องผูกเรื้อรัง และกลั้นอุจจาระไม่ได้ โดยในจำนวนนี้พบอาการท้องผูกเรื้อรังมากที่สุด จากการศึกษาที่ผ่านมาพบว่าความชุกของอาการท้องผูกในผู้ป่วยโรคเบาหวานเพิ่มมากขึ้น จึงควรให้ความสำคัญกับปัจจัยที่มีส่วนเกี่ยวข้องกับการสั่งจ่ายยาระบายและการลงวินิจฉัยอาการท้องผูก

วัตถุประสงค์: เพื่อหาอัตราการสั่งจ่ายยาระบายและปัจจัยที่มีผลต่อการสั่งจ่ายยาระบายในผู้ป่วยโรคเบาหวานชนิดที่ 2 ที่เข้ารักษาที่หน่วยบริการปฐมภูมิและคลินิกเวชปฏิบัติทั่วไป โรงพยาบาลสงขลานครินทร์

ผลการศึกษา: ผู้ป่วยโรคเบาหวาน จำนวน 386 คน อายุเฉลี่ย 63.3 ปี เป็นเพศหญิงร้อยละ 55.7 จำนวนปีที่เป็นโรคเบาหวานเฉลี่ย 7 ปี จำนวนครั้งของการเข้ารับการรักษาในระยะ 5 ปี เฉลี่ย 44 ครั้ง พบความชุกของการสั่งจ่ายยาระบายร้อยละ 16.6 อัตราการสั่งจ่ายยาระบายในระยะ 5 ปี ของผู้ป่วยโรคเบาหวานเท่ากับ ร้อยละ 1.7 พบการสั่งจ่ายยาระบายโดยไม่ได้ลงวินิจฉัยโรคตาม ICD-10 ร้อยละ 81.2 ของการสั่งจ่ายยาระบายทั้งหมด ปัจจัยที่มีความสัมพันธ์กับการสั่งจ่ายยาระบายที่มีความแตกต่างอย่างมีนัยสำคัญคือ อายุเฉลี่ย จำนวนครั้งของการเข้ารับการรักษาในระยะ 5 ปี จำนวนปีที่เป็นโรคเบาหวาน ส่วนสูง ค่าความดันตัวล่าง ค่าฮีโมโกลบิน ค่าฮีมาโตคริต ค่ากรดยูริกในเลือด และค่าอัตราการกรองของไต

สรุป: ผู้ป่วยโรคเบาหวานที่ได้รับยาระบายส่วนใหญ่ไม่ได้ลงวินิจฉัยอาการท้องผูก ปัจจัยที่มีความสัมพันธ์กับการสั่งจ่ายยาระบายคือ อายุเฉลี่ย จำนวนครั้งของการเข้ารับการรักษา จำนวนปีที่เป็นโรคเบาหวาน ส่วนสูง ค่าความดันตัวล่าง ค่าฮีโมโกลบิน ค่าฮีมาโตคริต ค่ากรดยูริกในเลือด และค่าอัตราการกรองของไต

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