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Management of gout in primary care of Hong Kong in accordance with international guidelines: any gaps to bridge?

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Abstract

Background The global prevalence of gout ranges from 1 to 6.8% in different countries, while around 3% in Hong Kong. Sudden elevated serum urate level (SUA) will result in acute arthritis and repeated flare-ups. If not properly managed, tophi formation and joint damage will occur, leading to disabilities. Gout is one of the most common conditions encountered in primary care. This study aims to assess urate control among gout patients managed in primary care settings of Hong Kong and to evaluate its associated risk factors.

Method This was retrospective cross-sectional study. Adult Chinese gout patients who had been followed up in public primary care clinics of Hong Kong from 1 January 2021 to 31 December 2021 were included. Patient demographics, clinical and biochemical parameters were retrieved from the clinical management computer system. Student's t-test was used for analyzing continuous variables and Chi-square test was used for categorical data. Multivariate stepwise logistic regression was used to determine the associated risk factors for poor urate control.

Results Among the 385 gout patients included, 115 (29.9%) met the target serum urate level (TSUL). 4.4% of gout patients developed tophaceous gout, while none of them could achieve the TSUL. 60.3% of gout patients were put on urate-lowering agents (ULT), while allopurinol was the most commonly used, i.e. 95.7%. In multivariate studies, patients who are male (OR 2.59, 95% CI: 1.37–4.87), active smokers (OR 3.17, 95% CI: 1.08–9.33), with chronic kidney disease (CKD) with stage 3a, 3b and 4, (OR 3.24, 3.12 and 10.25 respectively; 95% CI: 1.56–6.73, 1.11–8.76 and 1.08–97.48 respectively) were less likely to meet TSUL whereas those on urate-lowering agents (OR 0.23, 95% CI: 0.13–0.40) were more likely to achieve satisfactory urate control.

Conclusion 60.3% of gout patients were treated with urate-lowering agents in public primary care settings in Hong Kong, while only 29.9% of gout patients and none of tophaceous gout patients were adequately treated. Male patients, active smokers or comorbid with CKD stage 3a, 3b and 4 were less likely to achieve target urate control.

Keywords Gout, Primary care, Urate, Associated risk factor, Chronic kidney disease

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Introduction

Due to the aging population and changes in metabolic profiles, the prevalence of gout has been increasing globally and locally. Currently, the global prevalence of gout ranges from 1 to 6.8% in different countries [1], and increased from 1.56% in 2006 to 2.92% in 2016 locally in Hong Kong [2]. Gout is one of the most common conditions encountered in primary care. When the serum urate level (SUA) is elevated and exceeds the supersaturation level, monosodium urate crystals deposit in joints and surrounding tissues, resulting in acute arthritis and repeated flare-ups. If not properly managed, tophi formation and joint damage will occur, leading to disabilities. Apart from the detrimental effect on the joints locally, gout is also proven to be an important cardiovascular disease (CVD) risk factor [3]. For example, epidemiological studies have shown that SUA is positively correlated with the development of CVD including hypertension (HT), atherosclerosis, atrial fibrillation (AF) and congestive heart failure (CHF). The postulated mechanism is that hyperuricemia upregulates the molecular signals in the inflammatory response, oxidative stress and insulin resistance [4].

The use of urate-lowering agents (ULT) is an important clinical strategy to bring SUA to normal. A treat-to-target management strategy has been recommended by most international guidelines. The recommendations from the 2020 American College of Rheumatology Guideline for the Management of Gout suggest that SUA level should be regularly monitored and controlled to less than 0.36 mmol/l in general, and to less than 0.3 mmol/l if with tophaceous gout [5–7].

Although gout is of important health concern, suboptimal standard of gout management has been observed in primary care. For example, in a study done in UK primary care in 2007, treatment of gout was often suboptimal and poorly concordant with international recommendations [8]. Lifestyle advice was infrequently offered, and allopurinol was restricted to a minority. Another large-scale study from Australia found that only 22.4% of gout patients achieved target SUA in primary care and about half of the gout patients did not have SUA tested at any time during the 5-year study period [9]. Locally, studies revealed that only 17% of gout patients had achieved optimal SUA levels in primary care in 2004 [10] and 35.8% in specialist settings in 2016 [2], and only 24.5% of gout patients were on ULT despite poor urate control [2]. Many gout patients are regularly followed up (FU) in Hospital Authority (HA) primary care clinics in Hong Kong (HK). However, there is no information available regarding current practices and standards in the management of gout in general practice locally over the past 10 years. To address this knowledge gap, this study aims to assess the management of gout in accordance with recommendations from the latest international guidelines and to explore the associated risk factors for poor urate control. The result of this study will provide important background information on gout management locally and may help enhance care for gout patients to improve their clinical outcomes in the long run.

Objectives of the study

1. To assess the proportion of gout patients who have achieved the target SUA level.
2. To evaluate the risk factor associated with poor urate control.

Methods

Study design

Cross-sectional descriptive study.

Setting

13 public General Out-Patient Clinic (GOPCs) in Kowloon Central Cluster (KCC) under the Hospital Authority (HA) of Hong Kong.

Subjects

Inclusion criteria

All Chinese adult gout patients coded with the Hong Kong Clinical Terminology (HKCT) T92 Gout and had been regularly FU in 13 GOPCs of KCC from 1st January 2021 to 31st December 2021 are included.

Exclusion criteria

Gout patients with the following characteristics are excluded:

(1) Whose gout had been managed by Specialist Out-Patient Clinics (SOPD).
(2) Whose gout had been managed by clinics in clusters other than KCC.
(3) Whose gout had been managed under the Public-Private Partnership Programme (PPP).
(4) Whose gout had been wrongly labeled or with uncertain diagnosis of gout.
(5) Certified dead within the study period.

Data retrieval and determination of variables

A list of patients fulfilling the inclusion criteria is retrieved from the Clinical Data Analysis and Reporting System (CDARS) of HA, by using HKCT code T92 Gout. Study patients are randomly selected from the patient list according to computer-generated random numbers.

The patient's age, sex, smoking status, drinking status, Body Mass Index (BMI), Fasting Glucose (FG), lipid profile and SUA levels were retrieved from the Clinical Management System (CMS). A patient is considered a smoker

if he/ she currently smokes or is within the first 6 months of quitting. The BMI is calculated as body weight (kg)/ body height² (m^2). BMI ≥ 23 kg/m^2 is defined as overweight while BMI ≥ 25 kg/m^2 is defined as obesity (World Health Organization for Chinese population). The estimated Glomerular Filtration Rate (eGFR) was calculated by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation [11].

Clinical notes would be reviewed to detect the presence of tophi and the number of gouty attacks in the past year. The most recent reports were used for data analysis if more than one test had been performed during the study period. The comorbidities were retrieved by the HKCT code as follows:

K86, K87 for HT, U99 for CKD, K89, K90, K91 for Coronary artery disease (CAD)/ Ischemic heart disease (IHD), K77 for CHF, K92 for Peripheral vascular disease (PVD), T92 for gout, T82 for obesity and T93 for hyperlipidemia.

CKD was defined as eGFR < 60 mL/min/1.73 m^2. According to KDIGO 2012 criteria [12], patients were further staged into.

CKD 3a: eGFR 45–59 ml/min/1.73 m^2;
CKD 3b: eGFR 30–44 ml/min/1.73 m^2;
CKD 4: eGFR 15–29 ml/min/1.73 m^2;
CKD 5: eGFR < 15 ml/min/1.73 m^2.

ULT refers to the use of allopurinol, febuxostat or probenecid for urate control in the drug profile. Indications of ULT for gout patients include patients with recurrent flares (≥ 2 episodes per year), presence of tophi, comorbid with urate arthropathy and/ or renal stones [6].

Main outcome measures

Primary outcome

The proportion of gout patients achieving target SUA level. According to recommendations from the 2020 American College of Rheumatology Guideline for the Management of Gout [6], the target SUA level among gout patients is < 0.36 mmol/l in non-tophaceous gout and < 0.3mmol/l for tophaceous gout.

Secondary outcome

The risk factors associated with poor urate control.

Sample size estimation

According to findings from the literature, around 17–35.8% of gout patients could have adequate urate control with target SUA achieved [7, 8]. By using the sample size calculator for cross-sectional study (https://www2.ccrb.cuhk.edu.hk/stat/epistudies/x1.htm), α error being 0.05, the percentage of gout patients achieving the target SUA level being 20%, estimated effect size being 1.5, using 5% absolute precision with 95% level of significance, the minimal sample size would be **369**. To allow room for patient exclusion, **500** cases (35% more than the sample size) were recruited.

Sampling process

All included patients were listed in order of their outpatient case numbers. A list of 500 random numbers was generated from the research randomizer from which the 500 patients to be included were selected.

Statistical analysis

To compare any significant difference between groups, the Independent Samples T-test was used when the continuous variables were normally distributed, while the Mann-Whitney U test (2 groups comparison) was used when the continuous variables were not normally distributed. For categorical data, the Pearson Chi-square test or Fisher's Exact test was used to determine the statistical significance in different groups. The multiple logistic regression analysis (forward elimination procedure) included factors found to be significant at the level of $p < 0.2$ in the univariate analysis. Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk NY, USA computer software). A p-value of < 0.05 was considered to be statistically significant.

Results

From 1st January 2021 to 31st December 2021, a total of 8318 gout patients had at least one FU visit in the clinic. Among them, 500 patients were randomly selected, from which 32 were excluded according to exclusion criteria. 83 patients (17.7%) did not have regular SUA checked in the past 1 year. The remaining 385 cases were included in the data analysis. The selection and sampling process is summarized in Fig. 1.

The demographics and comorbidities of gout patients were demonstrated in Table 1. Among the 385 patients included in the data analysis, 303 (78.7%) were male, with an average age of 68.5 ± 14.7 years. For the smoking status, 250 (64.9%) were non-smokers, 37 (9.6%) were smokers, while 95 (24.7%) were ex-smokers. For the drinking status, 240 (62.3%) were non-drinkers, 81 (22.6%) were drinkers, while 31 (8.1%) were ex-drinkers. Body mass index was available for 341 patient, the mean BMI being 26.45 ± 4.2 kg/m^2, while 205 (60.1%) patients were obese, 4 (1.2%) of them were underweight, 61 (17.9%) had normal BMI, 71 (20.8%) were overweight. Regarding the comorbidities, 297 (77.1%) had HT, 123 (31.9%) had DM, 245 (63.6%) had hyperlipidemia, 35 (9.1%) had a history of CAD/ IHD, 10 (2.6%) had a history of CHF and 39 (10.1%) had a history of stroke. Concerning the renal function, the mean eGFR being 72.3 ± 22.8 ml/min/1.73 m^2, while 107 (27.8%) patients had CKD, with 69 (17.9%) had stage 3a, 27 (7.0%) had stage 3b, 11 (2.9%)

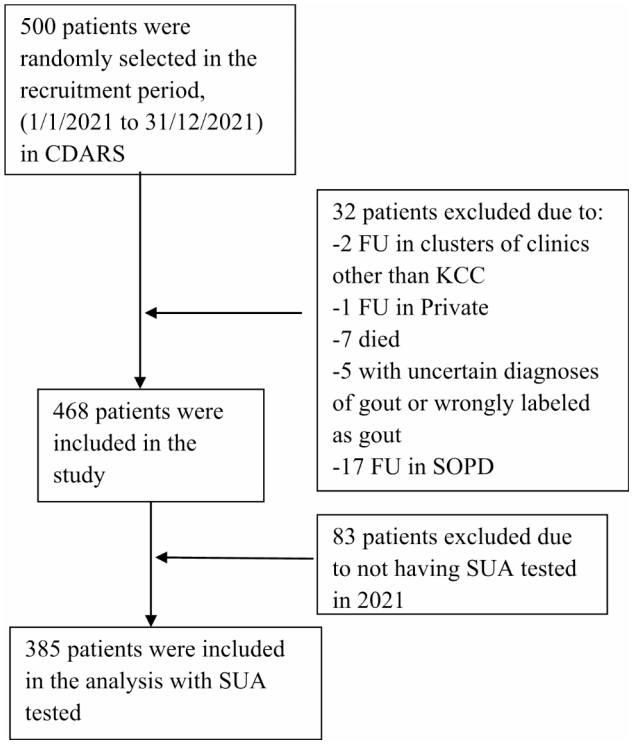

Fig. 1 Flow chart of case selection of the study

had stage 4 CKD respectively. Among the 385 patients, 17 (4.4%) were found to have tophaceous gout. The mean SUA of all patients was 0.42 ± 0.11 mmol/l. 232 (60.3%) patients were treated on ULT. Allopurinol was the most commonly used ULT (222, 95.7%), while 7 (3%) were on febuxostat and 3 (1.3%) on probenecid. 26 patients (6.8%) were on diuretics.

Factors associated with the achievement of target SUA

Among the 385 adult gout patients included in final studies, 115 met the target SUA with an overall proportion being 29.9% (Fig. 2). Among 17 patients with tophaceous gout, none of them could achieve the target SUA.

Table 1 also summarizes the univariate analysis of associated factors for meeting target SUA level among gout patients. It revealed that age, gender, smoking status, drinking status, comorbid of DM or hyperlipidaemia or stroke, eGFR level, tophaceous gout and those on ULT were related to the achievement of target SUA.

Multivariate logistic regression model was applied to identify the significant variables for not meeting target SUA (Table 2).

The result showed that gout patients who were male, active smokers, and with CKD stage 3a, 3b and 4 were less likely to achieve target SUA, whereas the use of ULT will help the patients achieve the target SUA level.

Discussion

Our study revealed that 60.3% of gout patients managed in primary care settings had received ULT, while 29.9% were able to achieve the target SUA. Compared with a population-based epidemiology study of gout management in Hong Kong, 25.6% of patients with gout were prescribed ULT in 2016, while 35.8% of them achieved the target serum urate level [2]. Although more patients had received with ULT, less percentage of gout patients had achieved target urate level in primary care. This finding of urate target achieving rate was similar to that worldwide, for example in Japan, in which 27.9% of patients achieved target SUA in the study from 2015 to 2017 [13]. Disappointingly, all patients with tophaceous gout were unable to meet the target SUA. In addition, 17.7% (83 out of 468) of our sampled individuals even did not have SUA tested in the past one year. Therefore, huge service gaps exist in gout management in primary care.

Concerning the associated factors of suboptimal urate control, our study revealed that patients who are male, active smokers and with CKD stage 3a, 3b and 4 were less likely to meet target SUA. These findings are consistent with the results of other studies worldwide. For example, the retrospective observational study in Japan from 2015 to 2017 yielded similar findings with higher achievement of target SUA in female patients [13]. The local study in HK SOPD in 2016 also showed that female gout patients have lower SUA [2]. It is postulated that female patients might have better adherence to treatment of comorbidities and have more frequent interaction with medical personnel [13].

Regarding the association between cigarette use and urate control, our study showed that active smokers were less likely to meet the target SUA and had poor urate control. Indeed, a consensus has yet to be reached on the effect of smoking on SUA and the risk of gout. For example, some studies suggest that smoking is an independent risk factor associated with lower SUA, lower prevalence and incidence of hyperuricemia. However, most of these studies are conducted among inpatients with acute gouty attacks upon admission and therefore its conclusion may not apply to active smokers in primary care in general [14]. Other studies have conclusive results pointing to the opposite or no effect [15].

On the other hand, CKD with stages 3a, 3b and 4 was found to be a barrier to meeting target SUA. This result was consistent with other studies in the USA [16] and Japan [13]. With the significant OR of CKD with stage 3a, 3b and 4 (reference group: No CKD) (OR 3.236, 3.122 and 10.250 respectively), we believe that CKD is the most important predictor of failure to achieve target SUA. The underlying reasons were multifold. First of all, impaired renal function placed concrete difficulties in dosage escalation in allopurinol prescription [17]. Allopurinol is the

Table 1 Demographics and comorbidities of all gout patients; Univariate analysis of associated factors for achieving target SUA level

	Total		**Target Urate Level Achieved**					
		±SD / %	**Yes**	**±SD / %**	**No**	**±SD / %**	***p*-value (Yes vs. No)**	
	N = 385	-	*N* = 115	29.9%	*N* = 270	70.1%	-	
Age	68.5	± 14.7	69.9	± 12.8	67.9	± 15.4	0.190	
Gender, **Male**	303	78.7%	81	70.4%	222	82.2%	0.010	
Smoking	-	-	-	-	-	-	0.108	
Non-smoker	250	64.9%	80	69.6%	170	63.0%	-	
Active smoker	37	9.6%	5	4.3%	32	11.9%	-	
Ex-smoker	95	24.7%	29	25.2%	66	24.4%	-	
Unknown	3	7.0%	1	0.9%	2	0.7%	-	
Drinking	-	-	-	-	-	-	0.041	
Non-drinker	240	62.3%	84	73.0%	156	57.8%	-	
Drinker	87	22.6%	20	17.4%	67	24.8%	-	
Ex-drinker	31	8.1%	6	5.2%	25	9.3%	-	
Unknown	27	7.0%	5	4.3%	22	8.1%	-	
Comorbidities	-	-	-	-	-	-	-	
Hypertension	297	77.1%	89	77.4%	208	77.0%	0.940	
Diabetes mellitus	123	31.9%	45	39.1%	78	28.9%	0.049	
Hyperlipidemia	245	63.6%	75	65.2%	170	63.0%	0.674	
CAD/IHD	35	9.1%	12	10.4%	23	8.5%	0.549	
CHF	10	2.6%	2	1.7%	8	3.0%	0.730	
CKD	107	27.8%	24	20.9%	83	30.7%	0.159	
Stage 3a	69	17.9%	16	14.0%	53	20.2%	-	
Stage 3b	27	7.0%	7	6.1%	20	7.6%	-	
Stage 4	11	2.9%	1	0.9%	10	3.8%	-	
Stage 5	0	-	0	-	0	-	-	
Stroke	39	10.1%	17	14.8%	22	8.1%	0.048	
Obese	205	60.1%	69	65.7%	136	57.6%	0.418	
Tophaceous Gout	17	4.4%	0	0.0%	17	6.3%	0.006	
On Diuretic	26	6.8%	6	5.2%	20	7.4%	0.433	
On Urate Lowering Agent	232	60.3%	92	80.0%	140	51.9%	< 0.001	
#BMI, *N* = 341	26.6	± 4.2	26.89	± 4.4	26.25	± 3.9	0.300	
Underweight (BMI < 18.5)		4	1.2%	0	0.0%	4	1.7%	0.418
Normal (BMI 18.5–22.9)		61	17.9%	17	16.2%	44	18.6%	-
Overweight (BMI 23-24.9)		71	20.8%	19	18.1%	52	22.0%	-
Obese (BMI ≥ 25)		205	60.1%	69	65.7%	136	57.6%	-
eGFR (ml/min/1.73m^2)		72.3	± 12.8	77.9	± 13.2	69.8	± 12.5	0.008
Serum urate acid, mmol/L		0.42	± 0.11	-	-	-	-	-

BMI = body mass index, eGFR = estimated glomerular filtration rate

#BMI: 44 cases did not have BMI data

first-line xanthine oxidase inhibitor under both GOPC and SOPD drug formularies for patients who are HLA B*58:01 negative. It has the proven benefit of lowering mortality and cardiovascular hospitalizations in CHF patients [18]. Another selective xanthine oxidase inhibitor Febuxostat, which could be used in gout patients with renal impairment eGFR ≥ 30 ml/min without any dosage adjustment, is under restricted use in primary care and could only be initiated under conditional review for gout patients if HLA B*58:01 positive or intolerant or allergic to allopurinol. And it is recommended to switch to other ULT in patients with a history of CVD or new cardiovascular events [6]. 7 out of 232 patients (3%) were on febuxostat in our study and they all had febuxostat as self-financed items at the time of study in 2021. Reduced efficacies of allopurinol in CKD patients and restricted use of febuxostat contributed to the failure to achieve target SUA in CKD patients. In addition, misconceptions about the adverse effects of ULT in worsening renal function as well as a higher risk of adverse effects of allopurinol hypersensitivity also impose difficulties of ULT use in gout patients with CKD. The active metabolite of allopurinol may be nephrotoxic in cumulative high doses in declining renal function [19].

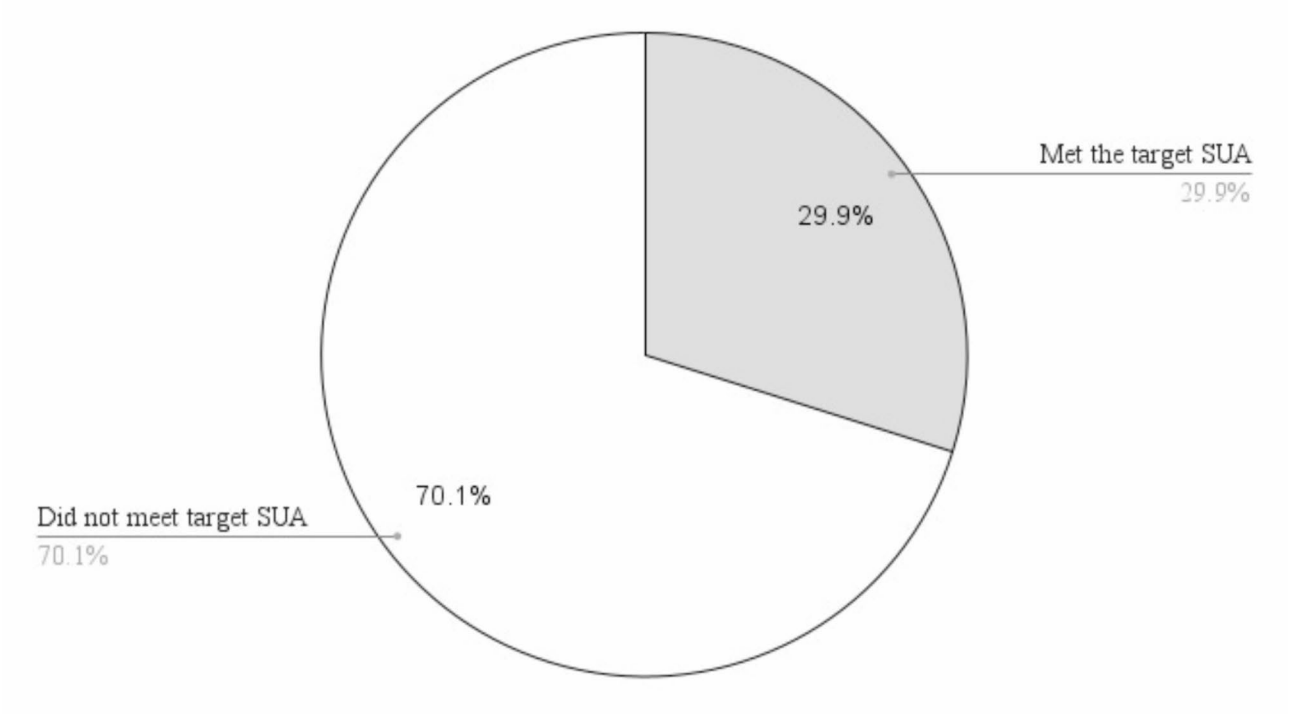

Fig. 2 Proportion of gout patients who had met the target SUA in the study

Table 2 Multivariate logistic regression analysis for risk factors of NOT achieving target SUA level

Variables	OR	95% CI	*p*-value
Age	0.99	0.98–1.02	0.905
Gender-Male	2.59	1.37–4.87	*0.003
Active smoker (vs. Non smoker/unknown)	3.17	1.08–9.33	*0.036
Ex-smoker (vs. Non-smoker/unknown)	0.70	0.37–1.33	0.278
Active Drinker (vs. Non-drinker/unknown)	1.71	0.87–3.34	0.118
Ex-Drinker (vs. Non-drinker/unknown)	2.13	0.75–1.98	0.157
CKD stage 3a (vs. No CKD)	3.24	1.56–6.73	*0.002
CKD stage 3b (vs. No CKD)	3.12	1.11–8.76	*0.030
CKD stage 4 (vs. No CKD)	10.25	1.08–97.48	*0.043
Comorbid of DM	0.99	0.49–1.98	0.967
Comorbid of Stroke	0.46	0.21–1.01	0.053
Comorbid of Hyperlipidaemia	1.46	0.99–2.14	0.057
On ULT (vs. Not on ULT)	0.23	0.13–0.40	*<0.001

*$p < 0.05$. OR-Odds Ratio, CI-Confidence interval, ULT-urate lowering agent

We found that the use of ULT was associated with higher achievement of target SUA. The result was consistent with other local and international studies. The local study in HK SOPD in 2016 also showed that gout patients treated with ULT had lower SUA [2]. 60.3% of patients in our study were put on ULT but with actual figures more than 60% of them cannot achieve target SUA even on ULT, in contrast with the previous study in HK SOPD with only one-quarter of patients being put on ULT and 35.8% of them could achieve target SUA. Failure to meet target SUA even with ULT use could be postulated to be related to the doubtful ULT adherence and doctors' low awareness of target SUA achievement thus hesitancy in dose escalation in the primary care setting. The UK Study on gout management in primary care in 2007 revealed a significant inverse relationship between allopurinol dose and SUA level [8]. Poor insight from patients whose ULT dosage needs to be further titrated to target could also be one of the barriers and medication inertia.

In our study, allopurinol was the majority of ULT used in the primary care, accounted for 95.7% of ULT prescribed. The results was similar to a local study conducted in Hong Kong [2]. In contrast to Ioanna Hotea et al. study conducted in Rheumatology Department, Uricosuric, i.e. Benzbromarone was the second commonly used ULT [20]. The local guideline on ULT suggested that uricosuric monotherapy was not preferred unless patient presented with a contraindication or intolerance to both xanthine oxidase inhibitors, i.e. allopurinol and febuxostat [7].

Strength of the study

It is the latest study on the standard of management of gout in general practice locally. This study is performed with data retrieved from computerized databases thus yielding accurate results. It involved a large population in HK primary care with a median age and sex ratio similar to other international studies of gout and can therefore represent the primary care sector in HK for comparison. Concerning other associated factors of gout, a systematic

review and meta-analysis of cohort studies showed that obesity, HT and diuretic use were the risk factors for incident gout with each more than doubling the risk compared to those without these risk factors [21]. Though these risk factors were not demonstrated to have statistically significant results in our studies, the focus of our study was the associated factors for not meeting target SUA. We emphasized the optimal urate control for reducing complications of local joint destruction and systemic CVD risk, instead of the incidence of gout or the risk factors for gout. Our research study had given reasonable outcomes to our research questions with study aims achieved.

Limitation of the study

First, this study has included gout patients who had been FU in public primary care clinics in the HA, therefore selection bias exists. The findings of this study may not generalize to the private or secondary healthcare setting. Also, 17.7% of gout patients who did not have serum urate tested in the study period had been excluded, this could introduce bias and generalizability. Secondly, as the data on comorbidities of gout patients were retrieved by HKCT coding in the CMS, the results of this finding might be affected by the accuracy of HKCT coding. However, this limitation may not be significant as a local study conducted in primary care had shown that the accuracy of ICPC coding for chronic diseases could be as high as 75.4% [22]. Thirdly, data on other variables that might be related to urate control such as dietary and excise profile and drug compliance, etc. had not been collected in this study due to incomplete documentation in the CMS, those lifestyle intervention factors and drug compliance could affect the rate of target urate control.

Direction of future study

Those patients, i.e. 17.7% who did not have SUA tested in the year of study can be further identified to compare their demographics with the study population. In addition, a qualitative research can be conducted to investigate and understand treatment barriers from a patient's perspective, reasons for non-compliance or difficulty in target achievement.

Conclusion

Management of gout in primary care had got more awareness, 60.3% of gout patients had received ULT. The treatment outcome was suboptimal, with only 29.9% of gout patients having achieved target urate level, this was particularly worse in tophaceous gouty patients. Gout patients who were male, active smokers, having CKD with stage 3a, 3b and 4 were less likely to meet the target SUA while those on ULT were more likely to meet it. As gout is proven to be an independent risk factor for the development of CVD, family physicians should enhance their awareness of urate control among gout patients and take proactive measures to optimize gout management, particularly in these high-risk patients.

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Author contributions

K Chan wrote the manuscript, conducted the literature review and designed the study, data acquisition. L Chiang was the major author for revising the manuscript. K Chan, CX Chen and L Chiang involved in data analysis and interpretation. CX Chen and L Chiang gave comments and major revisions on writing the manuscript. K Ho , Y Li and S Ko provided their continuous support and advice on the study design, data review, manuscript preparation and revision. All authors read and approved the final manuscript.

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Data availability

The data was stored and retrievable in the computer system of HA with restricted access according to the "need to care" policy, therefore not accessible to the public.

Declarations

Ethics approval and consent to participate

This study was approved by the Research Ethics Committee of Kowloon Central Cluster of Hospital Authority of Hong Kong. (Approval number: KC/KE-22-0083/ER-1). This was a cross sectional descriptive study involving clinical data retrieved from Computerized Medical System (CMS), written informed consent from participants were exempted by Research Ethics Committee of Kowloon Central Cluster of Hospital Authority of Hong Kong. All methods were carried out in accordance with the relevant guidelines and regulations,

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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