UNIVERSITI TEKNOLOGI MARA

The Development and Effectiveness Evaluation of Gout Treat-To-Target Booklet Intervention in Improving Gout Outcome

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Manuscript submitted in partial fulfilment
of the requirements for the degree of
Masters in Internal Medicine, 2023
Faculty of Medicine, Universiti Teknologi MARA

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ABSTRACT

Background: The treat-to-target serum uric acid (SUA) approach is recommended in gout management according to the 2016 European League Against Rheumatism (EULAR) guidelines. Instruction for initiation and dose escalation for urate-lowering therapy may confuse the patient. **Objectives**: We aimed to develop and validate the Gout Treat-To-Target booklet and to assess its effectiveness as an intervention in improving gout outcomes compared to standard practice alone. **Methods:** This study was conducted in two phases; Phase I involved the development and validation of the Gout Treat-To-Target booklet and Phase II was a single-centre interventional study on the effectiveness of validated Gout Treat-To-Target booklet in improving gout outcome. Patient were seen at two-monthly interval. **Result:** 50 patients were recruited. The mean age of the patient was 46.5 years old. The mean gout duration was 11.2 years and tophi were found in 50% of patients. The patients were randomized via stratified block randomization into two groups; the intervention group (24 patients) and the control group (26 patients). with a. All patient received formal education of at least secondary school. 50% of patients had tophi. The baseline mean SUA was 559.8 (77.9) μmol/L in the intervention group and 605.4 (90.6) μmol/L in the control group. At 16 weeks, 20 patients (41.6%) achieve target SUA. We found three factors associated with the achievement of serum uric acid (SUA); use of the Gout Treat-To-Target booklet, lower baseline SUA and presence of tophi. **Conclusion:** The Gout Treat-To-Target booklet was validated for use in clinical practice. It is an effective tool to achieve the desired SUA level in 41% of patients at 16 weeks, in addition to standard clinical practice.

Keywords Gout. Serum uric acid. Treat-To-Target

INTRODUCTION

Gout is the most common inflammatory arthritis. It is a spectrum of disorders ranging from asymptomatic hyperuricemia, acute gouty arthritis, inter-critical gout and advanced tophaceous gout (1). It is strongly associated with other metabolic disorders such obesity, hypertension, type 2 diabetes, and dyslipidaemia (2). The incidence of gout is on the rise due to increasing prevalence of metabolic syndrome (3-5). Two Malaysian studies conducted in two separate rheumatology centres in 2019 reported that gout was more common in men aged 53.1 and 57.5 years old. Tophi was found in 62.4 – 72.5% of patients with a baseline serum uric acid (SUA) 567.3 μmol/L and 599.9 μmol/L (6, 7).

Gout is a disabling but treatable disease (8). When left untreated, complications such as tophi, urate arthropathy and renal stones ensue (9). Guidelines recommend starting urate lowering therapy (ULT) when there are two or more episodes of gout flares in a year or when patients develop gout complications (1, 10, 11). The European League Against Rheumatism (EULAR) and American College of Rheumatology (ACR) also recommend initiation of ULT close to the time of first diagnosis in patients presented at the age less than 40 years old or with uric acid more than 480mmol/L and those with comorbidities that include renal impairment, hypertension, ischemic heart disease or heart failure (1, 10).

Maintaining SUA below the saturation point has been shown to reduce flare frequency and facilitate uric acid crystal dissolution (12, 13). Therefore, a treat-to-target strategy is recommended, where the treatment should target SUA level less than 360 μ mol/L in uncomplicated gout and less than 300 μ mol/L in complicated gout (8). The target SUA should be maintained for life if the ULT is well tolerated (1).

Gout is currently seen as a curable condition. However, only a small percentage of patients received ULT, which ranged from 29% in the United States to 34% in United Kingdom (14, 15). Among the key barriers to achieve target SUA level was inadequate ULT doses (16, 17). Barely half of general practitioners perform allopurinol up-titration and non-rheumatologists are hesitant to increase the dosage above 300 mg per day (18-20). Furthermore, only 10-46% of patients reported being adherent to ULT (21). Inadequate gout education and information from physicians are among the factors that contribute to non-adherence to therapy (22-24). Patients perceived gout attacks as an 'inconvenience' which had no negative impact on their overall health thus, they sought solely pain alleviation and dietary management (25). Patients' belief that gout does not justify long-term treatment and their scepticism over the efficacy of ULT also impede successful gout treatment (20, 26). Mikuls at el, reported that only 86% of their study population maintained their target SUA five years after treatment initiation (27). Patients felt that they were not receiving adequate and necessary gout information from their treating physician(18, 23), which includes dietary triggers (22), indication and side effects of medication (23, 28). Therefore, this Gout Treat-To-Target booklet can be used as a tool to reduce the gap in gout education so that patients will be more involved in their management of their disease.

This study was conducted with two main objectives. The first objective is to develop and validate a Gout Treat-To-Target booklet as a tool to achieve the Treat-To-Target strategy. The assessment for content validation was assessed for the degree of relevance using the assessment of Response Process Validation and Content Validity Index Calculation, while the assessment for face validation was assessed for degree of clarity and comprehension using the assessment of Response Process Validation and Face Validity Index Calculation.