were included in the final score, using a four-grade system (0-3). It was decided that each anatomical structure should be scored separately and then also summed in order to define the joint score. The sum of the assessed joints was the total score at patient level. The final scoring system with the definitions and the relative technical notes is represented in Figure 1. 33/41 members participated to the reliability exercise. The inter-reader reliability of the scoring was substantial (kappa of 0.72), and the intra-reader reliability was almost perfect (kappa of 0.82).

Conclusion: This is the first study for developing a scoring system for the extent of CPP crystal deposition in patients with CPPD. The scoring system demonstrated to be reliable in static images. The next step of the validation process is to assess the reliability of the scoring system in a patient-based exercise. This study represents a fundamental step in the OMERACT process of validating US as an outcome measure instrument, and above proposed scoring system will hopefully provide a useful tool for clinical practice and research.

The OMERACT scoring system for CPPD extent

Disclosure of Interests: None declared

O4P0649 INPATIENT DISCONTINUATION OF ALLOPURINOL – A QUALITATIVE IMPROVEMENT (QI) INITIATIVE

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Background: Gout is a chronic inflammatory arthritis induced by hyperuricemia and manifested by recurrent acute flares of debilitating joint pain, when left untreated. Allopurinol is often used as long-term urate lowering therapy. Discontinuation of allopurinol leads to worsening flares, disability, poor quality of life, and frequent use of acute care facilities. Recent data revealed that 56% of hospitalized patients had allopurinol discontinued during an episode of acute gout flare, suggesting an unmet need for ongoing provider education (1). Gout flares are 14 times more likely to develop in patients who have allopurinol discontinued upon admission to the hospital (2).

Objectives: We performed a qualitative analysis of the current rate of discontinuation of allopurinol during hospitalizations at an academic hospital in order to develop a qualitative improvement model.

Methods: We leveraged our electronic health records (EHR) to obtain data on gout patients admitted to the university hospital from 2019-2020, with IRB approval. Patients on allopurinol as an active home medication that was discontinued during hospitalization and/or after hospital discharge were included to calculate the rate of discontinuation. Lean thinking methodology with A3 process mapping for root cause analysis (RCA) was utilized. We first identified stakeholders involved in medication reconciliation – nurses and various providers, including trainees, and invited them to participate in an anonymous survey to understand the rationale behind allopurinol discontinuation during hospitalization. Next, we created countermeasures and actionable recommendations that could be implemented at an institutional level.

Results: A total of 2138 patients who were hospitalized had allopurinol listed as an active home medication. Of these, 364 (17%) did not receive allopurinol during hospitalization. Based on the survey data, providers chose to discontinue allopurinol due to the following factors – acute gout flare, renal impairment, gastrointestinal issues, cytopenia, drug interactions, NPO status, and always discontinued the medication. The RCA revealed layers of reasoning at various levels of the medication reconciliation process which impacted the decision-making algorithm. This in turn led to discontinuation during the admission and subsequent omission of allopurinol from the discharge medication list. Several actionable and high-impact recommendations emerged as countermeasures, including – a) pharmacy involvement at admission medication reconciliation, b) creation of a clinical practice guideline, and c) automated routing by EHR to standardized guidelines when allopurinol was discontinued on admission (Figure 1).
Conclusion: There is evidence of inappropriate discontinuation of allopurinol that leads to gout flares in the outpatient setting and unnecessary resource utilization. We developed an implementation plan to mitigate this systematically at an institutional level. Testing these recommendations next to devise a standardized protocol as a continuous improvement strategy may help improve gout care and patient outcomes.

REFERENCES:


Disclosure of Interests: None declared
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OP0170 PHASE 2A, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF THE EFFICACY AND SAFETY OF A TRANSDERMAL ALKALINIZING AND PAIN-RELIEVING TREATMENT FOR REDUCING PAIN ASSOCIATED WITH AN ACUTE GOUT FLARE

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Background: Monosodium urate (MSU) deposition is pathognomonic for gouty arthritis. MSU crystal formation and dissolution is affected by pH and theoretically, alkalinizing agents (eg, sodium bicarbonate, NaHCO₃) that raise the joint microenvironment pH, could facilitate MSU crystal dissolution and decrease the pain of an acute gout flare. However, oral NaHCO₃ use is fraught with intolerable gastrointestinal side effects.

Objectives: To determine if NaHCO₃ in a patented transdermal formulation could effectively and safely reduce the pain of an acute gout flare.

Methods: A Phase 2a prospective, double-blind, randomized, placebo-controlled study enrolled 418 subjects across 20 US sites. Patients with a diagnosis of gout using ACR/EULAR criteria (Score ≥ 8), ages 18-75, history of ≥ 2 gout flares in 12 months prior to randomization and on stable doses of urate-lowering therapy were included. Exclusion criteria were BMI > 40kg/m², > 12 gout flares in the year prior to randomization, history of rheumatoid arthritis, psoriatic arthritis, evidence of septic arthritis, acute polyarticular gout (≥ 4 joints), and arthritis of any other cause. Patients were randomized to receive placebo lotion or transdermal NaHCO₃. Upon flare they initiated colchicine (1.2 mg followed by 0.6 mg 1 hour later) and applied study product to the limb of the affected joint. Outcome measures included pain-numeric rating scale (NRS, 0-10), time to resolution of pain (50% reduction), rescue medication use, joint tenderness, and physical function (PROMIS PF-20). Data were collected in patient diaries for the pain and PROMIS measures at several time points from baseline through Day 7, as were adverse events. Statistical analyses utilized ANCOVA (baseline pain as a covariate), Kaplan-Meier curves for homogeneity, and two-proportion z-test, all with α=0.05.

Results: 98 patients had a gout flare during the 14-month study period. Those in the active arm (ITT, N=48) had an overall responder rate of 94.5% vs. 79.3% (p=0.01) in the placebo arm (ITT, N=50) over the 7-day follow up. Rescue medication use was lower in the active arm vs. placebo (6.3% vs. 20.0%, p=0.02); and PROMIS PF-20 showed greater improvements over 7 days (22.2 vs. 16.7 points, p=0.05). The most common adverse event was hypertension (14.2%) with no significant difference between arms. Per protocol analyses were conducted to adjust for adherence on Day 1 for time to resolution of pain (Figure 1) and additional 24hr endpoints (Table 1).

Table 1. Key 24hr Endpoints (Per Protocol, n = 57)

<table>
<thead>
<tr>
<th></th>
<th>Active (n=28)</th>
<th>Placebo (n=29)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median time to resolution, hrs¹</td>
<td>24</td>
<td>72</td>
<td>0.03</td>
</tr>
<tr>
<td>Change in 24hr PROMIS PF-20 score²</td>
<td>16.7</td>
<td>9.4</td>
<td>0.01</td>
</tr>
<tr>
<td>Physician-assessed moderate-to-severe joint tenderness 24hr³</td>
<td>28.0%</td>
<td>57.1%</td>
<td>0.02</td>
</tr>
</tbody>
</table>

¹≥ 50% reduction in pain; K-M Est.; Subjects using rescue medication, discontinuing study drug, or missing pain scores censored. ²Consists of 20, 0-5-point questions; higher scores indicate better function |LIKERT: 0 (no pain), 1 (pain), 2 (wincing), 3 (wincing and withdrawing) |

Disclosure of Interests: None declared

OP0171 A RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED, MULTICENTER, STUDY OF METHOTREXATE COMBINED WITH PEGLOTICASE IN PATIENTS WITH UNCONTROLLED GOUT

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Background: Patients (pts) with gout refractory to oral urate-lowering therapy (ULT) have few treatment options. Pegloticase (pegylated uricase) lowers serum uric acid (sUA) in these pts, but response rates are limited by anti-drug antibodies (ADA), which decrease urate-lowering efficacy and increase infusion reaction (IR) risk. Because methotrexate (MTX) is commonly used in RA...