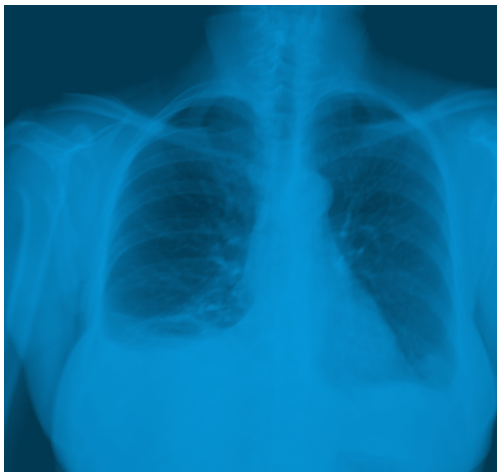
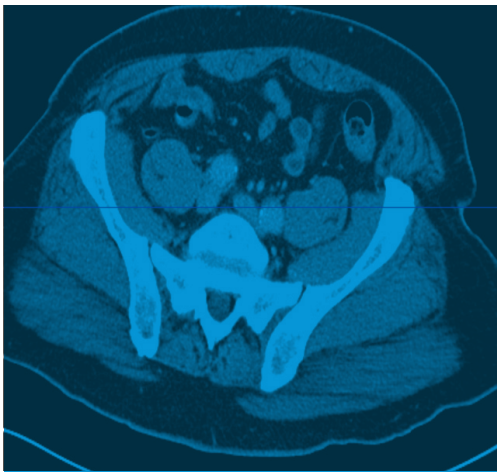
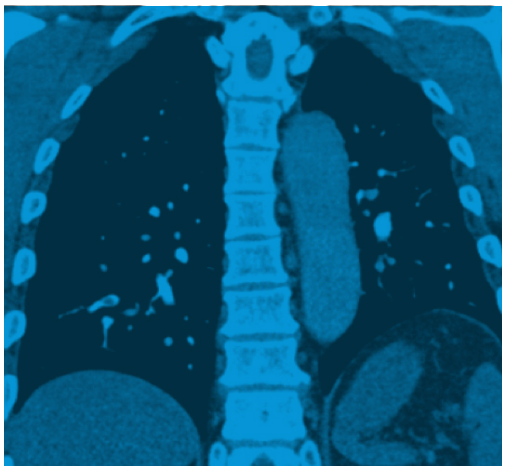
ST. VINCENT CHARITY MEDICAL CENTER

# JOURNAL

VOL. 9 ISSUE 1 | WINTER 2020







## IN THIS ISSUE



**ST. VINCENT CHARITY MEDICAL CENTER JOURNAL**
Vol. 9 Issue 1 | Winter 2020



## JOURNAL ARTICLES AND AUTHORS



ST. VINCENT CHARITY
MEDICAL CENTER

The St. Vincent Charity Medical Center family is committed to the healing mission of Jesus. We serve with: a deep respect for the dignity and value of all persons; our practice of quality care; our dedication to the poor; and, our commitment to education. St. Vincent Charity Medical Center, with the commitment of its caregivers and physicians, will be a leading model for health care delivery in Northeast Ohio based on its faith-based mission, dedication to education, commitment to the communities it serves, excellence in the patient experience it provides, focus on surgical services, and partnerships with physicians and other constituencies.

*St. Vincent Charity Medical Center Journal* ISSN 2577-9214

**St. Vincent Charity Medical Center**
2351 East 22nd Street | Cleveland, Ohio 44115
216-861-6200 | www.stvincentcharity.com

*We want to hear from you. Send your feedback to researchjournal@stvincentcharity.com*

# The unsung heroes

The last half century has seen a great deal of growth and development in the application of technology and innovation in the delivery of healthcare. Patient safety and healthcare quality, on the other hand, severely lagged behind. This lag was revealed in the famous Institute of Medicine report of 2001"To Err is Human". The report ushered in a new paradigm of healthcare delivery in the US and brought sweeping changes in how we viewed safe and quality care. New metrics and methods of evaluation were developed to assess the care patients received.

Keyvan Ravakhah, MD, MBA

Various aspects of healthcare have been studied including how patients are checked into the hospital, what happens during hospital stay and more importantly how patients are discharged from the hospital. High quality discharge planning has been associated with reduced hospital readmission and adverse events. One of the key components of successful discharge planning is the level of organizational and technical support for care providers. Other factors include the individual care provider, the patient, and the relationship between providers [1]. A recent patient encounter during rounds with a medical resident brought to fore the work of social workers, the unsung heroes of modern healthcare delivery.

The patient encounter involved a lady with advanced dementia who was terminal. The patient's family wanted her to be at home where she had lived for 50 years. The family had already met with hospice staff. I gave the go-ahead to the medical resident to discharge the patient and also tasked him to ensure everything is set at home for the patient. The resident politely asked what I meant. I explained that hospice might recommend hospital bed, bedside commode, suctioning device and other supplies that may be needed to make the last few days of a dying patient more comfortable. Who is going to arrange for these things for the patient, the resident asked? The social worker, I answered.

Social workers are the problem solvers and without them the flow of healthcare stops. They find the proper rehabilitation site for your postsurgical patient, find shelters for our homeless and support for our victims. They find the right resources for our patients and make sure they have everything they need from oxygen to a caring aide or nurse. They do everything without the visibility that our doctors or nurses have. The social worker's primary goal is *"help people in need and address social problems"* [2]. They just do their work and make things happen!

It is appropriate, therefore, that we thank our wonderful social workers, salute them and let them know how much we appreciate them. Let us mark the 3rd Tuesday in March of every year on our calendars because it marks the world social work day (WSWD). This year's WSWD fell on March 17, 2020. The theme focused on promoting the importance of human relationships. Congratulations to all social workers!

Percy Adonteng-Boateng, MD, MPH

Keyvan Ravakhah, MD, MBA

*References*

1. Hesselink G, Zegers M, Vernooij-Dassen M, et al. Improving patient discharge and reducing hospital re-admissions by using Intervention Mapping. *BMC Health Serv Res*. 2014;14:389. Published 2014 Sep 13. doi:10.1186/1472-6963-14-389
2. National Association of Social Workers Code of Ethics

# A case of lymphocytic pleural effusion while taking Dasatinib for CML

By **Arunbabu Sankaranarayanan, MD; Ryan Choudhury, MD; Basel Altaqi, MD; Keyvan Ravakhah, MD**


## ABSTRACT

We examined a case of dasatinib associated lymphocytic pleural effusion which occurs in approximately 20% of patients, according to prior studies. The intent of this report is to provide the readers a case demonstrating this side effect of Dasatinib and inform them of limited investigations strategies for lymphocytic pleural effusion.


## INTRODUCTION

Second-generation Tyrosine Kinase inhibitor, dasatinib, is approved as initial treatment for chronic myeloid leukemia (CML) chronic phase (CP). Studies have shown that the incidence of dasatinib associated pleural effusion is approximately 20%. Dasatinib-associated pleural effusions are generally lymphocyte-predominant exudates. Lymphocytic pleural effusion can also be seen in conditions like TB, malignancy, sarcoidosis and autoimmune disorders like SLE and Rheumatoid arthritis. Extensive investigations are needed to rule out the above mentioned conditions. Lymphocytic pleural effusion in a setting of Dasatinib does not warrant an extensive work up. After ruling out the red flag reasons for pleural effusion like pneumonia, CHF and other infections, switching to other tyrosine kinase inhibitors and watch for resolution is a reasonable option that can be cost efficient.

## CASE PRESENTATION

A 47-year-old female with a 26-month history of CML-CP presented with a one week history of sudden progressive dyspnea without cough. She started Dasatinib 100 mg PO daily with hydroxyurea at the time of her diagnosis with good response. Medical history is otherwise unremarkable. She reported multiple previous episodes of intermittent dyspnea on exertion, not treated. Three months prior, the patient underwent bone biopsy demonstrating remission of CML and low white blood cell count. Prior surgical history includes hysterectomy and hernia repair. She is a life-long non-smoker, denies alcohol or drugs. Her only medication was Dasatinib and she has no allergies. On admission, she reported orthopnea, but denied other symptoms.

Patient was afebrile, not tachycardic, blood pressure was stable, and she was saturating more than 94% on room air. Exam was unremarkable except for bilateral lower lung rales. Chest x-ray revealed bilateral pleural effusions (Fig. 1) and was confirmed with CT of the chest. Troponin I was < 0.015 and B-Natriuretic Peptide was 70.19. Electrocardiogram demonstrated sinus rhythm without ST-changes. Differential diagnosis for pleural effusions at that time included congestive heart failure, pulmonary edema, nephrotic syndrome, superior vena cava obstruction, malignancy, drug-induced pleural disease and hypothyroidism.

On day 2, the patient continued experiencing dyspnea on exertion. Echocardiogram showed normal systolic function with ejection fraction of 60-65%. Then she underwent right sided thoracentesis which drained 1100 mL of clotted cloudy tan fluid. On day 3, left sided thoracentesis drained 1050 mL of yellow turbid fluid. Post-procedure chest x-ray showed no evidence of pneumothorax and near resolution of effusion on both sides. Results of the pleural fluid reported no evidence of malignancy and numerous lymphocytes.

**Figure 1**

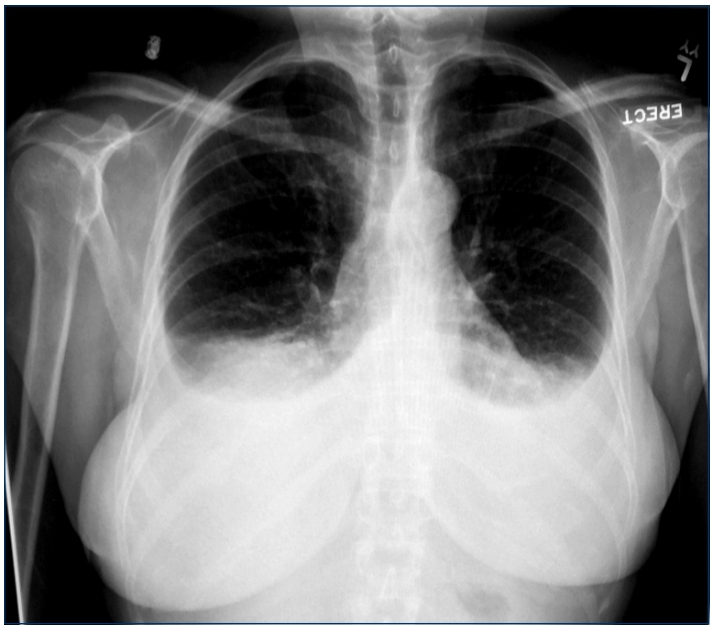



**Figure 1. Chest X-ray on Admission.**

At discharge, the patient had no chest pain or dyspnea and she was continued on inhalation medications. Dasatinib was held until follow up with the patient's oncologist and pulmonology visit was scheduled with repeat chest x-ray in 3-4 weeks.

Patient was switched to Bosutinib 400 mg PO daily at her oncology follow up. At her pulmonology visit, she reported new onset nausea since starting Bosutinib, but she denied any dyspnea. Chest x-ray at this visit demonstrated persistent bilateral effusion, small on the left and moderate on the right (Fig. 2).

## DISCUSSION

Dasatinib-induced lymphocyte predominant pleural effusion is relatively uncommon but a knowledge of this side effect could help us to stop at some time after negative basic investigations. Grade 3-4 pleural effusions are associated with increased dosages, severity of disease, and chronic phase (4). This adverse effect is not fully understood at this time. Several mechanisms are hypothesized to explain drug-induced effusions. Proposed explanations include hypersensitivity reaction, elevated free radical production, direct toxic effects, antitoxin defense suppression,

**Figure 2**

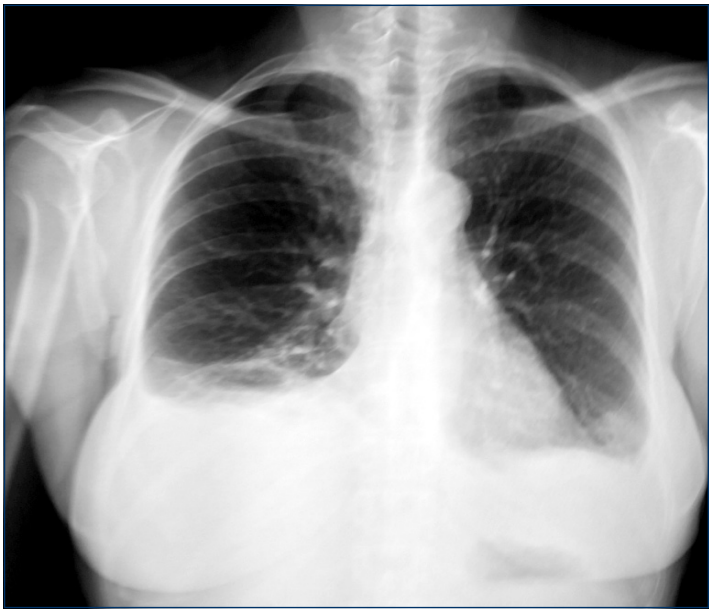


**Figure 2. Chest X-ray at Follow-up.**

inhibition of kinases and platelet-derived growth factor receptor- , and inflammation from chemical injury (5). These effusions could also be multifactorial in etiology. The proposed reason for Dasatinib induced pleural effusion may also be due to immune-mediated mechanism involving NK-cells.

In this case report, we examined a patient with CML-CP in which Dasatinib was the only medication and recurrent disease was ruled out by a recent bone marrow biopsy. Dasatinib-induced pleural effusions have been reported with doses of 100 mg daily (4). Factors associated with higher rates of pleural effusion include cardiac disease, hypercholesterolemia, hypertension, autoimmune disease and rash while taking dasatinib. In this patient other risk factors for pleural effusion were absent. However, the patient reported prior intermittent episodes of symptomatic dyspnea on exertion that resolved without any intervention. At the initiation of therapy with Dasatinib the patient's medication was held for one week due to low platelet count. No other medication interruption or alteration was documented prior to this admission for dyspnea.

Generally, symptomatic patients are conservatively managed with holding of the TKI, TKI dose reduction, diuretics, and steroids. Sometimes the work up for lymphocytic pleural effusion can be extensive and it may be important to rule out other causes of new onset pleural effusion. There is a question of whether to pursue further investigations for such a presentation. The intent of this article is to make physicians aware of this side effect of Dasatinib and translate this knowledge into reducing unnecessary testing for other causes of pleural effusion in such a patient. It is reasonable to switch to a different kinase inhibitor with scheduled follow up for resolution of the pleural effusion.

*References*


1. Cortes J, Rousselot P, Kim DW, Ritchie E, Hamerschlak N, Coutre S, Hochhaus A, Guilhot F, Saglio G, Apperley J, Ottmann O, Shah N, Erben P, Branford S, Agarwal P, Gollerkeri A, Baccarani M. Dasatinib induces complete hematologic and cytogenetic responses in patients with imatinib-resistant or -intolerant chronic myeloid leukemia in blast crisis. *Blood*. 2007;109(8):3207–3213.
2. Guilhot F, Apperley J, Kim DW, Bullorsky EO, Baccarani M, Roboz GJ, Amadori S, de Souza CA, Lipton JH, Hochhaus A, Heim D, Larson RA, Branford S, Muller MC, Agarwal P, Gollerkeri A, Talpaz M. Dasatinib induces significant hematologic and cytogenetic responses in patients with imatinib-resistant or -intolerant chronic myeloid leukemia in accelerated phase. *Blood*. 2007;109(10):4143–4150.
3. Hochhaus A, Kantarjian HM, Baccarani M, Lipton JH, Apperley JF, Druker BJ, Facon T, Goldberg SL, Cervantes F, Niederwieser D, Silver RT, Stone RM, Hughes TP, Muller MC, Ezzeddine R, Countouriotis AM, Shah NP. Dasatinib induces notable hematologic and cytogenetic responses in chronic phase chronic myeloid leukemia after failure of imatinib therapy. *Blood*. 2007;109(6):2303–2309.
4. Shah NP, Kantarjian HM, Kim DW, Réa D, Dorlhiac-Llacer PE, Milone JH, Vela-Ojeda J, Silver RT, Khoury HJ, Charbonnier A, Khoroshko N, Paquette RL, Deininger M, Collins RH, Otero I, Hughes T, Bleickardt E, Strauss L, Francis S, Hochhaus A. Intermittent target inhibition with dasatinib 100 mg once daily preserves efficacy and improves tolerability in imatinib-resistant and -intolerant chronic-phase chronic myeloid leukemia. *J Clin Oncol*. 2008;26(19):3204–3212.
5. de Lavallade H, Punnialingam S, Milojkovic D, Bua M, Khorashad JS, Gabriel IH, Chaidos A, Olavarria E, Goldman JM, Apperley JF, Marin D. Pleural effusions in patients with chronic myeloid leukaemia treated with dasatinib may have an immune-mediated pathogenesis. *Br J Haematol*. 2008;141(5):745–747.

# An underrepresented cause of venous thromboembolism, May-Thurner syndrome

By **Philip Tulio, MD; Ryan Choudhary, MD; Jehad Azar, MD; Randol Kennedy, MD; Mukul Pandit, MD**

## INTRODUCTION

The most common variant of May-Thurner syndrome (MTS) is due to compression of the left iliac vein between the overlying right common iliac artery and the fifth lumbar vertebrae. The exact incidence and prevalence of MTS are unknown but are likely to be underestimated given that most individuals with MTS anatomy do not have symptoms and require no treatment. Risk factors include female gender, scoliosis, dehydration and hypercoagulable disorders. Clinical features include acute lower extremity pain and swelling, with the swelling usually involving the entire limb. Claudicating pain can also be present. Diagnosis of MTS may be suspected based upon clinical features and initial diagnostic testing with venous duplex ultrasound, CT or MRI venography, however more invasive studies including catheter based venography and intravascular ultrasound (IVUS) might be done in the event of diagnostic uncertainty. Treatment of MTS depends on whether a deep venous thrombosis (DVT) is present. In the absence of DVT, treatment is conservative with compression stockings. For advanced nonthrombotic MTS with symptoms/signs of advanced chronic venous insufficiency, treatment is targeted toward reducing the severity of the stenotic venous lesion using angioplasty and stenting of the affected segment. Here, we present a patient who was found to have what was initially suspected to be an unprovoked DVT, only to confirm on further imaging the presence of MTS upon evaluation for predisposing conditions.

## CASE PRESENTATION

A 65-year-old African American male with a past medical history of hypertension and coronary artery disease status post stent in 2010 presented with left lower extremity pain in the popliteal region associated swelling for the past 5 days. He has no history of any leg trauma, recent surgery, bed rest, travel, malignancy, previous clotting episodes or family history of hyper-coagulable disorders. He denies any dyspnea or chest pain. His life style is not significantly sedentary. He is a lifetime non-smoker, with occasional alcohol, marijuana and cocaine use.

On physical examination, lung and cardiac exam were unremarkable. His left lower extremity was swollen, tense, erythematous and tense from the calf downward to the ankle and foot with a positive Homan's sign. Dorsalis pedis and posterior tibial pulses are weakly palpable.

A duplex ultrasound of the left lower extremity showed a large thrombus in the left popliteal, posterior tibial and peroneal veins (Fig: 1, 2, 3A and 3B). CT abdomen and pelvis with IV contrast demonstrated significant compression of the left common iliac vein as it crosses posterior to the left internal iliac artery, consistent with May-Thurner syndrome (Fig: 4). A spiral chest CT was significant for subsegmental emboli in the bilateral lobe pulmonary arteries (Fig: 5, 6 and 7). The patient was started on therapeutic dose of enoxaparin for venous thromboembolism and was later transitioned to apixaban. He was referred to an advanced vascular center to consider the need for angioplasty and stenting of the left common iliac vein.

**Figure 1**

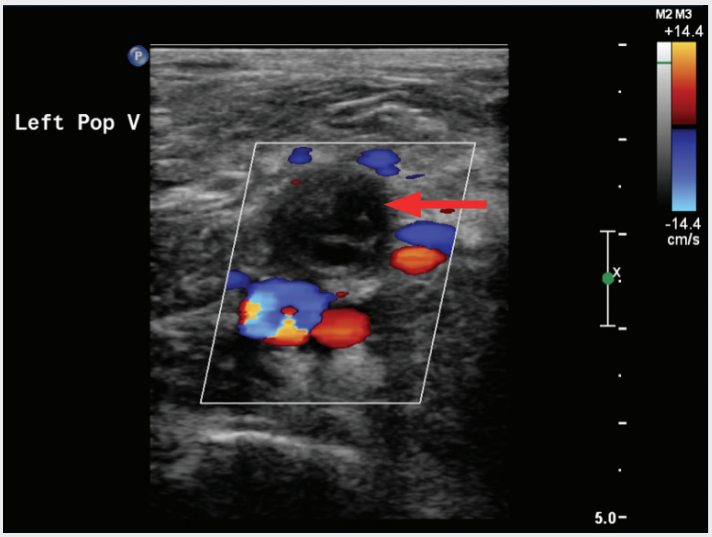



**Figure 1. Color doppler ultrasonography image of patient's left popliteal vein. Left popliteal vein is not compressible due to occlusive thrombus (arrow).**

**Figure 2**

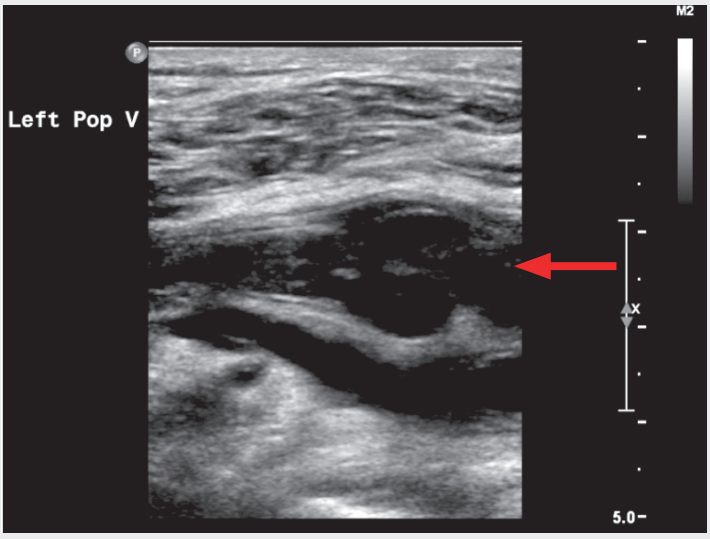
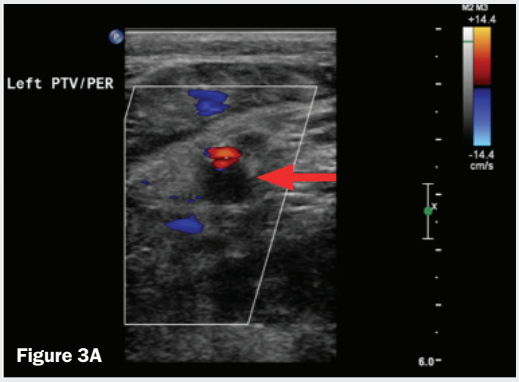
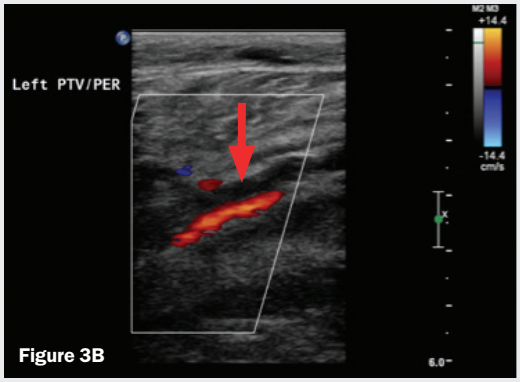



**Figure 2. Color doppler ultrasonography image of patient's left popliteal vein. Left popliteal vein is not compressible due to occlusive thrombus (arrow).**

Figures 3A, 3B




**Figures 3A, 3B. Color doppler ultrasonography image showing occlusive thrombus extending to involve the left posterior tibial and left peroneal veins (arrows).**

Figure 4

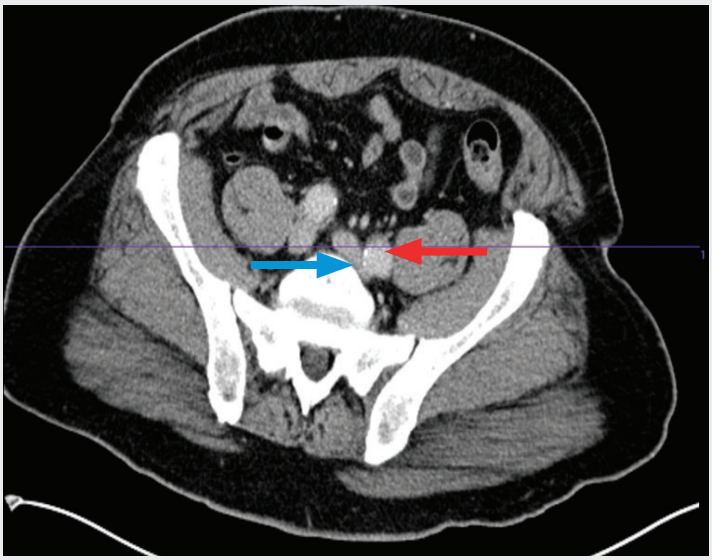


**Figure 4. Enhanced axial CT of the abdomen and pelvis, demonstrating compression of the left common iliac vein (blue arrow) between the left internal iliac artery (red arrow) and the vertebral body at the S1 level.**

Figure 5

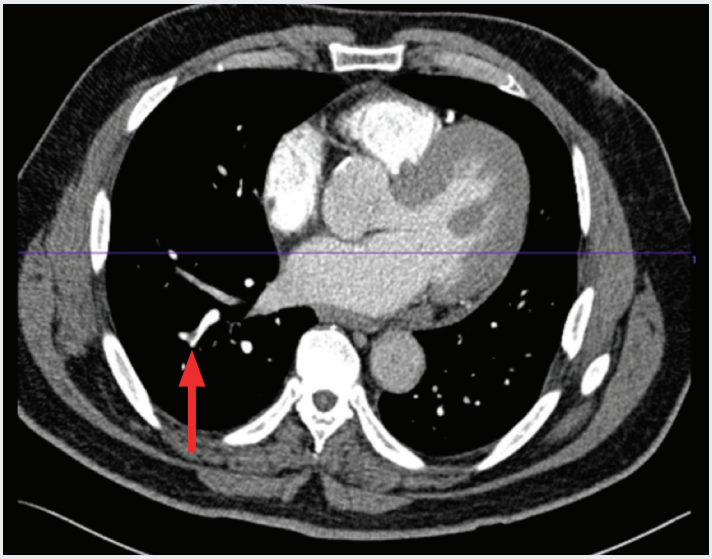


**Figure 5. Enhanced computed tomography (axial view) of the chest showing small filling defect in the sub segmental branches of the right lower lobe (arrow).**

## DISCUSSION

May-Thurner syndrome (MTS) was first described in 1908 by Virchow, who observed that iliofemoral vein thrombosis was five times more likely to occur in the left leg than in the right leg. The syndrome was not fully understood until the mid-20th century, when May and Thurner discovered an anatomical variant in 22% of 430 cadavers where the right iliac artery compressed the left iliac vein against the fifth lumbar vertebra. They postulated that the chronic pulsations of the overlying right iliac artery led to development of a "spur" in the vein wall and that this spur would result in partial venous obstruction [1].

The classic clinical presentation is that of a younger female in the second or third decade of life with left lower extremity swelling, which is contrasted with our patient's presentation as a 65-year-old male. Compression of the left common iliac vein in our patient was noted to be at the S1 level between the left internal iliac artery and the sacrum. Swelling was predominantly noted up to the level of the knee in our patient, which correlated with doppler results noting thrombi in the left peroneal, popliteal and posterior tibial veins.

Catheter-based venography is warranted if there is a sufficient level of suspicion for MTS in a patient with acute symptoms or if the patient has advanced clinical manifestations of chronic venous disease.

| continued on p.8

In the absence of DVT, patients with only mild symptoms warrant conservative management with compression stockings. For advanced nonthrombotic MTS with symptoms/signs of advanced chronic venous insufficiency, treatment is targeted toward reducing the severity of the stenotic venous lesion using angioplasty and stenting of the affected segment. Angioplasty of the venous stenotic lesion alone is not sufficient as is associated with high recurrence rates [2]. Stenting is not universally agreed upon, and recurrence rates may depend on stent type used [3]. Extending the stent into the inferior vena cava (IVC) has no negative impact [4]. Angioplasty and stenting of MTS lesions also decreases the recurrence rate of superficial reflux following ablation therapies.

If MTS is strongly suspected in a patient with venous thromboembolism (VTE), treatment begins with full therapeutic anticoagulation, if not contraindicated. Our patient was initiated on a full therapeutic dose of enoxaparin, and was then switched to apixaban. Therapeutic anticoagulation should be continued using similar dosing, monitoring and duration as VTE guidelines without the presence of MTS. The DVTs detected were considered to be provoked in nature by the external compression of the left iliac vein. Hence, a minimum of three months of full therapeutic anticoagulation is warranted [5]. This patient presented would have been subjected to indefinite anticoagulation if not further investigated, which brings to question the possible benefits of investigating for MTS in patients with unexplained VTE. Subsequent treatment is aimed at decreasing the volume of thrombus using catheter-directed thrombolysis or pharmaco-mechanical thrombolysis, evaluating for intrinsic venous stenosis, and, if present, angioplasty and stenting of the diseased iliocaval segment. With successful treatment of MTS, rates of post-thrombotic syndrome are less than 10%, compared to 80-90% if no treatment provided. Following stenting, concurrent antiplatelet therapy is reasonable, provided bleeding risk is low.

## CONCLUSION

The prevalence of May-Thurner syndrome (MTS) is unknown for certain and is likely underestimated, largely because most individuals with this anatomic anomaly remain asymptomatic. Clinicians should have a high index of suspicion for MTS in the presence of unprovoked DVT in the left lower extremity, recurrent left-sided DVT and/or signs of chronic venous hypertension. Angioplasty and stenting of the affected lesion and subsequent antiplatelet therapy is the definitive treatment for MTS. For patients with VTE in the presence of MTS, anticoagulation management is similar to patients with provoked VTE. Therefore, it can be argued that in patients with an unexplained cause with VTE, investigation for MTS can impact duration of anticoagulation.

**Figure 6**

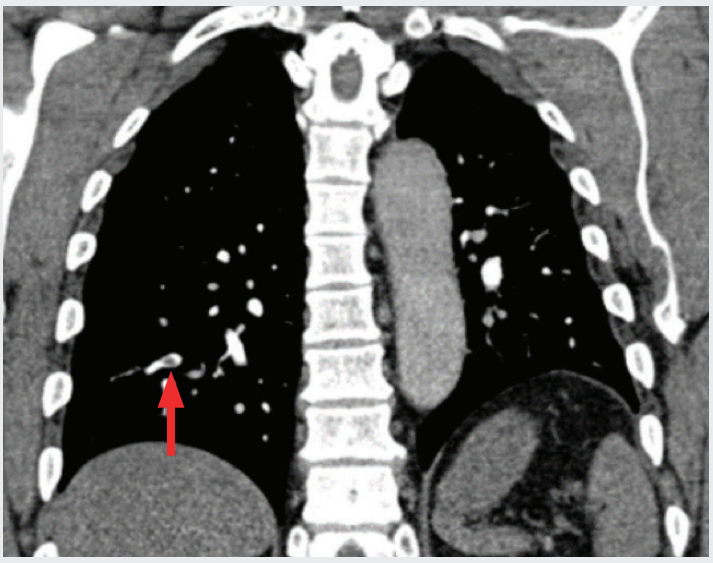


**Figure 6. Enhanced computed tomography (coronal view) of the chest showing small filling defect in the sub segmental branches of the right lower lobe (arrow).**

**Figure 7**

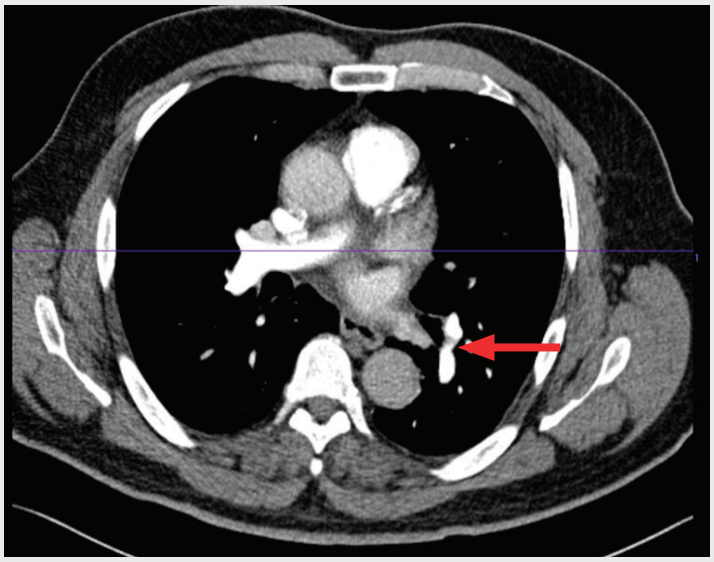


**Figure 7. Enhanced axial view of the CT chest showing small filling defect in the sub segmental branches of the left lower lobe (arrow).**

*References*

1. May R, Thurner J. The cause of the predominantly sinistral occurrence of thrombosis of the pelvic veins. Angiology. 1957; 8:419.
2. Mickley V, Schwagierek R, Rilinger N, et al. Left iliac venous thrombosis caused by venous spur: treatment with thrombectomy and stent implantation. *J Vasc Surg* 1998; 28:492.
3. Gloviczki P, Lawrence PF. Iliac vein stenting and contralateral deep vein thrombosis. *J Vasc Surg Venous Lymphat Disord* 2017; 5:5.
4. Neglen P, Hollis KC, Olivier J, Raju S. Stenting of the venous outflow in chronic venous disease: long-term sten-related outcome, clinical, and hemodynamic result. *J Vasc Surg* 2007; 46:979.
5. Jaff MR, McMurtry MS, Archer Sl, et al. Management of massive and submassive pulmonary embolism, iliofemoral deep vein thrombosis, and chronic thromboembolic pulmonary hypertension: a scientific statement from the American Heart Association. Circulation. 2011;-123:1788

# Could Pre-discharge BNP Predict 30 Day Readmission Rate?

By **Obinna Obiekezie, MD[12]; Gianpietro Zampogna, MD, MS[12]; Ryan Choudhury, MD[12]; Robert Steele, MD[1]; Keyvan Ravakhah, MD, MBA[12]**

Affiliations: [1]*St. Vincent Charity Medical Center, Internal Medicine Residency Program, 2351 E 22nd St, Cleveland, OH 44115*
[2] *Northeast Ohio Medical University, College of Medicine Faculty, 4209 OH-44, Rootstown, OH 44272*

## BACKGROUND

BNP is a hormone secreted by cardiac muscle cells of the ventricles in response to stretching caused by ventricular blood volume. It is currently been utilized in diagnosis of acute exacerbation of heart failure as well as for prognostic value post myocardial infarction. BNP levels change during heart failure exacerbation as well as after therapy (diuresis). Could pre-discharge BNP correlate with risk of 30-day readmission?

## METHOD

We conducted a prospective observational study on patients admitted with acute decompensated heart failure who received standard treatment based on current guidelines for the management of CHF exacerbation. BNP was obtained at the time of admission as well as on the day of or prior to the day of discharge. Clinisync was used to follow up patient's readmission within 30 days to our facility or any other facility within Ohio.

## RESULTS

Of 108 enrolled patients, 94 were included for analysis. 58 (54%) patients were evaluated with a pre-discharge BNP and 50 (46%) did not have pre-discharge BNP. Of the 58 patients who had pre-discharge BNP done, 18 patients were readmitted within 30 days and 40 patients were not readmitted within 30 days. The average admission BNP of the 30-day readmission group was 1375.92 vs 1050.81 for those not readmitted. The average discharge BNP of the readmitted patients was 1005.95 vs 623.28 for those not readmitted. The percentage BNP changes (admission to pre-discharge) in both groups were found to be statistically insignificant (p-value=0.418).

## CONCLUSION

Pre-discharge BNP did not objectively predict 30-day readmission rate in patients with acute decompensated heart failure. Though there was no statistical significance in the percentage change in BNP in 30 day readmitted group vs non admitted group, the mean pre-discharge BNP was found to be higher in patients readmitted within 30 days.

## KEYWORDS

CHF, BNP, Re-Admission, Pre-discharge

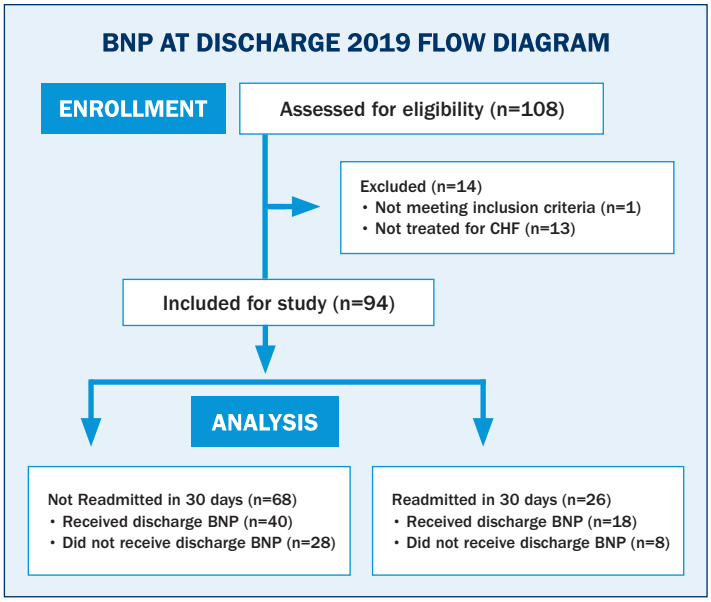
## INTRODUCTION

At many U.S. hospitals, heart failure accounts for the most common discharge diagnosis and it represents a huge cost for the national health care budgets. The current 30-day readmission rates are greater than 20% which is very high when compared to other disease conditions. According to data from the Center for Health Information and Analysis, hospital readmissions cost Medicare about $26 billion annually, $17 billion is spent on avoidable hospital trips after discharge. As a result, several studies and resources have been devoted to reduce these readmissions. Strategies like greater fluid removal during hospitalization, optimization of medical therapy on discharge (ACEI and Beta blocker) as well as early follow up within 7 days of discharge have been associated with a reduction in readmissions. However, there is currently no objective clinical criteria or scoring system for predicting early outcome after discharge.

BNP is a hormone secreted by cardiac muscle cells in the ventricles in response to distension caused by increased ventricular blood volume. It is currently been utilized as a supportive diagnosis of acute exacerbation of heart failure as well as for prognostication for post myocardial infarction. BNP levels change during heart failure therapy (diuresis) and as such; assessing pre-discharge level may help to identify patients at high risk for readmission.

However, after a review of the literature freely available on pubmed, conflicting results show no consensus on the utility of BNP at discharge. Papers such as Kolchi et al show that BNP and changes in BNP can be related to future outcomes [1]. Meanwhile a 2016 study demonstrated only the ability to stratify patients based on the BNP at discharge and not the changes in BNP [6]. Conflicting results like these exemplify the need to further study this question in detail and in new and differing populations of patients.

**Chart 1**




| continued on p.10

(cont. from previous page)

Table 1

| | COUNT | MEAN | STD. DEV. |
|---|---|---|---|
| Age | 94 | 69.3 | 13 |
| Admission BNP | 93 | 1141.7 | 1166.7 |
| Admission Weight (kg) | 94 | 94.34 | 29.49 |
| Height (cm) | 94 | 168.94 | 10.89 |
| Admission BMI | 94 | 32.87 | 9.07 |
| At Home Lasix (mg) | 93 | 36.56 | 27.127 |
| Discharge BNP | 58 | 742 | 868 |
| Change in BNP% | 58 | -31.97% | 33.33 |
| Discharge Weight | 93 | 92.18 | 28.05 |
| Change in Weight % | 93 | -2.04 | 4.58 |
| Length of Stay | 94 | 4.22 | 3.373 |

**Table 1. Overall Demographics**

## MATERIALS AND METHODS

### Patients

Patients were included if they were 18 years or older, were admitted with acute decompensated heart failure, as documented by the admitting physician, with BNP done on admission and prior to discharge. Patients were excluded if they were on dialysis or had end stage renal disease (eGFR < 15 ml/min/1.73m$^2$). Patients reserved the right to decline pre-discharge testing even after obtaining initial consent during admission. See Chart 1 for inclusion/exclusion.

### Study Design and Setting

This study was a prospective observational study that was conducted at St Vincent Charity Medical Center in Cleveland, Ohio which served as the primary admission site for the patients. CliniSync Health Information, which accesses patients' health information across Ohio, was utilized to follow up on possible 30-day readmission in other hospitals within Ohio region.

Enrolled patients received guideline directed management for acute decompensated heart failure and were assessed daily for response by the primary team. The choice of diuretic agent, route of administration, dosage and time of discharge were all determined by the managing team. Pre-discharge BNP was done a day prior to discharge or day of discharge.

### Trial Oversight

This study was designed by 2 residents, under the supervision of a cardiologist, at St. Vincent Charity Medical Center, Cleveland Ohio. Data were collected by the 3 residents involved in the study. All the authors had access to the data and contributed to the interpretation of results. The protocol was reviewed and approved by the institutional review board at the St Vincent Charity Medical Center and the study was performed in accordance with the principles stipulated by the institutional review board. All the authors in this study vouch for the accuracy and completeness of the data presented in this study.

### Statistical Analysis

For the categorical variables, sex and race, the results are summarized as frequency and percent. For those variables, to make comparisons between 30-day readmission groups Fisher's exact test and the chi-square test of contingency table data were used, respectively. Quantitative data are summarized separately for patients in several aggregations: for the entire group and by 30 day readmission (code 0 /code 1) type. Also, for the latter sub-groups, each sub-group has summary statistics for the variables (BNP and weight) only for patients whose paired data were used.

The summary statistics include the mean, standard deviation, median, 25th percentile, 75th percentile, maximum and minimum, as well as the sample sizes. To compare 30-day readmission groups for individual variables (except for eGFR), the "Student" t-test for independent groups was utilized*. For the paired data (admission and discharge BNP and weight), the "Student" t-test for paired data was employed. For the eGFR data (because of its truncated "> 60" values), it would not be apt to cite the mean and standard deviation, but rather summarize the central location and dispersion of those data using only the non parametric statistics the median and interquartile range (IQR) presenting them as "median (IQR)" with the form of presentation for the IQR being "(25th percentile – 75th percentile)" [which is the two values separated by a hyphen].

To compare 30-day readmission groups for eGFR, the non-parametric Mann-Whitney U-test was utilized. Statistical significance was taken as $p < 0.05$. No correction was made for multiple testing of data, but it should be noted that using Bonferroni's method would not have removed significance from any finding. The codes and variable names used are those listed in the EXCEL file.

When employing the "Student" t-test for independent groups, first Levene's Test for Equality of Variances was utilized and only when the latter had $p < 0.10$ as evidence of possible different variances in the two groups was the t-test option for different variances used (which occurred only with the "% Change in BNP" variable). This had no effect on any findings of statistical significance.

## RESULTS

A total of 94 patients were included for analysis in this prospective study. See Table 1 for average demographics of the participants. The average age of participants was 69.3 years with a standard deviation of +/- 13. Admission BNP was 1141.7 with a standard deviation of +/- 1166.7. Weight, height, and BMI on admission were 94.34 kg +/- 29.49, 168.94 cm +/- 10.89, and 32.87 kg/m2 +/- 9.07 respectively. Patients were taking an average lasix equivalence dose of 36.56 mg orally +/- 27.127. BNP at discharge was 742 +/- 868 which was equivalent to a change of -31.97% +/- 33.33. Average weight at discharge was 92.18 kg +/- 28.05, which was a change in weight of -2.04% +/- 4.58. Average length

Table 2

| SEX | Not Readmitted | Readmitted | Total |
|---|---|---|---|
| Male (%) | 42 (61.8%) | 13 (50%) | 55 (58.5%) |
| Female (%) | 26 (38.2%) | 13 (50%) | 39 (41.5%) |
| Total | 68 (72.3%) | 26 (27.7%) | 94 (100%) |
| **Race** | **Not Readmitted** | **Readmitted** | **Total** |
| AA – African American | 49 (72.1%) | 19 (73.1%) | 68 (72.3%) |
| AS – Asian | 2 (3%) | 0 | 2 (2.2%) |
| CA – Caucasian | 16 (23.5%) | 7 (26.9%) | 23 (24.5%) |
| LA - Latino | 1 (1.5%) | 0 | 1 (1.1%) |
| Total | 68 | 26 | 94 |

Table 2. 30-Day Readmission Demographics

Table 3

| MEAN | Not Readmitted | Readmitted | p-value |
|---|---|---|---|
| Age | 69.5 | 68.85 | .829 |
| Admission BNP | 1050.8 | 1375.9 | .230 |
| Admission Weight (kg) | 97.39 | 86.38 | .106 |
| Height (cm) | 169.4 | 167.8 | .52 |
| Admission BMI (kg/m2) | 33.7 | 30.7 | .158 |
| At Home Lasix (mg) | 37.91 | 33.1 | .444 |
| Discharge BNP | 623.3 | 1006 | .121 |
| Change in BNP (%) | -30 | -36.4 | .418 |
| Discharge Weight (kg) | 95.2 | 84 | .09 |
| Change in Weight (%) | -2.2 | -1.5 | .553 |
| Length of Stay (days) | 4.22 | 4.23 | .99 |

Table 3. 30-Day Readmissions

of stay was 4.22 days +/- 3.373.

There was no significant difference in proportions of 30-day readmissions for either sex (p = 0.353 Fisher's exact test) or race (p = 0.872, chi-square test), please see Table 2. Overall males accounted for 55 patients and females 39. Of the 26 readmissions interestingly they were half female and half male, 13 patients each. This correlates to 33% readmission for females and 25% readmission for males in our study.

African American ethnicity represented the majority of study participants in both readmission groups. Caucasians made up the next largest ethnic group, while Asian and Latino each accounted for 2 or 1 patients in this study. African Americans had 28% readmission rate, while Caucasians had 30% readmission rate.

See Table 3 comparing the following variables: Age in years, Admission BNP, Admission Weight, Height in cm, and Admission BMI between the groups based on readmission. All patients with data are included; the data are aggregated irrespective of 30-day readmission code. The means of these variables by 30-day readmission groups (other than eGFR whose non-parametric summary statistics are given below; N.B., for eGFR the sample means and standard deviations are not valid estimates of those parameters and should not be presented) were tested with student t-test for independent groups.

No p-values on this analysis were statistically significant. For comparisons between the not readmitted versus the readmitted groups the following were calculated: Admission BNP 1050.8 vs 1375.9, Admission Weight 97.39 vs 86.38, Height 169.4 vs 167.8, BMI 33.7 vs 30.7, Lasix use 37.91 vs 33.1, Discharge BNP 623.3 vs 1006, BNP change -30% vs -36.4%, Discharge weight 95.2 vs 84, Weight Change -2.2% vs -1.5%, and Length of Stay 4.22 vs 4.23.

For the paired values (admission and discharge) of BNP and weight the "Student" t-test for paired data was used to compare mean values of 30 day readmission groups, whereupon it was found that the discharge values were each very highly significantly less than the admission values

| continued on p.12

($p < 0.001$, "Student" t-test for paired data). The following table gives the means and standard deviations for those sets of paired data, See Table 4.

There were no significant differences in the distribution of eGFR values based on 30 day readmission group ($p = 0.408$, Mann-Whitney U-test). The following tables give the non-parametric summary statistics for those data for each 30-day readmission group, see Table 5.

Table 4

| SEX | Not Readmitted | Readmitted | Total |
|---|---|---|---|
| Male (%) | 42 (61.8%) | 13 (50%) | 55 (58.5%) |
| Female (%) | 26 (38.2%) | 13 (50%) | 39 (41.5%) |
| Total | 68 (72.3%) | 26 (27.7%) | 94 (100%) |
| **Race** | **Not Readmitted** | **Readmitted** | **Total** |
| AA – African American | 49 (72.1%) | 19 (73.1%) | 68 (72.3%) |
| AS – Asian | 2 (3%) | 0 | 2 (2.2%) |
| CA – Caucasian | 16 (23.5%) | 7 (26.9%) | 23 (24.5%) |
| LA - Latino | 1 (1.5%) | 0 | 1 (1.1%) |
| Total | 68 | 26 | 94 |

**Table 4. Paired Sample T-Testing**

## DISCUSSION

This prospective study documents and validates that high pre-discharge blood BNP levels are a strong predictor of readmission to the hospital within 30 days, however, the change in BNP from admission to discharge was found to be statistically insignificant as it correlates to readmission rates. This study showed that patients with pre-discharge BNP of 1000 and above are more likely to be readmitted within 30 days. This population of patients could be identified as high risk for 30 day readmission and hence might require closer follow up as well as optimization of their diuretics to obviate the need for readmission.

Enrolled patients received guideline directed management for acute decompensated heart failure and were assessed daily for response by the primary team. The choice of diuretic agent, route of administration, dosage and time of discharge were all determined by the managing team. All patients were judged to be stable at discharge, although approximately 26% were readmitted within 30 days.

Clinisync, a web based electronic Ohio health information partnership was used to follow up patient readmissions within 30 days to our facility or any other facility within Ohio. Of the 26 patients that were readmitted to the hospital within 30 days: 16 were readmitted for CHF exacerbation, 2 for chest pain, 2 for HAP, 1 NSTEMI, 1 lightheadedness and dehydration, 1 right distal femur fracture, 1 sepsis, 1 supratherapeutic INR, and 1 unknown. Since our study was statistically insignificant with regard to our primary endpoint, it is difficult to pinpoint why the above CHF patients were readmitted, especially since all variables that were compared also were determined to be statistically insignificant. For the patients that were not readmitted for CHF, but were admitted within 30 days for other reasons, we also can't say that CHF was not a factor in the patient readmissions.

The Hospital Readmissions Reduction Program (HRRP) is a Medicare value-based purchasing program that reduces payments to hospitals with excess readmissions. The program supports the national goal of improving healthcare for Americans by linking payment to the quality of hospital care[8]. The Affordable Care Act requires the Secretary of the Department of Health and Human Services (HHS) to establish HRRP and reduce payments to Inpatient Prospective Payment System (IPPS) hospitals for excess readmissions beginning October 1, 2012 (i.e., Federal Fiscal Year [FY] 2013). Additionally, the 21st Century Cures Act requires CMS to assess penalties based on a hospital's performance relative to other hospitals with a similar proportion of patients who are dually eligible for Medicare and full-benefit Medicaid beginning in FY 2019.[8]

CMS uses excess readmission ratios (ERR) to measure performance for each of the six conditions/procedures in the program:

- Acute Myocardial Infarction (AMI)
- Chronic Obstructive Pulmonary Disease (COPD)
- Heart Failure (HF)
- Pneumonia
- Coronary Artery Bypass Graft (CABG) Surgery
- Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA)[8]

As mentioned previously, According to data from the Center for Health Information and Analysis, hospital readmissions cost Medicare about $26 billion annually, $17 billion is spent on avoidable hospital trips after discharge. Furthermore, a retrospective, observational study done in Thousand Oaks, CA based on data from the national 5% sample of Medicare beneficiaries showed that data gathered from 63,678 inpatients with a mean age of 81.8 years were included in the analysis. All costs were inflated to $2,015 based on the medical care component of the Consumer Price Index. The mean per-patient cost of an HF-related hospitalization was $14,631. The mean per-patient cost of a cardiovascular (CV)-related or all-cause hospitalization was $16,000 and $15,924, respectively. The cumulative rate of all-cause hospital-

Table 5

| eGFR | | |
|---|---|---|
| N | Valid | 68 |
| | Missing | 0 |
| Median | | 62.00 |
| Minimum | | 16 |
| Maximum | | 62 |
| Percentiles | 25 | 45.00 |
| | 50 | 62.00 |
| | 75 | 62.00 |
| a. 30 Day Readmission = 0 | | |

| eGFR | | |
|---|---|---|
| N | Valid | 26 |
| | Missing | 0 |
| Median | | 56.50 |
| Minimum | | 23 |
| Maximum | | 62 |
| Percentiles | 25 | 45.00 |
| | 50 | 56.50 |
| | 75 | 62.00 |
| a. 30 Day Readmission = 1 | | |

**Table 5. eGFR Distribution**

ization was 218.8 admissions per 100 person-years, and the median length of stay for HF-related, CV-related, and all-cause hospitalizations was 5 days. Also, 22.3% of patients were readmitted within 30 days, 33.3% were readmitted within 60 days, and 40.2% were readmitted within 90 days. Essentially the costs associated with hospitalization for Medicare beneficiaries with HF are substantial and are compounded by a high rate of readmission.

Our results appear to be unfavorable with regard to statistical significance and relation to our primary endpoint. However it should not be overlooked that high pre-discharge BNP levels are a strong predictor of 30 day readmission to the hospital as seen in this study. Therefore, appropriate diuresis and other clinical management should be targeted to achieve a goal BNP that is less than arrival, which in turn should trigger clinicians to draw 2 BNPs, one on arrival and one on discharge. This practice will have a two fold effect: 1) we will attempt to achieve the best clinical outcome for our patients and 2) we will have potentially avoided a future payment reduction from CMS.

Limitations of the study can mainly be attributed to sample size and patient follow up.

## CONCLUSION

Pre-discharge BNP did not objectively predict 30-day readmission rate in patients with acute decompensated heart failure. Though there was no statistical significance in the percentage change in BNP in 30-day readmitted group vs not readmitted group, the average pre-discharge BNP was found to be higher in patients readmitted within 30 days.

## ACKNOWLEDGEMENTS

This study was conducted with the financial support of the Internal Medicine Graduate Medical Education Department of St. Vincent Charity Medical Center in Cleveland, Ohio. The authors would like to thank Dr. Rowland, Statistician, for his contribution to the statistical analysis section.

The authors report no conflicts of interest associated with the writing of this manuscript.

*References*

1. Kociol RD, Horton JR, Fonarow GC, et al. Admission, Discharge, or Change in BNP and Long-term Outcomes: Data from OPTIMIZE-HF Linked to Medicare Claims. *Circulation Heart failure.* 2011;4(5):628-636. doi:10.1161/CIRCHEARTFAILURE.111.962290.
2. Mizutani K, Hara M, Iwata S, et al. Elevation of B Type Natriuretic Peptide at Discharge is Associated With 2 Year Mortality After Transcatheter Aortic Valve Replacement in Patients With Severe Aortic Stenosis: Insights From a Multicenter Prospective OCEAN TAVI (Optimized Transcatheter Valvular Intervention–Transcatheter Aortic Valve Implantation) Registry. *Journal of the American Heart Association: Cardiovascular and Cerebrovascular Disease.* 2017;6(7):e006112. doi:10.1161/JAHA.117.006112.
3. Flint KM, Allen LA, Pham M, Heidenreich PA. B Type Natriuretic Peptide Predicts 30 Day Readmission for Heart Failure but not Readmission for Other Causes. *Journal of the American Heart Association: Cardiovascular and Cerebrovascular Disease.* 2014;3(3):e000806. doi:10.1161/JAHA.114.000806.
4. Caldwell MA, Howie JN, Dracup KD. BNP as discharge criteria for heart failure. *Journal of Cardiac Failure.* 2003;9(5):416-422. https://doi.org/10.1054/S1071-9164(03)00124-6.
5. Carey SA, Bass K, Saracino G, East CA, Felius J, Grayburn PA, Vallabhan RC, Hall SA. Probability of Accurate Heart Failure Diagnosis and the Implications for Hospital Readmissions. *The American Journal of Cardiology.* 2017;119(7):1041-1046. https://doi.org/10.1016/j.amjcard.2016.12.010.
6. Omar HR, Guglin M. Discharge BNP is a stronger predictor of 6-month mortality in acute heart failure compared with baseline BNP and admission-to-discharge percentage BNP reduction. *International Journal of Cardiology.* 2016;221:1116-1122. https://doi.org/10.1016/j.ijcard.2016.07.117.
7. Kilgore, M et al. Economic burden of hospitalizations of Medicare beneficiaries with heart failure. Risk Management and Healthcare Policy. 2017; 10: 63–70. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5436769/
8. Cms.gov. (2019). Hospital Readmissions Reduction Program (HRRP) - Centers for Medicare & Medicaid Services. [online] Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html [Accessed 26 Mar. 2019].
9. RevCycleIntelligence. (2019). 3 Strategies to Reduce Hospital Readmission Rates, Costs. [online] Available at: https://revcycleintelligence.com/news/3-strategies-to-reduce-hospital-readmission-rates-costs [Accessed 26 Mar. 2019].

# Podiatry Residents Share Care and Compassionate Ear at Annual Homeless Stand Down

"Hello, my friend. Come and sit down," is the familiar greeting many of Cleveland's homeless hear from the team of St. Vincent Charity Medical Center physicians, residents and students, participating in the annual Homeless Stand Down. The team is there to provide care for the primary of mode of transportation for the homeless—their feet—however, the greatest gift they give the 1,500 attendees is dignity.

Since the inception of the Stand Down in 1990, members of the St. Vincent Charity's Department of Podiatry have volunteered to serve and provide medical screenings at the annual event for Cleveland's homeless. The screenings begin with the washing of the feet of the men, women and children who come to Public Auditorium seeking medical care, food, clothing, respite and other necessities.

"As a Catholic, mission-driven hospital, I am always struck as I begin to care for each attendee of the image of Jesus washing the feet of his disciples, which symbolizes the humility and charity of Christ," said Dr. Michael Canales. "As we treat each attendee, this image reminds us of our call to service and the need to look at them not only as patients, but as members of the human race."

The Stand Down falls at a time for many of Cleveland's homeless that marks the lowest point of the year. The Christmas season, which provides many opportunities for meals and assistance, is over and the season's worst weather is upon Northeast Ohio. "We stand in the gap of services for a lot of people. Beyond the medical treatment we provide, sometimes it is simply respecting the dignity and value of each person, talking to them, giving them hope that provides the greatest relief," said Dr. Canales, who has assisted with the Stand Down for 12 years.

Dr. Canales' most striking memory from the Stand Down was a young woman who was homeless as the result of an abusive relationship. The woman shared with Dr. Canales how lonely she was after the holidays and her daily struggles moving from shelter to shelter.

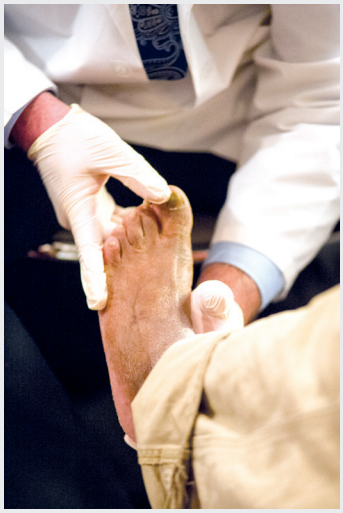
"We saw her at her darkest hour. While she did not necessarily need medical treatment, I talked with her for about 15 minutes, just as another person, trying to give her strength and hope. I gave her my card as she left in case she needed anything in the future" Canales said.

Several years later, the woman returned to St. Vincent Charity, still with his card in hand, seeking medical treatment. "She expressed how life-changing our conversation was. Since we met, she had turned her life around and was literally back on her feet. Simply extending the hand of humanity helped her change her life. It was uplifting at both ends—for her and for me," he said.

Third-year resident Dr. Erin Younce, who assisted Saturday with the event for her third year, said participation in the Stand Down is an important element of their medical training and education, helping them to embrace the value of mission-based care. "Participating in the Stand Down changes our perspective about homeless people. There are many misperceptions, but these are simply men, women and families who often still have jobs, but just don't earn enough to have a place to live. Seeing them, treating them and talking with them opens our minds and gives a better sense of humanity," she said.

In addition, the event provides practical clinical experience for the residents and students. Due to the time the homeless spend on their feet – on average more than 5 hours per day - their exposure to the elements and lack of access to adequate socks, shoes and hygiene facilities, the vast majority experience some form of foot and health issues, many of which are life threatening.

"The feet are a window into a patient's health. We can quickly see the obvious foot issues, such as an infection or fracture that causes immediate distress. However, by looking at the feet we can also see systemic issues such as peripheral neuropathy, alcoholism, circulation, diabetes, that we can refer them for further care at local clinics and, in some cases, the ER for treatment. This assessment can often save their lives," Dr. Canales said.



# Percutaneous Harvest of Calcaneal Bone Autograft: Quantification of Volume and Definition of Anatomical Safe Zone

Principal Investigator: **Duane J. Ehredt Jr., DPM, FACFAS[1]**

Co-investigator(s): **Brandon Rogers, BS[2]; Jaspreet Takhar, BS[2]; Paris Payton, DPM[3]; Kathy Siesel, DPM[4]**

[1] *Assistant Professor, Division of Foot and Ankle Surgery & Biomechanics, Kent State University College of Podiatric Medicine, Independence, OH, USA*
[2] *Podiatric Medical Student, Kent State University College of Podiatric Medicine, Independence, OH, USA*
[3] *Podiatric Medicine & Surgery Resident, Saint Vincent Charity Medical Center, Cleveland, OH, USA*
[4] *Associate Professor, Division of Foot and Ankle Surgery & Biomechanics, Kent State University College of Podiatric Medicine, Independence, OH USA*

Level of Clinical Evidence: **IV Cadaveric**

## ABSTRACT

Bone grafting is commonly used in reconstructive foot and ankle surgery. The calcaneus provides an excellent site for graft harvest due to its rich vascularity and access to corticocancellous or strictly cancellous bone. The relatively thin soft tissue envelope makes dissection easy compared to more proximal autograft sites. In this investigation we quantified cancellous autograft volume from the calcaneus while simultaneously defining anatomical safe zones and identifying anatomical structures at risk. Nine matched-pair (18 total) fresh-frozen cadaveric below-knee limbs were utilized. All limbs were thawed at room temperature prior to the procedure. Calcaneal autograft was harvested following the senior author's (DJE) technique. Bone graft was packed and quantified by podiatric medical students (BR and JT). An independent investigator (KS) meticulously dissected the lateral calcaneal soft tissue envelope to determine rates of neurovascular compromise. Anatomical safe zones were defined by measurements of the harvest site compared to vital anatomical structures. Cancellous autograft averaging 0.85 cc was obtained through an average cortical opening of 0.77 cm. The stab incision is approximately 2.2 cm anterior to the posterior aspect of the calcaneus and 1.6 cm superior to the inferior aspect of the calcaneus. This incision is an average 1.8 cm from the main branch of the sural nerve. No neurovascular damage was found. This study details percutaneous harvest of calcaneal autograft for use in forefoot or midfoot surgeries with an emphasis on feasibility of this additional procedure. The technique proposed is valuable based on simplicity, wide anatomic safe zone, and potential improvement of surgical outcomes.

## INTRODUCTION

Bone grafts are commonly used in orthopedic surgery to augment arthrodesis and non-union revision, enhance fracture healing, and treat osseous defects[1,2,3]. Despite the increasing availability of allograft bone and bone graft substitutes, autogenous bone graft has been shown to be superior in its ability to enhance bone healing and remains the gold standard for reconstructive procedures in the foot and ankle[2,4]. Unlike bone allograft, autogenous bone graft has properties which make it vital to bone healing, stimulation and growth. Autograft bone is osteoconductive in that it provides a scaffold for osseous and fibrovascular ingrowth and proliferation. It is also osteoinductive in nature as it promotes growth factors and matrix proteins, which help modulate cellular processes essential to bone growth. Additionally, bone autograft is osteogenic as it provides osteoblasts, osteocytes, and precursors that can actively form new bone[5,6].

Autografts are divided into three categories based upon harvest site: cancellous, cortical and cortico-cancellous. Some of the challenges of autogenous bone grafting include the potential for complications at the harvest site. Due to complications associated with iliac crest graft harvesting, like persistent donor site pain , alternative harvest sites in the lower extremity have been developed and utilized including the greater trochanter, distal and proximal tibial metaphysis and the fibula, as well as the calcaneus [3,7]. Graft harvest from iliac crest is associated with persistent pain which is commonly associated with a host of other complications including hematoma, wound infection, incisional pain, nerve injury, and/or stress fracture. Proximal tibial harvests have documented complications such as iatrogenic fracture and hematoma formation [3,6].

In the foot and ankle, the calcaneus is a convenient harvest site from which an autograft can be

**Figure 1**

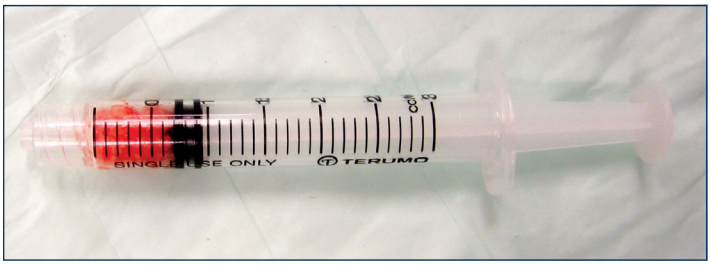



**Fig 1. Measurement of bone graft volume using 3cc syringe.**

| continued on p.16

(cont. from previous page)

Table 1

| Specimen | Age | Sex | Volume of Graft in Cubic Centimeters | Neuro-vascular injury? | Diameter (cm) | Distance from Lateral Malleolus (cm) | Distance from Inferior Calcaneus (cm) | Distance from Posterior Calcaneus (cm) | Distance from Sural Nerve (cm) | Distance from Peroneal Tendons (cm) |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 65 | Male | 0.7 | No | 0.5 | 4 | 1.5 | 2.2 | 1.8 | 2.8 |
| | 65 | Male | 1 | No | 0.6 | 3.2 | 2.3 | 3.4 | 3 | 2.1 |
| 2 | 54 | Male | 0.5 | Yes | 0.9 | 3.7 | 1.5 | 2.5 | 2.1 | 3 |
| | 54 | Male | 0.8 | No | 0.8 | 2.5 | 2 | 2.5 | 1.6 | 2 |
| 3 | 63 | Female | 0.8 | No | 0.9 | 3.4 | 1.5 | 1.8 | 1.7 | 1.5 |
| | 63 | Female | 0.8 | No | 1.5 | 2.9 | 1.2 | 1.1 | 1.4 | 1.8 |
| 4 | 70 | Male | 1.6 | No | 0.9 | 3.5 | 1.8 | 1.9 | 1.8 | 2.5 |
| | 70 | Male | 0.4 | No | 1 | 2.5 | 2.3 | 3.3 | 1.5 | 1 |
| 5 | 59 | Female | 0.9 | No | 0.7 | 2.4 | 1.7 | 2.4 | 1.4 | 1.8 |
| | 59 | Female | 0.8 | No | 0.7 | 1.9 | 1.6 | 2.1 | 1.3 | 2.4 |
| 6 | 63 | Female | 1.2 | No | 0.7 | 2.7 | 1.4 | 1.8 | 1.9 | 1.5 |
| | 63 | Female | 0.7 | No | 0.8 | 2.8 | 1.4 | 1.7 | 1.9 | 2 |
| 7 | 60 | Female | 0.5 | No | 0.7 | 3 | 1.7 | 2.2 | 2.1 | 2.1 |
| | 60 | Female | 0.7 | No | 0.45 | 3.3 | 1.2 | 2.3 | 1.7 | 2.3 |
| 8 | 66 | Female | 1.1 | No | 0.7 | 3.8 | 1.4 | 2.2 | 1.9 | 2.8 |
| | 66 | Female | 0.7 | No | 0.7 | 2.9 | 2 | 2.5 | 1.8 | 2.6 |
| 9 | 62 | Female | 1.3 | No | 0.6 | 3.8 | 1.3 | 2.4 | 2.4 | 2.7 |
| | 62 | Female | 0.9 | No | 0.7 | 3.2 | 1.7 | 2 | 1.8 | 2.4 |
| **Mean** | **62.44** | | **0.86** | | **0.77** | **3.08** | **1.64** | **2.24** | **1.84** | **2.18** |

**Table 1. Raw Data from 18 Cadaveric Limbs. Graft volume and distance of anatomic structures to harvest site are listed.**

obtained with low complication rates [2,8]. The calcaneus is a great source of richly cellular cancellous and cortico-cancellous autograft material [8,9]. Cancellous bone grafts possess an inherent quality of rapid revascularization and demonstrate complete incorporation over time through the process of creeping substitution [10]. It is typically used in areas that do not require significant structural support, such as filling small defects or applying it to prepared joint surfaces to aid in joint fusion. Advantages of cancellous bone graft harvest are that it requires a minimal incision and has low morbidity with minimal cost [11]. Additionally, the calcaneus' relative thin soft tissue envelope at its posterolateral aspect makes dissection comparatively easy to more proximal harvest sites.

The adjunct use of autologous calcaneal autografts in forefoot arthrodesis has limited complications due to minimally invasive technique and the small amount of harvested bone. The complications and morbidity associated with calcaneal autograft harvest is not widely studied, however theoretical disadvantages include the limited volume of available graft, the unknown quality of harvested bone, potential sural nerve injury and iatrogenic calcaneal fracture. A study evaluating calcaneal bone-graft outcomes in 210 patients treated by six surgeons found that 86.2% experienced no complications, 2.9% indicated only incisional nerve sensitivity, 1.9% experienced only incisional

pain, 2% reported only shoe limitations, and 4.8% of responders had a combination of symptoms. Only 3 patients (1.4%) showed more significant complications including fracture of the graft site and calcaneal stress fracture and one patient with permanent numbness along the sural nerve distribution [12]. These complications could very likely be a result of differing harvest techniques [5,8,10]]. Another case study on incidental CT imaging four years after calcaneal bone graft harvest for foot arthrodesis demonstrated the failure of the calcaneal trabecular bone to regenerate. The patient remained asymptomatic without an incidence of iatrogenic fracture, however the study suggests the calcaneal graft site should not be used for a repeat bone-graft harvest without advanced imaging to confirm reconstitution of the calcaneal harvest bed [13]. Hyer et al. previously reported pain levels and complications following percutaneous harvest of bone marrow aspirate of the calcaneus , however no other forms of morbidity were evaluated [14].

Various harvesting techniques have been described in the past with some limitations. For example, Biddinger et al. in 1998 described a technique utilizing an 8 mm round core biopsy for autograft harvest; however, with this approach, the medial and lateral calcaneal cortices were purchased, theoretically increasing neurovascular insult and iatrogenic fracture [8]. In 2006, Roukis et al. described a similar approach using this 8mm trephine without penetrating the medial cortex [5]. Similar complications are associated with this technique and specialized surgical instrumentation is also required. In 2006, DiDomenico and Harrow described a technique in which a 3.5 mm drill was used to breach the lateral wall and then a bone curette was utilized to harvest cancellous bone to achieve the desired amount of graft [9].

The current study aims to present a variation of the technique described by DiDomenico and Haro, identify the potential complications from the calcaneal donor site, and to define the anatomical safe zones for efficient execution of graft harvest. This modified percutaneous technique for harvesting calcaneal cancellous autograft requires no additional surgical equipment or power instrumentation, thereby increasing operating room efficiency and decreasing costs associated with allograft use.

## MATERIALS AND METHODS

### Specimen Preparation

Nine matched-pairs of fresh frozen human cadaveric below-knee limbs were obtained and thawed at room temperature prior to the procedure. All donors were matched to sex (6 Female, 3 male), general medical comorbidities, and age range (62.4 years). Donor criteria included a history free from previous foot and ankle surgery or systemic musculoskeletal diseases (osteoporosis, inflammatory arthropathies, spondylopathies, etc.). Calcaneal autograft was obtained via the senior author's technique (DJE). Bone graft was quantified by podiatric medical students (BR and JT) utilizing a 3cc syringe and plunger to pack and measure (Figure 1). An independent professor of lower extremity anatomy (KS) meticulously dissected the lateral calcaneal soft tissue envelope to determine rates of neurovascular compromise (Figure 2). Anatomical safe zones were defined by measurement of the harvest site compared to vital anatomical structures (Figure 3). An

**Figure 2**

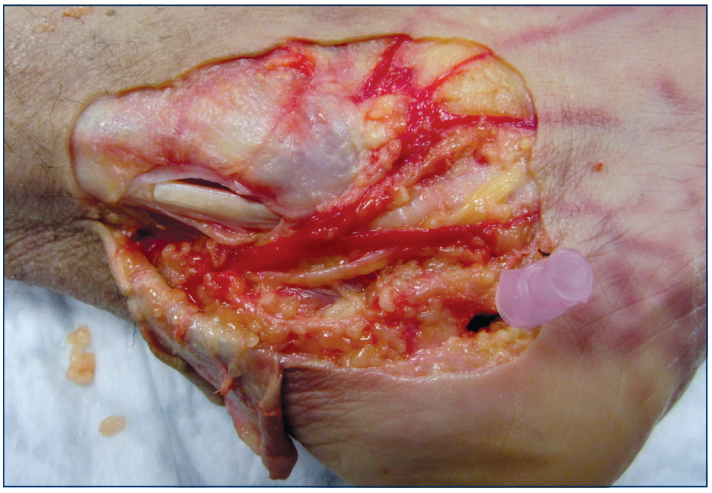


**Fig 2. Dissection of the Lateral Hindfoot.**

**Figure 3**

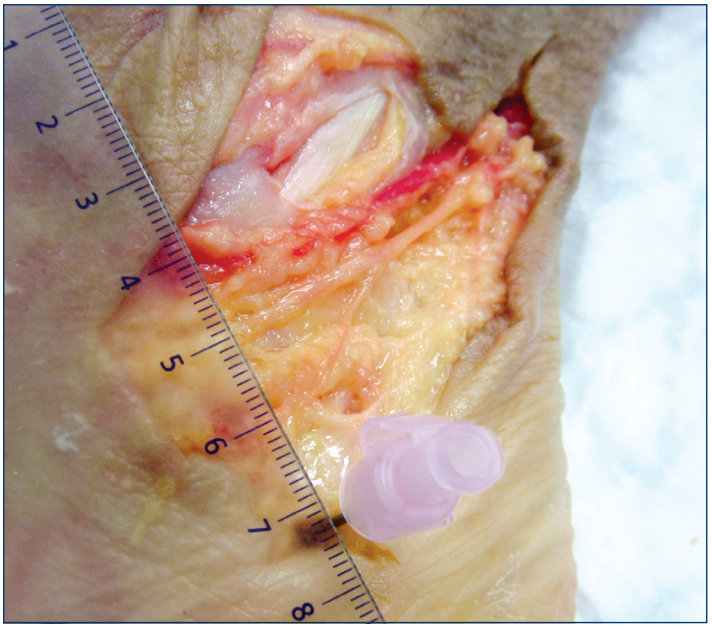



**Fig 3. Harvest site is marked with an 18G needle. Anatomical structures of the lateral hindfoot are identified and distance from harvest site is measured and recorded.**

L-shaped lateral extensile incision was performed and all soft tissue reflected off of the lateral calcaneus. The diameter of the cortical breach, any break in the cortex of lateral calcaneal wall, and location of the opening was measured and recorded (Table 1).

### Surgical Technique

The instrumentation necessary for adequate harvest includes: straight bone curettes, curved mosquito hemostat, #10 blade,

| continued on p.18

(cont. from previous page)

**Figure 4**

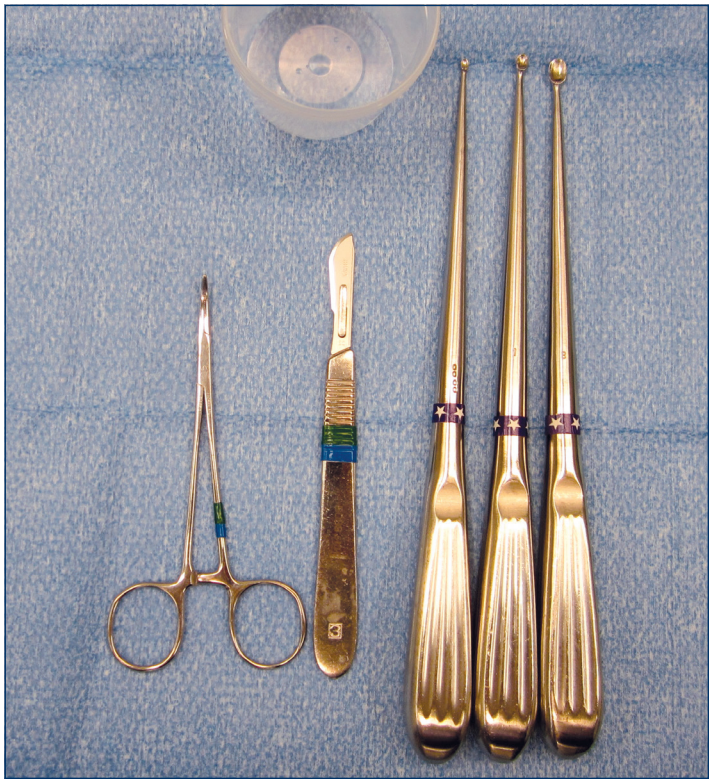


**Fig 4. Instrumentation for calcaneal bone graft harvest.**

**Figure 5**

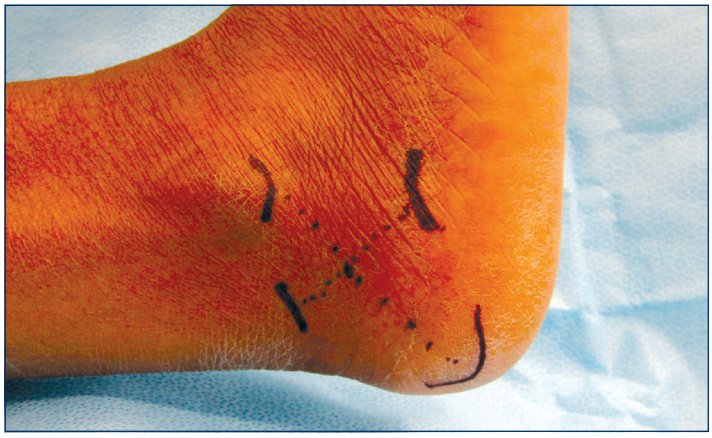


**Fig 5. Identification of harvest site.**

sterile cup (Figure 4). The incision should be made inferior to the sural nerve and peroneal tendons on the posterolateral aspect of the heel. The incision is placed at the bisection of imaginary lines drawn between the distal tip of the fibula and posterior/inferior calcaneus and the cranial and caudal borders of the lateral calcaneus (Figure 5). It is vital that the harvest site be located within the midsubstance of the posterior tubercle of the calcaneus. This ensures a maximum amount of graft harvest while avoiding the important weight bearing architecture of the anterior and posterior calcaneus.

Once the site is located, a small stab incision is made parallel to the sural nerve with a #10 blade (Figure 6). The incision is carried down to the lateral wall of the calcaneus. A curved mosquito hemostat may be used if blunt dissection is necessary. Next, a small straight bone curette is inserted into the lateral wall of the calcaneus. The curette is spun back and forth with the surgeon's fingers mimicking a "hand drilling" technique. Once the lateral wall is punctured the first curette is removed and a slightly larger curette is inserted and the process is repeated. Once a large enough curette is used (usually 3-4 mm) the surgeon can safely harvest cancellous bone graft in an efficient manner. One must be able to visualize the three-dimensional orientation of the calcaneus within his or her mind's eye. Cancellous bone is then curetted utilizing an "ice cream scoop" technique, with care to not violate the medial calcaneal wall (Figure 7). Once cancellous bone is extirpated it is placed into a sterile container for later use at the fusion site (Figure 8).

### Results

The average calcaneal cancellous autograft obtained was 0.85 cc through an average cortical opening of 0.77 cm. Incision placement was noted to be within the midsubstance of the posterior calcaneal tuber on all occasions. Distance of harvest site from the sural nerve was on average 1.85 cm. Distance of harvest site from the inferior calcaneus was on average 1.64 cm. Distance of harvest site from the tip of the lateral malleolus was on average 3.08 cm. Distance of harvest site from the posterior calcaneus was on average 2.24 cm. Distance of harvest site from the peroneal tendons was on average 2.18 cm. The medial calcaneal cortical wall remained intact on all limbs, and only 1 case of neurovascular compromise was noted. In that case, the nerve tran-sected was identified as the lateral calcaneal branch of the sural nerve.

## DISCUSSION

Using the above-described surgical approach, foot and ankle surgeons can feel confident that adequate bone harvest can be completed with little to no associated morbidity to the patient. Additionally, when following this technique, the surgeon does not need to rely on intraoperative fluoroscopy to guide incision placement. This ultimately saves operative time and cost, and limits exposure of the surgeon, staff, and patient to unnecessary ionizing radiation.

In this study, we determined the average graft volume to be 0.85 cc. The senior author has found this volume to be ideal for primary 1st MPJ arthrodesis and Lapidus arthrodesis cases. This volume can also be useful for digital arthrodesis procedures as well. The nearest structure of concern to the harvest site was identified as the sural nerve, which was on average 1.85 cm away from the incision. In no instances was the sural nerve violated, however there was one instance of transection of the lateral calcaneal branch. Additionally the cortical deficit was on average 0.77 cm in size. This is slightly bigger than the largest curette used for harvest. At our institution we have

Figure 6

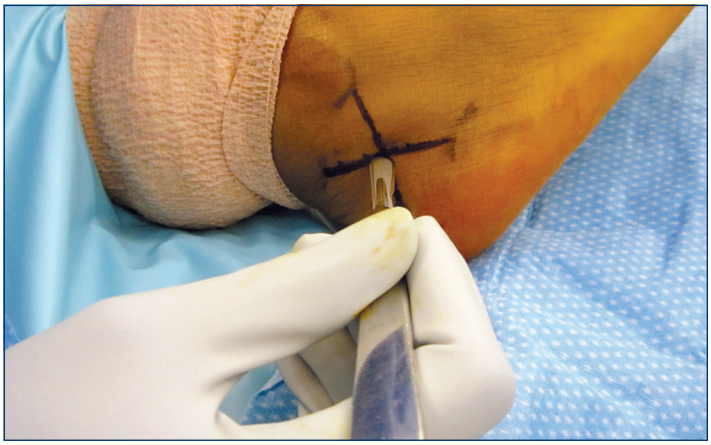


Fig 6. Incision with #10 blade parallel to the sural nerve.

Figure 8

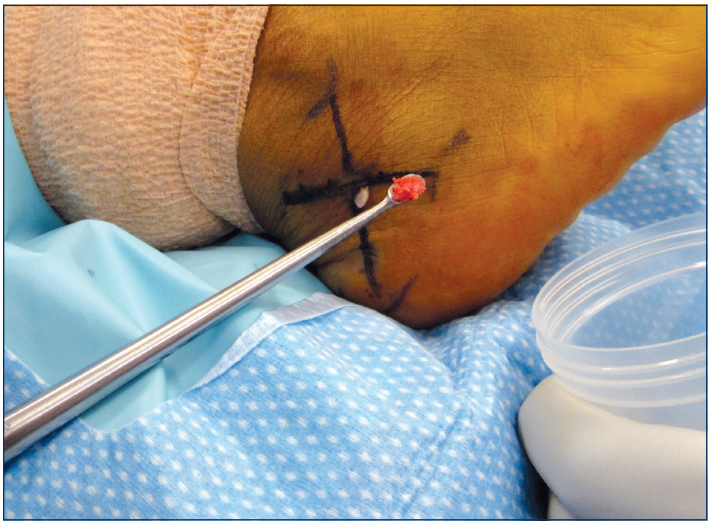


Fig 8. Bone graft is harvested and placed into a sterile container for later use.

access to weight bearing CT imagery. Many of our patients have participated in other research projects, and have been scanned after having calcaneal bone graft harvested in this fashion. We have anecdotally noticed that the medullary void is far greater in size than the small cortical deficit (Figure 7).

Harvesting of autogenous bone graft continues to be a reliable adjunctive procedure in many orthopedic surgical cases. Within the realm of the foot and ankle, the calcaneus has been identified as a viable source for autogenous bone graft [2,8,9]. Traditionally, the techniques employed for harvest of calcaneal bone graft required open procedures, or the need for power instrumentation [5,9]. To our knowledge, this is the first report of the quantification of graft volume, as well as evaluation of anatomical safe zones for performance of calcaneal autograft bone harvest without the need of power instrumentation or operative fluoroscopy.

Figure 7

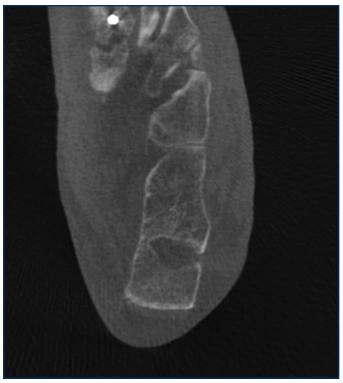


Fig 7. CT imaging of a post-operative patient. Note the large medullary void with minimal lateral wall puncture. The medial wall was not violated.

The limitations of this study involve the use of cadaveric specimens as a data source. Although we did evaluate the anatomical structures at risk, a clinical cohort would be necessary to properly evaluate subjective complaints from the patient, as well as other objective complications such as scarring and wound breakdown. Additionally, the use of fresh-frozen cadavers could slightly alter the quality of bone available for harvest, therefore skewing the volume results obtained. To limit this, limbs were thawed only once prior to graft procurement. A study on living patients would ultimately eliminate this confounder.

Given the simplicity of our proposed technique and the anatomically sound safety profile, percutaneous harvest of calcaneal bone graft should be a technique that all foot and ankle surgeons should be familiar with. Our study has demonstrated adequate volume for small joint procedures, and little risk to surrounding anatomical structures.

*References*


1. DiDomenico LA, Thomas ZM. Osteobiologics in Foot and Ankle Surgery. *Clin Podiatr Med Surg*. 2015;32:1-19.
2. Raikin SM, Brislin K. Local bone graft harvested from the distal tibia or calcaneus for surgery of the foot and ankle. *Foot Ankle Int*. 2005;26:449-453.
3. Brawley SC, Simpson RB. Results of an alternative autogenous iliac crest bone graft harvest method. *Orthopedics*. 2006;29:342-346.
4. Arner JW, Santrock, RD. A historical review of common bone graft materials in foot and ankle surgery. *Foot & Ankle Specialist*. 2014;7(2):143-151.
5. Roukis T. A simple technique for harvesting autogenous bone grafts from the calcaneus. *Foot Ankle Int* 27: 998-999, 2006.
6. Fitzgibbons TC, Hawks MA, McMullen ST, Inda D. Review article: bone grafting in surgery about the foot and ankle: indications and techniques. *J Am Acad Orthop Surg*. 2011;19:112-120.
7. Myeroff C, Archdeacon M. Autogenous bone graft: donor sites and techniques. *J Bone Joint Surg Am*. 2011;93(23):2227–2236.
8. Biddinger KR, Komenda GA, Schon LC, Myerson MS. A new modified technique for harvest of calcaneal bone grafts in surgery on the foot and ankle. *Foot Ankle Int*. 1998;19:322–26.
9. DiDomenico LA, Haro AA 3rd. Percutaneous harvest of calcaneal bone graft. *J Foot Ankle Surg*. 2006; 45:131-3.
10. O'Malley MJ, Sayres SC, Saleem O, Levine D, Roberts, Deland JT, Ellis S. Morbidity and complications following percutaneous calcaneal autograft bone harvest. *Foot Ankle Int*. 2014 Jan;35(1):30-37.
11. Chou LB, Mann RA, Coughlin MJ, McPeake WT 3rd, Mizel MS. Stress fracture as a complication of autogenous bone graft harvest from the distal tibia. *Foot Ankle Int*. 2007;28:199-201.
12. O'Keeffe RM, Riemer BL, Butterfield SL. Harvesting of autogenous cancellous bone graft from the proximal tibial metaphysis: a review of 230 cases. *J Orthop Trauma*. 1991;5:469-474.
13. Nwankwo EC, Grimes JS. Persistence of bone voids after calcaneal bone-graft harvest. *SAGE Open Medical Case Reports*. 2017;5:2050313X17740511.
14. Hyer CF, Berlet GC, Bussewitz BW, Hankins T, Ziegler HL, Philbin TM. Quantitative assessment of the yield of osteoblastic connective tissue progenitors in bone marrow aspirate from the iliac crest, tibia, and calcaneus. J Bone Joint Surg Am. 2013;95(14):1312-6.

# Quality of Hyperuricemia Management in Community - Based Primary Care Clinic Patients

By **Inna Perez, MD; James Tamesis, MD; Ryan Choudhury, MD; Anil Pai, MD**


## BACKGROUND

Gout is one of the most common rheumatologic diseases in adulthood, characterized by tissue deposition of monosodium urate crystals, and manifests most frequently as an acute episode of arthritis. It is a significant cause of morbidity, and can also be a source of significant financial burden to our health care system. The National Health and Nutrition Survey estimates that around 8.3 million people in the United States live with gout, costing $27.4 million annually for the management of incident cases [2,3].

## METHODS

A retrospective chart review was conducted on all patients from January 1, 2012 to November 2018. A total of 48 patients were identified as having a diagnosis of gout and have at least 1 uric acid measurement throughout their follow up with the health care clinic. The 48 patients were analyzed for reaching serum uric acid goals, associated comorbidities, appropriate follow up, and number of documented gout flares.

## RESULTS

A total of 48 patients were assessed with mean SUA (serum uric acid levels) of 7.94 mg /dL +/- 1.93 with an average follow up 6.76 months +/- 2.12. The study consisted of mostly male patients 70.83% and hypertension was the most common comorbidity 91.67%. In total, 7 patients (14.58%) reached goal SUA at least once. Analysis between the groups meeting goal SUA versus not meeting goal SUA showed gout flares 0.86 vs 1.44, respectively with p=.373. Age between these group was 71.43 versus 60.32, respectively p=0.029.

## CONCLUSION

Meeting target SUA did not reflect a statistically significant drop in the rate of gout flares in this study. Few patients met the researchers predetermined definition of adequate follow up and management for gout. For the outpatient clinic, gout is being treated sub-optimally. Improvements in follow up timing, SUA screening, medication changes, and surveillance protocols could be useful in improving patient management in the future.


## BACKGROUND

Gout is one of the most common rheumatologic diseases in adulthood, characterized by tissue deposition of monosodium urate crystals, which manifests most frequently as an acute episode of arthritis. The National Health and Nutrition Survey estimated 8.3 million people in the United States live with gout and it costs $27.4 million annually for the management of incident cases [2,3].

Acute gout attacks can be debilitating and are associated with decreased work productivity and decreased health-related quality of life [4,5]. Worldwide prevalence of gout, including the United States continues to increase likely due to increasing prevalence of its risk factors such as aging population, hypertension, obesity, metabolic syndrome, diabetes mellitus, and chronic kidney disease [6-8].

Majority of the acute and chronic care diagnoses and therapies occur at the primary care level. Recognition of risk factors and typical presentations, followed by demonstration of uric acid crystals in the joint aspirate, can establish the diagnosis with superior accuracy.

Several clinical societies have published guidelines establishing guidelines for effective and appropriate care. Furthermore, we have effective therapeutic modalities to reach target serum uric acid (SUA) and facilitate resorption of uric acid crystals from the tissues and achieve "cure" of gout [9]. Despite advanced understanding of the pathophysiology of hyperuricemia and gouty inflammation and the extensive provider practical experience, substantial quality of care gaps exist in gout management [10]. Recent research suggests that Urate - Lowering Therapies (ULT) are underutilized and patient adherence issues have been identified as well [11].

Not properly treated gout can cause long-term consequences, including irreversible joint damage and deformity. There are multiple lines of evidence that hyperuricemia may play a role in some renal, cardiovascular, and metabolic comorbidities also frequently associated with gout.

Given the current guidelines, we seek to examine the achievement of target SUA level in patients on ULT in the outpatient setting of our facility as well as identified gaps in hyperuricemia management. Additionally, we want to assess the quality of medical surveillance and identify possible barriers to achievement of target SUA or absence of active hyperuricemia management.

## METHODS

The study is a retrospective chart review of patients treated for hyperuricemia or gout in the outpatient clinics. For the purposes of this study we will use the following definitions.

- Recommended target uric acid level per 2012 ACR Guidelines for Management of Gout is minimum < 6 mg/dL for all gout case scenarios, < 5 mg/dL in individuals with tophi
- Urate Lowering Therapies (ULT) - allopurinol, febuxostat, probenecid or pegloticase for the treatment/prevention of acute gouty arthritis or chronic gouty arthritis.
- Quality of medical surveillance - frequency of follow up, which is set at 4 weeks after initiation or modification of treatment, followed by 6 months confirmation of SUA levels then annually thereafter, measurement of serum uric acid levels and subsequent changes to ULT

This study examined charts of the patients aged 18 and older of St.Vincent Charity Health Care

Continuity Clinic, who were treated with ULT (allopurinol, febuxostat, probenecid or pegloticase) or had their SUA level checked in the past 5 years. Patient information obtained with the cooperation of the Department of Laboratory Medicine. The charts were reviewed for the quality of gout management through acquisition of the following data points: last SUA level, SUA levels in the previous 5 years, frequency of SUA measurement, adjustment of ULT, discontinuation of ULT, frequency of follow up appointments, lost to follow up, comorbidities such as hypertension, diabetes and chronic kidney disease, and persistent social risk factors including tobacco and alcohol use. Once tabulated, the data was analyzed using the software SPSS and student t-test were performed between the groups meeting SUA goals and those not meeting SUA goals.

## INCLUSION CRITERIA

Patients included in this study were those at least 18 years of age, managed at our facility in the outpatient setting for acute and chronic gouty arthritis or hyperuricemia, with at least one SUA level checked within the past 5 years.

## EXCLUSION CRITERIA

Patient excluded were those with other overlapping rheumatological diseases, those without a formal diagnosis of gout, and those with contraindications to ULT.

## VARIABLES

Variables included in the study include age, gender, BMI, comorbidities: type 2 diabetes, hypertension, hyperlipidemia, chronic kidney disease, history of urolithiasis, use of thiazide or loop diuretics, tobacco and alcohol use history, urate lowering therapy on initiation and follow up, average dose of ULT, SUA at initial appointment and SUA on subsequent follow ups, average follow up time frame (in months), and titration of ULT.

## RESULTS

A total of 83 charts were flagged by the laboratory for having SUA levels checked at our outpatient clinic within the past 5 years. Out of the 83 charts review, 35 patients were excluded due to SUA levels being checked for reasons other than having a history of gout, while 48 patients were included for analysis. Average age was 61.94 years +/- 12.59 years for standard deviation. Mean BMI was 31.04 kg/m2 +/- 6.64, mean number of gout flares was 1.35 +/- 1.58. Average serum uric acid was 7.94 mg/dL +/- 1.93 and average months from initial visit to follow up was 6.76 +/- 2.12. Overall, males consisted of 70.83% of the study with females 29.17%. Hypertension was the most common comorbidity present within the population at 91.67%, followed by Hyperlipidemia, CKD and Type 2 diabetes at 56.25%, 47.92% and 25% respectively. Among the study population, 37.5% remained of Thiazide diuretics while 27.08% were receiving loop diuretics for other medical conditions. Finally, 47.92% of the patients continued to have documented alcohol use and 25% admitted to using tobacco products on follow up after diagnosis of gout.

Among the 48 patients reviewed, only 7 (14.58%) had achieved their SUA goal at least once on follow up. Furthermore,

| Uric Acid Overall Data | | |
|---|---|---|
| | Mean | Std. Deviation |
| Age | 61.94 | 12.59 |
| BMI (kg/m2) | 31.04 | 6.64 |
| Gout Flares | 1.35 | 1.58 |
| Serum Uric Acid | 7.94 | 1.93 |
| Months Until Follow Up | 6.76 | 2.12 |
| | Frequency | Percentage |
| Male | 34 | 70.83% |
| Female | 14 | 29.17% |
| Diabetes | 12 | 25% |
| No Diabetes | 36 | 75% |
| Hypertension | 44 | 91.67% |
| No Hypertension | 4 | 8.33% |
| Hyperlipidemia | 27 | 56.25% |
| No Hyperlipidemia | 21 | 43.75% |
| Chronic Kidney Disease | 25 | 47.92% |
| No Chronic Kidney Disease | 23 | 52.08% |
| Loop Diuretic Use | 13 | 27.08% |
| No Loop Diuretic Use | 35 | 72.95% |
| Thiazide Diuretic Use | 18 | 37.50% |
| No Thiazide Diuretic Use | 30 | 62.50% |
| Tobacco Use | 12 | 25% |
| No Tobacco Use | 36 | 75% |
| Alcohol Use | 23 | 47.92% |
| No Alcohol Use | 25 | 52.08% |
| Treatment Changed | 9 | 18.75% |
| Treatment Not Changed | 39 | 81.25% |
| Achieved Goal | 7 | 14.58% |
| Did not Achieve Goal | 41 | 85.42% |
| Good Follow Up | 2 | 95.83% |
| Not Good Follow Up | 46 | 4.17% |

| continued on p.22

(cont. from previous page)

39 (81.25%) patients did not have any changes made to their ULT. Despite this, there was no significant difference noted among those who had achieved their SUA goal with regards to change in medication regimen (p-value 0.176). There was a significant difference though among patients who had achieved their SUA goal in regards to timeframe for follow up, with 4.84 months to follow up for those with SUA < 6 vs 7.03 months for those with SUA > 6 (p-value 0.028). There was no significant difference though with number of flares between the two groups, with 0.86 episodes (SUA < 6) vs 1.44 episodes (SUA > 6) (p-value of 0.373). Significant difference was noted in terms of age groups, with individuals at a mean of 71.43 years of age more likely to have reached SUA goals compared to the mean of 60.32 years of age who did not reach SUA goals (p-value 0.029). Finally, there were no significant differences between the two groups in terms of comorbidities, social habits, and use of loop and thiazide diuretics.

## DISCUSSION

According to the American College of Rheumatology (ACR) 2012 Guidelines in Management of Gout, SUA goals should be less than 6 mg/dL in patients, with a goal of < 5 mg/dL in patients with tophaceous gout. Despite no actual consensus on frequency of follow up for SUA levels, experts recommend rechecking SUA levels 2-4 weeks after initiating ULTs, followed by 3 then 6 months interval for the first year, and annually thereafter. Applying the guidelines to our study, we can see that the majority of our patients did not achieve such goals. The poor adherence to the guidelines could be related to the lack of knowledge by the medical residents in managing hyperuricemia in gout per ACR guidelines, poor patient compliance and follow up, and the low number of patients being treated for gout at our outpatient clinic leading to lack of exposure for the residents.

Interestingly, there were no statistically significant differences in terms of SUA goals, other than average age. When ULT was titrated there was a significant difference in terms of closer follow up of SUA. Potentially, patients who were more likely to follow closely with their primary care physicians are also those who are more likely to be compliant with their regimen. Furthermore, there appears to be no correlation between achieving SUA goals and the number of documented flares experienced in the patient population. In contrast to ACR guidelines, American College of Physicians (ACP) 2017 guidelines for Management of Gout no longer recommend treating to a certain SUA level as they mention a paucity of studies supporting treating to goal to avoid gout flares [12]. The findings above may potentially support the ACP recommendation, though lack of strict follow up and titration to SUA goals were only accomplished in such a small amount of the study population that this conclusion cannot be made with certainty.

The larger number of males in the study (70.83%) coincide with the sex distribution of gout in the general population. In terms of risk factors, in this study there were no correlations seen between persistence of risk factors and achieving SUA goals, particularly being on thiazide diuretics and using alcohol, two commonly reported risk factors associated

| SUA Goal T–test | | | |
|---|---|---|---|
| | SUA < 6 | SUA > 6 | p–value |
| Mean Age | 71.43 | 60.32 | .029 |
| Mean BMI (kg/m2) | 30.81 | 31.08 | .925 |
| Mean Gout Flares | 0.86 | 1.44 | .373 |
| Mean Serum Uric Acid | 4.77 | 8.61 | <.001*** |
| Mean Months Until Follow Up | 4.84 | 7.03 | .028 |
| | | | |
| Total Frequency (Percent) | 7 (14.6%) | 41 (85.4%) | |
| Male | 4 (57%) | 30 (73%) | .399 |
| Female | 3 (43%) | 11(27%) | |
| Diabetes | 1 (17%) | 11 (27%) | .489 |
| No Diabetes | 6 (83%) | 30 (73%) | |
| Hypertension | 7 (100%) | 37 (90%) | .399 |
| No Hypertension | 0 | 4 (10%) | |
| Hyperlipidemia | 2 (29%) | 25 (61%) | .115 |
| No Hyperlipidemia | 5 (71%) | 16 (39%) | |
| Chronic Kidney Disease | 4 (57%) | 21 (51%) | .778 |
| No Chronic Kidney Disease | 3 (43%) | 20 (49%) | |
| Loop Diuretic Use | 3 (43%) | 10 (24%) | .320 |
| No Loop Diuretic Use | 4 (57%) | 31 (76%) | |
| Thiazide Diuretic Use | 2 (29%) | 16 (39%) | .607 |
| No Thiazide Diuretic Use | 5 (71%) | 25 (61%) | |
| Tobacco Use | 1 (14%) | 11 (27%) | .489 |
| No Tobacco Use | 6 (86%) | 30 (73%) | |
| Alcohol Use | 3 (43%) | 21 (51%) | .778 |
| No Alcohol Use | 4 (57%) | 20 (49%) | |
| Treatment Changed | 0 | 9 (22%) | .176 |
| Treatment Not Changed | 7 (100%) | 32 (78%) | |
| Good Follow Up | 0 | 1 (5%) | .560 |
| Not Good Follow Up | 7 (100%) | 40 (95%) | |

***p-value reported as part of standardized reporting for t-test, not for hypothesis testing

with acute flares in gout. Potentially being on ULT removes the risk associated with the above factors, though because of the low power of this study, it is difficult to make this assumption.

These results suggest that patients suffering gout could have potential to benefit from further optimization of their medical management per ACR guidelines. Based on our findings, quality improvement is necessary to initiate changes in the clinic setting to achieve these goals. A PDSA (plan, do, study, act) format project could potentially study and implement a standardized treatment algorithm for outpatients leading to improved follow up, medication titration, and achieving SUA goals. Introducing improvements to the EHR system is another possible improvement. This would benefit patients by likely reducing the number of gout flares while also preventing tophi formation. Additional studies looking at the ability to titrate patients off gout medication warrants investigation as no standards are currently advocated for practice.

Despite the findings of the study, it is difficult to come up with more generalized conclusions due to the low number of patients. Furthermore, there were also difficulties obtaining data due to inconsistencies with the documentation for gout, particularly the goals for when to follow up on SUA levels, medication compliance and reasons for modifying treatment regimens. Limitations of this study include small sample size and single urban center for patient demographics.

## CONCLUSION

Few patients met our predetermined definition of adequate follow up and management for gout. Meeting target SUA did not reflect a statistically significant drop in the rate of gout flares in this study. Also other factors such as thiazide use, smoking, or alcohol use did not significantly alter the number of gout flares. For the outpatient clinic, gout is being treated suboptimally and efforts to improve patient care are warranted. Improvements in follow up timing, SUA screening, medication changes, and surveillance protocols could be useful in improving patient management in the future.

## ACKNOWLEDGEMENTS

The authors would like to thank the Graduate Medical Education Department of St. Vincent Charity Medical Center for their support in the conduction of this study and writing of the manuscript. The authors do not report any conflicts of interest in regards to this project.

*References*

1. Khanna D, Fitzgerald JD, Khanna PP, Bae S, Singh MK, Neogi T, Pillinger MH, Merill J, Lee S, Prakash S, Kaldas M, Gogia M, Perez-Ruiz F, Taylor W, Lioté F, Choi H, Singh JA, Dalbeth N, Kaplan S, Niyyar V, Jones D, Yarows SA, Roessler B, Kerr G, King C, Levy G, Furst DE, Edwards NL, Mandell B, Schumacher HR, Robbins M, Wenger N, Terkeltaub R. 2012 American College of Rheumatology Guidelines for Management of Gout. Part 1: Systematic Nonpharmacologic and Pharmacologic Therapeutic Approaches to Hyperuricemia. *Arthritis Care & Research*. 2012 October;64(10):1431–1461. doi: 10.1002/acr.21772
2. Zhu Y, Pandya BJ, Choi HK. Prevalence of gout and hyperuricemia in the US general population: the National Health and Nutrition Examination Survey 2007–2008. *Arthritis Rheum*. 2011;63:3136 – 41.
3. Kim KY, Ralph Schumacher H, Hunsche E, Wertheimer AI, Kong SX. A literature review of the epidemiology and treatment of acute gout. *Clin Therap*. 2003; 25:1593-1617.
4. Brook RA, Forsythe A, Smeeding JE, Lawrence EN. Chronic gout: epidemiology, disease progression, treatment and disease burden. *Curr Med Res Opin*. 2010;26:2813–2821.
5. Edwards NL, Sundy JS, Forsythe A, Blume S, Pan F, Becker MA. Work productivity loss due to flares in patients with chronic gout refractory to conventional therapy. *J Med Econ*. 2011;14:10 –15.
6. Bhole V, de Vera M, Rahman MM, Krishnan E, Choi H. Epidemiology of gout in women: fifty-two–year follow up of a prospective cohort. *Arthritis Rheum*. 2010;62:1069 –76.
7. Roddy E, Doherty M. Epidemiology of gout. *Arthritis Res Ther*. 2010;12:223
8. Zhang W, Doherty M, Bardin T, Pascual E, Barskova V, Conaghan P, Gerster J, Jacobs J, Leeb B, Lioté F, McCarthy G, Netter P, Nuki G, Perez-Ruiz F, Pignone A, Pimentão J, Punzi L, Roddy E, Uhlig T, Zimmermann-Gòrska I. EULAR Standing Committee for International Clinical Studies Including Therapeutics. EULAR evidence based recommendations for gout. Part II: Management report of a task force of the EULAR Standing Committee for international clinical studies including therapeutics (ESCISIT). *Ann Rheum Dis*. 2006;65(Suppl 10):1312-24.
9. Singh JA, Hodges JS, Toscano JP, Asch SM. Quality of care for gout in the US needs improvement. *Arthritis Rheum*. 2007;57: 822–9.
10. Harrold LR, Andrade SE, Briesacher BA, Raebel MA, Fouayzi H, Yood RA, Ockene IS. Adherence with urate-lowering therapies for the treatment of gout. *Arthritis Res Ther*. 2009;11:R46.
11. Qaseem A, Harris RP, Forciea MA, for the Clinical Guidelines Committee of the American College of Physicians. Management of Acute and Recurrent Gout: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med*. ;166:58–68. doi: 10.7326/M16-0570

ST. VINCENT CHARITY
MEDICAL CENTER
JOURNAL



2351 EAST 22ND STREET
CLEVELAND, OHIO 44115
P. 216 861 6200
*stvincentcharity.com*

*A Ministry of the Sisters of Charity Health System*