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Original Article

The Role of Vitamin D Deficiency in Predicting Secondary Osteoporosis Among Geriatric Patients in West Texas Community: A Cross-Sectional Multi-Center Study

Nimat Alam[1], MD, FAAFP, AGSF ; Shakira Meltan[2] ,BA; Rachel Vopni[2], BA ; James Wang[1], MD; Myra Ahmed[1], MD; John Garza[3], PhD; Jammie Holland[4], LVN, CCRC

Abstract

Background: Vitamin D deficiency has been associated with osteoporosis and fracture risk. However, its role in secondary osteoporosis among community-dwelling elderly patients remains unclear.
Objectives: This study aimed to examine the relationships between vitamin D deficiency, bone mineral density, and fracture risk in elderly outpatients in West Texas.
Methods: In this cross-sectional multi-center study, 115 patients aged 65-89 years were recruited from outpatient clinics. Serum 25(OH)D levels, dual-energy x-ray absorptiometry scans, and Fracture Risk Assessment Tool (FRAX) scores were obtained. Patients were categorized by vitamin D status and the presence of secondary osteoporosis. Differences in bone health outcomes were analyzed.
Results: Patients with secondary osteoporosis (n=34) had significantly lower mean serum 25(OH)D levels (24.48 ng/mL) compared to patients without secondary osteoporosis (n=81, 39.90 ng/mL, $p<0.01$). This difference persisted across 23/26 subgroups. Hispanic patients also had lower 25(OH)D levels than non-Hispanics ($p=0.032$). No significant correlations existed between 25(OH)D and other risk factors. 25(OH)D level demonstrated good diagnostic ability for secondary osteoporosis (AUC 0.826).
Conclusion: Vitamin D deficiency appears strongly associated with secondary osteoporosis risk among community-dwelling elderly outpatients. Routine screening and correcting of deficiency may reduce this risk. Larger studies should validate these findings and further examine the mechanisms of this relationship.

Keywords: Vitamin D, Bone Health, Osteoporosis

Corresponding Author:
Nimat Alam, MD, FAAFP, AGSF,TTUHSC Permian Basin
Department of Family and Community Medicine/Geriatrics
Email address: Nimat.Alam@ttuhsc.edu

Introduction

Osteoporosis is a chronic condition characterized by progressive loss of bone mass and deterioration of bone tissue, resulting in increased bone fragility.[1] Low bone density meeting diagnostic requirements for osteoporosis and osteopenia is common among elderly patients. Dual-energy x-ray absorptiometry (DXA) scans are used clinically to measure spinal and hip bone mineral density (BMD), with World Health Organization (WHO) T-scores between -1 and -2.5 meeting criteria for osteopenia and less than -2.5 for osteoporosis.[2] An estimated 43.4 million American adults over the age of 50 have low bone mass, while 10.2 million older American adults meet the diagnostic criteria for osteoporosis.[3] Fracture is the primary complication among patients with osteoporosis, and patients with osteoporotic fractures suffer increased morbidity, risk of additional fractures, disability, and mortality.[4]

Osteoporosis is also of significant financial burden on the American healthcare system, with costs of osteoporosis and associated fractures projected to be $22 billion annually.[5] Fracture Risk Assessment Tool (FRAX) from the WHO is used clinically to estimate 10-year major osteoporotic fracture risk based on risk factors and DXA score results.[6] Osteoporotic fracture risk factors include drug use, cigarette smoking, low physical activity, and low intake of vitamin D.[7] Managing low bone density is of importance to the healthcare system in reduction of cost, morbidity, and mortality, and vitamin D supplementation to correct deficiency has been explored for its potential to cost-effectively reduce osteoporotic fracture risk.[8]

Vitamin D is a fat-soluble vitamin essential to proper calcium homeostasis and bone metabolism, and its role in human health has been of significant interest to researchers and clinicians.[9] Vitamin D is obtained either through synthesis by skin cells exposed to ultraviolet B radiation or obtained through the diet, and the risk of deficiency is highest among people with insufficient sun exposure, oral intake, or absorption.[10] Its active form calcitriol (1,25(OH)2D3) is involved in human immune, musculoskeletal, cardiac, and nervous systems, and deficiency has been linked to clinical issues including bone demineralization and fracture susceptibility.[11] Vitamin D deficiency is estimated to be at 42% in adults in the US, and 50% of post-menopause women are estimated to have severe vitamin D deficiency.[12,13] This prevalence is likely higher among elderly patients.[14] Race is also a risk factor, with African American adults having the highest prevalence of vitamin D deficiency followed by Hispanic adults.[15]

Vitamin D deficiency has also been found to be higher among rural populations compared to urban populations in Ireland and Iran.[16,17] Deficiency in vitamin D has been associated with lower BMD and higher fracture incidence while supplementation studies have demonstrated increased BMD with improvement of vitamin D status.[18] Serum 25(OH)D levels are used clinically to indicate vitamin D level.[19] Current bone-centric vitamin D guidelines recommend serum 25-hydroxyvitamin D (25(OH)D) of at least 20 ng/mL with daily vitamin D doses of 400-800 IU per day.[20] Patients with 25(OH)D less than 20ng/dL are classified as having a deficiency, and patients with less than 30ng/dL are classified as having insufficiency.[21] Vitamin D supplementation risk characterization has demonstrated its safety, with minimal risk of toxicity or adverse outcomes.[22]

Historical meta-analysis of randomized controlled clinical trials demonstrated the value of vitamin D supplementation in reducing risk for hip and nonvertebral fractures.[23] However, an updated study has returned mixed results. Among interventional studies, seven found decreased fracture incidence with vitamin D supplementation compared to nine studies that did not find significant changes between the control and treatment groups.[18] Vitamin D supplementation for osteoporosis prevention in community-dwelling adults has been called into question in the past decade.[24] Meanwhile, any benefit of vitamin D supplementation may be smaller in community-dwelling elderly and postmenopausal women compared to institutionalized elderly.[25]

The role of vitamin D deficiency and supplementation in the prevention of osteoporotic fracture is of clinical importance and relevance among physicians treating elderly patients. Demonstrated reduction of fracture risk with vitamin D supplementation has historically been inconsistent, and potential benefit may be relatively reduced for noninstitutionalized, community-dwelling elderly. Our study was conducted to assess the relationships between Vitamin D deficiency, bone density, and fracture risk among American rural out-patient elderly patients at our institution. We endeavor to delineate the relative benefits of vitamin D in the prevention of osteoporosis and osteoporotic fractures among community-dwelling rural elderly.

Materials and Methods

Study Population

This is a non-randomized, multi-center cross-sectional study. The study population is comprised of patients 115 between the ages of 65 and 89 years old recruited from Texas Tech University Health Sciences Center outpatient clinics in Odessa, TX from 01/03/2018-01/12/2021.

Inclusion and Exclusion Criteria

Patients included in the study were between ages 65 and 89 at the start of the study and meet at least one of the following criteria: diagnosis of osteopenia, history of fracture, history of falls, low body mass index, chronic steroid use, lack of sun exposure, low activity level, and/or generalized weakness/deconditioning. Study participants can qualify if they live at home, in an assisted living facility, or at a nursing home (if they receive <100% of their outpatient care at a nursing home facility). All subjects included were able to consent to participation or have a patient proxy or power of attorney who could consent on their behalf. Exclusion criteria are patients with active cancer not including squamous and basal cell carcinomas, chronic kidney disease stage IV or greater (GFR less than 30ml/L per 1.73 m^2, on dialysis, with recent fracture 2ithin 2 months, and/or a history of bilateral lower extremity amputation about the ankle. Patients unable to tolerate DEXA scans, home-bound patients, and nursing home patients who receive 100% of outpatient care at nursing home facilities are also excluded from the study.

Data Collection

Interview forms were administered to consenting patients who met inclusion criteria to collect data on demographics, ethnicity, co-morbid diseases, present medications and vitamins, history of fracture, DEXA scan, and other components of the FRAX scoring system. Results from DEXA scans done within 2 years of recruitment were extracted for the study. Age, sex,

weight, height, previous fracture history, parent hip fracture history, current smoking, glucocorticoids, rheumatoid arthritis, secondary osteoporosis, use of 3 or more alcohol units per day, and femoral neck BMD estimated through DEXA are used to calculate FRAX score, as an estimate of risk for both major osteoporotic and hip fractures.

The initial subject study visit entailed obtaining informed consent, filling out questionnaires, obtaining a medical history, and measuring vitamin D levels. A second visit for a DEXA scan was indicated if not obtained on the initial visit or if results were not already on file from the past 2 years. DEXA scans are done every two years as a standard of care for the study population aged 65 to 89 years and are typically covered by insurance.

Statistical Analysis

The project is an observational and cross-sectional study based on convenience sampling. Statistical analyses used two-sided p-values and a significance level of $\alpha = 0.05$. Adjustments to p-values for multiple comparisons are not made since the study intends to evaluate the plausibility of significant differences. Continuous variables are summarized using the mean and standard deviation. Categorical variables are summarized using counts and percentages. Standardized effect sizes are reported using the standardized mean difference (SMD). Statistical significance of differences is computed using the permutational unequal variance t-test and Fisher's test.[26] 95% confidence intervals for mean differences are computed using Monte-Carlo simulation.[27] The consistency of significant differences is reviewed using subgroup analyses. Power analyses for the t-test, Fisher test, and correlation tests are provided in supplementary figure 1.[28] Statistical analyses were completed using R version 4.1.1 and RStudio version 1.4.1717

Results

Characteristics and Outcomes of Patients

Table 1 summarizes the characteristics and outcomes of the patients included in the study. Continuous variables are summarized using the mean and standard deviation. Categorical variables are summarized using counts and percentages.

Table 1. Characteristics and Outcomes of Subjects

Continuous Covariates	**Mean (SD)**
Age (years)	72.71 (6.52)
Weight (kg)	77.60 (17.76)
Height (cm)	162.74 (9.32)
Neck BMD	0.68 (0.14)
Major Osteoporotic	15.57 (12.53)
Hip Fx	5.47 (9.55)
Vitamin D (ng / ml)	35.34 (14.61)
Categorical Covariates	**count / total no. (%)**
Ethnicity	
Non-Hispanic	71/115 (61.7)
Hispanic	37/115 (32.2)
African American	7/115 (6.1)
Sex (male)	88/115 (76.5)
Previous Fracture	55/115 (47.8)
Parent Fracture	14/115 (12.2)
Smoking	16/115 (13.9)
Gluco Cortiods	16/115 (13.9)
Rheumatoid Arthritis	7/115 (6.1)
Secondary Osteoporosis	34/115 (29.6)
Alcohol	7/115 (6.1)
Supplementation	49/115 (42.6)
Dex Scan	71/115 (61.7)

Association of Vitamin D Level with Categorical Covariates

Figure 1(a) displays 95% confidence intervals for the mean differences in Vitamin D levels. Secondary osteoporosis patients had lower mean vitamin D levels compared to patients without secondary osteoporosis (*Δm = -15.42 (ng/ml), 95% CI -19.44 to -*

11.40, P< 0.001), Hispanics had lower mean vitamin D levels compared to non-Hispanics (*Δm = -6.00 (ng/ml), 95% CI -11.05 to -1.10, P=0.032*), and patients with supplementation had higher mean vitamin D level compared to patients without supplementation (*Δm = 6.82(ng/ml), 95% CI 1.49 to 12.03, P=0.013*).

Association of Vitamin D Level with Continuous Covariates

Figure 1(b) displays 95% confidence intervals for the Spearman correlation of Vitamin D levels with continuous covariates. No correlations were identified as practically or statistically significant.

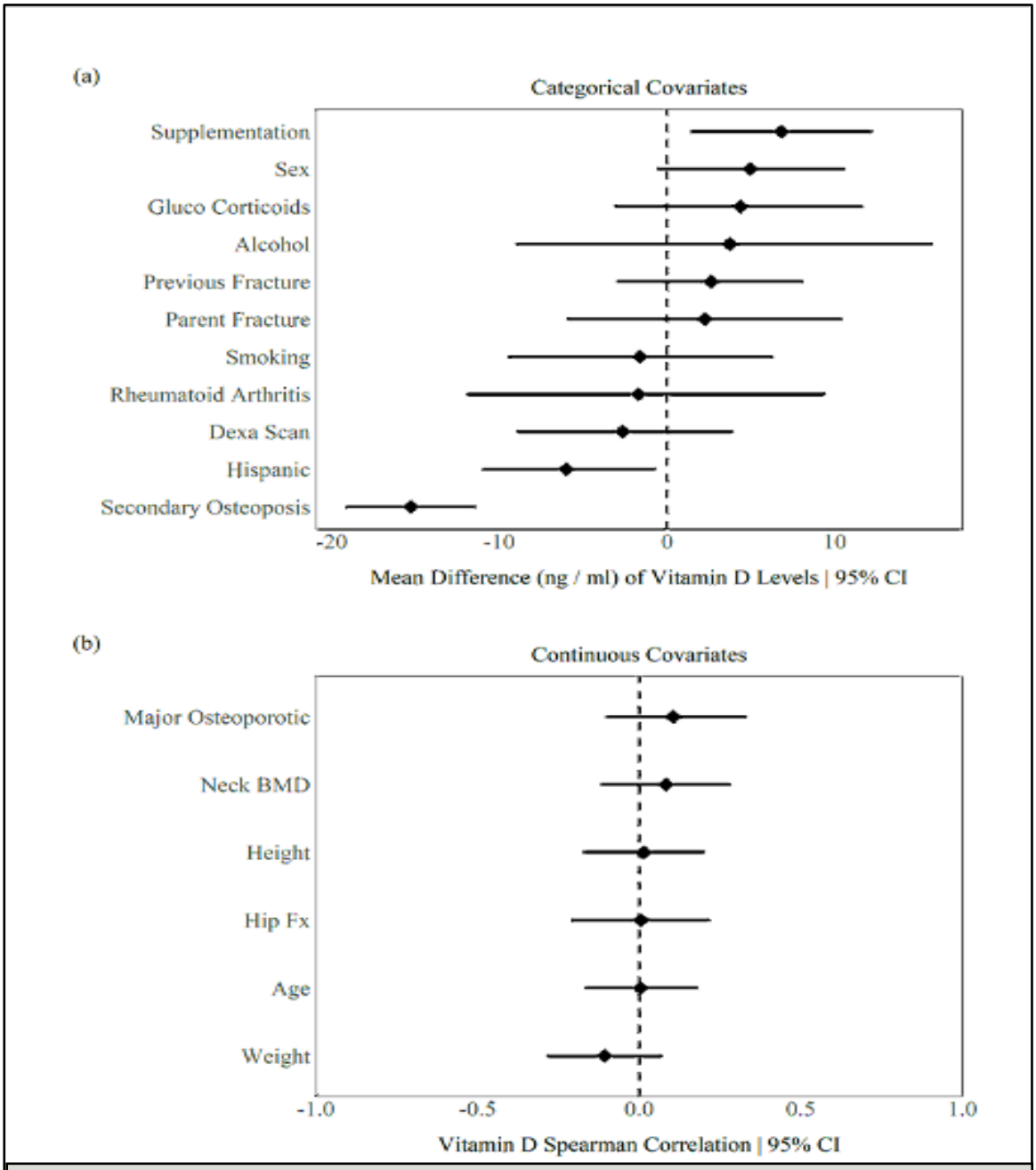


Figure 1. Associations of Vitamin D Level with Categorical and Continuous Covariates

Characteristics and Outcomes of Patients with and without Secondary Osteoporosis

Table 2 summarizes the characteristics and outcomes of patients with and without secondary osteoporosis.

Vitamin D level is the only variable identified as significantly different between the groups. Figure 2 displays the practical and statistical significance of the difference in vitamin D levels between patients with and without secondary osteoporosis.

Table 2. Characteristics and Outcomes of Patients with and without secondary osteoporosis

	Non-Secondary Osteoporosis	Secondary Osteoporosis	SMD	P Value
Age (years)	72.48 (6.53)	73.26 (6.54)	0.12	0.56
Weight (kg)	76.52 (17.09)	80.18 (19.27)	0.20	0.34
Height (cm)	161.88 (8.43)	164.76 (11.03)	0.29	0.18
Ethnicity			0.18	0.63
Non-Hispanic	52/81 (64.2)	19/34 (55.9)		
Hispanic	24/81 (29.6)	13/34 (38.2)		
Asian	5/81 (6.2)	2/34 (5.9)		
Sex (male)	62/81 (76.5)	26/34 (76.5)	<0.01	1.00
Previous Fracture	41/81 (50.6)	14/34 (41.2)	0.19	0.42
Parent Fracture	9/81 (11.1)	5/34 (14.7)	0.11	0.76
Smoking	10/81 (12.3)	6/34 (17.6)	0.15	0.56
Gluco Corticoids	10/81 (12.3)	6/34 (17.6)	0.15	0.56
Rheumatoid Arthritis	4/81 (4.9)	3/34 (8.8)	0.15	0.42
Alcohol	4/81 (4.9)	3/34 (8.8)	0.15	0.42
Neck BMD	0.70 (0.16)	0.64 (0.10)	0.50	0.02
Major Osteoporotic (%)	14.91 (12.97)	16.77 (11.78)	0.15	0.49
Hip FX (%)	5.39 (10.92)	5.62 (6.51)	0.03	0.90
Vitamin D (ng / ml)	39.90 (14.56)	24.48 (7.14)	1.35	<0.01
Supplementation	40/81 (49.4)	9/34 (26.5)	0.49	0.03
Dexa Scan	41/81 (50.6)	30/34 (88.2)	0.89	<0.01

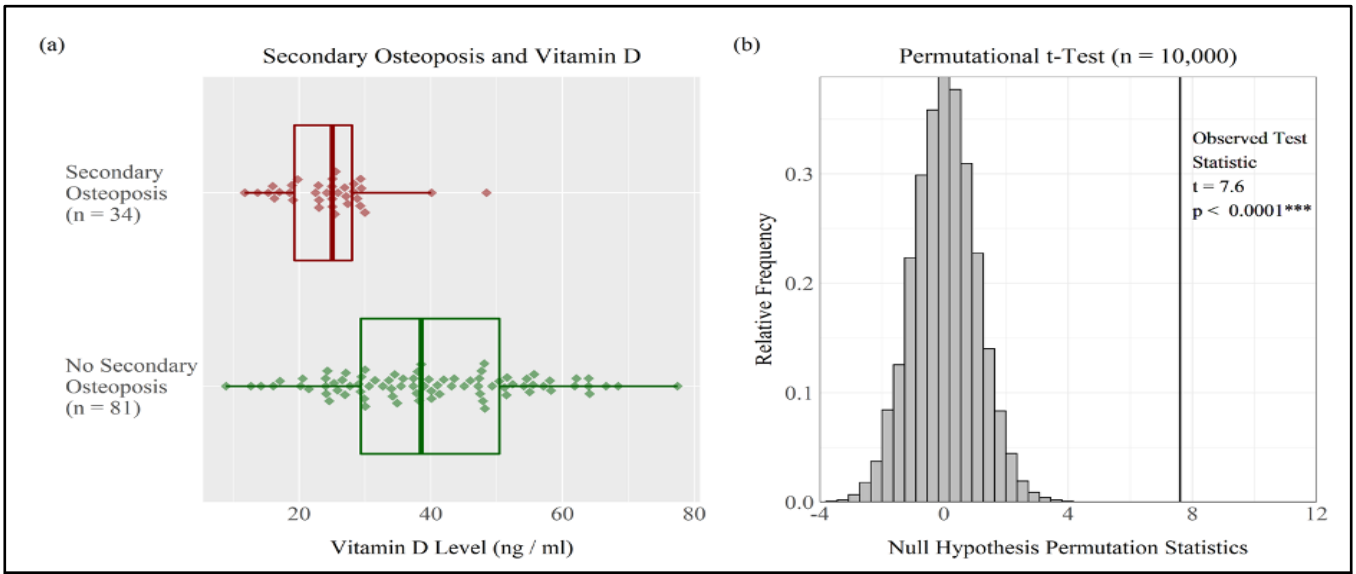


Figure 2. Mean vitamin D levels are significantly different based on secondary osteoporosis.

Subgroup Analyses for Association of Vitamin D Level and Secondary Osteoporosis

Table 3 summarizes the results of subgroup analyses for the association of vitamin D level and secondary osteoporosis.

The mean vitamin D level was consistently lower in secondary osteoporosis patients across all subgroups and twenty-three of the twenty-six subgroups demonstrated a statistically significant difference in vitamin D levels.

Table 3. Subgroup Analyses for Vitamin D Level and Secondary Osteoporosis

Subgroup	total no. (%)	Control Group	Study Group	Difference	P Value
All Data	115/115 (100.0)	39.90	24.48	-15.52	<0.01
Age (years)					
< 72	64 / 115 (55.7)	39.25	23.99	-15.26	< 0.01
73 - 79	32 / 115 (27.8)	39.55	23.31	-16.24	< 0.01
≥ 80	19 / 115 (16.5)	42.82	27.92	-14.91	0.05
Sex					
Male	88 / 115 (76.5)	33.26	27.36	-5.89	0.22
Female	27 / 115 (23.5)	41.94	23.59	-18.35	< 0.01
Race / Ethnicity					
White	71 / 115 (61.7)	41.44	25.88	-15.56	< 0.01
Hispanic	37 / 115 (32.2)	34.91	23.16	-11.76	< 0.01
Black	7 / 115 (6.1)	47.90	19.76	-28.14	0.14
Smoking					
Nonsmoker	99 / 115 (86.1)	40.16	23.95	-16.21	< 0.01
Smoker	16 / 115 (13.9)	38.11	26.98	-11.13	0.12
Parent Fracture					
No	101 / 115 (87.8)	39.38	24.41	-14.96	< 0.01
Yes	14 / 115 (12.2)	44.12	24.86	-19.26	0.02
Previous Fracture					
Yes	60 / 115 (52.2)	41.50	22.72	-18.79	< 0.01
No	55 / 115 (47.8)	38.26	25.71	-12.55	< 0.01
Alcohol					
No	108 / 115 (93.9)	39.31	24.70	-14.61	< 0.01
Yes	7 / 115 (6.1)	51.33	22.19	-29.15	0.03
Rheumatoid Arthritis					
No	108 / 115 (93.9)	39.72	24.84	-14.88	< 0.01
Yes	7 / 115 (6.1)	43.43	20.75	-22.68	0.03
Gluco Corticoids					
No	99 / 115 (86.1)	38.89	24.21	-14.68	< 0.01
Yes	16 / 115 (13.9)	47.10	25.76	-21.35	< 0.01
Supplementation					
No	66 / 115 (57.4)	37.17	24.76	-12.42	< 0.01
Yes	49 / 115 (42.6)	42.70	23.71	-18.99	< 0.01
Height (cm)					
< 157	33 / 115 (28.7)	38.64	22.49	-16.15	< 0.01
157 - 167	40 / 115 (34.8)	41.12	21.61	-19.52	< 0.01
≥ 167	40 / 115 (34.8)	40.28	27.18	-13.10	< 0.01
Weight (kg)					
< 70	42 / 115 (36.5)	41.08	23.39	-17.69	< 0.01
70 - 80	31 / 115 (27.0)	40.34	25.53	-14.82	< 0.01
≥ 80	42 / 115 (36.5)	38.42	24.70	-13.72	< 0.01

Diagnostic Ability of Vitamin D Level as Binary Classifier for Secondary Osteoporosis

The diagnostic ability of vitamin D level as a binary classifier for secondary osteoporosis is visualized with a receiver operating characteristic curve in Figure 3. The area under the curve, AUC = 0.826, suggests that vitamin D level has good diagnostic ability as a binary classifier for secondary osteoporosis.

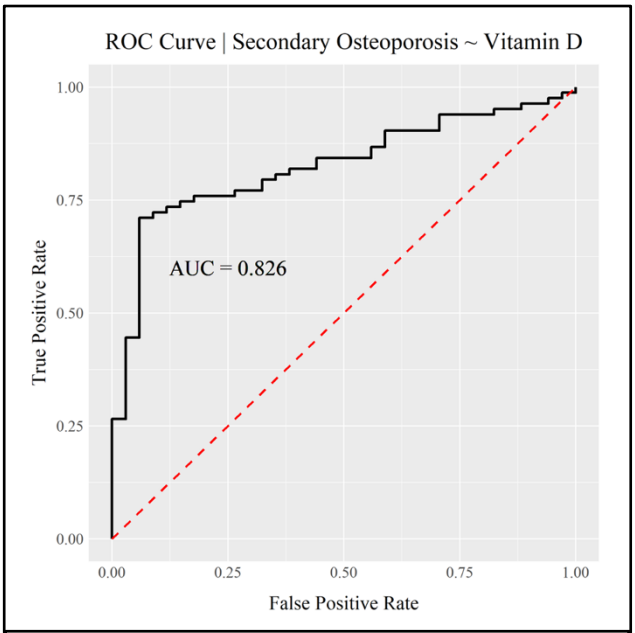


Figure 3. Receiver Operator Characteristics Curve

Summary of Key Findings:

1. Secondary osteoporosis patients had significantly lower mean vitamin D levels than those without the condition.

2. Hispanics had lower mean vitamin D levels compared to non-Hispanics.

3. Patients with vitamin D supplementation had higher mean vitamin D levels than those without.

4. No significant correlations were found between vitamin D levels and continuous covariates.

5. Vitamin D level was the only significant differentiating variable between patients with and without secondary osteoporosis.

6. In twenty-three out of twenty-six subgroups, secondary osteoporosis patients had statistically significantly lower vitamin D levels.

7. Vitamin D level demonstrated good diagnostic ability as a binary classifier for secondary osteoporosis with an AUC of 0.826.

Discussion

This study examined the potential link between vitamin D levels and secondary osteoporosis. The study was non-randomized and multi-centered, with patients aged 65 to 89 years old participating. The results revealed significant disparities in vitamin D levels across major categorical variables. A significant discovery was that patients with secondary osteoporosis consistently had lower mean vitamin D levels than those who did not have secondary osteoporosis. This crucial discovery suggests a probable link between low vitamin D levels and an increased risk of subsequent osteoporosis.

Furthermore, ethnicity was discovered to play an essential role in vitamin D levels, with Hispanics having lower mean vitamin D levels than non-Hispanics. This variation could be due to genetic, nutritional, or environmental variables influencing vitamin D synthesis and metabolism in various ethnic groups. Furthermore, the study found that patients who took vitamin D supplements had higher mean vitamin D

levels than those who did not, confirming the importance of vitamin D in bone health and the potential benefits of supplementation.

Despite these categorical differences, no significant correlations were discovered between vitamin D levels and many variables investigated in the study. In this patient population, variables such as age, gender, weight, height, previous fracture history, parent hip fracture history, current smoking habits, glucocorticoid use, presence of rheumatoid arthritis, and femoral neck BMD estimated via DEXA scans did not show a strong relationship with vitamin D levels. This finding shows that these factors may not significantly influence vitamin D levels or that their influence is overshadowed by other, more potent factors not investigated in this study. When comparing patients with and without secondary osteoporosis, vitamin D level emerged as the only variable significantly different between the two groups. This further underscores the potential role of vitamin D in secondary osteoporosis. More specifically, in almost all subgroups, vitamin D levels were distinctly lower in patients with secondary osteoporosis, suggesting a pervasive pattern regardless of other factors.

The study also shed light on the potential of vitamin D levels as a diagnostic tool and a binary secondary osteoporosis classifier. Using a receiver operating characteristic (ROC) curve, the area under the curve (AUC) was estimated to be 0.826. It supported the hypothesis that vitamin D levels have a significant diagnostic ability for recognizing secondary osteoporosis, potentially functioning as a valuable tool in therapeutic settings.

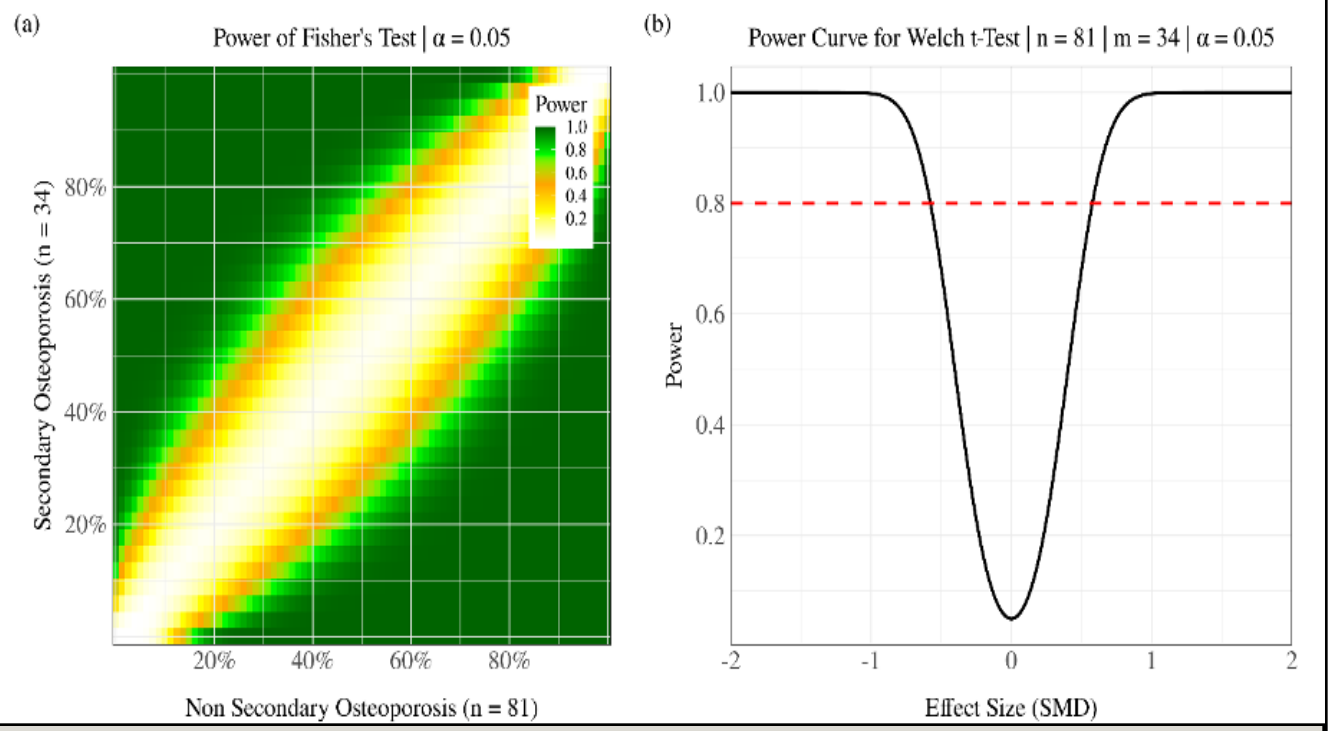
Conclusion:

Indeed, the findings of this study highlight the vital role vitamin D may play in the health of the geriatric population, particularly in the case of secondary osteoporosis. The study discovered a strong link between low vitamin D levels and secondary osteoporosis. This result highlights the significance of regular monitoring and maintaining adequate vitamin D levels in the geriatric population to prevent and manage this illness.

The study's findings shed light on vitamin D's possible impact on bone health in developing secondary osteoporosis. The persistently lower mean vitamin D levels in patients with secondary osteoporosis than those without it highlight the potential protective role of this vitamin in developing this condition. These findings not only underline the significance of prevention but also point to potential therapeutic approaches. Maintaining optimum vitamin D levels may effectively reduce the risk and progression of secondary osteoporosis. As a result, the study suggests that vitamin D could be a key component in developing novel, tailored treatments for managing and preventing secondary osteoporosis.

In terms of the future, the study provides a clear direction for additional research. It is now critical to probe deeper into these first findings. More research could be done to validate these relationships, investigate the underlying mechanisms, and investigate the significance of vitamin D supplementation in patients at risk of developing secondary osteoporosis. The possibility of developing preventive measures or therapies based on these findings throws up fascinating possibilities. Future studies must also focus on creating new dietary guidelines for the elderly population and maintaining adequate vitamin D levels in this population.

Supplementary



Supplementary Figure 1. Power Analyses

Affiliations:
[1] Texas Tech University Health Sciences Center Permian Basin, Department of Family and Community Medicine/Geriatrics
[2] Texas Tech University Health Sciences Center School of Medicine, Lubbock
[3] The University of Texas of the Permian Basin, Department of Mathematics
[4] Texas Tech University Health Sciences Center, Permian Basin, Clinical Research Institute

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Original Article

Influence of patient characteristics on provider deviation from guideline-directed medical therapy of heart failure with reduced ejection fraction in primary care clinics

Karlyn E. Nieto, Pharm.D., BCPS[1], Rachel Basinger, Pharm.D., CTTS, BCACP[2], Rodney B. Young[3], Tarek H. Naguib, M.D., MBA, FACP[4], Eric J. MacLaughlin[5]

Abstract

Background: Heart failure with reduced ejection fraction (HFrEF) is a significant cause of morbidity and mortality in the United States. Although data have demonstrated that guideline-directed medical therapy (GDMT) improves clinical outcomes, hospitalizations, and death due to HFrEF remain common.

Objective: To identify GDMT gaps for patients with HFrEF.

Methods: This retrospective cohort study evaluated adults with HFrEF at an academic internal medicine (IM) or family medicine (FM) clinic between 1/1/2018 and 2/29/2020. A chart review was conducted to characterize patient demographics, characteristics, and GDMT. Descriptive statistics and chi-squared tests were used to describe GDMT regimens and factors associated with improved guideline adherence.

Results: A total of 596 patients were evaluated and 96 included. Overall, 20% of patients were prescribed three GDMT agents (β-blocker+angiotensin converting enzyme inhibitor [ACEi]/angiotensin receptor blocker [ARB]/angiotensin receptor-neprilysin inhibitor [ARNI]+mineralocorticoid receptor antagonist [MRA]), 43.8% two agents (β-blocker + ACEi/ARB/ARNI), 27% one agent, and 9% no GDMT. Those with a payor status defined as commercial insurance were more likely to be on three GDMT agents than those with no commercial insurance (34.8% vs. 15.1%; p=0.039). Patients ≥65 years were less likely to be on three agents compared to those <65 years (8.3% vs. 32%, p=0.029), but more likely to be on a combination of a β-blocker+ACEi/ARB/ARNI (52.8% vs. 32%, p=0.01) or a β-blocker+MRA (11% vs. 2%; p=0.044).

Conclusions: GDMT was underutilized in these academic clinics. Differences in provider prescribing were identified based on age and funding status. Differences in prescribing could be due to demographics or other factors.

Keywords: HFrEF, GDMT, provider deviation, guideline-based treatment, primary care

Corresponding Author:
Rachel Basinger, Pharm.D., CTTS, BCACP, TTUHSC
Jerry H. Hodge School of Pharmacy, Dallas, Texas
Email: Rachel.basinger@ttuhsc.edu

Background

Heart failure with reduced ejection fraction (HFrEF) is a significant cause of morbidity and mortality in the United States. Although data have demonstrated that guideline-directed medical therapy (GDMT) improves clinical outcomes, hospitalization and death remain common.[1]

A critical component of GDMT in HFrEF includes the utilization of agents demonstrated to reduce morbidity and mortality. When the study was conducted in 2020 the 2013 ACC/AHA Guideline for Management of Heart Failure, along with the 2016/2017 focused updates to the guidelines, outlined optimized GDMT as an angiotensin-converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB), or angiotensin II receptor blocker-neprilysin inhibitor (ARNI), with an evidence-based β-blocker (i.e., bisoprolol, metoprolol succinate, carvedilol), and a mineralocorticoid receptor antagonist (MRA).[2-5] In 2022, the ACC/AHA Guideline for the Management of Heart Failure added sodium-glucose-like peptide-2 inhibitors (SGLT-2 inhibitor) as standard GDMT, along with recommending ARNI therapy over ACEi/ARB therapy in class C/D (NYHA Class II-III) heart failure, to optimize morbidity reduction.[5]

In addition to these guideline-based medications, it is critical that optimal doses are utilized.[2-5] These optimal, or "target doses", are those used in clinical trials that demonstrated improved clinical outcomes. With ACEis, ARBs, and β-blockers, these "target doses" are typically much higher than those used for other indications (e.g., high blood pressure). Available literature indicates that patients with HFrEF are frequently not on GDMT medications or at an optimal dose.[1,6-8]

It is currently unclear why many patients with HFrEF may not be on optimal therapy. Some studies suggest patient factors like contraindications, poor tolerability of recommended medications, or poor patient adherence as causes for suboptimal GDMT use.[1] Studies with HFrEF patient registries such as the CHAMP-HF, QUALIFY, and ASIAN-HF have found that women, older patients, different racial groups, and those with lower socioeconomic status are less likely to be prescribed guideline-based treatment or reach optimized doses of medication.[1,6-8] According to the CHAMP-HF study, among patients eligible for therapy, 27%, 33%, and 67% were not prescribed ACEI/ARB/ARNI, evidenced-based beta-blockers, and MRA respectively. Additionally, when medications were prescribed, very few patients received target doses of those medications. Finally, CHAMP-HF found that of patients on all classes of medication, only 1% of them were on target doses of all agents.[1]

There is little information known regarding possible HFrEF GDMT treatment gaps in academic teaching clinics. To address this knowledge gap, provider deviation rates from HFrEF GDMT (i.e., ACEi, ARB, ARNI, β-blocker, and MRA) were assessed in family medicine and internal medicine academic teaching clinics.

Objective

The primary outcome of this study was to describe the use of GDMT in this patient population and assess various factors (e.g., race, sex, age, payor status, healthcare

access, medication choice, and dosing) associated with guideline adherence. The secondary outcomes were to determine the percentage of patients on optimal and suboptimal HFrEF therapeutic regimens at each clinic independent of patient characteristics and identify a recommendation to improve care.

Methods

Study Design and Participants

This is a retrospective cohort analysis of outpatients who had an appointment addressing their heart failure condition at Texas Tech Family and Community Medicine (FM) and Internal Medicine (IM) clinics between 01/01/2018 and 02/29/2020. Medication data and labs that were from their most recent visit during this index period were collected. Patients were included if they were ≥18 years of age and diagnosed with chronic, acute on chronic, or unspecified HFrEF (I50.22; I50.23; I50.20), congestive HF (I50.9), HF due to hypertension (I11.0), or end-stage HF (I50.84) and had a left ventricular ejection fraction (EF) of ≤40%. Exclusion criteria included pregnancy, comfort care or hospice, recipients of a heart transplant, using a left ventricular assistive device, on dialysis, prisoners, or wards of the state, or had inadequate documentation in the medical record to meet inclusion criteria.

Data Collection

Patient data were extracted from the electronic health record after a manual record review and maintained in a Microsoft Excel (Redmond, WA) spreadsheet. Individuals responsible for collecting data were trained in the use of the database and audits on the individuals were conducted randomly to provide quality assurance. Subjects were identified by an Allscripts EHR query. These patients were then reviewed to ensure they met inclusion criteria. Baseline characteristics collected included age, race, sex, height, weight, body mass index (BMI), payor status, employment status, distance from home to clinic, left-ventricular ejection fraction, and clinic (FM or IM). Other data collected included the subject's past medical history, recent labs, vital signs, and laboratory values (e.g., chemistry panel, kidney function) to evaluate possible contraindications. Data were also collected on the medication prescribed including the medication name, dose, and dosing frequency. Finally, data on contraindications were also collected, including if the patient had hypotension (blood pressure <90/60 mmHg), bradycardia (heart rate <60 bpm), eGFR<30 mL/min/1.73m^2, or hyperkalemia (K>5 mEq).

Statistical Analysis

Descriptive statistics (i.e., mean, standard deviation, percentages) were used for the primary objective of characterizing the use of GDMT in HFrEF patients. Fisher's Exact test and chi-squared test were performed on the following patient categories (i.e., male vs. female; clinic type [FM vs. IM clinic], distance to clinic [<10 miles vs. ≥10 miles], age ≥65 vs <65, with a payor status defined as commercial insurance [private insurance] vs. non-commercial insurance [Medicare, Medicaid, or self-pay], and race [non-minority vs. minority]) to assess for differences in prescribing of GDMT in different patient demographic groups. The distance of radius of 10 miles is due to Amarillo being a mid-size city where most businesses and residences are within a 10-mile radius. The racial categories are defined as non-minority (Caucasian) and minority (Asian, African American, non-white Hispanic, unknown/unlisted, and other). For

all analyses conducted the *a priori* level of significance was 0.05 on Microsoft Excel (Redmond, WA).

To assess different GDMT regimens, patients were stratified and compared by grouping. Three-agent regimens were an evidence-based β-blocker + ACEi/ARB/ARNI + MRA, two-agent regimens were an evidence-based β-blocker + ACEi/ARB/ARNI, β-blocker + MRA, or an ACEi/ARB/ARNI + MRA, and one-agent regimens were an evidence-based β-blocker, ACEi/ARB/ARNI, or MRA. At the time the study was conceived and conducted, sodium glucose-like peptide-2 inhibitors (SGLT-2 inhibitors) were not recommended in the national guideline, and therefore, quadruple GDMT regimens were not assessed. Chi-squared test or Fisher's exact tests were used, depending on sample size, to compare the usage of these regimens based on patient characteristics.

Results

Five hundred ninety-six patients between January 1, 2018, to February 29, 2020, were identified by the electronic health records query. A total of 500 patients were excluded; 160 for an ejection fraction (EF) >40%, 130 because they had no recent laboratory values within the time frame of review, 116 for an unknown LVEF, 40 were deceased or dismissed from the clinic, 29 due to not being seen in clinic during the pre-specified dates, 15 due to hospice care, and 10 due to dialysis. The 29 patients excluded from the study were included in the query due to them having communication with an internal medicine or family medicine physician or resident during the index date. This left a study population of 96 patients for evaluation. Patient demographics are listed in Table 1.

Table 1. Demographic and Clinical Information for Patient Cohort

Characteristic	**Total (n=96)**
Male, No. (%)	60 (62.5)
Age (mean ± SD), y	60.8 (13.4)
BMI (mean ± SD), kg/m^2	31.6 (7.4)
Distance from clinic (mean ± SD), miles	12.4 (19)
Race, No. (%)	
Caucasian	67 (69.8)
Asian	0 (0)
African American	10 (10.4)
Hispanic	17 (17.7)
Other	1 (1.0)
Unknown/Unlisted	1 (1.0)
Vital Signs	
Systolic BP (mean ± SD), mmHg	129.2 (19.8)
Diastolic BP (mean ± SD, mmHg	77.4 (12.6)
Heart rate (mean ± SD), bpm	81.7 (14.3)
Laboratory Values	
Potassium (mean ± SD), mEq/L	4.2 (0.5)
Sodium (mean ± SD), mEq/L	139 (4)
Serum creatinine (mean ± SD), mg/dL	1.4 (0.7)
Patients with an eGFR >60 mL/min/1.73m^2 (%)	43.8
Payor Status, No. (%)	
Commercial insurance	23 (24.0)
Non-commercial insurance	
• Medicare/Medicaid	52 (54.2)
• Multiple insurances (Medicare/Medicaid primary)	15 (15.6)
• Self-pay (no insurance coverage)	6 (6.3)
Clinic site, No. (%)	
Internal Medicine Clinic	64 (66.7)
Family Medicine Clinic	32 (33.3)

For the primary outcome, there was no significant difference in prescribing patterns between sex, ethnicities, distances from clinic, or clinic type (See Table 2). HFrEF patients on GDMT with a payor status defined as commercial insurance were more likely to be on 3 GDMT agents than those without commercial insurance (34.8% vs. 15.1%; p=0.039). Compared with patients <65 years of age, those ≥65 years were less likely to be on 3 GDMT agents (8.3% vs. 32%, p=0.029), but were more likely to be on a combination of an evidence-based β-blocker + ACEI/ARB/ARNI (52.8% vs. 32%, p=0.01) or an evidence-based β-blocker + MRA (11% vs. 2%, p=0.044; see Figure 1.) No patients in the study were prescribed eplerenone for their MRA, thus it can be concluded that whenever a patient has an MRA in their regimen it's spironolactone.

The secondary outcome of this study found that of 96 patients included in this study, 19.8% were prescribed 3 GDMT agents (an evidence-based β-blocker + ACEi/ARB/ARNI + MRA), 43.8% were prescribed 2 GDMT agents (an evidence-based β-blocker + ACEi/ARB/ARNI, an evidence-based β-blocker + MRA, or an ACEi/ARB/ARNI + MRA). Twenty-seven percent (27.1%) were on a single GDMT agent and 9.4% were on no GDMT. Of 87 patients on GDMT agents with no contraindications to therapy or optimization, only 5 patients (6.1%) received optimized GDMT regimens. The percentage of patients on individual GDMT agents was collected (see Figure 1) along with the percentage of patients optimized on each GDMT agent (see Figure 2). For patients not on 3 GDMT medications, the majority (71%) had no contraindications to therapy. The remaining had an eGFR<30 ml/min (11%), hypotension (7%), hyperkalemia (5%), or bradycardia (3%).

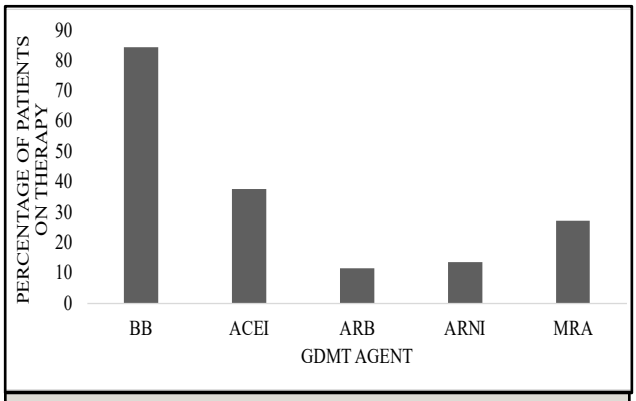

Figure 1. Percentage of patients on each respective GDMT agent

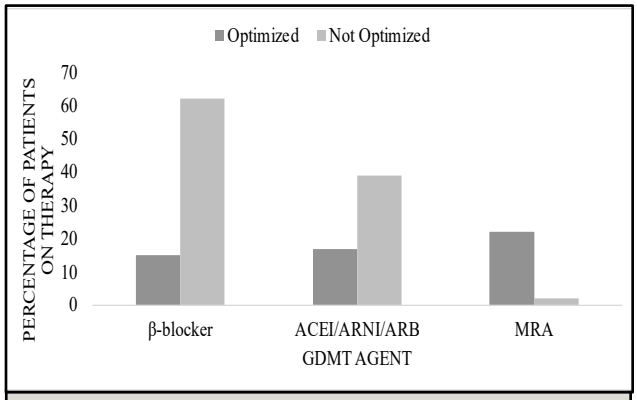

Figure 2. Percentage of patients on optimized versus non-optimized therapy

Table 2. Primary objective findings of inter-group comparisons of medication regimens

Medication Regimen	Comparison Group on Regimen, No. (%)	Comparison Group on Regimen, No. (%)	p-value
	Females	Males	
BB+ACEI/ARB/ARNI+MRA	7 (19.4)	12 (20)	0.947266
BB+ ACEI/ARB/ARNI	11 (30.5)	24 (40)	0.351975
BB+MRA	2 (5.5)	3 (5)	0.905592
ACEI/ARB/ARNI+MRA	1 (2.8)	1 (1.7)	0.712118
Single agent	12 (33)	14 (23.3)	0.285792
None	3 (8.3)	6 (10)	0.786218
	Non-minority	Minority	
BB+ACEI/ARB/ARNI+MRA	14 (20.6)	5 (17.9)	0.76016
BB+ ACEI/ARB/ARNI	26 (38.2)	9 (32.1)	0.572947
BB+MRA	2 (2.9)	3 (10.7)	0.119241
ACEI/ARB/ARNI+MRA	2 (2.9)	0 (0)	1
Single agent	16 (23.5)	10 (35.7)	0.222045
None	7 (10.3)	2 (7.1)	0.63018
	Commercial Insurance	Non-Commercial Insurance	
BB+ACEI/ARB/ARNI+MRA	8 (34.8)	11 (15.1)	**0.039521**
BB+ ACEI/ARB/ARNI	7 (30.4)	28 (38.4)	0.491279
BB+MRA	0 (0)	5 (6.8)	1
ACEI/ARB/ARNI+MRA	2 (8.7)	0 (0)	0.0555
Single agent	5 (21.7)	21 (28.8)	0.508363
None	1 (4.3)	8 (11)	0.342858
	Distance <10 miles	Distance ≥ 10 miles	
BB+ACEI/ARB/ARNI+MRA	11 (15.7)	8 (30.8)	0.074833
BB+ ACEI/ARB/ARNI	27 (38.6)	8 (30.8)	0.590201
BB+MRA	4 (5.7)	1 (3.8)	0.714307
ACEI/ARB/ARNI+MRA	2 (2.9)	0 (0)	1
Single agent	21 (30)	5 (19.2)	0.29135
None	6 (8.6)	3 (11.5)	0.657611
	Family Medicine	Internal Medicine	
BB+ACEI/ARB/ARNI+MRA	5 (15.6)	14 (21.9)	0.468738
BB+ ACEI/ARB/ARNI	15 (46.9)	20 (31.3)	0.133766
BB+MRA	0 (0)	5 (7.8)	1
ACEI/ARB/ARNI+MRA	1 (3.1)	1 (1.6)	1
Single agent	7 (21.9)	19 (29.7)	0.41679
None	5 (15.6)	4 (6.3)	0.137395
	≥ 65 Years Old	< 65 Years Old	
BB+ACEI/ARB/ARNI+MRA	3 (8.3)	16 (32)	**0.029062**
BB+ ACEI/ARB/ARNI	19 (52.8)	16 (32)	**0.010074**
BB+MRA	4 (11)	1 (2)	**0.043779**
ACEI/ARB/ARNI+MRA	0 (0)	2 (4)	0.5263
Single agent	12 (33.3)	14 (28)	0.285792
None	3 (8.3)	6 (12)	0.786218

Discussion

The current study highlights significant opportunities for quality improvement initiatives around GDMT for HFrEF patients in academic teaching clinics. Only 6.1% of patients were documented to be on optimized GDMT therapy. Significant differences between GDMT therapeutic regimens and patient characteristics were found in this study, including differences based on age groups and payor status. There may be several reasons for the low percentage of patients on documented optimized GDMT, including lack of cardiologist management, lack of follow-up documentation, missing data elements in the electronic health record, and undocumented contraindications or adverse effects.

Findings from this study are consistent with other research demonstrating treatment gaps with GDMT in HFrEF despite the availability of evidence-based guidelines.[1,6-8] Advanced age (i.e., ≥65 years of age) was associated with poorer provider adherence to GDMT agent triple therapy (i.e., ACEI/ARB/ARNI + an evidence-based β-blocker + MRA) compared to those <65 years old. Those ≥65 years of age, however, were more likely to be on dual therapy (an evidence-based β-blocker + ACEI/ARB/ARNI or an evidence-based β-blocker + MRA). This could be due to older patients having more comorbidities or being less able to tolerate more aggressive GDMT therapy than younger patients. However, consistent with other data, due to the lack of documentation, the exact reason(s) cannot be elucidated.[1] It was also found that those with commercial insurance were more likely to be on three GDMT agents than those with non-commercial insurance. Reasons for this difference could be cost or issues with being able to afford follow-up visits.

The secondary outcome of determining the percentage of patients on optimal and suboptimal HFrEF therapeutic regimens at each clinic independent of patient characteristics also yielded interesting results. Despite having a relatively low number of patients with contraindications to therapy optimization or specific GDMT agents (e.g., abnormal electrolytes, impaired kidney function) the majority (71%) were still on sub-optimal therapy. The most common contraindication to a GDMT agent was an eGFR <30 mL/min/1.73m^2, preventing patients from receiving an MRA. A small number of patients (7%) of patients had hypotension (blood pressure <90/60 mmHg), which could slow or limit the ability to up-titrate therapy but likely not result in a contraindication to use. Again, it is impossible to know precisely why specific agents were not used in certain patients due to a lack of documentation and the nature of a retrospective chart review.

There are several possible reasons why few patients were on optimized GDMT. First, many of these patients were seen and managed by outside cardiologists. If any of these patients had their HF regimens managed through their cardiologist, it is possible the medications in the primary care provider's records were not up to date despite the standard practice of nurses conducting medication reconciliations at each office visit. Also, many primary care providers may feel uncomfortable adjusting medications an outside specialist has been managing. Another reason for this treatment gap could be the lack of documentation on the type of heart failure. Many patients had a general diagnosis of heart failure without specific categorization regarding ejection fraction or other sub-categories (i.e., HFrEF, HFpEF, HFmrEF, HFimpEF). The lack of a specific diagnosis makes management difficult. Lastly, the electronic medical record

used in the FM and IM clinics lack a field for documentation of the patient's most recent LVEF, making documentation of the type of heart failure the patient has even more difficult.

There have been several studies conducted evaluating methods to improve provider adherence to GDMT. One study found that chart reminders within the electronic health record (EHR) led to an increase in the number of patients prescribed an indicated agent. Clinical pathways have also been shown to improve provider adherence to GDMT as they provide them with a resource to help navigate the treatment guidelines. Changes to EHR systems to address limitations were also shown to increase the percentage of patients prescribed their indicated GDMT agents.[9]

One approach, found to be particularly effective, utilized a team-based care approach with pharmacists. In a general cardiology (GC) clinic, the use of outpatient pharmacists to manage HFrEF patients in a medication titration assistance clinic (MTAC) was associated with a greater number of patients being prescribed an ACEi or ARB and an evidence-based β-blocker, and a higher likelihood of reaching the target, or maximally tolerated, doses compared to usual care. Of the patients previously stated 64% in the MTAC versus 40% in GC reached target or max tolerated doses (p=0.01). The MTAC was also found to be more likely than the GC clinic to achieve >50% of target doses for ACEi/ARBs (83% vs. 69%, p=0.04) and evidence-based β-blockers (64% vs. 41%, p=0.003).[10] In the IMPROVE-HF study, the impact of multidimensional, practice-specific performance improvement interventions on the use of GDMT in outpatient cardiology practices was evaluated. The intervention included incorporating a guideline-based clinical decision tool kit, educational materials, practice-specific data reports, and evidence-based best-practices algorithms. Participation in this study yielded statistically significant & clinically relevant improvements in the proportion of eligible patients treated at target doses for evidence-based β-blockers (20.5% vs. 30.3% at the 24-month mark, p<0.001). Similar improvements were not seen in other medication classes, however. This study suggests that enhanced systems of care are needed to better educate patients to expect dose up-titration even if HF symptoms are improving, to provide decision support tools to physicians for dose titration, and to ensure outpatient follow-up visits are set at certain intervals until target doses are achieved.[11]
There were several limitations to our study including the small sample size and limited sites, retrospective design, and limits of the EHR system used. Another limitation was that when comparing commercial insurance to non-commercial insurance, it was difficult to determine whether patients with Medicare coverage had Medicare Part D. If patients had Medicare Part D coverage, the reasoning behind the lack of adherence to GDMT may be less likely due to affordability issues. The clinic EHR (Allscripts) presented limitations as well, with no defined field for documentation of the most recent ejection fraction.

Improving the specificity of heart failure diagnosis in the electronic health record is imperative in improving the treatment and utilization of GDMT. This can be done by obtaining the most recent echocardiogram and having dedicated areas for it in the medical record. Communication with the patient's cardiologist and obtaining current medical records is also imperative to help optimize heart failure regimens. Lastly, thorough documentation behind the reasons for the lack of adherence to optimized GDMT

is important to aid in the continuity of care and dose optimization in the future.

Conclusion

GDMT was significantly underutilized in IM and FM academic clinics, particularly for older patients and those without commercial insurance. Results from this study suggest several challenges related to GDMT utilization, including the lack of documentation of heart failure type, ejection fraction, and outside medical records from specialists. Multidimensional efforts including improved documentation of HFrEF diagnosis, whether the patient is being managed by a cardiologist or only primary care, echocardiogram results, and reasons for not using GDMT agents and/or optimized doses are warranted in our clinics.

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Affiliations:
[1]Department of Pharmacotherapy, The University of North Texas Health Sciences Center at Fort Worth College of Pharmacy, Fort Worth,
[2]Department of Pharmacy Practice, TTUHSC Jerry H. Hodge School of Pharmacy, Dallas Texas
[3]Department of Family and Community Medicine, TTUHSC School of Medicine, Amarillo, Texas
[4]Department of Internal Medicine, TTUHSC School of Medicine, Amarillo, Texas
[5] Department of Pharmacy Practice, Texas TTUHSC Jerry H. Hodge School of Pharmacy, Amarillo

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Original Article

Breakthroughs and Barriers to Stoma Education: Wisdom Gained from a Pilot Study

Amy Sappington, MSN, APRN, ACNP-BC, FNP-BC[1], Izi Obokhare, M.D. FACS, FICS[2]

Abstract

Background: The Ostomy and Continence Diversion Patient Bill of Rights asserts ostomates should receive standardized ostomy education. These programs reduce anxiety, improve self-efficacy, and directly address and lower health disparities.
Objective: The aim of this project was to implement a structured perioperative ostomy education program and evaluate the program's effects on readmission rates due to ostomy complications, postoperative length of stay (PLOS), and quality of life after ostomy surgery.
Methods: A perioperative ostomy education program was implemented in an acute care hospital, with program evaluation. Adult patients undergoing fecal diversion surgery from July 1 to December 31, 2023, were recruited via convenience sampling. Participants completed two validated surveys: the Ostomy Self-Care Knowledge Assessment (OSCKA) (n = 7) and the Stoma Quality of Life survey (n = 7). Readmissions and PLOS were examined six months before (n = 13) and six months after implementation (n = 13).
Results: Seven ostomates completed the OSCKA, with mean scores of 20, a high level of understanding. Seven ostomates completed the two-week Stoma-QOL survey, and three of those seven repeated the survey within two months. Ostomates related improved self-confidence, but sleep and ostomy apparatus concerns persisted. No readmissions occurred in either cohort, but the PLOS decreased.
Conclusions: An evidence-based ostomy education protocol was implemented with subsequent evaluation. Participants showed a high level of comprehension at discharge. Quality of life measures show that further social support is needed. The postoperative length of stay was decreased by two days, and no readmissions occurred.

Keywords: structured clinical guidelines, preoperative site marking, structured patient education, peristomal complications, length of stay, readmissions, and quality of life

Background

An ostomate is a person who has undergone fecal diversion surgery.[1] Approximately 750,000 to one million ostomates reside in the United States, with a reported 15.6 million people living with ostomies worldwide.[2] The Ostomy and Continence Diversion Patient Bill of Rights (PBOR) outlines the rights of patients with ostomies

to receive an internationally agreed-upon standard of care.[1] The PBOR promotes the awareness of needs during the perioperative phase of care and specifically declares that patients have a right to ostomy education and supplies. The surgical creation of an ostomy can result in a myriad of issues. The care and treatment of an ostomy requires education, monitoring, and adjustment of care for the life of the ostomy.[1] Failure to treat complications promptly can lead to hospital readmission and prolonged length of stay. Standardized ostomy education programs reduce anxiety and improve self-efficacy, directly addressing and lowering health disparities for ostomy patients.[3,4]

Objective

A structured perioperative ostomy education program was implemented within an acute care hospital, followed by program evaluation. The aim of this project was to implement a structured perioperative ostomy education program to decrease readmissions related to ostomy complications, reduce the postoperative length of stay, and improve the quality of life for patients who underwent ostomy surgery. The program evaluation included a socio-behavioral study to evaluate the effect of perioperative education in addressing quality of life after stoma creation.

Methods

The design of this project was program implementation and evaluation. The study was performed in a 495-bed hospital in Texas. Participants who underwent colostomy formation during their hospitalization between July 1, 2023, through December 31, 2023, were recruited via convenience sampling. Inclusion and exclusion criteria are listed in Table 1.

Table 1. Inclusion and Exclusion Criteria for Study Participation

Inclusion Criteria	Exclusion Criteria
Age 18 and older Fecal diversion surgery Diagnoses: bowel carcinoma, inflammatory bowel disease, diverticulitis, bowel perforation, or bowel ischemia Trauma Ileostomy or colostomy patients	Under age 18 Inability to consent People who require a guardian People with a psychiatric diagnosis limiting capacity Ostomy revision patients Urostomy patients

The postoperative length of stay was studied. Trauma scores from one to four indicate the most severely injured patients require treatment in a trauma center, while scores from five to eight indicate increased survivability.[5] Patients with a trauma score less than four were expected to require a longer length of stay unless they unexpectedly succumbed to their injuries. Readmissions were recorded for patients who were readmitted only for ostomy complications.

Ethical Acknowledgment

The Texas Tech University Health Sciences Center (TTUHSC) Institutional Review Board for the Protection of Human Subjects reviewed and approved the study procedures, approval number L23-173. All patient and facility information were deidentified and patients were given ostomy education even if they did not elect to participate in the study. Participation in the study was discussed without coercion, and informed consent was obtained with signed consent by each participant, preserving autonomy. Participants completed the education evaluation and quality of life surveys by directly entering their answers into Qualtrics, completing the instruments on paper, or by telephone. Confidentiality was maintained by entering the paper or phone

surveys into Qualtrics and ensuring any written material was shredded after entry. Data was reported in aggregate, ensuring confidentiality.

Instruments

The reliable and valid Ostomy Self-Care Knowledge Assessment (OSCKA), as seen in Table 2, was used to measure patients' understanding of postoperative education before discharge.[6] The instrument includes 26 questions answered by the subjects via a Qualtrics link provided by an ostomy education team member. The OSCKA was scored with 1 point for each correct answer and 0 points for each incorrect or "I don't know" answer. The goal was a score of 18 or higher, indicating good ostomy care knowledge. A score of 10 to 17 indicates average stoma knowledge, while a score of 0 to 9 denotes poor knowledge.[6] Scores below 18 indicated a need for further education before discharge, which was completed with the teach-back method, where patients recount information they have been taught.[7]

Table 2. Ostomy Self-Care Knowledge Assessment: True-False Questions to Assess Knowledge of Ostomy Care[6]

Number	Phrases	True	False	I do not
1	An ostomy is an opening that is surgically created in a patient's abdominal	■		
2	The ostomy is placed only permanently.		■	
3	Drainable pouches can be used for 5-7 days.	■		
4	The best time to change the pouches for most people is in the early	■		
5	Choosing the right pouch plays an important role in preventing ostomy	■		
6	It is better to consume low fluids (1 to 2 glasses) during the day.		■	
7	It is better to eat small meals with more meals (4-5 servings) per day.	■		
8	Wearing a tight belt or tight abdominal band should be avoided.	■		
9	The skin around the stoma should only be cleaned with a damp cloth.		■	
10	Bathing with an ostomy pouch should be avoided.		■	
11	Strenuous exercise with an ostomy pouch should be avoided.	■		
12	The stoma bleeds easily from the impact.	■		
13	It is recommended to use hot water to clean the skin around the stoma.		■	
14	Shaving the hair around the stoma should be avoided.		■	
15	The size of the ostomy does not change in the first weeks after surgery.		■	
16	When 1/3 of the pouch is full, it is better to replace or empty the bag.	■		
17	The natural color of the stoma is dark purple or light red.		■	
18	Bleeding from around the ostomy is normal.		■	
19	Changes in the shape and size of the stoma (protrusion or indentation) are		■	
20	If you have abdominal pain or cramps with no stools coming out of the	■		
21	Persistent diarrhea from the ostomy site is normal.		■	
22	Use spinach and parsley to reduce the smell of feces.	■		
23	Consumption of legumes (lentils, beans, etc.) is recommended in patients		■	
24	Fish causes an unpleasant odor in the stool.	■		
25	Apple compote hardens the stool, so it is recommended.	■		
26	Nuts can clog the stoma if not chewed well.	■		

The Stoma Quality of Life survey (Stoma-QoL), as described in Table 3, was used to evaluate the participants' psychological adjustment and concerns regarding their stoma surgery.[8] The instrument is validated and has been proven to be a reliable instrument.[8] The survey consists of 20 Likert scale questions, with scores of 1 to 4 assigned to each category. Responses to the questions were scored as: Always = 1, Sometimes = 2, Rarely = 3, and Not at All = 4.[8]

Table 3. Stoma Quality of Life Survey Questions[8]

Please check the response that best describes how you are feeling at the moment.

	Always	Sometimes	Rarely	Not-at-all
1. I become anxious when the pouch is full.				
2. I worry that the pouch will loosen.				
3. I feel the need to know where the nearest toilet is.				
4. I worry that the pouch may smell.				
5. I worry about the noises from the stoma.				
6. I need to rest during the day.				
7. My stoma pouch limits the choice of clothes that I can wear.				
8. I feel tired during the day.				
9. My stoma makes me feel sexually unattractive.				
10. I sleep badly during the day.				
11. I worry that the pouch rustles.				
12. I feel embarrassed about my body because of my stoma.				
13. It would be difficult for me to stay away from home overnight.				
14. It is difficult to hide the fact that I wear a pouch.				
15. I worry that my condition is a burden to people close to me.				
16. I avoid close physical contact with my friends.				
17. My stoma makes it difficult for me to be with other people.				
18. I am afraid of meeting new people.				
19. I feel lonely even when I am with other people.				
20. I worry that my family feels awkward around me.				

Study Procedures

A structured ostomy education protocol was developed using the Wound, Ostomy, and Continence Nurses Society guidelines for ostomy care.[9] The ostomy program included preoperative, inpatient postoperative, and post-discharge phases. Preoperative skin marking for stoma placement and education were performed in the surgery clinic or hospital by a nurse practitioner, a certified Wound, Ostomy, and Continence Nurse (WOCN), or the surgeon. Postoperatively, daily education was performed from postoperative day one through postoperative day four. Literature was provided to reinforce the education, and families were included when available. For patients too ill to participate in the education process on postoperative day one, education began once the patient's condition allowed.

The project team included the primary researcher, the WOCN, hospital nursing staff, clinic nursing staff, and advanced practice provider staff. Each team member was educated on the study protocol. Patients were enrolled in the program from July 1, 2023, through December 31, 2023, and data were collected until the last patient reached the eight-week postoperative point. Participants completed the Ostomy Self-Care Knowledge Assessment on the day of hospital discharge. Participants were scheduled for follow-up with their surgeon one to two weeks post-discharge and again six to eight weeks after discharge. The Stoma-QoL survey was completed at each of the two visit timeframes. Thirty-day readmission rates for ostomy complications and initial hospitalization length of stay data from January 1, 2023, through June 30, 2023, were used as a pre-program baseline to compare the post-program readmission and length of stay. The post-implementation data was collected from July 1, 2023, through 30 days after discharge for the final program participant.

Outcome Measures

Outcomes were measured using the post-education Ostomy Self-Care Knowledge Assessment (OSCKA) to identify and address education gaps before discharge.[6] Outcomes also included comparing the postoperative length of stay and readmissions for ostomy complications pre- and post-implementation. Data were retrieved from the hospital's electronic medical record system, Cerner, based on specified CPT codes, listed in Table 4, for colostomy formation and complications. Patient quality of life scores via the Stoma-QoL survey were used to inform further development of the ostomy program.[8]

Table 4. CPT Codes Utilized for Data Collection at the Target Facility

CPT	Description
44141	Colectomy, partial; with skin level cecostomy or colostomy
44146	Colectomy, partial; with coloproctostomy, with colostomy
44187	Laparoscopy, Surgical ileostomy or jejunostomy, non-tube
44188	Laparoscopy, Surgical; Colostomy or skin level cecostomy
44206	Laparoscopy, Surgical; Colectomy, partial, with end colostomy and closure of distal segment (Hartmann type procedure)
44208	Laparoscopy, Surgical; colectomy, partial, with anastomosis, with coloproctostomy with colostomy
44320	Colostomy or skin level cecostomy

Data Analysis

The validated OSCKA and Stoma-QoL survey results were evaluated using the Stata/MP version 18.0 for analysis, and listwise deletion was applied to the missing data. Descriptive statistics were calculated for all variables, including frequency with percentages for categorical and mean with standard deviation or median with interquartile range for continuous, depending on the level of measurement. Data obtained from the hospital reflecting pre- and post-implementation measures were compared using the Fisher's exact test for categorical analysis and the Wilcoxon rank-sum test for comparison of repeated measures with an alpha of 0.05 established *a priori* for statistical significance.

Results

Full Sample

A total of 26 patients had colostomies placed during the study window, with 13 in each cohort (e.g., pre- and post-program). The majority were male and white, averaging 63.9 years **(Table 5)**. Only two patients in the pre-program cohort had colostomies placed due to trauma, though more than 90% were placed emergently due primarily to perforation, infection, or a mass with obstruction. Home, home health, or skilled nursing facilities were the primary dispositions of patients discharged after colostomy placement, and the median hospital length of stay was 12.5 days. The median postoperative length of stay was seven days.

Pre- and Post-Program Comparisons

There were no statistically significant differences across patient characteristics or outcomes between the pre- and post-program cohorts. However, there was a clinically significant reduction in the median post-surgery length of stay in the post-program cohort (six days) compared to the pre-program cohort (eight days), as noted in Table 5. Additionally, a more significant proportion of patients were discharged to home health in the post-program cohort (38.4%) compared to the pre-program cohort (0.0%). Lastly, no patients in either cohort were readmitted due to complications or concerns of the colostomy. Thus, we could not evaluate the differences in readmission rates between cohorts.

Table 5. Patient Characteristics and Outcomes: Pre- and Post-program Implementation Cohorts

Characteristic	**Full Sample (n = 26)**	**Pre-Program (n = 13)**	**Post-Program (n = 13)**
Age [Mean (SD)]	63.9 (14.4)	59.1 (13.7)	68.8 (13.9)
Gender [n (%)]			
Female	10 (38.5)	5 (38.5)	5 (38.5)
Male	16 (61.5)	8 (61.5)	8 (61.5)
Surgery status [n (%)]			
Emergent	24 (92.3)	11 (84.6)	13 (100.0)
Scheduled	2 (7.7)	2 (15.4)	0 (0.0)
Trauma [n (%)]	2 (7.7)[a]	2 (15.4)	0 (0.0)
Procedure – colostomy [n (%)]	26 (100.0)	13.0 (100.0)	13.0 (100.0)
Total length of stay [Median (IQR)]	12.5 (8.0, 19.0)	10.0 (8.0, 20.0)	13.0 (8.0, 17.0)
Post-surgery length of stay [Median (IQR)]	7.0 (4.0, 15.0)	8.0 (6.0, 13.0)	6.0 (3.0, 15.0)

Characteristic	Full Sample (n = 26)	Pre-Program (n = 13)	Post-Program (n = 13)
Discharge disposition [n (%)]			
Home	8 (30.8)	5 (38.4)	3 (23.1)
Home health	5 (19.2)	0 (0.0)	5 (38.4)
Acute rehabilitation	3 (11.5)	2 (15.4)	1 (7.7)
Skilled nursing facility	5 (19.2)	2 (15.4)	3 (23.1)
Long-term acute care	3 (11.5)	2 (15.4)	1 (7.7)
Outpatient therapy	2 (7.8)	2 (15.4)	0 (0.0)
Reason for surgery [n (%)]			
Diversion	6 (23.1)	4 (30.7)	2 (15.4)
Mass/obstruction	8 (30.8)	3 (23.1)	5 (38.5)
Perforation/infection	11 (42.3)	5 (38.5)	6 (46.1)
Trauma	1 (3.8)	1 (7.7)	0 (0.0)
Notes: SD = standard deviation, n = frequency, % = percentage, IQR = interquartile range [a]Trauma scores were 3 and 8			

Colostomy Knowledge Assessment

Of the 13 ostomy patients in the post-implementation cohort, only seven agreed to complete the OSCKA, as described in Table 6. There was a similar distribution of male and female patients, and patients were primarily discharged to home (n = 3) or with home health (n = 5). All surveyed patients underwent colostomy for medical diagnoses. The median hospital length of stay was 9.9 days, while the median post-surgery length of stay was three days. The mean score on the OSCKA was 20 points, with an expected score of 18 or greater, indicating a good level of post-education knowledge.

Patients demonstrated knowledge of ostomy placement, the temporality of the ostomy, and essential aspects of changing the pouch. They also demonstrated competency related to oral consumption of food and drinks and appropriate clothing. However, patients struggled to understand the normal and abnormal characteristics of the stoma. For example, only 57% of the patients correctly identified that bleeding or changes in the size and shape of the stoma are abnormal. A total of 72% of the patients

demonstrated uncertainty regarding shaving around the stoma and managing odor with food products.

Table 6. Characteristics of Participants Who Completed the OSCKA and Stoma-Qol Surveys

Characteristic	Study Participants (n = 7)
Age [Mean (SD)]	72.5 (12.1)
Gender [n (%)]	
Female	3 (42.9)
Male	4 (57.1)
Post-surgery length of stay [Median (IQR)]	
Discharge disposition [n (%)]	
Home	2 (28.7)
Home health	2 (28.7)
Acute rehabilitation	1 (14.2)
Skilled nursing facility	1 (14.2)
Long-term acute care	1 (14.2)
Notes: SD = standard deviation, n = frequency, % = percentage	

Stoma Quality of Life Survey

The seven consented patients completed the initial Stoma-QOL survey at the two-week follow-up, and three completed the survey during the six-to-eight-week follow-up. Scores from both intervals were compared. Improvement was noted in questions about comfort with interpersonal activities and the ability to return to normal daily activities. Difficulty sleeping and concern for potential loosening of the ostomy apparatus were persistent.

Discussion

The project met with breakthroughs and barriers, informing program modifications. The ostomy education program's success depended upon coordinating multiple services to address patient-specific issues. The following discussion describes the evolution of the program.

Colostomy Supplies

Planning for the ostomy education program required ensuring supplies were available and utilized appropriately. Pouching systems include an adhesive flange with a skin barrier and a pouch that typically snaps onto the affixed portion. Varied types of pouching systems are available. For this program, the ostomy supply representative for the facility was consulted. The representative ensured that the pouching systems were available in the central and operating supply rooms. Education was provided to staff members working in the departments caring for ostomates. The hospital WOCN provided each patient with a month of ostomy supplies and patient education folders on discharge.

Interdisciplinary Team Involvement

Nutrition services departments are responsible for providing nutrition education for patients. Adequate nutrition is required for proper healing. Dietitians were consulted for patient education when patients held a new diagnosis of diabetes or those with a diagnosis of malnutrition. A dietitian evaluated every person with a length of stay greater than five days.

Discharge Planning

Leaving the security of inpatient care can be daunting. Patients should feel their discharge planning is patient-centered and comprehensive; therefore, case management assisted with discharge planning.[10] Physicians agreed to standard orders for home health or outpatient wound care clinic follow-up for patients discharged to home. Charity follow-up wound care was arranged for uninsured patients when available. Ostomates qualifying for inpatient rehabilitation, skilled nursing care, or long-term acute care hospitalization were discharged to the facility of their choice for continued care.

Exceptions occurred. Over half of the counties in Texas are frontier counties, where the population averages less than twenty people per square mile.[11] Many frontier counties lack healthcare access. Uninsured patients who did not qualify for inpatient rehabilitation or skilled nursing care were discharged home. Those who lacked access to outpatient wound care services or home health due to the unavailability of medical services required more frequent outpatient follow-ups, including in-person surgical provider and telehealth appointments.

Readmissions

Previously published studies noted that 17 to 20.6% of ostomy patients are readmitted within 30 days of discharge, while there were no documented readmissions for ostomy complications for this study's pre and post-education study cohorts.[12,13] The limited number of ostomy surgeries at the target facility allowed individualized education. This could be a contributing factor to the lower-than-average readmission rate.

Postoperative Length of Stay

In a retrospective cohort study, the median length of stay (LOS) for patients with ostomy surgery was nine days, with a seven-day LOS postoperatively.[14] Although the ultimate goal of a four-day LOS was not reached during the study period, each inpatient hospital day averages $2,296 across the United States; therefore, the savings can be significant with the reduction of postoperative length of stay to six days.[15] Continued education program use is expected to reduce post-operative LOS further.

Follow-up Care: Unexpected Inconsistency

Program protocols were consistently followed while patients were hospitalized. Regardless of study participation, all ostomy patients received the expected ostomy education. The lack of insurance or access to outpatient care services created variability in discharge disposition planning.

Physician follow-up appointments were not adhered to as expected. Lack of follow-up was due to multiple factors, including incarceration, planned follow-up in another state, or patients who failed to follow-up. The second planned visit was even more inconsistent. Scheduling issues and physician clinic schedules permitted only three patients to complete the second Stoma-QOL survey in the specified time.

Limitations

This pilot program implementation and evaluation project had limitations. The average number of ostomy surgeries per year in the target facility was evaluated at the onset of program implementation. The team expected approximately 24 to 26 ostomy surgeries for the year, limiting the potential study population.

Readmissions after ostomy surgery were evaluated for the six months antecedent to the standardized program and the six months following implementation in the target hospital. A second acute care facility is in the same city, and patients periodically present at one or the other hospital. Ostomates included in the study could have been admitted to the second facility or another facility elsewhere.

Future Considerations

Further study regarding quality of life after ostomy surgery is recommended. Serial evaluations of the quality of life at six months or a year after ostomy surgery are warranted to identify ostomates who may be struggling. Physician support, counseling, and peer support may be needed.

Peer support groups can help reduce feelings of loss or disconnect.[4] Support groups should be offered to patients and their families to improve acceptance and quality of life and to manage expectations.[16] Future community peer support group meetings for ostomates should be included as an extension of the program.

Barriers to post-discharge follow-up appointment attendance were found. While

ensuring patients were provided the Stoma-QOL survey during their postoperative appointments, inconsistencies in scheduling were noted. If no follow-up visit had been scheduled, the patient was contacted via telephone and made an appointment. Limited physician clinic time was determined to be another barrier, and more consistent clinic routines are recommended. A quality improvement opportunity exists to address these concerns.

Conclusions

The Ostomy and Continence Diversion Patient Bill of Rights states that ostomy patients have a right to standardized ostomy education. The education protocol extended services with an interdisciplinary approach, including more comprehensive discharge planning. The effectiveness of the perioperative education was demonstrated by the high scores noted on the participants' Ostomy Self-Care Knowledge Assessment. While few, the Stoma Quality of Life scores indicated increased comfort with interpersonal relationships and a return to normal activities of daily living; however, continued concern regarding ostomy apparatus wear and disrupted sleep were noted. Further work is needed to assess patients' quality of life after stoma creation and to support them through healthcare services and peer support groups. Although challenges were encountered throughout this pilot perioperative ostomy education program, they only serve to illuminate opportunities for further program development important for those facing diversion surgery.

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Affiliations:
[1]Texas Tech University Health Sciences Center, Associate Faculty, Department of Surgery
[2]Texas Tech University Health Sciences Center Professor, Department of Surgery Associate Dean for Faculty Development

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Original Article

A Cross-Sectional Survey to Understand the Perception of Cancer Rehabilitation Amongst Healthcare Providers in a Rural Community

Jodi Goldman[1]; Vishwa Raj, MD[2]; Terrence Pugh, MD[2]; Cynthia Tiongco, PhD, OTR[3]; Stephanie Stroever, PhD, MPH[4]; and John Norbury, MD[1]

Abstract

With an aging population and the continued advancement of cancer therapies, the number of cancer survivors continues to increase at an unprecedented rate. Both cancer patients and survivors present with a complex symptomatology and unique functional impairments. Although there has been great effort to include cancer rehabilitation as a part of standard oncology care, more work is necessary to increase the reach of these services, particularly in rural area such as the West Texas community. This study is the first cross-sectional survey illustrating the perception amongst a variety of healthcare providers throughout different specialties located in a rural community in the United States without access to a cancer rehabilitation specialist or program.

Healthcare providers in this study acknowledge that incorporating rehabilitation services into cancer care may positively impact quality of life for patients with cancer. Structural barriers and medical complexity potentially hinder collaborative efforts amongst oncology and rehabilitation. Increasing awareness of cancer rehabilitation in this community can lead to more conversations amongst providers and their patients – the first step in improving access for this patient population.

Keywords: cancer, rehabilitation, healthcare providers, quality of life

Background

With an aging population and the continued advancement of cancer therapies, the number of cancer survivors is projected to be over 22 million by 2030 with an overall estimated 67% 5-year survival rate.[1] Due to the nature of the disease as well as treatment side effects, cancer patients and survivors often present with complex symptomatology with the most common symptoms including fatigue, neuropathy, and lymphedema. [(2-5)] Overall, functional impairments are estimated to affect 33-73% of patients with and survivors of cancer. [6,7] Many oncologists are not equipped to treat the functional deficits and disabilities faced by the ever-growing population of patients

Corresponding Author
Jodi Goldman, BS
Texas Tech University Health Sciences Center School of Medicine, Department of Physical Medicine & Rehabilitation, Lubbock, TX
Email: jodi.goldman@ttuhsc.edu

with cancer.[8] Care provided by a Physical Medicine and Rehabilitation (PM&R) specialist provides a holistic approach including preventative, restorative, supportive, and palliative care to ameliorate functional ability, increase independence, and improve quality of life for these patients.[8,9]

One of the leading causes of emotional distress in cancer survivors is physical disability, demonstrating that the unmet need for rehabilitation is quite detrimental to this population.[10] More so, rehabilitation has the potential to increase patient return to work, decrease the economic burden of cancer care, and improve patient quality of life.[11] A major challenge associated with treating patients with cancer is that these patients can be extremely medically complex beyond just their functional impairments.[12] As of 2020, there were only seven cancer rehabilitation fellowship programs in the country, and therefore, most oncologists are not interacting with physiatrists specifically trained to treat patients with cancer.[13] Overall, there is a training deficit and a lack of awareness of rehabilitation services for this patient population.

Although there has been great effort to include cancer rehabilitation as a part of standard oncology care via large professional groups such as the American Cancer Society and the National Comprehensive Cancer Network, more work is necessary to increase the reach of these services, particularly in rural area such as the West Texas community. Multiple prior studies have involved surveying specific groups of healthcare providers in urban or professional settings regarding perceptions of cancer rehabilitation.[14-18] The studies have generally demonstrated that, independently, different types of providers perceive the potential of cancer rehabilitation to be positive but also see multifactorial barriers in incorporating this type of care into oncology practice.[14-18] However, no study to date has analyzed perspectives of cancer rehabilitation amongst a healthcare community without a cancer rehabilitation specialist nor involved healthcare professionals who are not routinely active in cancer care. Patients with cancer could benefit in multiple respects from the inclusion of rehabilitation services as part of their care, including improved day-to-day physical functionality as well as a reduction in symptom burden.[19] This will be the first cross-sectional survey illustrating the perception amongst a variety of healthcare providers throughout different specialties located in a rural community in the United States without access to a cancer rehabilitation specialist or program.

Objectives/Hypothesis

The primary objective of this study is to explore differences in perception of cancer rehabilitation amongst various healthcare provider types (physicians vs advanced practice providers vs therapists vs social workers) across a span of medical specialties (i.e. Family Medicine, Internal Medicine, Pediatrics, etc.) in a rural community. The secondary objective is to better understand whether the root of access barriers for cancer rehabilitation in a rural community is primarily structural, educational, or financial.

Based on anecdotal data, the working hypothesis is that those providers with the highest percentage of respondents reporting that rehabilitation services have a positive

impact on patients with cancer include physicians, PTs, and OTs as they are the providers that generally have the most experience and training regarding rehabilitation medicine and management. Based on both prior literature and anecdotal data, the working hypothesis is that more providers in academic settings (vs non-academic settings) will report an attitude that rehabilitation is a necessary component of oncology-related care as there is a reported association between an academic setting and more patients with cancer being referred to inpatient rehabilitation.[14] Similarly, more providers with <5 years of experience (vs >5 years of experience) will report an attitude that rehabilitation is a necessary component of oncology-related care as there is an association between more reported clinical experience and a lower likelihood of referring patients with cancer for inpatient rehabilitation amongst oncologists and physiatrists.[14]

Methods

The study was deemed exempt from formal Institutional Review Board (IRB) review by the Lubbock IRB. The primary method for data collection will be survey responses.[20] Volunteer participants working as healthcare providers in the Texas Tech Physicians Network and Covenant Health Network received a survey via a QR code link. The survey was distributed to healthcare providers by Jodi Goldman and Dr. John Norbury from August 2022 to March 2023 during clinical rotations. The survey was composed of 22 multiple-choice questions as well as a consent statement which must be agreed to by the participant to proceed with the survey. The responses were anonymized. Participants input the last five digits of their phone number which then became the string of numbers associated with their responses. Six questions were focused on demographics, and 16 questions explored the perception of cancer rehabilitation with most responses reflecting a Likert Scale. There was a section at the end where participants could choose to leave comments about cancer rehabilitation, the survey, or the study. The survey underwent a process of expert validation to ensure content validity. A panel of cancer rehabilitation specialists, who have also published cross-sectional survey data on similar topics, from Atrium Health Carolinas Rehabilitation conducted an expert review of the survey questions. They assessed if the survey was clear and easy to understand, lacked important questions regarding the perception of cancer rehabilitation, and was relevant to the field of cancer rehabilitation. The survey was developed with the assistance of the Texas Tech University Health Science Center Information Technology Department and provided through Qualtrics.

Participants included healthcare providers including attending physicians, resident physicians, registered nurses/nurse practitioners (RN/NP), physician assistants (PA), physical therapists (PT), occupational therapists (OT), speech-language pathologists (SLP), case managers, and social workers in the Texas Tech Physicians Network and Covenant Health Network. Healthcare providers were recruited via email sent by a second-year medical student and a general physiatrist. Participants must be a(n) attending physician, resident physician, RN/NP, PA, PT, OT, SLP, case manager, or social worker registered with Texas Tech Health Physicians or Covenant Health Network in Lubbock, TX. If participants did not complete the entirety of the survey, they were excluded from the study.

Thirty-eight healthcare providers and

learners in various specialties have completed the survey. The cohort consisted of physical therapists (21%), occupational therapists (8%), registered nurses (16%), physicians (42%), case managers/social workers (5%), and other healthcare workers (8%). Sixty-six percent of respondents were female and 34% were male, and 68% identified as white, 13% as Hispanic, 11% as other. Forty-five percent of respondents had less than 5 years of experience as a healthcare provider, 26% had 5-10 years of experience, 16% had 10-15 years of experience, and 13% had greater than 20 years of experience. Fifty-three percent of respondents identified as working in an academic environment and 47% identified as working in a non-academic environment. Detailed descriptive statistics are outlined in Table 1.

Table 1. Descriptive statistics of healthcare providers participating in the survey

	All participants (n=38)
Age, median (range), year	34 (22-77)
Sex	
Male	13 (34)
Female	25 (66)
Race	
White	26
Black	3
Hispanic	5
Other	4
Healthcare Profession	
Physician	16 (42)
Registered Nurse	6 (16)
Physical Therapist/ Occupational Therapist	11 (29)
Case Manager/Social Worker	2 (5)
Other	3 (8)
Years of Experience	
<5	17 (45)
5-10	10 (26)
10-20	6 (18)
>20	5 (13)
Practice Setting	
Academic	20 (53)
Non-academic	18 (47)

All participants (100%) acknowledged that they care for patients with cancer. Ninety-seven percent of respondents agreed that rehabilitation providers should receive some level of training for treating patients with cancer, 89% agreed that it is necessary for these patients to receive screening on functional impairment, 84% agreed that oncologists should include rehabilitation as part of the treatment discussion, and 94% agreed that a rehabilitation healthcare provider should be included as part of the oncology team. However, 79% agreed that there are currently barriers to providing these patients with inpatient rehabilitation services. Lastly, 100% agreed that rehabilitation care could provide a smoother return to society, yet 68% believed this patient population is currently underserved by rehabilitation services. Overall relevant survey response data is shown in Figure 1.

Thirty percent of physicians, PTs, and OTs strongly agreed that a healthcare provider trained in rehabilitation services should be included as part of the oncology care team, while 70% agreed. Fifty-five percent of all other types of healthcare providers strongly agreed that a healthcare provider trained in rehabilitation services should be included as part of the oncology care team, while 36% agreed and 9% remained neutral. Forty-eight percent of physicians, PTs, and Ots strongly agreed that patients would experience a smoother return to society if they were receiving rehabilitation care, while 52% agreed. Fifty-five percent of all other types of healthcare providers strongly agreed that patients would experience a smoother return to society if they were receiving rehabilitation care, while 45% agreed. Thirty percent of healthcare providers in an academic setting strongly agreed that a rehabilitation provider is a necessary component of the oncology care team while 65% agreed and 5% remained

neutral. Forty-four percent of healthcare providers in a non-academic setting strongly agreed that a rehabilitation provider is a necessary component of the oncology care team while 50% agreed and 6% remained neutral. Of those providers with less than five years of experience, 35% strongly agreed that a rehabilitation provider is a necessary component of the oncology care team while 59% agreed and 6% remained neutral. Of those providers with more than five years of experience, 38% strongly agreed that a rehabilitation provider is a necessary component of the oncology care team while 57% agreed and 5% remained neutral.

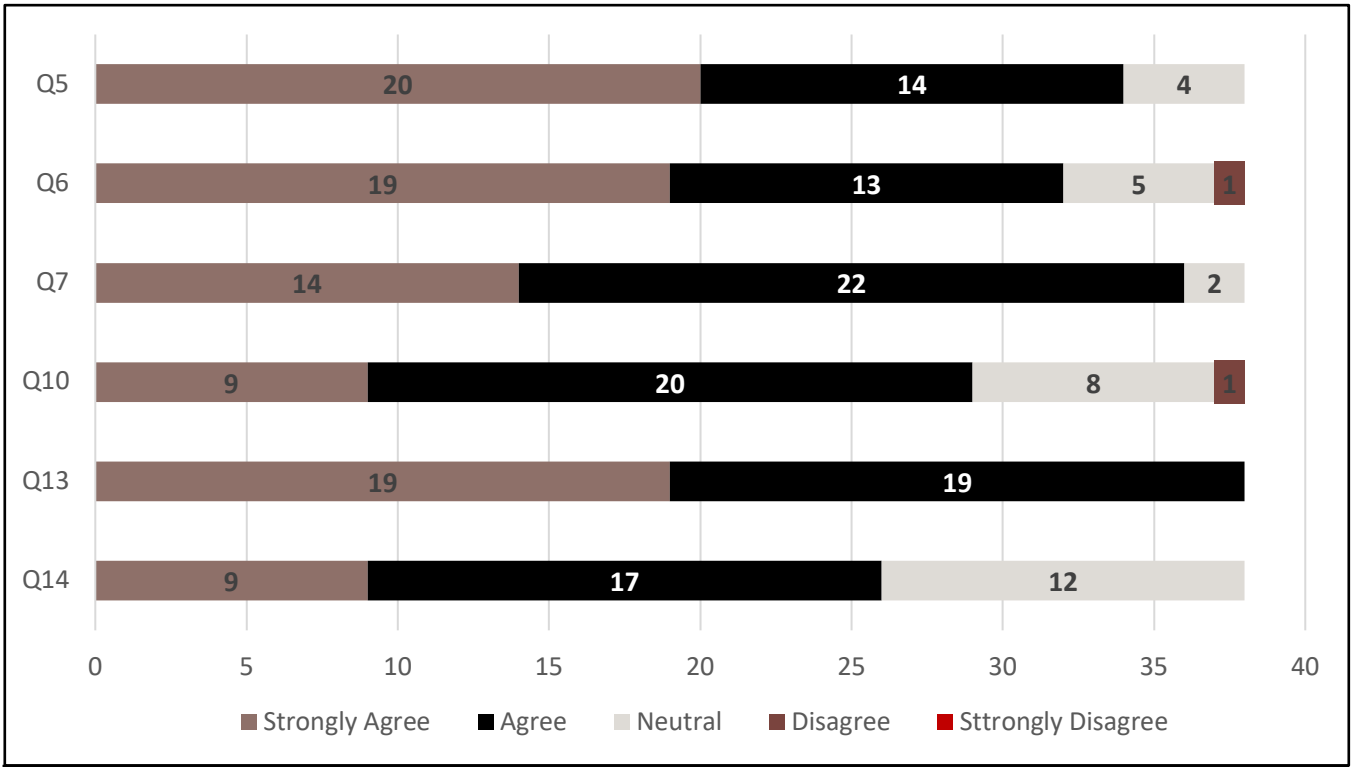

Figure 1. Relevant Survey Responses

Q5) It is necessary for patients with cancer to receive a routine screening for cancer- or therapy-related impairments
Q6) Oncologists should include a discussion of rehabilitation during a patient's initial appointment
Q7) A healthcare provider trained in rehabilitation services should be included as a necessary component of the oncology healthcare team
Q10) There are currently barriers to providing patients with cancer inpatient rehabilitation services
Q13) Patients in remission or under surveillance for disease progression could have a smoother return to society if they were receiving rehabilitation care
Q14) Patients with cancer are currently underserved by inpatient rehabilitation facilities

Considering the cohort consists of volunteer participants, the results will demonstrate a degree of bias. Because West Texas can be a relatively transient community, some healthcare providers may have experiences in more urban regions where cancer rehabilitation services are provided. This can lead to biased responses if these providers have witnessed the impacts of cancer rehabilitation themselves and removes the innovation of surveying providers in a community that does not have a cancer rehabilitation program. Secondly, surveys are inherently flawed as respondents may not interpret questions as the study designers intended. Lastly, this project is attempting to access the opinions of a large cohort which, particularly with surveys, can be quite challenging as historically response rates from physicians for web-based surveys are low, around 35%.[21]

Conclusion

Healthcare providers in this study acknowledge that incorporating rehabilitation services into cancer care may positively impact the quality of life for patients with cancer. Interestingly, more healthcare provider types other than physician, PT, and OT and those working in non-academic settings strongly agreed that a provider trained in rehabilitation should serve on the oncology care team, while there was no difference in perception between those with less than and greater than five years of experience. Structural barriers and medical complexity potentially hinder collaborative efforts amongst oncology and rehabilitation. Increasing awareness of cancer rehabilitation in this community can lead to more conversations among providers and their patients – the first step in improving access for this patient population.

Affiliations:
[1] Texas Tech University Health Sciences Center School of Medicine, Department of Physical Medicine & Rehabilitation, Lubbock, TX
[2] Carolinas Rehabilitation, Charlotte, NC
[3] Texas Tech University Health Sciences Center School of Health Professions, Lubbock, TX
[4] Texas Tech University Health Sciences Center School of Medicine, Department of Medical Education, Lubbock, TX

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West Texas Journal *of* Medicine

Case Report

Navigating the Enigma: A Case Study on Unmasking Idiopathic Small Fiber Sensory Neuropathy in a 69-year-old Patient Amidst a Complex Web of Paresthesia

Shakira Meltan, BA[1], Alisa White,BA[1], Nimat Alam, MD[2]

Abstract

This case report describes one case of idiopathic small fiber sensory neuropathy (ISFSN) in a 69-year-old female with a medical history of hypertension and hyperlipidemia. The patient had symptoms of periodic paresthesia and tingling in her lower extremities, occasional discomfort in the hip and lumbar region, as well as bilateral muscular spasms and rigidity in the calves. Despite numerous treatment modalities, the patient's symptoms exhibited a progressive deterioration, indicating the presence of progressive neuropathy. The absence of an underlying reversible cause was confirmed using laboratory tests, imaging, and electrodiagnostic examinations. The patient exhibited a positive response to the increase in gabapentin dosage administered by her neurologist, subsequently resulting in the identification of the condition as ISFSN. The case study illustrates the complicated aspects of clinical scenarios frequently found in primary care settings, emphasizing the importance of investigating less prevalent diseases when conventional treatment methods fail. This particular case highlights the imperative for further research in ISFSN to identify potentially reversible components and assess the efficacy of various therapeutic approaches.

Keywords:

Introduction

Neuropathy is defined as nerve damage resulting in the loss of sensation, movement, or other functions. The type of nerve affected determines their classification, which frequently considers nerve size. Small nerve neuropathies encompass a spectrum of conditions that impair the functioning of nerves smaller than five micrometers, including A-alpha, B, and C fibers. Small nerve neuropathies are frequently observed within the primary care setting as they are associated with common comorbid conditions, including but not limited to type 1 diabetes mellitus, hypertriglyceridemia, chronic alcohol use, hyper- and hypothyroidism, and vitamin deficiencies.[1] It

Corresponding Author:
Shakira Meltan, BA TTUHSC School of Medicine
Lubbock, TX
Email: Shakira.meltan@ttuhsc.edu

typically presents with a sensation of burning, numbness, and tingling in the distal periphery, which progresses in a length-dependent fashion. This proximal direction of nerve dysfunction is responsible for the frequently described "glove and stocking" distribution pattern. A diagnosis of exclusion, idiopathic small fiber sensory neuropathy is a condition characterized by damage to small sensory nerve fibers of the peripheral nervous system with no clear etiology. Previous studies frequently reported cases of small fiber sensory neuropathy affecting the trigeminal nerve or upper limb. This study presents a unique case of idiopathic small fiber sensory neuropathy with lower limb involvement resembling tarsal tunnel syndrome.

Case Presentation

A 69-year-old female patient with a significant medical history of hypertension and hyperlipidemia presented to her primary care physician complaining of intermittent tingling and numbness in her feet for the past 2 to 3 months. She described these symptoms as sporadic, manifesting even during rest and causing significant discomfort that interfered with her walking ability. Over the previous two months, she also complained of stiffness and pain in her hips and lower back, which was made worse by extended periods of standing. She displayed non-tender subcutaneous nodules over her left ankle and right foot during her physical examination. An initial laboratory workup, which included a comprehensive metabolic panel, hemoglobin A1c, and a lipid panel, yielded unremarkable results. She was prescribed naproxen (250 mg twice daily) and tizanidine (2mg twice daily) to treat presumptive sciatica. During her one-month follow-up, the patient exhibited new-onset hypertension, with systolic blood pressures ranging between 160-180 mmHg. She indicated that the naproxen had somewhat alleviated her hip and leg pains. The physician recommended lifestyle modifications to aid in weight loss and blood pressure control and advised her to continue taking tizanidine as needed for pain management.

Four months into her treatment, the patient reported experiencing new symptoms, including bilateral calf cramping and stiffness, occurring both during movement and at rest. She was prescribed diltiazem (30mg four times daily) to address the cramping. Two months after the initiation of diltiazem, her cramping had entirely resolved. However, she now reported experiencing constant bilateral tingling and numbness in her feet, which worsened at night and disrupted her sleep. Tinel's sign over the tarsal tunnels was absent. Electromyography and nerve conduction studies were ordered to assess the possibility of tarsal tunnel syndrome, along with bilateral foot and ankle X-rays. In response to suspected peripheral neuropathy, the patient was prescribed gabapentin (100mg twice daily). The patient could not undergo electromyography testing but reported mildly improved paresthesia with gabapentin at her 2-month follow-up. She also reported no further episodes of cramping on diltiazem. Six months into her journey, the patient was referred to a neurologist. Nerve conduction studies of her lower extremities returned normal results, with no indications of large fiber neuropathy. Her gabapentin dosage was increased to 300mg twice daily. One-month post-dose increase, the patient reported complete resolution of the paresthesia and numbness in her feet on a regimen of gabapentin

(300mg three times daily) and diltiazem. In conclusion, an extensive one-year workup encompassing laboratory tests, imaging, and electrodiagnostic studies failed to reveal an underlying cause for the patient's sensory symptoms. Her clinical journey, characterized by distal extremity sensory disturbances that responded to gabapentin, is most consistent with idiopathic small fiber sensory neuropathy.

Discussion

A 69-year-old female patient with a history of hypertension, hyperlipidemia, and morbid obesity (BMI: 41) presented with a constellation of sensory symptoms for over a year. Her condition was characterized by sporadic foot tingling and numbness, hip and lower back pain, and bilateral calf cramping and stiffness. Despite trials of various treatment strategies, the gradual worsening of these symptoms directed the diagnostic process toward exploring less common conditions. Idiopathic Small Fiber Sensory Neuropathy (ISFSN) is frequently characterized by escalating sensory issues in the peripheral nervous system. Small fiber neuropathy is a condition that impacts both the small myelinated Aδ-fibers and the unmyelinated C-fibers.[2] Although the patient's initial symptoms suggested a common medical condition like sciatica, her clinical trajectory, particularly her response to gabapentin, suggested ISFSN.

The patient's subjective ratings of symptom reduction were used to assess the efficacy of various treatments, with gabapentin showing the most significant improvement. Gabapentin and pregabalin are considered the preferred pharmacological options for ISFSN in this patient, given her comorbidities and advanced age. This preference is mostly attributed to the fact that both medications lack significant drug-drug interactions with other commonly prescribed drugs.[3]

The predominant causes of ISFSN include hereditary, infectious agents, toxic substances, immune-mediated processes, metabolic abnormalities, and idiopathic origins.[2] Small fiber neuropathy has been linked to autoimmune conditions such as celiac disease, connective tissue disorders, monoclonal gammopathy, hypothyroidism, and depression.[4] Moreover, this condition can be triggered by deficiencies in essential vitamins and minerals, such as B12 and copper.[2] Hence, it is crucial to address the fundamental cause, particularly if it is reversible.

Given the potential metabolic aspect of her condition, the patient was additionally counseled to implement lifestyle modifications to facilitate weight reduction and manage blood pressure. In some literature, integrative holistic treatments encompass the utilization of natural supplements, such as alpha-lipoic acid and acetyl-L-carnitine, which have been suggested to mitigate pain and enhance nerve function.[5] Mind-body therapies encompass many practices, such as yoga, meditation, and deep breathing techniques, which have been shown to relieve pain and enhance holistic wellness.[5] The patient's journey highlights the clinical complexity frequently seen in primary care settings. When typical treatment strategies fail, this can help direct healthcare professionals to be open to less prevalent diagnoses. The prompt identification and rapid referral of patients to a neurologist may have led to an earlier diagnosis, hence improving the patient's overall well-being at an earlier point.

Conclusion

Small fiber sensory neuropathy is a commonly occurring neurologic condition in the geriatric population. Idiopathic neuropathy, however, is a challenging diagnosis of exclusion, given its resemblance to a number of other etiologies of tingling in the lower limbs. One of the critical lessons that can be obtained from this case report is the importance of persistence and flexibility in the diagnosis process, particularly when faced with complex and ambiguous symptoms. Further research is needed to study ISFSN to pinpoint all the possible reversible causes of this debilitating condition.

Potential opportunities for future investigation may encompass exploring the potential correlation between age and the onset of ISFSN, investigating the impact of pre-existing medical conditions such as hypertension and hyperlipidemia, and assessing the efficacy of various therapeutic interventions with specific emphasis on gabapentin in the mitigation of ISFSN symptoms.

Affiliations:
[1] School of Medicine, Texas Tech University Health Sciences Center, Lubbock
[2] Family Medicine Department, Texas Tech University Health Sciences Center, Permian Basin

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Original Article

Local Infiltration of Liposomal Bupivacaine in Isolated Traumatic Rib Fractures

Kripa Shrestha, MBBS, MPH, MS[1], Hsin Fang Li, PhD[2], Ariel P Santos, MD, MPH, FRCSC, FACS, FCCM[1], Justin Vaughan, MD[1], Fangyuan Zhang, PhD[2], Anna Sabu Kurian, BS[1], Brandon Couch, BS[1], Charles Bayouth, V MD, FACS[2]

Abstract

Introduction: Adequate pain control is essential in the management of traumatic rib fractures. Local infiltration of liposomal bupivacaine (LB) to provide intercostal nerve block has been added to the multimodal pain control regimens. We explored the effectiveness of LB infiltration around the site of rib fracture on pain score and total opioid use.

Methods: Patients with isolated rib fractures receiving additional infiltration of LB at the fracture site were compared to patients receiving only conservative treatment. A linear mixed model was performed to evaluate the impact of LB on pain score and total opioid use [morphine milligram equivalent per day (MME)].

Results: Patients in the LB group experienced slightly, but insignificantly, greater pain scores. The adjusted mean MME was significantly higher compared to the control (44.6 vs 24.4, p= 0.01) and increased over time (Δ=5.7 and 6.6, p= 0.03 respectively at ~48h and ~96h, respectively).

Conclusion: No significant reductions in pain score and opioid requirement were achieved by additional local infiltration of LB in patients with isolated traumatic rib fractures.

Keywords: Liposomal bupivacaine, intercostal nerve block, rib fracture, pain score, total opioid dose

Background

Rib fractures are the common traumatic thoracic injuries associated with increased morbidity and mortality which is directly related to the number of fractured ribs and associated pain.[1] While patients with multiple fractured ribs (≥ 3 rib fractures) are expected to have concomitant lung injury, even isolated fractures can cause prolonged pain, leading to complications.[2] The associated pain limits the patient's ability to breathe deeply and to cough, restricting tidal lung volume and preventing the clearance of airway secretions, leading to atelectasis and pneumonia.[3] Therefore, early intervention with adequate pain management is the cornerstone of rib fracture management. Most rib fractures are treated conservatively without surgery, with adequate pain control,

physiotherapy, and respiratory assistance.[2,3] Different analgesic modalities and interventions are used in practice.

Multimodal analgesia- combining different classes of drugs, remains the standard for effective pain control.[4] Use of NSAIDs, acetaminophen, muscle relaxants, and low-dose narcotics have demonstrated improved outcomes in pain control.[5] Regional intercostal, paravertebral blocks, along with epidural analgesia, have shown benefit. Current studies have demonstrated bupivacaine, a widely used local anesthetic, inhibits NMDA pain receptors, thereby preventing pain sensitization.[6] Bupivacaine is a local anesthetic drug with a very short duration of action. Using DepoFoam extended drug delivery technology, the active drug bupivacaine is packaged in multivesicular liposomes (liposomal bupivacaine, [LB]). After infiltration, the lipid membranes are slowly absorbed, providing prolonged release and duration of action of bupivacaine.[6] Studies have shown the efficacy of LB in a variety of surgical procedures. However, only a few studies have investigated the use of LB injection as infiltration for nerve block in the control of rib fracture pain.

Objective

This study evaluated the effect of local LB administration in controlling pain in patients with isolated rib fractures treated non-surgically. In particular, we investigated whether LB provides better pain control and decreases the need for opioid analgesics.

Methods

Study type:

This was a retrospective study performed on patients admitted to a Level II Trauma Center in Lubbock, Texas, who were diagnosed with isolated rib fractures between January 1, 2016, and December 31, 2020. All work was conducted in compliance with Institutional Review Board Committee requirements.

Study Population:

The Trauma Registry was used to identify patients aged 18-89 years with a diagnosis of isolated rib fracture. Patients requiring surgery or presenting with complications such as hemothorax, pneumothorax, or massive pleural effusion were excluded. Additionally, patients who were intubated, pregnant, or incarcerated were excluded.

Data Collection:

Data were extracted from the electronic medical records of eligible patients, including demographic variables (age, sex, race, smoking history), rib fracture variables (mechanism of injury, laterality, number of ribs fractured), treatment variables, and in-hospital outcome variables. X-ray and CT scan reports were used to identify the number of rib fractures. The development of in-hospital post-fracture complications like pneumonia, adult respiratory distress syndrome, pleural effusion, atelectasis, and pneumothorax were retrieved from patient chart documentation and imaging reports.

Outcome Measures:

The primary outcomes of interest were pain score over time and MME/day over time.

1. Pain

The self-reported pain scores assessed using a numerical 11-point scale, ranging from 0-10, with higher scores meaning greater pain, were retrieved from the nursing assessment chart. The assessment record

was performed at discrete and irregular time intervals. However, the scores were retrieved close to the time point specified. The initial pain score retrieved was taken close to 24 hours post-admission, while subsequent scores were taken at 24-hour intervals at ~48, ~72, ~96, and ~120 hours.

2. Pain medications

Pain was controlled using a multiple pain control strategy using oral or injectable opioids, non-opioids, and gabapentin analgesics. The type, amount, and route of administration of opioid medication were extracted from the chart at the same time intervals as the pain score. The daily total opioid dose was calculated from all the opioid-containing analgesics, converted to a standard morphine milligram equivalent (MME) calculator- MDCalc.

For fentanyl, the calculation of MME was adjusted according to the route of administration. When delivered by continuous IV drip or a patch, the recommended conversion factor of 2.4 was used. For example, when 100µg/hour fentanyl was delivered, the calculated MME is 100µg (dose/hour) *24 (hours) *2.4 (conversion factor) = 240mg/day MME. When delivered by IV bolus or nasal spray at 0.1-0.2mg, 10µg fentanyl IV is equivalent to 1mg IV morphine.

The timing and dose of LB were collected from patients who received infiltration of LB at the fracture site. LB was administered by infiltration around the site of fracture under the guidance of ultrasound or computed tomography (CT) (Figure 1).

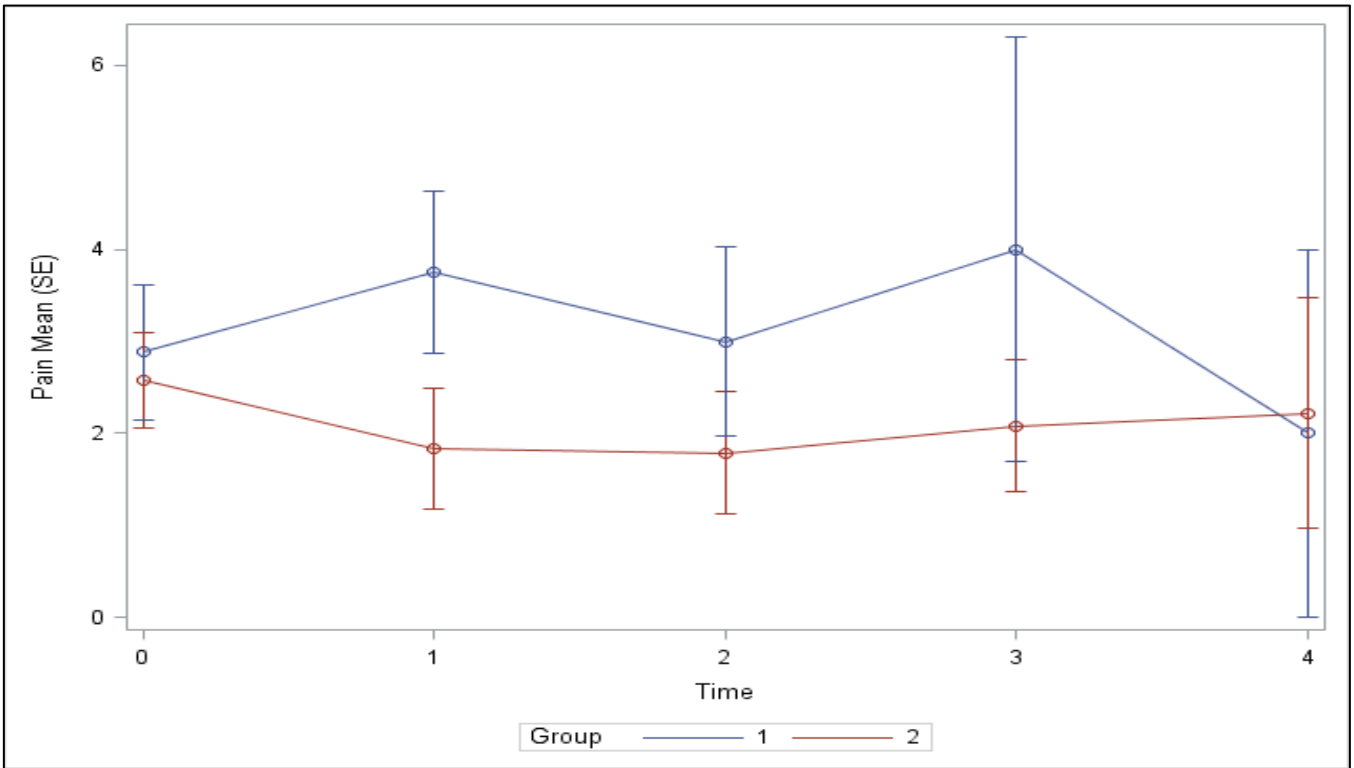

Figure 1. Comparison of mean Pain Score in LB (Group-1) vs conventional treatment (Group-2) over time. Time points 0, 1, 2, 3 & 4 indicate the days from admission in hours (~24h, ~48h, ~72h, ~96h, ~120h)

	Pain Score	
Time	Group 1	Group 2
24h	2.8 (3.1)	2.6 (3.2)
48h	3.7 (3.2)	1.9 (3.2)
72h	3.0 (2.5)	1.8 (2.9)
96h	4.0 (4.0)	2.1 (2.5)
120h	2.0 (3.5)	2.2 (3.8)

Statistical Analysis

Data were collected by retrospective chart review for patients who received LB + conventional treatment (Group_1) and a control group of patients who received only conventional treatment (Group_2). The differences in baseline demographics and characteristics were described using mean ± standard deviation or median with interquartile range for continuous variables and frequency count (%) for categorical variables. The associations of categorical variables between the groups were analyzed with Pearson's Chi-Square or Fisher Exact test. Wilcoxon rank-sum tests were used for continuous variables.

A linear mixed model was used to evaluate the impact of LB on pain score and MME over time while accounting for random effects. The random intercept (Subject) describes the pain score and MME/day for each patient and accounts for subject-specific variation. Age, sex, and treatment group were included in the model as fixed effects.

The change in population mean was examined using the plots of the individual profiles against time. All analyses were conducted using R (R Core Team, 2021; RStudio, version 4.1.2) and SAS.

Results

A total of 78 patients were identified with isolated rib fractures, of whom 20 received additional LB injection (Group_1) compared to 58 who received conventional treatment only (Group_2). The majority of patients (77%) were white males who sustained fractures mostly due to falls (72%) and road traffic accidents (23%). Most (92%) had fewer than six rib fractures. There was no significant difference in age, body mass index (BMI), smoking status, number, and laterality of rib fractures between the groups (Tables 1 and 2).

Table 1. Demographic Characteristics of Rib Fracture Patients

	Group 1	**Group 2**	**p value**
	Received LB (n=20)	**Not received LB (n=58)**	
Age (years)	68.6 ± 16.5	66.6 ± 19.1	0.86[+]
Sex			0.47[*]
Male	11 (55%)	39 (67%)	
Female	9 (45%)	19 (33%)	
Race			0.68[**]
White	15 (75%)	45 (78%)	
African	0	2 (3%)	
Hispanic	3 (15%)	4 (7%)	
Other	2 (10%)	7 (12%)	
Ethnicity			0.65[**]
Non-Hispanic or Latino	14	43	
Hispanic or Latino	5	14	
Declined to answer	1	1	
BMI (kg/m^2)	29.1 ± 5.12	26.7 ± 6.32	0.06[+]
Smoking			0.68[**]
Active Smoker	5 (25%)	8 (14%)	
Past Smoker	4 (20%)	14 (24%)	
Non Smoker	10 (50%)	31 (53%)	
Unknown	1 (5%)	5 (9%)	
[+] *Wilcoxson rank-sum Test* [*] *Chi square Test* [**] *Fisher Exact*			

Table 2. Rib Fracture Characteristics

	Group 1	Group 2	p value
	Received LB (n=20)	**Not received LB (n=58)**	
Mechanism of fracture			0.25**
Fall	12(60%)	44(76%)	
RTA	6(30%)	12(21%)	
Blunt trauma	2(10%)	2(3%)	
Number of fractures			
<2	8 (40%)	28 (48%)	
3-6	11 (55%)	25 (43%)	
>7	1 (5%)	5 (9%)	
Laterality of fracture			0.19**
Right	8 (40%)	35 (60%)	
Left	11 (55%)	22 (38%)	
Bilateral	1 (5%)	1 (2%)	
** *Fisher Exact*			

Out of 58 in the control group, seven had an initial X-ray finding of- atelectasis (5) and pleural effusion (2) at presentation, of whom only 3 developed persistent atelectasis and/or effusion complications. Similarly, of 20 in the LB group, eight had initial X-ray findings of atelectasis (4), effusion (3), and both atelectasis and effusion (1), of whom two developed complications of pneumonia, and one had increased pleural effusion and atelectasis.

None of the patients in either group required admission for ventilation support. There was no significant difference between the groups in length of hospital stay (3.4 ± 2.3 vs 3.15 ± 2.5, p=0.58) (Table 3).

Table 3. Hospital Outcomes of Rib Fracture Patients

	Group 1	Group 2	p value
	Received LB (n=20)	**Not received LB (n=58)**	
LOHS (days)	3.4 ± 2.3	3.15 ± 2.5	0.58+
Discharge			
Home	17	49	0.84**
Rehabilitation	3	7	
Nursing home	0	2	
+ *Wilcoxson rank-sum Test* ** *Fisher Exact*			

Almost all patients received opioid analgesics, 19/20 (95%) in the LB group compared with 52/58 (90%) in the conventional treatment group. One patient in the LB group, with one rib fracture, received LB only and left the hospital. Out of six patients who did not receive opioid analgesics in the conventional group, 2 left the hospital the same day, 3 received acetaminophen, and 1 received acetaminophen and ketorolac. The most commonly prescribed non-opioid drugs were acetaminophen (APAP), ketorolac, ibuprofen, celecoxib, naproxen, and lidocaine. Opioid prescriptions, both oral or parenteral medications calculated in morphine milliequivalent units (MME) were morphine, hydromorphone, hydrocodone, oxycodone, tramadol, fentanyl, codeine, and methadone. Two patients in the conventional treatment group received additional gabapentin compared to the LB group, in which three patients received gabapentin and four patients received pregabalin.

In the majority of patients, a single shot of LB was administered. The mean time to administer LB was 11.9 (±7.7) hours. One patient received LB on day 4, and another

patient received two doses on days 2 and 3. Most patients were discharged home. There were no deaths reported in either group. The adjusted means for pain score and MME over time were obtained using linear mixed models with random intercept. The within-subject covariance structure was modeled as instructed. The interaction of group and time was removed from both models due to insignificance. The final model included age, gender, and BMI to adjust for differences in demographic profile between the two comparison groups.

The pain scores did not change over time. Patients in the LB group, in general, appeared to experience slightly greater pain than those in the control group (Figure 2). However, the difference was not statistically significant (Table 4). In the model where MME was treated as the outcome, the adjusted mean of MME in the LB group was 20.2 units higher compared to that of the control group (44.6 vs 24.4, p=0.0111).

MME also changed over time, with the greatest change in MME observed at 48h and 96h (Δ=5.7 and 6.6, respectively) (Table 5).

Table 4. Linear Mixed Model of Pain Score

	Pain Score		
	Estimate (SE)	**Change (SE)**	***p value***
Baseline (24h)	2.8 (0.7)		0.5823
Time 2 (48h)	2.5 (0.7)	-0.3 (0.6)	
Time 3 (72h)	2.3 (0.8)	-0.5 (0.7)	
Time 4 (96h)	2.7 (0.8)	-0.1 (0.8)	
Time 5 (120h)	1.8 (0.9)	-1.0 (0.8)	
Group 1 (LB)	2.8 (0.9)		0.3664
Group 2 (Control)	2.0 (0.7)	-0.8 (0.8)	

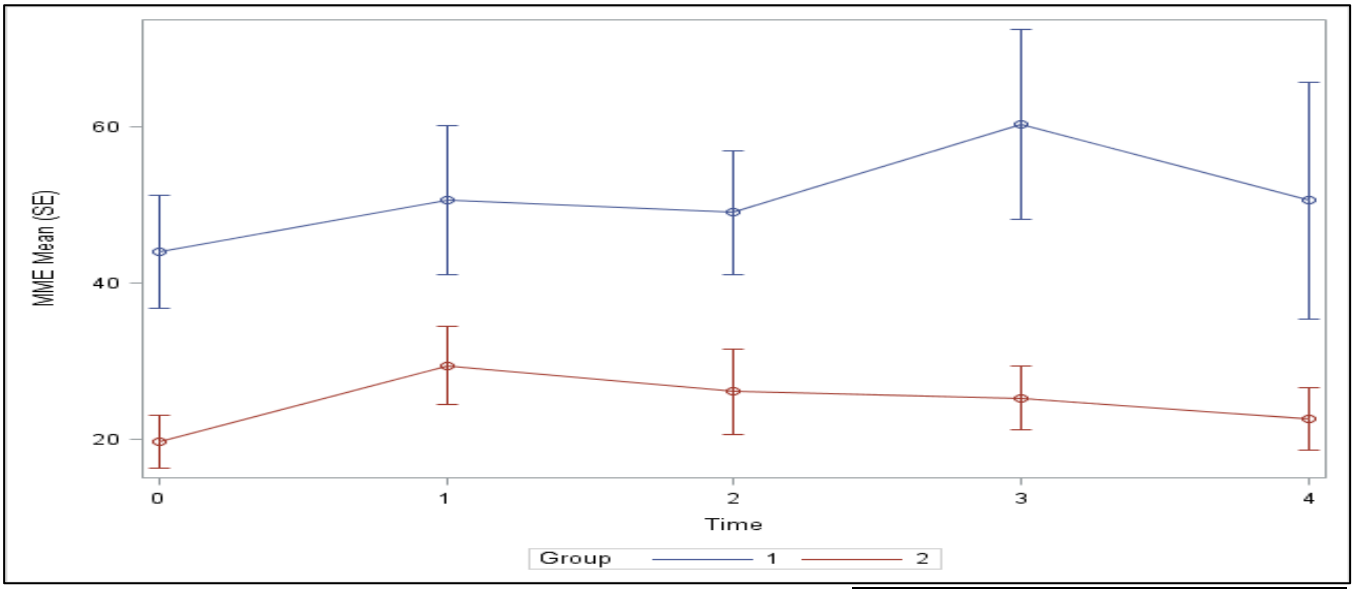

Figure 2. Comparison of mean MME/day in LB (Group-1) vs conventional treatment (Group-2) over time. Time points 0, 1, 2, 3 & 4 indicate the days from admission in hours (~24h, ~48h, ~72h, ~96h, ~120h)

	MME	
Time	Group 1	Group 2
24h	44.0 (31.3)	19.7 (24.7)
48h	50.7 (40.3)	29.5 (32.5)
72h	49.1 (29.7)	26.1 (28.7)
96h	60.3 (34.4)	25.4 (18.3)
120h	50.6 (33.8)	22.6 (16.5)

Table 5. Linear Mixed model of Morphine milligram Equivalents (MME)

	MME		
	Estimate (SE)	**Change (SE)**	***p value***
Baseline (24h)	31.2 (3.7)		0.0351
Time 2 (48h)	36.8 (4.5)	5.7 (2.5)	
Time 3 (72h)	33.8 (4.0)	2.7 (2.8)	
Time 4 (96h)	37.7 (4.4)	6.6 (2.8)	
Time 5 (120h)	33.1 (4.5)	1.9 (2.9)	
Group 1 (LB)	**44.6 (6.5)**		**0.0111**
Group 2 (Control)	**24.4 (4.1**)	**-20.2 (7.7)**	

Discussion

This retrospective study evaluated the effect of adding LB infiltration to conventional multimodal analgesic treatment of patients with isolated rib fractures. There was no significant reduction in pain score with added LB infiltration at the fracture site compared to conventional treatment using oral or parenteral opioids and non-opioid analgesics. The patient reported pain score was higher in the LB group, which, although not significant, was sustained at the same level over time. Moreover, a higher MME/day level was administered in the LB group compared to the conventional treatment group.

Adequate pain control remains the cornerstone in the non-surgical management of rib fractures for early ambulation and prevention of the development of pulmonary complications. LB (herein: Exparel; Pacira Pharmaceuticals) is a form of bupivacaine where the drug is formulated in microvesicles, which, upon administration, will slowly release the drug at a constant rate for an extended period of time for up to 96 hours with a single dose infiltration.[7-9] Previous studies have shown the efficacy of LB in providing effective analgesia in many orthopedic, colorectal, and plastic surgeries and has, too, been used in thoracic surgeries.[9] However, our study stands in contrast to those. Similar to this study, a recent prospective randomized trial comparing LB intercostal nerve block (ICNB) against peri-intercostal subcutaneous infiltration of saline demonstrated no significant difference in pain score and MME usage.[10] In addition, another randomized clinical trial comparing LB ICNB to continuous infusion of plain bupivacaine through an indwelling catheter in surgical stabilization of rib fracture showed no difference in the Sequential Clinical Assessment of Respiratory Function (SCARF) score. There was a lower opioid requirement in the LB group on postoperative days 2 to 4, but this was also not significant.[11]

Additionally, a randomized clinical trial of LB used as infiltration ICNB compared to epidural infusions in thoracic surgery (minimally invasive surgery or open thoracotomy) demonstrated no significant difference in mean pain score and opioid requirements[7]. Moreover, a retrospective study of surgical rib stabilization was conducted, in which LB added to ICNB with bupivacaine HCl was compared with bupivacaine with or without epinephrine. The outcome was non-inferior pain scores and non-significant differences in opioid use, leading to the conclusion that there was no benefit in adding LB to conventional treatment. Furthermore, there are other studies where the use of LB in different procedures/surgeries, such as robotically assisted thoracic procedure or video-assisted thoracoscopic surgery, showed no significant difference in pain scores, especially after the first 24 hours.[12, 13]

While regional nerve block has been shown

to be beneficial in various surgical settings, it is of interest to consider why intercostal nerve block using LB has been shown, in this study and those discussed above, to be ineffective. The perception of pain is subjective. Because this was not a randomized trial, it is possible that those patients who were administered the additional LB infusion were those who had self-reported higher pain scores. The use of opioid and non-opioid medications was not uniform, meaning that patients were given a variety of analgesics, making generalizations less certain. The absence of standard guidelines on the use of LB in these patients may have created a potential selection bias in surgeons' choice of LB infusion. Hence, the retrospective design is a limitation of this study.

Other issues include the wide range in the number of fractured ribs as a potential confounder affecting the outcome. There was only one case where infiltration of LB to multiple fracture sites was not achieved due to the distant location of fracture sites. The data were not available for patients who were discharged from the hospital before the specified time period to collect the reported pain score and MME use. The pain score data was collected from nursing assessment records and not from a protocol, although the pain scores were uniformly recorded in the medical record at specified time points.

Conclusion and Future Perspectives

Pain management is crucial to prevent complications of rib fractures. However, this study found that adding liposomal bupivacaine infiltration at the site of rib fracture neither reduced the pain score nor helped in reducing the total adjusted dose of opioid analgesics. Future prospective randomized clinical trials are required to confirm this effect.

Corresponding Author:
Charles V Bayouth, MD, FACS ; Providence Saint Joseph Health, Lubbock, TX
Email: cbayouth@covhs.org

Affiliations:
[1]Texas Tech University Health Sciences Center, Department of Surgery, Lubbock, TX
[2] Providence Saint Joseph Health, Lubbock, TX

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Image Challenge

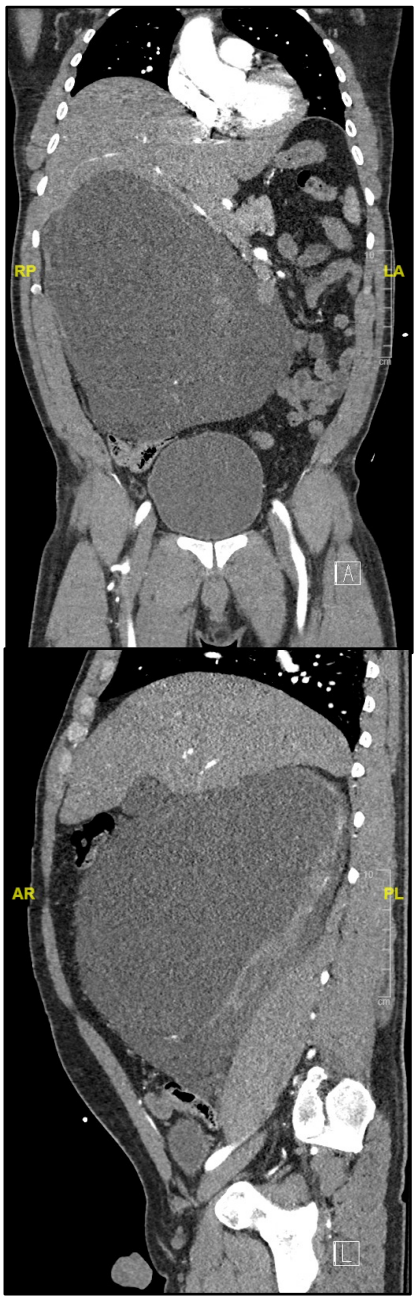
Spontaneous Kidney Mass Presenting as Acute Abdomen

Johnathan P. Tadlock, MS, David S. Harper, PA

Case
A 46-year-old male presented to the emergency department with chief complaints of severe, sudden-onset abdominal pain and inability to void urine.

History of Present Illness
The patient claimed that the symptoms began several hours prior to presentation when he was trying to pass urine and that the pain initially began as right-sided but became bilateral. He denied previously seeing any blood in the urine or any other changes in urine color or character. A review of systems was positive for nausea and “feeling constipated.” His past medical history was not significant for any renal diagnoses and the patient claimed to have not seen a physician in fifteen years. On presentation, he was hypertensive at 239/146 mmHg (MAP 184) and demonstrated abdominal rebounding and guarding on physical exam. A CT scan was performed to evaluate abdominal pathologies.

Challenge Identify the pathology demonstrated on the sagittal and coronal CT scans shown to the right.



Differential Diagnoses
- Hydronephrosis
- Malignancy
- Urinoma
- Nephrolithiasis

West Texas Journal of Medicine. 2024;2(1):55-57

Discussion

A urinoma is a collection of extravasated urine contained by the renal capsule. It is caused by urinary obstruction in the setting of renal trauma, abdominal surgery, malignancy, congenital anomalies, or other spontaneous causes.[1] The presentation of urinomas can range clinically from asymptomatic to symptoms of acute abdomen.[2]

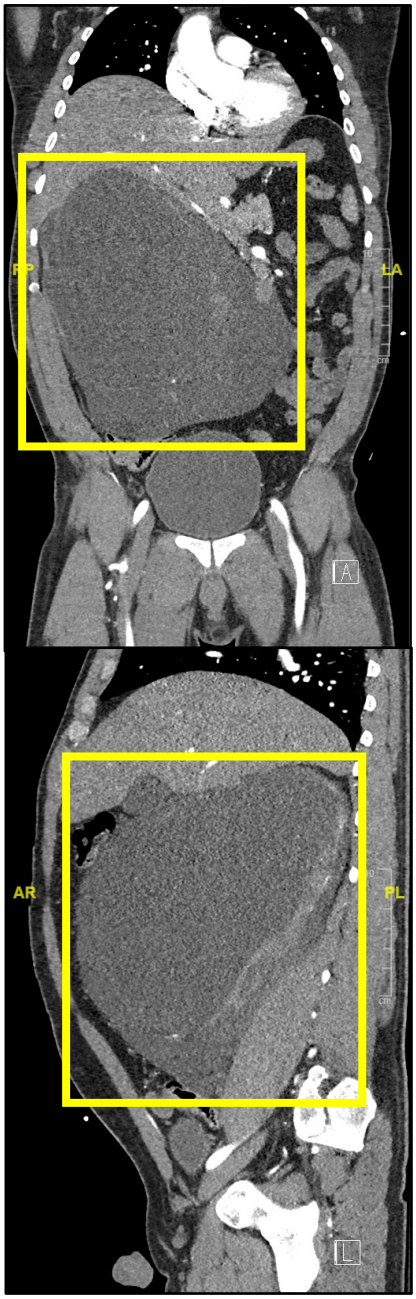
The computed tomography imaging revealed a massively hydronephrotic kidney with forniceal rupture consistent with a urinoma. This image reveals a cystic mass in the right retroperitoneum measuring 22 x 17 x 24 cm. Renal neoplasm was ruled out as no distinct renal masses nor lymphadenopathy were appreciated.

Given the patient's lack of intraabdominal malignancy, lack of recent surgical or traumatic events, and no history of prior urinary obstructive symptoms, it is believed that this urinoma was secondary to spontaneous obstruction at the ureteropelvic junction.

Urology was consulted, who decided that no surgical intervention was necessary, and placement of a nephrostomy drain for decompression by interventional radiology the next morning was planned.

The following day, the patient had mild relief after fluid restriction, and pain interventions, and had evacuated 400 milliliters of normal-appearing urine overnight before drain placement. He immediately evacuated 1,800 milliliters of blood-tinged urine at the time of nephrostomy drain placement.

The patient reported continued improvement of symptoms following drain placement, evacuating an additional 190 milliliters of urine in the next 48 hours while fluid restriction measures continued. He was discharged from the hospital on his third day.



Figures. Coronal and sagittal views of a cystic mass in the right retroperitoneum demonstrating a urinoma suspected to be caused by a spontaneous obstruction of the ureteropelvic junction.

Affiliations:
[1]Kansas City University School of Medicine, Kansas City, Missouri
[2]Texas Tech University Health Science Center, Department of Surgery, Amarillo, Texas

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