Do These Labs Really Matter?: Searching for the Benefit of Laboratory Monitoring in Outpatient Parenteral Antimicrobial Therapy (OPAT)

Kelsea Zukauckas, PharmD[1]; Russell Benefield, PharmD, BCPS-AQ ID[1]; Laura Certain, MD, PhD[2]

[1]University of Utah Health, Salt Lake City, Utah; [2]University of Utah School of Medicine, Salt Lake City, Utah

Abstract

Weekly laboratory monitoring is routinely performed for patients treated with Outpatient Parenteral Antimicrobial Therapy (OPAT). However, minimal evidence exists to guide this practice.

This was a single-center, retrospective cohort study to assess the value of laboratory monitoring in patients being treated with beta-lactam OPAT. This study included adult patients discharged from University of Utah Health (UUH) between January 1, 2018, and July 31, 2019, on beta-lactam OPAT with follow-up care with a UUH Infectious Diseases (ID) Provider. Patients discharged to a skilled nursing facility or long-term acute care hospital, or who received OPAT for a duration less than 7 days, were excluded. The primary aim was to describe how often abnormal laboratory values led to a therapy modification or documented adverse drug reaction (ADR) for patients receiving beta-lactam OPAT. Abnormal laboratory values were defined by consensus criteria for clinical significance (e.g., RIFLE criteria for kidney injury). Therapy modification and ADR occurrence was determined by chart review for UUH ID Provider documentation.

A total of 346 patients were included; two hundred seventy-four (79%) had abnormal laboratory values during OPAT. Of these, 12 patients had a modification to their OPAT due to abnormal laboratory values. The most common therapy modification due to abnormal laboratory values was a change of antibiotic (9/12). Two hundred thirteen of 274 patients (78%) with abnormal laboratory values were maintained on their OPAT regimen without a modification. Of the 67 therapy modifications observed, 55 (82%) were due to reasons other than abnormal laboratory results. Abnormal laboratory values meeting criteria for clinical significance and possible ADR were observed in 469 instances. Of these, 43 (9%) were considered ADRs by the ID provider.

Weekly laboratory monitoring was associated with therapy modifications and documented ADRs in a small number of patients receiving beta-lactam agents as OPAT. This supports current guideline recommendations for laboratory monitoring, even for beta-lactam agents, which are considered relatively safe. Further investigation into the cost-effectiveness of this approach is warranted.

Objectives

Primary Outcome

- To describe how often clinically significant abnormal laboratory values result in therapy modification for patients on beta-lactam OPAT therapy

Secondary Outcomes

- To evaluate how often clinically significant laboratory values precede a documented ADR
- To compare rates of therapy modifications between home infusion companies utilized
  - ❖ UUH Home infusion vs. outside home infusion

Inclusion and Exclusion Criteria

Inclusion Criteria

- Adults (≥ 18 years old)
- Patients discharged from the UUH with OPAT orders to be completed by the UUH home infusion service or an outside home infusion service
- Patients treated with beta-lactam therapy in OPAT
- Patients with outpatient follow-up care planned with a UUH Infectious Diseases Provider

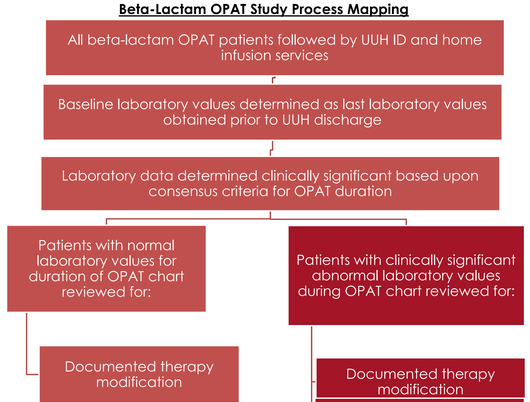
Exclusion Criteria

- Age < 18 years old
- Pregnant women
- OPAT duration < 1 week (7 days) from discharge
- OPAT patients discharged to skilled nursing facility or long term acute care
- OPAT patients discharged with no follow-up services
- OPAT patients being treated with non-beta-lactam monotherapy
- Patients with inadequate records to assess outcomes

Methods

- Study period: January 1, 2018—July 31, 2019
- Patient demographics, Charlson Comorbidity Index, OPAT therapy at discharge, other antimicrobial therapy, home infusion company and laboratory values obtained from the EDW
- Clinically significant laboratory values were defined by pre-specified criteria → **see QR code for details**
- Therapy modification considerations were defined by author criteria → **see QR code for details**
- Documented therapy modifications and ADRs were analyzed by chart review
- Descriptive statistics, student's *t*-test, chi-squared test as appropriate

Beta-Lactam OPAT Study Process Mapping



Abnormal laboratory values resulting in a therapy modification occurred in **3.5% (12/346) of patients** receiving beta-lactam OPAT

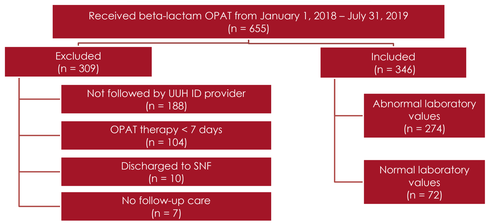
In the absence of further research, this study supports the use of weekly laboratory monitoring for beta-lactam OPAT

Contact Information

Kelsea Zukauckas, PharmD
PGY-2 Solid Organ Transplant Pharmacy Resident
University of Utah Health
50 N Medical Drive
Salt Lake City, UT 84132
Office: 801-585-7878
Email: kelsea.zukauckas@utah.edu

Results

Beta-Lactam OPAT Patient Selection



Baseline Characteristics

Baseline Characteristics	Total Patients n= 346	Patients with Abnormal Laboratory Values n= 274	Patients with Normal Laboratory Values n= 72	P-Value
Age in years --average, SD	53 (16)	53 (16)	52 (17)	0.54
Male sex --n, %	233 (67)	183 (67)	50 (69)	0.28
White race --n, %	297 (86)	232 (85)	65 (90)	0.61
Body Mass Index --average, SD	29 (7)	29 (7)	29 (8)	0.51
Charlson Comorbidity Index --median, IQR	3 (6)	3 (6)	3 (5)	0.12
Renal dysfunction --n, %	91 (26)	77 (28)	14 (19)	0.13
Liver dysfunction --n, %	74 (21)	64 (23)	10 (14)	0.08
Malignancy history --n, %	89 (26)	75 (27)	14 (19)	0.17
Chemotherapy --n, %	24 (7)	23 (8)	1 (1)	**0.04**
Immunotherapy --n, %	42 (12)	36 (13)	6 (8)	0.27
Duration between labs > 10 days --n, %	134 (39)	102 (37)	32 (44)	0.26
Beta-lactam therapy --n, %*				
Penicillins	75 (22)	59 (22)	16 (22)	0.9
Cephalosporins	240 (69)	187 (68)	53 (74)	0.38
Carbapenems	50 (14)	45 (16)	5 (7)	0.06
Other OPAT**	50 (14)	44 (16)	6 (8)	0.10

* Some patients received dual beta-lactam OPAT
** Included: amikacin, caspofungin, clindamycin, daptomycin, fluconazole, ganciclovir, gentamicin, metronidazole, vancomycin

Therapy Modifications in Beta-Lactam OPAT

Outcome	Total Patients (n = 346)	Abnormal Laboratory Values (n = 274)	No Abnormal Laboratory Values (n = 72)
Therapy modification: abnormal laboratory values --n, %	12 (3.5%)	12 (4.4%)	0 (0%)
Therapy modification: no laboratory values --n, %	55 (16%)	49 (18%)	6 (8%)
No therapy modification --n, %	279 (81%)	213 (78%)	66 (92%)

Adverse Drug Reactions in Beta-Lactam OPAT

Outcome	Abnormal Laboratory Values Indicating Potential Outcome (n = 274)	Documented ADR in Presence of Abnormal Laboratory Values
Nephrotoxicity --n, %	70 (26%)	19/70 (27%)
Hepatotoxicity --n, %	97 (35%)	10/97 (10%)
Leukopenia --n, %	69 (25%)	5/69 (7%)
Leukocytosis --n, %	110 (40%)	4/110 (4%)
Thrombocytopenia --n, %	31 (11%)	2/31 (6%)
Eosinophilia --n, %	82 (30%)	3/82 (4%)
Neutropenia --n, %	10 (4%)	0/10 (0%)

Therapy Modifications by Home Infusion Services in Beta-Lactam OPAT

Outcome	UUH Home Infusion (n = 194)	Outside Home Infusion (n = 152)	P-Value
Therapy modification due to labs --n, %	12 (8%)	0 (0%)	**0.0018**
Therapy modification not due to labs --n, %	32 (16%)	23 (20%)	0.73
No therapy modification --n, %	150 (77%)	129 (85%)	**< 0.001**
Duration between laboratory values > 10 days --n, %	49 (25%)	85 (56%)	**< 0.001**

Discussion

- Therapy modifications were uncommon in patients receiving beta-lactam OPAT
- Therapy modifications were due to several different types of laboratory abnormalities
- Therapy modification most often resulted in a complete therapy change rather than therapy frequency adjustment
- Abnormal labs preceding therapy modifications occurred for patients only followed by UUH Home Infusion Services likely correlated with more weekly laboratory monitoring
- Further work should evaluate the efficiency and cost-effectiveness of weekly laboratory monitoring
- Further work should take into consideration physician time spent evaluating abnormal laboratory values that ultimately have no clinical significance

Disclosures

- This study was considered except by the University of Utah IRB
- Conflicts of Interest:
  - ❖ Benefield: Merck and Co, Rempex Pharmaceuticals, and Paratek Pharmaceuticals for antimicrobial research unrelated to this project
  - ❖ Zukauckas and Certain: none

References

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