Disclosures. All Authors: No reported disclosures

625. The Hidden Cost of Dalbavancin: OPAT RN Time Spent on Coordination for Patients with Substance Use Disorder
Alyse Douglass, RN1; Heather Mayer, RN1; Kathleen Young, RN1; Amber C. Streifel, PharmD, BCPS3; Jina Makadia, MD3; James Lewis, PharmD3; Monica K. Sikka, MD2
1Oregon Health and Sciences University, Portland, Oregon; 2Oregon Health & Science University, Portland, OR; 3Oregon Health and Science University, Portland, Oregon
Session: P-27. Clinical Practice Issues

Background. The use of dalbavancin (DAL) enhances the management of serious gram-positive infections in people with substance use disorder (SUD) by eliminating the need for central lines, weekly lab monitoring, and may decrease length of hospitalizations. Though administered weekly, care coordination for DAL is often complex, due to variable access to resources, insurance variation and treatment settings. Our institution uses OPTIONS-DC, a multi-disciplinary discharge planning conference facilitated by an outpatient parenteral antimicrobial therapy (OPAT) registered nurse (RN) to determine safe treatment plans while emphasizing patient preference for hospitalized patients with SUD and serious infections. When DAL is selected for treatment, patients are enrolled in the RN-led OPAT program for coordination and monitoring. DAL has been shown to result in monetary savings but these estimates have yet to incorporate the true cost of coordination.

Methods. We conducted a retrospective chart review of OPAT staff interventions required to coordinate DAL doses for patients with SUD (identified via ICD-10 code or chart notes). Additionally, we recorded in real time, the amount of time spent per intervention over a one month period for 7 additional patients.

Results. 53 courses of DAL in patients with SUD were included with a variety of dosing regimens and treatment settings (Table 1). 41 (77%) patients endorsed IV substance use. 68% of patients received DAL for osteomyelitis or endocarditis. The majority were insured by Oregon Medicaid (70%). The number of RN interventions per course averaged 3.35 with the most common being coordinating with patients and vendors (Table 2). The average time spent per patient course during a one-month sample was 39.4 minutes (range 15 – 58 minutes). The most time-consuming interventions were coordinating the OPTIONS-DC conferences and attempting to reach patients after hospital discharge. Readmission for adverse effects or infection occurred for 4 (8%) patients.

Table 1. Patient Demographics and Dalbavancin Use
| Age (years): mean | 44.8 (STD 11.2) |
| Gender (Female) | 17 (32%) |
| Substance Use History |
| Intravenous substance use (opioids or methamphetamine) | 41 (77) |
| Inhaled use (methamphetamines) | 1 (2) |
| Opioid use disorder, unclear route | 1 (2) |
| Alcohol use | 10 (19) |
| Insurance Coverage |
| Medicaid | 37 (70) |
| Medicare | 5 (9) |
| Commercial | 2 (4) |
| Other | 0 (0) |
| Multiple insurance providers | 7 (13) |
| Uninsured | 0 (0) |
| Addiction Medicine Involvement |
| Addiction Medicine Consult | 28 (53) |
| Multi-disciplinary discharge planning conference (OPTIONS-DC) | 17 (32) |
| Indication |
| Bone and joint infection (non-vertebral) | 21 (40) |
| Vertebral osteomyelitis | 14 (26) |
| Skin and soft tissue infection | 12 (23) |
| Endocarditis | 4 (8) |
| Bacteremia | 7 (13) |
| Dosing Regimens |
| 1500 mg x 1 | 25 (47) |
| 1500 mg x 2 | 16 (31) |
| 1500 mg x 1, followed by 500 mg x 1 | 1 (2) |
| 1000 mg x 1 | 5 (9) |
| 1000 mg weekly | 1 (2) |
| 1000 mg x 1, followed by 500 mg weekly | 5 (9) |
| Treatment Setting Number of doses infused |
| Inpatient | 33 |
| Infusion Center | 38 |
| Home Infusion | 16 |
| Emergency Department | 5 |
| Correctional Facility | 2 |
Among participants who continued DOR in the DRIVE-FORWARD open-label extension, virologic suppression and favorable safety were maintained for an additional 96 weeks. Participants who switched from DRV/r to DOR maintained virologic suppression and demonstrated favorable safety for 96 weeks.

Table 1. DRIVE-FORWARD efficacy and safety outcomes at Week 192 in participants who entered study extension (Weeks 96–192)

| Efficacy outcomes | Randomized to DOR arm and maintained on DOR n=259 | Randomized to DRV/r arm and switched to DOR n=233 |
|-------------------|---------------------------------|---------------------------------|
| HIV-1 RNA <50 copies/mL | 210/229 (89.5) | 188/233 (80.7) |
| HIV-1 RNA <200 copies/mL | 204/229 (89.5) | 201/233 (86.4) |
| No virologic data in Week 192 window | 204/229 (89.5) | 25/233 (10.7) |
| HIV-1 RNA 50–200 copies/mL | 2/229 (0.9) | 5/233 (2.1) |
| Protocol-defined virologic failure | 8/229 (3.5) | 13/233 (5.6) |
| Genotypic resistance to DOR | 2/229 (0.9) | 13/233 (5.6) |
| Genotypic resistance to NRTI | 1/229 (0.4) | 1/233 (0.4) |
| Mean change (95% CI) | Mean change (95% CI) |
| CD4+ T-cell count (cells/μL)* | 302 (247, 336) | 53 (24, 81) |

Safety outcomes

| | One or more AE | 196 (75.7) | 162 (69.5) |
| | Drug-related AE | 21 (8.1) | 21 (9.0) |
| | Serious AE | 17 (6.4) | 16 (6.9) |
| | Discontinued because of an AE | 5 (1.9) | 1 (0.4) |

Mean change (95% CI) Mean change (95% CI)

Fasting LDL-cholesterol (mg/dL)** | 3.0 (0.0, 5.9) | -7.0 (-10.3, -3.7) |
Fasting non-HDL-cholesterol (mg/dL)** | 3.7 (0.4, 7.1) | -10.6 (-14.2, -4.9) |
Fasting triglycerides (mg/dL)** | 5.1 (1.5, 15.3) | -15.8 (-26.5, -4.7) |
Total cholesterol to HDL ratio | -0.2 (-0.4, 0.0) | -0.4 (-0.6, 0.0) |
Median change | Median change (min, max) | Median change (min, max) |
Weight (kg)* | 1.9 (352, 61.2) | 1.5 (15, -22.9) |

Data shown as number (%) of participants, unless otherwise indicated.

*Data not available for all participants.

**Protocol-defined virologic failure (PDVF) is defined as confirmed (2 consecutive measures at least 1 week apart) HIV-1 RNA ≥50 copies/mL at any time during the study.

**Observed failure approach for missing data; baseline carried forward for failures, after missing values excluded.

---

626. The Efficacy and Safety of Maintenance with Doravirine Plus Two NRTIs after Initial Suppression in Adults with HIV-1 in the DRIVE-FORWARD Clinical Trial: Results from the Study Extension through 192 Weeks

Pedro Cahn, MD, PHD1; Jean-michel Molina, MD, PhD2; Johann Lombardha, MBChB3; Kathleen Squires, MD4; Sushma Kumar, PhD3; Hong Wan, PhD3; Valerie Teal, MS5; Ernest Asante-Appiah, PhD3; Peter Sklar, MD, PhD; Elizabeth A. Martin, DO, MPH, MBA6

---

Session: P-28. Clinical Trials

Background. DRIVE-FORWARD is a phase 3 trial with a completed double-blind period comparing doravirine (DOR) 100 mg with ritonavir-boosted darunavir (DRV/r) 800/100 mg, both administered with two nucleos(t)ide reverse transcriptase inhibitors (NRTIs; tenofovir and emtricitabine, or abacavir and lamivudine), and an ongoing open-label extension. At Week (W) 48, DOR demonstrated superior non inferior efficacy to DRV/r, with a superior lipid profile. Those results were sustained at W96. Here we present efficacy and safety results through W192.

Methods. Participants who completed the 96-week double-blind phase and met inclusion criteria were eligible to receive open-label DOR plus two NRTIs in a 96-week extension. Efficacy and safety at W192 were assessed in two groups: participants initially randomized to DOR and maintained on DOR (n=259) and those who switched from DRV/r to DOR at W96 (n=233).

Results. HIV-1 RNA < 50 copies/mL were maintained through W192 in 81.1% of participants who continued DOR and 80.7% of those who switched from DRV/r to DOR. The mean increase in CD4 T-cell counts from W96 to W192 was similar for participants maintained on DOR (47 cells/mm³) and those switched from DRV/r (53 cells/mm³). Protocol-defined virologic failure occurred in 3.1% and 5.6% of participants maintained on DOR and switched from DRV/r, respectively, and development of genotypic resistance was low in both groups (Table 1). Discontinuation due to adverse events was also low (Table 1). Fasting LDL-cholesterol, non-HDL-cholesterol, and triglycerides showed minimal increase in participants maintained on DOR and were reduced in those switched from DRV/r to DOR (Table 1). Participants maintained on DOR had minimal weight gain after W96 (median 1 kg), and a small increase overall (median 1.9 kg, Day 1 through W192); participants who switched to DOR had a small increase after W96 (median 1.5 kg), similar to the median weight gain in the base study (DOR 1.8 kg; DRV/r 0.7 kg).

Conclusion. Among participants who continued DOR in the DRIVE-FORWARD open-label extension, virologic suppression and favorable safety were maintained for an additional 96 weeks. Participants who switched from DRV/r to DOR maintained virologic suppression and demonstrated favorable safety for 96 weeks.