Abstract #62:Real-world Treatment Patterns of Intrathecal Ziconotide

Tolga Suvar,[1] David Lindley,[2] Darren Leatherman,[3] Kendra Howard,[3] Rachel Lucia,[4] Nicole Duran,[4] Maureen Murray,[5] Gail McGlothlen,[5] Jacy Dagenhart,[5] Joan Cannon,[5] Salma Sayeed,[5] Timothy Lubenow[1]
Affiliations: [1] Rush University Medical Center, University Anesthesiologists, S.C.[2] Pain Practice of Norman Dozier MD; [3] Pentec Health; [4] IQVIA Inc; [5] TerSera Therapeutics LLC

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Background:

- Polyanalgesic Consensus Conference (PACC) guidelines have recommended intrathecal ziconotide as first-line monotherapy in patients with chronic non-malignant pain or with malignant pain and life expectancy ≥6 months.[1-2]
- Ziconotide's US FDA approved labeling recommends initiating therapy with a continuous infusion of ≤2.4 mcg/day; titrations of up to 2.4 mcg/day two-to-three times per week up to a maximum of 19.2 mcg/day are recommended based on patient response.[3]
- However, with the updates in the PACC guidelines and additional dosing studies, clinicians may be adopting more conservative initial dosing strategies and lower concentrations.[4]

Objective:

- To demonstrate the prescribing practices of intrathecal ziconotide using real-world evidence from a specialized pharmacy database.

Methods:

- A retrospective, non-interventional real-world study was performed using US dispensing and claims data from Pentec Health, a specialty care infusion pharmacy and nursing provider.
- Patients (18–90 years of age) with records of ziconotide prescriptions between 1 January 2017 and 31 December 2024 were identified. Patients with a non-trialing ziconotide prescription from 1 January 2017 to 30 June 2017 or patients with only trialing ziconotide prescriptions were excluded to capture new users at Pentec Health of ziconotide. Index date was first record of a ziconotide prescription on or after 1 July 2017.
- Prescription fill dates, formulation, and drug(s) administered with ziconotide were derived from medication delivery records and were available for all prescription fills.
- Dose, concentration, and refill intervals were recorded when patients' pumps were filled with medication.
- Clinical indications and prescribing patterns (e.g., ziconotide use as monotherapy versus combination therapy, medication used in combination therapy, ziconotide dose/concentration, and dosage changes) were assessed.

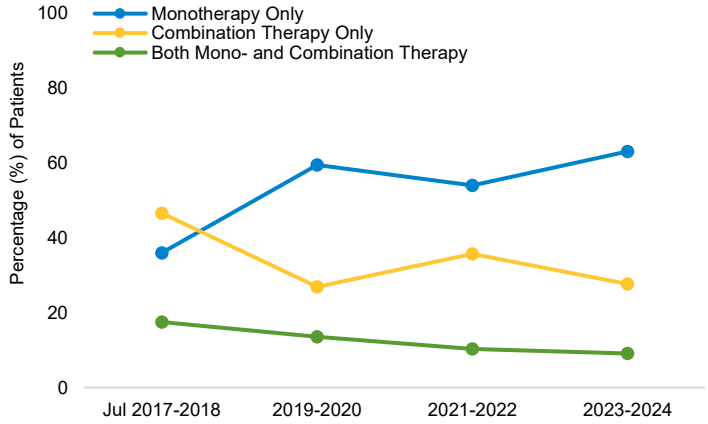
Results:

- 1,343 patients with a record of ziconotide were identified, 1,063 which were new users at Pentec (cohort of interest); median age was 62 years (**Table 1**).
- The most common indications consisted of chronic pain (45.7%), postlaminectomy syndrome (14.3%), low back pain (5.9%), and radiculopathy (5.8%).
- Monotherapy use accounted for 54.8% of fills (n=582) and combination therapy for 45.2% (n=481). Monotherapy use increased from 2017–2018 (36.0%) to 2023–2024 (63.1%), with a corresponding decrease in combination therapy (2017–2018=46.6%; 2023–2024=27.7%) (**Figure 1**).
- Treatment duration (median, mean [standard deviation]) was lower for monotherapy (161, 441.3 [579.7] days), compared with combination therapy=334, 650.2 [715.8] days) (**Table 1**).
- Median initial concentration was higher in monotherapy (15.0 mcg/mL), compared with combination therapy (5.0 mcg/mL); median dosages were similar (monotherapy=1.4 mcg/day, combination therapy=1.2 mcg/day) (**Table 2**). The overall percentage of patients prescribed lower initial ziconotide dosages increased between 2017–2018 (3.4%) to 2023–2024 (20.3%) (**Figure 2B**).
- Most common co-administered medications were bupivacaine (48.2%), hydromorphone (33.8%), and baclofen (29.3%).
- Rate of ziconotide infusion was mostly basal rate (64%), followed by basal rate with patient-controlled analgesia (37%) and variable (13%) (**Figure 3A**).
- Use of basal rate with patient-controlled analgesia steadily increased between 2017–2018 (23.7%) to 2023–2024 (45.3%) (**Figure 3B**).
- Limitations of this analysis are consistent with other real-world analyses, such as inability to verify use of ziconotide outside of Pentec Health and the possibility of incomplete or missing data (e.g., patient outcomes data).

Table 1: Patient Characteristics

	All patients (n = 1,063)	Patients receiving monotherapy only (n = 582)	Patients ever receiving combination therapy (n = 481)
Demographic characteristics			
Age at index date, years			
Median (IQR)	62 (52, 69)	63 (54, 71)	60 (51, 68)
Mean (SD)	60.3 (12.8)	61.8 (12.7)	58.5 (12.7)
Sex			
Female (n, %)	550, 53.3%	298, 53.4%	252, 53.2%
Male (n, %)	482, 46.7%	260, 46.6%	222, 46.8%
Unknown (n)	31	24	7
Duration of treatment (first prescription fill to last prescription fill), days			
Median (IQR)	245 (63, 786)	161 (37, 597)	334 (96, 973)
Mean (SD)	535.8 (652.9)	441.3 (579.7)	650.2 (715.8)
Missing (n)	0	0	0

Figure 1: Ziconotide regimens over time



Patients included in the "Both Mono- and Combination Therapy" cohort are part of the "Patients ever receiving combination therapy" group in Tables 1 and 2.

Table 2: Ziconotide Dosage

	All patients N = 1,063	Patients receiving monotherapy only n = 582	Patients ever receiving combination therapy n = 481	By calendar year of first ziconotide dose: Jul 2017-2018 n = 189	2019-2020 n = 309	2021-2022 n = 291	2023-2024 n = 274
Ziconotide Dosage							
Ziconotide dose, index date, mcg/day							
Median (IQR)	1.3 (0.8, 2.5)	1.4 (1.0, 2.6)	1.2 (0.7, 2.4)	2.0 (1.2, 3.0)	1.4 (0.8, 2.6)	1.2 (0.8, 2.4)	1.2 (0.5, 2.3)
Mean (SD)	2.1 (2.4)	2.1 (2.4)	2.1 (2.4)	2.5 (1.8)	2.2 (2.8)	2.1 (2.7)	1.8 (1.9)
Missing (n)	349	232	117	101	77	94	77
Ziconotide concentration, index date, mcg/mL							
Median (IQR)	8.0 (2.8, 25.0)	15.0 (5.0, 25.0)	5.0 (2.3, 10.0)	10.0 (6.2, 25.0)	6.8 (2.5, 25.0)	8.0 (2.1, 20.0)	5.0 (2.5, 25.0)
Mean (SD)	12.6 (13.0)	16.3 (14.4)	8.9 (10.4)	16.4 (12.2)	13.1 (14.8)	11.7 (13.1)	11.0 (10.4)
Missing (n)	346	232	114	101	75	94	76

Figure 2: Ziconotide index dose (mcg/day) by A) prescription pattern, and B) over time

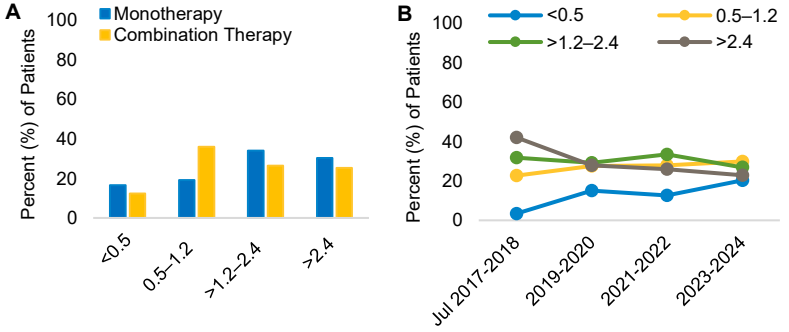
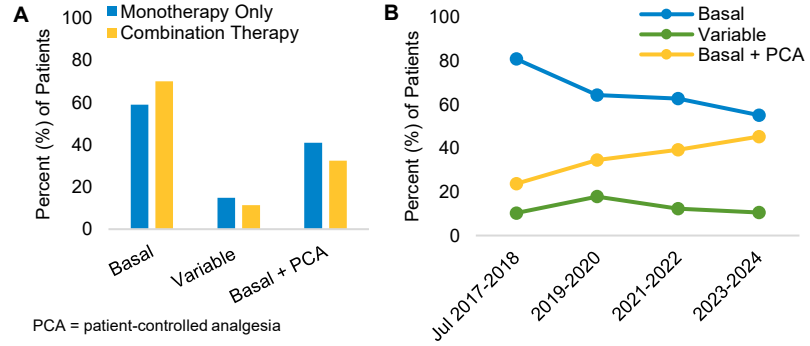


Figure 3: Type of infusion rate by A) prescription pattern, and B) over time



PCA = patient-controlled analgesia

Changes in prescription patterns between 2017 and 2025 suggest increased clinician familiarity with PACC guidelines as a >20% increase in the rate of patient-controlled analgesia and a ~40% decrease in starting dosage/concentration of ziconotide were observed over this time period.

References:1.Deer TR, Hayek SM, Pope JE, et al.. *Neuromodulation*. Feb 2017;20(2):133-154. 2.Deer TR, Pope JE, Hanes MC, McDowell GC. *Pain Med*. Apr 1 2019;20(4):784-798. 3. TerSera. PRIALT (ziconotide) solution, intrathecal infusion US FDA Label. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021060s012lbl.pdf 4. Lindley D. *Neuromodulation*. Oct 2021;24(7):1209-1214.