STEARNS et AL. 2019[1]

Intrathecal drug delivery systems for cancer pain: an analysis of a prospective, multicenter product surveillance registry

Anesthesia and Analgesia

STUDY BACKGROUND

Pain is prevalent throughout the cancer life cycle. The safety and efficacy of targeted drug delivery (TDD) for the treatment of cancer-related pain have been demonstrated in randomized controlled clinical trials.[2,3] Despite this positive evidence, TDD remains underutilized for treating cancer pain. This paper uses real-world registry data to augment existing safety and effectiveness data and broaden awareness of this therapeutic option for cancer-related pain treatment.

METHODS

37 centers from the United States, Western Europe, and Latin America enrolled 1,403 patients suffering from cancer-related pain from August 2003 to July 2017.

Data collection aligned with routine clinical practice. Data collection included safety data, pain evaluation (0=no pain, 10= worst pain), and quality of life measured with EQ-5D.

Data collection in the registry has evolved from its initiation in 2003, resulting in differences in data availability based on patient enrollment date and follow-up periods. The key protocol revisions resulting in different analysis sets are:

- 2010 - addition of pain assessment, adverse event reporting expanded to include all serious events
- 2013 - EQ-5D assessment of Quality of Life added

Table 1[1]

Outcome	Sample size
Safety	1,403
Pain	103 (6 mo), 55 (12 mo)
EQ-5D Index	41 (6 mo), 27 (12 mo)
EQ-5D VAS	41 (6 mo), 25 (12 mo)

RESULTS

SAFETY:

In the full cohort of 1,403 cancer pain patients:

- 3.2% experienced infection requiring surgical intervention (e.g., explant, replacement, revision, or debridement)
- Product performance events that occurred in >1% of patients included:
  - » Catheter dislodgement, 3.8%
  - » Pump motor stall, 1.8%
  - » Catheter occlusion, 1.5%
  - » Catheter kink, 1.5%
  - » Catheter break/cut, 1.2%
- MRI
  - » 73 MRIs were reported in 51 patients
  - » All MRI-induced motor stalls recovered as expected within 24 hours
  - » There were no reports of post-MRI drug withdrawal or sequelae

PAIN:

The subset of patients with both baseline and follow-up (6 and/or 12 months) pain scores demonstrated statistically significant improvement in average pain from baseline. (Figure 1)

QUALITY OF LIFE:

EQ-5D Index value and the EQ-5D Health-VAS, demonstrated statistically significant improvement compared to baseline at 6 months, (Figure 2) and numerical improvement — though not statistically significant — at 12 months.

CONCLUSION

Medtronic's Product Surveillance Registry provides a unique, long-term and real-world view of TDD for cancer pain.

This publication represents the largest cohort of TDD for cancer pain, with over 1,400 patients represented.

In addition, the more recent cohort of patients demonstrate improvement in pain and quality of life at 6 months.

Results from this large-scale, multicenter registry supplement existing RCT data that support IDDS as a safe and effective therapeutic option with a positive benefit–risk ratio in the treatment of cancer pain.

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Figure 1: Mean pain scores significantly decreased from baseline to 6 and 12 months.

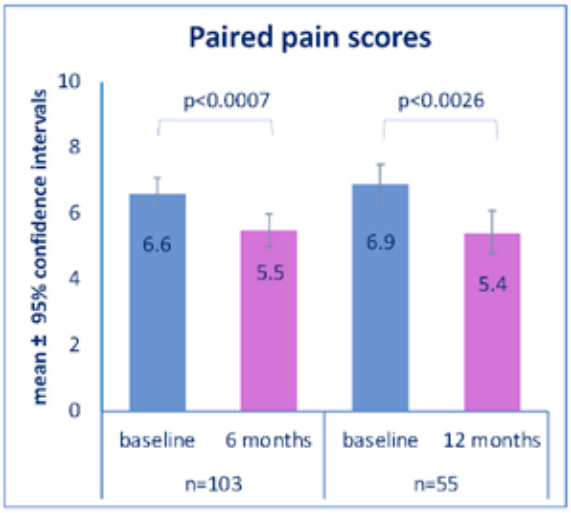
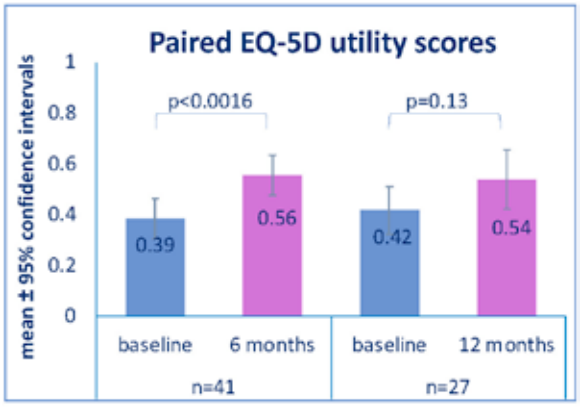
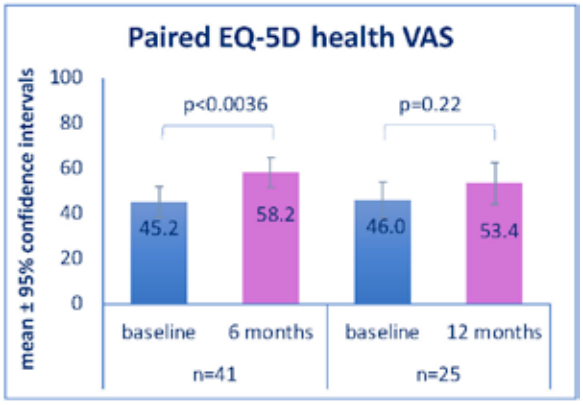


Figure 2: Mean EQ-5D utility score computed with the UK utility values (min -0.281, max 1) and health status VAS score improved from baseline to 6 and 12 months. The increase was statistically significant at 6 months.





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