Success of Epidural Trial Prior to Intrathecal Therapy (FR528)

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Background:

The success rate of intrathecal therapy (IT) in cancer/cancer related pain is not well reported. Patient satisfaction of “Good” or “Excellent” was reported to be 59% (249/422) in benign pain by Schultz et al, and "satisfaction" in 92% by Winkelmuller & Winkelmuller.

There is no published study of the success of IT preceded by epidural therapy trial for comparison. Additionally, Bruel & Burton draw attention to the need for additional research in cancer survivors' chronic pain.

The practice in our cancer center is to assess neuraxial analgesic effect with a tunneled epidural catheter for two weeks prior to the decision to implant an intrathecal pump for patients with somatic tumor pain and chronic cancer treatment related neuropathic and nociplastic pain alike.

The purpose of the study is to evaluate the success rate of intrathecal drug therapy for cancer/cancer related pain after epidural therapy trial.

Methods:

The study was performed by retrospective chart review.

The medical record was queried for all patients who underwent intrathecal pump refill between 1/1/2012 and 1/1/2024.

Chronic Pain Acceptance Questionnaire (CPAQ), treatment, and demographic data was collected for the period immediately prior epidural trial, within 6 months follow up after intrathecal pump implantation, and the last evaluation.

The data was analyzed against primary outcomes of overall satisfaction/global assessment, improvement in disability and pain interference, and pain relief. For each measure, a linear mixed model is fitted.

Secondary outcomes are opioid utilization and adverse events. A total of 25 patients were identified.

A total of 4 patients were excluded from analysis; 2 had pumps implanted before the electronic health record was created, and 2 expired prior to repeating the CPAQ.

Changes in record keeping systems precluded consistent comparison of opioid usage. Unreported scores are noted in totals.

Results:

Mean worst pain scores decreased from baseline 9.5 (7-10/10) to post implantation 7.4 (3-10/10) and last follow up 7.3 (3-10/10). Success in treatment scores increased; baseline 1.4 (0-4/4), implantation 2.5, (1-3/4), last follow up 2.5 (1-4/4). The global results of pain treatment over all also increased from baseline 5.3 (1-10/10) to implantation 8.2 (4-10/10), with diminished increase at last follow up 7.6 (1-10/10). No pain interference mean changed by more than +/- 0.7 points. Pain interference in sexual behavior was the most frequently omitted survey item, absent 38% of the time. At baseline 33% (6/18) reported overall satisfaction of 7-10/10, 95% (19/20) post implantation, and 68%(13/19) at last follow up; last follow up scores diverged between deceased (mean 6.1) and living (mean 8.4) groups. Amount of pain you can live with increased; baseline 2.9 (0-8/10), post implant 3.2 (0-6/10), follow up 3.3 (0-8/10). There was one adverse event, a granuloma which resolved with discontinuation of therapy.

Data Summary

Outcome Measures

Pre-Implantation					
Measure	Mean	Median	Standard deviation	Range	# of Missing value
Worst Pain at Start of Care	9.47	10	0.834	7 to 10	6
Level of Success of Tx	1.44	1	1.09	0 to 4	5
Least Pain	4.43	5	2.11	0 to 9	0
Worst Pain	8.71	9	1.59	5 to 10	0
Amount of pain you could live with	1.59	3	1.90	0 to 8	2
Interfered Family/Home Responsibilities	6.63	7	2.03	3 to 10	2
Interfered Recreation	6.39	7	2.68	0 to 10	3
Interfered Social Activity	6.06	7	2.95	0 to 10	4
Interfered Occupation	5.87	6	2.42	0 to 10	6
Interfered Sexual Behavior	4.38	3	3.28	0 to 9	8
Interfered Self-Care	4.11	4.5	3.38	0 to 10	3
Interfered Life Support Activity	4.56	4	3.55	0 to 10	3
Results of your pain treatment overall	5.28	5.5	2.47	1 to 10	3

Post-Implantation					
measure	Mean	Median	Standard deviation	Range	# of Missing value
Worst Pain at Start of Care	9.40	10	0.91	7 to 10	6
Level of Success of Tx	2.53	3	0.62	1 to 3	4
Least Pain	3.24	2	2.64	0 to 10	0
Worst Pain	7.38	8	2.13	3 to 10	0
Amount of pain you could live with	3.19	3	1.60	0 to 6	5
Interfered Family/Home Responsibilities	5.70	6.5	2.70	1 to 10	1
Interfered Recreation	6.57	7	2.84	1 to 10	0
Interfered Social Activity	5.89	7	2.98	1 to 10	2
Interfered Occupation	6.60	7	3.27	1 to 10	6
Interfered Sexual Behavior	5.93	7.5	4.23	0 to 10	7
Interfered Self-Care	4.10	4.5	2.97	0 to 10	1
Interfered Life Support Activity	4.1	5	3.16	0 to 10	2
Results of your pain treatment overall	8.20	8	1.51	4 to 10	1

Most Recent or Last					
measure	Mean	Median	Standard deviation	Range	# of Missing value
Worst Pain at Start of Care	9.30	10	1.17	5 to 10	1
Level of Success of Tx	2.48	3	0.93	1 to 4	0
Least Pain	3.95	4	2.40	0 to 8	0
Worst Pain	7.33	8	2.18	3 to 10	0
Amount of pain you could live with	3.25	3	2.10	0 to 8	1
Interfered Family/Home Responsibilities	6.05	6	2.701	1 to 10	1
Interfered Recreation	6.21	7	2.571	1 to 10	2
Interfered Social Activity	6.00	6	2.67	2 to 10	2
Interfered Occupation	5.80	6	2.76	0 to 10	6
Interfered Sexual Behavior	4.58	4	4.21	0 to 10	9
Interfered Self-Care	4.86	4	3.04	0 to 10	0
Interfered Life Support Activity	4.24	4	3.46	2 to 10	1
Results of your pain treatment overall	7.58	8	2.78	1 to 10	2

Demographic and Clinical Variables

Sex		
	Female	*Male*
Frequency	12	9
Relative Frequency	57.14%	42.86%
Tumor v.s. Neuropathy		
	Neuropathy	*Tumor*
Frequency	16	5
Relative Frequency	76.19%	23.81%

	Mean	Median	Standard Deviation	Range
Treatment Time	7.35	5.50	6.26	0.2 – 21.4
Age baseline	54.46	55.67	12.18	33.67 to 90.17
Age post implant	54.86	55.83	12.16	33.75 to 90.5
Age last	61.86	62.08	10.19	43.58 to 96.33

Comparison

For each measure, a linear mixed model is fitted.
Outcome: log(measure+1).
Predictors: time points, and a random subject intercept.

measure	p-value			
	Pre v.s. Post	Pre v.s. Last	Post v.s. Last	Overall P-value
Worst Pain at Start of Care	0.9666437	0.7004878	0.8438668	0.7060096
Level of Success of Tx	0.0004259	0.0006785	0.9367604	0.0001563
Least Pain	0.1189084	0.6986740	0.4508503	0.1381036
Worst Pain	0.0158740	0.0121499	0.9940649	0.0058930
Amount of pain you could live with	0.9628377	0.8394605	0.9595093	0.8522515
Interfered Family/Home Responsibilities	0.3680147	0.6963382	0.8409654	0.3968419
Interfered Recreation	0.8975741	0.9998304	0.9017762	0.8770636
Interfered Social Activity	0.9866300	0.9908361	0.9995649	0.9863397
Interfered Occupation	0.6492817	0.9895729	0.7258588	0.6253551
Interfered Sexual Behavior	0.6003324	0.9824009	0.5048938	0.4705129
Interfered Self-Care	0.9779899	0.3850126	0.4733583	0.3490413
Interfered Life Support Activity	0.9995933	0.9869586	0.9907915	0.9861688
Results of your pain treatment overall	0.0005193	0.0075044	0.6293440	0.0004970

Conclusions and Relevance:

IT can effectively decrease pain scores associated with tumor in cancer patients and in cancer survivors with neuropathic and nociplastic pain. There was no statistically significant difference between post-implant and last reported scores. This suggests some aspect of the IT is the driving factor. IT also increased self-reported sense of success in treatment and satisfaction of analgesia in this group. Again, these did not change significantly between post-implantation and last reported suggesting IT itself is the meaningful difference. This also suggests that that in this group IT deemed to be unsatisfactory after implant may not salvaged over time. Serious adverse events are very uncommon to rare. Patient selection remains critically important.

Cancer pain remains challenging despite modern tools of assessment and treatment, and as a condition of the aged gains prominence with aging populations. Chronic pain in cancer survivors is increasing as a function of increased cancer survivorship and demonstrates itself apart from benign pain syndromes. Intrathecal therapy offers promising options which certainly require more investigation.

References and Permissions:

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Ethical Permissions:
The proposal and design of this study was reviewed and approved by Roswell Park Comprehensive Cancer Center's institutional review board prior to data collection and analysis.