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ASPN

THE AMERICAN SOCIETY of PAIN & NEUROSCIENCE

CANCER PAIN CARE IN THE COVID ENVIRONMENT

IN THIS ISSUE

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Editors-in-Chief: Timothy Deer, M.D. & Krishnan Chakravarthy, M.D., Ph.D. Digital Editor: Dipan Patel, M.D.

PRESIDENT'S CORNER:

Tribute from Dawood Sayed, M.D. to Lisa Stearns, M.D.

Our entire interventional pain community was rocked by the recent news of the passing of our dear friend Dr. Lisa Stearns. I personally remember graduating from Fellowship in 2011 and spending a few days with Lisa as a junior attending at her practice in Phoenix Arizona. As a young aspiring cancer pain physician, I was in awe of her clinical acumen, surgical expertise, and knowledge of the field. Most importantly, I was inspired by her compassionate care for her patients. There did not appear to be anything she would not do to ensure the optimal outcomes for her patients. It is a great honor to announce the Annual Lisa Stearns Diversity & Inclusion Award in her name as well as a scholarship dedicated to her legacy. We hope that you can all meet us in Miami in September for this inaugural award to honor the passing of our dear friend,

Sincerely,

Dawood Sayed, M.D.

President

American Society of Pain & Neuroscience

Cancer Pain Care in the COVID environment:

DR. AMITABH GULATI, M.D. & DR. HEMANT KALIA, M.D.

Cancer Pain in times of COVID-19 Pandemic – Physician Perspectives

Amitabh Gulati MD
Memorial Sloan Kettering Cancer Center

Hemant Kalia MD
Rochester Regional Health System

Introduction:

Cancer pain care has a level of complexity that involves multiple specialties for optimal care. The introduction of a significant health concern such as the COVID-19 pandemic will put a strain on resources available for an already vulnerable population. A keen balance of pain care and safety is paramount for the continued success in treating this population. Resulting from the pandemic is a new opportunity to collaborate with our oncologic providers to improve cancer pain medicine.

Impact of COVID-19 on cancer pain care delivery

While the pandemic has had significant impact on elective surgeries and visits, cancer care may be considered urgent for many patients. Unfortunately, active cancer patients may be susceptible to the virus's deleterious effects, and thus, a discussion is needed whether to proceed with oncologic and surgical treatments. Since oncologic care may continue during the pandemic, pain care will also be needed. Safe access to pain treatments, whether pharmacologic or interventional, should be maintained during this pandemic. However, modifications may optimize the delivery of pain care to this population.

Similar to chronic pain patients, opioid monitoring strategies are needed to curb opioid potential abuse and divergence. On the other hand, given clinic visits may be less safe for cancer patients, telemedicine consultations may be an alternative to continue pain care. Opioids have been routinely used for the treatment of oncologic pain syndromes, and the pandemic should not deter this modality as a treatment option. Thus, monitoring strategies, such as random urine drug screens and the use of opioid risk assessment tools (ORT), should be maintained. A telemedicine visit may include a nursing assessment for the opioid risks in this population. Screening questions may be given to patients prior to the physician telemedicine visit. Urine toxicology results may be obtained once safe for patients to visit a laboratory, and home kits could be considered during the interim.

While telemedicine and virtual visits may not be ideal for patient care, the system does afford a pain practitioner to provide quicker access to care. At MSKCC, the hallmark of the pain service is to provide same day new and follow up visits and if indicated, interventional pain procedures. For a cancer patient, this is a welcomed option given their primary focus is treatment of cancer.

Furthermore, oncologic services can reliably utilize pain services given the speed of consultation. A similar approach may be used by physicians, allowing for rapid consultations using telemedicine services. This will allow for same day services to support our oncologic medical and surgical colleagues. Telemedicine allows for flexibility in scheduling patients which is a welcome addition to a busy in-person visit list.

Finally, delivery of pain care requires communication among multiple services which treat oncologic pain. For example, radiation oncologists, radiologists, orthopedic surgeons, palliative and rehabilitative physicians may each provide pain care for patients suffering from bone metastasis. At MSKCC, these patients are discussed at a tumor board, however, we have noticed improvement in attendance with the use of virtual meetings. This concept may extend to all pain providers, as virtual tumor boards may connect physicians which previously were unable to attend an in-person conference. Acceptance of telemedicine should create new opportunities for collaboration and consultations which is paramount for successful delivery of cancer pain medicine.

Impact of COVID-19 on Interventional Care

Pain, individually or in combination with fatigue and loss of appetite are among the most important predictors of survival in cancer patients. Balancing cancer treatments including pain management and protection from infectious complications during the Pandemic requires a careful risk benefit analysis.

Some of the identified risks and benefits of interventional procedures during COVID-19 outbreak can be elucidated as follows.

Risks:

1. Risk of potential exposure to patient
2. Risk of potential exposure to patient care team
3. Risk of procedure related complications
4. Risk of increased local health system resource utilization (PPE, post-procedure care, etc)
5. Risk of potential immunosuppression if using systemic vs targeted steroids

Benefits:

1. Reduced morbidity and mortality risk
2. Effective and targeted pain control
3. Potential decrease in Emergency Department (ED) and urgent care surge due to uncontrolled pain
4. Decrease health care utilization with targeted precision pain management

All these risks and benefits should be individualized on a case by case scenario.

Suboptimal pain control during a Pandemic has significant downstream effects on cancer treatments; primarily chemotherapy, radiation and surgery which impact survival. Unmanaged pain also compromises the success of a comprehensive rehabilitation plan which is critical for improving function and quality of life.

Ironically, COVID-19 forced us to reinvigorate the art of chemical neurolysis in our practice. As you weigh the risk-benefit ratio of doing advanced interventions which require use of operating room; chemical neurolysis using dehydrated ethyl alcohol or phenol can be effective strategies to manage cancer pain at bedside or in office under

ultrasound guidance. Intrathecal neurolysis using appropriate barometric compound with adherence to procedural protocol can also be highly effective in appropriately selected patients.

Targeted drug delivery using intrathecal devices are an integral part of cancer pain compendium. As we see a paradigm shift towards Telemedicine, role of home care pump refilling and management services will become more critical in future. Optimum use of modalities like patient-controlled boluses also play an important role in managing cancer related breakthrough pain. Cancer patients struggling with intractable pain may also benefit from direct implantation of intrathecal drug delivery device without a bolus trial to further optimize their care.

Understanding cancer treatments will occur as the pandemic continues, it will be critical to manage side effects, specifically pain, as undertreatment of pain may lead to poorer survival outcomes.

REVIEW OF TARGETED DRUG DELIVERY SYSTEMS:

- Mansoor M. Aman M.D.
- Ammar Mahmoud M.D.
- Ali Valimahomed M.D.
- Krishnan Chakravarthy M.D. Ph.D
- Dawood Sayed M.D.
- Timothy Deer M.D.

Review of Targeted Drug Delivery Systems

Mansoor M. Aman M.D., Ammar Mahmoud M.D., Ali Valimahomed M.D., Krishnan Chakravarthy M.D. Ph.D, Dawood Sayed M.D., Timothy Deer M.D.

Abstract:

Intrathecal drug delivery has an established role in the management of chronic pain and spasticity disorders. The purpose of this educational review is to highlight the important similarities and differences between the two current platforms including Medtronic SynchroMed™ II and Flowonix Prometra II.

Introduction:

Targeted drug delivery platforms are recognized as a safe, therapeutic and cost effective in managing spasticity, multifactorial refractory chronic non-cancer and malignant cancer-associated pain (1-7). An intrathecal spinal catheter is connected to a pump reservoir delivering medications that agonize or antagonize various receptors including opioid, sodium channel, calcium channel, alpha-adrenergic and gamma–aminobutyric acid (GABA-B) (8-10). The two current generation intra-thecal pump systems that are commonly utilized are the Medtronic SynchroMedTM II and Flowonix Prometra II. The decision for which device to utilize may be based upon physician preference and familiarity, differences in technology, MRI compatibility, and available support in locale. Both company's medical devices are FDA approved and undergo routine reviews as manufacturers change production methods or revise components of the pump in order to improve safety and accuracy. The purpose of this review is to highlight key similarities and differences in both available intrathecal pump systems.

Platform Selection:

Device selection should be individualized and guided by patient specific factors, while accounting for manufacturer differences. Both the Medtronic SynchroMed II and Flowonix Prometra II are indicated for the treatment of pain and spasticity, however the Flowonix Prometra II system was only recently approved for baclofen in February 2020.

Implant and Refill Procedure:

The surgical technique for implanting both pumps is relatively similar and beyond the scope of this review. Both catheters can be visualized on fluoroscopic examination. The Medtronic Ascenda catheter has a radiopaque tip (Figure 1A), while the Prometra II catheter has a larger radiopaque catheter tip improving visualization (Figure 1B). Both catheters offer a suture-less connection between the intraspinal catheter and pump. It is worth noting that the catheter stem for Prometra II is flexible and the SynchroMed™ II stem is rigid. This may impact the technique of implant, but no prospective comparative data exists in this two catheter materials. In regards to anchoring the pump to a fascial plane, the SynchroMed™ II has four prearranged metal rings (Figure 2A) while the Prometra II pump has a 360-degree silicon suture ring (Figure 2B). Ultrasound examination of both pumps demonstrates differences in the shape of the refill port, where the SynchroMed™ II port is flush and the Prometra II port is elevated (Figure 3A and 3B).

Differences in Core Technology and MRI Compatibility:

Movement of cerebral spinal fluid (CSF) is not laminar or circulatory, instead it is oscillatory and turbulent. It is influenced by both cardiac, and respiratory cycles, and the surrounding microenvironments created by various neural structures (12, 13). Although these properties of CSF flow can lead to limited intrathecal drug distribution, various intrathecal pump infusion settings can optimize drug delivery. Injection kinetics and volume are two of the main variables that influence the spread of intrathecal medications in the cerebral spinal fluid (CSF). Agent specific biochemical properties such as lipophilicity and hydrophilicity will also influence spread (13).

The Medtronic SynchroMedTM II utilizes a peristaltic pump roller system to drive the medication intrathecally. Average clinical accuracy is rated at 101% while manufacturer bench accuracy allows for ±14.5 % deviation for precision of flow rate between 85.5%-114.5%. Measurement error is ± 10% and based upon expected volume infused, and not actual reservoir residual. Wesemann et al. assessed the clinical accuracy and measured drug residual volumes at time of refill found an average of 2.5% over infusion than what was programmed when analysis was done on a per-refill basis (14). A recent retrospective review of 149 patients with 755 individual encounters over 2.5 years demonstrated a tendency to under infuse as both the 20 mL and 40 mL pumps aged, while remaining within the aforementioned error rates. (15). No over infusions were seen in this cohort. The SynchroMedTM II is labeled MRI conditional at 3.0 and 1.5 Tesla under specific conditions. Before MRI, the therapy should be discontinued, and restarted after the scan. In the event that therapy is not discontinued, a “motor stall event” will occur with automatic restart within 30 minutes of the scan. It is recommended to interrogate the system within 24 hours after MRI to ensure the pump has restarted appropriately.

The Flowonix Prometra II system uses a non-motorized gas pressurized valve gated dose regulation system and has an accuracy of 97.4%, with a 90% confidence interval of 96.8%-98.0% as evaluated in the prospective, multi-center PUMP study (16). Bench accuracy labeling specifications allow for a range of 85%-115%. Accuracy reported in a long-term follow up at an average of 2.5 years was 97.9% (17). Unlike the Medtronic device which has post market studies, the PUMP study was the only major trial conducted of this device published

in peer review. A long-term open label prospective study evaluating the safety of Prometra in 401 implanted patients between 2013-2016 reported promising interim results in 2017 at a national meeting (18). Primary endpoint was long term granuloma formation at five years with secondary measures of pump failure rate, battery end of life and device related adverse events. There was a 0.25% incidence of granuloma formation and 1.5% serious adverse events such as cellulitis at the implant site, pump pocket infection, bacterial meningitis, post dural puncture headache. The Polyanalgesic Consensus Conference (PACC) recommendations should be followed to improve long-term safety (19) and optimize therapy (13). Bolusing of intrathecal medications can be advantageous in order to increase injection velocity, overcome baseline pulsatile CSF flow, dose a larger portion of the spinal cord faster, increase medication density over a larger portion of the spinal cord, obtain more rostral spread of medication, and prevent higher local concentrations of medication at the catheter site – thus reducing incidence of granuloma (20). The Prometra II pump is labelled MRI conditional at 1.5 Tesla however it requires pre-MRI discontinuation of therapy, emptying the medication from the pump reservoir, followed by a post-MRI interrogation and re-initiation of therapy (21). In contrast to older generation Prometra pump; the Prometra II has a flow-activated valve, which serves as a safety measure to avoid over infusion of drug by shutting off drug flow when the pump is exposed to strong magnetic fields (emergent MRI). However, manufacturer guidance should be followed.

Programming capabilities:

Both systems offer a variety of programming capabilities through Bluetooth enabled, secure and intuitive physician programmers. Medtronic offers a touch screen tablet with a wireless communicator for programming, and a patient controlled demand bolus function through their Personal therapy Management (PTM) device. The Flowonix programmer is a touch screen phone (Figure 4A and 4B) and similarly allows for patient controlled demand blouses through their Personal therapy Controller (PTC) device. Both patient control devices need to be placed over the patients pump in order to deliver a bolus. Special consideration regarding the site of pump reservoir implantation is crucial especially in those where implantation is being considered at the back, to ensure the patient can reach the pump site to allow successful activation and accurate delivery of patient activated demand boluses. Both systems allow the clinician to program the number of boluses delivered each day, duration of time over which the bolus is administered, and designate lockout periods to tailor to patient specific needs.

Since the Flowonix's Prometra II intrathecal pump is a non-motorized gas pressurized valve-gated bolusing pump, the volume of medication which is delivered per bolus from the pump remains constant (reported 97% accuracy). It is dependent on the volume of the pump accumulator, which is approximately 2 mcL (varies between 2-3 mcL). The pump is capable of delivering a medication bolus once every six seconds, or ten times per minute, and can achieve a maximum of up to 28.8 ml of medication per day (22). This system does not require a basal flow rate and can be set to 0 ml/day. This may be particularly important when microdosing with potent chemical neuromodulation such as Ziconitide.

The Flowonix pump offers a “Constant Flow” regimen in which the provider sets the desired daily medication dose. Based on the medication concentration, the computer then calculates the number of boluses (2 mcL) that are needed in a 24-hour time period to achieve the correct daily dose. It will then equally disperse the medication delivery over the course of the day to maintain a relative steady state. The “Multiple Rates” regimen delivers up to four different rates which repeat daily. The dose and start / stop times for each period are programmed by the clinician for each rate. The minimum time period for each rate is 1 minute.

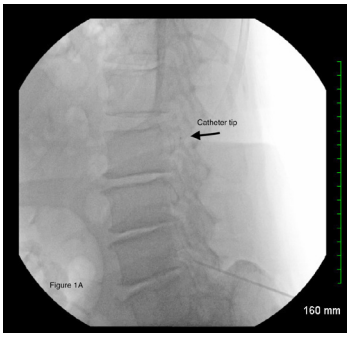
The "Periodic Flow" regimen delivers medication in a sequence of periodic infusions with a basal dose. It is worth noting that the basal rate on the pump can be set to zero; thus, in actuality no basal rate is required between boluses. The maximum number of bolus is 1 per hour or 24 periods in the course of a day.

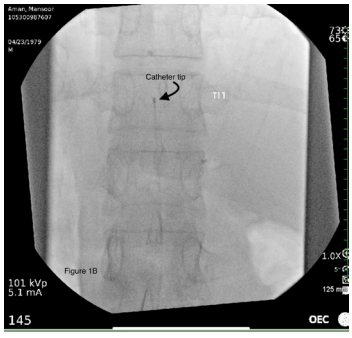
The Medtronic SynchroMedTM II has multiple programming capabilities that are available including the "Simple Continuous" setting, which allows for the total daily dose to be divided by twenty-four hours and constantly infused. A "Flex Dosing" regimen enables the physician to schedule fixed doses that are bloused at specified intervals throughout the day, in addition to a basal infusion. By decreasing the time over which the Flex Dosing is delivered, medication delivery velocity can be increased in order accomplish more cephalad spread of medication. A demand bolus at 1 ml/min will have sixty times the velocity of an infusion at 1 ml/hr.

Conclusion:

In summary, both Medtronic SynchroMedTM II and Flowonix Prometra II have clinical accuracy in their technology, established record of safety, and a multitude of programming capabilities [Table 1]. The important similarities and differences were discussed in this educational review as familiarity with both systems is advantageous when implanting and/or managing patients with targeted drug delivery devices.

Appendix:





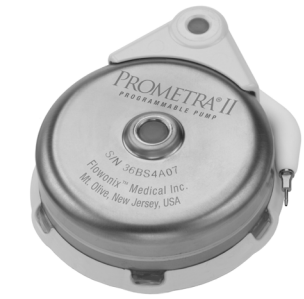
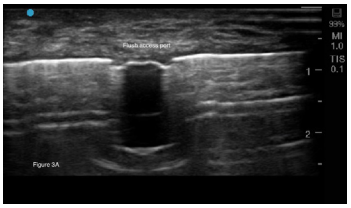
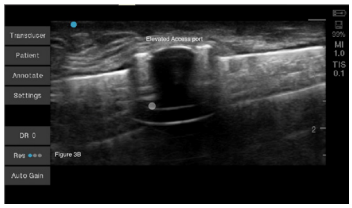


Figure 2B





Specification	Flowonix: Prometra II	Medtronic: Synchromed II
Delivery Mechanism	Valve-gated (gas pressurized) bolusing pump	Peristaltic (motorized) continuous pump
Dose Dispenser	Dosing Chamber surrounded by electronic valves	3 Rotors, motor and ball bearings
Dose Volume	2 mcL	Variable
Pump Stem	Flexible silicone	Rigid titanium
Cather Tip	Radiopaque (Tungsten)	Radiopaque (Titanium)
Catheter Length	110 cm	89 - 104.1 cm
Catheter Openings	8 side ports (located in distal 1 cm)	4
Resevoir Volume	20 cc or 40 cc	20 cc or 40 cc
Pump Diameter	69 mm	72 mm
Pump Height	20 mm	19.5 mm (20 cc), *** (40 cc)
Weight (Unfilled)	150 grams	165 grames (20 cc), *** (40 cc)
Anchoring	360 plastic suture ring	4 metal suture loop holes
Flow Rate	0.0 – 28.8 ml/day	0.048 – 24 ml/day
Minimal Flow Rate	0 ml/day	0.048 ml/day
Maximal Flow Rate	28.8 ml/day	24.0 ml/day
Clinical Flow Accurancy	98%	101%
Bench Flow Accuracy	Range of 85%-115%	Range of 85.5%-114.5%
Refill Septum	Elevated, 8 mm diameter	Flush, 6.8 mm diameter
Fill Port Pressure	22.5 PSI	3-5 PSI
Battery Life	10 years	7 years
MRI Compatibility	MRI Conditional: Empty prior to MRI; Refill following	Full body 1.5T & 3T MRI Conditional : Interrogate following MRI
On Label Medications	Morphine, Baclofen, Ziconitide	Morphine, Baclofen, Ziconitide
Flow modes	Continuous Flow, Multiple Flow, Periodic Flow, Demand Bolus	Simple Continuous, Flex Dosing, Demand Bolus
Patient controller	Touch screen, dedicated dosing button, must be placed over the pump, auditory tone when medication delivered	Touch screen phone device, dedicated dosing button, needs to be placed over device for demand bolusing
Interogator	Wireless touch screen phones	Wireless touch screen phones
Company Years on the Market	8	71
Disadvantages	Constant velocity, may be more difficult to target medication to small area, need to empty pump prior to MRI	Decreased accuracy, increased granuloma formation, potential for motor stalls, shorter battery life, basal rate required, need to interrogate after MRI
Advantages	Longer battery life, pressurized access port provides confidence that needle is inside pump possibly decreasing incidence of pocket fills, high velocity boluses allows more raustral medication spread, less affected by environmental factors such as altitude and tempera-ture, Periodic Flow, larger radioopaque catheter tip	Hassle free MRI workflow, intuitive tablet for physician programming and patient demand bolus smartphone, multiple peer reviewed publications documenting safety and accuracy within bench met-rics , radioopaque catheter tip

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22. Flowonix. PROMETRA® II PROGRAMMABLE PUMP (REF 93827)

For use with Intrathecal Catheter. 2017.

Tribute to Lisa Stearns, M.D.

from Jessica Jameson, M.D.

Dr. Lisa Stearns contributed more to the field of medicine than any physician I have known. She not only was passionate about her work and dedicated to her patients but above all else, she leaves a legacy of kindness that is unparalleled. Lisa Stearns was so much more than that to me and to the many women across the globe that she mentored. She was a mentor and an example. She modeled for us how to carry ourselves, how to ask for what we wanted, and how to not take "no" for an answer. She was a fierce champion for women in pain management. She was graceful yet persistent. Kind yet strong. Driven yet gentle. She would tell stories about what it was like to be a pregnant female resident in the early 1990s. What she endured was extremely difficult….and yet she persisted. She experienced criticisms from her peers at numerous points during her career….. and she persisted. She wasn't angry or bitter, although either of those would have been understandable, but remained positive and focused. She cared for her patients more than anyone I have known. Routinely putting in 16 hour days to ensure that her patients knew that during the most difficult times of their lives….Dr Stearns was there for them.

LISA STEARNS, M.D.

I remember being at our first Society for Women Innovators in Pain Management Conference last year. Lisa was instrumental in the formation of this society and passionate about what it stood for. The conference fell on my youngest child's fourth birthday which I had casually mentioned earlier that day over lunch. That evening we sauntered over to a park near the hotel and had a picnic. My son came down to the playground toward the end of the night and Lisa pulled out a wrapped birthday gift of a beautiful and special book with a matching stuffed animal. She bent down to his level and said "everyone needs an Auntie Lisa". She had taken the 30 min break we had in that day to go out of her way to make my son's birthday special. She was selfless and caring. We still read that book and he sleeps with that stuffed animal. The book has taken on a new meaning with the loss of Lisa. It's a daily reminder to love, to live, and to laugh. It reminds me of Lisa and her heart, her smile and her legacy.

Speaking for myself and every physician and patient that she has touched over her illustrious career, thank you Lisa. Thank you for your mentorship, for your example, for your leadership, for your passion, but most of all thank you for your friendship. You have left a mark that cannot be put into words. You will be a part of who we are and who we become and we are proud and honored to continue your great legacy.

Jessica Jameson, M.D.

UPCOMING EVENTS

ASPN
THE AMERICAN SOCIETY of PAIN & NEUROSCIENCE

ASPN DRG-SCS CME WEBINAR

June 18 at 9:00PM EST

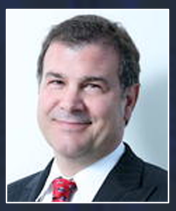
MODERATORS

Timothy Deer, MD

Krishnan Chakravarthy, MD, PhD

FACULTY

Pankaj Mehta, MD



Timothy Lubenow, MD

Jackie Weisbein, DO

Jason Pope, MD

Jonathan Carlson, MD

Kenneth Chapman, MD

CME CREDITS

TOPICS

Review of DRG Science • Review of DRG Technique
Review of DRG Clinical Data • Future Areas of Research/Indication Expansion


VIRTUAL HAPPY HOUR
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