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Patient Satisfaction Following Intrathecal Targeted Drug Delivery for Benign Chronic Pain: Results of a Single-Center Survey Study

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Objectives: Targeted Drug Delivery (TDD) is commonly used for the management of patients with intractable pain. Past studies have proven efficacy in pain relief and reduction in opioid use and cost-effectiveness in long-term pain management. There are few studies investigating satisfaction among patients with implanted pain pumps that are managed with targeted intrathecal medications.

Material and Methods: Patients in a single medical practice implanted with pain pumps for relief of intractable pain were identified and extracted from the electronic health record (EHR). Six hundred and ten active TDD patients were identified and an anonymous 18-question survey was administered to determine satisfaction with TDD therapy. During an 18-month period from May 2018 to August 2019, patients were invited to take a satisfaction survey. Both primary and secondary outcomes were reported as proportions; $P < 0.05$ was considered significant.

Results: Four hundred and forty-three patients (74% of the active pump population) completed the survey. The majority of patients reported improvement in pain, improvement of physical function, improvement in quality of life and reduction in opioid use. Complete discontinuation of oral opioid intake was reported in 38.9% of patients. The majority of patients had a 40 cc reservoir implanted in an upper buttock pocket site and overall, 91% of patients were happy with pump pocket location.

Conclusion: Intrathecal TDD therapy can relieve pain and improve quality of life in patients with intractable pain and offers a reasonable alternative to long-term oral or skin patch opioid management. Patients utilizing TDD therapy reported high degrees of satisfaction.

Keywords: Chronic pain, intrathecal, opioids, satisfaction

Conflict of Interest: Dr. Schultz is a paid consultant to Medtronic and Abbott. Dr. Abd-Elsayed is a consultant for Medtronic, StimWave, and Avanos. The other authors declare no conflicts of interest related to the present study.

INTRODUCTION

Intrathecal targeted drug delivery (TDD) via an implantable device was first utilized in the early 1980s as a method for treating intractable pain (1). Since then, many clinical studies have proven the efficacy of TDD in treating cancer pain and chronic pain of benign origin (2–10). TDD involves implantation of a programmable infusion pump and intrathecal catheter in a reversible, nondestructive procedure and is typically considered as a last resort option in patients who have failed all conservative treatments (11). Pump medications are "targeted" to the spinal cord rather than the brain, and block pain at the spinal cord level, thus keeping the brain free from drug effects. Compared to oral and transdermal opioid management for chronic pain, intrathecal TDD shows superior functional improvement and more tolerable side effects (11,12).

Currently, most studies of TDD focus on clinical improvement in pain. Commonly used primary outcome measures include visual analog scales (VAS) and numerical rating scales (NRS) (13–15). Other outcomes, less frequently assessed, include measurements of quality of life, disability scales, and reduction in use of oral opioids (16–19). Subjective patient satisfaction with intrathecal TDD is described to a lesser extent in most studies (20,21).

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Chronic pain is known to have a negative impact on quality of life and describing patient satisfaction as a means of evaluating efficacy of intrathecal TDD treatment provides researchers with an insight into patients' real world experiences and perceptions (22).

One of the author's (DS) private practice pain clinic has provided TDD with implanted pain pumps for the past 25 years and currently manages a large number of TDD patients. The therapeutic goal with TDD is to move patients from the "fix it" path of more surgeries and medical interventions to the "quality of life" path of reduced pain and improved function. We sought to determine the level of satisfaction with TDD among pump patients in this practice in order to validate our most common TDD practices.

The Polyanalgesia Consensus Conference statement in 2017 recommends morphine and ziconotide as first line while considering fentanyl and Marcaine only if first line recommendations fail (23,24). In our practice, we mostly used fentanyl-bupivacaine admixtures as well as morphine or hydromorphone instead of fentanyl depending on the location of pain. The continuous intrathecal infusion of fentanyl and bupivacaine with patient-administered bolus dosing per the Medtronic Patient Therapy Manager (PTM) was commonly adopted in our practice (25). Most pumps over the past five years in this practice were implanted with 40 cc Medtronic Synchromed II devices (Minneapolis, MN, USA), and over 80% of pumps were implanted in an upper buttock pocket site.

The main goal of this study is to evaluate patient satisfaction with TDD therapy as used in a busy private practice-pain setting and the impact of TDD on quality of life for patients suffering with benign chronic pain.

MATERIALS AND METHODS

Patient Population

At a single pain practice in Minnesota, patients with pain pumps initially implanted between 1994 and 2018 after psychological evaluation were identified. Of these patients, 610 were actively managed with TDD at the time of the survey by a team of specialized nurses and advanced practice providers headed by a physician implanter.

Typical TDD patients suffer from complex chronic pain that has failed previous pain management efforts and these patients are often referred to our center on high doses of oral or transdermal opioids. All patients who are considered for TDD must first fail conservative care, which typically includes medication management, physical therapy, psychology-based treatments, and minimally invasive interventional pain procedures. Many TDD patients have also failed to respond to one or more spinal surgeries. In addition, most patients who are ultimately implanted with a pain pump have failed to respond to neurostimulation with epidural electrodes.

Survey

In order to evaluate the satisfaction of our TDD patients, we offered an anonymous 18- question survey (Survey Monkey) to patients with active TDD therapy. We sought feedback on TDD as a pain management option and overall satisfaction with the implanted pain pump using multiple-choice questions (Supplemental Fig. S1) with a free-text section for additional comments. Patients were asked to complete the survey in clinic using an iPad. The survey was voluntary and anonymous, and patients did not receive any compensation for survey completion.

Outcomes

The primary outcomes of this survey were defined as patient satisfaction across three domains: relief of pain, improvement in quality of life, and improvement in physical function. Secondary outcomes evaluated opioid consumption, healthcare utilization, comfort of the implanted pump, and side effects.

Statistical Analysis

Survey responses were analyzed by investigators not involved in generation of survey questions. Data regarding the implant practices (size and location of implanted pump, catheter tip location, surgery times, infection rates) were analyzed from our medical practice electronic health record (NextGen, Irvine, CA, USA) for years 2018 and 2019 and from our private practice data contained within the Medtronic Patient Surveillance Registry (PSR) database (Medtronic) from 2003 to 2018. We report data as a number or percentage. Nominal data were analyzed using either chi-square or Fischer's exact test as it statistically fits. P values <0.05 were considered significant. Statistical tests were performed with the use of Stata Corp 2016 (Stata: Release 14.2, statistical software; College Station, TX, USA).

RESULTS

Of the 610 active pump patients in this practice, 443 responded to the survey (74% response rate). Respondents were aged 28 to 94 years old and 61% were female (Fig. 1). The most common indication for patients with targeted drug delivery therapy were post laminectomy syndrome (51.26%), lumbar spondylosis with radiculopathy (9.55%), lumbar intervertebral disc disorders with radiculopathy (5.53%), neoplasm related pain (4.52%), and unspecified abdominal pain (4.04%) (Fig. 2). Of the 166 patients with comorbidities listed, 46% had hypertension, 44% had BMI greater than 30 kg/m^2, 27% had a history of addiction, 19% had type 2 diabetes and hypertension, 9% had chronic obstructive pulmonary disease, 8% had type 2 diabetes and 8% had a combination of multiple comorbidities (Fig. 3).

Improvements in Pain, Physical Function, and Quality of Life

Overall, 94% (398/422) of patients reported improved pain control following pump implantation with 59% of patients stating their pump provides good to excellent pain relief (249/422). Six percent (24/422) of patients reported worsened pain control following pump implantation (Supplemental File, Question 1).

Importantly, 77.6% (318/410) of patients stated they had improved physical functioning after TDD. Only 3.4% reported worse functioning after pump implant (14/410). Overall, 86.4% (357/413) of patients responded that pump implantation improved their quality of life compared to preimplantation. Only 9/414 (2.18%) reported worsened quality of life following pump implantation.

Opioid Consumption

In regard to continued oral and transdermal opioid intake, 88.4% of survey responders reported taking less oral opioid medication than before pump implantation and no pump patients were taking transdermal or long-acting oral opioids after implant. Impressively, 38.9% of patients stated they had completely

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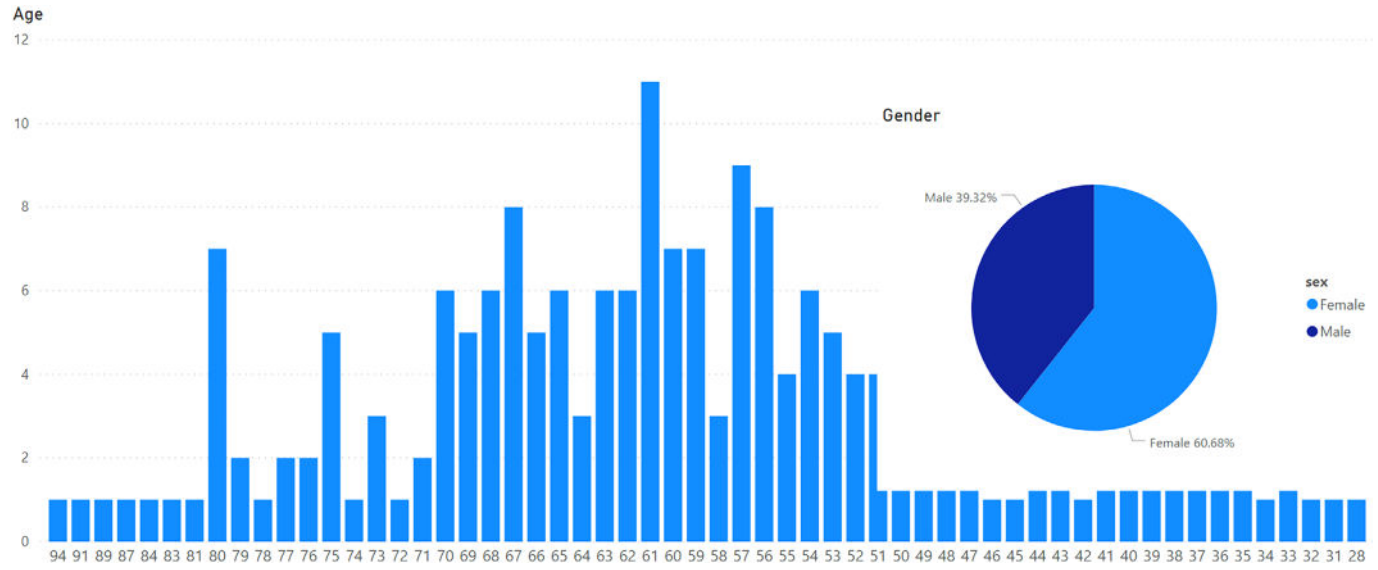

Figure 1. Age and gender distribution of patients included in our study. [Color figure can be viewed at wileyonlinelibrary.com]

stopped all opioid intake and solely relied on TDD for pain control.

Side Effects

Patient-reported side effects were also diminished following pump implantation. Seventy-two percent reported being more mentally alert. More than half of the patients reported having no side effects (57.8%) from TDD and, overall, 93.4% reported no or manageable side effects. Of those patients with side effects, constipation was the most common (38.11% of 307 respondents) (Supplemental file). Ten years of PSR data shows that the most common adverse events were untoward drug reactions and that serious adverse events were rare and usually involved device-related infections (Figs. 4, 5).

Pump and Catheter Tip Location

Our approach has always been to place the catheter tip at the site of maximal pain. The relative frequency of catheter tip locations with spinal levels ranged from C1 for head and face pain down to T12 for pain in lower extremities (Fig. 6). We have seen no increased incidence of side effects or complications related to placement of catheter tips at cervical spinal levels.

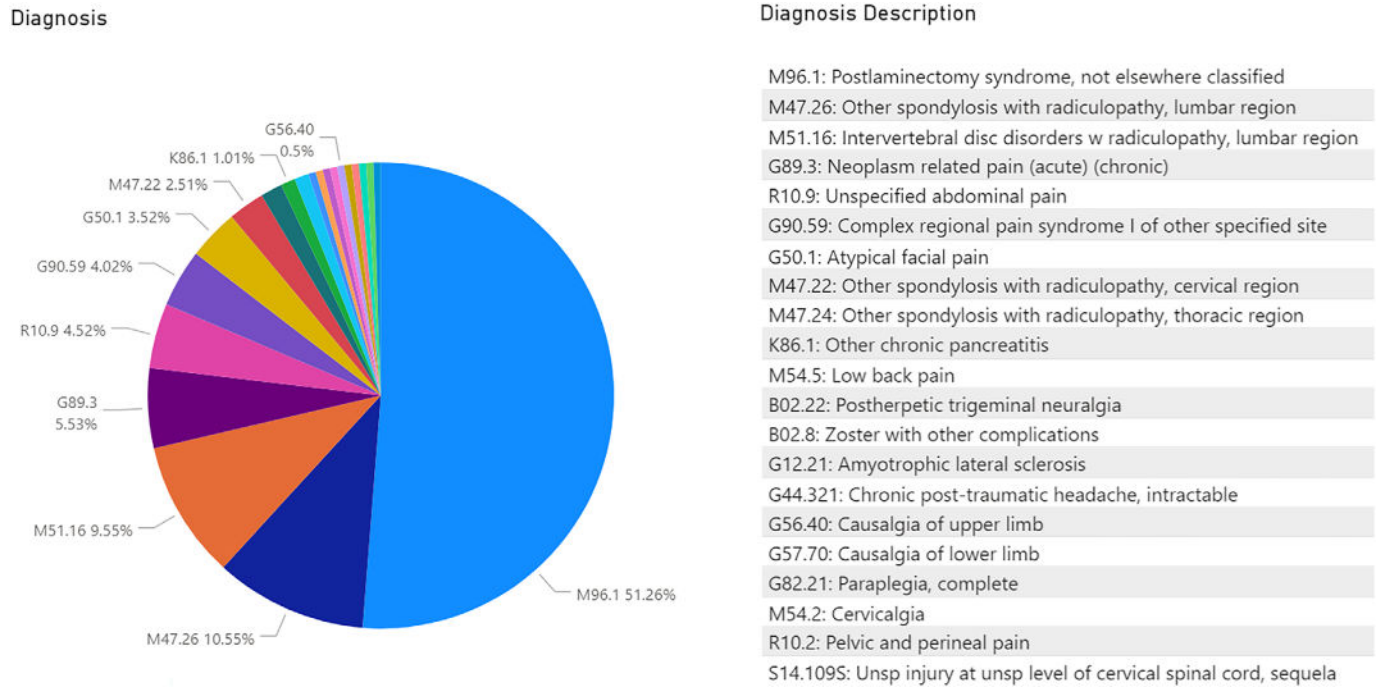

Figure 2. Diagnosis indications for patients with intrathecal pump therapy. [Color figure can be viewed at wileyonlinelibrary.com]

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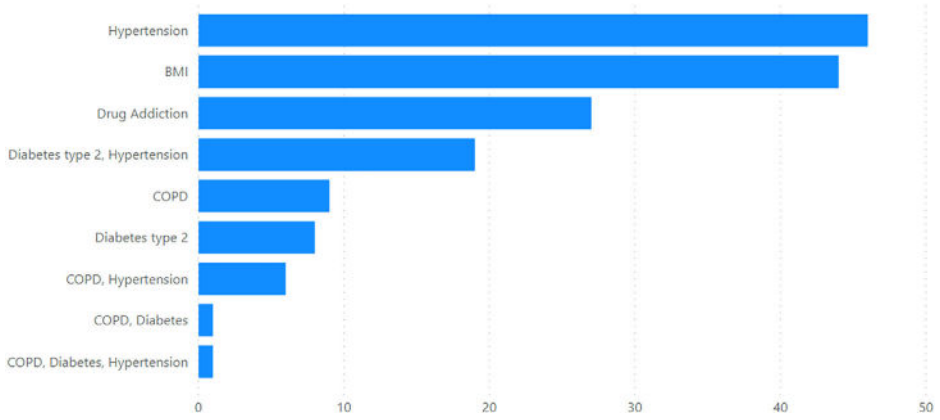

Figure 3. Distribution of patient comorbidities. [Color figure can be viewed at wileyonlinelibrary.com]

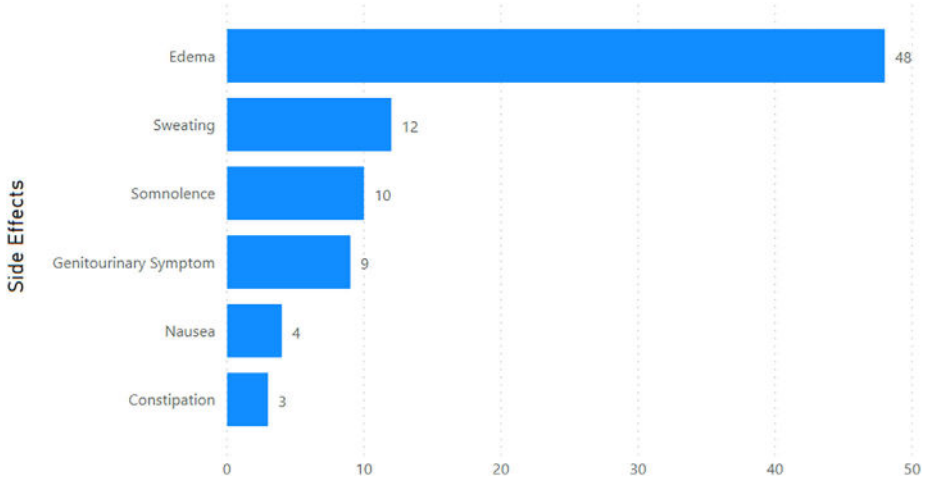

Figure 4. Distribution of side effect profiles reported from Medtronic Patient Surveillance Registry. [Color figure can be viewed at wileyonlinelibrary.com]

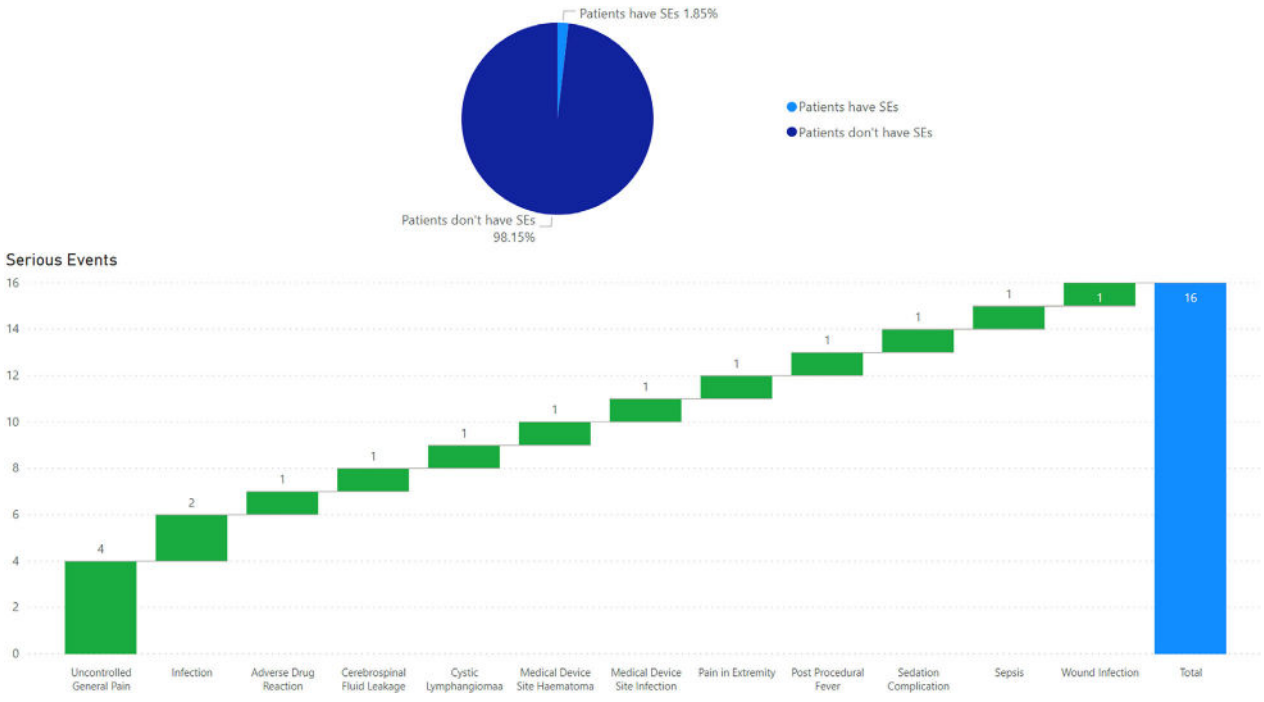

Figure 5. Serious adverse events reported from Medtronic Patient Surveillance Registry. [Color figure can be viewed at wileyonlinelibrary.com]

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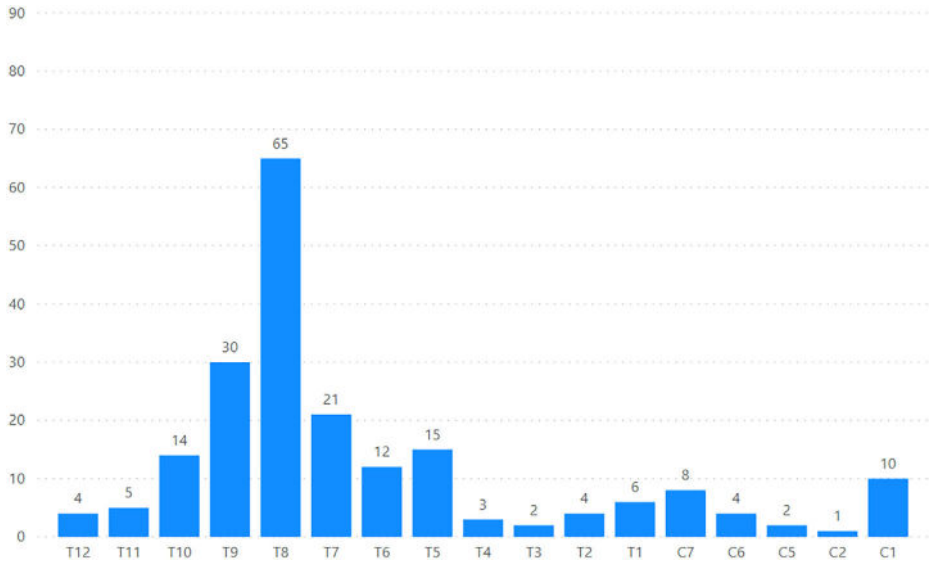

Figure 6. Distribution of location of catheter tips. [Color figure can be viewed at wileyonlinelibrary.com]

Pump discomfort and pocket site pain were additional concerns we addressed. The pump reservoir was implanted in the upper buttock in 76.4% (314/411) of patients and in the abdomen in 14.6% (60/411), and a majority of patients had the larger 40 cc pump size (Fig. 7). Upper buttock pump implant allows for prone positioning and decreased surgery times with infection rates less than 1% in this cohort (Fig. 5). The pump was reported as comfortable by 92.1% of respondents. Regardless of buttock or abdomen pump pocket, 91% of patients were happy with the location of their pump (Supplemental file).

Healthcare Utilization

In terms of healthcare utilization, 76.9% of survey respondents stated that they had not gone to the ER or hospital for pain since their pain pump was implanted. Another 15.1% reported going less often than before. Seven percent said they go to the ER/hospital about as often as before and only 1% of respondents said they went to the ER/hospital more after the pump implant than before.

DISCUSSION

Targeted drug delivery is a proven effective treatment choice for chronic pain of benign origin (13,14,16). Long-term pain relief and adverse events have been previously described (17,18,20). In this study, we focused on patient satisfaction including improvements in chronic pain, physical function, quality of life, opioid consumption, and commonly reported side effects.

Improvements in Pain, Physical Function, and Quality of Life

Since our survey was anonymous, we cannot correlate diagnosis for implant, intrathecal medication choices, TDD dosages, catheter tip location, or other specifics of management with patient satisfaction. We can provide additional data on common TDD practice in our clinic and plan to do so in a future publication.

Overall, 95.9% (328/342) of patients we surveyed reported some degree of benefit from intrathecal TDD therapy and 86.4% (357/413) patients reported improvement in quality of life compared to preimplantation. These rates are comparable to previous studies in which patient satisfaction is assessed, ranging between

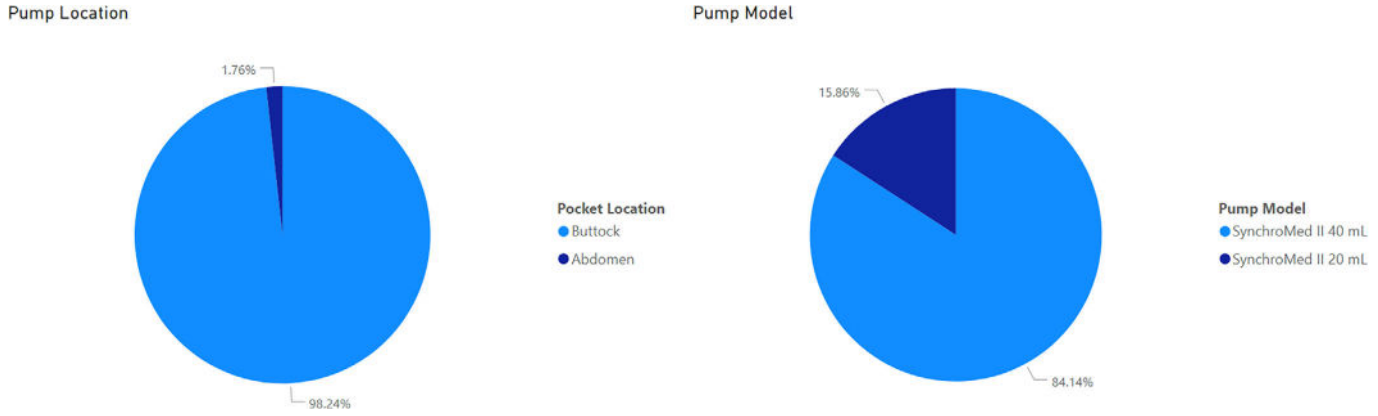

Figure 7. Pump location and size. [Color figure can be viewed at wileyonlinelibrary.com]

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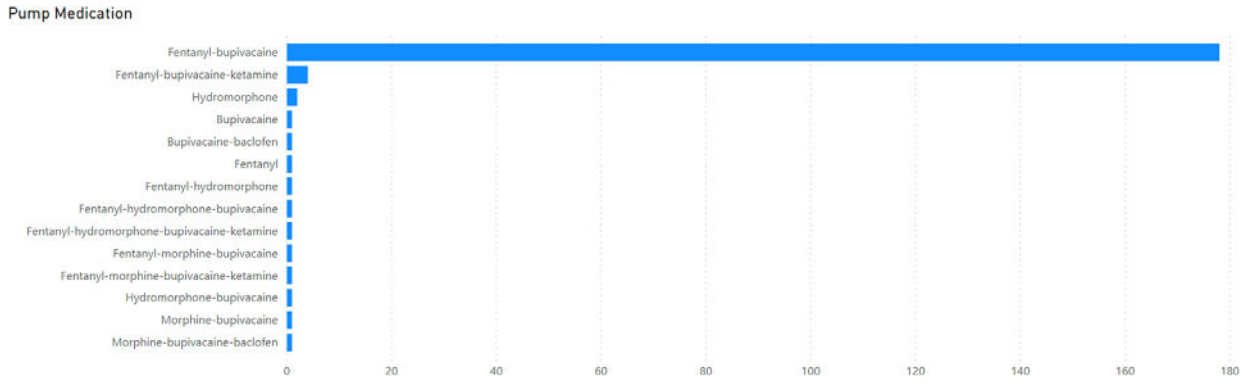

Figure 8. Distribution of intrathecal pump medications. [Color figure can be viewed at wileyonlinelibrary.com]

80 and 100% (12,13,19,26–29). However, one prospective study using intrathecal morphine therapy for the treatment of chronic nonmalignant pain observed a patient satisfaction rate of 63% (30), which may be explained by their small sample size of 16 subjects and their exclusive use of morphine monotherapy. The most commonly used pump medication in our practice is a compounded

Table 1. Free-Text Comments From Patients Following Targeted Drug Delivery Therapy.

Representative quote from positive review	Representative quote from negative review
Patient-related attributes	
The pump has saved my life. I know I could tolerate the pain for a week at a time, but I don't think I could have done it much longer. Life was getting very impossible for me.	My pain still needs a boost between fills. I also use my physical therapy to ease pain. Most if the time it does the trick.
I'm a full-time attorney and I can again focus and be successful, and most importantly I have been able to once again enjoy my time with my two boys. To say Dr. * was a life saver for me is an understatement.	My pump changed my life but I'm still unable to do a lot of things. My pain is still so severe that I remain disabled and cannot work.
I can honestly say that I wouldn't be alive today without the pump. I was in a wheelchair, on a feeding tube, spent as much time hospitalized as I did at home for pain control and dehydration. The pump not only took me out of the never-ending loop of hospitalizations, but my entire life resumed some normalcy that I never would have dreamt possible.	My pump has changed my life a lot, but sometimes the pain returns and is major. I also have new pain that I didn't have before.
The best thing I ever did since ending up disabled at 45 and barely able to walk. This was the right decision. Thanks DR * forgiving me my life back.	The pain in my lower back has improved, however cervical and thoracic pain is getting worse.
My pump literally saved my life. The chronic pain before my pump was intolerable and I had no quality of life!	
The pump saved my life. Prior to the pump, I had every type of therapy, chiropractic, every type of shots that exist, the process where they "burn" the nerves, and T1 though T12 fused. I was taking literally many, many hundreds of pain pills per day (oxycontin, tramadol, gabapentin and as much Tylenol as possible) and it had gotten to the point where it provide almost no pain relief.	
Physician-related attributes	
I feel very fortunate to have the pump, without it I do not think I could function anywhere near as well as I do now. I am very happy with my relationship I have with my doctors and staff at MAPS and thank them for all they continue to do to help me.	
Best thing I ever did for myself and my family. Changed my life! Referred multiple people here and will continue to do so!	
Procedure-related attributes	
This was my last resort to 10 years of going through everything possible to trying to control my pain. The pump saved my life, literally. It is my miracle in life. Thank you.	I still feel that it's not completely dialed in, I don't get anywhere close to the relief that I did with the trial.
My pump works so much better, now that I have the neurostimulator also they work better together.	It does help, unfortunately, my pump does work but the pump has been replaced once and the tubes have been replaced once.
I would like to consider the larger pump to reduce the fill trips, but I also really like having it in my rear hip area so that it is not very noticeable	I received my pump in 2015 and it worked so well for me and I was very happy to feel the relief that I received from it but in the last 8 months or so it has been working less & less to the point that now I am in much pain again.

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fentanyl/bupivacaine admixture, because we believe that simultaneously blocking spinal mu receptors and nerve conduction provides for better pain relief and lowers spinal opioid requirements (Fig. 8).

Technological advancements in pain pump technology (patient-controlled analgesia capability, improved catheter design, 40 cc pump reservoir) and evidence supporting the use of spinal medication admixtures (24) have had positive impacts on efficacy of TDD and subsequent improvements in physical function and quality of life (31). TDD has been shown to be a cost-effective alternative to traditional medication management of intractable chronic benign and cancer pain (31–33). With strong associations between improvement of chronic pain and its positive effect on physical function and quality of life, our results are consistent with reports of previous studies (13,18). The minority of survey respondents who reported worsening of physical function or quality of life postimplant may be explained by presence of rare adverse events or the small proportion of patients who do not respond to intrathecal TDD therapy.

Opioid Consumption

Postimplant, 88.4% of survey responders reported taking less oral opioid medication and 38.9% of patients stated they had completely stopped oral and transdermal opioid intake (Supplemental file). Different studies have assessed decrease in oral opioid use by measurements of changes in dose consumed, percentage of patients nonreliant on oral opioids and scoring scales of medication consumption (15–17,26,34–37). Throughout all these different measurements, there were observed decreases in oral opioid use following TDD therapy, with one study showing a 92% rate of elimination of oral opioid use over a 5-year follow-up period (16). Another study following long-term effects of oral opioid use in patients with intrathecal TDD therapy showed a reduction in oral opioid use over the follow-up period (38).

Side Effects

With regards to side effects following pump implant, 57.8% of respondents reported having no side effects with 93.4% reporting no or manageable side effects. Seventy-two percent of patients reported being more mentally alert with TDD compared to pre-implant oral or skin patch opioid consumption. The most commonly reported side effect in our sample was constipation, although this may be associated with continued use of oral opioids in some patients. Complications of TDD therapy can be divided into categories of mechanical system complications, pharmacological complications, surgical complications, patient-specific complications, and refill complications (25). Previously conducted studies report gastrointestinal symptoms, including nausea, vomiting, and constipation as the most commonly reported side effects (13,18,30,36). Other side effects following pump implantation include neurological symptoms, including dizziness, headache, confusion, and urinary retention (2,4,6,26,37). Although complications and side effects of TDD therapy are not uncommon, they are mostly milder, more manageable and less disabling than side effects from high-dose oral or skin-patch opioids.

Healthcare Utilization

In our patient sample, 76.9% of respondents stated that they had not gone to the ER or hospital for pain since their pain pump was implanted, 15.1% reported going less often than before, and 7% said they go to the ER/hospital about as often as before. Only 1% of respondents said they went to the ER/hospital more often after pump implant than before. Our results are consistent with a study in which inpatient and outpatient expenditures were assessed, and results showed a reduction of $3388 to $4465 in total annual cost, 120 to 210 days postimplant (35). The technical success rates of device implantation allow for fewer device explants and subsequent lower healthcare costs, with one study describing 559 implantations with 78 premature extractions (31). The premature extractions were most commonly due to infection, lack of efficacy, and surgical complications (31). The overall infection rate after implant in our practice is 0.5% and none of our survey respondents had their pumps explanted for surgical complications or lack of efficacy. This may be due in part to the short operating times with prone positioning. Compared to conventional opioid therapy for chronic pain, TDD therapy is more cost-effective in the long-term (33). According to one study, TDD costs are higher than conventional therapy 1 year postimplant but costs break even in 2 years, and over a lifetime span, the study concluded TDD costs to be $3111 less expensive per patient per year compared to conventional therapy (33). In addition to reduced oral opioid use in chronic pain patients with TDD implants, these patients also have fewer comorbidities, including depression and anxiety, and subsequent reduction in use of antidepressants and antianxiety medications (12). With these indirect effects, we can expect fewer hospital visits and lower healthcare costs.

Limitations

Our survey was conducted at a single center that has >25 years of experience in initiating and maintaining intrathecal TDD therapy. Therefore, our results may not be generalized to every site offering the therapy. In addition, though the survey responses were anonymous, the survey itself was distributed and completed in office. Thus, respondents' answers may have been unconsciously influenced, negatively or positively, by their interactions with our staff. Health providers' interpersonal care quality has been identified as an influential determinant of patient satisfaction (38). The survey also relied on patients' recall, which may not be perfect, and their experience of pain, which is uniquely subjective.

Collection of patient-reported outcome measures (PROMs) are intended to assess treatment from the patient's perspective with the goal of improving the quality of care (39). For patients with chronic, complex conditions, these intentions may be particularly relevant. Yet studies of patient satisfaction determinants have often been inconclusive (40). Satisfaction is shaped by prior expectations, and meeting expectations, with respect to emotional and human aspects of a consultation and outcomes, may play an important role (40). Our survey, which demonstrates that patients willingly share their impressions of TDD therapy and are satisfied with its outcomes, may serve as the basis for improving the lives of patients with chronic pain. Last, psychological comorbidities such as addiction have been correlated to poorer outcomes for neuromodulation therapy (41). Twenty-one percent of our patient population had a history of addiction that was subsequently treated during psychological evaluation. The presence of addiction may have skewed our reported patient satisfaction.

CONCLUSIONS

In this study, we were able to reach a large number of active pump patients and received an impressive response rate of 74%. In addition to the wide outreach, the survey design gives us good

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insight into patient satisfaction with intrathecal TDD therapy. The variety of choices when answering the 18 questions in our survey allowed patients to categorize their range of experiences with the implanted pumps. The unsolicited free-text comments are perhaps the most compelling indication of intense satisfaction with TDD noted by some patients (Table 1). We believe this study highlights an important therapy for chronic pain patients and provides further evidence of high patient satisfaction with TDD therapy.

Intrathecal TDD therapy continues to play a role in improving the clinical outcome of patients with complex chronic benign pain. Overall, patients with intrathecal TDD therapy reported significant improvements in pain, physical function and quality of life, and subsequent high patient satisfaction rates. Factors, which limit patient satisfaction, are events of mechanical failure, lack of efficacy or presence of complications. Larger studies are required to quantify the degree of improvements associated with the use of TDD therapy.

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Authorship Statement

Dr. David M. Schultz designed the study. Wen Chang performed the statistical analysis. All authors were involved in drafting the manuscript. All authors critically revised the manuscript, interpreted the results, and performed a critical review of the manuscript for intellectual content. There was no funding for this study.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the supporting information tab for this article.

COMMENTS

This study although somewhat unusual in higher level of patients with previous history of drug addiction (still a minority) and use of secondary line medications is interesting and more valid survey given the very high number of patients and uniform medications used in pump. It reinforces this reviewer's own experience with positive outcomes with pain pump therapy especially in terms of decreased ER visits, less side effects, and marked decrease in systemic opioid use and aberrant opioid behavior.

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This study examines patient satisfaction following intrathecal pain treatment by means of questionnaires. This questionnaire contained a number of simple and target-orientated questions and was administered to an impressive number of patients with an excellent return rate. From my experience with intrathecal drug therapy, the study conveys a realistic picture of patient satisfaction with this therapeutic option. Up to now a number of studies on intrathecal drug therapy included the question on patient satisfaction or whether patients would undergo pump implantation again. However, to my knowledge, there are few studies examining patient satisfaction with intrathecal drug therapy in such a detailed and purposeful way. The authors have to be commended for this endeavor.

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