Chapter

Postoperative Pain Control Following Cardiac Implantable Electronic Device Implantation

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Abstract

Postoperative pain following cardiac implantable electronic device (CIED) surgery may not always be adequately treated. The postoperative pain trajectory occurs over several days following the procedure with tenderness and limited arm range of motion lasting for weeks after surgery. Pain control typically commences in the perioperative period while the patient is in the hospital and may continue after discharge; outpatients may be given a prescription and advice for their analgesic regimen. It is not unusual for CIED patients to be discharged a few hours after implantation. While opioids are known as an effective analgesic to manage acute postoperative pain, growing scrutiny on opioid use as well as their side effects and potential risks have limited their use. Opioids may be considered for appropriate patients for a short course of treatment of acute postoperative pain, but other analgesics may likewise be considered.

Keywords: CIED implant, device surgery, ICD implant, ICD implant, implant pain control, implantable cardioverter defibrillator, pacemaker

1. Introduction

Postoperative pain of all types is often under-treated and may lead to chronic postsurgical pain, a centralized painful condition that can be challenging to treat [1]. Reports of postimplant pain can vary. In a survey of pacemaker patients, most patients were satisfied overall with their device and not affected by pain, soreness, or discomfort [2]. Yet in another study, over 40% of surgical patients from a single-center Italian study (n = 235) reported still having mild postsurgical pain at six months [3]. Despite the frequency of device implants for cardiac conditions, there is little study on the incidence, intensity, or duration of pain associated with cardiac implantable electronic device (CIED) implantation.

There is a paucity of literature to inform clinicians about pain management for those undergoing an implantable cardioverter-defibrillator (ICD) or pacemaker implantation. A single-center study from Europe (n = 372) analyzed pain control retrospectively over the course of device implant [4]. The study found about a quarter of patients received analgesia or sedation in advance of surgery. During surgery, all patients received local lidocaine anesthesia. Upon completion of the surgery, less than one-third (31%) were given pain medication or sedated. Using a 0 to 10 numeric rating scale, the highest pain rating during the implantation was 8.

Pain above 5 was reported one, three, six, eight, and 24 hours after surgery, with the most frequently reported pain sites being the surgical incision, shoulder area, and chest region [4].

2. Postoperative pain control

There has been a little systematic study of pain associated with CIED implantation even though, such procedures are increasingly prevalent. Further complicating the subject of postoperative pain control are differences between subcutaneous and transvenous devices and the fact that some implantation procedures are done on an outpatient basis.

2.1 Risk factors for postoperative pain

The BRUISE-CONTROL studies 1 and 2 used a visual analog scale to assess pain in 1308 patients who had a CIED implanted. Using multivariable regression analysis, the following were associated with clinically important postsurgical pain: clinically significant hematoma (odds ratio [OR] 3.8), *de novo* CIED implantation (OR 1.9), female sex (OR 1.6), age < 65 years (OR 1.5), and body mass index <20 (OR 2.1) [5].

In a study of 21 consecutive adult CIED patients (mean age 61 ± 11 years), patients were asked to rate their pain on a 0 to 100 visual analog scale, where 0 was no pain at all and 100 was the worst possible pain imaginable. Patients rate their pain 24 hours after surgery and again at one month postoperatively. At 24 hours postimplant, the mean VAS score was 34 ± 20. Only one patient in the study experienced severe pain, with the rest rating pain as moderate (48%) or mild (48%). Using regression analysis, it was found that the use of intraoperative fentanyl and a longer time spent in the procedure were significant predictors of more intense postoperative pain. The mean VAS score for pain at one month was 19 ± 18 and 17 out of 21 patients rated this pain as "mild" [6].

2.2 Inpatient versus outpatient pain control

Device implantation may be done on an inpatient or outpatient basis, depending on a variety of factors, including patient characteristics, comorbidities, physician preference, geography, patient frailty, and other factors. A retrospective chart review of 415 consecutive primary-prevention ICD patients found that same-day discharge was safe and feasible [7]. However, in real-world clinical practice, many such procedures are performed on inpatients. In a prospective study of 327 *de novo* ICD patients, 40.3% were implanted during acute hospitalization [8]. Of these inpatients, 57.6% were secondary-prevention patients [8]. Predictors of hospitalization include, a more complex device (non-single-chamber device), New York Heart Association (NYHA) class IV symptoms, low diastolic blood pressure, higher blood urea nitrogen levels, and lower hemoglobin [8].

2.3 Subcutaneous ICDs

Subcutaneous ICDs are often implanted under general anesthesia and postoperative pain may be managed with opioid analgesia. However, there is a trend toward moving away from general anesthesia and postoperative opioids to a different type of pain control [9]. Monitored anesthesia care (MAC) has been reported in the literature to be a safe and effective method for subcutaneous ICD implantation [10, 11]. The

truncal plane block along with perioperative nonopioid analgesics is being considered and appears feasible and effective [12]. A study of 91 consecutive patients undergoing subcutaneous ICD implantation at 10 centers found ultrasound-guided serratus anterior plane block was effective for anesthesia during the procedure and postoperative analgesia [13].

The Subcutaneous Defibrillator and Send Home (DASH) study investigated the feasibility and safety of subcutaneous ICD implant in patients (mean age 47 ± 14 years) discharged on the same day [14]. In total, 49 patients were enrolled and all were discharged following the surgery without staying overnight at the hospital. The protocol called for preoperative acetaminophen 975 mg and oxycodone 10 mg, local bupivacaine during the surgery, and limited fixed-dose combination oral analgesic of oxycodone plus acetaminophen (5/325 mg) after surgery, every 6 hours as needed. Using a 0 to 10 numerical pain rating scale, severe pain (defined as a score ≥ 8) occurred in 14.3% of patients on the day of surgery, 14.3% on postoperative day 1, and 8.2% of patients on a postoperative day 3 [14].

In a study of 104 adult patients undergoing subcutaneous ICD implantation, 69% were administered intraprocedural liposomal bupivacaine but there were no statistically significant differences between those who received bupivacaine and those who did not in terms of inpatient opioid consumption, outpatient opioid prescriptions, or overall opioid consumption in the postoperative period [15]. Similar findings were observed in a study of liposomal bupivacaine in knee arthroplasty [16].

In a study of opioid use following CIED implantations, patients who underwent subcutaneous ICD implantation were more likely to be prescribed opioids than those implanted with transvenous devices (25% vs. 20%) [17]. In a retrospective single-center study of structured interviews with female patients who were implanted with a subcutaneous ICD (mean time since implant 4.6 ± 3.1 years) 54% said their postsurgical pain was worse than they expected [18]. About half (44%) said that they experienced daily discomfort with their bra and the implanted device [18]. Thus, while postoperative pain can be managed following subcutaneous ICD implant, there are important gaps to be recognized in how pain is treated. In particular, patients should be advised about the nature, duration, and intensity of pain anticipated and provided with an analgesic regimen with specific instructions.

2.4 Device revision

ICDs and other CIEDs require replacement upon battery depletion, and the incidence of any type of complication within 45 days of device revision is 4.3% [19]. Device infections are more common for ICD and CRT-D system revisions than initial implants (2.9% and 3.9% for revisions, respectively, and 1.6% for both ICD and CRT-D *de novo* systems) [20]. It should be noted in this context that a CRT-D system is a more complicated device than a transvenous ICD, even a dual-chamber ICD, and requires a left-ventricular lead. This risk for infection may be cumulative with subsequent device revisions; in fact, each intervention at the same implant site appears to double the risk for infection [21]. There are no studies, comparing postoperative pain intensity or characteristics of initial and revised procedures. Since up to 40% of ICD procedures involve a generator replacement [22], this represents a significant knowledge gap.

In an analysis of opioid prescribing for CIED implantation, patients undergoing device upgrades and generator change-outs were less likely to receive opioids than those getting a *de novo* implant (18.3%, 11.6%, and 20%, respectively) [17].

2.5 Special populations

2.5.1 Pediatric

The number of pediatric device patients is a relatively small subset of the device population, but babies, as well as children and adolescents, may be recipients of CIEDs. Nerve blocks have been effectively used in pediatric patients undergoing implantation of a subcutaneous ICD [23]. In this case series of 10 patients, the combination of bilateral parasternal blocks with a left erector spinae plane block provided good pain control. Pectoral nerve blocks have been shown to reduce perioperative anesthetic requirements and postoperative pain in children undergoing transvenous ICD implantation [24].

2.5.2 Women

A study of 180 men and 60 women, who had a *de novo* ICD implantation, found that women were statistically significantly more likely to be younger and less likely to be married or have a history of coronary artery disease than men [25]. However, women had lower functional status, reported more intense pain, and had more sleep problems than men. Men and women were similar in terms of symptoms of anxiety and depression [25]. A study of 179 consecutive ICD outpatients (mean age 60.5 ± 15.9 years) found women reported significantly more intense pain than men [26].

Women have been historically under-represented in ICD clinical trials and historically were sometimes overlooked in consideration for ICD implantation. In a retrospective study of 5156 outpatients with an ejection fraction ≤35%, 25.0% of women had received an ICD compared to 36.3% men ($p < 0.01$) [27]. In an observational study based on Get with the Guidelines-Heart Failure Program, 21,059 patients with an ejection fraction ≤35%, were evaluated in the time frame from 2011 to 2014. During this time, women were less likely to be counseled about ICD therapy than men (19.3% vs. 24.6%, $p < 0.001$) [28]. It may be that women who receive ICDs are not adequately counseled about what to expect from surgery or treated for pain.

2.5.3 Overweight

Studies suggest that obese patients, defined as a body mass index >30 kg/m^2, are at an elevated risk for inappropriate shock and failed defibrillation testing when a subcutaneous device is implanted [29, 30]. Electrocardiographic testing before implant and appropriate patient selection may reduce such risks [10]. It is unknown whether obese patients experience more pain or more intense pain than normal-weight patients.

2.5.4 Racial/ethnic groups

In a retrospective analysis of 5156 outpatients with an ejection fraction ≤35%, 28.0% of Black compared to 33.2% of White patients had an ICD, $p = 0.02$ [27]. Although this difference was statistically significant, it was less pronounced than sex-based differences in ICD implantation, where men were more likely to receive an ICD than women [27]. Since Blacks Americans are less likely to have health insurance than Whites, it might be speculated that part of this difference can be traced back to differences in health coverage. However, a study from the United Kingdom found that despite free, universal healthcare, there were racial disparities

in ICD implantations; ICDs in the United Kingdom were significantly more likely to be implanted in White than South Indian residents [31]. Although the population of Caucasians in the area of Leicestershire was 77.7% and South Asians made up 15.9% of the population, 91.9% of all ICDs in that areas were implanted in Caucasians compared to 8.1% South Asians. These differences persisted for primary- and secondary-prevention patients although the gap between Caucasians and South Asians was even wider for secondary-prevention treatment [31]. It is unclear, why this marked difference occurs. The lower rate of Black patients for ICD therapy is particularly concerning because Blacks are at greater risk than Whites for sudden cardiac death [32]. However, in the United States, Blacks also had a higher ICD refusal rate than other groups when ICD therapy was presented to them as a consideration [32]. Among patients who are at higher risk of sudden cardiac death, Blacks had significantly less probability of getting an ICD [33].

2.5.5 Geriatric

Advanced age and frailty have been associated with less-frequent use of ICD systems and indications require the patient have a reasonable expectation to live at least one more year after device implant [34]. This life expectancy requirement is not always taken into account. In a survey of 386 physicians who refer selected patients for possible ICD implantation, 23% said that they do not consider life expectancy and 13% have knowingly referred patients with a life expectancy of under one year [35]. However, there is no specific age cutoff for ICD indications. More than 40% of all first implants of ICD systems occur in patients over the age of 70, and *de novo* patients over age 80 are not uncommon [36]. Biological age may be more important than chronological age in this regard [37].

Postsurgical pain in geriatric device patients is not well studied; indeed, elderly patients are often under-represented in clinical trials, if they are included at all. In a study of 150,264 primary-prevention patients, there were significantly more adverse events in the oldest patients (4.5% in those ≥80 years) compared to the youngest group (2.8% in those <65 years) [38]. This rate of adverse events plateaued at about 4.5% at age 80 and beyond. Comorbid conditions were stronger predictors for complications than age [38]. However, the proportions of older and younger patients who specifically experienced pain were not reported.

The control of postsurgical pain in geriatric patients can be challenging due to comorbid conditions, concurrent drug therapies (polypharmacy), and age-related pharmacokinetic and pharmacodynamic alterations [39]. Pain assessment maybe even more challenging in elderly patients with impaired communication skills or cognitive deficits. Because elderly patients may get benefit from ICD therapy and may have special limitations with respect to pain therapy, further study is much needed.

2.6 Opioid considerations

Opioids have come under increasing scrutiny as routine analgesics since the Centers for Disease Control and Prevention (CDC) published guidance to limit their use because of growing concerns for their risks, opioid-associated side effects, and opioid use disorder (OUD). In addition, opioids may increase the risk of atrial fibrillation or other arrhythmias [40]. Nevertheless, opioids are effective analgesic agents and are often used for appropriate patients under clinical supervision to manage the acute pain associated with surgery.

In a retrospective analysis of all CIED procedures done at the three Mayo Clinics in Minnesota, Arizona, and Florida, from 2010 to early 2018, opioids were prescribed to 20.2% of the 16,517 patients (mean age 70 ± 15 years) after device

implantation. Of this group, 80% were opioid naïve. Of the opioid-naïve patients, 9.4% refilled their opioid prescription at least once and 38.8% of patients received >200 oral morphine equivalents (ME) [17]. The mean amount of ME prescribed was 243 ± 346 overall. Opioid-experienced patients were prescribed significantly more opioids than opioid-naïve patients with 335 ME compared to 219 ME for the opioid-naïve patients ($p < 0.001$) [17].

Opioids are associated with many well-known side effects, including nausea, somnolence, mental fogginess, pruritus, and constipation [41]. In most cases, these side effects are mild to moderate although they can in some instances be severe and even treatment-limiting. A short course of postsurgical opioids typically does not result in treatment-limiting side effects, although some patients find opioid analgesics unpleasant. In a study of 250 surgical inpatients, who had a variety of different types of surgery, 25% of those who had received some form of analgesic reported having side effects, although 90% said that they were satisfied with the pain control medications they were administered [42].

2.7 Clinical strategies: Preoperative, perioperative, postoperative

Although this chapter deals with postoperative pain control following device implant, it is difficult to discuss pain management isolated to the specific postoperative period without describing preoperative and perioperative techniques, which can affect the pain experienced by the patient when the procedure has ended and the patient enters recovery.

2.7.1 Preoperative

The implant of an ICD or any CIED can be associated with severe acute pain. The pain is most intense immediately after the implant procedure and diminished gradually over the next few days as the implant site heals. Postoperative pain should be managed with preoperative, perioperative, and postoperative strategies. In discussing the device implant with the patient, the clinical team should educate the patient on pain control goals and available options with their risks and benefits. It is important to manage the patient's expectations because complete pain eradication is likely not possible. It has been found that oral gabapentin (600–1200 mg) or pregabalin (150–300 mg) administered an hour or two before surgery can reduce postsurgical opioid consumption [43, 44]. Likewise, oral celecoxib (200–400 mg) 30 minutes to 1 hour before surgery can likewise diminish the need for postoperative opioids [43, 45]. Note that the individual patient must be considered in any analgesic regimen; nonsteroidal anti-inflammatory drugs such as celecoxib may be contraindicated in certain cardiology patients.

A structured plan to help to reduce the pain associated with CIED implantation and other related procedures, such as catheter ablation, could significantly reduce pain up to 8–24 hours after the procedure [46]. The elements of such programs include patient education, regular pain assessments, analgesic protocols, and prompt referrals to pain specialists if the pain becomes severe or cannot be managed.

It is concerning that many device patients do not receive any preoperative analgesics. In a study from Croatia, it was found that 75% of patients undergoing CIED implantation received no preoperative pain medications at all [4].

2.7.2 Perioperative

Perioperative pain control is typically managed by local medications and/or regional anesthesia [4]. Proper device placement in the fascia and good hemostasis

during the procedure may reduce pain following the operation. Liposomal bupivacaine extended-release formulation may provide good anesthetic infiltration with an effect that can last up to 72 hours [47]. In some cases, general anesthesia is used but truncal plane blocks may also provide adequate anesthesia for difficult procedures or those involving a subcutaneous device [12]. For conventional ICDs and devices with transvenous lead systems, local anesthetic infiltration is probably adequate, but sometimes cervical or pectoral nerve block may be employed [48, 49]. Intravenous ketamine is not recommended because of the potential for myoclonus, which can interfere with device function and cause double-counting [17].

2.7.3 Postoperative

Following surgery, the patient may get benefit from oral analgesics to manage acute pain. Opioid analgesics may be considered for a short course in appropriate patients. A great concern about the use of opioids in any patient is the potential for OUD. Risk stratification tools exist that can help to determine which patients may be at elevated risk for opioid misuse and abuse [50] (see **Table 1**). Opioid overdose may result in potentially life-threatening respiratory depression; naloxone is a rapid-acting rescue drug. Patients taking opioids following CIED implantation may benefit from a prescription for naloxone and the family or caregivers should be trained in how to administer it in an emergency.

In a single-center retrospective study from Croatia (n = 372), 31% of patients being implanted with an ICD received pain medication following surgery; the highest intensity pain recorded in this study was 8 on a 0 to 10 scale [4]. The most frequently prescribed medications in this study were fixed-dose combination oral tramadol and acetaminophen 37.5/325 mg (29%), diazepam 5 mg (17%), tramadol 5 mg monotherapy (16%), and acetaminophen monotherapy

Instruments	Description	Optimal use	Comments
4-A	Observations Analgesia, activities of daily living, adverse events, aberrant drug-taking behaviors	Suitable for ongoing opioid therapy	Not validated
Diagnosis, Intractability, Risk, and Efficacy Inventory (DIRE)	Scoring system	More suitable for long-term therapy or ongoing therapy	Clinician does assessment
Opioid Risk Tool	Clinician-guided questionnaire-based interview; stratifies low, medium, and high risk for aberrant drug-taking behaviors	May be used before start of opioid therapy	High degree of sensitivity and specificity
Pain Medication Questionnaire (PMQ)	Questionnaire	Designed for chronic pain patients	Validated translated versions available
Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)	Questionnaire	To identify those at low risk of OUD	Validated translated versions available

Table 1.
While there is no consensus as to the best opioid-screening tool, a variety of validated instruments exist [51–53]. In place of an assessment tool, a clinical interview with the patient may be conducted to assess past drug experiences, familial history of substance use disorders, and attitudes about pain control. Note that these tools are often used in the setting of long-term opioid therapy, rather than short-term postoperative use.

500 mg (12%) [4]. It should be noted that in this study 69% of patients received no postoperative analgesic medications at all [4]. This strongly suggests that many CIED patients have poorly controlled pain after surgery. Of course, postoperative pain control may be inadequate for many types of surgery. In USA survey of surgical inpatients, who had a variety of procedures, about 80% reported they suffered pain following surgery with 86% of them ranking this pain as "moderate" to "severe" [42]. Perhaps most important is that pain was reported to occur more frequently after discharge than before [42]. Patients may not always know what to expect and some may accept moderate to severe postoperative pain following surgery, not knowing that postoperative pain can often be safely and effectively managed.

An important analgesic strategy involves a combination of multimodal analgesia. Multimodal analgesia is based on the use of two or more analgesics with different mechanisms of action to offer a synergistic benefit to patients. Some fixed-dose combination products offer oral acetaminophen plus, a small amount of opioid, such as oxycodone, in a single oral dose. Adjuvant agents may also be helpful such as gabapentin or pregabalin to help with a neuropathic component to postsurgical pain.

A challenge in pain management following implant is the fact that most device patients do not spend prolonged periods of time in the hospital. Most CIED patients are discharged home shortly after surgery, whether they are outpatients or spend the night in the hospital. Thus, most device patients must manage the longest duration of their postsurgical pain at home. For this reason, patients and their families or caregivers must be educated about the pain medications they are to take, the appropriate doses and timing, and the risks as well as the benefits of these medications. Following transvenous device implant, patients should be educated about arm movements to prevent capsulitis ("frozen shoulder") [54].

3. Conclusions

With millions of device patients around the world, it is important to develop good guidance in terms of how to manage postoperative pain in these patients. Most postoperative pain is moderate to severe but has a predictable trajectory in which the pain is most intense immediately after surgery and diminished day over day over the course of several days. A good strategy for pain control for CIED patients is to consider managing pain perioperatively and then offer the patient postoperative counseling for pain management at home along with appropriate analgesics. For appropriate patients, a short course of opioid analgesics may be appropriate but other nonopioid agents may be considered as well. Subcutaneous ICD implantation is likely associated with more severe or longer-duration postoperative pain although there are no specific head-to-head comparative pain studies. Barring complications, device patients recover over the course of days and weeks and should need analgesia only for a short duration of time.

Conflict of interest

Peter Magnusson has received speaker's fees or grants from Abbott, Alnylam, Amicus Therapeutics, AstraZeneca, Bayer, BMS, Boehringer-Ingelheim, Coala Life, Internetmedicin, Lilly, MSD, Novo Nordisk, Octopus Medical, Orion Pharma, Pfizer, Sanofi, Vifor Pharma, and Zoll.

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