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ORIGINAL ARTICLE

Postoperative intravenous patient-controlled analgesia improves pain management after subcutaneous implantable defibrillator implantation

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Abstract

Objective: Postoperative pain is a major issue with subcutaneous implantable cardioverter defibrillators (S-ICD). In 2020, we introduced intravenous patient-controlled analgesia (IV-PCA) in addition to the conventional, request-based analgesia for postoperative pain control in S-ICD. To determine the effect and safety, we quantitatively assessed the effect of IV-PCA after S-ICD surgery over conventional methods.

Methods: During the study period, a total of 113 consecutive patients (age, 50.1 ± 15.5 years: males, 101) underwent a de novo S-ICD implantation under general anesthesia. While the postoperative pain was addressed with either request-based analgesia (by nonsteroid anti-inflammatory drugs, $N = 68$, dubbed as "PCA absent") or fentanyl-based IV-PCA in addition to the standard care ($N = 45$, dubbed as "PCA present"). The degree of postoperative pain from immediately after surgery to 1 week were retrospectively investigated by the numerical rating scale (NRS) divided into four groups at rest and during activity (0: no pain, 1–3: mild pain, 4–6: moderate pain, 7–10: severe pain).

Results: Although IV-PCA was removed on Day 1, it was associated with continued better pain control compared to PCA absent group. At rest, the proportion of patients expressing pain (mild or more) was significantly lower in the PCA present group from Day 0 to Day 4. In contrast to at rest, a better pain control continued through the entire study period of 7 days. No serious adverse events were observed. A few patients experienced nausea in both groups and the inter-group difference was not found significant.

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Conclusion: IV-PCA suppresses postoperative pain in S-ICD without major safety concerns.

KEYWORDS
implantable cardioverter defibrillator (ICD), intravenous patient-controlled analgesia (IV-PCA), subcutaneous ICD (S-ICD)

1 | INTRODUCTION

Implantable cardioverter defibrillators (ICD), encompassing both transvenous (TV-ICD) and subcutaneous types (S-ICD), act as a safeguard against life-threatening ventricular tachyarrhythmias. S-ICD has proven advantageous for certain patients, such as those at an elevated risk of ICD infection and those who do not necessitate pacing, and are widely used worldwide, including Japan.[1–4] Postoperative pain is a distinctive challenge associated with S-ICD implantation which can sometimes be severe and significantly influences the quality of the patient journey.[5] The substantial pain is arguably due to the larger size of the device and the pocket required for it.[6] As the effective relief of pain is important for the patients with heart disease, intravenous patient-controlled analgesia (IV-PCA) is used after cardiac surgery.[7] Nonetheless, the utility of IV-PCA in postoperative management following S-ICD implantation remains largely unexplored. Thus, we elucidate the impact of postoperative IV-PCA during the acute period following S-ICD implantation. The aim of the study was to assess the effect of PCA to subjective pain score and recovery time based on the presence or absence of PCA (i.e., vs. historical cohort before introduction of PCA in the same hospital).

2 | METHOD

This is a single-center, retrospective observational study conducted in Saitama Medical University International Medical Center. The research protocol was approved by local institutional ethics committee (#2023-057) and conforms to the provisions of the Declaration of Helsinki (as revised in Fortaleza, Brazil, October 2013).

2.1 | Patient selection

All S-ICD implant was performed in accordance with the guideline from the Japanese Circulation Society/Japan Heart Rhythm Society (JCS/JHRS),[8] which is in good agreement with the HRS statement.[9] We introduced a routine use of IV-PCA for postoperative pain control in 2020. Based on the presence or absence of PCA, patients were classified as “PCA absent” vs. “PCA present.”

2.2 | General anesthesia and S-ICD implant

In all cases, certified anesthesiologists introduced and maintained general anesthesia. Rapid introduction with single intravenous propofol (1–2 mg/kg) and rocuronium bromide (0.6–0.8 mg/kg) followed by either sevoflurane or desflurane and remifentalyl (0.25 mcg/kg/min) at the maintenance dose. Fentanyl and rocuronium bromide were administered as needed. At the end of surgery, intravenous acetaminophen 1000 mg was given. No local infiltration anesthesia was given in both groups.

In PCA absent group, analgesia (either intravenous acetaminophen 1000 mg, oral acetaminophen 500 mg, or loxoprofen 100 mg) was given upon patient's request. In PCA present group, in addition to the request-based analgesia, IV-PCA was given. The IV-PCA consisted of fentanyl 1.0 mg in normal saline (in total 50 mL) and was started in the middle of surgery at a rate of 1 mL/h. The IV-PCA protocol was as follows: fentanyl infusion, 0.02 mg/h; bolus, 0.02 mg; and lockout time, 5 min. IV-PCA was removed upon patients request.

2.3 | Measurement

We assessed a longitudinal change in degree of subjective pain by means of the NRS pain score, which is an 11-step numerous rating scale (0 being none to 10 being the strongest). NRS was determined by a nurse at 1, 2, 4, 6, 12, 18, 24, 40, 36, 42, 48, and 70 h following the surgery by Day 3, and once daily from Day 4 and on. When additional analgesia was required, NRS was again assessed 1 h thereafter. In the present study, we used the highest NRS score in each day as the daily representative value.

2.4 | Statistics

The unpaired *t*-test and Fisher's exact test were used for continuous value and contingency, respectively. Two-way ANOVA was used to assess the difference in pain score between the two groups. p-value $< .05$ was considered significant. The logistics regression analysis was performed to determine relative influences of possible confounders.

3 | RESULTS

3.1 | Patient characteristics

Patient characteristics is described in Table 1. The assessed parameters were almost similar except for (1) three-incision technique was more common in PCA absent group than in PCA present group ($p < .001$); and (2) more intraoperative fentanyl citrate was given during the procedure in PCA present group than PCA absent group.

IV-PCA was given for 18.2 ± 4.8 h after the initiation, and in all cases, discontinued in Day 1 when the intravenous route was removed. Of note, no patients requested the extension of IV-PCA use beyond this time point.

3.2 | IV-PCA improves S-ICD postoperative pain

The NRS pain score at rest was notably lower in the PCA present group compared to the PCA absent counterpart in the initial 3 days post-implantation. Among those reporting subjective pain, the NRS score was significantly reduced in the PCA present group relative to the PCA absent group. Remarkably, except for one individual, none reported a high degree of pain throughout the postoperative period. PCA similarly demonstrated favorable effect in subjective pain throughout the study period of 7 days (at rest, Table 2, during activity, Table 3).

IV-PCA use was also associated with a marked reduction in use of additional analgesics use (Table 4). These observations underscore the pronounced efficacy of IV-PCA during the first 4 days following S-ICD implantation.

A multivariate analysis (Table 5) indicates that the three-incision technique was not the significant parameter that crucially affect the pain on Day 4. We have added the table as.

3.3 | No major PCA-associated safety events

There were no PCA-associated adverse events. Although the proportion of patients with nausea appears higher in PCA present group than the other, the difference was not statistically significant (13.2% vs. 24.4%, Table 6). No patients experienced vomit or required additional drip infusion for the treatment of nausea. There was no difference in a rate of constipation between the two groups (13.2% vs. 4.4%, $p < .1$, Table 6).

4 | DISCUSSION

The perception of postoperative pain during cardiac implantable electrical device placement seems ambiguous. While some study indicates that postoperative pain can be intense,[10] other indicates that it is not necessarily the case,[11] suggesting the importance of continuous research, especially with S-ICD, of which use is expanding. It is reasonable to assume that a relatively large pulse generator and direct damage to fascia on multiple muscles and lead tunnels cause egregious postoperative pain in an S-ICD implant.[12]

TABLE 1 Demographic and clinical characteristics of the studied patients.

	PCA absent ($n = 68$)	PCA present ($n = 45$)	p-value
Age	48.6 ± 15.8	52.4 ± 14.9	.32
Female	9 (13.2%)	3 (6.7%)	.27
BMI	24.4 ± 4.8	24.2 ± 4.2	.83
Diabetes	11 (16.2%)	4 (8.9%)	.26
Coronary artery disease	15 (22.1%)	11 (24.4%)	.39
Hemodialysis	8 (11.8%)	1 (2.2%)	.067
LVEF [%]	47.7 ± 22.5	42.8 ± 19.2	.22
Serum creatinine [mg/dL]	1.57 ± 2.42	0.98 ± 0.35	.051
eGFR [mL/m/1.73m^2]	67.8 ± 28.9	69.8 ± 27.3	.71
AST(GOP) [IU/L]	24.69 ± 12.31	24.5 ± 13.2	.94
ALT (GPT) [IU/L]	25.29 ± 21.74	37.9 ± 34.6	.19
Secondary prevention	41 (60.3%)	28 (62.2%)	.62
Three-incision	50 (73.5%)	5 (11.1%)	<.001
S-ICD implant procedure time [min]	107.3 ± 24.9	100.0 ± 20.2	.089
Total intraoperative fentanyl citrate [mg]	0.3 ± 0.2	0.6 ± 0.5	<.001
Total intraoperative Remifentanil Hydrochloride [mg]	0.97 ± 0.50	0.9 ± 0.4	.16

Note: Values are given as *n*, mean ± SD, or n (%) unless otherwise indicated.
Abbreviations: AST, asparate transaminase; ALT, alanin transaminase; BMI, body mass index.

TABLE 2 Pain assessment during rest.

		PCA absent $n=68$	PCA present $n=45$	p-value
Immediately after	0	33 (48.5%)	34 (75.6%)	.004
	1~3	10 (14.7%)	4 (8.9%)	
	4~6	13 (19.1%)	7 (15.6%)	
	7~10	12 (17.6%)	0 (0.0%)	
Day 1	0	22 (32.4%)	35 (77.8%)	<.001
	1~3	14 (20.6%)	5 (11.1%)	
	4~6	23 (33.8%)	5 (11.1%)	
	7~10	9 (13.2%)	0 (0.0%)	
Day 2	0	33 (48.5%)	38 (84.4%)	<.001
	1~3	12 (17.6%)	2 (4.4%)	
	4~6	19 (27.9%)	5 (11.1%)	
	7~10	4 (5.9%)	0 (0.0%)	
Day 3	0	46 (67.6%)	40 (88.9%)	.02
	1~3	10 (14.7%)	2 (4.4%)	
	4~6	12 (17.6%)	3 (6.7%)	
	7~10	0 (0.0%)	0 (0.0%)	
Day 4	0	52 (76.5%)	41 (91.1%)	.04
	1~3	10 (14.7%)	2 (4.4%)	
	4~6	5 (7.4%)	2 (4.4%)	
	7~10	1 (1.5%)	0 (0.0%)	
Day 5	0	61 (89.7%)	43 (95.6%)	n.s.
	1~3	4 (5.9%)	2 (4.4%)	
	4~6	2 (2.9%)	0 (0.0%)	
	7~10	1 (1.5%)	0 (0.0%)	
Day 6	0	64 (94.1%)	44 (97.8%)	n.s.
	1~3	1 (1.5%)	1 (2.2%)	
	4~6	3 (4.4%)	0 (0.0%)	
	7~10	0 (0.0%)	0 (0.0%)	
Day 7	0	67 (98.5%)	45 (100.0%)	n.s.
	1~3	1 (1.5%)	0 (0.0%)	
	4~6	0 (0.0%)	0 (0.0%)	
	7~10	0 (0.0%)	0 (0.0%)	

In the present study, IV-PCA demonstrated marked improvement in postoperative pain throughout 7 days of the entire study period. It is striking as most IV-PCA was terminated by Day 1, indicating the critical advantage of proactive appropriate pain control over passive, undertreatment on pain. We interpret our observation to suggest that good pain control in early postoperative days by IV-PCA is advantageous for a better pain control in later stage. The prolonged analgesic effect observed in our study may be attributed to several factors. First, effective pain control in the initial postoperative period can reduce the development of sensitization to pain, leading to a longer-lasting analgesic effect. Second, IV-PCA allows for a more consistent plasma concentration of analgesics, which might contribute to a more effective and prolonged pain control.

The postoperative pain is factored by (1) nociceptive pain, (2) neuropathic pain, and (3) cognitive pain. While the nociceptive and neuropathic pain are crucially determined by the procedure itself, cognitive pain can be alleviated by proactive pain control.[13] We assume that complex interaction between such factors might play a role in a better pain control in IV-PCA group.

Patient discomfort in acute phase of an implant depends on several factors including a type of anesthesia (e.g., general anesthesia vs. monitored anesthesia care[14]) and biological background (age, sex, etc.). According to a survey to female patients, more than half (54%) reported that the postoperative pain,[5] suggesting a potential usefulness of IV-PCA in females. Although merely a couple of patients were included in the present dataset, minor patients are another subpopulation of those who may suffer from postoperative pain. Future studies are required to assess the effect and safety of IV-PCA in these subpopulations. In the same context, although it was note tested in the present study, additional local infiltration anesthesia

TABLE 3 Pain assessment during activity.

		PCA absent n = 68	PCA present n = 45	*p*-value
Immediately after	0	28 (41.2%)	28 (62.2%)	.028
	1~3	9 (13.2%)	7 (15.6%)	
	4~6	17 (25.0%)	9 (20.0%)	
	7~10	14 (20.6%)	1 (2.2%)	
Day 1	0	11 (16.2%)	27 (60.0%)	<.001
	1~3	12 (17.6%)	7 (15.6%)	
	4~6	23 (33.8%)	9 (20.0%)	
	7~10	22 (32.4%)	2 (4.4%)	
Day 2	0	19 (27.9%)	26 (57.8%)	.0015
	1~3	3 (4.4%)	8 (17.8%)	
	4~6	33 (48.5%)	7 (15.6%)	
	7~10	13 (19.1%)	3 (6.7%)	
Day 3	0	30 (44.1%)	35 (77.8%)	<.001
	1~3	16 (23.5%)	6 (13.3%)	
	4~6	19 (27.9%)	3 (6.7%)	
	7~10	3 (4.4%)	1 (2.2%)	
Day 4	0	37 (54.4-%)	38 (84.4%)	<.001
	1~3	17 (25.0%)	4 (8.9%)	
	4~6	13 (19.1%)	3 (6.7%)	
	7~10	1 (1.5%)	0 (0.0%)	
Day 5	0	45 (65.2%)	41 (91.1%)	.002
	1~3	17 (25.0%)	4 (8.9%)	
	4~6	5 (7.4%)	0 (0.0%)	
	7~10	1 (1.5%)	0 (0.0%)	
Day 6	0	56 (82.4%)	43 (95.6%)	.03
	1~3	9 (13.2%)	2 (4.4%)	
	4~6	3 (4.4%)	0 (0.0%)	
	7~10	0 (0.0%)	0 (0.0%)	
Day 7	0	61 (89.7%)	45 (100.0%)	.02
	1~3	7 (10.3%)	0 (0.0%)	
	4~6	0 (0.0%)	0 (0.0%)	
	7~10	0 (0.0%)	0 (0.0%)	

Note: Values are given as *n* (%) unless otherwise indicated.
Abbreviation: n.s, not significant.

may also be useful to improve the postoperative pain. However, it should be noted that there is some physical limitation to apply local infiltration anesthesia to all areas in which S-ICD is implanted (e.g., lead tunnels).

Simplicity is a major advantage of IV-PCA over previously reported methods, such as echo-guided serratus anterior plane block.[15] A decrease in operative pain realized by complex analgesia protocol has been correlated with the expedited recovery, such as the possibility of same-day discharge.[16] However, such alternative method involves human resources and carries a risk of treatment-related complication. Thus, our study suggests that IV-PCA is not only effective but also advantageous over other measures in terms of simplicity.

An IV-PCA regimen used in this study was also safe. Although a few patients reported nausea and vomiting, there were no life-threatening side effects (Table 6). Given the clear positive effect on pain control, we conclude that IV-PCA is safe, easily deployable, and effective. The result of this study highlights the importance of collaboration between S-ICD implanters and anesthesiologists in order to relieve the postoperative pain and discomfort.

4.1 | Limitations

Because of the retrospective, descriptive nature of the study design, we are not free from various biases. For example, differences in patient

TABLE 4 Comparison of additional analgesics used.

		PCA absent	PCA present	*p*-value
Immediately after	0	38 (55.9%)	0 (0.0%)	<.001
1 day	0	48 (70.6%)	10 (22.2%)	<.001
2 days	0	35 (51.5%)	4 (8.9%)	<.001
3 days	0	25 (36.8%)	4 (8.9%)	<.001
4 days	0	17 (25.0%)	0 (0.0%)	<.001
5 days	0	10 (14.7%)	0 (0.0%)	.007
6 days	0	5 (7.4%)	0 (0.0%)	.06
7 days	0	1 (1.5%)	0 (0.0%)	n.s

Note: Values are given as *n* (%) unless otherwise indicated.
Abbreviation: n.s, not significant.

TABLE 5 Multivariate analysis (for the postoperative pain on Day 4 at rest).

	Coefficient	Std. err.	*p*-value
IV-PCA	4.914892	1.113448	.005643
Three-incision	−0.59323	1.01969	.560716
Female sex	0.201031	1.285142	.875697
Age > 60	−2.38344	1.009967	.018279
BMI > 25	0.538482	0.845189	.524051
Hemodialysis	−22.7895	90554.37	.999799

TABLE 6 Frequency of gastrointestinal symptoms.

	PCA absent *n* = 68	PCA present *n* = 45	*p*-value
Nausea	9 (13.2%)	11 (24.4%)	n.s.
Vomiting	0 (0.0%)	0 (0.0%)	n.s.
Constipation	0 (0.0%)	0 (0.0%)	n.s.
Anorexia	9 (13.2%)	2 (4.4%)	n.s.

Note: Values are given as *n* (%) unless otherwise indicated.
Abbreviation: n.s, not significant.

characteristics may act as confounding e.g., differential proportion of the 2-incision versus 3-incision technique in the two groups. However, limited difference in surgical areas between 2- and 3-incision technique and the negative signal in the multivariate analysis (Table 5) led us to view that this point is not necessarily impactful on the interpretation of the data. Ultimately, a randomized trial is required to address the concern. However, we think that a clear beneficial effect showcased in this study is sufficient to support our notion that IV-PCA provides better patient care compared to conventional treatments without IV-PCA.

5 | CONCLUSION

IV-PCA evidently mitigates postoperative pain following S-ICD implantation without major safe concerns. Even though it was used for only 1 day, pain control seems better in the following days.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest for this article.

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REFERENCES

1. Sasaki S, Tomita H, Tsurugi T, Ishida Y, Shoji Y, Nishizaki K, et al. Safety and efficacy of subcutaneous cardioverter defibrillator in patients at high risk of sudden cardiac death- primary Japanese experience. Circ J. 2018;82(6):1546–51.
2. Tsutsui K, Kato R, Asano S, Ikeda Y, Mori H, Tawara M, et al. Myopotential oversensing is a major cause of inappropriate shock in subcutaneous implantable defibrillator in Japan. Int Heart J. 2020;61(5):913–21.
3. Bardy GH, Smith WM, Hood MA, Crozier IG, Melton IC, Jordaens L, et al. An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med. 2010;363(1):36–44.
4. Boersma L, Barr C, Knops R, Theuns D, Eckardt L, Neuzil P, et al. Implant and midterm outcomes of the subcutaneous implantable cardioverter-defibrillator registry: the EFFORTLESS study. J Am Coll Cardiol. 2017;70(7):830–41.
5. van der Stuijt W, Quast ABE, Baalman SWE, Olde Nordkamp LRA, Wilde AAM, Knops RE. Improving the care for female subcutaneous ICD patients: a qualitative study of gender-specific issues. Int J Cardiol. 2020;317:91–5.
6. Lee JZ, Pasha AK, Glasgow AE, Habermann EB, Kusumoto FM, McLeod CJ, et al. Postoperative opioid prescription patterns and new opioid refills following cardiac implantable electronic device procedures. Heart Rhythm. 2019;16(12):1841–8.
7. Gurbet A, Goren S, Sahin S, Uckunkaya N, Korfali G. Comparison of analgesic effects of morphine, fentanyl, and remifentanil with intravenous patient-controlled analgesia after cardiac surgery. J Cardiothorac Vasc Anesth. 2004;18(6):755–8.
8. Nogami A, Kurita T, Abe H, Ando K, Ishikawa T, Imai K, et al. JCS/JHRS 2019 guideline on non- pharmacotherapy of cardiac arrhythmias. J Arrhythmia. 2021;37(4):709–870.
9. Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berul CI, Birgersdotter-Green UM, Carrillo R, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm. 2017;14(12):e503–e551.
10. Biocic M, Vidosevic D, Boric M, Boric T, Giunio L, Fabijanic D, et al. Anesthesia and perioperative pain management during cardiac electronic device implantation. J Pain Res. 2017;10:927–32.

11. Magnusson P, Liv P. Living with a pacemaker: patient-reported outcome of a pacemaker system. BMC Cardiovasc Disord. 2018;18(1):110.
12. Afzal MR, Okabe T, Hsu K, Cook S, Koppert T, Weiss R. How to minimize peri-procedural complications during subcutaneous defibrillator implant? Expert Rev Cardiovasc Ther. 2020;18(7):427–34.
13. Rawal N. Current issues in postoperative pain management. Eur J Anaesthesiol. 2016;33(3):160–71.
14. Afzal MR, Okabe T, Koppert T, Tyler J, Houmsse M, Augostini RS, et al. Implantation of subcutaneous defibrillator is feasible and safe with monitored anesthesia care. Pacing Clin Electrophysiol. 2019;42(12):1552–7.
15. Ziacchi M, Bisignani G, Palmisano P, Scalone A, Martignani C, Elvira Mocavero P, et al. Serratus anterior plane block in subcutaneous implantable cardioverter defibrillator implantation: a case-control analysis. J Cardiovasc Electrophysiol. 2020;31(1):144–9.
16. Okabe T, Miller A, Koppert T, Cavalcanti R, Alcivar-Franco D, Osei J, et al. Feasibility and safety of same day subcutaneous defibrillator implantation and send home (DASH) strategy. J Interv Card Electrophysiol. 2020;57(2):311–8.

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