Efficacy of Intravenous Acetaminophen in Periimplantation Pain of Cardiac Electronic Devices: A Randomized Double-Blinded Study

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Purpose: *Although intravenous acetaminophen has been administered to reduce postoperative pain, it has not been used during cardiac implantable electronic devices (CIEDs) implantation.*
Design: *This was a randomized double-blinded interventional study.*
Methods: *Thirty-two patients who were referred for new CIED implantation during July 2012 until April 2013 randomly received placebo or 1 g of intravenous acetaminophen. All patients were treated with local anesthesia. Pain score during incision, pocket creation, and in the recovery room, and the patients' need for analgesics during the 6 hours after the procedure were recorded in both groups.*
Findings: *Seventeen and 15 patients received acetaminophen and placebo, respectively. Pain scores in patients treated with acetaminophen were significantly lower (4.4 vs 2.9,* P = *.004), and they received less analgesics (17% vs 60%,* P = *.014).*
Conclusions: *Intravenous administration of acetaminophen is effective for pain relief in patients undergoing CIED implantation and decreases the need for postoperative analgesics.*

Keywords: *acetaminophen, pain, cardiac implantable electronic devices, analgesics.*

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Conflict of interest: None to report.

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INDICATIONS FOR PERMANENT PACEMAKER[1] and intracardiac defibrillators[2] have expanded. These procedures are usually performed by cardiac electrophysiologist (rather than cardiac surgeons) in electrophysiology laboratories (rather than operating rooms) under general anesthesia, moderate sedation, or local anesthesia.[3] Local anesthesia or sedation alone is inadequate for optimal patient comfort. The challenge for the physician in charge is the patient's comfort without the risk of oversedation and the resultant respiratory depression associated with narcotics or sedatives.[4]

Although intravenous acetaminophen has been used to reduce preoperative and postoperative pain,[5,6] it has not been used in the field of

cardiac implantable electronic devices (CIEDs) implantation. Considering its rapid onset (10 to 15 minutes) and duration of action (4 to 6 hours), it was decided to evaluate its usefulness in patients undergoing CIED implantation.

Materials and Methods

All patients who were referred to Imam Khomeini Hospital for new CIED implantation during July 2012 until April 2013 were included in the study. The protocol was approved by the Ethics Committee of Tehran University of Medical Sciences, and the study was conducted in accordance with the Declaration of Helsinki.

Fifteen minutes before the procedure, patients received placebo or 1 g of intravenous acetaminophen (Uni-Pharma S.A. Pharmaceutical Laboratories, Attica, Greece) in a randomized (balanced block randomization) double-blinded fashion. At the beginning of the procedure, all patients received 300 mg lidocaine (150 mg in the subclavicular and 150 mg in the prepectoral areas) without epinephrine as 2% solution. None of the patients received intravenous narcotics or benzodiazepines. During skin incision, pocket creation, and 1 hour after the termination of the procedure in the recovery room, pain was graded using the pain Numeric Rating Scale (NRS) from 1 to 10 in response to investigator's questions according to the patient's self-report of pain.[7] Meanwhile, the patients' need for intravenous opioid analgesics during the 6 hours after the procedure was also recorded. Exclusion criteria were a known history of hypersensitivity to acetaminophen, liver disease or abnormal liver function tests, and narcotic abuse; receiving any type of analgesics during the last 12 hours, and a pain NRS of more than 7. Statistical comparisons between the acetaminophen and placebo groups were performed with the Student *t* test at the .05 level of significance.

Results

Seventeen patients received acetaminophen, and 15 patients received placebo. Baseline characteristics of both groups are depicted in Table 1. The only statistical difference found between the two treatment groups was that the mean age was different (54.47 years ± 8.68 for the acetaminophen group and 68.57 years ± 10.56 for the placebo group, $P = .04$). The number of leads implanted and the duration of procedure were not statistically different between the two groups. The pain NRS of both groups is shown in Figure 1, which shows significantly less pain in patients who received acetaminophen ($P = .004$). Meanwhile, the patients treated with acetaminophen were more pain free during the 6-hour postoperative period and received less analgesic. Just 17.6% of patients who received acetaminophen needed analgesics 6 hour postoperatively in the recovery room as compared with 60% of patients who received placebo ($P = .014$) (Figure 2).

Discussion

Our study showed that administration of intravenous acetaminophen before CIED implantation

Table 1. Baseline Characteristics of Patients Receiving Acetaminophen and Placebo

Baseline Characteristics	Acetaminophen, n (%)	Placebo, n (%)	*P*
Number of patients	17	15	
Male	8 (47)	7 (47)	NS
Diabetes	3 (17)	5 (33)	NS
Hyperlipidemia	3 (17)	5 (33)	NS
Cigarette smoking	1 (6)	2 (13)	NS
Hypertension	5 (29)	6 (40)	NS
Mean age	54.47	68.57	.04
LVEF	38	32	NS
PPM	7 (41)	4 (26)	NS
ICD	10 (59)	11 (74)	NS

NS, nonsignificant; LVEF, left ventricular ejection fraction; PPM, permanent pacemaker; ICD, implantable cardioverter defibrillator.