Egyptian Journal of Anaesthesia (2013) **29**, 41–45

Egyptian Society of Anesthesiologists

Egyptian Journal of Anaesthesia

www.elsevier.com/locate/egja
www.sciencedirect.com

Research Article

The role of intravenous paracetamol in conscious sedation during Internal Cardioverter Defibrillator (ICD) insertion in geriatric patients

Mohamed A. Khalil [a,*], Abdelhay A. Ebade [a], Mohsen S. Abdel Azeem [b]

[a] *Department of Anesthesia, Faculty of Medicine, Cairo University, Egypt*
[b] *Department of Critical Care, Faculty of Medicine, Cairo University, Egypt*

Received 27 July 2012; revised 2 September 2012; accepted 4 September 2012
Available online 30 September 2012

KEYWORDS

Paracetamol;
Fentanyl;
Conscious sedation;
Internal Cardioverter Defibrillator (ICD)

Abstract *Background:* Insertion of Internal Cardioverter Defibrillator in high risk cardiac patients can be performed by many anesthetic techniques including local anesthesia with moderate sedation or general anesthesia. Many studies have proved that intravenous paracetamol infusion is effective in reducing narcotic requirements in many surgical procedures.
Purpose: The aim of this study was to assess the effect of paracetamol in reducing pain as well as apnea and upper airway obstruction during conscious sedation for Internal Cardioverter Defibrillator placement.
Patients and methods: In this prospective, randomized study, 100 patients undergoing elective transvenous placement of Internal Cardioverter Defibrillator (ICD) were enrolled in this study. Pain, respiratory events as apnea and airway obstruction in patients receiving intravenous paracetamol infusion 1 g over 30 min have been compared with those receiving fentanyl in a total dose of 1.5 μg/kg.

* Corresponding author. Address: Saad Specialist Hospital, Prince Faisal Bin Fahad Street, Al-Khobar 31952, Saudi Arabia. Tel.: +966 545965581.
E-mail address: mohamedkhalil404@hotmail.com (M.A. Khalil).
Peer review under responsibility of Egyptian Society of Anesthesiologists.

Production and hosting by Elsevier

http://dx.doi.org/10.1016/j.egja.2012.09.002

Results: The incidence of airway obstruction was lower in the paracetamol group than in the fentanyl one ($P < 0.05$). There was also a significant difference between the two groups as regards arterial carbon dioxide tension (PCO2), which was significantly higher in Group F (48.9 ± 0.63) in comparison to Group P (45.6 ± 0.64) ($P < 0.001$) as well as the degree of sedation where the sedation score was 2.2 ± 0.3 in group P. Also, the Visual Analog Scale (VAS) was significantly lower in Group P than in Group F ($P < 0.05$).

Conclusion: Intravenous paracetamol infusion was effective in reducing pain as well as the incidence of intraoperative respiratory events as upper airway obstruction in high risk cardiac patients undergoing Internal Cardioverter Defibrillator insertion.

1. Introduction

Many studies have shown that placement of Internal Cardioverter Defibrillator (ICD), prevents significantly sudden death in patients with moderate to severe impairment of systolic function [1,2]. Formerly, the implantation of ICD was performed under general anesthesia, however, the electrophysiologists tried in a study [3] to place it under local anesthesia with minimal sedation. Also, it has been proved that there was no influence of the type of anesthesia on the defibrillation threshold [4]. Other studies proved the safety and acceptability of implantation of ICD under local anesthesia with conscious sedation [5,6]. However, it has been proved that ICD insertion under conscious sedation may be associated with respiratory events as apnea and upper airway obstruction [7]. The goal of this study was to assess the effectiveness of intravenous paracetamol as an analgesic, in a trial to reduce the use of intravenous opioids in order to minimize the respiratory events which might happen during ICD placement.

2. Patients and methods

2.1. Anesthetic technique

After hospital ethical committee approval and informed written consent obtained, we studied 100 patients undergoing elective transvenous placement of an Internal Cardioverter Defibrillator (ICD) because of cardiomyopathic ventricle with severe impairment of systolic function and history of refractory paroxysmal ventricular tachyarrhythmias (ventricular tachycardia and/or ventricular fibrillation), this was at Saad Specialist Hospital, Saudi Arabia, in the period between January 2010 and June 2011. Excluded patients from the study were those who asked for either local or general anesthesia, those who developed severe intraoperative myocardial depression requiring cardiopulmonary resuscitation, patients with renal or hepatic disease and opioid naïve patients.

Patients were randomly allocated in this prospective study, into one of two groups: Group F ($n = 50$) or Fentanyl group and Group P ($n = 50$) or paracetamol group. Randomization was performed according to computer – generated list and the sequence of randomization was concealed using sequentially numbered envelopes provided by an independent investigator. Immediately before starting the surgical procedure, all patients received 0.02 mg/kg body weight intravenous midazolam. With the start of the procedure, all patients were given 1 μg/kg body weight intravenous fentanyl. In all patients, the surgical site was infiltrated with lidocaine hydrochloride 2%, together with continuous infiltration of the subcutaneous layers as surgery is progressing up to a maximum of 3 mg/kg of lidocaine. This was usually performed by the cardiologist performing the ICD implantation. Success of the local infiltration was examined before the start of the procedure. Before doing the defibrillation test, patients in Group F, were given an additional dose of 0.5 μg/kg body weight intravenous fentanyl, while patients in Group P, were given 1 g of intravenous infusion of paracetamol, infused over 30 min immediately after the surgical incision.

Standard monitoring technique was used in all patients. Electrocardiography electrodes were positioned on the chest wall for electrocardiographic monitoring. External pads were positioned on the chest wall and connected to the external defibrillator for emergency defibrillation if required. Pulse oximetry, invasive arterial blood pressure monitoring for continuous arterial pressure monitoring and blood gas check for oxygenation and ventilation and end tidal CO2 were used. Face mask was applied to deliver 5 L/min oxygen all through the procedure and continuing for 2 h postoperatively. End tidal CO2 was assessed by inserting the sampling CO2 line inside the face mask, close to the patient's nose. All intraoperative respiratory events which had happened, have been recorded including upper airway obstruction as well as apnea. This had been usually detected by continuous inspection of the chest movements as well as counting the respiratory rate per minute in addition to the presence of any abnormal respiratory sounds denoting upper respiratory tract obstruction. The degree of sedation during the surgical procedure had been assessed using the Ramsay Sedation Score, rating the degree of sedation from 1, where the patient may be anxious, agitated or restless, to 6 where there is no response to painful stimuli. Pain was assessed using the Visual Analog Scale (VAS), rating the pain intensity on a 10-point scale from 0 (no pain) to 10 (worst imaginable pain) at the end of the defibrillation test. After finishing the surgical procedure, the patients have been shifted to the recovery room for about 30 min, all through with continuous monitoring, then after making sure about hemodynamic stability, patients had been shifted to the Intermediate Care Unit (IMC). At any time of development of any hemodynamic instability (severe hypotension with mean arterial blood pressure < 60 mmHg, tachycardia with a heart rate > 120/min., malignant arrhythmias as ventricular tachycardia or ventricular fibrillation necessitating defibrillation), either in the operating room or in the recovery, this patient had been excluded from the study together with shifting to the Intensive Care Unit.

2.2. Procedural description

Two types of ICD have been used. The first one was a single chamber ICD which has been used in 20 patients (Virtuoso II VR, Medtronic). The second type was a dual chamber ICD which has been used in 80 patients (in 50 patients Lumax 500 DR-T, Biotronic; in 30 patients Protecta XT DR, Medtronic). The patient was prepped and draped in a standard sterile fashion. A dose of Cefazoline was administered. The skin was incised after local anesthetic infiltration and blunt dissection was employed together with continuous infiltration of the subcutaneous layers with the local anesthetic. The pocket was formed in the left pre-pectoral area. The vein was accessed with peel-away sheath as per the procedure log and the RV lead was advanced to RV and fixed at RV lower septum with good parameters as per the included measurements. The RA lead was advanced to the RA and fixed to RAA with good parameters as per the included measurements. The sheath was then peeled away. The position of leads was checked in lateral fluoroscopy to ensure correct position and appropriate course. Maximum output in this location did not stimulate the diaphragm. Then the leads were secured to the fascia with 0-silk using the lead sleeve. The leads were then connected to the generator. The hard ware was placed in the pocket after it was flushed with antibiotics. The pocket was then closed in two layers using 2.0 Dexon in reverse interrupted mattress suture. The skin was closed using absorbable 3.0 Dexon in subcuticular stitch. The wound was dressed with steri strip and sterile bandage.

2.3. Recommendation/plan

Routine device implant care, including wound care precaution, PA/LAT chest X-ray and device interrogation on next day morning of the procedure. Discharge if the patient remains clinically stable after overnight observation. Routine device interrogation in 2 months.

2.4. Statistical methods

Data were statistically described in terms of mean ± standard deviation (±SD), frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using Student t test for independent samples. For comparing categorical data, Chi square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. p Values less than 0.05 was considered statistically significant. All statistical calculations were done using computer programs SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 15 for Microsoft Windows.

3. Results

One hundred patients have been enrolled in this prospective randomized study, where fifty patients were in the fentanyl group (Group F) and another fifty patients in the paracetamol one (Group P).

Concerning the preoperative and demographic data, there were no statistically significant differences between the two groups (Table 1).

Table 1 Demographic Data.

	Group F (n = 50)	Group P (n = 50)
AGE (years)	75.9 ± 3.7	74.8 ± 3.3
Weight (kg)	74.7 ± 5.1	73.9 ± 4.7
Sex (M/F)	39/11	42/8
Hypertension	44	40
Diabetes	39	42
Ischemic cardiomyopathy	28	33
Idiopathic cardiomyopathy	22	17
Ejection fraction (%)	27.7 ± 1.5	28.3 ± 1.8
ASA 3/4	26/24	27/23

No significant difference between two groups; ASAs: American Society of Anesthesiologists.

As regards the intraoperative data, there was a significant difference between the two groups concerning airway obstruction ($P < 0.05$) where it happened in 39 patients in Group F in comparison to 28 patients only in Group P. For apnea, there was no statistically significant difference between the two groups, however six patients in Group F developed apnea in comparison to only one patient in Group P. Concerning the patients who did not develop any intraoperative respiratory events, there was a significant difference ($P < 0.05$) between the two groups, where 21 patients in Group P in comparison to five patients in Group F (Table 2).

Concerning oxygen saturation, it was insignificantly higher in Group P in comparison to Group F (96.0 ± 0.62% versus 95.8 ± 0.51%) (Table 2).

Carbon dioxide tension (PCO2) was significantly higher in Group F (48.9 ± 0.63 mmHg) in comparison to Group P (45.6 ± 0.64 mmHg) ($P < 0.001$) denoting more hypoventilation in the former group (Table 2).

Although patients in Group F were significantly more sedated than those in Group P ($P < 0.001$), these latter were adequately sedated, where their sedation score was 2.2 ± 0.3 denoting that they were cooperative, oriented and tranquil (Table 2).

There was a significant difference between the two groups as regards the Visual Analog Scale (VAS) ($P < 0.001$), where it was 5.1 ± 0.52 in Group F in comparison to only 3.5 ± 0.33 in Group P, denoting more pain free in this group of patients (Table 2).

4. Discussion

This study showed that intravenous paracetamol was effective in intraoperative pain relief in comparison to Fentanyl in high risk

Table 2 Intraoperative Data.

	Group F (n = 50)	Group P (n = 50)
Airway obstruction	39	28*
Apnea	6	1
No respiratory event	5	21*
Spo2 (%)	95.8 ± 0.51	96.0 ± 0.62
PCO2 (mmHg)	48.9 ± 0.63	45.6 ± 0.64*
Ramsay sedation score($1 \rightarrow 6$)	3.1 ± 0.29	2.2 ± 0.3*
Visual Analog Scale (VAS)($0 \rightarrow 10$)	5.1 ± 0.52	3.5 ± 0.33*

* Significant difference between two groups ($P < 0.05$).

patients undergoing Internal Cardioverter Defibrillator placement under conscious sedation. Additionally, paracetamol had its effect in reducing intraoperative respiratory events as upper airway obstruction and apnea. Although the incidence of respiratory events was significantly lower in the paracetamol group than in the Fentanyl one, the incidence was still high, about 56%, denoting that narcotics have a deleterious respiratory effects in such patients with poor myocardial function.

It is well known that old age patients have a limited physiological reserve with a reduced heart rate responsiveness to hypotension [8]. There is also a greater risk for apnea owing to the reduced ventilatory responses to hypoxia and hypercapnia. The changes in volume of distribution in the elderly population together with changes in bioavailability and receptor sensitivity, result in alterations in the pharmacokinetics of many drugs. Because a high percentage of the elderly patients have prolonged circulation time, longer periods are needed for additional doses. Therefore, titration to effect is mandatory in this group of patients [9].

A high percentage of the elderly surgical patients may develop delirium during sedation [10]. Therefore, caution must be taken during administration of hypnotics and sedatives in this population. It is important when sedating elderly patients, to choose drugs with a short half-life, with minimal active metabolites and limited side effects. A reduction in the standard doses calculated on mg/kg basis, should be practiced. The boluses mostly produce respiratory depression and hypotension. Midazolam and fentanyl is a common combination which has been frequently used for conscious sedation. Owing to the reduced clearance of these drugs and the increased sensitivity in the elderly patients, lower doses as little as 50% of the expected dose, should be administered. In addition, boluses or incremental doses should be delayed [11]. In our study, both groups of patients received an equal dose of fentanyl, as a baseline in order to synergize the analgesic effect of the local anesthetic infiltration in the wound area.

Intravenous paracetamol has a quick onset of action reaching a peak concentration after completion of the infusion which is about 15 min. The analgesic effect starts within 5 min, reaches its peak after 1 h and lasts for about 4–6 h. Paracetamol is considered to be an opioid sparing agent and many studies have showed its effect in reducing the narcotic doses in many surgical procedures and therefore reducing the untoward effects of narcotics [12–14]. One study showed the effect of repeated doses of intravenous paracetamol as a significant analgesic indistinguishable from that of intramuscular morphine [15]. Also, intravenous paracetamol had reduced the PCA morphine requirements after spinal surgery [16] and hip arthroplasty [17]. This was in agreement with our study, where the pain score was significantly lower in the patients who received paracetamol in comparison to those who received fentanyl only. The analgesic effects of paracetamol had been attributed to a number of central analgesic mechanism including opioid-like effects and activational effects on descending pain inhibitory system.

Many studies have shown the different modalities of the anesthetic management of patients undergoing Internal Cardioverter Defibrillator placement. In the initial experience of implantation of ICD by electrophysiologists [3], a comparative study had been done comparing the insertion under either general or local anesthesia with sedation. In this study, it has been proved the feasibility of use of local anesthesia and sedation with no need for general anesthesia. In a study done by Marquié et al. [18], investigating the implantation of ICD under minimal sedation, it has been proved that implantation can be done under minimal sedation even for the defibrillation test. In this study, a comparison had been done between minimal sedation and short general anesthesia and minimal sedation was effective during performing the defibrillation test. Another study done by Pinosky et al. proved also that intravenous sedation for the placement of ICD is a safe and effective technique [5]. A study done by Fox et al. [6], confirmed that ICD placement under local anesthesia with sedation is safe and acceptable to patients and that general anesthesia is no longer required for such procedure.

A study was done by Chow et al. [7], to detect the respiratory events during Monitored Anesthesia Care in high-risk cardiac patients undergoing placement of implantable cardioverter defibrillator. In this study, it has been proved that there is a greater incidence of intraoperative upper airway obstruction more than apnea. Also, in this study, all patients received local anesthesia with conscious sedation using different drugs including propofol, midazolam and fentanyl. Episodes of apnea and upper airway obstruction were abolished by early intraoperative interventions as verbal stimulation, jaw thrust and chin lift maneuvers or placement of a nasal airway. So, the reduction of such risky events during conscious sedation in these high risk patients is very important in reducing the intra and postoperative morbidity and mortality. The avoidance or the reduction of the use of opioids during such procedure is important to minimize the respiratory events. Additionally, in the study done by Bhananker et al. [19], to analyze the claims for Monitored Anesthesia Care (MAC) from the American Society of Anesthesiologists (ASAs) Closed Claims database, they concluded that adverse outcomes during MAC are on increase. The most common untoward effect is inadequate oxygenation/ventilation. Also, claims involved the older population and the higher risk or more sicker patients.

It is recommended to increase the use of intravenous paracetamol in conscious sedation for ICD placement in such high-risk group of patients in order to reduce pain as well as to minimize the deleterious respiratory events which might happen especially with the use of large dose of opioids. Some limitations were faced in this study, which were the limited number of patients, also, evaluation of pain was difficult where we used a simple tool for all patients.

In conclusion, paracetamol is effective in reducing the fentanyl use, so, reducing the incidence of intraoperative upper airway obstruction and apnea. Although the degree of sedation was significantly lower in the paracetamol patients than in those of the fentanyl group, paracetamol provides a good analgesic effect than fentanyl alone by the end of the procedure.

References

[1] Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346:877–83.

[2] Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter–defibrillator for congestive heart failure. N Engl J Med 2005;352:225–37.

[3] Schmitt C, Alt E, Plewan A, et al. Initial experience with implantation of internal/defibrillators under local anaesthesia by electrophysiologists. Eur Heart J 1996;17(11):1710–6.
[4] Moerman A, Herregods L, Tavemier R, et al. Influence of anesthesia on defibrillation threshold. Anesthesia 1998;53(12): 1156–9.
[5] Pinosky ML, Reeves ST, Fishman RL, et al. Intravenous sedation for placement of automatic implantable cardioverter–defibrillators. J Cardiothor Vascular Anesth 1996;10(6):764–6.
[6] Fox DJ, Davidson NC, Royle M, et al. Safety and acceptability of internal cardioverter defibrillator under local anesthesia and conscious sedation. Pacing Clin Electrophysiol 2007;30(8): 992–7.
[7] Chow JL, Hanowell LH, Williams DM, et al. Respiratory events during Monitored anesthesia care in high-risk cardiac patients undergoing placement of implantable cardioverter defibrillator. Anesthesiology 2004;101:A1270.
[8] Larsen B, Buch U, Wilhelm W, et al. Effects of propofol and fentanyl on the baroreceptor reflex in geriatric patients. Anasthesiol Intensivmed Notfallmed Schmerzther 1994;29:408–12.
[9] Darling E. Practical considerations in sedating the elderly. Crit Care Nurs Clin North Am 1997;9:371–80.
[10] O'Keeffe ST, Ni Chonchubhair A. Postoperative delirium in the elderly. Br J Anaesth 1994;73:673–87.
[11] Peacock JE, Lewis RP, Reilly CS, et al. Effect of different rates of infusion of propofol for induction of anaesthesia in elderly patients. Br J Anaesth 1990;65:346–532.
[12] Moote C. Efficacy of nonsteroidal anti-inflammatory drugs in the management of postoperative pain. Drugs 1992;44:14–30.
[13] Dahl JB, Kehlet H. Non-steroidal anti-inflammatory drugs: rationale for use in severe postoperative pain. Br J Anaesth 1991;66:703–12.
[14] Etches RC, Warriner CB, Badner N, et al. Continuous intravenous administration of ketorolac reduces pain and morphine consumption after total hip or knee arthroplasty. Anesth Analg 1995;81:1175–80.
[15] Van Aken H, Thys L, Veekman L, et al. Assessing analgesia in single and repeated administrations of propacetamol for postoperative pain: comparison with morphine after dental surgery. Anesth Analg 2004;98(1):159–65.
[16] Hernandez-Palazon J, Tortosa JA, Martinez-Lage JF, et al. Intravenous administration of propacetamol reduces morphine consumption after spinal fusion surgery. Anesth Analg 2001;92(6):1473–6.
[17] Peduto VA, Ballabio M, Stefanini S. Efficacy of propacetamol in the treatment of postoperative pain. Morphine-sparing effect in orthopedic surgery. Acta Anaesthesiol Scand 1998;42(2):293–8.
[18] Marquié C, Duchemin A, Klug D, et al. Can we implant cardioverter defibrillator under minimal sedation? Europace 2007;9:545–50.
[19] Bhananker SM, Posner KL, Domino KB, Lee LA, Cheney FW. Liability associated with monitored anesthesia care: ASA closed claims project. Anesthesiology 2003;99:A1356.