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Original article

Arthroscopic bankart surgery: Does gabapentin reduce postoperative pain and opioid consumption? A triple-blinded randomized clinical trial

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ABSTRACT

Background: The role of gabapentin as preemptive analgesia in managing acute pain following shoulder bankart arthroscopy is controversial and the studies addressing this issue are limited.
Hypothesis: The present study was undertaken to examine the effects of preemptive single dose of gabapentin on pain management and opioid consumption in patients undergoing arthroscopic bankart surgery.
Patients and methods: In the current triple-blinded randomized clinical trial, 76 eligible patients were randomly divided into two groups either taking gabapentin 600 mg (G group) or placebo (P group). The primary outcomes were pain intensity assessed based on Visual Analogue Scale (VAS) and secondary outcomes were opioid consumption and side effects, dizziness, sedation, nausea and vomiting at 6 h and 24 h follow-up visits.
Results: The pain intensity were not significantly different between the G and P groups ($P > 0.05$). The opioid consumption, however, was significantly reduced in G group at both 6 h and 24 h follow-up visits ($P < 0.001$). Dizziness and sedation were similar in both groups. Nausea and vomiting were significantly lower in G group only at 6 h visit but similar at 24 h follow-up visit ($P < 0.001$).
Discussion: The preemptive single dose of gabapentin 600 mg administered prior to arthroscopic bankart surgery does not decrease post-operation pain, but reduces opioid consumption. Gabapentin restrained postoperative nausea and vomiting for a short while (less than 6 h).
Level of evidence: Level I, treatment study.

1. Introduction

Arthroscopic methods for shoulder instability surgery are increasing mainly due to the early recovery, creation of small incision, and accessibility to the shoulder tendon [1]. However, moderate to severe acute pain may occur secondary to surgical interventions such as bone removal, resection of bursa tissue, insertion of surgical instruments into the joint and irrigation-induced soft tissue distension [2]. Such postoperative acute pain may go untreated or inadequately treated in 50% of all surgical procedures [3,4]. Up to two decades ago, despite their side effects such as respiratory depression and postoperative nausea and vomiting (PONV), opioids were the cornerstone for the treatment of postoperative pain [5,6]. Thus, multimodal analgesia, tended to target the routes of nerves and various neurotransmitters to inhibit hyperalgesia and nociception [7]. On the other hand, it has been demonstrated that such postoperative pains may not be pure nociceptive and may include inflammatory and neurogenic conditions [8,9].

In 1993, gabapentin was introduced as an anti-epileptic drug and it was subsequently administered for acute and chronic pain associated with different diseases such as post-herpetic neuralgia, diabetic neuropathy, trigeminal neuralgia and various headaches [10]. Gabapentin binds to the alpha2-delta-subunit of voltage-gated calcium channels and inhibits the release of

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nociceptive neurotransmitters including glutamates, P-substance and norepinephrine from presynaptic afferent neurons [11]. The anti-hyperalgesic feature of gabapentin may be the main reason for the reduction of pathologic postoperative pain [12]. Daul et al., in a systematic review, compared seven randomized clinical trials (663 patients) and demonstrated that gabapentin reduced pain significantly and decreased the need to opioids in 6 out of 7 studies [8]. However, In a systematic narrative review of 22 randomized clinical trial studies, 4 out of 10 studies using gabapentin as a single dose preemptive analgesia indicated that gabapentin did not reduce pain and opioid consumption [13,14].

The effectiveness of gabapentin as an adjuvant to analgesics has been addressed in several met-analyses [8,13,15–17], however its efficacy in relieving postoperative pain is still controversial and has been questioned in some studies [18–21]. While arthroscopic surgery, as a minimally-invasive procedure, has been increasing during the past decade, there are limited numbers of studies -particularly high quality RCTs-examining the effectiveness of gabapentin in arthroscopic surgeries, especially arthroscopic shoulder surgery [18,22,23]. In the present study, we examined the therapeutic effects of gabapentin as a preemptive analgesic in managing pain secondary to arthroscopic bankart surgery. We hypothesized that preoperative oral administration of 600 mg of Gabapentin to the patients undergoing arthroscopic bankart surgery will result in the reduction of pain and opioid consumption.

2. Materials and methods

2.1. Study design

The present study received the approval of vice chancellor of research and ethic committee of our University of Medical Sciences and was registered on the Registry of Clinical Trials. A triple blind randomized clinical trial study was designed and conducted in the academic hospital. Before recruitment, the patients were briefed about the pros and cons of the two treatment methods and signed the informed consent forms. The study was also in accordance with the ethical standards of Helsinki and Consolidated Standards of Reporting Trials (CONSORT) statement.

2.2. Inclusion and exclusion criteria

The patients diagnosed with shoulder bankart lesion, candidates for arthroscopic surgery, were registered for the study with the following inclusion criteria: aged between 18–75, types I or II in American Society of Anesthesiology (ASA) physical status, operation duration time less than one hour and no concomitant lesions diagnosed during arthroscopy. The exclusion criteria were the presence of any accompanied cartilage lesions, any known allergy to gabapentin, having previous history of epilepsy, hepatic, renal or psychological disorders, alcohol and/or drug abuse and daily consumption of analgesics, corticoesteriods or anticonvulsants.

The eligible patients were randomized based on random block design receiving either gabapentin 600 mg (G group) or identical placebo (P group). The placebo capsules were produced in the form identical to the active counterparts manufactored by the same company. The capsules were administered randomly to the patients two hours prior to the operation by one the author who was not involved in the rest of the research design. The rest of the researchers were blinded to the design of the study till the end of the final analysis. None of the patients received other opioids or analgesics perioperatively. The pain intensity was preoperatively measured using Visual Analog Scale (VAS) (0 = no pain and 10 = unbearable pain). All the patients underwent general anesthesia. Anesthesia was induced with Fentanyl 2 μg/kg and thiopental (4 mg/kg) and maintained with 0.8–1.5% Isoflurane and N_2O and O_2 in ratio of 50%. Atracurium (0.5/mg/kg) was applid for intubation. The patients were also required to receive 7–10cc/kg crystalloid and to be under surveillance with standard monitoring for capnometry, pulse oximetry and non-invasive blood pressure. The first author of the study performed the bankart lesion repair using three titanium anchor sutures via standard anterior and posterior portals.

To control postoperative pain, pethedine (0.5 mg/kg) was injected on demand and opioid consumption was recorded in the patient's questionnaire. The primary and secondary outcomes were evaluated at 6 h and 24 h postoperative visits by another author who was blinded to the study groups.

2.3. Therapeutic outcomes

Pain intensity as measured by (VAS) and opioid consumption were considered as primary outcomes and incidence of side effects (nausia, vommiting, dizziness and sedation score) as secondary outcomes. All the patients were evaluated for nausea and vomiting (level one: nausea, level two: vomiting, level three: vomiting requiring medical intervention); sedation score (a: fully aware; b: aware but drowsy; c: drowsy but capable of following the verbal orders; d: drowsy without the ability to respond to tactile stimulus; e: drowsy unresponsive to any stimulus) and dizziness. Sedation was defined as somnolence or drowsiness and dizziness as light headedness and/or vertigo. The physician aware of which capsule the patients had received coded the questionnaires but without any indication of the type of group and sent them to the study statistician for final statistical analysis.

2.4. Statistical analysis

The sample size required to compare the changes of pain intensity and opioid consumption between the two groups was calculated in accordance to a recent study [22] to be 34 cases in each group providing 80% power with a confidence of 95% with the help of two-sided test. Chi^2 or Fisher exact test was used to compare qualitative variables. Mann Whitney-*U* test was applied to assess the categorical variables and non-normally distributed continuous variables. Student *t*-test was used to evaluate normally distributed quantitative variables. SPSS software (ver.19) for Windows was applied for statistical analyses and $P < 0.05$ was considered to be significant.

3. Results

Out of 113 eligible patients referred to our clinic between May 2011 to May 2013, seventy six patients were randomly assigned to either of the following groups: gabapentin (38 patients) or placebo (38 patients). There were no significant differences between the demographic characteristics (age, gender and BMI), the operation duration time and pain intensity between the two groups prior to the study (all $P > 0.05$) (Table 1). One patient from G group and four

Table 1
Baseline assessments: the demographic characteristics and operation duration time for both groups.

	Group G	Group P
Number, *n*	38	38
Age (mean ± SD)	30.2 ± 5	28.3 ± 4.4
Gender (Female/Male)	11/27	8/30
Operation time (Mean ± SD)	46.9 ± 10.7	43.9 ± 9.5
Weight (Kg)	68.2 ± 1.8	67.4 ± 11.3
BMI	23.3 ± 1.8	24.1 ± 3.4

P was not significant in all the analyses, $P > 0.05$. SD: standard deviation; BMI: body mass index.