Continuous ropivacaine infusion vs transdermal fentanyl for providing postoperative analgesia following temporomandibular joint interpositional gap arthroplasty

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ABSTRACT

Aim: The purpose of this study was to evaluate the postoperative pain control and mouth opening in patients undergoing temporomandibular joint interpositional gap arthroplasty by either placing an epidural catheter in the incision wound and infusing ropivacaine 0.25% or by using a transdermal fentanyl patch. Materials and Methods: The study was prospective, randomized and double blind. Eighty patients belonging to American Society of Anesthesiologists grade I and II, 18–32 years of age, scheduled for temporomandibular joint interpositional gap arthroplasty were randomized into 2 groups; ropivacaine group (G rop): to receive 0.25% ropivacaine infusion and transdermal fentanyl group (G tf): to receive transdermal fentanyl patch. For postoperative pain (Visual Analog Score [VAS]) and analgesic requirements were assessed 2, 4 and 8 h after surgery and each morning, until and 4 days after surgery. Results: Time to first analgesic requirement was found to be significantly (P < 0.0001) higher in G rop (49 ± 6.7) as compared with G tf (32 ± 9.1) VAS were also significantly lower in G rop throughout the postoperative period. Postoperatively, mouth opening was better in G rop as compared with G tf, which was statistically significant. Conclusion: It was concluded that by placing an epidural catheter at the incision wound and continuously infusing with ropivacaine 0.25% effectively controls the postoperative pain in patients undergoing temporomandibular joint interpositional gap arthroplasty and provides better postoperative mouth opening.

Key words: Ropivacaine, temporomandibular joint interpositional gap arthroplasty, transdermal fentanyl

INTRODUCTION

Temporomandibular joint ankylosis is defined as the fusion of joint surfaces by bone or fibrous tissue. Inability to open the mouth in temporomandibular joint ankylosis results in inability to maintain oral hygiene, inability to chew properly and esthetic problems.[1-3]
This leads to dental caries, malocclusion, weight loss and growth retardation..Temporomandibular joint ankylosis is treated by temporomandibular joint interpositional gap arthroplasty. Immediate and delayed postoperative pain at the operative site is distressing to the patient and has considerable morbidity. Pain at the operative site prevents patients from opening their mouth and it is a major problem that hinders the early active physiotherapy. Adequate pain relief at the operative site becomes most important to restore early movements at the temporomandibular joint. This can be achieved by using systemic opioid analgesics or long-acting local anesthetic injection at the operative site.

The aim of the present study was to assess the postoperative pain control at the operated site and mouth opening by either placing an epidural catheter in the incision wound and infusing ropivacaine 0.25% or by using a transdermal fentanyl patch.

Materials and Methods

After getting a written informed consent from all the subjects, 80 patients, between 18 and 32 years, of American Society of Anesthesiologists physical status grade I or II, average height of 150–160 cm and ±20% of the ideal body weight, admitted for temporomandibular joint ankylosis surgery, were enrolled in the study as per protocol. Inclusion criteria included the subjects with unilateral and/or bilateral bony temporomandibular joint ankylosis, scheduled for temporomandibular joint interpositional gap arthroplasty. Obese patients, patients with any cardiac and/or respiratory disease and patients allergic to local anesthetic agents were excluded from the study.

The study design was double blind, randomized and prospective. All subjects were admitted a day before surgery. The Visual Analog Scale (VAS) for scoring pain was explained to all the subjects. Subjects were also informed that some treatment will be given, which might be helpful in decreasing the postoperative pain. Subjects were selected using simple randomized sampling and allocated to either of the 2 groups, using sealed opaque envelopes, by the numbers randomly generated by computer table. All the subjects were fasted for 12 h to eliminate the risk of aspiration during surgery. No sedative premedication was given preoperatively. Intravenous line established and 5% dextrose in normal saline started in the operating room. Standard monitoring with Non-Invasive Blood Pressure, electrocardiography and pulse oximetry was done. Flexible fiber optic laryngoscope and instruments for tracheostomy were kept ready for emergency access to a definitive airway. All subjects received injection glycopyrrolate 0.004 mg/kg body weight IV and injection ondansetron 0.08 mg/kg body weight IV and were preoxygenated for 3–4 min. This was followed by slow injection fentanyl 2 μg/kg IV plus injection midazolam 0.05 mg/kg body weight IV. Awake nasotracheal intubation was done with flexible fiber optic laryngoscope. Anesthesia was induced with propofol 2 mg/kg body weight IV and rocuronium 0.9 mg/kg body weight IV. Anesthesia was maintained with 1% Isoflurane and nitrous oxide/oxygen combination (60/40). At the end of interpositional gap arthroplasty, all patients were randomly divided into 2 groups. Ropivacaine group (G rop) patients received an epidural catheter in the incision wound at the operated site just above the galea aponeurotica with its tip in the temporomandibular joint and this was followed by the closure of surgical wound in layers [Figure 1]. After the closure of surgical wound, these patients received injection ropivacaine 0.25% infusion @ 1.6 mL/h through the epidural catheter.

Transdermal fentanyl group (G tf) patients did not receive epidural catheter instead a fentanyl patch (Duragesic, Johnson and Johnson Ltd, Mumbai, release at 25 μg/h) was applied to a clean, dry area on the upper arm, before conclusion of the surgery. Hairs were removed from the site, prior to applying the patch. The patch was pressed firmly for 30 s to make sure that the patch stays in place.

At the conclusion of surgery, neuromuscular block was antagonized with neostigmine 0.5 mg/kg body weight and glycopyrrolate 0.01 mg/kg body weight IV, patients were extubated and transferred to the Postanesthesia Care Unit (PACU). All subjects remained in the PACU for at least 8 h to observe respiratory depression. Subjects who complained of pain in PACU received 75 mg injection—diclofenac sodium intramuscular. In the ward, 100 mg diclofenac sodium tablets were given, if required. Postoperative pain was assessed by a senior resident (nonanesthetist) blinded to group allocation, using VAS scoring (horizontal line from 0 to 100, with 0 representing no pain and 100 representing maximal unbearable pain). The patients were asked to draw a point in the horizontal line denoting the present intensity of their pain. Pain was assessed 2, 4 and 8 h after surgery and each morning, until the 7th day after surgery and after that the epidural catheter and fentanyl patch were removed. Active physiotherapy was started from second postoperative day with a wooden spatula. Mouth opening was assessed in the immediate postoperative period, on day 4 and day 10. Sample size was calculated using power and sample size calculator by the Department of Biostatics, Vanderbilt University, USA. With 80% power (20% beta error) and
95% confidence level (5% alpha error), the sample size calculated was 34, in each group. Data obtained were statistically analyzed and compared for both the groups. Statistical calculations were made by analysis of variance test. Patient characteristics, duration of surgery, time to first analgesic requirements, number of diclofenac tablets consumed by each group of patients during the first 4 days after surgery and VAS scoring at rest were compared using paired and unpaired Student's t test. The SPSS 11 software was used for statistical analysis.

Results

Patient characteristics and duration of surgery were found to be similar among both the groups [Table 1].

The time to first analgesic requirement was found to be significantly ($P<0.001$) higher in G rop (189.30 ± 152.28) as compared with G tf (122.30 ± 88.46) [Table 2].

VAS scoring was found to be significantly lower in G rop as compared with G tf, throughout the 4 postoperative days [Figure 2].

Mouth opening in the immediate postoperative period was comparable in both the groups ($P > 0.001$), but it was significantly better in G rop at 4th and 10th postoperative days ($P < 0.001$) as compared with G tf [Table 3].

Discussion

Sensitization of dorsal horn neurons has been demonstrated in acute postoperative pain and this may

Table 1: Patient characteristics

|                  | G tf        | G rop       | t value | P value |
|------------------|-------------|-------------|---------|---------|
| Age (yr)         | 25.975 ± 6.023 | 26.700 ± 4.304 | 0.619   | 0.537   |
| Body weight (kg) | 52.800 ± 6.466 | 53.825 ± 5.957 | 0.737   | 0.463   |
| Height (cm)      | 153 ± 4.1   | 154 ± 4.3   | 1.190   | 0.2369  |
| Duration of surgery (min) | 140 ± 17.3 | 141 ± 19.2 | 0.2376   | 0.7850 |

G tf, transdermal fentanyl group; G rop, ropivacaine group.

Table 2: Time to first analgesic and analgesic requirement

|                                | G tf           | G rop          | P value |
|--------------------------------|----------------|----------------|---------|
| Time to first analgesic in PACU (min) | 122.30 ± 88.46 | 189.30 ± 152.28 | <0.001  |
| No. of patients requiring intramuscular injection diclofenac in PACU | 30             | 8              | <0.001  |
| Diclofenac tablets during the first 4 postoperative days | 5.00 ± 0.94    | 1.24 ± 0.27    | <0.001  |

G tf, transdermal fentanyl group; G rop, ropivacaine group; PACU, Postanesthesia Care Unit.

Table 3: Postoperative mouth opening

|                         | G tf            | G rop           | P value |
|-------------------------|-----------------|-----------------|---------|
| In immediate postoperative period (mm) | 33.6714 ± 1.7736 | 33.30003 ± 1.3367 | >0.001  |
| On the 4th postoperative day | 34.1736 ± 1.1146 | 40.4334 ± 2.1342 | <0.001  |
| On the 10th postoperative day | 36.6514 ± 1.7836 | 45.7143 ± 1.5439 | <0.001  |

G tf, transdermal fentanyl group; G rop, ropivacaine group.
also play a role in the development of chronic pain after surgery.[6,7] By reducing the hyperexcitability of dorsal horn neurons or by stabilizing the neuronal membrane, fentanyl and ropivacaine may have roles in the treatment of postoperative pain. Therefore, systemic opioid analgesics or long-acting local anesthetic injection at the operative site can be used for postoperative pain relief. Hypothesis of infiltrating the wound with bupivacaine in the operated site leads to significant reduction of pain.[8] Also with ropivacaine and morphine, similar results were obtained.[9,10]

Our results demonstrate that the drugs administered as per protocol of the study, significantly reduced the requirement of analgesics throughout the postoperative period. Fentanyl, a synthetic opioid agonist interacts primarily with the μ (mu) receptor. The low molecular weight, high potency and lipid solubility of fentanyl make it a suitable opioid analgesic.[11] The use of fentanyl is well established and accepted indication in the treatment of pain, as indicated by recent review articles.[12,13] In our study, transdermal fentanyl patch was applied once after the conclusion of surgery (t 1/2 β after transdermal administration: 13–22 h) and the patch was replaced at every 24 h for 3 days. Our aim was to achieve more consistent serum levels of fentanyl and to reduce analgesic requirement during the early postoperative period.

As with other opioid agents, the most frequently observed adverse event during transdermal fentanyl treatment is hypoventilation. It has occurred in 3 (2%) of the 153 patients with cancer pain during the previous premarketing trial.[14] Clinically relevant fentanyl-induced respiratory depression, however, was not observed during the previous 3 randomized trials.[15,16] In our study, for the doses given along with the duration of administration of transdermal fentanyl patch, there was no observable respiratory depression. Furthermore, any expected incidence of nausea and vomiting was prevented by the prophylactic use of ondansetron, as per the protocol of our study.

Ropivacaine is a new amide type long-acting local anesthetic agent mainly used for providing anesthesia and postoperative analgesia.[17] At higher doses it provides surgical anesthesia and at lower doses it provides analgesia.[18,19]

The drug at clinically relevant concentrations reduces the membrane voltage-gated sodium currents in nerve fibers. It produces analgesia by reversible blockade of impulse propagation along the nerve fibers by preventing the inward movement of sodium ions across the nerve cell membrane. Unlike bupivacaine, ropivacaine has no cardiotoxicity making it superior to bupivacaine for providing postoperative analgesia.[20,21]

Side effects of ropivacaine include nausea, paresthesia, dizziness, dyspnea, syncope and cardiac arrhythmias.[22,23] We did not observe intolerable side effects for the daily dose and the duration of treatment, as determined by the protocol of the study.

This analgesic treatment was not associated with adverse effects and may be appropriate for patients who have undergone temporomandibular joint interpositional gap arthroplasty. In our study, ropivacaine infusion provided superior analgesia and better mouth opening throughout the postoperative period as compared with transdermal fentanyl patch.

**Conclusions**

It is concluded that placing epidural catheter at the incision wound and continuously infusing with ropivacaine 0.25% effectively controls the postoperative pain and provides better mouth opening in patients who have undergone temporomandibular joint interpositional gap arthroplasty.

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