

## Comparison of ON-Q elastomeric pump system and thoracic epidural analgesia methods for pain management after thoracotomy

*Torakotomi sonrası ağrı yönetiminde ON-Q elastomerik pompa sistemi ile torasik epidural analjezi yöntemlerinin karşılaştırılması*

Gönül Sağıroğlu,<sup>1</sup> Ayşe Baysal,<sup>2</sup> Burhan Meydan,<sup>3</sup> Osman Gazi Kiraz,<sup>2</sup> Ahmet Erdal Taşçı<sup>2</sup>

*Institution where the research was done:*

Süreyyapaşa Chest Diseases Training and Research Hospital, İstanbul, Turkey

*Author Affiliations:*

<sup>1</sup>Department of Anaesthesiology and Reanimation, Medical Faculty of Trakya University, Edirne, Turkey

<sup>2</sup>Department of Anaesthesiology and Reanimation, Kartal Koşuyolu Yüksek İhtisas Training and Research Hospital, İstanbul, Turkey

<sup>3</sup>Department of Anaesthesiology and Reanimation, Süreyyapaşa Chest Diseases Training and Research Hospital, İstanbul, Turkey

### ABSTRACT

**Background:** This study aims to compare the results of continuous infusion of local anesthetics through either ON-Q elastomeric pump or thoracic epidural analgesia for management of pain after thoracotomy.

**Methods:** Ninety-seven patients (86 males, 11 females; mean age 56.37 years; range 34 to 86 years) were included in this prospective and randomized study. Patients were randomized into two groups to undergo either ON-Q elastomeric pump system (group 1, n=50) or thoracic epidural analgesia (group 2, n=47) for 24 hours. In both groups, continuous 0.125% bupivacaine infusion was performed from a catheter at a rate of 0.1 mL/kg/hour. Intravenous morphine was provided to all patients through patient controlled analgesia method. Postoperative pain was evaluated with visual analog scale during rest and coughing at baseline and postoperative first, sixth, 12<sup>th</sup>, and 24<sup>th</sup> hours.

**Results:** Although visual analog scale rest and coughing scores of group 1 at first, sixth, 12<sup>th</sup>, and 24<sup>th</sup> hours were significantly higher than group 2, its baseline values were similar to group 2. Total local anesthetic consumption of group 2 was higher than group 1. Although hypotension was not observed in any patient in group 1, significant hypotension was observed in seven patients (14.9%) in group 2. The incidences of nausea and vomiting were 4% (n=2) in group 1 and 17% (n=8) in group 2.

**Conclusion:** Thoracic epidural analgesia provides superior analgesia compared to ON-Q elastomeric pump system in pain treatment after thoracotomy. Still, having lesser incidence of hypotension and easier technical application, ON-Q elastomeric pump system may be considered as an alternative method to thoracic epidural analgesia.

**Keywords:** ON-Q elastomeric pump system; pain; thoracic epidural block; thoracotomy.

### ÖZ

**Amaç:** Bu çalışmada torakotomi sonrası ağrı yönetiminde ON-Q elastomerik pompa veya torasik epidural analjezi yoluyla devamlı lokal anestetik infüzyonunun sonuçları karşılaştırıldı.

**Çalışma planı:** Bu prospektif ve randomize çalışmaya 97 hasta (86 erkek, 11 kadın; ort. yaş 56.37 yıl; dağılım 34-86 yıl) dahil edildi. Hastalar 24 saat boyunca ON-Q elastomerik pompa sistemi (grup 1, n=50) veya torasik epidural analjezi (grup 2, n=47) uygulanmak üzere iki gruba randomize edildi. Her iki grupta devamlı %0.125 bupivakain infüzyonu kateterden 0.1 mL/kg/saat oranında uygulandı. Tüm hastalara hasta kontrollü analjezi yöntemi ile intravenöz morfin verildi. Ameliyat sonrası ağrı görsel analog ölçeği ile istirahat ve öksürük sırasında başlangıçta ve ameliyat sonrası birinci, altıncı, 12. ve 24. saatte değerlendirildi.

**Bulgular:** Grup 1'in birinci, altıncı, 12. ve 24. saatlerdeki görsel analog ölçeği istirahat ve öksürük puanları grup 2'den anlamlı olarak yüksek olmasına rağmen, başlangıç değerleri grup 2 ile benzerdi. Grup 2'nin toplam lokal anestezi tüketimi grup 1'den daha yüksek idi. Grup 1'deki hiçbir hastada hipotansiyon gözlemlenmemesine karşın, grup 2'de yedi hastada (%14.9) belirgin hipotansiyon gözlemlendi. Bulantı ve kusma sıklığı grup 1'de %4 (n=2), grup 2'de %17 (n=8) idi.

**Sonuç:** Torakotomi sonrası ağrı tedavisinde torasik epidural analjezi ON-Q elastomerik pompa sistemine göre daha iyi analjezi sağlar. Yine de daha az hipotansiyon sıklığı ve daha kolay teknik uygulaması olan ON-Q elastomerik pompa sistemi, torasik epidural analjeziye alternatif bir yöntem olarak düşünülebilir.

**Anahtar sözcükler:** ON-Q elastomerik pompa sistemi; ağrı; torasik epidural blok; torakotomi.



Available online at  
www.tgkdc.dergisi.org  
doi: 10.5606/tgkdc.dergisi.2017.12446  
QR (Quick Response) Code

Received: October 01, 2015 Accepted: March 27, 2016

Correspondence: Gönül Sağıroğlu, MD, Trakya Üniversitesi Tıp Fakültesi Anesteziyoloji ve Renimasyon Anabilim Dalı, 22030 Edirne, Turkey.

Tel: +90 284 - 235 76 41 e-mail: gonulsagirolu45@gmail.com

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Postoperative pain results in physiologic changes in whole body, affecting the function of the respiratory, cardiovascular, gastrointestinal, urinary, musculoskeletal, and neuroendocrine systems. Effective pain management after thoracotomy surgical procedures is often difficult because of surgical wound causing significant tissue damage.<sup>[1,2]</sup> Following thoracotomy, pain relief with effective analgesia reduces complication rates while speeding up recovery. Thus time of hospitalization may shorten with early mobilization of patient and negative effects of pain may be prevented.<sup>[3]</sup>

For post-thoracotomy pain, the use of continuous or single-shot epidural infusions, patient-controlled analgesia (PCA), or a combination of these techniques are currently the most preferred methods. As an alternative to thoracic epidural analgesia (TEA) and PCA pain managements, long-acting agents have been used to control pain at the site of incision or as a regional nerve block.

The ON-Q pump elastomeric pump system consists of an elastomeric pump that holds 270 mL of local anesthetic. The pump is connected by a flow limiting valve to a small flexible catheter that acts as a soaker hose and allows continuous infusion of the drug to nearby tissues.<sup>[4,5]</sup>

In this study, we aimed to compare the results of continuous infusion of local anesthetics through either ON-Q pump elastomeric pump system or thoracic epidural analgesia for management of pain after thoracotomy.

## PATIENTS AND METHODS

This prospective and randomized study was conducted between September 2012 and December 2013 at Süreyyapaşa Chest Disease and Thoracic Surgery Hospital. A total of 110 patients were enrolled to the study. Only 97 of the patients (86 males, 11 females; mean age 56.37 years; range 34 to 86 years) could able to have pain management after thoracotomy [three patients refused to participate although they had fulfilled the inclusion criteria and 10 patients were unable to complete the study secondary to problems related to severe hypotension (n=2), reintubation (n=1), misplacement of the catheter (n=6)]. The consort diagram was presented in Figure 1. The study protocol was approved by the Kartal Koşuyolu Yüksek İhtisas Training and Research Hospital Ethics Committee. A written informed consent from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patients were randomized to receive either ON-Q elastomeric pump system (group 1, n=50) or TEA (group 2, n=47) for 24 hours. Randomization into two groups was performed using random numbers method. The observers who collected visual analog scale (VAS) scores and other data were blinded to the pain relief protocol. Caregivers were not blinded, but they did not participate in data collection. All surgical procedures were performed by the same surgical team.

Exclusion criteria included; American Society of Anesthesiologists physical status >III, known drug or local anesthetics allergies, prior lumbar spine surgery or vertebral column deformity, pregnancy, abnormal coagulation tests (platelet count <80,000, prothrombin time >1.5 or partial thromboplastin time >45 seconds), history of comorbidities such as (i) clinical and laboratory findings of hepatic or renal disease, (ii) valvular heart dysfunction, (iii) chronic obstructive lung disease, (iv) hypertension, or (v) diabetes mellitus; forced expiratory volume in first second (FEV<sub>1</sub>) <60%, and/or forced vital capacity (FVC) <60% predicted, and neurological impairment causing inability to understand consent form or pain measurement.

The patient was placed in the sitting position, a thoracic epidural catheter (Portex Epidural Minipack; Smiths Medical ASD Inc., Keene, NH, USA) was positioned in the thoracic epidural space at the T<sub>5-7</sub> level using a 16-gauge Tuohy needle (Portex Epidural Minipack; Smiths Medical ASD Inc., Keene, NH, USA) with loss of resistance technique. The catheter was advanced 4 to 5 cm inside the epidural space and a test dose of 3 mL lidocaine (Jetmonal 2%, Adeka Pharmaceutical, Turkey) 2% with epinephrine 5 µg/mL was given to exclude misplacement of the catheter.

A percutaneous epidural catheter was inserted through a 16-gauge disposable Tuohy needle at the end of the operation before the chest was closed in group 1. We performed muscle-sparing posterolateral thoracotomy in all patients, preserving the serratus anterior and latissimus dorsi muscles. Postoperatively, the surgeon inserted the ON-Q elastomeric pump system's catheter with an introducer needle in inferior part of the thoracotomy incision. The catheter was stabilized with skin sutures, as close as possible through to intercostal nerve and profound surface of the serratus muscle. The tip was placed in periscapular space where the serratus muscle ends from the scapula. A bolus dose was not given through the catheter in both groups. A baseline pain intensity was obtained after extubation in the intensive care unit (ICU).

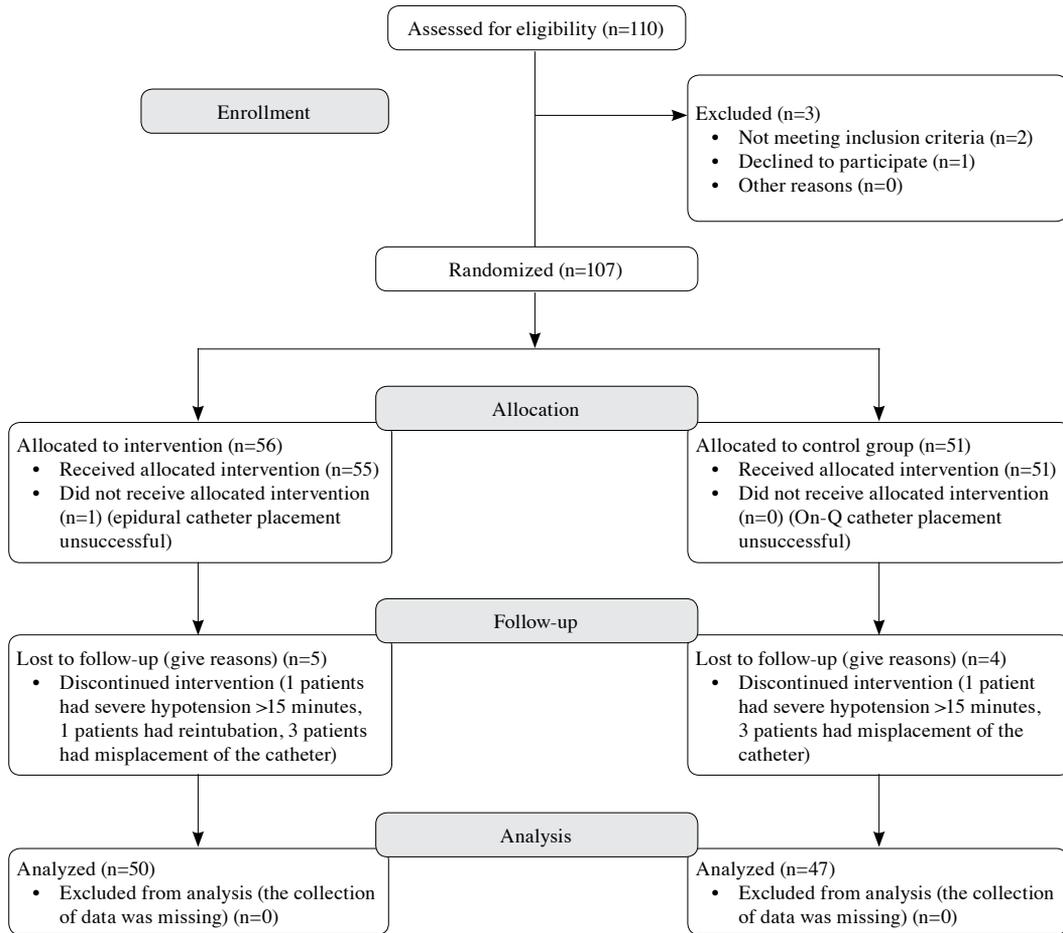


Figure 1. CONSORT 2010 flow diagram.

### Anesthesia and surgical management

In all patients, anesthesia induction was conducted with the use of intravenous doses of sodium thiopental 5-7 mg/kg (Pental, IE Ulugay Pharmaceutical, Turkey), fentanyl 2 µg/kg (Janssen fentanyl, Janssen Pharmaceutical, Belgium) and 0.15 mg/kg vecuronium (Blok-L, Mustafa Nevzat Pharmaceutical, Turkey). A double lumen endobronchial intubation was performed. After anesthesia induction, radial artery cannulation via 20-gauge needle was performed to collect hemodynamical data including blood pressure, heart rate, and arterial blood gas values. Anesthesia was maintained with sevoflurane (Sevorane, Abbott Pharmaceutical, USA) 0.5 to 2%, 70% oxygen, and 30% air. Duration of operation, total amount of packet red blood cells (RBC) and fresh frozen plasma (FFP) solutions during surgery, and duration of hospital stay were also recorded.

Analgesic solution which contains 0.125% bupivacaine (Bustesin 0.5%, Vem Pharmaceutical, Turkey) was prepared and infused at a rate of 0.1 mL/kg/hour from the inserted catheter in the postoperative care unit by using an infusion pump. The catheters were removed in postoperative first day.

Demographic data, age, height, weight, body mass index, pulmonary function parameters, comorbid diseases, and cancer histological types were recorded. In addition, arterial blood gas arterial partial pressure of oxygen (PaO<sub>2</sub>), arterial partial pressure of carbon dioxide (PaCO<sub>2</sub>), and arterial oxygen saturation values were recorded preoperatively and on postoperative first, sixth, 12<sup>th</sup>, 24<sup>th</sup> hours. All patients were monitored with two-lead electrocardiography (leads II and V<sub>5</sub>) for heart rate and ST segment changes, with non-invasive pulse oximetry (SpO<sub>2</sub>) and esophageal temperature. Airway pressures, ventilation parameters, inspired oxygen concentration (FiO<sub>2</sub>), expired end-tidal carbon dioxide concentration, and end-tidal sevoflurane concentration

were monitored. Systolic arterial pressure, diastolic arterial pressure, mean arterial pressure (MAP), heart rate (HR), and respiratory rate (RR) were measured at basal, second, fourth, eighth, 16<sup>th</sup>, and 24<sup>th</sup> hours postoperatively in the ICU.

First hemodynamic measurements in the ICU were recorded as baseline values. At any time point, episode of hypotension was defined as a fall in MAP more than 25% of baseline value for a period of less than 15 minutes. Severe hypotension was a fall in MAP more than 25% of baseline value for a period more than 30 minutes. Both of these conditions were treated with crystalloid fluid infusions. If infusion of crystalloid solution did not increase the blood pressure, 10 mg of ephedrine (Ephedrine, Osel Pharmaceutical, Turkey) bolus was administered. Bradycardia was defined as heart rate below 50 beats/minute and was treated with bolus doses of 0.4 mg atropine sulfate (Atropin sulfate, Biofarma Pharmaceutical, Turkey). In both groups of patients, intramuscular 50 mg diclofenac (Dikloron, Deva Pharmaceutical, Turkey) was administered every eight hour. At the end of surgery, patients were weaned from mechanical ventilation. Reintubation was necessary in some patients in the ICU. The criteria for weaning from mechanical ventilation included PaO<sub>2</sub> ≥60 mmHg, FiO<sub>2</sub> ≤0.40, peak end expiratory pressure ≤5 cmH<sub>2</sub>O, RR <30, minute ventilation of <12 liter to maintain partial PaCO<sub>2</sub> between 35 and 45 mmHg, appropriate level of consciousness, intact cough and gag reflex, vital capacity >10 mL/kg, and minimum inspiratory pressure <-30 cm H<sub>2</sub>O.

Postoperatively, the incidence of nausea or vomiting was noted. Nausea greater than 2/10 (measured by the VAS pain score) or vomiting was treated with 10 mg intravenous metoclopramide.

After extubation, patients were assessed by a physician in ICU to evaluate their pain at a scale from 0= no pain to 10= disabling pain by the use of VAS. Postoperative pain scores at rest (VAS-R) and after a strong cough (VAS-C) were evaluated. Sedation scores were judged by the observer (0= awake; 1= mild sedation; 2= moderate sedation, easily arousable; 3= heavily sedated/difficult to arouse; 4= over sedated, unarousable). In each case, pain and sedation scores were evaluated at basal, first, second, fourth, 16<sup>th</sup>, and 24<sup>th</sup> hours by a blinded resident to the study protocol on call in the ICU.

Excessive sedation was defined as a score 3 or 4 and either respiratory depression (defined as a ventilatory frequency below <8 breaths/minute) or hypercarbia

(PaCO<sub>2</sub> >50 mmHg) was treated with 100% oxygen supplementation via a face mask. Patients were discharged from the ICU when the following criteria were met: SpO<sub>2</sub> ≥90% at FiO<sub>2</sub> ≤0.5 by face mask, hemodynamical parameters including MAP, HR and RR within normal adult limits, chest tube drainage <50 mL/hour, urine output >0.5 mL/kg/hour, and no intravenous inotropic or vasopressor therapy. At a VAS score >3, breakthrough pain relief was provided through bolus doses of epidural analgesic agent at a dose of 0.1 mL/kg in addition to PCA. Additional pain relief was provided with intravenous morphine at a dose of 2 mg in both groups for a VAS score >3 at rest despite four consecutive PCA boluses.

The primary endpoint was pain at rest and coughing. Secondary endpoints were 24 hour morphine consumption, morphine-related side effects (nausea and vomiting, pruritus, and sedation), and complications.

### Statistical analysis

All analyses were performed using SPSS Statistical Package version 15.0 (SPSS Inc., Chicago, IL, USA). The sample size was determined depending on the below calculation: a difference of 20 cm/hour in the area under the curve of the VAS score during coughing with an expected standard deviation of 50 cm/hour, and alpha- and beta-errors of 0.05 at a power of 0.8; the calculated sample size was 60 patients. To compensate for unforeseen drop-outs and a possibly higher variability than expected, we planned to study 80 patients.<sup>[6]</sup> Data were presented as mean and standard deviation or as frequencies and percentages. Differences were assessed using chi square or Fisher exact test for categorical variables. Mann-Whitney U test was used for continuous or non-parametric data. After testing for normal distribution, data were compared using a two-way analysis of variance for repeated measurements. A *p* value of <0.05 was considered statistically significant.

## RESULTS

The comparison of the baseline characteristics between groups showed no significant difference (Table 1). Also, preoperative spirometric data including FEV<sub>1</sub> (86.7±16.5 versus 82.2±13.7) and FVC (84.8±17.2 versus 78.9±14.7) values were not different between groups.

The postoperative hemodynamic data including MAP, HR, and RR were not significantly different at any time interval between groups 1 and 2. The comparison of PaO<sub>2</sub>, PCO<sub>2</sub>, and SaO<sub>2</sub> values preoperatively and

**Table 1. Demographic data, American society of anesthesiologists classification, and operative and postoperative data in both groups**

| Variable                                | Group 1 (n=50) |    |            |        | Group 2 (n=47) |    |      |            | p    |           |        |
|---|----------------|----|------------|--------|----------------|----|------|------------|------|-----------|--------|
|   | n              | %  | Mean±SD    | Median | Range          | n  | %    | Mean±SD    |      | Median    | Range  |
| Age (years)                             |                |    | 55         | 38-77  |                |    |      | 53         |      | 34-86     | 0.556  |
| Gender                                  |                |    |            |        |                |    |      |            |      |           | 0.285  |
| Female                                  | 46             |    |            |        |                | 40 |      |            |      |           |        |
| Male                                    | 4              |    |            |        |                | 7  |      |            |      |           |        |
| Weight (kg)                             |                |    |            | 65     | 50-104         |    |      |            | 67   | 47-90     | 0.722  |
| Height (cm)                             |                |    |            | 170    | 158-181        |    |      |            | 167  | 150-186   | 0.183  |
| Body mass index (kg/m <sup>2</sup> )    |                |    |            | 23.8   | 16-36          |    |      |            | 25.2 | 19.5-33.7 | 0.11   |
| History of smoking                      | 41             | 84 |            |        |                | 36 | 77   |            |      |           | 0.511  |
| Neoadjuvant therapy                     | 7              | 14 |            |        |                | 4  | 9    |            |      |           | 0.394  |
| Comorbidity disease                     |                |    |            |        |                |    |      |            |      |           |        |
| Hepatic or renal disease                | 1              | 2  |            |        |                | 4  | 8.5  |            |      |           | 0.147  |
| Valvular heart dysfunction              | 6              | 12 |            |        |                | 9  | 17   |            |      |           | 0.482  |
| Chronic obstructive lung disease        | 14             | 28 |            |        |                | 11 | 23.4 |            |      |           | 0.605  |
| Hypertension                            | 17             | 34 |            |        |                | 15 | 31.9 |            |      |           | 0.827  |
| Diabetes mellitus                       | 4              | 8  |            |        |                | 9  | 19.1 |            |      |           | 0.107  |
| Histologic type of cancer               |                |    |            |        |                |    |      |            |      |           |        |
| Squamous cell                           | 36             | 72 |            |        |                | 30 | 63.8 |            |      |           | 0.388  |
| Adenocarcinoma                          | 11             | 22 |            |        |                | 15 | 31.9 |            |      |           | 0.271  |
| Undifferentiated                        | 3              | 6  |            |        |                | 2  | 4.3  |            |      |           | 0.698  |
| Type of resection                       |                |    |            |        |                |    |      |            |      |           |        |
| Lobectomy or bilobectomy                | 29             | 58 |            |        |                | 22 | 47   |            |      |           | 0.27   |
| Pneumonectomy                           | 13             | 26 |            |        |                | 20 | 43   |            |      |           | 0.085  |
| Segmentectomy                           | 8              | 16 |            |        |                | 5  | 11   |            |      |           | 0.439  |
| Surgical side                           |                |    |            |        |                |    |      |            |      |           |        |
| Right                                   | 38             | 76 |            |        |                | 28 | 59.6 |            |      |           | 0.083  |
| Left                                    | 12             | 24 |            |        |                | 19 | 40.4 |            |      |           |        |
| Duration of surgery (min)               |                |    | 208.2±58.3 |        | 120-360        |    |      | 227.3±57.0 |      | 130-330   | 0.106  |
| Additional morphine consumption (mg)    |                |    | 8.1±6.5    |        | 5-25           |    |      | 6.7±4.2    |      | 5-20      | 0.213  |
| Total local anesthetic consumption (mL) |                |    | 205.6±35.4 |        | 120-240        |    |      | 187.0±32.8 |      | 110-210   | 0.009* |
| Hospital stay (days)                    |                |    | 8.7±2.3    |        | 7-16           |    |      | 7.7±2.8    |      | 6-21      | 0.052  |

SD: Standard deviation; \* p<0.05: Statistically significant; Group 1: ON-Q group; Group 2: Thoracic epidural group.

**Table 2. Comparison of arterial blood gas values pre- and postoperatively at first, sixth, 12<sup>th</sup>, and 24<sup>th</sup> hour in both groups**

|                          | Preoperative | 1 <sup>st</sup> hour | 6 <sup>th</sup> hour | 12 <sup>th</sup> hour | 24 <sup>th</sup> hour |
|--------------------------|--------------|----------------------|----------------------|-----------------------|-----------------------|
|                          | Mean±SD      | Mean±SD              | Mean±SD              | Mean±SD               | Mean±SD               |
| PaO <sub>2</sub> (mmHg)  |              |                      |                      |                       |                       |
| Group 1                  | 145.5±72.2   | 140.5±41.7           | 134.8±39.9           | 131±39.0              | 152.9±76.3            |
| Group 2                  | 159±73.3     | 152.1±62.6           | 148.9±63.7           | 134.5±39.2            | 142.7±38.7            |
| PaCO <sub>2</sub> (mmHg) |              |                      |                      |                       |                       |
| Group 1                  | 42.3±5.7     | 43.4±6.1             | 41.8±5.4             | 42.4±5.2              | 42.1±6.3              |
| Group 2                  | 42.7±5.8     | 45.5±6.7             | 44.2±6.2             | 41.8±5.4              | 42.6±6.3              |
| SaO <sub>2</sub> (%)     |              |                      |                      |                       |                       |
| Group 1                  | 96.8±12.8    | 99.3±1.1             | 94.6±17.7            | 96.4±12.7             | 98.8±1.6              |
| Group 2                  | 96.5±13.1    | 99±1.4               | 99.0±1.4             | 96.8±13.2             | 98.8±1.3              |

SD: Standard deviation; Comparison between groups,  $p>0.05$ ; Group 1: ON-Q group; Group 2: Thoracic epidural group; PaO<sub>2</sub>: Arterial partial pressure of oxygen; PaCO<sub>2</sub>: Arterial partial pressure of carbon dioxide; SaO<sub>2</sub>: Arterial oxygen saturatin.

**Table 3. Comparison of postoperative visual analog scale scores during rest at basal, first, second, fourth, 16<sup>th</sup> and 24<sup>th</sup> hour postoperatively**

| Time (hours)     | Visual analog scale |                | Group 1 vs. group 2 | Within group comparison group 1 | Within group comparison group 2 |
|------------------|---------------------|----------------|---------------------|---------------------------------|---------------------------------|
|                  | Group 1 (n=50)      | Group 2 (n=47) |                     |                                 |                                 |
|                  | Mean±SD             | Mean±SD        |                     |                                 |                                 |
| Basal            | 5.4±1.1             | 5.0±0.9        | 0.067               | Δ                               | Δ                               |
| 1 <sup>st</sup>  | 4.6±0.9             | 4.1±1.0        | 0.011†              | 0.0001‡                         | 0.0001¶                         |
| 2 <sup>nd</sup>  | 4.4±0.8             | 3.6±1.4        | 0.0001†             | 0.002‡                          | 0.0001¶                         |
| 4 <sup>th</sup>  | 3.8±1.2             | 3.0±1.4        | 0.0001†             | 0.0001‡                         | 0.0001¶                         |
| 16 <sup>th</sup> | 3.1±1.9             | 2.1±1.6        | 0.002†              | 0.0001‡                         | 0.0001¶                         |
| 24 <sup>th</sup> | 2.9±1.7             | 2.1±1.5        | 0.004†              | 0.0001‡                         | 0.0001¶                         |

Statistically significant; Group 1: ON-Q group; Group 2: Thoracic epidural group; SD: Standard deviation; † Comparison between groups,  $p<0.05$ ; ‡ Comparison to basal value in group 1,  $p<0.05$ ; ¶ Comparison to basal value in group 2,  $p<0.05$ .

**Table 4. Comparison of postoperative visual analog scale scores during coughing at basal, first, second, fourth, 16<sup>th</sup> and 24<sup>th</sup> hour postoperatively**

| Time (hours)     | Visual analog scale |                | Group 1 vs. group 2 | Within group comparison group 1 | Within group comparison group 2 |
|------------------|---------------------|----------------|---------------------|---------------------------------|---------------------------------|
|                  | Group 1 (n=50)      | Group 2 (n=47) |                     |                                 |                                 |
|                  | Mean±SD             | Mean±SD        |                     |                                 |                                 |
| Basal            | 7.1±1.1             | 7.3±1.2        | 0.501               | Δ                               | Δ                               |
| 1 <sup>st</sup>  | 6.1±1.1             | 5.4±1.3        | 0.018†              | 0.0001‡                         | 0.0001¶                         |
| 2 <sup>nd</sup>  | 5.0±1.0             | 4.4±1.0        | 0.003†              | 0.0001‡                         | 0.0001¶                         |
| 4 <sup>th</sup>  | 4.7±1.0             | 4.0±0.9        | 0.0001†             | 0.0001‡                         | 0.0001¶                         |
| 16 <sup>th</sup> | 3.8±1.3             | 3.3±1.0        | 0.002†              | 0.0001‡                         | 0.0001¶                         |
| 24 <sup>th</sup> | 3.4±1.0             | 2.9±1.2        | 0.024†              | 0.0001‡                         | 0.0001¶                         |

Statistically significant; Group 1: ON-Q group; Group 2: Thoracic epidural group; SD: Standard deviation; † Comparison between groups,  $p<0.05$ ; ‡ Comparison to basal value in group 1,  $p<0.05$ ; ¶ Comparison to basal value in group 2,  $p<0.05$ .

**Table 5. Complications in 30-day postoperative period**

|                        | Group 1 |    | Group 2 |      | p      |
|------------------------|---------|----|---------|------|--------|
|                        | n       | %  | n       | %    |        |
| Nausea and vomiting    | 2       | 4  | 8       | 17   | 0.035* |
| Hypotension            | 0       | 0  | 7       | 14.9 | 0.005* |
| Bradycardia            | 1       | 2  | 5       | 10.6 | 0.078  |
| Respiratory failure    | 5       | 10 | 2       | 4.3  | 0.275  |
| Atelectasis            | 3       | 6  | 2       | 4.3  | 0.698  |
| Pneumonia              | 2       | 4  | 1       | 2.1  | 0.594  |
| Chest infection        | 3       | 6  | 0       | 0    | 0.088  |
| Sputum retention       | 2       | 4  | 3       | 6.4  | 0.596  |
| Reintubated            | 3       | 6  | 2       | 4.3  | 0.698  |
| Postoperative bleeding | 3       | 6  | 1       | 2.1  | 0.338  |
| Bronchopleural fistula | 3       | 6  | 0       | 0    | 0.088  |
| Rethoracotomy          | 4       | 8  | 1       | 2.1  | 0.161  |
| Pneumothorax           | 0       | 0  | 1       | 2.1  | 0.3    |
| In-hospital mortality  | 2       | 4  | 1       | 2.1  | 0.594  |

\* p<0.05: Statistically significant; Group 1: ON-Q group; Group 2: Thoracic epidural group.

postoperatively at 1, 6, 12 and 24 hours in both groups were similar (Table 2).

The comparison of VAS-R and VAS-C scores were presented in Tables 3 and 4.

Total 24-hour analgesic consumption was different between groups (p=0.009) (Table 1). Sedation scores were similar at basal, first, second, fourth, 16<sup>th</sup>, and 24<sup>th</sup> hours postoperatively (p=0.349; p=0.179; p=0.143; p=0.21; p=0.249, p=0.458, respectively). Three patients (6%) in group 1 versus none in group 2 had sedation score ≥3 for 24 hours (p=0.088).

There was no significant difference between groups 1 and 2 in terms of postoperative complications (Table 5). Six patients with vomiting received metoclopramide treatment. There was no incidence of any other complications in both groups.

There was no difference in the use of RBC (3.1±2.2 U vs 2.3±1.3 U; p=0.092) and FFP (3.2±0.5 U vs 2.8±0.9 U; p=0.106) solutions between groups.

## DISCUSSION

Infiltrating the surgical incision site with local anesthetic may modulate pain at the peripheral level by inhibiting transmission of nociceptive impulses from the site of injury and this can decrease pain for a prolonged period. The explanation for this effect has been related to a consequence of the initial anesthetic effect rather than an extended pharmacologic action.<sup>[7]</sup> The ON-Q elastomeric pump

system provides continuous pain relief for 24-hours in the early postoperative period. In our study, the main findings are that the quality of postoperative analgesia is superior with TEA in comparison to ON-Q elastomeric pump system. On the other hand, use of PCA is not greater with ON-Q elastomeric pump system compared to that of TEA. ON-Q elastomeric pump system is technically easier and safer to apply in comparison to TEA with significantly less incidence of hypotension. Thus ON-Q elastomeric pump system may be recommended in patients for which TEA is not preferable.

In a previous study, wound infiltration with a single injection of 0.25% bupivacaine was compared with physiologic saline and it was demonstrated that, in patients receiving local anesthetic, there was reduced requirement for opioids in comparison to patients receiving physiologic saline.<sup>[8]</sup> However, another study showed that a continuous infusion of bupivacaine into upper abdominal wounds did not produce greater pain relief in comparison to infusion of saline and later on, it did not influence the incidence of postoperative pulmonary complications.<sup>[9]</sup> We attempted to investigate the use of ON-Q elastomeric pump system as there were several controversial data on the use of continuous wound infiltration and its efficacy for postoperative pain relief.<sup>[10,11]</sup> Also, the use of this system for thoracotomies was not well-established.<sup>[12]</sup> In a study of seventy patients, continuous local wound perfusion of bupivacaine 0.5% was found to be as effective as use of intravenous PCA with opioids for postoperative pain relief after laparotomies.<sup>[10]</sup> A preliminary pilot study revealed that the ON-Q elastomeric pump system is an effective approach to postoperative pain control after laparotomies.<sup>[11]</sup> In a recent study including 50 adult patients, it has been demonstrated that patients receiving TEA had lower average pain scores postoperatively in comparison to patients receiving ON-Q elastomeric pump system.<sup>[12]</sup> Our results support this finding in a larger group of patients showing that TEA provides better control of pain in the first 24-hours. While the authors<sup>[12]</sup> showed their results in a 48-hour period postoperatively, our study comprised only 24-hours. In another study, continuous ON-Q elastomeric pump system for 24-hours was compared to single shot wound infiltration and TEA and it was shown that a continuous infusion of 0.25% bupivacaine at 4 mL/hour through the ON-Q elastomeric pump system results in lower pain scores compared with continuous TEA.<sup>[13]</sup> Adverse effects and complications were not compared in these studies either.<sup>[12,13]</sup> Our study differs from those studies since we were able

to collect adverse events related to local anesthetics and morphine. We were able to demonstrate that the incidence of hypotension was higher in the TEA group of patients in comparison to the ON-Q elastomeric pump system group. In these recent studies, the differences between adverse events were not demonstrated and we think that our work provides a valuable contribution to the current discussion.<sup>[12,13]</sup>

Adverse events related to medications for postoperative pain are important and this topic was the secondary end point of our study. Morphine is an opioid narcotic agent that is commonly preferred for acute pain control postoperatively and its side effects include respiratory depression, nausea, vomiting, sedation, pruritus, and urinary retention.<sup>[14]</sup> Thoracic epidural analgesia is a regional anesthesia technique that provides pain relief without significant side effects such as respiratory depression which are often associated with narcotics. Epidural anesthesia is considered the gold standard pain relief method after thoracotomies; however, there are certain conditions such as obesity, spine malformations, and problems with coagulation that may prevent consideration of placement of an epidural catheter. Also, there are complications associated with epidural analgesia including hypotension, nausea, headache, urinary retention, pruritus, and infection.<sup>[15]</sup> In our study, we have demonstrated that ON-Q elastomeric pump system is associated with less side effects including less incidence of hypotension, nausea, and vomiting in comparison to TEA.

The study has limitation that the statistical power of the study is relatively low.

In conclusion, the quality of postoperative analgesia is better with thoracic epidural analgesia in comparison to ON-Q elastomeric pump system. However, ON-Q elastomeric pump system is technically easier and safer to apply in comparison to thoracic epidural analgesia with significantly less incidence of side effects, mainly hypotension. Therefore, ON-Q elastomeric pump system may be recommended in patients undergoing thoracotomy, for which thoracic epidural analgesia is not preferable, for pain relief in the early postoperative period.

#### Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

#### Funding

The authors received no financial support for the research and/or authorship of this article.

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