Treatment of multiple rib fractures. Randomized controlled trial comparing ventilatory with nonventilatory management

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Treatment of Multiple Rib Fractures*

Randomized Controlled Trial Comparing Ventilatory with Nonventilatory Management

Chris T. Bolliger, M.D., B.Sc., Hon.;
and Stephan F. Van Eeden, M.Med.

We studied the treatment of multiple rib fractures in NIC, comparing ventilatory with nonventilatory methods in 69 patients who were randomly allocated to one of the following two treatments: (1) a CPAP mask combined with regional analgesia (n=36); or (2) endotracheal intubation and mechanical ventilation with PEEP (n=33). Clinical outcome was as follows: mean duration of treatment, 4.5±2.3 days for the group with CPAP and 7.3±3.7 days for the intubated group (p=0.0003); mean number of days spent in intensive care, 5.3±2.9 days and 9.5±4.4 days, respectively (p=<0.0001); mean period of hospitalization, 5.4±7.1 days and 14.6±5.6 days, respectively (p=0.0019); and patients developing complications: 25 percent (10/36) and 73 percent (24/33), respectively. Infections caused the difference in complications, primarily pneumonias, which occurred in 14 percent (5/36) of the group with CPAP but in 48 percent (16/33) of the intubated group. We conclude that treatment with a CPAP mask combined with regional analgesia can shorten and simplify treatment in these patients, mainly through a decreased infection rate, when compared with intubation and mechanical ventilation, and we recommend this treatment in patients similar to our sample.

(Chest 1990; 97:943-48)

NIC = nonpenetrating injury to the chest; ISS = injury severity score

The treatment of multiple rib fractures in NIC has undergone radical changes over the last three to four decades and is still evolving. Whereas up until the 1930s the stabilization of the chest wall was achieved by sandbags, external compression, and strapping, the utilization of different mechanical devices such as wires, hooks, screws, or pins became fashionable over the next 20 years. During the 1950s the radically different concept of internal pneumatic stabilization with positive-pressure breathing was developed. This technique required endotracheal intubation and mechanical ventilation of the patient. The evolution of the understanding of the pathophysiological effects of NIC directed the attention from the chest wall to the injury of the underlying lung resulting in gas exchange disturbances and complications such as the ARDS.

Mechanical ventilation has since become an accepted form of treatment for multiple rib fractures and flail chests; however, with the widespread use of this invasive form of treatment, complications such as respiratory infections, sepsis, barotrauma, and tracheal stenosis became evident.

Recently, there has been a return to noninvasive modes of treatment, such as optimal pain relief and CPAP via a tightly fitting face mask to increase the FRC. The use of CPAP via a mask maintains the principle of internal pneumatic stabilization but avoids the risks involved with intubation and mechanical ventilation.

Pain relief in mechanical ventilation does not present problems, as the respiratory depression due to systemically administered analgesics is often initially desired in patients on a ventilator; however, in a patient breathing spontaneously, any depression of the respiratory drive must be avoided. Therefore, systemic analgesia is often replaced by local or regional means of pain relief. The main options are intercostal nerve blocks or epidural analgesia.

Previous studies have shown the feasibility of nonventilatory treatment of NIC, but they were either retrospective, only descriptive, or lacked matching or randomization (or both) between the different treatment groups. We therefore conducted a randomized controlled trial to compare the use of a CPAP mask combined with regional analgesia to the conventional mode of management of multiple rib fractures, which is intubation and mechanical ventilation with PEEP. Our hypothesis was that in patients with moderate to severe NIC, treatment with the CPAP mask would be shorter and cause less complications than intubation and mechanical ventilation.

Materials and Methods

Population

Between January 1988 and March 1989, 70 patients admitted to our respiratory ICU with multiple rib fractures in NIC were sequentially randomized pairwise to either CPAP mask treatment combined with regional analgesia or to endotracheal intubation and...
ventilation. Informed consent was obtained. The study had been approved by the University of Stellenbosch Faculty of Medicine Ethics Committee. Patients with NIC were enrolled in the study according to the criteria listed in the following tabulation:

<table>
<thead>
<tr>
<th>Inclusion (all of the following):</th>
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<tr>
<td>More than three rib fractures</td>
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<tr>
<td>Admission to hospital within 24 hours after injury</td>
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<tr>
<td>Insufficient cough mechanism due to pain or preexisting pulmonary disease (or both)</td>
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</table>

<table>
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<th>Exclusion (any of the following):</th>
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<td>Depressed level of consciousness</td>
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<tr>
<td>Important facial injuries (excluding tolerance of CPAP mask)</td>
</tr>
<tr>
<td>Fractures to base of skull</td>
</tr>
<tr>
<td>Severe lung contusion (alveolar infiltrate underlying rib fractures on admission chest x-ray film and ( \text{PaO}_2 &lt; 8 \text{ kPa} ) on 40 percent oxygen mask)</td>
</tr>
<tr>
<td>Need for initial upper laparotomy or other major surgery</td>
</tr>
<tr>
<td>Spinal injury</td>
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<tr>
<td>Contraindications for regional analgesia (bleeding tendency)</td>
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-Procedures and Measurements-

On admission to the ICU, all patients received the following workup: detailed history regarding previous condition of the lungs; circumstances of injury; physical examination; and laboratory analyses, including blood chemistry, full blood cell count, chest x-ray film, ECG, arterial blood gas levels on room air and 40 percent oxygen, and FVC obtained with a portable spirometer (the best of three efforts was reported).

The patients randomly allocated to CPAP mask treatment underwent the insertion of a lumbar epidural catheter. Pain relief was obtained with buprenorphine (Temgesic; Beckitt & Colman), with 0.1 to 0.3 mg per injection diluted in 10 to 20 ml of physiologic saline solution. The volume of the injection was calculated by multiplying the number of segments between the insertion level of the epidural catheter and the level of the highest broken rib by 1.5 ml. The pain level was assessed by the patient on a straight line from 0 (no pain) to 10 (maximum pain) before and after regional analgesia. The number of injections depended on the patients’ needs, with the minimum interval being six hours. Alternatively, intercostal nerve blocks with bupivacaine hydrochloride (Marcaine) (maximum, 150 mg per dose) were used in patients with moderate NIC, ie, unilateral rib fractures only. The patients were then placed on a freestanding CPAP mask system.

The nonintubated patients were intubated and mechanically ventilated after the insertion of a lumbar epidural catheter and systemic pain relief with morphine (\( \pm 1 \text{ mg/kg/day} \)) and sedation with midazolam (Dormicum; Roche) (\( \pm 1.5 \text{ mg/kg/day} \)) as needed. They were kept in the IMV mode. The FIO2 and level of CPAP were adjusted in both groups to maintain adequate oxygenation (arterial oxygen saturation >90 percent and arterial carbon dioxide pressure \( \leq 6 \text{ kPa} \) [45 mm Hg]).

All patients received aggressive physiotherapy daily and were mobilized as early as possible. The duration of treatment for both groups was at least 48 hours after admission and continued until the patient could maintain (1) a \( \text{PaO}_2 \) greater than 8 kPa (60 mm Hg) on 40 percent oxygen, (2) a respiratory rate of less than 30/min, (3) FVC of more than 15 ml/kg, and (4) hemodynamic stability (normal pulse rate and blood pressure). Patients were discharged from the ICU within 24 hours after discontinuation of specific treatment. The pain level, FVC, and arterial blood gas levels were analyzed daily in all patients. Other examinations (white blood cell count, bacteriologic samples, and chest x-ray films) were obtained every third day or when indicated by the clinical course (or both).

Criteria for intubating and mechanically ventilating patients on the CPAP mask regimen were one or more of the following: (1) \( \text{PaO}_2 \) less than 8 kPa (60 mm Hg) on 40 percent oxygen and CPAP of 10 cm H2O; (2) \( \text{PaCO}_2 \) greater than 6.5 kPa (48.8 mm Hg) and rising; (3) respiratory rate greater than 35/min; (4) FVC less than 10 ml/kg; and (5) deterioration of level of consciousness.

Variables were defined as follows: (1) dyspnea = baseline dyspnea prior to injury according to the NYHA classification; (2) preexisting pulmonary disease = any clinical symptoms or previously documented signs as well as radiographic signs of preexisting pulmonary disease; (3) smoker = current smoking of 5 or more cigarettes per day or daily pipe smoking, including ex-smokers from both groups who ceased smoking less than six months prior to admission; (4) lung contusion = radiographic evidence of alveolar infiltrates subjacent to the fractured ribs within six hours of injury; (5) blunt abdominal trauma = contusion or rupture (or both) of internal organs (diagnosed clinically, sonographically, or by laparotomy); (6) acute bronchitis = purulent sputum (or bronchial washing) without pulmonary infiltrate, with positive culture or 25 neutrophils per high-power field (or both) with microorganisms on the Gram stain; (7) pneumonia = new pulmonary infiltrate (not explained by any other reason) with at least two of the following: purulent sputum, raised temperature (\( > 38.3{^\circ} \text{C} \) [100.9{^\circ} \text{F}])), raised white blood cell count (>12 x 10^9/cu mm and >90 percent neutrophils), and positive sputum Gram stain or culture (or both); (8) septicemia (all five of following) = (a) clinical evidence of infection, (b) fever (\( > 38.3{^\circ} \text{C} \) [100.9{^\circ} \text{F}]), rectal or hypothermia (<36.5{^\circ} \text{C} [97.7{^\circ} \text{F}]), rectal, (c) tachycardia (>90 beats per minute), (d) white blood cell count greater than 20 x 10^9/cu mm or less than 4 x 10^9/cu mm, and (e) at least one of the following criteria for an altered perfusion state: altered mentation (in relation to patient’s baseline), elevated lactate level (>2 mmol/L), and oliguria (output <30 ml or <0.5 ml/kg for at least one hour). \(^3\)

Statistical Analysis

We estimated the necessary sample size at 30 patients per group in order to demonstrate a one-day reduction of the ICU stay at the 95 percent confidence level. The duration of mechanical ventilation was likely to be seven to eight days according to our own previous records.

The criteria used to compare outcomes between the two methods of treatment were length of treatment (CPAP mask or mechanical ventilation), duration of stay in the ICU, duration of hospitalization, and presence of complications. The data were normally distributed. The statistical tests used were the Student’s t-test for continuous variables and \( \chi^2 \) test for categorical variables. Significant differences were compared at the 95 percent level.

In addition, both groups were stratified according to smoking history, evidence of preexisting pulmonary disease and grade of dyspnea prior to injury. Analysis within and between the two groups for these potential confounders was performed by analysis of variance.

Results

Of the 70 patients entered into the trial, one in the group with CPAP had to be excluded because serial chest x-ray films showed fewer than four rib fractures. Finally, 36 patients were treated by CPAP mask, and 33 by endotracheal intubation and mechanical ventilation. The groups were comparable in respect to sex, age, grade of dyspnea prior to the injury, preexisting pulmonary disease, smoking habits, the FVC before onset of treatment, and the \( \text{PaO}_2 \) with 40 percent oxygen by mask on admission (Table 1).

The number of rib fractures, the proportions of patients with hemothorax (pneumothorax), pulmonary...
patients with NIC data (PAP Iliausk lmmtuobauti omiio). No. of patients 36 33.

<table>
<thead>
<tr>
<th>Data</th>
<th>CPAP Mask</th>
<th>Intubation</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (No. of men)</td>
<td>26</td>
<td>22</td>
<td>NS+</td>
</tr>
<tr>
<td>Mean age</td>
<td>46.3 ± 15.7</td>
<td>47.8 ± 14.9</td>
<td>NS‡</td>
</tr>
<tr>
<td>Dyspnea (&gt; grade 2)</td>
<td>8</td>
<td>6</td>
<td>NS‡</td>
</tr>
<tr>
<td>Preexisting pulmonary disease</td>
<td>12</td>
<td>8</td>
<td>NS‡</td>
</tr>
<tr>
<td>Smokers</td>
<td>28</td>
<td>22</td>
<td>NS†</td>
</tr>
<tr>
<td>FVC/L</td>
<td>1.53 ± 0.63</td>
<td>1.48 ± 0.66</td>
<td>NS‡</td>
</tr>
<tr>
<td>PaO₂ with 40% oxygen by mask</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>kPa</td>
<td>15.7 ± 4.2</td>
<td>14.2 ± 3.4</td>
<td>NS‡</td>
</tr>
<tr>
<td>mm Hg</td>
<td>117.8 ± 31.5</td>
<td>106.5 ± 25.5</td>
<td>NS‡</td>
</tr>
<tr>
<td>No. of rib fractures</td>
<td>6.9 ± 2.2</td>
<td>6.9 ± 2.3</td>
<td>NS‡</td>
</tr>
<tr>
<td>Hemorrhage (pneumothorax)</td>
<td>16</td>
<td>17</td>
<td>NS†</td>
</tr>
<tr>
<td>Pulmonary contusion</td>
<td>6</td>
<td>5</td>
<td>NS†</td>
</tr>
<tr>
<td>No. of patients with</td>
<td>15</td>
<td>14</td>
<td>NS†</td>
</tr>
<tr>
<td>additional fractures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blunt abdominal trauma</td>
<td>2</td>
<td>7</td>
<td>NS†</td>
</tr>
<tr>
<td>ISS Score‡</td>
<td>11.5 ± 3.6</td>
<td>14.3 ± 5.9</td>
<td>0.021‡</td>
</tr>
</tbody>
</table>

*NS, not significant.
†χ² analysis.
‡t-test (mean ± SD).
§Injury severity score.

contusion, additional fractures outside the rib cage (Fig 1), and, finally, blunt abdominal trauma did not show any significant differences between the two groups either. When using the ISS, we found values of 11.5 ± 3.6 and 14.3 ± 5.9, which were significantly different at a 5 percent level (p = 0.0212).

The results of clinical outcome were as follows (Table 2): days on specific treatment, 4.5 ± 2.3 for the group with CPAP and 7.3 ± 3.7 for the intubated group (p = 0.0003); days spent in the ICU, 5.3 ± 2.9 and 9.5 ± 4.4 days, respectively (p < 0.0001); days of hospitalization, 8.4 ± 7.1 and 14.6 ± 8.6 days, respectively (p < 0.0019); and patients developing complications, 28 percent (10/36) and 73 percent (24/33) (p = 0.002).

Details of the complications during the period in the ICU are listed in Table 3. The average level of CPAP delivered to the group receiving CPAP was 5.4 ± 1.3 cm H₂O and to the intubated group was 6.6 ± 2.3 cm H₂O (p > 0.05). One patient in the group with CPAP developed a multifactorial respiratory failure (alcohol withdrawal; lung collapse; pneumonia) and had to be intubated and ventilated for two weeks before successful weaning. Two deaths occurred in the intubated group; a 74-year-old man with severe chronic obstructive pulmonary disease who had acute bronchitis at the time of injury died of respiratory failure, and a 70-year-old woman died suddenly in cardiac failure (the autopsy revealed a severe cardiac contusion and subdural...
hematoma without signs of herniation of the brain stem, neither of which had been clinically apparent on admission.

A stratified analysis within and between the two groups showed that there was no significant difference at the 5 percent level regarding outcome when comparing smokers and nonsmokers (p>0.05), patients with and without preexisting pulmonary disease (p>0.05), or dyspnea greater than or equal to grade 2 and dyspnea less than (p>0.05).

In the group with CPAP, 23 patients were given an epidural catheter, 12 received intercostal nerve blocks, and one patient did not need further pain relief after an initial intramuscular injection of diclofenac (Voltaren) in the emergency ward. Both analgesic methods provided good pain relief, reducing the amount of pain experienced by coughing after the application of the drug by an average of 50 percent as assessed by the patient on the linear scale; however, the two methods were not used equally. Intercostal blocks were given preferentially to patients with fewer fractures on one side of the chest only. On the average, the epidural catheters were left in place for three days (range, two to seven days), the average total number of injections was 4.4, and the average total dose of buprenorphine was 0.78 mg per patient. No complications were observed.

Both treated groups received the same intensity of chest physiotherapy, but due to the lack of initial sedation and the absence of an endotracheal tube, the patients in the group with CPAP could be mobilized earlier and participated more actively with the physiotherapist than the patients in the intubated group.

**DISCUSSION**

In this study, we conducted a randomized controlled trial to compare treatment by CPAP mask combined with regional analgesia to endotracheal intubation and mechanical ventilation with PEEP in patients with multiple rib fractures in NIC. In our sample, we could demonstrate that treatment by CPAP mask proved to be much shorter and had fewer complications than intubation and mechanical ventilation.

Previous studies showed that NIC with multiple rib fractures could be managed without intubation of the patient, but in general the nonventilated patients had less severe chest trauma. With a randomized study, we obtained two treated groups which were well matched for all parameters but for the ISS (Table 1). The higher ISS score for the intubated group can be accounted for by greater incidence of blunt abdominal trauma (seven vs two in the group with CPAP), which although on direct comparison was not different, reached significance in the ISS due to the quadratic nature of this score. Clinically, this difference was not important, as the blunt abdominal trauma was less severe than the chest trauma in all patients of both groups and did not influence the duration of treatment. Two patients in the intubated group underwent early laparotomies (one splenic rupture; one bladder rupture), with an uneventful postoperative course. From Figure 2, it is apparent that although the ISS score was 11.5 for the group with CPAP and 14.3 for the intubated group, both groups have similar mortality regardless of age. The ISS proved to be a good index of mortality, as both the deaths occurred in patients 70 years of age or older, whose risk of dying was greater than that of younger patients for a given score (Fig 2). The deaths were probably not related to the mode of treatment; however, the ISS was a relatively poor indicator of the considerable morbidity in our groups, whose major site of injury was the chest.

Apart from age and sex, we attached particular importance to the condition of the lung prior to the injury and obtained a detailed history of the degree of dyspnea between grade 0 and 4 (NYHA), evidence of preexisting pulmonary disease, and smoking status. We used the FVC as a measurement of initial respiratory impairment and the PaO2 as an indicator of the pulmonary gas exchange.

Our criteria for comparing outcomes between the two groups were the duration of the different treatments (specific treatment to increase FRC; stay in the ICU; total length of hospitalization) and the rate of complications in each group. The results showed a highly significant difference for all criteria, indicating that treatment by CPAP mask combined with regional analgesia shortened all periods considerably and caused far fewer complications.

Comparisons with other studies were difficult, as none of them used a severity score; however, Dittmann et al had two groups whose severity of chest trauma

![Figure 2. Injury severity score](image-url)
was comparable to our population. Their periods in the ICU, with 4.5 days for the nonventilated and 9.8 days for the ventilated group, were similar to ours (Table 2). The total length of hospitalization in a study by Trinkle et al\textsuperscript{14} for their nonventilated group (9.3 days) compared well with that of our group with CPAP but not for the ventilated group (31.3 days in their study). Despite some difficulties in comparing the studies mentioned, the common message is that nonventilatory treatment of NIC can shorten hospitalization dramatically.

A detailed view of our complications (Table 3) which occurred during the period in the ICU showed a very low incidence of pneumothorax, subcutaneous emphysema, lung collapse, and bronchitis for both groups; however, the number of severe infections was much more frequent in the intubated group, with pneumonia occurring in 48 percent (16/33 patients), compared with 14 percent (5/36 patients) in the group with CPAP. Sinusitis, laryngitis, bronchopleural fistula, and sepsis with positive blood culture only occurred in the intubated and mechanically ventilated group. Together with the pneumonias, these complications were the main factors contributing to increased morbidity and therefore longer duration of each period of treatment in this group. These findings agree well with the high rate and the type of complications due to mechanical ventilation reported in many studies.\textsuperscript{12,14,15} Trinkle et al\textsuperscript{14} even reported an incidence of pneumonia of 84 percent (16/19 patients) in their ventilated group.

Our overall rate of complications of 28 percent (10/36) in the group with CPAP and of 73 percent (24/33) in the intubated group, as well as the mortality of zero in the group with CPAP and of 6 percent (2/33) in the intubated group, were comparable to the trial of Trinkle et al.\textsuperscript{14} Their overall rate of complications in the nonventilatory group was 21 percent and in the ventilated group was 100 percent (19/19). Their mortality was 0 and 21 percent, respectively. Complications due to the CPAP mask per se were negligible (nasal pressure sores) and did not result in any discontinuation of the treatment.

The stratified analysis within and between our two treated groups excluded smoking, preexisting pulmonary disease, and degree of dyspnea prior to injury as possible confounders. This suggests that people with impaired pulmonary function with moderate to severe NIC can be treated without intubation and mechanical ventilation.

We see the successful outcome in our group with nonventilatory treatment as a result of the combination of CPAP by mask and regional analgesia, both of which have been shown to be beneficial in NIC on their own. The CPAP, by increasing the FRC, aims at the major problem in NIC, which is contusion of the underlying lung, with abnormalities in gas exchange.\textsuperscript{6,4} Epidural analgesia and intercostal nerve blocks, on the other hand, provide pain relief and allow early mobilization and aggressive chest physiotherapy with the patient's active participation. This, in turn, can potentiate the increase in FRC\textsuperscript{22} obtained with CPAP.

Epidural analgesia using the lumbar approach for thoracic pain relief\textsuperscript{25-26} proved very satisfactory in our trial. We primarily used this approach, since in our institution the majority of doctors are trained only in the lumbar technique. Buprenorphine proved to be safe and effective in the epidural space. Most of our patients needed only one to two injections per 24 hours to maintain adequate pain relief. Clinically important respiratory depression or catheter-related complications were not observed.

We conclude that in patients with NIC whose main site of injury is the chest and who do not meet any of the previously mentioned criteria for exclusion, the treatment of choice should be the use of a CPAP mask combined with regional analgesia, physiotherapy, and early mobilization. This treatment is cost-effective, has less associated additional morbidity, and shortens hospitalization dramatically.

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