

## Reduction of Anterior Shoulder Dislocation in Emergency Department; Is Entonox<sup>®</sup> Effective?

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### ABSTRACT

**Introduction:** An appropriate procedural sedation and analgesia (PSA) is crucial to reduce a dislocated shoulder successfully in emergency department. This study compares sedative effect of inhalational Entonox<sup>®</sup> (En) to intra-venous (IV) Midazolam plus Fentanyl (F+M). **Methods:** 120 patients with recurrent anterior shoulder dislocation were randomly assigned into two groups. 60 patients (group F+M) received 0.1 mg/kg IV Midazolam plus 3 $\mu$ g/kg IV Fentanyl and 60 patients (group En) received Entonox<sup>®</sup> with self administration face mask on an on-demand basis. Traction/counter-traction method was used to reduce the dislocated shoulder joint in both groups. **Results:** 48 out of 60 (80%) patients in group F+M and 6 out of 60 (10%) patients in group En had successful reduction ( $p < 0.0001$ ). The mean pain score reduction was  $6.3 \pm 1.2$  for group F+M and  $3 \pm 0.9$  for group En ( $p < 0.0001$ ). There was a statistically significant difference in mean patient satisfaction (assessed with Likert score) between two groups ( $4.45 \pm 0.6$  for group F+M and  $2.3 \pm 1$  for group En;  $p < 0.0001$ ). Duration of entire procedure (since the beginning of PSA up to the end of successful or unsuccessful reduction) was shorter in Group F+M, but successful reductions occurred earlier in group En. No major side effect such as airway compromise, retracted respiratory depression, or circulatory failure was occurred in any group. **Conclusion:** Entonox<sup>®</sup> may not be an appropriate agent to help reducing a dislocated shoulder.

### Introduction

Anterior shoulder dislocation is a common joint dislocation (Descamps *et al.* 2007). It is recently managed in the emergency department (ED) rather than the operating room (Daya and Nakamura 2009). To reduce it successfully in the ED, it is crucial to make the patient fully pain-free and comfortable through using a proper technique (Uglow 1998). Regardless of used technique, success rate has been between 70% and 96% (Rudzinski *et al.* 2011). An appropriate Procedural Sedation and Analgesia (PSA) helps the patient to cooperate in achieving a successful reduction. Therefore, the role of a proper method of pain management becomes more prominent. Of characteristics of an ideal PSA, it can be pointed to the safety, lack of side effects, simplicity of use, predictability, non-invasive delivery and a rapid onset and offset

(O'Sullivan and Bengner 2003). Different routes of administering anesthetic and/or analgesic agents are inhalational, intra-venous (IV), intra-muscular, trans-mucosal and local/regional. Inhalational route is preferred to the others because of non-invasiveness, lack of first pass effect and a rapid onset and offset. Nitrous oxide (N<sub>2</sub>O) has been known as one of the oldest inhalational anesthetic and analgesic agents used for a variety of purposes since 18<sup>th</sup> century (O'Sullivan 2003). Lack of taste and odor makes it tolerable for most of patients and rapid onset and offset of action, low incidence of major side effects and drug interactions make it favorable for most of health care providers (Onody *et al.* 2006). Entonox<sup>®</sup> is a mixture of oxygen and nitrous oxide (N<sub>2</sub>O) most commonly with a proportion of 1:1. This study compared inhalational Entonox<sup>®</sup> to IV Midazolam+Fentanyl to achieve a successful reduction.

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## Materials and methods

This Randomized clinical trial study was performed in Rasul-Akram ED, affiliated to Tehran University of Medical Sciences (TUMS), Tehran, Iran between March 2008 and May 2009.

120 patients with recurrent anterior shoulder dislocation were randomly allocated in two groups according to the table of random numbers. 60 patients (group F+M) received 0.1 mg/kg IV Midazolam plus 3 µg/kg IV Fentanyl and 60 patients (group En) received Entonox<sup>®</sup> with self administration face mask on an on-demand basis.

The patients' pain perception was recorded using a 10-point Visual Analogue Scale (VAS) and their satisfaction rate from the entire procedure was scored using a 5-point Likert scale.

We used traction/counter-traction method to reduce the dislocated shoulder joint in both groups. PSA were performed in resuscitation room under cardiac and pulse oximetry monitoring with stand-by equipment such as suction, oxygen and advanced airway management kits. A senior Emergency Medicine Resident (EMR) and an attending on call physician were supervising the patient and the procedures while two EMRs performed the reductions. All data were recorded by one physician during the study.

### Inclusion criteria

All patients with isolated and non-complicated recurrent anterior shoulder dislocation (diagnosed with physical exam and confirmed with imaging) were entered the study. No age or sex limitation was considered. Recurrent or habitual dislocation considered as two or more partial or total separation of the head of humerus from the glenoid cavity that occurs during normal daily activity without significant physical trauma.

### Exclusion criteria

Any patient with complicated dislocation (accompanied with fracture), any other trauma, and risk of increased intra-cranial or intra-ocular pressure, hemodynamic instability, use of illicit drugs, alcohol or analgesics 12 hours prior to PSA were omitted from the study.

Failed reduction was defined as persisted dislocation despite 2 successive attempts which led to patient non-cooperation, and successful reduction appreciated by both the patient and the operator, was confirmed with imaging.

A data sheet was designed to collect the needed points. The results were analyzed using SPSS 16. T test for two independent samples and Chi-square test were used to compare two groups. P value  $\leq 0.05$  (CI 95%) was considered as statistically significant difference.

## Results

A total of 120 patients with recurrent anterior dislocation of shoulder were enrolled in our investigation and were equally randomized into group F+M and group En. Demographic characteristic data of the two groups have been compared in Table 1; there was no significant difference between two groups.

**Table 1.** Demographic characteristics of patients

|     | Group F+M | Group En   | P value |
|-----|-----------|------------|---------|
| Age | 28.4 ± 11 | 31.8 ± 0.3 | 0.07    |
| Sex | Male      | 53 (88.4%) | 0.80    |
|     | Female    | 7 (11.6%)  |         |

48 out of 60 (80%) patients in group F+M and 6 out of 60 (10%) patients in group En had successful reduction; the difference was statistically significant ( $p < 0.0001$ ). The mean pain score reduction was  $6.3 \pm 1.2$  (range 3 - 10) for group F+M and  $3 \pm 0.9$  (range 1 - 5) for group En ( $p < 0.0001$ ). There was a statistically significant difference in mean patient satisfaction (assessed with Likert score) between two groups ( $4.45 \pm 0.6$  for group F+M and  $2.3 \pm 1$  for group En;  $p < 0.0001$ ). Table 2 demonstrates the comparison of two groups for different times related to the procedure. Duration of entire procedure (since the beginning of PSA up to the end of successful or unsuccessful reduction) was shorter in Group F+M, but successful reductions occurred earlier in group En. The duration of recovery time was significantly shorter in group En just in case of successful reduction.

**Table 2.** Durations of procedures

| Procedure            | Time (min)   |            | P value |
|----------------------|--------------|------------|---------|
|                      | Group F+M    | Group En   |         |
| Entire procedure     | 13.3 ± 03.00 | 14.4 ± 3.5 | 0.010   |
| Successful procedure | 13.0 ± 02.09 | 08.7 ± 2.5 | 0.006   |
| Entire recovery      | 11.6 ± 03.60 | 10.2 ± 5.1 | 0.530   |
| Successful recovery  | 10.6 ± 02.30 | 05.1 ± 4.1 | 0.009   |

No major side effect such as airway compromise, retracted respiratory depression, or circulatory failure was occurred in any group; mild and transient side effects were observed in 80% (48 of 60 patients) of group En and 8.4% (5 of 60 patients) of group F+M. These included nausea, vomiting and vertigo. One patient of group En experienced euphoria. Five cases in group F+M experienced apnea needing short time assisting bag-valve-mask ventilation.

## Discussion

By far, different studies have been carried out on the analgesic and anesthetic effects of Entonox<sup>®</sup> among various adults and pediatric population of patients (Anne-

quin *et al.* 2000, Wilson 1996, Gamis *et al.* 1989, Krauss 2001, Luhmann *et al.* 1999). It has been used to reduce pain in pre-hospital and ED settings to manage orthopedic procedures (Henrikus *et al.* 1995, Wattenmaker *et al.* 1990, Gleeson *et al.* 1999), burned dressings (Hanafiah *et al.* 2008), wound care (Sealey 2002, Burton *et al.* 1998, Luhmann *et al.* 2001), vaginal delivery (Rosen 2002), angina pectoris (Kerr *et al.* 1972, Thompson and Lown 1976), acute abdomen, renal colic (O'Sullivan and Benger 2003), migraine headache (Faddy and Garlick 2005) and so many other conditions.

To our knowledge, there are limited studies on Entonox<sup>®</sup> use in reducing dislocated shoulder. Uglow compared Entonox<sup>®</sup> with IV Morphine and Midazolam to reduce dislocated shoulder in 45 patients. A successful reduction was achieved in 80.9% of patients who received Entonox<sup>®</sup> and 100% of patients who were sedated with Morphine and Midazolam. Uglow did not find statistical significance in pain scores between the two groups (Ug-low 1998). Gleeson *et al.* conducted a prospective randomized trial to assess the relative analgesic effects of Entonox<sup>®</sup> and intra-articular Lidocaine (IAL) in 31 patients with acute anterior dislocation of the shoulder. A significantly greater decrease in pain scores was reported with Entonox<sup>®</sup> rather than IAL (Gleeson *et al.* 1999). We included more patients (120) and achieved significantly greater decrease in pain scores and patient satisfaction with F+M ( $6.3 \pm 1.2$ ; range 3 – 10 and  $4.45 \pm 0.6$  respectively) rather than En ( $3 \pm 0.9$ ; range 1- 5 and  $2.3 \pm 1$  respectively;  $p < 0.0001$ ). Successful reduction was recorded in just 10% of group En and 80% of group F+M. These results are different from the two aforementioned studies that seem to be resulted from failure of Entonox<sup>®</sup> to overcome muscle spasm. The only superiority of En on F+M was its shorter procedure and recovery time in cases successful reduction is achieved. No major complication was observed; however minor side effects were more frequent in En group.

## Conclusion

Entonox<sup>®</sup> may not be an appropriate agent to help in reducing a dislocated shoulder. Further studies can be designed including more patients to show better results.

## Limitations

At the time of study, this RCT did not register in RCT registries because of authors' unawareness about importance of registration.

Both the physician and the patient were aware of what-ever described, also, different physicians attempted reductions of different patients and their skills may affect the results.

## Ethical issues

We keep personal information of participants confident. All of participants already endorsed informed consent form provided by Research Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran. This committee approved proposal and final report of the project.

## Conflict of interests

Authors declared no conflicts of interests.

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