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Anterior shoulder dislocation reduction managed either with midazolam or propofol in combination with fentanyl

芬太尼聯合咪達唑崙或異丙酚使用在肩關節前脫位的復位

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Objective: Procedural Sedation and Analgesia is used in managing emergency painful procedures. The aim of this study is to compare the effects of propofol and midazolam on haemodynamic parameters when used in combination with fentanyl in isolated anterior shoulder dislocations and to measure the patient and physician satisfactions. ***Methods:*** The study is a randomised single blind prospective trial. All procedural sedations were performed by emergency medicine specialists and the shoulder reductions were performed by orthopaedic surgeons. Two groups were defined. Group A received intravenous fentanyl and midazolam and Group B received intravenous fentanyl and propofol. The orthopaedic surgeons were not informed about the drugs. The emergency medicine specialist observed the patients. The patients and the orthopaedic surgeons were asked for a satisfaction scoring. ***Results:*** Midazolam group consisted of 37 patients and propofol group consisted of 38 patients. Both groups were similar in demographic characteristics and pre-procedural vital signs. There was only one statistically significant difference at one time and it was the 5th minutes SpO_2 levels between groups. There were statistically significant changes in the measurements of vital parameters in both groups when compared with the baseline levels. However none of them was clinically important. In midazolam and propofol group, 10.8% and 10.5% respectively had respiratory compromise. Patient and physician satisfactions were similar in both groups. ***Conclusions:*** Midazolam and propofol are both relatively safe drugs using in combination with fentanyl in anterior shoulder dislocations. Patients and physicians can be highly satisfied with the two groups of drugs. (Hong Kong j.emerg.med. 2014;21:346-353)

目的：程序鎮靜和止痛常使用在處理急診中引起痛楚的手術程序。本研究的目的是在孤立的前肩脫位使用芬太尼時，比較異丙酚和咪達唑崙對血液動力學參數的影響，並測量患者和醫生的滿意度。**方法：**本研究是一項隨機單盲前瞻性研究。所有的鎮靜程序都由急診專科醫生負責，肩關節復位由骨科醫生進行。患者分為兩組。A組接受靜脈注射芬太尼和咪達唑崙，B組靜脈注射芬太尼和丙泊酚。骨科醫生沒有被告知使用的藥物。急診專科醫生負責觀察患者。病人和骨科醫生會被詢問有關滿意度得分。**結果：**咪達唑崙組有37例，丙泊酚組有38例。兩組患者的人口統計學特徵和進行程序前的生命體徵相似。只有第5分鐘的血氧飽和度，兩組之間有一個統計上顯著差異。與基線水平相比，兩組的生命體徵參數測量到有統計學上的顯著變化。但是他們臨床上都不是重要的。在咪達唑崙和異丙酚組，分別有10.8%和

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10.5%有呼吸抑制。兩組的患者和醫生滿意度相似。**結論：**在肩關節前脫位，芬太尼聯合咪達唑崙和異丙酚的組合，都是相對較安全的藥物。患者和醫生對兩組藥物都非常滿意。

Keywords: Conscious sedation, drug therapy, emergency medical service, randomized controlled trial, single-blind method

關鍵詞：清醒鎮靜、藥物治療、緊急醫療服務、隨機對照試驗、單盲法

Introduction

Procedural Sedation and Analgesia (PSA) is a technique, which is routinely used in managing emergency painful procedures. It is mostly done by administering sedatives or dissociative agents with or without analgesics.[1] During the procedure it aims to provide a state of unconsciousness to tolerate the painful event while maintaining full respiratory and cardiovascular function. It is used mostly for orthopaedic manipulations like fracture and dislocation reductions, and also for other emergency situations like abscess drainage, endoscopy, cardioversion, burn dressing, sutures, sedation of agitated patients for radiological evaluations, central venous catheterisation and tube thoracostomy.[2]

In emergency department, benzodiazepines (midazolam, diazepam), hypnotics (methohexital, propofol, ketamine, etomidate) and opioids (fentanyl, meperidine, morphine) have been used traditionally for this purpose for a long time.[3] The American College of Emergency Physicians recommends ketamine, propofol, midazolam, fentanyl and etomidate alone or in combinations for PSA in emergency room. Because the therapeutic indexes of these drugs are relatively narrow, it is emphasized that they should be administered in small incremental intravenous doses.[1] In this trial we have studied midazolam and propofol in combination with fentanyl.

Midazolam is a highly lipophilic agent that provides anxiolysis, amnesia, sedation, hypnosis and muscle relaxation, but it has no direct analgesic effect. It has been widely used in different groups of patients for the purpose of PSA.[3,4] In recent years propofol is becoming an agent of choice for PSA in emergency room because of its efficacy and safety profile.[5-7] It has antiemetic effect but no amnestic and analgesic effect. Fentanyl is an opioid analgesic that is 75 to 125 times more potent than morphine. The adverse effects like central nervous system and respiratory depression have been reported but these unwanted effects could be reversed with naloxone.[3]

Propofol, midazolam and fentanyl in different combinations were studied many times in PSA by researchers.[8-10] Anterior shoulder dislocation is one of the common painful presentations to emergency departments. There have been many methods of reduction described. But patients should be relaxed and painless as much as possible to overcome the muscle spasm at the site of injury independently of reduction method. We believed that both propofol and midazolam don't have direct analgesic effect, the exact comparison could be obtained only when applied in combination with same doses of analgesics like fentanyl.

The aim of this study was to compare the effects of propofol and midazolam on haemodynamic parameters when used in combination with fentanyl in isolated anterior shoulder dislocations and to measure the patient and physician satisfactions. We also measured the patient and physician satisfactions about the procedure.

Methods

This study was a randomised single blind prospective trial. It was carried out in an Education and Research Hospital Emergency Department between 1 April 2011 and 31 March 2012. Adult patients with isolated

anterior shoulder dislocations who gave written approval for application of the procedure and who accepted to take part in the study were enrolled. Block randomisation method was used for allocation of patients because of small sample size. All procedural sedations were performed by emergency medicine specialists and the shoulder reductions were applied by the last year residents or specialists in orthopaedic surgery in our hospital. The Kocher's Method was used in most of the reductions. Modified Hippocratic Technique was needed in a few cases. All patients were evaluated before the procedure according to American Society of Anaesthesiologists (ASA) Physical Status Classification.[3,11] Completely healthy fit patient (ASA 1) and patients with mild systemic disease (ASA 2) were included in the study.

Exclusion criteria were:
1. ASA 3, 4, 5 patients (moderate and severe systemic disease and moribund);
2. patients <18 years;
3. head trauma;
4. pregnancy;
5. known allergic reactions with the drugs;
6. associated fracture at the site of injury.

The procedures were applied at one of the resuscitation rooms in emergency department. Equipment for advanced life support was available at all times. Patients were observed with continuous cardiac monitoring. Emergency medicine nurse administered the ordered drugs. An emergency medicine specialist and a resident observed the patients and recorded the vital signs at the 0, 5, 10, 15, 30 and 60th minutes during the procedure. Isotonic saline was started at slow infusion rate and 2 litres of oxygen gas was started via nasal cannula according to our clinic's routine protocol.

Normal ranges for the haemodynamic parameters were accepted as; mean arterial pressure (MAP): 70-110 mmHg, heart rate (HR): 60-100 bpm, respiratory rate (RR): 12-20/minutes, O_2 saturations (SpO_2): >94%, and end-tidal CO_2 ($ETCO_2$): 32-42 mmHg.[3,4]

Respiratory compromise was defined as apnoea for more than 30 seconds or a SpO_2 of less than 90% requiring any clinical intervention like airway manoeuvres, bag-valve mask ventilation or intubation.[12]

Two groups of patients were defined and the patients were randomly allocated to one of them: 1) Group A patients received first intravenous fentanyl 1.5 mcg/kg with 50 ml normal saline in 2 minutes and additional doses if needed for pain control. Then midazolam were given 0.1 mg/kg intravenous bolus, and titrated with additional 0.05 mg/kg doses in two minutes up to the desired sedation level; 2) Group B patients received first intravenous fentanyl 1.5 mcg/kg with 50 ml normal saline in 2 minutes and additional doses if needed for pain control. Then propofol 1 mg/kg intravenous bolus was given and additional doses of 0.5 mg/kg in 3 minutes was administered if needed for predetermined sedation levels.

Patients over 65 years old received half doses of all drugs initially. The target sedation level was defined according to Modified Observer's Assessment of Alertness and Sedation Scale (OAA/S). The desired level of sedation was determined OAA/S 2 in our study.[13] The orthopaedic surgeons were invited in the room after the appropriate sedation level was reached and they were not informed about which groups of drugs were administered to the patients.

After the reduction of the shoulder the patients were observed at emergency medicine observation unit at least 60 minutes. And none of the patients were allowed to discharge if Modified Aldrete Discharge Score <9.[14,15] After the procedure the patients and the orthopaedic surgeons were asked for a satisfaction scoring which was demonstrated by using (0-100 mm) Visual Analogue Scale.[16,17] Patients were asked whether they would receive the same method of sedation and analgesia if needed in the future and the physicians were asked whether they are satisfied about the degree of convenience of the manipulation.

This study was carried out after obtaining the approval of the Ethics Committee of the institution. All subjects gave written informed consents to participate in the study. The investigation conforms to the principles outlined in the Declaration of Helsinki.

The data were analysed by using Statistical Analysis Software Package. Normally distributed variables were reported as means and standard deviation with 95% confidence interval (CI) and were compared using Student's t-test for independent variables. To test for normal distribution, which is the main assumption for a Student's t-test to be done, we used Kolmogorov-Smirnov and Levene's tests. Also, normal distribution was assessed using normal quantile plot and histograms. Categorical variables were presented as frequencies and percentages with ranges and were assessed using Fisher's exact test. Type I error is accepted as 5% for independent comparisons, and 1% for multiple comparisons.

Results

In one year period, 75 patients between 18-83 years who fulfilled the study criteria were enrolled in the study. Midazolam group consisted of 25 (67.6%) male and 12 (32.4%) female patients. Mean age was 43.5±19.4 (95% CI 37.0-50.0). Propofol group consisted of 26 (68.4%) male and 12 (31.6%) female patients. Mean age was 40.0±18.4 (95% CI 34.0-46.1). The number of ASA1 patients in midazolam group was 31 (83.8%) and ASA2 was 6 (16.2%). In propofol group the number of ASA1 patients was 29 (76.3%) and the number of ASA2 patients was 9 (23.7%). There was no statistical difference according to demographic characteristics and ASA stages between the groups (Table 1).

The data were analysed for the changes in the heart rate (HR), mean arterial pressure (MAP), respiratory rate (RR), SpO_2 and end tidal (ET) CO_2 levels at the 0, 5, 10, 15, 30 and 60th minutes. Comparisons of the variables at all time points between the groups showed that there was statistically significant difference at only one time point and it was at the 5th minutes of SpO_2 level measurements (midazolam: 96.9±2.3; propofol: 98.0±2.2; mean difference±standard deviation: 1.1±0.5 [95% CI: 0.07-2.15]; p=0.038) (Table 2).

The changes in the variables by time were also analysed within the groups. The changes in the HR, MAP, RR, SpO_2 and $ETCO_2$ levels at the 5, 10, 15, 30 and 60th minutes were compared with the pre-procedure levels. There was no statistically significant change in the HR and SPO_2 in both groups. The changes in the MAP were significant at 10, 15, 30, 60th minutes in midazolam group and 15, 30, and 60th minutes in propofol group when compared with the baseline measurements. The changes in the RR were observed significantly towards the end of the observation time (30 and 60th minutes in midazolam group and 60th minutes in propofol group). There was not any difference in the $ETCO_2$ levels in propofol group however $ETCO_2$ levels increased significantly at 10, 15th minutes in midazolam group (Table 2).

In midazolam group there were four patients (10.8%) who experienced respiratory compromise (apnoea for more than 30 seconds or a SpO_2 of less than 90%) requiring clinical intervention. Two of them were managed only with head tilt chin lift manoeuvre and two patients needed 1-2 minutes respiratory support with bag valve mask. Also in propofol group four (10.5%) patients experienced mild respiratory compromise. One of them was managed by 1-2 minutes of respiratory support with bag valve mask and the rest was managed with head tilt chin lift manoeuvre. No significant difference between respiratory compromise rates was found between the groups (p=1.000; Fisher's exact test). In propofol group, one humeral fracture was observed during the procedure and one unsuccessful reduction that required operation. The patients were also included in the study.

Mean patient satisfaction in midazolam group was 94.7±6.9 (95% CI 92.4-97.0) and mean physician satisfaction was 95.7±5.1 (95% CI 94.0-97.4). In propofol group mean patient satisfaction was 92.0±10.7 (95% CI 88.5-95.5) and mean physician satisfaction was 94.5±7.3 (95% CI 92.1-96.9). Statistical differences between two groups were not significant according to patient and physician satisfaction scores. P values were 0.203 and 0.421 respectively (Figure 1).

Discussion

Shoulder dislocation is a very common presentation to emergency room. Most (95%) of glenohumeral

Table 1. Demographic data

		Midazolam (n=37)		Propofol (n=38)		
		Mean±SD	95% CI	Mean±SD	95% CI	P value
Age		43.5±19.5	37.0-50.0	40.0±18.4	34.0-46.1	0.436
		n	%	n	%	
Sex	M	25	67.6%	26	68.4%	1.000
	F	12	32.4%	12	31.6%	
ASA class	ASA I	31	83.8%	29	76.3%	0.565
	ASA II	6	16.2%	9	23.7%	

ASA class: American Society of Anaesthesiologists Physical Status Classification
SD=standard deviation; CI=confidence interval

Table 2. Comparison of midazolam and propofol by haemodynamic parameters

	Midazolam		Propofol		p†
Variables	Mean±SD	p*	Mean±SD	p*	
Heart rate					
0.min	86.0±13.2	–	88.8±20.1	–	0.485
5.min	88.8±13.3	0.172	89.3±18.8	0.761	0.893
10.min	88.4±12.9	0.233	86.5±16.8	0.311	0.588
15.min	88.4±11.6	0.189	82.1±18.6	0.015	0.130
30.min	86.6±11.4	0.712	85.9±14.7	0.151	0.811
60.min	84.3±10.3	0.380	83.7±12.3	0.015	0.809
Respiratory rate					
0.min	18.7±4.9	–	18.1±4.7	–	0.638
5.min	17.2±4.6	0.103	17.8±5.0	0.513	0.621
10.min	16.9±5.1	0.057	16.8±4.8	0.074	0.873
15.min	16.4±4.6	0.011	16.8±3.5	0.018	0.726
30.min	16.4±3.3	0.008	16.6±3.7	0.021	0.807
60.min	15.6±2.3	0.000	16.1±2.7	0.002	0.388
MAP					
0.min	109.3±15.3	–	101.6±18.8	–	0.570
5.min	105.4±16.5	0.025	99.1±18.4	0.175	0.124
10.min	100.0±18.4	0.000	96.7±15.8	0.089	0.401
15.min	97.6±14.3	0.000	92.7±13.5	0.001	0.130
30.min	96.1±13.0	0.000	93.9±10.3	0.005	0.414
60.min	96.1±8.6	0.000	93.0±9.2	0.003	0.131
O_2 saturation					
0.min	97.4±1.9	–	98.1±1.6	–	0.135
5.min	96.9±2.3	0.249	98.0±2.2	0.835	0.038
10.min	96.4±3.6	0.104	96.8±3.4	0.036	0.615
15.min	97.7±1.5	0.549	97.3±2.3	0.074	0.469
30.min	97.8±1.5	0.335	98.1±1.5	0.928	0.386
60.min	98.2±1.5	0.044	98.4±1.0	0.218	0.423
End-Tidal CO_2					
0.min	35.2±8.1	–	34.8±7.3	–	0.812
5.min	38.1±10.1	0.039	36.3±6.4	0.119	0.354
10.min	39.2±9.5	0.004	37.2±7.4	0.024	0.310
15.min	38.9±9.2	0.006	36.6±7.1	0.043	0.230
30.min	37.0±8.0	0.075	35.8±7.4	0.270	0.537
60.min	36.0±7.4	0.414	35.2±5.5	0.662	0.590

p*: Comparisons of each variable with the pre-procedure levels within the groups; Paired samples t-test, p<0.01 accepted as significant
p†: Comparisons of the estimated marginal mean values at specific time points between the groups; Independent samples t-test, p<0.05 accepted as significant
SD=standard deviation; MAP=mean arterial pressure

dislocations is anterior. It is a painful event and shoulder should be reduced within the first 24 hours for successful stable closed reduction. For successful reductions patients should be relaxed and pain should be eliminated to overcome the muscle spasm independently from the method of reduction.[18] Patients are generally male and young or middle aged patients as in our study. This is probably due to high incidence of trauma among the defined group in the population. We choose this specific patient group because we believe that shoulder dislocation has a special situation among the other painful events in emergency department. Patients are generally anxious and involuntarily stretch their muscles at the site of injury due to severe pain.

Procedural sedation and analgesia offers many advantages. Conscious sedation provides cooperation of patients with the physician. Patients can easily return their daily life after the procedure. In the literature search, studies about shoulder reductions which are managed with intra-articular lidocaine injections as an alternative treatment modality stand out in recent years.[19-21] Comparisons with intravenous analgesia and sedations were studied by researchers. The results were promising in favour of intra-articular lidocaine. Same success rates with shorter duration of procedure were noted. But those were all short-term results. It is obvious that intra-articular injection is an invasive procedure and there is always a risk of infection like septic arthritis.[22,23] We thought that its safety profile should be supported with long-term follow-up studies. If security measures are taken and if the procedure is applied with appropriate doses procedural sedation and analgesia should be the treatment of choice.

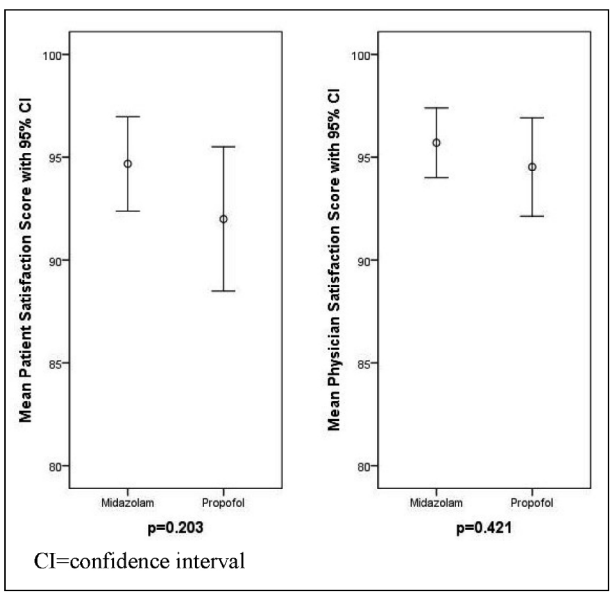

Figure 1. Patient and physician satisfactions of groups (Independent t-test).

Although several drug combinations had been studied for PSA in different types of painful events, there were limited studies about drug recommendations in this specific group of patients. Dunn and his colleagues compared propofol and remifentanyl combination with morphine and midazolam combination. Both combinations were observed equally effective but propofol plus remifentanyl group provided shorter duration of recovery.[24] Taylor studied propofol alone versus midazolam/fentanyl combination in anterior shoulder dislocations. Morphine was used as an analgesic in both groups and propofol was found to be as effective as midazolam and fentanyl combination. But according to Taylor's study, patients in propofol group had experienced more respiratory depression.[25] Burton compared etomidate and midazolam in anterior shoulder reductions and he concluded that both drugs were equally effective, but etomidate had shortened the duration of PSA.[26] To our knowledge our drug combinations were studied previously only by Rahman. But the study group did not consist of only anterior shoulder dislocation. Both drugs were found safe and did not cause major adverse effects in PSA.[27]

Our results also supported all these studies in general although small differences exist. As we stated before we have recorded the haemodynamic parameters at the 0, 5, 10, 15, 30 and 60th minutes in our study. There were statistically significant changes in the measurements of HR, RR and MAP in both groups when compared with the pre-procedure levels. However none of them required additional clinical intervention other than the routine precautions that was taken before the procedure. And also the mean measurements were in normal ranges at all times. Therefore they were not accepted as clinically important changes. Possible

explanation for these statistically significant differences might be the strong pain and anxiety that the patients experienced before the procedure.

Oxygen saturation levels reached the lowest degree at the 10th minutes in both groups. Similarly end tidal CO_2 measurements reached highest level at 10th minutes in both groups (Figure 1). Even at that time the mean values of SpO_2 and $ETCO_2$ were in normal ranges. However clinically we observed respiratory compromise with of apnoea for more than 30 seconds or a SpO_2 of less than 90% in eight patients. Although they did not have a statistically significant effect on results we thought that it was worth mentioning. None of these patients needed invasive measures to support ventilation. Two patients from the midazolam group and two patients from the propofol group required only 1-2 minutes of bag valve mask ventilation. The rest were managed with airway manoeuvres. As we mentioned in the methods according to our hospital PSA protocol we applied routinely 2 litres of O_2 via nasal cannula; this may also have provided protection against desaturation. Overall results about oxygenation and ventilation supported the literature.

The comparison of the changes in the vital parameters at specific times between the groups showed that there was only one statistically significant difference at one time and it was the 5th minutes SpO_2 levels. The rest of the changes in the measures were all similar in both groups. Therefore it is possible to say that both drugs have similar effects on the vital parameters at the given doses and they do not change the haemodynamic parameters which were clinically important when standard precautions have taken.

According to our results closed reduction success rates were similar between the two drug groups. In propofol group, one patient had failed reduction and one patient experienced iatrogenic humerus fracture. This could be due to insufficient muscle relaxation and inadequate sedation with propofol in these patients.

Patients and orthopaedic surgeon were asked for a satisfaction score one hour after the procedure which was demonstrated by using (0-100 mm) Visual Analogue Scale. The scores were very high in both groups and there were no statistically significant differences between the two groups. The measurements revealed a mild elevation in favour of midazolam (Figure 1). Amnestic effect of the midazolam may have caused this small difference.

Our sample size is unfortunately small in both groups. Because we have planned to carry out the study in one year we have reached only 75 patients during the study period. With larger groups more accurate results can be obtained. Most of the patients enrolled in the study were ready to discharge before the 60th minutes. But because we have planned to measure satisfaction scores at the 60th minutes, we could not record the exact discharge times.

Conclusion

In emergency room midazolam and propofol are both relatively safe drugs when used in combination with fentanyl with the doses recommended for procedural sedation and analgesia in anterior shoulder dislocations. They do not have clinically important effects on the haemodynamic parameters when standard precautions have taken and the patients and physicians are highly satisfied with the two groups of drugs.

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