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Randomized Trial of the Use of Dexmedetomidine vs. Propofol after Regional Blockade in Shoulder Surgery Patients in Beach Chair Position*

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Abstract

Background: Propofol is often the drug of choice for ambulatory orthopedic cases. However, propofol can be associated with apnea or other events requiring airway interventions. Dexmedetomidine (Dex) has the unique pharmacologic profile of providing sedation without respiratory depression. This is particularly relevant in patients with morbid obesity and/or challenging airways. The hypotheses were: 1) Propofol would cause more apnea or require more airway manipulations than dexmedetomidine; 2) Propofol would have shorter post anesthesia unit recovery times; and 3) Dexmedetomidine would be associated with more bradycardia and hypotension. Methods: After IRB approval, 50 patients were randomized to receive either propofol or Dex for Total Intravenous anesthesia (TIVA) after interscalene brachial plexus block was performed preoperatively under ultrasound guidance. The main end points that we measured where: airway interventions, intra-operative bradycardia, hypotension, and PACU length of stay. Results: There were more airway interventions in the propofol group compared to the Dex group. Additionally, the Dex group had significantly longer PACU stays. Conclusion: We would recommend that Dex should be preferentially considered for patients predisposed to airway obstruction; however, the standard use of Dex over Propofol needed to reconsider since the use of Dex as the agent for TIVA was associated with longer PACU stays.

*Some of the data were presented at the 2015 the International Anesthesia Research Society Meeting.

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Keywords

Dexmedetomidine, Propofol, Beach Chair, Regional Block

1. Introduction

Regional anesthetic techniques, supplemented with total intravenous anesthesia (TIVA), are increasingly utilized for operative shoulder arthroscopy in beach chair sitting position. Given the benefit of regional techniques for minimizing airway instrumentation and reducing intraoperative hemodynamic variability, a question arises as to which TIVA agent is the best suited for this surgery. Orthopedists often defer the decision on ambulatory anesthetic technique to the anesthesiologist. An ideal anesthetic agent would permit the surgeon to operate without requiring any repositioning or sudden airway loss. One agent, which may become an anesthetic of choice for both the orthopedist and the anesthesiologist, is the α_2 agonist dexmedetomidine due to its unique pharmacologic profile of providing sedation without respiratory depression [1]. This is particularly relevant in patients with morbid obesity and/or challenging airways.

In the past, some practitioners have deferred from utilizing dexmedetomidine given reports of profound bradycardia and hypotension [2], especially in the setting of hypovolemia, diabetes mellitus, chronic hypertension and antihypertensive therapy, heart block, ventricular dysfunction, in elderly, and in surgery in the head-up or sitting positions [3].

Propofol is often the drug of choice for ambulatory orthopedic cases. We evaluated how dexmedetomine fares against propofol TIVA in a prospective randomized controlled study of 50 patients following interscalene brachial plexus block. We measured intra- and post-operative hemodynamics: bradycardia and hypotension, adequacy of anesthesia, requirement for airway intervention and PACU length of stay.

2. Methods

We evaluated how dexmedetomidine (Dex) fares against propofol TIVA in a prospective randomized controlled study of 50 patients following interscalene brachial plexus block. The sample size was calculated based on the incidence of apnea in patients sedated with propofol 30% - 40%, and an expected reduction in apnea incidence with dexmedetomidine of 0%, a power of 0.8 at an alpha of 0.05 was calculated using Sigma Stat. Primary endpoints were: requirement for airway intervention, and PACU length of stay. Secondary endpoints were: intra- and post-operative hemodynamics (bradycardia and hypotension), adequacy of anesthesia intraoperative awareness, and nausea and vomiting. Midazolam was administered as a supplemental medication (2 mg) in both groups, and no narcotics were given.

This research was conducted at the Maimonides Medical Center, Brooklyn, NY. The trial was registered with Clinicaltrials.gov: NCT02469961. Patients that were included in the study were any patients booked for beach chair sitting shoulder arthroscopies from 21 to 90 years old of age who received a successful interscalene block. Exclusion Criteria included: failed interscalene block, refusal to participate in the study, allergy to any of the study drugs or local anesthetics, or deviation from protocol, *i.e.*, conversion to a general anesthesia.

After IRB approval, a randomized list of 50 patients spots (25 subjects in each group) using sequential numbers, was created by software available on the Internet (*i.e.*, http://www.graphpad.com/quickcalcs/randomize1.cfm) to receive either propofol or Dex for TIVA. An interscalene brachial plexus block was performed preoperatively under ultrasound guidance and nerve stimulation (40 - 50 mL mixture: 0.5% ropivacaine and lidocaine 1.5% with epinephrine 5 mcg/ml). All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 [4]. Informed consent was obtained from all patients for being included in this study. A separate HIPAA consent was obtained. After patients were consented the randomization list was checked for which group the patient was placed. The anesthesiologist was then given the protocol to follow. Four patients of the Dex group were not included in the final data analysis and 1 from the propofol group. For TIVA, dexmedetomidine bolus (1 mcg/kg over 10 min) was initiated during positioning and an infusion was continued at 0.7 - 1.0 mcg/kg/hr. Propofol was infused at 25 - 125 mcg/min/kg. We assessed incidence of hypoxia (SpO_2 < 92%), hypotension (SBP < 90 mm Hg), profound bradycardia (bpm < 45) and apnea (+/− airway manipulation).

The student t-test was used for continuous variables where there were only two groups, a Fisher's Exact Test was used to compare the two groups for discontinuous variables and the Pearson Chi-Square was used to compare multiple groups with discontinuous variables. For distributions that were skewed, the median values were compared using a Mann Whitney test. Additionally, a student t-test was used after the skewedness was corrected by a log transform.

3. Results

Demographics and ASA (American Society of Anesthesiologist) class distribution did not differ significantly between the two groups (**Table 1**). There were no significant differences in volume of local anesthetic, use of narcotics, respiratory instability and hemodynamic change either intra- or post-op. We found (**Table 2**) no difference in respiratory instability and hemodynamic change both intra- or post-operatively in our evenly matched groups. Although several patients experienced hypotension in both groups (dexmedetomidine: $n = 5$, propofol: $n = 4$), these episodes were easily corrected with ephedrine (**Table 2**). No bradycardia was noted in either group. There were no oral or nasal airways placed. In the dexmedetomidine group, all patients tolerated nasal cannula and no airway rescue maneuvers were required. Apnea resulted in repositioning in 2 patients among our propofol group (**Table 2**). Neither group reported intraoperative awareness (**Table 2**). Post-operative nausea and vomiting, and post-operative pain did not differ significantly (**Table 3**).

In our study, dexmedetomidine failed to elicit any hemodynamic changes with significant sequelae, but provided

Table 1. Preoperative demographics.

Parameter	Group		
	Dexmedetomidine	Propofol	P-Value
Age (Yr)	50.09 ± 2.47	50.41 ± 2.63	0.930 [a]
Weight (Kg)	85.61 ± 3.04	86.89 ± 3.51	0.788 [a]
Height (In)	65.40 ± 0.831	65.89 ± 0.944	0.702 [a]
Males	57.1% (12)	45.8% (11)	0.554
*MP I	19.0% (4)	20.8% (5)	0.565[b]
*MP II	76.2% (16)	75.0% (18)	
*MP III	0.0% (0)	4.2% (1)	
*MP IV	4.8% (1)	0.0% (0)	
ASA 1	23.8% (5)	29.2% (7)	0.870 [b]
ASA 2	61.9% (13)	54.2% (13)	
ASA 3	14.3% (3)	16.7% (4)	

[*] Mallampati; [a] t-test; [b] A Pearson Chi-Square was used to compare the groups.

Table 2. Intraopertive events.

Parameter	Group		
	Dexmedetomidine	Propofol	P-Value
Case Duration (Min)	105.80 ± 10.57	115.29 ± 8.05	0.472[a]
Hypotension Intra-Op	23.8% (5)	16.7% (4)	0.410[b]
Fentanyl (mcg)	7.1 ± 23.9	9 ± 24.2	0.76 [b]
Morphine (mg)	0.0 ± 0.0	0.2 ± 1.0	0.36 [b]
Apnea	0.0% (0)	8.3% (2)	0.292 [b]
Repositioning	0.0% (0)	4.2% (1)	0.533 [b]
Chin Lift	0.0% (0)	8.3% (2)	0.491 [b]
Awareness	0%	0%	n/a

[a] t-test; [b] A Fisher's Exact Test was used to compare the two groups.

Table 3. Postopertive events.

Parameter		Group		
		Dexmedetomidine	Propofol	P-Value
Time in PACU (min)[a]		159 ± 12 (X ± SD)	126 ± 12	<0.021
		143 (Median)	115	<0.05
Nausea and Vomiting[b]	Yes	4.8% (1)	0%	0.467
	No	95.2% (20)	100% (24)	
Hypoxia	Yes	0.0% (0)	0.0% (0)	n/a
	No	100.0% (21)	100.0% (24)	
Hypotension[b]	Yes	14.3% (3)	0.0% (0)	0.100
	No	85.7% (18)	100% (23*)	
Bradycardia	Yes	0.0% (0)	0.0% (0)	n/a
	No	100.0% (21)	100.0% (24)	

[a] Since the PACU stays distributions were skewed, the medians were compared using a Mann Whitney test which showed that Propofol PACU stays were significantly shorter. A log transform to correct for the skewness and using a t-test again found a significant difference between the groups.
[b] A Fisher's Exact Test was used to compare the two groups.

a particularly favorable respiratory profile. A number of researchers have sought to characterize how hemodynamic variation can result in adverse cerebrovascular events [5] [6], especially while in beach chair position; however, no definitive study using EEG or cerebral oximetry has been reported to date [7]-[9]. As a result we propose the use of dexmedetomidine in conjunction with regional blockade in sitting position as a viable anesthetic option, especially in patients with difficult airway presenting for shoulder surgery. We noted no significant residual sedation with dexmedetomidine as compared to propofol. However, the Dex group had significantly longer PACU stays (Dex: X = 159 ± 12 min, propofol: X = 126 ± 12 min, P < 0.021, **Table 3**).

4. Discussion

Peripheral nerve blocks (PNBs) have significant role in ambulatory anesthesia. The minimization of GA in the ambulatory setting leads to decreased demand for opioid requirements and subsequently fewer treatment-related side effects when compared with general anesthesia [10]. Advantages of the interscalene block include less need for analgesic intervention and opioids, and subsequently less nausea and vomiting [11]; and if performed without general anesthesia, the patients could move faster and more efficiently through the post anesthesia care unit and have a quicker subsequent discharge [12]. There are a number of drugs that can be used to sedate the patients during their operation, however, which drug provides the best conditions with the least amount of complications is not known.

5. Conclusion

Our results demonstrated safe and effective anesthesia for sitting patients using Dex after regional blockade. Although not statistically significant, none of the patients receiving Dex needed airway repositioning or chin lift. However, the lack of statistical significance may be due to under powering of the study. Our initial estimates for apnea and/or airway manipulation were 30% in the propofol group. In our study, the incidence of apnea with propofol (8%) was interestingly lower than we might have expected. We would recommend that Dex should be preferentially considered for patients predisposed to airway obstruction; however, the standard use of Dex over propofol needed to reconsider since the use of Dex as the agent for TIVA was associated with longer PACU stays.

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