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Research Article

A randomised comparative study of dexmedetomidine and midazolam for sedation during awake fiberoptic intubation in laproscopic cholecystectomy patients

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ABSTRACT

Background: Fiberoptic nasotracheal intubation is an effective method for the management of patients with difficult airways. An ideal sedation regimen would ensure patient's comfort, attenuation of airway reflexes, patient's co-ordination, haemodynamic stability and amnesia. It is critical for both the surgeon and the anesthesiologist to understand the physiologic consequences of laparoscopy and to work in cooperation to achieve a good surgical outcome.
Methods: Patients were randomly allocated to midazolam (MDZ) group (group 1) and dexmedetomidine (DEX) group (group 2). DEX patients received dexmedetomidine 1µg/kg, followed by an infusion of dexmedetomidine 0.1µg/kg/hr titrated to 0.7µg/kg/hr to achieve RSS ≥2. MDZ subjects received IV midazolam 0.05mg/kg with additional doses given to achieve a RSS ≥ 2.
Measurements: Pulse rate, systolic and diastolic blood pressures and SpO_2 recorded during pre-oxygenation, one minute prior to introduction of fiberscope and then every minute for the following five minutes and beginning one minute before endotracheal intubation and then every minute until the endotracheal tube was secured, patient's tolerance assessed on 5 point fiberoptic intubation score during fiberscopy and endotracheal intubation, total comfort score values assessed during pre-oxygenation, fiberscopy and endotracheal intubation and patient's response to 24 hour post op questionnaire assessment were measured.
Results: DEX group patients were significantly more quiet and more harmonius during awake fiberoptic intubation (AFOI) than were the MDZ group patients. The DEX group patients were found to have a lower mean Heart Rate than the MDZ patients.
Conclusions: Both dexmedetomidine and midazolam are effective for fibreoptic intubation. Dexmedetomidine allows better endurance, stable haemodynamic status and a patent airway.

Keywords: Awake fiberoptic intubation, Dexmedetomidine, Midazolam, Sedation

INTRODUCTION

Fiberoptic nasotracheal intubation is an effective method for the management of patients with difficult airways. Both optimal intubating conditions and patient comfort are important while preparing the patient for fiberoptic intubation. One hurdle is to provide adequate sedation while maintaining a patent airway and ensuring ventilation. An ideal sedation regimen would ensure patient comfort, attenuation of airway reflexes, patient co-ordination, hemodynamic stability, amnesia and the provision of a patent airway with spontaneous respiration. Many agents have been reported to provide sedation for intubation including fentanyl, ketamine, midazolam,

remifentanil, propofol, and dexmedetomidine.[1-5] Dexmedetomidine, an α2-adrenoceptor agonist, may be a wondrous drug for use during fiberoptic intubation as it produces sedation and analgesia without concomitant depressing respiratory function.[6,7] Thus, dexmedetomidine possess numerous properties that make it a convenient drug for use in managing patients with difficult airways.[3,8,9,10] In a study of volunteers, Bailey et al. reported that the combination of midazolam and fentanyl increased the chances of hypoxemia in 11 of 12 subjects and resulted in apnea in 6 of 12 subjects.[11] Chu and colleagues reported that a loading dose (1µg/kg) of intravenous dexmedetomidine produced conscious sedation without any concomitant respiratory depression for fiberoptic nasotracheal intubation.[12]

In this study, dexmedetomidine was compared with midazolam for sedation during elective nasotracheal AFOI in adult patients posted for laparoscopic cholecystectomy.

METHODS

After the Institutional Ethics Committee approval, the study was conducted in Rajindra Hospital, Patiala in 50 patients of either sex, aged 18 to 60yrs of ASA grade I and II scheduled to undergo laparoscopic cholecystectomy under general anaesthesia requiring intubation. A written informed consent was obtained from each patient. The patients were divided in two groups randomly of 25 patients each.

Exclusion criteria

Patient's refusing; known or admitted alcohol or drug abusers; allergic to the drugs involved in the study; prisoners; obesity, cardiovascular and endocrine diseases, bleeding disorders, history of nasal surgery or trauma, nasal polyp or on drugs known to produce changes in heart rate and blood pressure like beta blockers, digitalis, calcium channel blockers, oral contraceptives were excluded from study.

Patients' vital signs were monitored at one-minute intervals during the entire procedure. Fifteen minutes prior to introduction of the fiberoptic scope (the time point designated as FOS) patients were randomly allotted to the dexmedetomidine (DEX) or the midazolam (MDZ) groups. Before shifting the patient to the OT table, 0.1% Oxymetazoline nasal drops where put in both the nasal passages. All patients received intravenous (IV) glycopyrrolate 0.2 mg premedication and oxygen by nasal cannula. DEX patients were given dexmedetomidine 1µg/kg bolus infusion over 15 minutes followed by an infusion of dexmedetomidine 0.2µg/kg/hr infusion, which was then titrated up to 0.7µg/kg/hr until they were adequately sedated (RSS ≥2). MDZ subjects received IV midazolam 0.05 mg/kg with additional doses at 0.05 mg/kg given until they were adequately sedated, as defined by a Ramsay Sedation Score (RSS ≥2). Topical local anesthetics given to the airway were 2% lidocaine viscous gargles, 2% lidocaine jelly and 10% lidocaine spray.

Comfort Scale values were recorded during pre-oxygenation (Pre-Ox), at FOS, and at introduction of the endotracheal tube (time point designated as ET). Hemodynamic parameters, including heart rate (HR), systolic blood pressure (SBP), and diastolic blood pressure (DBP), as well as oxygen saturation, were recorded during Pre-Ox, one minute prior to FOS, and then every minute for the first 5 minutes. These parameters were also recorded beginning one minute prior to ET and then every minute until the endotracheal tube was in place. One of the independent, study-blinded observers assessed patient's reaction to placement of the fiberoptic scope and the endotracheal tube on a scale of 1 to 5 (1 = no reaction; 2 = slight grimacing; 3 = severe grimacing; 4 = verbal objection; and 5 = defensive movement of head, hands, or feet).

The surgical procedure then proceeded as planned. Within 24 hours of the surgical procedure, each patient was questioned by one of the blinded observers to assess his/her experience with the AFOI.

Statistical analysis

Total comfort scale score was computed as the total of all the items of the comfort scale, as modified from Ambuel et al., at each of the three time points (Pre-Ox, FOS, and ET).[13] The SPSS 6.0 statistical software package was used for all statistical analysis. The p value of <0.05 was considered to be statistically significant. Numerical data were expressed as mean and the statistical analysis was carried out using the Student t-test for the numerical data to compare the two groups.

RESULTS

Mean age, weight & M:F were statistically insignificant and so both groups were comparable demographically. Both groups underwent uncomplicated AFOI. Measurements of the heart rates in the two groups showed significant differences between the two groups during FOS and ET with the DEX group showing lower mean heart rates compared with the midazolam group. SBP and DBP showed a fall in both the groups as compared with the baseline during FOS and ET; however no significant differences were noted between the two groups. SpO_2 values were well maintained in both the patients groups and respiratory distress was not noted in any of the patients. The DEX group patients had a lower total comfort scores (they were more calm) during FOS and ET as compared to MDZ group of patients. 5 Point FOI scores were higher in the MDZ group of patients implying a better patient's tolerance achieved in the DEX group of patients. Within 24 hours of surgery, patients judged their own AFOI experience. The DEX group patients judged their sedation more positively than the

MDZ group patients did. In addition to sedation, the DEX group patients indicated they had experienced less pain and discomfort during the procedure. The overall satisfaction score was more with the DEX group patients, compared with the MDZ patients' satisfaction score.

Comfort scale, as modified from Ambuel et al.[13].

Parameter	Score	Assessment
Alertness	1	Deeply asleep
	2	Lightly asleep
	3	Drowsy
	4	Fully awake and alert
	5	Hyper-alert
Calmness	1	Calm
	2	Slightly anxious
	3	Anxious
	4	Very anxious
	5	Panicky
Respiratory response	1	No coughing
	2	Occasional cough
	3	Frequent coughing
	4	Coughing regularly
	5	Choking
Crying	1	Quiet breathing, no crying
	2	Sobbing or gasping
	3	Moaning
	4	Crying
	5	Screaming
Physical movement	1	No movement
	2	Occasional slight movements
	3	Frequent slight movement
	4	Vigorous movement limited to the extremities
	5	Vigorous movements including torso and head
Muscle Tone	1	Muscles totally relaxed, no muscle tone
	2	Reduced muscle tone
	3	Normal muscle tone
	4	Increased muscle tone and flexing of fingers & toes
	5	Extreme muscle rigidity and flexing of fingers and toes
Facial Tension	1	Facial muscle totally relaxed
	2	Facial muscle tone normal, no facial muscle tension evident
	3	Tension evident in some facial muscles
	4	Tension evident throughout facial muscles
	5	Facial muscles contorted and grimacing
Total Score	35	

The total comfort score for each patient was calculated by totaling the scores of the 7 comfort categories at each time point.

DISCUSSION

Fiberoptic nasotracheal intubation is an effective technique for the management of patients with difficult airways. Both optimal intubating conditions and patient comfort are important while preparing the patient for fiberoptic intubation. One challenge associated with this procedure is to provide adequate sedation while maintaining a patent airway and ensuring ventilation. An ideal sedation regimen would provide patient comfort, abolishing airway reflexes, patient cooperation, hemodynamic stability, amnesia and the maintenance of a patent airway with spontaneous respiration. The primary outcome of our current study showed that both Midazolam and Dexmedetomidine provided adequate conditions for awake nasotracheal fiberoptic intubation. Fiberoptic intubation could be accomplished in both group of patients with no complications reported in either of the patient's groups, and none of the 25 Dexmedetomidine group patients experienced any respiratory depression. This finding has been documented in other studies too.[7,14,15] Arterial oxygen saturation does not decrease to less than 90% and $PaCO_2$ does not increase differently than that seen during normal sleep.[16,17] Although obstructive apnea has been associated with dexmedetomidine.[18] Hall et al. suggest that this is more related to rapid loading doses (during 2 minutes).[7]

Cardiovascular response to Dexmedetomidine bolus has been described to be a transient rise in blood pressure and a decrease in heart rate followed by a fall in blood pressure.[16,19] High doses cause hypertension due to vasoconstriction caused by direct stimulation of α-2 receptors on blood vessels and low dose inhibits release of nor-epinephrine from sympathetic terminal resulting in hypotension.[20] Such consistent hemodynamic changes have not been found to increase morbidity and can be managed by increased i.v fluids.[7] A slow loading bolus of 1µg/kg administered during 10-20 minutes and maintenance doses ranging from 0.2-0.6µg/kg/hr are recommended for less hemodynamic alterations.[16,21] This biphasic response was not noted in the current study, which may have been abolished by reduction of dexmedetomidine bolus to 1µg/kg bolus and an increase of the duration of bolus to 15 minutes. Jorden et al. observed that high bolus doses of dexmedetomidine do not always result in hypertension[22], and Venn et al. reported that high doses of dexmedetomidine may be

used safely without changes in hemodynamics when they are infused over 10 minutes.[23]

Questionnaire assessment at 24 hours after surgery.

Question	Possible Answers
1. How did you find the sedation for your procedure?	1=Excellent
	2= Good
	3= Fair
	4= Poor
2. Do you consider any adjustment was needed in the amount of sedation you received?	1=Needed less
	2=Right amount
	3=Needed more
3. Do you remember the starting when the scope was inserted?	1= No
	2= Yes
4. Do you remember being awake at any time during the procedure?	1= No
	2= Yes
5. Do you remember the end when the scope was removed?	1= No
	2= Yes
6. Any discomfort you experienced during the procedure?	1= None
	2= Mild
	3= Moderate
	4= Severe
7. Overall, using this visual analog scale, where one end of the scale is complete dissatisfaction and other end of the scale is complete satisfaction, how would you rate your satisfaction with your intubation?	0= Complete Dissatisfaction
	10= Complete Satisfaction

Decreases in HR with dexmedetomidine occur most commonly during a bolus or within 10 minutes of the start of an infusion.[24] The DEX group patients in this study had a significant reduction in HR during FOS and ET time points as compared with the MDZ group of patients. This finding could a reflection of less sympathetic discharge in the DEX group patients and being pretreated with glycopyrrolate.

During follow-up assessment within 24 hours of the surgical procedure, the DEX group patients had less pain and discomfort during AFOI than the MDZ patients. The MDZ patients indicated that they needed more sedation during AFOI than the DEX group patients. However, there was no difference between groups in either recall of the AFOI or awareness of fiberoptic scope removal at the end of the procedure. Overall, the DEX-MDZ patients were more satisfied with the AFOI than the MDZ patients. These findings have been in consistence with the study conducted by Bergese et al., who found patients sedated with a combination of dexmedetomidine and midazolam to be significantly calmer and more cooperative during AFOI and had fewer adverse reactions to AFOI than did the patients sedated with midazolam alone.[5]

Table 1: Demographic data.

Variable	Group 1	Group 2	p value
Age(years)	38.80±8.97	46.30±7.67	>0.05
Weight(kg)	67.40±6.33	62.50±9.49	>0.05
Sex(F/M)	15/10	16/9	>0.05

Dexmedetomidine is an α2-adrenoreceptor agonist with several unique properties that make it ideally suited for the management of patients with difficult airways. First, a dexmedetomidine infusion provides a unique form of sedation in which patients appear to be sleepy, but if stimulated they are easily roused, cooperative, and communicative. Second, dexmedetomidine has moderate analgesic and antisialagogue effects. Third, dexmedetomidine causes minimal respiratory impairment. Finally, one important aspect of dexmedetomidine which needs to be mentioned is the need for infusion whereas midazolam can be given easily as an injection.

Limitations of the study

The patient population was small and a larger trial testing dexmedetomidine with other agents is warranted to detect greater differences in these agents.

To conclude, the use of Dexmedetomidine at 1µg/kg bolus over 15 minutes, with maintenance rates of 0.2-0.7µg/kg/hr is safe and beneficial for patients undergoing awake fiberoptic nasotracheal intubation.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional ethics committee.

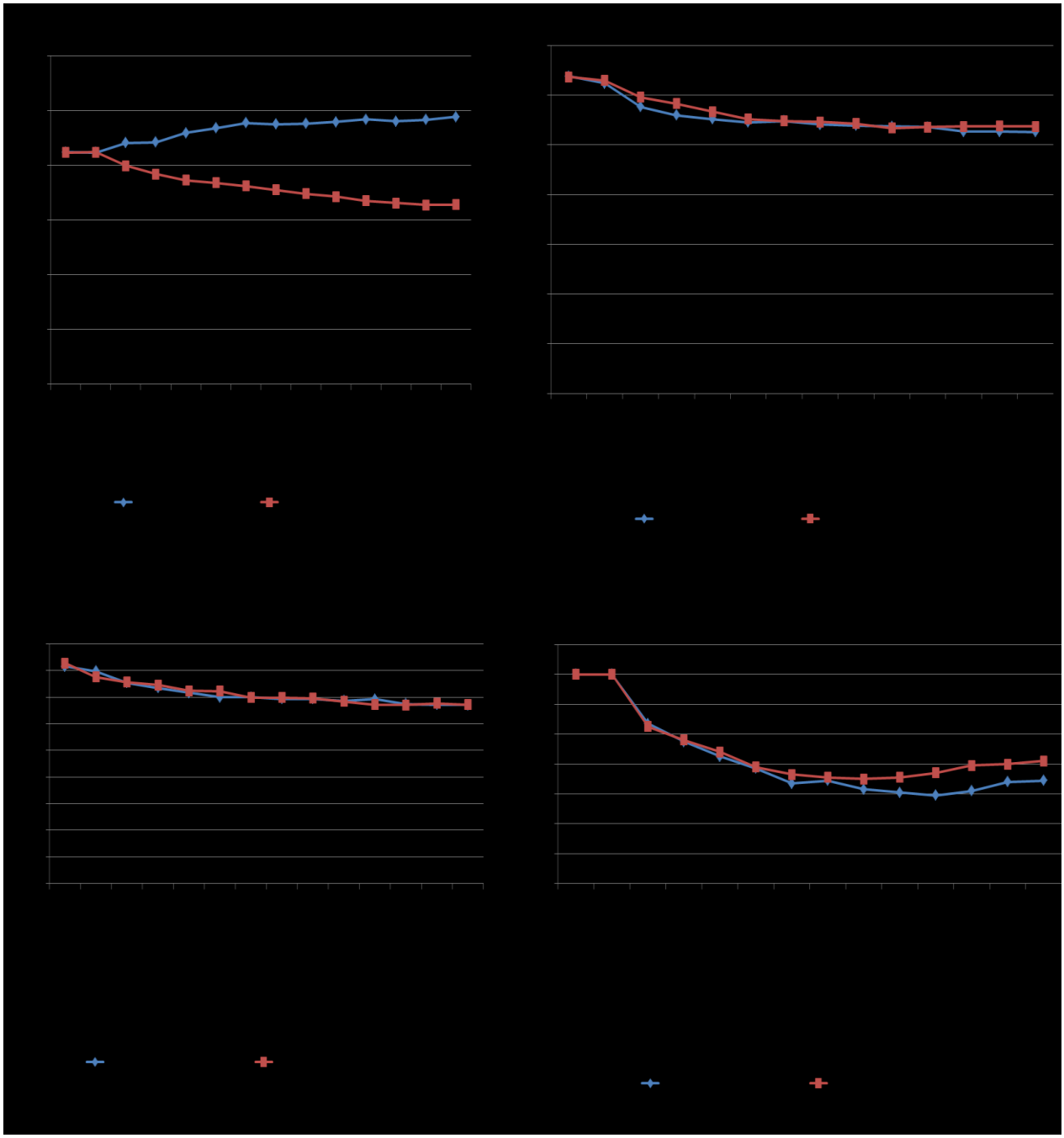

Figure 1: (A) Pulse rate (B) Systolic blood pressure (C) Diastolic blood pressure (D) SpO_2

Table 2: Pulse rate (per min) (Mean±S.D).

	Group 1		Group 2		p value
	Mean	SD	Mean	SD	
Base Line	84.80	4.442	84.60	6.535	0.9371
During Pre-oxygenation	84.60	4.993	84.70	6.634	0.9700
FOS -1	88.20	3.584	79.80	5.769	< 0.01*
FOS 0	88.40	5.232	76.80	5.432	< 0.01*
FOS 1	91.80	4.756	74.50	6.023	< 0.01*
FOS 2	93.60	3.748	73.60	5.399	< 0.01*
FOS 3	95.50	4.503	72.40	6.310	< 0.01*
FOS 4	95.00	4.830	71.00	5.907	< 0.01*
FOS 5	95.20	5.159	69.60	5.872	< 0.01*
ET -1	95.80	4.366	68.50	4.790	< 0.01*
ET 0	96.70	3.831	67.00	4.899	< 0.01*
ET 1	96.00	2.108	66.20	4.263	< 0.01*
ET 2	96.60	1.897	65.50	2.915	< 0.01*
ET 3	97.70	2.830	65.60	2.633	< 0.01*

Table 3: Systolic blood pressure (mmHg) (Mean±S.D).

Group	Group 1		Group 2		p value
	Mean	SD	Mean	SD	
Base Line	127.60	4.299	127.40	2.989	0.9052
During Pre-oxygenation	124.80	3.676	126.00	3.999	0.4938
FOS -1	115.40	6.398	119.20	3.155	0.1093
FOS 0	112.00	7.055	116.60	3.406	0.0788
FOS 1	110.40	5.399	113.40	3.777	0.1671
FOS 2	109.10	4.175	110.40	4.299	0.5015
FOS 3	109.60	3.893	109.60	3.748	1.00
FOS 4	108.20	4.467	109.20	3.425	0.5812
FOS 5	107.80	4.849	108.60	4.624	0.7101
ET -1	107.40	3.406	106.80	3.795	0.7142
ET 0	107.20	3.676	107.20	3.910	1.00
ET 1	105.40	2.836	107.40	5.254	0.3034
ET 2	105.40	2.836	107.60	3.748	0.1561
ET 3	105.20	2.348	107.40	5.420	0.2542

Table 4: Diastolic blood pressure (mmHg) (Mean±SD).

Group	Group 1		Group 2		p value
	Mean	SD	Mean	SD	
Base Line	81.60	3.864	82.80	3.795	0.4925
During Pre-oxygenation	79.80	3.327	77.60	3.098	0.1433
FOS -1	75.40	2.503	75.60	2.633	0.8637
FOS 0	73.40	2.675	74.60	3.890	0.4322
FOS 1	71.60	2.458	72.40	3.978	0.5951
FOS 2	70.00	3.528	72.20	4.263	0.2247
FOS 3	70.00	4.320	69.80	3.048	0.9061
FOS 4	69.40	3.777	69.80	4.467	0.8312
FOS 5	69.40	3.534	69.60	4.195	0.9095
ET-1	68.60	2.989	68.40	2.797	0.8789
ET 0	69.20	3.795	67.20	3.155	0.2163
ET 1	67.40	2.119	67.00	3.432	0.7574
ET 2	67.20	1.398	67.60	2.633	0.6764
ET 3	67.00	1.054	67.20	1.686	0.7541

Table 5: SpO_2(Mean±SD).

Group	Group 1		Group 2		P value
	Mean	SD	Mean	SD	
Base Line	100.00	0.00	100.00	0.00	1.00
During Pre-oxygenation	100.00	0.00	100.00	0.00	1.00
FOS -1	96.70	0.949	96.50	0.972	0.6470
FOS 0	95.50	1.581	95.60	1.713	0.8936
FOS 1	94.50	1.649	94.80	1.229	0.6503
FOS 2	93.70	1.494	93.80	1.476	0.8819
FOS 3	92.70	2.406	93.30	1.767	0.5330
FOS 4	92.90	2.601	93.10	1.449	0.8342
FOS 5	92.30	2.584	93.00	1.247	0.4504
ET -1	92.10	2.183	93.10	1.287	0.2281
ET 0	91.90	2.025	93.40	1.646	0.0858
ET 1	92.20	1.989	93.90	1.853	0.0635
ET 2	92.80	1.398	94.00	1.333	0.0652
ET 3	92.90	1.449	94.20	1.686	0.0809

Table 6: Total comfort score.

Group	Group 1		Group 2		p value
	Mean	SD	Mean	SD	
During Pre-oxygenation	15.10	0.738	14.70	0.823	0.2675
During FOS	21.30	1.159	15.50	1.080	< 0.01*
During ET	23.70	0.949	17.80	0.789	< 0.01*

Table 7: Patient's tolerance based on 5 point FOI score.

Group	Group 1		Group 2		p value
	Mean	SD	Mean	SD	
FOS	3.40	1.075	4.40	0.966	0.05*
ET	1.40	0.699	2.10	0.568	0.05*

Table 8: Questionnaire assessment at 24hr after surgery.

Group	Group 1		Group 2		P value
	Mean	SD	Mean	SD	
Q1	2.60	0.516	1.30	0.483	< 0.01*
Q2	2.70	0.483	1.60	0.516	< 0.01*
Q3	1.80	0.422	1.60	0.516	0.3553
Q4	1.60	0.516	1.50	0.527	0.6733
Q5	1.10	0.316	1.10	0.316	1.00
Q6	2.80	0.422	1.40	0.516	< 0.01*
Q7	5.00	0.667	8.20	0.422	< 0.01*

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