

Comparison of the Patients with Diabetes Mellitus using Either Insulin or Oral Antidiabetic Drug in Terms of Difficult Laryngoscopy: A Randomized Controlled Study

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ABSTRACT

Aim: We aimed to evaluate the differences in the difficult laryngoscopy as a general anesthetic component in patients with Diabetes Mellitus (DM) using either insulin or oral antidiabetic drug (OADD). **Materials and Methods:** This study was planned for a total of 230 patients including DM patients and non-DM patients as a control group who would undergo elective surgery between 30.01.2020–30.04.2020. Age, gender, body mass index (BMI), Mallampati scores, thyromental distance (TMD), inter-incisor distance (IID), and neck extension measurements were noted. Preoperative HbA_{1c} levels, DM type, diagnosis time, and duration of insulin or OADD use were recorded. Patients without DM (Group C), patients using insulin (Group I), and patients using OADD (Group D) were separated respectively. Cormack-Lehane (CL) classification of the airway, number of laryngoscopic attempts, intubation success at the first attempt, intubation duration, performance of backward-upward-rightward pressure (BURP) maneuver, and requirement of use of different airway equipment were compared between the groups. **Results:** The data of 192 patients were compared. The mean IID (mm) was lower in Groups I and D than C. It was the lowest in Group I. Presence of neck extension of more than 30° in Groups I and D was lower than C. Classification of CL in Groups I and D was higher than C. Number of laryngoscopic attempts was higher in Groups I and D than C. Intubation success at the first attempt was lower in Groups I and D than C. The intubation duration was longer in Groups I and D than C. It was the longest in Group I. The more BURP maneuvering was required in Groups I and D than C. In Groups I and D, the number of uses of different airway equipment was higher than in Group C. The rate of using a videolaryngoscope (VL) in Group I was higher than in Groups D and C. **Conclusion:** Difficult laryngoscopy was more common in DM patients. Moreover, in patients with DM using insulin, VL use was more often and intubation duration was longer than in patients with DM using OADD.

KEYWORDS: Anesthesia, diabetes mellitus, difficult laryngoscopy, insulin

INTRODUCTION

Life-threatening complications such as difficulty or failure in intubation, or conditions that lead the cases that cannot be intubated and ventilated constitute approximately 39% of the cases that occur during anesthesia.^[1] Especially in DM patients, a difficult airway is 1.5%–13% more than the patients without

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DM. Moreover, 30% of airway-related complications involve cases with DM.^[2] Nonenzymatic glycosylation in connective tissues due to chronic hyperglycemia in patients with DM may result in abnormal cross-linking of collagen. These tissues can then harden and cause limited joint mobility.^[3] In addition, loss of muscle tone in the upper respiratory tract due to general anesthesia and the standing of the root of the tongue and epiglottis up to the posterior wall of the pharynx are other reasons that make safe airway control difficult in DM patients.^[4]

While the literature agrees that providing a fast and safe airway in DM patients is a concern and a priority requirement,^[5,6] limited information about the effect of insulin and OADDs on airway muscles and their contribution to difficult laryngoscopy is available. In this study, we aimed to investigate whether laryngoscopy used as a component of general anesthesia in Type I and Type II DM patients scheduled for elective surgery is more difficult in patients using insulin or OADD.

MATERIAL AND METHOD

This clinical trial was registered <http://www.clinicaltrials.gov/web> database with I.D. 2020.01.2.05.015.

Study population: This study was approved by the Ethics Committee of the University of Health Sciences Istanbul Bagecilar Training and Research Hospital (date/number: 24.01.2020/2020.01.2.05.015). The study was planned for patients with DM who would undergo surgery under elective conditions between 25.01.2020 and 30.04.2020.

Data collection: According to the power analysis results, a total of 230 non-diabetic and DM patients who would undergo surgery were included in our study. Cases were selected among the patients from cardiovascular surgery, general surgery, and orthopedic surgery operating rooms due to the idea of using standard endotracheal tubes during the surgery. After explaining to the patients about the study, signed informed consent forms were obtained from the patients. Patient information including, age, gender, height, body weight, BMI, comorbid diseases, The American Society of Anesthesiologists (ASA) physical status, type of the operation, type of DM, duration of DM, HbA_{1c}, DM treatment approach, OADD/dose of insulin per day, and duration of OADD/insulin use (months) were recorded. Mallampati score, IID, TMD, and neck extension measurements (NEMs) were conducted by the same physician and recorded. Detailed medical histories of the patients were obtained, and physical examinations were performed.

Disoriented and non-cooperative patients, patients required rapid or awake endotracheal intubation, with

difficult airway and tracheostomy history, with neck movement difficulties, with a history of oral-pharyngeal cancer or a history of reconstructive surgery, with cervical spinal injury and facial anomalies, patients are younger than 18 years old, undergoing emergency surgery and morbidly obese patients (BMI >40 kg/m²) were excluded from the study. All measurements for the specific parameters, test evaluations, and endotracheal intubations in the study were performed by the same physician assistant with 4–5 years of experience and were confirmed by a specialist physician.

Preoperative preparation for anesthesia and monitoring: Vascular access of the patients was achieved by using a 20G venous cannula and all patients were administered 2 mg midazolam intravenously preoperatively as premedication. Electrocardiography (ECG; derivation: DII), systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), and peripheral oxygen saturation (SpO₂) monitoring were performed as standard. Short-acting insulin therapy on all patients was discontinued on the day of surgery while Type II DM patients were not given insulin. Type I DM patients were given 1/3 of the long-acting insulin that they took daily. Treatment was continued in patients with an insulin pump infusing at basal rate. In the preoperative period, blood sugar was checked in the morning and just before the operation.^[7] Preoperative blood sugar was aimed to be kept between 150–180 mg/dl.^[8]

Anesthesia management and intubation: DM patients were operated on as the first patient group in the morning. Thirty minutes before anesthesia induction, 50 mg ranitidine, and just before the induction 10 mg metoclopramide, and for surgical prophylaxis, 1 g cefazolin was administered intravenously. The patients were preoxygenated with 100% O₂ for three minutes. Due to the high risk of aspiration due to gastroparesis of diabetes patients during anesthesia induction, a rapid sequence induction technique was used. After administration of 2 mg/kg propofol (Propofol® %1, Fresenius Kabi, Hamburg), 1 µg/kg fentanyl citrate (Fentanyl®, Abbott, Chicago), and 1 mg/kg rocuronium bromide (Esmeron®, Organon, Holland) according to the corrected body weight of the patients, mask ventilation was provided with ambu bag at low pressure low tidal volume to avoid the risk of filling the stomach with air and aspiration. Direct laryngoscopy was performed by using Macintosh laryngoscope blades (grade 3 or 4). In endotracheal intubation, a disposable, cuffed, standard endotracheal tube with an internal diameter of 7.5 mm for women and 8.0 mm for men was used. Classification of CL score was graded according to the laryngoscopic view. CL scores were

evaluated as follows: Grade I: Glottis is fully visible; Grade II: Glottis is partly visible; Grade III: Only the epiglottis is visible; Grade IV: No epiglottis structure is visible. According to this classification, Grade I and II were considered easy laryngoscopy, Grade III and IV difficult laryngoscopy.^[9] First attempt success of intubation, number of laryngoscopy attempts, intubation duration (sec), performance of BURP maneuver, and whether there were different airway equipment requirements were noted. Although proper head and neck position was achieved and laryngoscope blades were used, the CL score was determined as Grade III and IV and it was accepted as difficult intubation.^[10] If SpO₂ fell below 90% during the intubation attempt, the intubation attempt was terminated, and the patient was ventilated until the saturation values before intubation were achieved. In the case of difficult ventilation and/or intubation, procedures were performed according to the difficult airway algorithm.^[11] Equal ventilation of the lungs after endotracheal intubation was confirmed by inspection, auscultation, and capnography. The time between the termination of the mask ventilation and placement of the bladder in the mouth and observation of the end-tidal CO₂ (ETCO₂) value was considered as a successful intubation duration (sec) and recorded. After intubation, the tube cuff was inflated at the appropriate pressure. Anesthesia was maintained with train-of-four (TOF)-guided 0.2 mg/kg rocuronium bromide (Esmeron®, Organon, Holland) administration as a muscle relaxant and sevoflurane (Sevorane®, Abbott, England) at 50% - 50% oxygen/air mixture and minimum alveolar concentration (MAC) of 2% inhalation. Perioperative analgesia was achieved with a 0.01–0.05 remifentanyl infusion of 0.01–0.05 µg/kg/min. Intraoperative blood sugar monitoring was performed hourly. Intraoperative blood sugar level was kept between

120–180 mg/dl to decrease mortality and morbidity rates during and after surgery.^[12] When necessary, patients were administered short- or fast-acting insulin. DM patients using insulin were administered with perioperative 5% glucose/insulin/KCl solution at a rate of 100 mL/h postoperatively, blood sugar monitoring, ECG monitoring, and consciousness monitoring were performed in the recovery room. Eight mg of ondansetron for nausea and vomiting prophylaxis, 1 g of paracetamol, and 1 mg/kg of tramadol for analgesia were administered. The patients were discharged from the service when the Aldrete Recovery Score (ARS) was higher than eight.

Statistical analysis

Mean, standard deviation, median, minimum, maximum value frequency, and percentage were used for descriptive statistics. The distribution of variables was checked with the Kolmogorov-Smirnov test. Mann-Whitney U test was used for the comparison of quantitative data. The Chi-Square test was used for the comparison of qualitative data. A *P* value lower than 0.05 was accepted as significantly different. SPSS 26.0 was used for statistical analysis.

RESULTS

In a recent study, 192 patients' data were presented.

The demographic characteristics of the patients are shown in Table 1. There were no significant differences between the groups in terms of age and gender distribution (*P* = 0.109 and *P* = 0.240), respectively. The distribution of patients according to ASA physical status classification was statistically different among Group I, Group D, and Group C (*P* = 0.0001). Significantly different mean BMI values in Group I, Group D, and Group C were observed (*P* = 0.001).

Table 1: Demographic characteristics of the patients

		Group I (n=64)		Group D (n=64)		Group C (n=64)		P
Age (year)		59.91±11.19		61.40±9.15		57.53±10.64		0.109 [‡]
Gender	Male (n) (%)	28	(43.75%)	38	(58.73%)	33	(51.56%)	0.240 ⁺
	Female (n) (%)	36	(56.25%)	26	(41.27%)	31	(48.44%)	
ASA	I (n) (%)	0	(0.00%)	0	(0.00%)	42	(65.63%)	0.0001 ⁺
	II (n) (%)	51	(79.69%)	46	(73.02%)	21	(32.81%)	
	III (n) (%)	13	(20.31%)	18	(26.98%)	1	(1.56%)	
BMI (kg/m ²)		26.06±2.47		26.08±2.35		24.52±3.12		0.001 [‡]
Duration of DM (year)		17.06±8.11		12.89±7.9		-		0.004 [*]
HbA1c (%)		6.65±1.22		7.12±1.46		-		0.049 [*]
DM type	Type I (n) (%)	10	(15.63%)	0	(0.00%)	-	-	0.001 ⁺
	Type II (n) (%)	54	(84.38%)	64	(100.00%)	-	-	

ASA: American Society of Anesthesiology, BMI: Body mass index, DM: Diabetes Mellitus, HbA1c: Hemoglobin A1c, [‡]One-way analysis of variance, ^{*}Independent *t*-test, ⁺Chi-Square test

Table 2: Types of the surgery that patients underwent

Type of the Surgery	Group I (n=64)		Group D (n=64)		Group C (n=64)	
ABF bypass (n (%))	1	(1.56%)	4	(6.35%)	0	(0.00%)
AVR (n (%))	3	(4.69%)	0	(0.00%)	2	(3.13%)
Intraabdominal mass (n (%))	0	(0.00%)	0	(0.00%)	1	(1.56%)
CABG (n (%))	11	(17.19%)	18	(28.57%)	4	(6.25%)
Fem-popliteal bypass (n (%))	2	(3.13%)	1	(1.59%)	0	(0.00%)
Gastrectomy (n (%))	0	(0.00%)	0	(0.00%)	2	(3.13%)
Hemicolectomy (n (%))	0	(0.00%)	1	(1.59%)	1	(1.56%)
Carotid endarterectomy (n (%))	9	(14.06%)	7	(11.11%)	2	(3.13%)
Incisional hernia (n (%))	0	(0.00%)	1	(1.59%)	1	(1.56%)
Laparoscopic Inguinal Hernia (n (%))	2	(3.13%)	2	(3.13%)	3	(4.69%)
Laparoscopic cholecystectomy (n (%))	24	(37.50%)	23	(36.51%)	31	(48.44%)
Breast prosthesis (n (%))	1	(1.56%)	0	(0.00%)	3	(4.69%)
MRM (n (%))	8	(12.50%)	7	(11.11%)	10	(15.63%)
MVR (n (%))	2	(3.13%)	0	(0.00%)	3	(4.69%)
PPFN (n (%))	1	(1.56%)	0	(0.00%)	0	(0.00%)
Tibial plateau/ARIF (n (%))	0	(0.00%)	0	(0.00%)	1	(1.56%)

ABF: Aortobifemoral bypass, AVR: Aortic valve replacement, CABG: Coronary artery bypass grafting, MRM: Modified radical mastectomy, MVR: Mitral valve replacement, PPFN: Percutaneous proximal femoral nailing

Table 3: Preoperative airway examination data of the patients

	Group I (n=64)		Group D (n=64)		Group C (n=64)		P
Inter-incisor distance (mm)	3.8±0.68		4.04±0.78		4.31±0.71		0.001 [‡]
Thyromental distance (cm)	6.75±0.56		6.74±0.81		6.95±0.89		0.063 [‡]
Mallampati score	I [n (%)]	16 (25.00%)	24 (38.10%)	26 (40.63%)	0.053 ⁺		
	II [n (%)]	34 (53.13%)	34 (53.97%)	33 (51.56%)			
	III [n (%)]	14 (21.88%)	5 (7.94%)	5 (7.81%)			
Neck extension (°)	<10	10 (15.63%)	4 (6.35%)	0 (0.00%)	0.001 ⁺		
	15	11 (17.19%)	9 (14.29%)	1 (1.56%)			
	20	2 (3.13%)	2 (3.17%)	3 (4.69%)			
	25	5 (7.81%)	2 (3.17%)	0 (0.00%)			
	>30	36 (56.25%)	46 (73.02%)	60 (93.75%)			

[‡]The Kruskal-Wallis Test (Mann-Whitney U Test), ⁺Pearson's Chi-Square Test

Table 4: Laryngoscopy and intubation data of patients

		Group I (n=64)		Group D (n=64)		Group C (n=64)		P
Cormack-Lehane	Class I [n (%)]	10	(15.63%)	16	(25.40%)	38	(59.38%)	0.001 ⁺
	Class II [n (%)]	27	(42.19%)	26	(41.27%)	22	(34.38%)	
	Class III [n (%)]	24	(37.50%)	20	(31.75%)	4	(6.25%)	
	Class IV [n (%)]	3	(4.69%)	1	(1.59%)	0	(0.00%)	
Number of laryngoscopy attempts		1.48±0.55		1.34±0.40		1.02±0.13		0.001 [‡]
Intubation success at the first attempt	Unsuccess. [n (%)]	8	(12.50%)	6	(9.52%)	1	(1.56%)	0.059 ⁺
	Successful [n (%)]	56	(87.50%)	57	(90.48%)	63	(94.44%)	
BURP maneuver	No [n (%)]	35	(54.69%)	39	(61.90%)	60	(93.75%)	0.001 ⁺
	Yes [n (%)]	29	(45.31%)	24	(38.10%)	4	(6.25%)	
Use of different airway devices	No [n (%)]	39	(60.94%)	48	(76.19%)	62	(96.88%)	0.0001 ⁺
	Yes [n (%)]	25	(39.06%)	15	(23.81%)	2	(3.13%)	
Airway device used	Guide (n (%))	3	(12.00%)	2	(13.33%)	1	(50.00%)	0.0001 ⁺
	Style (n (%))	2	(8.00%)	2	(13.33%)	0	(0.00%)	
	VL (n (%))	20	(80.00%)	11	(73.34%)	1	(50.00%)	
The duration of intubation (sec)		25.52±24.3		18.33±19.2		5.28±3.06		0.0001 [‡]

BURP: Backward upward right pressure VL: Videolaryngoscope, [‡]One-way analysis of variance, ⁺Independent t-test, ⁺Chi-Square test

The average duration of DM (years) was significantly shorter in Group D than in Group I (P = 0.004). HbA_{1c} in Group I was 6.65 ± 1.22 mmol/mol and was 7.12 ± 1.46 mmol/mol in Group D (P = 0.049).

Table 5: Inter-group comparisons of the IID, number of laryngoscopy attempts, and the duration of intubation

Tukey's multiple comparison test	IID (mm)	Number of laryngoscopy attempts	The duration of intubation (sec)
Group I/Group D	0.144	0.124	0.023
Group I/Group C	0.0001	0.001	0.0001
Group D/Group C	0.087	0.171	0.0001

The types of surgery patients underwent are shown in Table 2. 63.02% of the patients were followed in general surgery, 35.94% in cardiovascular surgery, and 1.04% in orthopedic surgery operating room.

Preoperative airway examination data of the patients are given in Table 3. There were no statistical differences in the distribution of the Mallampati scores between the groups ($P = 0.053$). There were no statistical differences in the mean TMD between the groups ($P = 0.063$). The mean IID (mm) was lower in Groups I and D than Group C. The mean IID was the lowest in Group I ($P = 0.001$). The presence of the neck extension more than 30° in Groups I and D was lower than Group C ($P = 0.001$).

Classification of CL in Groups I and D was higher than in Group C ($P = 0.001$). The number of patients in CL Class I was higher in Group C compared to Group I and Group D. No patients with CL Class IV view at the laryngoscopy were detected in Group C [Table 4]. Number of laryngoscopic attempts was higher in Groups I and D than Group C ($P = 0.001$) [Table 4]. Although intubation success rates at the first attempt were lower in Groups I and D than in Group C, there was no statistically significant difference was observed between the groups ($P = 0.059$). There were no patients who could not be intubated [Table 4]. More BURP maneuvering was required in Groups I and D than in Group C ($P = 0.001$) [Table 4]. There were statistically significant differences between Groups I, D, and C in terms of the distribution of using different airway equipment. In Groups I and D, the number of uses of different airway equipment were higher than in Group C ($P = 0.0001$). The rate of using VL in Group I was higher than in Groups D and C [Table 4]. The intubation duration was longer in Groups I and D than in Groups C ($P = 0.0001$). It was the longest in Group I ($P = 0.023$) [Tables 4 and 5].

DISCUSSION

Approximately 50% of DM patients need surgery at some time in their lives.^[13] For this reason, DM patients are among the patient groups frequently encountered by anesthesiologists in their daily practice. In DM patients,

the risk of complications such as limited joint mobility, neck stiffness, cardiac ischemia, cerebrovascular diseases, autonomic dysfunction, and nephropathy is increased.^[14] As anesthesiologists, the perioperative management of DM patients is important for us. Moreover, it has been reported in various studies that DM patients have a higher risk of a difficult airway and airway-related complications are more frequently encountered in this patient group.^[6,15] While the incidence of difficult airway is determined as 1.5%–13.2% in the general population,^[9] this rate is approximately 27%–31% in DM patients.^[5]

While the literature agrees on the incidence of a difficult airway in DM patients and the provision of a fast and safe airway, literature regarding the differences between DM patients using insulin and those using OADD is still limited.^[16,17] Insulin therapy is required for all patients with Type I DM.^[18] In type 2 diabetic patients, insulin therapy is often used in combination with OADD or after OADDs are no longer effective.^[19]

In a recent study, we found that the mean IID was lower in Group I. DM causes a variety of musculoskeletal complications. Protein glycosylation, collagen accumulation in the skin and periarticular area, microvascular abnormalities due to blood vessels and nerve damage cause changes in the connective tissue.^[20] The most important diabetic musculoskeletal complication that concerns anesthesiologists is stiff joint syndrome.^[21] Diabetic Cheiroarthropathy is also known as diabetic stiff joint syndrome or limited joint mobility syndrome.^[22] While it is encountered in 8%–50% of Type 1 DM patients, it is also seen in Type 2 DM patients.^[23] Its pathogenesis was explained by Chang *et al.*,^[3] as abnormal cross-linking and accumulation of collagen in joints by nonenzymatic glycosylation in connective tissues due to chronic hyperglycemia. Moreover, glycosylation of joints due to chronic hyperglycemia can result in limited mobility, which may also affect the cervical and laryngeal areas.^[24] If the cervical vertebrae and atlanto-occipital joint are affected, neck extension is restricted and leads to difficult intubation^[25,26] or, as in our patients, it decreases the mouth opening due to temporomandibular joint ankyloses.^[27] Another factor that causes a decrease in mouth opening may be the duration of DM. Because the duration of the DM in patients using insulin in our study was the longest with approximately 17 years. Much more comprehensive studies should be planned for the strength of the relationship between insulin use and mouth opening, which we can hardly speculate for now. Insulin regulates skeletal muscle development. It plays an anabolic role and stimulates myogenesis.

Therefore insulin may induce airway smooth muscle contraction.^[28,29] So, it causes muscle hypercontractility in patients.^[30] Gondane *et al.*,^[22] showed a strong correlation between DM duration and difficult laryngoscopy. The rate of difficult laryngoscopy in patients who were diagnosed with DM more than ten years ago was 27%.^[31] DM duration of more than ten years was indicated as a sensitive indicator for difficult laryngoscopy.^[32]

In our study, the mean HbA1c was found to be higher in OADD users compared to DM patients using insulin. Mashour *et al.*,^[33] found that the degrees of CL laryngoscopic view in DM patients with a mean HbA1c of $6.2 \pm 1.3\%$ were lower than those with a mean HbA1c of $8.7 \pm 1.9\%$. In our study, we did not find a significant correlation between HbA1c value and CL. HbA1c values in patients with difficult laryngoscopy suggest the possibility that the severity of DM may play a role in airway management.^[34]

Intubation duration was longer in those who use insulin compared to those who use OADD. The mean intubation time in DM patients was reported as 29.7 seconds.^[35] In our study, the mean intubation time was found to be 25.52 seconds in patients using insulin, 18.33 seconds in patients using OADD, and 5.28 seconds in non-DM patients.

The use of assistive airway devices and the number of intubation attempts in DM patients is also higher than in non-DM patients.^[36] In our study, using VL was more common than DM patients using insulin more often than those using OADD. We needed to use VL in 14 patients with DM patients using insulin, 11 patients using OADD, and one patient with non-DM. In light of these data, the relationship between DM patients and VL use is significant and worth investigating.

There are some limitations in the recent study. First, we did not classify the OADDs used by patients. Sulfonylureas are the oldest class of oral antihyperglycemic agents; they were first introduced in the 1950s.^[37] They work by blocking potassium channels, which causes an influx of calcium into the pancreatic beta cells. The result is an increase in insulin release, assuming that there are a sufficient number of functional beta cells present.^[38] Thiazolidinediones (TZDs) work by increasing insulin sensitivity in the liver, adipose, and skeletal muscle tissues. Also, they effectively work by increasing pancreatic beta-cell insulin secretion.^[37] Meglitinides work by increasing the amount of insulin secreted by the pancreas during the early phase of insulin release.^[36] Second, we also did not classify the type of insulin that patients use. They are usually

divided into 4 classes: (a) short and rapid-acting, (b) intermediate-acting, (c) long-acting, and (d) mixed insulins. We did not use data on the insulin regimens of the patients. In addition, plasma insulin levels of our patients were not measured.

In the results, we obtained in our study, we found that TMD and IID were shorter, neck extension was more limited, CL score was higher, the number of laryngoscopic attempts and the need for BURP maneuver, and the need for VL use was higher in DM patients. The mouth opening was narrower, neck extension was more limited in DM patients using insulin than in OADD. In patients with DM using insulin, VL use was more often and intubation duration was longer than in patients with DM using OADD.

Because of the higher incidence of difficult laryngoscopy in DM patients and the higher incidence of airway complications during induction, it is very important to predict the risk of difficult intubation. Currently, the relationship between DM and anesthesia is an iceberg most of the concepts are not known.

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Conflicts of interest

There are no conflicts of interest.

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