Risk Management of Anesthetics during General Surgery

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Conflicts of Interest: Nil

Abstract

Background and Aims: Safe airway management is the cornerstone of contemporary anaesthesia practice, and difficult intubation (DI) remains a major cause of anaesthetic morbidity and mortality. The surgical category, particularly cardiac surgery as a risk factor for DI has not been studied extensively. The aim of this study was to test the hypothesis whether cardiac surgical patients are at increased risk of DI.

Methods: During the study, 627 patients (329 cardiac and 298 noncardiac surgical) were enrolled. Pre- operative demographic and other variables associated with DI were assessed. Patients with Cormack Lehane grade III and IV or use of bougie in Cormack grade II were defined as DI. The incidence of anticipated and unanticipated DI was assessed. Factors associated with DI were described using univariate and multivariate logistic regression models.

Results: The overall incidence of DI was 122/627 (19.46%). The incidence of DI was higher in cardiac surgery patients (24%) as compared to non cardiac surgery patients (14.4% $P = 0.002$). On multivariate analysis, factors independently associated with DI were greater age, male sex, higher Mallampati grade, and anticipated DI, but not cardiac surgery. The incidence of unanticipated DI was 48.1% and 53.4% in cardiac and non cardiac surgery patients, respectively.

Conclusion: Although there was a higher incidence of DI in cardiac surgical patients, cardiac surgery is not an independent risk factor for DI. Rather, other factors play more important role. About half of the DI both in cardiac and non-cardiac surgeries was unanticipated.

Key words: Cardiac surgery, difficult intubation, Indian patients

Introduction

Safe airway management is the cornerstone of contemporary anaesthesia practice, and difficult intubation (DI) remains a major cause of anaesthetic morbidity and mortality. Recently published All India Difficult Airway Association (AIDAA) guidelines recommend that pre operative airway assessment be routinely performed to identify factors leading to difficult facemask ventilation, tracheal intubation and emergency surgical access. This may help identify potential problems before surgery leading to proper planning and preparation to reduce the risk of complications.[1] Many predictors of DI have been studied, but they have only poor to moderate discriminative power when used alone, and their clinical value remains limited.[2] Most important airway complications such as failed airway management, oesophageal intubation and pulmonary aspiration are unanticipated and can lead to harm and death.[3] The surgical category as a risk factor for DI has not been extensively studied. The majority of these studies are limited to obstetric or ear nose and throat surgeries.[2]

There is very limited and conflicting evidence of cardiac surgery as a risk factor for DI.

One report demonstrated that although more cases of difficult laryngoscopy were recorded in cardiac patients (10% vs. 5.2%; $P < 0.023$), cardiac surgery *per se* was not an independent predictor of difficult laryngoscopy.[4] Another larger report demonstrated that even with stratification for demographic risk factors, the rate of poor laryngoscopy views remained significantly higher in the cardiac surgery group (7.5% vs. 5.7%; $P = 0.005$).[5] The literature is sparse on the incidence of DI in Indian patients undergoing surgery.[6,11] To obtain further evidence on this issue, the authors conducted this prospective observational study to test the hypothesis whether cardiac surgical patients are at increased risk of DI.

Methods

This was a prospective observational study conducted in a tertiary care hospital from February to October 2016. The Institutional Review Board approved this study and written informed consent was obtained from all participants. During the study period of 9 months, 627 patients undergoing general anaesthesia with endotracheal intubation were enrolled; of this, 329 patients underwent cardiac surgery and 298 underwent various non-cardiac surgeries such as general surgery, spine surgery, neuro and urological surgery. Patients with planned regional anaesthesia and general anaesthesia with supraglottic airway devices (SADs) were excluded from the study. Patients undergoing both elective and emergency surgeries with the American Society of Anesthesiologists' (ASA) grades I, IV were included in the study.

On the pre anaesthesia visit, a qualified anaesthesiologist noted the following variables: demographic variables including age, gender, body mass index (BMI); comorbidities such as hypertension and diabetes, any systemic disorder, addiction in the form of tobacco or gutka chewing, smoking, abnormal dental status (malaligned or loose teeth or presence of dentures), any facial abnormalities like short neck or presence of beard. The modified Mallampati class was also assessed (Class I: Soft palate, fauces, uvula, anterior and posterior tonsil pillars visible; Class II: Uvula is obscured by the base of tongue; Class III: Soft palate and base of uvula are visible; Class IV: Only hard palate visible). A patient with a combination of modified Mallampati class III or IV, with facial anomalies or abnormal dental status was considered as a predicted DI. For every patient evaluated, the anaesthesiologist determined whether a difficult airway was anticipated or not. No premedication was given to any of the patients. In the operating room, monitoring was established as per the surgery planned which included an electrocardiogram, noninvasive blood pressure, pulse oximetry, capnography for non cardiac surgery and additional arterial line and pulmonary artery catheter for cardiac surgeries. A difficult airway cart with similar contents was available in all operation rooms as per the AIDAA guidelines containing working laryngoscopes, face masks, airways, SADs, AMBU bag, fibreoptic bronchoscope, cricothyroidotomy and tracheostomy tubes.[1] All the anaesthesiologists had more than 5 years of experience in anaesthesia.

The height of the operating table was adjusted to suit anaesthesiologist performing laryngoscopy and intubation. All patients were pre-oxygenated for 3 min using 100% O_2. Anaesthesia was induced with fentanyl 2 μg/kg intravenous (IV) and propofol 2–2.5 mg/kg IV or etomidate 0.2–0.4 mg/kg IV until loss of verbal contact. Intubation was facilitated by either suxamethonium 2 mg/kg IV or vecuronium 0.1 mg/kg IV. The anaesthesiologist performing the laryngoscopy had a choice of induction agent and muscle relaxant. Intubation

was performed using Trupti® (flexi tip) (Anaesthetics India Pvt. Ltd.) laryngoscope sizes three or four blades with the patients' head in sniffing position. Tracheal tubes size 7 and 8 were used in female and male patients, respectively. Laryngoscopic view was graded as per Cormack and Lehane grading. External laryngeal pressure, backwards, upwards, and rightwards pressure was applied for grading of the laryngoscopic view for grades II to IV. Patients with Cormack Lehane grade III and IV or use of bougie in Cormack grade II were defined as DI. Tracheal intubation was confirmed by assessment of chest movement, auscultation and capnography. In the case of failed intubation, Step 2 was to insert a SAD to maintain oxygenation, then Step 3 was attempting facemask ventilation one more time and lastly Step 4 was emergency cricothyroidotomy as per the AIDAA guidelines.[1] Since there is no report on the incidence of DI in Indian patients undergoing cardiac surgery, the authors performed a pilot study of 100 patients and found that there was incidence of 28% and 18% of DI in cardiacand non cardiac surgeries, respectively. Based on this incidence, the sample size for a power of 80% and an alpha error of 1% was 594 patients (297 patients in each group). We enrolled 627 patients for dropout of 5%.

Continuous variables are expressed as a mean ± standard deviation. Non continuous variables are expressed as a number of occurrences and percentages. For univariate analysis, the two tail Student's *t*-test was used for continuous variables and Chi-square or Fisher's exact test, as appropriate, for noncontiguous variables. Factors associated with DI were described using univariate and multivariate logistic regression models with forward stepwise method. Statistical significance was set at $P < 0.05$. Test characteristics of anticipated for actual DI were analysed using 2×2 tables for cardiac and non cardiac surgical populations. The Statistical Package for Social Sciences (SPSS) version 16.0.0 for Windows (SPSS Inc., Chicago, IL, USA) and R for statistics 3.3.1 (R Foundation for Statistical Computing Vienna, Austria, URL http:// www. R project. org) were used for analysis.

Results

All 627 patients could be intubated using direct laryngoscopy with Trupti® (flexi tip) blade. Of 627 patients, 586 (93.3%) of the patients could be intubated in the first attempt. Only two patients required more than two attempts for intubation. None of the patients required fibreoptic intubation or an SAD to maintain the airway. The overall incidence of DI was 122/627 (19.46%). The baseline differences in cardiac and non cardiac surgical patients are described in Table 1. The cardiac surgical patients were older, more likely to be male, with higher ASA grades and a higher burden of comorbidities and addictions. The incidence of DI was higher in cardiac surgery patients (24%) as compared to non‑ cardiac surgery patients (14.4% $P = 0.002$). Characteristics of patients with DI as compared to patients with no DI are shown in Table 2. Table 3 shows univariate logistic regression analysis of predictors DI and Table 4 shows multivariate logistic regression analysis, describing independent predictors of DI. The following factors were independently associated with DI: greater age, male sex, higher Mallampati grade, and anticipated DI, but not cardiac surgery ($P = 0.1$). Table 5 demonstrates the diagnostic accuracy of the anaesthesiologists' prediction of DI. The incidence of unanticipated DI was 48.1% and 53.4% in cardiac and non cardiac surgery patients, respectively.

Discussion

The main findings of this study are there was higher incidence of DI in patients undergoing cardiac surgery as compared to non‑ cardiac surgery, the independent variables associated with DI were greater age, male sex,

higher Mallampati grade, and anticipated DI but not cardiac surgery; almost half of the DI both in cardiac and non cardiac surgeries were unanticipated.

Difficult airway remains major cause of anaesthetic morbidity and mortality. Most important airway complications such as failed airway management, oesophageal intubation and pulmonary aspiration are unanticipated and can lead to harm and death. Various societies have proposed guidelines for management of DI.[1,12,13] All these guidelines have emphasised pre operative assessment of airway because airway management is safest when potential problems are identified before surgery, enabling the adoption of a strategy, a series of plans, aimed at reducing the risk of complications. This assessment should be performed to identify factors that might lead to difficulty with face mask ventilation, SAD insertion, tracheal intubation or front of neck access. In spite of these important concerns, a standard definition of the difficult airway cannot be identified in the available literature. Although the majority of literature has used CormackLehane grade III or IV as the definition of DI, we used additional indicator of DI, i.e., Cormack Lehane grade II with the use of bougie. The addition of the need to use to bougie although criticised has been used previously in the literature.[14] The reason being the use of bougie is indicated because anatomical

factors, which make these patients 'relatively difficult' are the same factors that in more extreme cases cause Cormack Lehane grade III or IV difficulty.[15] The incidence of DI in our cohort was 19.46% (24% in cardiac and 14.4% in non cardiac surgeries), higher than that shown in the previously published literature.[2] There can be multiple reasons for this, especially the definition used to label DI as mentioned above. We had certain limitations in terms of assessment of difficult airway. The authors did not include many established risk factors for the anticipation of DI such as thyromental, sternomental distance.

Table 1: Baseline differences in cardiac and non-cardiac surgery patients

Characteristics	Total (*n*=627), *n* (%) (*n*=329), *n* (%)	Cardiac surgery	Non-cardiac surgery (*n*=298), *n* (%)	*P*
Age (years)	51±22	57±31	47±15	0.001
Sex male/female (percentage male/female)	378/249 (61.29/39.71)	220/109 (66.9/33.1)	158/140 (53/47)	0.001
BMI (kg/m2)				
Normal	391(62.36)	199 (60.4)	192 (64.4)	0.07
Pre -obese	159(25.35)	95 (28.87)	64 (21.47)	

Obese I	61(9.72)	30 (9.11)	31(10.4)	
Obese II	7 (1.11)	1 (0.3)	6 (2.01)	
Obese III	11 (1.75)	4 (1.21)	5 (1.67)	
ASA grade				
				0.000
I	86 (13.72)	8 (2.4)	78(26.2)	1
II	238(37.96)	57 (17.3)	181 (60.7)	
III	280(44.66)	245 (74.5)	35 (11.7)	
IV	23(3.67)	19 (5.8)	4(1.3)	
Emergency surgeries				
(%)	22(3.51)	7 (2.1)	15 (5)	0.08
Addictions	63 (10.05)	31 (9.4)	32(10.7)	0.584
Abnormal dental status	141(22.49)	89 (27.1)	52(17.4)	0.001
Facial anomalies	74 (11.80)	31 (9.4)	43(14.4)	0.06
				0.000
HTN	236 (37.6)	160 (48.6)	76(25.5)	1
				0.000
DM	144 (23)	98 (29.8)	46(15.4)	1
				0.000
Any systemic disorder	282 (45)	186 (56.5)	96(32.2)	1
Mallampati grade				
				0.000
I	101 (16.11)	31 (9.4)	70(23.5)	1
II	419(66.83)	239 (72.6)	180 (60.4)	
III	96 (15.31)	55 (16.7)	41(13.8)	
IV	11 (1.75)	4 (1.2)	7(2.3)	
Anticipated difficult airway	143(22.81)	76 (23.1)	67(22.5)	0.924
CL grade				
				0.000
I	141(22.49)	56 (17)	85(28.5)	1
II	388(61.88)	220 (66.9)	168 (56.4)	
III	87 (13.88)	53 (16.1)	34 (11.4)	
IV	11 (1.75)	0	11 (3.7)	
Bougie used	119 (18.98)	77 (23.4)	42(14.1)	0.003
Number of attempts				

I	586 (93.3)	303 (92.4)	282 (95.3)	0.02
II	36 (5.74)	24 (7.6)	12 (4.1)	
III	1 (0.16)	0	1 (0.3)	
IV	1 (0.16)	0	1 (0.3)	
Difficult airway	122 (19.46)	79 (24)	43 (14.4)	0.002

ASA – American Society of Anaesthesiologists; BMI – Body mass index; HTN – Hypertension; DM – Diabetes mellitus; CL – Cormack Lehane mandibular protrusion and exact documentation of a range of neck movements; and obstructed sleep apnoea. In a meta‑ analysis of 35 studies representing 50,760 patients, the overall incidence of DI was 5.8% in patients with apparently normal airways.[2] There are anthropometric differences between the Indian population and the American or European population studied in the majority of published reports. The average height of an American adult male and female is considerably greater than that of an Indian male and female. This probably translates into differences in the anatomical indices that are commonly used to predict difficult laryngoscopy.[6] The AIDAA guidelines do not mention the incidence of DI in Indian patients. The reported incidence of DI in Indian population is 3.3%– 21% in various studies enrolling 60– 600 patients.[6- 11] In a study of 330 patients, the authors demonstrated that incidence of difficult laryngoscopy and intubation was 9.7% and 4.5%, respectively, in Indian patients with apparently normal airways. They also reported very high (48%) incidence of 'minor' difficulty in intubation.[6] Our study enrolled a large number of Indian patients with both apparently normal and DI. We included emergency surgical patients, who were in ASA grade IV physical status also in our analysis, which were excluded in the majority of previous reports.

Table 2: Characteristics of patients with difficult intubation as compared to those without difficult intubation

Characteristics	Difficult intubation		*P*
	Yes (*n*=122), *n* (%)	No (*n*=505), *n* (%)	
Age±SD (years)	57.08±11.48	49.89±15.07	0.001
Male:female	93:29	285:220	0.0001
ASA grade			

I	7 (5.7)	79 (15.6)	0.0001
II	41 (33.6)	197 (39)	
III	63 (51.6)	217 (43)	
IV	11 (9)	12 (2.4)	
Emergency surgery	7 (5.7)	15 (3)	0.17
Addictions	22 (18.2)	41 (8.1)	0.001
Abnormal dental status	45 (36.9)	96 (19)	0.0001
Facial anomalies	30 (24.6)	44 (8.7)	0.0001
HTN	57 (46)	179 (35.4)	0.02
DM	38 (31.14)	106 (20.9)	0.01
Any disorder	70 (57.37)	212 (40)	0.002
Mallampati grade			
I	7 (5.7)	94 (18.6)	0.001
II	77 (63.1)	342 (67.7)	
III	33 (27)	63 (12.5)	
IV	5 (4.1)	6 (1.2)	
Anticipated difficult intubation	61 (50)	82 (16.8)	0.001
Surgical category	79 (64.8)	250 (49.5)	0.003

ASA – American Society of Anesthesiologists; SD – Standard deviation; HTN – Hypertension; DM – Diabetes mellitus

Table 3: Univariate analysis of factors associated with difficult intubation

Variable	OR	Lower–upper 95% CI	*P*
Age	1.04	1.02-1.06	0.00
Female gender	0.4	0.26-0.64	0.00
BMI	1	0.99-1.00	0.96
ASA			
I	REF		
II	2.4	1.01-5.5	0.047
III	3.3	1.4-7.5	0.005
IV	10.35	3.4-31.9	0.00
Cardiac surgery	1.9	1.2-2.8	0.003
HTN	1.6	1.1-2.8	0.02
DM	1.8	1.1-2.7	0.01
Any disorder	1.9	1.3-2.8	0.002
Emergency surgery	1.9	0.79-4.9	0.14
Addictions	2.5	1.4-4.4	0.001
MP			
I	REF		
II	3.02	1.4-6.8	0.007
III	7.03	2.9-16.9	0.00
IV	11.2	2.7-46	0.001
Abnormal dentition	2.5	1.6-3.9	0.00
Facial anomalies	3.4	2.04-5.8	0.00
Anticipated difficult	5.2	3.4-7.9	0.00

intubation

REF – Reference category; OR – Odds ratio; ASA – American Society of Anaesthesiologists; SD – Standard deviation; Hypertension; DM – Diabetes mellitus; CI – Confidence interval; MP – Modified Mallampati class.

Table 4: Multivariate Analysis of factors associated with difficult intubation.

Variable	Odds Ratio	Lower 95 CI	Upper 95 CI	*P*
Age	1.02	1.003	1.04	0.02
Female gender	0.54	0.33	0.91	0.02
ASA I	REF			
ASA II	1.40	0.58	3.38	0.44
ASA III	1.73	0.73	4.10	0.21
ASA IV	6.48	1.96	21.45	0.002
Cardiac Surgery	1.7	0.91	3.1	0.1
Hypertension	0.73	0.32	1.67	0.46
Diabetes Mellitus	1.15	0.62	2.15	0.66
Any Disorder	1.06	0.41	2.75	0.90
Addictions	1.4	0.71	2.6	0.36
MP I	REF			
MP II	2.3	0.97	5.5	0.06
MP III	2.2	0.78	5.9	0.14
MP IV	6.9	1.4	32.7	0.02
Abnormal dentition	1.88	1.16	3.02	0.00
Facial anomalies	1.86	0.97	3.56	0.063
Anticipated difficult intubation	4.05	2.51	6.4	0.001

Table 5: Diagnostic accuracy of the anaesthesiologists'

prediction of difficult intubation		
In cardiac surgical population		

Test result	Disease positive	Disease negative	Total
Test positive	41	35	76
Test negative	38	215	253
Total	79	250	329

Point estimates and 95% CIs			
	Estimation	Lower CI	Upper CI
Apparent prevalence	0.231	0.187	0.280
True prevalence	0.240	0.195	0.290
Sensitivity	0.519	0.404	0.633
Specificity	0.860	0.811	0.901
Positive predictive value	0.539	0.421	0.655
Negative predictive value	0.850	0.800	0.891

In noncardiac surgical population			
	Disease positive	Disease negative	Total
Test positive	20	47	67
Test negative	23	208	231
Total	43	255	298

Point estimates and 95% CIs			
		Lower CI	Upper CI
Apparent prevalence	0.225	0.179	0.277
True prevalence	0.144	0.106	0.189
Sensitivity	0.465	0.312	0.623
Specificity	0.816	0.763	0.861
Positive predictive	0.299	0.193	0.423

	value		
Negative predictive value	0.900	0.854	0.936

CIs – Confidence intervals

Prediction of airway difficulties remains a challenging task. In a recent novel study of a cohort of 188 064 cases from the Danish Anaesthesia Database, investigated the diagnostic accuracy of the anaesthesiologists' predictions of difficult tracheal intubation and difficult mask ventilation. Of 3391 DIs, 3154 (93%) were unanticipated. When DI was anticipated, 229 of 929 (25%) had an actual DI.[18] In contrast, in our cohort, the incidence of unanticipated DI was 48.1% and 53.4% in cardiac and non cardiac surgery patients respectively. This suggests that more than 50% of difficult airway is unanticipated even now and one should be prepared for unanticipated difficulties always. The study has some notable limitations. The authors used Cormack Lehane grade II with the use of bougie as an additional factor to Cormack Lehane grade 3 or 4 for defining DI. That might have resulted in adding to a higher incidence of DI. The authors did not include many established risk factors as mentioned already. Furthermore, authors did not document incidence of difficult mask ventilation, which is often included in the definition of the difficult airway. However, using the more liberal definition of DI and adding a surgical category as a risk factor for DI authors represent contemporary clinical practices.

Conclusion

In this prospective study, comparing the incidence of DI, there was a higher incidence of DI in patients undergoing cardiac surgery as compared to non cardiac surgery. The independent variables associated with DI were greater age, male sex, higher Mallampati airway grades, and anticipated DI but not cardiac surgery *per se* About half of the DIs, both in cardiac and non cardiac surgeries were unanticipated.

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