Case Study:Ease of Intubation Pentax AWS vs Standard Macintosh laryngoscope with a #4 blade in obese patients

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Introduction:

"Difficult and failed tracheal intubations are among the principal causes of anesthetic-related mortality and morbidity," (*Laryngoscope – Teaching of Statistics in the Health Sciences*, n.d.)and the Pentax AWS, being a video laryngoscope, is designed to improve visualization and facilitate easy intubation. The proposed study investigates whether intubation with the Pentax AWS is easier and faster than a standard Macintosh laryngoscope with a #4 blade in obese patients (BMI 30-50 kg/m2) undergoing surgery. The secondary questions will be: Is the glottic view obtained with the Pentax AWS better than with the Macintosh laryngoscope (as assessed by the Cormack-Lehane grading system)? and Is the incidence of blood staining or postoperative sore throat lower with the Pentax AWS? A randomized controlled trial will be done, and the subjects will be grouped into Pentax AWS and Macintosh groups.

Dataset:

The instructors provided the dataset Laryngoscope; both Excel and CSV format files were provided by the instructors in Canvas. The data dictionary was also provided in Canvas. The dataset contains details of clinical studies comparing the effectiveness of the Pentax AWS video laryngoscope versus the standard Macintosh laryngoscope in obese patients undergoing surgery. The sample size is 99 subjects, and there are 22 variables. It contains variables related to patient demographics (age, gender, BMI), clinical assessment scores (ASA, Mallampati), details on the intubation process (attempt times, success/failure of attempts), and post-intubation outcomes (bleeding, ease of intubation, sore throat, view during intubation)

Exploratory Data Analysis:

Table1. Shows the summary table of the variables using the table one library in R. The data is stratified by randomization, i.e., patients intubated with a Macintosh #4 blade versus those with a Pentax AWS. Sample sizes were comparable across groups, with 49 and 50 patients, respectively. Age and BMI showed no significant differences, indicating a similar demographic profile. Gender distribution was nearly identical across groups, further supporting comparability. ASA physical status and Mallampati scores suggested variability in patient health and airway complexity, yet no statistical significance was found, hinting at balanced group health statuses. Randomization demonstrated perfect separation between the two devices. Incidence of bleeding was rare and comparable, while sore throat prevalence post-intubation was similarly distributed across groups, showing no significant differences. Ease of intubation significantly differed, favoring the Pentax AWS, and the view obtained during intubation was better with the Pentax AWS, although this did not reach statistical significance. This analysis provides insights into the clinical and procedural outcomes of each laryngoscope type, with notable differences in ease of use.

Graphical Summaries of the data are provided in Figures 1 to 7. Figure 1 shows a density plot that visualizes the age distribution across both treatment groups, highlighting demographic similarities or differences. Figure 2 shows the violin plot assessing the "ease" of intubation, combining distribution shape and density to give an idea of which group has more ease. Figure 3 shows the total intubation time's histogram, revealing frequency and duration insights. Though there is some overlap, we can say that the Macintosh shows less intubation time than the Pentax. Figure 4 is the boxplot that contrasts the ease of intubation with bleeding occurrences, and we can see there is no bleeding Macintosh #4 blade. Figure 5 shows the histogram, which examines sore throat severity post-intubation. Figure 6 is a scatter plot that correlates total intubation time with ease, all differentiated by treatment group, offering comprehensive insights into procedural outcomes and effectiveness. Figure 7 shows a Kaplan-Meier survival graph stratified by randomization, which compares the survival probability of successful intubation over time between two groups. The x-axis represents the total intubation time in seconds, and the y-axis shows the survival probability. Two curves represent the different groups, with the shaded areas indicating the confidence intervals. The curves' steepness suggests the rate at which the probability of successful intubation decreases over time. The p-value (< 0.0001) indicates a statistically significant difference between the groups. n the Kaplan-Meier survival curve, the Macintosh #4 blade curve being below the AWS curve suggests that the group using the Macintosh #4 blade had a lower survival probability over time compared to the group using the Pentax AWS

Methods:

In the analysis, I employed multiple statistical models to assess differences between two intubation techniques: the Macintosh #4 blade and the Pentax AWS. The methods included Cox Proportional Hazards models to evaluate intubation success rates and Kaplan-Meier curves for survival analysis, alongside multiple linear regression to control for confounders such as age and BMI. These approaches aim to identify significant variations in ease of intubation, total intubation time, and postoperative outcomes across the two groups, providing a comprehensive overview of their relative effectiveness.

Results:

Table 1 shows the summary table for the Cox Proportional Hazards model output, indicating that using the Pentax AWS significantly reduces the hazard of intubation failure compared to the Macintosh #4 blade, with a hazard ratio of 0.3824. This means patients intubated with the Pentax AWS have a 61.76% lower risk of intubation failure. The p-value (<0.00001) strongly supports this finding. The model's concordance index is 0.654, suggesting a moderate predictive accuracy. The confidence interval for the hazard ratio (0.2524 to 0.5794) further confirms the significance of this result.

Table 2. Provides the summary table for a multiple linear regression model that analyzed factors affecting the ease of tracheal intubation. The model included the type of laryngoscope used, the patient's age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) physical status classification, and Mallampati score as predictors. The results indicate that using the Pentax AWS ($p=0.0203$) and having an ASA status of III ($p=0.0402$) are significantly associated with an increased ease of intubation. Age and gender show a trend towards significance, suggesting a possible influence. The Mallampati scores, which assess the visibility of the throat structures, were not significantly associated with ease of intubation. The model explains approximately 20.6% of the variance in ease of intubation, indicating other factors may also play a role. This model's findings should be interpreted with its limitations in mind, including the moderate R-squared value and the potential for unmeasured confounding factors.

Conclusion:

The study aimed to determine the efficacy of the Pentax AWS compared to the standard Macintosh #4 blade in obese patients requiring tracheal intubation. The analysis revealed that the Pentax AWS is associated with a higher ease of intubation and a lower risk of intubation failure, as indicated by the significant findings in the

Cox Proportional Hazards model. However, other factors such as age, gender, and Mallampati scores showed a trend toward significance but did not conclusively affect the ease of intubation. The study's limitations include a moderate R-squared value, suggesting that other unmeasured variables may impact the outcomes, and the potential for confounding factors was present. The findings advocate for careful consideration of the Pentax AWS in clinical settings, particularly for obese patients, while also recognizing the need for more comprehensive research to corroborate these results and address the study's limitations.

Code

Exploratory Data Analysis

	x
age	0
gender	0
asa	0
BMI	2
Mallampati	1
Randomization	0
attempt1_time	0
attempt1_S_F	0
attempt2_time	89
attempt2_assigned_method	89
attempt2_S_F	89
attempt3_time	96
attempt3_assigned_method	96
attempt3_S_F	96
attempts	0
failures	0
total_intubation_time	0
intubation_overall_S_F	0
bleeding	0
ease	0
sore_throat	1
view	0

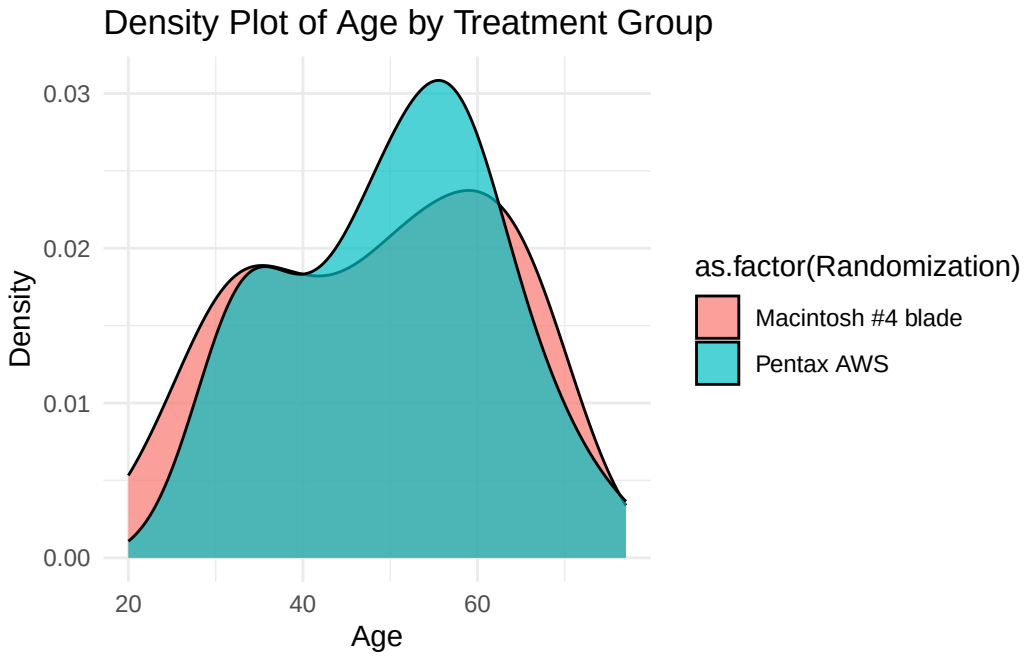
Creating labels, Table one

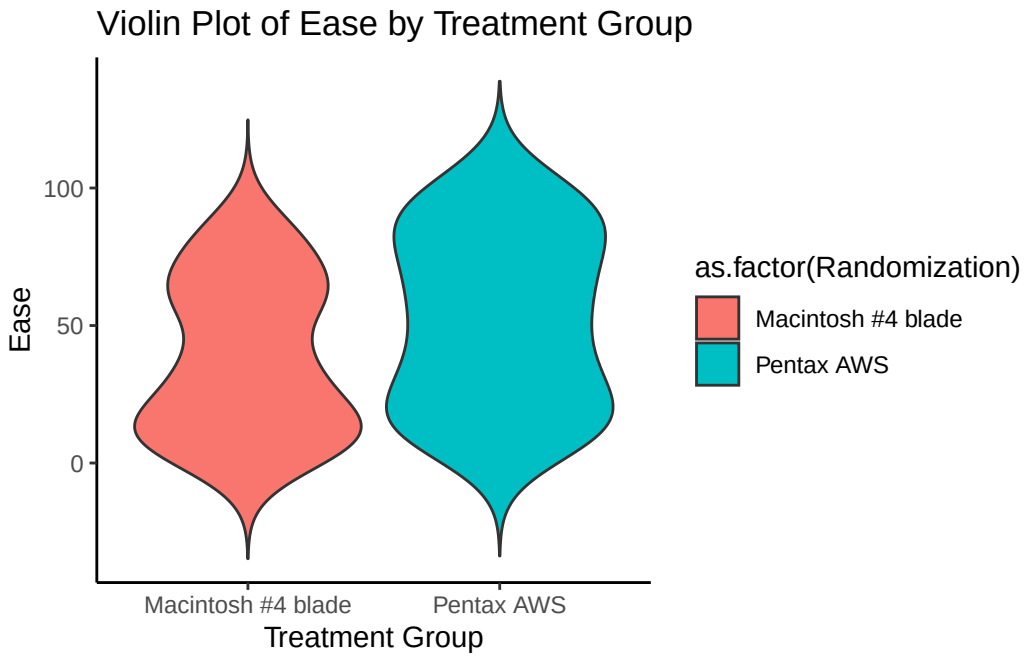
```
                          Stratified by Randomization
                           level
  n
  age (mean (SD))
  gender (%)               Female
                           Male
  BMI (mean (SD))
  asa (%)                  II
                           III
                           IV
  Mallampati (%)           Full visibility of tonsils, uvula and soft palate
                           Visibility of hard and soft palate, upper portion of tonsils and uvula
                           Soft and hard palate and base of the uvula are visible
                           Only Hard Palate visible
```

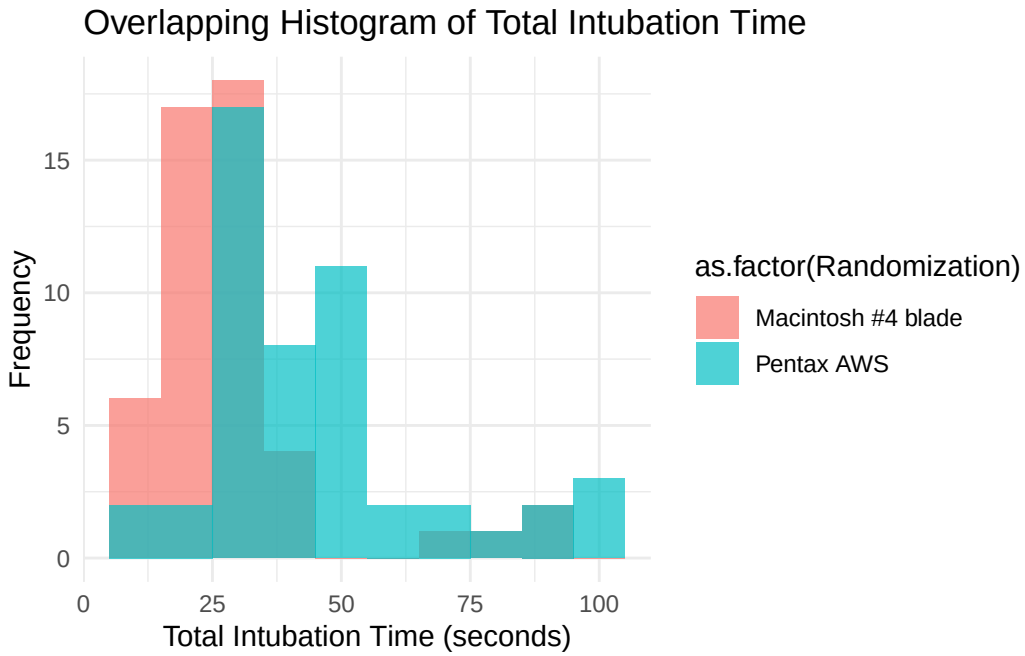
Randomization (%)	Macintosh #4 blade			
	Pentax AWS			
bleeding (%)	No			
	Yes			
sore_throat (%)	None			
	Mild			
	Moderate			
	Severe			
ease (mean (SD))				
view (%)	Not good			
	Good			
total_intubation_time (mean (SD))				
	Stratified by Randomization			
	Macintosh #4 blade	Pentax AWS	p	
n	49	50		
age (mean (SD))	48.51 (14.07)	50.32 (12.19)	0.495	
gender (%)	39 (79.6)	39 (78.0)	1.000	
	10 (20.4)	11 (22.0)		
BMI (mean (SD))	42.45 (5.91)	41.37 (4.44)	0.309	
asa (%)	7 (14.3)	15 (30.0)	0.136	
	40 (81.6)	32 (64.0)		
	2 (4.1)	3 (6.0)		
Mallampati (%)	14 (29.2)	21 (42.0)	0.060	
	21 (43.8)	18 (36.0)		
	13 (27.1)	7 (14.0)		
	0 (0.0)	4 (8.0)		
Randomization (%)	49 (100.0)	0 (0.0)	<0.001	
	0 (0.0)	50 (100.0)		
bleeding (%)	49 (100.0)	48 (96.0)	0.484	
	0 (0.0)	2 (4.0)		
sore_throat (%)	32 (66.7)	34 (68.0)	0.733	
	12 (25.0)	9 (18.0)		
	3 (6.2)	5 (10.0)		
	1 (2.1)	2 (4.0)		
ease (mean (SD))	38.20 (28.06)	52.10 (31.43)	0.022	
view (%)	11 (22.4)	7 (14.0)	0.407	
	38 (77.6)	43 (86.0)		
total_intubation_time (mean (SD))	29.57 (17.43)	45.23 (21.50)	<0.001	
	Stratified by Randomization			
	test			
n				
age (mean (SD))				
gender (%)				
BMI (mean (SD))				
asa (%)				
Mallampati (%)				
Randomization (%)				

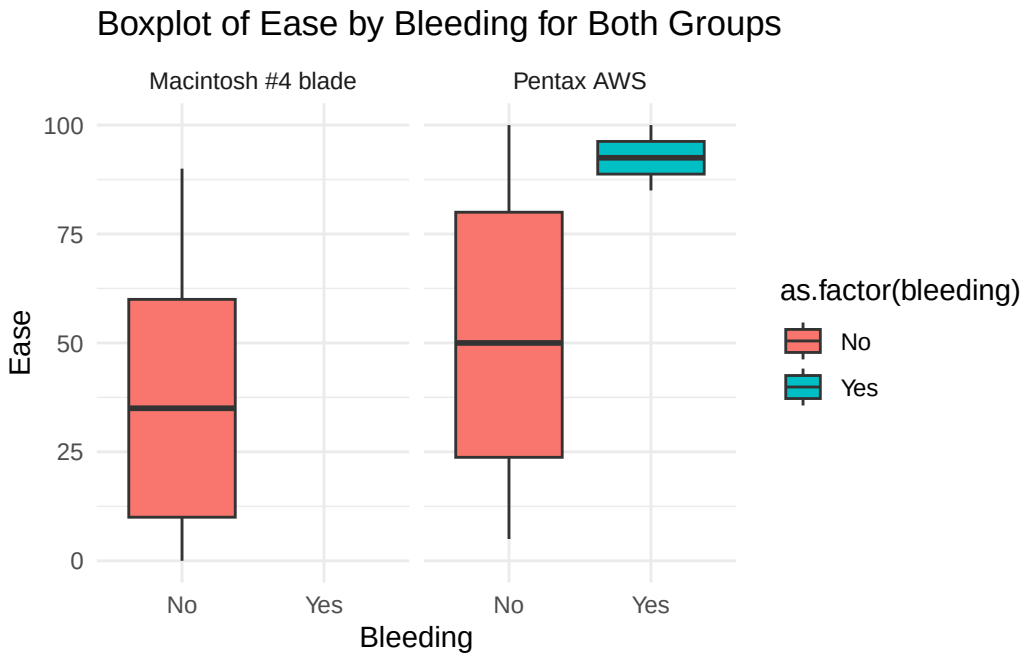
```
bleeding (%)

sore_throat (%)



ease (mean (SD))
view (%)

total_intubation_time (mean (SD))
```

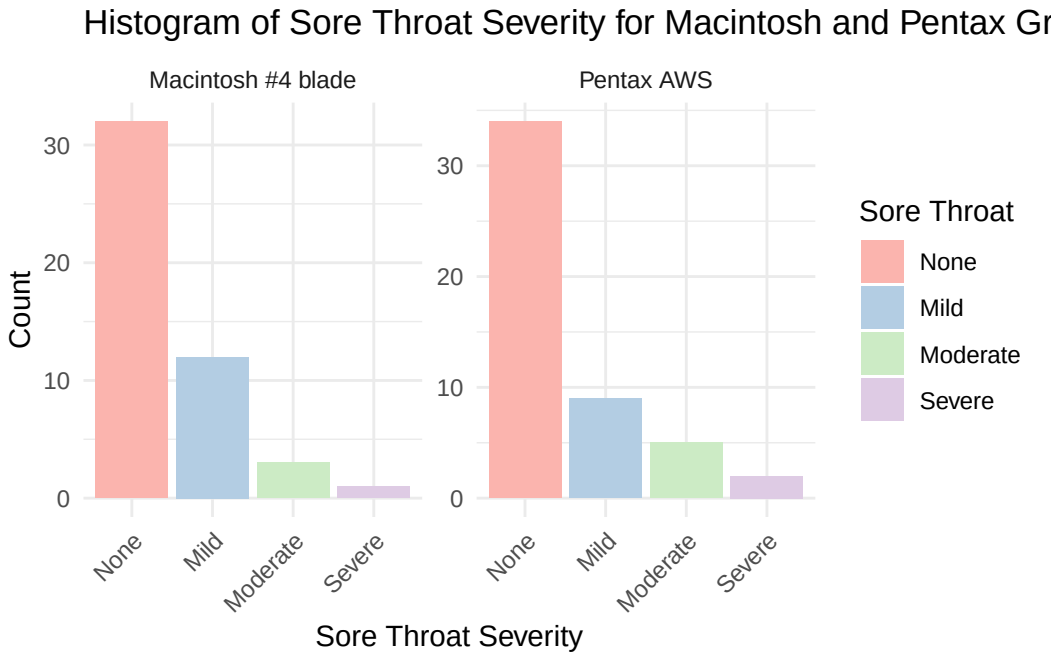
EDA Plots

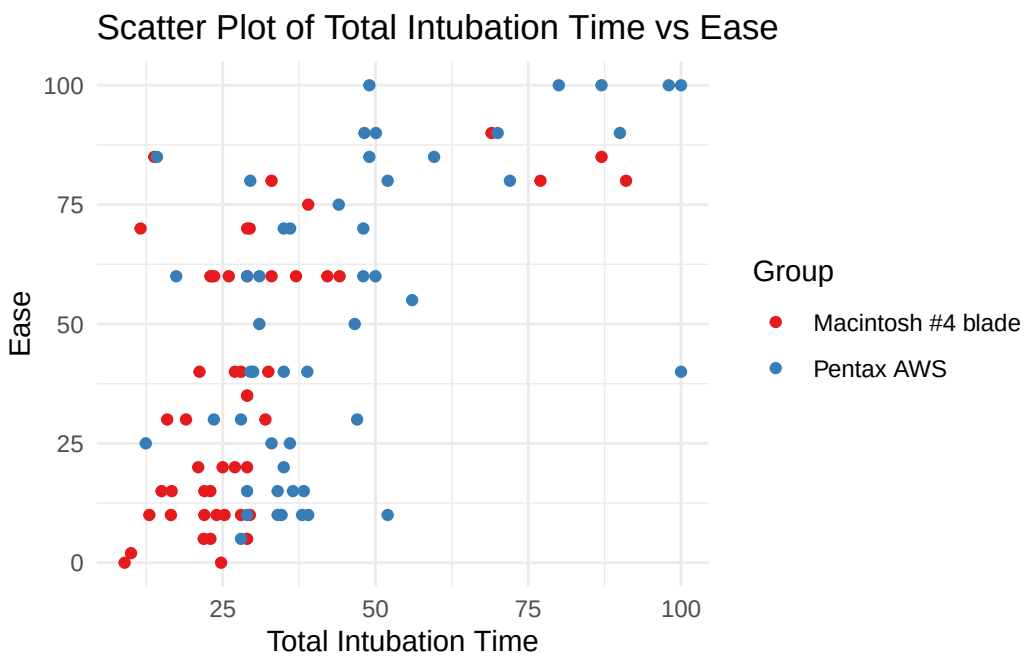



Violin Plot of Ease by Treatment Group
Ease
100
50
0
Macintosh #4 blade
Pentax AWS
Treatment Group
as.factor(Randomization)
Macintosh #4 blade
Pentax AWS


Overlapping Histogram of Total Intubation Time
Frequency
15
10
5
0
0
25
50
75
100
Total Intubation Time (seconds)
as.factor(Randomization)
Macintosh #4 blade
Pentax AWS


Boxplot of Ease by Bleeding for Both Groups
Macintosh #4 blade
Pentax AWS
Ease
100
75
50
25
0
No
Yes
No
Yes
Bleeding
as.factor(bleeding)
No
Yes


Histogram of Sore Throat Severity for Macintosh and Pentax Gr
Macintosh #4 blade
Pentax AWS
Count
30
20
10
0
None
Mild
Moderate
Severe
Sore Throat Severity
Sore Throat
None
Mild
Moderate
Severe



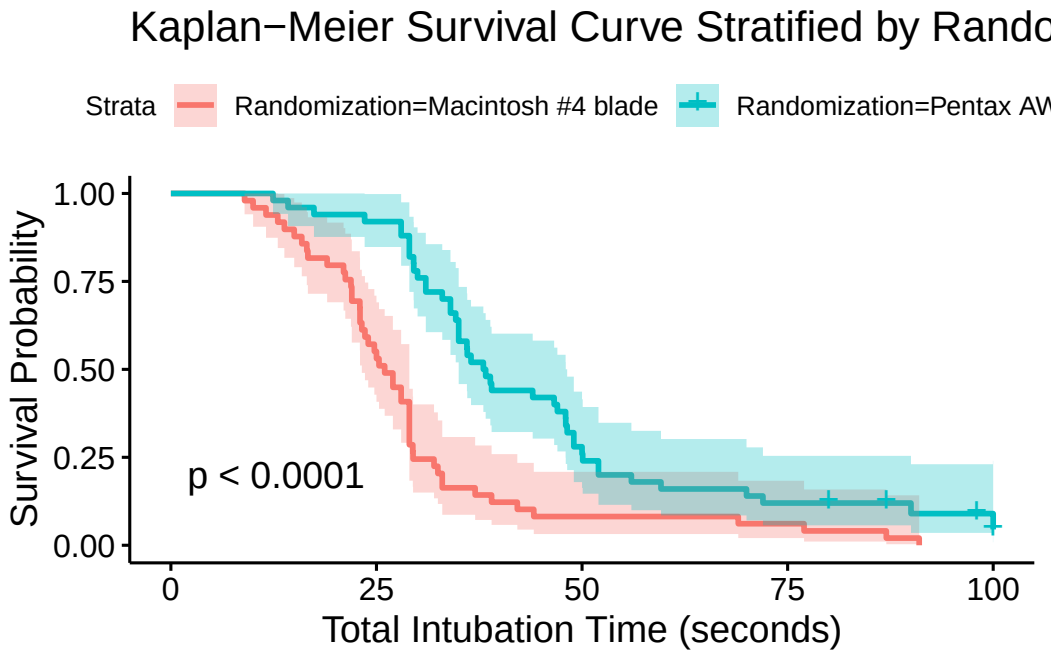
T Test for intubation time and ease

```
    Welch Two Sample t-test

data:  total_intubation_time by Randomization
t = -3.9851, df = 93.731, p-value = 0.0001334
alternative hypothesis: true difference in means between group Macintosh #4 blade and group Pentax AWS is not equ
95 percent confidence interval:
 -23.460558  -7.856585
sample estimates:
mean in group Macintosh #4 blade         mean in group Pentax AWS
                        29.57143                         45.23000


    Welch Two Sample t-test

data:  ease by Randomization
t = -2.3217, df = 96.173, p-value = 0.02236
alternative hypothesis: true difference in means between group Macintosh #4 blade and group Pentax AWS is not equ
95 percent confidence interval:
 -25.776137  -2.015699
sample estimates:
mean in group Macintosh #4 blade         mean in group Pentax AWS
                        38.20408                         52.10000
```

Cox Regression and Survival Plot

```
Call:
```

```
coxph(formula = surv_obj ~ Randomization, data = laryngoscope)

  n= 99, number of events= 95

                          coef exp(coef) se(coef)      z Pr(>|z|)
RandomizationPentax AWS -0.9612    0.3824   0.2120 -4.535 5.76e-06 ***
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

                        exp(coef) exp(-coef) lower .95 upper .95
RandomizationPentax AWS    0.3824      2.615    0.2524    0.5794

Concordance= 0.654  (se = 0.024 )
Likelihood ratio test= 20.13  on 1 df,   p=7e-06
Wald test            = 20.56  on 1 df,   p=6e-06
Score (logrank) test = 21.96  on 1 df,   p=3e-06
```

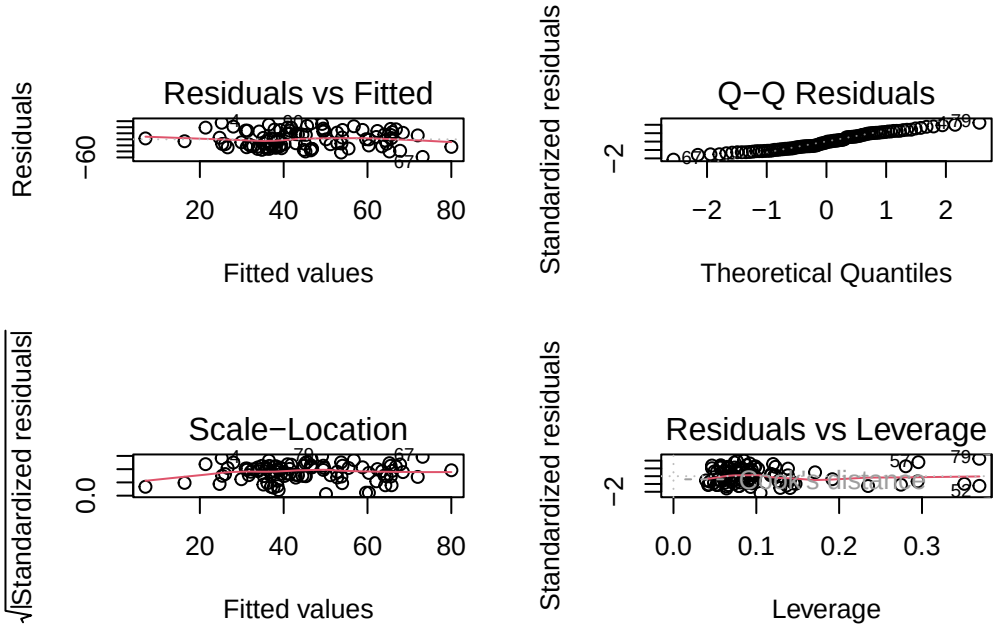


MLR for Ease

```
Call:
lm(formula = ease ~ Randomization + age + gender + BMI + asa +
    Mallampati, data = laryngoscope)

Residuals:
Ease of tracheal intubation
    Min      1Q  Median      3Q     Max
-58.160 -23.164  -1.937  24.442  54.782

Coefficients:
```

```
                                                                      Estimate
(Intercept)                                                            14.6433
RandomizationPentax AWS                                                14.8610
age                                                                     0.4369
genderMale                                                             14.4118
BMI                                                                    -0.1269
asaIII                                                                 15.4002
asaIV                                                                   3.2212
MallampatiVisibility of hard and soft palate, upper portion of tonsils and uvula  -7.6870
MallampatiSoft and hard palate and base of the uvula are visible      -15.2040
MallampatiOnly Hard Palate visible                                    -27.9491
                                                                      Std. Error
(Intercept)                                                             32.5026
RandomizationPentax AWS                                                  6.2833
age                                                                      0.2463
genderMale                                                               7.6865
BMI                                                                      0.6365
asaIII                                                                   7.3934
asaIV                                                                   14.2240
MallampatiVisibility of hard and soft palate, upper portion of tonsils and uvula     6.8017
MallampatiSoft and hard palate and base of the uvula are visible         8.4913
MallampatiOnly Hard Palate visible                                      19.0063
                                                                      t value
(Intercept)                                                             0.451
RandomizationPentax AWS                                                 2.365
age                                                                     1.774
genderMale                                                              1.875
BMI                                                                    -0.199
asaIII                                                                  2.083
asaIV                                                                   0.226
MallampatiVisibility of hard and soft palate, upper portion of tonsils and uvula  -1.130
MallampatiSoft and hard palate and base of the uvula are visible       -1.791
MallampatiOnly Hard Palate visible                                     -1.471
                                                                      Pr(>|t|)
(Intercept)                                                             0.6535
RandomizationPentax AWS                                                 0.0203
age                                                                     0.0797
genderMale                                                              0.0642
BMI                                                                     0.8425
asaIII                                                                  0.0402
asaIV                                                                   0.8214
MallampatiVisibility of hard and soft palate, upper portion of tonsils and uvula   0.2615
MallampatiSoft and hard palate and base of the uvula are visible        0.0769
MallampatiOnly Hard Palate visible                                      0.1451

(Intercept)
RandomizationPentax AWS                                                *
age                                                                    .
genderMale                                                             .
BMI
asaIII                                                                 *
asaIV
MallampatiVisibility of hard and soft palate, upper portion of tonsils and uvula
MallampatiSoft and hard palate and base of the uvula are visible       .
```

```
MallampatiOnly Hard Palate visible
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 28.62 on 86 degrees of freedom
  (3 observations deleted due to missingness)
Multiple R-squared:  0.206, Adjusted R-squared:  0.1229
F-statistic: 2.479 on 9 and 86 DF,  p-value: 0.01445
```



	GVIF	Df	GVIF^(1/(2*Df))
Randomization	1.156706	1	1.075503
age	1.219345	1	1.104240
gender	1.099165	1	1.048411
BMI	1.299535	1	1.139971
asa	1.118944	2	1.028495
Mallampati	1.396198	3	1.057202