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COMPARATIVE STUDIES BETWEEN ROBOTIC LAPAROSCOPIC MYOMECTOMY AND ABDOMINAL MYOMECTOMY WITH FACTORS AFFECTING SHORT-TERM SURGICAL OUTCOMES

by

AMY N. FOMO

Under the Direction of Dr. Yu-Sheng Hsu

ABSTRACT

The purpose of this study is to compare short-term surgical outcomes of robotic and abdominal myomectomy and to analyze the factors affecting the total operative time, estimated blood loss and length of hospital stay from a retrospective study of a consecutive case series of 122 patients with symptomatic leiomyomata. Wilcoxon, t tests, multiple linear and logistic regressions analyses were performed. Patients in abdominal group had larger number of leiomyomata, larger tumor size and BMI. The operative time was longer in robotic group and was affected by the size and number of tumors, parity and interaction between parity and BMI. Estimated blood loss was lower in robotic group and was affected by the size and number of tumors .The predicted odds of staying one day or less in the hospital for robotic group was 193.5 times the odds for abdominal group and was affected by the size and number of tumors.

INDEX WORDS: Myomectomy, Robotic, Leiomyomata, Laparoscopy

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AMY N. FOMO

A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of

Master of Science

in the College of Arts and Sciences

Georgia State University

2009

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Amy Nguemkam Fomo
2009

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December 2009

DEDICATION

I would like to dedicate this thesis to my Lord Jesus Christ who saved me and blessed me in so many ways and in every area of my life. I'm forever grateful to him. I would also like to dedicate this paper to my parents Mr. Fomo Jacob and Ms. Fomo Delphine who encouraged me and believed in me in the pursuit of my education. Thank you so much!

ACKNOWLEDGEMENTS

I would like to acknowledge with profound gratitude Dr Yu-Sheng Hsu who guided me through my thesis. I am sincerely amazed by how much he cares for the success of his students and I am thankful that, he provided me with all the experience he has and all the advice necessary for my thesis. I also express my gratitude to Dr. Yixin Fang and Dr. Jiawei Liu for reading and commenting on my thesis.

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1 Introduction

Leiomyoma commonly called fibroid tumor is the most common pelvic benign tumor in female patients and the leading indication for hysterectomy. Previous studies have shown that at least 20% of women between the ages of 25 and 64 years may require a hysterectomy for Leiomyoma with a peak incidence around the age of 45 years [1](Cramer Dw.1992) and that 70% of white women and more than 80% of black women have uterine leiomyomata by age 50 years [2] (Day Baird D; 2003). Obviously surgery is needed when leiomyomata are symptomatic, causing infertility, recurrent abortion, abnormal uterine bleeding or pain, jeopardizing future reproductive capacity [3]. Since 1931, myomectomy has been described as the gold standard for the conservative surgical treatment of symptomatic leiomyomata for women desiring future fertility or uterine conservation [4]. The goal of a myomectomy procedure is to remove the visible and accessible leiomyomata and to reconstruct the uterus. Traditionally, most cases of myomectomy have been performed by laparotomy, an abdominal myomectomy done through a larger bikini incision and is usually considered a more complicated operation, associated with higher morbidity, blood loss and adhesion formation when compared to hysterectomy [5-7]. Today many cases of leiomyoma are treated with laparoscopic myomectomy which provides a minimally invasive surgery as a result of the advent of modern-day laparoscopic surgical technique and equipments [8]. Despite laparoscopic benefits such as faster postoperative recovery, improved cosmesis, and potential fewer postoperative adhesions compared with laparotomy [10] , the existence of many technical challenges like enucleating the leiomyomata and repairing the uterine defect with multilayer sutured closure is overwhelming. Computerized enhanced robotic surgery using the Da Vinci robotic surgical system has been proposed to overcome the limitations of the tra-

ditional laparoscopy while still benefitting from the advantages of the minimally invasive technique [9]. The robotic-assisted laparoscopic surgery provides the surgeon with improved optics, including a three dimensional view and increased dexterity and precision.

Usually a patient with symptomatic uterine leiomyomata want to know what surgery treatment has better outcomes. By having a statistical evaluation of the factors that affect the total operative time, the total estimated blood loss, the length of hospital stay and of a comparison of consecutive cases of both surgery groups, the gynecologist will be able to give the patient appropriate advice regarding the choice of treatment.

The aim of this retrospective study was to compare the short-term surgical outcomes of robotic-assisted laparoscopic myomectomy (RALM) and abdominal myomectomy (AM) and to analyze the factors affecting the total operative time, the estimated blood loss and the length of hospital stay

2 Data and Methodologies

A consecutive series of 125 patients underwent either RALM or AM at Saint Joseph's Hospital of Atlanta by Dr Hanafi, from February 2007 to June 2009. Out of the 125 patients, 122 patients information was fully obtained with 77 cases of RALM and 45 cases of AM performed.

The hospital's electronic chart and the documented electronic medical report (EMR) office files provided patient's information. All the procedures followed were in accordance with the revised Declaration of Helsinki, and patients gave informed consent before surgery. Patients had pelvic examination and a transvaginal ultrasound to confirm the presence of the leiomyomata, number, sizes and location of the tumors which were recorded in a detailed cartoon drawing picture of the pelvic organs. This picture was brought to the operating room to guide the surgeon in locating the leiomyomata and subsequently their excisions.

The following variables were recorded: the surgery type (1=robotic, 0=abdominal), the patient's age (years) at the time of surgery, the body mass index (kg/m^2), the gravity, the parity, the number of leiomyomata at the time of surgery, the diameter of the largest tumor size (mm), the total operative time (min), the estimated blood loss (ml) and the length of hospital stay (days) after surgery.

Statistical analyses were performed using SAS 9.1 software (SAS Institute, Cary NC). We conducted Kolmogorov-Smirnov test to determine whether or not the data were normally distributed. Comparisons of the patient's pre-operative characteristics were performed using the student's t test for normally distributed data and the Wilcoxon test for non-normally distri-

buted data. Multiple linear regression analysis was used to account for the factors that have impact on the total operative time and the estimated blood loss. Bonferroni test was performed to compare these two surgical outcomes in both groups. A logistic regression analysis was used to evaluate the factors that affect length of hospital stay and to determine the odd of staying one day or less in the hospital after surgery in both groups. A p-value of less than or equal to 0.05 was considered statistically significant.

2.1 Pre-Operative Characteristics

Kolmogorov-smirnov test was performed on the preoperative characteristics in both groups to determine whether or not the variables were normally distributed in order to use the appropriate test to compare the means difference of the pre-operative characteristics of patients in both groups. A p value of less than 0.05 stipulates that the variable is not normally distributed.

The results displayed in Table1 reveal that the variable age was normally distributed in both groups, while tumor size, BMI, number of leiomyomata, gravity and parity were not normally distributed either in one group or in both groups.

Table 1. Test for normality of pre-operative characteristics in both groups.

Characteristics	Surgery Group	--Statistic---		-----p Value------	
Age	Abdominal	D	0.084859	Pr > D	>0.1500
	Robotic	D	0.087729	Pr > D	0.1472
Tumor size	Abdominal	D	0.083277	Pr > D	>0.1500
	Robotic	D	0.135384	Pr > D	<0.0100
Body mass index	Abdominal	D	0.116218	Pr > D	0.1293
	Robotic	D	0.151005	Pr > D	<0.0100
Number of leiomyomata	Abdominal	D	0.208564	Pr > D	<0.0100
	Robotic	D	0.180374	Pr > D	<0.0100
Parity	Abdominal	D	0.293689	Pr > D	<0.0100
	Robotic	D	0.288855	Pr > D	<0.0100
Gravity	Abdominal	D	0.190217	Pr > D	<0.0100
	Robotic	D	0.186034	Pr > D	<0.0100

The t-test was used to compare normally distributed data and the Wilcoxon test (nonparametric method) for non-normally distributed data and the results are summarized in Table2. No statistically significant differences were found regarding age, gravity and parity in both groups. The mean age was 38.42 ± 6.60 yrs (95%CI 36.91-39.91) in the robotic group compared to 37.33 ± 5.64 yrs (95%CI 35.64-39.03) in the abdominal group. The mean gravity was 2.12 ± 1.97 (95%CI 1.67-2.56) in the robotic group compared to 2.09 ± 1.5 (95%CI 1.64-2.54) in the abdominal group and the mean parity was 1 ± 1.15 (95%CI 0.74-1.26) in the robotic group compared to 0.98 ± 1.25 (95%CI 0.60-1.35) in the abdominal group. However there were significant differences in both groups regarding the body mass index, the number of leiomyomata and the tumor size. The body mass index was significantly larger in the abdominal group compared to the robotic group: the mean BMI was 31.02 ± 7.15 kg/m^2 (95% CI 28.87-33.16 kg/m2) in AM group compared to 28.05 ± 5.98 kg/m2 (95% CI 26.70-29.41; p=0.0281) in RALM group. The number of leiomyomata was significantly larger in the abdominal group compare to the robotic group: the average number of leiomyomata was 4.22 ± 3.36 (95% CI 3.21-5.23) in AM group compared to3.06 ± 1.44 (95%CI 2.74-3.40; p=0.0453) in RALM group. The tumor size was significantly larger in the abdominal compare to the robotic group: the mean tumor size was 53.11 ± 25.71 (95% CI 45.39-60.84 mm) in AM group compared to 42.93 ± 17.91 mm (95% CI 38.86-47.00 mm; p=0.0143) in RALM group.

Table 2. Comparative table of preoperative characteristics:

	Abdominal (n=45)			Robotic(n=77)			T test	Wilcoxon
item	Mean	SD	95%CI	Mean	SD	95%CI	p-value	p-value
Age at Diagnosis(yr)	37.33	5.64	35.64-39.03	38.42	6.60	36.91-39.91	0.3586	.
BMI (kg/m^2)	31.02	7.15	28.87-33.16	28.05	5.98	26.70-29.41	.	**0.0281**
Parity	0.98	1.25	0.60-1.35	1	1.15	0.74-1.26	.	0.7658
Gravity	2.09	1.5	1.64-2.54	2.12	1.97	1.67-2.56	.	0.6281
Number of Leiomyomata	4.22	3.36	3.21-5.23	3.06	1.44	2.74-3.40	.	**0.0453**
Tumor Size (mm)	53.11	25.71	45.39-60.84	42.93	17.91	38.86-47.00	.	**0.0143**

SD= Standard deviation

Considering these significant differences, it is of interest to find how these preoperative characteristics influence the postoperative outcomes and also to compare these postoperative outcomes in both groups.

2.2 Factors Affecting Total Operative Time and Total Estimated Blood Loss

To study the factors affecting the total operative and the estimated blood loss, we modeled the response variables with multiples regressions analyses. Prior to that, we did models selection and models adequacy checking.

2.2.1 Model Selection

We performed stepwise regression with SLE=0.15, SLS=0.15 and all possible regressions (mallows' Cp criteria) on total surgery time and the estimated blood loss to determine which subset of variables would create the model that best explains each dependent variable. The summary of the variables selected are displayed in Table3.

Table 3. Summary of Variables selected

Dependent variable	**Stepwise regression**	**All possible regression (Cp)**
operative time	Surgery type	Surgery type
	Age*tumor size	Number of tumors
		BMI
		Age*BMI
		Parity*BMI
		parity
		Age*number of tumors
		BMI*tumor size
Blood loss	Surgery type	Surgery type
	Age*number of tumors	Size of tumor
		Age*number of tumors
		Number tumors* tumor size

The variables selected for the total operative time were: the type of surgery, the number of tumors, the body mass index (BMI), the parity, the interaction between age and the tumor size, the interaction between age and the number of tumors, the interaction between age and the BMI, and the interaction between BMI and the tumor size. Meanwhile, the variables selected for the estimated blood loss: were the type of surgery, the tumor size, the interaction between age and the number of tumors, and the interaction between the number of tumors and the tumor size.

After that, two multiples regression analyses were performed on the total operative time and the estimated blood loss with the variables selected earlier as independents variables

to select the final models. The final model for the total operative time included the surgery type, the number of tumors, the tumor size, the BMI, the parity, and the interaction between parity and the BMI. Whereas, the final model for the estimated blood loss included the surgery type, the number of tumors, the tumor size, and the interaction between the number of tumors and the tumor size.

After we fitted the final models, the next step was to check for the model adequacy by analyzing the residuals.

2.2.2 Model Adequacy Checking: Residual Analysis

Two QQ plots and Kolmogorov-Smirnov tests reveal non-normality of the residuals in both models and the results are displayed in Table4, Figure1 and Figure2. Therefore a transformation is needed in each case on the response variable.

Table 4.Residuals tests of Normality

Variable	Test	--Statistic---		-----p Value------	
Operative time	Kolmogorov-Smirnov	D	0.130411	Pr > D	<0.0100
Blood loss	Kolmogorov-Smirnov	D	0.120754	Pr > D	<0.0100

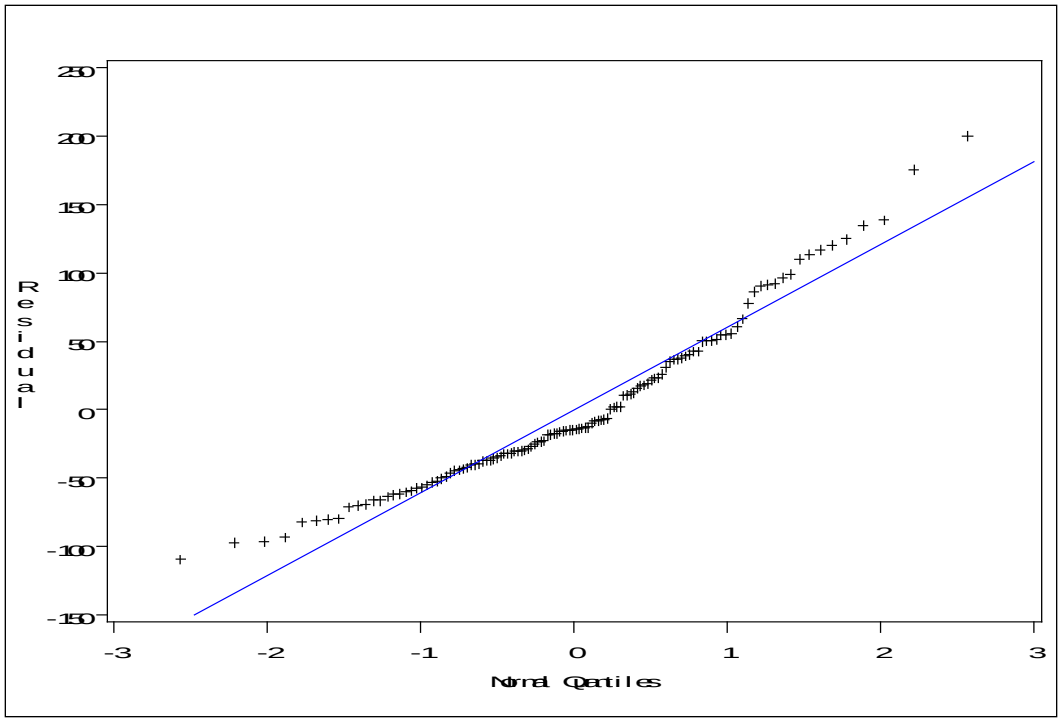

Figure 1. QQ plot for the residuals of total operative time

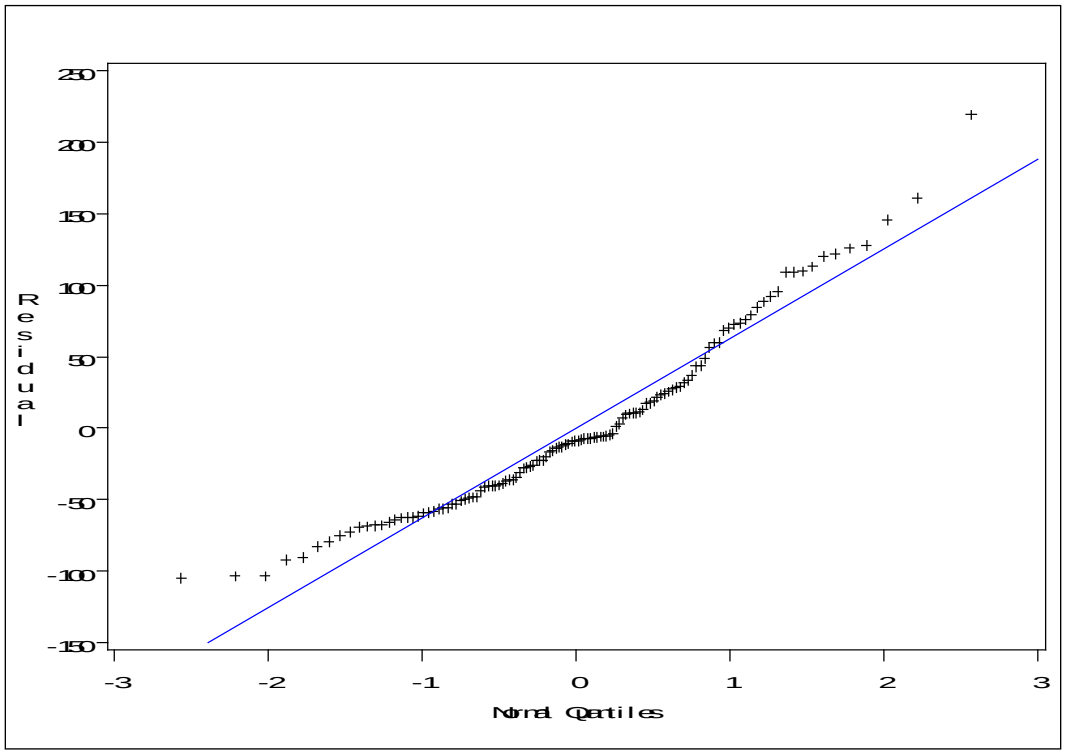

Figure 2. QQ plot for the residuals of blood loss

2.2.3 Variables Transformation

We used Box-Cox procedure to determine the power of the transformation. The Box-Cox method is a power transformation Y^{λ} used to correct non-normality and/or non-constant variance, where λ is the parameter, which can be determined using the method of maximum likelihood. The Box-Cox method in our case study was implemented by SAS through the "Transreg procedure" and the results (see Table5) reveal that for both models λ=0, suggesting a logarithmic transformation on total operative time and the estimated blood loss.

Table 5. Box-Cox Transformation Information

Total operative time			Total estimated blood loss		
Lambda	R-Square	Log Like	Lambda	R-Square	Log Like
-3.00	0.21	-713.974	-3.00	0.17	-624.886
-2.75	0.22	-683.807	-2.75	0.18	-608.098
-2.50	0.22	-654.949	-2.50	0.19	-591.870
-2.25	0.23	-627.635	-2.25	0.19	-576.279
-2.00	0.25	-602.139	-2.00	0.20	-561.422
-1.75	0.26	-578.772	-1.75	0.21	-547.416
-1.50	0.27	-557.861	-1.50	0.23	-534.403
-1.25	0.28	-539.714	-1.25	0.24	-522.555
-1.00	0.28	-524.574	-1.00	0.25	-512.075
-0.75	0.29	-512.575	-0.75	0.27	-503.201
-0.50	0.28	-503.708	-0.50	0.28	-496.192
-0.25	0.28	-497.831	-0.25	0.30	-491.327
0.00 +	0.27	-494.696 *	0.00 +	0.31	-488.871 <
0.25	0.26	-494.003 <	0.25	0.32	-489.057 *
0.50	0.25	-495.443 *	0.50	0.33	-492.053
0.75	0.24	-498.733	0.75	0.34	-497.937
1.00	0.23	-503.628	1.00	0.34	-506.687
1.25	0.22	-509.928	1.25	0.34	-518.196
1.50	0.21	-517.472	1.50	0.34	-532.281
1.75	0.20	-526.131	1.75	0.33	-548.722
2.00	0.19	-535.801	2.00	0.32	-567.277
2.25	0.19	-546.399	2.25	0.32	-587.710
2.50	0.18	-557.851	2.50	0.31	-609.798
2.75	0.17	-570.099	2.75	0.30	-633.341
3.00	0.17	-583.087	3.00	0.29	-658.160

< - Best Lambda * - Confidence Interval + - Convenient Lambda

After the log transformation on each dependent variable, we fitted the transformed models and performed another residual analysis and the results are displayed in Table6, Figure3 and Figure4.

For both Log operative time and log blood loss there is no evidence of non-normality. Thus the models with log transformation are adequate and we can therefore make inferences about factors affecting the log operative time and the log blood loss.

Table 6. Residuals tests of Normality of transformed variables

Variable	Test	--Statistic---		-----p Value------	
Log operative time	Kolmogorov-Smirnov	D	0.061287	Pr > D	>0.1500
Log blood loss	Kolmogorov-Smirnov	D	0.074237	Pr > D	0.0961

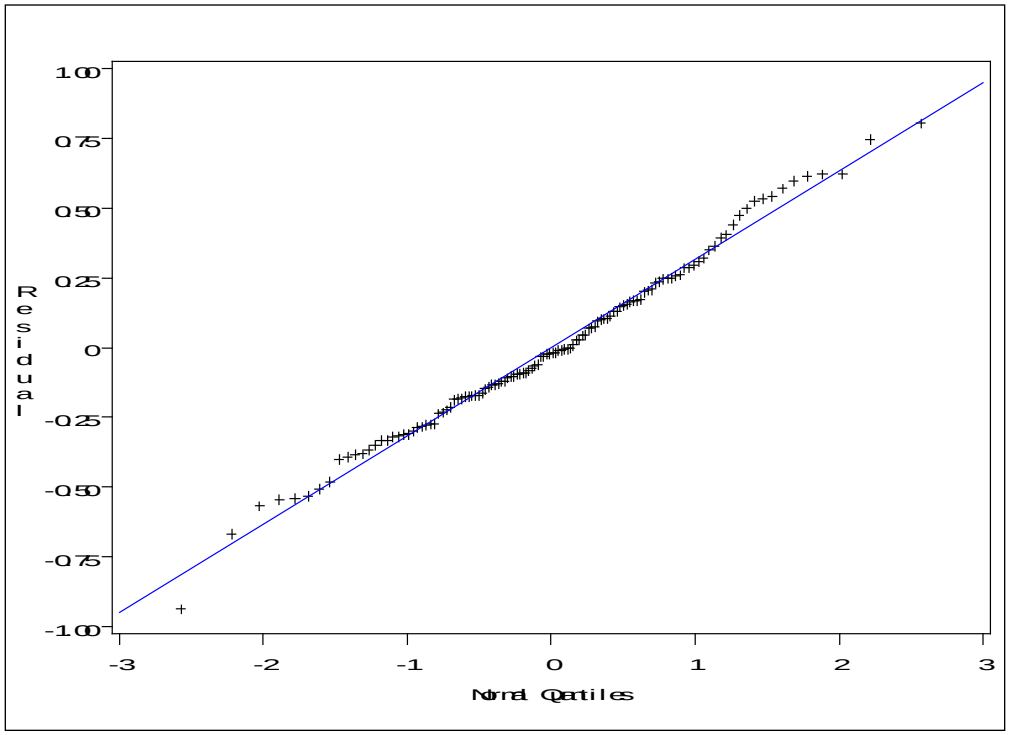

Figure 3. QQ plot for the residuals of log operative time

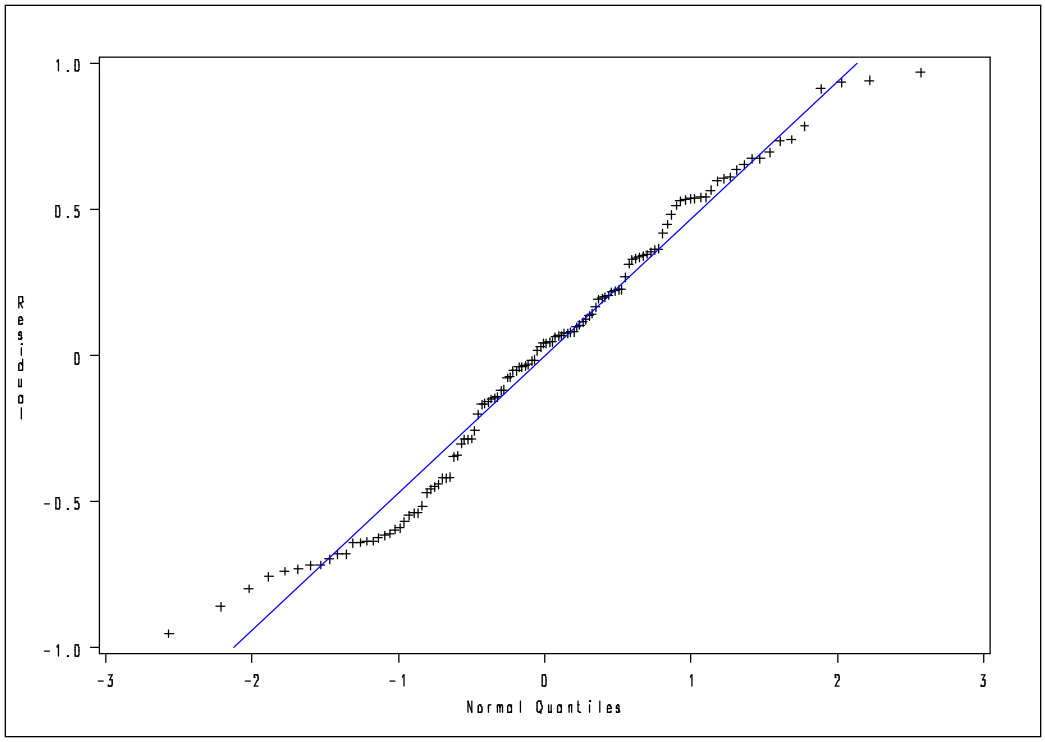

Figure 4. QQ plot for the residuals of Log blood loss

2.2.4 Multiple regressions analysis and interpretation

Two multiple regression analyses were performed on each transformed response variable. The ANOVA's tables (Table7 and Table8) reveal that the models for log operative and log blood loss were statistically significant, with F ratio of 7.20 and 13.21 respectively. Meaning that, there is a strong evidence of linear relationship between the transformed response variables and the selected independent variables.

Table 7.ANOVA of log operative time

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	6	4.57433	0.76239	7.20	<.0001
Error	115	12.17677	0.10588		
Corrected Total	121	16.75110			

Table 8. ANOVA of log blood loss

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	4	12.05792	3.01448	13.21	<.0001
Error	117	26.69171	0.22813		
Corrected Total	121	38.74963			

The first multiple regression analysis revealed that, the log total operative time was significantly affected by the type of surgery (P < 0.001), the number of tumors (p=0.0341), the size of tumor (P=0.0001), the parity (p=0.0306) and the interaction between parity and BMI (p=0.0263). (See Table9).

Table 9. Parameter estimates for log operative time

Variable	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	1	4.41408	0.21635	20.40	<.0001
Surgery type	1	0.32559	0.06597	4.94	<.0001
Number of tumors	1	0.02853	0.01330	2.14	0.0341
Size of tumor	1	0.00601	0.00150	4.00	0.0001
BMI	1	0.00622	0.00580	1.07	0.2858
parity	1	0.26845	0.12262	2.19	0.0306
parity * BMI	1	-0.00908	0.00403	-2.25	0.0263

Parity*BMI= interaction between parity and BMI

The regression equation for Log operative time is:

Log operative time = 4.41 + .3256 (Surgery type) + .0285 (Number of tumors) + .006 (tumor size) +.006 (BMI) + .2684 (parity) - .0091 (parity*BMI). (1).

From equation (1), when controlled for the number of tumors, the tumor size, the BMI, the parity and the interaction between parity and BMI, the log total operative time increases on average by 0.3256 in robotic group compared to abdominal group, i.e. the operative time for

robotic group is $e^{0.3256}$ =1.38 times longer than that of the abdominal group. Secondly, when controlled for the type of surgery, the tumor size, the BMI, the parity and the interaction between parity and BMI, the log total operative time increases on average by 0.0285 for every increase of the number of tumors by 1, i.e. the operative time increases on average approximately by $e^{0.0285}$ = 1. 03 times for every increase of the number of tumors by 1. Thirdly, when controlled for the type of surgery, the number of tumors, the BMI, the parity and interaction between parity and BMI, the log total operative time increases on average by 0.006 for every 1mm increase of the tumor size, i.e. the operative time increases approximately by $e^{0.006}$ =1. 006 times for every 1 mm increase of the tumor size. Also, when controlled for the surgery type, the number of tumors, the tumor size, and the interaction between parity and BMI, the log total operative time increases on average by 0.2684 for every increase of the parity by 1, i.e. the total operative time increases approximately on average by $e^{0.2684}$ =1.31 times for every increase of the parity by 1. Finally,

when controlled for the surgery type, the number of tumors, the tumor size, the BMI and the parity, the log total operative time decreases on average by 0.0091, for every increase of the interaction term between BMI and parity by 1, i.e. on average the total operative time decreases approximately by $e^{0.0091}$=1. 009 times for every increase of the interaction term by 1.

The second multiple regression analysis revealed that, the log blood loss was significantly affected by the type of surgery ($p < 0.001$), the number of tumors ($p=0.0091$) and the size of tumor ($p=0.0119$). (Table10.)

Table 10. Parameter estimates for log blood loss

Variable	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	1	4.30093	0.20606	20.87	<.0001
Surgery type	1	-0.38900	0.09418	-4.13	<.0001
Number of tumors	1	0.16764	0.06322	2.65	0.0091
Size of tumor	1	0.00822	0.00322	2.56	0.0119
Number of tumors * tumor size	1	-0.00156	0.00091890	-1.69	0.0929

The regression equation for log blood loss is:

Log Blood Loss = 4.3009 - .3890 (Surgery type) + .1676 (Number of tumors) + .0082 (tumor size) - .0016 (Number of tumors * tumor size). (2)

From equation (2), when controlled for the number of tumors and the tumor size, the log estimated blood loss decreases on average by 0.389 in robotic group compared to abdominal group, i.e. the estimated blood loss for robotic group is on average $e^{0.389}$=1.48 times less than that of the abdominal group. Also, when controlled for the surgery type and the tumor size, the log estimated blood loss increases on average by .1676 for every increase of the number of tumors by 1, i.e. the estimated blood loss on average increases by $e.^{1676}$=1.18 times for every increase of the number of tumors by 1. Finally, when controlled for the surgery type, and the number of tumors, the log estimated blood loss increases on average by 0082 for every increase of the tumor size by 1 mm, i.e. the estimated blood loss on average increases by 1.008 times for every increase of the tumor size by 1 mm.

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2.2.5 Test for Mean Difference of Total Operative Time and Total Estimated Blood Loss in Both Surgery Groups

We performed a bonferroni t test for log operative time and log estimated blood loss to compare their means in both robotic and abdominal groups.. However, this comparison is based on unconditional results. The results (Table11) will be valid only when other variables behave the same in this study sample and the true population.

Table 11. Comparative table of Log postoperative characteristics of patients

	Abdominal (n=45)			Robotic (n=77)					
item	Mean	SD	95%CI	Mean	SD	95%CI	Df	t value	pvalue
Log surgery Time(min)	5.03	0.33	4.93-5.14	5.26	.37	5.18-5.35	115	1.98081	.05
Log blood Loss (ml)	5.05	0.51	4.90-5.21	4.57	0.52	4.45-4.68	117	1.98045	.05

.The results displayed in Table 11 reveal that:

- The log total operative time was statistically longer in robotic group compared to abdominal group: the mean log operative time for RALM was 5.26 ± 0.37min (95% CI 5.18-5.35) compared to 5.03 ± 0.33min (95% CI 4.93-5.14 min; p= 0.05) for AM. Meaning that, the total operative time was statistically longer in robotic group compared to abdominal group with mean operative time of 192.48 ± 1.45min (95% CI 177.68-210.60) in RALM versus 152.93 ± 1.39 min (95% CI 138.38-170.72 min; p= 0.05) in AM.

- The estimated log blood loss was statistically lower in robotic group compared to abdominal group: the mean estimated log blood loss for RALM was 4.57 ± 0.52 ml (95% CI 4.45-4.68 ml) compared to 5.05 ± 0.51 ml (95% CI 4.90-5.21 ml; p=0.05) for AM. Meaning that, the estimated blood loss was statistically lower in robotic group compared to abdominal group with mean estimated blood loss of 96.54 ± 1.68 ml (95% CI 85.63-107.77 ml) in RALM versus 156.02 ± 1.67ml (95% CI 134.29-183.09 ml; p=0.05) in AM

2.3. Factors Affecting the Length of Hospital Stay

We were interested in the factors that affect the length of stay of a patient in the hospital after surgery. When we performed an ordinary multiple linear regression analysis on hospital stay, the assumption of normal and Constant variance were not satisfied, even after proper transformation. This problem came from the fact that, the variable hospital stay behaves as a dichotomous variable rather than a continuous variable (hospital stay= <1, 1, 2, 3, 4, 5 or 6 days) making it impossible to perform a multiple linear regression analysis. Therefore, we decided to discretize the variable hospital stay, and used a logistic regression to do the analysis. Since we had seven categories (<1, 1, 2, 3, 4, 5 or 6 days) in the variable hospital stay, we found it more reasonable and easy for interpretation to collapse those categories into two and used the binary logit analysis. Our variable was coded as:

$$\begin{cases} \text{Y=Hospital stay =1 if the patient did one day or less in the hospital after surgery} \\ \text{Y=Hospital stay =2 if the patient did more than one day at the hospital after surgery.} \end{cases}$$

2.3.1 Descriptive Statistics

A preliminary descriptive statistic was performed on the recoded variable of hospital stay and the results are displayed in table12 and Figure 5. Among patients receiving RALM, 72 (93.51%) had a hospital stay of one day or less, and 5(6.49 %) had a hospital stay of more than one day. Among the patients receiving AM, 9(20%) had a hospital stay of one day or less, and 36 (80%) had a hospital stay of more than one day.

Table 12. Hospital stays by type of surgery

Hospital Stay (days)	Robotic[N(%)]	Abdominal [N (%)]
<= 1	72 (93.5%)	9 (20%)
>1	5 (6.5%)	36 (80%)

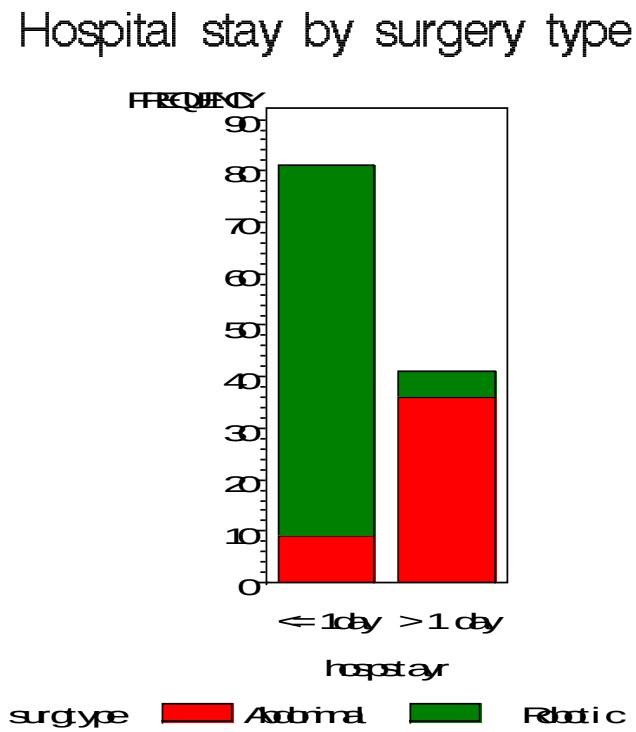

Figure 5. Hospital stays by surgery type

Our goal is to predict whether a patient will stay one day or less in the hospital considering the effect of all the other variables. So we started by selecting the variables that would create the model that best explains hospital stay using a logistic stepwise regression.

2.3.2 Model Selection

We performed a logistic stepwise regression to determine which variables should be selected for the model. The results displayed in Table13 suggested that the Surgery type, the tumor size and the number of tumors should be selected in the model.

Table 13. Summary of logistic stepwise regression

Step	Variable Entered	DF	Score Chi-Square	Wald Chi-Square Pr > ChiSq
1	surgery type 1	1	68.7774	<.0001
2	Size of tumor	1	17.2002	<.0001
3	Number of tumors	1	11.8891	0.0006

2.3.3 Logistic Regressions Analysis and Interpretation

Let $\pi(x) = pr(Y=1/X)$,

The probability modeled is hospital stay $\leq$ 1 day for a patient with covariate X.

A logistic regression analysis was performed on hospital stay with the variables selected earlier as independent variables. The results displayed in Table14 reveal that the surgery type, the number of tumors and the tumor size have significant impact on the probability of staying one day or less in the hospital after surgery with p-value of <0.0001, 0.0011 and 0.1113 respectively.

Table 14. Maximum likelihood estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	3.1567	1.0568	8.9223	0.0028
Surgery type 1	1	5.2651	0.9823	28.7311	<.0001
Number of tumors	1	-0.7996	0.2442	10.7234	0.0011
Size of tumor	1	-0.0512	0.0202	6.4177	0.0113

The probability model equation is:

$$\pi(x) = \frac{\exp(3.16 + 5.27.(surgery.type) - 0.8.(number.of.tumors) - 0.05.(size.of.tumor))}{1 + \exp(3.16 + 5.27.(surgery.type) - 0.8.(number.of.tumors) - 0.05.(sizeoftumor))} \quad (3)$$

And the logit (log-odds) equation is:

$$\text{Log}\left\{\frac{\pi(\text{X})}{1+\pi(X)}\right\} = 3.16 + 5.27 \text{ (surgery type) } -0.8 \text{ (number of tumors) } -0.05 \text{ (tumor size).} \quad (4)$$

Where $\left\{\frac{\pi(\text{X})}{1+\pi(X)}\right\}$ are the odds of staying in the hospital one day or less for a patient with covariates X.

From Table 14, we can see that the parameter estimate of the surgery type is $\beta_1 = 5.27 > 0$, therefore the log-odds of staying a day or less in the hospital increases from robotic myomectomy to abdominal myomectomy. Furthermore, the parameter estimate of the number of tumors is $\beta_2 = -0.80 < 0$, therefore the log-odds of staying a day or less in the hospital decreases as the number of tumors increases by one. Finally, the parameter estimate of the tumor size $\beta_3 = -0.05 < 0$, therefore the log-odds of staying a day or less in the hospital decreases as the tumor size increases by 1 mm.

In terms of odd ratio (Table15),

The predicted odds of staying one day or less in the hospital for patient receiving robotic Myomectomy is 193.5 times the odds for patients receiving abdominal Myomectomy, when we adjust for the number of leiomyomata and the tumor size. Also, for one unit-increase in the number of tumors, the expected change in odds is 0.45, i.e. we expect to see about 55 % decrease [100*(.45-1)= -55%] in the odds of staying one day or less in the hospital for every increase of

the number of tumors by 1 , when we adjust for the tumor size and the surgery type. Finally, for one unit-increase in the tumor size, the expected change in odds is 0.95, i.e. we expect to see about 5 % decrease [100*(.95-1)= -5%] in the odds of staying one day or less in the hospital for every increase of the tumor size by 1 mm, when we adjust for the number of leiomyomata and the surgery type.

Table 15. Odds ratio estimates

Effect	Point Estimate	95% Wald Confidence Limits	
Surgery type 1 vs 0	193.468	28.216	>999.999
Number of tumors	0.450	0.279	0.725
Size of tumor	0.950	0.913	0.988

3 Discussion

The primary surgical management of symptomatic leiomyomata for women desiring future fertility or uterine conservation is through a myomectomy. The ultimate goal of myomectomy is to improve patient's health, overall quality of life and, in some cases, to increase fertility. The da Vinci surgical robot is a major advance in the ability to precisely operate through small incisions and comprehensive reconstruction of the uterine wall regardless of the size or location of the fibroids. The Da Vinci system takes surgical precision and technique beyond the limits of the human hand and allows for rapid and precise suturing, dissection and tissue manipulation which are standard techniques for repair of the myomectrium.

Our current study aimed at comparing the short-term surgical outcomes in both RALM and AM and also at investigating the factors that affect the total operative time, the estimated blood loss and the length of hospital stay.

Our retrospective case series has confirmed that, patients with symptomatic leimyomata operated by RALM or AM have dissimilar preoperative characteristics. They differ in the number of leiomyomata, the tumor size and in the BMI. In particular, the number of leiomyomata, the tumor size and the BMI were all statistically higher in abdominal group than in Robotic group. The operative time was statistically longer in robotic group than the abdominal group (mean 192.48 ± 1.45min [95% CI 177.68-210.60] in RALM vs. mean 152.93 ± 1.39 min [95% CI 138.38-170.72 min] in AM). This additional time was mainly attributed to the console time, to the assembly and disassembly of the robot. Although the operative time was longer in robotic group, this was offset by significantly lower estimated blood loss than the abdominal group (mean

96.54 ± 1.68 ml [95% CI 85.63-107.77 ml] in RALM vs. mean 152.93 ± 1.39 min [95% CI 138.38-170.72 min] in AM) and shorter hospital stay than abdominal group. 93.5% of patients receiving RALM have a hospital stay of one day or less compared to 20% in AM. The predicted odds of staying one day or less in the hospital for patients receiving RALM was 193.5 times the odds for patients receiving AM when adjusted for the number of leiomyomata and the tumor size.

The total operative time was significantly affected by the type of surgery, the number of leiomyomata, the tumor size, the parity and the interaction between parity and BMI. The estimated blood loss was significantly affected by the type of surgery, the number of leiomyomata and the tumor size and, the probability of staying one day or less in the hospital after surgery was significantly affected by the type of surgery, the number of leiomyomata and the tumor size.

Other considerations of this study are feasible and should be the subject of future approach in the analysis of this study data. To account for the factors that affect the total operative time and the estimated blood loss, we could use Non-parametric method instead of “variables transformation”. For the variable hospital stay, there was a huge discrepancy between Robotic group and abdominal group and maybe more observations are needed. Finally, no population data can be used to adjust the logistic regression model.

4 Conclusion

Our study has shown that RALM provides the patient with increased operative time, shorter hospital stay and less blood loss. Also, the total operative time was significantly affected by the type of surgery, the numbers of leiomyomata, the tumor size, the parity and interaction between parity and BMI. Meanwhile, the estimated blood loss was significantly affected by the type of surgery, the number of leiomyomata and the tumor size, and that the probability of staying one day or less in the hospital after surgery was significantly affected by the type of surgery, the number of leiomyomata and the tumor size .

It should be noted that long-term surgical outcomes as the pregnancy rate, period improvement and recovery time to normal activity could not be assessed because of the short duration of the follow-up and should be the subject of future studies in order to better assess the advantage of this new technology of the operative field.

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APPENDICES

Appendix A: VARIABLES DEFINITIONS

Surgtype= Type of surgery (1= abdominal, 0=robotic)

Ntumors= Number of tumors (leiomyomata)

Stumor= Size of tumor (Diameter of the largest tumor size)

BMI= Body mass index

Surgtime= Total operative time

Robotictim= Console time

Bloodloos= Estimated blood loss

Hospstay= Length of hospital stay

Appendix B: SAS CODE FOR LAODING DATA FILES

```
/* LAODING DATA FILES */
option nodate nonumber;
PROC IMPORT DATAFILE="G:\robotic_abdominal\thesis_dataset.xls"
    OUT=robot_abdom
    DBMS=excel2000 REPLACE;
                        run;
proc print data=robot_abdom;run;
```

Appendix C: SAS CODE TO CLEAN THE DATA

```
/* CLEAN THE DATA.*/
data robot_abdom;
set robot_abdom;
drop MRN height weight robotictim;
if surgtype=.| age=.| gravity=.| parity=.| Ntumors=.| Stumor=.| BMI=.| surgtime=.|
bloodloos=.| hospstay=. then delete;run;
proc print data=robot_abdom;run;
```

Appendix D: SAS CODE TO SORT THE ENTIRE DATA SET BY SURGERY TYPE

```
/* TO SORT THE ENTIRE DATA SET BY SURGERY TYPE.*/
proc sort data=robot_abdom out=sortdata; by surgtype; run;
```

Appendix E: SAS CODE TO TEST THE NORMALITY OF PREOPERATIVE CHARACTERISTICS

```
/*age*/
proc univariate data=sortdata normal; by surgtype;
qqplot/ normal(mu=est sigma=est);
var age;
run
/*bmi*/
proc univariate data=sortdata normal; by surgtype;
qqplot/ normal(mu=est sigma=est);
var bmi;
run
/*parity*/
proc univariate data=sortdata normal; by surgtype;
qqplot/ normal(mu=est sigma=est);
var parity;
run;
/*gravity*/
proc univariate data=sortdata normal;by surgtype;
qqplot/ normal(mu=est sigma=est);
var gravity;
run;
 /*Number of leiomyomata*/
proc univariate data=sortdata normal ;by surgtype;
qqplot/ normal(mu=est sigma=est);
var Ntumors;
run
/*Tumor size*/
proc univariate data=sortdata normal ;by surgtype;
qqplot/ normal(mu=est sigma=est);
var Stumor;
run;
```

Appendix F: SAS CODE TO COMPARE THE PREOPERATIVE CHARACTERISTICS AND CREATE TABLE WITH ODS.

```
/* COMPARATIVE table with ods for preoperative characteristics*/

data summary;
if 1=1 then delete;
length item $30 g1 8 h1 8 i1 8 j1 8 g2 8 h2 8 i2 8 j2 8 prob 8 probW 8;
run;
ods listing close ;
ods trace on/label listing;
ods trace off;
/*overall count*/
ods output freq.table1.onewayfreqs=count;
proc freq data =robot_abdom;
tables surgtype;
run;
proc transpose data=count out=count;
var frequency;
run;
data one ;
item='count';set count(keep=col1 col2 rename=(col1=g1 col2=g2));
data summary;
set summary one;
run;

/*age at diagnosis*/
ods output Ttest.TTests=agep;
ods output Ttest.Statistics=agetab;
proc ttest data=robot_abdom;
class surgtype;
var age;
run;
data one ;
item='Age (yrs)';
set agetab (firstobs=1 obs=1 keep=LowerCLmean Mean UpperCLmean stddev re-
name=(LowerCLmean=i1 Mean=g1 UpperCLmean=j1 tddev=h1));
set agetab (firstobs=2 obs=2 keep=LowerCLmean Mean UpperCLmean stddev re-
name=(LowerCLmean=i2 Mean=g2 UpperCLmean=j2 tddev=h2));
set agep  (firstobs=1 obs=1 keep=probt rename=(probt=prob));
run;
data summary;
set summary one;
```

```
run;

/*BMI*/
proc means mean data= sortdata ; by surgtype;
var BMI;
output out=outbmitab MEAN=mean STD=std Lclm=lclm Uclm=uclm;
run;
proc transpose data=outbmitab out=bmitab;
var mean std lclm uclm ;run;
ods output Npar1way.WilcoxonMC=bmipw;
proc Npar1way data=robot_abdom wilcoxon ;
class surgtype;
var  BMI;
exact wilcoxon/alpha=0.05 seed=12345;
quit;run;
data one ;
item='BMI(kg/m2) ';
set bmitab (firstobs=1 obs=1 keep=col1 col2 rename=(col1=g1 col2=g2));
set bmitab (firstobs=2 obs=2 keep=col1 col2 rename=(col1=h1 col2=h2));
set bmitab (firstobs=3 obs=3 keep=col1 col2 rename=(col1=i1 col2=i2));
set bmitab (firstobs=4 obs=4 keep=col1 col2 rename=(col1=j1 col2=j2));
set bmipw (firstobs=7 obs=7 keep=nvalue1 rename=(nvalue1=probW));
run;
data summary;
set summary one;run;

/*parity*/
proc means mean data= sortdata ; by surgtype;
var parity;
output out=outparitytab MEAN=mean STD=std Lclm=lclm Uclm=uclm;
run;
proc transpose data=outparitytab out=paritytab;
var mean std lclm uclm ;run;
ods output Npar1way.WilcoxonMC=paritypw;
proc Npar1way data=robot_abdom wilcoxon ;
class surgtype;
var  parity;
exact wilcoxon/alpha=0.05 seed=12345;
quit;run;
data one ;
item='parity';
set paritytab (firstobs=1 obs=1 keep=col1 col2 rename=(col1=g1 col2=g2));
set paritytab (firstobs=2 obs=2 keep=col1 col2 rename=(col1=h1 col2=h2));
set paritytab (firstobs=3 obs=3 keep=col1 col2 rename=(col1=i1 col2=i2));
```

```
set paritytab (firstobs=4 obs=4 keep=col1 col2 rename=(col1=j1 col2=j2));
set paritypw (firstobs=7 obs=7 keep=nvalue1 rename=(nvalue1=probW));
run;
data summary;
set summary one;
run;

/*Gravity*/
proc means mean data= sortdata ; by surgtype;
var gravity;
output out=outgravitytab MEAN=mean STD=std Lclm=lclm Uclm=uclm;
run;
proc transpose data=outgravitytab out=gravitytab;
var mean std lclm uclm ;run;
ods output Npar1way.WilcoxonMC=gravitypw;
proc Npar1way data=robot_abdom wilcoxon ;
class surgtype;
var  gravity;
exact wilcoxon/alpha=0.05 seed=12345;
quit;run;
data one ;
item='Gravity ';
set gravitytab (firstobs=1 obs=1 keep=col1 col2 rename=(col1=g1 col2=g2));
set gravitytab (firstobs=2 obs=2 keep=col1 col2 rename=(col1=h1 col2=h2));
set gravitytab (firstobs=3 obs=3 keep=col1 col2 rename=(col1=i1 col2=i2));
set gravitytab (firstobs=4 obs=4 keep=col1 col2 rename=(col1=j1 col2=j2));
set gravitypw (firstobs=7 obs=7 keep=nvalue1 rename=(nvalue1=probW));
run;
data summary;
set summary one;
run;

/*Number of tumors*/
proc means mean data= sortdata ; by surgtype;
var Ntumors;
output out=outNtumorstab MEAN=mean STD=std Lclm=lclm Uclm=uclm;
run;
proc transpose data=outNtumorstab out=Ntumorstab;
var mean std lclm uclm ;run;
ods output Npar1way.WilcoxonMC=Ntumorspw;
proc Npar1way data=robot_abdom wilcoxon;
class surgtype;
var Ntumors;
exact wilcoxon/alpha=0.05 seed=12345;
```

```
quit;run;
proc print data=Ntumorspw;run;
data one ;
item='Number of Leiomyomata ';
set Ntumorstab (firstobs=1 obs=1 keep=col1 col2 rename=(col1=g1 col2=g2));
set Ntumorstab (firstobs=2 obs=2 keep=col1 col2 rename=(col1=h1 col2=h2));
set Ntumorstab (firstobs=3 obs=3 keep=col1 col2 rename=(col1=i1 col2=i2));
set Ntumorstab (firstobs=4 obs=4 keep=col1 col2 rename=(col1=j1 col2=j2));
set Ntumorspw (firstobs=7 obs=7 keep=nvalue1 rename=(nvalue1=probW));
run;
data summary;
set summary one;
run;


/* Tumor size*/
proc means mean data= sortdata ; by surgtype;
var Stumor;
output out=outStumortab MEAN=mean STD=std Lclm=lclm Uclm=uclm;
run;
proc transpose data=outStumortab out=Stumortab;
var mean std lclm uclm ;run;
ods output Npar1way.WilcoxonMC=Stumorpw;
proc Npar1way data=robot_abdom wilcoxon;
class surgtype;
var Stumor;
exact wilcoxon/alpha=0.05 seed=12345;
quit;run;
proc print data=Stumorpw;run;
data one ;
item='Tumor size (mm) ';
set Stumortab (firstobs=1 obs=1 keep=col1 col2 rename=(col1=g1 col2=g2));
set Stumortab (firstobs=2 obs=2 keep=col1 col2 rename=(col1=h1 col2=h2));
set Stumortab (firstobs=3 obs=3 keep=col1 col2 rename=(col1=i1 col2=i2));
set Stumortab (firstobs=4 obs=4 keep=col1 col2 rename=(col1=j1 col2=j2));
set Stumorpw (firstobs=7 obs=7 keep=nvalue1 rename=(nvalue1=probW));
run;
data summary;
set summary one;
run;

/*print the final table*/
ods listing;
title 'preoperative characteristics: Robotic Versus Abdominal Myomectomy';
```

```
proc print data=summary noobs label;
var item g1 h1 i1 j1 g2 h2 i2 j2 prob probw ;
label g1='Mean_Abdominal';
label h1='SD_abd';
label i1='95%LCI_abd';
label j1='95%UCI_abd';
label g2='Mean_Robotic';
label h2='SD_rob';
label i2='95%LCI_rob';
label j2='95%UCI_rob';
label prob='T_pvalue';
label probW='Wilcoxon p_value'; run;
```

Appendix G: SAS CODE TO CREATE INTERACTION TERMS.

```
data robot_abdom;
set robot_abdom;
age_bmi=age*BMI;
age_ntum=age*Ntumors;
age_size=age*Stumor;
bmi_ntum=Ntumors*BMI;
bmi_size=Stumor*BMI;
ntum_size=Ntumors*Stumor;
grav_par=gravity*parity;
grav_age=gravity*age;
grav_ntum=gravity*Ntumors;
grav_size=gravity*Stumor;
grav_bmi=gravity*bmi;
par_age=age*parity;
par_bmi=bmi*parity;
par_ntum=Ntumors*parity;
par_size=Stumor*parity;
run;
```

Appendix H: SAS CODE FOR STEPWISE REGRESSION.

```
/* stepwise regression*/
proc reg data=robot_abdom ;
model surgtime= surgtype age gravity parity Ntumors Stumor BMI age_bmi age_ntum age_size
bmi_ntum bmi_size ntum_size grav_par grav_age grav_ntum grav_size grav_bmi par_age
par_bmi par_ntum par_size/ selection=stepwise;
run;
proc reg data=robot_abdom ;
model bloodloos = surgtype age gravity parity Ntumors Stumor BMI age_bmi age_ntum
age_size bmi_ntum bmi_size ntum_size grav_par grav_age grav_ntum grav_size grav_bmi
par_age par_bmi par_ntum par_size/selection=stepwise ;
run;
```

Appendix I: SAS CODE FOR STEPWISE REGRESSION.

```
/* all possible regression*/
ods listing close ;
ods trace on/label listing;
ods trace off;
ods output  Reg.MODEL1.Selection.surgtime.SubsetSelSummary=stime_cp;
proc reg data=robot_abdom ;
model surgtime= surgtype age gravity parity Ntumors Stumor BMI age_bmi age_ntum
age_size bmi_ntum bmi_size ntum_size grav_par grav_age grav_ntum grav_size grav_bmi
par_age par_bmi par_ntum par_size/ selection= adjrsq cp mse rsquare press;quit;
run;
proc sort data=stime_cp out=sortstime_cp ;by cp;run; proc print data=sortstime_cp;run;

ods output Reg.MODEL1.Selection.bloodloos.SubsetSelSummary=bloss_cp;
proc reg data=robot_abdom ;
model bloodloos = surgtype age gravity parity Ntumors Stumor BMI age_bmi age_ntum
age_size bmi_ntum bmi_size ntum_size grav_par grav_age grav_ntum grav_size grav_bmi
par_age par_bmi par_ntum par_size/selection= adjrsq cp mse rsquare press;quit;
run;
proc sort data=bloss_cp out=sortbloss_cp ;by cp;run; proc print data=sortbloss_cp;run;
```

Appendix J: SAS CODE FOR MODEL ADEQUACY CHECKING OF OPERATIVE TIME.

```
 /*Testing the significance of all the variables selected from stepwise and all possible regression
*/
proc reg data=robot_abdom ;
model surgtime= surgtype Ntumors Stumor age bmi parity
age_Ntum age_size age_bmi bmi_size par_bmi;
run;
proc reg data=robot_abdom ;
model surgtime= surgtype Ntumors Stumor bmi parity
 bmi_size par_bmi;
run;

 /*Model adequacy checking on the final model: Residual analysis*/
proc reg data=robot_abdom ;
model surgtime= surgtype Ntumors Stumor bmi parity
par_bmi;
output out=res_surgt r=r;
run;
proc univariate data=res_surgt normal ;
histogram;
qqplot/ normal(mu=est sigma=est);
var r;
run;
```

Appendix K: SAS CODE FOR MODEL ADEQUACY CHECKING OF BLOOD LOSS.

```
/* Testing the significance of all the variables selected from stepwise and all possible regression
*/
proc reg data=robot_abdom ;
model bloodloos = surgtype Ntumors Stumor age age_Ntum ntum_size;
run;

/*Model adequacy checking on the final model: Residual analysis*/
proc reg data=robot_abdom ;
model bloodloos = surgtype Ntumors Stumor ntum_size;
output out=res_bl r=r;
run;
proc univariate data=res_bl normal ;
histogram;
qqplot/ normal(mu=est sigma=est);
var r;
run;
```

Appendix L: SAS CODE FOR BOX COX TRANSFORMATION.

```
/* Box COX Transformation*/
proc transreg data=robot_abdom;
model boxcox(surgtime )=identity(surgtype Ntumors Stumor bmi parity par_bmi);
run;
proc transreg data=robot_abdom;
model boxcox(bloodloos )=identity(surgtype Ntumors Stumor ntum_size);run;
```

Appendix M: SAS CODE FOR TRANSFORMED VARIABLES

```
data robot_abdom;
set robot_abdom;
log_surgtime = log(surgtime);
log_bloodloos = log(bloodloos);
run;
```

Appendix N: SAS CODE FOR MODEL ADEQUACY CHECKING OF TRANSFORMED VARIABLES.

```
/*Log operative time*/
proc reg data=robot_abdom ;
model log_surgtime= surgtype Ntumors Stumor bmi parity
par_bmi ;
output out=res_lsurgt r=r;
run;
proc univariate data=res_lsurgt normal ;
histogram;
qqplot/ normal(mu=est sigma=est);
var r;
run;
/*Log blood loos*/
proc reg data=robot_abdom ;
model log_bloodloos = surgtype Ntumors Stumor ntum_size ;
output out=res_lbl r=r;
run;
proc univariate data=res_lbl normal ;
histogram;
qqplot/ normal(mu=est sigma=est);
var r;run;
```

Appendix O: SAS CODE FOR MULTIPLE REGRESSION ANALYSIS AND BONFERRONI T TESTS.

```
/* Multiple regression analysis and bonferroni t test*/

proc reg data=robot_abdom ;
model log_surgtime= surgtype Ntumors Stumor bmi parity
 par_bmi ;
run;
proc reg data=robot_abdom ;
model log_bloodloos = surgtype Ntumors Stumor ntum_size;
run;

proc glm data=robot_abdom;
class surgtype ;
model log_surgtime= surgtype Ntumors Stumor bmi parity par_bmi/solution ;
MEANS surgtype/ BON;
run;
proc glm data=robot_abdom ;
class surgtype;
model log_bloodloos = surgtype Ntumors Stumor ntum_size/solution ;
means surgtype/ bon;
run;
```

Appendix P: SAS CODE FOR RECODED HOSPITAL STAY.

```
/*RECODE variable hosp stay*/
data robot_abdom;
set robot_abdom;
if hospstay<=1 then hospstayr=1;
else hospstayr=2;
run;

proc format;
value surgtype
1='Robotic'
0='Abdominal'
;
value hospstayr
1='<= 1day'
2='> 1 day'
;
run;

proc freq data= robot_abdom;
table hospstayr*surgtype/chisq;
format surgtype surgtype. hospstayr hospstayr.;
run;
```

Appendix Q: SAS CODE FOR CHART OF HOSPITAL STAY BY SURGERY TYPE.

```
Title1 ' Hospital stay by surgery type';
proc gchart data=robot_abdom;
format surgtype surgtype. hospstayr hospstayr.;
vbar hospstayr/ discrete
      subgroup=surgtype;
run;
```

Appendix R: SAS CODE FOR LOGISTIC SPETWISE REGRESSION.

```
proc logistic data=robot_abdom;
class surgtype /param=ref ref=first;
model hospstayr=surgtype age gravity parity Ntumors Stumor BMI age_bmi age_ntum
age_size bmi_ntum bmi_size ntum_size grav_par grav_age grav_ntum grav_size grav_bmi
par_age par_bmi par_ntum par_size/selection=stepwise;
run;
```

Appendix S: SAS CODE FOR LOGISTIC REGRESSION ANALYSIS.

```
proc logistic data=robot_abdom ;
class surgtype/param=ref ref=first;
model hospstayr=surgtype Ntumors Stumor;
run;
```