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Assessing American Thyroid Association Guidelines for Total Thyroidectomy in Graves' Disease.

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Abstract

Introduction: The American Thyroid Association (ATA) issued specific pre-operative preparatory guidelines for patients undergoing thyroidectomy for treatment of Graves' disease. Our goal is to determine if compliance with these guidelines is associated with better outcomes.

Methods: A retrospective review of a prospectively maintained database identified 228 patients with Graves' disease who underwent total thyroidectomy between 8/2007 and 5/2015. Patients treated in compliance with ATA guidelines were compared to those not in full compliance with the current preparatory guidelines.

Results: At the time of surgery, 52% of all patients followed ATA guidelines. Patients that were prepped per ATA guidelines had fewer episodes of intraoperative tachycardia (0.3 vs. 4.5, $p = 0.04$), but had no difference in peak systolic blood pressure (SBP) or in number of episodes of SBP >180 mm Hg. ATA prepped and non-prepped patients had similar mean operating room (OR) time and length of stay. ATA prepped and non-prepped patients had similar complication rates, including transient hypocalcemia (30.4% vs. 25.5%, $p=0.45$), prolonged hypoparathyroidism (0.98% vs. 4.3%, $p=0.15$), hoarse voice (10.8% vs. 7.5%, $p=0.42$), permanent recurrent laryngeal nerve paralysis (2.9% vs. 2.1%, $p=0.71$), and hematoma (2.9% vs. 0%, $p=0.09$).

Conclusions: Our data suggests that compliance with ATA guidelines for thyroidectomy preparation is not essential for a successful surgical outcome. While preparation per the guidelines decreased the frequency of intraoperative tachycardia, it did not impact intraoperative hypertension, OR time, or post-operative complications.

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All authors contributed extensively to the work presented in this paper.
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Introduction

Graves' disease, an autoimmune disorder of the thyroid gland, is the leading cause of hyperthyroidism.[1] The prevalence of hyperthyroidism is approximately 1.2% in the United States and nearly 80% of these cases are attributable to Graves' disease.[2,3] There are currently three main approaches for the treatment of Graves' disease including anti-thyroid drugs, radioactive iodine, and surgical thyroidectomy.[1,4] While all three of these treatment approaches can be effective in treating Graves' disease, they each have different advantages and utilization.[2] Antithyroid drugs, which primarily interfere with thyroid hormone synthesis, include thionamides (propylthiouracil or methimazole) and are often used as an initial therapy for Graves' disease.[2] Radioactive iodine therapy (RAI) is the most commonly used definitive treatment option for Graves' disease. The principal aim of radioiodine is to destroy the thyroid tissue in order to induce hypothyroidism to prevent the recurrence of Graves' disease.[2] Surgery is also a definitive treatment option that is used as a first line treatment, most commonly for patients with indications such as severe ophthalmopathy or goiter.[1,5,6] RAI is the most common definitive treatment approach for Graves' disease in the United States and surgery has been the least commonly used treatment approach.[1,2,6] Relapse rate is highest among patients receiving anti-thyroid drugs (approximately 40%), followed by RAI (21%), and lowest in patients having surgical thyroidectomy (<5%).[2,6–8]

With respect to surgical thyroidectomy, the American Thyroid Association (ATA) and American Association of Clinical Endocrinologists have issued specific pre-operative guidelines regarding the preparation of patients for surgery. These requirements include rendering the patient euthyroid through administration of methimazole. In cases where urgent thyroidectomy is needed or the patient is allergic to anti-thyroid medication, the patient should be treated with beta-blockade and potassium iodide (SSKI) in the immediate preoperative period. ATA guidelines state that potassium iodide should be given in the ten days leading up to surgery.[9] These guidelines are based on historical practice preferences but the efficacy of these requirements has not been well validated. Recent studies indicate that strict adherence to ATA guidelines may not lead to better outcomes for patients.[4,10]

We aim to determine if compliance with ATA guidelines for total thyroidectomy for Graves' disease is associated with better outcomes than for those patients who do not meet all preoperative preparation criteria. At our institution, over 50% of patients choose surgery over RAI as definitive treatment for Graves' disease, so we are in a unique position to study this question. We examined surgical complications and assessed intraoperative makers of hemodynamic stability, including blood pressure and heart rate, which have not been considered by previous studies.

Although pre-operative preparation is very important and we do not advocate taking an overtly hyperthyroid patient to the operative room with no preparation, there are several reasons why it can be difficult to meet the strict criteria laid out by the ATA. For instance, not all pharmacies have SSKI solution readily available; some patients may get dose dependent side effects from methimazole, and can only tolerate small doses of methimazole that reduce their T4 but not all the way to 1.5 ng/dL. In such cases, the ATA guidelines may prove to be too large an obstacle to overcome prior to thyroidectomy. Delays in treatment will lead patients to suffer from the symptoms of Graves' disease longer than they need to. We hypothesize that patients that do not meet all ATA guidelines for thyroidectomy can have their thyroid safely removed by experienced endocrine surgeons at a high-volume center, and that there is no significant harmful effect on patient outcomes when these ATA recommendations are not met.

Materials and Methods

Following approval by the local institutional review board, a retrospective review of a prospectively maintained endocrine surgery database was performed at the University of Wisconsin. All 228 patients undergoing a total thyroidectomy with a confirmed diagnosis of Graves' disease and seen from August 2007 through May 2015 were included. Data was extracted to assess preoperative clinical characteristics and medical history, intraoperative parameters, and treatment related complications. Preoperative variables including patient demographic information, thyroid function tests, status of Graves' ophthalmopathy, use of anti-thyroid drugs, RAI, and beta-blockers was collected. Intraoperative variables including estimated blood loss, operative time, initial heart rate and blood pressure, peak heart rate and blood pressure, and complications were also collected. Postoperative variables included gland weight, serum calcium level, parathyroid hormone levels, hematoma, recurrent laryngeal nerve injury, and hypocalcemia. Parathyroid hormone levels were measured one hour after surgery to determine risk for symptomatic hypocalcemia and that number was used to determine the appropriate dose of calcium and calcitriol to use.[4,11,12]

The initial diagnosis of Graves' Disease was established by either a referring endocrinologist or other referring physician based on patient signs and symptoms in addition to thyroid hormone and thyroid stimulating hormone levels, RAI uptake scans, and/or thyrotropin receptor antibody measurement. All surgical procedures were conducted by one of five high volume endocrine surgeons. Preoperative thyroid status was assessed based on the last set of laboratory results prior to the operation. Special emphasis was placed on T4 and T3 levels and euthyroid status was defined as T4 levels < 1.5 ng/dl. Patients were deemed in compliance with the ATA guidelines if they were treated pre-operatively with SSKI and were either rendered euthyroid with methimazole (T4<1.5 ng/dl), or if that was not feasible were treated with both SSKI and a beta-blocker.

The primary outcome of interest was any peri-operative complication. This category included: transient and permanent hypoparathyroidism, transient and permanent recurrent laryngeal palsy, and neck hematoma. Permanent hypoparathyroidism was defined as hypocalcemia requiring treatment persisting six months after surgery and permanent right laryngeal nerve palsy was defined as hoarseness lasting beyond six months or if the patient had a procedure to medialize the vocal cords. To ensure that we did not miss any cardiovascular complications, we also examined length of stay, return visits to the OR, ED visits, and readmissions to the hospital.

Analysis of these data was performed using Stata version 11 statistical software (Stata Corporation, College Station, TX) to compare differences across patients. The primary comparison of interest was between patients that met ATA guidelines and those who did not.

Additional comparisons were made for preoperative SSKI use, euthyroid status, and use of beta-blockers. A p value of <0.05 was deemed statistically significant.

Results

Overall Patient Demographics

The mean age of all patients was 39 years ± 16.0 and 83% were female. Nearly two fifths were smokers (39%); over half (52%) had some degree of ophthalmopathy, and over a third (37%) had nodules. Most patients were treated preoperatively with methimazole (84%), beta-blockers (82%), or both (50%). Only 11 % of patients received neither. Most patients were clinically euthyroid with a measured serum T4 level in the normal range prior to thyroidectomy (72%).

Intraoperative Findings

All patients underwent a total thyroidectomy, and the mean OR time was 115 ± 39.1 minutes. Heart rate (HR) and blood pressure (BP) logs from surgery were analyzed and intraoperative hemodynamic stability was assessed. Intraoperative tachycardia, defined as more than one episode of heart rate exceeding 120 beats per minute, was present in 18.7% (n=43) of patients. The median number of tachycardic episodes was 0 and the range was 0 to 155. Intraoperative hypertension, defined as a systolic blood pressure episodes exceeding 180 mm Hg, occurred in 5.6% of patients during surgery. The mean number of such hypertensive episodes was 0.2 ± 0.5. Hemodynamic changes led to the administration of intravenous beta-blockers intraoperatively in 14.7% (n=34) of patients.

Post-operative Outcomes

One third of patients were discharged from the hospital on the same day as their procedure (32.3%, n= 74) and the remaining two thirds (63.7%, n=145) were discharged the following day. The mean recovery room PTH level was 32.5 ± 25.7 pg/ml. 21% of patients had PTH values less than 10 pg/ml and were instructed to take calcitriol in addition to calcium. The mean two-week post-operative calcium level was 9.4 ± 5.7. Post-operative complications were identified in 38% of patients following thyroidectomy, with transient hypocalcemia being the most common complication (28%). Permanent complications were rare – permanent hypoparathyroidism (2%) and permanent recurrent laryngeal nerve palsy (2%).

ATA prepped versus non-ATA prepped

Of the 228 patients that had a total thyroidectomy done in our study, we analyzed 197 who had complete records to determine whether they met ATA guidelines or not. At the time of surgery, 52% of these 197 patients followed the ATA guidelines (TABLE 1). Patients that did not meet the ATA guidelines (n=95) had different reasons for not meeting the guidelines: 54% were not euthyroid, 39% were not on SSKI, and 37% did not have a normal heart rate (<90bpm). Patients that were prepped per the ATA guidelines had fewer episodes of intraoperative tachycardia (0.3 vs. 4.5, p = 0.04), but had no difference in peak SBP, number of episodes of SBP >180 mm Hg, mean OR time, and length of stay (TABLE 1). ATA prepped and non-prepped patients also had similar overall complication rates (39.2% vs. 32.6%, p = 0.34) (TABLE 2).

In addition to comparing patients that were prepped per ATA guidelines with those that were not, we conducted several sub comparisons to see if any specific aspects of the ATA criteria impacted outcomes. We looked specifically at preoperative euthyroid status, preoperative SSKI prescription, and preoperative heart rate control for all 228 patients. These sub comparisons were made across all the same parameters as the ATA vs. non-ATA comparisons and included evaluation of pre-operative characteristics, intraoperative values, and post-operative outcomes.

Euthyroid status:

Nearly three-fourths of all patients (72%, n= 165) were rendered euthyroid prior to undergoing their thyroidectomy. The highest pre-op T4 level was 8.5 ng/dl, but in over 95% of patients, the pre-op T4 level was under 3 ng/dl. Patients that were euthyroid were more likely to have a normal heart rate at the time of surgery, defined as having an initial heart rate in the OR less than 90 bpm (75.0% vs. 62.0%, p = 0.05) (TABLE 3). Euthyroid patients had fewer intraoperative instances of systolic blood pressure exceeding 180 mm Hg, but this difference was not statistically significant (p = 0.05). Given these hemodynamic differences, patients that were not euthyroid at the time of surgery were twice as likely to require administration of intraoperative beta-blockers (23.5% vs. 12%, p = 0.04). The higher rate of intraoperative hemodynamic changes in the non- euthyroid patients did not impact the presence of post-operative complications.

Preoperative SSKI:

Most patients (81%) were prescribed potassium iodide in the ten days leading up to their thyroidectomy (TABLE 4). Patients that were prescribed potassium iodide solution had better intraoperative blood pressure control. Mean instances of systolic blood pressure exceeding 180 mmHg were significantly lower if patients took potassium iodide (0.1 vs. 0.4, p = 0.002). Use of SSKI did not impact heart rate, beta-blocker usage, or incidence of post-operative complications. Estimated blood loss (EBL) is difficult to gauge quantitatively during thyroid surgery and most thyroidectomies had “minimal” recorded for estimated blood loss (EBL). If the blood loss was not “minimal”, it was classified as “measurable”. There was no significant difference in the percentage of cases with measurable EBL (32% in SSKI and 25% in no SSKI, p = 0.4).

Heart Rate control:

Normal heart rate was defined as HR <90 bpm prior to surgery and 79% of patients had a normal HR prior to surgery (TABLE 5). Not surprisingly, patients with a higher baseline HR had more HR instability intraoperatively defined as mean instances of HR over 120 (10.8 vs. 0.5, p = 0.0001) and significantly more likely to require intraoperative beta blockade (26% vs. 12%, p = 0.04). However, pre-operative Heart Rate control did not influence the likelihood of post-operative complications.

Over half (55%) of all patients were on beta-blockers preoperatively. Patients that were taking beta-blockers pre-operatively were also more likely to be taking methimazole pre-operatively (90% vs 76%, p = 0.007). As expected patients that were on preoperative beta-blockers had lower starting HRs (100.4 vs. 72.6, p = 0.01) and were less likely to have multiple episodes of HR >120 bpm intraoperatively (23.2% vs. 10.3%, p = 0.02). However, pre-operative beta-blocker usage did not decrease the need for intraoperative beta-blockers (18.3% vs. 12.1%, p = 0.22) or the likelihood of post-operative complications (32.0% vs. 42.4%, p = 0.10).

Impact of individual components:

In summary, achieving a euthyroid status pre-operatively increases the likelihood of having a normal heart rate at the start of surgery. Having a normal HR at the start of surgery lead to less intraoperative tachycardia and subsequently less intraoperative use of beta-blockers. Use of SSKI did not impact HR control, but was correlated with better blood pressure control intraoperatively. While intraoperative hemodynamics were impacted by thyroid status of the patient and the use of medications pre-operatively, this did not impact post-operative outcomes or complication rates.

Discussion

There were no significant differences between ATA prepped and non-prepped patients with respect to all post-operative outcomes and complications ranging from length of stay, transient hypocalcemia, hematoma, to permanent right laryngeal nerve palsy. The only significant difference between prepped and non-prepped patients was with respect to the number of intraoperative heart rate episodes exceeding 120 bpm.

We did several sub-comparisons to see if there were any components of the ATA guidelines that were especially beneficial. In these comparisons, the use of SSKI did not impact HR control, but was associated with improvements in intraoperative blood pressure control. Several other studies have looked at SSKI administration prior to thyroidectomy for Graves' Disease. Perioperative use of SSKI was first supported by Plummer in the 1920's as a means to reduce the risk of thyroid storm which was a major cause of morbidity in thyroidectomy.[13] This was at a time prior to the development of beta-blockers and sulfonamides which have greatly reduced the risk of thyroid storm.[2]

There have been several more recent studies done to see if SSKI administration leads to a safer thyroidectomy. Erbil et al found that use of SSKI decreased blood flow rate, thyroid vascularity, and intraoperative blood loss during thyroidectomy. They argued that the reduction of intraoperative bleeding may allow for better visualization and preservation of surrounding nerves, vasculature, and parathyroid glands.[14] Takata et al compared treatment involving MMI alone with MMI + SSKI treatment and found that use of SSKI in the pre-operative treatment helped achieve more effective control of free T4, T3, and TSH levels.[15] More recently, Whalen et al found that SSKI given pre-operatively reduces blood loss (62 mL of blood loss with SSKI and 162 mL in randomized control group) during thyroidectomy.[16] It's difficult to say whether 62 mL vs. 162 mL is clinically significant and neither is a cause of severe postoperative complications or a need for transfusion.

Our study did not find that the use of SSKI preoperatively reduced complication rates, but our analysis is limited by the fact that most patients in this cohort were treated with SSKI preoperatively. Shinall et al illustrated that there were no ill effects of failing to administer potassium iodide solution prior to total thyroidectomy for Graves ' disease, but in their study most patients did not receive SSKI.[2] Yabuta et al found that iodide administration actually makes thyroidectomy more difficult due to an iodide induced increase in thyroid gland size.[17] Through use of a four item, 20-point Thyroidectomy Difficulty Scale (TDS) to score the difficulty of thyroid operations, Mok et al identified three factors that make for a more difficulty thyroidectomy: a diagnosis of hyperthyroidism, preoperative evaluation of serum thyroglobulin, and anti-thyroglobulin antibodies.[18] Thyroid gland vascularity was not one of the factors that they identified.

ATA guidelines also include a recommendation to render patients euthyroid with use of methimazole preoperatively.[9] This recommendation arose from the notion that the stress of the operation could lead to thyroid storm.[4] In our patient population as well as the cohort in Shinall et al, no patients developed thyroid storm despite 28% of patients in our data set and 42% of patients in the Shinall et al data set remaining hyperthyroid at the time of operation.[4] We found that euthyroid status was correlated with more effectively managed pre-operative heart rate ($p = .05$) and less reliance on intraoperative beta-blockers ($p = .04$), but there was no difference in BP control. Despite the differences in intraoperative HR control, euthyroid status did not impact length of stay and was not correlated with any complications post-operatively. Considering these findings, administration of methimazole pre-operatively is still justified for symptomatic management but complete control may not be essential for optimizing intraoperative safety and post-operative outcomes.

Our study does have a few important limitations. First, this was a retrospective study and as with any retrospective study, our clinical data was limited to what clinicians entered in the medical record. Secondly, all data was collected from a single, large university academic center allowing for the possibility of institutional bias. Given the large size of 228 patients that had undergone a total thyroidectomy, however, it is likely that the findings can be generalized to other large centers. An additional potential limitation is that all procedures were performed by five high volume endocrine surgeons and it is possible that ATA guidelines may prove more useful in smaller practices with less experience operating on Graves' disease. While our numbers were large and the comparison between the ATA prepped and non-ATA prepped were large enough, the majority of patients received SSKI, had a normal HR, or were euthyroid at the time of surgery which limited the power of our analyses of any individual subcomponent.

Our data shows that following the ATA guidelines may have some impact on intraoperative HR and BP control, but the differences are small and may not be clinically significant. Additional studies are needed to further clarify the impact of each specific intervention to determine the optimal preoperative management of patients with Grave's disease.

Conclusions:

Our data suggests that compliance with ATA guidelines for thyroidectomy preparation is not a prerequisite for a successful postoperative outcome. While preparation per the guidelines decreased the frequency of intraoperative tachycardia, it did not impact intraoperative hypertension, OR time, or post-operative complications. Although the components of the

ATA guidelines are generally well tolerated, their use exposes patients to potential adverse effects and can delay definitive management of their disease. Considering these findings, we do not think that compliance with the ATA guidelines for thyroidectomy is necessary to optimize outcomes especially when surgery is performed by a high-volume surgeon.

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TABLE 1:

Comparing patients that met ATA guidelines with those that did not: Patient Characteristics.

Variable	ATA Prepped (n=102)	Not ATA Prepped (n=95)	P Value
Age (years)	41.6±1.4	37.5±1.7	0.07
BMI	28.9±6.2	27.9±6.7	0.31
Female Gender, %	77.0	87.4	0.07
Opthalmopathy, %	54.9	46.8	0.26
Thyroid Nodules, %	36.6	36.8	0.98
Current Smoker, %	47.1	31.0	0.02
Previous RAI, %	9.0	3.3	0.10
Thyrotoxic Crisis, %	3.9	2.1	0.46
Pregnant, %	0.0	2.1	0.14
Preoperative Methimazole, %	91.8	78.0	0.01
Months on Methimazole Preop	9.7±1.4	7.9±1.5	0.39
MMI Side Effect, %	6.9	6.3	0.88
Days on Beta-Blocker	203.4±446.5	127.6±334.0	0.19
Preoperative Lugol's/SSKI%	100.0	61.1	0.01
Euthyroid, %	100.0	46.3	0.01
TSH Preop	1.0±3.1	0.8±2.8	0.55
T4 Preop	1.0±0.3	4.4±24.0	0.01
T3 Preop	4.4±10.8	8.3±16.2	0.01

Data presented as mean± SD

TABLE 2:

Comparing patients that met ATA guidelines with those that did not: Intraoperative and Postoperative Parameters.

Variable	ATA Prepped (n=102)	Not ATA Prepped (n=95)	P Value
Thyroid Weight	32.3±23.6	38.4±36.0	0.16
OR Time	118.6±37.1	114.5±39.6	0.77
Normal Heart Rate, %	100.0	63.2	0.01
First Heart Rate in the OR	71.5±10.7	83.9±15.5	0.01
HR120 Episodes	0.34±1.1	4.5±20.5	0.04
HR 120 Multiple, %	8.9	24.2	0.01
First SBP	126.4±19.5	128±2.0	0.57
Highest SBP Intraop	151.5±30.5	148.5±27.9	0.47
SBP 180 Episodes	0.18±0.48	0.2±0.61	0.76
SBP 180 Multiple Episodes, %	4.0	0.1	0.30
EBL Measurable	37%	25.26%	0.07
Intraop Beta, %	11.8	17.9	0.23
Length of Stay	0.7±0.5	0.8±1.1	0.29
PACU PTH, y, mean ± SD	32±24	34±28.5	0.63
2week Ca,	9.0±0.6	9.0±0.7	0.72
2 week PTH,	40.1±32.9	41.1±28.5	0.82
Any Complication, %	39.2	32.6	0.34
Transient hypocalcemia, %	30.4	25.5	0.45
Permanent Hypoparathyroidism, %	1.0	4.3	0.15
Transient hoarseness %	10.8	7.5	0.42
Permanent RLN Palsy, %	2.9	2.1	0.71
Hematoma, %	2.9	0.0	0.09
Return to OR, %	2.0	1.1	0.60
ER Visit, %	2.9	3.2	0.93
Readmission, %	2.0	1.1	0.60
Other Complication, %	2.0	4.3	0.36

Data presented as mean± SD

Table 3:

Comparing patients that were Euthyroid prior to thyroidectomy with patients that were not Euthyroid prior to thyroidectomy.

Variable	**Euythyroid (n=165)**	**Not Euthyroid (n=63)**	**P Value**
OR time	117.3±37.9	111.0±41.9	0.29
Normal HR, %	75.2	61.9	0.05
HR 120 Episodes, %	2.6	1.0	0.60
HR 120 Multiple, %	12.9	25.5	0.07
First SBP	128.6	123.03	0.08
Highest SBP Intraop	153.1	140.9	0.01
SBP 180 Episodes	0.2	0.1	0.05
SBP 180 Multiple, %	6.8	2.0	0.19
Any complication, %	37.0	39.7	0.71
EBL Measurable, %	31.1	29.0	0.77
Intraop Beta-Blocker, %	11.6	23.5	0.04
LOS	0.8±1.1	0.7±0.5	0.24
PACU PTH	33.8±26.3	29.0±23.8	0.24

Data presented as mean± SD

Table 4:

Comparing patients that were on SSKI prior to thyroidectomy with patients that were not on SSKI prior to thyroidectomy.

Variable	**SSKI (n=184)**	**No SSKI (n=43)**	**P Value**
OR Time	114.7±39.1	118.5±39.9	0.60
Normal HR, %	70.7	74.4	0.62
HR 120 Episodes	2.6±15.9	1.03±2.6	0.54
HR 120 Multiple, %	16.3	13.5	0.11
First SBP	125.9±19.4	132.7±18.6	0.06
SBP 180 Episodes	0.1±0.4	0.4±0.9	0.01
SBP 180 Multiple, %	3.1	15.8	0.01
Any complication, %	38.6	32.6	0.46
EBL Measurable, %	31.9	25	0.39
Intraop Beta-Blocker, %	13.8	18.9	0.42
LOS	0.8±0.9	0.9±1.4	0.52
PACU PTH	31.7±25.2	36.7±27.9	0.26

Data presented as mean± SD

Table 5:

Comparing patients that had a normal initial heart rate in the OR with patients that did not have a normal initial heart rate in the OR.

Variable	**Normal Heart Rate (n=163)**	**NOT Normal Heart Rate (n=65)**	**P Value**
OR Time	117.5±38.6	109.3±40.4	0.19
HR 120 Episodes	0.5±1.7	10.8±33.0	0.01
HR 120 Multiple, %	10.4	42.9	0.01
First SBP	126.1±19.1	131.9±20.4	0.11
Highest SBP Intraop	149.7±30.1	151.1±25.1	0.79
SBP 180 Episodes	0.2±0.5	0.2±0.7	0.62
SBP 180 Multiple, %	4.9	8.33	0.42
Any complication, %	38.7	35.4	0.65
EBL Measurable, %	33.1	23.3	0.16
Intraop Beta, %	12.3	25.7	0.04
LOS	0.7±0.8	1.0±1.3	0.02
PACU PTH	32.8±25.4	31.9±26.6	0.82

Data presented as mean± SD