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MİDE KANSER CERRAHİSİ SONRASI "ANASTOMOZ / DUODENAL GÜDÜK" KAÇAKLARI İÇİN RİSK DEĞERLENDİRMESİNİN BAĞIMSIZ RİSK FAKTÖRÜ OLARAK "DÜŞÜK MODİFİYE CERRAHİ APGAR SKORU(mSAS)"

RISK ASSESSMENT FOR "ANASTOMOTIC/DUODENAL STUMP" LEAKAGE AFTER GASTRIC CANCER SURGERY THE LOW "MODIFIED SURGICAL APGAR SCORES (mSAS)" AS AN INDEPENDENT RISK FACTOR

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Anahtar Sözcükler: Mide kanseri, anastomoz kaçağı, duodenal güdük kaçağı, Cerrahi Apgar Skoru
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ÖZ

Giriş: *Mide kanseri en sık görülen beşinci kanser olarak karşımıza çıkmakta ve postoperatif komplikasyonları ölümcül olabilmektedir. Ameliyat sonrası genel komplikasyon gelişimini tahmin etmede kullanılan orijinal ve modifiye "Cerrahi Apgar Skoru"nun özellikle anastomoz/duodenal güdük kaçağını tahmin etmedeki başarısını değerlendirmeyi amaçladık.*

Gereç ve Yöntem: *Dokuz Eylül Üniversite Hastanesinde ameliyat edilen ve verileri prospektif kayıt altına alınan 318 hastanın raporları retrospektif inceleme yöntemi ile gözden geçirildi. Çalışmaya 241 hasta dâhil edildi.*

Bulgular: *Otuz bir(%12,8) hastada komplikasyon (>grade 3a) görüldü. Tek değişkenli analizde; yaş (p=0,001) preop hipo-albuminemi(p=0,024) düşük oSAS(p<0,0001),düşük mSAS(p<0,001) komplikasyon gelişimine etki eden değişkenler olarak saptandı. Tümör boyutu>5cm(p=0.049) ve mSAS<7(p=0.014)anastomoz/duodenal güdük kaçağı gelişimine etki ettiği görüldü. Çok değişkenli analizde sadece mSAS<7 anastomoz/duodenal güdük kaçağı gelişimi için bağımsız risk faktörü olarak saptandı.*

Sonuç: *Basit skorlama sistemleri olarak oSAS genel komplikasyonları, mSAS ise hem genel komplikasyonları hem de özellikle anastomoz/duodenal güdük kaçağını tahmin etmede başarılı bulundu. Özellikle mSAS ile mide kanser cerrahisi bitiminde basitçe yapılacak hesaplama, gelişebilecek komplikasyonlar ve kaçaklar için öngörüde bulunmaya yardımcı olarak, gerekli önlemlerin alınması mümkün kılabilir.*

SUMMARY

Introduction:*Gastric cancer is the fifth most common cancer worldwide. Surgeons want to estimate which patient may has leakage or any other morbidity after the operation. Several models have been developed for this enigma. Surgical Apgar Score(oSAS) has been proposed for general surgery and it was modified for gastric surgery(mSAS).We evaluated the predictability of the oSAS and mSAS for anastomotic/duodenal stump leakage after gastric cancer surgery.*

Material and Method: *We investigated prospective recorded data of 318 patients with gastric cancer and we included 241 patients who underwent elective gastrectomy at Dokuz Eylul University Hospital for gastric carcinoma.*

Results: *Thirty-one patients(12.8%) had severe complications. Univariate analyses showed age(p=0.001), preoperative hypo-albuminemia (p=0.024),low oSAS(p=<0.001),and low mSAS(p=<0.001) were associated with severe complications. Tumor size>5cm(p=0.049) and mSAS<7(p=0.014) are especially associated with anastomotic/duodenal stump leakage.In multivariate analysis just mSAS<7 was determined as independent risk factor for anastomotic/duodenal stump leakage after gastric cancer surgery.*

Conclusion: *The simple and easy calculating model mSAS is useful to evaluate the risk of anastomotic/duodenal stump leakage right after gastric cancer surgery. oSAS and mSAS were found suitable for estimation of postoperative severe complications. We are able to take precautions for complications and their serious results and we can organize the hospital's resources for postoperative follow up more effectively by using Surgical Apgar Scores.*

INTRODUCTION

952.000 new cases of gastric cancers have been detected annually, thereby gastric cancer has been decided the fifth most common malignancy worldwide(1). By the time of initial diagnosis, more than 50% of gastric cancer patients have concomitant lymph node metastases. Gastrectomy with lymph node dissection is the mainstay treatment for gastric cancer (2,3). Earlierpostoperative morbidity rates have been reported lying within the range of 14.3 - 34% after curative surgery. Anastomotic leaks are inevitable complications affecting 2 - 4% of patients undergoing gastrointestinal surgery (4–6). Although the leakage of the duodenal stump in these leaks is rare, the results are worse(7). Due to these complications, adjuvant chemotherapy might be delayed and moreover, the hospitalization time of patients might be increased thereby raising total treatment costs.

Some scoring models have been developed for predicting perioperative complications. Gawande et al. described the Surgical Apgar Score (*SAS*) in 2007. Intraoperative heart rate, intraoperative mean arterial pressure,and estimated blood loss during the operation are used to calculate this risk score (Table 1). This simple model has been validated for different surgical procedures (8–13). In 2014 Miki et al proposed minor changes and published a modified Surgical Apgar Score (*mSAS*) for gastric surgery (14) (Table 1). All these models have been found useful for predicting miscellaneous postoperative complications within 30 days after the surgery. However, their ability to predict the anastomosis complications which is the most worrying complication has not been investigated.

The aim of this study was to evaluate the SAS and SAS, especially towards the "anastomotic and/or duodenal stump leakage", for a cohort of patients undergoing gastrectomy at a single center.

MATERIAL AND METHOD

Primarily we obtained the ethical committee approval from the ethical committee of Dokuz Eylul University Medical Faculty. The prospectively recorded database of 318 operated gastric cancer patients between January 2009 and March 2015 at Dokuz Eylul University Hospital has been reviewed.

This study included 241 patients diagnosed with gastric cancer and underwent elective gastrectomy with D1+ (for stage IA gastric cancer) or D2 (for stage IB or higher gastric cancer) lymph node dissection via laparotomy without neoadjuvant therapy.

The parameters evaluated in this study included intraoperative heart rate (*HR*), mean arterial pressure (*MAP*), and estimated blood loss (*EBL*) as well as age, sex, body mass index (*BMI*), preoperative albumin level, type of surgery, extent of lymph node dissection, operation time, tumor size, tumor localization, hospitalization time, diabetes, cardiac and pulmonary disease and the American Society of Anesthesiologists (*ASA*) score, anastomotic / duodenal stump leakage and other complications.

In this study, intraoperative monitoring charts have been used for evaluating intraoperative heart rate, intraoperative mean arterial pressure and estimated blood loss parameters. The original *SAS* (*oSAS*) was calculated by using the original scoring model (8). The modified *SAS (mSAS)* was calculated using the modified cut-off value of the estimated blood loss parameter (14) (Table 1).

Morbidities observed within 30 days after the operation were graded using the Clavien – Dindo classification (15).Within this classification, grade IIIa or higher complications were defined as severe.

Moreover, duodenal stump leakage, esophago-jejunostomyand gastro-jejunostomy or jejuno-jejunostomy leakage were all defined as "anastomotic/duodenal stump leakage".

Surgical technique

Elective gastrectomy with D1+ (for stage IA gastric cancer) or D2 (for stage IB or higher gastric cancer) lymph node dissection was performed via laparotomy.None of the patients received neoadjuvant therapy. In the operationthe duodenum was transected above the gastroduodenal artery, using a DST Series™ GIA™ 60 or 80mm 3.8 linear staplers (Medtronic Norwalk, CT, USA). The staple line of the duodenal stump was never reinforced by oversewing sutures, but some stitches could be made for hemostatic purposes. Stomach was divided at its proximal third using a DST Series™ GIA™ 60 or 80mm 3.8 linear staplers (Medtronic Norwalk, CT, USA) in subtotal gastrectomy. A Roux-en-Y gastrojejunostomy was performed by two-layer hand-sewn technique to restore the digestive continuity. Esophago-jejunal anastomosis was performed by Premium Plus CEEA™ 25-31mm stapler (Medtronic Norwalk, CT, USA) in total gastrectomy. In the case of gastrojejunostomy or esophagojejunostomy on a Roux-en-Y, the entero-entero anastomosis was performed using a DST Series™ GIA™ 60mm 3.8 linear staplers (Medtronic Norwalk, CT, USA).

Statistical analysis

Results were expressed by using the mean ± SD or median (min-max). The distribution of the variables was assessed by applying the Kolmogorov Smirnov test. Surgical findings and clinical characteristics were analyzed for all patients and compared between patients with and without severe complications and with and without stump/anastomotic leakage separately. Categorical variables were compared by employing the Chi-square test. Continuous variables were compared among two groups using the Independent Samples t-Test or the Mann Whitney U test according to the respective distribution of the variables. The receiver operating characteristic (*ROC*) curve analysis assessed the cut-off value of original *SAS* and modified *SAS* with the best diagnostic accuracy for detecting postoperative complications grade IIIa or higher. Direct logistic regression was performed in subjects to assess the impact of age, preoperative albumin level*, oSAS* and *mSAS* on the likelihood of having postoperative grade IIIa or higher complications.

The receiver operating characteristic (*ROC*) curve analysis assessed the cut-off value of modified *SAS* with the best diagnostic accuracy for predicting anastomotic/duodenal stump leakage. Then direct logistic regression was performed in subjects to assess the impact of tumor size and *mSAS* on the likelihood of the occurrence of anastomotic/duodenal stump leakage.

Statistical analysis was performed by *SPSS* version 15.0 (SPSS Inc.,Chicago, IL, USA). A two-tailed value of p ≤ 0.05 was considered to be statistically significant.

The study was approved by the Research Ethics Committee at the Dokuz Eylul University Faculty of Medicine

Table 1. Surgical Apgar Score

	0 points	1 point	2 points	3 points	4 points
EBL (ml)	>1.000	601–1.000	101–600	≤100	–
EBL* (ml)	≥525	<525	<274	<147	–
Lowest MAP	<40	40–54	55–69	≥70	–
Lowest HR	>85	76–85	66–75	56–65	≤55

EBL Estimated Blood Loss,*EBL**Modified cut-off value for modified Surgical Apgar Score,*MAP* Mean Arterial Pressure, *HR* Heart Rate

RESULTS

The mean age of this cohort of patients was 61.2 years (26-88); including 153 males (63.5%) and 88 females (36.5%). The average *BMI* was 25.7 kg/m^2 (±4.82) and 41 (17%) patients had diabetes mellitus. The most frequently performed operation type was total gastrectomy for 170 (70.5%) patients. Distal gastrectomy was performed for 71 (29.5%) patients. The mean number of harvested lymph nodes was 28.45 (±12.9). Forty-five patients had additional organ resections, amongst them most frequently distal pancreatectomy and splenectomy (31.7%). The mean operative time was 244.9 min. (130-420 min.), the mean hospitalization time was 11.5 (±10.7) days and Intensive Care Unit (*ICU*) time was 0.55 (±2.7) days (Table 2).

Complications

There were 3 perioperative deaths (1.2%). Two of them caused by abdominal sepsis due to duodenal stump leakage and esophago-jejunostomy anastomosis leakage and the third one due to pneumonia induced respiratory sepsis. There were 48 (19.9%) perioperative morbidities. Thirty-one (12.8%) patients had major complications which could be defined as grade IIIa or higher with Clavien – Dindo classification. The most common complication was a superficial surgical site infection with surgical intervention requirement (n=17, 7%). This was followed by pneumonia/acute respiratory distress syndrome (ARDS) (n=7, 2.9%). Anastomotic/duodenal stump leakages were identified for 7 (2.9%) patients. The distribution of the patients by the *oSAS* and *mSAS* are shown in figure 1.

To predict all severe complications (≥grade IIIa), the area under the *ROC* curve (*AUC*) for the *oSAS* and *mSAS* was 0.706 and 0.710 respectively. The *ROC* analysis showed the best cut-off lines for the oSAS and mSAS were between 6 and 7, at which sensitivity plus specificity maximal. Univariate analyses showed, age (p= 0.001), preoperative albumin<3mg/dl (p= 0.027), *oSAS*≤6 (p= <0.001) and *mSAS*≤6 (p= <0.001) were associated with severe complications. Variables which had a probability value <0.50 in univariate analysis were included in the multivariate analysis to determine risk factors and hazard ratios. In multivariate analysis age, *oSAS* and *mSAS* were selected as independent predictive factors for severe complications after gastric cancer surgery. Relationships between *oSAS*/*mSAS* and severe complications are depicted in figure 2.

The area under the *ROC* curve (*AUC*) for predicting anastomotic/duodenal stump leakage by the *oSAS* and *mSAS* was 0.711 and 0.808 respectively. This analyses showed the best cut-off lines for the *oSAS* and *mSAS* were between 6 and 7 points. Univariate analyses showed, tumor size>5cm (p= 0.049) and *mSAS*<7(p= 0.014) were positively correlated with anastomotic/duodenal stump leakage (Table 3). These variables were included in the multivariate analysis to identify risk factors for anastomotic/duodenal stump leakage. In multivariate analysis *mSAS*≤6 was selected as an independent predictive factor for anastomotic/duodenalstump leakage (Table 2).

Table 2. Multivariate analysis of association between patient characteristics and anastomotic / duodenal stump leakage

Variables	Oddsratio	(95% C.I.)		*p* Value
		Lower	Upper	
Tumor size (>5cm)	0.171	0.020	1.469	0.107
modified SAS	8.620	1.006	73.871	<0.049

Table 3. Patientscharacteristicsassociatedwithanastomotic/duodenalstumpleakage. Univariate Analysis

Parameters	Total		Anastomotic Leakage (-)		Anastomotic Leakage (+)		*P* Value
<u>*Preoperative factors*</u>							
Age							0.136
≥60	134	(55.6%)	128	(54.7%)	6	(85.7%)	
<60	107	(44.4%)	106	(45.3%)	1	(14.3%)	
Cardiac comorbidity							1
+	98	(40.7%)	95	(40.6%)	3	(42.9%)	
-	143	(59.3%)	139	(59.4%)	4	(57.1%)	
Pulmonary comorbidity							1
+	14	(5.8%)	15	(6.1%)	0	(0%)	
-	226	(94.2%)	219	(93.9%)	7	(100%)	
DM							0.340
+	41	(17%)	39	(16.7%)	2	(28.6%)	
-	200	(83%)	195	(83.3%)	5	(71.4%)	
Sex							1
Male	153	(63.5)	148	(63.2%)	5	(71.4%)	
Female	88	(36.5)	86	(36.8%)	2	(28.6%)	
Body Mass Index (mean)	25.17	(±4.82)	25.20	(±4.78)	24.15	(±6.39)	0.573
ASA Score							1
0-1	28	(11.6%)	28	(11.9%)	0	(0%)	
2-5	213	(88.4%)	206	(88.1%)	7	(100%)	
Preoperative albumin level (g/dl)							0.65
≥3	223	(93.7%)	218	(94.4%)	5	(71.4%)	
<3	15	(6.3%)	13	(5.6%)	2	(28.6%)	
						(±)	
<u>***Perioperative factors***</u>							
Operation							0.423
Total gastrectomy	170	(70.5)	166	(70.9%)	4	(57.1%)	
Distalgastrectomy	71	(29.5)	68	(29.1%)	3	(42.9%)	
Lymph node dissection							1
<25 LN	109	(45.4%)	106	(45.3%)	3	(42.9%)	
≥ 25 LN	132	(54.6%)	128	(54.7%)	4	(57.1%)	
Operative time (min.)	244.96	(±49.34)	244.1	(±48.1)	273.57	(±79.3)	0.120
Additional organ resection							0.354
Performed	45	(18.8)	45	(19.2%)	0	(0%)	
Not performed	196	(81.3)	189	(80.8%)	7	(100%)	
Tumor size							***0.049***
<5cm	126	(54.5%)	125	(55.8%)	1	(14.3%)	
≥5cm	105	(45.5%)	99	(44.2%)	6	(85.7%)	
Intraoperative transfusion requirement							***0.041***
+	52	(21.6%)	48	(20.5%)	4	(57.1%)	
-	189	(78.4%)	186	(79.5%)	3	(42.9%)	
Blood loss (ml)							***0.029***
<250	194	(80.5%)	191	(81.6%)	3	(42.9%)	
≥250	47	(19.5%)	43	(18.4%)	4	(57.1%)	
Minimum mean arterial pressure (mmHg)	66.57	(±10.62)	66.71	(±10.62)	61.90	(±10.20)	0.238
SAS							0.218
0-6	78	(32.4)	74	(31.6%)	4	(57.1%)	
7-10	163	(67.6)	160	(68.4%)	3	(42.9%)	
mSAS							***0.014***
0-6	93	(38.6)	87	(37.2%)	6	(85.7%)	
7-10	148	(61.4)	147	(62.8%)	1	(14.3%)	

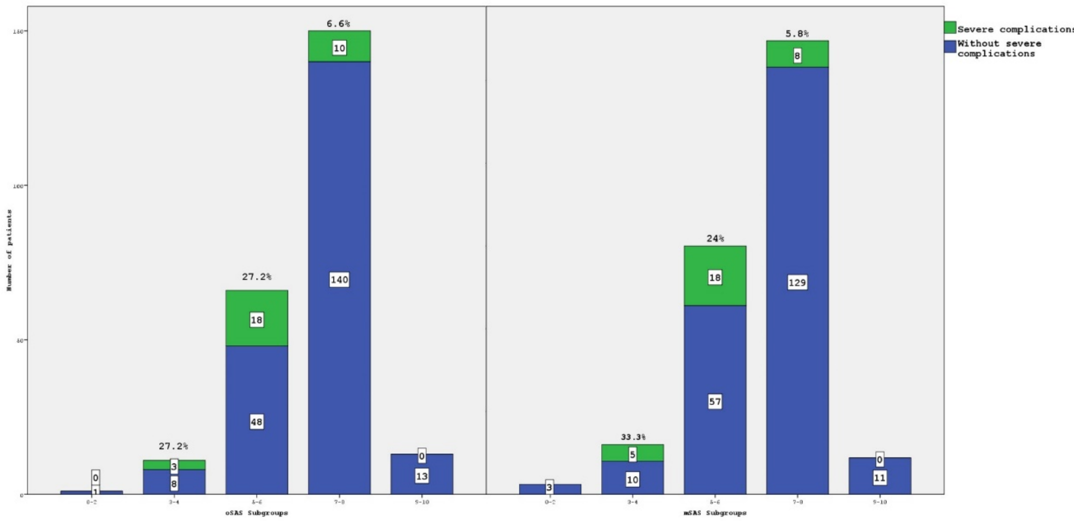

Figure 1. Thirty-day severe complications by the oSAS, and mSAS. *oSAS* original Surgical Apgar Score, *mSAS* modified Surgical Apgar Score

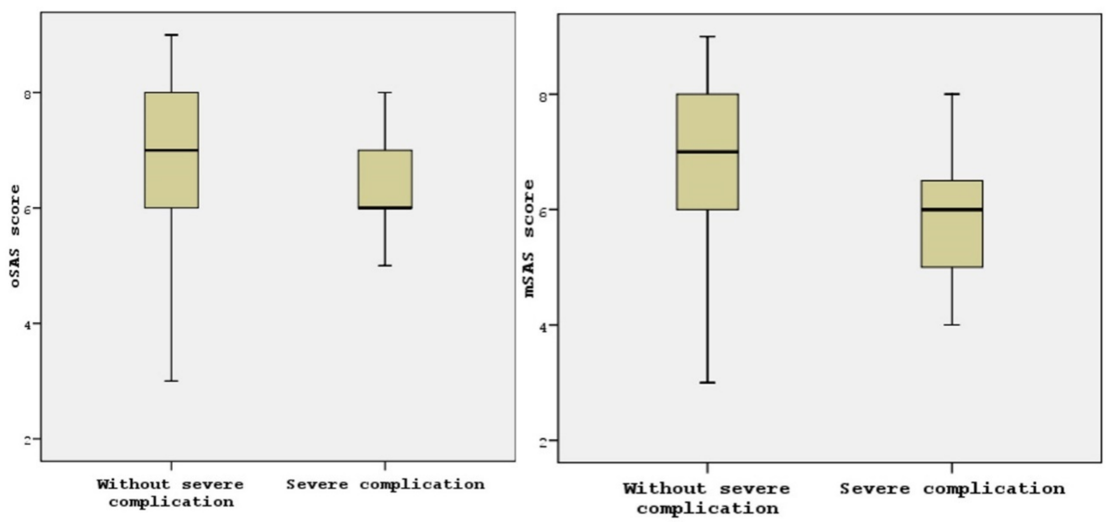

Figure 2. Relationship of oSAS and mSAS with severe complications

DISCUSSION

It has been shown, risks about concomitant diseases for perioperative morbidity and mortality can be reduced with appropriate preoperative evaluation for surgery (16). In spite of preoperative preparation, heart rate increasing and mean arterial pressure decreasing intra-operatively or in the early postoperative period, would be signs of hypovolemia and hypoperfusion due to surgical hemorrhage. Decreased tissue perfusion and oxygenation were related to perioperative morbidities (17). Surgical Apgar Scoreis calculated with three hemorrhage and hypoperfusion associated parameters (8).

In recent years various studies have been published which validated *oSAS* and demonstrated that lower Surgical Apgar Scores were associated with an increased risk of postoperative morbidity for different procedures such as radical cystectomy, hysterectomy, renal mass excision, spine surgery, knee arthroplasty (9–13,18). In 2014 Miki et al. validated the original SAS, and proposed rearranged cut-off values for EBL in gastrectomy procedures. This scoring model was named as ‘modified *SAS’* (mSAS) (14) (Table 1).

In this study, the Surgical Apgar Score, as well as the modified Surgical Apgar Score, have been calculated for all patients. For analytical purposes, the Receiver Operating Characteristic (*ROC*) has been appliedand result presents that both, *oSAS* and *mSAS* are useful predictors for severe complications. But*mSAS* has a better predictability for severe complications compared with *oSAS.* These findings are supporting what has been previously found in Miki’s study where *mSAS* has been proposed for gastrectomy procedures and revealed a better predictability for severe complications. Therefore, it can be concluded that the main difference is due to the variation of blood loss for different procedures andthe main *EBL* for the sample in this study is 237ml which is similar to a study of Miki et al. (14).

The *ROC* analysis results showed the maximal sensitivity plus specificity was between 6 and 7 for the *oSAS* and *mSAS*. When the *mSAS* results were examined, it has been found, while only 5.4% of patients with *mSAS* ≥7 developed severe complications, about one-fourth of patients (24.7%) with *mSAS*<7 experienced severe complications. These results were similar to the findings of Miki Yuichiro’s study. According to them, 3.8% of patients with *mSAS* ≥7 developed severe complications and 20.1% of patients with *mSAS*<7 experienced severe complications(14). When *oSAS* and *mSAS* subgroups were analyzed for the rates of severe complications, the highest severe complication rate was assessed for the *mSAS* 3-4 subgroup (Fig.1a, b). In this study 4 (33.3%) severe complications (2 duodenal stump leakage, 1 pancreatic fistula, 1 severe pneumonia and sepsis) were defined for the *mSAS* 3-4 subgroup.

The findings of this study revealed a lower original Surgical Apgar Score (*oSAS*) and a lower modified Surgical Apgar Score (*mSAS*) were both associated with an increased risk of postoperative morbidity. Furthermore, mSAS had a higher predictability for severe complications.

Anastomotic/duodenal stump leakage is not a frequent but nevertheless a fearful postoperative complication in gastric cancer surgery. Leakage of anastomosis and/or duodenal stump has an incidence range between 2.7 - 3% but this complication’s mortality rate is ranging from 7 - 67% (7,19,20). Age, preoperative albumin level, the presence of diabetes, intraoperative transfusion requirement, *ASA*, cardiac or pulmonary comorbidities, tumor size, operative blood loss, and perioperative hypotension have been defined as risk factors for anastomotic leakage in recent literature (6,19–21). That means there are so many patient or surgery-related factors for anastomotic leakage and some of them are not changeable in the postoperative period. Therefore, the estimation of anastomotic/duodenal stump leakage risk has a great importance right after the operation. Within the sample of this study, 7 (2.9%) early anastomotic/duodenal stump leakages were found. In this study, the p-values in univariate analyses were 0.136 and 0.65 for age and preoperative albumin levels respectively, and 0.041, 0.049, 0.029, 0.014 for intraoperative transfusion requirement, tumor size, operative blood loss, and *mSAS* respectively for anastomotic/duodenal stump leakage (Table 3). Intraoperative transfusion requirement, operative blood loss, and *mSAS* were significant for leakage, so this study found intraoperative blood loss and hypoperfusion/hypotension to be important factors for anastomotic leakage. These results were similar to the previously conducted studies (22,23).

All modified Apgar Score’s components were associated with intraoperative blood loss and hypotension. Intraoperative blood loss, intraoperative hypotension,and hypoperfusion were also identified as risk factors for anastomotic leakage(22,23). These knowledge may help to explain how *mSAS* evidence has a high predictability for anastomotic/duodenal stump leakage for gastrectomy procedure.

The obtained results showed, the patients withanastomotic/duodenal stump leakage have significantly lower modified Surgical Apgar Score. In the multivariate analysis *mSAS*<7 was determined as an independent risk factor with 8.620 Odds Ratio for anastomotic/duodenal stump leakage. (Table 2). The major findings of this study was the importance of *mSAS* in predicting anastomotic/duodenal stump leakage. It has also been the first time, lower *mSAS* was identified as an independent predictive factor for anastomotic/duodenal stump leakage.

Additionally, it has been shown, in comparison with group ≥7, increasing 3.8 days for length of stay hospital (14.5 vs. 10.7), and threefold ICU stay (0.3 vs. 1.07) for group <7 for modified Surgical Apgar Score. These findings are similar to the study of Sobol et al. which was published in 2013 and reported that a low *SAS* significantly associated with a higher likelihood of postoperative *ICU* admission (24).

Many different models have been proven as very successful for estimating postoperative morbidities. Acute Physiology and Chronic Health Evaluation (*APACHE*), National Surgical Quality Improvement Program (*NSQIP*), Physiological and Operative Severity Score for the Enumeration of Mortality and morbidity (*POSSUM*) and *E-PASS* are some examples. All these models have been reported as useful but they required different variables for the calculation which are not always readily available in the operation room (OR) or at the bedside (25–28). In contradistinction to these scoring models, *oSAS* / *mSAS* are using just three intraoperative parameters and that can easily be calculated in the *OR* and/or at the bedside in order to optimize patients' postoperative care.

There are some limitations for this study. First, this is a retrospective study in a single-institution where three surgeons are responsible for all gastric procedures. Furthermore, hand-written anesthesia records and surgical follow-up charts were used to calculate scores and to identify complications which might cause some bias.

In conclusion, *mSAS* and *oSAS* seem to be an easy and useful tool for evaluating the risk of severe complications during or right after gastric surgery. The *mSAS* has a better predictability than *oSAS* for gastrectomy procedures. Patients with *mSAS*<7 have a high risk for postoperative complications. Especially patients with *mSAS*<7 and tumor size > 5cm have a high risk for anastomotic/duodenal stump leakage. Due to this high risk, feeding jejunostomy for early enteral nutrition, extra drainage catheter placement around the anastomosis and duodenal stump, monitoring in *ICU* inthe early postoperative period and evaluation of anastomosis / duodenal stump radiologically before starting peroral feeding options may be taken carefully into consideration. In early postoperative periods, *mSAS* 1-4 patients are strongly recommended to be monitored in surgical *ICU* including one-to-one nursing care, hourly vital signs, and intake/ outputs determinations. On the other hand, patients with *mSAS* ≥7 could be taken care of in an intermediate care unit with less nursing care and regular monitoring. In this way this would allow for a more effective patient management, thereby optimizing hospital resources.

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