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Malignancy as a risk factor in single-stage combined approach for simultaneous elective surgical diseases

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ABSTRACT

Objective: To identify morbidity and mortality risk factors in patients with synchronous diseases who underwent single-stage combined (SSC) surgery.
Methods: We considered data of 328 patients, each with multiple, elective, synchronous surgical problems treated by a SSC operation. By univariate and multivariate analysis we evaluated many *patient*-, *disease*- or *treatment*-related variables with respect to post-operative mortality, morbidity, and hospital stay.
Results: Two combined procedures were synchronously performed in 283 patients (86%), 3 combined procedures in 45 patients (14%). Post-operative mortality and morbidity rates were 3% and 24%, respectively, and median duration of hospital stay was 9 days. The occurrence of a surgical oncology procedure emerged as the most important independent risk factor for post-operative mortality and morbidity.
Conclusions: The safety of SSC surgery for the treatment of synchronous problems appears similar to that of multi-stage procedures. The understanding of risk factors for this surgical approach could be useful in order to improve patient selection.

1. Introduction

With the population aging in the Western world, the incidence of some age-related surgical diseases has continuously increased.[1] Additionally, the diffusion of cancer screening programs and the development of imaging techniques additionally allowed diagnosis of asymptomatic disorders in surgical patients.[2] Hence, today there is a relatively high incidence (approximately 10%) of patients requiring single-stage combined (SSC) surgery for synchronous problems.[3] In the present surgical environment, patients could be offered the convenience of a single operation and anesthesia (SSC approach) for combined multispecialty procedures. However, the trend towards surgical specialization typically leads a surgeon, even though capable of performing different types of surgery, to refer patients to another surgeon for any operation outside his subspecialization.[3] Furthermore, the present climate of litigation might be a contributing factor, and surgeons may feel safer if they confine their activity to a narrow procedural spectrum. Thus, the unknown potential hazards related to several surgical procedures performed at the same time made surgeons reluctant to introduce another subspecialty, even though they are competent in it. In the literature, there is already extensive documentation of the multispecialty workload of many surgeons working in rural or underdeveloped areas,[4,5] but this problem is spreading. To date, the well-known concomitant occurrence of abdominal aortic aneurysm and an abdominal malignancy does not represent the only therapeutic dilemma.[6,7] Multiple surgical diseases also occur synchronously, with increasing frequency, in the fields of cardiothoracic[8,9] and gastrointestinal (GI) surgery.[10–12]

The main controversy revolves around whether it is better to treat lesions with single-stage combined or with multi-stage (MS) procedures.

This retrospective study on a large series of SSC procedures aims to calculate the morbidity and mortality rates associated with the SSC approach and to identify the factors to be considered in selecting patients for this strategy.

2. Patients and methods

From January 1991 to December 2012, 328 patients (167 males, 161 females; median age 66 years, range 15–89 years) underwent SSC procedures. The present analysis excluded patients treated in emergency or day-surgery setting as these conditions significantly affect the diagnostic work-up and the surgical strategy. Combined surgical procedures performed for well-defined technical needs (e.g., splenectomy associated with distal pancreatectomy for cancer) were not considered.

For all patients medical records, surgical reports and pathologic data were reviewed.

2.1. End-points and risk factors

The end-points of this study were post-operative in-hospital mortality, morbidity (i.e. incidence of medical and/or surgical complications), and length of stay.

In order to detect the risk factors correlated with the end-points, *patient*-, *disease*-, and *treatment*-related variables were considered. *Patient*-related factors were age, gender, cardiovascular/pulmonary/diabetic comorbidities, prior major surgery, prior malignancies, and pre-operative hemoglobin level. *Disease*-related factors were POSSUM operative severity, [13] anatomical region (soft tissues, GI tract, vascular district, or other), and malignant origin. Finally, *treatment*-related factors were diagnosis time (pre-operative or intra-operative), operative time, surgical team (with or without subspecialty surgeon), number and kind of surgical accesses (minimally invasive approach, too), surgical contamination grade, [14] and anastomosis.

For each patient the combination of SSC procedures (and all the treated diseases) was analyzed. In order to obtain a total POSSUM operative severity for the procedure combination a numerical value was assigned to each difficulty grade (minor = 0; moderate = 1; major = 2; major + = 3).

2.2. Statistical analysis

Results were expressed as percentages and median with range. For analysis, continuous variables were categorized according to the median value. The associations between end-points and *patient*-, *disease*-, and *treatment*-related factors were analyzed by non-parametric tests, as appropriate. Adjusting the covariates with $p < 0.1$ at bivariate analysis, a stepwise logistic regression model was built to identify variables independently associated with end-points. The statistical analysis was performed with SPSS software for Windows©. All reported P values were two-sided. A P value < 0.05 was considered statistically significant.

3. Results

Patient characteristics (*patient*-related variables) are detailed in Table 1. A combination of two procedures was performed in 283 cases (86%) and a combination of three in 45 (14%). Median operative time was 150.5 minutes (range 40–540 minutes). One hundred and fifty patients (46%) underwent surgery for malignancy and in most cases diagnosis and surgical planning were obtained in the pre-operative phase. The first and the second procedures most frequently involved the GI tract, while the third almost always involved soft tissues. The distributions of *disease*- and *treatment*-related variables specified for individual procedures and for procedure combinations are reported in Tables 2 and 3, respectively.

Table 1
Distribution of patient-related variables

Variable	#	%
Age (years)		
⩽66		
	163	49.7
>66	165	50.3
Gender		
Males	167	50.0
Females	161	49.1
Cardiovascular/pulmonary/diabetic comorbidities		
Yes	286	87.2
No	42	12.8
Prior major surgery		
Yes	222	67.7
No	106	32.3
Prior malignancies		
Yes	55	16.8
No	273	83.2
Preoperative hemoglobin level (g/dl)		
⩽12	78	23.8
>12	250	76.2

Table 2
Distribution of disease- and treatment-related variables specified for any procedure

Variable	Number (%)		
	First procedure	Second procedure	Third procedure
Disease-related variables			
POSSUM operative severity			
Minor	36 (11)	116 (35.4)	26 (57.8)
Moderate	92 (28)	112 (34.1)	11 (24.4)
Major	124 (37.8)	59 (18)	5 (11.1)
Major +	76 (23.2)	41 (12.5)	3 (6.7)
Anatomical region			
Soft tissues	41 (12.5)	110 (33.5)	21 (46.7)
Gastrointestinal tract	226 (68.9)	192 (58.5)	20 (44.4)
Vascular district	34 (10.4)	19 (5.8)	3 (6.7)
Other	27 (8.2)	7 (2.2)	1 (2.2)
Malignancy			
Yes	124 (37.8)	65 (19.8)	7 (15.6)
No	204 (62.2)	263 (80.1)	38 (84.4)
Treatment-related variables			
Time of diagnosis			
Pre-operative	321 (97.9)	288 (87.8)	38 (84.4)
Intra-operative	7 (2.1)	40 (12.2)	7 (15.6)
Anastomosis			
Yes	115 (35)	44 (13.4)	6 (13)
No	213 (65)	284 (86.6)	40 (87)
Minimally invasive approach			
Yes	51 (15.5)	38 (11.6)	2 (4.4)
No	277 (84.5)	290 (88.4)	43 (95.6)
Contamination grade			
Clean	142 (43.3)	191 (58.2)	31 (68.9)
Clean-contaminated	186 (56.7)	137 (41.8)	14 (31.1)

In the post-operative period 9 out of 328 patients (3%) died and 80 patients (24%) presented at least one post-operative complication. With regard to these outcomes differentiated by subspecialty, post-operative mortality rate after (combined) soft tissue surgery was 1% (1 out of 172 procedures) versus 3% (15/438) and 5% (3/56) after (combined) GI surgery and vascular surgery, respectively; similarly, the complication rate after (combined) soft tissues surgery was 17% (30/172), versus 29% (126/438) and 25% (14/56) after (combined) GI surgery and vascular surgery, respectively.

The median length of post-operative stay was 9 days (range 1–57 days), with half of the patients (158/328, 48%) experiencing a stay >9 days.

There are no statistically significant differences relative to the end-points between patients who underwent two combined procedures and patients who underwent three combined procedures.

Table 3
Distribution of disease- and treatment-related variables specified for combined procedures

Variable	Combined procedures, # (%)
Disease-related variables	
POSSUM operative severity	
0–1	73 (22.3)
2–3	150 (45.7)
4–6	105 (32)
Surgical accesses	
1	221 (67.4)
2	105 (32)
3	2 (0.6)
Malignancies	
0	178 (54.3)
⩾1	150 (45.7)
Treatment-related variables	
Operative time	
⩽150 min	162 (49.4)
> 150 min	166 (50.6)
Anastomoses	
0	175 (53.3)
1	141 (43)
> 1	12 (3.7)
Minimally invasive approaches	
0	267 (81.5)
1	33 (10)
> 1	28 (8.5)
Surgical teams	
1	274 (83.5)
> 1	54 (16.5)
Subspecialty surgeon	
Yes	65 (19.8)
No	263 (80.2)

The results of univariate and multivariate analysis are presented in Table 4. The stepwise modality selected operative time, malignant origin and POSSUM operative severity associated with the treated diseases as independent predictive factors for post-surgical morbidities; operative time and malignancy were independent predictive factors for longer post-operative stay. Finally, the regression model calculated for mortality selected only malignant origin associated with the treated diseases as independent predictive factor.

4. Discussion

The concomitant occurrence of multiple surgical diseases still remains a therapeutic dilemma, mainly with respect to which should be treated first. The surgeon must take into account the single operative risks related to each single problem, to its planned therapy, and to its combined treatment. Hence, his reluctance to perform combined procedures has been based on concerns about the severity of diseases and surgery/anesthesiology-related risks. Therefore, in order to select the best surgical strategy for each patient, an accurate estimation of combined risks should be carried out before treatment planning. The increase of cases with simultaneous surgical diseases made the choice between SSC and MS surgery a frequent problem. While surgeons should not fall into temptation for an unnecessary SSC approach, malignancy (if associated with any other life-threatening surgical condition) could push them towards a combined treatment. [15]

On the one hand, multiple surgical approaches could potentially affect the patient's condition and allow progression of the untreated problems; on the other hand, in SSC surgery complications related to the surgical procedure for the minor disease could prevent or delay the planned multimodal treatment for the major one. Clinical practice nowadays is becoming increasingly specialized and the exponential diffusion of knowledge and technology induces patients to refer to specialists. These new advances in surgery mean that subspecialization may be an essential requirement for an optimal management of surgical diseases. Consequently, MS approaches by subspecialized surgical teams could be considered mandatory for simultaneous surgical problems. In contrast, for patients who undergo a SSC operation, there are significant savings in money, time, anesthesia and hospitalization. In a study including 233 patients Wilson showed how two, three and four minor procedures combined in SSC surgery resulted in time and expense savings for both patients and health-care providers. [3]

In the literature there are only a few minor retrospective studies about the SSC approach for multiple simultaneous diseases [6–12,15–37]: up to now, according to these experiences, SSC surgery has been considered a needed-treatment for an additional (most often malignant) disease discovered during a cardiothoracic or vascular operation. In fact, SSC surgery has been proposed already in the 1980s for combined treatment of pulmonary neoplasia and cardiac surgical disorders. [17,38] Several years later, Danton et al. rejected the initial concerns about oncological outcomes after SSC surgery for lung cancer, [9] stating that simultaneous pulmonary and cardiac surgery was associated with acceptable post-operative morbidity and mortality rates with similar long-term survival results.

The lack of homogeneity of patients with simultaneous surgical diseases precludes the design of any randomized trial in order to compare SSC surgery versus MS surgery. However, a few non-randomized studies with a control arm (also historical) of MS surgery have been presented. Luebke et al. compared patients who underwent simultaneous GI surgery and elective abdominal aortic reconstruction versus those who underwent exclusive aortic procedures. In this study, carried out through a matched-pair analysis, no differences were found for post-operative morbidity or mortality rate or for length of hospital stay, [16] but the relevance of its conclusions was weakened by the small sample size (only 42 patients in the SSC group).

In such a wide irregular range a retrospective study seemed to be a suitable analysis and a reliable method in order to reduce the impact of classification limits of these patients. Our analysis focused on identifying *patient*-, *disease*- and *treatment*-related factors predictive for an unfavorable outcome (morbidity, mortality, and hospital stay). In order to have a comparison for this type of surgery it is necessary to refer to the traditional (MS) surgical approach for each single disease (neoplastic or not).

In our series morbidity and mortality rates were 24% (80/328) and 3% (9/328), respectively. Since most procedures included major surgery, we can safely compare our results with historical data reported for major surgery. Although in our analysis it is impossible to define the specific morbidity and mortality for each single procedure, our findings are similar to those reported both for SSC procedures [15,17] and for MS surgery. [39,40]

According to our analysis of predictive factors for morbidity, mortality and hospital stay, no *patient*-related variables were independently associated with an unfavorable outcome. The direct association between older age and length of stay at univariate analysis was not confirmed in the multivariate model and this association could be affected by surgeons' caution towards elderly patients (Table 4).

Table 4
Univariate and multivariate analyses. Only variables included in multivariate models are reported.

Variable	Patients with complications				Deaths				Hospital stay >9 days			
	#	Univariate	Multivariate		#	Univariate	Multivariate		#	Univariate	Multivariate	
			OR[a]	*p*			OR[a]	*p*			OR[a]	*p*
Patient characteristic												
Age												
⩽66 years	33/163	0.082	–	–	4/163	0.583	–	–	65/163	0.003	–	–
>66 years	47/165				5/165				93/165			
Gender												
Male	47/167	0.107	–	–	4/167	0.466	–	–	89/167	0.059	–	–
Female	33/161				5/161				69/161			
Previous major surgery												
Yes	62/222	0.031	–	–	8/222	0.168	–	–	107/222	0.481	–	–
No	18/106				1/106				51/106			
Procedure combination												
Teams												
1	75/274	0.004	–	–	9/274	0.217	–	–	137/274	0.135	–	–
>1	5/54				0/54				21/54			
Operative time												
⩽150 min	16/162	<0.001	1	<0.001	0/162	0.003			46/162	<0.001	1	<0.001
>150 min	64/166		12.126		9/166		–	–	112/166		10.126	
Accesses												
1	66/221				7/221				134/221		–	–
2	14/105	0.004	–	–	2/105	0.312	–	–	23/105	<0.001		
3	0/2				0/2				1/2			
Minimally invasive												
0	77/267				9/267				155/267			
1	1/33	<0.001	–	–	0/33	0.432	–	–	1/33	<0.001	–	–
>1	2/28				0/28				2/28			
Malignancies												
0	32/178	0.001	1	0.006	3/178	<0.001	1	0.033	51/178	<0.001	1	0.008
⩾1	48/150		14.018		6/150		6.011		107/150		13.941	
Contamination grade												
0	11/80				0/80				22/80	<0.001	–	–
1	46/173	0.027	–	–	8/173	0.079	–	–	85/173			
>1	23/75				1/75				51/75			
POSSUM operative severity												
0–1	3/73		1		0/73				6/73		–	–
2–3	42/150	<0.001	4.532	0.002	2/150	<0.001	–	–	73/150	<0.001		
4–6	35/105		6.887	0.369	7/105				79/105			
Anastomoses												
0	24/175				2/175				51/175			
1	51/141	<0.001	–	–	6/141	0.221	–	–	97/141	<0.001	–	–
>1	5/12				1/12				10/12			

[a] OR, odds ratio.

With regard to *disease*-related factors, the POSSUM operative severity significantly affected the post-operative findings in patients who underwent combined surgery, in accordance with well-known data.[13,41] The length of stay, as well as the complication rate, increased along with the severity of the procedure (Table 4). More significantly, oncological surgical indication increased the morbidity and the mortality rates: the inclusion of an oncological surgical procedure among the combined ones represented the only independent variable for mortality and the one with the strongest impact on morbidity and length of stay (Table 4).

While the identification of *disease*- and *patient*-related variables associated with outcome may yield useful criteria for selecting patients for SSC surgery, the identification of *treatment*-related predictive factors should be able to provide reliable criteria for choosing the most suitable surgical strategy. Among all the *treatment*-related factors, contamination level of the surgical procedure and operative time mainly affected the post-operative outcome. Contamination of the surgical field emerged as a significant predictive factor both for morbidity and for length of hospital stay after surgery (Table 4). With regard to the operative time, a combined surgical operation exceeding 150 minutes seemed to present a higher risk of post-operative complications and longer stay. This result seems to counter the apparently protective effect identified at univariate analysis for minimally invasive surgery, which generally requires longer operative time. On the other hand, the same remark could lead the surgeon to MS strategy, especially after an inappropriate preoperative planning. Similarly, the same surgical team could be reluctant to afford different surgical subspecialities in order to avoid longer operative time.

To the best of our knowledge, this study represents the first attempt to identify predictive factors for post-operative outcome after SSC surgery. However, it was biased by some unavoidable limitations: firstly, the sample was recruited retrospectively; hence, many data were missing or inappropriate and much information has been excluded. Secondly, we did not use any control group for comparison: even though this choice allowed us to minimize selection bias in our analysis, it obliged us to refer to historical data from published reports. Thirdly, the analyzed sample was very heterogeneous and we rigorously classified patients otherwise unclassifiable; this weakened the efficacy of our results and did not allow us to outline well-defined suggestions.

Nevertheless, we can reasonably give some warnings to consider before SSC surgical planning. Post-operative morbidity and mortality of SSC surgery are acceptable and comparable to MS surgery. However, the best surgical strategy for patients with simultaneous elective surgical diseases should be defined out of the operative room in order to avoid any improvisation.

In order to select low-risk patients, particular attention must be paid to oncological indication, POSSUM operative severity, contamination grade, and operative time. A patient with more than one unfavorable condition related to these factors could benefit from MS surgery.

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