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Prospective validation of a surgical complications grading system in a cohort of 2114 patients

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ABSTRACT

Background: We recently reported a grading system for surgical complications. This system proved to have a high sensitivity for recording minor but meaningful complications prolonging hospital stay in patients after colorectal surgery. We aimed to prospectively validate the complication grading system in a general surgery department over 1 year.

Methods: All surgical procedures and related complications were prospectively recorded between January 1st and December 31st, 2009. Surgical complications were graded on a severity scale of 1-5. The system classifies short-term outcome by grade emphasizing intensity of therapy required for treatment of the defined complication.

Results: During the study period, 2114 patients underwent surgery. Elective and oncological surgeries were performed in 1606 (76%) and 465 (22%) patients, respectively. There were 422 surgical complications in 304 (14%) patients (Grade 1/2: 203 [67%]; Grade 3/4: 90 [29%]; Grade 5: 11 [4%]).

Median length of stay correlated significantly with complication severity: 2.3 d for no complication, 6.2 and 11.8 d for Grades 1/2 and 3/4, respectively ($P < 0.001$). Older age (OR 2.75, $P < 0.001$), comorbidities (OR 1.44, $P = 0.02$), American Society of Anesthesiology score >2 (OR 2.07, $P < 0.001$), contamination Grade (OR 1.85, $P = 0.001$), oncological (OR 2.82, $P < 0.001$), open (OR 1.22, $P = 0.03$), prolonged >120 min (OR 2.08, $P < 0.001$), and emergency surgery (OR 1.42, $P = 0.02$) independently predicted postoperative complications.

Conclusions: This system of grading surgical complications permits standardized reporting of surgical morbidity according to the severity of impact. Prospective validation of this system supports its use in a general surgery setting as a tool for surgical outcome assessment and quality assurance.

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1. Introduction

You can't manage what you can't measure
William Hewlett.

Operative morbidity and mortality are the most frequently relied on performance measures of the quality of surgical care and vary considerably across the globe. A comparable, validated system to classify and report surgical morbidity using agreed on definitions and conventions would be an important addition to health care and concerted efforts to improve the quality and value of care. In 2004, the Clavien–Dindo grading system was published and revolutionized complication reporting [1]. The grading system shifted the focus from the mere presence of a complication to the grade of the complication as a function of the resulting outcome. Despite its wide acceptance, the Clavien–Dindo grading system intentionally does not refer to specific complications but rather provides a tool that can be adapted and applied to any given complication. The generality of the grading system is both an advantage and an Achilles' heel as at times the exact grade is not readily apparent.

Based on the same principle of a five-tiered grading system proposed by Clavien and Dindo, and by using the Common Terminology Criteria for Adverse Events version 3.0 classification system, we developed a more specific and detailed surgical complication reporting system [2]. The surgical complications recorded as part of a five-grade morbidity and mortality system are a modification of Clavien's original classification system, which emphasizes the intensity of therapy required for the treatment of the defined surgical complication. Each complication was detailed and the specific grade was outlined in a table. This simplified the reporting of the complications and increased its accuracy. We retrospectively evaluated this system on a cohort of patients that underwent colorectal resections and found that the system had a high sensitivity for recording minor but meaningful complications that were associated with increased hospital resource utilization and prolonged length of hospital stay (LOS) [2].

After our initial experience with capturing colorectal surgery complications, we significantly modified our reporting system to include more potential surgical complications that cover the entire spectrum of procedures performed at our Department of Surgery and decided to validate it in a prospective trial. The aim of this study was to prospectively validate the grading system on all procedures performed in a teaching institution's general surgery department over 1 year.

2. Methods

Before the initiation of the study, we revised our previously published surgical complication grading system to include all potential postoperative surgical complications. Combining the Common Terminology Criteria for Adverse Events system with systematic review of surgical complications reported in our institution over a period of 5 y, we generated a table including all potential surgical complications grouped by physiology–anatomy systems, coded, and each complication was divided into a five-tiered scale severity grading (Appendix A). The table was printed as a pocket book, laminated, and distributed to all of the department's surgical staff during a study initiation meeting with detailed explanations on its proper use. The study protocol was reviewed and approved by the Hadassah Medical Center Institutional Review Board (Helsinki Committee), protocol No. HMO_0646-08 (NCT01168193).

2.1. Procedures and patients

All surgical procedures performed at the Department of Surgery, Hadassah-Hebrew University Medical Center, Mount Scopus between January 1st and December 31st, 2009 were prospectively recorded and classified according to the International Classification of Diseases 9 codes. Data were verified by the study coordinator with the International Classification of Diseases 9 reported by the operating room personnel for billing purposes. Operative details included type of surgery, surgical approach (laparoscopy *versus* open), emergency *versus* elective procedure, and presence of oncological indication. Patients' demographics, American Society of Anesthesiology (ASA) score, current medications, and comorbid conditions were also recorded.

2.2. Complication recording

Complications were defined as secondary events (or unintended consequences) deviating from the ideal course of convalescence that occurred after the operation, resulting in changes in management (diagnostic or therapeutic intervention) and delay in complete recovery and or planned subsequent therapy, or chronic disability. This broad definition also includes asymptomatic documented complications. Complications that occurred during admission were recorded by the department staff on a daily basis. Inpatients were evaluated daily by the surgical staff and any complication encountered was classified and graded according to the table. On discharge, each patient was given a spreadsheet to be filled by a surgeon or a nurse at the follow-up clinic recording the presence of a complication or several complications, its code according to the table, and its severity. All complications were recorded in a computerized database designed for the study.

Data were collected for 30 postoperative days and analyzed by the patients' characteristics, procedure performed, complication code and grade, and hospital LOS.

To include all surgical complications, a study coordinator retrospectively reviewed all procedures performed and all patients not reported to have a complication were contacted by the medical staff and either interviewed or examined at the follow-up clinic. The study coordinator had access to the complications previously reported by the surgeons and documented complications that were not captured by the staff.

Preexisting medical conditions that did not change over the hospital course were not considered as adverse events. All

complications were classified, coded, and graded by severity according to the "Surgical Complications Severity Scoring System."

Grade 1 included minor, asymptomatic complications that did not require medical therapy or radiological nor surgical intervention (e.g., bedside wound care).

Grade 2 complications were defined as complications requiring pharmacologic therapy or any minor interventions (e.g., intravenous therapy, transfusions, or total parenteral nutrition [TPN]).

Grade 3 complications were defined as complications treated by invasive procedures other than surgery including interventional radiology or endoscopy (e.g., operative drainage of an abscess).

Grade 4 included complications that required surgical intervention and complications resulting in permanent loss of function of an organ (e.g., reduction in performance status after postoperative respiratory failure).

Grade 5 included complications resulting in death.

Any death occurring within 30-days of operation or during the same hospitalization was considered perioperative mortality. Hospital and intensive care unit length of stay as well as disposition at discharge (discharge home, to assisted living or to rehabilitation facility and death) were recorded, and calculated from the time of first operation to discharge or death.

2.3. *Statistical analysis*

Summary statistics were performed using established methods. Association between categorical factors was studied with Fisher exact test or Chi-square test, as appropriate. Association between noncategorical (continuous) variables was performed using Student *t*-test. The clinical outcomes studied were perioperative morbidity and mortality. For this study, any morbidity or mortality occurring during or within 30-days of operation were considered. To assess the independent predictive effect of a covariate for a nominal response, a logistic regression model was constructed and parameters estimated using maximum likelihood. Only those factors identified to be potentially significant ($P < 0.05$) on categorical contingency analysis were entered into the multivariate model to determine the independent prognostic effect of these variables. The Wald test statistic was computed for each effect in the model. Confidence limits and odds ratios were calculated for the maximum likelihood parameter estimates. Statistical Package for the Social Sciences package version 17.0 (SPSS Inc, Chicago, IL) was used for statistical analysis. Two-sided *P* value <0.05 was considered significant.

3. Results

Between January 1st and December 31st, 2009, 2114 patients underwent surgery at the Department of General Surgery. The median age was 47 y (range 18–100) and 55% were females. The three most common procedures were abdominal wall hernia repair (17%), laparoscopic cholecystectomy (13%), and breast surgery (12%). The majority of the patients underwent elective surgery (76%) and oncological indication for operation was documented in 22%. Most of the patients had an ASA score of 1–2 (86%) and only 14% had a score ≥3. Laparoscopic surgery was performed in 42% of the patients and surgery was defined as clean in 53%, clean-contaminated in 34%, contaminated in 6%, and infected in 7%. Median operative time was 56 min (range 22–800 min) and the medial length of hospital stay was 1 d (range 0–108 d).

A total of 422 complications were documented in 304 patients (14%; 1.4 complications per patient). A total of 1810 patients (86%) had no 30-day operative morbidity. A single complication was observed in 73% of the patients, two complications in 17%, three complications in 8%, and only 2% had four complications. Table 1 details the comparison between patients with and without complication.

Minor complications (Grades 1 and 2) accounted for 67% (203/304) of the complications. Superficial surgical site infections (SSI) were the most frequent Grades 1 and 2 complications (18/63, 24% and 37/140, 26%, respectively). Grade 3 and 4 ("major") complications represented 29% (90/304) of all perioperative morbidity. Deep SSI and anastomotic leak treated both with drainage represented the most common

Table 1 – Patient demographics according to the presence or absence of complications.

Variable	No complication	Complication	*P* value
Gender			
Female	998 (86%)	165 (14%)	0.68*
Male	822 (87%)	129 (13%)	
Age (mean, y)	46 ± 0.4	53 ± 1.1	<0.001†
Comorbidities			
0	901 (88%)	118 (12%)	0.002*
1–3	714 (83%)	147 (17%)	
4+	205 (88%)	29 (12%)	
Indication			
Benign	1472 (89%)	182 (11%)	<0.001*
Malignant	348 (76%)	112 (24%)	
Urgency			
Elective	1368 (85%)	241 (15%)	0.01*
Emergency	452 (90%)	53 (10%)	
ASA			
1 + 2	1588 (89%)	206 (11%)	<0.001†
≥3	227 (79%)	60 (21%)	
Contamination level			
Clean	979 (87%)	143 (13%)	0.002†
Clean-contaminated	601 (83%)	120 (17%)	
Contaminated	101 (82%)	22 (18%)	
Septic	139 (94%)	9 (6%)	
Surgical approach			
Open	746 (86%)	125 (14%)	0.03†
Laparoscopy	1074 (89%)	136 (11%)	
Operation time (mean, min)	68 ± 1.4	168 ± 8.4	<0.001*
Hospital stay (mean, d)	2.3 ± 0.1	8.38 ± 0.5	<0.001*

*T-test for independent samples.
†Chi-Square.

Table 2 – The ten most common complications and their prevalence among different procedure categories.

Category	No. of cases	S-1 G2 N = 37	S-1 G1 N = 18	G-11 G2 N = 15	G-6 G1 N = 15	R G2 N = 14	B-2 G1 N = 14	G-11 G3 N = 12	P-2 G2 N = 12	GU-5 G1 N = 12	S-1 G3 N = 11
Hernia	366	6	1				2			5	1
Gallbladder	281	1	3			3	2		1	1	2
Breast	256	8					6				
Bariatric	236	1		1		4	2		7	1	
Appendix	226	5	1	7	2	5		5		1	1
Anus and perianal	167								1		
Colorectal	130	3	8	4	11	1		3	2	1	1
Thyroid and parathyroid	112					1	1				
Melanoma	68	6					1				4
Exploratory laparotomy	62		2							2	
Skin and subcutaneous	44	1	1								1
Thoracoscopy	24										
Stomach	19	1	1	1				2	1	1	1
Liver	17			1							
Small intestine	15	1									
Pancreas	12	3	1	1	1			1			
Esophagus	10	1			1			1			
Other	69										

B-2 = hemorrhage; G-6 = intestinal obstruction; G-11 = anastamotic leak; GU-5 = urinary retention; P-2 = pneumonia; R = readmission (without mention of a specific complication); S-1 = surgical site infection.

Grade 3 morbidity (11/45, 24%, each). Anastomotic leak treated with surgery comprised the largest proportion of Grade 4 morbidity (7/45, 16%). The overall 30-day mortality rate was 0.5% (11/2114) and it accounted for 3.6% of the complications (11/304). Attributable causes were aspiration pneumonia ($n = 6$, 55%), myocardial infarction ($n = 3$, 27%), anastomotic leak ($n = 2$, 18%), and pulmonary embolism ($n = 1$, 9%).

The most common complication was superficial SSI (code S-1) that occurred in 6% (120/2114) of the patients and accounted for 28% (120/422) of all documented complications. This was followed by postoperative hemorrhage requiring blood transfusion (code B-2) that occurred in 1% (29/2114) of the patients and accounted for 7% (29/422) of all complications. The 10 most common complications by code for each category of surgical procedures are outlined in Table 2.

Table 3 – Correlation of clinical factors and postoperative surgical complications.

Variable	Odds ratio	95% CI	P value
Female gender	0.91	0.71–1.16	0.63
Open surgical approach	1.22	1.05–1.65	0.04
Emergency surgery	1.42	1.08–1.87	0.02
Comorbidities (>3)	1.44	1.18–1.78	0.02
Contamination level (Contaminated/dirty)	1.85	1.37–2.33	0.001
ASA score (>2)	2.07	1.51–2.82	<0.001
Prolonged procedures (>120 min)	2.48	1.87–3.21	<0.001
Age>60 y	2.75	2.12–3.48	<0.001
Malignant indication	2.82	2.18–3.65	<0.001

CI = confidence interval.

The impact of various patient-related and procedure-related parameters on the occurrence of complications was studied (Table 3). Advanced age, number of comorbidities, ASA score, operations for malignancy, degree of contamination within the operative field (wound classification), open, and emergency surgery were the independent predictors of operative morbidity.

To better understand the complication distribution, we analyzed the complications according to procedure type. The three surgical procedures associated with the highest rate of complications are pancreatic resections (75%), colorectal resections (50%), and gastric resection for malignant disorder (47%). Surgical procedures with the lowest complication rate were anal and perianal surgeries (0.6%), thoracoscopy (4%), and hernia repair (6%). All procedures with their related complications are outlined in Table 4.

The incidence of complications by grade is depicted in Figure 1. The correlation between complication severity grade and length of hospital stay was also studied. There was significant association between the presence of a complication and its grade to the length of hospital stay. Importantly, even patients with Grade 1 complications had a significantly longer LOS compared with patients with an uneventful hospital course (Fig. 2).

We compared the complications prospectively reported by the surgeons with the complications retrospectively collected by the study coordinator (Table 5). Overall, there were significantly more complications (43% increase) identified by the retrospective methods used by the study coordinator compared with the prospective reporting by the department's

Table 4 – Procedure group and their related complications by grade.

Procedure *n* (%)		Complications			
		Grades 1 and 2	Grades 3 and 4	Grade 5	Total
Hernia	366 (17%)	18 (5%)	4 (1%)	–	22 (6%)
Gallbladder	281 (13%)	20 (7%)	14 (5%)	2 (0.7%)	36 (13%)
Breast	256 (12%)	18 (7%)	7 (3%)	–	25 (10%)
Bariatric	236 (11%)	23 (10%)	8 (3%)	1 (0.4%)	32 (14%)
Appendix	226 (11%)	31 (14%)	9 (4%)	–	40 (18%)
Anus and perianal	167 (8%)	–	1 (0.6%)	–	1 (0.6%)
Colorectal	130 (6%)	38 (30%)	24 (18%)	3 (2%)	65 (50%)
Thyroid and parathyroid	112 (5%)	8 (7%)	–	–	8 (7%)
Melanoma	68 (3%)	11 (16%)	6 (9%)	–	17 (25%)
Exploratory laparotomy	62 (3%)	6 (10%)	4 (6%)	1 (2%)	11 (18%)
Skin and subcutaneous	44 (2%)	3 (7%)	1 (2%)	–	4 (9%)
Thoracoscopy	24 (1%)	1 (4%)	–	–	1 (4%)
Stomach	19 (0.9%)	5 (26%)	3 (16%)	1 (5%)	9 (47%)
Liver	17 (0.8%)	3 (18%)	2 (12%)	1 (6%)	6 (35%)
Small bowel	15 (0.7%)	1 (7%)	–	–	1 (7%)
Pancreas	12 (0.6%)	4 (33%)	4 (33%)	1 (8%)	9 (75%)
Esophagus	10 (0.5%)	3 (33%)	1 (10%)	0	4 (40%)
Other	69 (3%)	3 (4%)	–	–	3 (4%)

surgeons at our institution. This difference was the highest for Grade 1 complications (110%) and diminished as the complications grade increased (10% for grade 5).

4. Discussion

As part of the quality assurance (QA) program in our institution, we embarked on a strategy of long-term reduction in surgical complications. Our initial goal was to adopt a reliable system for measuring and reporting complications. The lack of uniform and detailed system accepted by most surgeons drove us to develop our own classification system. The process was initially studied retrospectively, the system improved until it was ready for this prospective trial. In the present study, we documented, classified, and graded all surgical complications occurring during 1 y in a general surgery department. Our classification and grading system was developed based on an existing principal, underlying many complications grading systems used for clinical trials and organ specific surgery [1,3–7]. After a retrospective, proof of concept study in a cohort of patients who underwent colorectal resections [2], the system was modified and expanded. Our classification and grading system was substantially modified to include all the complications encountered after a large variety of surgical procedures performed at our department. More than 160 different complications were included and were grouped by physiology–anatomy systems (Appendix A). Our system can be adapted by all institutions at no cost and easily modified to cover specific services at minimal effort by any surgeon.

Once again we learned that the sensitivity of our grading system is significantly higher in capturing minor; however, meaningful complications. As a result, we report a 75% and 50% complication rate for pancreatic and colorectal surgeries, respectively. Most of the complications were Grade 1 or 2 complications, and the rate of grade 3–5 complications is comparable with the reported rate in the literature [4,8–13]. The postoperative complication risk factors that were identified in this study are similar to what have been described in other studies [14–18]. As expected, we found that older age, higher ASA score, presence of comorbidities, oncologic

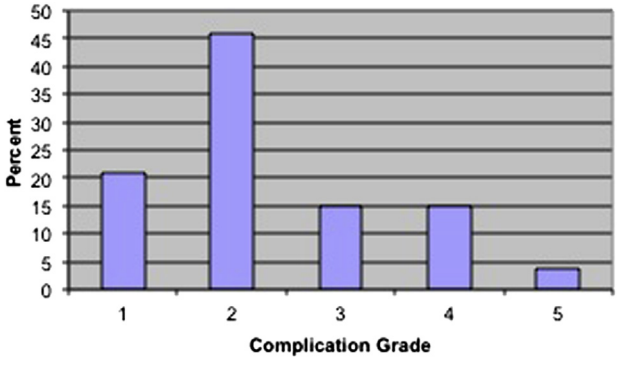

Fig. 1 – Complication incidence by grade. (Color version of figure is available online.)

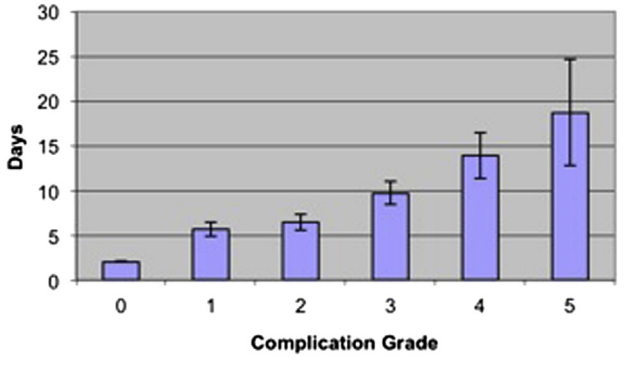

Fig. 2 – Association between length of stay and complication's grade ($P < 0.0001$). (Color version of figure is available online.)

Table 5 – Comparison between number of complications prospectively collected by surgeons using the grading reporting system and the number of complications retrospectively collected by the study coordinator.

Reporting modality	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
MD reporting	30	98	36	38	10	212
Study coordinator reporting	63	140	45	45	11	304
Percent increase in complication reporting	110%	42%	25%	18%	10%	43%

indication, open surgery, higher contamination level, and emergent procedures were all associated with increased complication rate.

An important finding that cannot be underscored enough is the association between Grade 1 or 2 complications and an increased hospital LOS (Fig. 2). This association has also been reported in our previous study and similarly identified by other studies as well [2,19–21]. This difference directly translates to increased costs as presented by Hemmila *et al.* [20] that reported that median hospital charges increased from $33,833 to $81,936 for trauma patients with no and minor complications, respectively. Although Grade 2 complications require some interventions and therefore are expected to increase LOS, the role of Grade 1 complications (no intervention required) needs to be further elucidated. We believe that Grade 1 complications represent an underlying factor that although may not require immediate therapy, affect the overall postoperative course. Moreover, a significant proportion of the patients with Grade 1 complication had either more than one Grade 1 complication (27%) or another higher-grade complication (17%).

To capture all complications and adverse events, we designed the study to include a dual data capturing system. Using surgeons and nurses reporting complications with a simple form designed for the study and a systematic data retrospective capture by a study coordinator. There was a significant difference (43%) between the complication rate reported by the department's staff and the actual complication rate captured systematically by reviewing every patient chart and actively interviewing all patients. Although the prospective data collected by the department's staff was available to the study coordinator, this only partially explains the significant difference between the reporting systems. Another limitation is that this methodology prevented us from performing inter-rater reliability comparison.

This difference in reporting of adverse events was shown in other studies, a systematic capture of postoperative complications resulted in an increased complication rate [4,7]. Under-reporting by the department's staff was more evident for minor complications (grade 1–2) with a reporting increase of 59% for such complications. In both our previous and present studies, the rate of minor complications observed was higher than the rate reported in the literature and in both studies, minor complications were associated with longer hospital stay. The fact that surgical complications with clinical and financial significance are under-reported by many, suggests that to improve quality of care, a QA personnel should be an integral part of every surgical service with the aim of capturing and reporting all complications periodically. This will allow performance improvement over time. Although the costs of distributing the complication table to the staff are negligible, the expenses associated with QA personnel vary dramatically between countries and may pose a financial burden to the implementation of such setup at all medical centers.

To benchmark performance over time or to compare between different institutions, a unified and acceptable coding system should be adopted. Using the same system will allow measurement over time with unified reporting and will align all institutions involved in a quality improvement program to "speak the same language." Using a web-based system will allow surgeons and institutions to compare outcomes with others using the same nomenclature. The Accordion system, developed by the Department of Surgery, Washington University St. Louis, offers an easy access Web site for reporting surgical complications [22]. However, their system, producing processed tables and graphs, is best suited for reporting clinical trials and does not provide the user with a coding system that can be used within an institution over time or to compare performance with other institutions.

Although multiple modifications were made to this grading system as a result of lessons learned from the clinical trials we conducted, it is still far from being perfect. We did not include complications related to transplant surgery, trauma surgery, vascular surgery, and many other subspecialties. We also have not developed the system to cover emergency and trauma services. Delayed or missed diagnosis should be considered a complication and, in the future, we will have to revise our system to include and accurately measure delay in diagnosis. Furthermore, intraoperative complications were not included. Developing an all-inclusive complication grading system will probably require the joint forces of international experts from different surgical practices.

5. Conclusions

In this prospective single-arm study, we proved once again that minor complications that are usually under-reported have clinical significance. We conclude that by coding and grading each complication, we were able to develop a system that may serve individual surgeons and institutions to compare outcomes over time using the same nomenclature. Further improvement can be achieved by addressing the whole variety of surgical services in the elective and emergency surgery.

Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.jss.2013.12.004.

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