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

*Haggi Mazeh, MD, Oded Cohen, MD, Ido Mizrahi, MD, Tamar Hamburger, BA, Alexander Stojadinovic, MD, Bassam Abu-Wasel, MD, Bilal Alaiyan, MD, Herbert R. Freund, MD, Ahmed Eid, MD, and Aviram Nissan, MD**

Department of Surgery, Hadassah-Hebrew University Medical Center, Mount Scopus, Jerusalem, Israel

ARTICLE INFO

Article history:
Received 19 September 2013
Received in revised form
19 November 2013
Accepted 6 December 2013
Available online 13 December 2013

Keywords:
Complications
Adverse events
Surgery
Severity score
Morbidity
Length of stay

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.

* *Corresponding author*. Department of Surgery, Hadassah-Hebrew University Medical Center, Ein Kerem, POB 12000, Kyriat Hadassah, Jerusalem, Israel, 91120. Tel.: +9 722 677 9500; fax +9 722 677 9510.
E-mail address: anissan@hadassah.org.il (A. Nissan).
0022-4804/$ – see front matter
http://dx.doi.org/10.1016/j.jss.2013.12.004

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