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Introduction of Surgical Safety Checklists in a Private Hospital in Mexico City, Does It Really Make a Difference?

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Abstract

Background: Evidence from observational studies on the use of surgical safety checklists with improvements in surgical outcomes quickly led to the rapid adoption of these lists worldwide.

Methods: A retrospective analysis was performed in which operative mortality, surgical complications rate, duration of hospital stay and readmission to hospital or emergency department within 30 days after discharge were compared among patients undergoing laparoscopic surgery before and after the adoption of the checklist.

Results: In the 3 months period before and after the adoption of the surgical safety checklist, 507 laparoscopic procedures were performed (274 without list and 233 with list). There were 57 (11.2%) complications in total. In the risk analysis for 30 days readmission, the following were observed for patients without checklist RR 1.4 (0.90 to 2.23 IC 95%) and for patients with checklist RR 0.73 ((0.54 to 0.98). 95% CI). For complications, it was observed for patients without checklist RR 1.2 (0.89 to 1.62 IC 95%) and for patients with checklist RR 0.82 (0.63 to 1.06 IC 95%).

Conclusion: The implementation of the surgical safety checklist was associated with a decrease in the number of complications and readmission at 30 days regardless of the score of the surgical complications scales.

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Introduction

Several types of untoward incidents can occur in the operating room; some are minor, others major and most are preventable avoidable [1]. A systematic review has shown that 1 in every 150 patients admitted to a hospital dies as a consequence of an adverse event and that almost two thirds of in-hospital events are associated with surgical care [2]. With the aim of improving patient safety following surgery, a checklist was developed by the WHO patient safety program. The list consists of 19 items and is used at three critical perioperative moments: induction, incision and before the patient leaves the operating room [3]. A study published in 2009 showed that implementation of the 19 items World Health Organization (WHO) surgical safety checklist substantially reduced the rate of surgical complications, from 11.0% to 7.0%, and reduced the rate of in-hospital death from 1.5% to 0.8% [4]. The WHO estimated that at least 500,000 deaths per year could be prevented through worldwide implementation of this checklist [5]. In recognition of the disproportionate number of such events that are associated with surgical care, several interventions have been proposed to increase patient safety, including relegating surgical procedures to high volume centers, establishing training programs for laparoscopic surgery, and improving the quality of team work in the operating room [6-8]. The Safe Surgery Saves Lives Study Group at the World Health Organization (WHO) recently published the results of instituting a perioperative surgical safety checklist [4]. The use of this checklist in eight hospitals around the world was associated with a reduction in major complications from 11.0% before introduction of the checklist to 7.0% afterward. However, the standardization of surgical processes should not be limited to the operating room: several studies have shown that the majority of surgical errors (53% to 70%) occur outside the operating room, before or after surgery, making it likely that a more substantial improvement in safety could be achieved by targeting the entire surgical pathway [9-11]. This awareness has led to the development of the Surgical Patient Safety System (Surpass) checklist, a multidisciplinary checklist that follows the surgical pathway from admission to discharge. The absence of consensus within the surgical community on the best way to report surgical complications has hampered proper evaluation of the surgeon's work and possibly progress in the surgical field. In 1992, Clavien et al. [12] proposed a classification of complications, which has subsequently been used for outcome assessment. The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) collects high-quality, standardized clinical data on preoperative risk factors and postoperative complications [13-16]. These data are used to provide hospitals with risk-adjusted 30 days outcomes comparisons, and we have previously leveraged these data to develop a risk prediction tool. We evaluated the effect of the use of this checklist on patient outcomes in our hospital that has high baseline standards of health care.

Methods

Overview

A retrospective analysis was performed and we analyzed the outcomes of surgical laparoscopic procedures performed 3 months before and after the adoption of surgical safety checklists, using the hospital health data. The study was approved by the research ethics board of Medica Sur Hospital.

Surgical procedures

We included all surgical laparoscopic procedures performed during each study interval. Some patients underwent more than one surgical procedure in one period; we limited the analysis to the first procedure.

Outcomes

Operative mortality, defined as the rate of death occurring in the hospital or within 30 days after surgery regardless of place, was the primary outcome. We used administrative data to assess the rates of complications occurring within 30 days after surgery. We also assessed length of hospital stay, rates of readmission within 30 days after discharge, and rates of emergency department visits within 30 days after discharge.

Covariates

We measured comorbidity using the NSQIP and Clavien-Dindo scales. We also assessed attributes of the surgical intervention: admission category (ambulatory or inpatient), procedure status (emergency or elective), and month performed.

Statistical analysis

In the analysis of the effect of checklists on surgical outcomes, we used generalized estimation equations to adjust for possible confounding factors and account for the grouping of observations within the hospital (Table 1). We used generalized Poisson models for estimating length of stay for patient procedures and binomial models (logistic regression) for other outcomes. Adjusted risks were estimated by using the average value of each adjustment variable in the study population (age, sex, procedural status, [emergency or elective surgery], admission category [hospitalized *vs.* ambulatory patients], procedure type, month of surgery, and the comorbidity score). To explore the associations between other variables and surgical outcomes, analyzes were also carried out with the adjustment of all these factors. A priori, five subgroup analyzes were planned to examine the effect of introducing a surgical safety checklist in the subgroups defined by age, sex, type of procedure. To test if the checklist had some kind of effect on different subgroups, we performed the adjustment with a generalized linear model for each subgroup analysis, with an interaction term specifying the joint effect

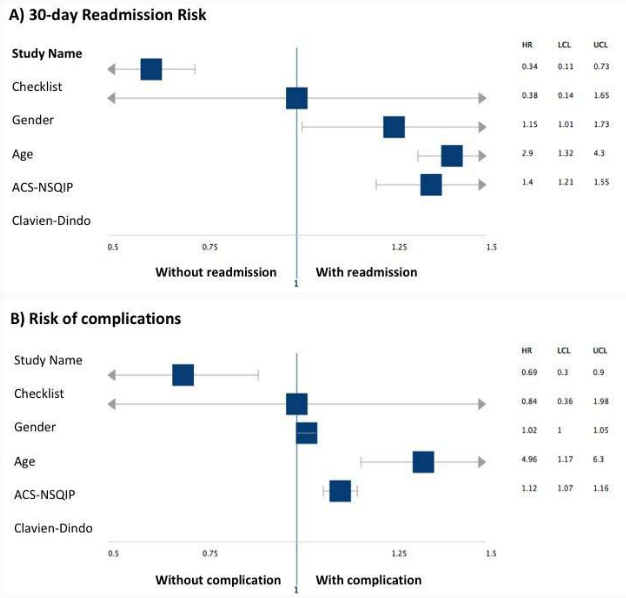

Figure 1: Hazard Ratios for 30 day readmission risk and risk of complications Stratified According to Age, Gender, ACS-NSQIP and Clavien-Dindo. Adjusted effect sizes for 30 day readmission risk (Panel A) and risk of complications (Panel B) in each stratum were estimated with the use of generalized linear models, with adjustment for all variables shown except the stratification variable.

Table 1: Characteristics of Patients before and after Implementation of the Surgical Safety Checklist.

General Characteristics of Patients			
	Before Implementation	After Implementation	P Value
No. of patients	274	233	0.08
Mean length of stay (days)	3.08 ± 3.05	4.13 ± 3.46	0.43
Mean age (year)	43.5 ± 16.03	43.6 ± 17.5	0.54
Male sex (%)	45.6	39.5	0.12
ACS-NSQIP (%)	2.7 % ± 1.8%	2.8% ± 1.5 %	0.17
Clavien Dindo	5.2 ± 6.16	6.2 ± 7.99	0.13

of the checklist and the subgroup, adjusting for all other variables of the subgroup, except those that define the analysis of subgroups. All the p values reported are double-tailed. P values less than 0.05 were considered statistically significant. In addition, an adjustment was made using 2 scales of surgical complications (NSQIP and Clavien-Dindo).

Results

In the 3 months period before and after the adoption of the surgical safety checklist, 507 laparoscopic procedures were performed (274 without list and 233 with list). (57.2%) were women. The most frequent procedures were: laparoscopic cholecystectomy 251 (49.5%) and laparoscopic appendectomy 146 (28.8%). 290. No death was recorded in this period of time. There were 57 (11.2%) complications in total (Table 2), the most frequent complications were: Pneumonia 11 (18.6%) and Conversion to Laparotomy 9 (15.3%). In the risk analysis for 30 days readmission, the following were observed for patients without a RR 1.4 checklist (0.90 to 2.23 IC 95%) and for patients with a RR 0.73 checklist ((0.54 to 0.98). 95% CI). For complications, it was observed for patients without a checklist RR 1.2 (0.89 to 1.62 IC 95%) and for patients with a checklist RR 0.82

Table 2: Type of complications.

Type of complications	Frequency	Percentage
Pneumonia	11	18.6
Conversion to Laparotomy	9	15.3
Abscess	6	10.2
Surgical wound infection	5	8.5
Urinary tract infection	4	6.8
Clostridium Difficile	3	5.1
Ileus	3	5.1
Pancreatitis	3	5.1
Pulmonary thromboembolism	2	3.4
Intestinal occlusion	2	3.4
Choledocholithiasis	2	3.4
Bleeding	2	3.4
Bile duct lesion	1	1.7
Dehiscence of surgical wound	1	1.7
Pleural effusion	1	1.7
Cardio respiratory arrest	1	1.7
Atelectasis	1	1.7
Pylephlebitis	1	1.7
Acute kidney injury	1	1.7
Total	59	100

(0.63 to 1.06 IC 95%). For the analysis of correlation between 30 days readmission and complications, it was found (RR 0.639 p¬ <0.05) for the use of the Clavien-Dindo scale and complications (RR 0.548 p ¬ <0.05) (Figure 1).

Discussion

According to other studies, in our study the use of checklists in our hospital, showed a significant reduction of perioperative complications, given the nature of our data we could not estimate the risk of death since we did not have any events. The use of checklists showed improvement in the risk of complications, 30 days readmission as well as number and type of complications, including high-risk groups, such as elderly patients, patients who underwent emergency procedures, and patients who underwent procedures that required hospitalization. The presence of significant improvements in the results after the surgical checklist was expected in the light of the conclusions of the studies that evaluate the effects of such lists. In a meta-analysis of before and after checklists the studies evaluate the effect of the lists, the combined relative risk of operative death was 0.57 (95% CI, 0.42 to 0.76), and the relative risk of complications was 0.63 (95% CI, 0.58 to 0.67). The possibility of replicating these effects could be explained by an adequate power; since our study included more than 507 surgical procedures in our hospital.

The self-report of compliance by the hospital is high, approximately 98%. In a hospital in the Netherlands, surgical safety checklists were completed completely only 39% of the surgical procedures after mandatory implementation. In that study, the odds ratio for death in the post-implementation period, compared to the pre-execution period, was reduced only among patients who underwent procedures with complete compliance checklist. There was no reduction in the probability of death ratio among patients in whom the checklist was partially completed or not completed. Although the selection bias of that study would probably explain much of the negative effect of non-compliance in hospitals where checklists are used, this study demonstrated the fact that lists are not always applied uniformly. Therefore, the presence of an effect of the application of the checklists in our study could be secondary to an adequate adherence to the checklist. It is possible that the surgical safety checklist had been found less effective in practice in some studies. This is probably secondary to the Hawthorne effect, which is defined as the tendency of some people to perform better when they perceive that their work is under control, which could explain the strong effect of surgical checklists in the studies in which the hospitals were aware of the intervention under study. However, in our study this effect would have no effect since, due to its retrospective nature; no one involved knew that performance would be evaluated. Previous studies are controlled observational designs however they have inherent limitations, and causality inferences should be made with caution.

The efficacy of a surgical safety checklist has never been demonstrated in a randomized controlled trial, despite the feasibility of using randomized designs in groups to test context-dependent interventions, such as strategies to ensure safety of the patient. Studies that show a substantial effect of a checklist, in addition to the WHO study that covered the care from the preoperative period to discharge from the hospital. Because thousands of hospitals around the world have implemented surgical safety checklists, many may have improvements in the results by chance. Hospital-based studies that show improvements in the results after the implementation of the checklist are more likely to be published than the negative studies, so a publication bias may exist at this time (Table 2). Something interesting to note in our study, is that although an effect of the checklist was demonstrated, we also managed to demonstrate that the use of the Clavien-Dindo scale and ACS-NSQIP served as independent prognostic factor after the unit and multivariate analysis and we propose that they should be used systematically, since the higher the score, the greater the number of complications, readmission at 30 days and the longer hospital stay. We also found that age was an independent risk factor to present some of these outcomes. Therefore, for patients who have a high score as well as a higher age, adequate precautions and closer follow-up should be taken due to the fact that they present some of these characteristics. At the same time, our study has a series of limitations. First, the large interventions during the period in which the checklists were introduced may have confused our results. Second, we have used administrative data to evaluate surgical complications. Although this method is commonly used, it is inferior to the prospective measurement or review and may have obscured changes in surgical complications after the implementation checklist. However, the other outcomes studied, including operative mortality, length of stay, emergency visits and readmission, are less susceptible to misclassification of administrative data.

Conclusion

In conclusion, our study of the application of surgical safety checklists did not show the remarkable improvement in the results of patients identified in previous studies. No particular subgroup that benefited from the checklists was identified. Although a greater effect of surgical safety checklists could occur with more intensive training or better compliance monitoring equipment, in our study we did not find such an effect. There may be value in the use of surgical safety checklists, such as improved communication and teamwork and the promotion of a hospital culture in which safety is a high priority. However, these potential benefits did not translate into significant improvements in the results we analyzed. It is worth mentioning that the scale of Clavien-Dindo and ACS-NSQIP served as an independent prognostic factor, so more research is needed in this regard in order to use these prognostic scales in favor of patient care.

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